Quality Manual
FMC Technologies
Measurement Solutions Operations
<table>
<thead>
<tr>
<th>Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Revision History ...............................................................</td>
</tr>
<tr>
<td>2  Company ........................................................................</td>
</tr>
<tr>
<td>2.1  Introduction ..................................................................</td>
</tr>
<tr>
<td>2.2  Quality Policy ...........................................................</td>
</tr>
<tr>
<td>2.3  Quality Organization ....................................................</td>
</tr>
<tr>
<td>2.4  Company Processes .......................................................</td>
</tr>
<tr>
<td>3  Scope and Exclusions ......................................................</td>
</tr>
<tr>
<td>3.1  Scope ..........................................................................</td>
</tr>
<tr>
<td>3.2  Exclusions ....................................................................</td>
</tr>
<tr>
<td>3.3  References ....................................................................</td>
</tr>
<tr>
<td>4  Quality Management System ............................................</td>
</tr>
<tr>
<td>4.1  General Requirements ..................................................</td>
</tr>
<tr>
<td>4.2  Documentation Requirements ........................................</td>
</tr>
<tr>
<td>4.2.1  General .....................................................................</td>
</tr>
<tr>
<td>4.2.2  Quality Manual .......................................................</td>
</tr>
<tr>
<td>4.2.3  Control of Documents ...............................................</td>
</tr>
<tr>
<td>4.2.4  Control of Records ..................................................</td>
</tr>
<tr>
<td>5  Management Responsibility ...............................................</td>
</tr>
<tr>
<td>5.1  Management Commitment ...............................................</td>
</tr>
<tr>
<td>5.2  Customer Focus ............................................................</td>
</tr>
<tr>
<td>5.3  Quality Policy ..............................................................</td>
</tr>
<tr>
<td>5.4  Planning ....................................................................</td>
</tr>
<tr>
<td>5.4.1  Quality Objectives ...................................................</td>
</tr>
<tr>
<td>5.4.2  Quality Management System Planning .........................</td>
</tr>
<tr>
<td>5.5  Responsibility, Authority and Communication ................</td>
</tr>
<tr>
<td>5.5.1  Responsibility and Authority .....................................</td>
</tr>
<tr>
<td>5.5.2  Management Representative .......................................</td>
</tr>
<tr>
<td>5.5.3  Internal Communication ............................................</td>
</tr>
<tr>
<td>5.6  Management Review ......................................................</td>
</tr>
<tr>
<td>5.6.1  General .....................................................................</td>
</tr>
<tr>
<td>5.6.2  Review Input ...........................................................</td>
</tr>
<tr>
<td>5.6.3  Review Output .........................................................</td>
</tr>
<tr>
<td>6  Resource Management ......................................................</td>
</tr>
<tr>
<td>6.1  Provision of Resources ..................................................</td>
</tr>
<tr>
<td>6.2  Human Resources ..........................................................</td>
</tr>
<tr>
<td>6.2.1  General .....................................................................</td>
</tr>
<tr>
<td>6.2.2  Competence, Training, and Awareness .........................</td>
</tr>
<tr>
<td>6.3  Infrastructure ...............................................................</td>
</tr>
<tr>
<td>6.4  Work Environment .......................................................</td>
</tr>
<tr>
<td>7  Product Realization ..........................................................</td>
</tr>
<tr>
<td>7.1  Planning of Product Realization ......................................</td>
</tr>
<tr>
<td>7.2  Customer Related Processes .........................................</td>
</tr>
<tr>
<td>7.2.1  Determination of Requirements Related to the Product .....</td>
</tr>
<tr>
<td>7.2.2  Review of Requirements Related to the Product ..........</td>
</tr>
<tr>
<td>7.2.3  Customer Communication ..........................................</td>
</tr>
<tr>
<td>7.3  Design and Development ...............................................</td>
</tr>
<tr>
<td>7.3.1  Design and Development Planning ................................</td>
</tr>
<tr>
<td>7.3.2  Design and Development Inputs ..................................</td>
</tr>
</tbody>
</table>
7.3.3 Design and Development Outputs ................................................................. 18
7.3.4 Design and Development Review ................................................................. 18
7.3.5 Design and Development Verification ......................................................... 19
7.3.6 Design and Development Validation ......................................................... 19
7.3.7 Control of Design and Development Changes ......................................... 19
7.4 Purchasing ........................................................................................................ 19
  7.4.1 Purchasing Process .................................................................................. 19
  7.4.2 Purchasing Information ........................................................................ 20
  7.4.3 Verification of Purchased Product ........................................................... 21
7.5 Production and Service Provision ................................................................. 21
  7.5.1 Control of Production and Service Provision ........................................ 21
  7.5.2 Validation of Process for Production and Service Provision ................. 22
  7.5.3 Identification and Traceability ............................................................... 22
  7.5.4 Customer Property .............................................................................. 22
  7.5.5 Preservation of Product ....................................................................... 23
7.6 Control of Monitoring and Measuring Equipment ................................... 23
8 Measurement, Analysis and Improvement .................................................. 24
  8.1 General ....................................................................................................... 24
  8.2 Monitoring and Measurement ................................................................. 24
    8.2.1 Customer Satisfaction ........................................................................ 24
    8.2.2 Internal Audit ....................................................................................... 24
    8.2.3 Monitoring and Measurement of Processes .................................... 25
    8.2.4 Monitoring and Measurement of Product ...................................... 25
  8.3 Control of Nonconforming Product ............................................................ 25
  8.4 Analysis of Data ......................................................................................... 26
  8.5 Improvement ............................................................................................. 26
    8.5.1 Continual Improvement ...................................................................... 26
    8.5.2 Corrective Action .............................................................................. 26
    8.5.3 Preventive Action .............................................................................. 26
1 Revision History

The following revisions have been made to this Quality Manual since its initial publication:

<table>
<thead>
<tr>
<th>Issue / Rev</th>
<th>Date</th>
<th>List of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>1/2008</td>
<td>Update Erie Location – (Torrance, CA)</td>
</tr>
<tr>
<td>1.0</td>
<td>6/2009</td>
<td>Totally revised to incorporate ISO9000-2008 and ATEX and related requirements</td>
</tr>
<tr>
<td>1.1</td>
<td>7/11/2011</td>
<td>Update to include Ellerbek facility in the reference scope</td>
</tr>
<tr>
<td>1.2</td>
<td>6/19/2013</td>
<td>Section 2.1 Update Ellerbek QMR; update signatory for FMC Global QP; 3.3 add ISO 9000:2005 and ISO 19011:2011 references Updated manual to requirements of EN ISO/IEC 80079-34 (was BS EN 1380-2002)</td>
</tr>
</tbody>
</table>
2 Company

2.1 Introduction

FMC Technologies, Measurement Solutions Inc. (aka, Measurement Solutions), is an operational business unit of FMC Technologies, Houston, Texas, USA. The operations and locations named herein are business units of FMC Technologies.

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. The quality of our products is a cornerstone of our success, upholding both the reputation and the existence of our company. We, therefore, continuously strive to provide our customers products and services meeting every expectation.

The management of FMC Technologies and its business units accept 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 FMC Technologies’ customers of the controls implemented to assure product quality. The Quality Manual provides for a quality management system to:

a) Consistently provide products that meet customer and applicable regulatory requirements.
b) Enhance customer satisfaction through effective application of the quality system, including processes for continual improvement of the system and assurance of conformity to customer and applicable regulatory requirements.


This manual and the quality system registration certificates are available for review at: www.FMCTechnologies.com

Title and signatures - date:

Chuck Lazan       Fredrik Jönsson       Jim Ertl
Global Quality Manager     VP and GM     Vice President and General Manager
QMR Erie Operation     QMR Ellerbek Operation    Measurement Products
2.2 Quality Policy

FMC Technologies Measurement Solutions Inc. is committed to the following Global Quality Policy:

FMC Technologies Inc. is dedicated to providing systems, products and services that meet all specified requirements for safety, reliability and delivery. We will focus on our customer’s success by insisting on continuous improvement and application of zero defect capable processes.

John Gremp  
Chairman and Chief Executive Officer  
October 2011

2.3 Quality Organization

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 FMC Technologies Measurement Solutions Inc is available on request.
2.4 Company Processes

Measurement Solutions identified the key processes and their interaction at Measurement Solutions and we fully integrated them in our ISO 9001 quality management system.

QMS- Process Interaction Diagram

Customer Mgmt
- Customer Needs
- Request for Input
- Customer PO
- Order Validation
- Regulatory Compliance
- Caliation
- Material Traceability
- Control Non-Conforming Product

Resource Management
- Human Resource Planning
- Infrastructure Management
- Work Environment
- Planning

Design and Development
- Engineering Project Request
- Design Review
- Verification / Validation
- Product Release
- Engineering Change Mgmt
- Special Order Engineering
- Design Output: Drawings, BOMs, Specs, Inspection Documents, etc

Order Management
- Order Entry
- Scheduling
- Quotation
- PO Release
- PO Mgmt
- Receive / Inspect
- Inventory

Production
- Inventory
- Inspect / Test
- Job Order Mfg & Mgmt
- Job Order Release
- Final Inspect
- Pick / Pack
- Ship

Purchasing
- Supplier Mgmt
- PO Release
- Customer Mgmt
- Field Service
- Customer Complaint
- RMA
- Invoicing / Collection

Key
- Customer Oriented Process
- Management Process
- Support Process
- Required Procedures
- Process Step

Quality Management System
- Management Responsibility
- Procedures / Objectives
- Quality Manual / Quality Policy
- Management Review

Measurement, Analysis and Improvement
- Internal Audit
- Preventative Action
- Corrective Action
- Continuous Improvement
- Customer Satisfaction

Quality, Analysis and Improvement
- Planning
- Material Traceability
- Required Procedure
- Process Step
- Customer Oriented Process

Control Non-Conforming Product
- Invoicing / Collection
- Customer Complaint
- RMA
- Field Service
- Customer Mgmt
- Ordering / Collection
- Supplier Mgmt
- PO Release
- PO Mgmt
- Receive / Inspect
- Inventory
- final Inspect
- Pick / Pack
- Ship

Customer Mgmt
- Customer Needs
- Request for Input
- Customer PO
- Order Validation
- Regulatory Compliance
- Calibration
- Material Traceability
- Control Non-Conforming Product

Training
- Document Control
- Record Management

Human Resource Planning
- Infrastructure Management
- Work Environment
- Planning

Design and Development
- Engineering Project Request
- Design Review
- Verification / Validation
- Product Release
- Engineering Change Mgmt
- Special Order Engineering
- Design Output: Drawings, BOMs, Specs, Inspection Documents, etc

Order Management
- Order Entry
- Scheduling
- Quotation
- PO Release
- PO Mgmt
- Receive / Inspect
- Inventory

Production
- Inventory
- Inspect / Test
- Job Order Mfg & Mgmt
- Job Order Release
- Final Inspect
- Pick / Pack
- Ship

Purchasing
- Supplier Mgmt
- PO Release
- Customer Mgmt
- Field Service
- Customer Complaint
- RMA
- Invoicing / Collection

Key
- Customer Oriented Process
- Management Process
- Support Process
- Required Procedures
- Process Step

Quality Management System
- Management Responsibility
- Procedures / Objectives
- Quality Manual / Quality Policy
- Management Review

Measurement, Analysis and Improvement
- Internal Audit
- Preventative Action
- Corrective Action
- Continuous Improvement
- Customer Satisfaction

Quality, Analysis and Improvement
- Planning
- Material Traceability
- Required Procedure
- Process Step
- Customer Oriented Process

Control Non-Conforming Product
- Invoicing / Collection
- Customer Complaint
- RMA
- Field Service
- Customer Mgmt
- Ordering / Collection
- Supplier Mgmt
- PO Release
- PO Mgmt
- Receive / Inspect
- Inventory
- final Inspect
- Pick / Pack
- Ship

Customer Mgmt
- Customer Needs
- Request for Input
- Customer PO
- Order Validation
- Regulatory Compliance
- Calibration
- Material Traceability
- Control Non-Conforming Product

Training
- Document Control
- Record Management

Human Resource Planning
- Infrastructure Management
- Work Environment
- Planning

Design and Development
- Engineering Project Request
- Design Review
- Verification / Validation
- Product Release
- Engineering Change Mgmt
- Special Order Engineering
- Design Output: Drawings, BOMs, Specs, Inspection Documents, etc

Order Management
- Order Entry
- Scheduling
- Quotation
- PO Release
- PO Mgmt
- Receive / Inspect
- Inventory

Production
- Inventory
- Inspect / Test
- Job Order Mfg & Mgmt
- Job Order Release
- Final Inspect
- Pick / Pack
- Ship

Purchasing
- Supplier Mgmt
- PO Release
- Customer Mgmt
- Field Service
- Customer Complaint
- RMA
- Invoicing / Collection

Key
- Customer Oriented Process
- Management Process
- Support Process
- Required Procedures
- Process Step

Quality Management System
- Management Responsibility
- Procedures / Objectives
- Quality Manual / Quality Policy
- Management Review

Measurement, Analysis and Improvement
- Internal Audit
- Preventative Action
- Corrective Action
- Continuous Improvement
- Customer Satisfaction

Quality, Analysis and Improvement
- Planning
- Material Traceability
- Required Procedure
- Process Step
- Customer Oriented Process

Control Non-Conforming Product
- Invoicing / Collection
- Customer Complaint
- RMA
- Field Service
- Customer Mgmt
- Ordering / Collection
- Supplier Mgmt
- PO Release
- PO Mgmt
- Receive / Inspect
- Inventory
- final Inspect
- Pick / Pack
- Ship
3  Scope and Exclusions

3.1  Scope
This Quality Manual documents our quality management system, and it demonstrates FMC Technologies Measurement Solutions Inc’s pursuit to consistently provide a product that meets customer and regulatory requirements.

This Quality Manual establishes compliance with ISO 9001:2008 and EN ISO/IEC 80079-34. It applies to all of our business activities including research and development, production, sales, marketing, installation and servicing activities. The schedule of activities may vary from location to location using this Quality Manual and are listed on the location’s Certificate of Approval.

Measurement Solutions provides product compliant to the following EC Directives:
- Pressure Equipment (PED) Directive 97/23/EC (Module D) and

3.2  Exclusions
None

3.3  References
Key for quality system requirements found in this Manual:

ISO 9001:2008
Selections in regular type apply across the organization.

EN ISO/IEC 80079-34
Italicized selections in [Brackets] are selectively applied to ATEX or IECEx products / processes.

ISO 9000:2005
Quality management systems -- Fundamentals and vocabulary

ISO 19011:2011
Guidelines for auditing management systems
4 Quality Management System

4.1 General Requirements

Measurement Solutions has established, documented, and implemented a quality management system that meets the requirements of ISO 9001:2008. Measurement Solutions maintains this Quality Management System and continually improves its effectiveness as required by ISO 9001:2008, EN ISO/IEC 80079-34, and specific customer and regulatory requirements.

a) Our Quality Management System determines the processes needed for its operation and their application throughout FMC Technologies, Measurement Solutions Inc. These processes include processes for management activities, provision of resources, product realization and measurement.

b) Our Quality Management System determines the sequence and the interaction of these processes.

c) Our Quality Management System determines the criteria and methods needed to ensure that both the operation and control of these processes are effective.

d) Our Quality Management System ensures the availability of resources and information necessary to support the operation and monitoring of these processes.

e) Our Quality Management System ensures that these processes are monitored, measured where applicable, and analyzed by us.

f) Our Quality Management System ensures that necessary actions are implemented to achieve planned results and continual improvement of these processes.

g) [Our Quality Management System ensures that product conforms to the type described in the Ex certificate and technical documentation.]

Where Measurement Solutions chooses to outsource any process that affects how our products meet requirements, Measurement Solutions ensures control over such processes and maintains responsibility for meeting customer requirements. Our Quality Management System identifies the type and extent of control of such outsourced processes (refer to Chapter 7.4).

4.2 Documentation Requirements

4.2.1 General

The documentation of our Quality Management System includes the following documents:

a) The documented Quality Policy (see 2.1) of Measurement Solutions and the documented Quality Objectives of FMC Technologies Measurement Solutions Inc.


c) The Quality Procedures are established to meet quality, customer and regulatory requirements. These documented processes and workflows are implemented and maintained.

d) All such documents (including work instructions and forms) that Measurement Solutions needs to ensure the effective planning, operation and control of our processes.

e) All records that are required by quality, customer and regulatory requirements to provide objective evidence of policy, product or process compliance.
The hierarchy of the Quality Management System documentation is depicted to the right / above.

**4.2.2 Quality Manual**

Measurement Solutions has established this ISO 9001:2008 Quality Manual, which includes the following important sections:

- The scope of our Quality Management System in Chapter 3.1.
- Any exclusion including details and justifications in Chapter 3.2.
- Our documented Quality Procedures (see Chapter 3.3 for details)
- A description of the interaction between the processes of our Quality Management System in Chapter 2.4.

**4.2.3 Control of Documents**

Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for the control of documents. This procedure defines how Measurement Solutions controls all documents that are required by our Quality Management System.

Records are a considered a special type of document; records are controlled according to the requirements in Chapter 4.2.4.

a) [Equipment documents and our documents are controlled;]

b) Documented procedures ensure that information contained within our documents is compatible with equipment documents. Measurement Solutions shall not initially approve or subsequently amend related drawings unless they are in compliance with approved parts of the schedule drawings;

c) Our quality system ensures that no factor (type, characteristic, position, etc.) defined within the Ex certificate and technical documentation (e.g. schedule drawings) is modified

d) Our documented system refers all related drawings to the relevant schedule drawings;

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

f) Where FMC Technologies 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;

g) FMC Technologies documents who is responsible for the quality system notification for each Ex certificate;

h) Where technical documentation or FMC Technologies documentation are passed to a third party, they shall be provided in a way that is not misleading;

i) FMC Technologies documents the process to annually check the validity of all Ex related certificates, standards, regulations and other external specifications.]

**4.2.4 Control of Records**

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

[Measurement Solutions retains adequate quality records to demonstrate conformity of the product and satisfy national regulation and legislation.]
As a minimum the list of documents requiring control and retention, as far as practical, are:

- 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).

Measurement Solutions has defined its Records Retention Policy in Financial Standard G.270. The retention guidelines defined in the G.270 Policy have been reflected in the Quality Procedure.

[NOTE: Examples of documents requiring control and retention are: those arising from regulatory requirements, customer order, 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

Top management at Measurement Solutions is not only committed to the development and implementation of our Quality Management System, but also to continually improving its effectiveness. Top management of Measurement Solutions clearly demonstrates its commitment by:

a) Communicating in all channels of internal communication the importance of meeting customer requirements, as well as statutory and regulatory requirements,
b) establishing and promoting our Quality Policy,
c) ensuring the Quality Objectives are established in our management by objectives system,
d) conducting management reviews of the Quality Management System, and
e) ensuring the availability of resources through the annual budget planning process.

### 5.2 Customer Focus

Top Management at Measurement Solutions ensures that customer requirements are first determined and then met with the aim of enhancing customer satisfaction (see Chapters 7.2.1 and 8.2.1).

### 5.3 Quality Policy

Top management at Measurement Solutions ensures that our Quality Policy

a) is appropriate to the purpose of FMC Technologies,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides the framework for establishing and reviewing quality objectives,
d) is communicated, understood and promoted throughout the organization, and
e) is reviewed during the annual quality management system review for continuing suitability.
5.4 Planning

5.4.1 Quality Objectives
Top management at Measurement Solutions ensures that quality objectives are established throughout Measurement Solutions at relevant functions and levels. These quality objectives meet the following requirements:

- They include (but are not limited to) objectives regarding meeting requirements for our products (see Chapter 7.1 a).
- They are measurable.
- They are consistent with our Quality Policy.

5.4.2 Quality Management System Planning
Top management at Measurement Solutions ensures

a) that our Quality Management System has been planned so that the requirements set forth in Chapter 4.1 are met, and
b) that the quality objectives are met.

Top management ensures that the integrity of our Quality Management System continues to be maintained at times when changes to our Quality Management System are planned and implemented. Changes to the Quality Management System are approved by applicable regulatory authorities and customers, if required, prior to implementation.

[The quality system ensures that the product conforms to the type described in the Ex certificate. All the elements, requirements and provisions adopted by FMC Technologies 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
Top management at Measurement Solutions ensures that responsibilities and authorities are defined and communicated throughout FMC Technologies, Measurement Solutions Inc.

[Responsibilities and authority for the following have been defined:
 a) the effective co-ordination of activities with respect to products intended for use in potentially explosive atmospheres;
 b) the liaison with the issuer of the Ex certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the Ex certificate and the technical documentation;
 c) the liaison with the body responsible for the verification of the quality system with respect to intended updating of the quality system.
 d) the authorizing of initial approval and changes to related drawings, where appropriate;
 e) the authorizing of concessions;
 f) informing its customers of any applicable special conditions of use and any schedules of limitations;
 g) the reviewing of Ex certificate and technical documentation and identifying any changes that effect product compliance with the certificate.]
NOTE: Certificates with a suffix X can contain special conditions for safe use. Component certificates with a suffix U can contain schedules of limitations.]

5.5.2 Management Representative

5.5.2.1 Quality Management Representative

Top management at Measurement Solutions has appointed an ISO 9001 Management Representative at each location. This Management Representative is a member of our company’s management who has the following responsibilities and authorities irrespective of other responsibilities:

a) The Management Representative ensures that the processes needed for our Quality Management System are established, implemented and maintained.
b) The Management Representative reports to our top management on the performance of our Quality Management System and any need for improvement.
c) The Management Representative ensures that a general awareness of customer requirements is promoted throughout FMC Technologies, Measurement Solutions Inc.
d) The Management Representative also serves as liaison with external parties on matters relating to our Quality Management System.

5.5.2.2 Ex Authorized Representative

In those facilities dealing with product manufactured to the requirements of an "Ex" type directive (e.g. ATEX or IECEx), an individual shall be appointed as the “authorized person” 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

5.5.2.3 PED/MID Authorized Representative

In those facilities dealing with product manufactured to the requirements of the Pressure Equipment Directive, PED, (97/23/EC) or the Measuring Instrument Directive, MID, (2004/22/EC), an individual shall be appointed as the “authorized person” 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.

5.5.3 Internal Communication

Top management at Measurement Solutions ensures that there are appropriate communication processes established throughout FMC Technologies, Measurement Solutions Inc. Top management further ensures that communication takes place regarding the effectiveness of our Quality Management System.
5.6 Management Review

5.6.1 General
Top management at Measurement Solutions conducts yearly reviews ([not to exceed 14 months]) of our quality management system (QMS). The top management and [the person(s) responsible for the activities as detailed in 5.5.2.2] review ensures that the QMS continues to be suitable, adequate and effective.

This review includes an assessment of opportunities for improvement and the need for changes to our Quality Management System, including our Quality Policy and the quality objectives.

[a] the maximum interval between reviews is normally 12 months and does not exceed 14 months;
b) top management chairs the review;
c) personnel responsible for the activities as detailed in 5.5.1 participates in the review.]

Measurement Solutions maintains records of these management reviews in compliance with section 4.2.4.

5.6.2 Review Input
The following information serves as input to the management reviews of our Quality Management System:

a) results of audits,
b) customer feedback,
c) process performance,
d) product conformance to requirements,
e) status of preventive and corrective actions,
f) follow-up actions from previous management reviews,
g) any changes that could affect our Quality Management System, and
h) recommendations for improvement.

[The review includes the overall effectiveness of the quality management system with respect to products intended for use in potentially explosive atmospheres.]

5.6.3 Review Output
The output from the management reviews of our Quality Management System includes the following:

a) decisions and actions related to improving the effectiveness of the our Quality Management System and its processes,
b) decisions and actions related to the improving our products relative to customer requirements, and
c) decisions and actions related to resource needs.
6 Resource Management

6.1 Provision of Resources
Measurement Solutions first determines and then provides the resources needed for:

a) the implementation and maintenance of our Quality Management System,
b) continually improving the effectiveness of our Quality Management System, and
c) the enhancement of customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General
Measurement Solutions ensures that all our personnel who perform work that affects our product quality are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Training, and Awareness
Measurement Solutions does the following regarding competence, awareness and training of our employees:

a) Measurement Solutions determines the necessary competence for personnel who perform work that affects how our products conform to their requirements.
b) Measurement Solutions provides the necessary training or takes other actions to achieve the necessary competence (where applicable).
c) Measurement Solutions evaluates the effectiveness of the training or other actions taken.
d) Measurement Solutions ensures that all our personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
e) Measurement Solutions maintains appropriate records of education, training, skills and experience in compliance with Chapter 4.2.4
f) Measurement Solutions ensures that all personnel having an impact on Ex compliance receive appropriate training.

6.3 Infrastructure
Measurement Solutions determines, provides and maintains the infrastructure necessary to achieve conformity to product requirements. This infrastructure includes, as applicable, the following:

a) buildings, workspace and associated utilities,
b) process equipment (this includes both hardware and software), and
c) supporting services (such as transportation, information systems and communication).

6.4 Work Environment
Measurement Solutions determines and manages the work environment that is necessary to achieve conformity to product requirements.
7 Product Realization

7.1 Planning of Product Realization
Measurement Solutions plans and develops the processes needed for product realization. This planning of product realization is consistent with the requirements of the other processes of our Quality Management System (see Chapter 4.1).

Measurement Solutions determines the following, as appropriate, during the planning phase for product realization:

a) quality objectives and requirements for the product;
b) the need to establish
• processes,
• documents, and
• provision of resources specific to the product;
c) the following activities that are required by the specifics of the product and the criteria for product acceptance:
• verification,
• validation,
• monitoring,
• measurement,
• inspection and test;
d) the records necessary to provide evidence that both the realization process and the resulting product meet requirements; these records are control in compliance with Chapter 4.2.4.

The output of this planning is in a form that is suitable for Measurement Solutions' method of operations.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product
Measurement Solutions determines the following requirements that are related to our product:

a) requirements that have been specified by our customers, including any such requirements for delivery and post-delivery activities,
b) requirements that have not explicitly stated by our customers but that are necessary for the specified or intended use of our products (where the use is known),
c) statutory and regulatory requirements applicable to our products, and
d) any additional requirements that Measurement Solutions considers necessary.
7.2.2 Review of Requirements Related to the Product
Measurement Solutions reviews the requirements related to products prior to Measurement Solutions’ commitment to supply a product to the customer (e.g., prior to the submission of tenders, prior to the acceptance of contracts or orders, prior to the acceptance of changes to contracts or orders). This review is designed to ensure that:

a) product requirements are defined,
b) any differences of contract or order requirements to previously expressed contract or order requirements are resolved, and
c) Measurement Solutions has the ability to meet the defined requirements.

[The review ensures 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.]

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

Measurement Solutions maintains records that show the results of the review and the actions arising from the review in compliance with Chapter 4.2.4.

In cases in which our customers don’t provide documented requirements, Measurement Solutions confirms the customer requirements before acceptance.

In cases in which product requirements are changed, Measurement Solutions ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication
Measurement Solutions determines and implements effective arrangements for communicating with our customers regarding the following:

a) product information,
b) inquiries, contracts or order handling,
c) handling of contract or order amendments, and
d) customer feedback including customer complaints.

7.3 Design and Development
[Section 7.3 is not within the scope of standard EN ISO/IEC 80079-34]

7.3.1 Design and Development Planning
Measurement Solutions plans and controls the design and development of our products. During this planning of design and development, Measurement Solutions determines the following:

a) the various stages of the design and development process,
b) the review, verification and validation activities that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.
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 output of design and development planning is updated, as appropriate, as the design and development process progresses.

### 7.3.2 Design and Development Inputs
Measurement Solutions determines the inputs related to product requirements. These inputs include:

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements that are essential for the design and development.

Measurement Solutions reviews these inputs for adequacy, and ensures that all requirements are complete, unambiguous and not in conflict with each other.

Measurement Solutions maintains records of these inputs in compliance with Chapter 4.2.4.

### 7.3.3 Design and Development Outputs
Measurement Solutions provides the outputs of the design and development process in a form that is suitable for verification against the design and development input. Measurement Solutions approves these outputs prior to release and ensures that these outputs meet the following conditions:

- a) The outputs meet the input requirements for design and development.
- b) The outputs provide appropriate information for purchasing, production and service provision.
- c) The outputs either contain or reference the criteria for product acceptance.
- d) The outputs specify the product characteristics that are essential for its safe and proper use.

### 7.3.4 Design and Development Review
Measurement Solutions performs systematic reviews of the design and development at suitable stages in accordance with our design and development plan (see Chapter 7.3.1). These reviews:

- a) evaluate if the results of design and development are able to meet requirements, and
- b) identify any problems and propose necessary actions.

Representatives of those functions concerned with the design and development states under review are participants in the reviews.

Measurement Solutions maintains records of the results of the reviews and of any necessary actions in compliance with Chapter 4.2.4.
7.3.5 Design and Development Verification
Measurement Solutions performs a design and development verification in accordance with the planned requirements (see Chapter 7.3.1). Verification is designed to ensure that the design and development outputs meet the design and development input requirements.

Measurement Solutions maintains records of the results of the verification and of any necessary actions in compliance with Chapter 4.2.4.

7.3.6 Design and Development Validation
Measurement Solutions performs a design and development validation in accordance with the planned requirements (see Chapter 7.3.1). Validation is designed to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use (where known). Wherever practicable, Measurement Solutions completes validation prior to the delivery or implementation of the product.

Measurement Solutions maintains records of the results of the validation and of any necessary actions in compliance with Chapter 4.2.4.

7.3.7 Control of Design and Development Changes
Measurement Solutions identifies any design and development changes and maintains records. Measurement Solutions reviews, verifies and validates (as appropriate) these changes, and approves them prior to their implementation. The review of design and development changes includes an evaluation on the effect of the changes on constituent parts and product already delivered.

Measurement Solutions maintains records of the results of the review of changes and of any necessary actions in compliance with Chapter 4.2.4.

7.4 Purchasing

7.4.1 Purchasing Process
Measurement Solutions ensures that the products we purchase conform to our specified purchase requirements. In order to achieve this, Measurement Solutions applies certain controls to our suppliers and to the purchased products; the type and extend of these controls depend on the effect that the purchase product has on our product realization or on our final product.

Measurement Solutions evaluates and selects our suppliers based on their ability to supply products in accordance with our requirements. Measurement Solutions establishes criteria that we use for the selection, evaluation and re-evaluation of our suppliers.

a) [While manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the Ex certificate will not be sub-contracted by Measurement Solutions.

b) Suppliers providing a product, process, or service that can affect the product’s compliance with the Ex certificate will 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.

1) documented objective evidence that a supplier can provide a product, process, or service that is fit for its purpose can be made by one 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) is 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, then the product, process, or service will be accepted by one of the following methods:
- Measurement Solutions will demonstrate the control process implemented by the subcontractor ensures Ex compliance,
- Measurement Solutions will verify the subcontractor quality system by performing periodic audits.

c) Suppliers not used for a period exceeding one year shall be re-evaluated by Measurement Solutions prior to the placing of the contract.

d) Requirements b) and c) are not mandatory for products, processes or services where the manufacturer fully 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) Measurement Solutions facilitates an arrangement whereby the body responsible for the verification of the Ex quality system may also verify any aspects of the supplier’s operation that affects the type of protection.

Measurement Solutions maintains records of the results of the evaluations and of any necessary actions in compliance with Chapter 4.2.4.

7.4.2 Purchasing Information

Measurement Solutions describes the products to be purchased and includes the following, as appropriate, in the purchasing information:

a) requirements for the approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

d) [The purchasing documents shall be clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the equipment documents (e.g. for process control, testing or inspection);

e) 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;

f) Measurement Solutions defines the method by which documents (e.g. technical specifications), stated in a particular purchase order remain traceable to the order.

g) Where Measurement Solutions does not provide such documents with subsequent orders, then Measurement Solutions has procedures for ensuring that suppliers have current copies of documents, and that they remain in good condition.]

Prior to communicating the purchase information to the supplier, Measurement Solutions ensures that the purchase requirements are adequate.
7.4.3 Verification of Purchased Product

Measurement Solutions establishes and implements inspection or other activities that are necessary to ensure that our purchased products meet our specified purchase requirements.

a) [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 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, Measurement Solutions considers 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 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 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 and every product. Either the supplier or the manufacturer may carry them out. 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. declaration of conformity according to ISO/IEC 17050-1 including test results if required;

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

g) when the supplier of Measurement Solutions requires training or specialist skills or knowledge to carry out a verification then the training material, specialist skill, knowledge or background is documented and training records maintained;

h) 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;

i) where a supplier provides product with evidence of conformity, (e.g. Ex certificate), then further verification is not required unless Measurement Solutions 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 is supplied.]

In cases in which Measurement Solutions or our customers intend to perform this verification at our supplier’s premises, Measurement Solutions states the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Measurement Solutions carries out our production and service provision under controlled conditions which include the following, as applicable:

a) Information that describes the characteristics of the product is available.

b) Necessary work instructions are available.
c) Suitable equipment is used.
d) Monitoring and measuring equipment are available and used.
e) Monitoring and measuring activities are implemented (see Chapter 7.5.2 for an exception).
f) Product release, delivery and post-delivery activities are implemented.

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 Ex certificate]

7.5.2 Validation of Process for Production and Service Provision

In such special situations in which we cannot use monitoring or measurement activities to verify the output of our production and service provision, and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered, Measurement Solutions validates the processes of such production and service provision. The process validation is designed to demonstrate that these processes are able to achieve the planned results. [Documented evidence is maintained to demonstrate compliance with the parameters]

Measurement Solutions establishes arrangements for these processes which include, as applicable:

a) defined criteria for review and approval of the processes;
b) approval of equipment and qualification of personnel;
c) use of specific methods and procedures;
d) requirements for records (refer to Chapter 4.2.4), and
e) revalidation.

7.5.3 Identification and Traceability

Measurement Solutions identifies our product, where appropriate, by suitable means throughout the product realization.

Measurement Solutions identifies the product status with respect to monitoring and measurement requirements throughout product realization. In cases in which traceability is a requirement, Measurement Solutions controls the unique identification of the product and maintains records in compliance with Chapter 4.2.4.

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.]

7.5.4 Customer Property

Whenever we use our customers’ property or whenever we have our customers’ property under our control, Measurement Solutions exercises care with such customer property (which can also include intellectual property and personal data). Measurement Solutions identifies, verifies, protects and safeguards customer property that has been provided for use or incorporation into our product.

If despite all our care any customer property is lost, damaged or otherwise found unsuitable for use, Measurement Solutions reports this to the customer and maintains records in compliance with Chapter 4.2.4.
Measurement Solutions is responsible for verifying the compatibility of customer-supplied product with the requirements of the Ex certificate.

7.5.5 Preservation of Product

Measurement Solutions preserves our products and their constituent parts during internal processing and during delivery to the intended destination in order to maintain conformity to product requirements. This preservation includes (as applicable):

- identification,
- handling,
- packaging,
- storage, and
- protection

The manufacturer shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements.

7.6 Control of Monitoring and Measuring Equipment

In order to provide evidence that our products conform to determined requirements (see Chapter 7.2.1), Measurement Solutions determines the monitoring and measuring activities to be undertaken, as well as the monitoring and measuring equipment needed.

Measurement Solutions establishes processes that ensure that monitoring and measurement can be carried out, and that monitoring and measurement is performed in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment:

a) is calibrated or verified, or both, at specified intervals or prior to use; this calibration or verification is done against measurement standards that are traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded;

b) is adjusted or re-adjusted as necessary; when measuring equipment is found not to conform to requirements, Measurement Solutions assesses and records the validity of previous measuring results; Measurement Solutions takes appropriate action on the equipment and any product that is affected;

c) has a form of identification that enables us to determine its calibration status;

d) is safeguarded from adjustments that would invalidate the measurement results;

e) is protected from damage and deterioration during handling, maintenance and storage.

f) 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.

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

Measurement Solutions maintains records of the results of calibration and verification in compliance with Chapter 4.2.4.

In cases in which we use computer software in the monitoring and measurement of specified requirements, Measurement Solutions confirms the software’s ability to satisfy the intended application. This is done prior to the initial use and reconfirmed as necessary.

8 Measurement, Analysis and Improvement

8.1 General
Measurement Solutions has planned and implemented the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate that our products conform to requirements, and
b) to ensure that our Quality Management System conforms to requirements, and to continually improve its effectiveness.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction
Customer satisfaction is one of the key indicators of the performance of our Quality Management System. FMC Technologies, Measurement Solutions Inc, therefore, monitors information relating to our customers’ perception as to whether Measurement Solutions has met customer requirements.

Measurement Solutions has determined and established the methods used to obtain and to use this information.

8.2.2 Internal Audit
Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for internal audits. This procedure defines the responsibilities and requirements for the planning and conducting of internal audits, for the reporting of audit results, and for maintaining records in compliance with Chapter 4.2.4.
[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. The maximum period between the audits should normally be 12 months and not exceed 14 months.]

8.2.3 Monitoring and Measurement of Processes
Measurement Solutions applies suitable methods for the monitoring and, where applicable, measurement of the processes of our Quality Management System in order to demonstrate that these processes achieve the planned results.

In cases in which the Quality Management Processes do not achieve planned results, Measurement Solutions applies correction and corrective action, as appropriate, to ensure that our products conform to requirements.

8.2.4 Monitoring and Measurement of Product
Measurement Solutions monitors and measures the characteristics of our products at appropriate states of the product realization process and in accordance with planned arrangements (see Chapter 7.1) in order to verify that product requirements have been met. Measurement Solutions maintains records (in compliance with Chapter 4.2.4) providing evidence of conformity to acceptance criteria; these records, also indicate the person(s) authorizing the release of our products for delivery to our customer.

Unless otherwise approved by a relevant authority and, where applicable, by the customer, Measurement Solutions ensures that the release of our products and the delivery of services to our customer do not proceed until the planned arrangements (see Chapter 7.1) have been satisfactorily completed.

[Where routine tests are required by the Ex certificate and by technical documentation, then those tests shall be performed as specified. Unless specifically permitted by the Ex certificate and the technical documentation, statistical methods will not be used.

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

8.3 Control of Nonconforming Product
Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for the control of nonconforming product. This procedure defines how Measurement Solutions ensures that those products that do not conform to product requirements are identified and controlled so that their unintended use or delivery is prevented.

a) [Measurement Solutions maintains a system such that in the event of product not complying with the Ex certificate and having been supplied, then Measurement Solutions customer can be identified;

b) Measurement Solutions takes action, appropriate to the degree of risk, where non-conforming product has been supplied to a customer;

c) Where unsafe, non-conforming product has been supplied to a customer, Measurement Solutions informs its customer, in writing, the body responsible for the verification of the quality system, and the issuer of the Ex certificate;]
d) 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;

e) 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 body responsible for the verification of the quality system in the case of nonconforming product;
   4) the action taken to implement corrective and preventative action;

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

8.4 Analysis of Data

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

The analysis of data is designed to provide information relating to

a) customer satisfaction (see Chapter 8.2.1),

b) conformity to product requirements (see Chapter 8.2.4)

c) characteristics and trends of processes and products including opportunities for preventive action (see Chapters 8.2.3 and 8.2.4), and

d) suppliers (see Chapter 7.4).

8.5 Improvement

8.5.1 Continual Improvement

Measurement Solutions continually improves the effectiveness of our Quality Management System. In order to achieve continual improvement, Measurement Solutions makes use of

- our Quality Policy and Quality Objectives,
- our audit results,
- the analysis of data,
- corrective and preventive actions, and
- Management review.

8.5.2 Corrective Action

Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for corrective action. This procedure defines how Measurement Solutions takes corrective actions to eliminate the cause of nonconformities in order to prevent those nonconformities from recurring.

8.5.3 Preventive Action

Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for preventive action. This procedure defines how Measurement Solutions takes preventive action to eliminate the causes of potential nonconformities in order to prevent the occurrence of those potential nonconformities.