



**PYLON ELECTRONICS INC.**

# **QUALITY MANUAL**

**DOCUMENT NO.: D001**

**REVISION 31**

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## **1.0 INTRODUCTION**

### **1.1 Purpose**

The purpose of this Quality Manual is to define the quality system for Pylon Electronics Inc., Pylon Atlantic – A Division of Pylon Electronics Inc., and Pylon Acquisitions Ltd., which includes Wescan Calibration and JEM Precision Ltd. hereafter referred to as Pylon which has offices at the following addresses:

-147 Colonnade Road, Ottawa, Ontario K2E 7L9

-6355 Danville Road, Unit 10, Mississauga, Ontario L5T 2L4

-31 Trider Crescent, Dartmouth, Nova Scotia B3B 1V6

-9-12240 Horseshoe Way, Richmond, BC V7A 4X9

-2228 Pegasus Way NE, Calgary, AB T2E 8M5, and

-102, 9615-56 Avenue, Edmonton AB T6E 0B2.

The quality system is designed to meet the requirements of ISO/IEC 17025:2017.

### **1.2 Scope**

This document is applicable to all of Pylon's calibration and repair services with the exception of the following exclusion:

- 1) The Instrumentation Division products and services because this division is not included in our scope.

### **1.3 Documentation Review**

This manual and all referenced procedures and work instructions shall be periodically reviewed and revised, as necessary, to ensure continuing suitability and compliance with the applicable requirements. All revisions shall be made in accordance with Pylon procedure D009 - Documentation Control Procedure.

The cognizant Manager(s) are responsible for the review. All new revisions shall receive the approval of the appropriate management levels.

Any individual may request a change to any part of the Quality Manual, referenced procedures and work instructions. All requests shall be addressed to the cognizant Manager(s).

## 1.4 Revision History

REV	EFFECTIVE DATE	REASON FOR RE-ISSUE
1	Sep 1995	First Version
2	Oct 1995	Corrected nonconformances noted during Registrar's review.
3	Jan 1996	Corrected concerns noted during implementation audits.
4	Jan 1997	Revised Organization Chart & responsibilities to match actual organization.
5	Jan 1997	Revised Paragraph 20 to address KPMG Nonconformance 046-NC-A1-02.
6	Jan 1998	Revised document to reflect new organizational structure and to add Mississauga operation.
7	Mar 1998	Revised Paragraph 2.1 to address KPMG Concern 046.2-CN-DR2-01.
8	Sep 1998	Revised to include ISO/IEC Guide 25 requirements.
9	Jun 1999	Revised to address NRC Level 1 Requirement (Quality Policy) and NRC Level 2 Requirement (Designates).
10	Sep 1999	Revised to address NRC Level 1 and 2 Requirements found during the quality system audit.
11	Feb 2001	Revised to remove references to the distribution and avionics processes and incorporate organizational changes.
12	Oct 2001	Revised to incorporate ISO/IEC 17025 requirements.
13	Jul 2003	Complete re-write to incorporate ISO 9001:2000 requirements.
14	Sep 2003	Revised to address BSI nonconformance on the sequence and interaction of the quality management processes that was raised during the ISO 9000:2000 upgrade documentation review. Also renumbered and moved the figures.
15	Sep 2004	Revised the quality policy to more accurately meet the ISO 9000:2000 requirements.
16	Jun 2005	Deleted D005 references and added ISO 10005:2004 reference. Updated Mississauga organization chart.
17	Dec 2005	Revised organization to add Pylon Atlantic and show new organization. Revised the quality policy to redefine the objectives. Minor updates and corrections to clarify the intent.
18	May 2006	Revised to update ISO/IEC 17025 reference, update Mississauga & Dartmouth organization charts, address NRC requirement 1.1 f), and make minor corrections.
19	Aug 2006	Revised to update corporate re-organization due to sale of Power Group and new Mississauga address. Updated Figure 1.
20	Feb 2007	Revised quality policy to meet the requirements of para 4.2.2 e) of ISO/IEC 17025:2005.

REV	EFFECTIVE DATE	REASON FOR RE-ISSUE
21	Jan 2009	Revised to update procedure title references, organization charts and make other minor revisions.
22	Aug 2010	Revised to meet the requirements of ISO 9001:2008, to add the permissible exclusions, and make other minor changes.
23	Sep 2012	Revised the scope to clarify the exclusions.
24	Jan 2015	Replaced CLAS and NRC references with appropriate generic ISO/IEC 17025 references.
25	Jan 2016	Complete re-write to replace ISO 9001 with ISO/IEC 17025.
26	Aug 2016	Clarified the type of calibration certificate for the contents described in para 3.10.2.
27	Sep 2018	Revised to update section 2.2.2.1 to correct A2LA identified deficiency. The Corporate Quality Assurance Manager was also updated. Removed reference to obsolete ISO 10005.
28	Sep 2019	Complete re-write to reflect the latest version of the standard, ISO/IEC 17025:2017
29	Mar 2020	Revised to remove references to ISO/IEC 17025:2005.
30	May 2022	Revised for a corporate reorganization.
31	Jun 2023	<a href="#">Updated section 3.0 Structural Requirements</a>

## 1.5 Approvals

This document has been approved by the following personnel:

Position	Name
President	Jarett Grant
Senior Manager, Operations	Sunil Ramesh
Senior Manager, Corporate Performance	Lydia Robinson
Senior Manager, Finance	Carolyn Crawford

## 1.6 Responsibility

All departments within Pylon are responsible for ensuring that the procedures described herein are followed.

The Senior Manager, Corporate Performance is responsible for this document. Any requests for change shall be addressed to the Senior Manager, Corporate Performance. Incomplete or ambiguous documentation shall be brought to the attention of the Senior Manager, Corporate Performance for resolution.

Throughout this document and the various referenced documents, only the position that has the main responsibility for the task is provided. However, the term “or designate” is implied in every case. A designate is defined as a person who can perform the tasks because of

education, training, experience and/or background. In the event that a suitable designate is not available, the matter shall be referred to the next level of management for resolution.

## **1.7 References**

1. ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
2. D002, Vendor Evaluation Procedure
3. D003, Incoming Inspection Procedure
4. D004, In-Process and Final Inspection Procedure
5. D007, Corrective and Preventive Action Procedure
6. D008, Electrostatic Discharge Protection Procedure
7. D009, Documentation Control Procedure
8. D012, Calibration Department Operating Procedures  
D013, Material Section Operating Procedures
9. D014, Traffic Section Operating Procedures
10. D015, Contract Review Procedure  
D022, Customer Supplied Product Control Procedure
11. D023, Training Procedure
12. D024, Management Review Procedure
13. D025, Quality Records Procedure
14. D026, Internal Audit Procedure
15. D031, Protection of Customer's Confidential Information Procedure
16. D032, Control of Nonconforming Product Procedure
17. D033, Risk and Opportunities Analysis Procedure
18. D034, Laboratory Information Management System Control Procedure
19. D035, DND Operations Procedure

## **2.0 GENERAL REQUIREMENTS**

### **2.1 Impartiality**

- 2.1.1 Pylon's activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.
- 2.1.2 Pylon's management shall be committed to impartiality.
- 2.1.3 Pylon shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressure to compromise impartiality.
- 2.1.4 Pylon shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationship of its personnel. However, such relationships do not necessarily present Pylon with a risk to impartiality.

2.1.5 If a risk to impartiality is identified, Pylon shall be able to demonstrate how it eliminates or minimizes such risk.

## 2.2 Confidentiality

2.2.1 Pylon shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of Pylon's activities. Pylon shall inform the customer in advance of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between Pylon and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

2.2.2 When Pylon is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

2.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and Pylon. The provider(source) of this information shall be confidential to Pylon and shall not be shared with the customer, unless agreed by the source.

2.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of Pylon's activities, except where required by law.

## 3.0 STRUCTURAL REQUIREMENTS

3.1 Pylon is a legal entity that is legally responsible for its laboratory activities.

3.2 Pylon shall and has identified management that has overall responsibility for the laboratory.

3.3 Pylon performs two types of calibrations- accredited and non-accredited calibrations. Accredited calibration shall be performed in accordance with ISO/IEC 17025:2017 and each laboratory location's capabilities are listed on their respective scopes of accreditation.

3.4 Pylon's activities shall be carried out in such a way as to meet the requirements of this document, Pylon's customers, regulatory authorities and organizations providing recognition. This shall include Pylon's activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

3.5 Pylon shall and has:

a) defined the organization and management structure of the laboratory, and the relationships between management, technical operations and support services.

- b) specified the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of laboratory activities;
- c) documented its procedures to the extent necessary to assure the consistent application of its laboratory activities and the validity of results.

### 3.5.1 Responsibility and Authority

Top management shall ensure that responsibilities and authorities are defined and communicated within Pylon. The following provides an overview of the organization, responsibilities, and authorities.

Figure 1 shows the Corporate Organization structure of Pylon Electronics Inc.

Figure 2 shows the Regional Lab Management structure.

Figure 3, 4, 5, 6, and 7 provide the Organization Charts for Ottawa, Mississauga, Dartmouth, Edmonton, and Calgary / Richmond respectively.



Figure 1- Pylon Electronics Inc. Corporate Organization Structure

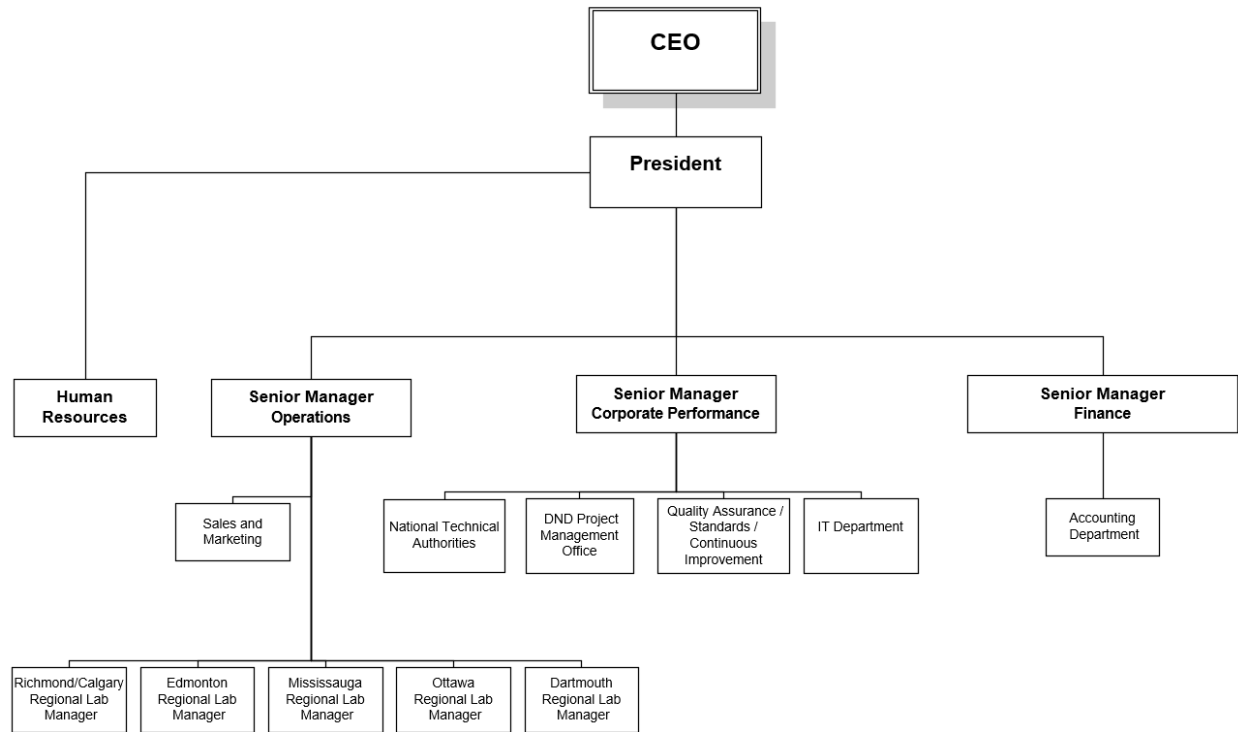


Figure 2- Pylon Electronics Inc. Regional Lab Structure

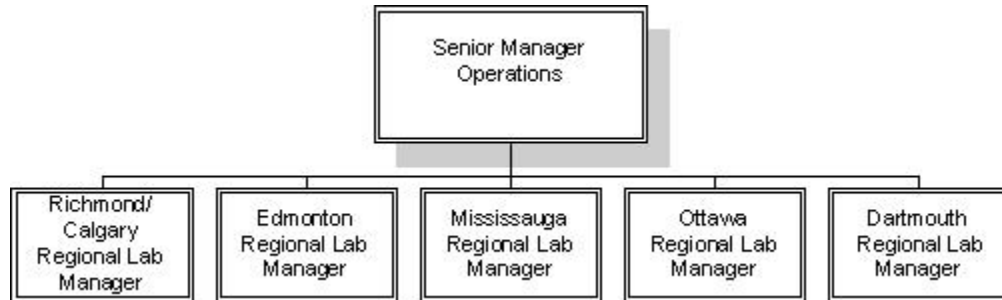


Figure 3- Ottawa Lab Organization Chart

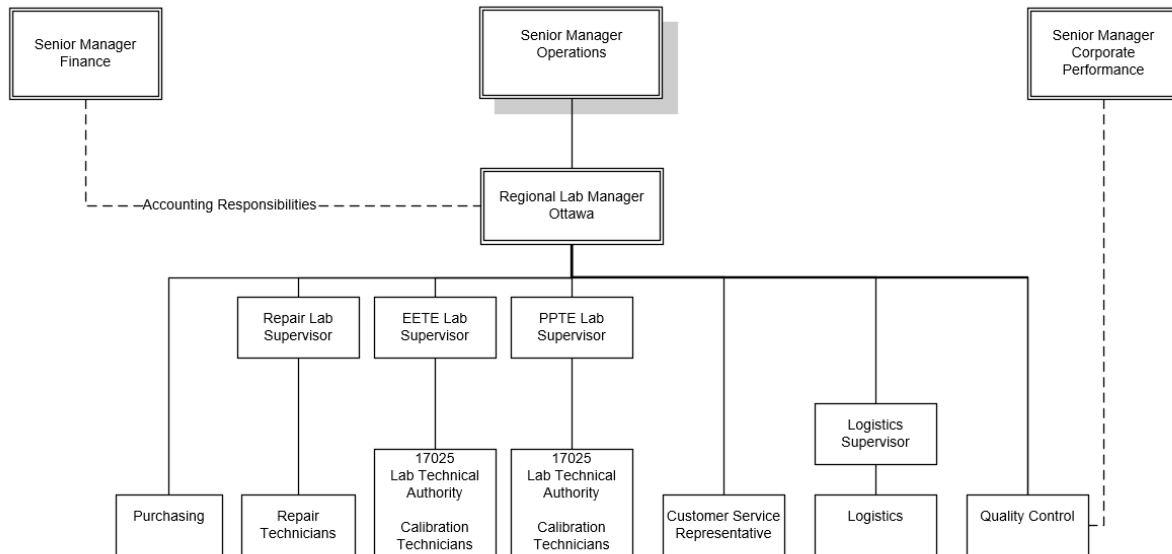


Figure 4- Dartmouth Lab Organization Chart

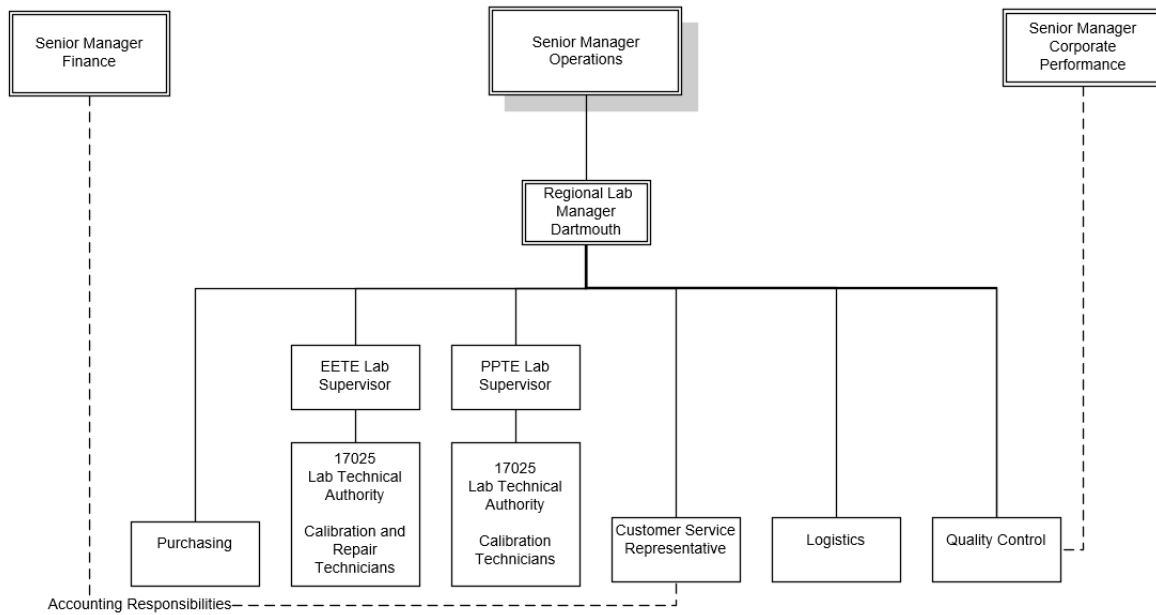


Figure 5- Mississauga Lab Organization Chart

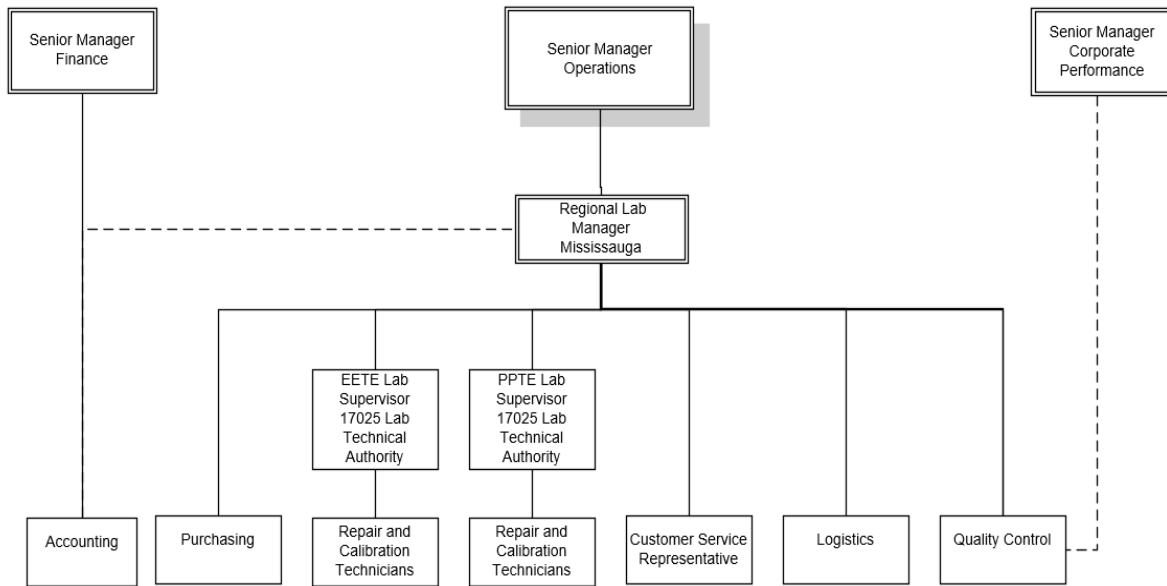


Figure 6- Edmonton Lab Organization Chart

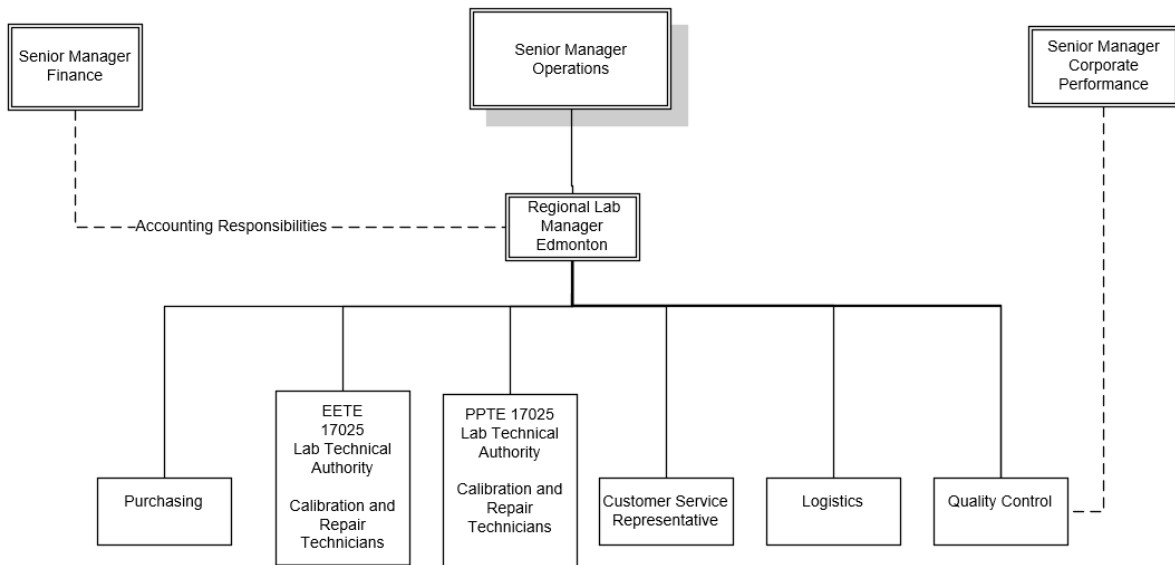
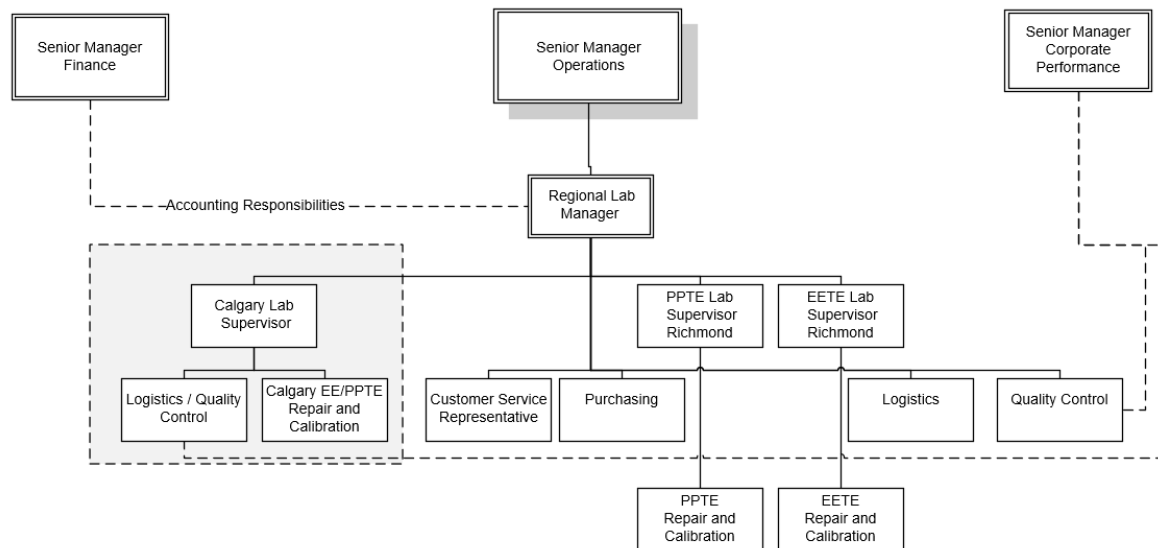


Figure 7- Richmond / Calgary Lab Organization Chart



### 3.5.1.1 General

All senior management, Regional Lab Managers and Lab Supervisors, and the 17025 Technical Authorities are responsible for ensuring compliance with ISO/IEC 17025:2017.

In the event that a key Manager, a key Supervisor or a 17025 Technical Authority is absent, a qualified deputy may be nominated and identified in advance of the absence in order to maintain continuity. The identity of the deputy shall be disseminated to the cognizant managers.

#### 3.5.1.1.1 President

The President has the responsibility and authority to direct and control the management of all aspects of the Pylon operations at the highest level.

#### 3.5.1.1.2 Senior Manager Operations

The Senior Manager Operations is responsible for all operations functions within the organization. This includes:

- Directing and approving the addition of new marketing and sales plans.
- Oversee the establishment of competitive pricing to ensure profitability and customer retention.
- Managing the financial performance and P&L of all labs including but not exclusive to, approving the addition or replacement of equipment used by the labs to conduct testing by either procuring new funds or relocation of existing funds.
- Ensuring all transportation needs are met, including but not limited to fleet maintenance management, pricing, additions to the fleet.
- Managing all facets of Commercial customer management.
- Directing the local training at all labs to ensure consistency across Pylon Electronics.
- Managing the HRM hire/fire of employees in collaboration with HRM and Operations Managers
- Collaborating with the Manager Corporate Performance in all specified areas; DND customer management, Business systems, operational processes, and continuous improvement.
- Other specific tasks as directed or developed by the President

#### 3.5.1.1.3 Senior Manager Corporate Performance

The Senior Manager of Corporate Performance is responsible to oversee and direct those business elements that promote effective and efficient operations including but not limited to continuous improvement initiatives focussed on a commitment to delivering quality calibration and customer service performance.

- Directing all necessary activities associated with Business Systems and IT security.
- Administrate/oversee the implementation of all Operational processes across all Pylon Electronics labs.
- Establishing and managing the overall direction of the quality system in accordance with industry standards.
- Directing all facets of DND customer management in collaboration with the President.
- Directing the Corporate improvements that need to be made across Pylon Electronics in collaboration with all Senior Managers and the President.
- Establishing the best Book value of calibrations and implementing them across Pylon Electronics.
- Ensuring optimal and on-time technical training including on-the-job training for the maintenance of technical credentials.
- Other specific tasks as directed or developed by the President



#### 3.5.1.1.4 Senior Manager Finance

The Senior Manager Finance is responsible for all accounting functions within the organization. This includes:

- Establishing the corporate budget in collaboration with the President, ensuring the growth and profitability of Pylon Electronics.
- Overseeing and approving monthly/annual lab budgets to ensure alignment with the financial goals of Pylon Electronic.
- Directing all necessary activities associated with corporate security, and controlled goods of personnel.
- Oversee the accounting function of Pylon, ensuring that accounting records are kept appropriately and that reported results comply with accounting standards
- Managing all/any relationships with external accounting personnel
- Providing both financial to the President.
- Other specific tasks as directed or developed by the CEO or President

#### 3.5.1.1.5 Regional Lab Manager

The Regional Lab Manager is responsible for the successful day to day administrative operation of the facility with an emphasis on ensuring the provision of quality technical calibration services that meet customer needs. This position reports directly to the Senior Manager of Operations with in-direct reporting duties to other members of the Senior Leadership Team as outlined in the Facility Organization Chart.

Responsibilities include but are not limited to:

- Managing day to day operations of both technical and administrative areas of Pylon's business which may include but not limited to:
  - Successful operation of calibration labs including effective management of Turn Around Times (TAT) and all other related customer needs such as Customer Support (including involvement in DND Customer Management), Communication, Scheduling and logistics, and Program/Asset Management,
  - Ensuring customer retention, promoting and tracking sales and profitability according to budget,
  - Accounting and Human Resource requirements as necessary including either assuming or delegating invoicing tasks,
  - Supporting and executing the operational processes for effective management of personnel, resources, and equipment for high quality calibrations,
  - Supporting the provision of timely technical training and personnel development,
  - Final approval of all leave/bank hours for facility personnel and timecard sign-off,

- Regular evaluation of direct-reports performance,
  - Addressing Quality Issues at the facility, and
  - Interfacing with other Pylon facilities for technical support.
- 
- Supporting all aspects of Pylon's Strategic Direction as outlined by the President of Pylon.
  - Other specific tasks as directed by the Senior Manager of Operations.
  - Reference the Senior Leadership Roles and Responsibilities Matrix.

#### 3.5.1.1.6 Quality Control

Under the direction of the Regional Lab Manager, with indirect reporting responsibilities to the Senior Manager Corporate Performance, Quality Control is responsible for carrying out final inspections on equipment.

Responsibilities include but are not limited to:

- Carrying out final inspection on equipment in for service,
- Ensuring customer requirements for calibration and repair have been carried out,
- Opening and documenting rejections and re-inspecting equipment upon fix being completed
- Liaising with receiving, customer service, and the lab regarding issues that arise
- Reporting directly to the Regional Lab Manager on any trends observed,
- Liaising with others within Pylon on matters relating to customer deliverables.
- Other specific tasks as directed or developed by the Regional Lab Manager.

#### 3.5.1.1.7 Logistics [Supervisor](#)

The Logistics [Supervisor](#) is responsible for coordinating the Traffic department within the facility. This is a working Supervisor position, and the person is responsible for carrying out tasks along with team members.

Responsibilities include but are not limited to:

- Overseeing the receiving of all material including customer equipment for repair or calibration and parts,
- Coordinating the packing and shipping all deliverables including subcontracted equipment,
- Overseeing customer equipment pick-ups and deliveries as well as company vehicle maintenance
- Responsible for receiving and shipping functions, and
- Other specific tasks as directed by the [Regional Lab Manager](#).

#### 3.5.1.1.8 Logistics

Reporting to the Logistics [Supervisor](#), Logistics is responsible for tasks supporting Traffic within the facility.

Responsibilities include but are not limited to:

- Adhering to all Shipping and Receiving procedures,
- Packing and shipping all deliverables including subcontracted equipment,
- Executing customer equipment pick-ups and deliveries in company vehicles,
- Responsible for executing receiving and shipping functions in POMS, and
- Other specific tasks as directed or developed by the Logistics [Supervisor](#).

#### 3.5.1.1.9 Purchasing

Reporting directly to the Regional Lab Manager, Purchasing is responsible to be the primary facility resource for all suppliers.

Responsibilities include but are not limited to:

- Negotiate with suppliers for quotes and contracts, and issue purchase orders as required,
- Ensure the inclusion of quality requirements in all purchase orders and contracts,
- Vendor maintenance and concern management,
- Follow-up of placed orders to ensure on-time delivery, and
- Other specific tasks as directed or developed by the Regional Lab Manager.

#### 3.5.1.1.10 Lab Supervisor

Reporting to the Regional Lab Manager, the Lab Supervisor is responsible for the day-to-day technical operations of the specific calibration labs (PPTE, EETE, and Electronics Repair) within the facility.

Responsibilities include but are not limited to:

- Ensuring that the outgoing equipment conforms to all calibration standards including overseeing the technical work performed by Lab Leads and technicians,
- Ensuring/facilitating meeting Turn Around Times (TATs) targets,
- Ensure appropriate Asset Management,
- Supervising lab technical personnel,
- Lab capability requirements/deficiencies are identified and raised for review,
- Participating in Technology planning for the specific labs,
- Ensuring on-time technician training and professional development,
- Ensuring adherence to all industry regulated calibration (ISO 17025) and repair processes as well as internal Operational and Quality processes

- Coordinating with customers concerning any problems or ambiguities with contract work, in cooperation with the Quality Control, [Customer Service Representatives](#) and the Regional Lab Manager,
- Coordination of leave/bank hours approval for technical staff and sign-off on time cards,
- Coordination of on-site work,
- Regular evaluation of technical performance, and
- Other specific tasks as directed or developed by the Regional Lab Manager.

#### 3.5.1.1.11 National Technical Authorities

The National Technical Authorities are responsible for tasks supporting Pylon's ISO/IEC 17025:2017 accreditation.

Responsibilities include but are not limited to:

- Technical oversight of the laboratories
- Assist Managers as required - special projects / assignments
- Conduct calibrations with technical staff
- Conduct quality assurance activities

#### 3.5.1.1.12 Lab Technical Authorities and Technicians

The Lab Technical Authorities (TA) and Technicians are responsible for the day-to-day operation of the electrical and physical calibration labs [at the local level](#).

Responsibilities include but are not limited to:

- Prioritizing and performing in-house and insitu calibrations according to standards.
- Other specific tasks as directed or developed by the Lab Supervisor.

The Lab TAs responsibilities are the same as the technicians with the following additions:

- Oversight of specific ISO 17025 activities

The Lab TAs and technicians report to the Lab Supervisor for the day-to-day operation of the lab including administrative and technical [issues](#).

#### 3.5.1.1.13 Customer Service Representative

Reporting to the [Regional Lab Manager](#), the Customer Service Representative is responsible for managing daily activities on customer accounts.

Responsibilities include but are not limited to:

- Maintaining customer records,
- Providing customers with quotations,
- Providing timely follow-up when required,
- Receiving any customer complaints and ensuring that the complaint is either addressed or identified for action to the Regional Lab Manager for a timely response,
- Scheduling on-site projects,
- Interfacing with technical and administrative staff, serving as the client advocate, and
- Other duties as directed by the Regional Lab Manager.

#### 3.5.1.1.14 Accounting

Reporting directly to the Senior Manager Finance, but with indirect reporting responsibilities to the Regional Lab Manager, Accounting is responsible for all accounting functions within the regional facility.

Responsibilities include but are not limited to:

- Accounting responsibilities as directed,
- Invoicing, and
- Other duties as directed by the Senior Manager Finance.

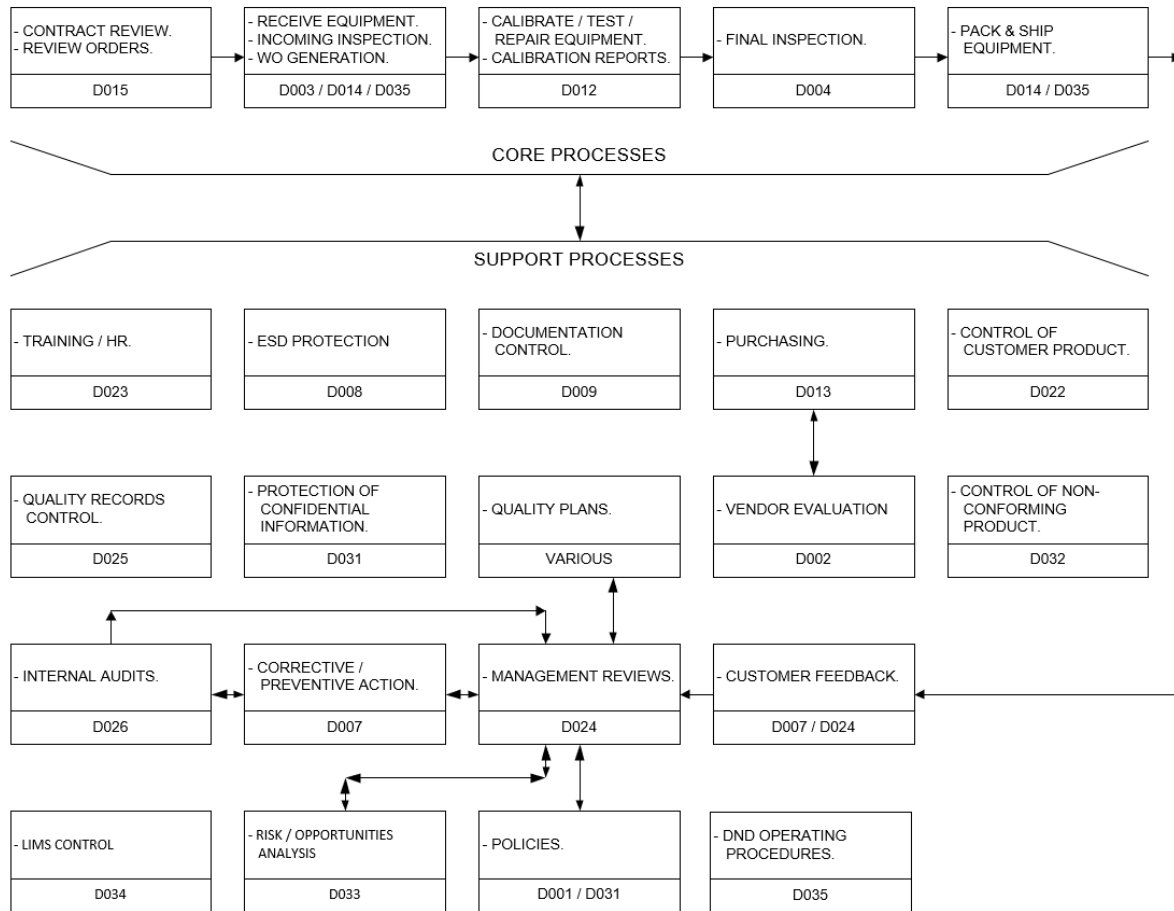
#### 3.5.1.1.15 Approved Signatories

Each manager is an approved signatory for the area of responsibility. The managers are responsible for identifying approved signatories within their department, when appropriate and required.

### 3.5.2 Interaction between Core and Support Processes

Figure 8 indicates the sequence and interaction of Pylon's core and support processes.

**Figure 8 - Sequence & Interaction of Pylon's Processes**



3.6 Pylon has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

- implementation, maintenance and improvement of the management system;
- identification of deviations from the management system or from the procedures for performing laboratory activities;
- initiation of actions to prevent or minimize deviations;

- d) reporting to Pylon's management on the performance of the management system and any need for improvement;
- e) ensuring the effectiveness of Pylon's activities.

3.7 Pylon's management shall ensure that:

- a) communications takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
- b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

## **4.0 RESOURCE REQUIREMENTS**

### **4.1 General**

Pylon shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

### **4.2 Personnel**

- 4.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall and will act impartially, be competent and work in accordance with Pylon's management system.
- 4.2.2 Pylon shall and has documented the competence requirements for each function influencing the results of Pylon's activities, including requirements for education, qualification, training, technical knowledge, skills and experience.
- 4.2.3 Pylon shall ensure that personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.
- 4.2.4 The management of Pylon shall communicate to personnel their duties, responsibilities, and authorities.
- 4.2.5 Pylon shall have procedure(s) and retain records for:
  - a) determining the competence requirements;
  - b) selection of personnel;
  - c) training of personnel;
  - d) supervision of personnel;

- e) authorization of personnel;
  - f) monitoring of competence of personnel.
- 4.2.6 Pylon shall authorize personnel to perform specific laboratory activities, including, but not limited to, the following:
- a) development, modification, verification and validation methods of methods;
  - b) analysis of results, including statements of conformity or opinions and interpretations;
  - c) report, review and authorization of results.
- 4.3 Facilities and environmental conditions
- 4.3.1 The facilities and environmental conditions shall be suitable for Pylon's activities and shall not adversely affect the validity of results.
- 4.3.2 The requirements for facilities and environmental conditions necessary for the performance of Pylon's activities shall be documented.
- 4.3.3 Pylon shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.
- 4.3.4 Measures to control facilities shall be implemented, monitored, and periodically reviewed and shall include, but not be limited to:
- a) access to and use of areas affecting Pylon's activities;
  - b) prevention of contamination, interference or adverse influences on Pylon's activities;
  - c) effective separation between areas with incompatible laboratory activities.
- 4.3.5 When Pylon performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.
- 4.4 Equipment
- 4.4.1 Pylon shall have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which are required for the correct performance of Pylon's activities and which can influence the result.



- 4.4.2 When Pylon uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.
- 4.4.3 Pylon shall have a procedure for handling, transport, storage, use and planned maintenance of equipment to ensure proper functions and to prevent contamination or deterioration.
- 4.4.4 Pylon shall verify that equipment conforms with specified requirements before being placed or returned into service.
- 4.4.5 The equipment used for measurement shall be capable of achieving the measurement of accuracy and/or measurement uncertainty required to provide a valid result.
- 4.4.6 Measuring equipment shall be calibrated when:
- the measurement accuracy or measurement uncertainty affects the validity of the reported results; and/or
  - calibration of the equipment is required to establish the metrological traceability of the reported results.
- 4.4.7 Pylon shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.
- 4.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.
- 4.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. Pylon shall examine the effect of the defect or deviation from specified requirements and shall initiate management of nonconforming work procedure.
- 4.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.
- 4.4.11 When calibration and reference material data include reference values or correction factors, Pylon shall ensure that reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.
- 4.4.12 Pylon shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

4.4.13 Records shall be retained for equipment which can influence Pylon's activities. The records shall include the following, where applicable:

- a) the identity of the equipment, including software and firmware version;
- b) the manufacturer's name, type identification, and serial number or other unique identification;
- c) evidence of verification that equipment conforms to with specified requirements;
- d) the current location;
- e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
- f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
- g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
- h) details of any damage, malfunction, modification to, or repair of, the equipment.

#### 4.5 Metrological traceability

4.5.1 Pylon shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

4.5.2 Pylon shall ensure that measurement results are traceable to the International System of Units(SI) through:

- a) calibration provided by a competent laboratory; or
- b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards

4.5.3 When metrological traceability to the SI units is not technically possible, Pylon shall demonstrate metrological traceability to an appropriate reference, e.g.:

- a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

#### 4.6 Externally provided products and services

##### 4.6.1 Pylon shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- a) are intended for incorporation into Pylon's own activities;
- b) are provided, in part or in full, directly to the customer by Pylon, as received from the external provider;
- c) are used to support the operation of the laboratory.

##### 4.6.2 Pylon shall have a procedure and records for:

- a) defining, reviewing and approving Pylon's requirements for externally provided products and services;
- b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
- c) ensuring that externally provided products and services conform to Pylon's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
- d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

##### 4.6.3 Pylon shall communicate its requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that Pylon, or its customers, intends to perform at the new external provider's premises

## 5.0 PROCESS REQUIREMENTS

### 5.1 Review of requests, tenders and contracts

- 5.1.1 Pylon shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:
- a) the requirements are adequately defined, documented and understood;
  - b) Pylon has the capability and resources to meet the requirements;
  - c) where external providers are used, the requirements of 4.6 are applied and Pylon advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;
  - d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.
- 5.1.2 Pylon shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.
- 5.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule shall be communicated to, and agreed with, the customer.
- 5.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to Pylon and the customer. Deviations requested by the customer shall not impact the integrity of Pylon or the validity of results.
- 5.1.5 The customer shall be informed of any deviation from the contract.
- 5.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.
- 5.1.7 Pylon shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring Pylon's performance in relation to the work performed.
- 5.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of Pylon's activities.
- 5.2 Selection, verifications and validation of methods
- 5.2.1 Selection and verification of methods
- 5.2.1.1 Pylon shall use appropriate methods and procedures for all laboratory activities and, where, appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

- 5.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to Pylon's activities, shall be kept up to date and shall be made readily available to personnel.
- 5.2.1.3 Pylon shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.
- 5.2.1.4 When the customer does not specify the method to be used, Pylon shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment are recommended. Laboratory-developed or modified methods can also be used.
- 5.2.1.5 Pylon shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.
- 5.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.
- 5.2.1.7 Deviations from methods for all Pylon activities shall only occur if the deviation has been documented, technically justified, authorized, and accepted by the customer.
- 5.2.2 Validation of methods
- 5.2.2.1 Pylon shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.
- 5.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.
- 5.2.2.3 The performance characteristics of validated methods as assessed for the intended use, shall be relevant to the customer's needs and consistent with specified requirements.
- 5.2.2.4 Pylon shall retain the following records of validation:
- a) the validation procedure used;

- b) specification of the requirements;
- c) determination of the performance characteristics of the method;
- d) results obtained;
- e) a statement on the validity of the method, detailing its fitness for the intended use.

### 5.3 Sampling

Pylon does not carry out sampling activities.

### 5.4 Handling of test or calibration items

5.4.1 Pylon shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the Pylon and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during the handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with item shall be followed.

5.4.2 Pylon shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of Pylon. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

5.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, Pylon shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, Pylon shall include a disclaimer in the report indicating which results may be affected by the deviation.

5.4.4 When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored, and recorded.

### 5.5 Technical Records

5.5.1 Pylon shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement results and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and identity of personnel responsible for each

laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

- 5.5.2 Pylon shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

5.6 Evaluation of measurement uncertainty

- 5.6.1 Pylon shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty all contributions which are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

- 5.6.2 When Pylon is performing calibrations, including on its own equipment, it shall evaluate the measurement uncertainty for all calibrations.

- 5.6.3 If Pylon is performing testing, it shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

5.7 Ensuring the validity of results

- 5.7.1 Pylon shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. The monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

- a) use of reference materials or quality control methods;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standard with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replicate tests or calibrations using the same or different methods;
- g) retesting or recalibration of retained items;
- h) correlation of results for different characteristics of an item;

- i) review of reported results;
  - j) intralaboratory comparisons;
  - k) testing of blind sample(s).
- 5.7.2 Pylon shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
- a) participation in proficiency testing;
  - b) participation in interlaboratory comparisons other than proficiency testing.
- 5.7.3 Data from monitoring activities shall be analysed and used to control and, if applicable, improve Pylon's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.
- 5.8 Reporting of results
- 5.8.1 General
- 5.8.1.1 The results shall be reviewed and authorized prior to release.
- 5.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. test report or a calibration certificate or report of sampling) and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.
- 5.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 5.8.2 to 5.8.7 that is not reported to the customer shall be readily available.
- 5.8.2 Common requirements for reports (test, calibration, or sampling)
- 5.8.2.1 Each report shall include at least the following information, unless Pylon has valid reasons for not doing so, thereby minimizing any possibility or misunderstanding or misuse:
- a) a title(e.g. "Test report", or "Calibration certificate");
  - b) the name and address of the laboratory;



- c) the location of performance of Pylon's activities, including when performed at a customer facility or at sites away from Pylon's permanent facilities, or in associated temporary or mobile facilities.
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e) the name and contact information of the customer;
- f) identification of the method used;
- g) a description, unambiguous identification, and, when necessary, the condition of the item;
- h) the date of receipt of the test or calibration item(s), or the date of sampling, where this is critical to the validity and application of the results;
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the report;
- k) a statement to the effect that the results relate only to the items tested or calibrated;
- l) the results with, where appropriate, the units of measurement;
- m) additions to, deviations, or exclusions from the method;
- n) identification of the person(s) authorizing the report;
- o) clear identification when results are from external providers;

5.8.2.2 Pylon shall be responsible for all the information provided in the report, except when the information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results.

### 5.8.3 Specific requirements for test reports

Pylon does not perform testing.

### 5.8.4 Specific requirements for calibration certificates

#### 5.8.4.1 In addition to the requirements listed in 5.8.2, calibration certificates shall include the following:

- a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);
- b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
- c) a statement identifying how the measurements are metrologically traceable;
- d) the results before and after any adjustment or repair, if available;
- e) where relevant, a statement of conformity with requirements or specifications (5.8.6);
- f) where appropriate, opinions and interpretations (see 5.8.7).

#### 5.8.4.2 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.

### 5.8.5 Reporting sampling – specific requirements

Pylon does not perform sampling.

### 5.8.6 Reporting statements of conformity

#### 5.8.6.1 When a statement of conformity to a specification or standard is provided, Pylon shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

#### 5.8.6.2 Pylon shall report on the statement of conformity, such that the statement clearly identifies:

- a) to which results that statement of conformity applies;
- b) which specifications, standard or parts thereof are met or not met;
- c) the decision rule applied (unless it is inherent in the requested specification or standard).

#### 5.8.7 Reporting opinions and interpretations

5.8.7.1 When opinions and interpretations are expressed, Pylon shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. Pylon shall document the basis upon which the opinions and interpretations have been made.

5.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

5.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

#### 5.8.8 Amendments to reports

5.8.8.1 When an issued report needs to be changed, amended or re-issued any change of information shall be clearly identified and, when appropriate, the reason for the change included in the report.

5.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number...[or as otherwise identified]”, or an equivalent form of wording.

Such amendments shall meet all requirements of this document.

5.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

#### 5.9 Complaints

5.9.1 Pylon shall have a documented process to receive, evaluate and make decisions on complaints.

5.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, Pylon shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. Pylon shall be responsible for all decisions at all levels of the handling process for complaints.

5.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

- b) tracking and recording complaints, including actions undertaken to resolve them;
  - c) ensuring that any appropriate action is taken.
- 5.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.
- 5.9.5 Whenever possible, Pylon shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.
- 5.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in questions.
- 5.9.7 Whenever possible, Pylon shall give formal notice of the end of the complaint handling to the complainant.
- 5.10 Nonconforming work
- 5.10.1 Pylon shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fails to meet specified criteria). The procedure shall ensure that:
- a) the responsibilities and authorities for the management of nonconforming work are defined;
  - b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
  - c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
  - d) a decision is taken on the acceptability of the nonconforming work;
  - e) where necessary, the customer is notified and work is recalled;
  - f) the responsibility for authorizing the resumption of work is defined.
- 5.10.2 Pylon shall retain records of nonconforming work and actions as specified in 5.10.1, b) to f).
- 5.10.3 Where the evaluation indicated that the nonconforming work could recur, or that there is doubt about the conformity laboratory's operations with its own management system, Pylon shall implement corrective action.

## 5.11 Control of data and information management

5.11.1 Pylon shall have access to the data and information needed to perform laboratory activities.

5.11.2 Pylon's laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management systems(s) by Pylon before introduction. Whenever there are any changes, including laboratory software configuration or modification to commercial off-the-shelf software, they shall be authorized, documented, and validated before implementation.

5.11.3 Pylon's laboratory information management system shall:

- a) be protected from unauthorized access;
- b) be safeguarded against tampering and loss;
- c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- d) be maintained in a manner that ensures the integrity of the data and information;
- e) include recording system failures and the appropriate immediate and corrective actions.

5.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, Pylon shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

5.11.5 Pylon shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

5.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

## 6.0 MANAGEMENT SYSTEM REQUIREMENTS

### 6.1 Options

#### 6.1.1 General

Pylon has established, documented, implemented and maintained a management system capable of supporting and demonstrating the consistent achievement of the requirements

of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of clauses 2 to 5, Pylon has implemented a management system in accordance with Option A from ISO/IEC 17025:2017.

#### 6.1.2 Option A

As a minimum, Pylon's management system addresses the following:

- management system documentation
- control of management system documents
- control of records
- action to address risks and opportunities
- improvement
- corrective action
- internal audits
- management review

#### 6.1.3 Option B

This option is not applicable to Pylon.

### 6.2 Management system documentation

6.2.1 Pylon's management shall and has established, documented and maintained policies and objectives for the fulfilment of the purposes of this quality manual and shall ensure that policies and objectives are acknowledged and implemented at all levels of Pylon's organization.

6.2.2 The policies and objectives shall and do address, amongst other things, the competence, impartiality and consistent operation of Pylon's laboratories.

Pylon's policies are to:

- 1) Provide quality services that meet all established requirements, while aiming to exceed the expectations of Pylon's customers. These services include calibration and repair services for electrical, electronic and physical property test equipment.

- 2) Provide correct and reliable calibration services in accordance with the requirements of ISO/IEC 17025:2017. All Pylon personnel concerned with calibration activities actively participate in ensuring quality in our organization by familiarizing themselves with Pylon's quality documentation, which finds its basis in the standard, and implementing those policies and procedures in their work.
- 3) Continually improve the effectiveness of the management system.
- 4) Act impartially in the performance of laboratory activities.

To meet these policies, Pylon is committed to the following objectives:

- 1) Meeting customer expectations regarding turnaround time to the best of our ability.
  - 2) Providing customer satisfaction to the best of our ability.
  - 3) Minimizing warranty return rates associated with Pylon's work.
  - 4) Monitoring the calibration and repair processes with rejection rates.
  - 5) Mitigating and controlling situations where lack of impartiality might exist.
- 6.2.3 Pylon's management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.
- 6.2.4 All documentation, processes, systems, and records related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.
- 6.2.5 All personnel involved in Pylon's activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.
- 6.3 Control of management system documents
- 6.3.1 Pylon shall control the documents (internal and external) that relate to the fulfilment of this document.
- 6.3.2 Pylon shall ensure that:
- a) documents are approved for adequacy prior to issue by authorized personnel;
  - b) documents are periodically reviewed, and updated as necessary;
  - c) changes and current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) documents are uniquely identified;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

#### 6.4 Control of records

6.4.1 Pylon shall establish and retain legible records to demonstrate fulfillment of the requirements in this document.

6.4.2 Pylon shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. Pylon shall retain records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality commitments and records shall be readily available.

#### 6.5 Actions to address risks and opportunities

6.5.1 Pylon shall consider the risk and opportunities associated with Pylon's activities in order to:

a) give assurance the management system can achieve its intended results;

b) enhance opportunities to achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts and potential failures in Pylon's activities;

d) achieve improvement.

6.5.2 Pylon shall plan:

a) actions to address these risks and opportunities;

b) how to:

- integrate these actions into its management system;

- evaluate the effectiveness of these actions.

6.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.



## 6.6 Improvement

6.6.1 Pylon shall identify and select opportunities for improvement and implement any actions.

6.6.2 Pylon shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities, and customer service.

## 6.7 Corrective actions

6.7.1 When a nonconformity occurs, Pylon shall:

a) react to the nonconformity and, as applicable:

-take action to control and correct it;

- address the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

-reviewing and analysing the nonconformity;

-determining the causes of the nonconformity;

-determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

6.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

6.7.3 Pylon shall retain records as evidence of:

a) the nature of nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

## 6.8 Internal audits

6.8.1 Pylon shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:

- Pylon's own requirements for its managements system, including the laboratory activities;

-the requirements of this document;

b) is effectively implemented and maintained.

6.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

b) define the audit criteria and scope of each audit;

c) ensure that the results of the audits are reported to the relevant management;

d) implement appropriate correction and corrective actions without undue delay;

e) retain records as evidence of the implementation of the audit programme and the audit results.

## 6.9 Management reviews

6.9.1 Pylon management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives relate to the fulfilment of this document.

6.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

- d) status of actions from previous management reviews;
  - e) outcome of recent internal audits;
  - f) corrective actions;
  - g) assessments by external bodies;
  - h) changes in the volume and type of the work or in the range of laboratory activities;
  - i) customer and personnel feedback;
  - j) complaints
  - k) effectiveness of any implemented improvements;
  - l) adequacy of resources;
  - m) results of risk identification;
  - n) outcomes of the assurance of the validity of results; and
  - o) other relevant factors, such as monitoring activities and training.
- 6.9.3 The outputs from the management review shall record all decisions and actions related to at least:
- a) the effectiveness of the management system and its processes;
  - b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
  - c) provision of required resources;
  - d) any need for change.

## 7.0 ISO/IEC 17025 - PYLON QUALITY SYSTEM CROSS REFERENCE LIST

Para	ISO/IEC 17025 Requirements (Title)	Manual Ref	Procedure Ref
4	General requirements	2.0	
4.1	Impartiality	2.1	
4.1.1		2.1.1	D001, D023
4.1.2		2.1.2	D001, D023
4.1.3		2.1.3	D001, D023
4.1.4		2.1.4	D033
4.1.5		2.1.5	D033
4.2	Confidentiality	2.2	
4.2.1		2.2.1	D031
4.2.2		2.2.2	D031
4.2.3		2.2.3	D031
4.2.4		2.2.4	D031
5	Structural requirements	3	
5.1		3.1	N/A
5.2		3.2	N/A
5.3		3.3	N/A
5.4		3.4	N/A
5.5		3.5	D023, WI
5.6		3.6	D023
5.7		3.7	N/A
6	Resource requirements	4	
6.1	General	4.1	D012,D023, WIs
6.2	Personnel	4.2	
6.2.1		4.2.1	D012,D023, WI
6.2.2		4.2.2	D012,D023, WI
6.2.3		4.2.3	D012,D023, WIs
6.2.4		4.2.4	D012,D023, WIs
6.2.5		4.2.5	D012,D023, D031, WI
6.2.6		4.2.6	D012,D023, WI
6.3	Facilities and environmental conditions	4.3	
6.3.1		4.3.1	D012, WI
6.3.2		4.3.2	D012, WI
6.3.3		4.3.3	WI
6.3.4		4.3.4	WI

<b>Para</b>	<b>ISO/IEC 17025 Requirements (Title)</b>	<b>Manual Ref</b>	<b>Procedure Ref</b>
6.3.5		4.3.5	WI
6.4	Equipment	4.4	
6.4.1		4.4.1	D012, WIs
6.4.2		4.4.2	D012, WIs
6.4.3		4.4.3	WIs
6.4.4		4.4.4	D003, D012, WIs
6.4.5		4.4.5	D012, WIs
6.4.6		4.4.6	D012
6.4.7		4.4.7	D012, WIs
6.4.8		4.4.8	D012, WI
6.4.9		4.4.9	D012, WI
6.4.10		4.4.10	D012
6.4.11		4.4.11	D012, WIs
6.4.12		4.4.12	D012, WI
6.4.13		4.4.13	D012, WIs
6.5	Metrological traceability	4.5	
6.5.1		4.5.1	D012
6.5.2		4.5.2	D012
6.5.3		4.5.3	D012
6.6	Externally provided products and services	4.6	
6.6.1		4.6.1	D002,D003, D012, WI
6.6.2		4.6.2	D002,D003, D012
6.6.3		4.6.3	D002, WI
7	Process requirements	5	
7.1	Review of requests, tenders and contracts	5.1	
7.1.1		5.1.1	D015, WIs
7.1.2		5.1.2	D012
7.1.3		5.1.3	D012
7.1.4		5.1.4	D012, D015, WI
7.1.5		5.1.5	D015
7.1.6		5.1.6	D015
7.1.7		5.1.7	D031
7.1.8		5.1.8	D015
7.2	Selection, verification and validation of methods	5.2	
7.2.1		5.2.1	
7.2.1.1		5.2.1.1	D012, WIs
7.2.1.2		5.2.1.2	D012, WIs

<b>Para</b>	<b>ISO/IEC 17025 Requirements (Title)</b>	<b>Manual Ref</b>	<b>Procedure Ref</b>
7.2.1.3		5.2.1.3	D012
7.2.1.4		5.2.1.4	D012
7.2.1.5		5.2.1.5	D012, WI
7.2.1.6		5.2.1.6	D012, WI
7.2.1.7		5.2.1.7	D012, WIs
7.2.2		5.2.2	
7.2.2.1		5.2.2.1	D012, WI
7.2.2.2		5.2.2.2	D012, WI
7.2.2.3		5.2.2.3	D012, WI
7.2.2.4		5.2.2.4	D012, WI
7.3	Sampling	5.3	N/A
7.3.1		N/A	N/A
7.3.2		N/A	N/A
7.3.3		N/A	N/A
7.4	Handling of test or calibration items	5.4	
7.4.1		5.4.1	D012, WI
7.4.2		5.4.2	D014, WI
7.4.3		5.4.3	D003, D012, WIs
7.4.4		5.4.4	D012, WI
7.5	Technical records	5.5	
7.5.1		5.5.1	D012,D023, WIs
7.5.2		5.5.2	D012, D025
7.6	Evaluation of measurement uncertainty	5.6	
7.6.1		5.6.1	D012, WI
7.6.2		5.6.2	D012, WIs
7.6.3		5.6.3	D012, WI
7.7	Ensuring the validity of results	5.7	
7.7.1		5.7.1	D012
7.7.2		5.7.2	D012
7.7.3		5.7.3	D024
7.8	Reporting of results	5.8	
7.8.1		5.8.1	
7.8.1.1		5.8.1.1	D004, WIs
7.8.1.2		5.8.1.2	D012, WI
7.8.1.3		5.8.1.3	N/A
7.8.2		5.8.2	
7.8.2.1		5.8.2.1	D012, WIs
7.8.2.2		5.8.2.2	D012
7.8.3		5.8.3	N/A
7.8.3.1		N/A	N/A

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7.8.3.2		N/A	N/A
7.8.4		5.8.4	
7.8.4.1		5.8.4.1	D012, D025, WIs
7.8.4.2		N/A	N/A
7.8.4.3		5.8.4.2	D012
7.8.5		5.8.5	N/A
7.8.6		5.8.6	
7.8.6.1		5.8.6.1	D012
7.8.6.2		5.8.6.2	D012
7.8.7		5.8.7	
7.8.7.1		5.8.7.1	D012, D023
7.8.7.2		5.8.7.2	D012,D025, WIs
7.8.7.3		5.8.7.3	D012
7.8.8		5.8.8	
7.8.8.1		5.8.8.1	D012
7.8.8.2		5.8.8.2	D012
7.8.8.3		5.8.8.3	D012
7.9	Complaints	5.9	
7.9.1		5.9.1	D007
7.9.2		5.9.2	D007, WI
7.9.3		5.9.3	D007, WI
7.9.4		5.9.4	WI
7.9.5		5.9.5	WI
7.9.6		5.9.6	WI
7.9.7		5.9.7	WI
7.10	Nonconforming work	5.10	
7.10.1		5.10.1	D007, WI
7.10.2		5.10.2	D025, WI
7.10.3		5.10.3	D007
7.11	Control of data and information management	5.11	
7.11.1		5.11.1	N/A
7.11.2		5.11.2	D025,D034, WI
7.11.3		5.11.3	D009,D012, D025,D031, D034, WI
7.11.4		5.11.4	D034
7.11.5		5.11.5	D009,D025, D034
7.11.6		5.11.6	D025,D031, WI

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8	Management system requirements	6	
8.1	Options	6.1	
8.1.1		6.1.1	N/A
8.1.2		6.1.2	D007,D024, D025,D026, D033
8.1.3		6.1.3	N/A
8.2	Management system documentation (Option A)	6.2	
8.2.1		6.2.1	N/A
8.2.2		6.2.2	N/A
8.2.3		6.2.3	N/A
8.2.4		6.2.4	N/A
8.2.5		6.2.5	N/A
8.3	Control of management system documents (Option A)	6.3	
8.3.1		6.3.1	D009
8.3.2		6.3.2	D009
8.4	Control of records (Option A)	6.4	
8.4.1		6.4.1	D025
8.4.2		6.4.2	D025
8.5	Actions to address risks and opportunities (Option A)	6.5	
8.5.1		6.5.1	D033
8.5.2		6.5.2	D033
8.5.3		6.5.3	D033
8.6	Improvement (Option A)	6.6	
8.6.1		6.6.1	D024
8.6.2		6.6.2	D024
8.7	Corrective actions (Option A)	6.7	
8.7.1		6.7.1	D007, D033, WIs
8.7.2		6.7.2	D007, WI
8.7.3		6.7.3	D025
8.8	Internal audits (Option A)	6.8	
8.8.1		6.8.1	D007, D026
8.8.2		6.8.2	D007,D004, D026
8.9	Management reviews (Option A)	6.9	
8.9.1		6.9.1	D025
8.9.2		6.9.2	D024
8.9.3		6.9.3	D024