PYLON ELECTRONICS INC.

QUALITY MANUAL

DOCUMENT NO.: D001

REVISION 26

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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. and Pylon Atlantic - A Division of Pylon Electronics Inc., hereafter referred to as Pylon which has offices at 147 Colonnade Road, Ottawa, Ontario K2E 7L9, 6355 Danville Road, Unit 10, Mississauga, Ontario L5T 2L4, and 31 Trider Crescent, Dartmouth, Nova Scotia B3B 1V6. The quality system is designed to meet the requirements of ISO/IEC 17025:2005.

1.2 Scope

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

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.

REV	EFFECTIVE DATE	REASON FOR RE-ISSUE
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.
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.

1.5 Approvals

This document has been approved by the following personnel:

Position	Name
Corporate Quality Assurance Manager	Art Heatley
General Manager - Ottawa	Jim Mullins
General Manager - Mississauga	Jim Mullins
General Manager - Dartmouth	Jarett Grant
Vice-President	Jim Mullins

1.6 Responsibility

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

The Corporate Quality Assurance Manager is responsible for this document. Any requests for change shall be addressed to the Corporate Quality Assurance Manager. Incomplete or ambiguous documentation shall be brought to the attention of the Corporate Quality Assurance Manager 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 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories
2. ISO 10005:2004, Quality Management - Guidelines for Quality Plans
3. D002, Vendor Evaluation Procedure
4. D003, Incoming Inspection Procedure
5. D004, In-Process and Final Inspection Procedure
6. D007, Corrective and Preventive Action Procedure
7. D008, Electrostatic Discharge Protection Procedure
8. D009, Documentation Control Procedure
10. D012, Calibration Department Operating Procedures
11. D013, Material Section Operating Procedures
12. D014, Traffic Section Operating Procedures
13. D015, Contract Review Procedure
14. D022, Customer Supplied Product Control Procedure
15. D023, Training Procedure
16. D024, Management Review Procedure
17. D025, Quality Records Procedure

18. D026, Internal Audit Procedure
19. D031, Protection of Customer's Confidential Information Procedure
20. D032, Control of Non-Conforming Product Procedure

2.0 MANAGEMENT REQUIREMENTS

2.1 Organization

2.1.1 Pylon is an entity that can be held legally responsible.

2.1.2 Pylon shall carry out its testing and calibration activities in such a way as to meet the requirements of ISO/IEC 17025 and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

2.1.3 Pylon's management system shall cover work carried out in Pylon's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

2.1.4 The responsibilities of key personnel in Pylon that have an involvement or influence on the testing and/or calibration activities of Pylon shall be and have been defined in order to identify potential conflicts of interest.

2.1.5 Pylon shall:

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system**,** and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures;

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

e) define the organization and management structure of Pylon, its place in any parent organization, and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) appoint a quality manager who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) appoint deputies for key managerial personnel;

k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

2.1.5.1 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 overall structure of Pylon Electronics Inc.

Figure 2 shows the senior management structure.

Figures 3, 4, and 5 provide the Organization Charts for the Ottawa, Mississauga, and Dartmouth labs respectively.

Figure 1 - Pylon Electronics Inc. Corporate Structure

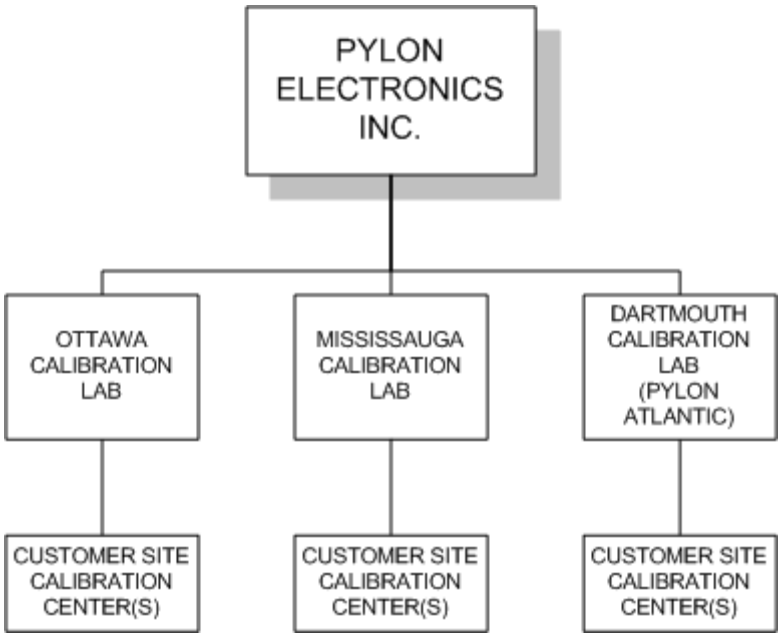


Figure 2 - Pylon Electronics Inc. Senior Management Structure

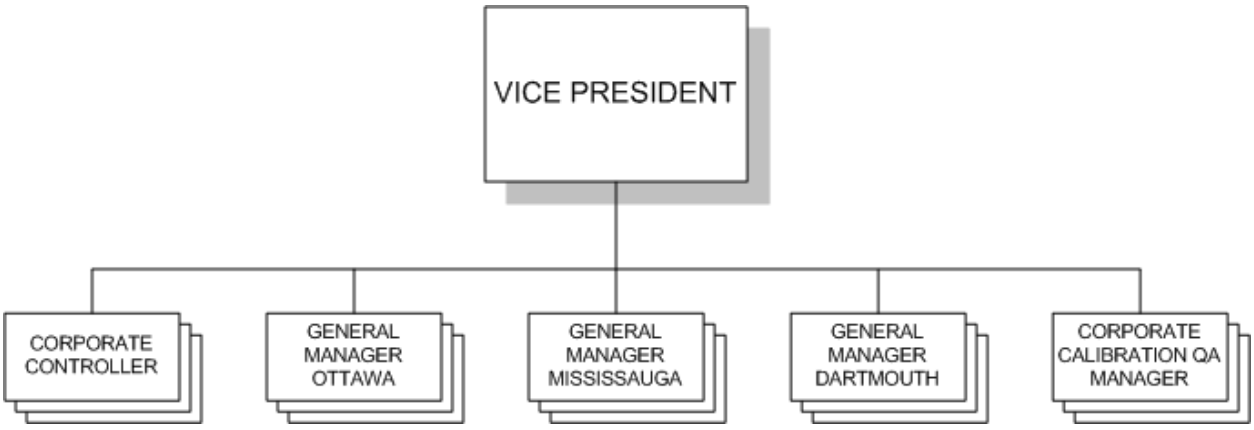


Figure 3 - Ottawa Lab Organization Chart

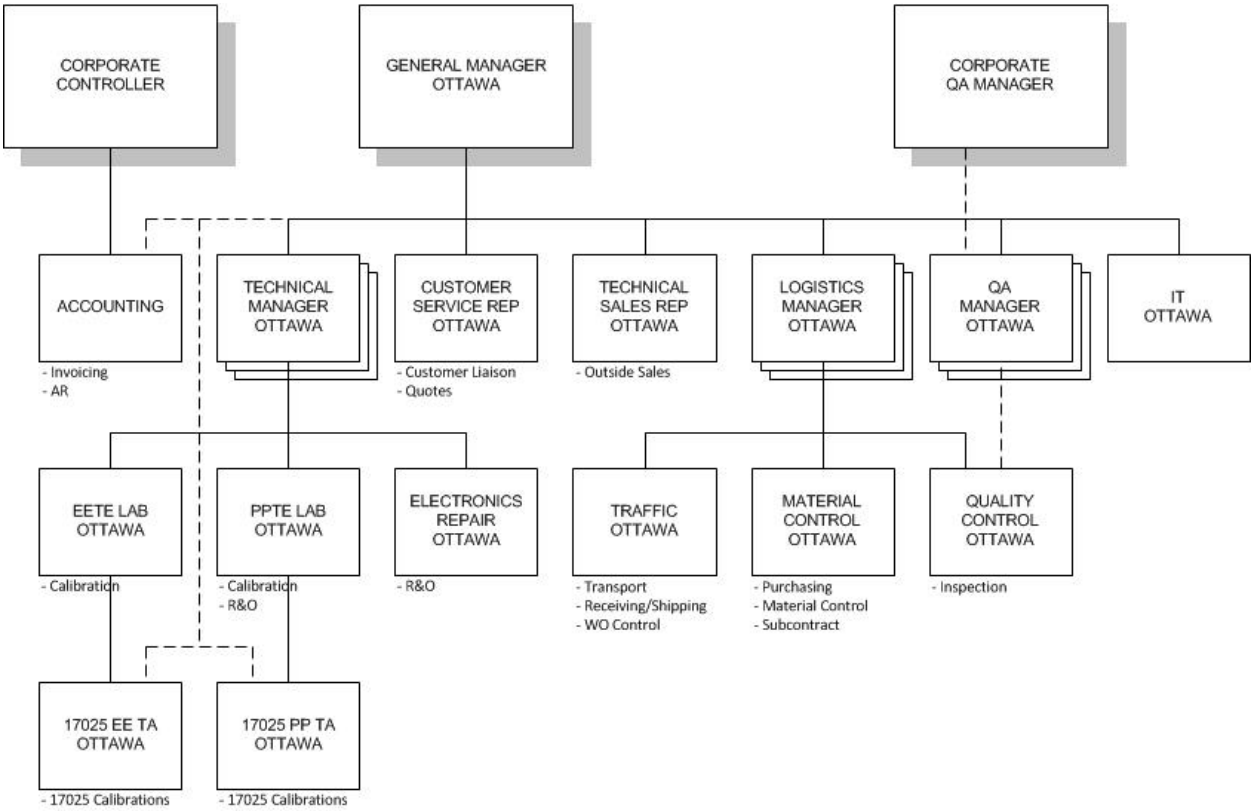


Figure 4 - Mississauga Lab Organization Chart

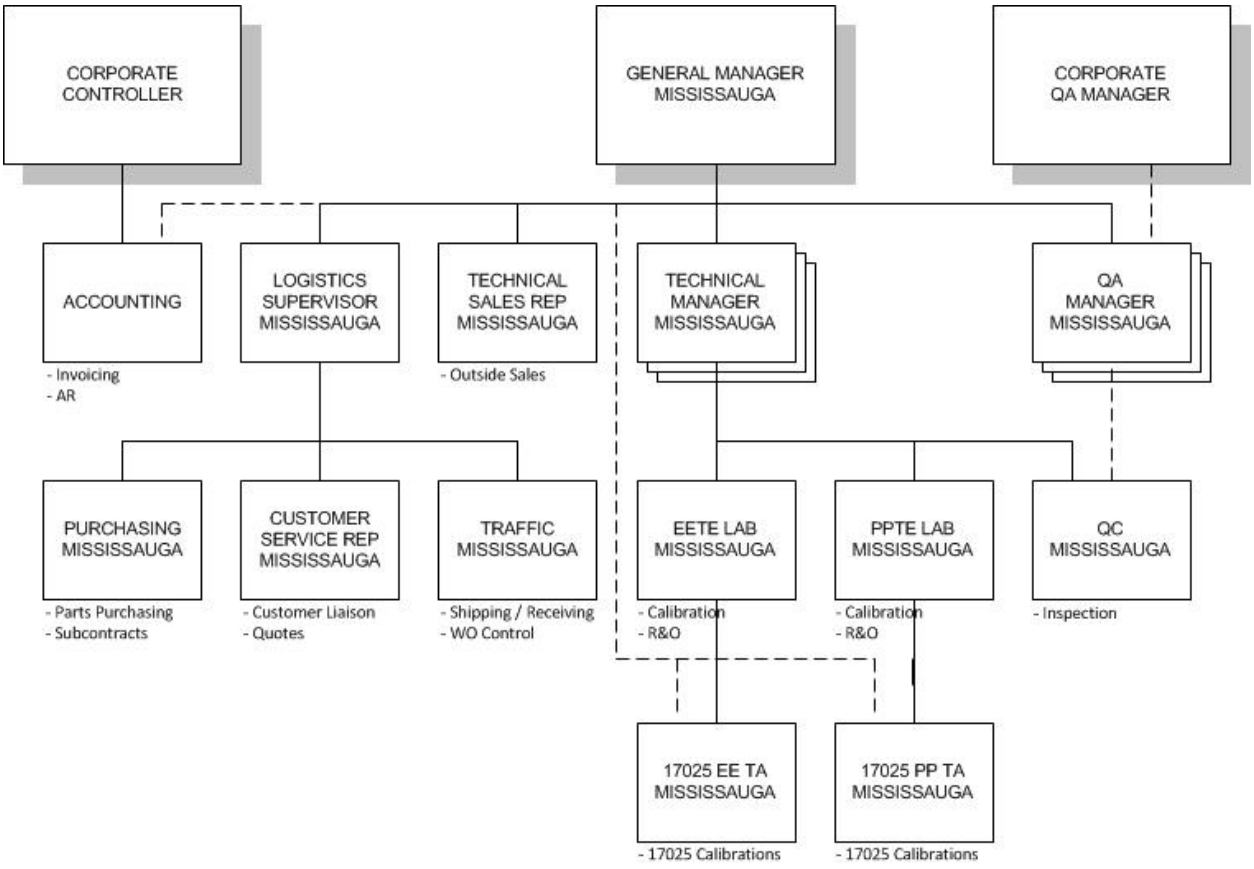
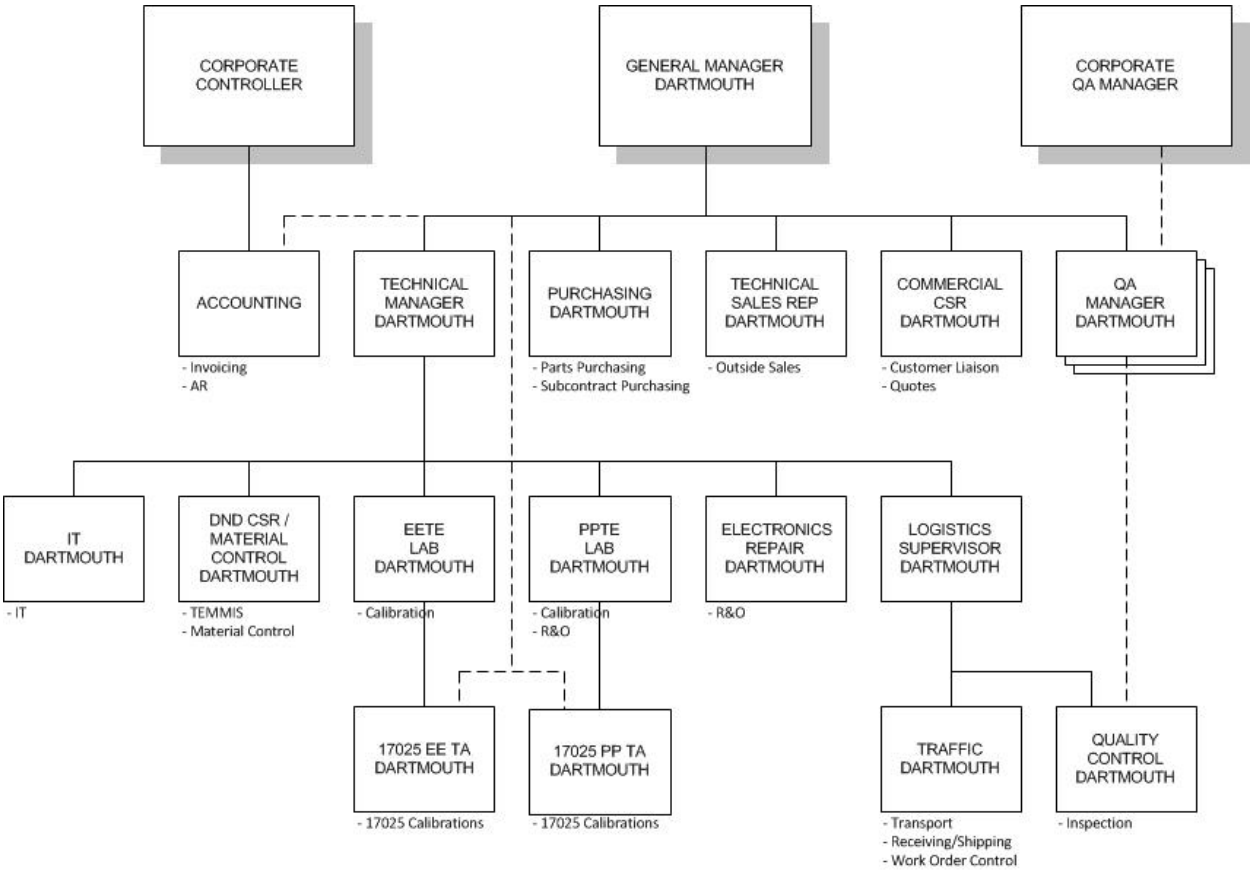


Figure 5 - Dartmouth Lab Organization Chart



2.1.5.1.1 General

All top management, Technical Managers and Supervisors, and the 17025 Technical Authorities are responsible for ensuring compliance with ISO/IEC 17025:2005.

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.

2.1.5.1.2 Vice President

The Vice President has the responsibility and authority to:

- Direct and control the management system of the Calibration Division at the highest level. This includes, in addition, the authority to provide, direct and control the laboratory resources (persons and material) necessary to conduct and maintain the testing activities on the scope of accreditation and maintaining Pylon's commitment to quality.
- Approve the addition of new staff or reallocation of existing staff.
- Approve the addition or replacement of the most expensive equipment used by the lab to conduct testing on the scope by either procuring new funds or authorizing the reallocation of existing funds.

2.1.5.1.3 Corporate Controller

The Corporate Controller is responsible for all accounting functions within the organization. Accounting is responsible for all the accounting functions required by Pylon. This includes accounts receivable, accounts payable, and payroll.

2.1.5.1.4 Corporate Quality Assurance Manager

The Corporate Quality Assurance Manager is responsible for the overall direction of Pylon's quality system. This includes setting policy and providing guidance to the Quality Assurance Managers.

2.1.5.1.5 General Manager

The General Manager is responsible for the day to day administrative operation of the lab including the monitoring of the quality status in consultation with the Quality Assurance Manager.

2.1.5.1.6 Quality Assurance Manager

Under the direction of the Corporate Quality Assurance Manager, the Quality Assurance Manager is responsible for implementing and enforcing the quality system in the lab.

Quality Assurance is responsible for monitoring, evaluating and reporting the effectiveness of all departments in meeting the objectives of the quality system. Customer interface relating to matters of quality shall be referred to the Quality Assurance Manager.

The Quality Assurance Manager is also responsible for:

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement,
c) ensuring the promotion of awareness of customer requirements throughout the organization,
d) initiating actions to prevent the occurrence of any nonconformity's relating to the product, process, and quality system,
e) identifying and recording any problems relating to the product, process, and quality system,
f) initiating, recommending, or providing solutions through designated channels,
g) verifying the implementation of solutions,
h) controlling further processing, delivery, or installation of nonconforming equipment until the deficiency or unsatisfactory condition has been corrected, and
i) liaison with external parties on matters relating to the quality management system.

2.1.5.1.7 Logistics Manager

The Logistics Manager is responsible for the Traffic and Material Control in the labs with these sections.

The Traffic section is responsible for receiving all material including customer equipment for repair or calibration and parts. The Traffic section is also responsible for packing and shipping all deliverables including subcontracted equipment. In addition, the Traffic section is responsible for scheduling customer equipment pick-ups and deliveries in company vehicles, maintaining control of GFE (Government Furnished Equipment), maintaining database records, and creating work orders.

The Material Control section is responsible for material purchasing and material control including inventory management, which ensures that only quality products and services are procured from qualified suppliers.

Purchasing is the focal point for all suppliers and no commitment shall be made to a supplier by anyone, except Purchasing.

Purchasing is also responsible for including the quality requirements specified by Quality Assurance in all purchase orders and contracts negotiated with suppliers. Quality Assurance will be notified of the need for evaluating suppliers when new or second sources are being considered.

2.1.5.1.8 Technical Manager

The Technical Manager is responsible for the day-to-day operations of the respective calibration labs, to ensure that the outgoing equipment conforms to all quality requirements.

The Technical Manager is also responsible for the calibration and repair processes and for coordinating with customers concerning any problems or ambiguities with contract work, in cooperation with the Quality Assurance Manager, the General Managers, and the Vice President.

2.1.5.1.9 Sales

The sales team consists of Customer Service Representatives and Technical Sales Representatives.

The Customer Service Representatives are responsible for coordinating all calibration/repair contracts with commercial customers including coordinating equipment pick-up and delivery. The Customer Service Representatives are also responsible for coordinating with commercial customers concerning any problems or ambiguities with contract work, in cooperation with the Quality Assurance Manager, the General Managers, and the Vice President.

The Technical Representatives are responsible for all commercial sales contacts. This includes visiting customers and potential customers to obtain feedback on the services that are provided or could be provided. They are also responsible for coordinating quotes to commercial customers with the Customer Service Representatives.

2.1.5.1.10 17025 Technical Authorities

The 17025 Technical Authorities are the Technical Authorities for all 17025 parameters within their areas of expertise (i.e., electrical or physical properties) for which Pylon becomes accredited.

The 17025 Technical Authorities report to the appropriate supervisors or managers for all matters but have a direct access to the General Manager for matters of concern related to the ISO/IEC 17025 accreditation.

2.1.5.1.11 Lab Supervisors

The Lab Supervisors are responsible for day-to-day operation of the electrical and physical calibration labs. The duties include supervising lab technical personnel, performing in-house and insitu calibrations, monitoring standards and their performance and providing sales assistance for quoting.

The Lab Supervisors report to the Technical Manager for the day-to-day operation of the lab including administrative and technical issues.

2.1.5.1.12 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.

2.1.5.2 Management Representative

Art Heatley - Corporate Quality Assurance Manager
Pylon Electronics Inc.
147 Colonnade Road
Ottawa, Ontario K2E 7L9

has been appointed as the corporate quality management representative. He has the authority to act for Pylon on all quality matters and is responsible for ensuring that Pylon's quality system meets the requirements of ISO/IEC 17025 including:

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

2.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

2.2 Management System

2.2.1 Pylon shall establish, implement and maintain a management system appropriate to the scope of its activities. Pylon shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system’s documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

2.2.1.1 General Requirements

Pylon shall and has established, documented, implemented, and maintained a quality management system and continually improves its effectiveness in accordance with the requirements of ISO/IEC17025:2005.

Pylon shall and has:

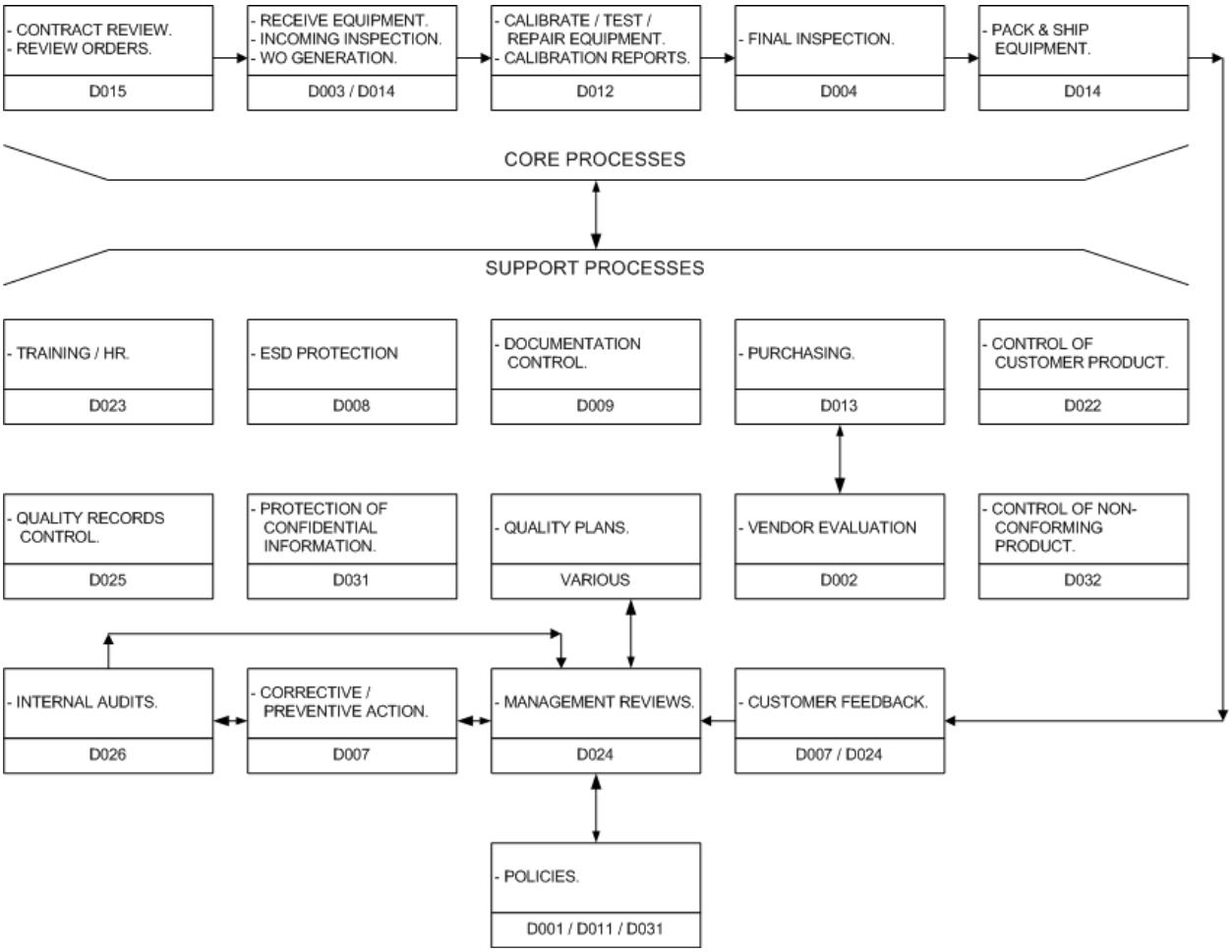
a) determined the processes needed for the quality management system and their application throughout Pylon,
b) determined the sequence and interaction of these processes,
c) determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensured the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitored, measured, where applicable, and analysed these processes, and
f) implemented actions necessary to achieve planned results and continual improvement of these processes.

Figure 6 provides a diagram of the sequence and interaction of Pylon's quality management processes.

Pylon shall and has managed these processes in accordance with the requirements of ISO/IEC17025:2005.

When Pylon chooses to outsource any process that affects service conformity to requirements, Pylon shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes have been defined within the quality management system.

Figure 6 - Sequence & Interaction of Pylon's Processes



2.2.2 Pylon's management system policies related to quality, including a quality policy statement, shall be and have been defined in this quality manual. The overall objectives shall be established, and reviewed during management review. The quality policy statement shall be and has been issued under the authority of top management. It shall include at least the following:

a) Pylon management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management's statement of Pylon's standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with testing and calibration activities within Pylon familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

e) Pylon management's commitment to comply with ISO/IEC 17025 and to including the continually improve of the effectiveness of the management system.

2.2.2.1 Quality Policy

Pylon's policy is 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 17025:2005.

3) Continually improve the effectiveness of the management system.

To meet the policy, Pylon is committed to the following objectives:

1) Meeting customer expectations regarding turn around 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.

To provide objective evidence that the quality system meets the specified requirements, Pylon shall track our performance in all areas related to our objectives

and obtain and maintain registration or certification, as appropriate, from recognized registration or accreditation organizations.

2.2.3 Pylon's top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.

2.2.4 Pylon's top management shall communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.

2.2.5 This quality manual shall and does include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

2.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with ISO/IEC 17025, shall be and are defined in this quality manual.

2.2.7 Pylon's top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

2.3 Document Control

2.3.1 General

Pylon shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

2.3.2 Document Approval And Issue

2.3.2.1 All documents issued to personnel in Pylon as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

2.3.2.2 The procedure(s) adopted shall ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of Pylon are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

2.3.2.3 Management system documents generated by Pylon shall be uniquely identified. Such identification shall include the revision identification, page numbering, the total number of pages, and the issuing authority(ies).

2.3.3 Document Changes

2.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

2.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

2.3.3.3 Pylon's document control system allows for the amendment of documents by hand pending the re-issue of the documents. The procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.

2.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

2.4 Review Of Requests, Tenders And Contracts

2.4.1 Pylon shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood;

b) Pylon has the capability and resources to meet the requirements;

c) the appropriate test and/or calibration method is selected and capable of meeting the customers' requirements.

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to Pylon and the customer.

2.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

2.4.3 The review shall also cover any work that is subcontracted by Pylon.

2.4.4 The customer shall be informed of any deviation from the contract.

2.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

2.5 Subcontracting Of Tests And Calibrations

2.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with ISO/IEC 17025 for the work in question.

2.5.2 Pylon shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

2.5.3 Pylon is responsible to the customer for the subcontractor’s work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

2.5.4 Pylon shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with ISO/IEC 17025 for the work in question.

2.6 Purchasing Services And Supplies

2.6.1 Pylon shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

2.6.2 Pylon shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

2.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

2.6.4 Pylon shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

2.7 Service To The Customer

2.7.1 Pylon shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring Pylon's performance in relation to the work performed, provided that Pylon ensures confidentiality to other customers.

2.7.2 Pylon shall seek feedback, both positive and negative, from our customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service.

2.8 Complaints

Pylon shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by Pylon.

2.9 Control Of Nonconforming Testing And/Or Calibration Work

2.9.1 Pylon shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the customer is notified and work is recalled;

e) the responsibility for authorizing the resumption of work is defined.

2.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of Pylon's operations with its own policies and procedures, the corrective action procedures given in 2.11 shall be promptly followed.

2.10 Improvement

Pylon shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

2.11 Corrective Action

2.11.1 General

Pylon shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

2.11.2 Cause Analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

2.11.3 Selection And Implementation Of Corrective Actions

Where corrective action is needed, Pylon shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. Pylon shall document and implement any required changes resulting from corrective action investigations.

2.11.4 Monitoring Of Corrective Actions

Pylon shall monitor the results to ensure that the corrective actions taken have been effective.

2.11.5 Additional Audits

Where the identification of nonconformities or departures casts doubts on Pylon's compliance with its own policies and procedures, or on its compliance with ISO/IEC 17025, Pylon shall ensure that the appropriate areas of activity are audited in accordance with 2.14 as soon as possible.

2.12 Preventive Action

2.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

2.12.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

2.13 Control Of Records

2.13.1 General

2.13.1.1 Pylon shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

2.13.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

2.13.1.3 All records shall be held secure and in confidence.

2.13.1.4 Pylon shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

2.13.2 Technical Records

2.13.2.1 Pylon shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

2.13.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

2.13.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to

records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

2.14 Internal Audits

2.14.1 Pylon shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and ISO/IEC 17025. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

2.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of Pylon's test or calibration results, Pylon shall take timely corrective action, and shall notify customers in writing if investigations show that Pylon results may have been affected.

2.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

2.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

2.15 Management Reviews

2.15.1 In accordance with a predetermined schedule and procedure, Pylon’s top management shall periodically conduct a review of Pylon's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- the results of interlaboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- customer feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as quality control activities, resources and staff training.

2.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

3.0 TECHNICAL REQUIREMENTS

3.1 General

3.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (3.2);
- accommodation and environmental conditions (3.3);
- test and calibration methods and method validation (3.4);
- equipment (3.5);
- measurement traceability (3.6);
- sampling (3.7);
- the handling of test and calibration items (3.8).

3.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. Pylon shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

3.2 Personnel

3.2.1 Pylon management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

3.2.2 The management of Pylon shall formulate the goals with respect to the education, training and skills of Pylon personnel. Pylon shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of Pylon. The effectiveness of the training actions taken shall be evaluated.

3.2.3 Pylon shall use personnel who are employed by, or under contract to, Pylon. Where contracted and additional technical and key support personnel are used, Pylon shall ensure that such personnel are supervised and competent and that they work in accordance with Pylon's management system.

3.2.4 Pylon shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

3.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. Pylon shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

3.3 Accommodation And Environmental Conditions

3.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. Pylon shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

3.3.2 Pylon shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

3.3.3 There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

3.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. Pylon shall determine the extent of control based on its particular circumstances.

3.3.5 Measures shall be taken to ensure good housekeeping in Pylon. Special procedures shall be prepared where necessary.

3.4 Test And Calibration Methods And Method Validation

3.4.1 General

Pylon shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or

calibration data. Pylon shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of Pylon shall be kept up to date and shall be made readily available to personnel (see 2.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

3.4.2 Selection of methods

Pylon shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. Pylon shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

When the customer does not specify the method to be used, Pylon shall select appropriate methods that have been 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. Laboratory-developed methods or methods adopted by Pylon may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. Pylon shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

Pylon shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

3.4.3 Laboratory-Developed Methods

The introduction of test and calibration methods developed by Pylon for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

3.4.4 Non-Standard Methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

3.4.5 Validation Of Methods

3.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

3.4.5.2 Pylon shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. Pylon shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

3.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

3.4.6 Estimation Of Uncertainty Of Measurement

3.4.6.1 Pylon shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

3.4.6.2 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

3.4.7 Control Of Data

3.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

3.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, Pylon shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

3.5 Equipment

3.5.1 Pylon shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where Pylon needs to use equipment outside its permanent control, it shall ensure that the requirements of ISO/IEC 17025 are met.

3.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets Pylon's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.

3.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

3.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

3.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

a) the identity of the item of equipment and its software;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification;

d) the current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

g) the maintenance plan, where appropriate, and maintenance carried out to date;

h) any damage, malfunction, modification or repair to the equipment.

3.5.6 Pylon shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

3.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. Pylon shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure.

3.5.8 Whenever practicable, all equipment under the control of Pylon and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

3.5.9 When, for whatever reason, equipment goes outside the direct control of Pylon, Pylon shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

3.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

3.5.11 Where calibrations give rise to a set of correction factors, Pylon shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.

3.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

3.6 Measurement Traceability

3.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. Pylon shall have an established programme and procedure for the calibration of its equipment.

3.6.2 Specific Requirements

3.6.2.1 Calibration

3.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by Pylon are traceable to the International System of Units (SI) (Système international d'unités).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

3.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable programme of interlaboratory comparisons is required where possible.

3.6.3 Reference Standards And Reference Materials

3.6.3.1 Reference Standards

Pylon shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 3.6.2.1. Such reference standards of measurement held by Pylon shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

3.6.3.2 Reference Materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

3.6.3.3 Intermediate Checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules

3.6.3.4 Transport And Storage

Pylon shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

3.7 Sampling

3.7.1 Pylon shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

3.7.2 Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

3.7.3 Pylon shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

3.8 Handling Of Test And Calibration Items

3.8.1 Pylon shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of Pylon and the customer.

3.8.2 Pylon shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in Pylon. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from Pylon.

3.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, Pylon shall consult the customer for further instructions before proceeding and shall record the discussion.

3.8.4 Pylon shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, Pylon shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

3.9 Assuring The Quality Of Test And Calibration Results

3.9.1 Pylon shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programmes;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

3.9.2 Quality control data shall be analysed and, where found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

3.10 Reporting The Results

3.10.1 General

The results of each test, calibration, or series of tests or calibrations carried out by Pylon shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results shall be reported, usually in a test report or a calibration certificate, and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 3.10.2, and 3.10.3 or 3.10.4.

In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 3.10.2 to 3.10.4 which is not reported to the customer shall be readily available in Pylon which carried out the tests and/or calibrations.

3.10.2 Test Reports And Calibration Certificates

Each test report or calibration certificate for accredited calibrations shall include at least the following information, unless Pylon has valid reasons for not doing so:

a) a title (e.g. "Test Report" or "Calibration Certificate");

b) the name and address of Pylon, and the location where the tests and/or calibrations were carried out, if different from the address of Pylon;

c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

d) the name and address of the customer;

e) identification of the method used;

f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;

h) reference to the sampling plan and procedures used by Pylon or other bodies where these are relevant to the validity or application of the results;

i) the test or calibration results with, where appropriate, the units of measurement;

j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

3.10.3 Test reports

3.10.3.1 In addition to the requirements listed in 3.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;

d) where appropriate and needed, opinions and interpretations (see 3.10.5);

e) additional information which may be required by specific methods, customers or groups of customers.

3.10.3.2 In addition to the requirements listed in 3.10.2 and 3.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

a) the date of sampling;

b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and procedures used;

e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

3.10.4 Calibration Certificates

3.10.4.1 In addition to the requirements listed in 3.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

c) evidence that the measurements are traceable.

3.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, Pylon shall record those results and maintain them for possible future reference.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.

3.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

3.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.

3.10.5 Opinions And Interpretations

When opinions and interpretations are included, Pylon shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

3.10.6 Testing And Calibration Results Obtained From Subcontractors

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

The subcontractor shall report the results in writing or electronically.

When a calibration has been subcontracted, Pylon performing the work shall issue the calibration certificate to the contracting laboratory.

3.10.7 Electronic Transmission Of Results

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of ISO/IEC 17025 shall be met.

3.10.8 Format Of Reports And Certificates

The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

3.10.9 Amendments To Test Reports And Calibration Certificates

Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of ISO/IEC 17025. When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

4.0 ISO/IEC 17025 - PYLON QUALITY SYSTEM CROSS REFERENCE LIST

Para	ISO/IEC 17025 Requirements (Title)	Manual Ref	Procedure Ref
4	Management Requirements	2.0	N/A
4.1	Organization	2.1	N/A
4.1.1		2.1.1	N/A
4.1.2		2.1.2	N/A
4.1.3		2.1.3	N/A
4.1.4		2.1.4	N/A
4.1.5		2.1.5	D031
4.1.6		2.1.6	D024
4.2	Management System	2.2	N/A
4.2.1		2.2.1	N/A
4.2.2		2.2.2	N/A
4.2.3		2.2.3	N/A
4.2.4		2.2.4	N/A
4.2.5		2.2.5	N/A
4.2.6		2.2.6	N/A
4.2.7		2.2.7	N/A
4.3	Document Control	2.3	N/A
4.3.1	General	2.3.1	D009, WI's
4.3.2	Document Approval and Issue	2.3.2	N/A
4.3.2.1		2.3.2.1	D009
4.3.2.2		2.3.2.2	D009, D026
4.3.2.3		2.3.2.3	D009
4.3.3	Document Changes	2.3.3	N/A
4.3.3.1		2.3.3.1	D009
4.3.3.2		2.3.3.2	D009
4.3.3.3		2.3.3.3	D009
4.3.3.4		2.3.3.4	D009, WI's
4.4	Review of Requests, Tenders and Contracts	2.4	N/A
4.4.1		2.4.1	D015
4.4.2		2.4.2	D015
4.4.3		2.4.3	D015
4.4.4		2.4.4	D015
4.4.5		2.4.5	D015
4.5	Subcontracting of Tests and Calibrations	2.5	N/A
4.5.1		2.5.1	D002
4.5.2		2.5.2	WI's
4.5.3		2.5.3	WI's
4.5.4		2.5.4	D002
4.6	Purchasing Services and Supplies	2.6	N/A
4.6.1		2.6.1	D013, WI's

Para	ISO/IEC 17025 Requirements (Title)	Manual Ref	Procedure Ref
4.6.2		2.6.2	D003, WI's
4.6.3		2.6.3	WI's
4.6.4		2.6.4	D002, WI's
4.7	Service to the Customer	2.7	N/A
4.7.1		2.7.1	D015, D031
4.7.2		2.7.2	D024
4.8	Complaints	2.8	D007, WI's
4.9	Control of Nonconforming Testing and/or Calibration Work	2.9	N/A
4.9.1		2.9.1	D032, WI's
4.9.2		2.9.2	N/A
4.10		2.10	D024
4.11	Corrective Action	2.11	D007, WI's
4.11.1	General	2.11.1	D007, WI's
4.11.2	Cause Analysis	2.11.2	D007, WI's
4.11.3	Selection and Implementation of Corrective Actions	2.11.3	D007, WI's
4.11.4	Monitoring of Corrective Actions	2.11.4	D007, WI's
4.11.5	Additional Audits	2.11.5	D007, WI's
4.12	Preventive Action	2.12	N/A
4.12.1		2.12.1	D007, WI's
4.12.2		2.12.2	D007, WI's
4.13	Control of Records	2.13	N/A
4.13.1	General	2.13.1	N/A
4.13.1.1		2.13.1.1	D025
4.13.1.2		2.13.1.2	D025
4.13.1.3		2.13.1.3	D025, D031
4.13.1.4		2.13.1.4	D025, D031
4.13.2	Technical Records	2.13.2	N/A
4.13.2.1		2.13.2.1	D012, D023
4.13.2.2		2.13.2.2	D012, WI's
4.13.2.3		2.13.2.3	D025
4.14	Internal Audits	2.14	N/A
4.14.1		2.14.1	D026
4.14.2		2.14.2	D007
4.14.3		2.14.3	D007, D026, WI's
4.14.4		2.14.4	WI's
4.15	Management Reviews	2.15	N/A
4.15.1		2.15.1	D024
4.15.2		2.15.2	D024
5	Technical Requirements	3.0	N/A

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5.1	General	3.1	N/A
5.1.1		3.1.1	N/A
5.1.2		3.1.2	N/A
5.2	Personnel	3.2	N/A
5.2.1		3.2.1	D012, D023
5.2.2		3.2.2	D023
5.2.3		3.2.3	D023
5.2.4		3.2.4	D023
5.2.5		3.2.5	D012, D023
5.3	Accommodation and Environmental Conditions	3.3	N/A
5.3.1		3.3.1	D012, WI's
5.3.2		3.3.2	WI'S
5.3.3		3.3.3	WI'S
5.3.4		3.3.4	N/A
5.3.5		3.3.5	N/A
5.4	Test and Calibration Methods and Method Validation	3.4	N/A
5.4.1	General	3.4.1	D012, WI's
5.4.2	Selection of Methods	3.4.2	D012, WI's
5.4.3	Laboratory-Developed Methods	3.4.3	D012, WI's
5.4.4	Non-Standard Methods	3.4.4	D012, WI's
5.4.5	Validation of Methods	3.4.5	N/A
5.4.5.1		3.4.5.1	N/A
5.4.5.2		3.4.5.2	D012, WI's
5.4.5.3		3.4.5.3	D012, WI's
5.4.6	Estimation of Uncertainty of Measurement	3.4.6	N/A
5.4.6.1		3.4.6.1	D012, WI's
5.4.6.2		N/A	N/A
5.4.6.3		3.4.6.2	D012, WI's
5.4.7	Control of Data	3.4.7	N/A
5.4.7.1		3.4.7.1	WI's
5.4.7.2		3.4.7.2	D012, D031, WI's
5.5	Equipment	3.5	N/A
5.5.1		3.5.1	D012, D023, WI's
5.5.2		3.5.2	D012, WI's
5.5.3		3.5.3	D009, D023, WI's
5.5.4		3.5.4	WI's
5.5.5		3.5.5	D012
5.5.6		3.5.6	D012, WI'S

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5.5.7		3.5.7	D032, WI's
5.5.8		3.5.8	D012, WI's
5.5.9		3.5.9	WI's
5.5.10		3.5.10	D012, WI's
5.5.11		3.5.11	D012, WI's
5.5.12		3.5.12	D012, WI's
5.6	Measurement Traceability	3.6	N/A
5.6.1	General	3.6.1	D012, WI's
5.6.2	Specific Requirements	3.6.2	N/A
5.6.2.1	Calibration	3.6.2.1	N/A
5.6.2.1.1		3.6.2.1.1	D012
5.6.2.1.2		3.6.2.1.2	D012
5.6.2.2	Testing	3.6.2.2	N/A
5.6.2.2.1		3.6.2.2.1	N/A
5.6.2.2.2		3.6.2.2.2	N/A
5.6.3	Reference Standards and Reference Materials	3.6.3	N/A
5.6.3.1	Reference Standards	3.6.3.1	D012, WI's
5.6.3.2	Reference Materials	3.6.3.2	D012, WI's
5.6.3.3	Intermediate Checks	3.6.3.3	D012, WI's
5.6.3.4	Transport and Storage	3.6.3.4	WI's
5.7	Sampling	3.7	N/A
5.7.1		3.7.1	N/A
5.7.2		3.7.2	N/A
5.7.3		3.7.3	N/A
5.8	Handling of Test and Calibration Items	3.8	N/A
5.8.1		3.8.1	D012, WI's
5.8.2		3.8.2	WI's
5.8.3		3.8.3	D003, WI's
5.8.4		3.8.4	D012, D031, WI's
5.9	Assuring the Quality of Test and Calibration Results	3.9	N/A
5.9.1		3.9.1	D012
5.9.2		3.9.2	D024
5.10	Reporting the Results	3.10	N/A
5.10.1	General	3.10.1	N/A
5.10.2	Test Reports and Calibration Certificates	3.10.2	D012, WI's
5.10.3	Test Reports	3.10.3	N/A
5.10.3.1		3.10.3.1	N/A
5.10.3.2		3.10.3.2	N/A
5.10.4	Calibration Certificates	3.10.4	N/A
5.10.4.1		3.10.4.1	D012, WI's

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5.10.4.2		3.10.4.2	D012
5.10.4.3		3.10.4.3	WI's
5.10.4.4		3.10.4.4	D012
5.10.5	Opinions and Interpretations	3.10.5	D012
5.10.6	Testing and Calibration Results Obtained from Subcontractors	3.10.6	WI's
5.10.7	Electronic Transmission of Results	3.10.7	D031
5.10.8	Format of Reports and Certificates	3.10.8	D012, WI's
5.10.9	Amendments to Test Reports and Calibration Certificates	3.10.9	D012