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**ENV-MAN-WES2-0001 v03\_Quality Manual**  
**Effective Date: 02/24/2025**

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## **Management Approval Page**

### **Local Quality Manual**

### **Pace Analytical Services, LLC (PAS)**

**Signatory Attestation:** The employee's electronic signature on this management approval page affirms the approver's obligation, commitment, and responsibility to uphold the requirements of the PAS Quality Management System (QMS) described in this Quality Manual (manual) at each location for which this manual is prepared.

Refer to the page for Quality Manual Signatories to view the job title and physical address for each approver.

# **Title Page**

## **Local Quality Manual**

### **Pace Analytical Services, LLC (PAS)**

**This manual has been prepared for the following PAS laboratories and subsidiaries:**

PAS-WES2 Pace Analytical  
Services, LLC - Westborough,  
MA

**Analytical Laboratory**

8 Walkup Drive  
Westborough, MA 01581  
Phone: 508-898-9220

PAS-MANS Pace Analytical  
Services, LLC - Mansfield, MA  
(320 Forbes)

**Analytical Laboratory**

320 Forbes Blvd.  
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PAS-MANS Pace Analytical  
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(120 Forbes)

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Phone: 716-783-9291

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**Maine Service Center**

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**Mid-Atlantic PA Service Center**

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Folcroft, PA 19032  
Phone: 610-532-5742

**Rochester, NY Service Center**

Metro Park Business Center, Suite M-105  
Rochester, NY  
Phone: 518-869-0394

**Syracuse, NY Service Center**

10 Adler Dr., Suite 104  
Syracuse, NY 13057  
Phone: 518-860-9724

**Cleveland, OH Service Center**

7575 Tyler Blvd, Bldg C, Suite C35  
Mentor, OH  
Phone: 614-357-3321

## Quality Manual Approver Information

The individuals listed below are approvers of this manual and are responsible for implementing the PAS Quality Management System and upholding the requirements of this manual at the location(s) for which this manual was prepared, at the time this version of the manual was made effective.

The manual is not revised and released under an updated version when there is a change to personnel. Personnel information is updated during the manual's normal review and revision cycle.

If an approver changes positions, leaves the company, or is on extended leave of absence, the responsibility to implement and uphold the PAS QMS automatically transfers to the primary or alternate deputy for the position until the approver is replaced and/or the approver returns to work. The individual replacing the approver automatically accepts the responsibilities associated with the original approver's attestation. Refer to Section 4.1.5.1.1 of this manual to view the deputies assigned to key personnel job titles.

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Stephen Witkowski	Quality Program Manager	Corporate	stephen.witkowski@pacelabs.com
Jason Hebert	Quality Manager	320 Forbes Blvd. Mansfield, MA 02048	jason.hebert@pacelabs.com
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## 1.0 PURPOSE AND SCOPE

### 1.1 Purpose

This quality manual (manual) outlines the quality management system and management structure of Pace<sup>®</sup> Analytical Services, LLC. Throughout this manual, Pace<sup>®</sup> Analytical Services, LLC is also referred to by the acronym PAS. Building Sciences laboratories are a subset of specialized laboratories within PAS and may also be referred to by the acronyms BSCI or BDSG within the quality management system.

The QMS is also called the quality program throughout this manual and other PAS documents. “Quality Management System” and “Quality Program” are synonymous and inferred by the acronym QMS.

The QMS is the collection of policies and processes established by the senior leaders of PAS (top management) to ensure the services and products provided by PAS consistently meet relevant requirements and achieves the goal of Pace<sup>®</sup> to provide customers with high quality, cost-effective, analytical measurements, and services.

The QMS is planned to establish conformance<sup>1</sup> and compliance with the current published versions of these international and national quality system Standards:

- ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*
- TNI Standard Volume 1: *Management and Technical Requirements for Laboratories Performing Environmental Analysis*

<sup>1</sup>The statement of conformity to these Standards pertains only to testing and sampling activities carried out by the laboratory at its physical address, in temporary or mobile facilities, in-network, or by laboratory personnel at a customer's facility.

The QMS is also planned to achieve regulatory compliance with the various federal and state programs for which PAS locations provide compliance testing and/or holds certification or accreditation. Federal or state requirements that do not apply to all PAS locations, are provided in addendum to this manual or in other documents that supplement the manual. Customer-specific project and program requirements are not included in the manual in order to maintain client confidentiality.

- A list of accreditation and certifications held by each location associated with this manual is provided in Appendix A.
- A list of analytical testing capabilities offered by each location associated with this manual is managed by local Quality and maintained in document ENV-FORM-WES2-0188 Analytical Testing Capabilities List.

### 1.2 Scope and Application

This manual applies to each location listed on the Title Page of this manual:

For purposes of the PAS QMS the term “location” refers to laboratories and/or service centers.

- The term “laboratory” refers to any PAS location, however named by Pace<sup>®</sup> that provides testing, collects samples (sampling), or conducts field measurement services in a fixed building, mobile unit, or in-situ (field).
- The phrase “service center” refers to any PAS location, however named by Pace<sup>®</sup> that does not perform any testing, sampling, or field measurements.



PAS locations are defined by their physical address and other information:

- Laboratories are defined by physical address and certification/accreditation ID.
- Mobile units are defined by the address of the location to which they are assigned, by VIN (vehicle identification number), or by certification/accreditation ID.
- The phrase “satellite laboratory” is used by PAS to refer to a limited-service laboratory affiliated with a larger PAS business unit or location. Some PAS business groups refer to satellite laboratories as service centers for accounting purposes. This designation is not consistent with the definitions specified in this manual or throughout the supporting documents associated with the QMS. Regardless of any internal reference or jargon, any PAS location that generates a test result is a “laboratory” and all laboratories must comply with all requirements specified in this manual for analytical testing services.

### 1.2.1 Quality Manual Template

This manual was prepared from the PAS Quality Manual Template (template) created by the PAS Corporate Quality team.

The template, known as document ID ENV-TMP-CORQ-0007, specifies the minimum requirements that every PAS location must abide by, regardless of scope of services or number of personnel, in order to achieve the objectives of the PAS Quality Policy (Refer to Section 4.2.2).

The template is the mechanism used by top management<sup>1</sup> to communicate their commitment to continuously develop and improve the QMS for effectiveness, to meet customer expectations, and to comply with any statutory and regulatory requirements. Their signature of approval for the template is the mechanism used to document their responsibility.

<sup>1</sup>Top Management is the phrase in the TNI Standard that refers to the leaders of an organization that develop and/or release the PAS Quality Policy Statement and manual under their authority. For PAS, top management includes the PAS President, Vice President of Quality, Risk Management Officer, Senior Vice President of Operations (Sr. VPO), and the Chief Technical Officer (CTO).

The template and instructions for use of the template are released by corporate quality personnel to the local quality managers responsible for each location (Local Quality Manager (QM)). The local QM uses the template to prepare the location’s manual by following the instructions provided to them. The local QM may not alter the font, structure, or content of the template, except where specified by instruction to do so.

The template is reviewed by corporate quality personnel annually and updated, if needed. More frequent review and revision may occur to manage change, to maintain conformance and compliance to relevant standards or to improve the QMS.

Refer to standard operating procedure (SOP) ENV-SOP-CORQ-00015 *Document Management and Control* for more information.

### 1.2.2 Quality Manual

The template and the manual include references to other organization documents that support the QMS such as policies and standard operating procedures (SOPs).

These references may include the document's document control number (DC#) and the document title. This information is subject to change at the discretion of PAS. The manual and/or template are updated to reflect the editorial change during the manual's next scheduled review/revision cycle or the next time a version of the manual is released, whichever is sooner.

Each location maintains a current list of documents used by the location to support the QMS. This list, known as the controlled document or master list is readily available to personnel for their use and it provides a cross reference to the legacy document ID, where applicable. Parties external to PAS may contact the location of interest to obtain the most current version of controlled document list if desired.

### 1.2.3 References to Supporting Documents

The template and the manual include references to other organization documents that support the QMS such as policies and standard operating procedures (SOPs).

These references may include the document's document control number (DC#) and the document title. This information is subject to change at the discretion of PAS. The manual and/or template are updated to reflect the editorial change during the manual's next scheduled review/revision cycle or the next time a version of the manual is released, whichever is sooner.

Each location maintains a current list of documents used by the location to support the QMS. This list, known as the controlled document or master list is readily available to personnel for their use and it provides a cross reference to the legacy document ID, where applicable. Parties external to PAS may contact the location of interest to obtain the most current version of controlled document list if desired.

## 2.0 REFERENCES

Incorporated by reference are the following documents that were used for the preparation of the quality manual, ensuring compliance with accreditation requirements.

- "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act." Federal Register, 40 CFR Part 136, most current version.
- "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods." SW-846.
- "Methods for Chemical Analysis of Water and Wastes," EPA 600/4-79-020, 1979 Revised 1983, U.S. EPA.
- U.S. EPA Contract Laboratory Program Statement of Work for Organic Analysis, current version.
- U.S. EPA Contract Laboratory Program Statement of Work for Inorganic Analysis, current version.
- "Standard Methods for the Examination of Water and Wastewater." Current Edition APHA-AWWA-WPCF.
- "Annual Book of ASTM Standards," Section 4: Construction, Volume 04.04: Soil and Rock; Building Stones, American Society of Testing and Materials.
- "Annual Book of ASTM Standards," Section 11: Water and Environmental Technology, American Society of Testing and Materials.

- “NIOSH Manual of Analytical Methods,” U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, most current version.
- “Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water,” U.S. EPA, Environmental Monitoring and Support Laboratory – Cincinnati (Sep 1986).
- Quality Assurance of Chemical Measurements, Taylor, John K.; Lewis Publishers, Inc. 1987.
- Methods for Non-conventional Pesticides Chemicals Analysis of Industrial and Municipal Wastewater, Test Methods, EPA-440/1-83/079C.
- Environmental Measurements Laboratory (EML) Procedures Manual, HASL-300, US DOE, February 1992.
- Requirements for Quality Control of Analytical Data, HAZWRAP, DOE/HWP-65/R1, July 1990.
- AIHA Laboratory Accreditation Programs, LLC Policy Modules, AIHA, most current version.
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, 2<sup>nd</sup> Edition 2005-05-15; 3<sup>rd</sup> Edition 2017-11

The following are implemented by normative reference to ISO/IEC 17025:

- ISO/IEC Guide 99, International vocabulary of metrology –Basic and general concepts and associated terms
- ISO/IEC 17000, Conformity assessment – Vocabulary and general principles
- Department of Defense Quality Systems Manual (QSM), most current version.
- TNI (The NELAC Institute) Standard, 2016 version.
- UCMR Laboratory Approval Requirements and Information Document, most current version.
- US EPA Drinking Water Manual, most current version.
- National Voluntary Laboratory Accreditation Program (NVLAP) - Procedures and General Requirements. NIST Handbook 150: 2020
- National Voluntary Laboratory Accreditation Program (NVLAP) - Bulk Asbestos Analysis. NIST Handbook 150-3: 2006
- National Voluntary Laboratory Accreditation Program (NVLAP) – Airborne Asbestos Analysis. NIST Handbook 150-13: 2006
- EPA National Lead Laboratory Accreditation Program: Laboratory Quality System Requirements, Revision 3.0, July 05, 2007

### **3.0 TERMS AND DEFINITIONS**

Refer to Appendix C for terms, acronyms, and definitions used in this manual and in other documents used by PAS to support the QMS.

## **4.0 MANAGEMENT REQUIREMENTS**

### **4.1 Organization**

#### **4.1.1 Legal Identity**

Pace® Analytical Services, LLC is the responsible entity authorized by the State of Minnesota to do business as a limited liability company, under the parent company, PAS Parent, Inc.

##### **4.1.1.1 Change of Ownership**

If there is a change of ownership, if a PAS location goes out of business, or if the entire organization ceases to exist, PAS management must notify regulatory authorities of the change within the time required by each state agency for which the location is certified or accredited.

Specifications for retention of records and other business information are addressed in the ownership transfer agreement and in accordance with appropriate regulatory requirements. These details are not included in this manual because each situation is specific to the change event.

#### **4.1.2 Compliance Responsibility**

PAS management has the responsibility and authority to establish and implement procedures and to maintain resources necessary to ensure its testing activities are carried out in such a way to meet applicable federal and statutory requirements in addition to the requirements specified in this manual and QMS supporting documents

#### **4.1.3 Scope of the Quality Management System**

The QMS applies to work carried out at each location covered by this manual including permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

The permanent and mobile facilities to which this manual applies are listed on the Title Page of this manual.

#### **4.1.4 Organization History and Information**

Founded in 1978, Pace® Analytical Services, LLC is a privately held scientific services firm operating one of the largest full-service contract laboratory and service center networks in the United States.

The business purpose of PAS is to deliver the highest standard of testing and scientific services in the market. We offer the most advanced solutions in the industry, backed by transparent data, a highly trained team, and the service and support that comes from over four decades of experience.

##### **4.1.4.1 Organization Structure**

Each PAS location is led by a management team referred to as local management<sup>1</sup>. Local management is responsible for making day-to-day decisions regarding the operations of the facility and implementing, and sustaining the requirements, policies, and procedures of the PAS quality program.

<sup>1</sup> The term “local management” does not mean “on-site” management. Some of the roles included in the local management team, work off site or from a different PAS location.

For purpose of the QMS, the job titles associated with the local management team include Vice President of Operations (VPO), General Manager (GM), Director of Laboratory Operations (DLO), Quality Program Manager (QPM), and Quality Manager.

The local management team is supported by department supervisors and team leaders, and business groups that support the organization such as HR, IT, Sales & Marketing, Finance, and EHS (Environmental Health & Safety).

Technical oversight for each location is provided by local personnel with support and guidance from the PAS Chief Technical Officer. Locations that hold TNI accreditation, also have personnel appointed to serve as the “acting technical manager for TNI, however named” to perform the duties and responsibilities of this designation per the TNI Standard. Refer to Section 4.1.5.2.1 for more information on this TNI requirement.

The reporting relationships and responsibilities of quality personnel are independent of operations in order to safeguard impartiality. Refer to Section 4.1.5.2 for more information.

Refer to the organization charts provided in Appendix D to view the organization structure, reporting relationships, and the interrelationships between positions.

#### 4.1.5 Management Requirements

##### 4.1.5.1 Personnel

Each PAS location is staffed with administrative and/or technical personnel who perform and verify work under the supervision of their direct line supervisor.

All personnel are required to perform their duties in accordance with the policies and processes outlined in this manual and in accordance with standard operating procedures and other quality system documents. PAS policies and procedures are designed for impartiality and integrity. When these procedures are fully implemented, personnel remain free from undue pressure and other influences that adversely impact the quality of their work or data.

##### 4.1.5.1.1 Key Personnel

Key personnel are management positions that have the authority and responsibility to plan, direct, and control activities related to the QMS for the entire division (PAS Corporate), or for one or more PAS locations (Local).

##### PAS Key Personnel Positions & Deputy Assignments by Role

Job Title	Primary / Alternate Deputy
Chief Executive Officer	President

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Chief Compliance Officer	VPQ / As Assigned
President	CEO / Sr. VPO
Vice President of Quality	RMO or CTO
Quality Program Manager	CQD / Peer QPM / As Assigned
Chief Technical Officer	VPQ / As Assigned
Risk Management Officer	VPQ or CTO
Sr. VP of Operations	President / VPO
Vice President of Operations	Sr. VPO / Peer VPO
Director of Lab Operations <sup>1</sup>	VPO / Peer DLO or Sr. VPO
Health and Safety Director	As Assigned
IT Director	CIO
Quality Manager	QPM / Peer QM / QAA
General Manager <sup>1</sup>	VPO / Sr. VPO or Peer GM
Operations Manager <sup>1</sup>	GM / DL or VPO
Technical Manager (TM) <sup>1</sup>	CTO / Peer TM
TNI or NLLAP Approved TM <sup>2</sup>	Another Qualified Employee

<sup>1</sup>Position is not in place at all locations.

<sup>2</sup>The TNI TM is not a PAS position. Refer to Section 4.1.5.2.1 for more information.

Some certification and accreditation programs require notification any time there is a change in key personnel. Notification requirements are tracked and upheld by the local QM, when these requirements apply.

#### 4.1.5.2 Roles and Responsibilities

The qualifications, duties, and responsibilities for each position at Pace<sup>®</sup> are detailed in job descriptions maintained by the Pace<sup>®</sup> Human Resource (HR) personnel.

The following sections provide a general overview of various management and supervisory roles and are presented in no particular order.

**Chief Executive Officer:** Provides leadership for overall operations; development of growth strategies; and long-range capital and strategic planning for Pace<sup>®</sup>.

**Chief Compliance Officer:** Provides leadership for compliance related activities.

**President:** Provides leadership for overall operations; oversight of regulatory and compliance standards; development of growth strategies; and long-range capital and strategic planning for PAS.

**Chief Technical Officer:** Provides technical oversight and leadership to all PAS locations. Responsible for innovation and standardization of technical activities.

**Vice President of Quality (VPQ):** Responsible for developing the PAS quality program and the policies and procedures that support the QMS. The VPQ leads the

quality team, establishing functions, responsibilities, duties, and organizational structure for PAS.

**Risk Management Officer (RMO):** Responsible for the risk management program and initiatives within PAS. Specializes in the identification, assessment, and mitigation of operational and regulatory risk. The RMO leads the risk management team to ensure the development and implementation of risk management strategies.

**Corporate Quality Program Manager:** Responsible for helping local management implement, monitor, maintain and improve the PAS quality program for one or more locations in the network and for direct supervision of Quality Manager(s).

**Director of Information Technology:** Oversees and delivers the systems and processes of information technology used by PAS. These systems include Laboratory Information Management Systems (LIMS); data acquisition, reduction, and reporting software; virus-protection, communication tools, and ensuring the integrity, security of electronic data, and associated policies and procedures.

**Sr. Vice President of Operations:** Provides leadership, direction, and insight necessary to achieve strategic initiatives. Develops and improves processes, structure, and allocation of resources for operations for all PAS.

**Vice-President of Operations:** Provides leadership, guidance, and resources, including allocation of personnel, necessary to achieve the strategic goals of the organization and the PAS quality program to one or more PAS locations.

**Director of Laboratory Operations:** Refer to descriptions for VPO and General Manager. The DLO is an intermediary management position that provides leadership and resources to one or more locations.

**General Manager:** The GM is responsible for overall administration and operation of one or more PAS locations. Although task duties associated with this responsibility may be delegated, the GM is responsible for ensuring all duties and activities of the locations they oversee comply with the PAS QMS, the PAS EHS program, and with any applicable statutory, regulatory requirements or program requirements. If a GM is not assigned to the location, these responsibilities are transferred to the Operations Manager (OM) or DLO; if no DLO, to the VPO.

Any GM of a TNI Accredited laboratory is also responsible for the designation of technical personnel to serve as acting technical managers for TNI for the fields of accreditation held by the laboratory (Refer to Section 4.1.5.2.1) and for notifying the quality team of any extended absence or reassignment of these designations.

**Quality Manager:** The QM oversees and monitors the implementation, compliance, and improvement of the QMS and communicates gaps, deviations, and opportunities for improvement to local and corporate laboratory management. The QM is independent of the operation and analytical activities for which they provide oversight and has the authority to carry out the roles and responsibilities of their position without outside influence.

The QM:



- serves as the focal point for QA/QC protocol decisions and oversees review of QC data for trend analysis;
- evaluates data objectively and performs assessments without outside influence;
- has documented training and experience in QA/QC procedures and the PAS quality system;
- has a general knowledge of the analytical methods offered by the laboratory;
- coordinates and conducts internal systems and technical audits;
- notifies laboratory management of deficiencies in the quality system;
- monitors corrective actions;
- provides support to technical personnel and may serve as the primary deputy for the acting TNI Technical Manager(s).

**Client Services Manager (CSM):** This position is responsible for the training and supervision of project manager(s) and/or shipping, receiving and courier personnel. The primary responsibility of the CSM is to ensure projects are successfully managed to meet the expectations and needs of PAS customers.

**Department Managers, or however named:** These positions are responsible for administrative and operations management and implementation of the QMS in the work area he/she oversees. These responsibilities include but are not limited to: training and supervision of personnel, monitoring work activity to maintain compliance with this manual, SOPs, policies and other instructional documents that support the QMS; method development, validation and the establishment and implementation of SOPs to assure regulatory compliance and suitability for the intended purpose; monitoring QA/QC performance, proper handling and reporting of nonconforming work; purchasing of supplies and equipment adequate for use; maintaining instrumentation and equipment in proper working order and calibration; and general maintenance of administrative and technical processes and procedures established by the laboratory.

**Operations Manager:** The OM is responsible for management of production and/or other duties assigned by the GM..

#### **4.1.5.2.1 Approved Technical Manager (TNI or ELLAP/NLLAP Accreditation Only)**

The requirements in this subsection apply only to PAS locations that are NELAC/TNI or ELLAP/NLLAP accredited.

The TNI Standard and National Lead Laboratory Accreditation Program: Laboratory Quality System Requirements (NLLAP LQSR) specify requirements for the qualification and duties of technical personnel. The TNI Standard lists these duties under the reference “technical manager(s), however named.”



At PAS, these duties closely correlate with the responsibilities and duties outlined in the PAS job descriptions for managers, supervisors, team leads, and/or scientists. However, these duties do not need to be associated with any specific job title and can be assigned to any one or more PAS employees that meets the qualifications specified in the TNI Standard.

Refer to the applicable version of the TNI Standard to view the required qualifications for each discipline. The required qualifications for a laboratory accredited by ELLAP/NLLAP shall be the same as those listed in the TNI Standard.

PAS locations that are TNI accredited must designate one or more employees to perform these duties and submit these qualifications to the TNI accreditation body for approval.

Employees approved by the TNI AB, to perform these duties retain their Pace<sup>®</sup> assigned job title.

When TNI Accreditation Bodies refer to these employees as ‘technical manager’ or ‘technical director’ on the official certificate or the scope of accreditation, this reference is referring to their approval to perform duties of the ‘technical manager, however named’ as specified in the TNI Standard and not to a PAS job title.

The duties of any approved technical manager for TNI, however named, can be completed in person or remotely. If an employee that is an approved technical manager for TNI is completely absent from work or on a leave of absence for more than 15 calendar days, the duties and responsibilities specified in the TNI Standard are temporarily reassigned to another employee that meets the qualifications for the technology or field of accreditation. If the employee’s absence exceeds 35 calendar days, the local QM must formally notify the TNI primary AB of the absence and the details of reassignment of duties in writing.

#### 4.1.5.3 Conflict of Interest

A conflict of interest is a situation where a person has competing interests that may affect impartiality. It is the policy of Pace<sup>®</sup> to ensure business relationships, decisions and transactions do not place personal interest ahead of the organization, customers, colleagues, job responsibilities or the public we serve. Conflict of interest is avoided by making personnel aware of circumstances that conflict or appear to conflict with impartiality and/or designing process and procedures to include checks and balances to prevent conflict and ensure impartiality.

Refer to the current version of policy COR-POL-0004 *Code of Ethics and Professional Conduct* for more information.

#### 4.1.5.4 Confidentiality

PAS management is committed to preserving the confidentiality of Pace<sup>®</sup> customers and confidentiality of Pace<sup>®</sup> business information.

Client information obtained or created during work activities is considered confidential and is protected from intentional release to any person or entity other than the client or the client's authorized representative, except when Pace<sup>®</sup> is required by law to release confidential information to another party, such as a regulatory agency or for litigation purposes. In which case, Pace<sup>®</sup> will notify the client of the release of information and the information provided, unless notification is prohibited by law.

When Pace<sup>®</sup> obtains information about the customer from a source other than the customer, Pace<sup>®</sup> will keep the source of the information confidential unless disclosure is agreed upon by the source.

The terms of client confidentiality are included in PAS Standard Terms and Conditions (T&C) which can be found on the Hub (<https://info.pacelabs.com/hubfs/pas-standard-term.pdf>). With the acceptance of the T&C and/or the implicit contract for analytical services that occurs when the client sends samples to PAS for testing, the client authorizes Pace<sup>®</sup> to release confidential information when required. Other procedures used by PAS to maintain confidentiality include:

- A Code of Ethics and Professional Conduct policy that covers this topic (COR-POL-0004);
- A Confidentiality Agreement which supervisory and sales personnel and other positions are required to sign at the time of employment and abide by the conditions of throughout employment;
- Record retention and disposal procedures that ensure confidentiality is maintained; and
- Physical access controls and encryption of electronic data.

Refer to policy COR-POL-0004 *Code of Ethics and Professional Conduct* for more information.

#### 4.1.5.5 Communication

Communication is defined as the imparting or exchanging of news and information. Effective (good) communication occurs when the people included in the communication get the point and understand it.

##### 4.1.5.5.1 Workplace Communication

Effective communication in the workplace is necessary to ensure work is performed correctly, efficiently, and in accordance with client specifications.

Instructions for how to conduct testing and other work activities are communicated to personnel via written policies, standard operating procedures, and other work instructions.

Information about PAS performance (positive and negative) and ideas for improvement are communicated to personnel using various communication channels such as face to face meetings, video conferencing, conference calls, email, memoranda, written reports, and posters.

#### **4.1.5.2 External Communication**

Communication with external parties such as customers, vendors, business partners, and regulatory agencies takes place every day.

PAS management is responsible for training personnel to communicate in professional and respectful ways to build strong relationships and to avoid misunderstanding.

## **4.2 Quality Management System**

### **4.2.1 Quality Management System Objectives**

The objectives of the PAS QMS are to provide clients with consistent, exemplary professional service, and objective work product that is of known and documented quality that meets their requirements for data usability and regulatory compliance.

Objective work products are analytical services, data, test results, and information that is not influenced by personal feeling or opinions. The quality of being objective is also known as ‘impartiality.’

#### **4.2.1.1 Impartiality**

PAS achieves and maintains impartiality by establishing an organizational structure that safeguards impartiality (Refer to Section 4.1.4.1) and implementing and adhering to the policies and processes of the QMS outlined in this manual, which are based on industry accepted standards and methodologies.

PAS procedures for handling nonconforming work (Refer to Section 4.9), corrective and preventive actions (Refer to Section 4.11, 4.12) and management review (Refer to Section 4.15) are the primary mechanisms used to identify risk to impartiality and to prompt actions necessary to eliminate or reduce the threat when risk to impartiality is suspected or confirmed.

#### **4.2.1.2 Risk and Opportunity Assessment**

Risks are variables that make achieving the goals and objectives of the QMS uncertain.

An opportunity is something that has potential positive consequences for the organization.

PAS personnel manage risks and opportunities on a daily basis by following policies, procedures and processes that support the QMS. Some ways in which the QMS is designed to identify, minimize, or eliminate risk on a daily basis include but are not limited to:

- Capability and capacity reviews of each analytical service request to assure the laboratory can meet the customer’s requirements;

- Maintenance of accreditation and certification for test methods in multiple states and programs to cover a broad range of authority for regulatory compliance;
- SOPs and other controlled instructional documents are provided to personnel to eliminate variability in the process. These documents include actions to counter risk factors inherent in the process and are reviewed on a regular basis for on-going suitability and relevancy;
- Participation in proficiency testing programs and auditing activities to verify on-going competency and comparability in performance;
- Provision of on-the-job training and established protocol for quality control (QC) corrective action for nonconforming events;
- An established program for ethics, and data integrity;
- Tiered data review process;
- Culture of continuous improvement;
- Monitoring activities to assess daily and long-term performance; and
- Annual critical review of the effectiveness of the QMS.

PAS also promotes a continuous improvement culture based on the principles of lean manufacturing. These principles include 3P (Process, Productivity, Performance) and Kaizen. 3P is a platform used by PAS to share best practices and standardization across the network to achieve operational excellence. Kaizen is a team-based process used to implement tools and philosophies of lean to reduce waste and achieve flow with the purpose of improving both external and internal customer satisfaction. The PAS lean program and activities help to mitigate risk because they generate a collective understanding of vulnerabilities and utilize group-effort to develop and implement solutions at all levels.

Risk and opportunities may also be formally identified using specific risk and opportunity assessment methods such as SWOT Analysis (Strength, Weakness, Opportunity, Threats) and 3-Stage Impact/Probability Grids.

#### **4.2.1.3 Communication of the Quality Management System**

This manual is the primary mechanism used by PAS management to communicate the QMS to personnel.

To ensure personnel understand and implement the quality program outlined in the manual:

- PAS personnel are required to sign a Read and Acknowledgement Statement to confirm the employee has:
  - 1) been informed of the manual by management;
  - 2) has access to the manual;

- 3) has read the manual;
- 4) understands the content of the manual; and
- 5) agrees to abide by the requirements, policies, and procedures therein.
- Personnel are informed that the manual provides the “what” of the QMS. The “how to” implementation of the QMS is provided in policy, SOPs, standard work instructions, and other instructional documents.
- This manual and supporting policies and procedures are made readily accessible to personnel in the area where the work activity is performed.

#### 4.2.2 Quality Policy Statement

The quality policy of PAS is to provide customers with data of known and documented quality fit for their intended purpose. PAS achieves this policy by implementing the QMS defined in this manual, by following industry accepted protocol for analytical testing and quality assurance and quality control activities, by conformance with published and industry accepted testing methodologies, and by compliance with international and national standards for the competency and/or accreditation of testing laboratories.

Intrinsic to this policy statement is each of the following principles:

- PAS will provide customers with reliable, consistent, and professional service. This is accomplished by making sure each PAS location has the resources necessary to maintain capability and capacity; that staff are trained and competent to perform the tasks they are assigned; that client-facing staff are trained and prepared to find solutions to problems and to assist customers with their needs for analytical services. Customer feedback, both positive and negative, is shared with personnel and used to identify opportunities for improvement.
- PAS maintains a quality program that complies with applicable state, federal, and industry standards for analytical testing and competency.
- PAS management provides training to personnel so that all personnel are familiar with the QMS outlined in this manual and that they understand that implementation of the QMS is achieved by adherence to the Pace<sup>®</sup> and PAS policies and procedures.
- PAS management continuously evaluates and improves the effectiveness of the QMS by responding to customer feedback, and other measures of performance, such as but not limited to the results of internal/external audits, proficiency testing, metrics, trend reports, and annual and periodic management reviews..

##### 4.2.2.1 Ethics Policy / Data Integrity Program

Pace<sup>®</sup> has established a comprehensive ethics and data integrity program that is communicated to all Pace<sup>®</sup> employees so that they understand what is expected of them. The program is designed to promote a mindset of ethical behavior and professional conduct that is applied to all work activities.

The key elements of the Pace<sup>®</sup> Ethics / Data Integrity Program include:

- Ethics Policy (COR-POL-0004);

- Standardized data integrity training course taken by all new employees on hire and a yearly refresher data integrity training course for all existing employees;
- Policy Acknowledgement Statements that all Pace® personnel, including contract and temporary, are required to sign at the time of employment and again during annual refresher training to document the employee's commitment and obligation to abide by the company's standards for ethics, data integrity and confidentiality;
- SOPs that provide instructions for how to carry out a test method or process to ensure tasks are done correctly and consistently by each employee;
- On the Job Training;
- Data integrity monitoring activities which include, but are not limited to: primary, secondary and completeness data reviews, internal technical and system audits, data audits, data surveillance, and proficiency testing; and
- Confidential reporting process for alleged ethics and data integrity issues.

All PAS managers and supervisors are expected to provide a work environment where personnel feel safe and can report unethical or improper behavior in complete confidence without fear of retaliation. Retaliation against any employee that reports a concern is not tolerated.

Pace® has engaged Lighthouse Services, Inc. to provide personnel with an anonymous reporting process available to them 24 hours per day/7 days per week. The alert line may be used by any employee to report potential violations of the company's ethics and data integrity program. Reports are forwarded to Pace® leadership to investigate and resolve the matter. Investigations concerning data integrity are kept confidential.

Refer to COR-POL-0001 *Compliance Alertline* for more information.

Posters and flyers with the compliance alert line information must be prominently posted in each PAS location for personnel reference.

**Compliance Alert Line Information:**

English Speaking US & Canada	(844) 940-0003
Spanish Speaking North America	(800) 216-1288
Internet	<a href="http://www/lighthouse-services.com/pacelabs">www/lighthouse-services.com/pacelabs</a>
Email	<a href="mailto:reports@lighthouse-services.com">reports@lighthouse-services.com</a>

**4.2.3 Management Commitment: Quality Management System**

Evidence of management's commitment for the development, maintenance, and on-going improvement of the QMS is provided by the application of their signature of approval to the template and/or manual. Their signature confirms they understand their responsibility to implement the QMS outlined in this manual, to communicate the quality program to personnel, and to uphold requirements of the program during work activities.

#### 4.2.4 Management Commitment: Customer Service

Management communicates the importance of meeting customer and regulatory requirements to personnel by training personnel on the QMS outlined in this manual, implementing the QMS outlined in this manual, and upholding these requirements for all work activities.

#### 4.2.5 Supporting Procedures

References to processes and procedures that support the QMS are included throughout this manual. The structure of the document management system is outlined in SOP ENV-SOP-CORQ-0015 *Document Management* and summarized in the following subsections.

##### 4.2.5.1 Quality Management System Document Structure

Documents associated with the QMS are classified into document types that identify the purpose of the document and establish how the document is managed and /or controlled.

##### Examples: Types of PAS Internally Created Documents

Document Type	Purpose
Quality Manual	Outlines the PAS QMS and structure and how it works for a system including policy, goals, objectives and detailed explanation of the system and the requirements for implementation of system. Includes roles and responsibilities, relationships, procedures, systems, and other information necessary to meet the objectives of the system described.
Policy	Provide requirements and rules for a process and is used to set course of actions and to guide and influence decisions. Policy describes the “what,” not the “how.”
Standard Operating Procedure	Provide written and consistent set of instructions or steps for execution of a routine process, method, or set of tasks performed. Ensures that activities are performed properly in accordance with applicable requirements.
Standard Work Instruction	Provide step by step visual and/or written instruction to perform a specific task to improve competency, minimize variability, reduce work injury and strain, or to boost efficiency and quality of work (performance). SWI are associated with an SOP unless the task described is unrelated to generation of or contribution to environmental data or analytical results.
Template	Pre-formatted document that serves as a starting point for a new document.
Guide	Assists users in using a particular product; or a technical interpretation of a method or process by which PAS locations must abide.
Form / Worksheet	Used for a variety of purposes such as to provide a standardized format to record observations, to provide information to supplement an SOP.

##### Examples: Types of External Documents used by PAS

Certificate	Lists parameters, methods, and matrices for which the location is certified/accredited to perform within the authority of the issuing regulatory agency or accreditation body.
Reference Document	Provide information, protocol, instructions, and/or requirements. Issued by the specifier. Examples include ISO/IEC, TNI, DoD/DOE and published referenced methods such as Standard Methods, ASTM, SW846, EPA, and federal and state regulatory bodies.



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Project Document	Provides requirements necessary to meet individual client expectations for intended use of data. Examples include project quality assurance plans (QAPP), client-program technical specifications, contracts, and other agreements.
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Project documents are managed as external documents and any requirements for work specified are followed when work for the project is performed. If the project document is less stringent than the PAS QMS, policies, or SOPs, and/or is less stringent than applicable federal or state requirements, PAS locations are still required to meet the minimum requirements of the PAS QMS and any applicable statutory or federal requirements in addition to the requirements specified in the project document. Information and requirements from project documents are not incorporated into PAS policy or SOPs in order to maintain client confidentiality.

Document types are ranked to identify which documents take precedence when there is an actual or perceived conflict between documents and to establish the hierarchal relationships between documents. The ranking system also provides information to document writers and reviewers to ensure downline documents agree with documents of higher rank.

### PAS Document Hierarchy

Rank	Document Type
1	External Reference Documents (Standards, Test Methods)
2	Quality Manual Template
3	Corporate & Division Policy
4	Corporate & Division SOP
5	Division SWI, Guides, Forms/Worksheets
6	Local Quality Manual
7	Local SOP
8	Local SWI, Guides, Forms/Worksheets

#### 4.2.6 Roles and Responsibilities

The roles and responsibilities for technical management and the quality manager are provided in section 4.1.5.2.

#### 4.2.7 Change Management

When significant changes to the PAS QMS are planned, these changes are managed by corporate quality personnel to assure that the integrity of the QMS is maintained.

### 4.3 Document Control

#### 4.3.1 General

PAS uses electronic document management software (eDMS) to control documents that support the PAS QMS. eDMS provides centralized distribution and access to all documents used by PAS. All PAS locations must use the PAS eDMS system unless an exemption to this requirement has been granted by the PAS Corporate Quality Director.



eDMS automates the process for unique document identification, version control, approval, access, and archival and restricts access to archived documents except to authorized users to prevent the use of obsolete documents.

The local QM maintains a master list of controlled documents used at each location. The master list minimally includes the document control number, document title, and current revision status and is made available to personnel for their reference.

Refer to SOP ENV-SOP-CORQ-0015 *Document Management* for more information.

#### 4.3.2 Document Approval and Issue

Documents that support the QMS are reviewed by qualified personnel and approved by management prior to release for use.

Only the approved versions of documents are available to personnel for use unless a draft document is authorized by management.

The managers responsible for authorization of each document are specific to the document type.

Refer to SOP ENV-SOP-CORQ-0015 *Document Management* for more information.

#### 4.3.3 Document Review and Change

Unless a more frequent review is required by regulatory, certification or accreditation program documents are reviewed at least every two years to ensure the documents remain current, appropriate, and relevant.

Documents are also informally reviewed every time the document is used. Personnel are expected to refer to and follow instructions in controlled documents when they conduct their work activities. Consequently, any concerns or problems with the document should be caught and brought to the attention of management on an on-going basis.

Documents are revised whenever necessary to ensure the document remains usable and correct. Older document versions and documents no longer needed are made obsolete and archived for historical purposes.

PAS does not allow hand-edits of documents. If an interim change is needed pending re-issue of the document, the interim change is communicated to those that use the document using a formal communication channel, such as change in progress form, email, or memorandum.

The document review, revision, and archival process is managed by quality personnel at the location from which the document was released using the procedures established in SOP ENV-SOP-CORQ-0015 *Document Management*.

### 4.4 Analytical Service Request, Tender, and Contract Review

PAS management and/or client service personnel perform thorough reviews of requests and contracts for analytical services to verify the location(s) performing the work has the capability, capacity, and resources necessary to successfully meet the customer's needs. These review procedures are described in SOP ENV-SOP-WES2-0125 Review of Analytical Requests.

The procedures in this SOP(s) are established to ensure:

- The PAS location(s) performing the work understands the purpose of data collection in order to ensure the test methods requested are appropriate for the intended use of the data and capable of meeting the client's data quality objectives;
- PAS locations and any external subcontractor(s) have the capability, capacity, and resources to meet the project requirements and expectations within the requested time for delivery of work product;
- Any concerns that arise from review are discussed and resolved with the client;
- Any discrepancies between the PAS QMS, statutory or regulatory requirements and the client request are resolved; and
- The results of review and any correspondence with the client related to this process and/or any changes made to the contract are recorded and retained for historical purposes.

Capability review confirms that the PAS locations contracted to perform the work and any internal or external subcontractors hold required certification/accreditation for the test method, matrix, and analyte and verifies the location can achieve the client's target compound list and data quality objectives (DQOs) for analytical sensitivity and reporting limits, QA/QC protocol, and hardcopy test report and electronic data deliverable (EDD) formats.

Capacity review verifies that the in-network locations and any potential subcontractors are able to manage the sample load and deliver work production within the delivery time requested.

Resource review verifies that the location and any potential subcontractors have adequate qualified personnel with the skills and competency to perform the test methods and services requested and sufficient and proper equipment and instrumentation needed to perform the services requested.

Customers must be notified when there is a deviation from the contract after acceptance of the contract by both parties. Instructions for this notification process must be included in the laboratory's SOP for this process.

#### 4.5 Subcontracting (Internal and External)

The terms 'subcontract' and "subcontracting" refers to analytical work done by an organization external to Pace<sup>®</sup> (External Subcontracting) or by a Pace<sup>®</sup> location with an address different than the address listed on the cover page of the test report (Internal Subcontracting).

The PAS network offers comprehensive analytical capability and capacity to ensure Pace<sup>®</sup> can meet a diverse range of client needs for any type of project. If a PAS laboratory receives a request for analytical services and it cannot fulfill the project specifications, the location's client services team will collaborate with the client to place the work within the PAS network.

When it is not possible to place the work within network, the location will, with documented client approval, subcontract the work to a subcontractor that has the capabilities to meet the project specifications and can meet the same commitment agreed on between the location and the client.

Whenever work is subcontracted, the PAS location responsible for management of the project verifies each of these qualifications:

- The internal or external subcontractor has the proper accreditation/certifications required for the project and these are current; and

- The use of the internal or external subcontractor is approved by the client and/or regulatory agency when such approval is required by the customer. Record of customer approval is retained in the project record.

External subcontractors selected by Pace<sup>®</sup> must be pre-qualified by quality personnel to verify their QMS is similar to Pace<sup>®</sup> and complies with all relevant Standards such as ISO/IEC 17025 and the TNI Standard(s) and/or federal and state regulatory requirements. The list of approved subcontractors for each location is maintained by local quality personnel. Pre-qualification of a subcontractor does not eliminate the requirement for the PAS location placing work to verify the subcontractor has the certifications, capability, capacity, and resources to perform work on behalf of Pace<sup>®</sup> on a project-specific basis.

For all subcontracted work, the PAS location placing the work internally or externally is responsible to ensure project specifications are always communicated to and understood by the subcontractor.

## 4.6 Purchasing Services and Supplies

Vendors that provide services and supplies to PAS are qualified to meet the needs of Pace<sup>®</sup>. These needs include but are not limited to competitive pricing, capacity to fill purchase orders, quality of product, customer service, and business reputation and stability. Evidence of this qualification is the availability to purchase services and supplies from the vendor in the corporate purchasing system.

PAS locations may purchase goods and services from any supplier in the purchasing system.

The specifications (type, class, grade, tolerance, purity, etc.) of supplies, equipment, reagents, standard reference materials and other consumables used in the testing process are specified in SOPs. The SOP specifications are based on the governing requirements of the approved reference methods and any additional program driven regulatory specification, such as drinking water compliance.

All requisitions for materials and consumables are approved by local management who is responsible for ensuring the services and supplies procured and received are fit for intended use.

## 4.7 Customer Service

Project details and management are managed by PAS client services personnel.

### 4.7.1 Commitment to Meet Customer Expectations

PAS personnel collaborate closely with our customers to ensure their needs are met and to establish their confidence in the capability of PAS to meet their needs for analytical services and expectations for service.

The project manager (PM) is the customer's primary point of contact for each analytical service request (work order). The PM gathers information from the customer to ensure the details of their request are understood. After samples are received, the PM monitors the progress of the project and alerts the customer of any delays or excursions that may adversely impact data usability. Supervisors are expected to keep the PM informed of project status and any delays or key issues, so that the PM can keep the client informed.

PAS encourages customers to visit our locations to learn more about the capabilities, observe performance and to meet personnel.

PAS customers expect confidentiality. Personnel will not divulge or release information to a third party without proper authorization unless the information is required for litigation

purposes. Refer to Section 4.1.5.4 of this manual and policy COR-POL-0004 *Code of Ethics and Professional Conduct* for more information on the policy for client confidentiality.

#### 4.7.2 Customer Feedback

PAS actively seeks positive and negative feedback from customers through surveys and direct communication. Information from the client about their experience working with PAS and their satisfaction with work product is used to enhance processes and practices and to improve decision making. Customer feedback is reviewed to identify risk and opportunity. Corrective, preventive, or continuous improvement actions are taken based on nature of and/or feedback trends.

Refer to Sections 4.9, 4.10, 4.11, 4.12, 4.14, and 4.15 for more information about how customer feedback is managed by PAS and used to enhance the QMS.

### 4.8 Complaints

Per ISO/IEC 17025:2017, a complaint is a formal expression of dissatisfaction with the performance of a service or product originating from a party external to the organization. PAS believes complaints provide opportunities to improve processes and/or build stronger working relationships with our clients.

The PAS complaint resolution process is specified in corporate SOP ENV-SOP-CORQ-0020 and all PAS locations are required to use this SOP as their process.

Complaints are thoroughly reviewed to determine if they are valid. If the complaint is valid, action is taken to resolve the situation with the customer. In accordance with ISO/IEC 17025 requirements, the response to the customer is independently reviewed before it is given to ensure the response from PAS is thorough and proper for the situation.

Complaint information is captured in a centralized database and the data is used by PAS management personnel to identify trends and opportunities for improvement during Annual Management Review – Refer to Section 4.15 for more information about annual management review.

### 4.9 Nonconforming Work

#### 4.9.1 Definition of Nonconforming Work

Nonconforming work is work that does not conform to customer requirements, standard specifications, policies, and procedures, or that does not meet acceptance criteria.

The discovery of non-conforming work comes from various sources which include, but are not limited to:

- results of quality control samples and instrument calibrations;
- quality checks on consumables and materials;
- general observations of personnel;
- data review;
- proficiency testing;
- internal and external audits;

- complaints and feedback;
- management review and reports; and
- regulatory and certification and accreditation actions.

The way in which the laboratory or service center manages nonconforming work depends on the significance and impact (risk) of the issue. Some issues may simply require correction, others may require investigation, corrective action (Refer to Section 4.11) and/or data recall (Refer to Section 4.16). When the location releases data and test results associated with nonconforming QC and acceptance criteria, test results are qualified, or non-conformances are noted in the final analytical report to apprise the data user of the situation. (Refer to Section 5.10)

Nonconforming work also includes unauthorized departure from policies, procedures, and test methods. Authorized departures are explained in the following subsections. Situations that do not conform to these conditions are considered unauthorized departure(s).

#### 4.9.1.1 Authorized Departure from SOPs

Departures from an SOP may sometimes be necessary to correct an error in an SOP or to resolve a complex problem. For example, to mitigate complex matrix interference.

An authorized departure from a test method SOP is one that has been reviewed and approved by the department leader, however named, of the work area in which the test method is performed. The leader, when authorizing a departure from an SOP, accepts full responsibility to ensure the departure does not conflict with Pace<sup>®</sup> or PAS policy or procedure, does not affect statutory, regulatory or program compliance and does not adversely affect data integrity or usability.

Departure from administrative or process-oriented SOPs must be approved by the local QM.

Documentation of the reason for the SOP departures must be retained with management approval. Approved departures from test method SOPs should be noted in the final test report to advise the data user.

Refer to SOP ENV-SOP-CORQ-0016 *SOP for SOPs and SWI*, for more information.

#### 4.9.1.2 Authorized Departure from Test Methods (Method Modifications)

When test results are associated with a published reference test method, the location's test method SOP must be consistent with the test method. If the test method is mandated for use by a specific regulatory program such as drinking water, wastewater or a certification or accreditation program, such as TNI/NELAC, the SOP must comply with or include these requirements, or the resulting data and test results cannot be used for regulatory compliance purposes.

If the procedures in the SOP are modified from the test method, these modifications must be clearly identified in the SOP. The conditions under which the location may establish an SOP that is modified from these reference methods or regulatory

program and what is considered a modification are specified in ENV-SOP-CORQ-0011 *Method Validation and Instrument Verification*.

Client requests to deviate from the test method are managed as client requests to depart from the test method SOP since it is the SOP that the location follows when performing work.

#### 4.9.1.3 Stop Work Authority

Stop Work Authority provides PAS personnel with the capability to temporarily stop work when there is a perceived unsafe condition or situation that may affect data integrity or the safety of personnel.

All personnel have the authority to initiate and request a stop work order when necessary to preserve data integrity or safety of workers.

The need for the stop work order and resolution of the problem must be confirmed by subject matter experts and resumption of work must be approved as follows:

- For stop work orders related to environmental health and safety and/or waste management, the decision to stop work may be made in real time to protect the safety of the worker. Actions taken to correct the problem and lift the stop work order are made by the EHS Director, or the deputies assigned to these positions.
- Any employee may request a temporary stop work order for concerns related to data integrity. However, the request must be reviewed and the need to stop work affirmed by the Quality Manager to confirm the concern is valid. The decision to uphold the stop work order must be made jointly by the local QM, the QPM, the GM or DLO, and the VPO. The Corporate Quality Director and Chief Technical Officer, and other members of PAS management are consulted as needed. The actions taken to correct the problem and authorization to lift the stop work order are made by the same management team.

### 4.10 Continuous Improvement

The PAS QMS is designed to achieve continuous improvement through the implementation of the quality policy and objectives outlined in this manual. Information about laboratory and service center activities and performance is gained from sources such as customer feedback, audits, QC, trend analysis, business analytics, management reports, proficiency testing, and management systems review. This information is subsequently used during the corrective action (Refer to Section 4.11) and preventive action (Refer to Section 4.12) processes and during annual review of the management system (Refer to Section 4.15) to establish goals and objectives for improvement.

PAS also promotes a continuous improvement culture based on the principles of lean manufacturing. These principles include 3P and Kaizen. 3P is a platform used by Pace to share best practices and standardization across the network to achieve operational excellence. Kaizen is a team-based process used to implement tools and philosophies of lean to reduce waste and achieve flow with the purpose of improving both external and internal customer satisfaction. All activities of 3P and Lean must conform with the requirements of this quality manual and supporting policies and procedures.

## 4.11 Corrective Action

Corrective action is a process used to eliminate the cause of a detected nonconformity. It is different from a correction. A correction is an action taken to fix an immediate problem but that does not resolve the underlying cause of why the problem occurred. The objective of corrective action is to find the underlying cause(s) of the problem and to put in place fixes to prevent the problem from happening again. The corrective action process, referred to as CAPA, is one of the most effective tools used by PAS to prevent nonconforming work, identify risk and opportunity, and improve service to our customers.

PAS has two general processes for corrective action, the application of which process is used depends on the type of nonconformity.

Quality control (QC) exceptions (nonconformance) that occur during routine testing is investigated through troubleshooting and required actions for correction is specified in policies and SOPs. When action is not taken, cannot be taken, or is not successful, test results associated with the nonconforming work are qualified in the final test report. Documentation of the nonconformance and corrective action taken is documented in the analytical record.

A 7-stage corrective action process is used when there is a recurring problem. These problems are identified through various activities such as but not limited to quality control trends, internal and external audits, management review, customer feedback, and general observation.

The 7 Stage CAPA Process for PAS includes:

- 1) Identification and Containment
- 2) Evaluation
- 3) Investigation
- 4) Cause Analysis
- 5) Action Plan
- 6) Implementation
- 7) Follow Up and Effectiveness Review

PAS procedures for corrective action are specified in corporate SOP ENV-SOP-CORQ-0018, *Procedure for Corrective and Preventive Action*. Some key concepts and activities related to the PAS corrective action process are provided in the next three subsections.

### 4.11.1 Cause Analysis (AKA Root Cause Analysis)

Cause analysis is the process of investigation used to identify the underlying cause(s) of the problem. After causal factors are identified, ways to mitigate the causal factors are identified and action(s) most likely to eliminate these factors are taken.

PAS uses different methods to conduct cause analysis. The most common approach is 5-Why, 4M, Fishbone Diagrams, or brainstorming may be appropriate depending on the situation. The method used is case specific and is documented in the CAPA record.

### 4.11.2 Effectiveness Review

Monitoring corrective actions for effectiveness is an essential part of the corrective action process. Effectiveness means the actions taken were appropriate and sustainable. Appropriate



means the action(s) taken prevented recurrence of the problem since the time corrective action was taken and sustainable means the actions taken are still in place.

The data from CAPA records are used by PAS to identify opportunities for preventive action or to gain lessons learned when actions taken were not adequate to solve the problem. Refer to Section 4.12 (Preventive Action) and 4.15 (Management Review) for more information.

#### **4.11.3 Additional Audits**

When cause analysis and investigation of a problem casts doubt on compliance with PAS policies, procedures, or to regulatory requirements; a special audit of the area of activity may be performed as part of the corrective action process. These special audits are used to determine the scope of the problem and to provide information for the CAPA process. Additional full-scale audits are done when a grave issue or risk to the business is identified.

### **4.12 Preventive Action**

Preventive action(s) are actions taken to eliminate the cause of a potential nonconformity before it happens.

Some examples of preventive action include, but are not limited to:

- Routine instrument maintenance (Preventive maintenance)
- Addition of Staff and Equipment
- Professional Development Activities
- Implementation of New Technology

PAS looks for opportunities for preventive action from a variety of sources including employee ideas, customer feedback, business partners input, trend analysis, business analytics, management reviews, proficiency testing results, and risk-benefit analysis.

PAS management evaluates the success of preventive actions taken in any given year during annual management review. Refer to Section 4.15 for more information.

#### **4.12.1 Change Management**

Preventive actions may sometimes result in significant changes to processes and procedures used by PAS locations. PAS management evaluates the risks and benefits of change and includes in its implementation of change process, actions to minimize or eliminate any risk. The types of changes for which risk are considered and managed include infrastructure change, change in analytical service offerings, certification or accreditation status, instrumentation, LIMS changes, and changes in key personnel.

### **4.13 Control of Records**

PAS records document activities and provide evidence of conformity to the requirements established in the QMS. These records may be hardcopy or electronic on any form of media.



### **4.13.1 General Requirements**

#### **4.13.1.1 Procedure**

PAS requirements for control of records are specified in corporate policy ENV-POL-CORQ-0013 *Record Management*.

The policy was established to assure quality and technical records are identified, retained, indexed, and filed to allow for retrieval during the entire retention time. During storage, records are kept secure and protected from deterioration. At the end of the retention time, the records are disposed of properly in order to maintain client confidentiality and to protect the interests of the company.

In general, PAS records fall into three categories: quality, technical, and administrative.

**Examples of each are provided in the following table:**

Record Type	Includes Records of:
Quality	Audits: Internal and External Certificates and Scopes of Accreditation Corrective & Preventive Action Management Review Data Investigations Method Validation Instrument Verification Training Records
Technical	Raw Data Logbooks Certificates of Traceability Analytical Record Test Reports & Project Information Technical Training Records & Demonstration of Capability
Administrative	Personnel Records Finance/Business

#### **4.13.1.2 Record Legibility and Storage**

Records are designed to clearly identify the information recorded. Manual entries are made in indelible ink; automated entries are in a typeface and of sufficient resolution to be read. The records identify personnel that performed the activity or entered the information. Records are archived and stored in a way that they are retrievable. Access to archived records is controlled and managed.

For records stored electronically, the capability to restore or retrieve the electronic record is maintained for the entire retention period. Hardcopy records are filed and stored in a suitable environment to protect from damage, deterioration, or loss. Hardcopy records may be scanned to PDF for retention. Scanned records must be checked against the hardcopy to verify the scan is complete and legible.

Administrative records are kept for a minimum of 5 years and technical and quality records are kept for 10 years unless otherwise specified by the client or regulatory program. All records for Building Science and Absaroka Air Science (Sheridan, WY) laboratories are kept for 5 years.

The date from which retention time is calculated depends on the record. In general, the retention time of technical records of original observation and measurement is calculated from the date the record is created. If the technical record is kept in a chronological logbook, the date of retention may be calculated from the date the logbook is archived. The retention time of test reports and project records, which are considered technical records, is calculated from the date the test report was issued. The retention time of quality records is usually calculated from the date the record is archived.

Refer to the record management policy and the location specific SOP for more information

#### 4.13.1.3 Security

PAS locations are secure facilities and access to records is restricted to authorized personnel.

#### 4.13.1.4 Electronic Records

The data systems used to store electronic records is backed up in accordance with SOP ENV-SOP-WES2-0115, *Computer System Backup Control*. Access to archived records stored electronically is maintained by personnel responsible for management of the electronic system.

#### 4.13.1.5 Electronic Signature Policy

Work done by PAS locations includes activities that require the application of a signature. Some work products are in electronic format and signatures are applied electronically.

The Electronic Signatures in Global and National Commerce Act (E-Sign Act) clarifies that electronic signatures are legally valid and enforceable under United States law.

Refer to guide ENV-GUI-CORQ-0007 *Electronic Signatures* for more information.

### 4.13.2 Technical Records

In addition to the requirements specified in subsections 4.13.1.1 through 4.13.1.5, the requirements in the following subsections also apply to technical records.

#### 4.13.2.1 Description

Technical records are the accumulation of data and information generated from the analytical process. These records may include forms, worksheets, workbooks, checklists, notes, raw data, calibration records, final test reports, and project records. The accumulated record needs to provide adequate detail to historically reconstruct the process and identify the personnel that performed the tasks associated with a test result.

#### **4.13.2.2 Real Time Recordkeeping**

Personnel are instructed and expected to always record observations, data, and calculations at the time they are made. PAS managers are responsible for ensuring that data entries, whether made electronically or on hardcopy, are identifiable to the task

#### **4.13.2.3 Error Correction**

Errors in records must never be erased, deleted, or made illegible. Use of correction fluid, such as white-out is prohibited. In hardcopy records, the error is corrected by a single strike through the original entry and the new entry recorded alongside or footnoted to allow for readability. Corrections are initialed and dated by the person making the correction. If the correction is not self-explanatory, a reason for the correction is recorded. Maintenance of proper practices for error correction is monitored through the tiered data review process described in Section 5.9.3.

For electronic records, equivalent measures of error correction or traceability of changes made are kept. For example, audit trails provide records of change.

### **4.14 Audits**

Quality personnel, or their designee, perform internal systems and technical audits to assess implementation of the QMS and compliance to this manual, policy, and procedures that make up the QMS.

PAS locations are also audited by external parties such as regulatory agencies, customers, consultants, and non-government assessment bodies (NGAB).

Information from internal and external audits is used by local and corporate PAS management to address deficiencies and to identify opportunities to improve customer service and quality of work, including reliability and usability of data and test results.

Deficiencies, observations, and recommendations from audits are managed by the local QM using the CAPA process. Refer to Section 4.11 for more information.

#### **4.14.1 Internal Audit**

Internal audits are conducted to ensure laboratory and business practices match what we say we do and what we say we do is compliant with the PAS QMS and relevant standards and requirements.

The internal audit program is managed by the local QM who prepares an audit plan at the beginning of each calendar year. The schedule is prepared to ensure that all work areas are reviewed over the course of the year and test methods are audited every two years, unless a more frequent test method audit is required by program. Conformance to the schedule is monitored on a monthly basis.

PAS management is responsible for ensuring the audit schedule is maintained. PAS supervisors are expected to cooperate with the quality personnel to provide them with complete access to the work area, personnel, and records needed to conduct the audit.

Internal audits may be performed by non-quality personnel when the auditor is approved by the local QM. Non-quality personnel may not audit their own work activities unless it can be

demonstrated that an effective and objective audit will be conducted. The person conducting the audit must be trained, qualified, and familiar enough with the objectives and policies of the PAS QMS and knowledgeable with process and test method SOPs related to the activities audited. The auditor should be trained in auditing practices in order to perform a thorough and effective evaluation.

Test method audits include reviews of test reports to verify the product is consistent with customer/project requirements, the work was conducted in accordance with policy and SOPs, the SOP complies with the cited reference method, test results are accurate, and of known and documented quality and properly qualified, when necessary.

Special audits are performed as needed to follow up on a specific issue such as a client complaint, negative feedback, concerns of data integrity or ethics, or a problem identified through other audits. Special audits may be scheduled or unscheduled. Unscheduled internal audits are conducted whenever doubts are cast on compliance with regulatory requirements or its own policies and procedures. These unscheduled internal audits may be conducted at any time and may be performed without an announcement to the location or work area audited.

When observations and findings from any audit (internal or external) cast doubt on the validity of testing results, the location takes immediate action to investigate the problem and take corrective action. (Also refer to Section 4.11 and 4.16)

#### 4.14.1.1 Corporate Compliance Audit

PAS locations may also be audited by Pace<sup>®</sup> corporate personnel at discretion. The purpose of the corporate compliance audit is to assess whether the location's practices, processes and procedures conform with the PAS QMS and to identify risk and opportunity.

### 4.15 Management Review

Local management conducts an annual business review of each location under their purview to assess performance and to establish goals, objectives, and action plans for the upcoming year.

The procedure used to conduct this review is specified in corporate SOP ENV-SOP-CORQ-0005 *Management Review*.

At a minimum, the following topics are reviewed and discussed during annual management review:

- Changes in internal and external issues relevant to the location;
- Fulfillment of objectives and initiatives;
- suitability of policies and procedures, including EHS and waste management;
- status of actions from previous performance reviews;
- 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 and personnel feedback, including complaints;
- Effectiveness of improvements / preventive actions made since last review;
- Adequacy of resources;
- results of risk identification;
- Proficiency testing performance and other measures related to the assurance of validity of test results; other relevant factors, such as QC trends and training status.

The discussion and results of this review are documented in a report prepared by local management. This report includes a determination of the effectiveness of the management system and its processes, goals, and objectives for improvements in the coming year with timelines and responsibilities, and any other need for change.

Goals and action items from annual management systems review are shared with local employees and with corporate management to highlight focus areas for improvement in addition to areas in which the location has excelled.

#### 4.16 Data Integrity

PAS procedures for the investigation and response to events that may affect data integrity are described in the PAS corporate SOP ENV-SOP-CORQ-0017 *Data Impact Assessments*.

Customers whose data are affected by the problem are notified in a timely manner, usually within 30 days after the impact of the problem is understood. Some accreditation programs also require notification to the accreditation body within a certain timeframe from date of discovery. PAS locations must follow any program or project specific requirements for notification, when applicable.

## 5.0 TECHNICAL REQUIREMENTS

### 5.1 General

Multiple factors contribute to the correctness and reliability of the technical work performed by PAS. These factors fall under these broad categories:

- Human Performance
- Facility and Environmental Conditions
- Test Method Performance and Validation
- Measurement Traceability
- Handling of Samples

The impact of each of these factors varies based on the type of work performed. To minimize negative effects from each of these factors, PAS accounts for the contribution from each of these categories

when developing test method and process (administrative) SOPs, evaluating personnel qualifications and competence, and in the selection of equipment and supplies used.

## 5.2 Personnel

### 5.2.1 Personnel Qualifications

PAS personnel are qualified and competent to perform the roles and responsibilities of their position based on education, experience, and training.

Qualifications, duties, responsibilities, and authorities of each position are specified in job descriptions maintained by corporate HR (Refer to Section 5.2.4). These job descriptions provide the general basis for the selection of personnel for hire and are used by the location to communicate to personnel the duties, responsibilities, and authorities of their position. Qualification records may include but are not limited to diploma, transcripts, and curriculum vitae (CV).

The term “personnel” refers to individuals employed by PAS or a PAS subsidiary directly as full-time, part-time, or temporary, and individuals employed by PAS by contract, such as through an employment agency. The term “personnel” is used interchangeably with the term “employee” throughout this manual. For the purposes of this manual, these terms are equivalent.

#### 5.2.1.1 Competence

Competence is the ability to apply a skill or series of skills to complete a task or series of tasks correctly within defined expectations.

PAS requirements for competence of personnel (education, qualification, work experience, technical skills, and responsibilities) are specified in job descriptions created by management and kept by human resources. The job description provides the basis for the selection of personnel for each position.

An employee is considered competent when they have completed the required training specified in Section 5.2.2.

### 5.2.2 Required Training

Training requirements are outlined in Pace® policies COR-POL-0023 *Mandatory Training Policy*, COR-POL-0004 *Code of Ethics and Professional Conduct* and this Quality Manual.

#### 5.2.2.1 Training Program

The PAS training program includes these elements:

- Scheduling
- Execution
- Documentation
- Evaluation of Effectiveness

Training is scheduled by corporate personnel, local quality personnel, and the employee’s direct supervisor.

Training is delivered using various methods that incorporate techniques that appeal to the four main learning styles: visual, aural, linguistic, and kinesthetic. Delivery methods include, on-the-job (OJT), instructor-led, self-study, eLearning, and blended.

Training must be documented with a training record to prove training occurred. Required training (Section 5.2.2.1.1-5.2.2.1.5) must be complete before the employee is authorized to work independently on client samples. Complete means the employee has successfully completed training and evidence of training is filed in the employees training record maintained by the corporate training group, the corporate group that assigned training, such as IT, HR, or EHS, and/or and the local quality department.

The employee's direct supervisor is responsible for monitoring completion of the employee's required training program and for providing adequate time to the employee to complete training assignments. The supervisor and employee are jointly responsible to ensure the employee's training status and training records for all required training are current, complete, documented and the training records are accessible.

Until the required training is complete, the employee's direct supervisor is responsible and accountable for all work produced by the employee under their supervision.

Training status is tracked by local quality personnel and made readily available to all employees so they can access and monitor their status in real time.

The following subsections specify the required PAS training for new hires and requirements for on-going training.

#### **5.2.2.1.1 New Hire Required Training**

New hire training requirements apply to personnel new to Pace<sup>®</sup> and to existing employees starting in a new position or different work area.

Required new hire training includes each of the following topics:

- Ethics and Data Integrity (5.2.2.1.3)
- Quality Management System Policy and Procedure (5.2.2.1.4)
- Environmental Health and Safety
- Demonstration of Capability (DOC) (5.2.2.1.5): Employees that prepare and test samples may also be required to successfully complete a DOC for the test method they are assigned before working independently on customer samples and to verify capability on a routine basis thereafter. Independent means without direct supervision of the work activity by the supervisor or a qualified trainer.

#### **5.2.2.1.2 On-Going Required Training**

All personnel receive on-going training on each of the following topics:

- Ethics and Data Integrity
- Quality Management System Policy and Procedure

- EHS

#### 5.2.2.1.3 Ethics and Data Integrity

Ethics and data integrity training is provided to all new personnel upon hire and refresher training is provided to all employees minimally on an annual basis and more frequently as needed.

The training materials emphasize expectations, what to do, what not to do and the potential consequences that result from scientific misconduct and improper practices. Employees are informed that Pace<sup>®</sup> has a Zero Tolerance Policy for scientific misconduct, improper practices, and fraud. The employment of any employee found to have conducted, sanctioned, or instructed an employee to engage in these infractions will be terminated and the employee may be subject to debarment, and civil/criminal prosecution.

The following topics are covered:

- Pace<sup>®</sup> Policy for honest, transparent, and objective reporting of test results and data;
- Practices that are considered scientific misconduct, fraudulent and improper;
- How and when to report data integrity concerns or ethical violations;
- Record Keeping. The training emphasizes the importance of accurate, complete, and legible documentation of work activities;
- Procedures used by Pace<sup>®</sup> to prevent and monitor for infractions;
- Specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

Refer to COR-POL-0004 for more information.

#### 5.2.2.1.4 Management System Documents Training

The primary documents that support the PAS QMS include the Quality Manual, policies, and SOPs.

These documents specify what we do, how, and why and are the documents all employees must abide. The employee's commitment to abide by these documents is acknowledged with a Read and Acknowledgement Attestation (R&A). PAS employees must have an R&A on record for the local Quality Manual, and the policies and SOPs relevant to their job responsibilities. The R&A acknowledges the employee has received, read, and understands the content of the management system document, the employee agrees to follow any instructions and requirements specified in the document when carrying out their work tasks; and the employee understands that unauthorized changes or departure



from procedures and requirements specified in the documents not allowed unless authorized, documented and disclosed.

Other documents that support the management system include forms and worksheets that record original observations and/or calculate test results, guides, project-specific documents, or other reference materials. Employees are not required to have a R&A for these types of documents – how to use the document is learned on the job.

Employee understanding, application, and adherence to the content specified in management system documents is continuously reinforced by on-the-job training and routine checks and balances, such as secondary data review and internal audits.

#### 5.2.2.1.5 Demonstration of Capability (DOC) Requirements

A DOC is a procedure that establishes the ability of the analyst to perform a test procedure and obtain test results with acceptable accuracy and/or precision.

Newly hired employees that prepare or test samples are required to successfully complete an initial demonstration of capability (IDOC) for the test method before they are permitted to work independently on real world samples.

On-going demonstration of capability (ODOC) must be demonstrated on an annual basis thereafter.

The procedure for IDOC and ODOC can differ based on technology, analyte group and/or the regulatory or accreditation/certification program requirements that apply. In general, the options for ODOC are more flexible than for an IDOC on the premise that the analyst has routinely analyzed samples by the test method during the calendar year.

When more than 365 days (1 Year) have passed since the employee last analyzed real world samples by the test method; the employee must successfully redemonstrate capability with an IDOC to remain authorized to independently test real world samples.

A successfully complete DOC (IDOC or ODOC) is one where:

- 1) The DOC study data has been compiled, reviewed, and verified to meet acceptance criteria;
- 2) The DOC record has been approved by the department supervisor;
- 3) The DOC record has been verified complete by local quality personnel; and
- 4) The DOC record has been archived in the employee's training file for accessibility and reference.

If any of the above conditions is not met, the DOC is not complete.

Until the required training is complete, the employee's direct supervisor is responsible and accountable for all work produced by the employee under their supervision.

DOC procedures and acceptance criteria vary by program, technology, analyte group - therefore all options are not specified in this manual.

PAS locations must put in place a local DOC program appropriate for the testing services offered and that complies with relevant regulatory and/or accreditation/certification program requirements.

For example – an acceptable DOC program for laboratories accredited to the TNI Standard might look like this:

- A DOC for chemistry test methods where spiking is an option is based on the employee's capability to achieve acceptable precision and accuracy for each analyte accredited from a series (usually 4) of replicates that were spiked at a specific concentration, and prepared and analyzed using the laboratory's test method SOPs.
- A DOC for a test method where spiking is not an option is based on an employee's capability to achieve comparable results to a peer.

If the above options are not feasible, a DOC may consist of:

- Analysis of one or more blind samples. Blind samples may be prepared by the trainer or other personnel and may consist of in-house prepared samples, reference slides, or previous PT studies.
- ODOC may be demonstrated through continued analysis of blind samples or successful completion of inter- and intra-analyst QC performed on five (5) percent of samples, or at least one (1) each month samples are received, whichever is greater.

AIHA-LAP, LLC Procedure for Initial D.O.C. of Lead Analysts & Technicians:

- For each matrix (wipe, air, paint, soil) prepare five aliquots of a suitable reference material. Prepare and analyze by routine procedures. Repeat this process on four different days for each matrix. Acceptance criteria shall meet the criteria of the method. Any outlier shall be addressed as a non-conforming event.

Specific instructions and acceptance criteria for DOCs for each test method may be specified in the test method SOP or a stand-alone SOP for DOC.

#### 5.2.2.2 Effectiveness of Training

Training effectiveness is measured by the employee's demonstrated ability to comprehend the training material and apply knowledge and skills gained to their job task. These evaluations include but are not limited to:

- Testing of the employee's knowledge of the QMS, policies, and technical and administrative procedures through various mechanisms, such as quizzes, and interviews.
- Demonstrated ability to convey information correctly and factually in written and verbal communication.
- Demonstrated ability to follow instructions and adhere to policy and procedure.
- Demonstrated ability to make sound decisions based on guidance and information available and to defend decisions made.
- Demonstrated initiative to seek help or guidance when the employee is unsure of how to proceed.

#### 5.2.2.3 Supplemental Learning

Supplemental learning objectives may be established for newly hired personnel to aid in their development of administrative and technical skills. These learning objectives and materials, referred to as Learning Plans (LP), are managed by the employee's direct supervisor.

Pace® also offers a wide variety of supplemental learning courses that are made available to all employees for professional development. The learning may be self-initiated based on an employee's interest or may be assigned to the employee at the discretion of management as professional development as part of an employee's annual goals.

Supplemental learning assignments are not prerequisites for competency (Section 5.2.1.1) and are not included in the required training program.

#### 5.2.3 Personnel Supervision

Every employee is assigned a direct supervisor, however named, who is responsible for their supervision.

General supervisory responsibilities may include but are not limited to:

- Hiring Employees
- Training Employees
- Performance Management
- Development, oversight, and execution of personnel training plans
- Monitoring personnel work product to ensure the work is conducted in accordance with this quality manual, policies, SOPs, and other documents that support the QMS.

#### **5.2.4 Job Descriptions**

Job Descriptions that define the required education, qualifications, experience, skills, roles and responsibilities, and reporting relationships for each Pace<sup>®</sup> position are established by top management and kept by corporate HR. The job descriptions apply to employees who are directly employed by Pace<sup>®</sup>, part-time, temporary, technical, and administrative and by those that are under contract with Pace<sup>®</sup> through other means.

The job descriptions include the education, expertise, and experience required for the position and the responsibilities and duties, including any supervisory or managerial duties assigned to the position.

#### **5.2.5 Authorization of Technical Personnel**

Technical personnel are authorized to perform the technical aspects of their position after laboratory management has verified that the employee meets the qualifications for the position and has successfully completed the required training (Section 5.2.2.1). After initial authorization, technical personnel are expected to maintain a current and complete training record, demonstrate on-going capability at least annually for each test method performed, and produce reliable results through accurate analysis of certified reference materials, proficiency testing samples, and/or routine quality control samples in order to remain authorized to continue to perform their duties.

Records used to support authorization which may include but are not limited to, transcripts, resumes, training records, experience, training, and certificates are kept by the PAS location or business function to which the employee is assigned, if the employee is in a role that support more than one location or business unit.

### **5.3 Accommodations and Facilities**

#### **5.3.1 Facilities**

PAS facilities are designed to support the activity performed. Access to PAS facilities is controlled by various measures, such as card access, locked doors, and staffed main entry.

#### **5.3.2 Environmental Conditions**

Each location is equipped with energy sources, lighting, heating, and ventilation necessary to facilitate proper and safe performance of calibrations and tests. Local management ensures that housekeeping, electromagnetic interference, humidity, line voltage, temperature, sound, and vibration levels are appropriately controlled to ensure the integrity of specific measurement results and to prevent adverse effects on accuracy or increases in the uncertainty of each measurement.

Environmental conditions are monitored, controlled, and recorded as required by the relevant specifications, methods, and procedures. Operations are stopped if it is discovered that the environmental conditions would jeopardize the integrity of analytical results or other work products.

#### **5.3.3 Separation of Incompatible Activities**

The layout and infrastructure of each work area including air handling systems, power supplies, and gas supplies of each work area are designed for the type of analytical activity performed. Effective separation between incompatible work activities is maintained. For example, sample

storage, preparation, and chemical handling for volatile organic analysis (VOA) is kept separate from semi-volatile organic analysis (SVOA).

Samples known or suspected to contain high concentration of analytes are separated from other samples to avoid the possibility of cross-contamination. If contamination is found, the source of contamination is investigated and resolved

#### **5.3.4 Security**

Security is maintained by controlled access to the building and by surveillance of work areas by authorized personnel. Access to each area may be controlled depending on the required personnel, the sensitivity of the operations performed, and potential safety concerns.

#### **5.3.5 Good Housekeeping**

Local management must maintain good housekeeping practices in their facilities and maintain a standard of cleanliness necessary for analytical integrity and personnel health and safety.

### **5.4 Test Methods**

#### **5.4.1 General Requirements**

PAS locations must use test methods and procedures that are appropriate for the scope of analytical test services the laboratory offers.

Instructions on the use and operation of equipment and sample handling, preparation, and analysis of samples must be specified in SOPs. The instructions in SOPs may be supplemented with other documents including, but not limited to, standard work instructions, manuals, guides, project documents, and other reference materials..

#### **5.4.2 Method Selection**

The test methods offered by PAS are primarily industry accepted published reference test methods. Each PAS laboratory bases its test method SOP on the latest version of the reference method unless regulatory requirements specify an earlier version must be used.

The laboratory confirms that it can perform the test method and achieve desired outcome before analyzing samples following method validation protocols specified in Section 5.4.5.

The test methods used by the laboratory to test real world samples must meet the needs of the customer, be appropriate for the intended use of the data, and must conform with applicable federal, statutory, or program requirements.

When a customer does not specify the test method(s) to be used, the laboratory may suggest test methods that are appropriate for the intended use of the data and the type of samples to be tested. The laboratory will also inform customers when test methods requested are considered inappropriate for their purpose and/or out of date. This discourse takes place during review of analytical service requests (Refer to Section 4.4).

#### **5.4.3 Laboratory Developed Methods**

A laboratory developed method is a test method developed wholly by PAS or a modification to a published method that is substantially modified from the specifications and procedures of a published test method.

Laboratory developed methods must be validated prior to use (Refer to Section 5.4.5) and the procedure documented in a test method SOP.

The requirements for non-standard methods (Section 5.4.4) also apply to PAS developed methods.

#### **5.4.4 Non-standard Methods**

A non-standard method is a testing protocol that is not published or approved for use by conventional industry standards.

Use of a non-standard method for testing must be agreed upon with the customer. The agreement, which is retained by the laboratory in the project record, must include the specifications of the client's requirements, the purpose of testing, and their authorization for use of the non-standard method.

#### **5.4.5 Method Validation**

The laboratory confirms that it can successfully perform the test method before analyzing samples through a process called method validation. Method validation is partially or fully repeated when there is a change in the published reference method or a change in the way the laboratory performs the test method that may affect selectivity, sensitivity, accuracy, precision, or general performance of the method.

##### **5.4.5.1 Validation Description**

Validation is the process of confirmation and the provision of objective evidence that the stated requirements for a specific method/procedure are fulfilled.

The laboratory's requirements and procedures for method validation are outlined in SOP ENV-SOP-CORQ-0011 *Method Validation and Instrument Verification*.

##### **5.4.5.2 Validation Summary**

All test methods offered by the laboratory are validated before use to confirm the procedure works as expected and the data and test results are accurate and precise.

The record of validation is retained and kept in accordance with method validation SOP and PAS corporate policy ENV-CORQ-POL-0013 *Record Management*.

##### **5.4.5.3 Validation of Customer Need**

The laboratory's validation process includes measures to assess accuracy, precision, sensitivity, selectivity, linearity, repeatability, reproducibility, robustness, and cross-sensitivity of the laboratory's procedure against general customer expectations for data usability.

The following subsections describe some of these concepts in relation to organic and inorganic chemistry (chemical testing). These descriptions and the requirements specified are pertinent to chemical testing and may not apply in the same context to other testing services offered by PAS such as radiochemistry, whole effluent toxicity (WET), asbestos, and microbiology. For more information about validation measures for these testing services, refer to the laboratory's test method SOPs.

#### 5.4.5.3.1 Accuracy

Accuracy is the degree to which the result of a measurement, calculation, or specification conforms to the correct value or a standard. When the result is within a range from the known value (control limit); the result is considered accurate.

#### 5.4.5.3.2 Precision

Precision refers to the closeness of two or more measurements to each other. It is measured by calculating the relative percent difference (RPD) or relative standard deviation (RSD) of results from separate analysis of the same sample. Precision provides information about repeatability, reproducibility, and robustness of the laboratory's procedure.

#### 5.4.5.3.3 Sensitivity in Chemical Testing

Sensitivity refers to the smallest amount of substance in a sample that can accurately be measured.

In chemical testing, this threshold is commonly known as the detection limit (DL) or method detection limit (MDL).

The DL is defined as the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results.

The DL is either a statistically derived value obtained by multiplying the standard deviation from a series of spiked replicates by the student-T value that correlates to the number of replicates analyzed or it is set to the concentration greater than found in a population of method blanks.

Detections of target analytes below the DL are not reported – unless specified by regulatory program protocol, because presence of target analytes at this level cannot be differentiated from noise.

Limits of Quantitation represent the threshold of the laboratory's procedure for quantitative sensitivity.

- The LOQ is the minimum level, concentration, or quantity of a target analyte that can be reported with a specified degree of confidence.
- The LLOQ is simply the concentration of the lowest calibration standard included in the calibration curve.

Although the LOQ and LLOQ may be and often are the same value; the definitions are not the same.

The LOQ is static – it is set when the DL is determined. The LOQ value must be routinely verified to confirm the laboratory can detect the concentration within a range of accuracy.

The LLOQ fluctuates based on the series of standards included in each calibration curve – the LLOQ is always the concentration of the lowest



calibration standard included in the curve fit and for which samples are quantitated against. The LLOQ is not the concentration of the lowest standard analyzed, if the lowest concentration standard is not included in the curve, it is not relevant to sample quantitation. Unless otherwise specified by test method, regulatory program or project-specific protocol, accuracy at the LLOQ does not need to be verified independent of the evaluation of relative error or relative standard error.

Target analytes detected at concentrations between the DL and LOQ are known as estimated values – they are within the range of qualitative identification and outside the range of quantitative accuracy. If reported, the results must be qualified to indicate the test result is estimated.

The meaning of Limit of Detection (LOD) varies based on the context by which the term is used. Outside of the DoD program, LOD is another term used to refer to the DL or MDL.

PAS laboratories that are accredited for DoD, must also establish an LOD. The DoD defines the LOD as the smallest concentration of a substance that must be present in a sample in order to be detected at the DL with 99% confidence. This definition is different from the definition of DL - the DL represents the theoretical value at which a detection is distinguishable from a blank.

For DoD, the LOD is a value between the DL and the LOQ. The value of the LOD set by the laboratory must meet all criteria for qualitative identification and quantitative accuracy based on the signal to noise ratio.

For DoD/DOE project work, target analytes that are not detected at the DL are reported as undetected at the LOD and results between the DL and the LOQ are reported as estimated values.

The reporting limit (RL) is the value to which test results are reported as detected or not detected. The RL may be project-defined based on project data quality objectives and it may be above or below the LOQ or LLOQ. In the absence of project specific requirements, the RL is usually the same value as the LLOQ. The RL is also called the practical quantitation limit (PQL) – but this can be misleading if the RL is less than the LLOQ or LOQ.

In general, the RL should always be greater than or equal to the value that establishes the threshold for quantitative sensitivity, but it is common for clients to request laboratories to report undetected target analytes at the DL value. This instruction has evolved as an acceptable reporting practice; however, data users should understand the DL is a statistically derived value that does not represent the limit of quantitation.

Unless otherwise specified by regulatory program or test method, detection, quantitation, and reporting limits are adjusted for the amount of sample used (preparation factor) and the dilution factor and are adjusted for percent moisture when samples are reported on a dry weight basis.



To ensure detection and quantitation limits are sound and defensible, the procedures that PAS laboratories use to establish detection, quantitation and reporting limits for chemical testing must comply with the current version of each of the following documents:

- EPA document EPA-821-R-16-006 Definition and Procedure for the Determination of the Method Detection Limit;
- 2016 TNI Environmental Laboratory Standard Volume 1 Module 4; and
- TNI GUID-3-109-Rev. 0, V1M4 2016 Standard Update Guidance on Detection and Quantitation.

#### 5.4.5.3.4 Sensitivity in Microbiological Testing

In microbiological testing, the detection limit (DL) is the lowest microbial density that can be measured. It is determined by using dilutions of reference cultures and measuring recovery among replicates of each dilution. For most microbiological methods the sensitivity is defined in the method. For example, in most colony counting methods the sensitivity is 1 cfu. In microbial testing, the LOQ and LLOQ are the same as the DL.

#### 5.4.5.3.5 Sensitivity in Asbestos Testing

Analytical sensitivity for Transmission Electron Microscopy (TEM) in waters is defined as the waterborne concentration represented by the finding of one asbestos structure in the total area of filter examined. This value will depend on the fraction of the filter sampled and any dilution factor.

Analytical sensitivity for (TEM) in air is defined as the airborne concentration represented by the finding of one asbestos structure in the total area of filter examined. This value will depend on the effective surface area of the filter, the filter area analyzed, and the volume of air sampled.

The normal quantitative working range for Phase Contrast Microscopy (PCM) is 0.04 to 0.5 fiber/ cm<sup>2</sup> for a 1000 L air sample. An ideal counting range on the filter shall be 100 to 1300 fibers/mm<sup>2</sup>. The limit of detection (LOD) is estimated to be 5.5 fibers per 100 fields or 7 fibers/mm<sup>2</sup>. The LOD in fiber/cc will depend on sample volume and quantity of interfering dust but shall be <0.01 fiber/cm<sup>2</sup> for atmospheres free of interferences.

Refer to the method SOP for analytical sensitivity for Polarized Light Microscopy (PLM).

#### 5.4.5.3.6 Selectivity

Selectivity refers to the ability of a method to correctly determine an analyte or species without interference from the surrounding matrix.

#### 5.4.5.3.7 Linearity

Linearity is a mathematical concept applied to calibration models that employ multiple points to establish a calibration range used for quantitative analysis. Linearity is measured differently based on the calibration model. In general, if linearity is demonstrated then the slope of the response of standards is sufficiently close to one another. The accuracy of the linear regression and non-linear curves is verified by checking percent error or relative standard error (RSE), which is the process of refitting calibration data back to the model to determine if the results are accurate. For linear curves that use average calibration or response factor, error is measured by relative standard difference. Linearity also establishes the range of quantitation for the test method used which directly impacts the sensitivity of the test method and uncertainty in measurement results. As previously noted, the LLOQ establishes the lower limit of quantitation. The upper range of linearity establishes the upper limit of quantitation. For most technologies, results outside of this range are considered qualitative values. However, some inorganic test methods allow the linear range to be extended above the upper limit of quantitation when accuracy at this level is verified. Linearity can also be used to establish repeatability, reproducibility, and robustness of the laboratory's test method. When linearity is demonstrated using a specific calibration model during method validation, then use of this same calibration model to achieve linearity on a day-to-day basis confirms the laboratory's method is repeatable, reproducible, and robust.

#### 5.4.6 Measurement Uncertainty

PAS provides an estimate of uncertainty with analytical results on request, or when required. For example, for radiochemistry testing, uncertainty is always reported with the test result.

For chemistry the uncertainty of the test method is embedded in the control limits used to assess performance of quality control samples. Language in ISO/IEC 17025 clarifies that measurement uncertainty is satisfied when a well-recognized test method specifies limits that account for source of bias, the laboratory has satisfied the requirements on analytical uncertainty by following the test method and reporting instructions. Refer to Section 5.9.1.1.9 for more information.

For BDSG microbiology and asbestos refer to ENV-GUI-BDSG-0009 *Measurement of Uncertainty*

#### 5.4.7 Control of Data

PAS has policies and processes in place to ensure that reported data is free from calculation and transcription errors, manual changes to data are thoroughly reviewed for need and correctness, and software systems used to generate or store data is secure.

##### 5.4.7.1 Calculations, Data Transfer, Reduction and Review

Data reduction is performed using commercially available data processing/reduction software, the LIMS and/or programs and worksheets created by PAS.

PAS does not permit manual calculation of results – that is the calculation of a test result by pen and paper or calculator. When there is no commercial software or LIMS option, PAS laboratories must create a worksheet from a spreadsheet program, such as Excel, to calculate results based on raw inputs and original observations. Spreadsheets for these purposes must be validated and controlled in accordance with policy ENV-POL-CORQ-0015 *Spreadsheet Validation*.

#### 5.4.7.1.1 Manual Integration

The PAS policy and procedures for manual integration are specified in PAS SOP ENV-SOP-CORQ-0006 *Manual Integration*.

This SOP includes the conditions under which manual integration is allowed and the requirements for documentation.

Required documentation of manual integration minimally includes:

- complete audit trail to permit reconstruction of before and after results;
- identification of the analyst that performed the integration and the reason the integration was performed; and
- identification of the individual(s) that reviewed the integration and verified the integration was done and documented in compliance with the SOP.

#### 5.4.7.2 Use of Computers and Automated Acquisition

Whenever possible, PAS uses software and automation for the acquisition, processing, recording, reporting, storage, and/or retrieval of data.

In-house developed software is validated by Pace® corporate IT for adequacy before release for routine use. Commercial off-the-shelf software is considered sufficiently validated when the location follows the manufacturer or vendor's manual for set-up and use. Records of validation are kept by the corporate information technology group or by the group that performed the validation.

The PAS process for the protection of data stored in electronic systems includes:

- Individual usernames and passwords for Laboratory Information Management Systems and auxiliary systems used to store or process data.
- Employee Training in Computer Security Awareness
- Validation of spreadsheets used for calculations to verify formulas and logic yield correct results and protection of these cells to prevent unauthorized change.
- Operating system and file access safeguards
- Protection from Computer Viruses
- Regular system backup; and testing of retrieved data

- Verification the software application works as expected and is adequate for use and fulfills compliance requirements, such as the need to record date/time of data generation.
- Change control to ensure requests for changes are reviewed and approved by management before the change is made.
- Communication channels to assure all staff are aware of changes made.
- Version Control and maintenance of historical records.

## 5.5 Calibration Requirements

### 5.5.1 Availability of Equipment

Local management ensures the laboratory is furnished with all equipment and instrumentation necessary to correctly perform the tests offered in compliance with the specifications of the test method and to achieve the accuracy and sensitivity required.

### 5.5.2 Calibration

Equipment and instrumentation are checked prior to use to verify it performs within tolerance for its intended application.

#### 5.5.2.1 Support Equipment

Support equipment is verified to be in proper working order, and to meet the tolerance specifications for the purpose(s) for which it will be used prior to placement in service. Thereafter, periodic checks are performed to verify on-going performance per a schedule maintained by local quality personnel. Support equipment that does not meet specifications is removed from service and either repaired or replaced. Records of repair and maintenance activities are maintained.

Procedures used to conduct and record these checks are outlined in SOP SOP ENV-SOP-WES2-0036, *Balance Calibration Verification*, ENV-SOP-WES2-0039 *Thermometer Calibration*, ENV-SOP-WES2-0123 *Autopipet and Wet Chem Titrator Calibration Verification*.

#### 5.5.2.2 Analytical Instruments

Analytical instruments are checked prior to placement in service in accordance with SOP ENV-SOP-CORQ-0011 *Method Validation and Instrument Verification*. After the initial service date, the calibration of instruments and verification of calibration is performed in accordance with local test method SOPs.

The calibration procedures in the test method SOPs must comply with the requirements for acceptable calibration practices outlined in corporate policy ENV-POL-CORQ-0005 *Acceptable Calibration Practices*, the reference methods, and any applicable regulatory or program requirements.

### 5.5.3 Equipment Use and Operation

Up-to-date instructions and procedures for the use and maintenance of analytical equipment are included in SOPs and/or supplemental documents such as standard work instructions or

instrument manuals which are made readily accessible in the work area to all laboratory personnel.

#### **5.5.4 Equipment Identification**

Each piece of equipment is uniquely identified by serial number or any other unique ID system. The identifier is included in the equipment list maintained by the quality department and may not be reused or used interchangeably. New equipment and replacement equipment are assigned a new unique ID. When transferring equipment between PAS locations, the laboratory receiving the equipment assigns a new unique ID and the lab that sent the equipment retires the ID previously assigned.

#### **5.5.5 Equipment Lists and Records**

##### **5.5.5.1 Equipment List**

Each PAS location maintains a list of equipment that includes information about the equipment including a description, manufacturer, serial number, date placed in service, condition when received, identity, and the work area where the equipment is used. The equipment list(s) for each location covered by this manual is managed by local Quality and maintained in the QA groups in Teams.

##### **5.5.5.2 Equipment Records**

In addition to the equipment list, other equipment records maintained by PAS include:

- Verification that equipment conforms with specifications.
- Calibration records including dates, results, acceptance criteria, and next calibration dates.
- Maintenance plan and records.
- Records of damage, malfunction, or repair.

The laboratory follows an equipment maintenance program designed to optimize performance and to prevent instrument failure which is described in the analytical method SOPs.

The maintenance program includes routine maintenance activities which are performed as recommended by the manufacturer at the frequency recommended and non-routine maintenance, which is performed to resolve a specific problem such as degradation of peak resolution, shift in calibration relationship, loss of sensitivity, or repeat failure of instrument performance checks and quality control samples.

Maintenance is performed by PAS personnel or by outside service providers.

All maintenance activities performed by PAS personnel are recorded by the individual(s) that performed the activity at the time the maintenance was performed in an instrument maintenance log.

The maintenance record minimally includes the date of maintenance, the initials of the person(s) performing maintenance, a description of the activity performed, why

(when the maintenance is non-routine), and the return to analytical control. When maintenance is performed by an external vendor, the service record must be maintained and accessible for easy retrieval. The location must provide personnel with unrestricted access to instrument maintenance logs in order to promote good instrument maintenance and recordkeeping practices.

If an instrument must be moved, the location will use safe practices for handling and transport to minimize damage and contamination

#### 5.5.6 Out of Service Protocol

Equipment that has been subjected to overloading, mishandling, gives suspect results, has been shown to be defective, or is performing outside of specified limits is taken out of service and either removed from the work area or labeled to prevent accidental use until it has been repaired and verified to perform correctly.

When analytical equipment is taken out of service because it no longer meets tolerance specifications, the potential effect the nonconformity may have had on previously reported analytical results is evaluated.

#### 5.5.7 Calibration Status

Support equipment is labeled to identify its calibration status.

The calibration status of analytical instruments is identified in the instrument run log, in the data processing software or other systems the laboratory may use for processing of data. Analysts verify on-going acceptability of calibration status prior to use and with instrument performance check standards. These procedures are described in test method SOPs.

#### 5.5.8 Returned Equipment Checks

When equipment or an instrument is sent out for service, the function and calibration status of the equipment must be rechecked and shown to be satisfactory before the equipment is returned to service. This requirement must be included in the laboratory's protocols for servicing equipment.

#### 5.5.9 Intermediate Equipment Checks

PAS performs intermediate checks on equipment to verify the on-going calibration status. For example, most test methods require some form of continuing calibration verification check, and these procedures are included in the test method SOP. Periodic checks of support equipment are also performed; Refer to SOP ENV-SOP-WES2-0036 *Balance Calibration Verification*, ENV-SOP-WES2-0039 *Thermometer Calibration*, ENV-SOP-WES2-0039 *Autopipet and Wet Chem Titrator Calibration Verification* for more information.

#### 5.5.10 Safeguarding Equipment Integrity

Equipment integrity is maintained by:

- Following manufacturer's specification for instrument use so that settings do not exceed manufacturer's recommendation or stress the performance of the equipment;
- Established maintenance programs;
- Transparent maintenance records and unrestricted access to maintenance logs;

- Validation and approval of software before use;
- Audits to confirm instrument settings are consistent with SOPs; and
- On-the-job training for safe and proper use of laboratory equipment.

## 5.6 Measurement Traceability

### 5.6.1 General

Measurement traceability is best described as the way to ensure measurements take into consideration all uncertainties and are representative of the most accurate measurement captured. Traceability is accomplished with the recording of the lot numbers of materials and equipment used in the testing process and by purchasing materials traceable to the international standards of units (SI), International Bureau of Weights and Measures (BIPM) and/or National Measures Institute (NMI).

When traceability to SI units, BIPM, or NMI cannot be achieved, traceability is accomplished with the use of reference standards and equipment obtained from competent suppliers that provide calibration certificates and/or certificates of analysis (COA).

### 5.6.2 Equipment Correction Factors

Measurements are adjusted by the correction factor when the equipment used for the measurement has a correction factor.

#### 5.6.2.1 Requirements for Calibration Laboratories

PAS does not offer calibration services, therefore, the ISO/IEC 17025 requirements for calibration laboratories do not apply.

#### 5.6.2.2 Requirements for Testing Laboratories

Requirements to verify equipment is calibrated prior to being put into service and to maintain measurement traceability are described in sections 5.5.2 and 5.6, respectively.

### 5.6.3 Reference Standards and Reference Materials

#### 5.6.3.1 Reference Standards

The laboratory uses measurement reference standards to verify adequacy of working weights and thermometers. The working weights are the weight(s) used for daily balance calibration checks and the working thermometers are used for daily temperature measurements.

Working weights and thermometers are periodically checked to verify on-going adequacy for use between the calibrations performed by an external calibration laboratory using reference standards traceable to SI or a national standard and that are used solely for verification purposes.

For example:

- An acceptable reference standard to verify working thermometers is a NIST Certified thermometer or a NIST Traceable thermometer that is not used for any other purpose other than to check the adequacy of the working thermometer.



- An acceptable reference standard for the working weights is a set of Class S weights that is not used for any other purpose than to verify the weights used daily.

The working weights are checked against the reference standard annually and recertified by an ISO accredited calibration body every 5 years. “Annually” means within thirteen (13) months from the date of the last check.

Working thermometers are checked against the reference thermometer prior to placement in service to establish a correction factor (CF) and then re-checked annually (within 13 months from date of last check) or if electronic, every three (3) months (within 100 days from date of last check).

Exceptions to the 3-month recheck for battery operated sensors are allowed when the sensor is embedded in a unit and the manufacturer/vendor has evidence to show that the accuracy of the sensor is not affected by battery life.

Liquid in Glass NIST Certified reference thermometers must be recertified by an ISO/IEC accredited calibration laboratory every 5 years. If the reference thermometer is NIST Traceable or is a digital NIST Certified thermometer, the reference thermometer must be recertified annually by an ISO/IEC 17025 accredited calibration laboratory or service provider that provides traceability to a national standard.

#### 5.6.3.2 Reference Materials

PAS purchases chemical reference materials (also known as stock standards) from vendors that are accredited to ISO 17034 or Guide 34. Purchased reference materials must be received with a Certificate of Analysis where available. If a reference material cannot be purchased with a COA, it must be verified by analysis and comparison to a certified reference material and/or there must be a demonstration of capability for characterization. COAs are reviewed for adequacy and retained by the laboratory for future reference.

All prepared standards, reference materials, and reagents are verified to meet the requirements of the test method through routine analyses of quality control samples.

The laboratory procedure for traceability and use of these materials is provided in SOP ENV-SOP-WES2-0038 *Reagent Solvent and Standard Control*.

This SOP must minimally include each of the following requirements:

- Procedures for receipt and tracking of reference and working standards to ensure the record includes material name, name of the material, lot number, receipt date, and manufacturer’s expiration date.
- Storage conditions and the requirement that reference standards are stored separately from samples, extracts, and digestates.
- Requirements to assure that preparation of intermediate or working solutions are recorded and assigned a unique identification number for tracking. Records of preparation include the lot number of the stock standard(s) used, the type and lot number of the solvent, the formulation, date, new expiration date, and the

preparer's initials. The lot number of working standards is recorded in the analytical record to provide traceability to the standard preparation record. The preparation record provides traceability to the COA, which is traceable to SI or the national measurement standard.

- A requirement that the expiration dates of prepared standards may not exceed the expiration date of the parent standard. Standards, reference materials, and reagents are not used after their expiration dates unless it is not possible to procure a new standard, and the reliability of the expired material is verified and documented by the location using a procedure approved by corporate quality personnel. Otherwise, the expired material is promptly removed from the work area or clearly labeled as acceptable for qualitative/troubleshooting purposes only.
- The second source materials used for verification of instrument calibration are obtained from a different manufacturer or may be a different lot from the same manufacturer, when only one vendor or manufacturer provides the standard.
- Procedures to check reference materials for degradation and replacement of material if degradation or evaporation is suspected.
- Procedures for labeling. At a minimum, the container must identify the material, the ID of the material and the expiration date. Original containers should also be labeled with date opened.

#### 5.6.3.3 Intermediate Checks

Checks to confirm the acceptability of reference standards and materials are specified in test method SOPs and are appropriate for the purpose for which the standard is used. For example, a second source standard analyzed after an initial calibration may help the analyst identify if degradation of the standards used for calibration has occurred.

#### 5.6.3.4 Transport and Storage

PAS handles, transports and stores reference standards in a manner that protects the integrity of the materials. The integrity of the reference standard is protected by segregation from incompatible materials and/or minimizing exposure to degrading environments or materials. As previously stated, standards and reference materials are stored separately from samples, extracts, and digestates to prevent contamination. All standards are stored according to the manufacturer's recommended conditions. Temperatures colder than the manufacturer's recommendation are acceptable if it does not compromise the integrity of the material (e.g., remains in liquid state and does not freeze solid).

Specific requirements are provided in test method SOPs.

### 5.7 Sampling

Sampling refers to both the field collection of samples and to subsamples taken by the laboratory for analysis.

Subsampling procedures are included in each test method SOP or a stand-alone SOP to assure the aliquot used for testing is representative of the field collected sample.

The requirements in the following subsections apply when sampling is performed by PAS.

#### **5.7.1 Sampling Plans and SOPs**

When PAS performs field collection of samples, the sampling is conducted in accordance with a project sampling plan and sampling SOPs to ensure representative samples are collected.

#### **5.7.2 Customer Requested Deviations**

When the customer requests deviations, additions, or exclusions from the project sampling plan and/or the SOP, the laboratory records the client's change request in detail with the sampling record, communicates the change to sampling personnel, and includes this information in the final test report..

#### **5.7.3 Recordkeeping**

PAS assures the sampling record includes the sampling procedure used, any deviations from the procedure, the date and time of sampling, the identification of the sampler, environmental conditions (if relevant), and the sampling location.

### **5.8 Sample Management & Handling**

#### **5.8.1 Procedures**

The procedures for sample management and handling are outlined in SOP ENV-SOP-WES2-0003 *Sample Receipt and Login* and SOP ENV-SOP-WES2-0002 *Sample Custody and Tracking*. The procedures in the local SOP must meet the requirements specified in this quality manual to guarantee the integrity of the sample from receipt to disposal.

##### **5.8.1.1 Chain of Custody**

All samples received by PAS must be accompanied by a Chain of Custody (COC). The COC is the legal record that documents the collection of samples and the transfer of samples to the laboratory. The COC provides PAS with information about the samples collected and tests requested.

The COC is completed by the sample collector and must minimally include the following information:

- Client name, address, phone number;
- Project Reference;
- Client Sample Identification (Client ID);
- Date, Time, and Location of Sampling;
- Sampler's Name or Initials;
- Matrix;
- Type of container, and total number collected;
- Preservative;

- Analyses Requested;
- Mode of collection;
- Any special instructions; and
- The date and time and signature of sample transfer from collection to PAS. When samples are shipped to the laboratory by a 3<sup>rd</sup> party such as UPS or Fed EX, the COC is placed inside the sealed shipping container at time of collection and the container is not opened until it is received by PAS. Thus, the intermediate courier does not sign the COC. The shipping manifest and/or air bill is the record of possession of samples during transport to the laboratory. The shipping manifest and/or air bill is part of the COC record and must be retained and provided in the test report with the COC record, when required. (Refer to Section 5.10.3).

A complete and legible COC is required. When the COC is incomplete, illegible, or cannot be understood, the client is contacted for resolution.

Hand entries on the COC must be made in indelible ink and errors corrected by drawing a single line through the original entry, so the original entry is not obscured and entering the correct information with the date the change was made and the initials of the person making the change.

#### 5.8.1.2 Legal Chain of Custody

Legal chain of custody is an industry defined protocol that is sometimes used for evidentiary or legal purposes that establishes an intact, continuous record of the physical possession, storage, and disposal of samples, including sample aliquots and prepared samples.

The legal COC record accounts for all time periods associated with the samples and identifies all individuals who physically handled them from the point established by legal authority, which is usually at the time the sample containers are provided for sample collection or at the time of sample collection.

A sample is in someone's legal custody if:

- It is in one's physical possession;
- It is in one's view after being in one's physical possession;
- It has been in one's physical possession and then locked or sealed so that no one can tamper with it; and/or
- It is kept in a secure area, restricted to authorized personnel only.

Legal COC is not a common request, but if it is requested and the laboratory agrees to the project specification; the laboratory must maintain a procedure or process to guarantee all aspects of the protocol are met.

### **5.8.2 Unique Identification**

Each sample received by PAS is assigned a unique identification number (Lab ID) after the sample has been accepted by PAS in accordance with the PAS sample acceptance policy (Refer to Section 5.8.3). The Lab ID is affixed to the sample container using a durable label.

The lab ID is linked to the field ID (client ID) in the sample receipt and log-in record so that both IDs are traceable to testing activities performed.

### **5.8.3 Sample Receipt Checks and Sample Acceptance Policy**

The condition and integrity of samples is checked on receipt and the samples received are verified to match the COC. Any problem with the samples or discrepancy between the COC is recorded. If the problem impacts the suitability of the sample for analysis or if the COC is incomplete, the client is notified for resolution. Decisions and instructions from the client regarding the samples are maintained in the project record.

#### **5.8.3.1 Sample Receipt Checks**

The following checks are performed:

- The COC is complete and legible;
- Sample container labels include the client sample ID, the date and time of collection, and the preservative used;
- The container type and preservative are appropriate for the test requested;
- The required volume is received for each test requested;
- There is no evidence of damage or tampering;
- There is no headspace in VOA vials greater than 5-6 mm (the size of a pea);
- Thermal Preservation, when required. When thermal preservation is required, temperature on receipt is typically considered acceptable if the temperature is  $\leq 6^{\circ}\text{C}$  and the samples are not frozen solid unless otherwise specified by federal, statutory, program or test method. If samples are received on the same day of collection, there must be evidence that the chilling process has begun, such as arrival of the samples on ice.
- Chemical Preservation, as required.
- Holding Time. When the holding time for the test method is longer than 15 minutes from time of collection and samples are received out of hold, the client is notified of the situation so they can make a decision to proceed or cancel analysis. Tests with a holding time of 15 minutes or less from time of collection are those where the method specifies the holding time as “immediate” are excluded from the notification requirement because the customer is aware that the holding time cannot be met unless the test is performed in the field (in situ).

#### 5.8.3.2 Sample Acceptance Policy

PAS maintains a sample acceptance policy to clearly establish the circumstances in which samples are accepted.

When these conditions are not met, the exception must be documented, and the client notified. Decisions to accept or reject the samples are documented and when required, test results are qualified in the test report. How the notification requirement is achieved must be included in a laboratory SOP.

Criteria for Sample Acceptance:

- All samples received must be listed on the COC and the information provided must include the client ID of the sample, date and time of collection, collector's name, preservation type and type of sample;
- The sample containers must be properly labeled to uniquely identify the sample; and the label must be both durable and legible;
- The sample container must be appropriate for the tests requested;
- Samples must be received within holding time. Exceptions are made for samples where the test method specifies a holding time of "immediate or immediately" – which is translated to within 15 minutes from sample collection. For these test methods, samples are always received out of hold and/or there is no expectation that the laboratory perform the test within the 15-minute holding time.
- Sufficient sample volume must be provided to perform the test method per the laboratory's SOP. If the test is performed for regulatory compliance and the method requested is mandated; the volume provided must be adequate for the laboratory to perform the test per the test method without modification.
- Be received within appropriate temperature ranges unless program requirements or customer contractual obligations mandate otherwise.
- Be free of evidence of tampering or signs of contamination; and
- Meet applicable requirements for thermal and chemical preservation.

Additional conditions may also apply depending on the services offered. For example, some PAS locations will not accept samples known to be radioactive.

#### 5.8.4 Sample Control and Tracking

Samples received by PAS are tracked using the laboratory's Laboratory Information Management System (LIMS).

After the sample receipt process is complete, samples are logged into the LIMS and a Lab ID is assigned and affixed to each container with a durable label. The Lab ID is used to track the samples through the testing process through test report generation and sample disposal.

Minimally, the following information is included in the log-in for each sample:

- Client Name and Contact Information;

- The laboratory ID linked to the client ID;
- Date and time of sample collection;
- Date and time of sample receipt;
- Matrix; and
- Tests Requested.

After log-in is complete, the log-in record must be independently reviewed by the PAS Project Manager (PM) responsible for the work order to verify the log-in is complete and correct per the testing agreement with the customer and the chain-of-custody so that any log-in errors or questions about the samples received are corrected and resolved before work begins.

## 5.8.5 Sample Storage, Handling, and Disposal

### 5.8.5.1 Sample Storage

The samples are stored according to the specification in the test method and any applicable program and regulatory requirements. Samples are stored separately from standards, reagents, or other potential sources of contamination and in a manner that prevents cross contamination. All sample fractions, extracts, leachates, and other sample preparation products are stored in the same manner as actual samples or as specified by the analytical method.

Refrigerated storage areas are maintained at  $\leq 6$  (but not frozen) and freezer storage areas are maintained at  $\leq -10^{\circ}\text{C}$ , unless otherwise required per method or regulatory program. The temperature of each storage area is checked and documented at least once for each day of use. If the temperature falls outside the acceptable limits, corrective actions are taken and documented.

Samples are placed in the storage location immediately after sample receipt and log-in procedures are completed. All sample storage areas have limited access. Samples are removed from storage areas by designated personnel and returned to the storage areas as soon as possible after the required sample quantity has been taken.

### 5.8.5.2 Sample Retention and Disposal

The procedures used by the location for sample retention and disposal are detailed in SOP ENV-SOP-WES2-0002 *Sample Custody and Tracking* and ENV-SOP-MANS-0077 *Hazardous Waste Management and Sample Disposal*.

In general, PAS retains unused sample volume and prepared samples such as extracts, digestates, distillates and leachates (samples) per Pace® Terms & Conditions, <https://info.pacelabs.com/hubfs/pas-standard-terms.pdf>.

After analysis, samples may be stored at ambient temperature until time of sample disposal, unless otherwise specified by regulation or agreed upon contract specifications.

After the retention time has expired non-hazardous samples are properly disposed. Hazardous samples are returned to the customer, unless other arrangements for disposal have been made with the laboratory.



## 5.9 Assuring the Quality of Test Results

### 5.9.1 Quality Control (QC) Procedures

PAS monitors the validity and reliability of test results using quality control samples that are prepared and analyzed concurrently with and in the same manner as field samples. QC results are always associated with and reported with the field samples they were prepared and analyzed with.

When the results are not within acceptance criteria correction and corrective action(s) are taken. These actions may include retesting or qualification of test results and/or disclosure of the situation in the test report to alert the data user of the situation.

Other control measures to maintain quality of test results include the use of certified reference materials (Refer to Section 5.6.3), participation in interlaboratory proficiency testing (Refer to Section 5.9.1.2), verification that formulae used for reduction of data and calculation of results is accurate (Refer to Section 5.9.3), on-going monitoring of environmental conditions that could impact test results (Refer to Section 5.3.2), and evaluation and verification of method selectivity and sensitivity (Refer to Section 5.4.5).

QC results are also used for trend analysis and to establish acceptance criteria when no method or regulatory criteria exist. (Refer to Section 5.9.1.1.9).

#### 5.9.1.1 Essential QC

QC protocol is technology and test method specific and is specified in test method SOPs. The SOP includes the type of QC required, frequency for analysis, acceptance criteria, recommended corrective actions, and procedures for reporting test results associated with QC exceptions.

PAS ensures the QC requirements in the SOP conform to the reference method and applicable regulations for which results of the test are used and to any program requirements for the process required by the certification/accreditation program required for testing.

- When a project requires more stringent QC protocol than specified in PAS policy or the test method SOP, the project specification is followed.
- When the project requires less stringent QC protocol than PAS policy or the SOP, the project specification may be followed as an authorized departure if the project specification still meets the requirements in the test method and any applicable regulatory and certification/accreditation requirements.

The following sections describe essential QC for chemistry. These QC types may not apply to other technologies and disciplines such as microbiology, radiochemistry, whole effluent toxicity, and/or asbestos. For essential QC for these test offerings, refer to test method SOPs.

##### 5.9.1.1.1 Calibration Verification (Second Source)

A second source standard is a standard from a different vendor or from a different lot than the standards used for initial calibration. A different lot

from the same vendor is permissible, when the standard is only available from a single vendor.

It is a positive control used to verify the accuracy of instrument calibration relative to the purity of the standards used for calibration. This check may be referred to in published test methods and quality system standards as the initial calibration verification (ICV) or a quality control sample (QCS). For most test methods, it is analyzed immediately after the calibration and before analysis of any samples. When the ICV is not within acceptance criteria, a problem with the purity or preparation of the standards may be indicated. The source of the problem should be investigated and corrected prior to use of the calibration/instrument for sample analysis.

#### 5.9.1.1.2 Calibration Verification (CCV)

The CCV is used to determine if the analytical response has significantly changed since calibration. The CCV is usually made from the same standards used for initial calibration, but a second source standard may be used.

When the response of the CCV is within criteria, the calibration is considered valid. If not, there may be a problem that requires further investigation and correction. The actions taken are technology and method specific.

It is sometimes acceptable to report test results associated with a CCV that does not meet criteria.

For example, when a CCV exceeds criteria above the limit; high bias is suspected in the measurement system. If the analyte is not detected in the sample; then the high bias has no impact on the validity of the test result. If the analyte is detected in sample, then corrective action to bring the CCV within criteria is expected to eliminate the possibility that the detection is biased.

#### 5.9.1.1.3 Blanks

Blanks are negative controls used to assess for contamination.

The method blank (MB) is a clean matrix similar to the associated samples that is known to be free of analytes of interest. The MB, unless otherwise specified by the test method, is processed with, and carried through all preparation and analytical steps as the associated samples.

The criteria used to assess for contamination depends on the intended use of data. In general, detections in the MB above the RL or ½ the RL indicate contamination. When contamination is indicated, the source is investigated, and corrections are taken to reduce or eliminate it. Analytical results associated with MB that do not meet criteria are qualified in the final test report.

Other types of blanks that serve as negative controls in the process may include:

- Trip Blanks (VOA)
- Storage Blanks
- Equipment Blanks
- Field Blanks
- Calibration Blanks
- Cleanup Blanks
- Instrument Blanks

#### 5.9.1.1.4 Laboratory Control Sample (LCS)

The LCS is a positive control used to measure accuracy. The LCS is a blank matrix spiked with standard solution that includes target analytes or it may be a pre-made certified reference standard. Like the MB, unless otherwise specified in the test method, the LCS is processed with and carried through all preparation and analytical steps as the associated samples.

When the percent recovery (%R) of the LCS is within the established control limit, the test is within control. If not, the cause of the problem is investigated and corrected, and the procedure may be repeated. Analytical results associated with LCS that do not meet criteria are qualified in the final test report.

#### 5.9.1.1.5 Matrix Spike (MS) and Matrix Spike Duplicate (MSD)

The MS and MSD are replicates of a client sample that is spiked with known amount of target analyte. When there is not a client-designated matrix spike on any sample in the batch, the MS/MSD may be performed on a randomly selected sample and these MS/MSD are called “batch” MS/MSD.

MS/MSD results provide information about the effects the sample matrix has on recovery and reproducibility of target analytes on site samples. MS/MSD results are not used to control performance of the preparation or analytical batch because the way in which the matrix impacts efficiency and robustness of the test cannot be mitigated or controlled by the laboratory.

The heterogeneity of the sample submatrix influences accuracy and precision. For example, MS/MSD results for a sample that is mostly sand will not be the same for a sediment sample even though both matrices are “soil” and both samples subjected to the same test procedure in the same batch. For this reason, batch MS/MSD results may not be representative of the effect the matrix has on accuracy and precision on test results for all

samples in the batch – except when all samples in the batch are from the same collection site and are identical in composition.

#### **5.9.1.1.6 Sample Duplicate (SD)**

A sample duplicate is a second replicate of sample taken through the testing process used to measure precision and/or homogeneity of samples collected.

The relative percent difference between replicates is evaluated against the established acceptance criteria and if the RPD is not met, associated test results are reported with qualification.

#### **5.9.1.1.7 Surrogates**

Surrogates are compounds not normally found in the environment but that have similar physical and chemical properties of target analytes that are added to environmental samples, QC, and calibration standards prior to preparation and analysis. They are used to evaluate extraction efficiency and matrix interference on a sample specific basis.

The percent recovery of surrogates is evaluated against method-specified limits or statistically derived in-house limits. Project-specific limits and/or program-specific limits are used when required. Results with surrogate recovery out of limits in samples are reported with qualification. Samples with surrogate failures can also be re-extracted and/or re-analyzed to confirm that the out-of-control value was caused by the matrix of the sample and not by some other systematic error.

#### **5.9.1.1.8 Internal Standards**

Internal Standards are compounds not expected to occur naturally in field samples. They are added to every standard and sample at a known concentration prior to analysis for the purpose of adjusting the response factor used in quantifying target analytes. The location follows specific guidelines for the treatment of internal standard recoveries and further information can be found in the applicable test method SOP.

#### **5.9.1.1.9 QC Acceptance Criteria and Control Limits**

QC acceptance criteria are specified in test method SOPs. The criteria in the SOP are based on the requirements in the published test method or regulatory program. When there are no established acceptance criteria, the location develops acceptance criteria in accordance with recognized industry standards.

Some methods and programs require the laboratory to establish control limits for LCS, MS/MSD, and surrogate evaluation using historical data. PAS developed limits are referred to as “in-house” control limits. In-house control limits represent  $\pm 3$  Standard Deviations (99% confidence level) from the average recovery of at least 20 data points generated using the same preparation and analytical procedure in a similar matrix.

Refer to SOP SOP ENV-SOP-WES2-0119 *Control Limit Generation* for more information about the procedures used to establish in-house control limits.

#### 5.9.1.2 Proficiency Testing (PT)

PAS participates in interlaboratory proficiency testing studies to measure our performance of the test method.

PT participation is based on the certification and accreditation requirements held by the laboratory. The PT samples are obtained from accredited proficiency testing providers (PTP) and treated as field samples which means they are incorporated into our normal analytical processes and do not receive extraordinary attention due to their nature.

PAS locations do not share PT samples with other PAS locations, does not communicate with other PAS locations regarding current PT sample results during the duration of the study, and does not attempt to obtain the assigned value of any PT sample from the PT provider.

PT results scored unacceptable are investigated and correction action taken, when necessary.

Refer to corporate policy ENV-POL-CORQ-0002, *PT Policy* for more information.

#### 5.9.2 QC Corrective Action

When the results of QC are not within acceptance criteria or expectations for method performance, correction and corrective action(s) are taken per the specifications in the test method SOP. These actions may include retesting or reporting of data with qualification to alert the end user of the situation.

#### 5.9.3 Data Review

PAS uses a tiered system for data review. The tiered process includes a series of sequential checks to verify data transfer is complete; manual calculations, if performed, are correct, manual integrations are appropriate and documented, calibration and QC requirements are met, appropriate corrective action was taken when required, test results are properly qualified, process and test method SOPs were followed, project specific requirements were met, when applicable, and the test report is complete.

The sequential process includes multi-tier review consisting of a primary review, a secondary review, and where applicable and appropriate, an administrative/completeness review.

Detailed procedures for the review process are described in SOP ENV-SOP-WES2-0124 *Data Review*. General expectations for the tiered data review process are specified in the following sections:

##### 5.9.3.1 Primary Review

Primary review is performed by the individual that performed the task. All PAS personnel are responsible for the review of their own work to ensure it is complete, accurate, documented, and consistent with PAS policy and SOPs.

Checks performed during primary review include but are not limited to:

- Verification that data transfer and acquisition is complete;
- Manual calculations, if performed, are documented and accurate;
- Manual integrations, if performed, are documented, and comply with SOP ENV-SOP-CORQ-006 *Manual Integration*;
- Calibration and QC criteria were met, instrument calibration conforms with policy ENV-POL-CORQ-005 *Acceptable Calibration Practices*, and/or proper correction and corrective actions were taken, and data and test results associated with QC and criteria exceptions are properly qualified;
- Work is consistent with SOPs and any other relevant instructional document such as SWI, program requirements, or project quality assurance plans.

#### 5.9.3.2 Secondary Review

Secondary review is an independent review of the data set performed by qualified personnel. Secondary review includes a repeat of the checks performed during primary review in addition to chromatography review to verify the accuracy of quantitative analyte identification.

#### 5.9.3.3 Completeness Review

Completeness review is an administrative review that is performed prior to release of the test report to the customer to verify the final test report is complete and meets project specifications. This review also ensures that information necessary for the client's interpretation of results is explained in the case narrative or footnoted in the test report.

#### 5.9.3.4 Data Audits

Test reports are randomly audited by local quality personnel to verify compliance with SOPs and to check for data integrity, technical accuracy, and compliance with the PAS QMS and any applicable federal, statutory, and program requirements. These audits are not part of the tertiary data review process that is performed prior to release of the test report. These audits are performed on test reports that have been previously released to the customer to avoid potential risks to impartiality and other factors that may influence thoroughness of review.

If any problems with the data or test results are found during the data audit, the impact of the nonconforming work is evaluated using the process described in Section 4.9.

Also refer to Section 4.14 for internal audits

#### 5.9.4 Calibration Certificates

PAS does not perform calibration activities for its customers and calibration certificates are not offered or issued.

### **5.9.5 Opinions and Interpretations**

PAS provides objective data and information to its customers of sufficient detail for their interpretation and decision making. Objective data and information are based solely on fact and PAS does not attempt to explain the meaning (interpret) or offer a view or judgement (opinion) on usability of data.

PAS personnel are not permitted to provide opinions on how a nonconformance impacts the usability of results or how test results and information should be used, or suggestions or guidance to the customer for improvement.

### **5.9.6 Subcontractor Reports**

When analytical work is subcontracted to an organization external to PAS or its subsidiaries, PAS includes the test report from the subcontractor in its entirety as an amendment to the final test report.

Test results performed by multiple locations within the PAS network (internal subcontracting) may be merged into a single test report so long as the test report issued clearly identifies the location and address of each network location that performed testing, and which tests each PAS location performed. (Refer to Section 5.10.2)

### **5.9.7 Electronic Transmission of Results**

When test results and/or reports are submitted to the customer through electronic transmission, the procedures established in this manual for confidentiality and protection of data apply.

### **5.9.8 Format of Test Reports**

The test formats offered by PAS are designed to accommodate each type of analytical test method performed and to minimize the possibility of misunderstanding or misuse of analytical results. The format of electronic data deliverables follows the specifications for the EDD.

### **5.9.9 Amendments to Test Reports**

Test reports that are revised or amended by the location after the date of release of the original final test report to the customer are issued as a new test report that is clearly identified as an amendment or revision and that includes a reference to the originally issued final test report.

The customer is the organization doing business with PAS external to PAS.

Changes made to test results and data before the final test report is issued to the customer are not amendments or revisions and do not need to be tracked or marked as such, these changes are simply corrections to errors found during data review.

The procedure for report amendments and revision are outlined in SOP ENV-SOP-WES2-0120 *Report Generation and Approval*.

## **5.10 Reporting**

### **5.10.1 General Requirements**

PAS offers a wide variety of test report formats to meet project needs of Pace® customers and federal and state regulatory program requirements



The type and level of deliverable, including the electronic data deliverable format is established between PAS and the customer during the contracting process. The report specifications include the test report format, protocol for the reporting limit, conventions for the reporting of results less than the limit of quantitation, and specification for the use of project or program specific data qualifiers. Information about review of analytical service requests is provided in Section 4.4.

### **5.10.2 Test Reports: Required Items**

Regardless of deliverable or report requested, every test report issued by PAS and its subsidiaries includes each of the following items:

- a) A Title;
- b) The name and address of the location issuing the test report and for each location where testing was performed if different than address of the location issuing the report. When testing is done at multiple PAS locations, the report must also clearly identify which PAS location performed each test method;
- c) Unique identification of the test report and on each page an identification number to link each page to the test report, and clear identification of the end of the report;
- d) The name and address of the customer;
- e) Identification of test methods used. When testing is done at multiple PAS locations, the report must also clearly identify which PAS location performed each test method;
- f) Cross reference between client sample identification number (Sample ID) and the identification number for the sample (Lab ID) to provide unambiguous identification of samples;
- g) The date of receipt of samples, condition of samples on receipt, and identification of any instance where receipt of the samples did not meet sample acceptance criteria;
- h) Date and times of sample collection, receipt, preparation, and analysis;
- i) Dilution and/or preparation factor;
- j) Test results and units of measurement, and qualification of results associated with QC criteria exceptions, and identification of reported results outside of the calibration range;
- k) All chains of custody including records of internal transfer between locations within PAS;
- l) Name, title, signature of the person(s) authorizing release of the test report and date of release;
- m) A statement that the results in the test report relate only to the items tested; and
- n) Statement that the test report may not be reproduced except in full without written approval from PAS.

### **5.10.3 Test Reports: Supplemental Items**

#### **5.10.3.1 Supplemental Requirements**

The following items are included in the test report when required or relevant:

- a) Shipping manifests/bill of lading as applicable when common couriers are utilized for shipment of samples,
- b) Explanation of departure from test method SOPs including what the departure was and why it was necessary.
- c) Statistical methods used. (Required for Whole Effluent Toxicity)
- d) For solid samples, specification that results are reported on a dry weight or wet weight basis.
- e) Signed Affidavit, when required by client or regulatory agency.
- f) A statement of compliance/non-compliance with requirements or specifications (client, program, or standard) that includes identification of test results that did not meet acceptance criteria.
- g) When requested by the client, statement of estimated measurement uncertainty. In general, for environmental testing, estimated uncertainty of measurement is extrapolated from LCS control limits. Control limits incorporate the expected variation of the data derived from the laboratory's procedure. When the control limits are specified by the test method or regulatory program, the control limits represent the expected variation of the test method and/or matrices for which the test method was designed.
- h) If a claim of accreditation/certification is included in the test report, identification of any test methods or analytes for which accreditation/certification is not held by the location if the accrediting body offers accreditation/certification for the test method/analyte. The fields of accreditation/certification vary between agencies, and it cannot be presumed that because accreditation/certification is not held that it is offered or required.
- i) Certification Information, including certificate number and issuing body.

For PAS locations accredited to ISO/IEC 17025:2017:

- Data included in the test report provided by a customer should be clearly identified.
- A statement that the test results apply only to the samples as received.

PAS does not provide opinion or interpretations about usability of data or test results in order to maintain impartiality with the testing services provided.

#### 5.10.3.2 Test Reports: Sampling Information

The following items are included in the test report when samples are collected by PAS or when this information is necessary for the interpretation of test results:

- a) Date of Sampling.
- b) Unambiguous identification of material samples.
- c) Location of sampling including diagrams, sketches, or photographs.
- d) Reference to the sampling plan and procedures used.

- e) Details of environmental conditions at the time of sample that may impact test results.
- f) Any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

## 6.0 REVISION HISTORY

### This Version (Template Version 4):

SECTION	DESCRIPTION OF CHANGE
Header	Updated Copyright
Approval Page	Changed Address, City, State, Zip to Location. Changed Phone to Email. Added a line for Laboratory Supervisor (State LAP).
1.1	Added information on Building Sciences acronyms. Removed NELAC. Removed reference to Appendix B, testing capabilities and referenced where these could be found.
1.2.1	Changed who created the template to Corporate Quality team. Updated list for top management.
2.0	Updated References
4.1.5.1.1	Updated Key Personnel
4.1.5.2	Added Vice President of Quality and Risk Management Officer. Clarified under General Manager who to notify for extended absences/reassignments.
4.1.5.2.1	Added ELLAP/NLLAP information to this section.
4.1.5.4	Added location of the Terms & Conditions
4.13.1.2	State Building Sciences and Absarka Air Sciences use 5 year record retention.
5.2.2.1.5	Added more options for DOC and DOC requirements for AIHA-LAP, LLC
5.4.5.3.3	Removed 2-4x greater than DL but less than LLOQ or LOQ for DoD LOD.
5.4.5.3.4	New section for Microbiology
5.4.5.3.5	New Section for Asbestos
5.4.5.3.6	Add species for micro methods
5.4.6	Added reference to BDSG Uncertainty SOP
5.5.4	Added requirement for transferring equipment to another location
5.5.5.1	Removed reference to appendix E. Added see local quality and where to find the list.
5.6.3.1	Changed +/- to within
5.8.3.1	Changed 0-6 to <6

## ENV-MAN-WES2-0001 v03\_Quality Manual

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5.8.4	Removed reference to Sample Acknowledgement Form. Deleted a paragraph due to redundant information.
5.8.5.1	Changed to $\leq 6$ and $\leq -10$ .
5.9.3	Changed to multi-tier review
5.9.3.2	Clarified secondary review is completed by qualified personnel
5.10.2	Added dilution and/or prep factor
Appendix B	Updated to remove the table and add location the information can be found.
Appendix C	Added definition of Analyst. Updated definitions for Analyte, Annual, Batch, Confirmation, Holding time, Incremental Sampling Method, Quantitation Range, Selectivity, Sensitivity, Traceability
Appendix D	Updated Org Charts
Appendix E	Updated to remove the table and add location the information can be found.
8.1	Updated information to be consistent with DoD QSM 6.0
8.2	Added information on changes to personnel
8.3	Added information from AIHA-LAP, LLC manual
8.5	New section on UCMR 5
Throughout Document	Grammatical fixes and removal of redundant acronyms.

**This document supersedes the following documents:**

Document Number	Title	Version
ENV-TMP-CORQ-0007	Quality Manual Template	03
ENV-TMP-CORQ-0007	Quality Manual Template	02
ENV-TMP-CORQ-0007	Quality Manual Template	01
ENV-MAN-CORQ-0001	Quality Manual	00

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## 7.0 APPENDICES

### 7.1 Appendix A: Certification / Accreditation Listing

**Disclaimer:** The certifications / accreditation lists provided in this Appendix are those that were held by the PAS location on the effective date of this manual. This information is subject to change without notice and must not be considered valid proof of certification or accreditation status. This manual is not updated with each change made. Current certificates are accessible via the eDMS Portal for PAS employees. External parties should contact the location for the most current information.

#### 7.1.1 PAS-WES2 8 Walkup Drive, Westborough, MA

Authority	ID	Authority	ID
Connecticut	PH-0826	North Carolina (DW)	25700
Illinois	200077	North Carolina (NPW/SCM)	666
Indiana	C-MA-03	Ohio - VAP	Based on NH
Kentucky	KY98045	Oregon	MA-1316
Maine	MA00086	Pennsylvania	68-03671
Maryland	348	Rhode Island	LAO00065
Massachusetts	M-MA086	Texas	T104704476-17-14
New Hampshire Primary	2064	Vermont	VT-0935
New Jersey	MA935	Virginia	460195
New York	11148		

#### 7.1.2 PAS-MANS 320 Forbes Blvd. Mansfield, MA

Authority	ID	Authority	ID
Connecticut	PH-0825	New Jersey	MA015
ANAB/DoD	L2474	New York	11627
Illinois	200081	North Carolina	685
Indiana	C-MA-04	Ohio-VAP	Based on NH
Kentucky	KY98046	Oregon	MA-0262
Louisiana	3090	Pennsylvania	68-02089
Maine	MA00030	Rhode Island	LAO00299
Maryland	350	Texas	T104704419
Massachusetts	M-MA030	Vermont	VT-0015
Michigan	9110	Virginia	460194
Minnesota	025-999-495	Washington	C954
New Hampshire Primary	2062		

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### 7.1.3 PAS-MANS 120 Forbes Blvd. Mansfield, MA

Authority	ID	Authority	ID
ANAB/DoD	L2474	New York	12191
Maine	MA01156	Oregon	4203
Minnesota	025-999-498	Texas	T104704583
New Hampshire Primary	2249	Virginia	460311
New Jersey	MA025	Washington	C1104

## 7.2 Appendix B: Capability Listing

- The capabilities for PAS-WES2, PAS-MANS 320 Forbes Blvd., and PAS-MANS 120 Forbes Blvd. are maintained by the Quality Assurance department. For a current listing of laboratory capabilities, consult the Quality Assurance Manager identified in the QAM approval list on page 3 of this document.

## 7.3 Appendix C: Glossary

This glossary provides common terms and definitions used in environmental testing; it is not intended to be a complete list of all terms and definitions used; some terms are defined in the context of the document or application. The definitions have been compiled mostly from the TNI Standard and DoD QSM. Although this information has been reproduced with care, errors cannot be entirely excluded.

Term	Definition
Acceptance Criteria	Specified limits placed on characteristics of an item, process, or service defined in requirement documents.
Accreditation	The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.
Accreditation Body	The organization having responsibility and accountability for environmental laboratory accreditation, and which grants accreditation.
Accuracy	The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.
Aliquot	A discrete, measured, representative portion of a sample taken for analysis.
Analysis	A combination of sample preparation and instrument determination.
Analysis Sequence	A compilation of all samples, standards and quality control samples run during a specific amount of time on a particular instrument in the order they are analyzed.
Analyst	The designated individual who performs the “hands-on” analytical methods and associated techniques, and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

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Analyte	A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being analyzed. DOD Clarification - The specific chemicals or components for which a sample is analyzed; it may be a group of chemicals that belong to the same chemical family and are analyzed together.
Analytical Method	A formal process that identifies and quantifies the chemical components of interest in a sample.
Analytical Uncertainty	A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.
Annual (or annually)	A period not to exceed 13 months
Assessment	The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its system to defined criteria (to the standards and requirements of laboratory accreditation).
Atomic Absorption Spectrometer	Instrument used to measure concentration in metals samples.
Audit	A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.
Batch	Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A <b>preparation batch</b> is composed of one to 20 environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours or the time specified by the regulatory program. An <b>analytical batch</b> is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples. DOD Clarification - An analytical batch/sequence shall use the same instrument calibration and shall be bracketed by calibration verifications within acceptance criteria.
Bias	The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).
Blank	A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results (Refer to Method Blank).
Blind Sample	A sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.
Calibration	A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.



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Calibration Curve	The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.
Calibration Method	A defined technical procedure for performing a calibration.
Calibration Range	The range of values (concentrations) between the lowest and highest calibration standards of a multi-level calibration curve.
Calibration Standard	A substance or reference material used for calibration.
Certified Reference Material	Reference material accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute.
Chain of Custody	An unbroken trail of accountability that verifies the physical security of samples, data, and records.
Client /Customer	Any individual or organization external to Pace for whom items or services are furnished or work performed in response to defined requirements and expectations.
Code of Federal Regulations (CFR)	A codification of the general and permanent rules published in the Federal Register by agencies of the federal government.
Comparability	An assessment of the confidence with which one data set can be compared to another.
Completeness	The percentage of valid data obtained from a measurement system compared to the amount of valid data expected under normal conditions. This attribute is always calculated by the end data user, not by the laboratory.
Confirmation	Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. DOD Clarification - Includes verification of the identity and quantity of the analyte being measured by another means (e.g., by another determinative method, technology, or column). Additional cleanup procedures alone are not considered confirmation techniques.
Continuing Calibration Blank (CCB)	A blank sample used to monitor the cleanliness of an analytical system at a frequency determined by the analytical method.
Continuing Calibration Check Compounds (CCC)	Compounds listed in mass spectrometry methods are used to evaluate an instrument calibration from the standpoint of the integrity of the system.
Continuing Calibration Verification (CCV) Standard	A standard used to verify the initial calibration of compounds in an analytical method. May be referred to as a CCC in some programs, such as UCMR.
Control Limit	A range within which specified measurement results must fall to verify that the analytical system is in control.
Correction	Action taken to eliminate a detected non-conformity.
Corrective Action	The action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence.
Data Integrity	The condition that exists when data are sound, correct, and complete, and accurately reflect activities and requirements.
Data Quality Objective (DQO)	Strategic planning tool that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use or end user.

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Data Reduction	The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more usable form.
Demonstration of Capability (DOC)	A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.
Detection Limit (DL)	The minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from the method blank results.
Dry Weight	The percent of sample that is not water, which may be used to adjust the reported results.
Electronic Data Deliverable (EDD)	A summary of environmental data which clients request for ease of data review and comparison to historical results.
Environmental Protection Agency (EPA)	An agency of the federal government of the United States which was created for the purpose of protecting human health and the environment by writing and enforcing regulations based on laws passed by Congress.
Equipment Blank	A sample of analyte-free media used to rinse common sampling equipment to check effectiveness of decontamination procedures.
Extracted Internal Standard Analyte	Isotopically labeled analogs of analytes of interest added to all standards, blanks and samples analyzed. Added to samples and batch QC samples prior to the first step of sample extraction and to standards and instrument blanks prior to analysis. Used for isotope dilution methods.
False Negative	A result that fails to identify (detect) an analyte to be present.
False Positive	A result that erroneously identifies (detects) an analyte to be present.
Field Blank	A blank sample prepared in the field by filling a clean container with reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken.
Field Measurement	Testing performed in the field outside of a fixed-laboratory or outside of an enclosed structure that meets the requirements of a mobile laboratory.
Flame Atomic Absorption Spectrometer (FAA)	Instrumentation used to measure the concentration of metals in an environmental sample based on the fact that ground state metals absorb light at different wavelengths. Metals in a solution are converted to the atomic state by use of a flame.
Flame Ionization Detector (FID)	A type of gas detector used in GC analysis where samples are passed through a flame which ionizes the sample so that various ions can be measured.
Gas Chromatography (GC)	Instrumentation which utilizes a mobile carrier gas to deliver an environmental sample across a stationary phase with the intent to separate compounds out and measure their retention times.
Gas Chromatograph/Mass Spectrometry (GC/MS)	In conjunction with a GC, this instrumentation utilizes a mass spectrometer which measures fragments of compounds and determines their identity by their fragmentation patterns (mass spectra).
Gasoline Range Organics (GRO)	A range of compounds that denote all the characteristic compounds that make up gasoline (range can be state or program specific).

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Graphite Furnace Atomic Absorption Spectrometry (GFAA)	Instrumentation used to measure the concentration of metals in an environmental sample based on the absorption of light at different wavelengths that are characteristic of different analytes.
High Pressure Liquid Chromatography (HPLC)	Instrumentation used to separate, identify, and quantitate compounds based on retention times which are dependent on interactions between a mobile phase and a stationary phase.
Holding Time	The maximum time that may elapse from the time of sampling to the time of preparation or analysis, or from preparation to analysis, as applicable.
Homogeneity	The degree to which a property or substance is uniformly distributed throughout a sample.
Incremental Sampling Method (ISM)	Structured composite sampling and processing procedure that is designed to reduce data variability and provide a reasonably unbiased estimate of mean contaminant concentrations in a volume of particulate material (e.g., soil and sediment).
Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES)	Analytical technique used for the detection of trace metals which uses plasma to produce excited atoms that emit radiation of characteristic wavelengths.
Inductively Coupled Plasma- Mass Spectrometry (ICP/MS)	An ICP that is used in conjunction with a mass spectrometer so that the instrument is not only capable of detecting trace amounts of metals and non-metals but is also capable of monitoring isotopic speciation for the ions of choice.
Infrared Spectrometer (IR)	An instrument that uses infrared light to identify compounds of interest.
Initial Calibration (ICAL)	The process of analyzing standards, prepared at specified concentrations, to define the quantitative response relationship of the instrument to the analytes of interest.
Initial Calibration Blank (ICB)	A blank sample used to monitor the cleanliness of an analytical system at a frequency determined by the analytical method.
Initial Calibration Verification (ICV)	A standard obtained or prepared from a source independent of the source of the initial calibration standards to verify the initial calibration.
Instrument Blank	An analyte free matrix processed through the instrumental steps of the measurement process; use to determine instrument contamination.
Interference	The suppression or elevation of result of an analyte of interest due to the presence of other compounds.
Internal Standard	A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.
International Organization for Standardization (ISO)	An international standard-setting body composed of representatives from various national standards organizations.
Intermediate Standard Solution	Reference solutions prepared by dilution of the stock solutions with an appropriate solvent.

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International System of Units (SI)	The coherent system of units adopted and recommended by the General Conference on Weights and Measures.
Ion Chromatography (IC)	Instrumentation or process that allows the separation of ions and molecules based on the charge properties of the molecules.
Isomer	One of two or more compounds, radicals, or ions that contain the same number of atoms of the same element but differ in structural arrangement and properties. For example, hexane (C <sub>6</sub> H <sub>14</sub> ) could be n-hexane, 2-methylpentane, 3-methylpentane, 2,3-dimethylbutane, 2,2-dimethylbutane.
Laboratory	A facility that performs testing, whether in-house or in the field.
Laboratory Control Sample (LCS)	Also known as laboratory fortified blank (LFB): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, which is taken through all sample preparation and analytical steps of the procedure.
Laboratory Information Management System (LIMS)	The entirety of an electronic data system (including hardware and software) that collects, analyzes, stores, and archives electronic records and documents.
Legal Chain-of-Custody Protocols	Industry defined protocol that is sometimes used for evidentiary or legal purposes that establishes an intact, continuous record of the physical possession, storage, and disposal of samples, including sample aliquots and prepared samples.
Limit(s) of Detection (LOD)	The smallest concentration of a substance that must be present in a sample in order to be detected at the DL with 99% confidence.
Limit(s) of Quantitation (LOQ)	The minimum level, concentration, or quantity of a target analyte that can be reported with a specified degree of confidence.
Lower Limit of Quantitation (LLOQ)	The concentration of the lowest calibration standard included in the calibration curve.
Linear Dynamic Range	Concentration range where the instrument provides a linear response.
Liquid chromatography/tandem mass spectrometry (LC/MS/MS)	Instrumentation that combines the physical separation techniques of liquid chromatography with the mass analysis capabilities of mass spectrometry.
Lot	A definite amount of material produced during a single manufacturing cycle and intended to have uniform character and quality.
Matrix	The substrate of a test sample.
Matrix Duplicate	A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.
Matrix Spike (MS)	A sample prepared, taken through all sample preparation and analytical steps of the procedure, to which a known amount of target analyte is added to a specified amount of sample for which an independent test result of target analyte concentration is available.
Matrix Spike Duplicate (MSD)	A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

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Measurement System	A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).
Measurement Uncertainty	An estimate of the error in a measurement often stated as a range of values that contain the true value within a certain confidence level.
Method	A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification).
Method Blank	A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures.
Method Detection Limit (MDL)	The minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.
Method of Standard Additions	A set of procedures adding one or more increments of a standard solution to sample aliquots of the same size in order to overcome inherent matrix effects.
Minimum Detectable Activity (MDA)	Estimate of the smallest true activity that ensures a specified high confidence, $1 - \beta$ , of detection above the Critical Value, and a low probability $\beta$ of false negatives below the Critical Value. For radiometric methods, $\beta$ is often set at 0.05.
Negative Control	A sample included in the method that is treated the same as all others but is expected to have a detection of analytes of interest.
Nonconformance	An indication or judgment that a product or service has not met the requirement of the relevant specifications, contract, or regulation; also, the state of failing to meet the requirements.
Positive Control	A sample included in the method that is treated the same as all others and is expected to have a detection of the analytes of interest.
Practical Quantitation Limit (PQL)	Another term for a method reporting limit.
Precision	The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves.
Preservation	Any conditions under which a sample must be kept in order to maintain chemical, physical, and/or biological integrity prior to analysis.
Primary Accreditation Body (Primary AB)	The TNI-approved state agency responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.
Procedure	Written instructions detailing the performance of a task, process, or other laboratory activity.
Proficiency Testing (PT)	A means to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.
Proficiency Testing Reporting Limit (PTRL)	A statistically derived value that represents the lowest acceptable concentration for an analyte in a PT sample, if the analyte is spiked into the PT sample. The PTRLs are specified in the TNI FoPT tables.
Qualitative Analysis	Analysis designed to identify the components of a substance or mixture.

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Quality Assurance (QA)	An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.
Quality Assurance Project Plan (QAPP)	A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.
Quality Control (QC)	The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality.
Quality Control Sample (QCS)	A sample used to assess the performance the measurement system.
Quality Manual	A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.
Quality Management System	A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control activities.
Quantitation Range	The range of values (concentrations) in a calibration curve between the LOQ and the highest successfully analyzed initial calibration standard used to relate instrument response to analyte concentration. The quantitation range (adjusted for initial sample volume/weight, concentration/dilution, and final volume) lies within the calibration range.
Quantitative Analysis	Analysis designed to determine the amounts or proportions of the components of a substance.
Raw Data	The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.
Record	Documentation, data, or other records constituting a piece of evidence about the past, especially an account of an act or occurrence kept in writing or some other permanent form. Records may be in electronic or hardcopy media. Unless otherwise specified, the term “record” refers to both electronic and hardcopy media.
Reference Material	Material or substance one or more of whose property values are sufficiently homogenized and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
Reference Method	A published method issued by an organization recognized as competent to do so. (When the ISO language refers to a “standard method,” that term is equivalent to “reference method”).

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Reference Standard	Standard used for the calibration of working measurement standards in a given organization or at a given location.
Relative Percent Difference (RPD)	A measure of precision defined as the difference between two measurements divided by the average concentration of the two measurements.
Reporting Limit (RL)	The value to which test results are reported as detected or not detected.
Representativeness	A quality element related to the ability to collect a sample reflecting the characteristics of the part of the environment to be assessed.
Retention Time	The time between sample injection and the appearance of a solute peak at the detector.
Sample	The item submitted for testing.
Sampling	Activity related to obtaining a representative sample for analysis.
Selected Ion Monitoring (SIM)	A mode of analysis in mass spectrometry where the detector is set to scan over a very small mass range, typically one mass unit.
Selectivity	The ability to analyze, distinguish, and determine a specific analyte from another component that may be a potential interferent or that may behave similarly to the target analyte within the measurement system.
Sensitivity	The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.
Serial Dilution	The stepwise dilution of a substance in a solution.
Standard Operating Procedure (SOP)	A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps.
Standard Reference Material (SRM)	A certified reference material produced by the US NIST or other equivalent organization and characterized for absolute content, independent of analytical method.
Stock Standard	A concentrated reference solution containing one or more analytes prepared in the laboratory using an assayed reference compound or purchased from a reputable commercial source.
Storage Blank	A sample of analyte-free media prepared by the laboratory and retained in the sample storage area.
Suitability	The quality of being appropriate for a particular purpose.
Surrogate	A substance with properties that mimic the analyte of interest, and unlikely to be found in environmental samples.
Systems Audit	An on-site inspection or assessment of a laboratory's quality system.
Target Analytes	Analytes or chemicals of primary concern identified by the customer on a project-specific basis.
Technology	A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.



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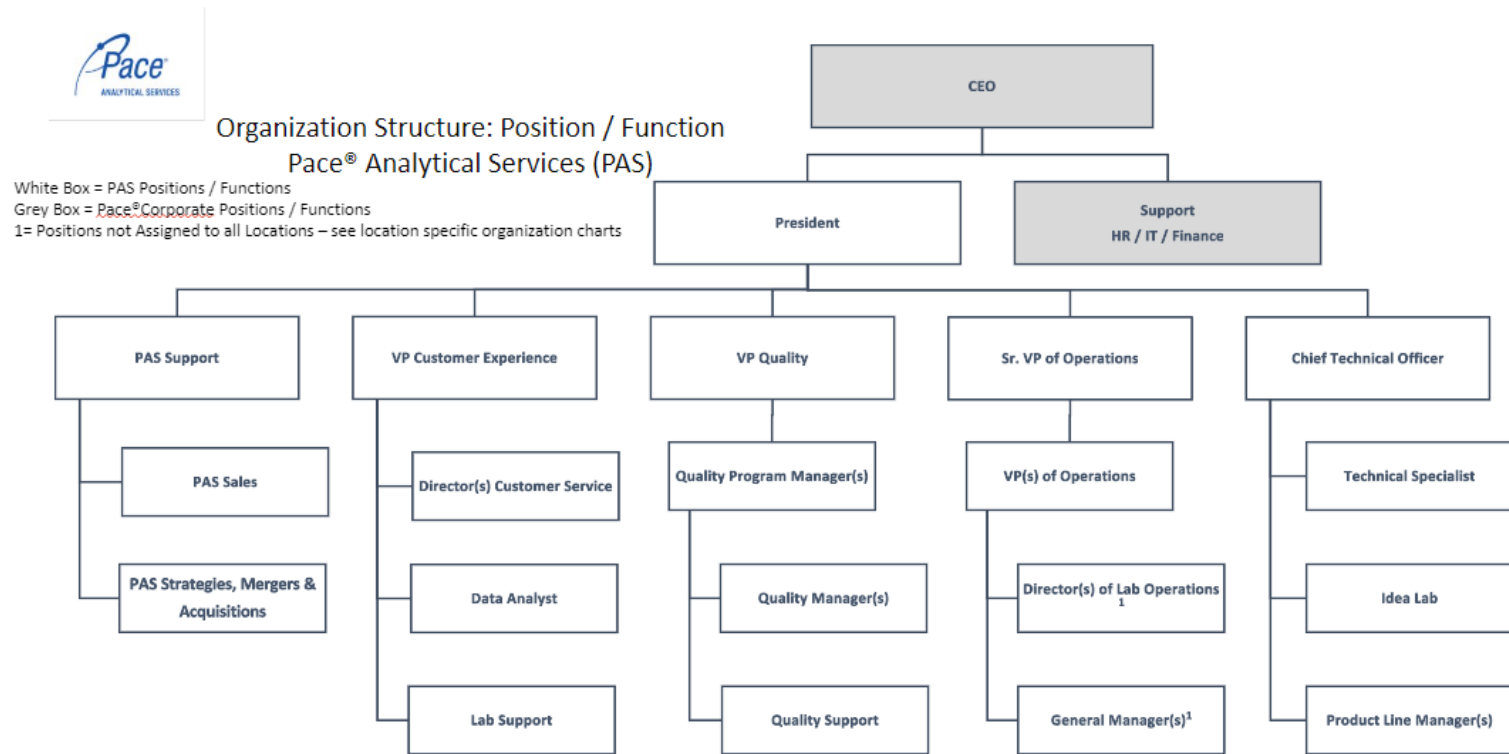
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Traceability	The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.
Trip Blank	A cleaned sample container filled with laboratory reagent water that is stored, shipped, and analyzed with its associated samples to detect sample contamination during transport and storage of the sample.
Tuning	A check and/or adjustment of instrument performance for mass spectrometry as required by the method.
Validation	The confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
Verification	Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation, or specification peculiar to the management of the measuring equipment.
Working Standard	Dilution made of a stock or intermediate standard used in the analytical process.

## 7.4 Appendix D: Organization Chart(s)

### 7.4.1 PAS Corporate Organization Chart(s)

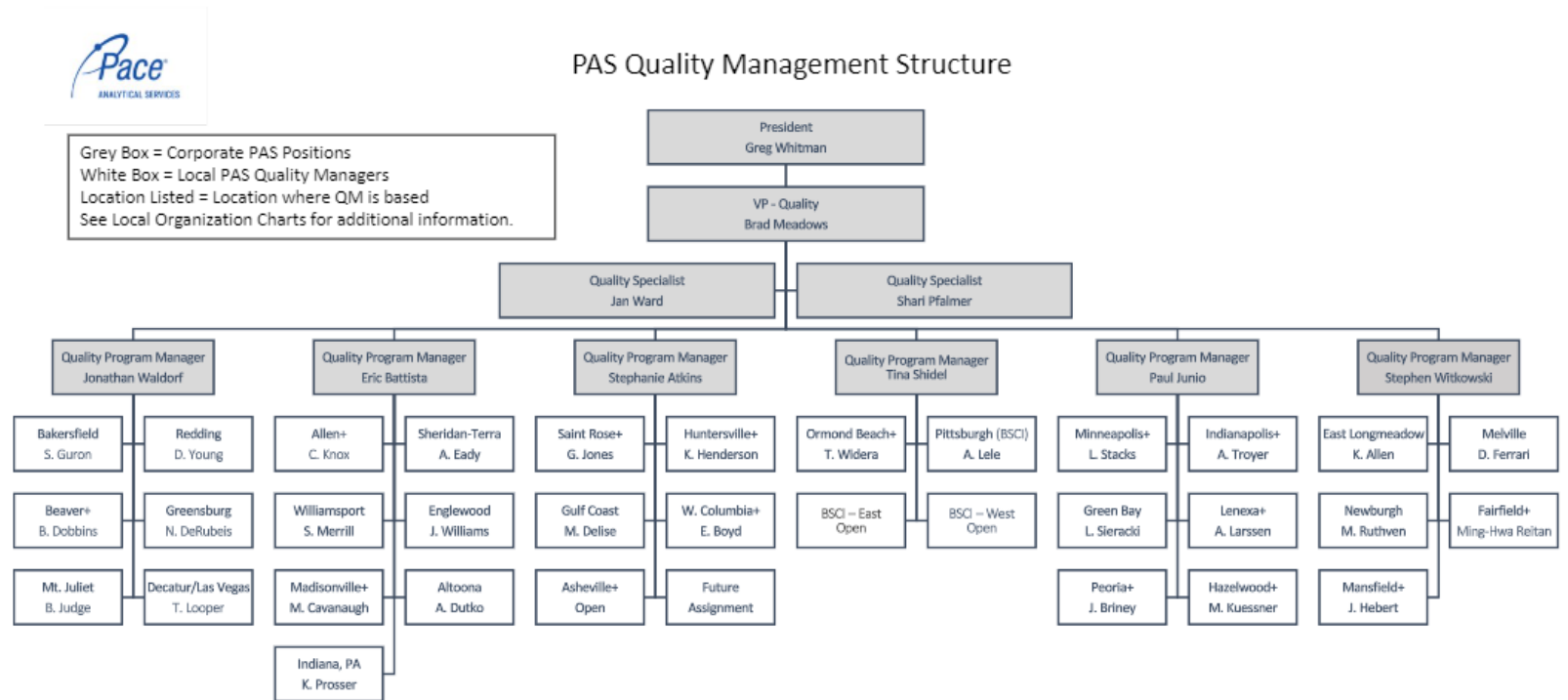
*The information in this organization chart is subject to change. Please contact PAS for the most up-to-date version.*



Effective 01.01.25  
Subject to Change

## 7.4.2 PAS Quality Systems Management Organization Chart

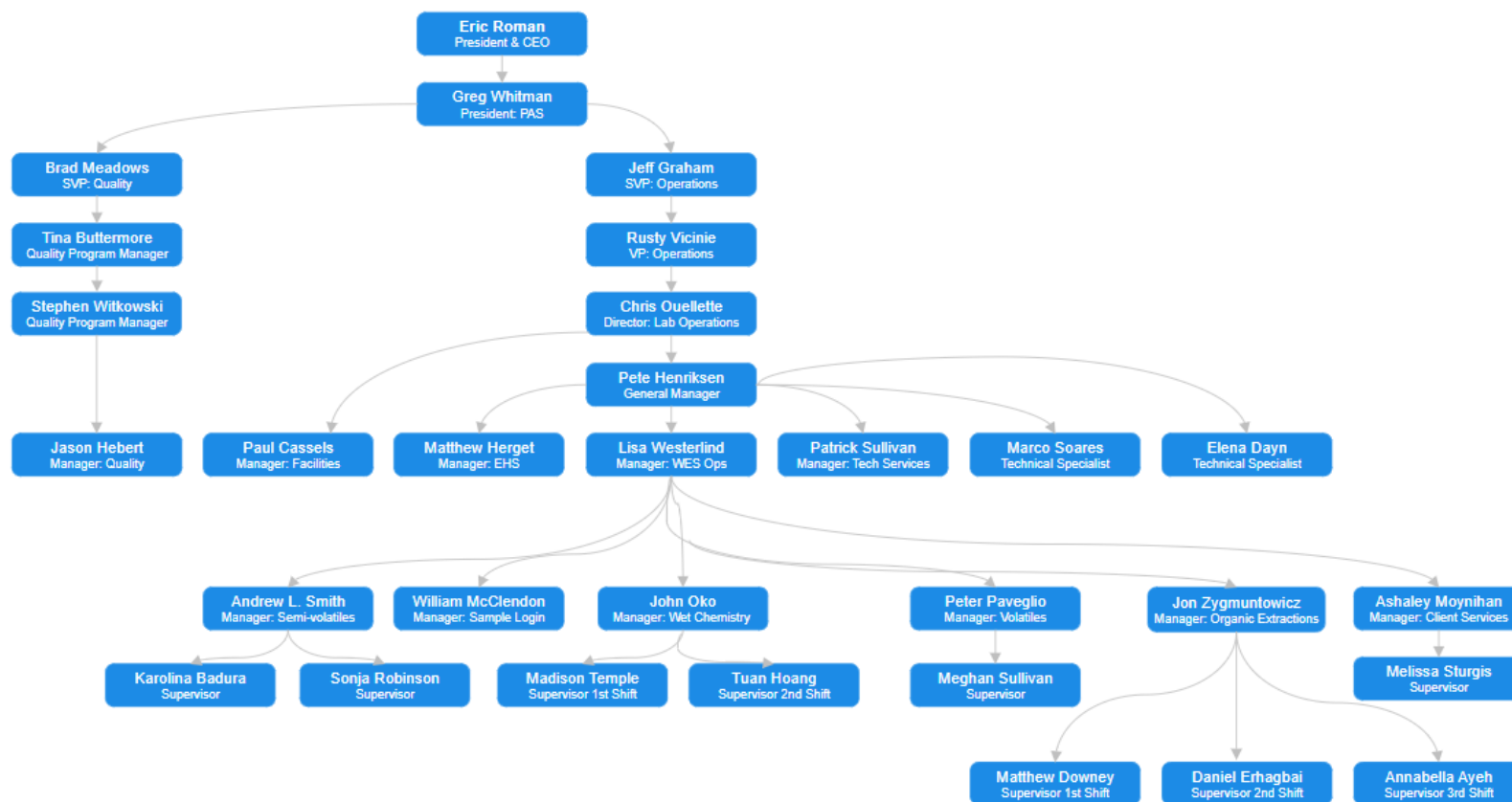
*The information in this organization chart is subject to change. Please contact PAS for the most up-to-date version.*



Effective 01.01.25  
Subject to Change

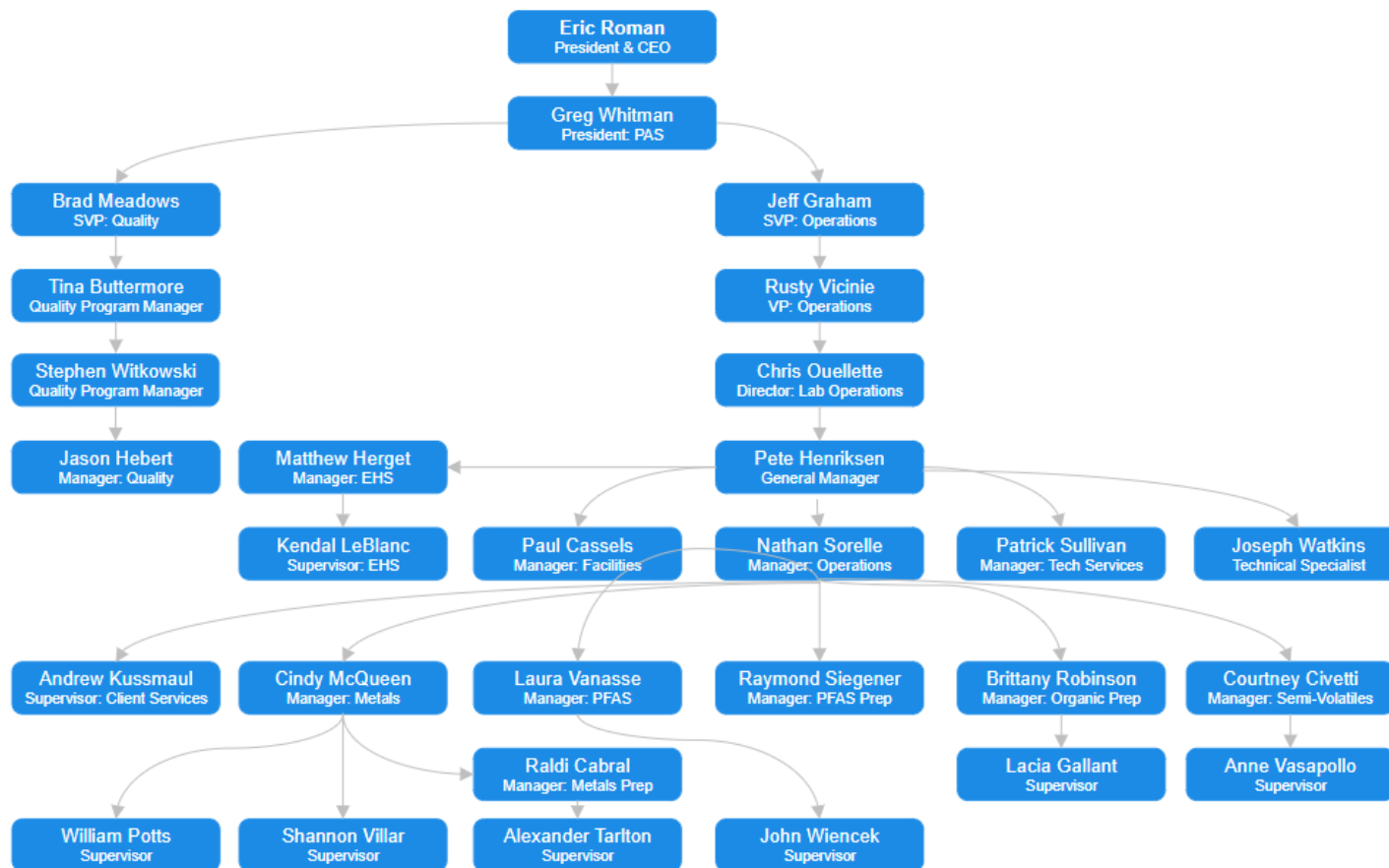
### 7.4.3 PAS-WES2 8 Walkup Drive, Westborough, MA – Organization Chart

*The information in this organization chart is subject to change. Please contact PAS for the most up-to-date version.*



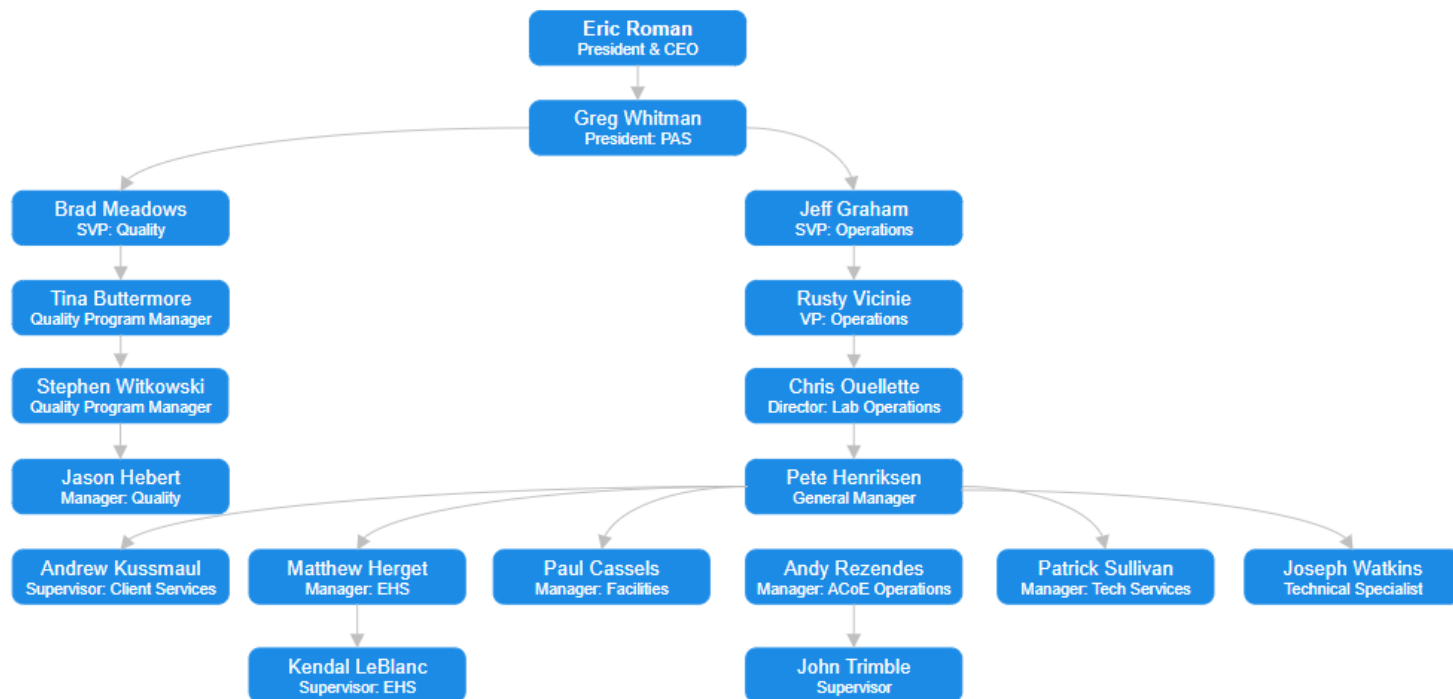
#### 7.4.4 PAS-MANS 320 Forbes Blvd, Mansfield, MA – Organization Chart

*The information in this organization chart is subject to change. Please contact PAS for the most up-to-date version.*



#### 7.4.5 PAS-MANS 120 Forbes Blvd. Mansfield, MA – Organization Chart

*The information in this organization chart is subject to change. Please contact PAS for the most up-to-date version.*



## **7.5 Appendix E: Equipment Listing**

The equipment list for PAS-WES2, PAS-MANS 320 Forbes Blvd., and PAS-MANS 120 Forbes Blvd. is maintained by the Quality Assurance department. For a current listing of laboratory equipment, consult the Quality Assurance Manager identified in the QAM approval list on page 3 of this document.



## 8.0 ADDENDUM: PROGRAM REQUIREMENTS

Section 8.0 provides additional requirements the locations covered by this manual are required to follow when performing work under the program. Only requirements that are not covered by the main body of the manual are listed in addendum.

### 8.1 DoD

PAS-MANS maintains accreditation for DoD Environmental Laboratory Approval Program (ELAP).

This addendum outlines additional policies and processes established by this laboratory to maintain compliance with DoD program specific requirements as outlined in the DoD Consolidated Quality Systems Manual (QSM) for Environmental Laboratories. The QSM incorporates ISO/IEC 17025 and the TNI Standard and includes additional program-specific requirements for laboratories that perform analytical testing services for DoD, and which must be followed for DoD projects.

#### Section 4.2.1.2 Risk and Opportunity Assessment

The laboratory identifies and plans mitigation measures for risks and opportunities associated with its activities, as outlined in QSM 6.0, Module 2, clauses 8.5.4.a through 8.5.4.o. The Risk Management Officer (RMO) maintains records of risk identification and mitigation. For further details, refer to the DoD/DOE QSM 6.0 Risk Mitigation Plan.

#### Section 4.3.3 Document Review and Change

The review frequency for technical SOPs used for DoD testing is annual, instead of every 2 years.

#### Section 4.4 Review of Analytical Service Requests

Laboratory deviations from the requirements specified in the DoD/DOE QSM are requested on a project basis and include technical justifications for the deviation. These requests are submitted to and approved by the DoD project chemist or contractor, as well as the PAS client. Records of approval are maintained by the laboratory and included in all affected data packages.

For DoD projects, customer clarification or feedback is sought for the following situations:

- Methods which require modification to ensure achievement of customer objectives contained in planning documents;
- Project planning documents are missing or requirements in the documents require clarification;
- The laboratory has encountered problems with sampling that may impact results (e.g. improper sample preservation)

The laboratory maintains records of customer approval for use of an external provider to perform any of the following:

- Sampling or subsampling;
- Sample preparation;
- Sample analysis;
- Data reduction;

- Data review; or
- Reporting

#### **Section 4.5 Subcontracting**

The laboratory verifies that subcontractors hold the necessary accreditation or certifications required for the project and maintains records of their accreditation. Approval from the customer is obtained before any subcontracted laboratory analyzes samples.

The requirements for subcontracted laboratories also apply to laboratories within the same corporate group but located at different facilities or locations.

All subcontracted or outsourced management system elements (e.g., data review, data processing, project management, and IT support), as well as outsourced personnel, must comply with accreditation requirements.

#### **Section 4.6 Purchasing and Supplies**

The laboratory establishes procedures detailing the selection, purchasing, receipt, and storage of services and supplies impacting laboratory activities.

If the laboratory provides sample containers to customers, it maintains records demonstrating that each lot of containers, along with any included preservatives, is free of likely contaminants exceeding  $\frac{1}{2}$  the LOQ for the associated analysis.

#### **Section 4.9.3 Nonconforming Work**

The laboratory shall upon discovery of potential data quality issues resulting from nonconforming work, notify all affected customers within 15 business days. Records of corrective actions taken or proposed corrective actions to resolve the nonconformance shall be submitted to the customer within 30 business days of discovery. For data reported to affected customers more than 90 days prior to the discovery of the potential data quality issue, the AB shall also be notified. Notification shall be performed according to the laboratory's procedure for client notification.

#### **Section 4.13 Control of Records**

All records shall be maintained for five years from last use. A record is considered in use when it supports current laboratory activities.

Requirements for amendments to technical records also apply to changes to the original output of the automated software algorithms such as manual integrations and eliminating laboratory determined "false positives" (e.g. "Q delete"). These changes to the original output of the automated software algorithms shall be reviewed by a technically qualified supervisor or data review specialist. Records of this review shall be maintained.

For the purpose of preparation batch processing, the start and stop dates and times of the preparation batch preparation shall be recorded. The start time of sample preparation is the time when analytes from the first sample in a batch of samples begin to be removed from the matrix. The stop time of sample preparation is the time when the last sample extract or digestate is ready for additional clean up or analysis.

#### **Section 4.14 Internal Audit**

The internal audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year, with no area exceeding a period of 18 months between audit events.

### Section 5.2.1 Personnel Qualifications

Records of communication with personnel regarding their duties, responsibilities, and authorities in their positions shall be maintained.

### Section 5.2.2 Required Training

Employees shall receive initial training in computer security awareness upon employment, followed by annual refresher training. Records of the training shall be maintained.

### Section 5.3 Accommodations and Facilities

Standards and reference materials shall be stored separately from samples, extracts, and digestates.

### Section 5.4.5.3.3 Sensitivity in Chemical Testing

For each combination of analyte-matrix-method listed on the laboratory's scope of accreditation, the laboratory shall determine a DL, LOD, and LOQ, unless it falls within one of the stated exceptions below:

- DL, LOD, and LOQ determinations are not required for methods/analytes for which a DL, LOD and LOQ is not applicable such as pH, color, odor, temperature, residues, or leaching procedures.
- DL determinations, LOD determinations, and LOD and LOQ verifications are not required for analytes for which no low-level spiking solutions are available.
- DL and LOD determinations are not required if results are not reported below the LOQ, unless required by regulation or method.

The laboratory is not required to establish separate DL, LOD, and LOQ for every combination of preparation and cleanup techniques. However, it shall determine these values using the combination of processes most likely to impact sensitivity, including preparation methods and all applicable cleanup steps, such as drying, grinding, and incremental sampling, where relevant.

The DL, LOD and LOQ shall be reported for all analyte-matrix-method combinations unless it is not applicable to the test or specifically excluded by customer requirements.

Records of all supporting data for DL, LOD, and LOQ determinations and verifications shall be maintained. The laboratory shall provide the following when DL, LOD, and LOQ summary information is requested:

- an indication of which analyte/matrix/prep method/analytical method and instrument used;
- DL;
- claimed LOD;
- concentration of initial LOD spike and verification spike, if different;
- statement of compliance with analyte identification requirements;
- signal-to-noise value or statement of compliance with requirements;
- claimed LOQ;
- concentration of LOQ spike;

- recovery or result of LOQ spike;
- calculated precision and bias at the LOQ that incorporates historic and current data;
- accuracy acceptance criteria at the LOQ;
- description of precision and bias calculations; and
- if specifically requested, raw data to support parameters reported.

### **Limit of Detection (LOD)**

For DoD, the LOD is defined as the lowest concentration empirically determined to consistently provide a response meeting identification and minimum signal requirements for a specific analyte-matrix-method combination. This is an estimate of the smallest concentration of an analyte that shall be present in order to be detected with a result at or above the DL with 99% confidence. The LOD is also the minimum concentration for reliably reporting a non-detect result for an analyte.

After each DL determination, the laboratory establishes the LOD by spiking a quality system matrix at a concentration greater than or equal to the DL. The LOD is equal to the concentration of this spike.

The laboratory verifies the LOD at least quarterly. For methods used infrequently, the laboratory may opt to perform LOD verification on a per-batch basis prior to sample analysis as an alternative to quarterly verification. The chosen verification frequency must be maintained consistently for a minimum of 12 months. If the laboratory chooses per-batch LOD verification, the verification data must be reported to the customer.

LOD verification is performed by repeating the LOD spike process at a concentration between half and double the current/claimed LOD, provided the spike concentration is greater than or equal to the DL (i.e.  $DL \leq 1/2x \text{ LOD} \leq \text{Ongoing LOD Spike} \leq 2x \text{ LOD}$ ).

The ongoing LOD verification must meet the same acceptance criteria as the initial LOD verification for signal-to-noise ratio and analyte identification. If the acceptance criteria are met, the initial LOD is verified and may continue to be used. If the verification fails, the laboratory shall redetermine the LOD and, if necessary, the DL, or implement its nonconforming work procedure, until the requirements are met.

If there are multiple instruments that will be assigned the same LOD, then the LOD verification spikes shall be distributed across all the instruments and the results shall meet the acceptance criteria on each instrument.

If the method is altered in a way other than routine maintenance, and the change can be expected to elevate the detection limit, the LOD shall be reverified using the ongoing LOD verification procedure.

### **Limit of Quantitation (LOQ)**

For DoD, the LOQ is defined as the smallest concentration that produces a quantitative result with known and recorded precision and bias.

For methods using multi-level calibration, the laboratory shall select an LOQ for each analyte that is greater than or equal to the LOD and greater than or equal to the lowest non-zero calibration standard. For methods using a single-point calibration, the LOQ shall be greater than or equal to the LOD and greater than or equal to the low-level calibration check standard.

The LOQ is verified by analyzing verification samples. The LOQ verification sample consists of a spiked quality system matrix with a concentration greater than or equal to the LOD or half the LOQ, whichever is lower, and less than or equal to double the LOQ (i.e.  $\text{LOD or } \frac{1}{2} \text{ LOQ} \leq \text{LOQ spike} \leq 2 \times \text{LOQ}$ ).

The LOQ verification must meet the same criteria as the initial LOD verification for signal-to-noise ratio and analyte identification and must fall within the laboratory's stated acceptance criteria. These criteria are determined as a maximum of three standard deviations from the mean of historical data but must not exceed the LCS acceptance criteria with an additional allowance of  $\pm 20\%$ . Furthermore, the lower limit must be greater than or equal to 10% recovery.

In the event the verification fails, the laboratory shall redetermine the LOQ and, if necessary, the DL and/or LOD; or implement its nonconforming work procedure, until the requirements are met.

If there are multiple instruments that will be assigned the same LOQ, then these LOQ verification spikes shall be distributed across all the instruments and the results shall be included in the precision and bias determination.

The laboratory shall verify the LOQ quarterly, at a minimum. The precision and bias shall be updated annually, at a minimum, using any additional LOQ verification sample results.

In situations where methods are set up and used on an infrequent basis, the laboratory may choose to perform Ongoing LOQ verifications on a one-per-batch basis, before sample analysis, in lieu of quarterly verification. The verification data shall meet requirements and be reported to the customer. Whichever verification frequency is chosen shall be continued for a minimum of 12 months.

The LOQ and associated precision and bias shall be reported in each data package. When reporting precision and bias at the LOQ within a data package, a table for each analyte-matrix-method must present the LOQ concentration and the associated precision and bias at that concentration. The table should also identify how precision and bias were calculated, the spike concentration if different from the LOQ, and how many data points (results) were used in the calculation.

The laboratory's procedure for DL, LOD, and LOQ determination and verification is detailed in SOP ENV-SOP-WES2-0112.

#### **Section 5.4.7 Control of Data**

The laboratory shall have a procedure to ensure all LIMS users have unique login authentication credentials. The mechanism employed may be a unique username and password combination, or biometric authentication. Where passwords are used, the passwords shall be changed a minimum of once per year.

Physical access to servers shall be limited by security measures such as locating the system within a secured facility or room and/or utilizing cipher locks or key cards.

#### **Section 5.5.5.2 Equipment Records**

Records retained for equipment shall include instrument configuration and settings.

#### **Section 5.7 Sampling**

Subsampling procedures shall address recording the presence of extraneous materials present in samples. The procedure shall comply with recognized consensus standards, where applicable.

#### **Section 5.8 Sample Management and Handling**

The laboratory shall maintain procedures for communicating to all affected laboratory personnel when samples that require non-routine analysis, additional sample preparation steps, or customer-required deviations are received. Records of these communications shall be maintained.

Chemical preservation shall be checked at the time of sample receipt for all samples, unless it is not technically acceptable to check preservation upon receipt (e.g. VOA and Oil and Grease samples).

Samples that are completely consumed during analysis shall be recorded as such for their final disposition.

### **Section 5.9.1 Quality Control**

For DoD, storage blanks are essential QC to monitor the storage of samples for volatile organic analysis (VOA). The SOP for storage of VOA samples must include a contamination monitoring program based on the performance of storage blanks.

A storage blank shall be stored with all volatile organic samples, regardless of suspected concentration levels. Storage blanks shall be used to determine if cross-contamination may have occurred. If cross-contamination greater than ½ LOQ (Methylene chloride, Acetone, 2-Butanone, greater than LOQ) is found in the storage blank, the laboratory shall implement the nonconforming work procedure. The laboratory shall have procedures and acceptance criteria for evaluating storage blanks appropriate to the types of samples being stored. The storage blanks shall be stored in the same manner as the customer samples. The storage blanks shall be analyzed every 14 days at a minimum.

#### **Section 5.9.1.1.9 QC Acceptance Criteria and Control Limits**

Control limits are monitored at least quarterly to identify shifts in mean recovery, changes in standard deviation, and emerging trends. The laboratory may use representative compounds for control charts to conduct trend analyses. The basis for selecting representative compounds shall be documented and shall be scientifically valid.

### **Section 5.10.2 Test Reports: Required Items**

Unless specifically waived by the customer, reports shall include:

- LOQ and associated precision and bias at the LOQ, where determination of precision and/or bias at the LOQ is required and the LOD and LOQ verification data when the infrequent method option described in module 4 is used.
- Records of customer approval and technical justification for any waiver from QSM requirements shall be included in all affected reports
- All QC required by the method and specified in the applicable Appendix B Table, including acceptance criteria used by the laboratory.
- Case narrative identifying deviations of any calibration standards or QC sample results from acceptance limits and a discussion of the associated actions taken by the laboratory to address the deviation.
- Case narrative identifying a list of preparation batches for which no matrix spike and/or matrix spike duplicate were performed due to lack of adequate sample material
- Case narrative identifying occurrence of analytes for which manual integration occurred.

## 8.2 Unregulated Contaminant Monitoring Rule 5 (UCMR5)

This addendum outlines additional policies and processes established by this laboratory to maintain compliance with UCMR 5 program specific requirements. These requirements are outlined in the UCMR 5 Laboratory Approval Requirements and Information Document. Data may not be uploaded to the Safe Drinking Water Accession and Review System (SDWARS) if it does not comply with these requirements.

### Section 5.8.3: Sample Receipt Checks and Sample Acceptance Policy

Samples that are not received in a secure manner, are received in inappropriate containers, are received outside the required temperature range, are received outside the recognized holding time, are received with inadequate identification on sample containers and/or COC or are improperly preserved cannot be reported to SDWARS for UCMR compliance.

#### Section 5.8.3.1: Sample Receipt Checks - Thermal Preservation

Samples must be received at the laboratory within 48 hours of collection and must be  $\leq 10^{\circ}\text{C}$ . After arrival or within 48 hours of collection, whichever is sooner, the samples must be refrigerated at  $\leq 6^{\circ}\text{C}$ . Samples received more than 48 hours after collection are valid only if they are received at  $\leq 6^{\circ}\text{C}$  and the laboratory can obtain documentation from the client to verify that they were refrigerated between collection and shipment. Temperature requirements apply to all UCMR samples with the exception of metals by EPA 200.8.

#### Section 5.9.1.1.3: Method Blank

The method blank will be considered contaminated if the concentration of any target analyte in the method blank is greater than  $1/3$  the MRL for that analyte. If samples cannot be re-processed, then samples must be re-collected. Data with a failing method blank cannot be reported to SDWARS.

#### Section 5.9.1.1.4: Laboratory Control Sample (LCS)

If the LCS recovery fails, then all data for the problem analyte are considered invalid for all samples in the Extraction or Digestion Batch. Data associated with a failing LCS must not be reported to SDWARS. If the LCS surrogate or internal standard fails QC criteria, all data for the Extraction or Digestion Batch must not be reported to SDWARS.

#### Section 5.9.1.1.5: Matrix Spikes (MS/MSD)

A UCMR sample must be used as the parent sample for the MS/MSD in batches containing UCMR samples. The spike concentration of the MS/MSD must be alternated between a low- and mid-level concentration.

There are no method analyte recovery acceptance criteria specific for MS/MSD results. Data should not be rejected based on the recovery of the fortified target analytes or on the precision between the MS and MSD, provided internal standard and surrogate standard recoveries and all other QC results are valid. If surrogate or internal standard recovery fails criteria in the MS and MSD, do not report results. If one of the fortified samples fails QC, the results of the fortified sample that passes, should be reported as the MS. The entire analysis batch does not need to be reanalyzed because of a failure of a surrogate or internal standard in MS or MSD. Recollection of the field sample is not required with a surrogate or internal standard fails criteria in the MS/MSD.



#### **Section 5.9.1.1.7: Surrogates**

A sample that fails QC criteria for surrogate recovery should be rerun in case a mis-injection occurred. If the sample continues to fail surrogate QC criteria, the laboratory should process a new aliquot of the sample. Typically, data for samples with failed surrogate recovery must not be reported to SDWARS.

If the surrogate recovery fails the acceptance criteria in a MB or LCS, the MB or LCS may be reanalyzed later in the Analysis Batch. If surrogate recovery fails again, all field sample results for the associated Extraction Batch are invalid and must not be reported. If the surrogate recovery fails in an MB that is needed to pass an Analysis Batch, all data for that Analysis Batch are invalid and must not be reported. If possible, the laboratory should process new aliquots of the affected samples; if this is not possible, the affected field samples must be recollected. One LCS must pass surrogate recovery within a 24-h period of analysis. If not, the samples in the Analysis Batches that correspond to that required LCS, cannot be reported.

#### **Section 5.9.1.1.8: Internal Standards**

If the internal standard recovery in a sample fails the acceptance criteria, then the results for the analytes that are associated with the internal standard in that sample are invalid. Data that fail internal standard criteria must not be reported to SDWARS. If possible, the laboratory should process a new aliquot of the sample; if this is not possible, the field sample must be recollected.

For an Extraction Batch or Digestion Batch, if the internal standard recoveries in an MB or LCS fail the acceptance criteria, all data for the analytes that are associated with that internal standard in that Extraction Batch or Digestion Batch are invalid and must not be reported. If the internal standard recoveries in a MB or LCS fail the acceptance criteria in an Analysis Batch, all data for the analytes that are associated with that internal standard in the Analysis Batch are invalid and must not be reported. If possible, the laboratory should process new aliquots of the affected samples.