



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Manual Approval Signatories

Approval of this manual by managerial personnel is recorded on the Signature Manifest located before the Title Page of this manual.

The individuals listed below represent the management team that was in place on the effective date of this version of the manual for the following location:

Pace Analytical Services, LLC
 1638 Roseytown Road, Suites 2, 3 & 4
 Greensburg, PA, 15601
 Phone: 724-850-5630

Each of the following individuals is a signatory for the manual for the location listed above. The application of their signature to the manual signifies their commitment to communicate, implement, and uphold the requirements, policies and procedures specified in this manual and their commitment to continuously improve the effectiveness of the quality management system based on customer feedback and internal assessment.

Name ¹	Title	Address ²	Phone ²
Colin Walters	Regional Director - Operations		724-433-5223
William Billings	General Manager		
Nasreen DeRubeis	Quality Manager		
Rachel Christner	Client Services Manager		
Jesse Woodring	EHS Analyst		
Tom Sylvester	Regional Manager - Systems		
Brayan Hampton	Department Manager ³		
Danette Cavalier	Department Manager		
Richard Kinney	Department Manager ³		

¹ Members of the local management team are subject to change during the life-cycle of this document version.

² Include if different from the physical address and phone number of the facility.

³ This individual serves as an Acting Technical Manager for TNI for one or more fields of accreditation.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Manual Approval Signatories

Approval of this manual by managerial personnel is recorded on the Signature Manifest located before the Title Page of this manual.

The individuals listed below represent the management team that was in place on the effective date of this version of the manual for the following location:

Pace Analytical Services, LLC
 5020 Ritter Road, Suite 102
 Mechanicsburg, PA, 17055
 Phone: 609-389-5468

Each of the following individuals is a signatory for the manual for the location listed above. The application of their signature to the manual signifies their commitment to communicate, implement, and uphold the requirements, policies and procedures specified in this manual and their commitment to continuously improve the effectiveness of the quality management system based on customer feedback and internal assessment.

Name¹	Title	Address²	Phone²
Colin Walters	Regional Director - Operations		724-433-5223
William Billings	General Manager		
Nasreen DeRubeis	Quality Manager		
Jesse Woodring	EHS Analyst		
Tom Sylvester	Regional Manager - Systems		
Kelli Dabler	Supervisor		

¹ Members of the local management team are subject to change during the life-cycle of this document version.

² Include if different from the physical address and phone number of the facility.

³ This individual serves as an Acting Technical Manager for TNI for one or more fields of accreditation.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Manual Approval Signatories

Approval of this manual by managerial personnel is recorded on the Signature Manifest located before the Title Page of this manual.

The individuals listed below represent the management team that was in place on the effective date of this version of the manual for the following location:

Pace Analytical Services, LLC
 6521B State Route 61
 Shamokin, PA, 17872
 Phone: 570-648-2216

Each of the following individuals is a signatory for the manual for the location listed above. The application of their signature to the manual signifies their commitment to communicate, implement, and uphold the requirements, policies and procedures specified in this manual and their commitment to continuously improve the effectiveness of the quality management system based on customer feedback and internal assessment.

Name¹	Title	Address²	Phone²
Colin Walters	Regional Director - Operations		724-433-5223
William Billings	General Manager		
Nasreen DeRubeis	Quality Manager		
Jesse Woodring	EHS Analyst		
Tom Sylvester	Regional Manager - Systems		
Kelli Dabler	Supervisor		

¹ Members of the local management team are subject to change during the life-cycle of this document version.

² Include if different from the physical address and phone number of the facility.

³ This individual serves as an Acting Technical Manager for TNI for one or more fields of accreditation.



LABORATORY QUALITY MANUAL
Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Manual Approval Signatories

Approval of this manual by managerial personnel is recorded on the Signature Manifest located before the Title Page of this manual.

The individuals listed below represent the management team that was in place on the effective date of this version of the manual for the following location:

Pace Analytical Services, LLC
 12 World's Fair Drive, Suite L
 Somerset, NJ 08873
 Phone: 732-652-6452

Each of the following individuals is a signatory for the manual for the location listed above. The application of their signature to the manual signifies their commitment to communicate, implement, and uphold the requirements, policies and procedures specified in this manual and their commitment to continuously improve the effectiveness of the quality management system based on customer feedback and internal assessment.

Name¹	Title	Address²	Phone²
Colin Walters	Regional Director - Operations		724-433-5223
William Billings	General Manager		
Nasreen DeRubeis	Quality Manager		
Jesse Woodring	EHS Analyst		
Tom Sylvester	Regional Manager - Systems		
Kelli Dabler	Supervisor		

¹ Members of the local management team are subject to change during the life-cycle of this document version.

² Include if different from the physical address and phone number of the facility.

³ This individual serves as an Acting Technical Manager for TNI for one or more fields of accreditation.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Table of Contents

1.0	PURPOSE AND SCOPE	10
1.1	PURPOSE	10
1.2	SCOPE AND APPLICATION	10
1.2.1	QUALITY MANUAL TEMPLATE	11
1.2.2	LABORATORY QUALITY MANUAL	11
1.2.3	REFERENCES TO SUPPORTING DOCUMENTS	11
2.0	REFERENCES	12
3.0	TERMS AND DEFINITIONS	13
4.0	MANAGEMENT REQUIREMENTS	13
4.1	ORGANIZATION	13
4.1.1	LEGAL IDENTITY	13
4.1.2	COMPLIANCE RESPONSIBILITY	13
4.1.3	SCOPE OF THE QUALITY MANAGEMENT SYSTEM	13
4.1.4	ORGANIZATION HISTORY AND INFORMATION	14
4.1.5	MANAGEMENT REQUIREMENTS	15
4.2	QUALITY MANAGEMENT SYSTEM	20
4.2.1	QUALITY MANAGEMENT SYSTEM OBJECTIVES	20
4.2.2	QUALITY POLICY STATEMENT	22
4.2.3	MANAGEMENT COMMITMENT: QUALITY MANAGEMENT SYSTEM	24
4.2.4	MANAGEMENT COMMITMENT: CUSTOMER SERVICE	24
4.2.5	SUPPORTING PROCEDURES	24
4.2.6	ROLES AND RESPONSIBILITIES	26
4.2.7	CHANGE MANAGEMENT	26
4.3	DOCUMENT CONTROL	26
4.3.1	GENERAL	26
4.3.2	DOCUMENT APPROVAL AND ISSUE	26
4.3.3	DOCUMENT REVIEW AND CHANGE	27
4.4	ANALYTICAL SERVICE REQUEST, TENDER, AND CONTRACT REVIEW	27
4.5	SUBCONTRACTING AND IN-NETWORK WORK TRANSFER	28
4.6	PURCHASING SERVICES AND SUPPLIES	28
4.7	CUSTOMER SERVICE	29
4.7.1	COMMITMENT TO MEET CUSTOMER EXPECTATIONS	29
4.7.2	CUSTOMER FEEDBACK	29



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

4.8 COMPLAINTS	30
4.9 NONCONFORMING WORK	30
4.9.1 DEFINITION OF NONCONFORMING WORK	30
4.10 CONTINUOUS IMPROVEMENT	31
4.11 CORRECTIVE ACTION	32
4.11.1 ROOT CAUSE ANALYSIS	33
4.11.2 EFFECTIVENESS REVIEW	33
4.11.3 ADDITIONAL AUDITS	33
4.12 PREVENTIVE ACTION	33
4.12.1 CHANGE MANAGEMENT	34
4.13 CONTROL OF RECORDS	34
4.13.1 GENERAL REQUIREMENTS	34
4.13.2 TECHNICAL RECORDS	35
4.14 AUDITS	36
4.14.1 INTERNAL AUDIT	36
4.15 MANAGEMENT REVIEW	38
4.16 DATA INTEGRITY	38
5.0 TECHNICAL REQUIREMENTS	39
5.1 GENERAL	39
5.2 PERSONNEL	39
5.2.1 PERSONNEL QUALIFICATIONS	39
5.2.2 TRAINING	40
5.2.3 PERSONNEL SUPERVISION	44
5.2.4 JOB DESCRIPTIONS	45
5.2.5 AUTHORIZATION OF TECHNICAL PERSONNEL	45
5.3 ACCOMMODATIONS AND FACILITIES	45
5.3.1 FACILITIES	45
5.3.2 ENVIRONMENTAL CONDITIONS	45
5.3.3 SEPARATION OF INCOMPATIBLE ACTIVITIES	46
5.3.4 LABORATORY SECURITY	46
5.3.5 GOOD HOUSEKEEPING	46
5.4 TEST METHODS	46
5.4.1 GENERAL REQUIREMENTS	46
5.4.2 METHOD SELECTION	46
5.4.3 LABORATORY DEVELOPED METHODS	47
5.4.4 NON-STANDARD METHODS	47
5.4.5 METHOD VALIDATION	48
5.4.6 MEASUREMENT UNCERTAINTY	50
5.4.7 CONTROL OF DATA	51
5.5 EQUIPMENT	52
5.5.1 AVAILABILITY OF EQUIPMENT	52



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

5.5.2	CALIBRATION	52
5.5.3	EQUIPMENT USE AND OPERATION	53
5.5.4	EQUIPMENT IDENTIFICATION	53
5.5.5	EQUIPMENT LISTS AND RECORDS	53
5.5.6	OUT OF SERVICE PROTOCOL	54
5.5.7	CALIBRATION STATUS	54
5.5.8	RETURNED EQUIPMENT CHECKS	54
5.5.9	INTERMEDIATE EQUIPMENT CHECKS	54
5.5.10	SAFEGUARDING EQUIPMENT INTEGRITY	54
5.6	MEASUREMENT TRACEABILITY	55
5.6.1	GENERAL	55
5.6.2	EQUIPMENT CORRECTION FACTORS	55
5.6.3	SPECIFIC REQUIREMENTS	55
5.6.4	REFERENCE STANDARDS AND REFERENCE MATERIALS	55
5.7	SAMPLING	58
5.7.1	SAMPLING PLANS AND SOPS	58
5.7.2	CUSTOMER REQUESTED DEVIATIONS	58
5.7.3	RECORDKEEPING	58
5.8	SAMPLE MANAGEMENT & HANDLING	58
5.8.1	PROCEDURES	58
5.8.2	UNIQUE IDENTIFICATION	60
5.8.3	SAMPLE RECEIPT CHECKS AND SAMPLE ACCEPTANCE POLICY	60
5.8.4	SAMPLE CONTROL AND TRACKING	61
5.8.5	SAMPLE STORAGE, HANDLING, AND DISPOSAL	62
5.9	ASSURING THE QUALITY OF TEST RESULTS	63
5.9.1	QUALITY CONTROL (QC) PROCEDURES	63
5.9.2	QC CORRECTIVE ACTION	67
5.9.3	DATA REVIEW	67
5.10	REPORTING	68
5.10.1	GENERAL REQUIREMENTS	68
5.10.2	TEST REPORTS: REQUIRED ITEMS	68
5.10.3	TEST REPORTS: SUPPLEMENTAL ITEMS	69
5.10.4	CALIBRATION CERTIFICATES	70
5.10.5	OPINIONS AND INTERPRETATIONS	70
5.10.6	SUBCONTRACTOR REPORTS	71
5.10.7	ELECTRONIC TRANSMISSION OF RESULTS	71
5.10.8	FORMAT OF TEST REPORTS	71
5.10.9	AMENDMENTS TO TEST REPORTS	71
6.0	REVISION HISTORY	71
7.0	APPENDICES	72



LABORATORY QUALITY MANUAL
Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

7.1	APPENDIX A: CERTIFICATION / ACCREDITATION LISTING	72
7.1.1	PAS-GREENSBURG	72
7.2	APPENDIX B: CAPABILITY LISTING	73
7.2.1	PAS-GREENSBURG	73
7.3	APPENDIX C: GLOSSARY	78
7.4	APPENDIX D: ORGANIZATION CHART(S)	93
7.4.1	PLEASE CONTACT THE LABORATORY FOR CURRENT ORGANIZATION CHARTS FOR CORPORATE PERSONNEL.	93
7.4.2	PAS - GREENSBURG	93
7.5	APPENDIX E: EQUIPMENT LISTING	94
7.5.1	PAS-GREENSBURG	94
8.0	ADDENDUM: PROGRAM REQUIREMENTS	103
8.1	DoD/DOE	103
9.0	ADDENDUM: RADIOLOGICAL REQUIREMENTS	105
9.1	ESTIMATE OF ANALYTICAL UNCERTAINTY	105
9.2	RADIOLOGICAL EQUIPMENT CALIBRATION	105
9.3	MATRIX SPIKE/MATRIX SPIKE DUPLICATE (MS/MSD)	105



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

1.0 PURPOSE AND SCOPE

1.1 Purpose

This quality manual (manual) outlines the quality management system and management structure of the laboratories and service centers affiliated with Pace Analytical Services, LLC (PAS). A laboratory is defined by PAS as any PAS facility, however named, that provides testing, sampling, or field measurement services. When the term "laboratory" is used in this manual, the term refers to all locations listed on the Title Page of this manual and in Section 4.1.3 unless otherwise specified.

The PAS quality management system is also referred to as the quality program throughout this document. In this context, the phrase "quality management system" and "quality program" are synonymous.

The quality management system is the collection of policies and processes established by PAS management to consistently meet customer requirements and expectations, and to achieve the goals to provide PAS customers with high quality, cost-effective, analytical measurements and services.

The quality management system is also intended to establish conformance¹ and compliance with the current versions of the following international and national quality system standards:

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

¹The 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.

In addition to the international and national standards, the quality management system is designed to achieve regulatory compliance with the various federal and state programs for which the laboratory provides compliance testing and/or holds certification or accreditation. When federal or state requirements do not apply to all PAS locations, the requirements for compliance 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 laboratory associated with this manual is provided in Appendix A.
- A list of analytical testing capabilities offered by each laboratory associated with this manual is provided in Appendix B.

1.2 Scope and Application

This manual applies to each of the PAS locations listed on the Title Page and in Section 4.1.3.

The manual was prepared from a quality manual template (template) created by PAS corporate quality personnel. The template outlines the minimum requirements PAS management considers necessary for every PAS laboratory, regardless of scope of services or number of personnel, to establish in order to maintain a quality management system that achieves the objectives of PAS's Quality Policy (See 4.2.2). In this regard, the template is the mechanism used by the corporate officers (a.k.a. 'top management') to communicate their expectations and commitment for the PAS quality program to all PAS personnel.

The laboratory also has the responsibility to comply with federal and state regulatory and program requirements for which it provides analytical services and holds certification or accreditation. When those requirements are more stringent than the template, the requirements for compliance are provided in



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

addendum to this manual or in other documents that supplement the manual. This document structure maintains consistency in the presentation of the quality management system across the network while providing the laboratory a mechanism to describe and achieve compliance requirements on a program basis.

1.2.1 Quality Manual Template

The quality manual template is developed by the Corporate Quality Director with contribution and input from corporate quality personnel and the corporate officers. Approval of the template by the corporate officers (aka “top management”) confirms their commitment to develop and maintain a quality management system appropriate for the analytical services offered by the organization and to communicate their expectations of the quality program to all personnel.

The template and instructions for use of the template are released by corporate quality personnel to quality assurance manager(s) responsible for each laboratory (Local QA). Local QA uses the template to prepare the laboratory’s manual by following the instructions provided. Since the template provides the minimum requirements by which all PAS locations must abide, the laboratory may not alter the font, structure or content of the template except where specified by instruction to do so. As previously stated, program specific requirements are provided in addendum or in documents that supplement this manual.

The template is reviewed by corporate quality personnel every two years and updated if needed. More frequent review and revision may be necessary to manage change, to maintain conformance and compliance to relevant standards, or to meet customer expectations.

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

1.2.2 Laboratory Quality Manual

The manual is approved and released to personnel under the authority of local management. The manual is reviewed annually and location specific information is updated, if needed. More frequent review and revision may be necessary when there are significant changes to the organizational structure, capabilities, and resources of the laboratory. Review and revision of the manual is overseen by local QA. If review indicates changes to the main body of the manual are necessary to maintain conformance and compliance to relevant standards, or to meet customer expectations, local QA will notify corporate quality personnel to initiate review and/or revision of the template.

See SOP ENV-SOP-CORQ-00015 *Document Management and Control* for more information.

1.2.3 References to Supporting Documents

The template and the manual includes references to other laboratory documents that support the quality management system such as policies and standard operating procedures (SOPs). These references include the document’s document control number and may include the document title.

This information is subject to change. For example, an SOP may be converted to a policy or the document’s title may change. For these types of administrative changes, the manual and template are updated to reflect the editorial change during the document’s next scheduled review/revision cycle or the next time a new version of the document is released, whichever is sooner.

Local QA maintains a current list of controlled documents used at each PAS location to support the quality management system. This list, known as the Master List, lists each document used by document control number, title, version, effective date, and reference to any document(s) that the



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

current version supersedes. When there is a difference between the template and/or manual and the Master List, the document information in the Master List takes precedence. The current Master List is readily available to personnel for their use and cross-reference. Parties external to the laboratory should contact the laboratory for the most current version.

2.0 REFERENCES

References used to prepare this manual include:

- “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.
- Quality Assurance Manual for Industrial Hygiene Chemistry, AIHA, most current version.
- National Environmental Laboratory Accreditation Conference (NELAC) Standard- most current version.
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories- most current version.

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*



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

- Department of Defense Quality Systems Manual (QSM), most current version.
- TNI (The NELAC Institute) Standard- most current version applicable to each lab.
- UCMR Laboratory Approval Requirements and Information Document, most current version.
- US EPA Drinking Water Manual, most current version.

3.0 TERMS AND DEFINITIONS

Refer to Appendix C for terms, acronyms, and definitions used in this manual and in other documents used by the laboratory to support the quality management system.

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.1 Legal Identity

Pace Analytical Services, LLC is authorized under the State of Minnesota to do business as a limited liability company.

4.1.1.1 Change of Ownership

If there is a change of ownership, if a location goes out of business, or if the entire organization ceases to exist, Pace Analytical Services, LLC ensures that regulatory authorities are notified of the change within the time-frame required by each state agency for which the location is certified or accredited.

Requirements for records and other business information are addressed in the ownership transfer agreement or in accordance with appropriate regulatory requirements, whichever takes precedence.

4.1.2 Compliance Responsibility

Laboratory management has the responsibility and authority to establish and implement procedures and to maintain sufficient resources necessary to assure its activities are carried out in such a way to meet the compliance requirements of the quality management system.

4.1.3 Scope of the Quality Management System

The quality management system 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 includes:

Name	Pace Analytical Services, LLC
Address:	1638 Roseytown Road Suites 2, 3 & 4
City, State, Zip	Greensburg, PA 15601
Phone Number	724-850-5600
Service Type:	Laboratory

Name	Pace Analytical Services, LLC
------	-------------------------------



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Address:	5020 Ritter Road, Suite 202
City, State, Zip	Mechanicsburg, PA 17055
Phone Number	609-389-5468
Service Type:	Service Center

Name	Pace Analytical Services, LLC
Address:	6521B State Route 61
City, State, Zip	Shamokin, PA 17872
Phone Number	570-648-2216
Service Type:	Service Center

Name	Pace Analytical Services, LLC
Address:	12 World's Fair Drive, Suite L
City, State, Zip	Somerset, NJ 08873
Phone Number	732-652-6452
Service Type:	Service Center

4.1.4 Organization History and Information

Founded in 1978, Pace Analytical Services, LLC (PAS) 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 company's network offer inorganic, organic and radiochemistry testing capabilities; specializing in the analysis of trace level contamination in air, drinking water, groundwater, wastewater, soil, biota, and waste.

With over 90 laboratories and services centers in the contiguous US and in Puerto Rico, the network provides project support for thousands of industry, consulting, engineering and government professionals.

Pace delivers the highest standard of testing and scientific services in the market. We offer the most advanced solutions in the industry, backed by truly transparent data, a highly trained team, and the service and support that comes from four decades of experience.

4.1.4.1 Organization Structure

Each location maintains a local management structure under the oversight and guidance of corporate personnel. Local management is responsible for making day-to-day decisions regarding the operations of the facility, implementing the quality management system, upholding the requirements of the quality program, and for supervision of personnel.

Local management is provided by a General Manager (GM), Quality Manager (QM), Client Services Manager (CSM), Information Technology (IT) Manager, Department Managers (DM) and/or Department Supervisors (DS), however named.

Some locations may also have any one of the following management positions: Senior Quality Manager (SQM), Operations Manager (OM), Technical Director (TD), or Technical Manager (TM). When the location does not have a TD or TM, technical management is provided jointly by the GM, QM, DM, and DS.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

The GM (or AGM), however named reports to a Senior General Manager (SGM), who is responsible for the management of multiple laboratories and service centers within a geographical region, and who reports directly to the Chief Operating Officer (COO). The QM and SQM have indirect reporting relationship to the Corporate Director of Quality.

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

4.1.5 Management Requirements

4.1.5.1 Personnel

The laboratory is staffed with administrative and technical personnel who perform and verify work under the supervision of managerial personnel.

- Technical personnel include analysts and technicians that generate or contribute to the generation of analytical data and managerial personnel that oversee day to day supervision of laboratory operations. Including the reporting of analytical data and results, monitoring QA/QC performance, and monitoring the validity of analysis to maintain data integrity and reliability.
- Administrative personnel support the day-to-day activities of the laboratory.
- IT personnel maintain the information technology systems and software used at the laboratory.
- Client services personnel include project managers and support staff that manage projects.
- Managerial personnel make day-to-day and longer term decisions regarding the operations of the facility, supervise personnel, implement the quality management system and uphold the requirements of the quality program.

All personnel regardless of responsibilities are expected to carry out their duties in accordance with the policies and processes outlined in this manual and in accordance with standard operating procedures (SOPs) and other quality system documents. The laboratory's 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 include the management positions that have the authority and responsibility to plan, direct, and control, activities of the division (corporate) or the laboratory.

The following tables list key personnel positions by PAS job title and the position's primary deputy:

Key Personnel: Corporate

Key Personnel	Primary Deputy
Chief Executive Officer	Chief Operating Officer
Chief Operating Officer	Chief Executive Officer
Chief Compliance Officer	Quality Director



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Corporate Quality Director	Chief Compliance Officer
Health and Safety Director	Chief Compliance Officer
IT Director	LIMS Administrator, however named.

Key Personnel: Laboratory

Key Personnel	Primary Deputy
Regional Director - Operations	Chief Operating Officer or as designated.
General Manager	Regional Director - Operations
Quality Manager	Corporate Quality Manager or as designated.
Client Services Manager	General Manager
Regional Manager - Systems	Corporate IT Director or as designated.
Department Manager	General Manager
Technical Director ¹ /Manager ¹	Quality Manager
Acting Technical Manager TNI	

¹ Position may not be staffed at each location.

Some state certification programs require the agency to be notified when there has been a change in key personnel. Program-specific requirements and time-frames for notification by agency, are tracked and upheld by local QA, when these requirements apply.

4.1.5.2 Roles and Responsibilities

The qualifications, duties, and responsibilities for each position are detailed in job descriptions maintained by PAS's corporate Human Resource's Department (HR).

The following summaries briefly identify the responsibility of key personnel positions in relation to the quality management system.

Chief Executive Officer (CEO): The CEO has overall responsibility for performance of the organization and endorses the quality program. Working with corporate and laboratory management, the CEO provides the leadership and resources necessary for PAS locations to achieve the goals and objectives of the quality management system and quality policy statement.

Chief Operating Officer (COO): The COO oversees all aspects of operations management including, strategic planning, budget, capital expenditure, and management of senior management personnel. In this capacity, the COO provides leadership and resources necessary to help top management at each PAS location achieve the goals and objectives of the quality management system and quality policy statement.

Chief Compliance Officer (CCO): The CCO oversees the quality assurance and environmental health and safety programs (HSE) for each business unit. The CCO is responsible for planning and policy development for these groups to ensure regulatory compliance and to manage risk. The position provides leadership and guidance necessary for all PAS locations to achieve the goals and objectives of the quality and HSE programs.

The CCO also serves as the Ethics Officer (ECO). The ECO develops the Ethics and Data Integrity Policy and Training Program, and provides oversight for reporting and investigation of ethical misconduct to maintain employee confidentiality during the



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

process. The ECO provide guidance and instruction for follow-up actions necessary to remedy the situation and deter future recurrence.

Corporate Director of Quality: The Corporate Director of Quality is responsible for developing and maintaining the PAS quality program under guidance and assistance from the CEO, COO, and CCO. This position helps develop corporate quality policy and procedure and analyzes metric data and other performance indicators to assess and communicate the effectiveness of the quality program to top management. The position provides leadership and guidance for implementation of the quality program across all PAS locations.

Corporate Director of Information Technology: The Corporate Director of IT oversees the systems and processes of information technology used to support the quality program. These systems include Laboratory Information Management Systems (LIMS); data acquisition, reduction, and reporting software; virus-protection, communication tools, and ensuring the integrity and security of electronic data.

Regional Director - Operations (RDO): The RDO has full responsibility for administrative and operations management and performance of a group of PAS laboratories and service centers. Working with the COO and local laboratory management, the RDO provides leadership, guidance and resources, including allocation of personnel, necessary to achieve the goals of PAS quality program.

General Manager (GM) / Assistant General Manager (AGM): The GM or AGM is responsible for the overall performance and administrative and operations management of a PAS location and associated service center(s). This position is responsible to provide leadership and resources, including allocation and supervision of personnel, necessary for the location to implement and achieve the goals of the PAS quality program. In this capacity, the position assures laboratory personnel are trained on and understand the structure and components of the quality program defined in this manual as well as the policies and procedures in place to implement the quality management system.

The GM/AGM of NELAC/TNI Accredited laboratories are 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 (See Section 4.1.5.2.2) and for notifying the accreditation body (AB) of any extended absence or reassignment of these designations.

Quality Manager (QM): The QM oversees and monitors implementation of the quality management system and communicates deviations to laboratory management. The QM is independent of the operation activities for which they provide oversight and has the authority to carry out the roles and responsibilities of their position without outside influence.

Additionally, in accordance with the TNI Standard, the QM:

- serves as the focal for QA/QC and oversees review of QC data for trend analysis;
- evaluates data objectively and perform assessments without outside influence;
- has document training and experience in QA/QC procedures and the laboratory's quality system;



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

- 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 supports to technical personnel and may serve as the primary deputy for the acting TNI Technical Manager(s).

Client Services Manager (CSM): The CSM oversees project management personnel. This position is responsible for training and management of client facing staff that serve as the liaison between PAS and the customer to ensure that projects are successfully managed to meet the expectations and needs of PAS customers. This position is also responsible for sharing positive and negative customer feedback with laboratory management so that this information may be used to improve the quality program.

Regional Manager - Systems: Local IT managers are responsible for maintaining the IT systems used to support the quality program. These systems include Laboratory Information Management Systems (LIMS); data acquisition, reduction, and reporting software; virus-protection, communication tools, and ensuring the integrity and security of electronic data.

Department Manager (DM): The DM is responsible for administrative and operations management and implementation of the quality management system 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 quality management system; method development, validation and the establishment and implementation of SOPs to assure regulatory compliance and suitability for 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.

Technical Director (TD): The TD provides technical oversight and guidance to laboratory personnel. Responsibilities may include but are not limited to: research and development, method development and validation, development of standard operating procedures, proposal and contract review. The TD may also be responsible for QA/QC trend analysis, technical training, and technology improvement.

4.1.5.2.1 Acting Technical Manager (TNI Accreditation):

For PAS locations that are NELAC/TNI accredited:

The TNI Standard specifies requirements for the qualification and duties of technical personnel with managerial responsibility. These requirements are associated in the Standard to the designation 'technical manager(s), however named'. These responsibilities may be assigned to multiple individuals and are not associated with any specific job title.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

For PAS, these TNI requirements for personnel that provide technical oversight correlate with PAS's job descriptions for Department Manager or Supervisor. However, the duties may be assigned to any PAS employee that meets the TNI specified qualifications.

Personnel assigned this designation retain their PAS assigned job title. The job title may be appended with "*acting as technical manager for TNI*" and the technology or field of accreditation for which the employee is approved, if necessary.

When TNI Accreditation Bodies (AB) 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 carry out duties of the 'technical manager, however named' as specified in the TNI Standard.

In accordance with the TNI Standard, the acting Technical Manager(s) for TNI are responsible for monitoring the performance of QC/QA in the work areas they oversee.

If the absence of any employee that is approved as acting technical manager for TNI exceeds 15 calendar days, the duties and responsibilities specified in the TNI Standard are reassigned to another employee that meets the qualifications for the technology or field of accreditation or they are assigned to the position's deputy, the quality manager.

4.1.5.3 Conflict of Interest

A conflict of interest is a situation where a person has competing interests. Laboratory management looks for potential conflict of interest and undue pressures that might arise in work activities and then includes countermeasures in policies and procedures to mitigate or eliminate the conflict.

See policy COR-POL-0004 *Ethics Policy* for more information.

4.1.5.4 Confidentiality

Laboratory management is committed to preserving the confidentiality of PAS customers and confidentiality of business information.

Procedures used by the laboratory to maintain confidentiality include:

- A Confidentiality Agreement which all employees are required to sign at the time of employment and abide by the conditions of throughout employment;
- Record retention and disposal procedures that assure confidentiality is maintained;
- Physical access controls and encryption of electronic data; and
- Protocol for handling Confidential Business Information (CBI).

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



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

client's authorized representative information provided to PAS, except when the laboratory is required by law to release confidential information to another party, such as a regulatory agency or for litigation purposes. In which case, the laboratory will notify the client of the release of information and the information provided.

The terms of client confidentiality are included in PAS Standard Terms and Conditions (T&C). With the acceptance of PAS Terms and Conditions and/or the implicit contract for analytical services that occurs when the client sends samples to the laboratory for testing, the client authorizes PAS to release confidential information when required.

See policy COR-POL-0004 *Ethics Policy* 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 person(s) you are exchanging information with actively gets the point and understands it.

4.1.5.5.1 Workplace Communication

Good communication in the workplace is necessary to assure work is done correctly, efficiently, and in accordance with client expectations.

Instructions for how to carry out work activities are communicated to personnel via written policy, standard operating procedures, and standard work instructions.

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

4.1.5.5.2 External Communication

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

Laboratory management ensure personnel learn to communicate in professional and respectful ways in order to build strong relationships, and learn to communicate effectively to avoid misunderstanding.

4.2 Quality Management System

4.2.1 Quality Management System Objectives

The objectives of the laboratory's quality management system 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 product is 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'.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

4.2.1.1 Impartiality

The laboratory achieves and maintains impartiality by implementing and adhering to the policies and processes of the quality management system, which are based on industry accepted standards and methodologies.

The laboratory's procedures for handling nonconforming work (See 4.9), corrective and preventive actions (See 4.11) and management review (See 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 quality management system uncertain. An opportunity is something that has potential positive consequences for the laboratory.

Laboratory personnel manage risks and opportunities on a daily basis by carrying out the processes that make up the quality management system. Some of the ways in which the quality management system 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 jurisdiction for regulatory compliance;
- SOPs and other controlled instructional documents are provided to personnel to eliminate variability in 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 quality management system.

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 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



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

purpose of improving both external and internal customer satisfaction. PAS's lean programs 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 laboratory management to communicate the quality management system to laboratory personnel.

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

- All laboratory personnel are required to sign a Read and Acknowledgement Statement to confirm the employee has: 1) been informed of the manual by laboratory 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 quality management system. The “how to” implementation of the quality management system is provided in policy, SOPs, standard work instructions, and other controlled instructional documents.

4.2.2 Quality Policy Statement

The quality policy of the laboratory is to provide customers with data of known and documented quality fit for their intended purpose. The laboratory achieves this policy by implementing the quality management system defined in this manual, by following industry accepted protocol for analytical testing and quality assurance and quality control (QA/QC) 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:

- The laboratory will provide customers with reliable, consistent, and professional service. This is accomplished by making sure the laboratory 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.
- The laboratory maintains a quality program that complies with applicable, state, federal, industry standards for analytical testing and competency.

ISO/IEC 17025 and the TNI (The NELAC Institute) Standard is used by PAS to establish the minimum requirements of the PAS quality program.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

ISO/IEC 17025 is a competency standard that outlines the general requirements for the management system for calibration and testing laboratories. It is the primary quality system standard from which other quality system standards, such as the TNI Standard, are based. The TNI Standard are consensus standards that provides management and technical requirements for laboratories performing environmental analysis.

- Laboratory management provides training to personnel so that all personnel are familiar with the quality management system outlined in this manual and that they understand that implementation of the quality management system is achieved by adherence to the organization's policies and procedures.
- Laboratory management continuously evaluates and improves the effectiveness of the quality management system 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

PAS has established a comprehensive ethics and data integrity program that is communicated to all PAS employees in order 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 PAS Ethics / Data Integrity Program include:

- Ethics Policy (COR-POL-0004);
- Ethics Compliance Officer;
- 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 PAS 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 assure tasks are done correctly and consistently by each employee;
- On the Job Training;
- Data integrity monitoring activities which include, but are not limited to, secondary and tertiary data review, internal technical and system audits, raw data audits, data mining scans, and proficiency testing; and
- Confidential reporting process for alleged ethics and data integrity issues.

All laboratory managers 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.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

PAS has engaged Lighthouse Services, Inc. to provide personnel with an anonymous reporting process available to them 24 hours a day/7 days per week. The alert line may be used by any employee to report possible violations of the company's ethics and data integrity program. When using the reporting process, the employee does need to specify the location of concern and when reporting by email, also include the company name. Messages are collected, documented, reviewed, and will be followed up on by the Ethics Compliance Officer to resolve the matter. Investigations concerning data integrity are kept confidential.

Lighthouse Compliance Alert Lines:

English Speaking US & Canada	(844) 940-0003
Spanish Speaking North America	(800) 216-1288
Internet	www.lighthouse-services.com/pacelabs
Email	reports@lighthouse-services.com

4.2.3 Management Commitment: Quality Management System

Evidence of management's commitment for the development, maintenance, and on-going improvement of the quality management system is provided by the application of their signature of approval to this manual. Their signature confirms they understand their responsibility to implement the quality management system 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 quality management system outlined in this manual, implementing the quality management system outlined in this manual, and upholding these requirements for all work activities.

4.2.5 Supporting Procedures

Documents that support this manual and quality management system are referenced throughout this manual. The structure of the document management system is outlined in SOP ENV-SOP-CORQ-0015 *Document Management and Control* and summarized in the following subsections.

4.2.5.1 Quality Management System Document Structure

Documents associated with the quality management system are classified into document types that identify the purpose of the document and establish how the document is managed and controlled.

Document types are ranked to establish which documents takes 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 assure downline documents are in agreement with documents of higher rank. Project specific documents are not ranked because client specific requirements are not incorporated into general use documents in order to maintain client confidentiality.

PAS Quality Management System Documents: Internal



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Document Type	Purpose
Quality Manual	Outlines the laboratory's quality management system 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 PAS 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 by PAS. Includes both fundamental and operational elements for implementation of the systems described in PAS manual(s). Assures that activities are performed properly in accordance with applicable requirements. Designed to ensure consistency, protect EHS of employees and environment, prevent failure in the process and ensure compliance with company and regulatory requirements. SOPs describes the "how" based on policy.
Standard Work Instruction	Provide step by step visual and/or written instruction to carry out 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	Provide assistance to carry out a task. Most often used for software applications.
Form	Used for a variety of purposes such as to provide a standardized format to record observations, to provide information to supplement an SOP.

PAS Quality Management System Documents: External

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

Document Hierarchy



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Rank	Document
1	Reference Documents
2	Corporate Manual
3	Corporate Policy
4	Corporate SOP
5	Corporate SWI, Templates & Forms
6	Laboratory Manual
7	Laboratory SOP
8	Laboratory SWI, Templates, & Forms
NA	Project Documents ¹

4.2.6 Roles and Responsibilities

The roles and responsibilities of technical management and of the quality manager are provided in section 4.1.5.1.2.

4.2.7 Change Management

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

4.3 Document Control

4.3.1 General

The laboratory's procedures for document control are provided in SOP ENV-SOP-CORQ-0015 *Document Management and Control*.

The documents that support the quality management system include internally generated documents such as manuals, policies, standard operating procedures, standard work instructions, forms, guides, and templates and external source documents such as but not limited to, regulations, standards, reference methods, manuals, and project-specific documents.

The laboratory uses electronic document management software (eDMS) to carry out the procedures of the SOP. eDMS automates the process for unique document identification, version control, approval, access, and archival.

4.3.2 Document Approval and Issue

Documents that are part of the quality management system are reviewed by qualified personnel and approved by laboratory management prior to release for general use.

Local QA maintains a master list of controlled documents used at the laboratory. The master list includes the document control number, document title, and current revision status and is made available to personnel for their reference.

Only the approved versions of documents are available to personnel for use. The eDMS system does not allow user access to draft versions of documents except to personnel assigned to work on the draft. eDMS also restricts access to archived documents except to authorized users, such as local QA, in order to prevent the use of obsolete documents.

See SOP ENV-SOP-CORQ-0015 *Document Management and Control* for more information.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

4.3.3 Document Review and Change

Unless a more frequent review is required by regulatory, certification or accreditation program, the laboratory formally reviews documents at least every two years to ensure the document remains 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 carry out their work activities. Consequently, any concerns or problems with the document should be caught and brought to the attention of laboratory 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.

The laboratory does not allow hand-edits to 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 SOP Change in Progress form, email, or memorandum.

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

4.4 Analytical Service Request, Tender, and Contract Review

The laboratory's management and/or client service personnel perform thorough reviews of requests and contracts for analytical services to verify the laboratory has the capability, capacity, and resources necessary to successfully meet the customer's needs. These review procedures are described in laboratory SOP ENV-SOP-GBUR-0010 *Review of Analytical Requests*.

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

- The laboratory 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;
- The laboratory and any subcontractor has the capability, capacity, and resources to meet the project requirements and expectations within the requested time frame for delivery of work product;
- Any concerns that arise from review are discussed and resolved with the client; 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 in-network laboratories and any potential subcontractors hold required certification/accreditation for the test method, matrix, and analyte and verifies the laboratory 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 laboratories and any potential subcontractors are able to handle the sample load and deliver work production within the delivery time-frame requested.

Resource review verifies that the laboratory 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.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

4.5 Subcontracting and In-Network Work Transfer

The terms 'subcontract' and "subcontracting" refers to work sent to a business external to Pace Analytical Services, LLC (PAS) and the term 'subcontractor' refers to these external businesses, which are also called vendors.

Work transferred within the PAS network is referred to as interregional work orders (IRWO) and network laboratories are referred to as IRWO or network laboratory.

The network of PAS laboratories offers comprehensive analytical capability and capacity to ensure PAS can meet a diverse range of client needs for any type of project. If the laboratory receives a request for analytical services and it cannot fulfill the project specifications, the laboratory's client services team will work with the client to place the work within the PAS network. When it is not possible to place the work within network, the laboratory will, with 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 laboratory and the client. Some client programs require client consent even for IRWO work transfer, and when this applies, the client services team obtains consent as required. The laboratory retains the record of client notification and their consent in the project record for historical purposes.

Whenever work is transferred to a subcontractor or an IRWO laboratory, the laboratory responsible for management of the project verifies each of these qualifications:

- The subcontractor or IRWO laboratory has the proper accreditation/certifications required for the project and these are current; and
- The use of the subcontractor or IRWO laboratory is approved by the client and/or regulatory agency, when approval is required. Record of approval is retained in the project record.

When possible, the laboratory selects subcontractors that maintain a quality management system similar to PAS and that complies with ISO/IEC 17025 and the TNI Standard(s).

PAS also evaluates and pre-qualifies subcontractors as part of company's procurement program. The complete list of approved vendors is maintained by the corporate procurement department and is made available to all PAS locations. Pre-qualification of a subcontractor does not replace the requirement for the placing laboratory to verify the capability, capacity, and resources of any selected subcontractor on a project-specific basis to confirm the subcontractor can meet the client's needs.

For both subcontracting and in-network work transfer, the project specifications are always communicated to the subcontractor or the IRWO laboratory by the project manager so that the laboratory performing the work is aware of and understands these requirements.

The procedures for subcontracting are outlined in laboratory SOP ENV-SOP-GBUR-0002 *Subcontracting Samples*.

4.6 Purchasing Services and Supplies

Vendors that provide services and supplies to the laboratory are prequalified by corporate procurement personnel to verify the vendor's capability to meet the needs of PAS. 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. The records of vendor evaluation and the list of approved vendors is maintained by the corporate procurement department.

The laboratory may purchase goods and services from any supplier on the approved vendor list.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

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 the department supervisor to confirm the purchase conforms with specified requirements. After approval the requisition is handled by the laboratory's designated purchasing agent. On receipt, the product is inspected and verified before use, when applicable.

The laboratory's procedure for the purchase of services and supplies is specified in laboratory SOP ENV-SOP-GBUR-0042 *Purchasing of Laboratory Supplies*.

4.7 Customer Service

Project details and management is handled by the laboratory's customer service team. Each customer is assigned a Project Manager (PM) that is responsible for review of contract requirements and handling laboratory to customer communication about the project status.

4.7.1 Commitment to Meet Customer Expectations

The laboratory cooperates and works closely with our customers to ensure their needs are met and to establish their confidence in the laboratory's capability to meet their needs for analytical services and expectations for service.

Each customer's project is handled by a project manager (PM) that is the customer's primary point of contact. 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. Laboratory supervisors are expected to keep the PM informed of project status and any delays or major issues, so that the PM can keep the client informed.

PAS also has a team of subject matter experts (SME) available to provide customers with advice and guidance and any other assistance needed. SME are selected by top management based on their knowledge, experience, and qualifications.

The laboratory encourages customers to visit the laboratory to learn more about the laboratory's capabilities, observe performance and to meet laboratory personnel.

PAS customers expect confidentiality. Laboratory personnel will not divulge or release information to a third party without proper authorization unless the information is required for litigation purposes. See Section 4.1.5.3 of this manual and policy COR-POL-0004 *Ethics Policy* for more information on the laboratory's policy for client confidentiality.

4.7.2 Customer Feedback

The laboratory actively seeks positive and negative feedback from customers through surveys and direct communication. Information from the client about their experience working with the laboratory and their satisfaction with work product is used to enhance processes and practices and to improve decision making. Customer feedback is communicated to laboratory management and corporate personnel in monthly reports and analyzed yearly during management review (See 4.15) to identify risk and opportunity. Corrective, preventive, or continuous improvement actions are taken based on nature of and/or feedback trends.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Also see sections 4.9, 4.10, 4.11, 4.12, 4.14, and 4.15 for more information about how customer feedback is managed by the laboratory and used to enhance the quality management system.

4.8 Complaints

Complaints provide opportunities to improve processes and build stronger working relationships with our clients.

The laboratory's complaint resolution process includes three steps. First, handle and resolve the complaint to mutual satisfaction. Second, perform corrective action to prevent recurrence (See 4.11). Third, record and track the complaint and use these records for risk and opportunity assessment and preventive action (See 4.12)

4.9 Nonconforming Work

4.9.1 Definition of Nonconforming Work

Nonconforming work is work that does not conform to customer requirements, standard specifications, laboratory 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 laboratory 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 handles nonconforming work depends on the significance and impact (risk) of the issue. Some issues may simply require correction, others may require investigation, corrective action (See 4.11) and/or data recall (See 4.16). When the laboratory 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. (See 5.10)

Nonconforming work also includes unauthorized departure from laboratory 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 SOP

An authorized departure from a test method SOP is one that has been reviewed and approved by the Department Manager, Technical Manager, Acting Technical Manager for TNI, Quality Manager, or the General Manager. Review is conducted to confirm the



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

departure does not conflict with regulatory compliance requirements for which the data will be used or does not adversely affect data integrity. The departure may originate from client request or may be necessary to overcome a problem.

An authorized departure from administrative or process-oriented SOP is typically necessary to correct an error in the SOP. These departure requests are reviewed and pre-approved by the local QA Manager. Documentation of SOP departures and approval decisions are retained by the laboratory as evidence that the departure was authorized. When necessary, approved departures from test method SOPs are noted in the final test report to advise the data user of any ramification to data quality.

4.9.1.2 Authorized Departure from Test Methods (Method Modifications)

When test results are associated to a published reference test method, the laboratory'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 or wastewater or a certification or accreditation program, such as TNI/NELAC, the SOP must also comply with or include these requirements. 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 laboratory may establish an SOP that is modified from these reference documents, and what is considered a modification are specified in ENV-SOP-CORQ-0011 *Method Validation and Instrument Verification*.

Modifications that do not meet the requirements of this SOP (ENV-SOP-CORQ-0011) are unauthorized. Client requests to deviate from the test method are handled as client requests to depart from the test method SOP since it is the SOP that the laboratory follows when performing work.

4.9.1.3 Stop Work Authority

Stop Work Authority provides laboratory personnel with the responsibility and obligation to stop work when there is a perceived unsafe condition or behavior that may result in an unwanted event.

All laboratory and corporate personnel have the authority to stop work when needed to preserve data integrity or safety of workers.

Once a stop work order has been initiated and the reason for doing so is confirmed valid; laboratory management is responsible for immediate correction and corrective action (see section 4.10) before resumption of work.

4.10 Continuous Improvement

The laboratory's quality management system is designed to achieve continuous improvement through the implementation of the quality policy and objectives outlined in this manual. Information about the laboratory's activities and performance is gained from many 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 laboratory's corrective action (see section 4.11) and preventive action (see section 4.12) processes and to establish goals and objectives during annual review of the management system (see section 4.15).



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

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 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.

4.11 Corrective Action

Corrective action is process used to eliminate the cause of a detected nonconformity. It is not the same as a correction. A correction is an action taken to fix an immediate problem. The goal of the corrective action process 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 by PAS, is one of the most effective tools used by the laboratory to prevent nonconforming work, identify risk and opportunity, and improve service to our customers.

The laboratory has two general processes for corrective action:

The process used for actions taken in response to day to day quality control (QC) and acceptance criteria exceptions (nonconformance) that occur during the day to day testing process are called corrections. These events do not usually include formal methods for cause analysis; instead the reason for the failure is investigated through troubleshooting or other measures. Required actions for correction of routine nonconformance is specified in laboratory SOPs. When corrective 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 formal 7 step corrective action process is used when there is a problem or departure from the quality management system, technical activities, or when the extent of a single problem has significant impact on data, regulatory compliance or customer needs. 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 laboratory's 7 Step CAPA Process includes:

- 1) Define the Problem
- 2) Define the Scope of the Problem
- 3) Contain the Problem
- 4) Root Cause Analysis
- 5) Plan Corrective Action
- 6) Implement Corrective Action
- 7) Follow Up / Effectiveness Check

The formal CAPA process may be initiated by any employee. Once the process is initiated it is overseen and coordinated by laboratory management. The CAPA process is documented using an electronic or paper-based system. The CAPA record includes tracking information, dates, individuals involved, those responsible for action plan implementation and follow-up, and timelines and due dates.

For more information about the laboratory's procedure for corrective action, see laboratory SOP ENV-SOP-GBUR-0048 *Corrective and Preventive Action*. Additional explanation about certain aspects of the laboratory's corrective action process are outlined in the next three subsections.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

4.11.1 Root Cause Analysis

Root cause analysis (RCA) is the process of investigation used by the laboratory to identify the underlying cause(s) of the problem. Once causal factors are identified, ways to mitigate the causal factors are reviewed and corrective action(s) most likely to eliminate the problem are selected.

The laboratory uses different methods to conduct this analysis. The most common approach is 5-Why, but fishbone diagrams, or even brainstorming may be appropriate depending on the situation. The method used is documented in the CAPA record.

4.11.2 Effectiveness Review

Monitoring corrective actions for effectiveness is shared by laboratory supervisors and quality assurance personnel. Effectiveness means the actions taken were sustainable and appropriate. Sustainable means the change is still in place. Appropriate means the action(s) taken prevented recurrence of the problem since the time corrective action was taken.

The time-frame in which effectiveness review takes place depends on the event and is recorded in the CAPA record with any addition actions that need to be taken.

Corrective action trends are also monitored by laboratory management and used to identify opportunities for preventive action or to gain lessons learned when actions taken were not adequate to solve the problem. See Section 4.12 (Preventive Action) and 4.15 (Management Review) for more information.

4.11.3 Additional Audits

When non-conformances or other problems cast doubt on compliance with the laboratory's policies, procedures, or compliance to regulatory requirements; laboratory management schedules a special audit of the area of activity in accordance with Section 4.14.1 as soon as possible. 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 serious issue or risk to the laboratory's business is identified.

4.12 Preventive Action

Preventive action is an action taken to eliminate the cause of a potential nonconformity and to achieve improvement. Preventive action is a forward thinking process designed to prevent problems opposed to reacting to them (corrective action).

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

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

The laboratory looks for opportunities for preventive action from a variety of sources including but not limited to: employee idea's, customer feedback, business partners input, trend analysis, business analytics, management reviews, proficiency testing results, lean management events, and risk-benefit analysis.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

The process for preventive actions follows the same 7 step process for corrective action except “problem” is replaced with “opportunity”, “cause analysis” is replaced with “benefit analysis”, and “corrective action” is replaced with “preventive action”.

Laboratory management evaluates the success of preventive actions taken in any given year during annual management review. See 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 the laboratory. Laboratory 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.

For more information about the laboratory’s procedures for preventive action see laboratory SOP ENV-SOP-GBUR-0056 *Management of Change*.

4.13 Control of Records

A record is a piece of evidence about the past, especially an account of an act or occurrence kept in writing or some other permanent form. Laboratory records document laboratory activities and provide evidence of conformity to the requirements established in the quality management system. These records may be hardcopy or electronic on any form of media.

4.13.1 General Requirements

4.13.1.1 Procedure

The laboratory’s procedures for control of records is provided in laboratory SOP ENV-SOP-GBUR-0039 *Archiving Laboratory Documents*.

The procedures in the SOP are established to assure quality and technical records are identified, retained, indexed, and filed to allow for retrieval during the entire retention time frame. 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, laboratory records fall into three categories: quality, technical, and administrative.

Examples of each are provided in the following table:

Record Type	Includes Records of:
Quality	Documents: Document Types listed in SOP ENV-SOP-CORQ-016 Audits: Internal and External Certificates and Scopes of Accreditation Corrective & Preventive Action Management Review Data Investigations Method Validation Instrument Verification Training Records



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Record Type	Includes Records of:
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 be legible and 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 laboratory personnel that performed the activity or entered the information.

Records are archived and stored in a way that they are retrieved. 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 record 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.

Records are kept for a minimum of 10 years unless otherwise specified by the client or regulatory program.

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 laboratory's record management SOP for more information.

4.13.1.3 Security

The laboratory is a secure facility and access to records is restricted to laboratory personnel.

4.13.1.4 Electronic Records

The data systems used to store electronic records is backed up in accordance with laboratory SOP ENV-SOP-GBUR-0163 *Electronic Record Backup*. Access to archived records stored electronically is maintained by personnel responsible for management of the electronic system.

4.13.2 Technical Records

In addition to the requirements identified in subsections 4.13.1.1 through 4.13.1.4, the requirements in the following subsections also apply to technical records.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

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 record. The accumulated record essentially need to provide sufficient 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. Laboratory managers are responsible to assure 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 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.

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

Maintenance of proper practices for error correction is monitored through the tiered data review process described in Section 5.9.3. Laboratory records are reviewed throughout the data review process. Individuals performing these reviews flag errors that are not properly corrected and bring these to the attention of the department manager or supervisor of the work area in which the record was generated so that the problem may be addressed and corrected with the individual(s) that did not make the correction properly.

4.14 Audits

The laboratory performs internal systems and technical audits to assess compliance to this manual and to other laboratory procedures, such as policy, SOP and SWI. Since the processes in this manual are based on the relevant quality system standards and regulatory and accreditation/certification program requirements the laboratory provides services for, the internal audits also assess on-going compliance to these programs.

The laboratory is 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 laboratory management to address compliance concerns and opportunities where improvement will increase the reliability of data.

Deficiencies, observations and recommendations from audits are managed by local QA using the laboratory's formal CAPA process. See Section 4.11 for more information.

4.14.1 Internal Audit

The laboratory's internal audit program is managed by local QA in accordance with a pre-determined audit schedule established at the beginning of each calendar year. The schedule is prepared to assure that all areas of the laboratory are reviewed over the course of the year.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Conformance to the schedule is reported to both laboratory management and corporate quality personnel in a monthly QA report prepared by the quality manager.

Although the QA Manager creates the audit schedule, it is the shared responsibility of local QA and laboratory managers to assure the schedule is maintained. Laboratory supervisors cooperate with QA to provide the auditors with complete access to the work area, personnel, and records needed.

Internal audits are performed by personnel approved by the quality manager. In general, personnel may not audit their own activities unless it can be demonstrated that an effective and objective audit will be carried out. The auditor must be trained, qualified, and familiar enough with the objectives, principles, and procedures of laboratory operations to be able to perform a thorough and effective evaluation.

The laboratory's internal audit program includes:

- **System Audits & Method Audits:** The purpose of these audits is to determine if daily practice is consistent with laboratory's SOPs and if SOPs are compliant with adjunct policy and procedures. Auditing techniques includes analyst interviews and observation and records review. These audits are performed per the pre-determined schedule.
- **Raw Data / Final Test Report Audits:** The purpose of these audits is to review raw data and/or a final test reports to verify the final product is consistent with customer/project requirements and supported as compliant to SOPs, reference methods, with test results that are properly qualified when necessary, accurate, and of known and documented quality. The reviews should also identify opportunities for improvement and best practices.
- **Special Audits:** Special audits are those performed ad hoc to follow up on specific 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 the laboratory's 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 laboratory personnel.

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

The laboratory's internal audit program and auditing procedures are further described in laboratory SOP ENV-SOP-GBUR-0049 *Internal and External Audits*.

4.14.1.1 Corporate Compliance Audit

The laboratory may also be audited by corporate quality personnel to assess the laboratory's compliance to the company's quality management program and to evaluate the effectiveness of implementation of the policies and procedures that make up the quality management system. The purpose of the compliance audit is to identify risks and opportunities and to assist laboratory management achieve the goals and objectives of the company's quality program.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

4.15 Management Review

The laboratory's management team formally reviews the management system on an annual basis to assess for on-going suitability and effectiveness and to establish goals, objectives, and action plans for the upcoming year.

At a minimum, following topics are reviewed and discussed:

- The on-going suitability of policies and procedures including HSE (Health, Safety and Environment) and waste management;
- Reports from managerial and supervisory personnel including topics discussed at regular management meetings held throughout the year;
- 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;
- Internal and external issues of relevance and risk identification;
- A review of the status of actions from prior management reviews; and
- Other relevant factors, such as quality control activities, resources, and staff training.

The discussion and results of this review are documented in a formal report prepared by laboratory 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, any other need for change. See laboratory SOP ENV-SOP-CORQ-0005 *Review of Laboratory Management System* for more information.

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

4.16 Data Integrity

The laboratory's procedures for data integrity reviews are described in SOP ENV-SOP-CORQ-0010 *Data Recall*.

Customers whose data are affected by these events are notified in a timely manner, usually within 30 days of discovery. Some accreditation programs also require notification to the accreditation body (AB) within a certain time-frame from date of discovery when the underlying cause of the issue impacts accreditation. The laboratory follows any program or project specific client notification requirements for notification, when applicable.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

5.0 TECHNICAL REQUIREMENTS

5.1 General

Many factors contribute to the correctness and reliability of the technical work performed by the laboratory. These factors are fall under these general 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 these factors, the laboratory takes into account 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

The laboratory's program for personnel management is structured to ensure personnel are selected, 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 (See Section 5.2.4). These job descriptions provide the general basis for the selection of personnel for hire and are used by the laboratory to communicate to personnel the duties, responsibilities, and authorities of their position.

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

The personnel management program is structured to establish and maintain records for each of the following:

- Selection of personnel;
- Training of personnel;
- Supervision of personnel;
- Authorization of personnel; and
- Monitoring Competence of personnel.

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.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Competence for technical personnel authorized by PAS to provide opinion and interpretation of data to customers also includes the demonstrated ability to:

- Apply knowledge, experience, and skills needed to safely and properly use equipment, instrumentation, and materials required to carry out testing and other work activities in accordance with manufacturer specifications and laboratory SOPs;
- Understand and apply knowledge of general regulatory requirements necessary to achieve regulatory compliance in work product; and
- Understand the significance of departures and deviations from procedure that may occur during the analytical testing process and the capability and initiative to troubleshoot and correct the problem, document the situation and decision making process, and to properly qualify the data and analytical results.

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

An employee is considered competent when he/she has completed required training.

The policies and standard operating procedures (SOPs) for the following topics are established by management as minimum required training for all personnel:

- Ethics and Data Integrity
- Quality Manual
- Safety Manual
- Quality Management System
- Technical Process and Procedure relevant to their job tasks
- Successful Demonstration of Capability (DOC) – Analytical Personnel Only

Personnel are initially authorized competent to independently carry out their assigned duties when required training is complete and documented.

Records of training and qualification provide the record of competence for the individual. Qualification records may include but are not limited to diploma, transcripts, and curriculum vitae (CV).

The on-going competence of each employee is monitored by laboratory management through on-the-job performance. Analytical employees are also required to successfully complete another demonstration capability for each test method performed on an annual basis.

5.2.2 Training

Training requirements are outlined in policies COR-POL-0023 *Mandatory Training Policy*, COR-POL-0004 *Ethics Policy*, and laboratory SOP ENV-SOP-GBUR-0059 *Orientation and Training*



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

Procedures. Additional training requirements may also be specified in other documents, such as manuals

5.2.2.1 Training Program and Goals

The laboratory's training program includes 4 elements:

- Identification of Training Needs
- Training Plan Development and Execution
- Documentation and Tracking
- Evaluation of Training Effectiveness

Laboratory management establishes goals and training needs for individual employees based on their role, education, experience, and on-the-job performance.

Training needs for all employees are based on business performance measures that include but are not limited to:

- Quality Control Trends
- Process Error / Rework Trends
- Proficiency Testing Results
- Internal & External Audit Performance
- Management Review Goals

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

The employee's direct supervisor is responsible for oversight of the employee's training plan and for providing adequate time to the employee to complete training assignments. Both the supervisor and employee are responsible to make sure the employee's training status and training records are current and complete.

The laboratory's QA department monitors the training status of personnel and provides the status to the General Manager (GM or AGM) at least monthly or more frequently, if necessary. The status report is used by laboratory management to identify overdue training assignments, the reasons for the gaps, and to make arrangements for completion.

The following subsections highlight specific training requirements:

5.2.2.1.1 New Hire Training

New hire training requirements apply to new personnel and to existing employee's starting in a new position or different work area.

Required new hire training includes each of the following:

- Ethics and Data Integrity (See 5.2.2.1.3)
- Quality Manual / Quality Management System (See 5.2.2.1.4)



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

- Safety Manual and any training requirements specified in the manual.
- Policies & SOPs relevant to their job tasks
- Technical personnel that test samples must also successfully complete an initial demonstration of capability (IDOC) for the test methods performed before independently testing customer samples. (See 5.2.2.1.5). Independent testing means handling of client samples without direct supervision of the work activity by the supervisor or a qualified trainer.

All required training must be current and complete before the employee is authorized to work independently. Until then, the employee's direct supervisor is responsible for review and acceptance of the employee's work product.

5.2.2.1.2 On-Going Training

Personnel receive on-going training in each of the following topics:

- Ethics and Data Integrity (See 5.2.2.1.3)
- Quality Manual / Quality Management System (See 5.2.2.1.4)
- Safety Training
- Changes to Policies & SOPs
- Specialized Training
- Technical employees that carry out testing must also successfully complete on-going demonstration of capability (ODOC) for all test methods performed on an annual basis. (See 5.2.2.1.5)

Personnel are expected to maintain their training status and records of training current and complete and to complete training assignments in a timely manner.

5.2.2.1.3 Ethics and Data Integrity Training

Data integrity training is provided to all new personnel and refresher data integrity training is provided to all employees on an annual basis. Personnel are required to acknowledge they understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment, or civil/criminal prosecution.

The initial data integrity training and the annual refresher training is documented with a signature attendance sheet or other form of documentation to provide evidence that the employee has participated in training on this topic and understand their obligations related to data integrity.

The following topics and activities are covered:



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

- Policy for honesty and full disclosure in all analytical reporting;
- Prohibited Practices;
- How and when to report data integrity issues;
- Record keeping. The training emphasizes the importance of proper written documentation on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially nonconforming;
- Training Program, including discussion regarding all data integrity procedures;
- Data integrity training documentation;
- In-depth procedures for data monitoring; and
- Specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

All PAS personnel, including contract and temporary, are required to sign an “Attestation of Ethics and Confidentiality” at the time of employment and during annual refresher training. This document clearly identifies inappropriate and questionable behavior. Violations of this document result in serious consequences, including prosecution and termination, if necessary.

Also see SOP-ENV-COR-POL-0004 *Ethics Policy* for more information.

5.2.2.1.4 Management System Documents Training

PAS Manuals, policies, and SOPs are the primary documents used by regulatory bodies and PAS customers to verify the laboratory’s capability, competency, and compliance with their requirements and expectations.

In addition to on-the-job training, employees must have a signed Read and Acknowledgement Statement on record for the laboratory quality manual, and the policies and SOPs relating to his/her job responsibilities. This statement when signed by the employee electronically or by wet signature, confirms that the employee has received, read, and understands the content of the document, that the employee agrees to follow the document when carrying out their work tasks; and the employee understands that unauthorized change to procedures in an SOP is not allowed except in accordance with the SOP departure policy (See 4.9.9.1) and SOP ENV-CORQ-0016 *Standard Operating Procedures and Standard Work Instructions* for more information.

5.2.2.1.5 Demonstration of Capability (DOC)

Technical employees must also complete an initial demonstration of capability (IDOC) prior to independent work on client samples analyzed by the test methods they perform. After successful IDOC, the employee



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

must demonstrate continued proficiency (CDOC) for the test method on an annual basis. If more than a year has passed since the employee last performed the method; then capability must be re-established with an IDOC.

Demonstration of capability (IDOC and DOC) is based on the employee's capability to achieve acceptable precision and accuracy for each analyte reported by the laboratory for the test method using the laboratory's test method SOP.

Records of IDOC and ODOC are kept in the employee's training file.

For more information, see laboratory SOP ENV-SOP-GBUR-0059 *Orientation and Training Procedures*.

5.2.2.2 Effectiveness of Training

The results of the performance measures used to identify training needs are the same measures used by the laboratory to measure effectiveness of the training program. Improvement in key performance measures suggest the training program is successful. (See 5.2.2.1)

Effectiveness of individual employee training is measured by their demonstrated ability to comprehend the training material and apply knowledge and skills gained to their job task. Measurements include but are not limited to:

- Testing of the employee's knowledge of the quality management system, policies, and technical and administrative procedures through various mechanisms, such as quizzes, observation, and interviews.
- Demonstrated ability to convey information correctly and factually in written and verbal communication to internal and external parties.
- Demonstrated ability to carry out tasks in accordance with SOPs and other work instructions.
- Demonstrated ability to make sound decisions based on guidance and information available.
- Demonstrated initiative to seek help or guidance when the employee is unsure of how to proceed.

5.2.3 Personnel Supervision

Every employee is assigned a direct supervisor, however named, who is responsible for their supervision. Supervision is the set of activities carried out by the supervisor to oversee the progress and productivity of the employees that report to them.

General supervisory responsibilities may include but are not limited to:

- Hiring Employees
- Training Employees
- Performance Management



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

- Development, oversight, and execution of personnel training plans
- Monitoring personnel work product to assure the work is carried out in accordance with this quality manual, policies, SOPs, and other documents that support the quality management system.

5.2.4 Job Descriptions

Job Descriptions that define the required education, qualifications, experience, skills, roles and responsibilities, and reporting relationships for each PAS position are established by top management and kept by corporate HR. PAS laboratories use these job descriptions as the source of positions and job titles for the laboratory. The job descriptions apply to employees who are directly employed by PAS, part-time, temporary, technical and administrative and by those that are under contract with PAS 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

Laboratory management authorizes technical personnel to perform the technical aspects of their position after it has been verified that the employee meets the qualifications for the position, has successfully completed required training, and the employee has demonstrated capability. 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 to support authorization including, education, experience, training, and other evaluations are kept by the laboratory.

5.3 Accommodations and Facilities

5.3.1 Facilities

The laboratory is designed to support the correct performance of procedures and to not adversely affect measurement integrity or safety. Access to the laboratory is controlled by various measures, such as card access, locked doors, main entry. Visitors to the laboratory are required to sign-in and to be escorted by laboratory personnel during their visit. A visitor is any person that is not an employee of the laboratory.

5.3.2 Environmental Conditions

The laboratory is equipped with energy sources, lighting, heating, and ventilation necessary to facilitate proper performance of calibrations and tests. The laboratory 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. Laboratory operations are stopped if it is discovered that the laboratory's environmental conditions jeopardize the analytical results.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

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 laboratory work area is specifically 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 (SVOA).

The laboratory separates samples known or suspected to contain high concentration of analytes from other samples to avoid the possibility for cross-contamination. If contamination is found, the source of contamination is investigated and resolved in accordance with laboratory SOPs.

5.3.4 Laboratory Security

Security is maintained by controlled access to the building and by surveillance of work areas by authorized personnel. Access is controlled to each area depending on the required personnel, the sensitivity of the operations performed, and possible safety concerns. The main entrance is kept unlocked during normal business hours for visitors, and is continuously monitored by laboratory staff. All visitors must sign a visitor's log, and a staff member must accompany them during the duration of their stay.

5.3.5 Good Housekeeping

The laboratory ensures good housekeeping practices in work areas to maintain a standard of cleanliness necessary for analytical integrity and personnel health and safety. Minimally, these measure include regular cleaning of the work area. Where necessary, areas are periodically monitored to detect and resolve specific contamination and/or possible safety issues.

5.4 Test Methods

5.4.1 General Requirements

The laboratory uses test methods and procedures that are appropriate for the scope of analytical services the laboratory offers.

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

These documents are managed using the procedures described in SOP ENV-SOP-CORQ-0015 *Document Management and Control* and SOP ENV-SOP-CORQ-0016 *Standard Operating Procedures and Standard Work Instructions*.

Deviations to test method and SOPs are allowed under certain circumstances. See sections 4.9.1.1 and 4.9.1.2 for more information.

5.4.2 Method Selection

The test methods and protocols used by the laboratory are selected to meet the needs of the customer, are appropriate for the item tested and intended use of the data, and to conform with regulatory requirements when regulatory requirements apply.

In general, the test methods offered are industry accepted methods published by international, regional, or national standards. The laboratory bases its procedure on the latest approved edition



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

of a method unless it is not appropriate or possible to do so or unless regulatory requirements specify otherwise.

The laboratory confirms that it can perform the test method and achieve desired outcome before analyzing samples (see section 5.4.5). If there is a change in the published analytical method, then the confirmation is repeated.

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 (See Section 4.4).

5.4.3 Laboratory Developed Methods

A laboratory developed method is a method developed from scratch (no published source method), a procedure that modifies the chemistry from the source method, or a procedure that exceeds the scope and application of the source method.

Laboratory developed methods must be validated prior to use (see 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 laboratory developed methods.

5.4.4 Non-standard Methods

A non-standard method is a method that is not published or approved for use by conventional industry standards for the intended purpose of the data. Non-standard methods must be validated prior to use (see section 5.4.5) and the procedure developed and documented in a test method SOP.

At a minimum, the following information must be included in the procedure:

- Title / Identification of Method;
- Scope and Application;
- Description of the type of item to be analyzed;
- Parameters or quantities and ranges to be determined;
- Apparatus and equipment, including technical performance requirements;
- Reference standards and reference materials required;
- Environmental conditions required and any stabilization period needed
- Description of the procedure, including:
 - Affixing identification marks, handling, transporting, storing and preparing of items;
 - Checks to be made before the work is started;
 - Verifying equipment function and, where required, calibrating and/or adjusting the equipment before each use;
 - Method of recording the observations and results;



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

- Any safety measures to be observed;
- Criteria and/or requirements for approval/rejection;
- Data to be recorded and method of analysis and presentation; and
- Uncertainty or procedure for estimating uncertainty.

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

5.4.5.1 Validation Description

Validation is the process of conformation 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 and the data and results achieved meet the goals for the method. The extent of validation performed is based on technology and other factors as defined in the validation SOP (ENV-SOP-CORQ-0011).

Results of validation are retained are kept in accordance with the laboratory's SOP ENV-SOP-GBUR-0039 *Archiving Laboratory Documents* for retention of technical records.

The need to repeat validation is assessed by laboratory management when there are changes to the test method.

5.4.5.3 Validation of Customer Need

Laboratory management reviews the results of test method validation, which include accuracy, precision, sensitivity, selectivity, linearity, repeatability, reproducibility, robustness, and cross-sensitivity, against general customer needs to ensure the laboratory's procedure for the test method will meet those needs.

The review procedure is detailed in SOP ENV-SOP-CORQ-0011 *Method Validation and Instrument Verification*.

The following subsections highlight some of these concepts:

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 recovers within a range from the known value (control limit); the result generated using the laboratory's test method SOP is considered accurate.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

5.4.5.3.2 Precision

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

5.4.5.3.3 Limits of Detection (LOD) (Chemistry)

The LOD is the minimum result which can be reliably discriminated from a blank with a predetermined confidence level. The LOD establishes the limit of method sensitivity and is also known as the detection limit (DL) or the method detection limit (MDL).

Values below the LOD cannot be reliably measured and are not reported by the laboratory unless otherwise specified by regulatory program or test method.

The LOD is established during method validation and after major changes to the analytical system or procedure that affect sensitivity are made.

The laboratory's procedure for LOD determination is detailed in laboratory SOP ENV-SOP-GBUR-0046 *MDL/LOD/LOQ*. The SOP complies with 40 CFR 136 Appendix B or the current industry approved and accepted guidance for this process.

5.4.5.3.4 Limits of Quantitation (LOQ) and Reporting Limit (RL)

The LOQ is the minimum level, concentration, or quantity of a target analyte that can be reported with a specified degree of confidence. The LOQ is established at the same time as the LOD. The laboratory's procedure for determination and verification of the LOQ is detailed in laboratory SOP ENV-SOP-GBUR-0046 *MDL/LOD/LOQ*.

The LLOQ is the value of the lowest calibration standard. The LOQ establishes the lower limit of quantitation.

The LOQ and LLOQ represent quantitative sensitivity of the test method.

- The LOQ must always be equal to or greater than the LLOQ and the LLOQ must always be greater than the LOD.
- Any reported value (detect or non-detect) less than the LLOQ is a qualitative value.

The RL is the value to which the presence of a target analyte is reported as detected or not-detected. The RL is project-defined based on project data quality objectives (DQO). In the absence of project specific requirements, the RL is usually set to the LOQ or the LLOQ. Depending



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

on the relationship of the RL to the LLOQ or LOQ, both the RL value may be or quantitative.

For more information, refer to laboratory SOP ENV-SOP-GBUR-0046 *MDL/LOD/LOQ*.

5.4.5.3.5 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 are 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 (RSD).

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. Similarly, the upper range of linearity establishes the upper limit of quantitation. In general, results outside of this range are considered qualitative values. However, some inorganic methods allow for extension of the linear range above the upper limit of quantitation when accuracy at this value 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.

5.4.5.3.6 Demonstration of Capability (DOC)

The DOC performed during method validation confirms that the test method acceptable precision and accuracy. The procedure used for DOC for method validation is the same as described in section 5.2.2.1.5 for demonstration of analyst capability.

5.4.6 Measurement Uncertainty

The laboratory provides an estimate of uncertainty in testing measurements when required or on client request. In general, the uncertainty of the test method is reflected in the control limits used to evaluate QC performance. (See 5.9.1.1.10). ISO/IEC supports this concept with language that reads when a well-recognized test method specifies limits to the values of the major source of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory has satisfied the requirements on analytical uncertainty by following the test method and reporting instructions.



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

COPYRIGHT © 2019 Pace Analytical Services, LLC.

When measurement uncertainty cannot be satisfied through control limits, the laboratory will provide a reasonable estimation of uncertainty. A reasonable estimation is based on knowledge of method performance and previous experience. When estimating the analytical uncertainty, all uncertainty components which are of importance in the given situation are taken into account.

5.4.7 Control of Data

The laboratory has policies and processes in place to assure that reported data is free from calculation and transcription errors, that quality control is reviewed and evaluated before data is reported, and to address manual calculation and integration.

5.4.7.1 Calculations, Data Transfer, Reduction and Review

Whenever possible, calculations, transfer of data, and data reduction are performed using validated software programs. (See 5.4.7.2)

If manual calculations are necessary, the results of these calculations are verified during the data review process outlined in section 5.9.3.

5.4.7.1.1 Manual Integration

The laboratory's policy and procedures for manual integration are provided in 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 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
- 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 the laboratory uses software and automation for the acquisition, processing, recording, reporting, storage, and/or retrieval of data.

Software applications developed by PAS are validated by corporate IT for adequacy before release for general use. Commercial off the shelf software is considered sufficiently validated when the laboratory follows the manufacturer or vendor's manual for set-up and use. Records of validation are kept by the corporate information technology (IT) group or by the local laboratory, whichever group performed the validation.

The laboratory's process for the protection of data stored in electronic systems include:

- Individual user names and passwords for Laboratory Information Management Systems (LIMS) and auxiliary systems used to store or process data.
- Employee Training in Computer Security Awareness