



The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at *wvOASIS.gov*. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at *WVPurchasing.gov* with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.

Header 3

[List View](#)**General Information** | [Contact](#) | [Default Values](#) | [Discount](#) | [Document Information](#) | [Clarification Request](#)**Procurement Folder:** 783123**Procurement Type:** Central Master Agreement**Vendor ID:** **Legal Name:** PACE ANALYTICAL SERVICES LLC**Alias/DBA:****Total Bid:** \$33,600.00**Response Date:** **Response Time:** **Responded By User ID:** **First Name:** **Last Name:** **Email:** **Phone:** **SO Doc Code:** CRFQ**SO Dept:** 0313**SO Doc ID:** DEP2100000013**Published Date:** 10/7/20**Close Date:** 10/27/20**Close Time:** 13:30**Status:** Closed**Solicitation Description:** **Total of Header Attachments:** 3**Total of All Attachments:** 3

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Prepare fillets from whole-fish samples	250.00000	EA	25.000000	6250.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per fish to prepare fillets from whole-fish samples. Includes both left and right side fillets. Section 3.1.2.1

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
10	Cost per hour for professional staff representation of data	1.00000	HOUR	100.000000	100.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per hour for professional staff representation of data in legal/administrative meetings. (Section 3.1.3.5)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Prepare homogenate of fillet specimens	100.00000	EA	25.000000	2500.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per sample (up to 10 fillets) to prepare homogenate of fillet specimens. (Section 3.1.3.2.1)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Prepare homogenate for whole-fish samples	50.00000	EA	35.000000	1750.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per fish to prepare homogenate for whole-fish samples. Small fish may be grouped and considered one sample. (Section 3.1.3.2.2)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Perform % lipids analysis	100.00000	EA	75.000000	7500.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per sample to perform % lipids analysis. (Section 3.1.3.3.6)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
5	Perform % moisture analysis	100.00000	EA	10.000000	1000.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per sample to perform % moisture analysis. (Section 3.1.3.3.3)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
6	Perform Hg analysis	100.00000	EA	60.000000	6000.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per sample to perform Hg analysis. (Section 3.1.3.3.4)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
7	Perform PCBs analysis	100.00000	EA	70.000000	7000.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per sample to perform PCBs analysis. (Section 3.1.3.3.5)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
8	Perform Se analysis	25.00000	EA	60.000000	1500.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Cost per sample to perform Se analysis. (Section 3.1.3.3.3)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
9	Fee per trip to WVDEP HQ to pick up samples.	1.00000	EA	0.000000	0.00

Comm Code	Manufacturer	Specification	Model #
81102600			

Commodity Line Comments:

Extended Description:

Fee per trip to WVDEP HQ to pick up samples. (Section 3.1.3.1)

ADDITIONAL INFORMATION

Request for Quotation - Open End Contract

The West Virginia Purchasing Division is soliciting bids on behalf of the West Virginia Department of Environmental Protection (WVDEP) to establish an open-end contract to process and analyze fish tissue samples for total mercury, total PCBs, and/or total selenium to support the development of consumption advisories and for body burden and bioaccumulation studies per the attached specifications and terms and conditions.

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	Prepare fillets from whole-fish samples	250.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:

Cost per fish to prepare fillets from whole-fish samples. Includes both left and right side fillets. Section 3.1.2.1

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Prepare homogenate of fillet specimens	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:

Cost per sample (up to 10 fillets) to prepare homogenate of fillet specimens. (Section 3.1.3.2.1)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Prepare homogenate for whole-fish samples	50.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:

Cost per fish to prepare homogenate for whole-fish samples. Small fish may be grouped and considered one sample. (Section 3.1.3.2.2)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
4	Perform % lipids analysis	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:

Cost per sample to perform % lipids analysis. (Section 3.1.3.3.6)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
5	Perform % moisture analysis	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:
Cost per sample to perform % moisture analysis. (Section 3.1.3.3.3)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
6	Perform Hg analysis	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:
Cost per sample to perform Hg analysis. (Section 3.1.3.3.4)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
7	Perform PCBs analysis	100.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:
Cost per sample to perform PCBs analysis. (Section 3.1.3.3.5)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
8	Perform Se analysis	25.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:
Cost per sample to perform Se analysis. (Section 3.1.3.3.3)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
9	Fee per trip to WVDEP HQ to pick up samples.	1.00000	EA		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:

Fee per trip to WVDEP HQ to pick up samples. (Section 3.1.3.1)

INVOICE TO	SHIP TO
ENVIRONMENTAL PROTECTION OFFICE OF ENVIRONMENTAL REMEDIATION 601 57TH ST SE CHARLESTON WV 25304 US	STATE OF WEST VIRGINIA JOBSITE - SEE SPECIFICATIONS No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
10	Cost per hour for professional staff representation of data	1.00000	HOUR		

Comm Code	Manufacturer	Specification	Model #
81102600			

Extended Description:

Cost per hour for professional staff representation of data in legal/administrative meetings. (Section 3.1.3.5)

SCHEDULE OF EVENTS

<u>Line</u>	<u>Event</u>	<u>Event Date</u>
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DESIGNATED CONTACT: Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

Jason Clark - Sales Manager
(Name, Title)

Jason Clark - Sales Manager
(Printed Name and Title)

P.O. Box 286 Beaver, WV, 25813
(Address)

304-255-2500 / 304-255-2572
(Phone Number) / (Fax Number)

Jason.Clark@pacelabs.com
(email address)

CERTIFICATION AND SIGNATURE: By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Pace Analytical Services LLC
(Company)

[Signature] Operations Manager
(Authorized Signature) (Representative Name, Title)

Brian Richards Operations Manager
(Printed Name and Title of Authorized Representative)

10-19-2020
(Date)

304-255-2500 / 304-255-2572
(Phone Number) (Fax Number)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.:

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:

(Check the box next to each addendum received)

- | | |
|---|--|
| <input type="checkbox"/> Addendum No. 1 | <input type="checkbox"/> Addendum No. 6 |
| <input type="checkbox"/> Addendum No. 2 | <input type="checkbox"/> Addendum No. 7 |
| <input type="checkbox"/> Addendum No. 3 | <input type="checkbox"/> Addendum No. 8 |
| <input type="checkbox"/> Addendum No. 4 | <input type="checkbox"/> Addendum No. 9 |
| <input type="checkbox"/> Addendum No. 5 | <input type="checkbox"/> Addendum No. 10 |

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Pace Analytical Services LLC
Company

[Signature]
Authorized Signature

10-19-2020
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

CONSTRUCTION CONTRACTS: Under W. Va. Code § 5-22-1(i), the contracting public entity shall not award a construction contract to any bidder that is known to be in default on any monetary obligation owed to the state or a political subdivision of the state, including, but not limited to, obligations related to payroll taxes, property taxes, sales and use taxes, fire service fees, or other fines or fees.

ALL CONTRACTS: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceeds five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (W. Va. Code §61-5-3) that: (1) for construction contracts, the vendor is not in default on any monetary obligation owed to the state or a political subdivision of the state, and (2) for all other contracts, that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Pace Analytical Services LLC

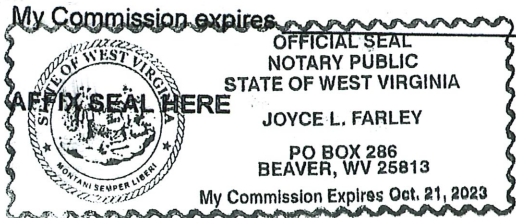
Authorized Signature: [Signature] Date: 10-19-2020

State of WV

County of Raleigh, to-wit:

Taken, subscribed, and sworn to before me this 19 day of October, 2020

My Commission expires 10/21, 2023.



NOTARY PUBLIC [Signature]

West Virginia Ethics Commission



Disclosure of Interested Parties to Contracts

Pursuant to *W. Va. Code* § 6D-1-2, a state agency may not enter into a contract, or a series of related contracts, that has/have an actual or estimated value of \$1 million or more until the business entity submits to the contracting state agency a Disclosure of Interested Parties to the applicable contract. In addition, the business entity awarded a contract is obligated to submit a supplemental Disclosure of Interested Parties reflecting any new or differing interested parties to the contract within 30 days following the completion or termination of the applicable contract.

For purposes of complying with these requirements, the following definitions apply:

"Business entity" means any entity recognized by law through which business is conducted, including a sole proprietorship, partnership or corporation, but does not include publicly traded companies listed on a national or international stock exchange.

"Interested party" or *"Interested parties"* means:

- (1) A business entity performing work or service pursuant to, or in furtherance of, the applicable contract, including specifically sub-contractors;
- (2) the person(s) who have an ownership interest equal to or greater than 25% in the business entity performing work or service pursuant to, or in furtherance of, the applicable contract. (This subdivision does not apply to a publicly traded company); and
- (3) the person or business entity, if any, that served as a compensated broker or intermediary to actively facilitate the applicable contract or negotiated the terms of the applicable contract with the state agency. (This subdivision does not apply to persons or business entities performing legal services related to the negotiation or drafting of the applicable contract.)

"State agency" means a board, commission, office, department or other agency in the executive, judicial or legislative branch of state government, including publicly funded institutions of higher education: Provided, that for purposes of *W. Va. Code* § 6D-1-2, the West Virginia Investment Management Board shall not be deemed a state agency nor subject to the requirements of that provision.

The contracting business entity must complete this form and submit it to the contracting state agency prior to contract award and to complete another form within 30 days of contract completion or termination.

This form was created by the State of West Virginia Ethics Commission, 210 Brooks Street, Suite 300, Charleston, WV 25301-1804. Telephone: (304)558-0664; fax: (304)558-2169; e-mail: ethics@wv.gov; website: www.ethics.wv.gov.

West Virginia Ethics Commission Disclosure of Interested Parties to Contracts

(Required by W. Va. Code § 6D-1-2)

Name of Contracting Business Entity: Pace Analytical Services LLC Address: P.O. Box 286

Beaver, WV 25813

Name of Authorized Agent: Brian Richards Address: P.O. Box 286 Beaver, WV 25813

Contract Number: DEP2100000013 Contract Description: Homogenization + Analysis of Fish

Governmental agency awarding contract: WV DEP

Check here if this is a Supplemental Disclosure

List the Names of Interested Parties to the contract which are known or reasonably anticipated by the contracting business entity for each category below (attach additional pages if necessary):

- 1. Subcontractors or other entities performing work or service under the Contract
 Check here if none, otherwise list entity/individual names below.
- 2. Any person or entity who owns 25% or more of contracting entity (not applicable to publicly traded entities)
 Check here if none, otherwise list entity/individual names below.
- 3. Any person or entity that facilitated, or negotiated the terms of, the applicable contract (excluding legal services related to the negotiation or drafting of the applicable contract)
 Check here if none, otherwise list entity/individual names below.

Signature: [Handwritten Signature] Date Signed: 10-19-2020

Notary Verification

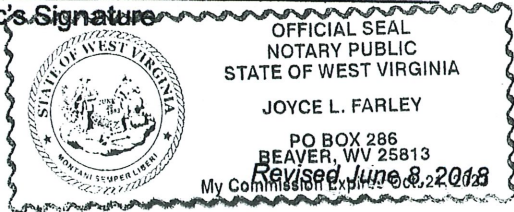
State of WV, County of Raleigh:

I, Brian Richards, the authorized agent of the contracting business entity listed above, being duly sworn, acknowledge that the Disclosure herein is being made under oath and under the penalty of perjury.

Taken, sworn to and subscribed before me this 19th day of October, 20.

[Handwritten Signature]
Notary Public's Signature

To be completed by State Agency:
Date Received by State Agency: _____
Date submitted to Ethics Commission: _____
Governmental agency submitting Disclosure: _____



7.2.3 Any other remedies available in law or equity.

8. MISCELLANEOUS:

- 8.1 **No Substitutions:** Vendor shall supply only Contract Items submitted in response to the Solicitation unless a contract modification is approved in accordance with the provisions contained in this Contract.
- 8.2 **Vendor Supply:** Vendor must carry sufficient inventory of the Contract Items being offered to fulfill its obligations under this Contract. By signing its bid, Vendor certifies that it can supply the Contract Items contained in its bid response.
- 8.3 **Reports:** Vendor shall provide quarterly reports and annual summaries to the Agency showing the Agency's items purchased, quantities of items purchased, and total dollar value of the items purchased. Vendor shall also provide reports, upon request, showing the items purchased during the term of this Contract, the quantity purchased for each of those items, and the total value of purchases for each of those items. Failure to supply such reports may be grounds for cancellation of this Contract.
- 8.4 **Contract Manager:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: Kara Frampton
Telephone Number: 304-757-8954
Fax Number: 304-757-9676
Email Address: kara.frampton@pacelabs.com

Homogenization and Analysis of Fish Tissue Samples for Metals and Polychlorinated Biphenyls

Vendor must provide the following information:

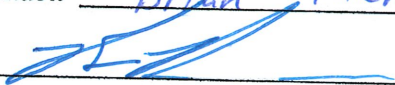
Analytical method number with a brief description and the approximate Minimum Detection Limit the lab is able to attain for each analyte (bidders must use format below): If vendor is certified for and wishes to provide bids for additional methods for the parameters below, provide the Analytical method number, brief description and the approximate Minimum Detection Limit on separate page.

- a. Total Mercury:
 - a. Method # and description: EPA 7471 B / Mercury Analysis
 - b. MDL 0.0259 mg/kg

- b. Total Selenium:
 - a. Method # and description: EPA 6010 C / ICP
 - b. MDL 0.7729 mg/kg

- c. Total PCBs:
 - a. Method # and description: EPA 8082 A / PCB Analysis
 - b. MDL 0.02564 mg/kg

Name of Laboratory Contact: Brian Richards

Contact's Signature: 

Contact's Phone Number: 304-255-2500

Contact's Address: P.O. Box 286
Beaver, WV 25813

4.2.1.1

WV DEP – Janice Smithson

304-926-0499

Janice.e.smithson@wv.gov

Potesta – Leah Creathers

304-342-1400

ljcreathers@potesta.com

Decota Consulting – Shawn Huffman

304-776-3333

shawnhuffman@decotaconsulting.com

Marshall University – Mindy Yeager-Armstead

304-696-3170

myeager@marshall.edu

4.2.1.2

No Subcontracting necessary. All testing will be completed by Pace Analytical.

4.2.1.3

EPA Document 823-B-00-007

Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories

4.2.1.4

See Quality Manual Attached.



Document Information

Document Number: ENV-MAN-BEAV-0001	Revision: 01
Document Title: Quality Manual	
Department(s): Quality	

Date Information

Effective Date: 03 Apr 2020

Notes

Document Notes:

All Dates and Times are listed in: Central Time Zone

Signature Manifest

Document Number: ENV-MAN-BEAV-0001

Revision: 01

Title: Quality Manual

All dates and times are in Central Time Zone.

ENV-MAN-BEAV-0001

QM Approval

Name/Signature	Title	Date	Meaning/Reason
Lisa Eads (007015)	Manager - Quality	02 Apr 2020, 03:17:55 PM	Approved

Management Approval

Name/Signature	Title	Date	Meaning/Reason
Lisa Eads (007015)	Manager - Quality	02 Apr 2020, 03:18:06 PM	Approved
Richard Clinkscales (990506)	General Manager 1	02 Apr 2020, 03:23:34 PM	Approved
Joshua Cox (007008)	Supervisor	02 Apr 2020, 03:23:50 PM	Approved
Nellie Cooper (007006)	Supervisor	02 Apr 2020, 03:34:04 PM	Approved
Ed Kirk (007048)	Manager	02 Apr 2020, 03:47:49 PM	Approved
Colin Walters (005945)	Regional Director - Operations	02 Apr 2020, 03:54:16 PM	Approved
Jackie Jones Jr (007044)	Supervisor	03 Apr 2020, 05:41:15 AM	Approved
Alexa Hammond (007641)	Supervisor	03 Apr 2020, 09:30:54 AM	Approved
Michael Hofe (007039)	Manager	03 Apr 2020, 11:09:59 AM	Approved



LABORATORY QUALITY MANUAL
Pace Analytical Services, LLC

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TITLE PAGE

LABORATORY QUALITY MANUAL

Prepared for:

Pace Analytical Services, LLC
225 Industrial Park Road
Beaver, WV 25813
Phone: 304-255-2500
(AKA: Pace West Virginia)

Pace Analytical Services, LLC
782 N. Lee Highway
Lexington, VA 24450
Phone: 540-464-1880

Pace Analytical Services, LLC
16 Commerce Drive
Westover, WV 26501
Phone: 304-241-5861



LABORATORY QUALITY MANUAL
Pace Analytical Services, LLC

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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
225 Industrial Park Road
Beaver, WV 25813
Phone: 304-255-2500

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	Senior General Manager	1638 Roseytown Rd, Greensburg, PA 15601	724-433-5223
Richard Clinkscapes ³	General Manager		
Lisa Eads	Quality Manager		
Brian Richards	Operations Manager	5 Weatheridge Drive, Hurricane, WV 25526	304-964-4142
Michael Hofe	Client Services Manager		
Lisa Eads/Luke Harvey	Health & Safety, however named		
Angie Robertson	IT Manager		
Josh Cox	Volatiles Department Manager		
Nellie Cooper	Semi-Volatiles Department Manager		
Alexa Hammond	Metals Department Supervisor		
Jay Jones	Wet Chemistry Department Manager		
Ed Kirk ³	Biological Department Manager		
Tim Keeney	Geological Department Manager		
Andrea Crone	Sample Custody Supervisor		
Blane Williams	Courier 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

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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
 782 N. Lee Highway
 Lexington, VA 24450
 Phone: 540-464-1880

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	Senior General Manager	1638 Roseytown Rd, Greensburg, PA 15601	724-433-5223
Richard Clinkscales ³	General Manager	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Lisa Eads	Quality Manager	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Michael Hofe	Client Services Manager	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Lisa Eads	Health & Safety, however named	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Angie Robertson	IT Manager	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Matthew Vess ³	Service Center 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.



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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
16 Commerce Drive
Westover, WV 26501
Phone: 304-241-5861

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Name¹	Title	Address²	Phone²
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Michael Hofe	Client Services Manager	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Lisa Eads	Health & Safety, however named	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
Angie Robertson	IT Manager	225 Industrial Park Rd, Beaver, WV 25813	304-255-2500
John McGee	Service Center Supervisor		

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1.0 PURPOSE AND SCOPE

1.1 Purpose

This quality manual (manual) outlines the quality management system and management structure of 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*
- NELAC/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.



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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 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-0015 *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-0015 *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.



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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 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.



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- 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*
- 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.



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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:	225 Industrial Park Road
City, State, Zip	Beaver, WV, 25813
Phone Number	304-255-2500
Service Type:	Laboratory

Name	Pace Analytical Services, LLC
Address:	782 N. Lee Highway
City, State, Zip	Lexington, VA 24450
Phone Number	540-464-1880
Service Type:	Laboratory

Name	Pace Analytical Services, LLC
Address:	16 Commerce Drive
City, State, Zip	Westover, WV 26501
Phone Number	304-241-5861
Service Type:	Laboratory

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.



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Local management is provided by a General Manager (GM) or Assistant (AGM), 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.

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.



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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
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
Senior General Manager	Chief Operating Officer or as designated.
General Manager / Assistant GM	Senior General Manager
Quality Manager	Corporate Quality Manager or as designated.
Client Services Manager	General Manager
Local IT	Corporate IT Director or as designated.
Department Manager	General Manager
Senior Quality Manager ¹	Corporate Quality Manager
Technical Director ¹ /Manager ¹	Quality Manager
Acting Technical Manager TNI	
Operations Manager ¹	General Manager or Assistant GM.

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.



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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 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.

Senior General Manager (SGM): The SGM 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 SGM 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.



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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;
- 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.

Local IT Manager, however named: 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



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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.

Senior Quality Manager (SQM): The SQM provides support to the quality manager and assists the quality manager with implementation of the quality management system for one or more site locations.

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.

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

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.

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.



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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 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.



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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'.

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.



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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 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:



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- 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.

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



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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.

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



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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

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



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	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

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

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.



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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.

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.



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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-BEAV-0071.

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.

4.5 Subcontracting and In-Network Work Transfer

The terms 'subcontract' and "subcontracting" refers to work sent to a business external to 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



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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 the laboratory Subcontracting SOP.

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.

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 the laboratory's Purchasing SOP.



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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.

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)



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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 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.



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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).

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



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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 the laboratory SOP ENV-SOP-BEAV-0124 *Corrective and Preventative Actions*. Additional explanation about certain aspects of the laboratory's corrective action process are outlined in the next three subsections.

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.



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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 additional 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.

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.



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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 the laboratory's SOP on Corrective and Preventative Actions (CAPA).

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 the laboratory's SOP on Data Retention.

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
Technical	Raw Data Logbooks Certificates of Traceability Analytical Record Test Reports & Project Information Technical Training Records & Demonstration of Capability
Administrative	Personnel Records Finance/Business



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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 records are filed and stored in a suitable environment to protect from damage, deterioration, or loss. Hardcopy records may be scanned to PDF for retention. Scanned records must be checked against the hardcopy to verify the scan is complete and legible.

Records are kept for a minimum of 5 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 policy 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 Pace policy ENV-POL-CORQ-0013, the Record Management Policy. 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.

4.13.2.1 Description

Technical records are the accumulation of data and information generated from the analytical process. These records may include forms, worksheets, workbooks, checklists, notes, raw data, calibration records, final test reports, and project records. The accumulated record essentially need to provide sufficient detail to historically



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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 be erased, deleted or made illegible. Use of correction fluid, such as white-out is prohibited. In hardcopy records, the error is corrected by a single-strike through the original entry and the new entry recorded alongside or footnoted to allow for readability. Corrections are initialed and dated by the person making the correction. If the correction is not self-explanatory, a reason for the correction is recorded.

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.



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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-BEAV-0129 *Internal 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 to achieve the goals and objectives of the company's quality program.



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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 Pace SOP ENV-SOP-CORQ-0005 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

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.



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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.



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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.



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5.2.2 Training

Training requirements are outlined in policies COR-POL-0023 *Mandatory Training Policy* and COR-POL-0004 *Ethics Policy*. 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:



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



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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:

- 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



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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 (IDOC)

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 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 method SOPs.

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.



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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
- 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



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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.

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



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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 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;



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- 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;
 - 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 method validation SOP (ENV-SOP-CORQ-0011).

Results of validation are retained and kept in accordance with the laboratory's policy for retention of technical records.

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



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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.

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-BEAV-0120 *Determination of Detection and Quantitation Limits*. 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



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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-BEAV-0120 *Determination of Detection and Quantitation Limits*.

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 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-BEAV-0120 *Determination of Detection and Quantitation Limits*.

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.



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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.

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:



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- 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
- Validation of spreadsheets used for calculations to verify formulas and logic yield correct results and protection of these cells to prevent unauthorized change.
- Operating system and file access safeguards
- Protection from Computer Viruses
- Regular system backup; and testing of retrieved data

The laboratory's process for software development and testing process includes:

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



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5.5 Equipment

5.5.1 Availability of Equipment

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

5.5.2 Calibration

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

Laboratory management is made aware of the status of equipment and instrumentation and any needs for either on a daily basis. This information is obtained during laboratory walkthroughs (LDM) that are conducted as part of the laboratory's lean program.

5.5.2.1 Support Equipment

The laboratory confirms support equipment is in proper working order and meets the specifications for general laboratory use prior to placement in service and with intermediate checks thereafter. Equipment that does not meet specifications is removed from service until repaired or replaced. Records of repair and maintenance activities are maintained.

Procedures used to carry out and record these checks are outlined laboratory SOP ENV-SOP-BEAV-0128 *Support Equipment*.

5.5.2.2 Analytical Instruments

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

The calibration procedures in the test method SOPs comply with the requirements for acceptable calibration practices outlined in the corporate calibration policy, the reference methods, and any applicable regulatory or program requirements.

5.5.3 Equipment Use and Operation

Equipment is operated and maintained by laboratory personnel that are trained on the test method SOP. Up-to-date instructions and procedures for the use and maintenance of analytical equipment are included in SOPs and/or supplemental documents such as standard work instructions (SWI) or instrument manuals which are made readily accessible in the work area to all laboratory personnel.

5.5.4 Equipment Identification

The laboratory uniquely identifies equipment by serial number or any other unique ID system, when practical. The identifier is included in the equipment list maintained by QA.



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5.5.5 Equipment Lists and Records

5.5.5.1 Equipment List

The laboratory maintains a master list of equipment that includes information about the equipment including a description, manufacturer, serial number, date placed in service, condition when received, identity, and the current location in the laboratory. The date of purchase is tracked by the procurement record. The equipment list(s) for each location covered by this manual is provided in Appendix F.

5.5.5.2 Equipment Records

In addition to the equipment list, the laboratory maintains records of equipment that include:

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

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

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

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

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

The maintenance record minimally includes the date of maintenance, the initials of the person(s) performing maintenance, a description of the activity performed, why (when the maintenance is non-routine), and the return to analytical control. When maintenance is performed by an external vendor, the laboratory staples the service record into hardcopy maintenance logs or scans the record easy retrieval. The laboratory provides unrestricted access to instrument maintenance logs in order to promote good instrument maintenance and recordkeeping practices.

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



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5.5.6 Out of Service Protocol

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

When analytical equipment is taken out of service, the laboratory examines the potential effect it may have had on previous analytical results to identify any non-conforming work. (See section 4.9).

5.5.7 Calibration Status

The laboratory labels support equipment to indicate calibration status, whenever practicable or otherwise maintains the calibration status in a visible location in the work area. These procedures are described in laboratory SOP ENV-SOP-BEAV-0128 *Support Equipment*.

The calibration status of analytical instruments is documented in the analytical record. Analysts verify on-going acceptability of calibration status prior to use and with instrument performance check standards. These procedures are described in test method SOPs.

5.5.8 Returned Equipment Checks

When equipment or instrument is sent out of the laboratory for service, the laboratory ensures that the function and calibration status of the equipment is checked and shown to be satisfactory before the equipment is returned to service. These procedures are outlined in SOP ENV-SOP-CORQ-0011 *Method Validation and Instrument Verification*.

5.5.9 Intermediate Equipment Checks

The laboratory performs intermediate checks on equipment to verify the on-going calibration status. For example, most test methods require some form of continuing calibration verification check and these procedures are included in the test method SOP. Periodic checks of support equipment are also performed.

5.5.10 Safeguarding Equipment Integrity

The laboratory safeguards equipment integrity using a variety of mechanisms that include but are not limited to:

- Adherence to manufacturer's specification for instrument use so that settings do not exceed manufacturer's recommendation or stress the performance of the equipment.
- Established maintenance programs.
- Transparent maintenance records and unrestricted access to maintenance logs.
- Validation and approval of software before use.
- Audits to confirm instrument settings are consistent with SOPs.
- On-the-job training for safe and proper use of laboratory equipment.



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5.6 Measurement Traceability**5.6.1 General**

Measurement traceability refers to a property of a measurement result whereby the result can be related to a reference through an unbroken chain of calibration, each contributing to the measurement uncertainty. Traceability requires an established calibration hierarchy of equipment (instruments) used during testing including equipment used for subsidiary measurements. The laboratory assures this equipment is calibrated prior to being put into service and that the reference standard and materials used for calibration are traceable to the international standard of units (SI) or national measurement standard.

When strict traceability to SI units cannot be made, the laboratory establishes traceability with the use of reference standards and equipment obtained from competent supplier that provide calibration certificates and/or certificates of analysis (COA).

5.6.2 Equipment Correction Factors

When correction factors are used to adjust results the laboratory will assure that results in computer software are also updated. For example, if the direct instrument or reading output must be corrected based on preparation factor or concentration factors, laboratory management will assure the corrected result is also updated in the software, whenever possible.

5.6.3 Specific Requirements**5.6.3.1 Requirements for Calibration Laboratories**

The laboratory does not offer calibration services to customers.

5.6.3.2 Requirements for Testing Laboratories

The laboratory has procedures in place to verify equipment is calibrated prior to being put into service. (See 5.5.2) and ensures the reference standard and materials used for calibration are traceable to the international standard of units (SI) or national measurement standard. When strict traceability to SI units cannot be made, the laboratory establishes traceability with the use of reference standards and equipment obtained from competent suppliers that provide calibration certificates and/or certificates of analysis (COA).

5.6.4 Reference Standards and Reference Materials**5.6.4.1 Reference Standards**

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

Intermediate checks of the working reference measurement standards are performed to verify adequacy between calibration from an external calibration laboratory. The measurements from working weights and thermometers are compared to measurement taken by the reference standard which is traceable to SI or a national standard. The reference weights and thermometers are used solely for verification



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purposes unless the laboratory can prove that daily use does not adversely affect performance of the reference standard.

The laboratory performs intermediate checks of the working weights at least annually.

Working thermometers (glass and digital) are checked against the reference thermometer prior to placement in service to establish a correction factor and then rechecked annually (glass) or quarterly (digital) thereafter.

The calibration of liquid in glass reference thermometers is verified every 5 years and the calibration of digital reference thermometers is verified annually by an ISO/IEC 17025 accredited calibration laboratory or service provider that provides traceability to a national standard.

The calibration of the reference weight(s) is verified every 5 years by an ISO/IEC 17025 accredited calibration laboratory.

If criteria for the intermediate checks or recertification is not acceptable, the impact on previously reported results is evaluated using the process for evaluation of nonconforming work (See 4.9)

See laboratory Support Equipment SOP for more information about this process.

5.6.4.2 Reference Materials

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

The laboratory procedure for traceability and use of these materials is provided in the laboratory SOP regarding Pace Standards and Traceability.

This SOP includes each of the following requirements:

- Procedures for documentation of receipt and tracking. The record of entry includes name of the material, the lot number, receipt date, and expiration date.
- Storage conditions and requirements. Reference materials must be stored separately from samples, extracts, and digestates.
- Requirements to assure that preparations of intermediate or working solutions are recorded and assigned a unique identification number for tracking. Records of preparation include the lot number of the stock standard(s) used, the type and lot number of the solvent, the formulation, date, expiration date, and the preparer's initials. The lot number of the working standards is recorded in the analytical record to provide traceability to the standard preparation record. The preparation record provides traceability to the COA, which is traceable to SI or the national measurement standard.



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- A requirement that the expiration dates of prepared standards may not exceed the expiration date of the parent standard. Standards, reference materials, and reagents are not used after their expiration dates unless their reliability is thoroughly documented and verified by the laboratory. If a standard exceeds its expiration date and is not re-certified, the laboratory removes the standard and/or clearly designates it as acceptable for qualitative/troubleshooting purposes only. All prepared standards, reference materials, and reagents are verified to meet the requirements of the test method through routine analyses of quality control samples.
- The second source materials used for verification of instrument calibration are obtained from a different manufacturer or different lot from the same manufacturer.
- Procedures to check reference materials for degradation and replacement of material if degradation or evaporation is suspected.
- Procedures for labeling. At a minimum the container must identify the material, the ID of the material and the expiration date. Original containers should also be labeled with date opened.

5.6.4.3 Intermediate Checks

Checks to confirm the calibration status of standards and materials are described in laboratory SOPs. These checks, include use of second source standards and reference materials reserved only for the purpose of calibration checks.

5.6.4.4 Transport and Storage

The laboratory handles and transports reference standards and materials in a manner that protects the integrity of the materials. Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments or materials. Standards and reference materials are stored separately from samples, extracts, and digestates. All standards are stored according to the manufacturer's recommended conditions. Temperatures colder than the manufacturer's recommendation are acceptable if it does not compromise the integrity of the material (e.g. remains in liquid state and does not freeze solid). In the event a standard is made from more than a single source with different storage conditions, the standard will be stored according to the conditions specified in the analytical method.

See the applicable analytical SOPs for specific reference material storage and transport protocols.

5.7 Sampling

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

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



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

5.7.1 Sampling Plans and SOPs

When the laboratory performs field collection of samples, sampling is carried out in accordance with a written sample plan prepared by the customer or by the laboratory and by relevant sampling SOPs. These documents are made readily accessible at the sampling location. Sampling plans and SOPs are, whenever reasonable, based on appropriate governing methods and addresses the factors to be controlled to ensure the validity of the analytical results.

5.7.2 Customer Requested Deviations

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

5.7.3 Recordkeeping

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

5.8 Sample Management & Handling

5.8.1 Procedures

The laboratory's procedures for sample management and handling are outlined in the laboratory SOP ENV-SOP-BEAV-0125 *Sample Acceptance Criteria*, or equivalent subsequent revision.

The procedures in these SOPs are established to maintain the safe handling and integrity of samples from transport, storage, to disposal and during all processing steps in-between; to maintain client confidentiality, and to protect the interests of PAS and its customers.

5.8.1.1 Chain of Custody

All samples received by the laboratory must be accompanied with a Chain of Custody (COC) record. The COC provides information about the samples collected and submitted for testing and documents the possession of samples from time of collection to receipt by the laboratory.

The COC record must minimally include the following information:

- Client name, address, phone number
- Project Reference
- Client Sample Identification (Client ID)
- Date, Time, and Location of Sampling
- Samplers Name or Initials
- Matrix



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- Type of container, and total number collected each sample
- Preservatives
- Analyses Requested
- Mode of collection
- Any special instructions
- The date and time and signature of each sample transfer from time of collection to receipt in the laboratory. When the COC is transported inside the cooler, independent couriers do not sign the COC. Shipping manifests and/or air bills are the records of possession during transport.

A complete and legible COC is required. If the laboratory observes that the COC is incomplete or illegible, the client is contacted for resolution. The COC must be filled out in indelible ink. Personnel correct errors by drawing a single line through the initial entry so the entry is not obscured, entering the correct information, and initialing, and dating the change.

5.8.1.2 Legal Chain of Custody

Legal chain of custody is a chain of custody protocol used for evidentiary or legal purposes. The protocol is followed by the laboratory when requested by customer or where mandated by a regulatory program.

Legal chain of custody (COC) protocol establishes an intact, continuous record of the physical possession*, storage, and disposal of “samples” which includes, sample aliquots, and sample extracts/digestates/distillates.

Legal COC records account for all time periods associated with the samples, and identifies all individuals who physically handled individual samples. Legal COC begins at the point established by legal authority, which is usually at the time the sample containers are provided by the laboratory for sample collect or when sample collection begins.

*A sample is in someone’s custody if:

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

5.8.2 Unique Identification

Each sample is assigned a unique identification number by the laboratory (Lab ID) after the sample has been checked and accepted by the laboratory in accordance with the laboratory’s sample acceptance policy (See 5.8.3). The Lab ID is affixed to the sample container using a durable label.



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The unique identification of samples also applies to subsamples, and prepared samples, such as extracts, digestates, etc.

The lab ID is linked to the field ID (client ID) in the laboratory's record. Both IDs are linked to the testing activities performed on the sample and the documentation records of the test.

Also see 5.8.4.

5.8.3 Sample Receipt Checks and Sample Acceptance Policy

The laboratory checks the condition and integrity of samples on receipt and compares the labels on the sample containers to the COC record. Any problem or discrepancy is recorded. If the problem impacts the suitability of the sample for analysis or if the documentation is incomplete, the client is notified for resolution. Decisions and instructions from the client are maintained in the project record.

5.8.3.1 Sample Receipt Checks

The following checks are performed:

- Verification that the COC is complete and legible.
- Verification that each sample's container label includes the client sample ID, the date and time of collection and the preservative in indelible ink.
- The container type and preservative is appropriate for each test requested.
- Adequate volume is received for each test requested.
- Visual inspection for damage or evidence of tampering.
- Visual inspection for presence of headspace in VOA vials. (VOA = volatile organic analysis).
- Thermal Preservation: For chemical testing methods for which thermal preservation is required, temperature on receipt is acceptable if the measurement is above freezing but $<6^{\circ}\text{C}$. For samples that are hand-delivered to the laboratory immediately after sample collection, there must be evidence that the chilling process has begun, such as arrival on ice. The requirements for thermal preservation vary based on the scope of testing performed. For example, for microbiology, temperature on receipt is acceptable if the measurement is $<10^{\circ}\text{C}$. Refer to the laboratory's SOP for sample receipt for more information.
- Chemical Preservation
- Holding Time: Sample receiving personnel are trained to recognize tests with tests where the holding time is 48 hours or less and to expedite the log-in of these samples. Except for tests with immediate holding times (15 minutes from time of collection or less), when samples are received out of hold, the laboratory will notify the client and request instruction. If the decision is made to proceed with analysis, the final test report will include notation of this instruction.



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5.8.3.2 Sample Acceptance Policy

The laboratory maintains a sample acceptance policy in accordance with regulatory guidelines to clearly establish the circumstances in which sample receipt is accepted or rejected. When receipt does not meet acceptance criteria for any one of these conditions, the laboratory must document the noncompliance, contact the customer, and either reject the samples or fully document any decisions to proceed with testing. In accordance with regulatory specifications, test results associated with receipt conditions that do not meet criteria are qualified in the final test report.

All samples received must meet each of the following:

- Be listed on a complete and legible COC.
- Be received in properly labeled sample containers.
- Be received in appropriate containers that identify preservative.
- The COC must include the date and time of collection for each sample.
- The COC must include the test requested for each sample.
- Be in appropriate sample containers with clear documentation of the preservatives used.
- Be received within holding time. Any samples received beyond the holding time will not be processed without prior customer approval.
- Have sufficient sample volume to proceed with the analytical testing. If insufficient sample volume is received, analysis will not proceed without customer approval.
- Be received within appropriate temperature ranges (not frozen but $\leq 6^{\circ}\text{C}$) unless program requirements or customer contractual obligations mandate otherwise. The cooler temperature is recorded directly on the COC. Samples that are delivered to the laboratory immediately after collection are considered acceptable if there is evidence that the chilling process has been started. For example, by the arrival of the samples on ice. If samples arrive that are not compliant with these temperature requirements, the customer will be notified. The analysis will NOT proceed unless otherwise directed by the customer. If less than 72 hours remain in the hold time for the analysis, the analysis may be started while the customer is contacted to avoid missing the hold time. Data associated with any deviations from the above sample acceptance policy requirements will be appropriately qualified.

5.8.4 Sample Control and Tracking

The samples are controlled and tracked using the Laboratory Information Management System (LIMS). The LIMS stores information about the samples and project. The process of entering information into the LIMS is called login. After log-in, a label is generated and affixed to each sample container. Information on this label, such as the lab ID, links the sample container to the information in LIMS.



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At a minimum, the following information is entered during log-in:

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

5.8.5 Sample Storage, Handling, and Disposal

The laboratory procedures for sample storage, handling and disposal are detailed in laboratory SOP ENV-SOP-BEAV-0075, or equivalent subsequent replacement.

5.8.5.1 Sample Storage

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

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

The laboratory is operated under controlled access protocols to ensure sample and data integrity. Visitors must register at the front desk and be properly escorted at all times. Samples are taken to the appropriate storage location immediately after sample receipt and login procedures are completed. All sample storage areas have limited access. Samples are removed from storage areas by designated personnel and returned to the storage areas as soon as possible after the required sample quantity has been taken.

5.8.5.2 Sample Retention and Disposal

The procedures used by the laboratory for sample retention and disposal are detailed in laboratory SOP ENV-SOP-BEAV-0075, or equivalent subsequent replacement.

In general, unused sample volume and prepared samples such as extracts, digestates, distillates and leachates (samples) are retained by the laboratory for the period of time necessary to protect the interests of the laboratory and the customer.

Samples may be stored at ambient temperature when all analyses are complete, the hold time is expired, the report has been delivered, and/or when allowed by the customer or program. Samples requiring storage beyond the minimum sample retention time due to special requests or contractual obligations may be stored at



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ambient temperature unless the laboratory has sufficient capacity and their presence does not compromise the integrity of other samples.

After this period expires, non-hazardous samples are properly disposed of as non-hazardous waste. The preferred method for disposition of hazardous samples is to return the excess sample to the customer.

5.9 Assuring the Quality of Test Results

5.9.1 Quality Control (QC) Procedures

The laboratory monitors the validity and reliability of test results using quality control (QC) samples that are prepared and analyzed concurrently with field samples in the same manner as field samples. QC results are always associated to and reported with the field samples they were prepared and analyzed with from the same preparation or analytical batch. See the glossary for definition of preparation and analytical batch.

The results of QC performed during the testing process are used by the laboratory to assure the results of analysis are consistent, comparable, accurate, and/or precise within a specified limit. When the results are not within acceptance criteria or expectations for method performance, correction and corrective action(s) are taken. These actions may include retesting or reporting of data with qualification to alert the end user of the situation.

Other QC measures performed include the use of certified reference materials (see 5.6.2), participation in interlaboratory proficiency testing (see 5.9.1.1), verification that formulae used for reduction of data and calculation of results is accurate (see 5.9.3), on-going monitoring of environmental conditions that could impact test results (see 5.3.2), and evaluation and verification of method selectivity and sensitivity (see 5.4.5).

QC results are also used by the laboratory to monitor performance statistical trends over time and to establish acceptance criteria when no method or regulatory criteria exist. (see 5.9.1.4).

5.9.1.1 Essential QC

Although the general principles of QC for the testing process apply to all testing, the QC protocol used for each test depends on the type of test performed.

QC protocol used by the laboratory to monitor the validity of the test are specified in test method SOPs. The SOP includes QC type, frequency, acceptance criteria, corrective actions, and procedures for reporting of nonconforming work.

These requirements in the SOP conform to the reference method and any applicable regulations or certification and accreditation program requirement for which results of the test are used. When a project requires more stringent QC protocol than specified in the SOP, project specification is followed. When the project requires less stringent QC protocol, the project specification may be followed as an authorized departure from the SOP when the project specifications meet the requirements in the mandated method and any regulatory compliance requirements for which the data will be used.

The following are examples of essential QC for Chemistry:



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5.9.1.1.1 Second Source Standard (ICV/QCS)

The second source standard is a standard obtained from a different vendor than the vendor of the standards used for calibration. It is a positive control used to verify the accuracy of a new calibration relative to the purity of the standards used for calibration. This check is referred to in test method and quality system standards as the initial calibration verification (ICV) or quality control sample (QCS). The second source standard is analyzed immediately after the calibration and before analysis of any samples. When the ICV is not within acceptance criteria, a problem with the purity or preparation of the standards may be indicated.

5.9.1.1.2 Continuing Calibration Verification (CCV)

CCV is to determine if the analytical response has significantly changed since initial calibration. If the response of the CCV is within criteria, the calibration is considered valid. If not, there is a problem that requires further investigation. Actions taken are technology and method specific.

5.9.1.1.3 Method Blank (MB) / Other Blanks

A method blank is a negative control used to assess for contamination during the prep/analysis process. The MB consists of a clean matrix, similar to the associated samples that is known to be free of analytes of interest. The MB is processed with and carried through all preparation and analytical steps as the associated samples.

In general, contamination is suspected when the target analyte is detected in the MB above the reporting limit. Some programs may require evaluation of the MB to $\frac{1}{2}$ the reporting limit or the detection limit. When contamination is evident, the source is investigated and corrections are taken to reduce or eliminate it. Analytical results associated with MB that does not meet criteria are qualified in the final test report.

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

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



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5.9.1.1.4 Laboratory Control Sample (LCS)

The LCS is positive control used to measure the accuracy of process in a blank matrix. The LCS is spiked by the laboratory with a known amount of analyte. The spike is a standard solution that is pre-made or prepared from a certified reference standard. The LCS is processed with and carried through all preparation and analytical steps as the associated samples.

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

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

Matrix spikes measures the effect the sample matrix has on precision and accuracy of the determinative test method. The MS and MSD are replicates of a client sample that is spiked with known amount of target analyte.

Due to the heterogeneity of matrices even of the same general matrix type, matrix spike results mostly provide information on the effect of the matrix to the client whose sample was used and on samples of the same matrix from the same sampling site. Therefore, MS should be client-specific when the impact of matrix on accuracy and precision is a project data quality objective. When there is not a client-specified MS for any sample in the batch, the laboratory randomly selects a sample from the batch; the sample selected at random is called a "batch" matrix spike.

The MS/MSD results for percent recovery and relative percent difference are checked against control limits. Because the performance of matrix spikes is matrix-dependent, the result of the matrix spike is not used to determine the acceptability of the test.

5.9.1.1.6 Sample Duplicate (SD)

A sample duplicate is a second replicate of sample that is prepared and analyzed in the laboratory along another replicate. The SD is used to measure precision.

The relative percent difference between replicates are evaluated against the method or laboratory derived criteria for relative percent difference (RPD), when this criterion is applicable. If RPD is not met, associated test results are reported with qualification.

5.9.1.1.7 Surrogates

Surrogates are compounds that mimic the chemistry of target analytes but are not expected to occur naturally in real world samples. Surrogates are added to each sample and matrix QC



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samples (MS, MSD, SD) at known concentration to measure the impact of the matrix on the accuracy of method performance. Surrogates are also added to the positive and negative control samples (MB, LCS) to evaluate performance in a clean matrix, and included in the calibration standards and calibration check standards.

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

5.9.1.1.8 Internal Standards

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

5.9.1.1.9 QC Acceptance Criteria and Control Limits

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

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

See laboratory SOP ENV-SOP-BEAV-0117 or equivalent subsequent revision for more information.

5.9.1.2 Proficiency Testing (PT)

The laboratory participates in interlaboratory proficiency testing (PT) studies to measure performance of the test method and to identify or solve analytical problems. PT samples measure laboratory performance through the analysis of unknown samples provided by an external source.



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The PT samples are obtained from accredited proficiency testing providers (PTP) and handled as field samples which means they are included in the laboratory's normal analytical processes and do not receive extraordinary attention due to their nature.

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

The laboratory initiates an investigation and corrective action plan whenever PT results are deemed unacceptable by the PT provider.

The frequency of PT participation is based on the certification and accreditation requirements held by the laboratory.

5.9.2 QC Corrective Action

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

5.9.3 Data Review

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

The sequential process includes three tiers referred to as primary review, secondary review, and administrative/completeness review.

Detailed procedures for the data review process are described in laboratory SOP ENV-SOP-BEAV-0118 or equivalent subsequent revision. The general expectations for the tiered review process are described in the following sections:

5.9.3.1 Primary Review

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

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

- Verification that data transfer and acquisition is complete
- Manual calculations, if performed, are documented and accurate
- Manual integrations, if performed, are documented and comply with SOP ENV-SOP-CORQ-006 *Manual Integration*



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- Calibration and QC criteria were met, and/or proper correction and corrective actions were taken, and data and test results associated with QC and criteria exceptions are properly qualified
- Work is consistent with SOPs and any other relevant instructional document such as SWI, program requirements, or project QAPP

5.9.3.2 Secondary Review

Secondary review is performed by qualified peer or supervisor. Secondary review is essentially a repeat of the checks performed during primary review by another person. In addition to the checks of primary review, secondary review includes chromatography review to check the accuracy of quantitative analyte identification.

5.9.3.3 Completeness Review

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

5.9.3.4 Data Audits

In addition to the 3 tier data review process, test reports may be audited by local QA to verify compliance with SOPs and to check for data integrity, technical accuracy, and regulatory compliance. These audits are not usually done prior to issuance of the test report to the customer. The reports chosen for the data audits are selected at random.

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

Also see Section 4.14 for internal audits.

5.10 Reporting**5.10.1 General Requirements**

The laboratory reports results of testing in a way that assures the results are clear, and unambiguous. All data and results are reviewed prior to reporting to assure the results reported are accurate and complete.

Test results are summarized in test reports that include all information necessary for the customer's interpretation of the test results. Additional information necessary to clarify the data or disclose nonconformance, exceptions, or deviations that occurred during the analytical process are also reported to the customer in the test report.

The specifications for test reports and electronic data deliverables (EDD) are established between the laboratory and the customer at the time the request for analytical services is initiated. The report specifications include the test report format, protocol for the reporting limit (RL), conventions for the reporting of results less than the limit of quantitation (LOQ), and specification for the use of project or program specific data qualifiers. Information about review of analytical service requests is provided in Section 4.4.



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5.10.2 Test Reports: Required Items

Test Reports are prepared by the laboratory at the end of the testing process. The format of the report depends on the level of reporting requested by the customer. The laboratory offers a variety of standardized test report formats and can also provide custom test report formats, when necessary.

The level of detail required in the test report depends on the customer's needs for data verification, validation, and usability assessments that occur after the laboratory releases the test report to the customer. The test report formats offered by the laboratory provide gradient levels of detail to meet the unique needs of each customer. The laboratory project manager helps the customer select the test report format that best meets their needs. When a specific report format or protocol is required for a regulatory or program compliance, the laboratory project manager must ensure the test report selected meets those requirements.

Every test report issued by the laboratory includes each of the following items:

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

5.10.3 Test Reports: Supplemental Items

5.10.3.1 Supplemental Requirements

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



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

5.10.3.2 Test Reports: Sampling Information

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

- a) Date of Sampling.
- b) Unambiguous identification of material samples.
- c) Location of sampling including and diagrams, sketches, or photographs.
- d) Reference to the sampling plan and procedures used.
- e) Details of environmental conditions at time of sample that may impact test results.
- f) Any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration Certificates

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



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5.10.5 Opinions and Interpretations

The laboratory provides objective data and information to its customers of sufficient detail for their interpretation and decision making. Objective data and information is based solely on fact and does not attempt to explain the meaning (interpret) or offer a view or judgement (opinion). Sometimes the customer may request the laboratory provide opinion or interpretation to assist them with their decisions about the data.

When opinions and interpretations are included in the test report, the laboratory will document the basis upon which the opinions and interpretations have been made and clearly identify this content as opinion or interpretation in the test report.

Examples of opinion and interpretation include but are not limited to:

- The laboratory's viewpoint on how a nonconformance impacts the quality of the data or usability of results.
- The laboratory's judgment of fulfillment of contractual requirements.
- Recommendations for how the customer should use the test results and information.
- Suggestions or guidance to the customer for improvement.

When opinions or interpretations are verbally discussed with the customer, the content of these conversations is summarized by the laboratory and kept in the project record.

5.10.6 Subcontractor Reports

When analytical work has been subcontracted to an organization external to PAS, the test report from the subcontractor is included in its entirety as an amendment to the final test report.

Note: Test results for analytical work performed within the PAS network may be merged into a single test report. The test report issued clearly identifies the location and address of each network location that performed testing and which tests they performed. (See 5.10.2)

5.10.7 Electronic Transmission of Results

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

5.10.8 Format of Test Reports

The test formats offered by the laboratory are designed to accommodate each type of analytical test method carried out by the laboratory and to minimize the possibility of misunderstanding or misuse of analytical results. The format of electronic data deliverables (EDD) follow the specifications for the EDD.

5.10.9 Amendments to Test Reports

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

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



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Changes made to test results and data before the final test report is issued to the customer are not amendments or revisions, these are corrections to errors found during the laboratory's data verification and review process.

6.0 REVISION HISTORY

This Version:

Section	Description of Change
All	This version is a complete rewrite of the document this version supersedes.

This document supersedes the following documents:

Document Number	Title	Version
ENV-MAN-CORQ-0001	Quality Manual	00



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7.0 APPENDICES

7.1 Appendix A: Certification / Accreditation Listing

The certifications / accreditation lists provided in this manual represent those that were held by the named location on the effective date of this manual. This information is subject to change without notice and must not be considered valid proof of certification or accreditation status. Current certificates are maintained by Local QA and a copy of the certificate is posted to PAS's eDMS Portal for access by all PAS employees. External parties should contact the laboratory for the most current information.

7.1.1 PAS - Beaver

Accrediting Authority	Program Category	Accrediting Agency	Certificate Number
Virginia (Primary TNI)	DW, NPW, SCM	DGS (VELAP)	10095
Virginia	DW	DCLS	10460
West Virginia	NPW, SCM	WV DEP	060
West Virginia	DW	WV DHHR	00412CM
Pennsylvania (Secondary TNI)	NPW, SCM	PA DEP	15
North Carolina	NPW	NC DEQ	466
Kentucky	NPW	KY DEP	90039

7.1.2 PAS - Lexington

Accrediting Authority	Program Category	Accrediting Agency	Certificate Number
Virginia (Primary TNI)	DW, NPW, SCM	DGS (VELAP)	10692

7.1.3 PAS - Morgantown

Accrediting Authority	Program Category	Accrediting Agency	Certificate Number
West Virginia	NPW	WV DEP	387
West Virginia	DW	WV DHHR	00312M



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7.2 Appendix B: Capability Listing

The capabilities listed in this Appendix were held by the location referenced on the effective date of this manual. This information is subject to change without notice. External parties should contact the laboratory for the most current information.

Table Legend:

- DW = Drinking Water
- NPW = Non-Potable Water
- SCM = Solid and Chemical Materials
- Waste = Non-Aqueous Phase Liquid (NAPL), Oil
- Tissue = Biota and Tissue

7.2.1 PAS - Beaver

Parameter	Method	Matrices							
		Air	DW	NPW	SCM	Waste	Tissue		
Acidity	SM 2310 B			X					
Alkalinity	SM 2320 B			X					
Ammonia	EPA 350.1			X					
Ammonia	SM 4500-NH3 B			X	X				
Ammonia	SM 4500-NH3 C			X	X				
Anions	EPA 300.0		X	X	X				
Anions	SW 9056 A				X				
Nitrate, Nitrite, Nitrate-Nitrite	SM 4500-NO3 F			X	X				
Nitrate-Nitrite	Lachat 10-107-04-1-C		X	X					
Nitrate-Nitrite	SM 4110 B			X					
Carbon, Total Organic (TOC)	SM 5310 C			X					
Carbon, Total Organic (TOC)	SW 9060			X					
Chlorine, Residual	SM 4500-Cl G			X					
Chromium VI, Dissolved	EPA 218.6			X					
Chromium VI, Dissolved	SM 3500-Cr C			X					
Chromium VI, Dissolved	SW 3060 A				X				
Chromium VI, Dissolved	SW 7196 A				X				
Color	SM 2120 B			X					
Color	SM 2120 E			X					
Conductivity, Specific	SM 2510 B			X					
Cyanide, Amenable	SM 4500-CN E			X					



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Parameter	Method	Matrices						
		Air	DW	NPW	SCM	Waste	Tissue	
Cyanide, Amenable	SM 4500-CN G			X				
Cyanide, Total	EPA 335.4		X	X	X			
Cyanide, Total	SW 9010 B			X				
Cyanide, Total	SW 9010 C				X			
Cyanide, Total	SW 9012 B			X	X			
Cyanide, WAD	SM 4500-CN E			X				
Cyanide, WAD	SM 4500-CN I			X				
Hardness, Calcium	SM 2340 B			X				
Hardness, Total	SM 2340 B			X				
TKN	EPA 351.2			X	X			
Oil & Grease	EPA 1664 A			X				
BOD	SM 5210 B			X				
COD	SM 5210 B			X				
Dissolved Oxygen	Hach 10360			X				
Dissolved Oxygen	SM 4500-O C			X				
Dissolved Oxygen	SM 4500-O G			X				
pH	SM 4500-H B			X				
pH	SW 9040 C			X	X			
pH	SW 9045 D				X			
Phenolics, Total	EPA 420.1			X				
Phosphorus, Total	SM 4500-P B(5)			X				
Phosphorus, Total	SM 4500-P e			X				
TDS	SM 2540 C			X				
Settleable Solids	SM 2540 F			X				
TSS	SM 2540 D			X				
TVS	SM 2540 E			X				
Total Solids	SM 2540 B			X				
TFS & TVS	SM 2540 G				X			
Sulfide	SM 4500-S F			X				
Sulfite	SM 4500-SO3 B			X				
Surfactants (MBAS)	SM 5540 C			X				
Turbidity	EPA 180.1			X				



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Parameter	Method	Matrices						
		Air	DW	NPW	SCM	Waste	Tissue	
ICP Metals	EPA 200.7		X	X				
ICP Metals	SW 6010 C			X	X			
ICP-MS Metals	EPA 200.8		X	X				
ICP-MS Metals	SW 6020 B			X				
Mercury	EPA 1631 E			X				
Mercury	EPA 245.1		X	X				
Mercury	EPA 245.7			X				
Mercury	SW 7470 A			X	X			
Mercury	SW 7471 A				X			
Mercury	SW 7471 B				X			
Selenium	SM 3114 B (Modified)			X				
Selenium	SW 7742 (Modified)				X			
TCLP Leach (Metals & Organics)	EPA 1311					X		
Flashpoint	EPA 1010 A					X		
Corrosivity	SW 9045 D					X		
Paint Filter Test	SW 9095 B					X		
Coliform, Fecal (MF)	SM 9222 D			X	X			
Coliform, Fecal (MPN)	Colilert 18			X				
Coliform, Total (MPN)	Colilert 18			X				
Total Coliforms (P/A)	SM 9223 B		X					
Total Coliforms (MPN)	SM 9223 B		X					
E. Coli (MPN)	Colilert 18			X				
E. Coli (MPN)	SM 9223 B			X				
E. Coli (P/A)	SM 9223 B		X					
E. Coli (MPN)	SM 9223 B		X					
HPC	Simplex		X					
Halogenated & Aromatic Volatiles	SW 8021 B			X				
Purgeable Aromatic Volatiles	EPA 602			X				
Purgeable Volatiles	EPA 624.1			X				
TPH – GRO	SW 8015 C			X	X			
Volatile Organic Compounds	SW 8260 B			X	X			
Volatile Organic Compounds	EPA 524.2		X					



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7.2.2 PAS - Lexington

Parameter	Method	Matrices						
		Air	DW	NPW	SCM	Waste	Tissue	
HPC	Simplex		X					
Total Coliform (P/A)	SM 9223B		X					
Escherichia Coli (P/A)	SM 9223B		X					
Escherichia Coli (MPN)	SM 9223B			X				
Escherichia Coli (MPN)	Colilert-18			X	X			
Fecal Coliforms	SM 9222D			X	X			

7.2.3 PAS - Morgantown

Parameter	Method	Matrices						
		Air	DW	NPW	SCM	Waste	Tissue	
Total Residual Chlorine	Hach 8167			X				
pH	SM 4500-H B			X				
Temperature	SM 2550B			X				
Fecal Coliforms	SM 9222D			X				
Total Coliform (P/A)	SM 9223B		X					
Total Coliform (MPN)	SM 9223B		X					
Escherichia Coli (P/A)	SM 9223B		X					
Escherichia Coli (MPN)	SM 9223B		X					

7.3 Appendix C: Glossary

This glossary provides common terms and definitions used in the laboratory. **It is not intended to be a complete list of all terms and definitions used.** The definitions have been compiled mostly from the TNI Standard and DoD QSM. Although this information has been reproduced with care, errors cannot be entirely excluded. Definitions for the same term also vary between sources. When the meaning of a term used in a laboratory document is different from this glossary or when the glossary does not include the term, the term and definition is included or defined in context in the laboratory document.

Term	Definition
3P Program	PAS-The continuous improvement program used by PAS that focuses on Process, Productivity, and Performance.



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Acceptance Criteria	TNI- Specified limits placed on characteristics of an item, process, or service defined in requirement documents.
Accreditation	TNI- The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. DoD- Refers to accreditation in accordance with the DoD ELAP.
Accreditation Body (AB)	TNI- The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program. DoD- Entities recognized in accordance with the DoD-ELAP that are required to operate in accordance with ISO/IEC 17011, <i>Conformity assessment: General requirements for accreditation bodies accrediting conformity assessment bodies</i> . The AB must be a signatory, in good standing, to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement (MRA) that verifies, by evaluation and peer assessment, that its signatory members are in full compliance with ISO/IEC 17011 and that its accredited laboratories comply with ISO/IEC 17025.
Accuracy	TNI- The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.
Activity, Absolute	TNI- Rate of nuclear decay occurring in a body of material, equal to the number of nuclear disintegrations per unit time. NOTE: Activity (absolute) may be expressed in becquerels (Bq), curies (Ci), or disintegrations per minute (dpm), and multiples or submultiples of these units.
Activity, Areic	TNI- Quotient of the activity of a body of material and its associated area.
Activity, Massic	TNI- Quotient of the activity of a body of material and its mass; also called specific activity.
Activity, Volumic	TNI- Quotient of the activity of a body of material and its volume; also called activity concentration. NOTE: In this module [TNI Volume 1, Module 6], unless otherwise stated, references to activity shall include absolute activity, areic activity, massic activity, and volumic activity.
Activity Reference Date	TNI- The date (and time, as appropriate to the half-life of the radionuclide) to which a reported activity result is calculated. NOTE: The sample collection date is most frequently used as the Activity Reference Date for environmental measurements, but different programs may specify other points in time for correction of results for decay and ingrowth.
Aliquot	DoD- A discrete, measured, representative portion of a sample taken for analysis.
American Society for Testing and Materials (ASTM)	An international standards organization that develops and publishes voluntary consensus standards for a wide range of materials, products, systems and services.
Analysis	DoD- A combination of sample preparation and instrument determination.
Analysis Code (Acode)	All the set parameters of a test, such as Analytes, Method, Detection Limits and Price.
Analysis Sequence	A compilation of all samples, standards and quality control samples run during a specific amount of time on a particular instrument in the order they are analyzed.
Analyst	TNI- The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.
Analyte	TNI- A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being analyzed. DoD- The specific chemicals or components for which a sample is analyzed; it may be a group of chemicals that belong to the same chemical family and are analyzed together.
Analytical Method	DoD- A formal process that identifies and quantifies the chemical components of interest (target analytes) in a sample.
Analytical Uncertainty	TNI- A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.
Aliquot	DoD- A discrete, measured, representative portion of a sample taken for analysis.
Annual (or Annually)	Defined by PAS as every 12 months \pm 30 days.
Assessment	TNI - The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its system to defined criteria (to the standards and requirements of laboratory accreditation). DoD- An all-inclusive term used to denote any of the following: audit, performance evaluation, peer review, inspection, or surveillance conducted on-site.
Atomic Absorption Spectrometer	Instrument used to measure concentration in metals samples.
Atomization	A process in which a sample is converted to free atoms.



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Audit	TNI- A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.
Batch	TNI- Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours or the time-frame specified by the regulatory program. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples.
Batch, Radiation Measurements (RMB)	TNI- An RMB is composed of 1 to 20 environmental samples that are counted directly without preliminary physical or chemical processing that affects the outcome of the test (e.g., non-destructive gamma spectrometry, alpha/beta counting of air filters, or swipes on gas proportional detectors). The samples in an RMB share similar physical and chemical parameter, and analytical configurations (e.g., analytes, geometry, calibration, and background corrections). The maximum time between the start of processing of the first and last in an RMB is 14 calendar days.
Bias	TNI- The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).
Blank	TNI and DoD- A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results (See Method Blank). DoD- Blank samples are negative control samples, which typically include field blank samples (e.g., trip blank, equipment (rinsate) blank, and temperature blank) and laboratory blank samples (e.g., method blank, reagent blank, instrument blank, calibration blank, and storage blank).
Blind Sample	A sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.
BNA (Base Neutral Acid compounds)	A list of semi-volatile compounds typically analyzed by mass spectrometry methods. Named for the way they can be extracted out of environmental samples in an acidic, basic or neutral environment.
BOD (Biochemical Oxygen Demand)	Chemical procedure for determining how fast biological organisms use up oxygen in a body of water.
Calibration	TNI- A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. 1) In calibration of support equipment, the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI); 2) In calibration according to test methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.
Calibration Curve	TNI- The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.
Calibration Method	A defined technical procedure for performing a calibration.
Calibration Range	DoD- The range of values (concentrations) between the lowest and highest calibration standards of a multi-level calibration curve. For metals analysis with a single-point calibration, the low-level calibration check standard and the high standard establish the linear calibration range, which lies within the linear dynamic range.
Calibration Standard	TNI- A substance or reference material used for calibration.
Certified Reference Material (CRM)	TNI- Reference material accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute.
Chain of Custody	An unbroken trail of accountability that verifies the physical security of samples, data, and records.
Chain of Custody Form (COC)	TNI- Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and type of containers; the mode of collection, the collector, time of collection; preservation; and requested analyses.
Chemical Oxygen Demand (COD)	A test commonly used to indirectly measure the amount of organic compounds in water.



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Client (referred to by ISO as Customer)	Any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.
Code of Federal Regulations (CFR)	A codification of the general and permanent rules published in the Federal Register by agencies of the federal government.
Comparability	An assessment of the confidence with which one data set can be compared to another. Comparable data are produced through the use of standardized procedures and techniques.
Completeness	The percent of valid data obtained from a measurement system compared to the amount of valid data expected under normal conditions. The equation for completeness is: $\% \text{ Completeness} = (\text{Valid Data Points} / \text{Expected Data Points}) * 100$
Confirmation	TNI- Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: second-column confirmation; alternate wavelength; derivatization; mass spectral interpretation; alternative detectors; or additional cleanup procedures. DoD- Includes verification of the identity and quantity of the analyte being measured by another means (e.g., by another determinative method, technology, or column). Additional cleanup procedures alone are not considered confirmation techniques.
Conformance	An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.
Congener	A member of a class of related chemical compounds (e.g., PCBs, PCDDs).
Consensus Standard	DoD- A standard established by a group representing a cross-section of a particular industry or trade, or a part thereof.
Continuing Calibration Blank (CCB)	A blank sample used to monitor the cleanliness of an analytical system at a frequency determined by the analytical method.
Continuing Calibration Check Compounds (CCC)	Compounds listed in mass spectrometry methods that are used to evaluate an instrument calibration from the standpoint of the integrity of the system. High variability would suggest leaks or active sites on the instrument column.
Continuing Calibration Verification	DoD- The verification of the initial calibration. Required prior to sample analysis and at periodic intervals. Continuing calibration verification applies to both external and internal standard calibration techniques, as well as to linear and non-linear calibration models.
Continuing Calibration Verification (CCV) Standard	Also referred to as a Calibration Verification Standard (CVS) in some methods, it is a standard used to verify the initial calibration of compounds in an analytical method. CCVs are analyzed at a frequency determined by the analytical method.
Continuous Emission Monitor (CEM)	A flue gas analyzer designed for fixed use in checking for environmental pollutants.
Continuous Improvement Plan (CIP)	The delineation of tasks for a given laboratory department or committee to achieve the goals of that department.
Contract Laboratory Program (CLP)	A national network of EPA personnel, commercial labs, and support contractors whose fundamental mission is to provide data of known and documented quality.
Contract Required Detection Limit (CRDL)	Detection limit that is required for EPA Contract Laboratory Program (CLP) contracts.
Contract Required Quantitation Limit (CRQL)	Quantitation limit (reporting limit) that is required for EPA Contract Laboratory Program (CLP) contracts.
Control Chart	A graphic representation of a series of test results, together with limits within which results are expected when the system is in a state of statistical control (see definition for Control Limit)
Control Limit	A range within which specified measurement results must fall to verify that the analytical system is in control. Control limit exceedances may require corrective action or require investigation and flagging of non-conforming data.
Correction	DoD- Action taken to eliminate a detected non-conformity.
Corrective Action	DoD- The action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence. A root cause analysis may not be necessary in all cases.
Corrective and Preventative Action (CAPA)	The primary management tools for bringing improvements to the quality system, to the management of the quality system's collective processes, and to the products or services delivered which are an output of established systems and processes.



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Critical Value	TNI- Value to which a measurement result is compared to make a detection decision (also known as critical level or decision level). NOTE: The Critical Value is designed to give a specified low probability α of false detection in an analyte-free sample, which implies that a result that exceeds the Critical Value, gives high confidence $(1 - \alpha)$ that the radionuclide is actually present in the material analyzed. For radiometric methods, α is often set at 0.05.
Customer	DoD- Any individual or organization for which products or services are furnished or work performed in response to defined requirements and expectations.
Data Integrity	TNI- The condition that exists when data are sound, correct, and complete, and accurately reflect activities and requirements.
Data Quality Objective (DQO)	Systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use or end user.
Data Reduction	TNI- The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more usable form.
Definitive Data	DoD- Analytical data of known quantity and quality. The levels of data quality on precision and bias meet the requirements for the decision to be made. Data that is suitable for final decision-making.
Demonstration of Capability (DOC)	TNI- A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision. DoD- A procedure to establish the ability of the analyst to generate analytical results by a specific method that meet measurement quality objectives (e.g., for precision and bias).
Department of Defense (DoD)	An executive branch department of the federal government of the United States charged with coordinating and supervising all agencies and functions of the government concerned directly with national security.
Detection Limit (DL)	DoD- The smallest analyte concentration that can be demonstrated to be different than zero or a blank concentration with 99% confidence. At the DL, the false positive rate (Type 1 error) is 1%. A DL may be used as the lowest concentration for reliably reporting a detection of a specific analyte in a specific matrix with a specific method with 99% confidence.
Detection Limit (DL) for Safe Drinking Water Act (SDWA) Compliance	TNI- Laboratories that analyze drinking-water samples for SDWA compliance monitoring must use methods that provide sufficient detection capability to meet the detection limit requirements established in 40 CFR 141. The SDWA DL for radioactivity is defined in 40 CFR Part 141.25.c as the radionuclide concentration, which can be counted with a precision of plus or minus 100% at the 95% confidence level (1.96σ where σ is the standard deviation of the net counting rate of the sample).
Deuterated Monitoring Compounds (DMCs)	DoD- SIM specific surrogates as specified for GC/MS SIM analysis.
Diesel Range Organics (DRO)	A range of compounds that denote all the characteristic compounds that make up diesel fuel (range can be state or program specific).
Digestion	DoD- A process in which a sample is treated (usually in conjunction with heat and acid) to convert the target analytes in the sample to a more easily measured form.
Document Control	The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.
Documents	DoD- Written components of the laboratory management system (e.g., policies, procedures, and instructions).
Dry Weight	The weight after drying in an oven at a specified temperature.
Duplicate (also known as Replicate or Laboratory Duplicate)	The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results of duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory.
Electron Capture Detector (ECD)	Device used in GC methods to detect compounds that absorb electrons (e.g., PCB compounds).
Electronic Data Deliverable (EDD)	A summary of environmental data (usually in spreadsheet form) which clients request for ease of data review and comparison to historical results.
Eluent	A solvent used to carry the components of a mixture through a stationary phase.
Elute	To extract, specifically, to remove (adsorbed material) from an adsorbent by means of a solvent.
Elution	A process in which solutes are washed through a stationary phase by movement of a mobile phase.
Environmental Data	DoD- Any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology.
Environmental Monitoring	The process of measuring or collecting environmental data.



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Environmental Protection Agency (EPA)	An agency of the federal government of the United States which was created for the purpose of protecting human health and the environment by writing and enforcing regulations based on laws passed by Congress.
Environmental Sample	A representative sample of any material (aqueous, non-aqueous, or multimedia) collected from any source for which determination of composition or contamination is requested or required. Environmental samples can generally be classified as follows: <ul style="list-style-type: none"> • Non Potable Water (Includes surface water, ground water, effluents, water treatment chemicals, and TCLP leachates or other extracts) • Drinking Water - Delivered (treated or untreated) water designated as potable water • Water/Wastewater - Raw source waters for public drinking water supplies, ground waters, municipal influents/effluents, and industrial influents/effluents • Sludge - Municipal sludges and industrial sludges. • Soil - Predominately inorganic matter ranging in classification from sands to clays. • Waste - Aqueous and non-aqueous liquid wastes, chemical solids, and industrial liquid and solid wastes
Equipment Blank	A sample of analyte-free media used to rinse common sampling equipment to check effectiveness of decontamination procedures.
Extracted Internal Standard Analyte	Isotopically labeled analogs of analytes of interest added to all standards, blanks and samples analyzed. Added to samples and batch QC samples prior to the first step of sample extraction and to standards and instrument blanks prior to analysis. Used for isotope dilution methods.
Facility	A distinct location within the company that has unique certifications, personnel and waste disposal identifications.
False Negative	DoD- A result that fails to identify (detect) an analyte or reporting an analyte to be present at or below a level of interest when the analyte is actually above the level of interest.
False Positive	DoD- A result that erroneously identifies (detects) an analyte or reporting an analyte to be present above a level of interest when the analyte is actually present at or below the level of interest.
Field Blank	A blank sample prepared in the field by filling a clean container with reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken.
Field Measurement	Determination of physical, biological, or radiological properties, or chemical constituents that are measured on-site, close in time and sPAS to the matrices being sampled/measured, following accepted test methods. This testing is performed in the field outside of a fixed-laboratory or outside of an enclosed structure that meets the requirements of a mobile laboratory.
Field of Accreditation	TNI- Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.
Field of Proficiency Testing (FoPT)	TNI- Matrix, technology/method, analyte combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the PTPEC.
Finding	TNI- An assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement. DoD- An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive, negative, or neutral and is normally accompanied by specific examples of the observed condition. The finding must be linked to a specific requirement (e.g., this standard, ISO requirements, analytical methods, contract specifications, or laboratory management systems requirements).
Flame Atomic Absorption Spectrometer (FAA)	Instrumentation used to measure the concentration of metals in an environmental sample based on the fact that ground state metals absorb light at different wavelengths. Metals in a solution are converted to the atomic state by use of a flame.
Flame Ionization Detector (FID)	A type of gas detector used in GC analysis where samples are passed through a flame which ionizes the sample so that various ions can be measured.
Gas Chromatography (GC)	Instrumentation which utilizes a mobile carrier gas to deliver an environmental sample across a stationary phase with the intent to separate compounds out and measure their retention times.
Gas Chromatograph/Mass Spectrometry (GC/MS)	In conjunction with a GC, this instrumentation utilizes a mass spectrometer which measures fragments of compounds and determines their identity by their fragmentation patterns (mass spectra).
Gasoline Range Organics (GRO)	A range of compounds that denote all the characteristic compounds that make up gasoline (range can be state or program specific).



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Graphite Furnace Atomic Absorption Spectrometry (GFAA)	Instrumentation used to measure the concentration of metals in an environmental sample based on the absorption of light at different wavelengths that are characteristic of different analytes.
High Pressure Liquid Chromatography (HPLC)	Instrumentation used to separate, identify and quantitate compounds based on retention times which are dependent on interactions between a mobile phase and a stationary phase.
Holding Time	TNI- The maximum time that can elapse between two specified activities. 40 CFR Part 136- The maximum time that samples may be held prior to preparation and/or analysis as defined by the method and still be considered valid or not compromised. For sample prep purposes, hold times are calculated using the time of the start of the preparation procedure. DoD- The maximum time that may elapse from the time of sampling to the time of preparation or analysis, or from preparation to analysis, as appropriate.
Homogeneity	The degree to which a property or substance is uniformly distributed throughout a sample.
Homologue	One in a series of organic compounds in which each successive member has one more chemical group in its molecule than the next preceding member. For instance, methanol, ethanol, propanol, butanol, etc., form a homologous series.
Improper Actions	DoD- Intentional or unintentional deviations from contract-specified or method-specified analytical practices that have not been authorized by the customer (e.g., DoD or DOE).
Incremental Sampling Method (ISM)	Soil preparation for large volume (1 kg or greater) samples.
In-Depth Data Monitoring	TNI- When used in the context of data integrity activities, a review and evaluation of documentation related to all aspects of the data generation process that includes items such as preparation, equipment, software, calculations, and quality controls. Such monitoring shall determine if the laboratory uses appropriate data handling, data use and data reduction activities to support the laboratory's data integrity policies and procedures.
Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES)	Analytical technique used for the detection of trace metals which uses plasma to produce excited atoms that emit radiation of characteristic wavelengths.
Inductively Coupled Plasma- Mass Spectrometry (ICP/MS)	An ICP that is used in conjunction with a mass spectrometer so that the instrument is not only capable of detecting trace amounts of metals and non-metals but is also capable of monitoring isotopic speciation for the ions of choice.
Infrared Spectrometer (IR)	An instrument that uses infrared light to identify compounds of interest.
Initial Calibration (ICAL)	The process of analyzing standards, prepared at specified concentrations, to define the quantitative response relationship of the instrument to the analytes of interest. Initial calibration is performed whenever the results of a calibration verification standard do not conform to the requirements of the method in use or at a frequency specified in the method.
Initial Calibration Blank (ICB)	A blank sample used to monitor the cleanliness of an analytical system at a frequency determined by the analytical method. This blank is specifically run in conjunction with the Initial Calibration Verification (ICV) where applicable.
Initial Calibration Verification (ICV)	DoD- Verifies the initial calibration with a standard obtained or prepared from a source independent of the source of the initial calibration standards to avoid potential bias of the initial calibration.
Injection Internal Standard Analyte	Isotopically labeled analogs of analytes of interest (or similar in physiochemical properties to the target analytes but with a distinct response) to be quantitated. Added to all blanks, standards, samples and batch QC after extraction and prior to analysis.
Instrument Blank	A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination.
Instrument Detection Limits (IDLs)	Limits determined by analyzing a series of reagent blank analyses to obtain a calculated concentration. IDLs are determined by calculating the average of the standard deviations of three runs on three non-consecutive days from the analysis of a reagent blank solution with seven consecutive measurements per day.
Interference, spectral	Occurs when particulate matter from the atomization scatters incident radiation from the source or when the absorption or emission from an interfering species either overlaps or is so close to the analyte wavelength that resolution becomes impossible.
Interference, chemical	Results from the various chemical processes that occur during atomization and later the absorption characteristics of the analyte.



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Internal Standard	TNI and DoD- A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.
International Organization for Standardization (ISO)	An international standard-setting body composed of representatives from various national standards organizations.
Intermediate Standard Solution	Reference solutions prepared by dilution of the stock solutions with an appropriate solvent.
International System of Units (SI)	The coherent system of units adopted and recommended by the General Conference on Weights and Measures.
Ion Chromatography (IC)	Instrumentation or process that allows the separation of ions and molecules based on the charge properties of the molecules.
Isomer	One of two or more compounds, radicals, or ions that contain the same number of atoms of the same element but differ in structural arrangement and properties. For example, hexane (C ₆ H ₁₄) could be n-hexane, 2-methylpentane, 3-methylpentane, 2,3-dimethylbutane, 2,2-dimethylbutane.
Laboratory	A body that calibrates and/or tests.
Laboratory Control Sample (LCS)	TNI- (also known as laboratory fortified blank (LFB), spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst-specific precision and bias or to evaluate the performance of all or a portion of the measurement system.
Laboratory Duplicate	Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.
Laboratory Information Management System (LIMS)	DoD- The entirety of an electronic data system (including hardware and software) that collects, analyzes, stores, and archives electronic records and documents.
Learning Management System (LMS)	A web-based database used by the laboratories to track and document training activities. The system is administered by the corporate training department and each laboratory's learn centers are maintained by a local administrator.
Legal Chain-of-Custody Protocols	TNI- Procedures employed to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a Chain-of-Custody (COC) Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.
Limit(s) of Detection (LOD)	TNI- The minimum result, which can be reliably discriminated from a blank with predetermined confidence level. DoD- The smallest concentration of a substance that must be present in a sample in order to be detected at the DL with 99% confidence. At the LOD, the false negative rate (Type II error) is 1%. A LOD may be used as the lowest concentration for reliably reporting a non-detect of a specific analyte in a specific matrix with a specific method at 99% confidence.
Limit(s) of Quantitation (LOQ)	TNI- The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. DoD- The smallest concentration that produces a quantitative result with known and recorded precision and bias. For DoD/DOE projects, the LOQ shall be set at or above the concentration of the lowest initial calibration standard and within the calibration range.
Linear Dynamic Range	DoD- Concentration range where the instrument provides a linear response.
Liquid chromatography/tandem mass spectrometry (LC/MS/MS)	Instrumentation that combines the physical separation techniques of liquid chromatography with the mass analysis capabilities of mass spectrometry.
Lot	TNI- A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality.
Management	Those individuals directly responsible and accountable for planning, implementing, and assessing work.
Management System	System to establish policy and objectives and to achieve those objectives.
Manager (however named)	The individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual.
Matrix	TNI- The substrate of a test sample.



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Matrix Duplicate	TNI- A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.
Matrix Spike (MS) (spiked sample or fortified sample)	TNI- A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.
Matrix Spike Duplicate (MSD) (spiked sample or fortified sample duplicate)	TNI- A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.
Measurement Performance Criteria (MPC)	DoD- Criteria that may be general (such as completion of all tests) or specific (such as QC method acceptance limits) that are used by a project to judge whether a laboratory can perform a specified activity to the defined criteria.
Measurement Quality Objective (MQO)	TNI- The analytical data requirements of the data quality objectives are project- or program-specific and can be quantitative or qualitative. MQOs are measurement performance criteria or objectives of the analytical process. Examples of quantitative MQOs include statements of required analyte detectability and the uncertainty of the analytical protocol at a specified radionuclide activity, such as the action level. Examples of qualitative MQOs include statements of the required specificity of the analytical protocol, e.g., the ability to analyze for the radionuclide of interest given the presence of interferences.
Measurement System	TNI- A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s). DoD- A test method, as implemented at a particular laboratory, and which includes the equipment used to perform the sample preparation and test and the operator(s).
Measurement Uncertainty	DoD- An estimate of the error in a measurement often stated as a range of values that contain the true value within a certain confidence level. The uncertainty generally includes many components which may be evaluated from experimental standard deviations based on repeated observations or by standard deviations evaluated from assumed probability distributions based on experience or other information. For DoD/DOE, a laboratory's Analytical Uncertainty (such as use of LCS control limits) can be reported as the minimum uncertainty.
Method	TNI- A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.
Method Blank	TNI- A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.
Method Detection Limit (MDL)	TNI- One way to establish a Detection Limit; defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.
Method of Standard Additions	A set of procedures adding one or more increments of a standard solution to sample aliquots of the same size in order to overcome inherent matrix effects. The procedures encompass the extrapolation back to obtain the sample concentration.
Minimum Detectable Activity (MDA)	TNI- Estimate of the smallest true activity that ensures a specified high confidence, $1 - \beta$, of detection above the Critical Value, and a low probability β of false negatives below the Critical Value. For radiometric methods, β is often set at 0.05. NOTE 1: The MDS is a measure of the detection capability of a measurement process and as such, it is an a priori concept. It may be used in the selection of methods to meet specified MQOs. Laboratories may also calculate a "sample specific" MDA, which indicates how well the measurement process is performing under varying real-world measurement conditions, when sample-specific characteristics (e.g., interferences) may affect the detection capability. However, the MDA must never be used instead of the Critical Value as a detection threshold. NOTE 2: For the purpose of this Standard, the terms MDA and minimum detectable concentration (MDC) are equivalent.
MintMiner	Program used by PAS to review large amounts of chromatographic data to monitor for errors or data integrity issues.
Mobile Laboratory	TNI- A portable enclosed structure with necessary and appropriate accommodation and environmental conditions for a laboratory, within which testing is performed by analysts. Examples include but are not limited to trailers, vans, and skid-mounted structures configured to house testing equipment and personnel.



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National Environmental Laboratory Accreditation Conference (NELAC)	See definition of The NELAC Institute (TNI).
National Institute of Occupational Safety and Health (NIOSH)	National institute charged with the provision of training, consultation and information in the area of occupational safety and health.
National Institute of Standards and Technology (NIST)	TNI- A federal agency of the US Department of Commerce's Technology Administration that is designed as the United States national metrology institute (or NMI).
National Pollutant Discharge Elimination System (NPDES)	A permit program that controls water pollution by regulating point sources that discharge pollutants into U.S. waters.
Negative Control	Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.
Nitrogen Phosphorus Detector (NPD)	A detector used in GC analyses that utilizes thermal energy to ionize an analyte. With this detector, nitrogen and phosphorus can be selectively detected with a higher sensitivity than carbon.
Nonconformance	An indication or judgment that a product or service has not met the requirement of the relevant specifications, contract, or regulation; also the state of failing to meet the requirements.
Not Detected (ND)	The result reported for a compound when the detected amount of that compound is less than the method reporting limit.
Operator Aid	DoD- A technical posting (such as poster, operating manual, or notepad) that assists workers in performing routine tasks. All operator aids must be controlled documents (i.e., a part of the laboratory management system).
Performance Based Measurement System (PBMS)	An analytical system wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner.
Physical Parameter	TNI- A measurement of a physical characteristic or property of a sample as distinguished from the concentrations of chemical and biological components.
Photo-ionization Detector (PID)	An ion detector which uses high-energy photons, typically in the ultraviolet range, to break molecules into positively charged ions.
Polychlorinated Biphenyls (PCB)	A class of organic compounds that were used as coolants and insulating fluids for transformers and capacitors. The production of these compounds was banned in the 1970's due to their high toxicity.
Positive Control	Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects.
Post-Digestion Spike	A sample prepared for metals analyses that has analytes spike added to determine if matrix effects may be a factor in the results.
Power of Hydrogen (pH)	The measure of acidity or alkalinity of a solution.
Practical Quantitation Limit (PQL)	Another term for a method reporting limit. The lowest reportable concentration of a compound based on parameters set up in an analytical method and the laboratory's ability to reproduce those conditions.
Precision	TNI- The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.
Preservation	TNI and DoD- Any conditions under which a sample must be kept in order to maintain chemical, physical, and/or biological integrity prior to analysis.
Primary Accreditation Body (Primary AB)	TNI- The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.
Procedure	TNI- A specified way to carry out an activity or process. Procedures can be documented or not.
Proficiency Testing (PT)	TNI- A means to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.
Proficiency Testing Program (PT Program)	TNI- The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.
Proficiency Testing Provider (PT Provider)	TNI- A person or organization accredited by a TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT Program.
Proficiency Testing Provider Accreditor (PTPA)	TNI- An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.



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Proficiency Testing Reporting Limit (PTRL)	TNI- A statistically derived value that represents the lowest acceptable concentration for an analyte in a PT sample, if the analyte is spiked into the PT sample. The PTRLs are specified in the TNI FoPT tables.
Proficiency Testing Sample (PT)	TNI- A sample, the composition of which is unknown to the laboratory, and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.
Proficiency Testing (PT) Study	TNI- a) Scheduled PT Study: A single complete sequence of circulation and scoring of PT samples to all participants in a PT program. The study must have the same pre-defined opening and closing dates for all participants; b) Supplemental PT Study: A PT sample that may be from a lot previously released by a PT Provider that meets the requirements for supplemental PT samples given in Volume 3 of this Standard [TNI] but that does not have a pre-determined opening date and closing date.
Proficiency Testing Study Closing Date	TNI- a) Scheduled PT Study: The calendar date by which all participating laboratories must submit analytical results for a PT sample to a PT Provider; b) Supplemental PT Study: The calendar date a laboratory submits the results for a PT sample to the PT Provider.
Proficiency Testing Study Opening Date	TNI- a) Scheduled PT Study: The calendar date that a PT sample is first made available to all participants of the study by a PT Provider; b) Supplemental PT Study: The calendar date the PT Provider ships the sample to a laboratory.
Protocol	TNI- A detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) that must be strictly followed.
Qualitative Analysis	DoD- Analysis designed to identify the components of a substance or mixture.
Quality Assurance (QA)	TNI- An integrated system of management activities involving planning, implementation, assessment, reporting and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.
Quality Assurance Manual (QAM)	A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.
Quality Assurance Project Plan (QAPP)	A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.
Quality Control (QC)	TNI- The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality.
Quality Control Sample (QCS)	TNI- A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.
Quality Manual	TNI- A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.
Quality System	TNI and DoD- A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control activities.



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Quality System Matrix	<p>TNI and DoD- These matrix definitions shall be used for purposes of batch and quality control requirements and may be different from a field of accreditation matrix:</p> <ul style="list-style-type: none"> • Air and Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device • Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, groundwater effluents, and TCLP or other extracts. • Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish or plant material. Such samples shall be grouped according to origin. • Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined. • Drinking Water: Any aqueous sample that has been designated a potable or potentially potable water source. • Non-aqueous liquid: Any organic liquid with <15% settleable solids • Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake. • Solids: Includes soils, sediments, sludges, and other matrices with >15% settleable solids.
Quantitation Range	DoD- The range of values (concentrations) in a calibration curve between the LOQ and the highest successively analyzed initial calibration standard used to relate instrument response to analyte concentration. The quantitation range (adjusted for initial sample volume/weight, concentration/dilution and final volume) lies within the calibration range.
Quantitative Analysis	DoD- Analysis designed to determine the amounts or proportions of the components of a substance.
Random Error	The EPA has established that there is a 5% probability that the results obtained for any one analyte will exceed the control limits established for the test due to random error. As the number of compounds measured increases in a given sample, the probability for statistical error also increases.
Raw Data	TNI- The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.
Reagent Blank (method reagent blank)	A sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps.
Reagent Grade	Analytical reagent (AR) grade, ACS reagent grade, and reagent grade are synonymous terms for reagents that conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society.
Records	DoD- The output of implementing and following management system documents (e.g., test data in electronic or hand-written forms, files, and logbooks).
Reference Material	TNI- Material or substance one or more of whose property values are sufficiently homogenized and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
Reference Method	TNI- A published method issued by an organization generally recognized as competent to do so. (When the ISO language refers to a "standard method", that term is equivalent to "reference method"). When a laboratory is required to analyze by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is no regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology.
Reference Standard	TNI- Standard used for the calibration of working measurement standards in a given organization or at a given location.
Relative Percent Difference (RPD)	A measure of precision defined as the difference between two measurements divided by the average concentration of the two measurements.
Reporting Limit (RL)	<p>The level at which method, permit, regulatory and customer-specific objectives are met. The reporting limit may never be lower than the Limit of Detection (i.e., statistically determined MDL). Reporting limits are corrected for sample amounts, including the dry weight of solids, unless otherwise specified. There must be a sufficient buffer between the Reporting Limit and the MDL.</p> <p>DoD- A customer-specified lowest concentration value that meets project requirements for quantitative data with known precision and bias for a specific analyte in a specific matrix.</p>



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Reporting Limit Verification Standard (RLVS)	A standard analyzed at the reporting limit for an analysis to verify the laboratory's ability to report to that level.
Representativeness	A quality element related to the ability to collect a sample reflecting the characteristics of the part of the environment to be assessed. Sample representativeness is dependent on the sampling techniques specified in the project work plan.
Requirement	Denotes a mandatory specification; often designated by the term "shall".
Retention Time	The time between sample injection and the appearance of a solute peak at the detector.
Revocation	TNI- The total or partial withdrawal of a laboratory's accreditation by an accreditation body.
Sample	Portion of material collected for analysis, identified by a single, unique alphanumeric code. A sample may consist of portions in multiple containers, if a single sample is submitted for multiple or repetitive analysis.
Sample Condition Upon Receipt Form (SCURF)	Form used by sample receiving personnel to document the condition of sample containers upon receipt to the laboratory (used in conjunction with a COC).
Sample Delivery Group (SDG)	A unit within a single project that is used to identify a group of samples for delivery. An SDG is a group of 20 or fewer field samples within a project, received over a period of up to 14 calendar days. Data from all samples in an SDG are reported concurrently.
Sample Receipt Form (SRF)	Letter sent to the client upon login to show the tests requested and pricing.
Sample Tracking	Procedures employed to record the possession of the samples from the time of sampling until analysis, reporting and archiving. These procedures include the use of a chain-of-custody form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples.
Sampling	TNI- Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.
Selected Ion Monitoring (SIM)	A mode of analysis in mass spectrometry where the detector is set to scan over a very small mass range, typically one mass unit. The narrower the range, the more sensitive the detector. DoD- Using GC/MS, characteristic ions specific to target compounds are detected and used to quantify in applications where the normal full scan mass spectrometry results in excessive noise.
Selectivity	TNI- The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system.
Sensitivity	TNI- The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.
Serial Dilution	The stepwise dilution of a substance in a solution.
Shall	Denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification as long as the requirement is fulfilled.
Should	Denotes a guideline or recommendation whenever noncompliance with the specification is permissible.
Signal-to-Noise Ratio (S/N)	DoD- A measure of signal strength relative to background noise. The average strength of the noise of most measurements is constant and independent of the magnitude of the signal. Thus, as the quantity being measured (producing the signal) decreases in magnitude, S/N decreases and the effect of the noise on the relative error of a measurement increases.
Source Water	TNI- When sampled for drinking water compliance, untreated water from streams, rivers, lakes, or underground aquifers, which is used to supply private and public drinking water supplies.
Spike	A known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.
Standard (Document)	TNI- The document describing the elements of a laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies.
Standard (Chemical)	Standard samples are comprised of a known amount of standard reference material in the matrix undergoing analysis. A standard reference material is a certified reference material produced by US NIST and characterized for absolute content, independent of analytical test method.
Standard Blank (or Reagent Blank)	A calibration standard consisting of the same solvent/reagent matrix used to prepare the calibration standards without the analytes. It is used to construct the calibration curve by establishing instrument background.
Standard Method	A test method issued by an organization generally recognized as competent to do so.



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Standard Operating Procedure (SOP)	TNI- A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.
Standard Reference Material (SRM)	A certified reference material produced by the US NIST or other equivalent organization and characterized for absolute content, independent of analytical method.
Statement of Qualifications (SOQ)	A document that lists information about a company, typically the qualifications of that company to compete on a bid for services.
Stock Standard	A concentrated reference solution containing one or more analytes prepared in the laboratory using an assayed reference compound or purchased from a reputable commercial source.
Storage Blank	DoD- A sample of analyte-free media prepared by the laboratory and retained in the sample storage area of the laboratory. A storage blank is used to record contamination attributable to sample storage at the laboratory.
Supervisor	The individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses.
Surrogate	DoD- A substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes.
Suspension	TNI- The temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed 6 months or the period of accreditation, whichever is longer, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.
Systems Audit	An on-site inspection or assessment of a laboratory's quality system.
Target Analytes	DoD- Analytes or chemicals of primary concern identified by the customer on a project-specific basis.
Technical Director	Individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory.
Technology	TNI- A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.
Test	A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.
Test Method	DoD- A definitive procedure that determines one or more characteristics of a given substance or product.
Test Methods for Evaluating Solid Waste, Physical/ Chemical (SW-846)	EPA Waste's official compendium of analytical and sampling methods that have been evaluated and approved for use in complying with RCRA regulations.
Test Source	TNI- A radioactive source that is tested, such as a sample, calibration standard, or performance check source. A Test Source may also be free of radioactivity, such as a Test Source counted to determine the subtraction background, or a short-term background check.
The NELAC Institute (TNI)	A non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. Previously known as NELAC (National Environmental Laboratory Accreditation Conference).
Total Petroleum Hydrocarbons (TPH)	A term used to denote a large family of several hundred chemical compounds that originate from crude oil. Compounds may include gasoline components, jet fuel, volatile organics, etc.
Toxicity Characteristic Leaching Procedure (TCLP)	A solid sample extraction method for chemical analysis employed as an analytical method to simulate leaching of compounds through a landfill.
Traceability	TNI- The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical conditions or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.
Training Document	A training resource that provides detailed instructions to execute a specific method or job function.
Trip Blank	This blank sample is used to detect sample contamination from the container and preservative during transport and storage of the sample. A cleaned sample container is filled with laboratory reagent water and the blank is stored, shipped, and analyzed with its associated samples.



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Tuning	A check and/or adjustment of instrument performance for mass spectrometry as required by the method.
Ultraviolet Spectrophotometer (UV)	Instrument routinely used in quantitative determination of solutions of transition metal ions and highly conjugated organic compounds.
Uncertainty, Counting	TNI- The component of Measurement Uncertainty attributable to the random nature of radioactive decay and radiation counting (often estimated as the square root of observed counts (MARLAP). Older references sometimes refer to this parameter as Error, Counting Error or Count Error (c.f., Total Uncertainty).
Uncertainty, Expanded	TNI- The product of the Standard Uncertainty and a coverage factor, k, which is chosen to produce an interval about the result that has a high probability of containing the value of the measurand (c.f., Standard Uncertainty). NOTE: Radiochemical results are generally reported in association with the Total Uncertainty. Either if these estimates of uncertainty can be reported as the Standard Uncertainty (one-sigma) or as an Expanded Uncertainty (k-sigma, where k > 1).
Uncertainty, Measurement	TNI- Parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.
Uncertainty, Standard	TNI- An estimate of the Measurement Uncertainty expressed as a standard deviation (c.f., Expanded Uncertainty).
Uncertainty, Total	TNI- An estimate of the Measurement Uncertainty that accounts for contributions from all significant sources of uncertainty associated with the analytical preparation and measurement of a sample. Such estimates are also commonly referred to as Combined Standard Uncertainty or Total Propagated Uncertainty, and in some older references as the Total Propagated Error, among other similar items (c.f., Counting Uncertainty).
Unethical actions	DoD- Deliberate falsification of analytical or quality control results where failed method or contractual requirements are made to appear acceptable.
United States Department of Agriculture (USDA)	A department of the federal government that provides leadership on food, agriculture, natural resources, rural development, nutrition and related issues based on public policy, the best available science, and effective management.
United States Geological Survey (USGS)	Program of the federal government that develops new methods and tools to supply timely, relevant, and useful information about the Earth and its processes.
Unregulated Contaminant Monitoring Rule (UCMR)	EPA program to monitor unregulated contaminants in drinking water.
Validation	DoD- The confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
Verification	TNI- Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.
Voluntary Action Program (VAP)	A program of the Ohio EPA that gives individuals a way to investigate possible environmental contamination, clean it up if necessary and receive a promise from the State of Ohio that no more cleanup is needed.
Whole Effluent Toxicity (WET)	The aggregate toxic effect to aquatic organisms from all pollutants contained in a facility's wastewater (effluent).

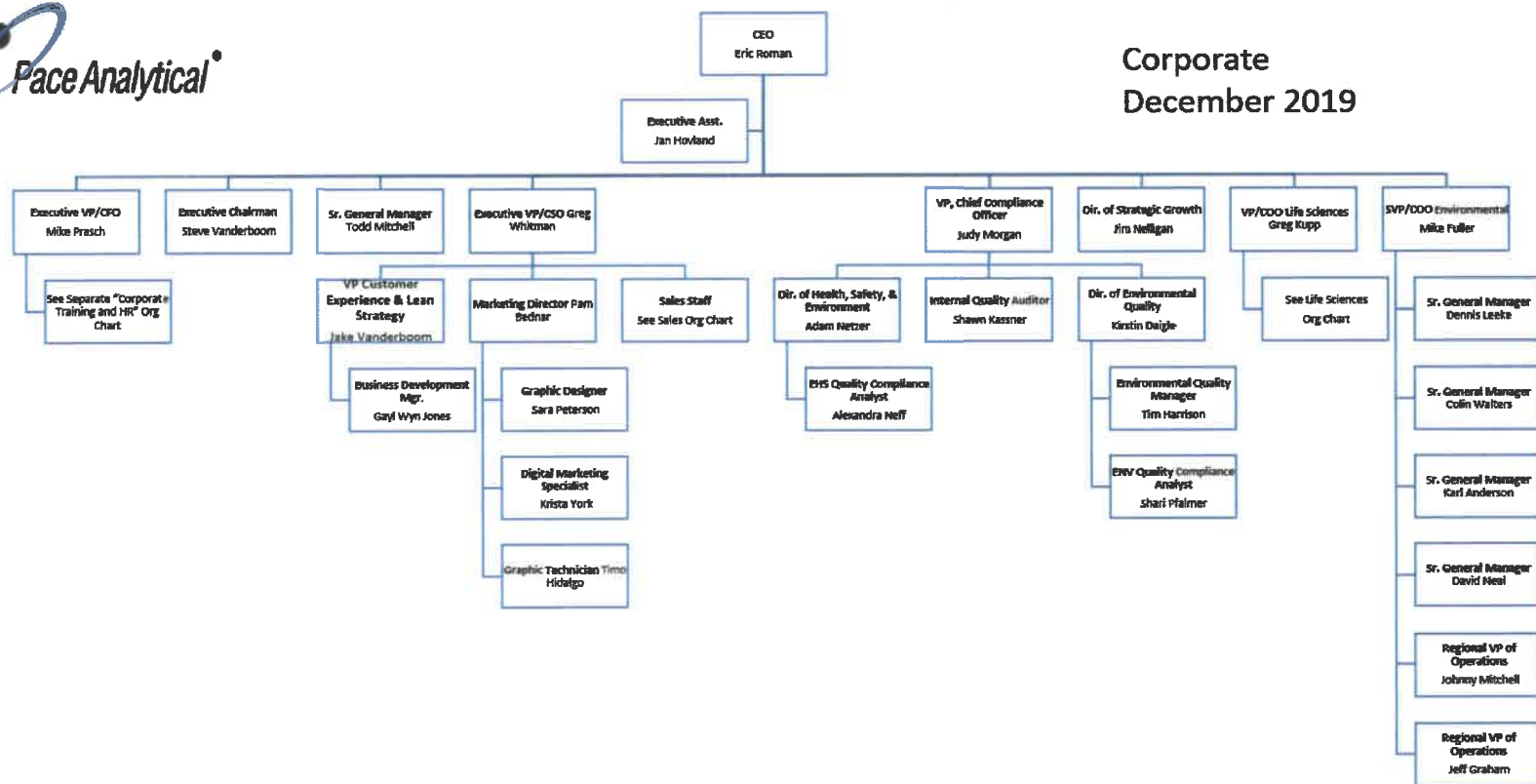


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7.4 Appendix D: Organization Chart(s)

7.4.1 PAS - Corporate





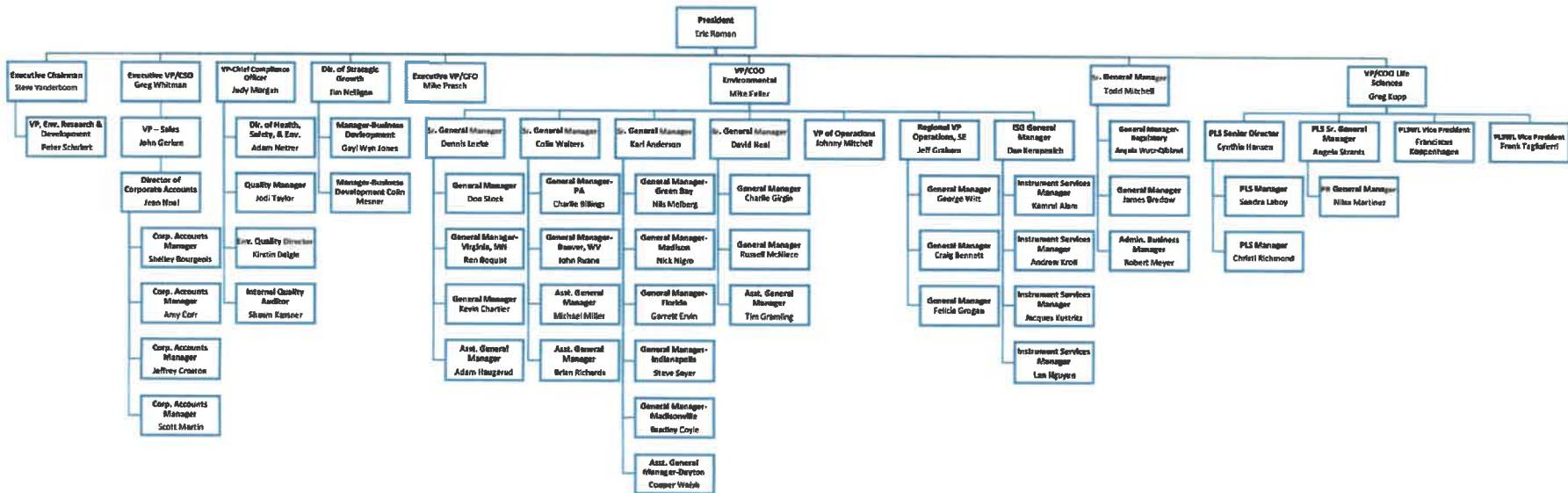
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7.4.2 PAS - Corporate



Management Staff
December 2019





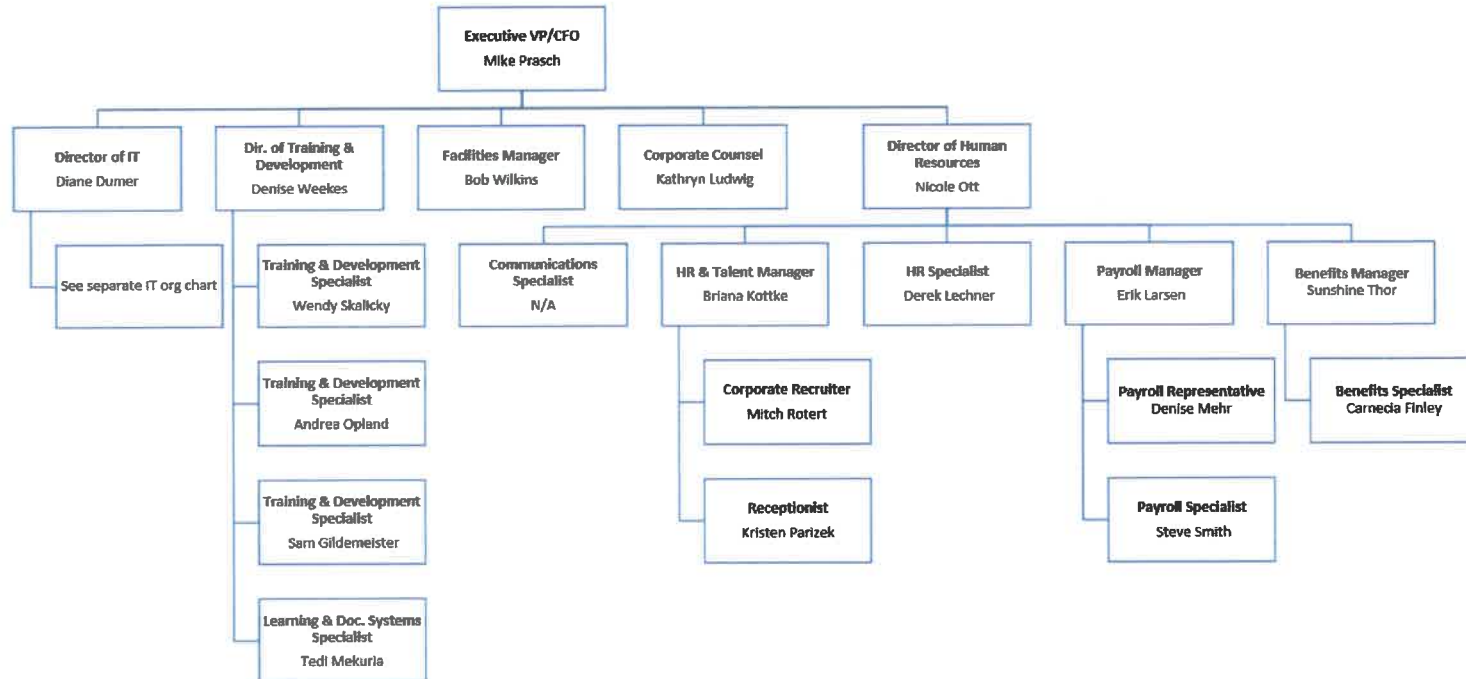
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7.4.3 PAS - Corporate



**Corporate Staff
 Training and HR
 December 2019**

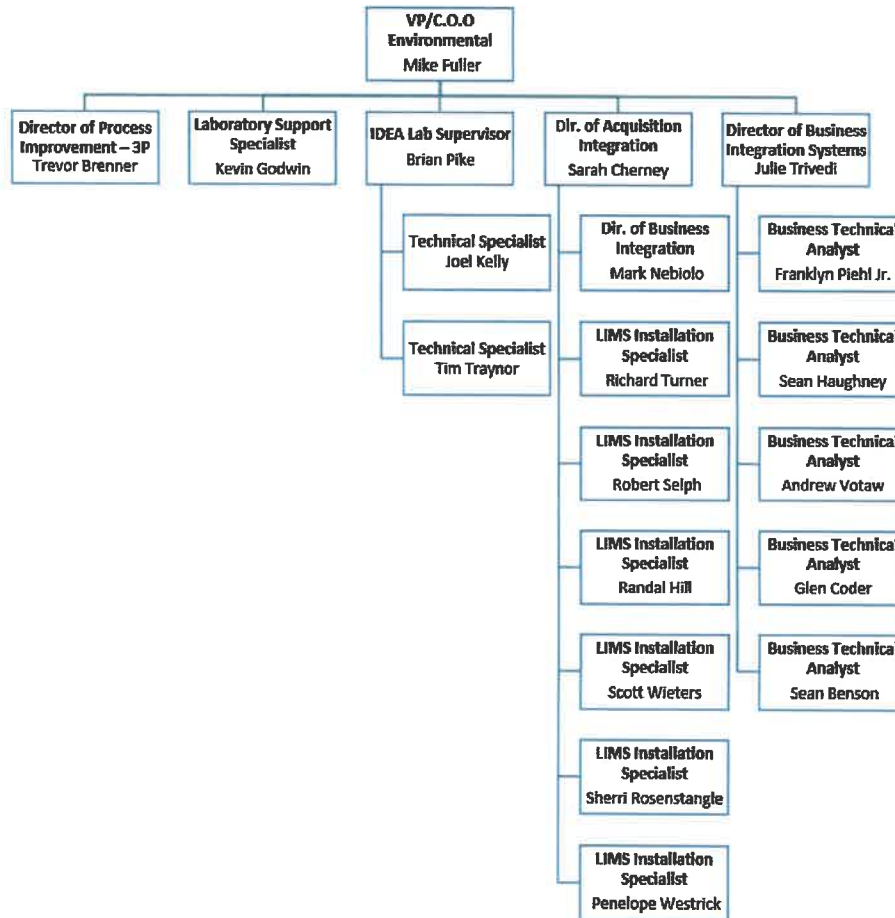




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7.4.4 PAS - Corporate



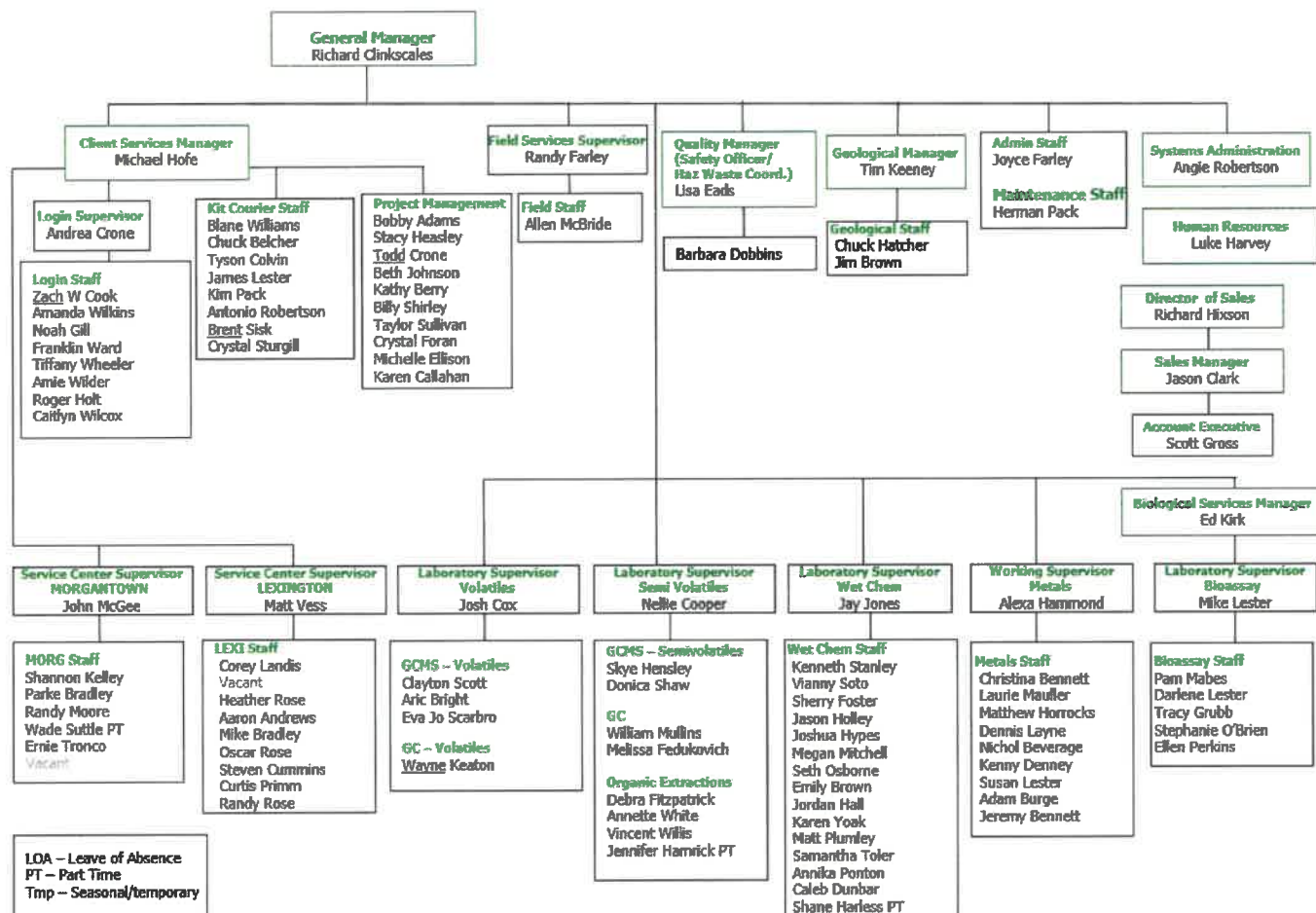
Corporate Staff
ENV Operations
December 2019



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7.4.5 PAS - WV (Beaver, Lexington, Morgantown)



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7.5 Appendix E: Equipment Listing

The equipment listed represents equipment were held by each location on the effective date of this manual. This information is subject to change without notice. External parties should contact the location for the most current information.

7.5.1 PAS - Beaver

Equipment List: PAS-Beaver

Description	Manufacturer	Model	Serial Number	Service Date	Condition	Location	Internal ID	Manual Location
Analyzer, Discrete	Westco	Smartchem 200	W0902153	2009	Used	Wet Lab	73WA06	Instrument
Analyzer, Flow	Lachat	QuikChem 8500	151000001897	2015	Used	Wet Lab	73WA07	Instrument
Analyzer, HGAF	PS Analytical	Millennium Excalibur	231/4749A12769	2008	Used	Metals	73HG03	Instrument
Analyzer, ICP-MS	Agilent	7700X	JP11431358	2012	Used	Metals	73IM01	Instrument
Analyzer, ICP-MS	Agilent	7900	SG19314540	2019	New	Metals	73IM02	Instrument
Analyzer, ICP-OES	Agilent	5100	MY15260010	2016	Used	Metals	73IP03	Instrument
Analyzer, ICP-OES	Agilent	5110	MY19320005	2019	New	Metals	73IP04	Instrument
Analyzer, Mercury	CETAC	M-7500	041104QTA	2011	Used	Metals	73HG01	Instrument
Analyzer, Mercury	CETAC	M-8000	014402QM8	2014	Used	Metals	73HG02	Instrument
Analyzer, Mercury	Teledyne	Hydra II	112-00101-1/4005	2019	New	Metals	73HG04	Instrument
Analyzer, TOC	Tekmar Dohrmann	Phoenix 8000	US01249002	2001	Used	Wet Lab	73WA05	Instrument
Autosampler, 5100	Agilent	SPS-4	AU15190132	2016	Used	Metals	73IP04	Instrument
Autosampler, 7700	CETAC	ASX-500	US101198A520	2012	Used	Metals	73IM01	Instrument
Autosampler, 7900	Agilent	SPS-4	AU19066325	2019	New	Metals	73IM02	Instrument
Autosampler, Excalibur	PS Analytical	20.4	4749A12769	2008	Used	Metals	73HG03	Instrument
Autosampler, M7500	CETAC	ASX-520	041109A520	2011	Used	Metals	73HG01	Instrument
Autosampler, M8000	CETAC	ASX-520	111310A520	2014	Used	Metals	73HG02	Instrument
Chiller, 5100	Agilent	8481A	1A1560062	2016	Used	Metals	73IP03	Instrument
Chiller, 7700	Agilent	G1879B	2D11A1613	2012	Used	Metals	73IM01	Instrument
GC	Hewlett-Packard	6890+	US00024533	1998	Used	SVOA	73GS1A	Instrument
GC	Hewlett-Packard	6890+	US00024533	1998	Used	SVOA	73GS1B	Instrument
GC	Agilent	6890N	CN10431060	2004	Used	SVOA	73GS2A	Instrument
GC	Agilent	6890N	CN10431060	2004	Used	SVOA	73GS2B	Instrument
GC	Hewlett-Packard	5890 Series II	3223A43710	1990	Used	SVOA	73GS3A	Instrument
GC	Hewlett-Packard	5890 Series II	3223A43710	1990	Used	SVOA	73GS3B	Instrument
GC	Hewlett-Packard	5890 Series II	3019A28629	1990	Used	SVOA	73GS5A	Instrument
GC	Hewlett-Packard	5890 Series II	3019A28629	1990	Used	SVOA	73GS5B	Instrument
GC	Agilent	6890+	US00043338	2005	Used	SVOA	73GS6A	Instrument



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GC	Agilent	6890+	US00043338	2005	Used	SVOA	73GS6B	Instrument
GC	Hewlett-Packard	5890 Series II	3133A37645	1996	Used	SVOA	73GS7A	Instrument
GC	Hewlett-Packard	5890 Series II	3133A37645	1996	Used	SVOA	73GS7B	Instrument
GC	Hewlett-Packard	5890 Series II	3308A46965	1992	Used	SVOA	73GS8A	Instrument
GC	Hewlett-Packard	5890 Series II	3308A46965	1992	Used	SVOA	73GS8B	Instrument
GC	Agilent	6890+	US00025299	2011	Used	SVOA	73GS9A	Instrument
GC	Agilent	6890+	US00025299	2011	Used	SVOA	73GS9B	Instrument
GC	Hewlett-Packard	5890 Series II	3303A33205	1991	Used	VOA	73GV03	Instrument
GC	Hewlett-Packard	5890 Series II	32003A41263	1999	Used	VOA	73GV04	Instrument
GC	Hewlett-Packard	5890 Series II	3336A55673	2009	Used	VOA	73GV05	Supervisor Office
GC/MS	Agilent	6890+	US00037590	2003	Used	SVOA	73MS02	Instrument
GC/MS	Agilent	6890+	US00021893	2016	Used	SVOA	73MS03	Instrument
GC/MS	Agilent	7890A	CN10844080	2009	Used	SVOA	73MS04	Instrument
GC/MS	Hewlett-Packard	6890+	US00020797	2017	Used	VOA	73MV01	Supervisor Office
GC/MS	Agilent	6890+	US00038210	2001	Used	VOA	73MV02	Instrument
GC/MS	Agilent	7890A	CN10721037	Unknown	Used	VOA	73MV04	Instrument
GC/MS	Agilent	6890N	CN10403035	Unknown	Used	VOA	73MV05	Instrument
GC/MS	Agilent	7890A	CN10721046	2016	Used	VOA	73MV06	Supervisor Office
IC	Dionex	ICS2000	6060369	2006	Used	Wet Lab	73WA02	Disc
IC	Dionex	ICS2100	10091223	2010	Used	Wet Lab	73WA03	Disc
IC	Dionex	ICS5000	12042016	2012	Used	Wet Lab	73WA04	Disc
Meter, Chlorine	Hanna	H1 96781	H0293621	Unknown	Used	Bioassay	73WT22	Server
Meter, Chlorine	HACH	Pocket Colorimeter II	07080E077089	Unknown	Used	Wet Lab	73WT13	Server
Meter, Conductivity	Hanna	Edge	C0122154	Unknown	Used	Bioassay	73WT23	Server
Meter, Conductivity	Orion	105	1129	Unknown	Used	Bioassay	73WT24	Supervisor Office
Meter, Conductivity	Oakton	CON 510	1582842	2010	Used	Wet Lab	73WT14	Server
Meter, DO	HACH	HQ40d	120700075963	Unknown	Used	Bioassay	73WT25	Server
Meter, DO	HACH	HQ40d	70400008461	Unknown	Used	Wet Lab	73WT09	Server
Meter, DO	HACH	HQ40d	110400054688	Unknown	Used	Wet Lab	73WT10	Server
Meter, DO	HACH	HQ40d	140300101142	2014	Used	Wet Lab	73WT11	Server
Meter, DO	HACH	HQ40d	180200002687	2018	Used	Wet Lab	73WT12	Server
Meter, pH	Oakton	pH 100	12559	Unknown	Used	Bioassay	73WT26	Server
Meter, pH	Oakton	pH700	2709420	Unknown	Used	Bioassay	73WT27	Server
Meter, pH	Orion	520A	10889	Unknown	Used	Metals	73WT16	Server
Meter, pH	Orion	720A	44584	Unknown	Used	Wet Lab	73WT01	Server
Meter, pH	Oakton	pH 150	2489253	2016	Used	Wet Lab	73WT02	Server
Meter, pH	Oakton	pH 11	524243	Unknown	Used	Wet Lab	73WT03	Server



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Microwave	CEM	MARS 6	MJ9797	2019	New	SVOA	73MW01	Instrument
Spectrometer	Thermo	Genesys 10S	2L6N176001	2015	Used	Wet Lab	73WT05	Server
Spectrometer	Thermo	Helios Gamma	UVG112025	2003	Used	Wet Lab	73WT08	Instrument
Titration	Schott	D65719	441895	2002	Used	Wet Lab	73WA08	Supervisor Office
Titration	Schott	D65720	441894	2002	Used	Wet Lab	73WA09	Supervisor Office
Titration	Schott	D65719	445628	2011	Used	Wet Lab	73WA10	Supervisor Office
Turbidimeter	HACH	2100AN	990800002052	Unknown	Used	Wet Lab	73WT55	Server