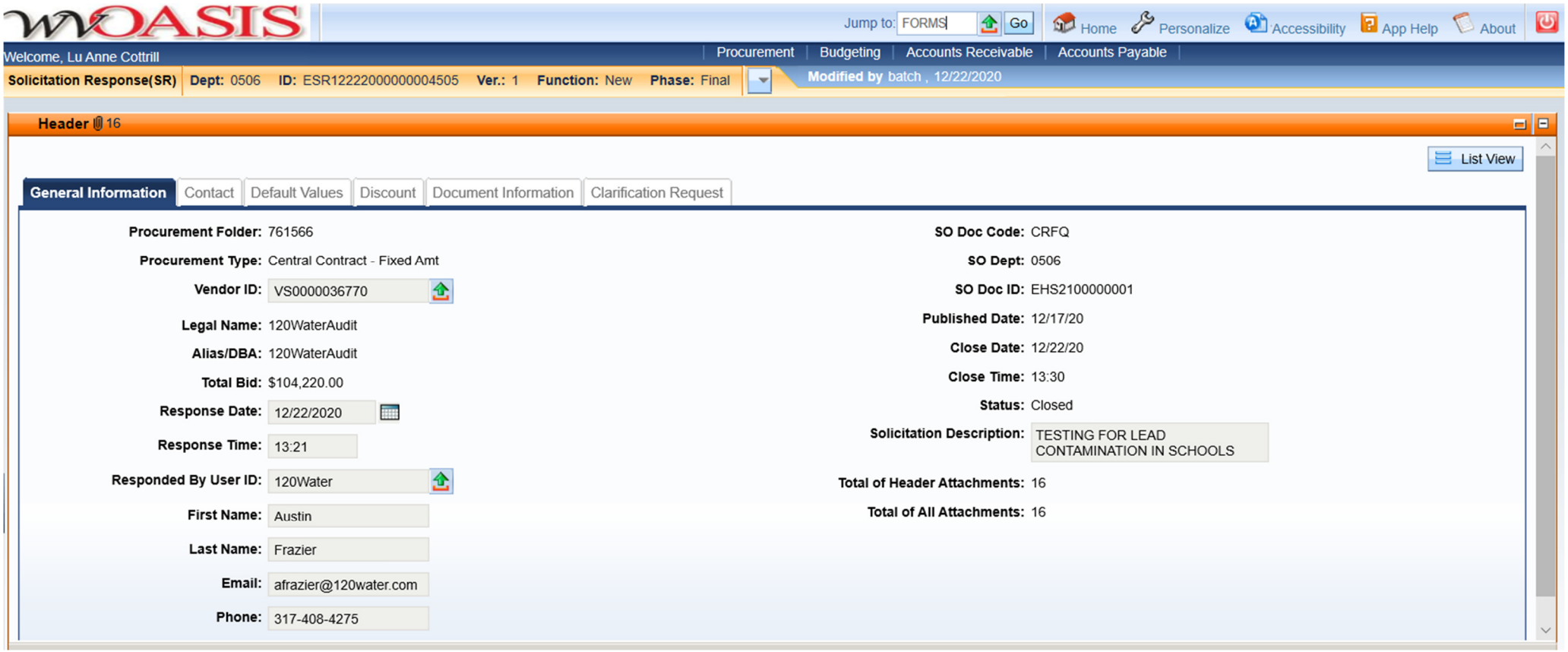
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency 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.


wvOASIS
Jump to: FORMS Go
Home
Personalize
Accessibility
App Help
About
Welcome, Lu Anne Cottrill
Procurement | Budgeting | Accounts Receivable | Accounts Payable
Solicitation Response(SR) Dept: 0506 ID: ESR12222000000004505 Ver.: 1 Function: New Phase: Final
Modified by batch , 12/22/2020
Header 16
List View
General Information
Contact
Default Values
Discount
Document Information
Clarification Request
Procurement Folder: 761566
Procurement Type: Central Contract - Fixed Amt
Vendor ID: VS0000036770
Legal Name: 120WaterAudit
Alias/DBA: 120WaterAudit
Total Bid: $104,220.00
Response Date: 12/22/2020
Response Time: 13:21
Responded By User ID: 120Water
First Name: Austin
Last Name: Frazier
Email: afrazier@120water.com
Phone: 317-408-4275
SO Doc Code: CRFQ
SO Dept: 0506
SO Doc ID: EHS2100000001
Published Date: 12/17/20
Close Date: 12/22/20
Close Time: 13:30
Status: Closed
Solicitation Description: TESTING FOR LEAD CONTAMINATION IN SCHOOLS
Total of Header Attachments: 16
Total of All Attachments: 16

Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Solicitation Response

Proc Folder:	761566
Solicitation Description:	TESTING FOR LEAD CONTAMINATION IN SCHOOLS
Proc Type:	Central Contract - Fixed Amt

Solicitation Closes	Solicitation Response	Version
2020-12-22 13:30	SR 0506 ESR12222000000004505	1

VENDOR

VS0000036770
120WaterAudit

Solicitation Number: CRFQ 0506 EHS2100000001

Total Bid: 104220 **Response Date:** 2020-12-22 **Response Time:** 13:21:40

Comments:

FOR INFORMATION CONTACT THE BUYER
Crystal G Hustead
(304) 558-2402
crystal.g.hustead@wv.gov

Vendor
Signature X **FEIN#** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Contractor to provide cloud-based software/ platform				13570.00

Comm Code	Manufacturer	Specification	Model #
60104202			

Commodity Line Comments: Please reference the attached document for program specifics to this line: EHS2100000001 - Submission Doc

Extended Description:

Spec 4.1.1 - Contractor to provide cloud-based software/platform
Estimated Annual Quantity: 1
Unit Price x Estimated Quantity=Total Price

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Managing the cloud-based software/platform				0.00

Comm Code	Manufacturer	Specification	Model #
60104202			

Commodity Line Comments: This is included in SPEC 4.1.1 - Contractor to provide cloud-based software/platform

Extended Description:

Managing the cloud-based software/platform
Estimated Annual Quantity: 1
Unit Price x Estimated Quantity=Total Price

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Provide Test Kits and Sample Analysis				57150.00

Comm Code	Manufacturer	Specification	Model #
60104202			

Commodity Line Comments: Please reference the attached document for program specifics to this line: EHS2100000001 - Submission Doc

Extended Description:

Spec 4.1.3 - Provide Test Kits and Sample Analysis
Estimated Annual Quantity: 1905
Unit Price x Estimated Quantity=Total Price

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Provide training, consultation, and remediation services				33500.00

Comm Code	Manufacturer	Specification	Model #
60104202			

Commodity Line Comments: Please reference the attached document for program specifics to this line: EHS2100000001 - Submission Doc

Extended Description:

Spec 4.1.4 - Provide training, consultation, and remediation services
Estimated Annual Quantity: 80
Unit Price x Estimated Quantity=Total Price

SOLICITATION NUMBER: CRFQ EHS2100000001
Addendum Number: 2

The purpose of this addendum is to modify the solicitation identified as **CRFQ EHS2100000001** ("Solicitation") to reflect the change(s) identified and described below.

Applicable Addendum Category:

[ ] Modify bid opening date and time

[X] Modify specifications of product or service being sought

[X] Attachment of vendor questions and responses

[ ] Attachment of pre-bid sign-in sheet

[ ] Correction of error

[ ] Other-

Additional Documentation: This addendum is to provide modifications to the specification and to answer vendor questions. No other changes.

Terms and Conditions:

1. All provisions of the Solicitation and other addenda not modified herein shall remain in full force and effect.

2. Vendor should acknowledge receipt of all addenda issued for this Solicitation by completing an Addendum Acknowledgment, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

To revise **General Terms and Conditions** 3. CONTRACT TERM; RENEWAL; EXTENSION

From: Initial Contract Term: Initial Contract Term: This Contract becomes effective on award and extends for a period of one (1) year(s).

To: Initial Contract Term: Initial Contract Term: This Contract becomes effective on award and extends for a period ending September 30, 2021.

To revise **Commodity Line 3** - Specification 4.1.3 – Provide Test Kits and Sample Analysis

From: Spec 4.1.3 - Provide Test Kits and Sample Analysis
Estimated Annual Quantity: 44
Unit Price x Estimated Quantity=Total Price

To: Spec 4.1.3 - Provide Test Kits and Sample Analysis for each of the 80 School/Daycare facilities
Estimated Annual Quantity: Estimated at 1,905 Test Kits and sample analysis as determined by facility specific sample plans. This includes an estimated average 20 test kits and analysis per facility with additional flush samples collected at 10% of the sample locations per facility and an additional 145 test kits and analysis for re-sampling.
Unit Price x Estimated Quantity=Total Price

To revise **Commodity Line 4** - Specification 4.1.4 – Provide training, consultation, and remediation services

From: Spec 4.1.4 - Provide training, consultation, and remediation services
Estimated Annual Quantity: 24
Unit Price x Estimated Quantity=Total Price

To: Spec 4.1.4 - Provide training, consultation, and remediation services
Estimated Annual Quantity: 80
Unit Price x Estimated Quantity=Total Price

To ***remove*** **Commodity Line 5** - Specification 4.1.1 – Contractor to provide cloud-based software/platform

Spec 4.1.1 – Contractor to provide cloud-based software/platform – year 2
Estimated Annual Quantity: 1
Unit Price x Estimated Quantity=Total Price

To ***remove*** **Commodity Line 6** - Specification 4.1.1 – Managing the cloud-base software/platform

Spec 4.1.1 – Managing the cloud-base software/platform– year 2
Estimated Annual Quantity: 1
Unit Price x Estimated Quantity=Total Price

To ***remove*** **Commodity Line 7** - Specification 4.1.3 – Provide Test Kits and Sample Analysis

Spec 4.1.3 - Provide Test Kits and Sample Analysis
Estimated Annual Quantity: 101
Unit Price x Estimated Quantity=Total Price

To ***remove*** **Commodity Line 8** - Specification 4.1.4 – Provide training, consultation, and remediation services

Spec 4.1.4 - Provide training, consultation, and remediation services
Estimated Annual Quantity: 56
Unit Price x Estimated Quantity=Total Price

Question 1: **4.1.1** What level of end user interaction is required with the cloud-based platform? (i.e. live data vs static pages updated daily/weekly/monthly)

Answer 1: A static page updated weekly

Question 2: **4.1.1.4, 4.1.1.7, 4.1.2.3, 4.1.2.4, 4.1.4.2, 4.1.5.1, 4.1.5.2** What is the scope of requirement under this contract for Vendor required lead reduction and remediation at participating facilities?

Answer 2: The vendor can provide guidance for lead reduction and remediation under the USEPA's 3T's guidance, however, this grant will not cover the cost for the vendor nor the facilities to implement lead reduction or remediation.

Question 3: What is the projected schedule of performance?

Answer 3: The project period ends on September 30, 2021 with an optional 1 one-year renewal.

Question 4: In Section 3 Qualifications, it states "Vendor or Vendor's staff if requirements are inherently limited to individuals rather than corporate entities, shall have the following minimum qualifications with proof to be provided prior to award" How does the WVPD want the vendors to provide proof of qualifications and prior experience for the listed qualifications?

Answer 4: The vendor should provide details of past projects, including sample plans, sample collections, and strategy for communicating results that focused on environmental sampling and creating/maintaining cloud-based software databases.

Question 5: In Section 4 Mandatory Requirements, it states "Contract Services must meet or exceed the mandatory requirements listed below" How does the WVPD want the vendors to provide detail on how the requirements would be met or exceeded?

Answer 5: The agency wants to be able to view and/or have limited access to a development or existing cloud-based system that the vendor has created and maintained in order to verify functionality and that it meets the requirements listed. The vendor should also provide an example of a communication plan for a previous project. The vendor should provide a list of laboratories that are certified by WV or have reciprocity in WV. Vendor should provide example training materials and communication strategies to verify capabilities under the training and taking action sections.

Question 6: On the WVOASIS Portal, Solicitation Commodity Lines, Response to Lines, Line Number 3, Spec 4.1.3 – Provide Test Kits and Sample Analysis Estimated Annual Quantity: 44 Unit Price x Estimated Quantity = Total Price. Does the Annual Quantity of 44 units represent the number of 250ml sample kits with included analysis?

Answer 6: No. **See Revision to Commodity Line 3. The revised quantity is 1,905 total sample kits and analysis during the contract period**. It is estimated that each school will require approximately 20 sample kits and analysis with additional flush samples collected at 10% of the sample sites for each of the 80 facilities. There are also 145 additional sample kits and analysis included for additional sites or resampling that may be required due to elevated sample results. The program was designed to sample for lead at all water fixtures used by children ages 6 or less for drinking or cooking after a stagnation period at 80 facilities with flush samples collected at 10% of the fixtures.

Question 7: On the WVOASIS Portal, Solicitation Commodity Lines, Response to Lines, Line Number 4, Spec 4.1.4 – Provide training, consultation, and remediation services Estimated Annual Quantity: 24 Unit Price x Estimated Quantity = Total Price. Does the Annual Quantity of 24 units represent the number of facilities to provide training, consultation and remediation services for?

Answer 7: Yes, but see **Revision to Commodity Line 4.** All 80 facilities will need to receive training, consultation, sampling according to facility specific plans, and remediation guidance during the contract period.

Question 8: On the WVOASIS Portal, Solicitation Commodity Lines, Response to Lines, Line Number 7, Spec 4.1.3 – Provide Test Kits and Sample Analysis Estimated Annual Quantity: 101 Unit Price x Estimated Quantity = Total Price. Does the Annual Quantity of 101 units represent the number of 250ml sample kits with included analysis?

Answer 8: No. **See Revision to Commodity Line 3. The revised quantity is 1,905 total sample kits and analysis during the contract period**. It is estimated that each school will require approximately 20 sample kits and analysis with additional flush samples collected at 10% of the sample sites for each of the 80 facilities. There are also 145 additional sample kits and analysis included for additional sites or resampling that may be required due to elevated sample results. The program was designed to sample for lead at all water fixtures used by children ages 6 or less for drinking or cooking after a stagnation period at 80 facilities with flush samples collected at 10% of the fixtures.

Question 9: On the WVOASIS Portal, Solicitation Commodity Lines, Response to Lines, Line Number 8, Spec 4.1.4 – Provide training, consultation, and remediation services Estimated Annual Quantity: 56 Unit Price x Estimated Quantity = Total Price. Does the Annual Quantity of 56 units represent the number of facilities to provide training, consultation and remediation services for?

Answer 9: **Yes.** but see **Revision to Commodity Line 4.** All 80 facilities will need to receive training, consultation, sampling according to facility specific plans, and remediation guidance during the contract period.

Question 10: How many schools, and how many child care facilities are eligible to participate in the program, and how many of each are expected to participate in the program?

Answer 10: There are 363 Elementary schools, 331 Headstart and Early Headstart facilities, and 442 child care facilities in WV. This is a total of 1,136 potentially eligible sites. Since this is a voluntary program, participation will be determined through an application process.

Question 11: What is the anticipated program timeline: start date, and target completion date?

Answer 11: The project period is October 1, 2019 to September 30, 2021with an optional 1 one-year renewal.

Question 12: Does the state intend to expand the program longer term, or to additional facilities beyond the initial program scope?

Answer 12: If additional funds become available, WV would consider expanding the program.

Question 13: How many schools and/or child care facilities are anticipated to be included in the scope of work in the year 1? If renewed for a second year, how many schools and/or child care facilities are anticipated to be included in the scope of work in year 2?

Answer 13: We anticipate 80 schools and/or daycare facilities to be included in the scope of work during the project period.

Question 14: How many samples are anticipated to be collected on an annual basis?

Answer 14: Each target facility will need to have a facility specific sample plan designed to sample all taps used by children 6 years and under for

drinking and cooking purposes after a stagnation period. Flush samples will also be collected at 10% of those taps. Additional samples may also be required for taps with elevated results. Samples are anticipated to be collected at 80 facilities.

Question 15: How many samples are anticipated to be included in the scope of work in year 1? If renewed for a second year, how many samples are anticipated to be included in the scope of work in year 2?

Answer 15: Each target facility will need to have a facility specific sample plan designed to sample all taps used by children 6 years and under for drinking and cooking purposes after a stagnation period. Flush samples will also be collected at 10% of those taps. Additional samples may also be required for taps with elevated results. Samples are anticipated to be collected at 80 facilities.

Question 16: Does the State prefer that the awardee provide onsite sample collection services, or remote training to existing facility personnel? If neither method is preferred over the other, how will the State determine which option best suits the program?

Answer 16: Remote training to existing personnel is the preferred method.

Question 17: Would the State consider working with multiple bidders for the project if determined to be in the best interest of the program?

Answer 17: No. One vendor will be responsible for the whole project.

Question 18: How will the evaluation team determine a cost score? Is West Virginia a low bid State?

Answer 18: The procurement method utilized for this solicitation is Request for Quotation. The contract will be awarded to the lowest responsible bidder meeting all mandatory requirements listed in the specifications.

Question 19: Is the State open to accepting alternative cost structure proposals, if it benefits the State, and is a proven model in other states?

Answer 19: No.

Question 20: Testing that will be provided for the schools and/or child care facilities, will there be an anticipated percentage of taps that will require additional sampling (e.g. follow-up flush sampling)?

Answer 20: Each facility will have follow-up flush sampling at 10% of their sampled sites. The budget also allows for 145 additional samples as needed for additional sites and/or re-sampling at taps with elevated results.

Question 21: Does the Primary Agency have a specific list of schools and/or facilities that will be selected or enrolled in the program?

Answer 21: There are 363 Elementary schools, 331 Headstart and Early Headstart facilities, and 442 Daycare facilities in WV. This is a total of 1,136 potentially eligible sites. Since this is a voluntary program, participation will be determined through an application process.

Question 22: Will the selected Vendor be responsible for enrollment coordination? If so, can you explain the ideal enrollment processes?

Answer 22: No. The state agency will set up an application process and determine eligibility.

Question 23: Are there specific certifications beyond EPA Method 200.8 that must be met regarding the selected laboratory whom of which will be analyzing the collected water samples?

Answer 23: WV state certified laboratory or another state that has lab certification reciprocity with WV.

Question 24: Is there a preferred laboratory for sample analysis?

Answer 24: WV state certified laboratory or another state that has lab certification reciprocity with WV.

Question 25: Would the amount of sample bottles be equal to the estimated quantity of the kits?

Answer 25: The amount of sample bottles required will be determined based on specifically designed sample plans for each of the 80 facilities. The vendor will work with each facility to design a sample plan and determine the amount of samples required.

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ EHS2100000001

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)

[ ]	Addendum No. 1	[ ]	Addendum No. 6
[x]	Addendum No. 2	[ ]	Addendum No. 7
[ ]	Addendum No. 3	[ ]	Addendum No. 8
[ ]	Addendum No. 4	[ ]	Addendum No. 9
[ ]	Addendum No. 5	[ ]	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 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.

120Water
Company

Authorized Signature

12/17/2020
Date

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

In Response To:

Testing for Lead Contamination in Schools
EHS2100000001

Submission To:

Department of Administration
Purchasing Division
2019 Washington Street, East
Charleston, West Virginia 25305-0130

Response Submitted By:

120 Water Audit, Inc.
250 S Elm St
Zionsville, IN 46077

Primary Contact:

Logan Turner
Senior Account Executive
765.618.1222
logan@120wateraudit.com
December 14, 2020

120Water

Table of Contents

120Water

1.0 Project Description

120 Water Audit, Inc under OEHS, will offer educational material concerning lead in drinking water and testing for lead contamination in drinking water at approximately 80 facilities.

120 Water Audit, Inc is utilizing EPA's 3Ts guidance to implement the Collaborative Action for Testing H2O Initiative (the Initiative). This includes efforts to (1) Communicate, throughout the implementation of the program, the results and important lead information to facility administration, parents, teachers, and interested community action groups; (2) Train on the risks of lead in drinking water and testing for lead; (3) Test using appropriate testing protocols and a certified laboratory; and (4) Take Action, including the development of a plan for responding to results of testing conducted and making recommendations for potential elevated lead where necessary.

With the Implementation of 120 Water Audit, Inc's Cloud-Based Software, Tech Enabled Sample Kits and Programmatic Services, 120 Water Audit, Inc will work to meet and surpass the key objectives determining the lead concentration by analyzing 1,905 samples at drinking water fixtures within the enrolled 80 OEHS facilities. Facility partners will also gain greater awareness for monitoring for presence of lead in drinking water at their facility.

If a drinking water test returns a result for a lead equal to or exceeding 15 ppb, then the remediation technician will direct the facility partner to isolate the source of drinking water through appropriate and approved actions. If a facility partner enrolls in the program they will have access to all sample data and will have the necessary resources to properly and effectively communicate with the community.

120Water

1.1 Cover Letter

Logan Turner
Senior Account Executive
120 Water Audit, Inc.
250 S Elm St
Zionsville, IN 46077

December 14, 2020

Crystal G Hustead
Department of Administration
Purchasing Division
2019 Washington Street, East
Charleston, West Virginia 25305-0130

To Crystal and the entire West Virginia Team:

It is with great excitement that 120 Water Audit, Inc. submits our proposal for *Testing for Lead Contamination in Schools.* Managing drinking water programs can be highly complex and cumbersome. 120 Water Audit, Inc. is on a mission to help state governments, public and private utilities, and facilities streamline these programs, making them clear and simple, for everyone involved, from agency personnel to members of the community.

Our technology, services, and partnerships are purpose-built to simplify the process of ongoing compliance and voluntary sampling programs, such as lead testing in school and childcare facilities. For statewide programs or individual facilities, the 120 Water Audit, Inc's Digital Water Platform scales to meet the evolving needs of our customers. We are confident that the State of West Virginia will be able to build and maintain a model Lead Testing in Schools and Child Care Facilities on the 120 Water Audit, Inc foundation, based on the successes with similar programs with clients such as The Indiana Finance Authority, The State of South Dakota, Chicago Public Schools, Chicago Department of Children and Family Services (Daycares), The State of New Hampshire, Maryland Department of Environment, and Pittsburgh Water & Sewer Authority.

120 Water Audit, Inc. is a privately held, venture-backed, national firm, founded in March 2016 in Indianapolis, IN.Company operations are overseen by Megan Glover, CEO and Co-founder, and supported by six executive department leaders. The majority of 120 Water Audit, Inc's 38 employees are based in the principal place of business of Indianapolis, IN headquarters, with a small concentration of services team members based in Pittsburgh, PA. The executive leadership team, investors, and board members have deep roots in environmental consulting, high growth technology companies, logistics, and

water quality and infrastructure. 120 Water Audit, Inc is a non-resident vendor certified as a small business under W. Va. CSR 148-22-9. 120 Water Audit, Inc, will furnish proof of the insurance identified on the Solicitation Terms and Conditions Document upon contract award.

We've spent countless hours alongside state and municipal agencies, utilities, and facilities providing high-value technology and services to efficiently manage drinking water voluntary and compliance programs. These solutions, developed in partnership with customers and industry thought leaders, are founded on a deep understanding of the public health and cost impact to these organizations, and consumers. Lead testing in school and childcare facility initiatives are highly sensitive and involve many stakeholders, from state agencies to school staff, parents, and children. We are committed to empowering this team to effectively communicate and manage all elements of your Lead Testing in Schools and Child Cares program in a thoughtful and efficient manner, consistent with our established track record of success partnering with other state agencies across the country to implement a 3Ts based program, founded on the guidance provided by the US EPA.

120 Water Audit, Inc's solution includes the development and implementation of West Virginia's Testing for lead contamination in schools outreach campaign and educational materials, collaboration with childcare facility operators to create sample plans, step-by-step water sampling instructions and protocol for the collection of water samples, sample kit logistics to and from childcare facility program participants, completion of the chain of custody, technical guidance for the childcare facility operators, communication strategy for conveying sampling results and a remediation resource guide for childcare facility participants and corresponding reports and program progress reports to all stakeholders.

120 Water Audit, Inc supplements our technology, logistics, and consulting services with a broad network of national, regional, and local services partnerships including West Virginia State Certified laboratories. We have received commitments from our lab partners that they are willing and able to perform the sample analysis work in accordance with the work plan and volume.

120 Water Audit, Inc will manage all communications, logistics, and reporting related to sampling kits and laboratory analysis within the 120 Water Audit, Inc Digital Water Platform. 120 Water Audit, Inc's cloud-based software will
store all data and documents generated from the project including sampling chain of custody, consent to participate, and all other documentation required by the project work plan. Additionally, 120 Water Audit, Inc's solution tracks actions completed including training courses, educational materials, program-specific mailers, and outreach activities conducted to encourage and increase participation in the project while tracking outputs and outcomes of actions taken.

120 Water Audit, Inc's Digital Water Platform will collect any other data requested in the project work plan and grant agreement. Access to the cloud base software will be available to users specified by West Virginia Department of Administration, and user accounts with permissions to view, edit, and export certain data may be filtered according to the user and/or user account type. Stakeholders will have access to generating standard and customizable reports per the request of West Virginia Department of Administration to meet the requirements of the work plan and grant agreement.

120Water

Leveraging the combined domain expertise of 120 Water Audit, Inc running these programs at scale, we trust you'll find our solution and unified team approach to tackling your program building blocks - data management, planning, logistics, sampling, and communication - one that provides not only a superior model program but also one that is thoughtful, cost-effective and built with long-term sustainability in mind. Throughout the duration of the project, 120 Water Audit, Inc's Digital Water Platform will facilitate access to the West Virginia Department of Administration annual progress report, and a final project report that meets the requirements outlined in the grant agreement.

120 Water Audit, Inc's proposed solution for the project meets all the requirements of this RFP.

This response was prepared by:

Megan Glover, Co-Founder & CEO
Antony Rhine, VP of Sales
Laura Breedlove, VP of Technology
Ali Roach, VP of Marketing
Abby Warner, VP of Client Success
Erica Walker, Director of Policy & Programs
Sarah Young, Director of Sales
Logan Turner, Senior Account Executive

Logan Turner, Senior Account Executive is the main point of contact, representing 120 Water Audit, Inc., and has the authority to answer questions regarding this proposal. Logan's information is listed below.

We thrive on the trust and consultative relationships we build with our clients and look forward to the opportunity to support the State of West Virginia in building a scalable program that works for your facilities and communities.

Respectfully,

Contract Manager:

Logan Turner
Senior Account Executive
765.618.1222
logan@120water.com
Fax Number: N/A
250 S Elm St
Zionsville, IN 46077

1.2 Distribution List

The following is a list of organizations who will partake in the coordination of this program:

Primary:

West Virginia Office of Environmental Health Services
Capitol and Washington Streets, Suite 20
Charleston, WV 25301-1798

West Virginia Department of Health and Human Resources
One Davis Square, Suite 100 East
Charleston, West Virginia 25301

120WaterAudit, Inc
625 S. Main St
Zionsville, IN 46077

Eurofins/ Eaton
110 S. Hill St.
South Bend, IN 46617

Secondary, if needed or advised by the state

CWM Environmental
101 Parkview Drive Extension
Kittanning, PA 16201

State of West Virginia preferred Laboratory

120Water

1.3 120 Water Audit, Inc Qualification

120 Water Audit, Inc has developed and implemented 4 statewide sampling programs, and additional municipal and individual school district programs across the country focused on both schools and child care facility programs. We anticipate launching or expanding at least 10 additional statewide programs for lead in facilities testing programs in 2020 and 2021 in accordance with the WIIN Grant. Current 120 Water Audit, Inc customers have consistently renewed and expanded their contracts with 120 Water Audit, Inc due to the positive outcomes and experiences they have had implementing our program methodology.

120 Water Audit, Inc has more than three years of prior experience in administering lead testing in drinking water programs. 120 Water Audit, Inc has the ability to assist the state in developing a lead testing in drinking water school strategy that supports robust training, monitoring, and maintenance plan that protects children from lead exposure now and in the future. 120 Water Audit, Inc has more than three years of experience creating and maintaining a cloud-based software database, communication strategies for sampling planning, sample collection and conveying sample results. 120 Water Audit, Inc has more than three years of working with external laboratories analyzing lead in drinking water using EPA method 200.8.

Use of the 120 Water Audit, Inc platform will allow OEHS to support the management and planning of sampling at each facility, connect and communicate with all stakeholders in the program, from facility personnel to parents, and access to future product enhancements purpose built to support lead in school and child care facility testing programs.

120 Water Audit, Inc has been planning, executing, and managing statewide lead testing programs for over 3 years. The following five projects exemplify state wide, municipal, and district level programs that required a similar products and services to those of WV requested scope:

1. The Indiana Finance Authority
2. The City of Chicago Public Schools
3. The State of Maryland, Department of the Environment
4. The City of Chicago, Department of Family & Shared Services
5. State of South Dakota, Department of Environmental and Natural Resources

1. In 2017, The Indiana Finance Authority (IFA) used 120 Water Audit, Inc's software, kits and services to manage the execution of a state-wide lead testing in schools program, collecting 57,000 total samples across 915 schools, gaining data insights and executing effectively at scale.

   120 Water Audit, Inc helped IFA launch and maintain state-wide lead sampling in schools program assisted at all program levels, including communication plans for voluntary testing;

coordination with populations at high risk of lead exposure; coordination and work with accredited labs to analyze sample; and compliance with federal and state reporting requirements, project schedules, etc.

Through 120 Water Audit, Inc's solution, IFA was able to use software to manage program at scale, including sample kit ordering and integrated lab analysis, and deliver quick remediation decisions when fixtures exceed action levels via software.

By the end of 2019, the IFA reported these accomplished goals:
- Over 57,000 sample collected
- Audit trail for each fixture and sample
- Communications to regulators and public stakeholders achieved
- Standardized testing & reporting increased confidence in data

2. In 2018, the City of Chicago Public Schools (CPS) tapped 120 Water Audit, Inc to run their water quality testing in schools, using the software to manage the planning, testing and distribution of results data. They had a goal of testing 526 school campuses between then, and 2022.

   The program had an emphasis on school testing scheduling and distribution of results, mitigation management and tracking, and ease of access to program dashboards and sample results data.

   Using 120 Water Audit, Inc, CPS has drastically reduced the time required to schedule sample events, create documentation, collect and log samples, and distribute results. 120 Water Audit, Inc has become the single source for all testing program data.

3. Maryland passed a new law in 2017 that required schools to test for lead in their drinking water. The law said that any drinking water fixture with readings above 20.5 ppb must be remediated. The Maryland Department of the Environment (MDE) tried to implement this program using Excel spreadsheets and forms that schools filled out, signed, and either mailed or faxed to MDE.

   Swimming in paperwork and data, MDE hired 120 Water Audit, Inc in mid-2018 to import its historical data and give them a software solution that would better track, utilize and report data. A specific challenge of the MDE project is that each school was responsible for developing its sample plan without specific training on the regulations. Also, each school could select its lab partner, meaning the 120 Water Audit, Inc software must be adapted to receive results from several labs at once while still enforcing the sampling program's quality constraints.

Thus, management of historical data was imperative. 120 Water Audit, Inc partnered to clean, format, and import historical results into 120 Water Audit, Inc's software. We then developed training materials to teach schools how to use the software – and the highlights of the program's requirements.

The program is on-going, but to date we have:
- Assisted schools and their labs with formatting results to fit the program.
- Simplified access for schools to track remediation efforts.
- Incorporated MDE's forms into the software so the process is paperless
- Currently tracking more than 2,275 school facilities and nearly 67,000 sample results

4. City of Chicago, Department of Family & Shared Services came to 120 Water Audit, Inc with Legislation requiring the testing of water in daycares in the City of Chicago. They only had three and a half months to test and identify short- and long-term remediation for an initial 230 daycare facilities, with expanded testing of up to 2,000. With a short timeframe, and synchronization across facilities management, field collectors and lab coordination, there was no room for error.

   120 Water Audit, Inc's Platform, the sampling protocol was standardized and workflows automated to ensure timely sampling and remediation activities were not only executed but tracked and each step of the way. Globetrotters Engineering Corporation, the contractor of the Chicago daycare facilities, employed a team of field sampling staff. The 120 Water Audit, Inc Client Success Manager trained and managed the team and project using 120 Water Audit, Inc's kits and software.

   For near-term remediation, when sample results were above the action limit, 120 Water Audit, Inc automatically triggered the fulfillment of a ZeroWater pitcher filter and six-month quantity of filters. Following the initial six-month supply, triggered notifications drive additional fulfillment of additional filters for drop-ship delivery as necessitated by the program. - The 120 Water Audit, Inc commercial off-the-shelf solution ensured the program could be implemented and executed at a speed that is impossible to achieve with a custom solution. Standardization and sustainability of the program mitigated future compliance risk.

5. The South Dakota Department of Environment and Natural Resources (DENR) sought 120 Water Audit, Inc to manage the launching and running of a Lead Sampling Program to help public schools investigate sources of lead within their plumbing systems. This program is being offered during the 2019-2020 school year and was funded by the Environmental Protection Agency's WIIN Act 2107 grant.

Public K-12 schools are eligible to participate in this program, and elementary schools and districts serving a high percentage of disadvantaged students were prioritized.

Using 120 Water Audit, Inc's Software management, each school received software access to design sample plans, collect samples, track remediation and communicate results. The facility administrators were trained on sample planning and collection.

This program is on-going, and 120 Water Audit, Inc is routinely providing sample bottles and lab analysis, communication templates, technical support if remediation is needed, and email/phone support for all questions related to software use, sampling and remediation.

1.3.1 Project Distribution Team

Contract Manager: Logan Turner

- Acts as the primary point of contact for commercial elements of the program, and the main point of contact through the bid process
- Acts as ongoing support to align business objectives with program outcomes

Executive Sponsor: Abby Warner

- Acts as the customer advocate and final point of escalation for any WV Office of Environment critical needs
- Responsible for advocating on behalf of the state as a final point of escalation for any critical quality assurance or quality control needs for this program
- Manages capacity planning for all team members

Program Manager: Jennifer Whitson

- Acts as the owner and manager of the Implementation, Project Management, Delivery and Fulfillment operations for this program
- Serves as a direct point of escalation for any team needs
- Acts as a direct point of escalation for any critical quality assurance or quality control needs as they relate to this program
- Approves the PMB, QMP, and control system(s)
- Establishes communication plan
- Oversees the implementation, and continued improvement of the plan
- Provides management reviews of the QMS and approval of internal audits
- Identifies, initiates, and monitors quality improvement efforts
- Reviews feedback and project deliverable review comments with stakeholders
- Verifies that sufficient risk assessments have been carried out
- Monitors the status of the Program using weekly Program control meetings
- Assures qualified and adequate resources are available
- Assigns project staff responsibilities and the engagement of outside services where necessary
- Supports, guides and mentors the Program Manager and 120 Water Audit, Inc internal team members

Assistant Project Manager: Taylor Smith

- Manages the ongoing, day-to-day execution of the program once go-live is achieved
- Completes the program on time, budget and to required quality level

- Identifies and manages project risks
- Oversees the maintenance of Program records
- Reviews the state of the Program with the Program Director at weekly project control meetings
- Develops a strong, collaborative working relationship with West Virginia Office of Environment staff
- Performs ongoing change control regarding scope, budget, and schedules
- Arranges and responds to quality audits
- Communicates and meets with designated WV Office of Environment staff on a regular basis during the execution of the program

Quality Assurance Manager: Dan Moyers

- Reports on the status and effectiveness of the Quality Assurance and Quality Control Programs
- Reviews documents to identify project quality requirements
- Oversees the Development, Issuance, and Maintenance of the Quality Management Plan and associated Quality Assurance Procedures
- Oversees surveillance and auditing of product suppliers, shipping partners, and 120 Water Audit, Inc platform
- Identifies, analyzes, tracks, and provides follow-up for nonconformances
- Oversees the development of corrective actions
- Verifies the implementation of corrective actions
- Coordinates with the Program Director and Program Manager for quality issues and problem resolution

Program Implementation Manager: Phil Ortman

- Partners with Office of Environment from the program design phase through go-live to ensure that all parties are aligned on expectations, statements of work and go-forward planning both technically and programmatically
- Fully manages all implementation activities to take the program from design to go-live
- Develops a strong, collaborative working relationship with staff
- Liaises with to understand the various program requirements
- Confirms the scope of work for all program elements and tasks, creating and maintaining the PMB
- Identifies and manages project risks
- Performs change control regarding scope, budget, and schedules
- Organizes completion and approves project deliverables and documentation, in accordance with agreed upon schedules
- Ensures the executional proficiency of the 120 Water Audit, Inc Team, in accordance with program requirements.

- Demonstrates how the project can be delivered effectively and efficiently
- Establishes project control(s)
- Reviews the state of the Program with the Program Director at daily project control meetings throughout the Implementation phase
- Reviews Contract documents to identify project quality requirements

Developes, Issues, and Maintains the Quality Management Plan and associated Quality Assurance Procedures

1.3.2 Project Team Resumes

See Addendum - Exhibit 1 - Project Team Resumes

1.4 Laboratory Partner

For the laboratory analysis portion of this project, 120 Water Audit, Inc will work with an external laboratory. We will be routing all water samples to be analyzed at **EUROFINS EATON ANALYTICAL, LLC.**

This laboratory is certified to conduct lead testing in drinking water utilizing EPA Method 200.8. 120 Water Audit, Inc has been working with Eurofins for many years, specifically for the analysis of lead and copper in drinking water as demonstrated in the EPA Lead and Copper Rule.

Please see addendum, Exhibit 1 for EUROFINS EATON ANALYTICAL, LLC Certification.

For any additional laboratory analysis needs **IF NEEDED**, for example, sample load balancing, 120 Water Audit, Inc may work with an additional external laboratory, **CWM ENVIRONMENTAL.**

This laboratory is certified to conduct lead testing in drinking water utilizing EPA Method 200.8. 120 Water Audit, Inc has been working with CWM ENVIRONMENTAL for many years, specifically for the analysis of lead and copper in drinking water as demonstrated in the EPA Lead and Copper Rule.

CWM ENVIRONMENTAL is in the process of getting their certification for conducting lead testing in the state of West Virginia. Prior to any coordination of sample being analyzed at CWM ENVIRONMENTAL, 120 Water Audit, Inc will ensure certification has been approved and has written approval from OEHS.

120 Water Audit, Inc is willing to work with a West Virginia preferred laboratory of the state's choosing if they would prefer.

1.5 Background/Problem Definition

Lead is a toxic metal that can be harmful to human health when ingested. Young children under the age of six are particularly sensitive to the effects of lead because their bodies are still undergoing development. Lead can get into drinking water if it is present in the source water or by interaction of the water with plumbing materials containing lead (through corrosion). Common sources of lead in drinking water include solder, fluxes, pipes and pipe fittings, fixtures, and sediments. It is possible that different drinking water fixtures in a given building could have dissimilar concentrations of lead.

See Addendum - Exhibit 2 - 2019 Study "Cost Analysis: Reducing Lead in School and Childcare Facility Drinking Water" Prepared by Erica Walker, Director of Lead Programs, 120 Water Audit, Inc

1.6 Project Task

The State of West Virginia anticipates available funding will provide sampling at 80 Facilities, providing 1,905 sample kits to test fixtures for lead.

Once a Facility has been accepted into the program, the Facility Partner will work with the Program Manager to create a sampling plan. Facility Partners will receive a testing kit from 120 Water Audit, Inc containing all the materials they will need to implement their sampling plan.

The Facility Partner will collect drinking water samples from all drinking water sources, including: water fountains (chilled and non-chilled), food preparation fixtures (located in the cafeteria, kitchen, and home economics classrooms) and other fixtures where children might drink the water. Concession stands and outside water fountains (such as in playgrounds and athletic fields) shall also be sampled. Custodial sinks and outside spigots may be sampled if Facility Partners indicate they are used for drinking water.

The Facility Partner will collect first draw samples at all fixtures. They may also collect 30- second flush samples at drinking water fixtures specified in the Sampling Protocol. West Virginia certified laboratories will perform the analysis for lead. Remediation Technicians will review sample results and coordinate with the Facility Partner on appropriate lead remediation actions, if necessary. Results will be made available for the public’s awareness.

1.7 Project Objectives

The overall objective for the State of West Virginia Lead Sampling Program is to determine the lead concentration at drinking water fixtures within enrolled West Virginia Facilities. Facility Partners will also gain greater awareness of monitoring for the presence of lead in drinking water at their Facility.

At the recommendation of the state, the lead sampling program will use an approved drinking water action level such as 15 parts be billion (“ppb”), which follows the EPA Lead and Copper Rule.

Decisions to be made with the data include:

If a drinking water test returns a result for lead equal to or exceeding 15 ppb, then the Remediation Technician will direct the Facility Partner to isolate the source of drinking water by turning off the fixture or providing a barrier to the consumption of the water (i.e. tape and bag). The Remediation Technician will then work with the Facility Partner to suggest remediation activities

If a Facility Partner enrolls in the Lead Sampling Program and receives lead sampling data, then they will make the results available to their stakeholders (parents, staff, etc.).

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1.8 120 Water Audit, Inc Project Execution

120 Water Audit, Inc's proposed solution for the project meets and exceeds all the requirements of this RFP.

The 120 Water Audit, Inc Approach

120 Water Audit, Inc is experienced in partnering with state agencies to deliver all of the outcomes and outputs specified in the scope of work, specifically for statewide lead testing in school and child care facility programs. The success of this program will be largely dependent upon close collaboration and alignment between 120 Water Audit, Inc and the West Virginia Department of Administration and key state agencies to achieve these outcomes. Our innovative approach to supporting states, districts, and childcare facilities involves three primary elements:

1. **Cloud-Based Software**
2. **Tech Enabled Sample Kits**
3. **Programmatic Services**

Proposed Methodology for West Virginia's Lead Sampling Program

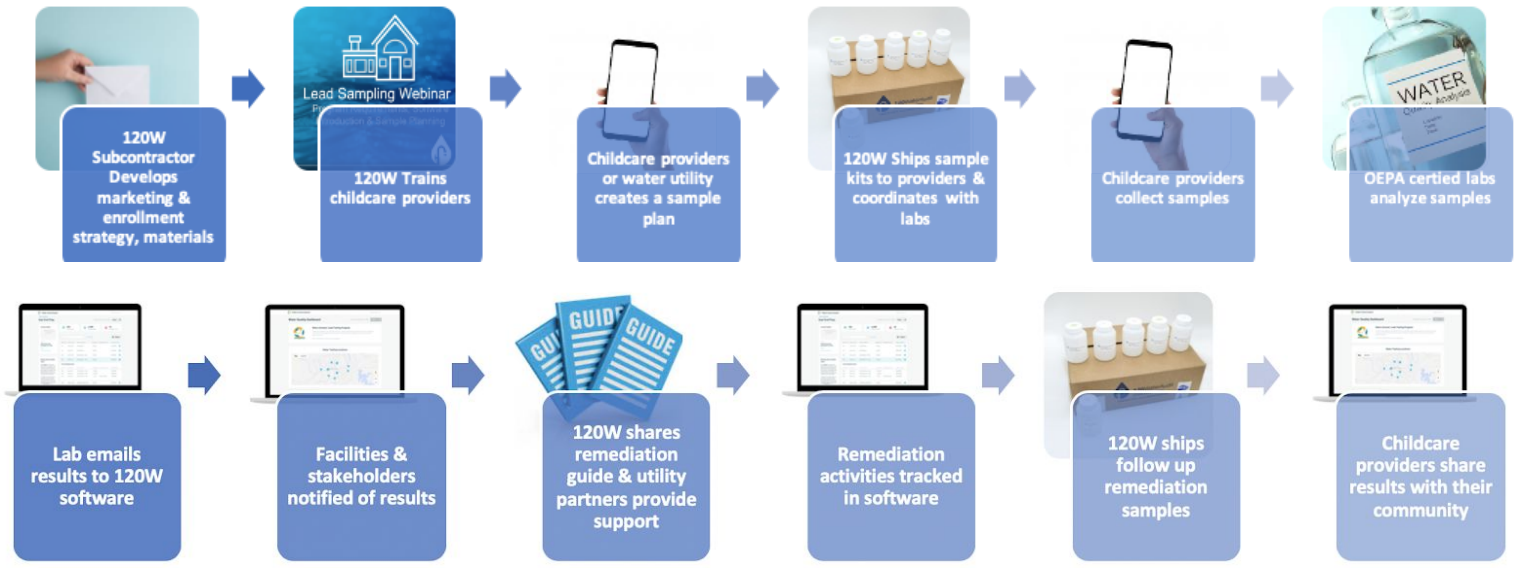

Figure 1. 120 Water Audit, Inc's proposed workflow for the West Virginia Lead Sampling Program.

1.8.1 Taking Action

We've spent countless hours alongside state and municipal agencies, utilities, and facilities providing high-value technology and services to efficiently manage drinking water voluntary and compliance programs. These solutions, developed in partnership with customers and industry thought leaders, are founded on a deep understanding of the public health and cost impact to these organizations, and consumers. Lead testing in school and childcare facility initiatives are highly sensitive and involve many stakeholders, from state agencies to school staff, parents, and children. We are committed to empowering OEHS, to effectively communicate and manage all elements of your statewide program in a thoughtful and efficient manner, consistent with our established track record of success partnering with other state agencies across the country.

OEHS will be able to build and maintain a model lead testing in schools program on the 120 Water Audit, Inc foundation, that can meet shorter term needs, while scaling to address longer term state objectives. The 120 Water Audit, Inc software, kits, and program management services were purpose-built to execute the EPA's 3T's Lead Sampling in School Best Practices, and directly align with the requested outcomes outlined in the OEHS's requested Scope of Work. Clients leverage the 120 Water Audit, Inc Program Management Platform as a centralized data management solution to facilitate all aspects of the program from planning and sampling, to communication and reporting. A typical statewide lead testing program includes the following phases:

Program Design & Implementation: This phase includes finalizing the work plan, QAPP, program participation criteria, program objectives, documentation of processes and procedures, training for state agency stakeholders, communication materials, and reporting criteria.

Awareness & Enrollment: This phase focuses on communicating program plans and details to all eligible participants, vetting applicants, finalizing program participants, enrollment procedures for participating facilities, educating program and community stakeholders, and providing initial educational content to participating facilities. Even though the State will prioritize enrollment, 120 Water Audit, Inc will support where and as needed.

Program Execution: This phase includes finalizing facility cohorts, collecting all relevant data on participating facilities, training participants and stakeholders, facility fixture mapping, sample planning, sample collection, troubleshooting/issue resolution, holding facilities accountable to timelines and deliverables, sending samples to the lab for analysis.

Reporting: This phase includes reporting results of sample analysis, communicating all other relevant data to appropriate stakeholders, establishing public access to program information, state agency results review, notifying and reviewing results with facility personnel, and determining any actions based on results.

Remediation: This phase focuses on remediation recommendations, strategies, and actions that can be taken to address any fixtures that result in action level exceedances. Follow up sampling, result reporting, and connecting participants with additional resources or 3rd party plumbing expertise if desired.

We will work with OEHS to finalize the resource allocation for each phase according to the program plan. 120 Water Audit, Inc currently supports efforts in each phase of the program for lead testing in school and childcare facility clients. Together, we will establish the responsibilities for all stakeholders in each phase, including the State, 120 Water Audit, Inc, facility staff, and any other relevant parties.

120 Water Audit, Inc is the only company that has custom-designed and developed kits, purpose-built software, and hands-on training for standardizing lead sampling in schools programs. Our software, kits, and services are informed by years of experience with EPA 3T's protocols. These solutions were created to provide a stand alone, out of the box program management option that would not necessarily require engagement with subcontractors.

To alleviate time and labor costs associated with field facility mapping, fixture inventory, logistics, and sample collection, 120 Water Audit, Inc implements a technology enabled program focused on empowering existing facility personnel to accomplish these tasks during program execution. Most of the lead testing in school and child care facility program clients we've worked with have adopted this model, affording them the opportunity to test a greater number of facilities in a shorter time period. A couple of programs have engaged a 3rd party consulting group to help with planning, sample collection, and remediations, in which case 120 Water Audit, Inc works closely with these partners to execute the program.

The following structure outlines 120 Water Audit, Inc's typical engagement in the project phases outlined above:

Program Design & Implementation: 120 Water Audit, Inc will assist OEHS in finalizing the project plan, requirements, KPIs, documentation of policies and processes, and technical implementation of the software platform. We are predominately the secondary resource in this phase, with the State being the primary resource.

Awareness & Enrollment: OEHS would continue to be the primary resource in this phase, with support from 120 Water Audit, Inc. We would assist in finalizing participation criteria, mutually agree upon a communication plan based on recommendations from 120 Water Audit, Inc's experience, and create communication/marketing materials. The agency would distribute communication and enrollment details. 120 Water Audit, Inc would assist in reviewing applications, and collecting all enrollment data. Once participants are selected, all relevant data on participating facilities will be uploaded into the software platform.

Program Execution: 120 Water Audit, Inc transitions to being the primary resource in this phase, with necessary support provided by OEHS. We will evaluate participants and determine cohorts, groups of 10-20 facilities, who will progress through the program together. These cohorts will function on the same timeline through the project, attending remote webinar training sessions together, completing “homework” on the same cadence, and generally moving through program phases simultaneously. 120 Water Audit, Inc will provide virtual technical and programmatic training webinars throughout the event, provide supporting content, and one off questions/issue resolution support. Facility personnel will map fixtures directly in the 120 Water Audit, Inc platform and create sample plans in the software. These would ideally be QA/QC’d and approved by a OEHS user remotely through the platform. Once approved, 120 Water Audit, Inc’s fulfillment team will label bottles with fixture IDs and sample types according to the sample plans. These bottles are packaged into kits that include additional samping instructions, COC forms, and return labs. The kits are shipped directly to the facilities, where the facility personnel then collect samples according to the plans. Once samples are collected, that are placed back into the packaging, the collector puts the return label on the box, and it will be shipped directly to the laboratory. Once the laboratory has analyzed the samples, results are automatically uploaded into the platform for review by users.

Reporting: All of the data in the software platform will be reportable, with pre configured report templates and dashboards included to quickly disperse information to all appropriate stakeholders, including the public. Laboratory results are automatically uploaded into the platform once they are analyzed. Users will have real time access to these results in the platform. 120 Water Audit, Inc will often support the communication and interpretation of results to facility personnel. Training would be provided to facilities on public communication, objection handling, and pursuit of remediation for exceedances.

Remediation: The 120 Water Audit, Inc platform facilitates documentation and tracking of all remediation efforts. We can provide remediation guidance and recommendations on appropriate actions, including an educational e-book on remediation for facility personnel. A subcontractor would be engaged to perform physical remediation work.

1.8.2 Cloud-Based Software

The 120 Water Audit, Inc Digital Water Cloud Platform was purpose-built to execute the **EPA's 3T's Lead Sampling in School & Childcare Facilities** best practices. Our software provides a cloud-based foundation that centralizes and facilitates oversight and management of all aspects of the program, automates workflows and communications, tracks logistics, and simplifies reporting to all stakeholders. State agencies, cities, childcare facility staff, water utilities, and stakeholders can collaborate, manage, monitor and report on results in real-time. **The ability to access the software on an ongoing basis beyond the sample completion date will rely on successful renewal of the software. Data resulting from the program completion will be made available if the software renewal does not occur.** The following details the features and functionality included for use by West Virginia program users:

User & Role Permissions
120 Water Audit, Inc's multi-tenant database with user permission structure allows users to manage platform access across multiple program stakeholders such as state, district/franchise, school/childcare level, field samplers, consultants, and regulators. Each user has a unique view of the platform and limited access to data based on their specific permissions.

Facility & Asset Management
120 Water Audit, Inc's Facility Management product and documents library serve as the database of records for lead sampling programs. Facilities are organized with parent-child relationships, meaning **a group of childcare facilities owned by the same group can be related and managed by the user under one account**. Each facility has access to a document library to store documents and photos, and contact management tracking.

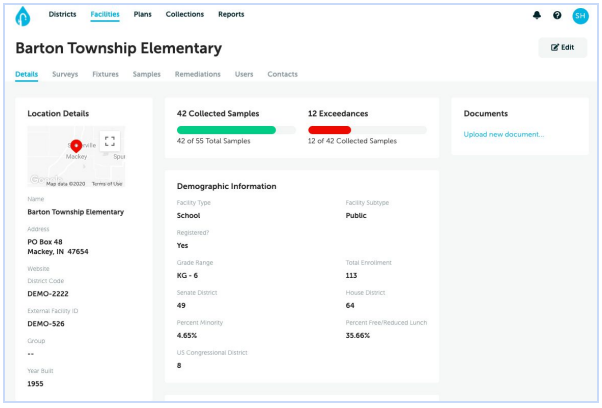

Figure 2. Facility & asset management functionality example on the facility profile.

Sample Planning
120 Water Audit, Inc's Sample Planning workflow allows the states, consultants, water utilities, or facility staff to inventory assets, fixtures, **capture fixture photos**, **designate fixtures as active or non active, add samples to fixtures** and manage different sampling events in a simple, step by step process. Users can add information **capturing fixture level data, based on 3 T's best practices, about each fixture that supports informed remediation decision-making when results arrive.**

Tablet & Mobile Field Use
Field team members have the **ability to create Sample Plans & Collect Samples directly from a mobile or tablet device.** This capability dramatically improves data integrity and field work efficiency. We feel this functionality is essential for childcare providers, as it makes the software quick and easy to use.

Remediation Management
120 Water Audit, Inc's Remediation Management feature allows users to provide recommendations and **track remediation** work on fixtures that exceed lead levels the program considers high (1ppb-20ppb typically). 120 Water Audit, Inc has the ability to capture discrete remediation actions taken by participating facilities and to report those to the state.

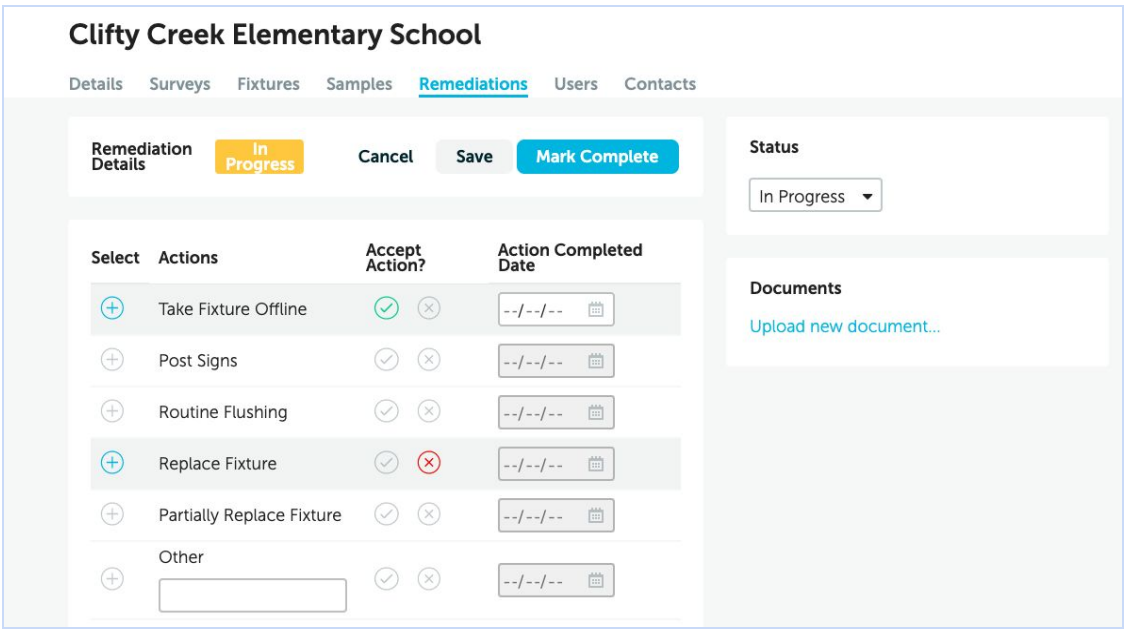

Figure 3. 120 Water Audit, Inc's Remediation Management Module

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Dashboards, Reports & Notifications

120 Water Audit, Inc's software includes internal facing dashboards, notifications, and provides real-time access to key program metrics to track program outcomes. In-platform and automatic email notifications ensure that the appropriate users get assigned workflow tasks, are sent reminders to keep programs on track, and provide visibility through every step of the process such as sample plan completion, sample kit collection and sample analysis, etc. Custom fields functionality can be leveraged to enable stakeholders to capture and track any additional metrics about the school/childcare programs the state deems valuable.

120 Water Audit, Inc's **Public Transparency Dashboard** allows each facility or the state to share results information about the program with school/child care stakeholders and answer the primary questions the community has: Why was testing done? What was found? How were issues resolved?

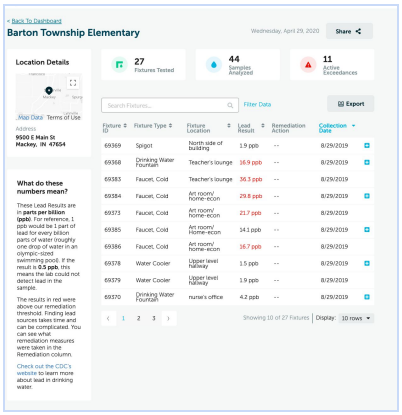

Figure 4. 120 Water Audit, Inc's Public Transparency Dashboard (PTD) to help facilities and states communicate lead results simply and clearly to the public

Real-Time Reporting

Real-time reporting allows users the ability to sort/filter and download program reports for internal or public consumption related to sampling plans, sample and lab results, field team visits, enrollment metrics, and state-wide program progress. Document libraries for all schools/childcare facilities are within the 120 Water Audit, Inc platform.

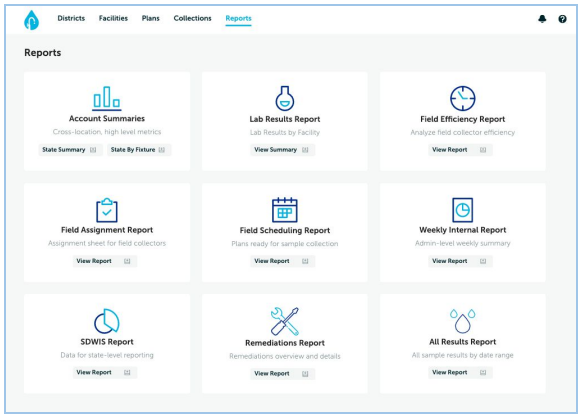

Figure 5. 120 Water Audit, Inc's standard reports library

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1.8.3 Program Services

Mandatory Contract Services

120 Water Audit, Inc will provide assistance in developing a lead testing in drinking water strategy that supports training, monitoring and maintenance plan that protects children from lead exposure now and in the future. 120 Water Audit, Inc will establish a communication plan for presenting result findings and mitigations when recommended within alignment of the West Virginia Department of Administration. 120 Water Audit, Inc will provide educational materials on lead sampling and remediation to all program stakeholders, participants and affected populations. 120 Water Audit, Inc will provide technical support (phone/email) to school or childcare staff on questions related to lead sample planning, collection and remediation. 120 Water Audit, Inc will provide project management to support schools and childcare facilities, keeping them accountable for completing sample plans, sample collection, submission to the laboratory, sharing results to the schools, childcare facilities and community and other programmatic support initiatives. These services, as well as the ones listed below will be remote based to existing personnel.

Implementation

120 Water Audit, Inc's implementation and success methodology is phased to align with the lifecycle of the program, and long term client objectives for the partnership. 120 Water Audit, Inc will work through the following process with OEHS:

Contract Execution and Program Model Blueprint Approval:

In this phase, we are formalizing our relationship with you through our contract and laying the foundation for our mutual success. A critical element of this phase is establishing our Program Model Blueprint which drives clear, holistic understanding and agreement on your program details and how 120 Water Audit, Inc's products and services will be implemented to support it and then utilized in the ongoing execution of your program.

Program Implementation:

In this phase, we focus on timeliness and regular communication to design materials, configure your account and ensure program standards are clearly aligned according to the Program Model Blueprint. We create a program implementation plan at the outset of implementation and use it to track and manage the implementation effort as well as facilitate ongoing communication.

Go-Live:

This phase represents the milestone of "going live" with your program as program implementation concludes and as ongoing program execution begins. 120 Water Audit, Inc has created an efficient, repeatable program process to maintain uniformity in sampling procedures and data input across numerous facilities. *Please see Addendum H* for illustrative Process Overview. During this phase we will begin the enrollment of facilities into the program.

Ongoing Program Execution:
This phase continues throughout your program. During this phase, we will guide facilities through the sampling of their buildings leveraging the 120 Water Audit, Inc Platform to ensure data accuracy and consistency.

Program Timeline

A program timeline will be impacted by the program launch date, and is structured to be completed within 24 months of contract execution. Most phases of the programming are rolling throughout the time frame, for example, one cohort of facilities may begin training and program execution, while awareness and enrollment efforts are still in motion to gain additional participation. An official timeline for the OEHS program will be finalized in a collaborative meeting between all parties. The following table represents a sample plan of deliverables for each program phase, with the typical time frame it takes to complete each step. For the program execution sections, this will be an ongoing set of deliverables for each cohort. Participants will be grouped in cohorts of 10-20 facilities.

Phase	Description / Deliverable	Primary Resource	Secondary Resource	Estimated Time
Implementation & Program Design	Design and Submit QAPP	120 COE	OEHS	1 week
Implementation & Program Design	Develop and Manage Program Process and Plan	120 Client Success	OEHS	1-4 weeks
Implementation & Program Design	Finalize School Selection Criteria & Submission Process	OEHS	120 Client Success	1 week

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Implementation & Program Design	Outline process for Approval of Schools, Documents and Communications	OEHS	120 Client Success	2-3 weeks
Implementation & Program Design	Document process for Objection and Risk Handling	120 Client Success	OEHS	1 week
Implementation & Program Design	Determine Agreed upon Success Criteria for the program	OEHS	120 Client Success	1 week
Implementation & Program Design	Determine KPIs and reporting milestones	120 Client Success	OEHS	1 week
Implementation & Program Design	State Training - How to Access and Leverage the 120 Water Audit, Inc Software	120 Client Success	OEHS	2 hour virtual training prior to program kickoff
Awareness & Enrollment	Create Email Communication Templates to Educate & Invite Participants	OEHS	120 Client Success	1-2 weeks
Awareness & Enrollment	Send Communication	OEHS	120 Client Success	2 weeks
Awareness & Enrollment	Create Enrollment Form	120 Client Success	OEHS	1-2 weeks
Awareness & Enrollment	Create Program Intro Document (to be included in the Water Sampling Kit)	120 Client Success	OEHS	1 week
Awareness & Enrollment	Create Communication templates including - Kit Return Reminders & Results Notification	120 Client Success	OEHS	2 weeks
Awareness & Enrollment	Training Design to Align Program Process to School Execution	120 Client Success	OEHS	1-2 weeks
Training	120 Water guides state stakeholders on how to leverage the 120 Platform to check program status	120 Client Success	OEHS	2 hour virtual session upon completion of above steps
Program Management	Final Selection of Schools from Submissions	OEHS	120 Client Success	2-4 weeks

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Program Management	Create Facilities in the 120Platform	120 Client Success	OEHS	1 week
Training	Schools Training 1: Program Overview and Sample Planning	120 Client Success	WV Facility Participants	2-3 hour virtual session for each cohort
Program Management	Following Training, Schools will have assignments to create their Sampling Plans for each of the buildings and fixtures they will sample. The 120 Water team will be available to answer any questions along the way. We will ask that these are completed within approx 2 weeks to help move the program along	WV Facility Participants	120 Client Success	2-3 weeks
Program Management	OEHS will QA / QC all facility sampling plans to ensure the school is set up for success when their sampling kits arrive	OEHS	WV Facility Participants	2-3 weeks
Program Management	Once Samples Plans are set, 120 will prepare custom sample kits - personalized to each facility and each fixture within that facility	120 Fulfillment	120 Client Success	1-2 weeks
Training	Schools Training 2: How to take your samples, results and how to prepare for communication and the Transparency Dashboard	120 Client Success	WV Facility Participants	2-3 hour virtual session for each cohort
Program Management	Once kits Arrive, schools will have approx. 2 weeks to take their samples. Once completed, they will repackage the samples, place the label on the box and schedule a pickup to ship these samples to the lab for analysis	WV Facility Participants	Lab Partner	2-3 weeks

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Phase	Description / Deliverable	Primary Resource	Secondary Resource	Estimated Time
Training	120 Water guides state stakeholders on how to leverage the 120 Platform to check program status	120 Client Success	OEHS	2 hour virtual session upon completion of above steps
Program Management	Final Selection of Schools from Submissions	OEHS	120 Client Success	2-4 weeks
Program Management	Create Facilities in the 120Platform	120 Client Success	OEHS	1 week
Training	Schools Training 1: Program Overview and Sample Planning	120 Client Success	WV Facility Participants	2-3 hour virtual session for each cohort
Program Management	Following Training, Schools will have assignments to create their Sampling Plans for each of the buildings and fixtures they will sample. The 120 Water team will be available to answer any questions along the way. We will ask that these are completed within approx 2 weeks to help move the program along	WV Facility Participants	120 Client Success	2-3 weeks
Program Management	120 Water will QA / QC all facility sampling plans to ensure the school is set up for success when their sampling kits arrive	120 Client Success	WV Facility Participants	2-3 weeks
Program Management	Once Samples Plans are set, 120 will prepare custom sample kits - personalized to each facility and each fixture within that facility	120 Fulfillment	120 Client Success	1-2 weeks
Program Management	Lab Analysis - Samples will be analyzed and results reported into the 120 Platform	Lab Partner	120 Client Success	2 weeks

Training	School Training 3: Exceedance Management, Remediations, Communications & Reporting	120 Client Success	WV Facility Participants	2-3 hour virtual session for each cohort
Program Management	Parent and Teacher communication - 120 will support and guide the schools on communication best practices	WV Facility Participants	120 Client Success	1-2 weeks
Program Management	Reporting to State Stakeholders - based on the determined KPIs, 120 will work with the school to submit any required reporting to the state stakeholders	WV Facility Participants	120 Client Success	1-2 weeks
Program Management	Remediation Planning and Execution - in the case of exceedances, 120 will be available to answer questions on how to create and manage exceedances in the 120 Platform. OEHS will be responsible for advising on the technical best practices to ensure a fix for the issue follows proper plumbing protocols	WV Facility Participants	OEHS	2-4 weeks
Program Management	Remediation Sampling - once the remediation is complete, the schools will create the necessary plan for resampling, which will generate an order for 120 to fulfill and ship kits direct to the school.	WV Facility Participants	120 Client Success	2 - 4 weeks + analysis
Program Management	Reporting Coordination: Upon completion of the program, 120 Client Success team will work with state stakeholders to compile required federal reporting. OEHS will be responsible for finalizing &	OEHS	120 Client Success	2-3 weeks

	making the submission.			
Program Management	Lab Analysis - Samples will be analyzed and results reported into the 120 Platform	Lab Partner	120 Client Success	2 weeks
Training	School Training 3: Exceedance Management, Remediations, Communications & Reporting	120 Client Success	TX Facility Participants	2-3 hour virtual session for each cohort
Program Management	Parent and Teacher communication - 120 will support and guide the schools on communication best practices	WV Facility Participants	120 Client Success	1-2 weeks
Program Management	Reporting to State Stakeholders - based on the determined KPIs, 120 will work with the school to submit any required reporting to the state agencies	WV Facility Participants	120 Client Success	1-2 weeks
Program Management	Remediation Planning and Execution - in the case of exceedances, 120 will be available to answer questions on how to create and manage exceedances in the 120 Platform. OEHS will be responsible for advising on the technical best practices to ensure a fix for the issue follows proper plumbing protocols	WV Facility Participants	OEHS	2-4 weeks
Program Management	Remediation Sampling - once the remediation is complete, the schools will create the necessary plan for resampling, which will generate an order for 120 to fulfill and ship kits direct to the school.	WV Facility Participants	120 Client Success	2 - 4 weeks + analysis
Program Management	Reporting Coordination: Upon	OEHS	120 Client	2-3 weeks

	completion of the program, 120 Client Success team will work with state stakeholders to compile required federal reporting. OEHS will be responsible for finalizing & making the submission.		Success	

Training

120 Water Audit, Inc will have a training content focused meeting with OEHS post contract signature to tailor templates to reflect the specific requirements and goals of the program. Training sessions will be delivered online via webinars, or on site throughout the course of the program. Other training content includes videos and FAQ sheets to reinforce learning objectives.

120 Water Audit, Inc will provide a series of training templates based on EPA 3 T's methodology that covers the following concepts:

- Education resources on the potential sources of lead, health risks of lead in drinking water and testing for lead to the community of surrounding residential area that is impacted by testing, as well as key partnerships to support the program
- General information about the program, its partners, and its requirements
- Introduction to the software
- Creating sample plans and collecting samples according to 3 T's protocols
- Remediation strategies
- Communicating with the public about lead risks and lead sampling
- Training and implementation to agency and facility staff on software use
- Webinars for the school staff on program requirements, enrollment, sample planning, collection, remediation and communicating with the public

120 Water Audit, Inc will provide training and education materials on the risks of lead in drinking water and testing for lead to the community of the surrounding residential area that is impacted by testing, as well as key partnerships to support the program.

120 Water Audit, Inc will provide a series of training to State Stakeholder and Facilities

participating in the program including:

State Training 1:120 Water guides state stakeholders on how to leverage the 120 Platform to check program status

Schools Training 1: Program Overview and Sample Planning

Schools Training 2: How to take your samples, results and how to prepare for communication and the Transparency Dashboard

School Training 3: Exceedance Management, Remediations, Communications & Reporting

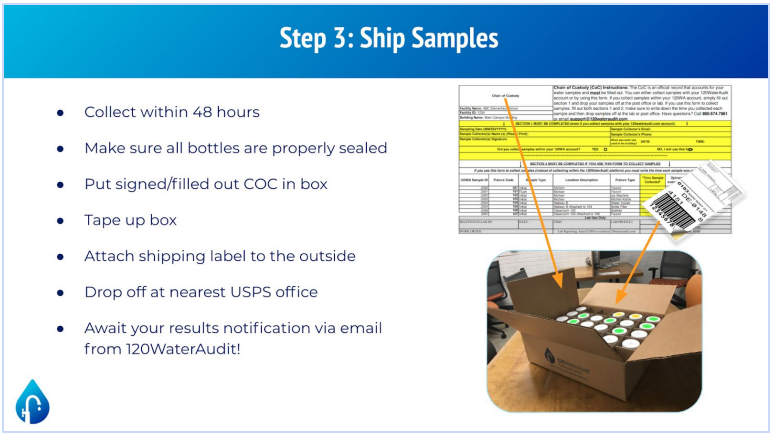

Figure 6. An example of a training webinar 120 Water Audit, Inc gave to facilities in a state-wide lead sampling program for public schools in late 2019.

Sample Planning & Collection

- We propose to develop cohorts based on the enrollment timeline and deliverables. Participants will be organized into cohorts within quarters. Each cohort will go through training, sample planning and sample collection together with support from the 120 Water Audit, Inc Program Manager. Assistance with remediation and communication will be ongoing for all cohorts.
- Following the series of online and in-person trainings, each cohort will be asked to submit sample plans. Participants will be instructed on how to identify all sources of cooking, drinking, and handwashing water. They will also be given instructions about which fixtures to avoid (such as utility sinks) and asked to label these fixtures as “not for drinking”.
- 120 Water Audit, Inc will QA/QC each sample plan and work with facilities to resolve issues. The 120 Water Audit, Inc fulfilment team will send sample kits containing **both initial and 30-second**

flush draw bottles for every identified cooking/drinking/hand washing water source directly to the facility.

- We propose to work with utility partners to provide field assistance to facilities that lack the resources or ability to create sample plans using the software. For example, it may be helpful to create sample plans on behalf of the facilities with more than 20 fixtures. If the state is agreeable to this strategy, all utility partners would be trained on software.
- Per EPA 3 T's guidelines, prior to sample collection, participants will be instructed to let all water in the building stagnate for a minimum of 8 hours but not more than 18 hours. Sample collection instructions will be provided both in the training and on document included in the sample kit. The instructions detail:
    - Stagnation time requirements
    - How to collect an initial vs a 30-second flush sample
    - Place the lid bottom-side up and screw on tightly when complete
    - Collect samples from the cold side of each faucet
    - How to collect a sample from an ice machine
    - Contact number for 120 Water Audit, Inc if questions arise
- Once samples are collected and the CoC has been completed, facility staff will apply the pre-postage label back on the sample box, and drop the kit off at the nearest post office.
- The chosen laboratory subcontractor will intake and preserve the samples, analyze them according to EPA 200.8 methods for ICP-MS, and submit an Electronic Data Deliverable (EDD) to the 120 Water Audit, Inc platform along with the official lab report for thorough record keeping.
- The 120 Water Audit, Inc platform will automatically notify each participant when their results have arrived. In the notification email, we will provide a call number and links to helpful resources.
- Water utility partners will have access to the platform, and receive results notifications. If LSLs are suspected, 120 Water Audit, Inc and the utility can coordinate with the facility and other stakeholders to pursue replacement.

Remediation

- Based on the State's Work Plan and the RFP, 120 Water Audit, Inc proposes to share a remediation guide with each participant. This includes information about immediate, short term, and long term mitigation strategies, as well as measures the facility can take to support water quality throughout the year. We propose to review our guide with the state and stakeholders and make updates to match the goals and objectives of the program.
- 120 Water Audit, Inc will also provide participants with information about potential funding opportunities for remediation and will connect them with the appropriate state contact when needed.

Communication Support

- 120 Water Audit, Inc will provide assistance in developing a lead testing in drinking water strategy that supports training, monitoring and maintenance plan that protects children from lead exposure now and in the future
- 120 Water Audit, Inc will establish a communication strategy plan for result findings and mitigations when recommended
- 120 Water Audit, Inc will provide educational materials on lead sampling and remediation
- OEHS & Childcare providers will have access to 120 Water Audit, Inc's **Public Transparency Dashboard (PTD)**. This solution was developed based on 5 years of experience with public risk communication around lead sampling. Each participant will have the ability to link and/or host the PTD on their website.
- 120 Water Audit, Inc will provide all participants with template letters to use within their communities. Facilities that do not have a website can post the results publicly inside the center, send the letters home with children, or mail them directly to caretakers and parents.

Technical Assistance

- As part of the Program Management services provided in this proposal, Jennifer Whitson (PM) will work directly with each facility to complete sample plans and answer any questions related to site assessments, sample collection, kits, communication, and program requirements.
- Remediation Technician (RT) will help facilities navigate remediation options. We do not include RT services in this proposal, but would like to discuss it with the state if selected.

Program Management

120 Water Audit, Inc will act as the primary facilitator of the state sampling program through Program Management services. Program Managers guide facilities through the entire process of sample planning to communication and serve as the primary points of contact for the state, field users, facilities, labs, and other stakeholders. Roles and responsibilities can vary based on the program but typically include:

- Being a technical resource to participants on all questions related to completing sample plans, collecting samples, and meeting the expectations of the state.
- QA/QCing sample plans so reduce bottle waste and to ensure all appropriate fixtures are included in the program
- Holding facilities accountable for completing plans, collecting samples, communicating with the public by the deadline, and submitting all other deliverables

- Resolving issues between field teams, labs, and program partners
    1. I.e. undeliverable kits, chain of custody errors, missing sample data, leaking bottles, etc.
- Preparing and submitting reports to stakeholders

Lab Coordination

- Communication with the lab to ensure samples are accepted and analyzed in a timely manner
- Also ensuring results are properly documented for appropriate reporting

Remediation Technicians

Remediation Technicians (RT) have expertise in water chemistry, lead reduction strategies and plumbing design and can provide tailored assistance to enrolled participants looking to identify the most effective and efficient remediation strategies. RTs review all facility and results data, develop and submit mitigation proposals, and field questions from facilities on how to implement the proposal. RT's will prioritize:

- Review each set of results and facility data
- Provide each facility with a tailored mitigation plan with short term and long term remediation recommendations
- Track remediation recommendations in platform for reporting
- Provide technical assistance to facilities during execution of the remediation plans (phone and email assistance)

Technical Support & Services

The 120 Water Audit, Inc software platform allows you to easily manage, track and report on all aspects of the program. This software serves as the foundation that enables all components of the program workflows, therefore we place heavy emphasis on technical training and support throughout the engagement with 120 Water Audit, Inc. The platform is designed to be simple and easy for all users, regardless of technical acumen, and limits opportunities for human error to occur during the process. Platform administration is handled by 120 Water Audit, Inc, so OEHS will not require a designated technical administrator. The following technology based services and support are included with the 120 Water Audit, Inc offering:

- Software Platform Setup

- Account Provisioning
- Users and Roles

- Software Training
  - Your 120 Water Audit, Inc Client Success Manager will conduct software platform training for you and your team during the program implementation phase prior to Go-Live.

- Software Support
  - 120 Water Audit, Inc provides user support for any questions, issues or bugs that arise during their utilization of the 120 Water Audit, Inc Platform.
  - Users can contact 120 Water Audit, Inc Customer Support:
    - 800-674-7961
    - Support@120WaterAudit.com
    - Online by Clicking the “Support” link in the 120 Water Audit, Inc Platform 60
  - 120 Water Audit, Inc’s standard support SLAs are:

Priority	First Response	Resolution
Urgent ● Site or customer outage; business stopping issues.	1 Hour	8 Hours
High ● Any issue which significantly degrades performance for some or all users and for which there is no reasonable workaround.	4 Hours	48 Hours
Medium ● Any issue which significantly degrades performance for some or all users and for which there is at least (1) reasonable workaround. ● Issues that have no significant business impact for some or all users, and/or an acceptable	1 Business Day	1 Month

workaround		
Low • All other issues	2 Business Days	1 Month

1.8.5 Sample Kits

Sample Kits

120 Water Audit, Inc is the only company that has custom-designed and developed kits for standardized lead sampling programs. We provide these kits to help facilities effectively manage testing plans and ensure accuracy during facility sample collections. **120 Water Audit, Inc Sample Kits are tracked within the platform throughout the sample kits lifecycle, such as kit shipments, kit collection, kit analysis, etc.** Each sample kit is prepared with pre-labeled bottles to the corresponding facility and fixture which enables operators or staff to effectively and efficiently collect samples. We maintain lab partnerships with your state certified drinking water labs to ensure consistent EPA sampling methods and protocols across schools. This data is standardized and exported into the platform automatically from the lab. Kits are drop shipped directly to the facility based on the sample plan, then shipped to our partner labs.

Kits include:

- 250mL Certified Bottles (not acidified) for first-draw and 30-second flush samples
- Pre-printed, color-coded bottle labels based on the flush type that corresponds to Sample Plan
- Bottles placed in order of sample codes/sample plan for easy collection
- Site-Specific Chain of Custody forms
- Sample Collection Instructions
- Return Shipping Label to 120 Water Audit, Inc partner lab

Figure 7. 120 Water Audit, Inc's Lead Sampling Kits for facilities

1.9 QAPP, QMP and Report Examples and Templates

- The benefit of the QAPP for this initiative will be to communicate, to all parties, the specifications for implementation of the project design and to ensure that the quality objectives are achieved for the project. The Program Director will deliver the QAPP for this testing program. The 120 Water Audit, Inc team has experience writing EPA QAPPs for other state-wide initiatives and relies on EPA's most recent *Guidance for Quality Assurance Project Plans.* Our most recent collaborative submission was approved by EPA R5. The West Virginia Lead Sampling in Childcare Facilities QAPP will define and describe the following basic elements:
    - Who will use the data
    - Project goals, objects, and questions
    - Decisions made from the information obtained
    - How, when, and where project information will be generated or gathered
    - Problems that may arise and what actions may be taken to mitigate those challenges
    - Type, quantity, and quality of data involved
    - Qualification of "good" \data to support decision making
    - Information on how the data will be analyzed, assessed, and reported
- To ensure the QAPP meets EPA requirements, The Program Director will:
    - Ensure that the information is accurate and complete
    - Ensure all appropriate elements are included and addressed
    - Ensure the plan identifies the technical and quality objectives of the project and that the intended measurement and data acquisition methods will satisfy these objectives
    - Ensure assessment produces are adequate to evaluate the project
    - Include process to identify any limitations in the use of the data
- The Program Director will work with named 120 Water Audit, Inc lab partners to include and complete sections relevant to labs analysis.

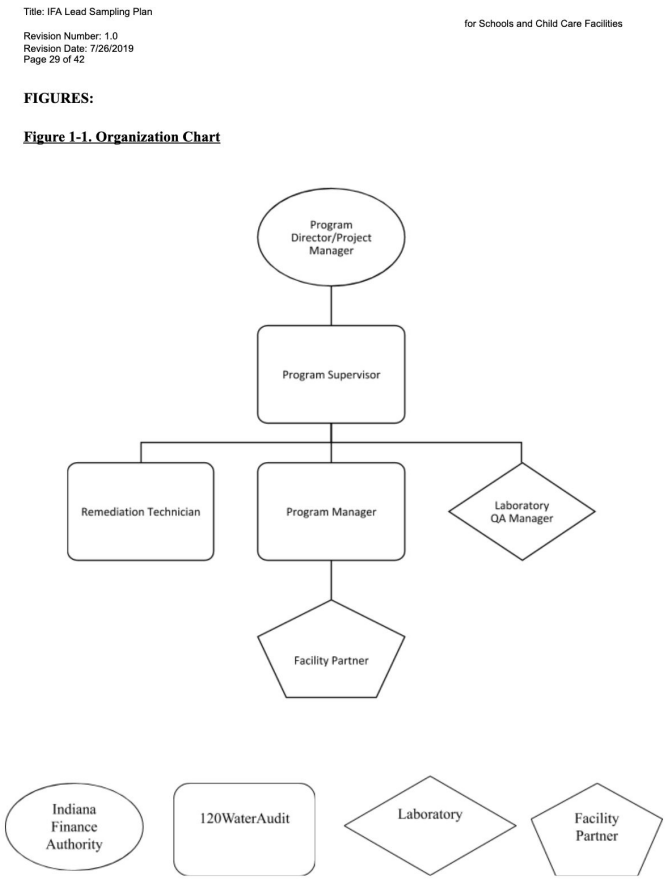

Figure 8. Example of a WIIN-related QAPP submitted and approved by EPA R5

120 Water Audit, Inc has supported clients such as the State of Indiana in drafting a Quality Assurance Project Plan. We will submit a QAPP for this program to the Agency at least 45 days prior to any data being collected to provide EPA adequate time to review (timeline flexible based on OEHS and EPA requirements). **IFA's QAAP is located in addendum exhibit - 2**

120 Water Audit, Inc has developed a Quality Management Overview to describe specific quality assurance and control practices as they relate to the Drinking Water Sampling and Analysis Program. The purpose of this overview is to define 120 Water Audit, Inc's policy and procedures on quality assurance and control practices. A specialized Quality Management Plan (QMP) can be created upon award from OEHS that details plan specifics

as they relate to the tasks and requirements of the specified program. **A detailed QMP example from the EPA is located in addendum - exhibit 3.**

A detailed quarterly and annual report example is located in addendum - exhibit 4.

120 Water Audit, Inc's objective is to deliver quality products and program execution services to OEHS in accordance with their expectations, as outlined in the RFP. 120 Water Audit, Inc has developed a systematic approach to ensure that OEHS contracted products and services are produced and delivered with the level of quality outlined by this RFP.

This overview addresses the requirements critical to the quality of the products and services provided by 120 Water Audit, Inc and describes how processes are to be implemented, audited, and when necessary, corrected or improved.

120 Water Audit, Inc shall define and document its policy and objectives for, and commitment to, quality. All parties shall ensure that this Quality Policy is understood, implemented, and maintained at all levels, throughout the 120 Water Audit, Inc organization.

120 Water Audit, Inc will establish and maintain a documented quality management process to ensure that the products and services that 120 Water Audit, Inc provides are produced and delivered in accordance with OEHS requirements, as outlined in the scope of work. This will include the preparation and effective implementation of documented Quality Program procedures, including:

- Quality Management System
- Document Control and Submittal Management
- Inspection
- Identification, Control, and Correction of Non-conforming Conditions
- Corrective Actions
- Documentation by Quality Records
- Training

The key roles and responsibilities of the 120 Water Audit, Inc Team involved in the management and execution of this program are described below:

120 Water Audit, Inc QA/QC Organization Roles and Responsibilities:

<u>Executive Sponsor</u>

- Acting as the customer advocate and final point of escalation for any OEHS critical needs as they relate to this program
- Acting as the customer advocate and final point of escalation for any critical quality assurance or quality control needs as they relate to this program

Primary Account Owner

- Acting as the Primary Account Owner and the main point of contact for OEHS
- Acting as a point of escalation for any OEHS critical needs as they relate to this program
- Acting as a point of escalation for any critical quality assurance or quality control needs as they relate to this program

Quality Assurance Manager

- Reporting on the status and effectiveness of the Quality Assurance and Quality Control Programs
- Reviewing documents to identify project quality requirements
- Overseeing the Development, Issuance, and Maintenance of the Quality Management Plan and associated Quality Assurance Procedures
- Overseeing surveillance and auditing of product suppliers, shipping partners, and 120 Water Audit, Inc platform
- Identifying, analyzing, tracking, and providing follow-up for nonconformance
- Overseeing the development of corrective actions
- Verifying the implementation of corrective actions
- Coordinating with the Program Director and Program Manager for quality issues and problem resolution

Program Director

- Acting as the owner and manager of the Implementation, Project Management, Delivery and Fulfillment operations as they relate to this program
- Acting as a direct point of escalation for any OEHS critical needs as they relate to this program
- Acting as a direct point of escalation for any critical quality assurance or quality control needs as they relate to this program
- Approving the PMB, QMP, and control system(s)
- Overseeing the establishment, implementation, and continued improvement of the QMS

- Providing management reviews of the QMS and approval of internal audits
- Identifying, initiating, and monitoring quality improvement efforts
- Reviewing feedback and project deliverable review comments received from OEHS and other stakeholders
- Verifying that sufficient risk assessments have been carried out
- Monitoring the status of the Program using weekly Program control meetings
- Assuring qualified and adequate resources are available
- Assignment of project staff responsibilities and the engagement of outside services where necessary
- Supporting, guiding and mentoring the Program Manager and 120 Water Audit, Inc Team Members

Program Implementation Manager

- Partnering with OEHS from the program design phase through go-live to ensure that all parties are aligned on expectations, statements of work and go-forward planning both technically and programmatically
- Fully managing all implementation activities to take the program from design to go-live
- Developing a strong, collaborative working relationship with OEHS staff
- Liaising with OEHS to understand the various Program requirements
- Confirming the scope of work with MDH for the Program elements and tasks and creating and maintaining the PMB
- Identifying and managing project risks
- Performing change control regarding scope, budget, and schedules
- Organizing completion and approving project deliverables and documentation, in accordance with agreed upon schedules
- Ensuring the executional proficiency of the 120 Water Audit, Inc Team, in accordance with program requirements.
- Demonstrating how the project can be delivered effectively and efficiently
- Establishing project control(s)
- Reviewing the state of the Program with the Program Director at daily project control meetings throughout the Implementation phase
- Reviewing Contract documents to identify project quality requirements
- Developing, Issuing, and Maintaining the Quality Management Plan and associated Quality Assurance Procedures

Program Manager

- Managing the ongoing, day-to-day execution of the program once go-live is achieved
- Completing the program on time, budget and to required quality
- Identifying and managing project risks
- Overseeing the maintenance of Program records
- Reviewing the state of the Program with the Program Director at weekly project control meetings
- Developing a strong, collaborative working relationship with OEHS staff
- Performing ongoing change control regarding scope, budget, and schedules
- Arranging and responding to quality audits
- Communicating and meeting with designated OEHS staff on a regular basis during the execution of the program

120Water

Addendum

Exhibit 1. - Project Team Resumes

Exhibit 2. - EUROFINS EATON ANALYTICAL, LLC Certification

Exhibit 3 - 2019 Study "Cost Analysis: Reducing Lead in School and Childcare Facility Drinking Water" Prepared by Erica Walker, Director of Lead Programs, 120 Water Audit, Inc

Exhibit 4. - Quality Assurance Protection Plan

Exhibit 5. - Quality Management Plan Example

Exhibit 6. - Quarterly and Annual Report

Exhibit 7. - Addendum Acknowledgement

120Water

Exhibit 1. - Project Team Resumes

Included Resumes: Uploaded in the WVOasis Portal as separate PDF files with titles:

- **Logan Turner - Resume**
- **Abby Warner - Resume**
- **Phil Ortman - Resume**
- **Jennifer Whitson - Resume**
- **Taylor Smith - Resume**
- **Dan Moyers - Resume**

Exhibit 2. - EUROFINS EATON ANALYTICAL, LLC Certification

See Attachment “EUROFINS EATON ANALYTICAL, LLC Certification”

120Water

Exhibit 3 - 2019 Study "Cost Analysis: Reducing Lead in School and Childcare Facility Drinking Water" Prepared by Erica Walker, Director of Lead Programs, 120 Water Audit, Inc

120Water

EXECUTIVE SUMMARY

In the years following the Flint water crisis, public attention has turned to lead in school drinking water. There is no federal mandate to test water in all schools and childcare facilities and, though states have initiated a series of legislative and voluntary initiatives, many facilities remain untested. School mandates have outpaced childcare facilities mandates even though young children under 6 are most vulnerable to lead exposure. Because many schools and childcare buildings are older than the earliest laws reducing lead in plumbing materials, we suggest a majority of schools and childcare facilities will discover at least some sources of lead throughout their drinking water systems. Results from several state-wide programs in Massachusetts and Indiana support this (IFA, 2019; MDEP, 2017).

To provide of a sense of what it could cost to address the issue of lead in school and childcare facility drinking water, we estimate financial needs for state-wide lead reduction programs across the United States. Modeled costs are similar across facility types for field collection, lab analysis, and agency oversight. However, childcare facilities, especially those in small or residential buildings, may face higher remediation costs as these buildings are more likely to have lead service lines. At a minimum, we believe all cooking and drinking water fixtures in schools and childcare facilities should be tested to provide baseline water quality information. We also suggest that state environmental and public health agencies, if given adequate resources, are best positioned to offer technical assistance to schools and childcare facilities.

KEY FINDINGS

Regulated Childcare Facilities

- **368,049 facilities** in 2017-2018
- **$136-$194 Million** to analyze samples
- **$445-$657 Million** to sample, analyze, remediate fixtures, and run programs
- **9 states** have regulatory requirements

Public Schools

- **98,456 facilities** in 2015-2016
- **$156-$209 Million** to analyze samples
- **$326-$418 Million** to sample, analyze, remediate fixtures, and run programs
- **13 states** have regulatory requirements

OVERVIEW OF PUBLIC SCHOOLS & CHILDCARE FACILITIES

Lead in School & Childcare Facilities

Every day children and infants consume water in baby formula, eat school lunches prepared with water, and drink water from dozens of fixtures in classrooms, hallways, and athletic facilities. Unfortunately, lead in brass plumbing components, solder, and service lines can leach into facility drinking water or be transferred into food during the cooking process. High lead concentrations in drinking water are linked to decreased mental ability, learning difficulties, reduced growth in young children, blood anemia, and brain damage (ATDSR, 2007) and there is evidence that even low levels of exposure may cause neurological harm (Bellinger et al., 2003; Canfield et al., 2013). In this report, we provide an estimate of what it could cost to first understand the extent of lead sources in school and daycare drinking water systems and then to reduce these sources across the country. We focus on drinking water, but other important pathways of lead exposure inside and outside of school and childcare facilities include paint, soil, and dust.

Fixtures: Faucets, water coolers fountains, coffee makers, ice machines, and other plumbing products conveying drinking or cooking water

The Lead and Copper Rule (LCR) requires Public Water Systems to test a limited number of homes on a biannual, annual, or triennial basis for lead and copper. The law primarily serves as a check on water treatment and was not written to help systems strategically locate and remove lead sources. A system in which the 90th percentile sample for lead exceeds 15 ppb may have to apply corrosion control treatment to reduce the potential for lead to leach into drinking water or initiate other protective measures. A very limited number of schools and childcare facilities are considered Non-Community Non-Transient Water Systems and are required to test a portion of fixtures under the LCR. Typically, these facilities either source drinking water from a private well or provide some water treatment on site. Although older facilities are particularly at risk, lead in drinking water will likely be an issue for most schools and daycares. To understand why, we first look at how the meaning of "lead-free" plumbing has evolved over the past 33 years.

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Lead Regulation for U.S. Plumbing Products & Impact on School/Childcare Facilities

In 1986 congress defined "lead-free" as solder and flux with not more than 0.2% lead and pipes with not more than 8% lead in a section of the Safe Drinking Water Act (SDWA). In 1988, the Lead Contamination Control Act (LCCA) required EPA to guide states and localities on testing and reducing lead in school and childcare drinking water. The LCCA also identified and banned water coolers that were not lead-free. Then in 1996, the SDWA was amended to include other plumbing products such as elbows, shut-off valves, and faucets. In 2011, following the realization that plumbing products with 8% lead could still leach high levels of this contaminant in drinking water, EPA lowered the maximum lead content of plumbing products to 0.25% of the "wetted surface" but this law was not enforced until 2014. The average public school building was constructed in 1957, according to the most recent data (NCES, 1999). This is twenty-nine years before Congress passed any lead regulation for plumbing products, which suggests many schools across the country have unknowingly installed leaded faucets, water coolers, and plumbing parts throughout buildings. We provide a diagram of the regulatory history below (figure 1). Water chemistry varies within plumbing systems and dictates the time, composition, and extent of lead leaching into drinking water. In addition, corrosive water and intermittent fixture use can influence high lead concentrations in large buildings (Elfland et al., 2010). For these reasons, older schools and childcare facilities are at a higher risk of lead contamination but all facilities built before 2014 face some risk.

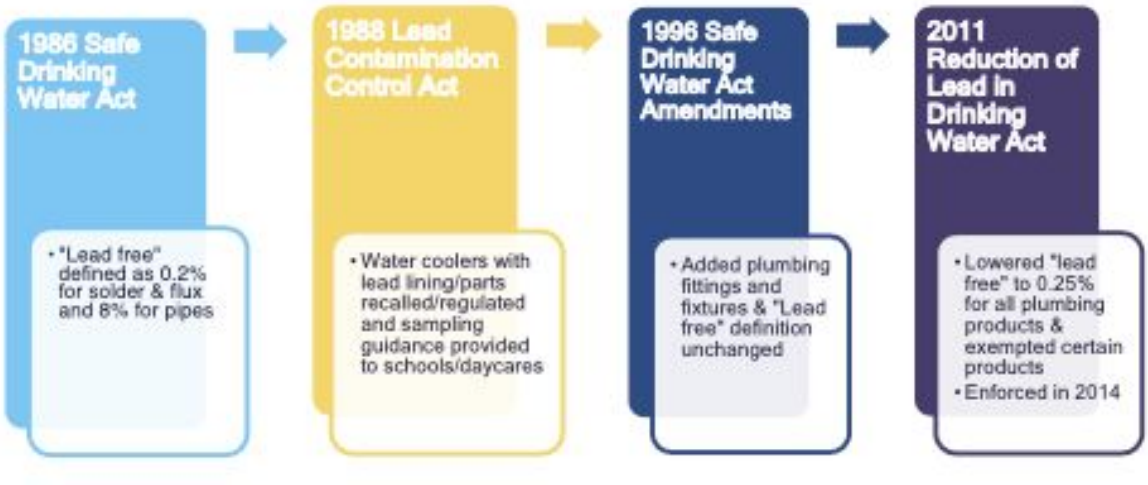

Figure 1. Regulatory history of "lead-free" plumbing definitions and standards in the U.S.

Number of Public Schools & Childcare Facilities in the United States

There were 98,456 operating public schools in the 2015-2016 academic year (NCES, 2017). A majority of states operated less than 2,000 schools, and 46 states had less than 5,000 schools (figure 2). Regulated childcare facilities are defined differently in each state but generally fall into three categories: smaller family or residential facilities, childcare centers, and school programs. We assess school childcare programs independently from public schools as these facilities have separate fixtures. Where possible, we obtained facility numbers from Childcare Aware America's annual report which includes head start programs (2017). We gathered the remaining data from agency websites and personal correspondence with licensing staff. There were 363,117 facilities regulated in 2017-2018 with 38 states overseeing less than 10,000 facilities. This results in a total of 461,573 childcare facilities (79%) and public schools (21%) across the country.

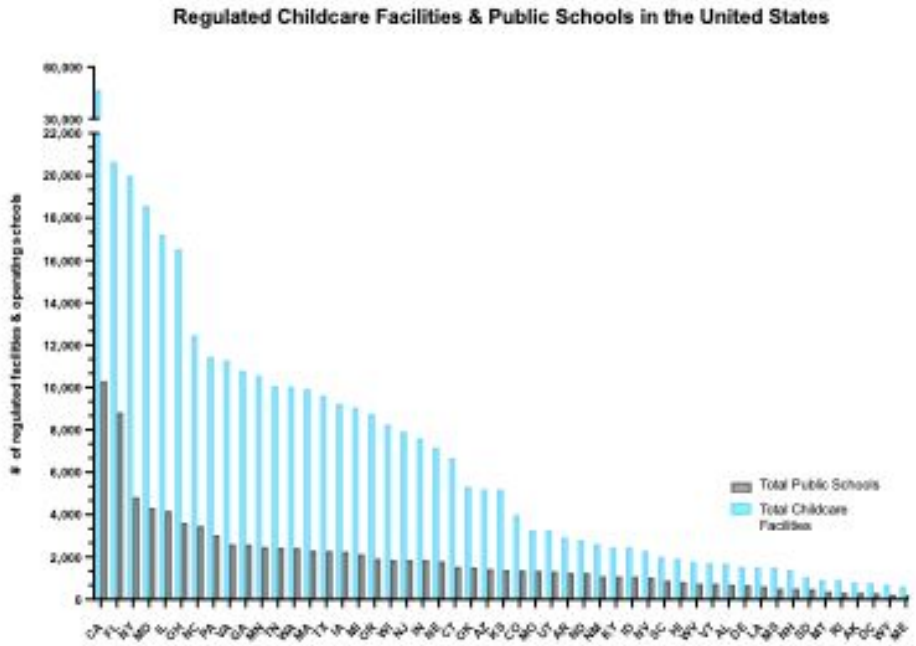

Figure 2. Operating public schools (2015-2016) and regulated daycares (2017-2018) across the United States.

It is important to note that private schools (serving an estimated 5.7 million children), foster homes (serving an estimated 427,400 children) and unregulated childcare buildings were not included in this report due to a lack of available facility data (NCES, 2017; AFCARS, 2017). However, these facilities serve a large number of children and should be included in testing and remediation efforts.

CURRENT LEGISLATIVE & VOLUNTARY EFFORTS

The community-driven response to lead risk in children's drinking water in the absence of a federal mandate is a colorful patchwork quilt of voluntary and mandatory state programs with a wide variety of standards. Programs exhibit different sampling protocols, remediation thresholds, levels of funding and technical support (Cradock et al., 2019). We now provide an overview of current regulatory and voluntary efforts in the U.S.

School Programs

As of this report, 13 states and Washington D.C. have passed or promulgated lead sampling laws and regulations for schools, 11 states have carried out voluntary testing initiatives ranging in size from small district pilots to full state coverage, and 10 states are considering new legislation. In 16 states no regulatory initiatives or voluntary programs appear to be active (figure 3). It is important to note that this report looks only at state-driven programs and does not account for lead sampling efforts initiated by school districts.

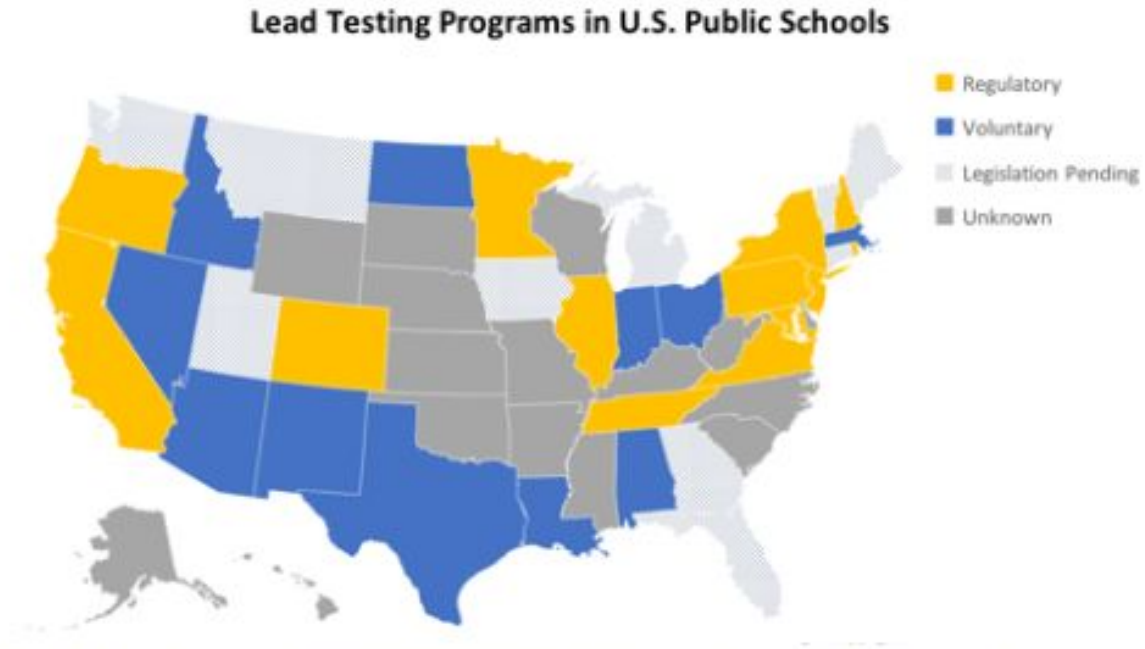

Figure 3. A map of state lead sampling initiatives in regulated public schools across the U.S. as of March 2019.

Programs for Childcare Facilities

Despite the reality that children under the age of 6 are most vulnerable to risks associated with lead exposure, lead sampling efforts in childcare centers lag notably behind school initiatives (figure 4.). As of this report, only 9 states have passed legislation with some variation of lead reduction requirements and only 2 states have initiated voluntary programs, though some school-based childcare facilities were likely tested during voluntary school sampling programs. Legislation is currently pending in 6 states, and activities in 33 states and Washington D.C. are unknown.

Figure 4. A map of state lead sampling initiatives in regulated childcare facilities across the U.S. as of March 2019.

NATIONAL COST ESTIMATES FOR LEAD REDUCTION IN PUBLIC SCHOOLS & CHILDCARE FACILITIES

Given the public health risks, the reality that many facilities will contain leaded plumbing products, and the landscape of current lead testing efforts in this country, we now present an estimate of what it could cost to sample, remediate, and oversee lead reduction in drinking water programs in every state. For this cost analysis, we break up each state program into four components: Field Collection, Lab Analysis, Remediation, and Agency Oversight (figure 6). Table 1 provides total costs estimated by state.

Field Collection & Lab Analysis

In most cases, states either require facilities to collect water samples or provide field teams to assist schools with this task. When schools and childcare facility staff are expected to take water samples, states provide technical assistance through webinars, on-site training, and agency guidance documents. Field teams can be comprised of agency staff, consulting firms, or university partners. For this report, we assume the state provides funds for sample planning and collection but do not include extra costs associated with training, transportation, or additional field materials. These costs can be considerable, especially for large states where more transportation funds and field staff may be needed to cover the same number of facilities. To determine lab costs, we looked at the advertised fees for 27 labs in 6 different states for analyzing water samples for total lead. Costs per sample ranged from $15 to $60 with an average cost of $26.48. We then calculated total lab cost by-state using average fixtures and sample counts obtained from existing state programs (IFA, 2019; MDEP, 2017). Our high cost estimate accounts for a higher number of fixtures and samples in both types of facilities and includes follow up samples for remediation.

Remediation

Based on results from an existing lead sampling program in Indiana, we assume that 62% of all public schools and childcare facilities will have at least 1 fixture in need of remediation at an average cost of $550 per school (IFA,2019). While this is likely a conservative cost estimate, it reflects the reality that many schools will choose from a variety of low to high-cost remediation options including fixture removal, updates to plumbing components (shut off valves, elbows, etc.), complete fixture replacement, or filtration for example. A report released this year found that 44% of all school buildings tested in 12 state-wide programs had at least one fixture over the state action level

(Craddock et al., 2019). We used IFA's (2019) less conservative value (62% of facilities at an action level of 15 ppb) since not all of the programs in the study collected from all drinking and cooking water fixtures.

In addition to fixture remediation needs, we suggest childcare facilities are more likely to contain to lead service lines (LSLs) as lead was more commonly used in residential homes or small buildings before 1940 and even until the mid 1980's in some cities. To determine the minimum LSL remediation cost for childcare facilities by state, we calculated the probability of finding an LSL in a childcare facility using national LSL survey-derived estimates by Cornwell (2016) and the number of service lines of any material by state. Due to a lack of facility-specific information, we assumed a uniform probability, meaning that childcare facilities are no more or less likely to contain an LSL than any other building in the state. To calculate our higher remediation cost estimate, we assumed state programs would find LSLs in 10% of all facilities in each state. In both scenarios, we assume an average service line replacement cost of $6,000 per line. While EPA estimated service line replacement costs vary from $2,500 to $8,000 per line (EPA, 2016), we selected a less conservative estimate because we expect childcare facilities will be less cost-effective at replacement than utilities which may be able to reduce average costs with different technologies and strategic execution.

These estimates are only meant to provide states and policymakers with a method of accounting for LSLs in state planning and should not be used to determine the location and frequency of LSLs as more facility information would be needed to evaluate this question. States should take into account that a program in Illinois, a state with approximately 17,000 childcare facilities and an estimated 726,000 LSLs, is more likely to encounter LSLs than California, a state with over 46,000 childcare facilities but with fewer expected LSLs (65,700) and should prepare to assist facilities in reducing these substantial sources of lead.

Agency Oversight

State-wide programs require dedicated leadership from agency professionals who often provide oversight to field teams and technical assistance to schools. Existing programs in Indiana and Massachusetts utilized 3-5 FTEs to do this work (IFA, 2019; MDEP, 2017). We assume agencies will need 3 FTES for every 1,000 schools, while childcare programs will need 3 FTEs for every 2000 facilities and use median household income by state ($43,904-$81,084) to model agency staffing costs (U.S. Department of Commerce, 2018).

Sources of Uncertainty

Our model is primarily based on and adapted from the reported experiences of two state-wide school testing programs (IFA, 2019; MDEP, 2017) and some cost assumptions may not hold for all childcare facilities. In terms of field collection, cost inputs embedded in sampling such as hourly wages for field staff may vary significantly by professional entity and by state. However, remediation costs present the highest amount of uncertainty. The lack of available data diminishes our ability to estimate how many LSLs will be found in each state program. We also assume state programs will find no LSLs in public schools based on service line materials conventionally used in large buildings, but no program has attempted to investigate this issue. In addition, some states require testing every 1-5 years, but we focused only on gathering baseline sampling data for this model. Finally, state action levels determine the scope of remediation needed, and these vary from 2 ppb - 20 ppb. Our model utilized an action level of 15 ppb, but a lower action level would be more protective of children's health and increase the cost of remediation.

Table 1. Total program costs (sampling, analysis, remediation, and oversight) for all U.S Public Schools & Childcare Facilities.

State	Childcare Facilities (Low)	Childcare Facilities (High)	Public Schools (Low)	Public Schools (High)
Alabama	$2,011,049	$3,294,780	$4,954,257	$6,361,550
Alaska	$985,434	$1,597,010	$1,700,018	$2,173,779
Arizona	$6,259,067	$8,827,057	$7,567,292	$9,697,350
Arkansas	$3,475,094	$5,249,949	$3,564,600	$4,579,269
California	$56,859,398	$89,436,047	$34,402,510	$44,011,088
Colorado	$4,877,178	$7,316,668	$6,242,012	$7,978,514
Connecticut	$8,138,357	$11,340,448	$4,583,604	$5,860,333
Delaware	$1,849,913	$2,727,89[illegible]	$739,636	$947,606
District of Columbia	$955,455	$1,372,060	$770,628	$983,260
Florida	$24,630,652	$33,617,317	$14,223,023	$18,253,721
Georgia	$12,933,110	$18,170,695	$7,582,048	$9,724,230
Hawaii	$2,341,857	$3,473,924	$971,652	$1,242,106
Idaho	$2,950,032	$4,083,078	$2,462,955	$3,156,810
Illinois	$20,871,027	$31,844,015	$13,876,143	$17,769,748
Indiana	$9,125,466	$12,471,353	$6,351,631	$8,143,155
Iowa	$11,193,317	$16,972,591	$4,479,008	$5,737,085
Kansas	$6,243,462	$9,947,462	$4,360,509	$5,591,541
Kentucky	$2,923,725	$4,635,602	$5,060,404	$6,497,540
Louisiana	$1,786,650	$2,937,601	$4,533,498	$5,829,812
Maine	$721,118	$1,180,546	$2,007,008	$2,576,827
Maryland	$22,929,122	$31,545,190	$4,847,076	$6,187,222
Massachusetts	$17,115,546	$24,562,660	$6,236,734	$7,973,235
Michigan	$11,919,979	$19,069,328	$11,454,457	$14,688,714
Minnesota	$12,974,161	$20,904,620	$8,290,298	$10,601,280
Mississippi	$1,765,589	$2,903,642	$3,507,892	$4,511,370
Missouri	$3,911,244	$6,120,147	$8,000,303	$10,260,925
Montana	$1,088,240	$1,775,063	$2,721,711	$3,489,241
Nebraska	$8,638,376	$12,169,844	$3,589,893	$4,601,764
Nevada	$2,739,058	$4,261,168	$2,184,236	$2,801,617
New Hampshire	$1,691,407	$2,427,449	$1,643,559	$2,100,533

New Jersey	$9,671,727	$13,993,716	$8,666,671	$11,080,240
New Mexico	$3,102,209	$4,661,242	$2,893,655	$3,718,073
New York	$24,140,017	$37,605,782	$16,001,888	$20,500,751
North Carolina	$14,801,001	$20,753,117	$8,539,998	$10,967,556
North Dakota	$3,358,115	$4,728,478	$1,714,299	$2,197,386
Ohio	$19,897,640	$27,935,489	$11,975,647	$15,350,727
Oklahoma	$6,362,047	$9,138,659	$5,930,672	$7,609,352
Oregon	$10,572,250	$14,966,886	$4,127,948	$5,286,238
Pennsylvania	$13,797,984	$19,644,721	$10,021,024	$12,836,543
Rhode Island	$1,094,626	$1,717,277	$1,041,968	$1,333,871
South Carolina	$2,403,019	$3,929,550	$4,111,802	$5,275,687
South Dakota	$1,279,072	$2,000,145	$2,303,736	$2,954,691
Tennessee	$12,035,306	$16,305,956	$6,126,372	$7,860,075
Texas	$11,553,560	$18,382,518	$29,193,628	$37,424,755
Utah	$3,961,472	$5,628,530	$3,454,101	$4,417,477
Vermont	$2,066,904	$3,080,386	$1,042,862	$1,335,698
Virginia	$13,759,771	$20,781,446	$7,132,067	$9,121,303
Washington	$12,280,964	$16,907,447	$8,145,143	$10,408,563
West Virginia	$2,097,318	$3,386,249	$2,429,886	$3,123,741
Wisconsin	$9,976,791	$13,873,417	$7,486,945	$9,589,958
Wyoming	$846,716	$1,381,893	$1,222,225	$1,567,287
Totals	**$444,962,591**	**$657,038,112**	**$326,471,133**	**$418,291,198**

CONCLUSION

We present a financial estimate to sample, remediate, and manage state-wide lead reduction in drinking water programs. Our analysis suggests it could cost between $771 million to $1.08 billion to enable states to run lead reduction in drinking water programs for both public schools and regulated childcare facilities across the nation. Costs associated with field sampling, lab analysis, and agency oversight are similar though childcare centers represent 79% of all facilities, which is because childcare centers will likely have fewer drinking water fixtures on average (figure 6.). The possibility of lead service lines in childcare buildings, particularly in residential homes, drove total estimated remediation costs up for these facilities.

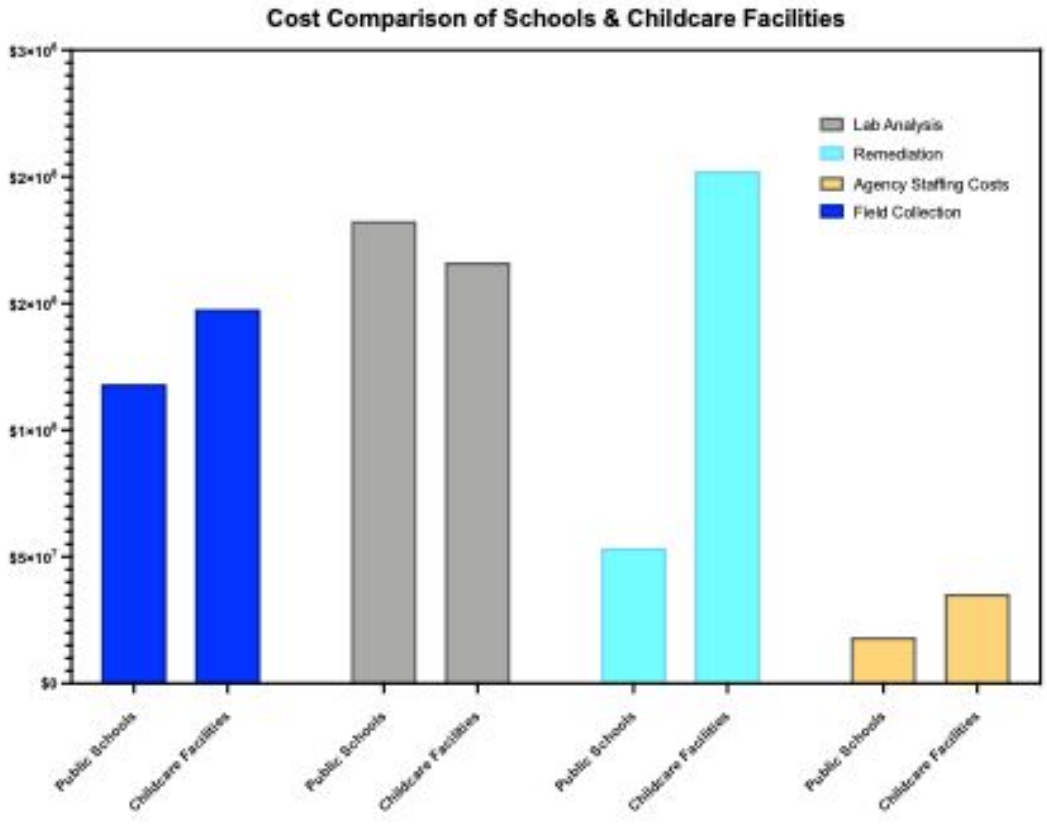

Figure 6. Total estimated cost to collect, analyze, remediate and oversee lead reduction in drinking programs for all public schools & childcare facilities in the U.S.

In place of a federal mandate to test lead in water in most schools and childcare facilities, states have initiated a flurry of legislative and voluntary initiatives. Almost 11,000 schools had been sampled as of February 2018 (Craddock et al., 2019) and, though this number is likely higher today, many facilities around the country have not yet received the support they need. Because the average school is older than regulatory efforts to reduce lead in plumbing materials, we suggest a majority of schools and childcare facilities will discover sources of lead throughout their drinking water systems. Though less is known about the state of child care infrastructure, we assume similar risks for this group of facilities. Environmental justice is also a concern as many schools and childcare centers in low-income areas with older infrastructure may not have the financial capacity to both test for and reduce sources of lead. We believe environmental and public health agencies are in an excellent position to assist if given adequate financial support and the potential benefits associated with an investment this size are notable. For example, one researcher found that $7-$221 dollars could be returned in health benefits, increased IQ, higher lifetime earnings, tax revenue, reduced spending on special education, and reduced criminal activity for every $1 spent on lead hazard control (Gould, 2009).

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Exhibit 4. - Quality Assurance Protection Plan

See “IFA - QAPP” Document attachment in the WVOasis Portal

Exhibit 5. - Quality Management Plan Example

See “QMP-EPA Template” attachment in the WVOasis Portal

Exhibit 6. - Quarterly and Annual Report

See “Quarterly/Annual Report” attachment in the WVOasis Portal

Exhibit 7. - Addendum Acknowledgement

See “Quarterly/Annual Report” attachment in the WVOasis Portal

GENERAL TERMS AND CONDITIONS:

1. CONTRACTUAL AGREEMENT: Issuance of a Award Document signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

2. DEFINITIONS: As used in this Solicitation/Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation/Contract.

2.1. "Agency" or **"Agencies"** means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.

2.2. "Bid" or **"Proposal"** means the vendors submitted response to this solicitation.

2.3. "Contract" means the binding agreement that is entered into between the State and the Vendor to provide the goods or services requested in the Solicitation.

2.4. "Director" means the Director of the West Virginia Department of Administration, Purchasing Division.

2.5. "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.

2.6. "Award Document" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the contract holder.

2.7. "Solicitation" means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

2.8. "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.

2.9. "Vendor" or **"Vendors"** means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3. CONTRACT TERM; RENEWAL; EXTENSION: The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:

☑ **Term Contract**

Initial Contract Term: Initial Contract Term: This Contract becomes effective on award and extends for a period of one (1) year(s).

Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal should be delivered to the Agency and then submitted to the Purchasing Division thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Unless otherwise specified below, renewal of this Contract is limited to one (1) successive one (1) year periods or multiple renewal periods of less than one year, provided that the multiple renewal periods do not exceed the total number of months available in all renewal years combined. Automatic renewal of this Contract is prohibited. Renewals must be approved by the Vendor, Agency, Purchasing Division and Attorney General's office (Attorney General approval is as to form only)

☐ **Alternate Renewal Term** – This contract may be renewed for _____ successive _____ year periods or shorter periods provided that they do not exceed the total number of months contained in all available renewals. Automatic renewal of this Contract is prohibited. Renewals must be approved by the Vendor, Agency, Purchasing Division and Attorney General's office (Attorney General approval is as to form only)

Delivery Order Limitations: In the event that this contract permits delivery orders, a delivery order may only be issued during the time this Contract is in effect. Any delivery order issued within one year of the expiration of this Contract shall be effective for one year from the date the delivery order is issued. No delivery order may be extended beyond one year after this Contract has expired.

☐ **Fixed Period Contract:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within _____days.

☐ **Fixed Period Contract with Renewals:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and part of the Contract more fully described in the attached specifications must be completed within _____ days. Upon completion of the work covered by the preceding sentence, the vendor agrees that maintenance, monitoring, or warranty services will be provided for _____ year(s) thereafter.

☐ **One Time Purchase:** The term of this Contract shall run from the issuance of the Award Document until all of the goods contracted for have been delivered, but in no event will this Contract extend for more than one fiscal year.

☐ **Other:** See attached.

4. NOTICE TO PROCEED: Vendor shall begin performance of this Contract immediately upon receiving notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the fully executed Award Document will be considered notice to proceed.

5. QUANTITIES: The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.

☐ **Open End Contract:** Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. It is understood and agreed that the Contract shall cover the quantities actually ordered for delivery during the term of the Contract, whether more or less than the quantities shown.

☐ **Service:** The scope of the service to be provided will be more clearly defined in the specifications included herewith.

☑ **Combined Service and Goods:** The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.

☐ **One Time Purchase:** This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.

6. EMERGENCY PURCHASES: The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.

7. REQUIRED DOCUMENTS: All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

☐ **BID BOND (Construction Only):** Pursuant to the requirements contained in W. Va. Code § 5-22-1(c), All Vendors submitting a bid on a construction project shall furnish a valid bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.

☐ **PERFORMANCE BOND:** The apparent successful Vendor shall provide a performance bond in the amount of 100% of the contract. The performance bond must be received by the Purchasing Division prior to Contract award.

☐ **LABOR/MATERIAL PAYMENT BOND:** The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be delivered to the Purchasing Division prior to Contract award.

In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under $100,000. Personal or business checks are not acceptable. Notwithstanding the foregoing, West Virginia Code § 5-22-1 (d) mandates that a vendor provide a performance and labor/material payment bond for construction projects. Accordingly, substitutions for the performance and labor/material payment bonds for construction projects is not permitted.

☐ **MAINTENANCE BOND:** The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.

☐ **LICENSE(S) / CERTIFICATIONS / PERMITS:** In addition to anything required under the Section of the General Terms and Conditions entitled Licensing, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits upon request and in a form acceptable to the State. The request may be prior to or after contract award at the State's sole discretion.

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The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications regardless of whether or not that requirement is listed above.

8. INSURANCE: The apparent successful Vendor shall furnish proof of the insurance identified by a checkmark below and must include the State as an additional insured on each policy prior to Contract award. The insurance coverages identified below must be maintained throughout the life of this contract. Thirty (30) days prior to the expiration of the insurance policies, Vendor shall provide the Agency with proof that the insurance mandated herein has been continued. Vendor must also provide Agency with immediate notice of any changes in its insurance policies, including but not limited to, policy cancelation, policy reduction, or change in insurers. The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed in this section.

Vendor must maintain:

☑ **Commercial General Liability Insurance** in at least an amount of: $1,000,000-***See Below per occurrence.

☑ **Automobile Liability Insurance** in at least an amount of: $1,000,000 per occurrence.

☐ **Professional/Malpractice/Errors and Omission Insurance** in at least an amount of: _____ per occurrence. Notwithstanding the forgoing, Vendor's are not required to list the State as an additional insured for this type of policy.

☐ **Commercial Crime and Third Party Fidelity Insurance** in an amount of: _____ per occurrence.

☑ **Cyber Liability Insurance** in an amount of: $1,000,000 per occurrence.

☐ **Builders Risk Insurance** in an amount equal to 100% of the amount of the Contract.

☐ **Pollution Insurance** in an amount of: _____ per occurrence.

☐ **Aircraft Liability** in an amount of: _____ per occurrence.

☑ ***STATE OF WEST VIRGINIA MUST BE LISTED AS ADDITIONAL INSURED ON INSURANCE CERTIFICATE

☑ ***INSURANCE CERTIFICATE HOLDER SHOULD READ AS FOLLOWS:
WV DHHR
350 CAPITOL STREET, RM 313, CHARLESTON, WV 25301

☐

☐

Notwithstanding anything contained in this section to the contrary, the Director of the Purchasing Division reserves the right to waive the requirement that the State be named as an additional insured on one or more of the Vendor's insurance policies if the Director finds that doing so is in the State's best interest.

9. WORKERS' COMPENSATION INSURANCE: The apparent successful Vendor shall comply with laws relating to workers compensation, shall maintain workers' compensation insurance when required, and shall furnish proof of workers' compensation insurance upon request.

10. [Reserved]

11. LIQUIDATED DAMAGES: This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy. Vendor shall pay liquidated damages in the amount specified below or as described in the specifications:

☑ n/a _____ for _____

☐ Liquidated Damages Contained in the Specifications

12. ACCEPTANCE: Vendor's signature on its bid, or on the certification and signature page, constitutes an offer to the State that cannot be unilaterally withdrawn, signifies that the product or service proposed by vendor meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise indicated, and signifies acceptance of the terms and conditions contained in the Solicitation unless otherwise indicated.

13. PRICING: The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification. Notwithstanding the foregoing, Vendor must extend any publicly advertised sale price to the State and invoice at the lower of the contract price or the publicly advertised sale price.

14. PAYMENT IN ARREARS: Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears.

15. PAYMENT METHODS: Vendor must accept payment by electronic funds transfer and P-Card. (The State of West Virginia's Purchasing Card program, administered under contract by a banking institution, processes payment for goods and services through state designated credit cards.)

16. TAXES: The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

17. ADDITIONAL FEES: Vendor is not permitted to charge additional fees or assess additional charges that were not either expressly provided for in the solicitation published by the State of West Virginia or included in the unit price or lump sum bid amount that Vendor is required by the solicitation to provide. Including such fees or charges as notes to the solicitation may result in rejection of vendor's bid. Requesting such fees or charges be paid after the contract has been awarded may result in cancellation of the contract.

18. FUNDING: This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.

19. CANCELLATION: The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may also cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules § 148-1-5.2.b.

20. TIME: Time is of the essence with regard to all matters of time and performance in this Contract.

21. APPLICABLE LAW: This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.

22. COMPLIANCE WITH LAWS: Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendor acknowledges that it has reviewed, understands, and will comply with all applicable laws, regulations, and ordinances.

> **SUBCONTRACTOR COMPLIANCE:** Vendor shall notify all subcontractors providing commodities or services related to this Contract that as subcontractors, they too are required to comply with all applicable laws, regulations, and ordinances. Notification under this provision must occur prior to the performance of any work under the contract by the subcontractor.

23. ARBITRATION: Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.

24. MODIFICATIONS: This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any change to existing contracts that adds work or changes contract cost, and were not included in the original contract, must be approved by the Purchasing Division and the Attorney General's Office (as to form) prior to the implementation of the change or commencement of work affected by the change.

25. WAIVER: The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.

26. SUBSEQUENT FORMS: The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.

27. ASSIGNMENT: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments.

28. WARRANTY: The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.

29. STATE EMPLOYEES: State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.

30. PRIVACY, SECURITY, AND CONFIDENTIALITY: The Vendor agrees that it will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the Agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the Agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/default.html.

31. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

32. LICENSING: In accordance with West Virginia Code of State Rules § 148-1-6.1.e, Vendor must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agency or political subdivision. Obligations related to political subdivisions may include, but are not limited to, business licensing, business and occupation taxes, inspection compliance, permitting, etc. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.

SUBCONTRACTOR COMPLIANCE: Vendor shall notify all subcontractors providing commodities or services related to this Contract that as subcontractors, they too are required to be licensed, in good standing, and up-to-date on all state and local obligations as described in this section. Obligations related to political subdivisions may include, but are not limited to, business licensing, business and occupation taxes, inspection compliance, permitting, etc. Notification under this provision must occur prior to the performance of any work under the contract by the subcontractor.

33. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Award Document from any agency of the State of West Virginia, the Vendor agrees to convey, sell, assign, or transfer to the State of West Virginia all rights, title, and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to Vendor.

34. VENDOR CERTIFICATIONS: By signing its bid or entering into this Contract, Vendor certifies (1) that its bid or offer was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services; (2) that its bid or offer is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this Solicitation in its entirety; understands the requirements, terms and conditions, and other information contained herein.

Vendor's signature on its bid or offer also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency. The individual signing this bid or offer on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or offer or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

35. VENDOR RELATIONSHIP: The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting, supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, etc. and the filing of all necessary documents, forms, and returns pertinent to all of the foregoing.

Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

36. INDEMNIFICATION: The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

37. PURCHASING AFFIDAVIT: In accordance with West Virginia Code §§ 5A-3-10a and 5-22-1(i), the State is prohibited from awarding a contract to any bidder that owes a debt to the State or a political subdivision of the State, Vendors are required to sign, notarize, and submit the Purchasing Affidavit to the Purchasing Division affirming under oath that it is not in default on any monetary obligation owed to the state or a political subdivision of the state.

38. ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE: This Contract may be utilized by other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"), provided that both the Other Government Entity and the Vendor agree. Any extension of this Contract to the aforementioned Other Government Entities must be on the same prices, terms, and conditions as those offered and agreed to in this Contract, provided that such extension is in compliance with the applicable laws, rules, and ordinances of the Other Government Entity. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.

39. CONFLICT OF INTEREST: Vendor, its officers or members or employees, shall not presently have or acquire an interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.

40. REPORTS: Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:

☑ Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.

☐ Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at purchasing.requisitions@wv.gov.

41. BACKGROUND CHECK: In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision. The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304) 558-9911 for more information.

42. PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS: Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:

a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.

b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process. The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:

c. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars ($2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or

d. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

43. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars ($50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a

"substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products. This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

44. INTERESTED PARTY SUPPLEMENTAL DISCLOSURE: W. Va. Code § 6D-1-2 requires that for contracts with an actual or estimated value of at least $1 million, the vendor must submit to the Agency a supplemental disclosure of interested parties reflecting any new or differing interested parties to the contract, which were not included in the original pre-award interested party disclosure, within 30 days following the completion or termination of the contract. A copy of that form is included with this solicitation or can be obtained from the WV Ethics Commission. This requirement does not apply to publicly traded companies listed on a national or international stock exchange. A more detailed definition of interested parties can be obtained from the form referenced above.

45. PROHIBITION AGAINST USED OR REFURBISHED: Unless expressly permitted in the solicitation published by the State, Vendor must provide new, unused commodities, and is prohibited from supplying used or refurbished commodities, in fulfilling its responsibilities under this Contract.

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.

Logan Turner - Senior Account Executive
(Name, Title)
Logan Turner - Senior Account Executive
(Printed Name and Title)
625 South Main Street Zionville, IN 46077
(Address)
765-618-1222
(Phone Number) / (Fax Number)
logan@120water.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.

120WaterAudit
(Company)


(Authorized Signature) (Representative Name, Title)

Antony Rhine Vice President of Sales
(Printed Name and Title of Authorized Representative)

December 22. 2020
(Date)

317317-379-7001
(Phone Number) (Fax Number)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ EHS2100000001

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.

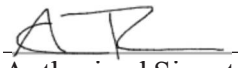
Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

☒ Addendum No. 1	☐ Addendum No. 6
☒ Addendum No. 2	☐ Addendum No. 7
☐ Addendum No. 3	☐ Addendum No. 8
☐ Addendum No. 4	☐ Addendum No. 9
☐ Addendum No. 5	☐ 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.

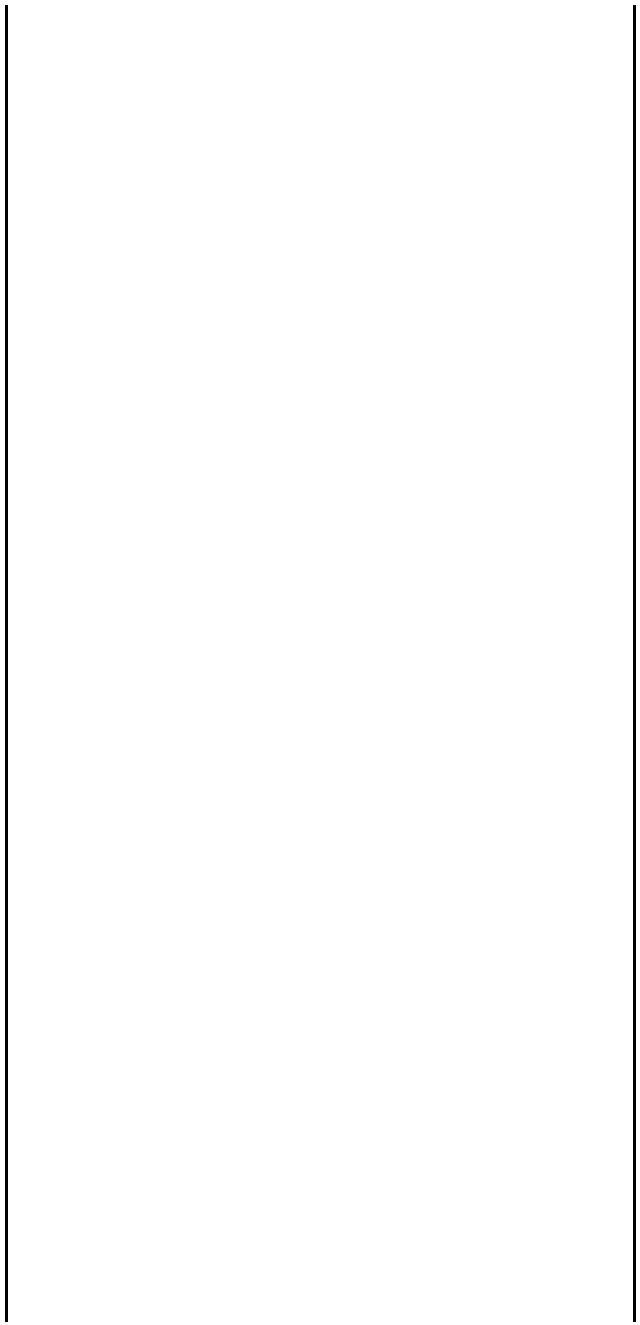
120WaterAudit
Company

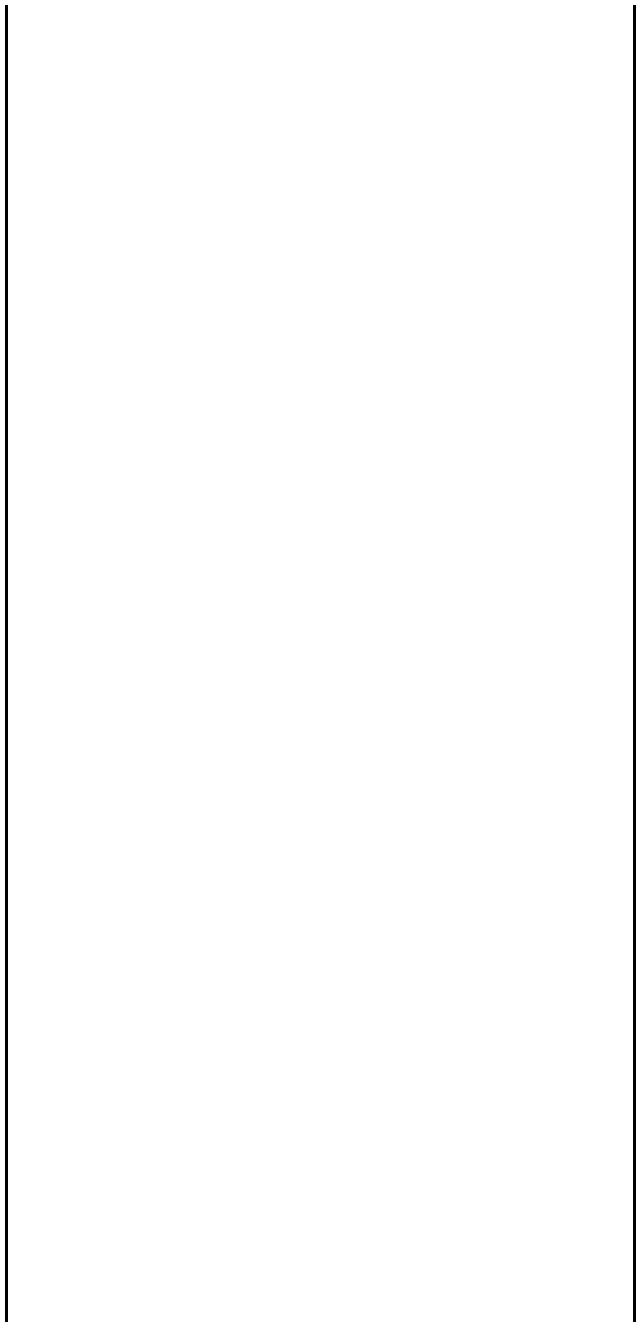

Authorized Signature

December 22, 2020
Date

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

Count of Unique Towns	Count of unique webinar attendees		
24	25	Total	106
Bargersville	adam.heckber@nwcs.k12.in.us	No plan filed	58
Bloomington	chadsmith@zcs.k12.in.us	Plan filed - not approved	7
Bluffton	daves@earlylearningindiana.org	Boxes at school	31
Cloverdale	Dfields@wrv.k12.in.us	Collected	9
East Chicago	dmreyes@hammond.k12.in.us	Tested - no exceedance	1
Gary	dstewart@matchbooklearning.com	Tested - needs remediation	0
Greenfield	gleissnerfelp@gmail.com	Communication noted	0
Greenwood	grantnesbit@msdlt.k12.in.us	Remediation Completed	0
Hammond	jjburggraf@hammond.k12.in.us	Re-tested, if applicable	0
Indianapolis	jmiller@ics-charter.org		
Jeffersonville	josullivan@k12.com		
Kingsford Heights	jsneed@nhj.k12.in.us		
Lafayette	jstok@csdunes.org		
LaPorte	krkleinfeldt@hammond.k12.in.us		
Lyons	lemmons@wrv.k12.in.us		
Mishawaka	lfish@wrv.k12.in.us		
Ossian	maria.jimenez@eastchicago.lha.net		
Rising Sun	mcizewski@lpcsc.k12.in.us		
Switz City	miqbal@csdunes.org		
Trafalgar	tburks@theprojectschool.org		
Whitestown	tpbryak@hammond.k12.in.us		
Whiting	tshields@cloverdale.k12.in.us		
Worthington	tthatcher@k12.com		
Zionsville	veronica.eskew@leonagroup.com		
	watersb@centergrove.k12.in.us		





WEST VIRGINIA
Department of
Health & Human Resources
BUREAU FOR PUBLIC HEALTH

Certification Number: **9927 C**
Date Issued: ***January 01, 2020***
Expiration Date: ***December 31, 2020***

Office of Laboratory Services
Environmental Drinking Water Laboratory Certification Program

Certifies that

Eurofins Eaton Analytical, LLC - South Bend
110 South Hill Street
South Bend, IN 46617

Having duly met the requirements of the regulation (64CSR 3-13) for the Certification of Laboratories Analyzing Drinking Water
Is hereby approved as a

State Certified Drinking Water Laboratory

To perform the analyses as indicated on the Certified Parameter List which must accompany this certificate

James C. Kramer PhD
Laboratory Director

Associate Director of Environmental Programs

Surrender Upon Revocation
Certificate Not Transferable
Customers are urged to verify the laboratory's current certification status.
Conspicuously display in the laboratory with the Certified Parameter List in a location on the premises visible to the public.

Not Valid Unless Embossed

WEST VIRGINIA
Department of
Health & Human Resources
BUREAU FOR PUBLIC HEALTH

Office of Laboratory Services

Environmental Drinking Water Laboratory Certification Program

LABORATORY CERTIFIED PARAMETER LIST

Eurofins Eaton Analytical, LLC - South Bend
110 South Hill Street
South Bend, IN 46617

Certification reciprocity certificate
State of Oregon Laboratory ID 4074

Certificate: ***9927 C***
Issue Date: ***1/1/2020***
Expiration Date: ***12/31/2020***

Group: *Microbiology - Group II*		Method	Status	Description
	Cryptosporidium	US EPA 1623	Certified	Filtration/IMS/FA

Group: *Trace Metals*		Method	Status	Description
	Antimony	US EPA 200.8 R 5.4	Certified	
	Arsenic	US EPA 200.8 R 5.4	Certified	
	Barium	US EPA 200.8 R 5.4	Certified	
	Beryllium	US EPA 200.8 R 5.4	Certified	
	Cadmium	US EPA 200.8 R 5.4	Certified	
	Chromium	US EPA 200.8 R 5.4	Certified	
	Copper	US EPA 200.8 R 5.4	Certified	
	Lead	US EPA 200.8 R 5.4	Certified	
	Mercury	US EPA 245.1 R 3.0	Certified	
	Nickel	US EPA 200.8 R 5.4	Certified	
	Selenium	US EPA 200.8 R 5.4	Certified	
	Sodium	US EPA 200.7 R 4.4	Certified	
	Thallium	US EPA 200.8 R 5.4	Certified	

Group: *Inorganics*		Method	Status	Description
	Bromate	US EPA 317 R 2.0	Certified	
	Bromate	US EPA 300.1 R 1.0	Certified	
	Chlorite	US EPA 300.0 R 2.1	Certified	
	Cyanide	US EPA 335.4 R 1.0	Certified	
	Fluoride	US EPA 300.0 R 2.1	Certified	
	Fluoride	SM4500F C	Certified	
	Nitrate-N	US EPA 353.2 R 2.0	Certified	
	Nitrate-N	US EPA 300.0 R 2.1	Certified	
	Nitrite-N	US EPA 353.2 R 2.0	Certified	

This is to certify that the laboratory has been approved to perform the indicated procedures on drinking water in accordance with West Virginia 64CSR 3-13.

WEST VIRGINIA
Department of
Health & Human Resources
BUREAU FOR PUBLIC HEALTH

Office of Laboratory Services

Environmental Drinking Water Laboratory Certification Program

LABORATORY CERTIFIED PARAMETER LIST

Eurofins Eaton Analytical, LLC - South Bend
110 South Hill Street
South Bend, IN 46617

Certification reciprocity certificate
State of Oregon Laboratory ID 4074

Certificate: ***9927 C***
Issue Date: ***1/1/2020***
Expiration Date: ***12/31/2020***

Group: Organics, Pesticides	Method	Status	Description
Alachlor	US EPA 525.2 R 2.0	Certified	
Aldicarb	US EPA 531.2 R 1.0	Certified	
Aldicarb Sulfone	US EPA 531.2 R 1.0	Certified	
Aldicarb Sulfoxide	US EPA 531.2 R 1.0	Certified	
Atrazine	US EPA 525.2 R 2.0	Certified	
Carbofuran	US EPA 531.2 R 1.0	Certified	
Chlordane	US EPA 505 R 2.1	Certified	
Endrin	US EPA 525.2 R 2.0	Certified	
Heptachlor	US EPA 525.2 R 2.0	Certified	
Heptachlor Epoxide	US EPA 525.2 R 2.0	Certified	
Hexachlorobenzene	US EPA 525.2 R 2.0	Certified	
Hexachlorocyclopentadiene	US EPA 525.2 R 2.0	Certified	
Lindane	US EPA 525.2 R 2.0	Certified	
Methoxychlor	US EPA 525.2 R 2.0	Certified	
Oxamyl (Vydate)	US EPA 531.2 R 1.0	Certified	
Simazine	US EPA 525.2 R 2.0	Certified	
Toxaphene	US EPA 505 R 2.1	Certified	

This is to certify that the laboratory has been approved to perform the indicated procedures on drinking water in accordance with West Virginia 64CSR 3-13.

WEST VIRGINIA
Department of
Health & Human Resources
BUREAU FOR PUBLIC HEALTH

Office of Laboratory Services

Environmental Drinking Water Laboratory Certification Program

LABORATORY CERTIFIED PARAMETER LIST

Eurofins Eaton Analytical, LLC - South Bend
110 South Hill Street
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Certification reciprocity certificate
State of Oregon Laboratory ID 4074

Certificate: ***9927 C***
Issue Date: ***1/1/2020***
Expiration Date: ***12/31/2020***

Group: *Organics, Haloacetic Acids (HAA5)*	Method	Status	Description
Bromoacetic Acid	US EPA 552.2 R 1.0	Certified	
Bromoacetic Acid	US EPA 552.3 R 1.0	Certified	
Chloroacetic Acid	US EPA 552.3 R 1.0	Certified	
Chloroacetic Acid	US EPA 552.2 R 1.0	Certified	
Dibromoacetic Acid	US EPA 552.2 R 1.0	Certified	
Dibromoacetic Acid	US EPA 552.3 R 1.0	Certified	
Dichloroacetic Acid	US EPA 552.3 R 1.0	Certified	
Dichloroacetic Acid	US EPA 552.2 R 1.0	Certified	
Trichloroacetic Acid	US EPA 552.2 R 1.0	Certified	
Trichloroacetic Acid	US EPA 552.3 R 1.0	Certified	
Total Haloacetic Acids	US EPA 552.3 R 1.0	Certified	
Total Haloacetic Acids	US EPA 552.2 R 1.0	Certified	

Group: *Organics, Herbicides*	Method	Status	Description
2,4,5-TP (Silvex)	US EPA 515.3 R 1.0	Certified	
2,4-D	US EPA 515.3 R 1.0	Certified	
Dalapon	US EPA 515.3 R 1.0	Certified	
Dinoseb	US EPA 515.3 R 1.0	Certified	
Diquat	US EPA 549.2 R 1.0	Certified	
Endothall	US EPA 548.1 R 1.0	Certified	
Glyphosate	US EPA 547	Certified	
Pentachlorophenol	US EPA 515.3 R 1.0	Certified	
Picloram	US EPA 515.3 R 1.0	Certified	

This is to certify that the laboratory has been approved to perform the indicated procedures on drinking water in accordance with West Virginia 64CSR 3-13.

WEST VIRGINIA
Department of
Health & Human Resources
BUREAU FOR PUBLIC HEALTH

Office of Laboratory Services

Environmental Drinking Water Laboratory Certification Program

LABORATORY CERTIFIED PARAMETER LIST

Eurofins Eaton Analytical, LLC - South Bend
110 South Hill Street
South Bend, IN 46617

Certification reciprocity certificate
State of Oregon Laboratory ID 4074

Certificate: ***9927 C***
Issue Date: ***1/1/2020***
Expiration Date: ***12/31/2020***

Group: *Organics, Trihalomethanes*	Method	Status	Description
Bromoform	US EPA 551.1 R 1.0	Certified	
Bromoform	US EPA 524.3	Certified	
Bromoform	US EPA 524.2 R 4.1	Certified	
Bromodichloromethane	US EPA 524.3	Certified	
Bromodichloromethane	US EPA 551.1 R 1.0	Certified	
Bromodichloromethane	US EPA 524.2 R 4.1	Certified	
Chloroform	US EPA 524.3	Certified	
Chloroform	US EPA 551.1 R 1.0	Certified	
Chloroform	US EPA 524.2 R 4.1	Certified	
Chlorodibromomethane	US EPA 524.3	Certified	
Chlorodibromomethane	US EPA 551.1 R 1.0	Certified	
Chlorodibromomethane	US EPA 524.2 R 4.1	Certified	
Total Trihalomethanes	US EPA 551.1 R 1.0	Certified	
Total Trihalomethanes	US EPA 524.3	Certified	
Total Trihalomethanes	US EPA 524.2 R 4.1	Certified	

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Issue Date: ***1/1/2020***
Expiration Date: ***12/31/2020***

Group: Organics, Volatile Organic Chemicals	Method	Status	Description
1,1,1-Trichloroethane	US EPA 524.2 R 4.1	Certified	
1,1,2-Trichloroethane	US EPA 524.2 R 4.1	Certified	
1,1-Dichloroethylene	US EPA 524.2 R 4.1	Certified	
1,2,4-Trichlorobenzene	US EPA 524.2 R 4.1	Certified	
1,2-Dichlorobenzene	US EPA 524.2 R 4.1	Certified	
1,2-Dichloroethane	US EPA 524.2 R 4.1	Certified	
1,2-Dichloropropane	US EPA 524.2 R 4.1	Certified	
1,4-Dichlorobenzene	US EPA 524.2 R 4.1	Certified	
Benzene	US EPA 524.2 R 4.1	Certified	
Carbon Tetrachloride	US EPA 524.2 R 4.1	Certified	
Chlorobenzene	US EPA 524.2 R 4.1	Certified	
cis-1,2-Dichloroethylene	US EPA 524.2 R 4.1	Certified	
Dichloromethane	US EPA 524.2 R 4.1	Certified	
Ethylbenzene	US EPA 524.2 R 4.1	Certified	
Styrene	US EPA 524.2 R 4.1	Certified	
Tetrachloroethylene	US EPA 524.2 R 4.1	Certified	
Toluene	US EPA 524.2 R 4.1	Certified	
trans-1,2-Dichloroethylene	US EPA 524.2 R 4.1	Certified	
Trichloroethylene	US EPA 524.2 R 4.1	Certified	
Vinyl Chloride	US EPA 524.2 R 4.1	Certified	
Xylenes (Total)	US EPA 524.2 R 4.1	Certified	

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State of Oregon Laboratory ID 4074

Certificate: ***9927 C***
Issue Date: ***1/1/2020***
Expiration Date: ***12/31/2020***

Group: Organics, Synthetic Organic Chemicals	Method	Status	Description
Benzo(a)pyrene	US EPA 525.2 R 2.0	Certified	
Dibromochloropropane (DBCP)	US EPA 504.1 R 1.1	Certified	
Dibromochloropropane (DBCP)	US EPA 524.3	Certified	
Di(2-ethylhexyl)adipate	US EPA 525.2 R 2.0	Certified	
Di(2-ethylhexyl)phthalate	US EPA 525.2 R 2.0	Certified	
Ethylene dibromide (EDB)	US EPA 524.3	Certified	
Ethylene dibromide (EDB)	US EPA 504.1 R 1.1	Certified	
PCBs (As Aroclors)	US EPA 505 R 2.1	Certified	

Group: Radionuclides	Method	Status	Description
Gross Alpha	SM7110B 20ED	Certified	
Gross Alpha	SM7110C 20ED	Certified	
Gross Beta	SM7110B 20ED	Certified	
Radium-226	SM7500Ra B 20ED	Certified	
Radium-228	SM7500Ra D 20ED	Certified	
Tritium	US EPA 906.0	Certified	
Uranium	US EPA 200.8 R 5.4	Certified	

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Quality Assurance Project Plan

for

Indiana Lead Sampling Program for Schools & Child Care Facilities

Water Infrastructure Improvements for the Nation Act Grant

Prepared by:

Indiana Finance Authority
100 N Senate Ave, RM 1275
Indianapolis, IN 46204

Prepared for:

US EPA Region 5
77 W. Jackson Blvd.
WS-15J
Chicago, IL 60604

September 10, 2019

Approval Signatures:

_____ Date: _____
IFA Director

_____ Date: _____
IFA Program Director

_____ Date: _____
120WaterAudit Program Manager

_____ Date: _____
EPA Project Manager/Officer

_____ Date: _____
EPA Quality Assurance Manager/Representative

_____ Date: _____
Element Materials Technology Laboratory Manager

_____ Date: _____
Pace Analytical Services Laboratory Manager

List of Abbreviations

3T's – 3T's (Train, Test, and Take Action) for Reducing Lead in Drinking Water in Schools Report
CAS – Chemical Abstracts Service
COC – Chain of Custody
DL – Detection Limit
DQI – Data Quality Indicators
EDD – Electronic Data Delivery
EPA – United States Environmental Protection Agency
IDEM – Indiana Department of Environmental Management
IFA – Indiana Finance Authority
LSP – Lead Sampling Program for Schools and Child Care Facilities
LCS – Laboratory Control Sample
MS – Matrix Spike
PAL – Project Action Limit
Pb – Lead
ppb – Parts Per Billion
PPE – Personal Protection Equipment
PQL – Practical Quantitation Limit
QA – Quality Assurance
QAPP – Quality Assurance Project Plan
QC – Quality Control
QL – Quantification Limit
RL – Reporting Limit
SOP – Standard Operating Procedures
S.U. – Standard Unit
WIIN – Water Infrastructure Improvements for the Nation Act
WRIPP – Water Resources and Infrastructure Planning Program

Table of Contents

1.0 PROJECT MANAGEMENT

This Quality Assurance Project Plan ("QAPP") has been prepared for Indiana's Lead Sampling Program for Schools and Child Care Facilities ("LSP"). This sampling project adds to Indiana's efforts to safeguard the health of Hoosier children by sampling for the presence of lead in drinking water at schools and child care facilities and schools ("Facilities"). This section of the QAPP describes how the project will be managed, organized, and implemented.

1.1 Title and Approval Page – See Page 1-2

1.2 Table of Contents- see Pages 4-6

1.3 Distribution List

The following is a list of organizations and persons who will receive copies of the approved QAPP and any subsequent revisions:

Indiana Finance Authority
100 North Senate Avenue
Suite 1275
Indianapolis, IN 46204

Jim McGoff
Director, Environmental Programs
317-233-4337

Sarah Hudson
Program Director, Water Resources and Infrastructure Planning
317-232-2812

Daniel Lundberg
Project Manager, Water Resources and Infrastructure Planning
317-232-3195

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Lafayette, IN 70508

Tristian Davis
Manager, Quality Assurance
337-443-4011

Pace Analytical Services, LLC
7726 Moller Road
Indianapolis, IN 46268

Beth Schrange
Quality Manager
317-228-3100

1.4 Project Organization

The Indiana Finance Authority ("IFA") is Indiana's designated administrator for the Lead Testing in School and Child Care Program Drinking Water Grant Program as authorized by Section 2107 of the Water Infrastructure Improvements for the Nation Act ("WIIN Act"). The participating agency is the U.S. Environmental Protection Agency, Region 5 ("EPA"). 120WaterAudit is a technology company that will coordinate laboratory testing, provide technical assistance, and host sampling data in an online database. If, in the future, 120WaterAudit no longer provides these services, this QAPP will be amended accordingly.

The roles and responsibilities of those involved in this program are listed below.

1.4.1 IFA Water Resources & Infrastructure Planning Program Director

The IFA Water Resources & Infrastructure Planning Program ("WRIPP") Director ("Program Director") will be the responsible official for this project. They will oversee the overall project and budget, and guide coordination between program partners.

1.4.2 IFA Water Resources & Infrastructure Planning Program Project Manager

The IFA WRIPP Project Manager will act as the IFA's point of contact for the LSP. They will assist the Program Director in tasking contractors with the work required to complete this project. They will be responsible for the day-to-day tasks needed to keep the project on schedule.

1.4.3 120WaterAudit Program Supervisor

The 120WaterAudit Program Supervisor will have responsibility for assigning appropriate trained personnel to complete the tasks contracted to 120WaterAudit in this plan. They will ensure that responsible parties adhere to sampling and remediation assistance protocol. They will communicate with the Program Director on work accomplished in this plan and any problems or deviations that need to be resolved within 120WaterAudit's work plan. They will be responsible for assigning appropriate laboratory staff to perform the analyses specified in this plan.

1.4.4 120WaterAudit Program Manager

The 120WaterAudit Program Manager will collaborate with Facility staff over the course of the program to manage and review Facility sample designs, samples received, and other Facility requests related to the program.

1.4.5 120WaterAudit Remediation Technician

The 120WaterAudit Remediation Technician will have a background in engineering and water quality management. They will assess lab results and infrastructure data, make remediation recommendations, and support Facilities in selecting and implementing remediation strategies.

1.4.6 Facility Partner

The Facility Partner will be responsible for providing information and decision-making for the Facility during this program. They will enroll the Facility in the program, undergo lead sampling training, design a sampling plan and map, collect samples, determine and conduct remediation steps (if any), and communicate findings with stakeholders.

1.4.7 Laboratory Partner

The Laboratory Partner will provide sample analysis and internal Quality Assurance ("QA") and Quality Control ("QC") for all analytical data it generates. All Laboratory Partners will designate a Laboratory QA Manager to ensure all samples are testing in accordance with this QAPP. The IFA intends to work with Element Materials Technology and Pace Analytical Services, LLC (henceforth referred to as "laboratories").

See Figure 1-1. Organization Chart

1.5 Background/Problem Definition

Lead is a toxic metal that can be harmful to human health when ingested. Young children under the age of six are particularly sensitive to the effects of lead because their bodies are still undergoing development. Lead can get into drinking water if it is present in the source water or by interaction of the water with plumbing materials containing lead (through corrosion). Common sources of lead in drinking water include solder, fluxes, pipes and pipefittings, fixtures, and sediments. It is possible that different drinking water fixtures in a given building could have dissimilar concentrations of lead.

In 2017, the IFA began the Lead Sampling Program for Public Schools to assess the presence of lead in school drinking water. The IFA collected and analyzed over 57,000 samples across 915 schools, assisting schools in their effort to reduce potential lead exposure in drinking water.

With the funding appropriated under section 1464(d) of the Safe Drinking Water Act, amended by section 2107 of the WIIN Act, the IFA plans to sample for the presence of lead in drinking water in school and child care facilities. This will include the prioritization of facilities serving young children (ages six and under), underserved and low-income communities, and facilities that are older and more likely to contain lead plumbing. This new program focuses on child care facilities, as well as schools serving the target population that were not a part of the IFA's 2017 Lead Sampling Program.

The IFA is using EPA's 3Ts guidance[1] as a model to: (1) **Communicate** the results and important lead information to the public, parents, and teachers throughout the program; (2) **Train** Facility staff on the risks of lead in drinking water and testing for lead, as well as developing key partnerships to support the program; (3) **Test** using appropriate testing protocols and a certified laboratory; and (4) **Take Action**, including the development of a plan for responding to results of testing conducted and addressing potential elevated lead where necessary.

This QAPP incorporates the EPA 3Ts document, as well as the Indiana Department of Environmental Management's ("IDEM") school lead sampling guidance[2].

1.6 Project/Task Description and Schedule

The IFA anticipates available funding will provide sampling at 660 Facilities. The IFA will prioritize Facilities if they: 1) serve children that are low-income and under the age of 6; 2) are located in buildings constructed before 1988; and 3) have factors indicating the Facility will continue to serve children in the future.

Once a Facility has been accepted into the program, the Facility Partner will work with the Program Manager to create a sampling plan. Facility Partners will receive a testing kit from 120WaterAudit containing all the materials they will need to implement their sampling plan.

The Facility Partner will collect drinking water samples from all drinking water sources, including: water fountains (chilled and non-chilled), food preparation fixtures (located in the cafeteria, kitchen, and home economics classrooms) and other fixtures where children might drink the water. Concession stands and outside water fountains (such as in playgrounds and athletic fields) shall also be sampled. Custodial sinks and outside spigots may be sampled if Facility Partners indicate they are used for drinking water. The Sampling Protocol (Appendix A-1) provides more detail on appropriate sampling locations.

The Facility Partner will collect first draw samples at all fixtures. They may also collect 30-second flush samples at drinking water fixtures specified in the Sampling Protocol. Indiana certified laboratories will perform the analysis for lead. Remediation Technicians will review sample results and coordinate with the Facility Partner on appropriate lead remediation actions, if necessary.

The LSP schedule is as follows:

Prior to Sample Collection:

April-June 2019: Design Project Strategy
September 2019: Submit Draft QAPP, receive and review comments on QAPP from USEPA
October 2019: Submit Final QAPP
November 2019 Obtain QAPP approval

Program Implementation:

November 2019: Rolling enrollment begins, training available for sampling plan and map
December 2019: Testing kits available, sample collection begins

Program available until funds expended or until two years from grant award date, whichever comes first.

1.7 Quality Objectives and Criteria for Measurement Data

This section describes the overall objectives and criteria for measurement for the IFA LSP.

1.7.1 Objectives and Project Decisions

The overall objective for the IFA LSP is to determine the lead concentration at drinking water fixtures within enrolled Indiana Facilities. Facility Partners will also gain greater awareness of monitoring for the presence of lead in drinking water at their Facility.

At the recommendation of IDEM, the LSP will use a drinking water action level of 15 parts per billion (“ppb”), which follows the EPA Lead and Copper Rule.
Decisions to be made with the data include:

- If a drinking water test returns a result for lead equal to or exceeding 15 ppb, then the Remediation Technician will direct the Facility Partner to isolate the source of drinking water by turning off the fixture or providing a barrier to the consumption of the water (i.e. tape and bag). The Remediation Technician will then work with the Facility Partner to suggest remediation activities.

- If a Facility Partner enrolls in the LSP and receives lead sampling data, then they will make the results available to their stakeholders (parents, staff, etc.).

1.7.2 Action Limits/Levels

As recommended by IDEM, this LSP will follow the action level set by the EPA Lead and Copper Rule of 15 ppb. Remediation actions will be suggested for all fixtures at 15 ppb or greater.

Table 1-1 lists the parameter to be sampled (lead) and its associated Project Action Limit ("PAL"). This information demonstrates that the analytical methods selected for this project are capable of providing data with quantification limits ("QLs") which exceed the PAL. In addition, Table 1-1 provides analytical detection limits ("DLs"). Detection Limits are minimum concentrations that can be detected above instrumental background or baseline/signal noise, providing further assurance that the analytical methods are capable of meeting the data needs of the project in terms of sensitivity (see Section 1.7.3.6).

The QL listed is deemed acceptable to meet the project objectives.

1.7.3 Measurement Performance Criteria/Acceptance Criteria

Data generated in this project must be of known and acceptable quality. The IFA identified Data Quality Indicators ("DQI") for lead sampling parameters. Each DQI has unique assessment criteria. The DQIs include: precision, accuracy/bias, representativeness, comparability, completeness, and sensitivity.

For quantitative assessment of laboratory methodology, the laboratories' QA Manuals and analytical standard operating procedures ("SOPs") have been reviewed by the LSP project team and the associated laboratory QC (types and frequencies of QC samples and QC acceptance limits) have been determined to be adequate to meet the data quality needs of this project.

1.7.3.1 Precision

Precision is a measure of the ability to reproduce analytical results and is usually assessed by analyzing laboratory duplicates and calculating the relative percent difference of the sample results. The lower the relative percent difference the greater the precision of the laboratory procedures. A QC Sample, which is typically required as an initial demonstration of capability and quarterly thereafter, is a check on laboratory and instrument performance. Duplicate QC

samples must be analyzed within the analytical batch by the testing laboratory as a requirement of this QAPP. This is to access precision where the relative percent difference must be less than or equal to 20%.

1.7.3.2 Bias

Bias is a measure of a systematic or inherent error that can occur in the sample collection, sample handling and/or sample analysis processes. Bias which may occur during sample collection and handling includes brushing the sample bottle against the fixture or placing sample container lids on tables, countertops or other surfaces. Facility Partners will receive thorough training regarding appropriate protocols to reduce bias due to contamination of the water sample from lead sources present in the sampling environment. Laboratories will use method blanks during sample analysis to quantify bias during sample analysis process. These protocols emphasize reducing environmental contamination to the maximum extent possible.

1.7.3.3 Representativeness

Representativeness is the ability of a sample to represent the environmental conditions at the time of collection. This DQI will be met qualitatively, by verifying that documented sample collection and analytical methods (including sample handling and chain-of-custody procedures, sample preservation, and sample holding time protocols) were followed.

The procedures identified throughout this QAPP were chosen to optimize the potential for obtaining samples that reflect the true state of the Facility's water quality, within practical limits. In addition, efforts were made in developing the sampling design to ensure samples would be collected which assess the entirety of the facility's plumbing profile. First draw samples provide data regarding the presence of lead at a specific fixture. Flush samples provide information on the presence of lead in the plumbing beyond the fixture.

Additionally, sampling plans will be designed to identify all drinking water fixtures in a Facility. Possible sampling locations include: drinking water fountains (bubblers), water coolers, food preparation fixtures and other potential consumption fixtures, such as those in the medical office and teachers' lounge.

1.7.3.4 Comparability

Comparability is the degree to which data can be compared directly to similar studies. This is accomplished by maintaining uniformity with collection procedures, analyses and reporting.

The sampling plan described in this QAPP uses approved analytical methods for lead analysis in drinking water (see Table 2-2) and follows the 2017-2018 IFA Lead Sampling Program for Public Schools. Maintaining uniformity with this plan will allow for statewide comparisons between past and future samples.

Analytical results from the initial first draw and follow-up flush samples at the same drinking water fixture will be compared to assist in determining the source of lead contamination. Upon receiving results, the Remediation Technician will suggest remediation measures, if needed, to the Facility Partner.

1.7.3.5 Completeness

In order to satisfy the objective of the project, samples will be collected from drinking water fixtures according to the Sampling Plans submitted by Facility Partners and approved by the Program Manager.

One hundred percent (100%) of collected, valid initial first draw samples and flush samples will be analyzed and reported.

1.7.3.6 Sensitivity

Laboratories must use a reporting limit ("RL") less than or equal to 2 ppb for lead in drinking water samples. This RL is lower than the regulatory Practical Quantitation Level ("PQL") for lead of 0.005 mg/L (5 ppb) from 40 CFR141 Subpart I of the National Primary Drinking Water Contaminant Regulations. The reporting limit of 2 ppb, required in this QAPP, is achievable with the EPA approved method listed in Table 2-2 of this QAPP.

See Table 2-3. Quality Control Requirements for Analyses

1.8 Special Training Requirements/Certification

1.8.1 Facility Partners

Facility Partners will receive online training by 120WaterAudit in: 1) designing a Sampling Plan and Map, 2) collecting drinking water samples, and 3) selecting and implementing lead remediation procedures. These trainings will adhere to EPA's 3Ts and IDEM's lead sampling in drinking water guidance.

1.8.2 Laboratory Personnel

Laboratory personnel analyzing drinking water samples will have successfully completed required demonstrations of capability for the methods used. The laboratories must be certified by the Indiana Department of Health for the analysis of lead using EPA drinking water methods. This certification must be renewed by the Indiana Department of Health every five years. These methods are listed in Table 2-2.

1.9 Documents and Records

This section details the records created during the LSP, as well as their delivery and storage.

1.9.1 QAPP Distribution

The IFA will act as the point of contact for all QAPP distributions. The IFA will maintain an updated and accurate email contact list and will distribute the amended QAPP to the individuals listed in Section 1.3.

1.9.2 Field Documentation and Records

Records generated during this program include: sampling plans, photographs, sampling maps, and pre-printed forms (such as labels and chain-of-custody forms). All field activities must be conducted according to the SOPs explained in the Sampling Protocol (Appendix A-1). The Project Manager is responsible for maintaining updated revisions to the SOPs at all times and to distribute updated SOPs to Facility Partners and other program contacts, as needed. All documentation generated by the sampling program will be keeping on file by 120WaterAudit. Table 1-2 details which partner or partners will store originally created records.

1.9.2.1 Sampling Plans

Sampling plans will be used to determine the number and location of samples in order to guide sampling activities. Facility Partners will create sampling plans using a tool developed by 120WaterAudit. This tool can be accessed online or through a paper copy provided to the Facility Partner. Virtual training will be available to guide creation of sampling plans. At a minimum, the information to be recorded in a sampling plan for each Facility includes:

- Fixture location
- Fixture description
- Fixture type
- Sample type: initial draw, 30-second flush, or both

1.9.2.2 Photographs

Facility Partners will have the option to add digital photographs to the Sampling Plan. These photographs provide an image of the fixture described in the sampling plan in order to assist the Project Manager when approving the plan. Photographs will also aid Facility Partners during sample collection by clarifying potential sources for errors. Photographs will be stored in 120WaterAudit's online data platform.

For each photograph, the following information will be gathered:

- Time, date, and location
- Fixture ID number
- User ID of photographer

1.9.2.3 Sampling Maps

Sampling Maps will show the location of each fixture to be sampled. Facility Partners may create these from scratch, or may adapt pre-existing maps (fire route/emergency map, etc). Program managers will approve and use these maps when evaluating sampling plans and assigning sampling types to fixtures. Approved sampling maps will be stored on 120WaterAudit's data platform. These maps will contain the following information:

- Date created
- Facility name and ID
- Facility Partner contact information
- Program Manager ID
- Approval date
- Fixture locations
- Fixture type
- Fixture legend

1.9.2.4 Sample Bottle Labels

A pre-filled label will be affixed to each sample bottle shipped from 120WaterAudit to the facility to be sampled. The sampling plan is the source for all information contained on the labels. The sample labels will have preassigned, identifiable, and unique numbers. At a minimum, each label will include:

- Location name
- Location ID
- Fixture ID
- Fixture type
- Sample ID
- Sample draw type

1.9.2.5 Chain-of-Custody Forms

Facility Partners will fill out Chain-of-Custody ("COC") forms during sampling. 120WaterAudit will make an electronic COC forms available during sampling. A back-up paper copy will also be provided by 120WaterAudit in the testing kit.

All sample shipments will be accompanied by a COC form. The forms will be completed and sent with each shipment of samples to the laboratories. If multiple testing kits are sent to a laboratory on a single day, forms will be completed and sent with the samples for each kit. The original form will be included with the samples and sent to the laboratories. 120WaterAudit will retain digital copies of the COC on their online data platform.

The COC form will identify the contents of each shipment and maintain the custodial integrity of the samples. Procedures for completion and distribution of the COC forms are detailed in the Sampling Protocol (Appendix A-1).

1.9.3 Laboratory Documentation and Records

The laboratories will keep a sample receiving log and all completed COC forms submitted with the samples collected for this project. The laboratories will also keep records of all analyses performed, as well as associated QC information required by their QA/QC Manual (Appendix B-1 and B-2).

The laboratories will compile the data generated by each sampling event into individual electronic data delivery packages ("EDD"). The EDDs will be sent to 120WaterAudit, who will then upload them to the online data platform. The EDD will include the following information (Appendix B-3):

- Sample number and type
- Sample collection date and time
- Lab name and internal tracking ID
- Sample preparation and analysis date
- Chemical Abstracts Service ("CAS") Number
- Test result, with units
- Analyte type
- Reporting limit
- Testing method
- Minimum detect level
- Batch number
- Test qualifiers

Project team members may request additional information from the laboratories regarding a discussion of problems or unusual events. This may include, but is not limited to, topics such as: receipt of samples in incorrect, broken, or leaking containers, with improperly or incompletely filled out COC forms, receipt and/or analysis of samples after the holding times have expired; summary of QC results exceeding acceptance criteria, etc.

The Laboratories' QC Managers will review all EDDs before delivery to 120WaterAudit to ensure the accurate documentation of any deviations from sample preparation, analysis, and/or QA/QC procedures, highlights of any excursions from the QC acceptance limits, and pertinent sample data. Once finalized, the laboratories will send the EDD to 120WaterAudit.

Information about the documentation to be provided by the analytical laboratory is contained in the laboratories' QA Manuals (Appendix B-1 and B-2).

1.9.4 Technical Review and Evaluation

Remediation Technicians will conduct a technical review for all fixtures where the sample results equal or exceed the 15 ppb action level. This technical review does not have a specific format, but will be handled in a way that best meets the needs of the Facility.

1.9.5 Quarterly and/or Final Reports

Result emails serve as the official documentation for enrolled facilities.

2.0 DATA GENERATION AND ACQUISITION

This section of the QAPP describes how samples will be collected, shipped, and analyzed.

2.1 Sampling Design (Experimental Design)

All sample design will follow SOPs listed in the Sample Protocol (Appendix A-1). If a SOP is updated or revised, the updated or revised SOP will be used for the subsequent sampling event(s). The IFA will document any revisions or updates or both to the SOPs in an amendment to the QAPP.

Before conducting sampling, each Facility Partner will create a sampling plan and sampling map detailing each source of drinking water in the Facility. See Table 2-1 for an example of a sampling plan; see Figure 2-1 for an example of a sampling map. Drinking water sources may include water fountains (bubblers), water coolers, kitchen sinks and kettles, outside spigots, and others. Facility Partners will only include fixtures which are used as a drinking water source. The Program Manager will review each sampling plan and assign an initial draw sample to each fixture and a 30-second flush as needed. Criteria for selecting a 30-second flush sample is found in the Sampling Protocol (Appendix A-1).

2.2 Sampling Methods

2.2.1 Drinking Water Sampling

All samples will be collected using the SOPs included in the Sampling Protocol (Appendix A-1). If an SOP is updated or revised, the amended SOP will be used for the subsequent sampling event(s). Any revisions/updates to SOPs will be documented in an amendment to the QAPP.

Before sampling begins, the Facility Partner must verify water at the Facility had been stagnant between 8 – 18 hours prior to sampling. The Facility Partner will collect drinking water samples in pre-cleaned rigid plastic 250 mL bottles. Facility Partners will always collect water at a medium rate of speed and only at a cold temperature. The Program Manager may designate a hot water sample if the Facility Partner indicates hot water is used for consumption (kitchen kettle, cooking, etc.).

The Facility Partner will verify the bottle label matches the location of the fixture on the sampling map and the fixture description on the sample collection form before collecting water in the sample bottle. The Facility Partner will begin sampling at the drinking water fixture closest to where water enters the Facility (“entry point”). Sampling will then proceed towards the drinking water fixture furthest from the entry point. In multistory facilities, sampling will proceed from the lowest floor to the highest. The Facility Partner will reduce potential sample contamination by ensuring the bottle’s lip does not touch any other surface.

Once all samples have been collected, the Facility Partner will place the filled sample bottles back into the testing kit and use the provided shipping label to send the samples to a predetermined laboratory. Table 2-2 summarizes the analytical method, containers, preservation technique, and holding time requirements for each analysis.

2.2.2 Field Health and Safety Procedures

Facility Partners will use Level D personal protection equipment ("PPE") when collecting drinking water samples.

Laboratory staff will follow their own protocols when handling and testing drinking water samples.

2.2.3 Field Variances

As conditions at each Facility vary, it may become necessary to implement minor modifications to the sampling procedures and protocols described in this QAPP. If or when this is necessary, the Facility Partner will notify the Program Manager to obtain verbal or written approval prior to implementing any changes. The Program Manager will note this approval in the sampling plan on 120WaterAudit's online data platform and communicate this update to the Project Manager.

2.2.4 Disposal of Residual Materials

Various types of potentially contaminated wastes will be generated in the process of collecting water samples for this project. These contaminated wastes may include:

- Used PPE
- Disposable sampling bottles/containers or equipment
- Excess water collected for sample container filling

The above will be disposed as follows:

- Used PPE and disposable containers/equipment will be double bagged and placed in a municipal refuse dumpster. These wastes are not considered hazardous and can be sent to a municipal landfill. Any used PPE and disposable containers or equipment (even if it appears to be reusable) will be rendered inoperable before disposal in the refuse dumpster.
- Excess water collected for sample container filling will be poured onto the ground or down a drain.

2.2.5 Quality Assurance for Sampling

Documentation of deviations from this QAPP or applicable SOPs is the responsibility of the Facility Partner. The Facility Partner will record deviations noted during sample collection, preapproved by the Program Manager (see section 2.2.3) or otherwise, in the sampling plan

stored on 120WaterAudit's online data platform.

2.3 Sample Handling and Custody

This section describes the sample handling and custody procedures from sample collection through transport and laboratory analysis. It also includes procedures for the ultimate disposal of the samples.

2.3.1 Sample Container and Preservatives

The Program Manager will utilize the Sampling Plan to determine the number of sampling bottles needed at a particular Facility. 120WaterAudit will source the correct number and type of sample bottles and deliver them to the facility in a testing kit. The sample bottles will be pre-cleaned and require no washing or rinsing by Facility Partner prior to sample collection.

2.3.2 Sample Packaging and Shipping

All sample bottles will arrive and leave from the Facility in the testing kit provided by 120WaterAudit. A return shipping label will be included with the kit. Once the Facility Partner finishes sampling, they will seal the sample bottles in the testing kit, seal the box, attach the return label, and send the testing kit to the laboratories.

2.3.3 Sample Custody

The Facility Partner is responsible for custody of the samples from when they have been collected until they have been shipped to the laboratories. (Note: As few people as possible will handle the samples to ensure sample custody.) The Facility Partner must complete the COC form (see Appendix A-2) in the field.

Once at the laboratories, laboratory personnel are then responsible for the care and custody of samples. The laboratories will track sample custody through their Facility using a separate sample tracking form, as discussed in the laboratories' QA Manuals included as Appendix B-1 and B-2.

One has custody of a sample if:

- The sample is in the sampler's physical possession
- The sample has been in the sampler's physical possession and is within sight of the sampler
- The sample is in a secure/designated area, and/or
- The sample has been in the sampler's possession and has been locked up

2.3.4 Sample Disposal

Following sample analysis, the laboratories will store the unused portions for 1 month. At that time, the laboratories will properly dispose of all the samples. Sample disposal procedures at the laboratories are discussed in the laboratories' QA Manuals included as Appendix B-1 and B-2.

2.4 Analytical Methods

The laboratory must use the EPA approved drinking water method listed in Table 2-2 for the analysis of lead. The laboratory must be capable of reporting lead to a reporting limit of less than or equal to 2 ppb.

Once samples are acidified with concentrated nitric acid to a pH of less than 2 Standard Unit ("S.U."), the samples must sit for 24 hours, after which the pH measurement is repeated. The pH must be less than 2 S.U. before proceeding with the analysis. If a sample result exceeds 90% of the linear dynamic range, the sample must be diluted and re-analyzed.

The laboratories will summarize the data and deliver it in the EDD format (Appendix B-3) requested by 120WaterAudit within fourteen (14) business days after receiving samples.

2.5 Quality Control Requirements

This section identifies the QC checks that are in place for the sample collection, field measurement, and laboratory analysis activities that will be used to access the quality of the data generated from this project.

See Table 2-3: Quality Control Requirements for Analyses

2.5.1 Laboratory Analysis Quality Control

The Laboratory QC Manager is the responsibility of the personnel and QA/QC department of the contracted analytical laboratory. The laboratories' QA Manuals details the QA/QC procedures it follows (see Appendix B-1 and B-2). The following elements are part of standard laboratory quality control practices:

- Analysis of method blanks
- Analysis of laboratory control samples
- Instrument calibration (including initial calibration, calibration blanks, and calibration verification)
- Analysis of matrix spikes
- Analysis of duplicates

The data quality objectives for the laboratories (including frequency, QC acceptance limits, and

corrective actions if the acceptance limits are exceeded) are detailed in their QA Manuals (as in Appendix B-1 and B-2) or in this QAPP. The laboratories must document any excursions from these objectives and report them to the Program Manager.

The IFA has reviewed these laboratories control limits and corrective action procedures and feels that these will satisfactorily meet the state's project data quality needs. A summary of this information is included in Table 2-3. These include laboratory (or method) blanks, laboratory control samples, matrix spikes, and laboratory duplicates.

Method Blanks - A method blank is an analyte-free matrix, analyzed as a normal sample by the laboratories using normal sample preparation and analytical procedures. A method blank is used for monitoring and documenting background contamination in the analytical environment. Method blanks will be analyzed at a frequency of one per sample batch (or group of up to 20 samples analyzed in sequence using the same method).

Corrective actions associated with exceeding acceptable method blank concentrations (as depicted in Table 2-3) include isolating the source of contamination and re-digesting and/or re-analyzing the associated samples. The laboratories will document these corrective actions in their data report.

Laboratory Control Samples - Laboratory control samples ("LCS") are laboratory-generated samples analyzed as a normal sample and by the laboratories using normal sample preparation and analytical procedures. An LCS is used to monitor the day-to-day performance (accuracy) of routine analytical methods. An LCS is an aliquot of clean water spiked with the analytes of known concentrations corresponding to the analytical method. LCS are used to verify that the laboratories can perform the analysis on a clean matrix within QC acceptance limits. Results are expressed as percent recovery of the known amount of the spiked analytical parameter.

One LCS is analyzed per sample batch. Acceptance criteria (control limits) for the LCS are defined by the laboratories and summarized in Table 2-3. In general, the LCS acceptance criteria recovery range is 70 to 130 percent of the known amount of the spiked analytical parameter. Corrective action, consisting of a rerunning of all samples in the affected batch, will be performed if LCS recoveries fall outside of control limits. The laboratories will document such problems in their data report.

Matrix Spikes - Matrix spikes ("MS") are prepared by adding a known amount of the analyte of interest to a sample. MS are used as a similar function as the LCS, except that the sample matrix is a real-time sample rather than a clean matrix. Results are expressed as percent recovery of the known amount of the spiked analytical parameter. Matrix spikes are used to verify that the laboratories can determine if the matrix is causing either a positive or negative influence on sample results.

One MS is analyzed per sample batch. MS acceptance criteria are defined by the laboratories and

summarized in Table 2-3. In general, the MS acceptance criteria recovery range is of 70 to 130 percent of the known amount of the spiked analytical parameter. Generally, no corrective action is taken for MS results exceeding the control limits, as long as the LCS recoveries are acceptable. However, the matrix effect will be noted in laboratory report's narrative statement and documented in the tribe's reports for each sampling event.

Laboratory Duplicates - A laboratory duplicate is a laboratory-generated split sample used to document the precision of the analytical method. Results are expressed as relative percent difference between the laboratory duplicate pair.

One laboratory duplicate will be run for each laboratory batch or every 20 samples, whichever is more frequent. Acceptance criteria (control limits) for laboratory duplicates are specified in the laboratories' QA Manual and are summarized in Table 2-3. If laboratory duplicates exceed criteria, the corrective action will be to repeat the analyses. If results remain unacceptable, the batch will be rerun.

Specific information regarding acceptance criteria and corrective actions is documented in the laboratories' QA Manuals for the approved drinking water method(s) used for the lead analysis of the drinking water samples. Laboratories may elect to develop an SOP specific for the analysis of lead in drinking water for samples collected in Indiana Facilities that contain the requirements of this QAPP.

If any sample result(s) is qualified (does not meet the above requirements), this must be clearly indicated on the Electronic Data Deliverable ("EDD"). The Project Manager must be consulted in order to determine how to address the qualified results.

2.6 Instrument/Equipment Testing, Inspection, and Maintenance

2.6.1 Field measurement Instruments/Equipment

No field instruments or measurements are anticipated for this project.

2.6.2 Laboratory Analysis Instruments/Equipment (Off-Site)

Inspection and maintenance of laboratory equipment is the responsibility of the laboratories. All laboratory equipment will be tested, calibrated, and maintained in accordance with existing SOPs approved by the laboratories and described in each laboratory's QA manual (Appendix B-1 and B-2).

2.7 Instrument/Equipment Calibration and Frequency

2.7.1 Laboratory Analysis Instruments/Equipment (Off-Site)

Laboratory instruments will be calibrated according to the appropriate analytical methods (Appendix B-1 and B-2). The EPA approved analytical methods for lead listed in the National Primary Drinking Water Contaminant Regulations at 40 CFR 141.23 and Appendix A to Subpart C require that the instrument calibration be performed on a daily basis.

2.8 Inspection/Acceptance Requirements for Supplies and Consumables

2.8.1 Field Sampling Supplies and Consumables

120WaterAudit will ship testing kits to the Facilities before the day of sampling. Testing kits contain:

Shipping container: Cardboard box holding up to 30 sample bottles. Box is organized with individual compartments for each sample bottle. Provides sequenced manner for sample collection.

Sample Bottle: Sampling bottles are unpreserved, certified 250 ml wide-mouth plastic bottles. Facility Partners will inspect bottles for cracks, dents or other damage. 120WaterAudit will replace any damaged bottles.

Bottle Label: Includes the following information:

- Location name
- Location ID
- Fixture ID
- Fixture type
- Sample ID
- Sample draw type

Sampling Instructions: Describes steps to collect samples. See Appendix A-1.

Paper Chain of Custody form (Appendix A-2) includes:

- Sample collector name, phone number, signature
- Collection date and time
- Returned date and time
- Fixture type

Return shipping label: Returns shipping container directly to laboratory

2.8.2 Laboratory Analyses (Off-Site) Supplies and Consumables

The laboratories' requirements for supplies and consumables are described in their QA Manual, which is provided in Appendix B-1 and B-2.

2.9 Data Acquisition Requirements (Non-Direct Measurements)

Facility Partners may choose to use preexisting Facility maps to create sampling maps. Additional data sources may come from IDEM, the Indiana Geological and Water Survey, and the Family and Social Services Administration, depending on program needs. No guarantee is made regarding the accuracy or availability of information obtained through non-direct measurements.

2.10 Data Management

All data collected by the LSP will be maintained in an electronic database. The laboratories will send results via EDD to 120WaterAudit. 120WaterAudit will email results to the facilities and upload results to the online data platform.

3.0 ASSESSMENT AND OVERSIGHT

This section describes how activities will be checked to ensure that they are completed correctly and according to procedures outlined in this QA Project Plan.

3.1 Assessments/Oversight and Response Actions

The Program Supervisor and Program Manager will assess any problem that arises in the field. If necessary, modifications to technical procedures may be considered. Any changes in technical procedures will be reported by the Facility Partner to the Project Manager and evaluated to determine if there will be any impact to the data.

Laboratory personnel will perform self-audits and institute corrective actions in accordance with their respective written procedures (Appendix B- and B-2).

3.2 Reports to Management

The Program Manager will provide biweekly program management updates to the Program Director. At a minimum, the Program Manager will provide a verbal report on:

- The number of facilities enrolled in each step of the program
- The total number of samples with results completed
- Program implementation successes and challenges
- Other issues, as deemed necessary by the Program Director

Additional, less formal internal reports may take place throughout the program (see 1.9.2 - 1.9.5).

4.0 DATA REVIEW AND USABILITY

This section describes the criteria and procedures for reviewing and interpreting the project's data.

4.1 Data Review, Verification, and Validation Requirements

Setting data review, verification, and validation requirements helps ensure objective and consistent evaluation of project data. For the current project, such requirements have been defined for information gathered and documented as part of field sampling activities, as well as for data generated by the off-site laboratories.

4.1.1 Field Sampling Data

Any information collected or generated during sample collection is considered field data. This includes sampling plans, sampling maps, photographs, chain of custody forms, and any other documented information created during field sampling.

Following field sampling, the Program Manager will conduct a technical review of the field data to ensure that all information is complete and was collected in accordance with the Sampling Protocol SOPs (Appendix A-1).

4.1.2 Laboratory Data

Partner laboratories are responsible for their own internal data review and verification before submitting the associated data results package to 120WaterAudit. The details of the laboratories' review are discussed in the QA Manuals (Appendix B-1 and B-2).

If the laboratories "flag" any sample results based on poor or dubious data quality, the Program Manager will coordinate resampling of that sample. The Program Manager will also evaluate whether trends of flagged data develop which could be traced back to incorrect field sampling techniques. The Program Manager will have the authority to suggest new training techniques for the Facility Partners in order to improve sample collection. Any changes will be incorporated into the Sampling Protocol (Appendix A-1) and this QAPP, as necessary.

4.2 Verification and Validation Methods

Defining the data verification and validation methods helps to ensure that project data are evaluated in an objective and consistent manner.

4.2.1 Field Data

The Program Manager will review field data in accordance with the discussion provided in section 4.1.1.

4.2.2 Laboratory Data

Data review of all laboratory generated data is performed by the laboratories QA Managers. The QA Manager is responsible of ensuring that all data generated are correct and of known and documented quality. Once the review is completed, the QA Manager will sign and date the appropriate QA/QC checklist according to the laboratories' SOP utilized for the analysis for lead in the drinking water samples.

The Remediation Technician and Facility Partner will review the EDD report and identify any limitations on the use of the data. Any limitations on the use of data will be noted in the 120WaterAudit software.

4.3 Reconciliation with User Requirements

The purpose of the LSP is to assess the presence of lead in drinking water at Indiana Facilities. Data collected must fulfill the requirements of this QAPP to be useful for the overall program. This section describes the steps to be taken to ensure data usability (after all the data have been assembled, reviewed, verified, and validated) prior to providing any remediation suggestions.

Once all the data from the field and laboratory have been evaluated (as described in Sections 4.1 and 4.2), the Remediation Technician will make an overall assessment concerning the final usability of the data in meeting the project's needs. The initial steps of this assessment will include, but not necessarily be limited to:

- Review of deviations from the QAPP or associated SOPs
- Review for completeness of EDD
- Evaluation of result accuracy given known context (does the data make sense or are their unexpected outliers)
- Review of external factors, such as insufficient stagnation period

After thorough review of the above, the Remediation Technician will review the results to see how they compare to the program's Action Level. Suggestions will follow the "…if…then…" statements included in Section 1.7.1.

Additionally, the Program Manager and Program Director will regularly assess the effectiveness of the sampling program and data collection. Sampling SOPs, trainings, and assessments will be modified as needed to reflect the changing needs and project objectives of the LSP. This QAPP will be revised, or amended, or both accordingly.

5.0 REFERENCES

1. 3Ts for Reducing Lead in Drinking Water Toolkit. Environmental Protection Agency. https://www.epa.gov/ground-water-and-drinking-water/3ts-reducing-lead-drinking-water-toolkit
2. School Lead Sampling Attached to Community Public Water System. Indiana Department of Environmental Management. (http://www.state.in.us/idem/cleanwater/files/dw_compliance_lead_school_sampling.pdf) .

FIGURES:

Figure 1-1. Organization Chart

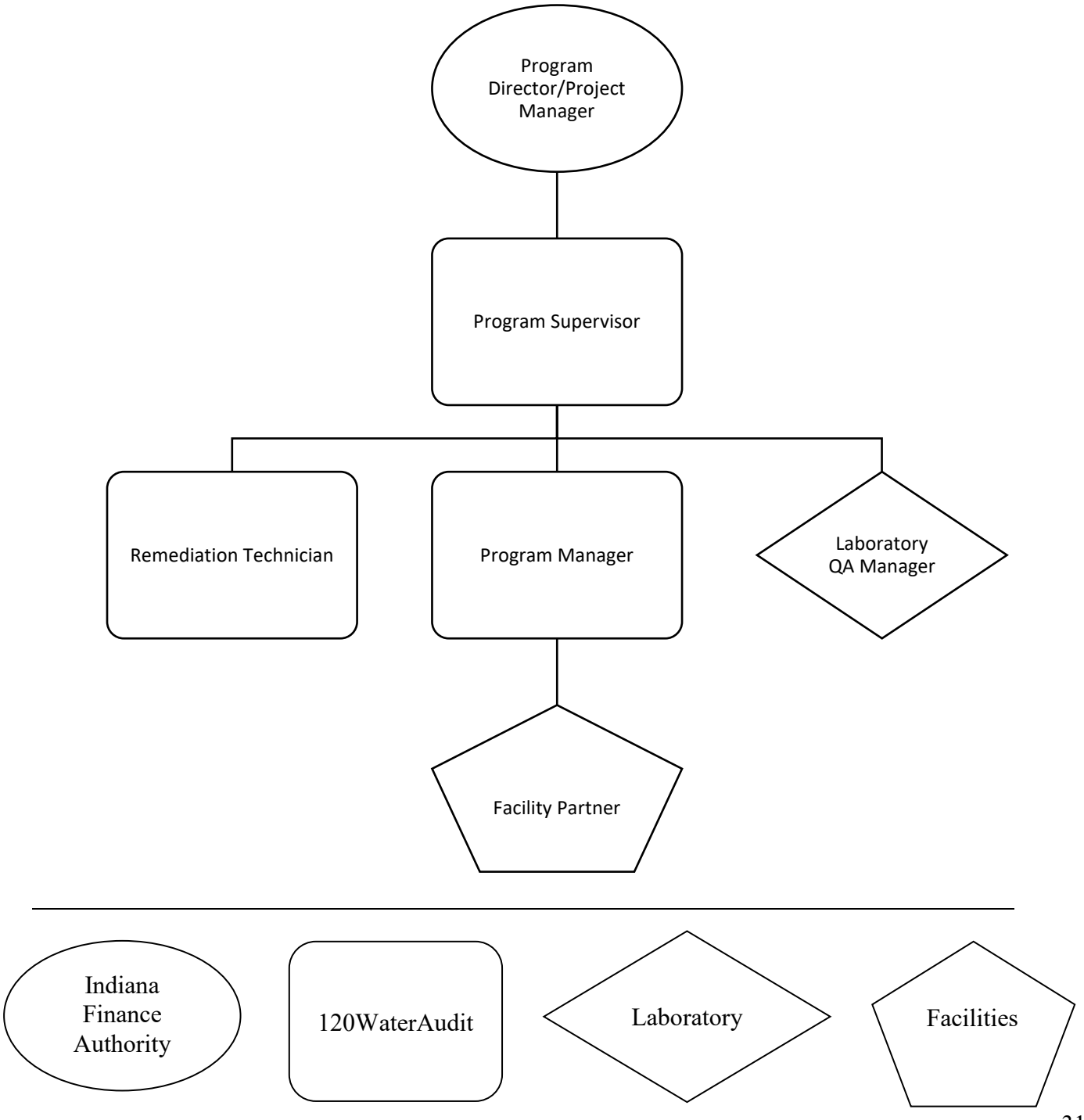
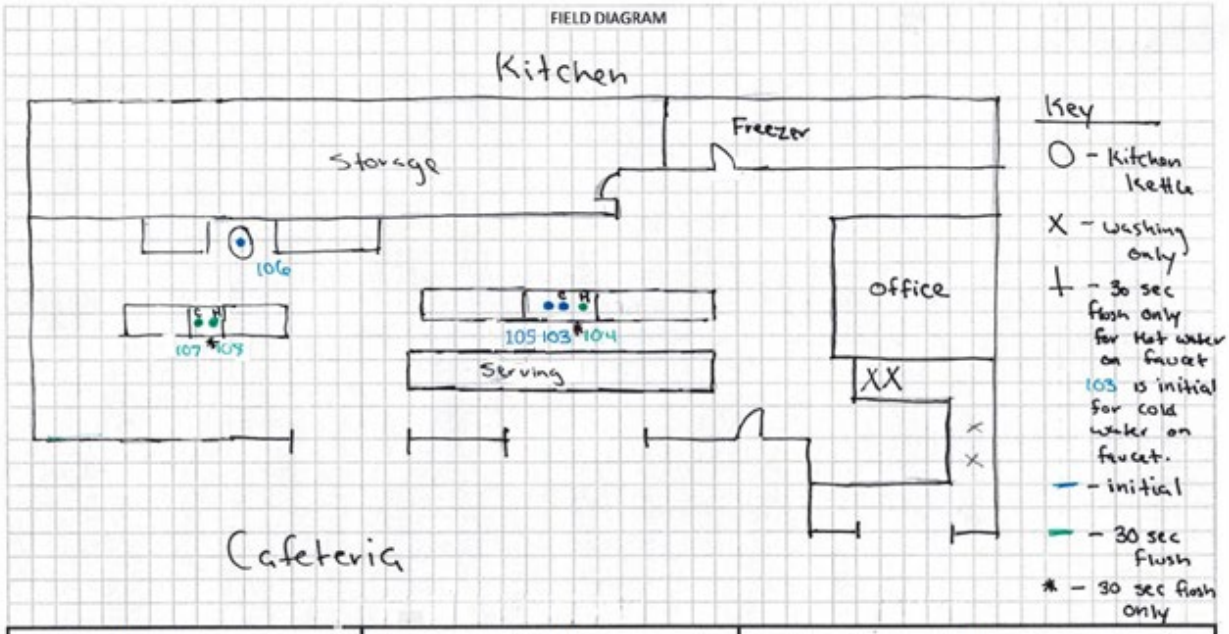


Figure 2-1. Example Sampling Map with Fixture Locations



DRAWING NOT TO SCALE		DIAGRAM	NOTES:
Prepared By:			Middle School
School Name			
Drawing Number:			
Drawing Date:	09/22/17		

TABLES:

Table 1-1. Analytical Parameters and Target Limits

Analytical Parameters and Target Limits Matrix/Media:			
Analytical Parameter	Project Action Limit/Level (ppb)	Laboratory Limits[1] (ppb)	
		Quantitation Limits	Detection Limits (if appropriate)
Lead (Pb)	15 ppb	**Element Materials Technology – Fort Wayne**	
		0.5	0.0507
		Pace Analytical Services, LLC	
		1	0.11

[1] Laboratory quantitation limits and detection limits are those that an individual laboratory or organization is able to achieve for a given analysis on a routine basis.

Quantitation limits are the minimum concentrations that can be identified and quantified above the detection limit within some known limits of precision and accuracy/bias. It is recommended that the quantitation limit is supported by the analysis of a standard of equivalent concentration (typically, the lowest calibration standard).

Detection limits are the minimum concentration that can be detected above background or baseline/signal noise of an instrument.

Table 1-2 Document Creation and Storage

Original documents (X) will be stored as follows:

Document:	Facility Partner	Program Supervisor	Program Director	Laboratory Partner
QAPP	Copy	Copy	X	Copy
Sampling Protocol	Copy	Copy	X	Copy
Laboratory QA Manual	n/a	Copy	Copy	X
Sampling Map	Copy	X	Copy	n/a
Sampling Plan	Copy	X	Copy	n/a
Sample Bottle Labels	n/a	X	n/a	Copy
Photographs	X	X	Copy	n/a
Chain of Custody	Copy	Copy	Copy	X
Training Documents	Copy	X	Copy	n/a
Laboratory Electronic Data Delivery	Copy	X	Copy	X
Results Email	Copy	X	Copy	n/a
Remediation Recommendations	Copy	X	Copy	n/a
Online data platform	Copy	X	Copy	n/a

Table 2-1. Sampling Design and Rationale

Sampling Design and Rationale				
Fixture Types	Matrix/ Media	Draw Type	Analytical Parameter[1]	Rationale for Sampling Design[2]
Faucets, drinking water coolers, drinking water fountains, kitchen kettles, spigots, bottle fillers, and other	Drinking Water	Initial or 30-second flush	Total Lead, EPA 200.8 ICP-MS	All sources of cooking/drinking water supplied to children in the facility

[1] Analytical parameters include all planned laboratory analyses.
[2] Rationale supports the selection of sampling locations and associated analytical parameters.

Table 2-2. Analytical Method, Containers, Preservation, and Holding Times Requirements

Analytical Method, Containers, Preservation, and Holding Times Requirements Matrix/Media:				
Analytical Parameter[1]	Analytical Method Number	Containers (number, size/volume, type)	Preservation Requirements (chemical, temperature, light protection)	Maximum Holding Times[2]
ANALYTICAL PARAMETER:				
Lead	EPA 200.8 for ICP Mass Spectrometry	250 ml rigid plastic wide-mouth bottles	Preserve to pH < 2 with HNO3	Within 14 days of collection

[1] Analytical parameter refers to laboratory analysis.
[2] Maximum holding times include all pertinent holding times for each analytical parameter (e.g., from sample collection to sample preparation, from sample preparation to analysis, from sample collection to analysis, etc.) and field measurement (e.g., from sample collection to measurement).

Table 2-3. Quality Control Requirements for Analyses

Quality Control Requirements for Analyses (Drinking Water for Analyses of Lead) Analytical Method/SOP: EPA Method 200.8					
QC Sample:	Data Quality Indicator (DQI)	Frequency/ Number	Method/SOP QC Acceptance Limits	Acceptance Criteria/ Measurement Performance Criteria[1]	Corrective Action
Laboratory Analysis					
Element Materials Technology – Fort Wayne					
	CCB	1 per 10 samples and at end of run	≤MDL or PQL/RL if project-specific	≤MDL or PQL/RL if project-specific	Evaluate against sample data / rerun affected samples as needed
	CCV	1 per 10 samples and at end of run	90-110 %	90-110 %	Evaluate prior samples / bring instrument in control and rerun affected samples as necessary
	MBLK	1 per batch	<PQL/RL	<PQL/RL	Evaluate against sample data / rerun affected samples as necessary
	LFB (LCS)	1 per batch	85-115 %	85-115 %	Rerun low LCS sample data / Evaluate high LCS sample data and rerun affected samples as necessary
	MS/MSD	1 per batch	70-130 % / 20 % RPD	70-130 % / 20 % RPD	Evaluate for laboratory error and report/qualify/ narrate if no internal errors

Quality Control Requirements for Analyses
(Drinking Water for Analyses of Lead)

Analytical Method/SOP: EPA Method 200.8

QC Sample:	Data Quality Indicator (DQI)	Frequency/ Number	Method/SOP QC Acceptance Limits	Acceptance Criteria/ Measurement Performance Criteria[1]	Corrective Action
Laboratory Analysis					
Pace Analytical Services, LLC					
	Method Blank	One per batch of samples	Target analyte must be below 2.2x the established MDL	Target analyte must be below 2.2x the established MDL	Refer to SOP
	LCS	One per batch of samples	85-115% Recovery	85-115% Recovery	Refer to SOP
	MS/MSD	One MS/MSD set per batch of samples plus an additional MS if >10 samples in the batch.	70-130% Recovery ≤20%RPD	70-130% Recovery ≤20%RPD	Refer to SOP
	CRDL	One per analytical batch	50-150% Recovery	50-150% Recovery	Refer to SOP

[1] Information supports the acceptance criteria/measurement performance criteria introduced in Section 1.7.3.

APPENDICES

Appendix A. Field Documentation and Procedures

A-1: Sample Design and Collection Procedures
A-2: Chain of Custody

Appendix B. Laboratory Documentation

B-1: Element Materials Technology – Quality Assurance Manual
B-2: Pace Analytical Services, LLC – Quality Assurance Manual
B-3: Electronic Data Deliverable

APPENDIX A:
Field Documentation and Procedures

APPENDIX A-1:
Sampling Design and Collection Procedures

Sample Design and Collection Procedures

Sample Design Protocol

I. Conducting the Sample Design

1. Building map
    a. Edit a rough draft of map with appropriate colors, throughout creation of sample design
        i. See Appendix E for more details
2. Create Sample Design using the 120Water Audit Platform (http://schools.120wateraudit.com)
    a. First, determine where water enters the building
        i. Mark this location on the building map
    b. From where water enters the building, determine the closest faucet or bubbler used for drinking (do NOT use a water fountain).
    c. Non-drinking fixtures are not to be sampled.
    d. Before adding a drinking fixture to the Sample Design, verify that it is operational by simply turning on the water.
        i. Verify with the status of any non-operational fixtures found with additional stakeholders, if necessary.
    e. Creating a fixture (to be completed at each fixture)
        i. Fixture Code
            1. Always choose your first fixture nearest to where water enters the building at "101" with fixtures following in ascending order (e.g. 102, 103, etc.)
        ii. Fixture Code Suffix
            1. If the fixture is part of a series, then use a letter designating the outlet in that series. (See Appendix A: Numbering Conventions)
                a. Stand-alone fixtures NOT part of a series will not have a letter after the fixture type designator.
        iii. (Fixture) Type
            1. e.g., Water cooler, bubbler, faucet (cold or hot), kitchen kettle (cold or hot), etc.
                a. Be sure to use 'Other' and list exactly what the fixture is, if needed
        iv. Fixture Location
            1. Where the fixture is located (e.g., coaches hall, home economics room 123, etc.)
                a. Where you are standing (room #, hallway, kitchen, etc.)
            2. Use the facility's naming convention for the location of the fixture.

v. Location Description
    1. Any additional information that helps to describe the fixtures location.
    2. Example: across from Rm 12, between refrigerator & mixer, etc.
vi. Status
    1. Active, Inactive, Winterized, Removed
vii. Does this fixture have a water filter present?
viii. Does this fixture have an aerator (e.g., screen) present?
    1. Be sure to look and/or feel for a screen at each fixture.
ix. Other Notes:
    1. Add anything noteworthy about the fixture
        a. e.g., water color, staining, corrosion, reverse osmosis, frequency of use, etc.

f. After completing the Fixture Questionnaire for that fixture, hit "SAVE"

3. It is **highly** encouraged to take pictures of fixtures during a design & collection. A picture can be uploaded to a particular fixture in the 120WaterAudit Platform.

Appendix A: Numbering Convention of Fixtures in Series

1. The Fixture Code assigned to the fixtures will start off with "101" and the ones following will be numbered as 102, 103, etc.
2. Suffixes: If there are several fixtures at one location a suffix (A, B, C… etc.) will be added to the end of the fixture code.
    a. Suffixes always indicate where a fixture is from left to right when facing.
    a. Example: If there are two fixtures located at one location (Figure 1), they could be given the fixture codes: 101 A, 102 B. The suffixes "A" and "B" denotes that the fixtures are part of a series.
    b. In Figure 1 below, post-it notes are posted on each of the fixtures with the Sample ID and suffix written on them.

Figure 1: An example of two fixtures in a series. The post-it note has written the fixture code and appropriate suffix. In this example, the fixture on the left would have the suffix "A" and the fixture to the right "B".

3. Fixtures in a series will always be numbered from left to right
    a. A series is defined as two or more water fixtures located side by side on the same wall. (Figure 1)
        I. Commonly seen where fixtures are set at different heights above the ground to accommodate wheel chair access and small children.

    For example, if a series of sinks contains three fixtures, they will be numbered in the following manner from left to right: 101A, 102B, 103C.
4. If a fixture is a stand-alone fixture and not part of a series, no suffix will be assigned.
5. If there are three or more fixtures in a room (i.e., kitchen, home economic room, etc.)
    a. Draw out a sketch map indicating the layout of the fixtures with the Sample Code indicated for each fixture.

Appendix B: Initial Samples

- The purpose of the initial sample is to test the water at the fixture itself. It represents the first drink a child would take at a fixture in the morning of a normal facility day.
- All fixtures that are used for drinking/consumption *always* receive an initial sample.

Appendix C: 30-second Flush Samples

- The purpose of 30-second flush samples is to test the internal plumbing upstream of the outlet to get a representative idea of the internal plumbing.
- Based on the facility's plumbing system age and layout, the Program Manager will assign flushed samples as needed.

1. 30-second flush sample criteria
    a. **All** water coolers shall be assigned a 30-second flush
        i. Water coolers have a storage tank that significantly reduces the chances of a compromising a nearby fixture

Appendix D: Kitchens

1. When designing samples for a kitchen, be sure to ask the kitchen staff which fixtures they use for cooking & consumption
    a. Be sure to include all of these fixtures in your sample design
2. The Program Manager will use Rule of Right to assign 30-second flush samples in kitchens
    a. If a flush sample is determined to be taken from fixtures that are arranged in a series:
        i. **Rule of Right** is a general standard used for deciding where to take a flush sample when fixtures are visibly connected by an incoming water line or close to one another.
        ii. **RULE OF RIGHT**: always choose the fixture furthest to the right as you are looking at it to be designated for the flush sample
        iii. Under most circumstances, it is not necessary to take flush samples from all fixtures in a series.
3. Kitchen Kettles (& faucets that use hot water)

a. Ask Facility Official or Kitchen staff "Is this fixture used for drinking?"
    i. If 'Yes'
        1. Include in sample design & collection as follows:
            a. If a kitchen kettle has a single faucet but is used for both hot & cold water. (See Figure 2)
                i. Take Figure 2 for example.
                    1. The **cold side** would be the next sample code in sequence. e.g., '123a'
                        a. Include 'Cold water' in fixture location. e.g., 'kitchen, cold water'
                        b. **Take an Initial & 30-second flush sample**
                    2. The hot side would be the next sample code in sequence. e.g., '124b'
                        a. Include 'Hot water' in fixture location. e.g., 'kitchen, hot water'
                        b. **Take only a 30-second flush sample**
                            i. This is one of the only situations where you would not take an initial sample at a fixture. (Technically you already collected an initial sample on the cold side, which is the reason you don't need to again)

Figure 2:

b. If a kitchen kettle only serves water at one temperature (e.g., Hot water only) (See Figure 3).
    i. Take Figure 5 for example
        1. Name the fixture the next sample code in sequence. e.g., '125'
        2. Include 'Hot water only' in fixture location. e.g., 'Kitchen, hot water only'
        3. Take an Initial & 30-second Flush samples

Figure 3:

Appendix E: Marking the school map

1. As the Sample Design plan is being constructed, there will be a requirement to annotate various items on a schematic of the school.
2. Required items on the map shall include (Figure 4)
a. Fixture code, locations and sample types
b. Names of hallways given by the facility
c. Legend

d. Name of facility
e. Professional license number for that facility, if applicable
f. Directional arrows indicating the path to be taken during the sample session
g. Locations indicated where more detailed sketch maps were created (Figures 4 & 5)
    i. Home economic rooms, kitchens, etc.
h. Where water enters the building
i. North Arrow
j. Map creator's name & date

3. Fixture color codes
    a. Initial draw – blue
    b. 30-second flush – green (initial sample implied)
    c. Water main entry point to building – red circle
    d. Location of sketch maps – Yellow circle around the room being sketched
        i. Add additional colors if multiple schematics need to be drawn
4. Map creation
    a. Facility Partner will have two copies (working copy and final copy) of the facility map
    b. Working copy
        i. The working copy will be used as the sample design is being constructed and shall serve as the rough draft
    c. Final copy
        i. Upon completion of the working copy, a final copy needs to be produced
        ii. Upload the digital final map into the 120WaterAudit Platform – in the documents tab of the school
            1. Press 'Sample Design Complete' on 120WaterAudit Platform after map has been uploaded.
        iii. May create map on computer/tablet using Paint/ Illustrator/ Photoshop.
        iv. If hand writing map – map must be scanned – no photos.
5. Additional schematic of kitchen is ***always*** required (Figure 6 & 7).
    a. Kitchen schematic must include everything listed in required items as well as:
        i. An 'X' where fixtures not used for drinking are located
            1. This includes handwashing sinks, kitchen kettles not used, etc.
            2. **Along with the 'X', note what type of fixture it is.**
    b. <u>A picture</u> is required to be taken of the kitchen (during a sample design or collection) (Figure 5).

Figure 4:

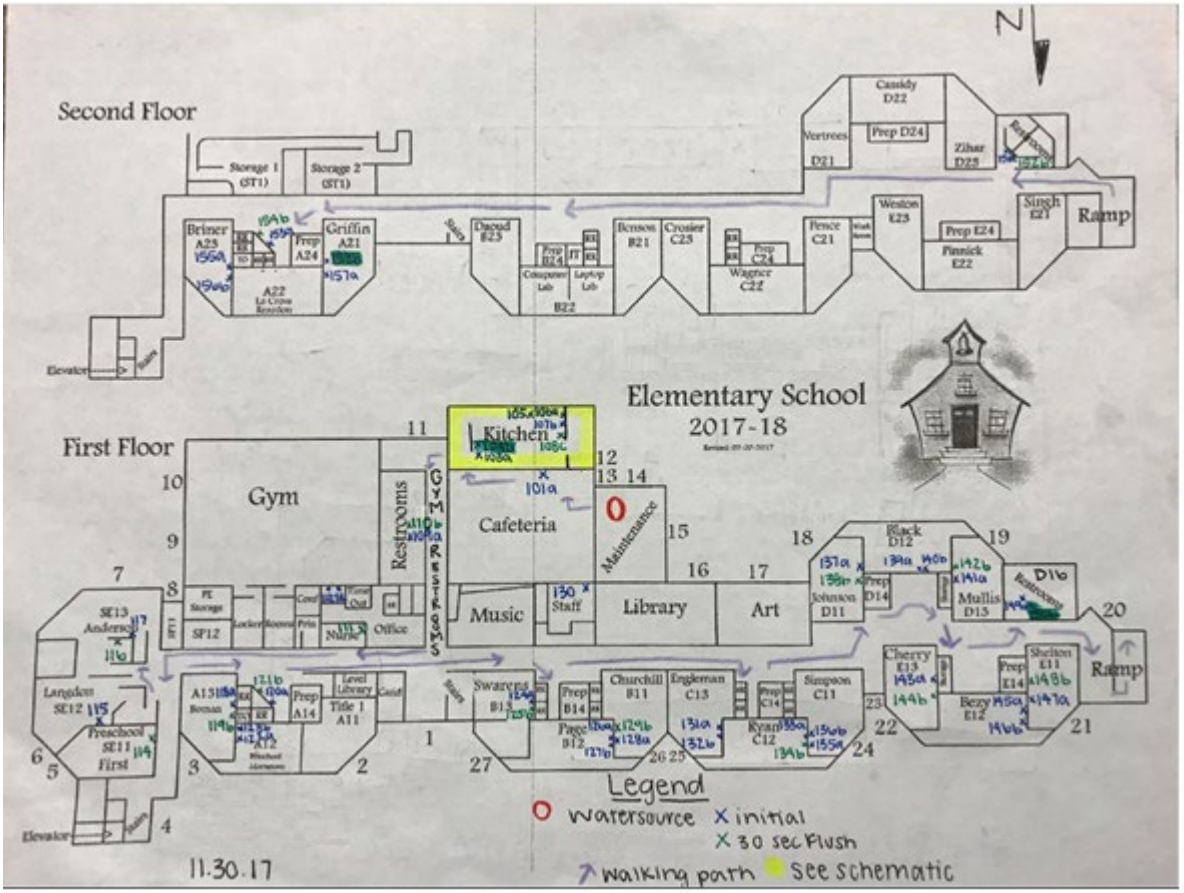


Figure 5: Photograph of kitchen is required. Upload to 120WaterAudit Platform in Documents tab of school

Figure 6: Note the 'X's labeled as KK, dishwashing (faucet), sink, etc. Indicates fixtures are not to be sampled.

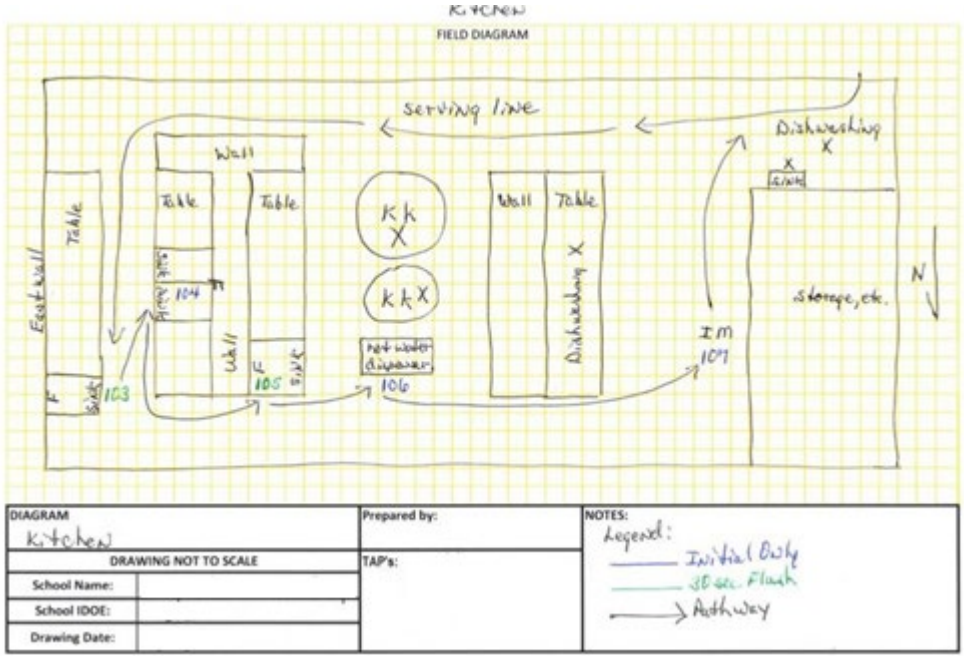
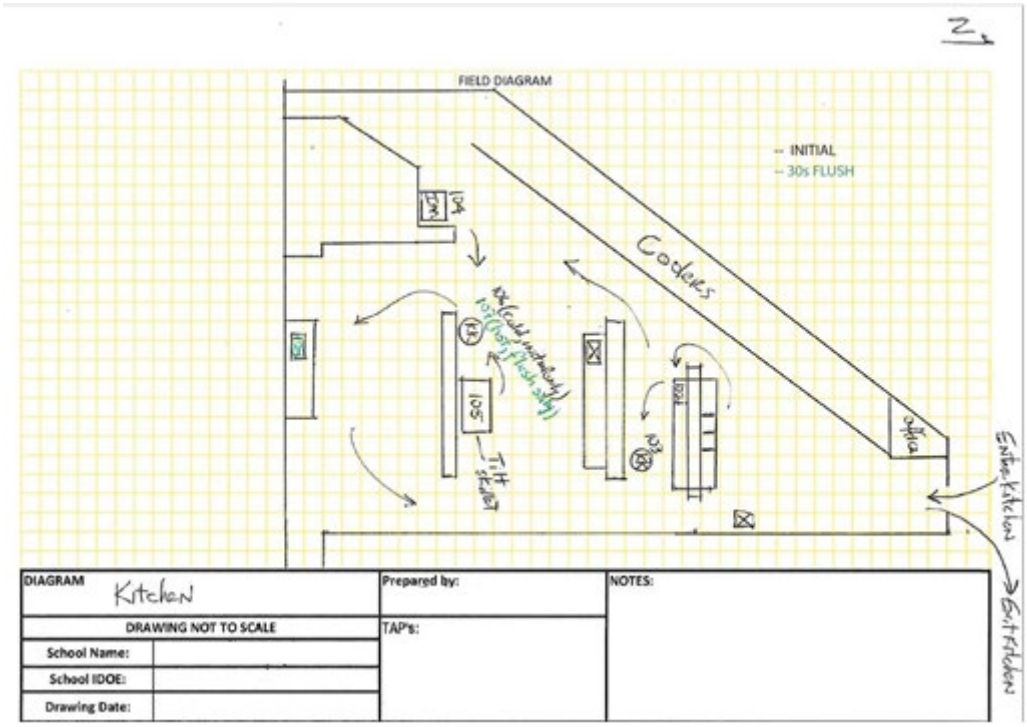


Figure 7: Note how Kitchen Kettle (with hot & cold water sampled) is indicated on map. It is clear that there is one kitchen kettle & it needs a hot & cold water sample from it.



Appendix F: Unique fixtures for sample design

1. Fixtures with filtered water bottle fillers (Figure 8)
    a. The Project Manager will only designate an initial sample from water bottle fillers
    b. 30-second flush samples will only be taken from the unfiltered outlet

Figure 8: Water cooler unit with filtered water bottle filler

2. Refrigerator/Ice Dispenser (Figure 9)
    a. If a refrigerator dispenses both ice and water, the Project Manager will designate an initial sample from the water source, no flush necessary
    b. If a refrigerator only dispenses ice, an initial sample will be designated.

Figure 9: Refrigerator Ice and Water Dispenser

3. Tilt Skillet
    a. Treat a tilt skillet (Figure 10) as you would a kitchen kettle that uses cold and hot water (if kitchen staff indicates both temperatures are used for consumption)

Figure 10: Tilt Skillet

Sample Collection Protocol

I. Prior to sample collecting
   a. Ensure that the following conditions exist
      i. Water stagnation time falls between 8-18 hours
         1. Verify with the facility staff that water has not been used that morning
      ii. Samples will not be drawn following weekends, facility breaks, or any other extended periods of non-use.
   b. Sample bottles will be mailed directly to facilities, coordinated by 120WaterAudit;
      i. A return mailing label will be included;
      ii. Box will include a few extra bottles; if extra bottles are not used – hold on to them for later use.
      iii. Box will include sample collection form
      iv. Inspect 250 ml bottles to ensure the following:
         1. Adequate number of bottles available for sampling
         2. Bottles have not been compromised in anyway
            a. Have not been opened
            b. If bottles have been opened or contaminated in any way, they must not be used.
   c. Ensure hands are clean
   d. Do not eat while sampling
   e. If taps or faucets have an aerator or screen DO NOT REMOVE.
      i. In some cases, some facilities will have a routine cleaning process for the aerators.
      ii. If this is the case, ask that the screens are not cleaned immediately prior to testing and that janitorial staff simply follow the normally scheduled cleaning routine.

II. General procedure
   a. Each fixture to be sampled will be identified on the sample collection form (Figures 11 & 12) and on the labeled sample bottles.
   b. The bottles for collecting each sample will be color-coded based on sample type (Figure 12).
      i. Initial samples – white sticker on lid
      ii. 30-second flush sample – green sticker on lid
   c. If a fixture not identified during sample design is found during sample collection
      i. In the field (on paper)
         1. Add samples to paper sample collection form (don't worry about reordering anything, just add it to the end)
         2. Collect the sample (using an extra bottle), record the time sample collected
         3. Add appropriate labels to sample bottle
         4. Add appropriate label to the map

ii. When you have connectivity (on the 120WA platform – the SAME DAY of the sample collection) – preferably on site
    1. Assign new fixture a fixture code – add it to the platform like you would during a design
        a. Inventory the new fixture; be sure to include all information
    2. Assign sample(s) on the platform after fixture is created
    3. Finalize the updated map and upload the final map to the platform
    4. Alert Program Manager of the change

III. Sample collection
- a. **Before each sample is taken**, verify that the fixture you are sampling from matches the following:
    - i. The location of the fixture on the building map
    - ii. The description on the sample collection form
    - iii. The label on the bottle
- b. Always collect water at a medium rate of flow
- c. No refrigeration or acidification (e.g. preservatives) of bottles is needed
- d. Collecting Ice samples:
    - i. Fill bottle ¾ of the way full
    - ii. **Never** use a metal scoop
    - iii. Use plastic scoop or gloved hand.
- e. Initial sample
    - i. *Before* turning on the water
        1. Place 250 mL container under faucet or tap being tested
    - ii. Fill sample bottle without allowing it to overflow and then secure the lid to the bottle
    - iii. Wipe down sample bottle with paper or cloth towel before putting it in the box.
        1. This will ensure that the box stays dry and prevents losing its structural integrity
- f. 30-second flush sample
    - i. The 30-second flush sample bottes will have a green sticker on the lid of the sample bottles and will be highlighted green on the sample collection form.
    - ii. 30-second flush samples will not necessarily be taken from every fixture.
    - iii. After collecting the initial sample, use a timer (on the tablet) and let the water run down the drain for 30 seconds
    - iv. Immediately following the 30-second flush, collect sample in the same manner that it was taken during the initial sample

IV. Documentation (Figure 11):
- a. Sample Collection Form
    - i. The sample collection form will be filled in based on information collected from sample design
        1. The sample collection form can be accessed online or in a paper form
        2. Will include fixture code, sample type, fixture location, fixture type, & location description
    - ii. Documenting a collected sample
        1. Fill in the time each sample is drawn
        2. Write sampler's name at each sample taken

3. If sampling over 2 days
    a. Include a <u>date</u> for which samples were taken on which day
4. <u>Note anything and everything</u> seemingly peculiar about a particular sample or fixture
    a. Examples: brown water, doesn't seemed used, aerator seems clogged, water came out warm

iii. Documenting a cancelled samples
1. If using paper:
    a. Draw a single strikethrough through the entire row
    b. Write in the cancellation reason
    c. *Never* write in a time when you cancel a sample
2. If using the online platform:
    a. Follow the directions found on the platform

iv. When filling out any paper form, always use <u>black</u> or <u>blue</u> ink

v. If you make a mistake writing – never scribble/white out your mistake – mark a single strike-through, write the correction next to it, and initial the change.

Figure 11: Sample Collection Form example

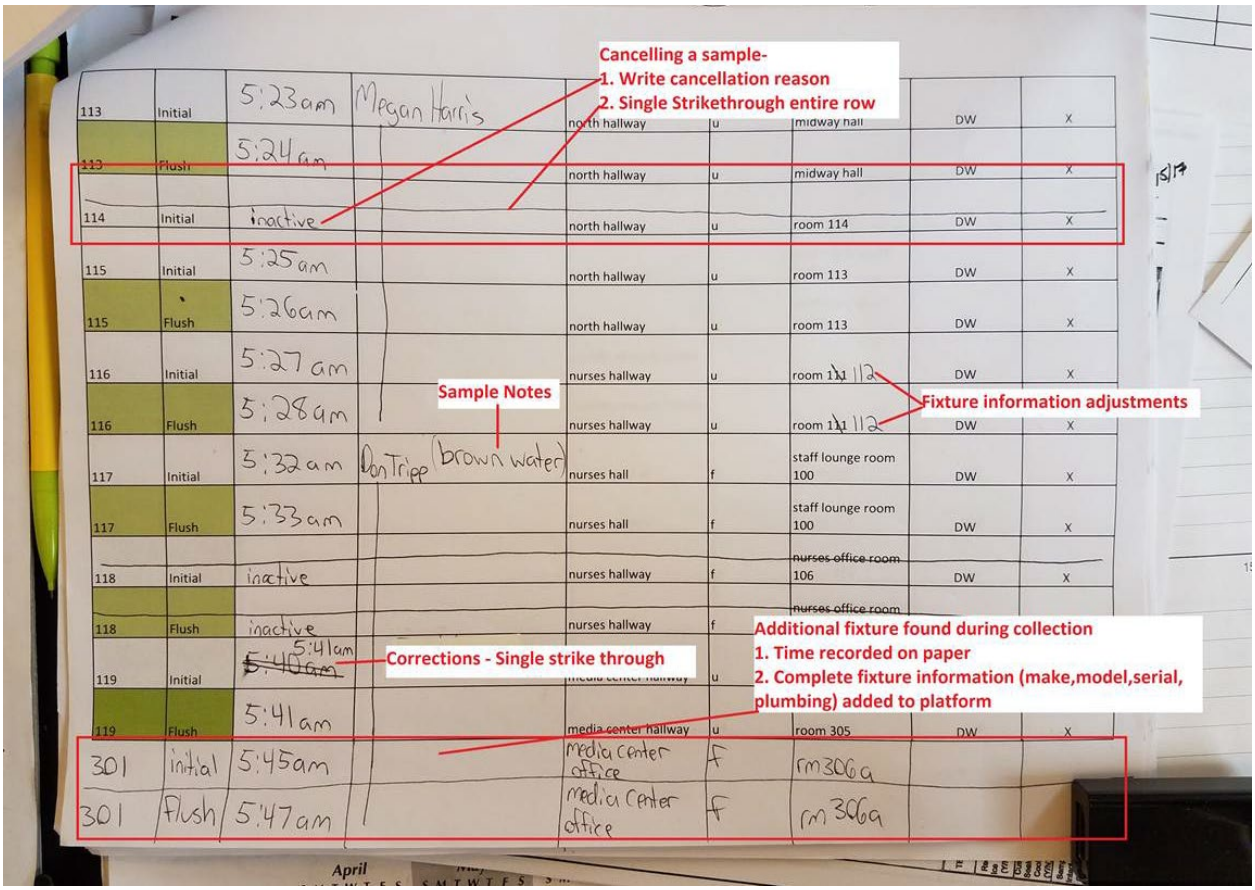


Figure 12: This figure shows the colored stickers on the sample bottles based on sample type.

V. <u>After collecting samples but *before* leaving facility</u>

a. Take pictures of each page of the sample collection form
b. Upload the pictures to the documents tab of the school on 120WaterAudit Platform
c. *After* the pictures are uploaded – send a text or an email to the Program Manager
    i. This indicates to the Program Manager that a sample collection was completed
d. **Take a picture of the kitchen!**
    i. It does not have to be during collection (if you are short on time) just remember to take a picture before you leave.

VI. <u>Shipping Samples</u>

a. Prepare shipping box in accordance with instructions given by 120WaterAudit.
b. Ensure that the sample collection form has your signature and place it in the shipping container.
c. Secure box with packing tape.
d. Proceed to the nearest US Post Office for shipment.
e. If there were a large amount of samples collected, arrangements may be made by 120WaterAudit to have a courier pick those samples up from the school.
    i. This will be pre-determined after the sample design has been constructed for that particular school.
f. All samples must be shipped the day of collection
    i. The exception here would be if a sampling event occurred over the course of 2 days.
        1. In this case take the samples home with you (don't leave out in the car)
        2. Ship out all samples together the following day.

APPENDIX A-2:
Field Data Forms and Chain-of-Custody Documentation

Chain of Custody	
Facility Name:	
Facility Number:	
Building Name:	

SECTION 1 MUST BE COMPLETED (even if you collect samples within the 120WA facilities platform)

Sampling Date (MM/DD/YYYY):	**Sample Collector's Email:**
Sample Collector(s) Name (s) (Please Print):	**Sample Collector's Phone:**

When was water last used in the building? DATE:_____ TIME: _

Did you collect samples within the 120WA platform? YES NO, I will use this form

Chain of Custody: This section MUST be filled out anytime samples change hands after collection. If you personally collected the samples and are dropping them off at the post office, simply sign your name and provide the date you shipped them below.

1. Released By (signature):	**Date/Time:**	**Received By (signature):**	**Date/Time:**
2. Released By (signature):	**Date/Time:**	**Received By (signature):**	**Date/Time:**
3. Released By (signature):	**Date/Time:**	**Received By (signature):**	**Date/Time:**

****

SECTION 2 MUST BE COMPLETED IF YOU USE THIS FORM TO COLLECT SAMPLES

If you use this form to collect samples (instead of collecting within the 120WaterAudit platform) you must write the time each sample was collected below.

Fixture Code	Sample Type	Location Description	Fixture Type	*Time Sample Collected*	Optional Sample Notes (discolored water, leaky fixture, out of service, etc.)	FOR LAB USE ONLY LAB Sample ID	FOR LAB USE ONLY HNO3 Preservation

Note: additional rows added as needed

Need to add fixtures not included in your 120WA Sample Plan? Simply give them a new fixture code, fill out the columns below, and fill out the blank sample bottles we provided in the box!

Note: additional rows added as needed

Matrix: DW-Lead	**Laboratory Reporting**	**Email EDD to results@120wateraudit.com.**
Analyte: Total Lead		
Sample Type: Grab		

APPENDIX B:
Laboratory Documentation

APPENDIX B-1:
Element Materials Technology - Quality Assurance Manual

Element-Daleville
9301 Innovation Dr.
Daleville, IN 47334
TX: 765-378-4103

Element-South Bend
3371 Cleveland Rd.
Suite B
South Bend, IN 46628
TX: 574-277-0707

Element-Fort Wayne
328 Ley Rd.
Suite 100
Fort Wayne, IN 46825
TX: 260-471-7000

Element-Warsaw
909 Executive Dr.
Warsaw, IN 46580
TX: 574-267-3305

Element-Columbus
629 Washington St.
Columbus, IN 47201
TX: 812-375-0531

Quality Manual

Element Materials Technology Daleville, LLC

Approved by: _____ _____

(General Manager)

_____

(Quality Manager)

Quality Manual

This Quality Manual meets the requirements of ISO 17025 and other applicable quality standards. This Quality Manual pertains to the laboratories as outlined below.

Issued to: Element-Columbus, Element-Daleville, Element-Fort Wayne, Element-South Bend, Element-Warsaw and collectively referred to as Element-EFW.

☐ Controlled Copy, NE-ADM-039
☒ Uncontrolled Copy

Table of Contents

Introduction

Purpose

This Quality Manual contains all the requirements that our laboratories use to demonstrate our quality management system, technical competence, and valid results.

Section 4 specifies how we demonstrate sound management and maintain client satisfaction.

Section 5 specifies how we demonstrate technical competence in our laboratory.

In addition, this Quality Manual outlines how we meet:

- ISO 17025
- ISDH Certification for Chemical and Microbiological Testing of Drinking Water
- Other applicable ISBOAH, USDA, and FDA standards for chemical and microbiological analysis of food and food products
- Good Laboratory Practice Standards, 40 CFR Part 160

All personnel are to take an active role in establishing, implementing, and maintaining our quality management program. We do not separate quality from our daily business. Quality is integrated into every facet of the decision-making process in the management of our laboratory and the science that we practice.

Distribution List

The Quality Manager maintains a distribution list for controlled copies of the Quality Manual.

1. Scope

1.1 This Quality Manual facilitates:

- recognition of technical competence for standardized methods, non-routine methods, and laboratory-developed methods we perform
- total quality for our administrative and technical systems
- audits by clients, regulatory authorities and accreditation bodies
- meeting the requirements of ISO 17025, ISDH, ISBOAH, USDA/FSIS, AOAC Guidelines for Microbiological and Chemical Analyses of Food and Pharmaceuticals, and other government or regulatory agencies where applicable
- client satisfaction

Revision History
Revision 0.1: Added ISBAH, USDA/FSIS, AOAC Guidelines for Microbiological and Chemical Analyses of Food and Pharmaceuticals
Revision 1.0: Removed “Level 2” in title.
Revision 1.0 – No changes to this section.
Revision 2.0 – No changes to this section.

2. References

Reference List

ISO 17025:2005 – General Requirements for the Competence of Testing and Calibration Laboratories.

AOAC Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals, 2015

Cross-references

This manual is numerically aligned with the international standard ISO 17025. It is expected that this will prove useful during accreditation audits and expedite the process.

For ease of use, each section starts with a brief summation of what the section addresses and a listing of the quality terminology and key words.

System Procedures issued by Element Materials Technology, Director of Quality Assurance

Administrative Standard Operating Procedures issued by Element Materials Technology-Daleville, LLC Quality Manager

Revision History
Revision 0.1: Specified Quality Manager as Element Materials Technology-Daleville, LLC to cross references section
Revision 1.0: Removed “Level 2” in title. Added reference to Element System Procedures.
Revision 2.0: Removed reference to ISO 17000, added AOAC reference

3. Terms and Definitions

For the purposes of this manual, the following documents and their corresponding definitions apply: ISO 17025; AOAC; and International Vocabulary of Basic and General Terms in Metrology (VIM).

Accreditation – formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests

Accuracy – The degree of agreement between an observed value and an accepted reference value.

Audit – A systematic and independent examination of the facility, equipment, personnel, procedures, record keeping, data management and reporting aspects of the quality system. The term “inspection” may be used interchangeably.

Batch – Samples that are prepared and/or analyzed together with the same process, reagents, equipment and personnel. If the method does not define a batch number, the lab has defined a batch number as 20 samples. Quality control samples are not included as part of the 20 samples.

Chain of Custody Form – The record that documents the sample identification and the sample possession from the time of collection to receipt in the lab

Demonstration of Capability – A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision

Holding Times – The maximum time that can elapse between the collection of the sample and the sample analyses

Limit of Detection (LOD) - An estimate of the minimum amount of an analyte in a given matrix that can be reliably detected

Limit of Quantitation (LOQ) – The minimum concentration of an analyte that can be quantitated and reported with a specified degree of confidence

Precision – The degree to which a set of measurements of the same analyte obtained under similar conditions, conform to themselves and typically expressed as standard deviation in either absolute or relative terms

Proficiency Testing – A means of evaluating a lab’s performance through analysis of unknown samples provided by an external source

Raw Data – The documentation generated during sampling and analysis and may include field notes, instrument printouts, hand written records, electronic data files

Standard Operating Procedures (SOPs) – A written document that outlines the steps for performing specific test procedures, repetitive tasks, or administrative procedures

Traceability – The ability to track the history of a sample or a measurement by means of documented identifications. In a calibration sense, traceability links instruments to

national/international standards, primary standards, or reference materials. In a data collection sense, traceability links calculations and data back to the samples.

Revision History
Revision 0.1: Added “Quality control samples are not included as part of the 20 samples” to the definition of Batch.
Revision 1.0: Removed “Level 2” from title. Added “The term “inspection” may be used interchangeably” to definition of Audit. Added “administrative procedures” to definition of Standard Operating Procedures”.
Revision 2.0: Removed EL-VIM2-ISO-2009 reference

4.1 Organization

The Ten Second Tutorial

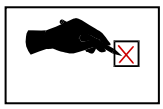
This section tells you our laboratory has:

1. Appointed a Quality Manager
2. Organized the workforce to achieve quality
3. Provided adequate resources to ensure quality

Key Words

Quality Manager
Organizational Chart
Authority
Resources
Confidential Information
Proprietary Rights
Responsibilities
Undue Pressure

Cross-references



ISO 17025:2005 Section 4.1
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.1.1 Legal Identification / Registration

Element Materials Technology Daleville, LLC
9301 Innovation Dr. Suite 115
Daleville IN 47334
TX: 765-378-4103
FAX: 765-378-4109

4.1.2 Laboratory Requirements

The laboratory facilities of Element Materials Technology Daleville, LLC (herein after referred to as Element-EFW) have been organized to implement and adhere to the standards defined by our quality system, to meet the international standard ISO 17025, the Indiana State Department of Health, FDA/FSIS/USDA, and other regulatory authorities as applicable to satisfy the needs of our customers and of our accreditation agencies. Element-EFW is composed of the following laboratory facilities:

Corporate Offices and Laboratory: 9301 Innovation Dr., Daleville, IN 47334
Laboratory: 2121 E. Washington Blvd., Fort Wayne, IN 46803
Laboratory: 629 Washington St., Suite 300, Columbus, IN 47201
Laboratory: 3371 Cleveland Rd, Suite B, South Bend, IN 46628
Laboratory: 909 Executive Blvd, Warsaw, IN 46580

4.1.3 Scope of Management System

The management system covers activities in the laboratory's permanent facilities and satellite facilities. See Appendix 1 for a list of tests performed at each facility.

The fields of activities include:

Drinking water testing
Wastewater testing
General inorganics testing
Organics testing
Biosolids and Solid waste testing
Swimming pool testing
Sample collection of drinking water & wastewater
Microbiological testing
Pesticide residue testing
Fertilizer testing
Food Chemisty and Microbiological Testing
HACCP testing
Microbiological identification
Pathogen testing
Shelf life studies
Medical Device testing
GLP Storage stability testing

4.1.4 Potential Conflicts of Interest

Element-EFW is a division of Element Materials Technology Company. The Operation Managers of Element-EFW report to the General Manager who in turn reports to the Divisional Director. The Quality Manager reports to the General Manager of the respective business sector and is in contact with the Director of Quality Assurance.

This management structure ensures the independence of the laboratory from the rest of the organization.

Executive management of Element has taken appropriate steps to ensure impartiality and freedom from commercial and financial pressures that might influence technical judgement. Employee responsibilities in such areas as business ethics and conduct are emphasized in annual ethics training.

4.1.5 Organization

A) Management and Technical Personnel

Policy:
The laboratory managerial and technical personnel, irrespective of other responsibilities, have the necessary authority and resources needed to meet the mandates assigned to their areas.

Details:
Responsibilities are detailed in Section 4.1.5 (F).

Departures from the organizational and management policies in this manual can only be approved by the Operation Managers and/or General Manager of Element-EFW.

Departures from quality management system procedures can only be approved by the Quality Manager.

Departures from test methods or technical standard operating procedures (SOPs) can only be approved by the Quality Manager and/or Operations Managers.

See also section 5.2.

B) Undue Pressure

Policy:
Management and personnel are to be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. The integrity of test results is the responsibility of all personnel. Management ensures that employees are never instructed or forced to alter or falsify data.

Element-EFW management has established documented policies to address undue pressure in the addendum to Element System Procedure (SP) 301-Training & Qualification of Personnel. Ethics and data integrity training are conducted and documented annually at each facility. This training also includes customer confidentiality and proprietary rights (Section 4.1.5.C of this manual).

Details:
The following list provides some guidelines on how employees avoid conflict of interest situations. Employees shall not:

- falsify records, prepare fraudulent reports, or make false claims
- seek or use privileged or confidential company information, or data from any customer, for any purpose beyond the scope of employment
- conduct non-laboratory business on laboratory time, or use company facilities or equipment to conduct outside interests in business, unless prior approval has been obtained
- solicit business on their own behalf (rather than the laboratory) from a customer
- be employed by, or affiliated with, organizations whose products or services compete with laboratory products or services

- have employment that negatively affects or interferes with their performance of laboratory duties
- compete with the laboratory in the purchase, sale, or leasing of property or goods
- allow association, family, or friends to influence business decisions to their benefit - decisions must be made on a strictly business basis, always in the best interest of the laboratory
- make any decision that provides gains or benefits to the employee and/or others
- have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal.

C) Customer Confidentiality

Policy:
It is the policy of our laboratory to protect the confidential information and proprietary rights of our customer including the electronic storage and transmission of results. Element SP 508-Protecting Confidentiality and Proprietary Rights provides details to address this policy.

Details and Procedures:
All employees receive annual training on customer confidentiality and proprietary rights in reference to SP 508. Employees are obligated to maintain all company trade secrets, proprietary information, and confidential information. Confidential information includes, without limitation, the name of any Element client, manufacturing processes, computer programs, financial data, and marketing plans. Employees shall not copy, transmit, publish, summarize, quote, or make any commercial or other personal use of customer confidential information.

Test results are only released to the customer. Release to someone other than the customer requires the express permission of the customer, except when the situation contravenes State or Federal Legislation and the results must be provided to the appropriate agency.

Laboratory reports are reviewed for accuracy prior to release. Electronic files of lab reports are maintained in the laboratory management system (LIMS). The LIMS database is backed up both on site weekly and off site daily. Laptops are backed up daily.

Data files from automated instruments running Windows XP or greater are backed up nightly. The hard drive of older instruments is copied to another hard drive and stored for disaster recovery.

Specific information regarding the Element backup policies of servers, workstations, and instruments may be referenced in the most current version of the Element ICT Exec Backup Policy.

All records, both paper and electronic, shall be archived in a secure manner for a period of 7 years unless otherwise directed by the client.

D) Operational Integrity

Policy:
The laboratory will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

Details and Procedures:

To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through check sample programs such as the proficiency testing programs and the routine analysis of quality control samples. Impartiality is assessed through audits. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving his or her skills. Operational integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through corrective action procedures.

Element-EFW employees are obligated to be free of conflicts of interest in discharging professional responsibilities. Conflicts of interest include, but are not limited to, acquisition or commitment to acquire any direct or material indirect financial interest in a customer and participation as a promoter, voting trustee, director, or officer of a customer.

E) Organizational Structure

Policy:
The organization and management structure of the laboratory, its place in the parent organization, and the relationships between management, technical operations, support services, and the quality management system is defined through the aid of an organizational chart.

Details:
Senior management (Human Resources) maintains the most current organizational chart on file for the business sectors. The Operations Managers or Quality Managers maintain the most current organizational chart for each location.

F) Responsibility and Authority

Operations Manager of Element-EFW, Indiana – Environmental Services
Operations Manager of Element-EFW, Warsaw, Indiana – Food and Microbiology

- develops primary goals, operating plans, policies, and short and long range objectives for the laboratory; implements these following Board of Directors' approval
- directs and coordinates activities to achieve profit and return on capital
- establishes organizational structure and delegates authority to subordinates
- leads the laboratory towards objectives, meets with and advises other executives, and reviews results of business operations
- determines action plans to meet the needs of stakeholders
- represents organization to major customers, government agencies, shareholders, and the public
- ensures compliance with applicable quality standards such as ISO 17025, USDA, FDA, and ISDH
- prescribes and monitors corrective actions
- hires and/or terminates employees
- May also act as the quality officer as long as he/she is not responsible for laboratory testing

Operations Manager Signatory Authority

- Lab reports
- Quotations
- Purchase requests
- Standard Operating Procedures
- Corrective Actions
- QA documentation
- Non-conformance documentation

- Employee training records
- Chain of custody forms

Laboratory Department Manager – Environmental Services

- are knowledgeable of the scope of all processes under their supervision
- provides the necessary resources (personnel, equipment, supplies) for the quality assurance program, in order to ensure confidence in the laboratory's results
- ensures equipment is maintained and calibrated, reporting all deficiencies (e.g., equipment malfunctions) in the appropriate manner
- ensures personnel are trained for the duties they perform - includes substitutes when regular personnel are absent
- maintains current job descriptions
- maintains records and manages all aspects of testing activities
- hires personnel
- orientates new personnel
- determines technical training needs of personnel
- conducts employee performance reviews
- prioritizes workload
- facilitates operational concerns in their area
- ensures accurate and consistent testing procedures through the validation of all current procedures and by developing, validating and implementing new procedures
- coordinates purchasing requests
- ensures that the operational needs are within budget and advising management of any discrepancies
- ensures that all health and safety regulations are followed

Laboratory Department Manager Signatory Authority

- Employee training records
- Quality assurance documentation
- Non-conformance documentation
- Corrective action reports
- Chain of custody forms
- Lab reports
- Quotations
- Purchase requisitions

Quality Manager

- ensures that the Quality Management System is established, implemented and maintained in accordance with the ISO 9001, ISO 17025, USDA, FDA, ISDH standards, and any other applicable standards
- manages the internal audit program
- coordinates laboratory accreditation activities
- handles the maintenance and distribution of the Quality Manual and associated documents
- maintains a master list of current versions of quality documentation
- trains personnel on Quality Management System activities
- monitors the Quality Management System
- reports on the performance of the Quality Management System to senior management for review and as a basis for improvement of the Quality Management System
- supervises the laboratory's inter-laboratory proficiency testing program
- responds to deficiencies in the quality system and notifies management of deficiencies and monitors corrective actions

- partners with project managers to meet customers' expectations while maintaining the necessary independence to assure data integrity
- initiates and reviews corrective action reports
- signs off on all corrective action reports

Quality Manager Signatory Authority
- Quality Manual
- Standard Operating Procedures
- Audit Reports
- Corrective Actions
- QA Documentation
- Non-conformance documentation
- Lab reports
- Employee training records
- Chain of custody forms

Quality Officer/Administrator/Team Member
- assists the quality manager to develop and implement the quality procedures within the lab to ensure consistent data quality
- assists in the writing of quality manuals and procedures
- maintains records and archives of all records
- distributes PT samples and reports results
- initiates corrective actions
- assists the quality manager in maintaining the document control system
- assists the quality manager in documenting client feedback

Quality Officer/Administrator Signatory Authority
- Standard operating procedures
- Employee training records
- Audit reports
- Quality assurance documentation
- Non-conformance documentation
- Chain of custody forms
- Lab reports

Project Managers – Environmental Services
- acts as point of contact for designated clients
- reviews client requirements for applicability and ensures the lab is capable of performing the requested work
- works with functional managers to make sure analyses are performed in accordance with client needs
- reviews analytical reports
- resolves client issues
- communicates issues with clients and the lab staff

Project Managers Signatory Authority
- Chain of custody forms
- Sample receipt checklists
- Lab reports
- Corrective action records
- Quotations

Chemists, Biologists, Microbiologists, and Lab Technicians
- have a working knowledge of the quality program
- maintains records of all quality activities as documented in SOPs and test methods
- handles samples and performing analyses according to SOPs and test methods
- writes SOPs and test methods
- maintains and calibrates equipment
- reports deficiencies or malfunction to the lab manager
- identifies and communicates nonconformities to the Quality Manager
- identifies and communicates potential nonconformities to the Quality Manager
- corrects nonconformities and potential nonconformities
- improves laboratory and/or quality activities on a continuous basis

Chemists, Biologists, Microbiologists, Lab Technicians Signatory Authority
- Standard operating procedures
- Benchsheets
- Chain of custody forms

Customer Service and Administrative Personnel
- performs work functions (sample shipping, receiving, login, log review, report and invoice generation, and general clerical duties) and keeps records as per approved SOPs and/or laboratory policies
- sample bottle prep
- identifies and communicates nonconformities to the Quality Manager
- identifies and communicates potential nonconformities to the Quality Manager
- corrects nonconformities and potential nonconformities
- improves laboratory and/or quality activities on a continuous basis

Customer Service/Administrative Signatory Authority
- Chain of custody forms
- Delivery receipts
- Sample receipt checklists

Field Technicians
- sample bottle prep
- customer deliveries and pick ups
- sample collection
- field measurement testing

Field Technicians Signatory Authority
- Chain of custody forms
- Field logs

G) Laboratory Supervision
Policy:
Adequate supervision is provided in each area of the laboratory for all testing and calibration personnel, including trainees, by persons familiar with the methods and procedures.

Details:
Adequate supervision is ensured through designated managers as well as through documentation such as this Quality Manual, test methods and SOPs. A thorough orientation and

training program is adhered to for all new employees. Ongoing training for regular personnel is required and documented.

H) Technical Management
Policy:
A technical (operations) manager is assigned to the local laboratories. They have overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.

Details:
While the technical manager may at times delegate duties to other personnel, the technical manager is accountable for any nonconforming activities.

I) Quality Manager
Policy:
The Quality Manager, who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed. The Quality Manager has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

Details:
The Quality Manager is identified on the cover page of this quality manual. Any change in this position requires the update to the cover page. The Quality Manager communicates regularly with senior management and this communication affirms senior management's commitment to the policies and procedures set forth in this manual.

J) Managerial Substitutions
Policy:
Deputies for key personnel are appointed to fulfill the key personnel's duties in their absence.

Details:
In the absence of the Operations Manager, the department managers will assume responsibility in their respective testing divisions for all technical decisions and interpretations involving test procedures, methods, and reports. The Quality Manager or Officer will assume responsibility for all issues related to data quality. Customer service representatives will assume responsibility for customer issues.

In the absence of the Quality Manager, the Quality Officer/Administrator and/or Operations Managers will assume his/her responsibilities.

In the absence of the Quality Officer/Administrator, the Quality Manager will assume his/her responsibilities.

In the absence of the department manager, the Operations Manager and/or project managers will assume his/her responsibilities.

In the absence of the Project Manager, the department manager and/or Operations Manager will assume his/her responsibilities.

Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent.

If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

K) Awareness
Policy:
Management ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

Details:
Lab department managers review the details of each employee's job description with the appropriate employee and how the overall Quality Policy Statement (Section 4.2.2) relates to their activities to achieve the objectives of the management system.

Regular communication between management and lab staff takes place to review laboratory scheduling, performance, and goals. Employees are encouraged to provide input regarding process improvements and preventive actions.

Annually, employees receive training on their roles in and responsibilities for the laboratory quality system.

4.1.6 Communication Processes

Policy and Details:
Top management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

Staff meetings are held throughout the year that include one or more members of top management to review laboratory performance and goals as it relates to each facility and to the entire laboratory network.

A management review meeting is also held annually to evaluate the effectiveness of the quality system and to identify actions for improvement. The results of the management review meeting are shared with all staff members at each location.

Reference: Element SP 901, Audits

Revision History

Revision 18
Reformatted entire section

Revision 19
Section 4.1.3 – Updated scope of tests
Section 4.1.4 – Changed Sherry Holdings to division of Element-EFW Materials Technology Company
Section 4.1.5.E – Removed record archive storage for 10 years after Jan 1, 2012.

Section 4.1.5 I – Removed signature line

Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Section 4.1.4 – Updated organization structure of management and replaced Senior Vice President of Quality and Technology with Senior Manager of Quality
Section 4.1.5.C – Updated IT backup procedures for servers, computers and instruments
Replaced Lab Director with Operations Manager throughout all sections.
Revision 0.1
Section 4.1.2: Updated current address of Element-EFW-Warsaw
Section 4.1.4: Removed reference to Senior Manager of Quality
Section 4.1.5 C): Replaced Human Resources file with training file. Updated ICT backup policy information
Section 4.1.5 E): Updated Details section of the maintenance of org charts for the business sectors and the labs.

Revision 1.0
Removed “Level 2” from title. Section 4.1.3: added “Medical Device testing”. Section 4.1.5.C: added reference to SP 508. Section 4.1.16 added reference to Element SP 901, Audits.

Revision 2.0
Section 4.1.5B: Replaced reference to NE-ADM-011-Ethics with reference to addendum to SP 301-Training. Section 4.1.5C: Removed reference to signed ethics agreement and replaced with annual training to SP-508.

4.2 Management System

The Ten Second Tutorial

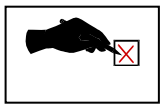
This section tells you that our Management System (or Quality Management System) is based on:

1. A well-defined quality policy statement
2. Say what you do through documentation
3. Do what you say following your documentation
4. Record what you did

Key Words

Establish, Implement, and Maintain
Policies, Systems, Processes, Programs, Procedures, Instructions
Communicate, Understand
Quality Policy Statement
Quality Manual
SOP
Test Method

Cross-references



ISO 17025:2005 Section 4.2
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.2.1 Policies and Procedures

Policy:
The Quality Management System is established, implemented, and maintained by management. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

Details:
The purpose of our Quality Management System is to ensure that all services and products satisfy the customer's requirements and have been designed, manufactured, and delivered under controlled conditions.

The effectiveness of the Quality Management System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality management system
- by regular management reviews of the suitability and effectiveness of the quality management system
- by analysis of potential and actual problems as shown by customer complaints and supplier and subcontractor assessments
- by other methods approved from time to time by the Quality Manager

This Quality Manual and associated documents (including procedures) and records serves as the quality plan for the laboratory. Other documents and records include:

- standard operating procedures for test methods
- standard operating procedures for administrative processes
- original test methods
- quality control plans in test methods
- organizational charts
- HQMS quality program records
- the laboratory information management system program
- project management schemes

4.2.2 Quality Policy Statement

Statement: To deliver to our internal and external customers a consistent, rigorous and integrity based quality system that provides the highest assurance of testing, services and product quality and excellence.

Policy:
The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement and reviewed during management review. The Quality Policy Statement is issued under the authority of the General Manager.

Quality Policy Statement Purpose:
Element-EFW will provide quality services and products consistent with the needs of our customers, implement and adhere to the standards defined by our quality system, ISO 17025

standards, Indiana State Department of Health and government or regulatory agencies where applicable.

Element-EFW management shall appoint a member of the staff as quality manager for each facility who irrespective of duties and responsibilities shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.
\
Element-EFW shall report results of each test accurately, clearly, unambiguously and objectively with specific instructions for the test method in a legally defensible manner.

Element-EFW shall assure that all personnel concerned with testing activities familiarize themselves with the pertinent quality documentation and implement these procedures in their work.

4.2.3 Commitment to the Management System

Policy:
Top management is committed to the development and implementation of the management system and continually improving its effectiveness.

Details:
The results of the management system are regularly reviewed during management review (see Section 4.15 and Element SP 901 Audits) and continual improvements are made as outlined in Section 4.10 – Improvements.

The quality staff routinely submits reports to the Operations Managers, General Manager, and Executive Vice President for their review. Discussion on quality related activities are also an integral part of a weekly Leadership meeting.

4.2.4 Communication of Requirements

Policy:
Top management communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

Details:
In general, the underlying message in all oral and written management communications involves meeting the aforementioned requirements. Meeting customer requirements ensures that ongoing business relationships secure the contracts that keep everyone employed. Meeting statutory and regulatory requirements ensures that laboratory operations will not be disrupted and the organization can continue to meet customer needs.

Communication to the laboratory staff is routinely accomplished through staff meetings, performance reviews, ethics and data integrity training, and through the quality manual.

4.2.5 Quality Manual

Policy:

This Quality Manual outlines the structure of the documentation used in the quality management system. This Quality Manual makes reference to supporting procedures including technical procedures and is maintained up to date.

Details:
This quality management system is structured in four tiers of documentation. The tiers are as follows:
I. Quality Manual
II. System Procedures, Standard Operating Procedures and Test Methods
III. Benchsheets
IV. Forms, Logs and tags/labels

For most customers, this Quality Manual and the associated documents form a general Quality Plan. If necessary, specific Quality Plans will be prepared on a 'per-customer' basis. These Quality Plans may modify the general requirements stated in the Manual and associated documents or provide more specific requirements as per customer or project needs.

The following records and directive documents are referenced in the Quality Manual, but maintained separately:
- organizational chart (section 4.1.5.E)
- management review (section 4.15.1)
- job descriptions (section 5.2.4)
- statistical techniques (section 5.9)
- test reports (section 4.13.2 and 5.10)
- identification of the laboratory's approved signatures (section 5.10.2)
- laboratory's scope of tests (section 4.1.3)
- equipment inventory and records (sections 5.5.4 and 5.5.5)
- calibration status indicators (section 5.5.8)
- reference standards inventory (section 5.6.3)
- verification records (section 5.9)
- corrective action records (section 4.11)
- preventive action records (section 4.12)
- customer complaint records (section 4.8.1)
- audit schedule and records (section 4.14.3)
- procurement and subcontracting records (sections 4.6 and 4.5.4)
- training records (section 5.2.5)
- master list of documentation (section 4.3.2)
- confidentiality agreements (section 4.1.5 C)
- contract review (section 4.4.2)
- validation of test methods (section 5.4.5)

4.2.6 Technical Management and the Quality Manager

The roles and responsibilities for technical management and the Quality Manager are outlined in Section 4.1.5 (F) of this manual.

Technical management supports the Quality Manager and helps to ensure that Section 5 of this manual is implemented and maintained. The Quality Manager ensures that Section 4 of this manual is implemented and maintained.

4.2.7 Maintenance

Policy and Details:
Top management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

Revision History

Revision 18
Reformatted entire section
Revision 19
Section 4.2.2 – Removed signature line
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes

Revision 1.0
Removed “Level 2” in title. Section 4.2.3 added Divisional Director. Section 4.2.5 added detail to Quality Plans.

Revision 2.0
Section 4.2.3 added reference to SP 901 and weekly Leadership meeting.

4.3 Document Control

The Ten Second Tutorial

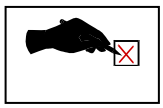
This section tells you that Document Control involves:

1. Writing good procedures
2. Getting them to the users
3. Keeping procedures good

Key Words

Controlled Document
Master List
Unique Identification
Revise
Revision Number
Effective Date
Review and Approval
Obsolete
Archive
Hand-written changes

Cross-references



ISO 17025:2005 Section 4.3
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.3.1 Policies and Procedures

Policy:
Element SP 101-Document Control is used to control all quality management system documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as specifications, instructions, and manuals.

Details:
Document means any information or instructions including procedures, specifications, calibration tables, charts, text books, notices, memoranda, and software. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:
- Quality Manual
- System Procedures
- Standard Operating Procedures
- Forms & Benchsheets
- Quality System Standards
- External methods
- Calculation spreadsheets
- Generic training forms
- Lab postings of instructions or specifications which are unique to the Quality System

The control of data related to testing and calibration is covered in section 5.4.7. The control of records is covered in section 4.13.

4.3.2 Document Approval and Issue

4.3.2.1 Review / Approval / Master List

Policy and Details:
All documents issued to personnel in the laboratory as part of the quality management system are reviewed and approved for use by authorized personnel prior to issue (i.e., reviewed by personnel knowledgeable in the documented activity and then approved by management). A master list identifying the current revision status and distribution of documents in the quality management system is readily available in order to preclude the use of invalid and/or obsolete documents. A revision history of documents is also maintained. Specific documents (SOPs) are formally reviewed on a biennial basis to ensure their continuing suitability unless more stringent requirements are identified for specific programs.

4.3.2.2 Availability and Obsolete Documents

Policy and Details:
The master list shows the current status of all controlled documents. The master list document is organized with the following information:
- Document #
- Title
- Revision #
- Date of issue/Effective Date
- Date of last review
- Locations

Controlled documents are approved before issue.

Element SP 101-Document Control ensures that:
- authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed
- documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements
- invalid or obsolete documents are promptly removed from all points of issue or use to assure against unintended use
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked (i.e., stamped "OBSOLETE" and dated)

4.3.2.3 Identification

Policy and Details:
All quality management system documentation is identified by:

- document title
- document number
- date of issue/effective date and/or revision number
- page numbering
- total number of pages (e.g., page 5 of 5)
- issuing authority (i.e., approval signature)

4.3.3 Document Changes

4.3.3.1 Review / Approval

Policy:
Changes to documents are reviewed and approved by the same function (i.e., personnel or position) that performed the original review unless specifically designated otherwise. The designated personnel must have access to pertinent background information upon which to base their review and approval.

Details:
Developments in policies and procedures require documents to be changed from time to time. Changes to documents receive the same level of review and approval as the originals.

The Quality Manual is reviewed by the Quality Manager. Records are kept of this review in the revision history.

Test methods and administrative SOPs are reviewed on a biennial basis unless stricter requirements are specified by an accrediting agency.

Obsolete documents are withdrawn, but are retained for archive purposes and clearly labeled as obsolete or archived.

4.3.3.2 Identification of Changes

Policy:
The nature of document changes is identified in the document under the revision history.

Details:

Changes to documents are detailed in Element SP 101-Document Control. In general, the nature of changes is identified by one of three options; boldface type, color type, and/or a line in the margin to identify the section.

4.3.3.3 Amendments by Hand
Policy and Details:
Hand-written amendments to documents are not permitted as per Element SP 101-Document Control.

4.3.3.4 Computerized Documents
Policy and Details:
Element SP101-Document Control details how changes in documents maintained in computerized systems are made and controlled. In general, electronic files are maintained by the quality staff and are password protected. Changes may be entered by the reviewer or the issuing authority and the revisions are entered in the revision history for the document. The master list is then updated to reflect the newest revision number and the distribution of the document.

4.3.3.4 Laboratory Benchsheets and Lab Records
Policy and Details:
Benchsheets and forms are reviewed as needed and if changes are made the original document is revised, the revision number is updated, the document is reviewed and issued for use. The revised document is entered into the Master Document List and the previous one is archived.

4.3.3.5 Error correction
Policy and Details:
Corrections on hard copies are made by striking a single line through the error, entering an error code to describe the nature of the error, initialing and dating. Write-overs are not permitted.

Revision History

Revision 18
Reformatted entire section
Revision 19
Section 4.3.3.4 Added entire section
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes

Revision 1.0
Removed “Level 2” in title. Section 4.3.2 added “unless more stringent requirements are identified for specific programs” in reference to review schedule of quality documents. Section 4.3.3.2 added reference to entering a code for errors on hardcopies. Added Section 4.3.3.5 Error Correction.

Revision 2.0
Replaced reference to NE-ADM-016 Document Control with Element SP 101-Document Control throughout the section. Revised Sections 4.3.3.2, 4.3.3.3 and 4.3.3.4 as per SP 101.

4.4 Review of Requests, Tenders, and Contracts

The Ten Second Tutorial

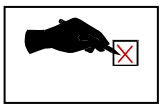
This section tells you that you must:

1. Clearly understand customer requirements

Key Words

Requirements
Subcontractor
Request
Tender
Contract
Review

Cross-references



ISO 17025:2005 Section 4.4
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.4.1 Policies and Procedures

Policy:

Element SP 705-Review of Requests, Tenders, and Contracts is used to review proposals of new work, changes to current customer requirements and requests for quotes. This procedure ensures that:

a) the customer requirements including the methods to be used are adequately defined, documented and understood
b) the laboratory has the capability and resources to meet the requirements
c) the appropriate test method is selected and capable of meeting the customer's requirements
d) Non-accredited tests shall be identified if the scope of work requires accredited tests

Any differences between the request or tender and the contract are resolved before any work commences. Each contract must be acceptable by both the laboratory and the customer.

Details:

The request, tender and contract review is conducted in a practical and efficient manner, and the effect of financial, legal, and time schedule aspects are taken into account.

The review of capability establishes that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial tests using samples or items of known value in order to determine uncertainties of measurement, limits of detection, and confidence limits.

The contract review ensures that each customer's requirements are adequately defined and documented before samples are submitted. This should ensure that any order, once accepted, can be completed without delay, and that the customer's requirements including delivery date, technical specification, and cost can be met.

If the contract review highlights any ambiguities or uncertainties then the customer will be contacted and the problem resolved before the order is accepted.

The Element SP 705 procedure also describes the activities that take place should there be a subsequent amendment to a customer's order. Typical types of contracts include:

- approved quotations
- purchase orders
- confidentiality agreements
- non-disclosure agreements
- chain of custody forms
- contracts
- documented verbal orders or agreements

4.4.2 Records of Review

Policy:
Records of request, tender and contract review, including significant changes, are maintained. Records of pertinent discussions with a customer relating to the customer's requirements or the work during the period of execution of the contract are also maintained.

Details:
For review of routine and simple tasks, the date and the identification (e.g., initials) of the person in the laboratory responsible for carrying out and/or reviewing the contracted work are considered adequate. For repetitive routine tasks, the initial review is made at the initial inquiry stage or on grant of the quote or contract for on-going routine work performed under a general agreement with the customer. The log review process in the laboratory LIMS serves as the review for repetitive work provided that the customer's requirements remain unchanged. For new, complex or advanced testing tasks, a more comprehensive record is maintained.

4.4.3 Review of Subcontracted Work

Policy:
Request, tender, and contract review also includes work that is subcontracted by the laboratory.

Details:
Subcontractor laboratories are reviewed as described in section 4.5. The environmental laboratory policy for subcontracted work is detailed in Element SP 704-Purchasing and Subcontracting of Testing and Calibrations.

4.4.4 Notification of Customer

Policy and Details:
Customers are informed of deviations from the contract. This is typically communicated to the customer prior to performing the deviation in order to get their permission for the deviation.

4.4.5 Contract Amendment

Policy and Details:
If a contract needs to be amended after the work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel. For GLP work, a specific procedure is followed as outlined in NE-ADM-049, Issuing Protocol Amendments and Documenting Protocol and SOP Deviations.

Revision History

Revision 18
Reformatted entire section
Revision 19
Section 4.4.3 – Added reference to SOP# NE-ADM-005, Purchasing, Receiving, Storage and Subcontracting.
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1

Section 4.3.3.1 – Added statement that SOPs will be reviewed more frequently than every 2 years if stricter requirements apply.
Revision 1.0
Removed “Level 2” in title. Section 4.4.1 added reference to Element-EFW SP 705. Section 4.4.5 added reference to NE-ADM-049 for GLP work.
Rev 2.0
Added 4.4.1 d, Added purchase orders as typical contract

4.5 Subcontracting of Tests and Calibrations

The Ten Second Tutorial

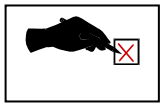
This section tells you that we must:

1. Know what tests and calibrations need to be done by another laboratory
2. Check out the other laboratories

Key Words

Competence
Register of Subcontractors
Assessment

Cross-references



ISO 17025:2005 Section 4.5
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.5.1 Subcontractor Competence

Policy:
Work that must be subcontracted due to:

- unforeseen circumstances
- workload
- large contracts
- contracts requiring some extra technical expertise
- testing outside the scope of the lab

is subcontracted to a technically competent laboratory. Element SP 704, Purchasing and Subcontracting of Testing & Calibrations, addresses the details involving subcontracting testing services as well as calibration services and quality critical supplies.

Details:
The subcontracted laboratory demonstrates technical competence by possession or receipt of one or more of the following:

- recognized technical accreditation
- registration under the ISO 9001 standard
- satisfactory performance of appropriate quality control check samples, certified reference material, in-house reference material or replicate analysis
- audit of the subcontractor's quality management system by our auditors

It is the responsibility of the Quality Manager to assess and approve the competence level of subcontractor laboratories. A listing of approved subcontractors is maintained in the LIMS

4.5.2 Customer Approval

Policy:
Customers are advised of work (or any portion thereof) that is being subcontracted to another laboratory and their approval is obtained (preferably in writing).

Details:
Customers are advised of subcontracted work through fee schedules or any type of contract listed in section 4.4.1. For subcontracted work reported within the laboratory report, the analyst shall be designated as "SUB". Subcontracted work attached to the report shall be reported in its entirety from the subcontract lab.

4.5.3 Assurance of Subcontractor Competence

Policy:
The laboratory is responsible to the customer for the subcontractor's work. Technical competence of subcontractor laboratories is demonstrated through various records.

> **Note** – there may be circumstances where the customer specifies which subcontractor is to be used. In such cases we may not be able to demonstrate the competence of the subcontractor and therefore are not responsible for the results.

Details:
Records of subcontractor competence include, but are not limited to, the following:

- accreditation certificates or documentation
- registration certificates

- check sample results
- audit results
- approval by the Quality Manager

4.5.4 Subcontractor Register

Policy:
A register of all subcontractors performing tests and calibrations is maintained in the LIMS.

Details:
The approved register of subcontractors and all assessment records are maintained by the Quality Manager. All approved vendors are entered into the LIMS and linked to their certifications and vendor survey responses.

References:
Element SP 704, Purchasing and Subcontracting of Testing & Calibrations

Revision History

Revision 18
Reformatted entire section
Revision 19
Section 4.5.1- Added testing outside the scope of the lab
Section 4.5.4 – Added additional information in Details
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” in title. Added Section “References” with SP 704 and NE-ADM-005.
Revision 2 – Removed reference to NE-ADM-005

4.6 Purchasing Services and Supplies

The Ten Second Tutorial

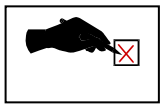
This section tells you that we must:

1. Know what we want
2. Check out our suppliers

Key Words

Selection
Verify
Specifications
History

Cross-references



ISO 17025:2005 Section 4.6
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.6.1 Policies and Procedures

Policy:
Element SP 704, Purchasing is used to select and purchase quality critical services and supplies. The SOP# NE-ADM-005 is used for procurement, reception, and storage of supplies.

Details:
The process for approval of vendors is needed to ensure quality critical supplies, equipment and services acquired by each Element-EFW location will meet established requirements as set forth in applicable accreditation standards, test method procedures or customer requirements.

4.6.2 Specifications

Policy:
Only services and supplies of the required quality are used. These quality requirements are detailed in laboratory SOPs under the "*Equipment" and "Supplies or Reagents and Standards"* sections and will identify the appropriate minimum specifications when necessary. Customer specific requirements may be identified in contracts or the GLP study protocol.

Details:
Packing slips are checked against package content labels and matched with the Purchase Order if there is a question. Once accepted, the packing slip is dated and initialed as evidence of compliance. Certificates of analysis (COA) are maintained on file after the COA is checked to ensure the received item meets minimum specifications.

Chemicals are purchased with manufacturer's certificates where possible. Where applicable, Guide 34 certified reference materials are purchased. Uncertified chemicals are generally purchased from ISO 9000 registered companies. Whatever the source, the laboratory verifies the quality of the standards by comparing the new batch of standards to the old. Due regard is paid to the manufacturer's recommendations on storage and shelf life.

Reagents are generally purchased from manufacturers who have a quality management system based on ISO 9000. The grade of any reagent used is stated in the method together with guidance on any particular precautions to be observed in its preparation or use. Reagent water is assumed to be Type II unless otherwise specified.

Where no independent assurance of the quality of procured goods or services is available or the supplier's evidence is insufficient, the laboratory ensures that purchased goods and services comply with specified requirements. Where possible and practical the laboratory ensures that goods are inspected, calibrated, or are otherwise in compliance with any standard specification relevant to the calibrations or tests concerned.

4.6.3 Purchasing Documents

Policy:
Purchasing requests are recorded on the weekly order form and contain data describing the product ordered. The weekly order form is reviewed for technical content prior to release. Major equipment requests are recorded on a capitol expense request.

Details:

The description may include type, class, grade, precise identification, specifications, or other technical data including, quality required and quality management system standard under which they were produced.

The completion of the order form is the responsibility of the originator. They review the order form for accuracy and approve the technical content prior to release with their initials and the date.

Requests for major equipment are reviewed and approved by the operations managers.

4.6.4 Approved Suppliers
Policy:
Suppliers of quality critical services are evaluated and approved before use. An approved supplier list is maintained.

Details:
Audits or tender evaluation is conducted to qualify suppliers of critical services prior to use. The criteria for evaluation may include, but is not limited to the following:

- references
- accreditation
- formal recognition
- vendor survey

The records are maintained by the Quality Manager.

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes

Revision 1.0
Removed “Level 2” from title. Section 4.6.1 added reference to SP 704, Purchasing, and revised Details of the Section 4.6.1. Section 4.6.2 added reference to customer contracts or GLP study protocol. Section 4.6.2 added reference to Guide 34 reference materials.

4.7 Service to the Customer

The Ten Second Tutorial

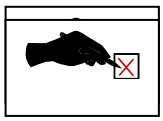
This section tells you that we must:

1. Facilitate clarification of the customer's request
2. Give customer access to relevant testing area
3. Maintain customer contact
4. Inform customer of delays or deviations
5. Utilize customer surveys

Key Words

Clarification
Deviations
Delays
Customer Satisfaction Survey

Cross-references



ISO 17025:2005 Section 4.7
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.7.1 Service

Policy:

Customer requests are clarified for the customers or their representatives. Furthermore the customer or their representative will be afforded the right to monitor the performance of the laboratory in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

Details and Procedures:

Service to the customer includes:

- Affording the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of work performed for the customer; it is understood that such access should not conflict with rules of confidentiality of work for other customers or with safety.
- Preparing, packaging, and dispatching of test results needed by the customer for verification purposes.
- Maintaining of open contacts. The customer values advice and guidance in technical matters, and opinions and interpretations based on results. Contact with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests.

4.7.2 Feedback

Policy and Details:

The laboratory seeks feedback from the customer. Positive and negative feedback can be obtained passively through ongoing communications with the customer (e.g., review of test reports with customers) or actively through customer satisfaction surveys. The feedback is documented and is used to improve the quality management system, testing activities, and customer service. When a response to customer feedback is needed, the response is assigned to the appropriate staff member. The response may vary from a phone call, a visit or a corrective action report. Additional information is available in Element SP 903, Customer Complaints and Feedback.

Revision History

Revision 18
Reformatted entire section
Revision 19
Section 4.7.2- Added additional details including reference to NE-ADM-017
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed "Level 2" from title. Section 4.7.2 added reference to Element SP 903.
Revision 2.0
Removed reference to NE-ADM-017

4.8 Complaints

The Ten Second Tutorial

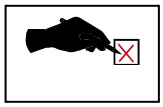
This section tells you that you must:

1. Maintain records of Complaints
2. Maintain records of Corrective Action

Key Words

Resolving
Investigation
Corrective Action
Follow-up Verification

Cross-references



ISO 17025:2005 Section 4.8
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.8.1 Policies and Procedures

Policy:
Element SP 903, Customer Complaints and Feedback is used for resolving complaints received from customers or other parties. Records are maintained of all complaints and follow-up.

Details:
Complaints are defined as any grievance, problem, difficulty, or concern, and can be associated with quality, laboratory reports, communication, customer service, turn time, or pricing.
Records of complaints include the following information:

- details of the complaint
- the department or work area involved
- investigation
- resolution or corrective action
- follow-up verification if needed

All personnel are responsible for recording and responding to complaints. When appropriate, a corrective action response is initiated See Section 4.11 for information on the corrective action process.

Positive customer feedback is also recorded.

All customer feedback is reviewed in the annual management review meeting.

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title. Section 4.8.1 added reference to Element SP 903 under Policy and defined complaints in Details.
Revision 2.0
Removed reference to NE-ADM-017.

4.9 Control of Nonconforming Testing and Calibration Work

The Ten Second Tutorial

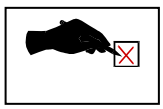
This section tells you that you must:

1. Stop testing when nonconforming work is identified
2. Determine what is causing nonconforming work

Key Words

Nonconforming
Root Cause

Cross-references



ISO 17025:2005 Section 4.9
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.9.1 Procedures to Control Nonconforming Work

Policy:

The laboratory must have a policy and procedure to control any aspect of testing, or the results of this work, when they do not conform to the test methods or the agreed requirements of the customer.

Details:

The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports as necessary) are defined and taken into consideration when nonconforming work is identified.
  - The Operations Manager, department manager and/or Quality Manager are the authorities to be notified immediately. The General Manager shall be notified by the Operations Manager or Quality Manager.
- an evaluation of the significance of the nonconforming work is made
- correction is taken immediately, together with any decision about the acceptability of the nonconforming work
  - The Operations Manager and/or Quality Manager shall evaluate the significance of the non-conformance and determine if testing is to be suspended.
  - The Quality Manager shall determine if a corrective action is to be initiated in order to correct the non-conformance or if an internal audit is necessary.
- where necessary, the customer is notified and the work is recalled
  - The Quality Manager shall determine if any released results must be re-issued and either the Quality Manager or project manager shall notify the customer.
- the responsibility for authorizing the resumption of work is defined
  - The Quality Manager and/or Operations Manager shall decide when any suspended testing may be resumed.

Identification of nonconforming work or problems with the quality management system or with testing activities can occur at various locations within the quality management system and technical operations such as:

- customer complaints
- quality control
  - QC data repeatedly outside of warning or control limits or method prep blanks repeatedly showing contaminants above acceptable levels
- instrument calibration
  - Calibration does not meet acceptable criteria
- proficiency test sample analysis
- checking of consumable materials
  - The quality of products or services used by the lab is not acceptable
- staff observations or supervision
  - Departures from documented policies or procedures, including test methods and administrative procedures
- test report checking
  - Deviations from test methods or inappropriate test methods used
- management reviews
- internal or external audits

Any non-conformances originating from defective equipment and deviation from lab policies and processes must be reported on Nonconformance Report Form SP904/1 or a comparable form.

The Element System Procedure 904, Control of Nonconformances and Corrective and Preventive Action provides further guidance on procedures to address non-conformances in the lab. Additional details are found in Element SP 501, Calibration and Maintenance of Test Equipment, Section 5.7.

4.9.2 Root Cause Analysis

Policy:
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 are followed to identify the root cause(s) of the problem and to eliminate this (these) cause(s).

Details:
Element SP 904 outlines the recording of the root cause analysis for investigating nonconforming work.

Situations warranting corrective action investigation include:
- failure to comply with test method including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- presentation of uncertain knowledge as to compliance with test methods including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- failure or suspected failure in method performance as demonstrated by results provided by quality control samples
- lack of relevant evidence provided by quality audit, proficiency testing, or customer feedback
- lack of relevant evidence provided by data validation
- neglect to check the inherent property of the sample that compromises the testing

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed "Level 2" from title. Sections 4.9.1 and 4.9.2 added reference to Element SP 904, Control of Nonconformances and Corrective and Preventive Action and Element SP 501, Calibration and Maintenance of Test Equipment.
Revision 2.0
Removed reference to NE-ADM-014.

4.10 Improvements

The Ten Second Tutorial

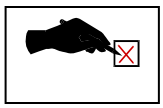
This section tells you that you must:

1. Review procedures for improvements
2. Continually implement improvements

Key Words

Continually
Effectiveness
Analysis of data

Cross-references



ISO 17025:2005 Section 4.10
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.10.1 Policies and Procedures

Policy:
The laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective actions, and management review.

Details:
The laboratory has implemented a continual improvement philosophy within the management system. Every employee in the laboratory is encouraged to suggest new ideas for improving services, processes, systems, productivity, and the working environment.

Opportunities for improvement of operations and processes are identified by managers on a continual basis from ongoing feedback on operations and through management reviews. Opportunities for improvement of services are identified by anyone within the organization including Sales and Marketing.

Inputs for improvement opportunities are obtained from the following sources:
- customer satisfaction surveys and any other customer feedback documented in the client feedback log
- market research and analysis
- employees, suppliers, and other interested parties
- internal and external audits of the management system
- records of service nonconformities

Opportunities for improvement may also be identified on a special project basis. The following are listed only as examples:
- improving usefulness of bench space
- reducing excessive handling and storage
- reducing test/calibration failures

Opportunities for improvement from daily feedback on operational performance (i.e., internal audits, customer feedback, test failures) are evaluated by the Operations Manager, department managers or Quality Manager. Typically, they are implemented through the corrective and preventive action system.

Opportunities for improvement from analysis of longer-term data and trends are evaluated and implemented through the management review process. They are prioritized with respect to their relevance for achieving quality objectives. When opportunities for improvement are no longer supported by the current policy and objectives, management will establish new quality objectives, and possibly change the policy. The process for this evaluation is described in Section 4.15. Longer-term improvement projects are initiated through the management review process, as well as the corrective and preventive action system.

Service improvement opportunities are evaluated by management. They are implemented through the Operations Manager and/or department managers of the laboratory who ensure that the improvements are validated as outlined in Section 5.4 of this manual and appropriate level of quality control is performed on an ongoing basis.

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections and replaced “Lab Director” with “Operations Manager”
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title.
Revision 2.0 – No changes

4.11 Corrective Action

The Ten Second Tutorial

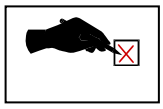
This section tells you that you must:

1. Identify problems
2. Determine why the problem occurred
3. Fix the cause of the problem
4. Verify that your changes worked

Key Words

CAR (Corrective Action Report)
Root Cause
Monitor
Audit
Nonconforming work

Cross-references



ISO 17025:2005 Section 4.11
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.11.1 General

Policy:
Element SP 904, Control of Nonconformances and Corrective and Preventive Action is utilized for implementing corrective action when nonconforming work or departures from policies and procedures in the quality management system or technical operations have been identified. The procedures require that appropriate authority be designated for the implementation of corrective actions. The procedure includes cause analysis, selection and implementation of corrective action, and monitoring of actions.

Details:
Problems with the quality management system or technical operations of the laboratory may be identified through a variety of activities, such as

- control of nonconforming work
- departures from documented policies and procedures, including test methods and administrative procedures
- deficiencies from proficiency testing sample results
- unacceptable quality of products, supplies or services from vendors
- internal or external audits
- management reviews
- feed-back from customers
- staff observations

Corrective action investigations are documented using the laboratory's HQMS 7-D program and required changes to operational procedures are implemented. The corrective action request, investigation, root cause and resolution are recorded on a corrective action report (CAR) form.

4.11.2 Cause Analysis

Policy:
Corrective action always begins with an investigation to determine root cause(s) of the problem. This will involve determining the extent or impact of the nonconformance and identifying potential corrective actions for resolution of the nonconformance.

Details:
Potential causes of the problem could include customer requirements, the samples, sample specifications, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration.

4.11.3 Selection and Implementation of Corrective Actions

Policy and Details:
After determining the cause(s) of the problem, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the problem and to prevent recurrence. It should be noted that any corrective actions taken to eliminate the cause(s) of nonconformities or other departures are to a degree appropriate to address the magnitude of the problem and commensurate with the risks encountered (Note – in plain language, this means determine whether the benefit outweighs the cost). Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations. Support documentation is attached to the corrective action report.

4.11.4 Monitoring of Corrective Action

Policy:
After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

Details:
Monitoring is assigned to an appropriate individual such as the originator of the CAR or the originator's manager. Changes resulting from corrective action are documented. Corrective actions are also reviewed during internal audits to verify the action(s) have been effective.

4.11.5 Additional Audits

Policy:
Where the identification of nonconformities or departures casts doubts on compliance of policies, procedures, regulations, international quality standards, the appropriate areas of activity are promptly audited in accordance with section 4.14.

Details:
Special audits follow the implementation of corrective actions to confirm their effectiveness. A special audit is only necessary when a serious issue or risk to the business is identified. Special audits are carried out by trained and qualified personnel who are whenever resources permit independent of the activity to be audited. See section 4.14 for more details.

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections
Revision 0.1 – No changes
Revision 1.0
Removed "Level 2" from title. Section 4.11.1 added Element SP 904, Control of Nonconformances and Corrective and Preventive Action.
Revision 2.0 – Removed reference to NE-ADM-014

4.12 Preventive Action

The Ten Second Tutorial

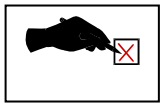
This section tells you that you must:

1. Identify potential problems
2. Determine why the problem could occur
3. Fix the cause of the potential problem
4. Verify that your changes worked

Key Words

PAR (Preventive Action Report)
Potential Nonconformity
Action Plan

Cross-references



ISO 17025:2005 Section 4.12
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.12.1 Preventive Action Identification

Policy:
Opportunities for needed improvement and potential sources of nonconformities, either technical or with the quality management, system shall be identified. If action is required, action plans are developed, implemented and monitored, to reduce the likelihood of occurrence of such nonconformities and to take advantage of the improvement opportunities.

Details:

Records of preventive action include the following information:

- details of potential nonconformities
- investigation
- preventive action
- follow-up verification

These records are maintained in HQMS or by using Preventive Action Form SP 904/4.

4.12.2 Preventive Action Plans

Policy:
The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective.

Details:
Preventive action may result from the review of operational procedures and analysis of data. Analysis of data includes trend analysis, analysis of proficiency testing results, and risk analysis.

Element SP 904, Control of Nonconformances and Corrective and Preventive Action and is utilized to implement opportunities for needed improvement and prevent potential sources of nonconformities.

Revision History

Revision 18
Added entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title. Section 4.12.2 added reference to Element SP 904, Control of Nonconformances and Corrective and Preventive Action
Revision 2.0
Removed reference to NE-ADM-014

4.13 Control of Records

The Ten Second Tutorial

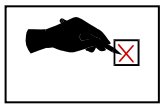
This section tells you that you must:

1. Identify the records to be kept
2. Keep identified records in a useful state
3. Destroy records when they are no longer needed

Key Words

Collection
Indexing
Access
Storage
Maintenance
Disposition
Legible
Traceable
Retrievable
Secure

Cross-references



ISO 17025:2005 Section 4.13
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.13.1 General

4.13.1.1 Procedures

Policy:
Element SP 102, Control of Records is used to identify, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective and preventive action records. Technical records include benchsheets, instrument printouts, SOPs, LIMS, equipment records, prep books, and instrument software.

Details:
Records are available to demonstrate conformance to requirements and effective operation of the Quality Management System. Quality records from suppliers are also controlled.

All records, including test reports, are safely stored and held in secured areas, and in confidence to the customer. Records are maintained in the designated archival area for seven years. If a customer's requirements specify a retention period longer than the lab's policy, the lab must receive written notification from the client.

The master inventory list of records is organized with the following information:
- Record Name
- Time Period
- Storage ID number
- Destroy After date

The dating format for records is DD/MM/YY or DD/MM/YYYY. This list is maintained by the Quality Manager and/or Quality Officer.

4.13.1.2 Record Integrity

Policy:
All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Details:
Records shall be stored in steel file cabinets or fully enclosed containers. Records placed in containers shall be stored off the floor. Records may be in the form of any type of media, such as hard copy or electronic media.

4.13.1.3 Record Security

Policy:
All records are held secure and in confidence. The storage area shall minimize unauthorized access.

Details:
Access to records is secured through locked rooms and/or restricted access to the laboratory.

4.13.1.4 Record Backup

Policy:

The Element procedure SP 102 is followed to protect and backup data/records held on computers at all times and to prevent unauthorized access to or amendment of data/records on computers.

Details:
Data records such as calculation spreadsheets are password protected and/or opened as read only files. Quality documentation is also stored with restricted access.

Backups by the IT department ensure integrity and availability of data / information in the event of a system / power failure.

4.13.2 Technical Records

4.13.2.1 Record Information

Policy:
Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records, personnel records and a copy of each test report issued are retained for seven years.

The records for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the test uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for sampling, performing of each test and checking of results.

Details:
Technical records are accumulations of data (see 5.4.7) and information that result from carrying out tests and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, note books, instrument printouts, magnetic media, check sheets, work notes, control graphs, test reports, calibration certificates, customer's notes, papers and feedback, and test reports to customers.

The records for each test contain sufficient information to permit its repetition. Records include:
- date of sampling
- sample receipt
- sample handling and storage
- identification of personnel
- analyst proficiency
- equipment identification and performance
- calibration records
- media performance, where appropriate
- test organism batch # or lot #, where appropriate
- results
- reports (mailed, faxed)
- review

Note – the above records may be stored in separate locations.

4.13.2.2 Recording

Policy:
Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific job at the time they are made.

Details:
Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected, and/or after calculations are made. Handwritten records must not be recorded on unauthorized forms or scraps of paper for later transfer.

4.13.2.3 Corrections to Records
Policy:
Changes to test data are made so as not to obscure or delete the previous data entry.

Details:
Mistakes are crossed out with a single line and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records are signed or initialed and dated by the person making the correction. An error code is included to indicate the cause for the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data. The original data is not deleted from the analytical run file.

Revision History

Revision 18
Reformatted entire section
Revision 19
Sections 4.13.1.2 & 4.13.2.1- Changed record retention from 10 years after January 1, 2012 to all records retained for 7 years
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections
Revision 0.1 – Added “Handwritten records must not be recorded on unauthorized forms or scraps of paper for later transfer” to Details of Section 4.13.2.2
Revision 1.0
Removed “Level 2” from title. Section 4.13.1 and 4.13.1.4 added reference to Element SP 101.
Revision 2.0
Corrected Element SP reference from SP 101 Document Control to SP 102 Control of Records.

4.14 Internal Audits

The Ten Second Tutorial

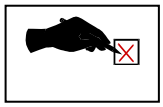
This section tells you that:

1. Trained internal auditors examine your internal operations for quality
2. Auditors report the results to those in charge
3. You must correct any areas that need fixing

Key Words

Schedule
Independent
Nonconformity
CAR

Cross-references



ISO 17025:2005 Section 4.14
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.14.1 Internal Audit Program

Policy:
The internal audit program involves periodic audits conducted according to a predetermined schedule for each year. This program is defined on an annual basis and conducted as outlined in this section with further details found in Element SP 901 Audits. Elements of this Quality Manual will be audited and all relevant laboratory records are available to personnel conducting the audit. These audits are performed to verify operations continue to comply with the requirements of this Quality Manual and are effective.

Details:
The Quality Manual, test procedures, and laboratory results are verified for compliance. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are carried out by trained and qualified personnel who are wherever resources permit independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.11.5). Audits are performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit.

Generally, the types of audits include:
- quality management system
- processes and procedures
- products, services, and reports
- record keeping and documentation of quality critical activities

4.14.2 Corrective Action

Policy:
When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken and customers are notified if investigations show that laboratory results may have been affected.

Details:
Nonconformities that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformities that require a more involved resolution are recorded on a CAR and resolved as described in section 4.11.

Corrective actions and customer modifications must be kept on record for each audit deviation that casts doubt as described in this section.

4.14.3 Records and Management

Policy:
Records are made of the activity being audited, the audit findings, and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.

Details:
A report is prepared by the auditors and distributed to those audited and/or the area manager/supervisor within an appropriate and agreed timeline. The audit report may include the following sections, as appropriate:

- audit objective and scope
- area or section audited
- personnel involved – auditors and auditees
- date of audit
- reference documents
- observations including nonconformities and commendations
- opening and closing meetings
- recommendations
- audit report distribution

The appropriate manager is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are kept in the laboratory.

4.14.4 Follow-up Audits
Policy:
Follow-up audits are performed as necessary to verify and record the implementation and effectiveness of the corrective action taken.

Details:
The follow-up audit is performed at a mutually acceptable time between the area implementing corrective action and the auditor. This time is determined when the CAR is issued.

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” in title. Section 4.14.1 added reference to Element SP 901 and added “record keeping and documentation of quality critical activities” to examples of types of audits.
Revision 2.0
Removed reference to NE-ADM-018.

4.15 Management Reviews

The Ten Second Tutorial

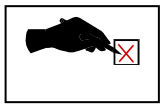
This section tells you that management must:

1. Periodically review technical competence and customer satisfaction
2. Keep records of reviews
3. Ensure follow-up is executed
4. Measure progress

Key Words

Supervisor Reports
Audit Reports
CAR / PAR
Proficiency Results
Customer Satisfaction Survey
Resources

Cross-references



ISO 17025:2005 Section 4.15
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

4.15.1 Review of Quality Management System and Testing

Policy:
Top management periodically (at least annually) and in accordance with a predetermined schedule and Element SP 901 Audits, conducts a review of the laboratory's quality management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

Details:
The review takes account of:

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

A minimum period for conducting a management review is once a year. Results of the review feed into the laboratory planning system and include goals, objectives and action plans for the coming year.

A management review can be supplemented by consideration of related subjects at regular management meetings.

4.15.2 Findings, Actions, and Records

Policy and Details:
Findings from management reviews and the actions that arise are recorded in the minutes of the meeting and an action list is created. Management will ensure that the actions are discharged within an appropriate and agreed upon timeline.

The action list is reviewed at the next management review meeting to ensure all items have been addressed and completed.

4.15.3 Data Integrity Investigations

Policy and Details:
All investigations resulting from data integrity issues shall be conducted in a confidential manner until they are completed. These investigations shall be documented, as well as any notifications made to clients receiving any affected data.

Revision History

Revision 18
Added entire section
Revision 19: No changes
Revision 0: Replaces Revision 19 to update the company name from Sherry Laboratories to Element-EFW throughout all sections
Revision 0.1: Renumbered Data Integrity Investigations as 4.15.3
Revision 1.0:
Removed “Level 2” in title. Section 4.15.1 added reference to Element SP 901.
Revision 2.0
Removed reference to NE-ADM-018.

5.1 General

The Ten Second Tutorial

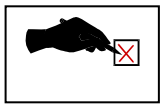
This section informs you that:

1. Many factors contribute to the correctness and reliability of tests and/or calibrations
2. The laboratory must account for these factors

Key Words

Correctness
Reliability
Uncertainty

Cross-references



ISO 17025:2005 Section 5.1
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.1.1 Correctness and Reliability

Policy and Details:

Correctness and reliability of the tests performed have many contributing factors including:

- human factors (see section 5.2)
- accommodation and environmental conditions (see section 5.3)
- test and calibration methods and method validation (see section 5.4)
- equipment (see section 5.5)
- measurement traceability (see section 5.6)
- sampling (see section 5.7)
- handling of test items (see section 5.8)

5.1.2 Measurement Uncertainty

Policy:

The laboratory shall take account of these factors in determining measurement uncertainty.

Details:

The extent to which the factors contribute to total measurement uncertainty differs between (types of) tests and between (types of) calibrations. The laboratory will, upon request, estimate measurement uncertainty using the standard deviation of at least 50 LCS data points. For in-house calibrations, when requested, the lab shall estimate the uncertainty, taking into account all contributing factors.

See section 5.4.6 for more details.

Revision History

Revision 18
Added entire section
Revision 19 – No changes
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title.
Revision 2.0 – No changes

5.2 Personnel

The Ten Second Tutorial

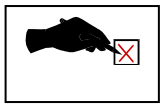
This section tells you that management:

1. Analyzes training needs
2. Provides training to employees for them to do their jobs
3. Qualifies people performing specific tasks

Key Words

Competence
Qualification
Authorize
Training Needs
Job Description
Registry of Skills

Cross-references



ISO 17025:2005 Section 5.
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.2.1 Competence and Qualification

Policy:

Management ensures the competency of all specific equipment operators, those performing tests, those evaluating results and signing test reports. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in test reports also have:

- relevant knowledge of the technology used for the samples tested
- knowledge of the method used for the samples tested
- an understanding of the significance of deviations or non-conformances associated with the samples tested

Details:

Management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. These are documented in the job descriptions.

Initial and continued competence is monitored and documented and where this is not achieved, the need to retrain personnel is considered. Where a method or technique is not in regular use, verification of personnel performance before they undertake tests, may be necessary.

5.2.2 Training Policies and Procedures

Policy:

Management will formulate the goals with respect to the education and the skills of the laboratory personnel. The training program is relevant to the present and anticipated tasks of the laboratory. Element System Procedure SP 301 Training is utilized to provide the necessary training protocol for personnel.

Details:

The skills and knowledge are defined in the job description for each job function as described in section 5.2.4. Management compares the job description to the skills and knowledge of the new incumbent to determine the training needs.

Training in the laboratory must include all methods or parts of methods and techniques that personnel are asked to perform. Minimally, the analyst must demonstrate competency through observation by the trainer and verification using replicate and/or unknown samples. For technicians who perform only parts of the method, confirmation of competency may be verified by observation only. Re-qualification of all personnel must be performed annually on all methods or techniques pertinent to their job description.

In some cases, such as field sampling, it may be appropriate to define competence related to a particular technique or instrument rather then methods. If so, it will be necessary to define for each method, the necessary technique-based competence required together with any additional requirements. Laboratory SOPs are used to train field personnel and trainer observation is also required.

5.2.3 Employees

Policy:
Competent permanent or contractual employees may be employed in the laboratory. The technical manager ensures that contractual, additional technical employees, and key support personnel are supervised and work in accordance to the policies and procedures of this Quality Manual.

Details:
Testing must be either performed or supervised by an experienced employee. Personnel must have relevant practical work experience and complete training requirements before being allowed to perform accredited and non-accredited work.

5.2.4 Job Descriptions

Policy:
Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained centrally in the Human Resources department.

Details:
Minimum contents of job descriptions include:
- the duty of performing tests
- the act of planning tests and evaluation of results
- the responsibility of developing and validating new methods as / when requested
- expertise and experience
- qualifications and training programs
- managerial duties

Job descriptions are dated and signed to demonstrate that each incumbent has read it and is in agreement. They are maintained current.

5.2.5 Authorized Personnel

Policy:
Management authorizes specific personnel to perform particular types of sampling, testing, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. Records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel and contracted personnel are maintained. This information is readily available and includes the date on which authorization and/or competence was confirmed and the criteria on which the authorization is based and the confirming authority.

Details:
The purpose of these records is to provide evidence that personnel have been adequately trained and their competence to perform particular tests has been assessed. In some cases it may be pertinent to state any particular limitations to competence. The records are maintained in the employee training record files and may include:
- academic and professional qualifications
- external and internal courses attended
- relevant on-the-job training and retraining as necessary (i.e., demonstration of competence)
- skills and experience (i.e., resume)
- relevant authorizations

Records are attached to the employee files in the QA software, HQMS, or a comparable system and are maintained by the quality staff or operations manager.

Revision History

Revision 18
Added entire section
Revision 19 – No changes
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title. Section 5.2.5 Details added “may” include.
Revision 2.0
Removed reference to NE-ADM-013.

5.3 Accommodation and Environmental Conditions

The Ten Second Tutorial

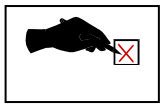
This section tells you:

1. That laboratory facilities are suitable for attaining correct performance of tests and calibrations
2. Critical environmental conditions are monitored, controlled and recorded
3. Incompatible activities are separated
4. Access to laboratories is controlled
5. Good housekeeping is practiced

Key Words

Incompatible activities
Prevent cross-contamination
Controlled access

Cross-references



ISO 17025:2005 Section 5.3
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.3.1 Facility

Policy:
Laboratory facilities are appropriate to attain correct performance of tests. This may include, but not limited to, energy sources, lighting, heating, ventilation and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when sampling and testing are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented in the test method SOP.

Details:
This section deals with the test areas in the laboratory and premises for support such as sample receipt and storage. Central laboratory supplies and services, such as water purification systems, air supply, heating/air conditioning, vacuum source, and sample storage, are appropriate to facilitate proper performance of tests.

5.3.2 Monitoring

Policy:
Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Due attention is paid, for example, to biological sterility, dust, air quality, humidity, electrical supply, temperature, and vibration levels, as appropriate to the technical activities concerned. Tests are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

Details:
Laboratories are ventilated to reduce the levels of contamination, lower humidity, and control temperature. Laboratories' test areas are air-conditioned. The relative humidity and/or temperature in appropriate test areas are monitored. Arial microorganisms are controlled by air systems with filters where necessary. Verification is done using air settling plates and surface swabs as needed.

Bench tops and floors are made of impervious, smooth and easily cleaned materials. Critical work surfaces are monitored for pathogens where pertinent to the scope of the laboratory facility.

5.3.3 Separation of Incompatible Activities

Policy:
Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

Details:
Reference materials and certified reference materials must be kept separated from samples (log-in and storage). Sample log-in and storage must include proper sanitation to exclude the possibility of cross-contamination. Segregation of activities is achieved through time and space allocations.

An example of space segregation would be for a trace analysis. Physical separation of the trace analysis from high-level analysis or samples known to have high concentrations of the target analyte is achieved through the use of separate rooms. An example of time segregation would be the coordination of activities at different times. It may be appropriate to perform work on "cleaner" samples first before starting "dirtier" type samples.

Samples in transit by Element field personnel are separated by the use of separate coolers for drinking water samples versus wastewater samples to prevent contamination.

5.3.4 Controlled Access

Policy:
Access to and use of areas affecting quality of the tests is defined and controlled.

Details:
Access to the laboratory is restricted to authorized personnel. The authorized personnel are made aware of the following items:

- the intended use of the area
- the restrictions imposed on working within such areas
- the reasons for imposing the restrictions

Additional details are in Element SP 503 Access to and Control of Working and Storage Areas.

5.3.5 Good Housekeeping

Policy:
Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary. The lab staff are responsible for maintaining clean and safe work conditions within their respective work areas.

Details:
Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the corporate health and safety plan to maintain a safe, clean, and well organized work environment. Housekeeping is also addressed in routine internal inspections.

Reference:
Element SP 502, Housekeeping, Safety, and Environmental Control
Element SP 503, Access to and Control of Working Areas

Revision History
Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Revision 0.1
Added additional information in details for Good Housekeeping
Revision 1.0
Removed "Level 2" from title. Added Element SP 502 and SP 503 as references for this section.
Revision 2.0 – No changes.

1

5.4 Tests and Calibration Methods and Method Validation

The Ten Second Tutorial

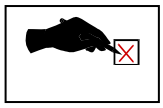
This section tells you:

1. Preference is given to the use of a standard method when selecting procedures
2. All methods must be validated before use
3. Measurement uncertainty is estimated

Key Words

Standard Methods
Laboratory-Developed Methods
Non-standardized Methods
Validation
Uncertainty of Measurement
Data Checks

Cross-references



ISO 17025:2005 Section 5.4
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

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5.4.1 General

Policy:

Methods and procedures used for all tests are appropriate as per:

- sampling, handling, transport, storage, and preparation of items to be tested
- an estimation of the measurement of uncertainty (when requested) as well as statistical techniques for analysis of test data where appropriate

Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing are available. All instructions, standards, manuals and reference data relevant to the work of the laboratory are maintained current and readily available to personnel. Deviation from test methods must be documented, technically justified, authorized, and accepted by the customer.

Details:

There are SOPs for sampling, sample handling, transport, storage, preparation of test items, QA/QC procedures (media QC, incubation times and temperatures, equipment calibration and maintenance), and standards for approving / rejecting results. These may be combined with or separate from the method. The content of a test method includes:

- method summary
- scope and application
- method references
- interferences
- limit of detection/limit of quantitation
- holding times, preservation, containers and storage
- materials and equipment required
- physical environmental conditions required (incubation times and temperatures, pH requirements)
- description of procedures
- method of recording observations and results
- safety measures
- method for data analysis and calculations
- quality control requirements

International, national, or regional standards or other recognized specifications that contain sufficient and concise information on how to perform the tests are not necessarily supplemented or rewritten as an internal procedure when they are written in a way that can be used as published by laboratory staff. Consideration may need to be given to providing additional documentation for optional steps in the method or where the method does not provide sufficient detail to perform the method.

5.4.2 Selection of Methods

Policy:

Test methods, including methods for sampling, meet the needs of the customer and are appropriate for the tests it undertakes. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

Details:

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Methods that have been published either in international, national, or regional standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer are selected when the customer does not specify the method to be used. These methods may be adopted from the AOAC, FDA, USDA FSIS & AMS, APHA Compendium of Methods for the Microbiological Examination of Foods, ISO, National Food Processors, American Association of Cereal Chemists, Environmental Protection Agency, Standard Methods for the Examination of Water and Wastewater, and ASTM.

At the time of method SOP review, the referenced method is verified as the latest edition.

The ability of the laboratory to achieve satisfactory performance against documented performance characteristics is verified before samples are analyzed. Refer to administrative SOP# NE-ADM-027, Change Request, regarding validation of changes in methods.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer is informed as to the method chosen. The laboratory confirms that it can properly operate standardized methods before introducing the tests or calibrations. If the standardized method changes, the confirmation is repeated.

The customer is informed when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.3 Laboratory-Developed Methods

Policy:

Introduction of test methods developed internally is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and ensures effective communication amongst all personnel involved.

Details:

Methods developed in-house are validated and authorized before use. Where available, Certified Reference Materials (CRMs) are used to determine any systemic bias, or results are compared with other techniques, preferably based on different principles of analysis. Determination of uncertainty may be part of this validation process as applicable and when essential for ongoing quality control.

5.4.4 Non-Standard Methods

Policy:

Utilization of non-standard methods is subject to agreement with the customer and includes a clear specification of the customer's requirements and the purpose of the test. The developed method is validated appropriately before use.

Details:

Discussion and agreement for the use of non-standard methods is recorded as part of contract review procedures (see section 4.4).

All non-standard and new tests are validated for their intended purpose. Qualitative test methods must be validated to demonstrate estimated sensitivity and specificity, relative accuracy to official

1
methods (if appropriate), positive and negative deviation, limit of detection, matrix effect, repeatability, and reproducibility. Refer to administrative SOP# NE-ADM-027, Change Request.

Quantitative test methods are validated to demonstrate specificity, sensitivity, relative accuracy, positive and negative deviation, repeatability, reproducibility, and limit of determination.

For new methods where procedures are developing rapidly, especially for emergency situations, it may be necessary to circumvent normal validation procedures. Minimally, this must be a demonstrated recovery in replicate.

New test methods are documented prior to providing test results to customers and contain at least the following information:

- appropriate identification
- scope
- description of the type of item to be tested or calibrated
- parameters or quantities 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
  - ensuring checks are made before the work is started
  - checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use
  - listing method of recording the observations and results
  - indicating any safety measures to be observed
- criteria and/or requirements for approval/rejection (quality control plan)
- data to be recorded and method of analysis and calculations
- uncertainty or procedure for estimating uncertainty if required

5.4.5 Validation of Methods

5.4.5.1 Performance Characteristics

Policy:

Validation of a new or non-standard method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the test results.

Details:

The performance characteristics of a validation plan includes, as applicable:

- selectivity and specificity
- range
- linearity
- sensitivity
- limit of detection
- limit of quantitation/reporting limit
- accuracy
- precision
- repeatability
- reproducibility
- recovery

1

- confirmation techniques
- criteria for the number of samples tested to validate method as per defined scope of method
- action levels where defined by regulation
- quality control incorporating statistics as applicable
- interpretation of population results as applicable

Performance characteristics that are selected take into account the intended use of the method, whether for screening, confirmatory analysis, or quantitation.

The design, verification of the method and documentation procedures for validation are planned and conducted by qualified personnel, equipped with adequate resources. The laboratory utilizes a validation plan form within administrative SOP #NE-ADM-027, Change Request, to outline the requirements for method/equipment validation.

This section lists a few acceptable validation procedures. The choice of the procedure depends on the extent of the deviation from the published method.

Validation of methodology is a value judgment in which the performance parameters of the method are compared with the requirements for the test data. A prerequisite for a valid method is that data produced by the method must attain a state of statistical control. Such a state is obtained when the mean value of a large number of individual values tends to approach a limiting value called the limiting mean.

Methods may be validated by one or more alternative procedures. Some of these procedures are described below. Apparent differences can be analyzed statistically to confirm their significance. In all cases, the reasons for choosing one or more alternatives must be documented.

- analysis of standard reference materials (SRM) that are identical or almost identical to the test samples
- in the absence of suitable SRMs, analysis of reference materials that are similar in all respect to the test samples; the use and validity of this reference material must be documented
- using an alternative method to measure the same parameter provides a very high level of confidence if results are confirmed
- recovery studies by the addition of a known concentration of the parameter of interest to some of the replicates being measured

The parameters to be determined include:

- the scope of the method and any known interference
- detection limit
- the range of concentration where the method is valid
- precision and bias
- intra-laboratory variations
- inter-laboratory variations

Judgment is required to determine if some or all of the above is required. Requirements will depend largely on the extent of deviation from the original method.

Developments in methodology and techniques require methods to be changed from time to time. The difference in performance between revised and obsolete methods is established so that it is possible to compare old and new data.

1
Where a change in method involves only minor adjustments, such as sample size, or different reagents, the amended method is validated and the changes brought to the attention of the accreditation body at the next accreditation audit. Where the proposed change involves technology or methodology, the laboratory seeks the approval of the accreditation body.

Records are kept on all validation activities. The records include any of the performance characteristics chosen, reference procedures or guidance documents followed to validate the method or custom validation procedure, and a final confirmation that the method validation results are acceptable for continued use of the method. An example statement would be “This memo serves as record that the validation of the XYZ Test Method has been approved for use by [name and title of approver]”.

5.4.5.2 Fit for Use
Policy:
The laboratory validates non-standardized methods, laboratory-designed/developed methods, standardized methods used outside their intended range, and amplifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs in the given application or field of application (may include procedures for sampling, handling, and transportation). The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

Details and Procedure:
Validation records are kept as in section 5.4.5.1. Included in these records is the validation procedure. The procedure used for the validation is likely to vary between different methods. Therefore, the procedures included in the laboratory records are not as detailed as a typical SOP, but are sufficient enough to re-create how the method was validated.

The techniques used for the determination of the performance of a method, are one of, or a combination of, the following:
- calibration using reference standards or reference materials
- comparison of results achieved with other methods
- inter-laboratory comparisons
- systematic assessment of the factors influencing the result
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When changes are made in the validated non-standard method, the influence of such changes carried out is documented and if appropriate a new validation is performed.

5.4.5.3 Customer’s Needs
Policy:
The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use is relevant to the customer’s needs.

Details:

1
Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

As method development proceeds, regular review is required to verify that the needs of the customer are still being fulfilled. Changing requirements requiring modifications to the development plan are approved and authorized.

Validation is always a balance between costs, risks, and technical possibilities.

5.4.6 Uncertainty of Measurement
5.4.6.1 Calibration
Policy:
Physical, chemical, and biological standards are calibrated or characterized by qualified subcontractors.

Details and Procedures:
Repeatability and reproducibility data are components of measurement uncertainty and are determined as a first step towards producing estimates of this parameter. The uncertainty of measurement is available on the certificate of analysis or calibration certificate from a subcontractor.

5.4.6.2 Testing
Policy:
For test methods that do not have a published uncertainty, the laboratory will, upon request, estimate an uncertainty using the standard deviation of 50 or more lab check sample data points. For in-house calibrations or methods without a lab check sample, the laboratory shall upon request estimate the uncertainty taking into account all factors contributing to the uncertainty.

Details:
The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:
- requirement of the test method
- requirement by the customer
- if there are narrow limits on which decisions on conformity to a specification are based

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the reporting instructions (see section 5.10).

5.4.6.3 Uncertainty Components
Policy:
When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

Details:
Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested or calibrated and the operator.

1

The predicted long-term behavior of the tested and/or calibrated item is normally not taken into account when estimating the measurement uncertainty.

5.4.7 Control of Data

5.4.7.1 Calculations and Data Transfers

Policy:
Calculations and data transfers are subject to appropriate checks in a systematic manner.

Details:
Test data are validated through the following arrangements by the analyst or a second analyst experienced with the testing procedure:

- checks to determine accuracy of calculations, conversions, and data transfers
- checks for transcription errors, omissions, and mistakes
- checks to determine consistency with normal or expected values

For those analyses where manual data reduction is required, it is performed according to the instructions provided in the test method or lab SOP. Where lab created spreadsheets are used to calculate results, the spreadsheets are verified annually. Refer to Element SP 401 Control of Application Software.

5.4.7.2 Computers and Automated Equipment

Policy:
When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

- computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use
- procedures are established and implemented for protecting the integrity of data; such procedures include, but are not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing (see section 4.13.1.4)
- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data
- data is securely maintained by preventing unauthorized access to, and unauthorized amendment of, computer records

Details and Procedures:
Data generated using computer software programs that are interfaced directly to instruments generally incorporates all dilutions and calculations, thereby eliminating the need for manual data reduction.

Commercially developed software in general use within its designed application range may be considered sufficiently validated. Laboratory software configuration / modifications are validated as outlined in Element SP 401.

Electronic records, electronic signatures, and handwritten signatures executed to electronic records must be equivalent to proper records and handwritten signatures to paper.

Policy:

1

The Information Technology staff is responsible to protect and backup data/records held on computers at all times and to prevent unauthorized access to or amendment of data/records on computers.

Details:

Data is password protected. Backups of the hard drives and the data files ensure integrity and availability of data / information in the event of a system / power failure.

Revision History

Revision 18
Reformatted entire section
Revision 19
Section 5.4.5.1 – Added reference to NE-ADM-027, Change Request
Section 5.4.7.1 – Added annual verification of spreadsheets
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Sections 5.4.2 & 5.4.4 – Added reference to NE-ADM-001, Validation of Computer Spreadsheets and In-house Developed Calculation Software
Revision 0.1
Section5.4.2 – Added “At the time of method SOP review, the referenced method is verified as the latest edition”.
Revision 1.0
Removed “Level 2” from title. Section 5.4.7 added reference to Element SP 401.
Revision 2.0
Removed reference to NE-ADM-001.

5.5 Equipment

The Ten Second Tutorial

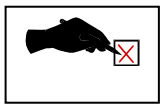
This section tells you to:

1. Identify information needs for accept / reject decisions
2. Install equipment capable of providing that information
3. Use the equipment in the proper environment
4. Periodically check the equipment calibration

Key Words

Required Equipment and Accuracy
Authorized Personnel
Unique Identification
Inventory
Maintenance
Procedures
Out of Service
Calibration Status
Re-verification
Checks
Correction Factors
Safeguards against Adjustment

Cross-references



ISO 17025:2005 Section 5.5
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.5.1 Required Equipment

Policy:
The laboratory is furnished with all items for sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). When equipment is used outside the laboratory's permanent control, it ensures that the requirements of this Quality Manual are met.

Details:
Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method.

5.5.2 Required Accuracy

Policy:
Equipment and software used for testing, calibration and sampling are capable of achieving the accuracy required and comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant affect on the results. When received, equipment, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with section 5.6 before use.

Details:
The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement. Validation of new equipment is planned and documented through the use of the Validation Plan form within Administrative SOP #NE-ADM-027, Change Request.

5.5.3 Authorized Personnel

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

Details:
Access to laboratory equipment is controlled to ensure that only authorized personnel use equipment. Analysts must complete training requirements before operation of lab equipment.

5.5.4 Unique Identification

Policy:
Each item of equipment used for testing and calibration is uniquely identified as appropriate.

Details:
Measuring and testing equipment is uniquely identified through asset identification. This list is maintained at the location and is reviewed by the Quality Manager. Measuring and testing equipment includes any instrument that could affect the quality of test results. Components that can be interchanged between various instruments are tracked in equipment logbooks but may not be assigned individual asset identifications.

5.5.5 Inventory and Maintenance Records

Policy:

Records are maintained for each item of equipment significant to the tests performed. The records include the following:

- identity of the item of equipment (and its software)
- manufacturer's name, type identification, and serial number and/or other unique identification
- checks that equipment complies with the specification (see section 5.5.2)
- current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)
- damage, malfunction, modification or repair to the equipment

Details:

A database is used to capture the above inventory information. The above information related to service and maintenance is kept in individual equipment files and/or binders. Other information kept in these files and/or binders may include:

- date received and date placed in service
- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification
- performance history, where appropriate (e.g., response time, drift, noise level)

5.5.6 Equipment Procedures

Policy:

Element SP 501 Calibration and Maintenance of Test Equipment, and Element-EFW SOP# NE-ADM-008, Equipment Calibration and Verification are utilized as established plans for safe handling, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and in order to prevent contamination or deterioration.

Note – additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests and/or calibrations (currently not applicable at Element-EFW).

Details and Procedures:

The manuals for each piece of measuring equipment are located in the appropriate room where the equipment is located or maintained on a public drive. Procedures may be referenced in the appropriate test method SOP. These procedures detail any information for safe handling, transport, storage, use, and maintenance of measuring equipment or reference where that information may be found.

5.5.7 Out of Service Equipment

Policy:

Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly.

Details:
Routine testing work is completely discontinued on equipment that even shows minor nonconformances. Not only do we do this for ethical reasons in support of our customers, but minor nonconformances are often indicative of major breakdowns in expensive equipment. These breakdowns need to be avoided wherever possible.

Out of service equipment is clearly marked as outlined in section 5.5.8.

The laboratory examines the effect of the defect or departure from specified limits on previous tests and institutes the "Control of Nonconforming Work" procedure as outlined in section 4.9.

5.5.8 Calibration Status

Policy:
Equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate. Instruments that are calibrated before use (i.e. Ion Chromatographs, Gas Chromatographs, etc) are not marked. All equipment shall have calibration points to encompass the entire range of use or are calibrated to the manufacturer's specifications as applicable.

Details:
Calibration labels have a write-on surface and a pressure sensitive adhesive. The areas that are filled out include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, and the equipment's serial number or other specific identification. Correction factors are listed for thermometers. Calibration certificates from external sources are reviewed by the Quality Manager or designee and documented on the Calibration Acceptance Checklist-065 Form.

Measuring equipment that has failed calibration or is deemed out of service is labeled with one of the following labels:

CALIBRATION VOID **DO NOT USE** **Effective Date:**

OUT OF SERVICE **DO NOT USE** **Effective Date:**

A piece of equipment that is not calibrated or checked or a guage that is not calibrated on a piece of equipment is labeled with the following label:

FOR REFERENCE ONLY

5.5.9 Return to Service

Policy:
When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

Details and Procedures:

The procedures used to check and ensure that the function and calibration status of the equipment are satisfactory before the equipment is returned to service are outlined in the manufacturer's equipment manual. Any additional quality control checks are outlined in the Validation Plan Form, within SOP# NE-FOR-027, Change Request.

5.5.10 Periodic Checks

Policy:
When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedures.

Details and Procedures:
As stated in section 5.5.6, the procedures for each piece of measuring equipment are located in the appropriate room where the equipment is located and/or maintained by the QA staff. Equipment maintenance manuals, test method SOP's and/or SOP# NE-ADM-008, Equipment Calibration and Verification, outline a general maintenance plan for equipment and include various checks to verify calibration. Internal quality control checks are specified in individual test method procedures that readily available to the staff, thereby providing procedures for intermediate checks.

5.5.11 Correction Factors

Policy
Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software or on lab forms).

Details and Procedures:
The updating of correction factors, including all copies, is assured by following SOP# NE-ADM-008, Equipment Calibration and Verification, and the Document Control Master List of Forms. It is the responsibility of the Quality Manager or designee to ensure that all copies are updated.

5.5.12 Safeguards against Adjustments

Policy:
Test and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate test and/or calibration results/status.

Details:
Safeguards against adjustment for laboratory equipment include:
- detailed SOPs and manufacturer's manuals on the operation of the equipment
- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel

Safeguards against adjustment for software include:
- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel

5.5.13 Support Equipment

Policy:
Support equipment shall be maintained in proper working order. Maintenance and repair records shall be kept. All support equipment shall be calibrated or verified according to a schedule (annual or as specified).

Details:

Maintenance manuals are available for each piece of support equipment such as balances, ovens, refrigerators, autoclaves, waterbaths, digestion blocks. Each day of use, the operating temperature of each temperature controlled unit is checked and documented. Thermometers are calibrated annually within the lab. The NIST traceable reference thermometers are calibrated every 3-5 years unless stricter standards apply. Reference weights are calibrated annually for ISO accredited facilities and every 5 years for all other facilities. Mechanical pipettes are verified for calibration quarterly.

Administrative SOP# NE-ADM-008, Equipment Calibration and Verification, describes the calibration and verification of calibration activities and frequency for support equipment.

Any item not meeting the calibration/verification specifications shall be removed from service and labeled as out of service until repaired. Any effect of the calibration non-conformance must be evaluated.

Revision History

Revision 18
Added entire section
Revision 19
Section 5.5.4 – Added statement that IT maintains equipment identification system
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Section 5.5.13 – Removed “NELAC”
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title. Section 5. Section 5.5.4 Details changed “maintained by IT” to “maintained at the location and is reviewed by the Quality Manager.” Section 5.56 added reference to Element SP 501, Calibration and Maintenance of Test Equipment. Section 5.5.8 added ” Instruments that are calibrated before use (i.e. Ion Chromatographs, Gas Chromatographs, etc) are not marked.” Section 5.5.13 added “unless stricter standards apply” to NIST reference thermometer 5 year calibration schedule.
Revision 2.0
Section 5.5.8 Policy – added “All equipment shall have calibration points to encompass the entire range of use or are calibrated to the manufacturer’s specifications as applicable. Section 5.5.8 Details – added “Calibration certificates from external sources are reviewed by the Quality Manager or designee and documented on the Calibration Acceptance Checklist-065 Form. Sectoin 5.5.11 Details and Procedures – replaced Quality Administrator with designee.

5.6 Measurement Traceability

The Ten Second Tutorial

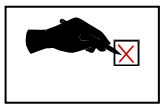
This section tells you:

1. Measurements are traceable to SI units (when applicable)
2. Reference Standards and Reference Materials are used

Key Words

System International
Reference Standard
Reference Material
Traceability

Cross-references



ISO 17025:2005 Section 5.6
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.6.1 General

Policy:

Test and/or calibration equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test or calibration verification are calibrated before being put into service. All measurement and test equipment having an effect on the accuracy or validity of tests is calibrated and/or verified before being put into service. As mentioned in section 5.5, the SOP# NE-ADM-008, Equipment Calibration and Verification, the maintenance manuals and the test method SOP's outline an established program for the maintenance of equipment and includes calibration. Additional details are found in Element SP 501 Calibration and Maintenance of Test Equipment.

Details:

The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform tests and calibrations
- traceability of measurement data

All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained for each standard. These records include, as applicable:

- date of receipt
- expiration date
- supplier, grade, lot #
- dates of preparation or verification
- measurement of weights, volumes, time intervals, temperatures, and pressures and related calculations used in the preparation
- relevant processes (e.g., pH adjustment, sterilization)
- verification results if required
- identification of personnel involved

Reagents prepared in the laboratory are labelled to identify substance, strength, any special precautions or hazards, restrictions of use, storage conditions, date of preparation and expiration. The person responsible for the preparation of the reagent is identified either from the label or from records. The prep of all reagents is recorded to identify the constituents, date of prep, source, lot #, amount used, final volume, diluents, and preparer's initials.

Purchased standards, reagents and stock cultures are logged into the HQMS database or comparable system for traceability and record keeping.

Test methods and quality related procedures are documented where appropriate by the use of standard operating procedures, benchsheets, calculation spreadsheets, temperature logs, standard and reagent logs, and maintenance books. These records are periodically reviewed for completeness to provide traceability of data.

5.6.2 Specific Requirements

5.6.2.1 Calibration
Policy:
The program for calibration equipment is designed and operated to ensure that calibration measurements are traceable.

Details:
Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories show that there is a link to a primary standard by an unbroken chain of calibrations. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also section 5.10.4.2). Additional details are included in Element SP 501, Calibration and Maintenance of Test Equipment.

Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

The term “identified metrological specification” means that it must be clear from the calibration certificate against which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

The lab maintains certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability. Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

Reference standards, such as thermometers and weights, are traceable to a national or international standard (e.g., NIST). Where available, reference materials should be purchased from manufacturers accredited to ISO Guide 34. The distributors for the manufacturers do not need to be ISO Guide 34 accredited.

5.6.2.2 Testing
5.6.2.2.1
Policy:
The requirements given in section 5.6.2.1 apply to measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that equipment used can provide the accuracy of measurement needed.

Details:
The extent to which the requirements in section 5.6.2.1 are followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements are strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in section 5.6.2.2.2.

5.6.2.2.2
Policy:
Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:
- the use of suitable reference materials certified to give a reliable characterization of the material
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned

- participation in a suitable program of inter-laboratory comparisons or proficiency testing

Details:
Reliable characterization involves an estimate of recovery.

The laboratory participates in proficiency testing and/or check sample programs. The list of programs is maintained by the Quality Manager.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

Policy:
The SOP# NE-ADM-028, Reference Standards and Materials, outlines the program for the calibration of reference standards. Reference standards are obtained or calibrated by a body that can provide traceability as described in section 5.6.2.1. Such reference standards of measurement held by the laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

Details:
Reference standards and materials are traceable to the National Institute of Standards and Technology (NIST) or Guide 34 as applicable. A copy of the certificate of accuracy is maintained at the lab.

5.6.3.2 Reference Materials

Policy:
Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

Details:
Reference materials, including calibration standards, used in chemical measurement are prepared so that the point of measurement is similar or equivalent to that of the samples. The matrix, prior to the addition of the analyte does not have a detectable concentration of the analyte. Reagents used in the preparation of reference materials, including calibration standards are of certified purity.

Certified reference cultures are traceable to a national or internationally recognized type culture collection. Reference cultures from laboratory sources must be identified to standard reference sources. A copy of the certificate of analysis is kept at the lab. These reference cultures must be handled to maintain their biochemical reaction and physiological characteristic integrity. All Reference Cultures and Certified Reference Cultures are not transferred more than five times from a type culture collection. Alternatively, re-identify the culture for key biochemical and physiological characteristics using national or internationally recognized reference sources. Another alternative is to grow the type culture, then freeze it (or freeze-dry it), and use periodically, thus extending the length of time required before repurchase or re-identification. These may also be commercially available and purchased for use. Companies selling Certified Reference Cultures must comply with the requirements of ISO 17025 for a calibration laboratory.

5.6.3.3 Intermediate Checks

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

Details and Procedures:
The control check standards used to verify the accuracy of all the other standards are prepared independently from all the other standards used to establish the original calibration. These control check standards are preferably prepared from a separate lot # or source. It is the responsibility of the Quality Manager to establish the individual schedule for each SOP and/or test method and the responsibility of the analyst to maintain this schedule.

5.6.3.4 Transport and Storage
Policy:
The SOP# NE-ADM-028, Reference Standards and Materials, outlines safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

Details:
Proper conditions are established for storing, handling, and care of reference standards and reference materials. Expired standards are identified and removed from use in the lab.

Revision History

Revision 18
Added entire section
Revision 19
Added “traceability of measurement data” to 5.6.1 Details and “Test methods and quality related procedures are documented where appropriate by the use of standard operating procedures, benchsheets, calculation spreadsheets, temperature logs, standard and reagent logs, and maintenance books. These records are periodically reviewed for completeness to provide traceability of data”.
Added “Expired standards are identified in HQMS and removed from use in the lab” to 5.6.3.4.
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Section 5.6.3.2 –Added certificate of analysis is kept at the lab for CRM’s.
Revision 0.1
Section 5.6.1 Added “The prep of all reagents is recorded to identify the constituents, date of prep, source, lot #, amount used, final volume, diluents, and preparer’s initials“ to Details.
Revision 1.0
Removed “Level 2” from title. Section 5.6.1 added “storage conditions” to reagent label requirements and “comparable system” to HQMS reference. Section 5.6.2 added reference to Element SP 501, Calibration and Maintenance of Test Equipment.
Revision 2.0
Section 5.6.2.1 Details – added “Where available, reference materials should be purchased from manufacturers accredited to ISO Guide 34. The distributors for the manufacturers do not need to be ISO Guide 34 accredited.”

5.7 Sampling

The Ten Second Tutorial

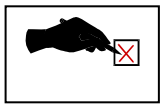
This section tells you:

1. There must be a sampling plan and procedure
2. Appropriate records of sampling are kept
3. Deviations, additions, and exclusions from the plan or procedure are recorded

Key Words

Sampling Plan and Procedure
Deviation, Addition, or Exclusion

Cross-references



ISO 17025:2005 Section 5.7
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.7.1 Sampling Plan and Procedures

Policy:
The laboratory has specific sampling SOPs for any off-site sampling of substances, matrices, materials or products for subsequent testing. A copy of the sampling plan and procedures are available at the location where sampling is performed for unique sampling events. For routine sampling events, a copy of the procedure is maintained at the laboratory. Sampling plans are based on appropriate statistical methods whenever reasonable or based on the client's requirements. The sampling process addresses the factors to be controlled to ensure validity of the test and calibration results.

Details:
Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide for testing as a representative sample of the whole. Sampling can also be required by the appropriate specification for which the substance, matrix, material or product is to be tested. In certain cases, the sample may not be representative, but determined by availability.

The sampling plan describes the allocation, withdrawal and preparation of a sample or samples from a substance, matrix, material or product to yield the required information. All samples are collected and placed in sealed containers.

The laboratory maintains field sampling procedures used by the field staff for sampling drinking water, wastewater, and stormwater. SOP# NE-ADM-007, Subsampling and Compositing, describes the compositing and/or subsampling activities within the laboratory to ensure a representative portion of the submitted sample is tested.

5.7.2 Deviations, Additions or Exclusions

Policy:
Where the customer requires deviations, additions or exclusions from the sampling procedure, these are recorded in detail with the appropriate sampling data and included in all documents containing test results, and communicated to the appropriate personnel.

Details:
The physical condition and temperature of all test items are observed and recorded upon receipt. Any deviations from specifications or observations are discussed with the customer as to the suitability of the sample. Cross-contamination is the most critical issue from broken, leaking samples for both qualitative and quantitative tests.

Upon receipt at the lab, samples are checked for conformance to the lab sample acceptance policy. Any samples that deviate from the policy are held until the client has been contacted for further instruction, unless holding the sample would compromise the sample hold time. The protocol for sample receipt is described in Element SP 706, Handling of Test Items, and Element-EFW NE-ADM-019, Sample Handling.

5.7.3 Records

Policy:
The laboratory specific sampling SOPs outline the procedures for recording relevant data and operations relating to sampling that form part of the testing that is undertaken. These records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant)

and any diagrams or other equivalent means to identify the sampling location as necessary, and, if appropriate, the statistics upon which the sampling procedures are based.

Details:
Adequate sample identification upon receipt in the laboratory includes:

- unique and unambiguous sample identification, typically a work order number, retained throughout the testing life of the test item
- name of person(s) the report will be sent to
- date and time of sample collection
- identification number or description from (customer) if any
- tests desired and/or methods requested
- preservatives
- number of containers and type
- date of receipt
- delivery carrier
- sample condition, including temperature

A chain of custody and/or sample receipt checklist is used to document the above information and to document the transfer of ownership of the sample. Samples not meeting the lab sample acceptance policy require contact with the customer for further instruction.

Revision History

Revision 18
Added entire section
Revision 19
Section 5.7.1 – Added reference to field sampling procedures for field activities
Section 5.7.2 – Added paragraph to Details referencing the sample acceptance policy
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” in title. Section 5.7.2 added reference to Element SP 706, Handling of Test Items, and Element-EFW NE-ADM-019, Sample Handling and replaced physical appearance with physical condition.
Revision 2.0-no changes

5.8 Handling of Test and Calibration Items

The Ten Second Tutorial

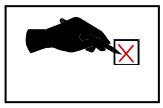
This section tells you to:

1. Keep samples in good condition.

Key Words

Identification
Receipt
Protection

Cross-references



ISO 17025:2005 Section 5.8
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.8.1 Procedures

Policy:
Element SP 706, Handling of Test Items, and Element-EFW NE-ADM-019, Sample Handling, outline the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items, including all provisions necessary to protect the integrity of the test item, and the interests of the laboratory and the customer.

Details:
Samples received at the laboratory are stored so as to ensure their integrity by preventing against deterioration, contamination, and loss of identity. Upon receipt, samples are assigned a unique identification and the condition of the samples is documented.

Samples are stored in designated refrigerators unless testing will begin upon arrival. Samples for volatile organics testing are stored separately to prevent cross-contamination. Additional handling procedures are outlined in SOP# NE-ADM-019, Sample Handling.

5.8.2 Identification of Test Items

Policy:
Test items are systematically identified as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

Details:
Sample labelling indicates the unique identification of the sample. Where conformity of possession of a test sample must be maintained for evidentiary purposes, the laboratory establishes and documents a system for appropriate chain-of-custody within the laboratory LIMS.

5.8.3 Receipt

Policy:
Upon receipt of the test item, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, sample acceptance policy, and sample handling SOP #NE-ADM-019, are recorded. When there is any doubt as to the suitability of an item for testing, or when an item does not conform to the description provided, or the test required is not specified in sufficient detail, the laboratory consults the customer for further instructions before proceeding and keeps a record of the discussion.

Details:
Conformance is to applicable regulations or contractual arrangements. The condition of the sample may include or relate to damage, quantity, preparation, packaging, preservation or temperature. Preparation may include addition of chemical preservative, removal of moisture, isolation of portion of sample to be tested, homogenization, or subsampling.

Arrangements are in place to ensure that elapsed time between sampling and testing does not exceed test method specifications (holding time). If the sample hold time will be expired prior to analysis due to either late arrival at the lab or a lab error, the client will be consulted for further instruction.

5.8.4 Protection

Policy:

Element SP 706, Handling of Test Items, and Element-EFW NE-ADM-019, Sample Handling, outline the procedures and appropriate facilities for avoiding deterioration, loss or damage to the test item during storage, handling and preparation for testing. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded. Where a test item is to be held secure (e.g., for reasons of record, safety or value, or to enable complementary test to be performed later), the laboratory has arrangements for storage and security that protect the condition and integrity of the secured item concerned.

Details:

A sampling procedure and information on storage and transport of samples, including all information that may influence the test result, is provided to those responsible for taking and transporting the samples.

The laboratory establishes whether the sample has received all necessary preparation or whether the customer requires preparation to be undertaken or arranged by the laboratory. Proper requirements for packaging, environmental conditions, and separation from incompatible materials are observed. Where samples have to be stored or conditioned under specific conditions, these conditions are maintained, monitored, and recorded, where necessary.

Where a sample, or portion of a sample, is to be held secure (e.g., for reasons of record, safety, or value, or to enable check tests to be performed later), the laboratory will implement the actions necessary and communicate the requirements to the appropriate personnel.

Revision History

Revision 18
Reformatted entire section
Revision 19 – No changes
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Label 2” from title. Section 5.8.2. and 5.8.4 added reference to Element SP 706, Handling of Test Items. Section 5.8.3 added “sample acceptance policy”.
Revision 2.0-No changes

5.9 Assuring the Quality of Test and Calibration Results

The Ten Second Tutorial

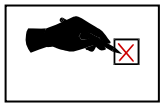
This section tells you:

1. That results are monitored
2. There is a plan for monitoring

Key Words

Internal Quality Control
Statistical Techniques
Inter-laboratory Comparisons
Proficiency Testing
Certified Reference Materials
Secondary Reference Material
Replicates
Re-testing
Correlation

Cross-references



ISO 17025:2005 Section 5.9
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.9.1 Quality Control / Quality Assurance

Policy:

Quality control procedures are utilized to monitor the validity of test results. These procedures are for each test method utilized in the laboratory. The resulting data are recorded so that trends are detectable (and where practicable, statistical techniques are applied to the reviewing of the results). This monitoring is planned and reviewed and may include, but not limited to, the following:

- regular use of certified reference materials and/or internal quality control using secondary reference materials
- participation in proficiency testing programs
- replicate tests using the same or different methods
- re-testing of retained items
- correlation of results for different characteristics of an item

Details:

The methods utilized from the above list will be appropriate for the type and volume of the work undertaken. Records are maintained of assurance activities and any actions taken.

As a guide, for routine analyses the level of internal quality control is typically 5 - 10% of the sample throughput. This will typically involve the use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the sample and/or spiked sample. Systematic quality control procedures incorporating the use of control charts and check samples are implemented. These procedures are documented in the "Quality Control Section" of each test method SOP.

Proficiency testing helps to highlight not only repeatability and reproducibility performance between laboratories, but also systematic errors such as bias. It is important to monitor proficiency testing results as a means of checking quality assurance and take action as necessary.

The Quality Manager maintains a list of all the current proficiency testing programs the laboratory participates in, monitors the results, and notifies the appropriate personnel of both problematic and successful results. Proficiency test results are also communicated to management in monthly quality reports and in the annual management review.

Technical personnel use certified reference materials and reference materials to evaluate test performance on a daily basis and include daily process control checks. These data are used to evaluate the validity of the test results.

Re-testing of test items is performed occasionally at the discretion of the supervisor or when test results seem anomalous or at the request of the customer. When retesting occurs, the retest is logged into Omega in duplicate. Instruction is provided in Element SP 210 Retesting and Replacement Testing.

5.9.2 Correction and Prevention

Policy:

Quality control data are analyzed and, where they are found to be outside pre-defined criteria, planned action is taken to correct and to prevent incorrect results from being reported.

Details:
Test method SOPs include a corrective action section to address quality control results that are outside of the test method acceptance ranges. If the actions taken do not correct the non-conformance, the data is reviewed by the manager or quality staff to determine actions to be taken and the affect on the associated sample data.

Actions taken may include but not be limited to re-analysis, re-making of the quality control standards, analysis by an alternative method, reporting of the data with a narrative or re-sampling where hold times have expired.

Revision History

Revision 18
Added entire section
Revision 19
Section 5.9.2 – Added Details paragraph
Revision 0
Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Revision 0.1 – No changes
Revision 1.0
Removed “Level 2” from title. Section 5.9.1 added “When retesting occurs, the retest is logged into Omega in duplicate” and added reference to NE-ADM-042, Protocol for ReAnalysis.
Revision 2.0 –Added reference of Element SP 210 to Section 5.9.1

5.10 Reporting of Results

The Ten Second Tutorial

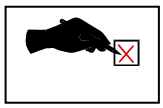
This section tells you:

1. What needs to be on a report
2. How to handle amendments to reports

Key Words

Specific Information
Required Information
Interpretation
Opinion
Subcontractor
Electronic Transmission of Results
Format
Amendments

Cross-references



ISO 17025:2005 Section 5.10
Applicable Element System Procedures are cited in this section
Applicable Element-EFW Administrative Standard Operating Procedures are cited in this section

5.10.1 General

Policy:
The results of each test, or series of tests, are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results are reported, normally in a test report and include all the information requested by the customer and necessary for the interpretation of the test results and all information required by the method used. This information may include what is outlined in section 5.10.2, 5.10.3 and 5.10.4.

In the case of tests performed for internal customers, and in the case of a written agreement with the customer, the results may be reported in a simplified way. The information listed in section 5.10.2 to 5.10.4, and not reported, is kept readily available.

Details:
Test reports are issued as either hard copy or by electronic data transfer.

5.10.2 Test reports

Policy:
Test reports include the following information, as appropriate:

- a title (e.g., “Analytical Report”)
- name and address of laboratory, and location where tests were carried out if different from the address of the laboratory
- unique identification of the test report (work order number), and on each page an identification in order to ensure that the page is recognized as a part of the test report and a clear identification of the end of the test report
- name and address of the customer
- identification of the method used
- description, condition, and unambiguous identification of the item(s) tested
- date of receipt of the test item and date(s) of performance of the test
- reference to sampling procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results
- test results with, where appropriate, units of measurement
- the name(s), function(s) and signature(s) or equivalent of person(s) authorizing the test report
- where relevant, a statement to the effect that the results relate only to the items tested

Details:
Signing authority for test reports is the responsibility of the project managers and Operations Manager. Records for individuals with signing authority for test reports are approved and maintained by the Quality Manager.

Hard copies and electronic copies of test reports include the page number and total number of pages.

A statement is included specifying that the test report is not to be reproduced except in full, without written approval of the laboratory. Data reported to the customer contains the appropriate significant digits for each test method. Low level data are identified with a qualifier as being below specified limits. Additional data qualifiers are defined in the report.

5.10.3 Test Reports

5.10.3.1

Policy and Details:

In addition to the requirements listed in section 5.10.2, test reports include the following, where necessary for the interpretation of results:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when uncertainty affects compliance to a specification limit
- where appropriate and needed opinions and interpretations (see section 5.10.5)
- additional information required by specific methods, customers, or groups of customers

5.10.3.2

Policy and Details:

In addition to the requirements listed in sections 5.10.2 and 5.10.3.1, test reports containing the results of sampling include the following, where necessary for the interpretation of test results:

- date of sampling
- unambiguous identification of substance, matrix, material or product sampled (including name of manufacturer, model or type of designation and serial numbers as appropriate)
- location of sampling, including any diagrams, sketches or photographs
- reference to sampling plan and procedures used
- details of any environmental condition during sampling that may affect the interpretation of the test results
- 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

5.10.4.1

Policy:

The testing laboratories of Element-EFW do not issue calibration certificates. However, the laboratory often receives calibration services from a calibration laboratory and needs to be familiar with the information on a calibration certificate.

Details:

The calibration certificate should include the following, where necessary for the interpretation of calibration results:

- clearly marked as a Calibration Report or Calibration Certificate
- name and address of calibration laboratory
- unique report certificate number and total number of pages
- Element lab name and location
- description of item
- date of calibration
- calibration method and any deviations
- the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results
- description of any limitations associated with the final results
- name, job title, and signature of person authorized and/or approving the results

- the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof
- evidence that the measurements are traceable (see 5.6.2.1.1)
- calibration agency's accreditation (A2LA, IAS, NVLAP, ACLASS)

All calibration certificates must be submitted to the Quality Manager for review. The review ensures all of the above items have been documented in the certificate. The copies with the review form are maintained by Quality.

5.10.4.2
Policy:
This section is not applicable to a testing laboratory.

5.10.4.3
Policy:
This section is not applicable to a testing laboratory.

5.10.4.4
Policy:
A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer or it is to be used by the laboratory itself.

5.10.5 Opinions and Interpretations

Policy:
When opinions and interpretations are included in the test report, the basis upon which the opinions and interpretations have been made is documented. Opinions and interpretations are clearly marked as such in the test report.

Details:
Opinions and interpretations included in a test report may comprise, but not be limited to the following:

- opinion on conformity of the results with requirements
- fulfilment of contractual requirements
- recommendations on how to use the results
- guidance to be used for improvements

In many cases it is appropriate to communicate the opinions and interpretations by direct dialogue with the customer. This dialogue is written down. If the communication is included with the report, it is documented in the case narrative of the report.

5.10.6 Testing and Calibration Results Obtained from Subcontractors

Policy and Details:
Test reports containing the results of tests performed by subcontractors are clearly identified for the subcontracted results. The subcontractor reports the results either in writing or electronically to our laboratory.

5.10.7 Electronic Transmission of Results

Policy:
In the case of transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of the policies and procedures of the Quality Manual continue to apply (see also 5.4.7).

Details:
Reports that are "published" electronically contain an electronic signature. A copy of the original signatures for verification purposes is maintained by the Quality Manager.

5.10.8 Format of Reports

Policy:
The format of reports is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

Details:
The layout of the test report is such that the presentation of the test data facilitates ease of assimilation by the reader. Results are associated with the appropriate sample identification and date and time of collection.

The headings are standardized as far as possible. A guide to the data qualifiers is at the bottom of each page of the report. The pages of the report are numbered to maintain the organization of the report.

5.10.9 Amendments to Reports

Policy:
Material amendments to a test report after issue are made only in the form of a further document, or data transfer, which includes the statement "Supplement to Test Report, serial number...[or as otherwise identified]", or an equivalent form of wording. Such amendments meet all the requirements in this Quality Manual.

Details:
Original reports are marked as "original" and re-issued reports are marked as "revision v1" to indicate the revision number. A narrative is included in the report to provide details regarding the reason for the re-issued report. Corrected reports indicate results have changed and amended reports indicate a change or correction to information in the report (correction to sample ID or date/time of collection) while results have not changed.

References:
Element SP 708, Reporting Results
Element-EFW NE-ADM-000 Data Review

Revision History

Revision 18
Added entire section
Revision 19
Section 5.10.8 – Added to Details section regarding page numbering of reports
Section 5.10.9 – Added reference to using narrative page in reports for notations of amendments
Revision 0

Replaces Revision19 to update the company name from Sherry Laboratories to Element throughout all sections.
Section 5.10.2 – Replaced “Lab Director” with “Operations Manager”
Revision 0.1
Section 5.10.9 – Added “Corrected reports indicate results have changed and amended reports indicate a change or correction to information in the report (correction to sample ID or date/time of collection) while results have not changed” to Details.

Revision 1.0
Removed “Level 2” from title. Added References as Element SP 708, Reporting Results and Element-EFW NE-ADM-000 Data Review

Procedure No.	Procedure Name	Columbus	Ft. Wayne	Daleville	South Bend	Warsaw
General Chemistry						
5210 B	BOD, CBOD		X	X		
4500 Cl G	Chlorine, Colorimetric	X	X	X	X	X
2510 B	Conductance		X			
SW846-9045D	Corrosivity		X	X		
2540 G	% Solids		X	X		
2540 E	Percent Volatile Solids		X			
4500-H+ B	pH	X	X	X	X	X
2540 C	Residue, TDS		X			
2540 B	Residue, TS		X	X		
2540 D	Residue, TSS		X	X		
EPA 160.4 Rev. 1983	Residue, VS		X			
2550 B	Temperature	X	X	X	X	
2130 B	Turbidity		X			
Wet Chemistry						
2320 B	Alkalinity, Phenolphthalein		X			
2320 B	Alkalinity, Titrimetric		X			
350.1	Ammonia-N Semi-Automated		X			
4500-NH3 BC	Ammonia-N Distill/Titration		X			
5220 D	COD, Colorimetric		X			
4500-Cl E SW846 9251	Chloride, Automated		X			
EPA 300.0	Chloride		X			
3500-Cr B	Chromium, Hexavalent		X			
4500-CN C	Cyanide Distillation		X			
10-204-00-1-X	Cyanide, Auto.		X			
4500-CN G	Cyanide, Amenable		X			
EPA 335.4	Cyanide, Auto.		X			
SW846 1010A	Flashpoint, Closed Cup		X			

Procedure No.	Procedure Name	Columbus	Ft. Wayne	Daleville	South Bend	Warsaw
EPA 300.0	Fluoride		X			
200.7 Rev. 4.4	Total Hardness Ca + Mg			X		
329 IAC 10-7.1-4	Neutral Leachate Extraction			X		
EPA 353.2 Rev. 2.0, 1993	Nitrate+Nitrite-N		X			
EPA 353.2 Rev. 2.0, 1993	Nitrate-N		X			
EPA 353.2 Rev. 2.0, 1993	Nitrite-N		X			
EPA 300.0	NO2, NO3		X			
EPA 1664A/B	Oil & Grease		X			
EPA 1664A/B	Oil & Grease-SGT-HEM		X			
SW846 9095B	Paint FilterTest			X		
EPA 420.1, SW846 9065	Phenolics, Dist		X			
EPA 420.1 SW846 9065	Phenolics, Total		X			
4500-P F	Phosphorous, Total		X			
6010C	Phosphorus, Total			X		
10-115-01-1-A	Phosphorous, Ortho		X			
EPA 300.0	Sulfate		X			
EPA 375.2, SW846 9036	Sulfate, Automated		X			
SM4500S2-F	Sulfide		X			
6010C	Sulfur			X		
EPA 351.2	Total Kjeldahl Nitrogen		X			
SM5310C	TOC					X
Metals						
EPA 200.7 Rev. 4.4	Total Hardness Ca + Mg			X		

Procedure No.	Procedure Name	Columbus	Ft. Wayne	Daleville	South Bend	Warsaw
EPA 245.1, SW846 7470A	Mercury in Water			X		
SW846 7471B	Mercury in Soils, Wastes			X		
EPA 200.7, SW846 6010C	Metals, ICP			X		
EPA 200.8	Metals, ICP MS			X		
EPA 200.7 EPA 200.8	Metals Digestion			X		
SW846 3005A	Metals – Dissolved Digestion			X		
SW846 3010A	Metals –Totals Digestion			X		
SW846-3050B	Metals Digestion			X		
SW846-1311	TCLP Extraction			X		
329 IAC-Rule 9	IN Neutral Leachate			X		
Organics						
SW846 5035	Purge and Trap for VOCs			X		
SW846-3550C	PCB Extraction		X	X		
SW846-8082A	PCB, Solids		X	X		
EPA 608 SW846-8082A	PCB, Waters & Wastewaters			X		
SW846-3550B	PCB Wipes Extraction			X		
SW846-3510C	PCB/Pesticide Extraction			X		
SW846-8081B	Organochlorine Pesticides			X		
SW846-3550C	SVOA Extraction for Solids			X		
SW846-3510C	SVOA, TCLPE, TTO			X		
	Extraction for liquid					
SW846-1311	ZHE			X		
EPA 624	VOCS, Waters & Wastewaters			X		
EPA 524.2	VOCS, TTHMs			X		
SW846-8260B	VOCs, Solids, Soils			X		
EPA 625	SVOCs, Waters			X		
SW846-8270D	SVOCs Water, Wastes, Soils			X		
SW846-5030B	Purge-and-Trap - Aqueous samples			X		
EPA 504.1	DBCP, EDB		X			
EPA 505	Pesticides		X			
EPA 515.3	Chlorinated Acids		X			
EPA 525.2	Organic Compounds		X			
EPA 531.1	Carbamates		X			
EPA 547	Glyphosate		X			
EPA 548.1	Endothall		X			
EPA 549.2	Diquat		X			
EPA 552.2	HAA5		X			
Microbiology						
SM 9223 B	Coliform, Total & E. Coli	X	X	X	X	X
SM 9222 D	Fecal Coliform, MF	X	X	X	X	
SM 9221 E	Fecal Colif, MPN	X	X			
SM9223 B	E.coli, Q-tray	X	X	X		X
Coliscan	E.Coli . MF				X	

Procedure No.	Procedure Name	Columbus	Ft. Wayne	Daleville	South Bend	Warsaw
SM 9215 B	Heterotropic Plate Count	X	X	X		X
SM 9215 D	Heterotropic Plate Count, MF					X
SM 9213E	Pseudomonas aeruginosa					X
IDEXX Pseudalert, SOP 1022	Pseudomonas aeruginosa					X
SOP 1048	Container Rinse, Closure Testing					X
SOP-1084	Percent Fat in Egg					X
Indicators						
AOAC 2003.01	Enterobacteriaceae Petrifilm					X
AOAC 990.12,986.33, 989.08	Aerobic Plate Count Petrifilm					X
SOP 7043	Lactic Acid Bacteria Petrifilm					X
AOAC 998.08,991.14	Coliform/E.coli Petrifilm	X	X	X		X
AOAC 997.02	Yeast & Mold Petrifilm					X
AOAC 2003.07,2003. 08,2003.11	Coagulase Positive Staph Petrifilm					X
SOP 1050	Petrifilm Plate Set Up					X
AOAC 986.32	Total Bacterial Count Iso-Grid					X
AOAC 990.11	Coliform/E.coli Iso-Grid					X
AOAC 995.21	Yeast & Mold Iso-Grid					X
SOP 7049	Clostridium perfringens					X
SOP 7044	Sensient – Pepsi Cloud TCB, Y/M					X

Procedure No.	Procedure Name	Columbus	Ft. Wayne	Daleville	South Bend	Warsaw
SOP 7055	FDA Container Rinse					X
Pathogens						
AOAC 990.11E, 998.08	E.coli 1-49000 CFU/g					X
AOAC RI 031201	Salmonella - spp					X
AOAC 2000.14	E.coli, 0157:H7					X
SOP 7029	Salmonella enteritidis, Drag Swabs					X
PCR Pathogens						
AOAC RI 120301 SOP 1229	Salmonella - Spp.					X
PCR AOAC RI 070401 SOP 1230	Listeria monocytogenes					X
PCR AOAC RI 070401 SOP 1231	Listeria-Spp.					X
SOP 7011	Salmonella enteritidis PCR					X
Food Chemistry						
SOP 1185	Ca in Meat by EDTA					X
SOP 1212	Gliadin (Gluten) Allergen					X
SOP 1213	Peanut Allergen					X
AOAC 978.18	Water Activity					X
AOAC 925.10, 926.08, 950.46	Moisture (Loss On Drying)					X
SOP 1219	Percent Fat in Foods					X

Procedure No.	Procedure Name	Columbus	Ft. Wayne	Daleville	South Bend	Warsaw
AOAC 923.03	Ash					X
AOAC 992.15, 990.03	Protein					X
AOCS Am-5-04	Fat					X
AOCS Ba 6A-05	Fiber					X
Medical Devices						
USP 31	LAL IQA by Kinetic-QCL					X
SOP 1142	Product Validation by Kinetic-QCL					X
SOP 1143	LAL Assay					X
Residue Analysis						
EPA 507, 508, 525.2, 608 SM 6630 B FDA PAM 302/SPE	Pesticides, Insecticides & Herbicides		X			
Formulation Analysis						
Trade Method	Pesticides		X			
Trade Method	Insecticides		X			
Trade Method	Herbicides		X			
GLP Studies						
Storage Stability	Per Study Protocol		X			

APPENDIX B-2:
Pace Analytical Services, LLC- Quality Assurance Manual

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Document Number: ENV-MAN-IND1-0001 **Revision:** 01

Document Title: Quality Manual

Department(s): Quality

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Next Review Date: **Last Review Date:**

Notes

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All Dates and Times are listed in: Central Time Zone

Signature Manifest

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Title: Quality Manual

All dates and times are in Central Time Zone.

ENV-MAN-IND1-0001 Quality Manual

QM Approval

Name/Signature	Title	Date	Meaning/Reason
Elizabeth Schrage (008534)	Quality Manager	20 Apr 2019, 10:40:23 AM	Approved

Management Approval

Name/Signature	Title	Date	Meaning/Reason
Steven Sayer (004775)	General Manager	22 Apr 2019, 07:29:45 AM	Approved
Anne Troyer (008754)	Quality Analyst II	22 Apr 2019, 08:21:52 AM	Approved

QUALITY ASSURANCE MANUAL

Quality Assurance/Quality Control Policies and Procedures

Pace Analytical Services, LLC

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5560 Corporate Exchange Court SE, Grand Rapids, MI 49512 (616)975-4500

Table of Contents

1.0. INTRODUCTION AND ORGANIZATIONAL STRUCTURE

"Working together to protect our environment and improve our health"
Pace Analytical Services LLC - Mission Statement

1.1. Introduction to Pace

1.1.1. Pace Analytical Services, LLC (Pace) is a privately held, full-service analytical testing firm operating a nationwide system of laboratories. Pace offers extensive services beyond standard analytical testing, including: bioassay for aquatic toxicity, air toxics, dioxins and coplanar PCB's by high resolution mass spectrometry, radiochemical analyses, product testing, pharmaceutical testing, field services and mobile laboratory capabilities. This document defines the Quality System and Quality Assurance (QA)/Quality Control (QC) protocols.

1.1.2. Pace laboratories are capable of analyzing a full range of environmental samples from a variety of matrices, including air, surface water, wastewater, groundwater, soil, sediment, biota, and other waste products. Methods are applied from regulatory and professional sources including EPA, ASTM, USGS, NIOSH, Standard Methods, and State Agencies. Section 11 of this document is a representative listing of general analytical protocol references.

1.2. Statement of Purpose

1.2.1. To meet the business needs of our customers for high quality, cost-effective analytical measurements and services.

1.3. Quality Policy Statement and Goals of the Quality System

1.3.1. Pace management is committed to maintaining the highest possible standard of service and quality for our customers by following a documented quality system that is compliant with all current applicable state, federal, and industry standards, such as the NELAC Standard, the TNI Standard, and ISO standards and is in accordance with the stated methods and customer requirements. The overall objective of this quality system is to provide reliable data of known quality through adherence to rigorous quality assurance policies and quality control procedures as documented in this Quality Assurance Manual.

1.3.2. All personnel within the Pace network are required to be familiar with all facets of the quality system relevant to their position and implement these policies and procedures in their daily work.

1.4. Core Values

1.4.1. The following are the Pace Core Values:

- **Integrity**
- **Value Employees**
- **Know Our Customers**
- **Honor Commitments**
- **Flexible Response To Demand**
- **Pursue Opportunities**
- **Continuously Improve**

1.5. Code of Ethics and Standards of Conduct

1.5.1. **Code of Ethics**:

1.5.1.1. Each Pace employee is responsible for the propriety and consequences of his or her actions;

1.5.1.2. Each Pace employee must conduct all aspects of Company business in an ethical and strictly legal manner, and must obey the laws of the United States and of all localities, states and nations where Pace does business or seeks to do business;

1.5.1.3. Each Pace employee must reflect the highest standards of honesty, integrity and fairness on behalf of the Company with customers, suppliers, the public, and one another.

1.5.1.4. Each Pace employee must recognize and understand that our daily activities in environmental laboratories affect public health as well as the environment and that environmental laboratory analysts are a critical part of the system society depends upon to improve and guard our natural resources:

1.5.2. **Standards of Conduct:**

1.5.2.1. **Data Integrity**

1.5.2.1.1. The accuracy and integrity of the analytical results and its supporting documentation produced at Pace are the cornerstones of the company. Employees are to accurately prepare and maintain all technical records, scientific notebooks, calculations, and databases. Employees are prohibited from making false entries or misrepresentations of data for any reason.

1.5.2.1.2. Managerial staff must make every effort to ensure that personnel are free from any undue pressures that may affect the quality or integrity of their work including commercial, financial, over-scheduling, and working condition pressures.

1.5.2.1.3. The data integrity system includes in-depth, periodic monitoring of data integrity including peer data review and validation, internal raw data audits, proficiency testing studies, etc.

1.5.2.1.4. Any documentation related to data integrity issues, including any disciplinary actions involved, corrective actions taken, and notifications to customers must be retained for a minimum of five years.

1.5.2.2. **Confidentiality**

1.5.2.2.1. Pace employees must not use or disclose confidential or proprietary information except when in connection with their duties at Pace. This is effective over the course of employment and for an additional period of two years thereafter.

1.5.2.2.2. Confidential or proprietary information, belonging to either Pace and/or its customers, includes but is not limited to test results, trade secrets, research and development matters, procedures, methods, processes and standards, company-specific techniques and equipment, marketing and customer information, inventions, materials composition, etc.

1.5.2.3. **Conflict of Interest**

1.5.2.3.1. Pace employees must avoid situations that might involve a conflict of interest or could appear questionable to others. This includes participation in activities that conflict or appear to conflict with the employees' Pace responsibilities. This would also include offering or accepting anything that might influence the recipient or cause another person to

believe that the recipient may be influenced to behave or in a different manner than he would normally (such as bribes, gifts, kickbacks, or illegal payments).

1.5.2.3.2. Employees are not to engage in outside business or economic activity relating to a sale or purchase by the Company. Other problematic activities include service on the Board of Directors of a competing or supplier company, significant ownership in a competing or supplier company, employment for a competing or supplier company, or participation in any outside business during the employee's work hours.

1.5.3. Strict adherence by each Pace employee to this Code of Ethics and to the Standards of Conduct is essential to the continued vitality of Pace and to continue the pursuit of our common mission to protect our environment and improve our health.

1.5.4. Failure to comply with the Code of Ethics and Standards of Conduct will result in disciplinary action up to and including termination and referral for civil or criminal prosecution where appropriate. An employee will be notified of an infraction and given an opportunity to explain, as prescribed under current disciplinary procedures.

1.5.5. Compliance: all employees undergo annual Data Integrity/Ethics training which includes the concepts listed above. All employees also sign an annual Ethic Policy statement.

1.6. Anonymous Compliance Alertline

1.6.1. An ethical and safe workplace is important to the long-term success of Pace and the well-being of its employees. Pace has a responsibility to provide a work environment where employees feel safe and can report unethical or improper behavior in complete confidence. With this in mind, Pace has engaged Lighthouse Services, Inc. to provide all employees with access to an anonymous ethics and compliance alertline for reporting possible ethics and compliance violations. The purpose of this service is to ensure that any employee can report anonymously and without fear of retaliation.

1.6.2. Lighthouse Services provides a toll-free number along with several other reporting methods, all of which are available 24 hours a day, seven days a week for use by employees and staff.

1.6.3. Telephone: English speaking USA and Canada: (844)-970-0003.

1.6.4. Telephone: Spanish speaking North America: (800)-216-1288.

1.6.5. Website: www.lighthouse-services.com/pacelabs.

1.6.6. Email: reports@lighthouse-services.com (must include company name with report).

1.7. Laboratory Organization

1.7.1. Each laboratory within the system operates with local management, but all labs share common systems and receive support from the Corporate Office. See Attachment III for the Corporate Organizational structure.

1.7.2. A Senior General Manager (SGM) oversees all laboratories and service centers in their assigned region. Each laboratory or facility in the company is then directly managed by an SGM, a General Manager (GM), an Assistant General Manager (AGM), or an Operations Manager (OM). Quality Managers (QM) or Senior Quality Managers (SQM) at each laboratory report directly to the highest level of local laboratory management, however named, that routinely makes day-to-day decisions regarding that facility's operations. The QMs and SQMs will also receive guidance and direction from the corporate Director of Environmental Quality.

1.7.3. The SGM, GM, AGM or OM, or equivalent functionality in each facility, bears the responsibility for the laboratory operations and serves as the final, local authority in all matters. In the absence of these managers, the SQM/QM serves as the next in command, unless the manager in charge has assigned another designee. He or she assumes the responsibilities of the manager, however named, until the manager is available to resume the duties of their position. In the absence of both the manager and the SQM/QM, management responsibility of the laboratory is passed to the Technical Director, provided such a position is identified, and then to the most senior department manager until the return of the lab manager or SQM/QM. The most senior department manager in charge may include the Client Services Manager (CSM) or the Administrative Business Manager (ABM) at the discretion of the SGM/GM/AGM/OM.

1.7.4. A Technical Director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical director to temporarily perform this function. The laboratory SGM/GM/AGM/OM or SQM/QM has the authority to make this designation in the event the existing Technical Director is unable to do so. If this absence exceeds 35 consecutive calendar days, the primary accrediting authority shall be notified in writing.

1.7.5. The SQM/QM has the responsibility and authority to ensure the Quality System is implemented and followed at all times. In circumstances where a laboratory is not meeting the established level of quality or following the policies set forth in this Quality Assurance Manual, the SQM/QM has the authority to halt laboratory operations should he or she deem such an action necessary. The SQM/QM will immediately communicate the halting of operations to the SGM/GM/AGM/OM and keep them posted on the progress of corrective actions. In the event the SGM/GM/AGM/OM and the SQM/QM are not in agreement as to the need for the suspension, the Chief Operating Officer (COO) and Director of Environmental Quality will be called in to mediate the situation.

1.7.6. The technical staff of the laboratory is generally organized into the following functional groups:

- Organic Extractions
- Wet Chemistry Analysis
- Metals Analysis
- Volatiles Analysis
- Semi-volatiles Analysis

1.7.7. The organizational structure for Pace – Indianapolis is listed in Attachment IIA and for Pace - Grand Rapids in Attachment IIB. In the event of a change in SGM/GM/AGM/OM, SQM/QM, or any Technical Director, the laboratory will notify its accrediting authorities per their individual required timeframes, not to exceed 30 days. The QAM will remain in effect until the next scheduled revision.

1.8. Laboratory Job Descriptions

1.8.1. **Senior General Manager**

- Oversees all functions of all the operations within their designated region;
- Oversees the development of local GMs/AGMs/OMs within their designated region;
- Oversees and authorizes personnel development including staffing, recruiting, training, workload scheduling, employee retention and motivation;
- Oversees the preparation of budgets and staffing plans for all operations within their designated region;
- Ensures compliance with all applicable state, federal and industry standards;
- Works closely with Regional Sales Management.

1.8.2. General Manager

- Oversees all functions of their assigned operations;
- Authorizes personnel development including staffing, recruiting, training, workload scheduling, employee retention and motivation;
- Prepares budgets and staffing plans;
- Monitors the Quality Systems of the laboratory and advises the SQM/QM accordingly;
- Presents the Ethics/Data Integrity training annually to all employees in their facilities as an instructor-led training.
- Ensures compliance with all applicable state, federal and industry standards.

1.8.4. Quality Manager

- Responsible for implementing, maintaining and improving the quality system while functioning independently from laboratory operations. Reports directly to the highest level of local laboratory facility management, however named, that routinely makes day-to-day decisions regarding laboratory operations, but receives direction and assistance from the Corporate Director of Environmental Quality;
- Ensures that communication takes place at all levels within the lab regarding the effectiveness of the quality system and that all personnel understand their contributions to the quality system;
- Monitors QA/QC activities to ensure that the laboratory achieves established standards of quality (as set forth by the Corporate Environmental Quality office). The QM is responsible for reporting the lab's level of compliance to these standards to the Corporate Director of Environmental Quality on a quarterly basis;
- Maintains records of quality control data and evaluates data quality;
- Conducts periodic internal audits and coordinates external audits performed by regulatory agencies or customer representatives;
- Reviews select laboratory data and final reports;
- Reviews tenders, contracts and QAPPs to ensure the laboratory can meet the data quality objectives for any given project;
- Reviews and maintains records of proficiency testing results;
- Maintains the document control system;
- Assists in development and implementation of appropriate training programs;
- Provides technical support to laboratory operations regarding methodology and project QA/QC requirements;
- Maintains certifications from federal and state programs;
- Ensures compliance with all applicable state, federal and industry standards;
- Maintains the laboratory training records, including those in the Learning Management System (LMS), and evaluates the effectiveness of training;
- Monitors corrective and preventive actions;
- Maintains calibration of support equipment such as balances and thermometers;
- Maintains the currency of the Quality Manual.

1.8.5. Laboratory Technical Director

- Monitors the standards of performance in quality assurance and quality control data;
- Monitors the validity of analyses performed and data generated;
- May review tenders, contracts and QAPPs to ensure the laboratory can meet the data quality objectives for any given project;

- Serves as the manager of the laboratory in the absence of the SGM/GM/AGM/OM and SQM/QM;
- Provides technical guidance in the review, development, and validation of new methodologies.

1.8.6. Administrative Business Manager

- Responsible for financial and administrative management for the entire facility;
- Provides input relative to tactical and strategic planning activities;
- Organizes financial information so that the facility is run as a fiscally responsible business;
- Works with staff to confirm that appropriate processes are put in place to track revenues and expenses;
- Provide ongoing financial information to the SGM/GM/AGM/OM and the management team so they can better manage their business;
- Utilizes historical information and trends to accurately forecast future financial positions;
- Works with management to ensure that key measurements are put in place to be utilized for trend analysis—this will include personnel and supply expenses, and key revenue and expense ratios;
- Works with SGM/GM/AGM/OM to develop accurate budget and track on an ongoing basis;
- Works with entire management team to submit complete and justified capital budget requests and to balance requests across departments;
- Works with project management team and administrative support staff to ensure timely and accurate invoicing.

1.8.7. Client Services Manager

- Oversees all the day to day activities of the Client Services Department which includes Project Management and, possibly, Sample Control;
- Responsible for staffing and all personnel management related issues for Client Services;
- Serves as the primary senior consultant to customers on all project related issues such as set up, initiation, execution and closure;
- Performs or is capable of performing all duties listed for that of Project Manager.

1.8.8. Project Manager

- Coordinates daily activities including taking orders, reporting data and analytical results;
- Serves as the primary technical and administrative liaison between customers and Pace;
- Communicates with operations staff to update and set project priorities;
- Provides results to customers in the requested format (verbal, hardcopy, electronic, etc.);
- Works with customers, laboratory staff, and other appropriate Pace staff to develop project statements of work or resolve problems of data quality;
- Responsible for solicitation of work requests, assisting with proposal preparation and project initiation with customers and maintain customer records;
- Mediation of project schedules and scope of work through communication with internal resources and management;
- Responsible for preparing routine and non-routine quotations, reports and technical papers;
- Interfaces between customers and management personnel to achieve customer satisfaction;
- Manages large-scale complex projects;
- Supervises less experienced project managers and provide guidance on management of complex projects;

- Arranges bottle orders and shipment of sample kits to customers;
- Verifies login information relative to project requirements and field sample Chains-of-Custody;
- Enters project and sample information in the Laboratory Information Management System (LIMS) for scheduling, tracking and reporting purposes.

1.8.9. **Project Coordinator**

- Enters project and sample information in the Laboratory Information Management System (LIMS) for scheduling, tracking and reporting purposes.

1.8.10. **Department Manager/Supervisor**

- Oversees the day-to-day production and quality activities of their assigned department;
- Ensures that quality assurance and quality control criteria of analytical methods and projects are satisfied;
- Assesses data quality and takes corrective action when necessary;
- Approves and releases technical and data management reports;
- Trains analysts or oversees training of analysts in laboratory operations and analytical procedures;
- Ensures compliance with all applicable state, federal and industry standards.

1.8.11. **Quality Assurance Analyst**

- Assists the SQM/QM in the performance of quality department responsibilities as delegated by the SQM/QM;
- Reviews select laboratory data and final reports;
- Generates and reviews QC data validation packages;
- Assists in monitoring QA/QC data;
- Assists in internal audits;
- Assists in maintaining training records;
- Assists in maintaining the document control system.

1.8.12. **Group Supervisor/Leader**

- Trains analysts in laboratory operations and analytical procedures;
- Organizes and schedules analyses with consideration for sample holding times;
- Implements data verification procedures by assigning data verification duties to appropriate personnel;
- Evaluates instrument performance and supervises instrument calibration and preventive maintenance programs;
- Reports non-compliance situations to laboratory management including the SQM/QM.

1.8.13. **Laboratory Analyst**

- Performs detailed preparation and analysis of samples according to published methods and laboratory procedures;
- Processes and evaluates raw data obtained from preparation and analysis steps;
- Generates final results from raw data, performing primary review against method criteria;

- Monitors quality control data associated with analysis and preparation. This includes examination of raw data such as chromatograms as well as an inspection of reduced data, calibration curves, and laboratory notebooks;
- Reports data in LIMS, authorizing for release pending secondary approval;
- Conducts routine and non-routine maintenance of equipment as required;
- Performs or is capable of performing all duties associated with that of Laboratory Technician.

1.8.14. **Laboratory Technician**

- Prepares standards and reagents according to published methods or in house procedures;
- Performs preparation and analytical steps for basic laboratory methods;
- Works under the direction of a Laboratory Analyst on complex methodologies;
- Assists Laboratory Analysts on preparation, analytical or data reduction steps for complex methodologies;
- Monitors quality control data as required or directed. This includes examination of raw data such as chromatograms as well as an inspection of reduced data, calibration curves, and laboratory notebooks.

1.8.15. **Field Technician**

- Prepares and samples according to published methods, PACE Quality Assurance Manual and/or customer directed sampling objectives;
- Capable of the collection of representative environmental or process samples;
- Reviews project documentation for completeness, method compliance and contract fulfillment;
- Train less experienced environmental technicians and provide guidance on sampling and analysis;
- Responsible for project initiation and contact follow-up;
- Develop sampling plans and prepare test plan documents.

1.8.16. **Sample Receiving Personnel**

- Signs for incoming samples and verifies the data entered on the Chain of custody forms;
- Stages samples according to EPA requirements;
- Assists Project Managers and Coordinators in filling bottle orders and sample shipments;
- May enter project and sample information in the Laboratory Information Management System (LIMS) for scheduling, tracking and reporting purposes;
- Manages sample storage areas and sample disposal procedures.

1.8.17. **Systems Administrator or Systems Manager**

- Assists with the creation and maintenance of electronic data deliverables (EDDs);
- Coordinates the installation and use of all hardware, software and operating systems;
- Performs troubleshooting on all aforementioned systems;
- Trains new and existing users on systems and system upgrades;
- Maintains all system security passwords;
- Maintains the electronic backups of all computer systems.

1.8.18. **Safety/Chemical Hygiene Officer**

- Maintains the laboratory Chemical Hygiene Plan;
- Plans and implements safety policies and procedures;
- Maintains safety records;
- Organizes and/or performs safety training;
- Performs safety inspections and provides corrective/preventative actions;
- Assists personnel with safety issues.

1.8.19. **Hazardous Waste Coordinator**

- Evaluates waste streams and helps to select appropriate waste transportation and disposal companies;
- Maintains complete records of waste disposal including waste manifests and state reports;
- Assists in training personnel on waste-related issues such as waste handling and storage, waste container labeling, proper satellite accumulation, secondary containment, etc.;
- Conducts a weekly inspection of the waste storage areas of the laboratory.

1.9. Training and Orientation

1.9.1. Training for Pace employees is managed through web-based training systems. Employees are provided with several training activities for their particular job description and scope of duties. These training activities may include:

- Hands-on training led by supervisors;
- Job-specific training checklists and worksheets;
- Lectures and instructor-led training sessions;
- Method-specific training;
- External conferences and seminars;
- Reading Standard Operating Procedures (SOPs);
- Reading the Quality Assurance Manual and Safety Manual/Chemical Hygiene Plan;
- Core training modules (basic lab skills, etc.);
- Quality system training modules (support equipment use, corrective actions/root causes, etc.);
- Data Integrity/Ethics training;
- Specialized training by instrument manufacturers;
- On-line courses.

1.9.2. All procedures and training records are maintained and available for review during laboratory audits. Additional information can be found in the *Training Procedures* SOP or its equivalent replacement.

1.10. Laboratory Safety and Waste

1.10.1. It is the policy of Pace to make safety and waste compliance an integral part of daily operations and to ensure that all employees are provided with safe working conditions, personal protective equipment, and requisite training to do their work without injury. Each employee is responsible for his/her own safety as well as those working in the immediate area by complying with established company rules and procedures. These rules and procedures as well as a more detailed

description of the employees' responsibilities are contained in the local Safety Manual/Chemical Hygiene Plan.

1.11. Security and Confidentiality

1.11.1. Security is maintained by controlled access to laboratory buildings. Exterior doors to laboratory buildings remain either locked or continuously monitored by Pace staff. Keyless door locks are accessible only to authorized personnel through the use of assigned key fobs. All visitors, including PACE staff from other facilities, must sign the Visitor's Logbook maintained by the receptionist. A staff member will accompany them during the duration of their stay on the premises unless the SGM/GM/AGM/OM, SQM/QM, or Technical Director specify otherwise. In this instance, the staff member will escort the visitor back to the reception area at the end of his/her visit where he/she signs out.

1.11.2. Additional security is provided where necessary, (e.g., specific secure areas for sample, data, and customer report storage), as requested by customers, or cases where national security is of concern. These areas are lockable within the facilities, or are securely offsite. Access is limited to specific individuals or their designees.

1.11.3. All information pertaining to a particular customer, including national security concerns will remain confidential. Data will be released to outside agencies only with written authorization from the customer or where federal or state law requires the company to do so.

1.12. Communications

1.12.1. Management within each lab bears the responsibility of ensuring that appropriate communication processes are established and that communication takes place regarding the effectiveness of the management/quality system. These communication processes may include email, regular staff meetings, senior management meetings, etc.

1.12.2. Corporate management bears the responsibility of ensuring that appropriate communication processes are established within the network of facilities and that communication takes place at a company-wide level regarding the effectiveness of the management/quality systems of all Pace facilities. These communication processes may include email, quarterly continuous improvement conference calls for all lab departments, and annual continuous improvement meetings for all department supervisors, quality managers, client services managers, and other support positions.

2.0. SAMPLE CUSTODY

2.1. Project Initiation

2.1.1. Prior to accepting new work, the laboratory reviews its performance capability. The laboratory confirms that sufficient personnel, equipment capacity, analytical method capability, etc., are available to complete the required work. Customer needs, certification requirements, and data quality objectives are defined and the appropriate sampling and analysis plan is developed to meet the project requirements by project managers or sales representatives. Members of the management staff review current instrument capacity, personnel availability and training, analytical procedures capability, and projected sample load. Management then informs the sales and client services personnel whether or not the laboratory can accept the new project via written correspondence, email, and/or daily operations meetings.

2.1.2. Additional information regarding specific procedures for reviewing new work requests can be found in the *Review of Analytical Requests* SOP or its equivalent replacement.

2.2. Sampling Materials and Support

2.2.1. Each individual Pace laboratory provides shipping containers, properly preserved sample containers, custody documents, and field quality control samples to support field-sampling events. Guidelines for sample container types, preservatives, and holding times for a variety of methods are listed in Attachment VIII. Note that all analyses listed are not necessarily performed at all Pace laboratories and there may be additional laboratory analyses performed that are not included in these tables. Customers are encouraged to contact their local Pace Project Manager for questions or clarifications regarding sample handling. Pace may provide pick-up and delivery services to their customers when needed.

2.2.2. Some Pace facilities provide sampling support through a Field Services department. Field Services operates under the Pace Corporate Quality System, with applicable and necessary provisions to address the activities, methods, and goals specific to Field Services. All procedures and methods used by Field Services are documented in SOPs and Procedure Manuals.

2.3. Chain of Custody

2.3.1. A chain of custody (COC) provides the legal documentation of samples from time of collection to completion of analysis.

2.3.2. Field personnel or client representatives must complete a COC for all samples that are received by the laboratory. Samplers are required to properly complete a COC. This is critical to efficient sample receipt and to ensure the requested methods are used to analyze the correct samples. If sample shipments are not accompanied by the correct documentation, the Sample Receiving department notifies a Project Manager. The Project Manager then obtains the correct documentation/information from the customer in order for analysis of samples to proceed.

2.3.3. The COC is filled out completely and legibly with indelible ink. Errors are corrected by drawing a single line through the initial entry and initialing and dating the change. All transfers of samples are recorded on the chain of custody in the "relinquished" and "received by" sections. All information except signatures is printed.

2.3.4. Additional information can be found in the *Sample Management* SOP or its equivalent replacement.

2.4. Sample Acceptance Policy

2.4.1. In accordance with regulatory guidelines, Pace complies with the following sample acceptance policy for all samples received.

2.4.2. If the samples do not meet the sample receipt acceptance criteria outlined below, the laboratory is required to document all non-compliances, contact the customer, and either reject the samples or fully document any decisions to proceed with analyses of samples which do not meet the criteria. Any results reported from samples not meeting these criteria are appropriately communicated to the client.

2.4.3. Sample Acceptance Policy requirements:

- Sample containers must have unique client identification designations that are clearly marked with indelible ink on durable, water-resistant labels. The client identifications must match those on the chain-of-custody (COC).
- There must be clear documentation on the COC, or related documents that lists the unique sample identification, sampling site location, date and time of sample collection, and name of the sample collector.
- There must be clear documentation on the COC, or related documents that lists the requested analyses, the preservatives used, and any special remarks concerning the samples (i.e., data deliverables, samples are for evidentiary purposes, field filtration, etc.).
- Samples must be in appropriate sample containers. If the sample containers show signs of damage (i.e., broken or leaking) or if the samples show signs of contamination, the samples will not be processed without prior client approval.
- Samples must be correctly preserved upon receipt, unless the method requested allows for laboratory preservation. If the samples are received with inadequate preservation, and the samples cannot be preserved by the lab appropriately, the samples will not be processed without prior client approval.
- Samples must be received within required holding time. Any samples with hold times that are exceeded will not be processed without prior client approval.
- Samples must be received with sufficient sample volume or weight to proceed with the analytical testing. If insufficient sample volume or weight is received, analysis will not proceed without client approval.
- All samples that require thermal preservation are considered acceptable if they are received at a temperature within 2°C of the required temperature, or within the method-specified range. For samples with a required temperature of 4°C, samples with a temperature ranging from just above freezing to 6°C are acceptable. Samples that are delivered to the lab on the same day they are collected are considered acceptable if the samples are received on ice. Any samples that are not received at the required temperature will not be processed without prior client approval.
- Samples for **drinking water compliance** analyses will be rejected at the time of receipt if they are not received in a secure manner, are received in inappropriate containers, are received outside the required temperature range, are received outside the recognized holding time, are received with inadequate identification on sample containers or COC, or are improperly preserved (with the exception of VOA samples- tested for pH at time of analysis and TOC- tested for pH in the field).
- Some specific clients may require custody seals. **For these clients**, samples or coolers that are not received with the proper custody seals will not be processed without prior client approval.

Note 1: Temperature will be read and recorded based on the precision of the measuring device. For example, temperatures obtained from a thermometer graduated to 0.1°C will be read and recorded to ± 0.1°C. Measurements obtained from a thermometer graduate to 0.5°C will be read to ± 0.5°C. Measurements read at the specified precision are not to be rounded down to meet the ≤ 6°C limit. Please reference the Support Equipment SOP for more information.

Note 2: Some microbiology methods allow sample receipt temperatures of up to 10°C. Consult the specific method for microbiology samples received above 6°C prior to initiating corrective action for out of temperature preservation conditions.

2.4.4. Upon sample receipt, the following items are also checked and recorded:

- Presence of custody seals or tapes on the shipping containers;
- Sample condition: Intact, broken/leaking, bubbles in VOA samples;
- Sample holding time;
- Sample pH and residual chlorine when required;
- Appropriate containers.

2.4.5. Additional information can be found in the *Sample Management* SOP or its equivalent replacement.

2.5. Sample Log-in

2.5.1. After sample inspection, all sample information on the COC is entered into the Laboratory Information Management System (LIMS). The lab's permanent records for samples received include the following information:

- Customer name and contact
- Customer number
- Pace Analytical project number
- Pace Analytical Project Manager
- Sample descriptions
- Due dates
- List of analyses requested
- Date and time of laboratory receipt
- Field ID code
- Date and time of collection
- Any comments resulting from inspection for sample rejection

2.5.2. If the time collected for any sample is unspecified and Pace is unable to obtain this information from the customer, the laboratory will use 08:00 as the time sampled. All hold times will be based on this sampling time and qualified accordingly if exceeded.

2.5.3. The LIMS automatically generates a unique identification number for each sample created in the system. The LIMS sample number follows the general convention of 50XXXXXX. This unique identification number is placed on the sample container as a durable label and becomes the link between the laboratory's sample management system and the customer's field identification; it will be a permanent reference number for all future interactions.

2.5.4. Sample labels are printed from the LIMS and affixed to each sample container.

2.5.5. Additional information can be found in the *Sample Management* SOP or its equivalent replacement.

2.6. Sample Storage

2.6.1. Additional information on sample storage can be found in the *Sample Management* SOP or its equivalent replacement and in the *Waste Handling and Management* SOP or its equivalent replacement.

2.6.2. **Storage Conditions**

2.6.2.1. Samples are stored away from all standards, reagents, or other potential sources of contamination. Samples are 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.

2.6.2.2. Storage blanks are stored with volatile samples and are used to measure cross-contamination acquired during storage. Laboratories must have documented procedures and criteria for evaluating storage blanks, appropriate to the types of samples being stored.

2.6.2.3. Additional information can be found in the *Monitoring Temperature Controlled Units* SOP or its equivalent replacement**.**

2.6.3. **Temperature Monitoring**

2.6.3.1. Samples are taken to the appropriate storage location immediately after sample receipt and check-in procedures are completed. All sample storage areas are located in limited access areas and are monitored to ensure sample integrity.

2.6.3.2. The temperature of each refrigerated storage area is maintained at $\leq 6^{\circ}C$ but above freezing unless state, method or program requirements differ. The temperature of each freezer storage area is maintained at $\leq -10^{\circ}C$ unless state, method or program requirements differ. The temperature of each storage area is checked and documented each day of use. If the temperature falls outside the acceptable limits, the following corrective actions are taken and appropriately documented:

- The temperature is rechecked after a period of time, usually two hours, to verify temperature exceedance. Corrective action is initiated and documented if necessary.
- The SQM/QM and/or laboratory management are notified if the problem persists.
- The samples are relocated to a proper environment if the temperature cannot be maintained after corrective actions are implemented.
- The affected customers are notified and/or documentation is provided on the final report, if necessary.

2.6.3.3. Additional information can be found in the *Monitoring Temperature Controlled Units* SOP or its equivalent replacement.

2.6.4. **Hazardous Materials**

2.6.4.1. Samples designated by clients upon receipt as pure product or potentially heavily contaminated samples, or samples found to be designated as such following analysis, must be labeled to indicate the hazard and stored separately from other samples.

2.6.5. **Foreign/Quarantined Soils**

2.6.5.1. Foreign soils and soils from domestic USDA quarantined areas must be adequately segregated to prevent cross-contamination and enable proper sample disposal. The USDA requires these samples and by-products to be properly identified and handled and to be treated by an approved procedure prior to disposal or as part of disposal.

2.6.5.2. Additional information regarding USDA regulations and sample handling can be found in the laboratory's *Regulated Soil Handling* SOP or its equivalent replacement.

2.7. Subcontracting Analytical Services

2.7.1. Every effort is made to perform all analyses for Pace customers within the laboratory that receives the samples. When subcontracting to a laboratory other than the receiving laboratory, whether inside or outside the Pace network becomes necessary, a preliminary verbal communication with that laboratory is undertaken. Customers are notified in writing of the laboratory's intention to subcontract any portion of the testing to another laboratory. Work performed under specific protocols may involve special considerations. When possible, subcontracting will be to a TNI-accredited laboratory.

2.7.2. Potential subcontract laboratories must be approved by Pace based on the criteria listed in SOP S-IN-C-003 *Subcontracting Samples* or its equivalent revision or replacement. All sample reports from the subcontracted labs are appended to the applicable Pace final reports.

2.7.3. Any Pace work sent to other labs within the Pace network is handled as inter-regional work and all final reports are labeled clearly with the name of the laboratory performing the work. Any non-TNI work is clearly identified. Pace will not be responsible for analytical data if the subcontract laboratory was designated by the customer.

2.7.4. Additional information can be found in the *Subcontracting Samples* SOP or its equivalent replacement.

2.8. Sample Retention and Disposal

2.8.1. Samples, extracts, digestates, and leachates must be retained by the laboratory for the period of time necessary to protect the interests of the laboratory and the customer.

2.8.2. The minimum sample retention time is 45 days from receipt of the samples. Samples requiring thermal preservation may be moved to ambient temperature storage when the hold time is expired, when the report has been delivered, and/or when allowed by the customer, program, or contract. Samples requiring storage beyond the minimum sample retention time due to special requests or contractual obligations may be stored at ambient temperature unless the laboratory has sufficient capacity and their presence does not compromise the integrity of other samples.

2.8.3. After this period expires, non-hazardous samples are properly disposed of as non-hazardous waste. The preferred method for disposal of **hazardous** samples is to return the excess sample to the customer. If it is not feasible to return samples, or the customer requires Pace to dispose of excess samples, proper arrangements will be made for disposal by an approved contractor.

2.8.4. Additional information can be found in the *Waste Handling and Management* SOP and the *Sample Management* SOP or their equivalent replacements.

3.0. QUALITY CONTROL PROCEDURES

3.1. Quality Control Samples

3.1.1. The quality control samples described in this section are analyzed per batch as applicable to the method used. Acceptance criteria must be established for all quality control samples and if the acceptance criteria are not met, corrective actions must be performed and samples reanalyzed, or the final report must be appropriately qualified.

3.1.2. Quality control samples must be processed in the same manner as associated client samples.

3.1.3. Please reference the glossary of this Quality Manual for definitions of all quality control samples mentioned in this section.

3.1.4. Any deviations to the policies and procedures governing quality control samples must be approved by the QM/SQM.

3.2. Method Blank

3.2.1. A method blank is a negative control used to assess the preparation/analysis system for possible contamination and is processed through all preparation and analytical steps with its associated client samples. The method blank is processed at a minimum frequency of one per preparation batch and is comprised of a matrix similar to the associated client samples. Method blanks are not applicable for certain analyses (i.e., pH, flash point, temperature, etc.).

3.2.2. Each method blank is evaluated for contamination. Corrective actions for blank contamination may include the re-preparation and re-analysis of all samples (where possible) and quality control samples. Data qualifiers must be applied to results that are affected by contamination in a method blank.

3.2.3. Please reference method-specific SOPs for acceptance criteria and associated corrective actions for method blanks.

3.3. Laboratory Control Sample

3.3.1. The Laboratory Control Sample (LCS) is a positive control used to assess the performance of the entire analytical system including preparation and analysis. The LCS is processed at a minimum frequency of one per preparation batch and is comprised of a matrix similar to the associated client samples.

3.3.2. The LCS contains all analytes required by a specific method or by the customer or regulatory agency, which may not include the full list of target compounds. In the absence of specified components, the laboratory will spike the LCS with the following compounds:

- For multi-peak analytes (e.g. PCBs, technical chlordane, toxaphene), a representative standard will be processed.
- For methods with long lists of analytes, a representative number of target analytes may be chosen. The following criteria is used to determine the number of LCS compounds used:
    - For methods with 1-10 target compounds, the laboratory will spike with all compounds;
    - For methods with 11-20 target compounds, the laboratory will spike with at least 10 compounds or 80%, whichever is greater;
    - For methods with greater than 20 compounds, the laboratory will spike with at least 16 compounds.

3.3.3. The LCS is evaluated against the method default or laboratory-derived acceptance limits. Any compound that is outside of these limits is considered to be 'out of control' and must be qualified appropriately. Any sample containing a compound that was 'out-of-control' in the associated LCS must either be re-analyzed with a successful LCS or reported with the appropriate data qualifier. When the result of the LCS exceeds the upper control limit, indicating high bias, associated samples determined to be non-detect may be reported without qualification.

3.3.4. For LCSs containing a large number of analytes, it is statistically likely that a few recoveries will be outside of control limits. This does not necessarily mean that the system is out of control, and therefore no corrective action would be necessary other than proper documentation. TNI has allowed for a minimum number of marginal exceedances, defined as recoveries that are beyond the LCS control limits (3X the standard deviation) but within than the marginal exceedance limits (4X the standard deviation). The number of allowable exceedances depends on the number of compounds in the LCS. If more analyte recoveries exceed the LCS control limits than is allowed (see below) or if any one analyte exceeds the marginal exceedance limits, then the LCS is considered non-compliant and corrective actions are necessary. The number of allowable exceedances is as follows:

- >90 analytes in the LCS- 5 analytes
- 71-90 analytes in the LCS- 4 analytes
- 51-70 analytes in the LCS- 3 analytes
- 31-50 analytes in the LCS- 2 analytes
- 11-30 analytes in the LCS- 1 analyte
- <11 analytes in the LCS- no analytes allowed out)

3.3.5. A matrix spike (MS) can be used in place of a non-compliant LCS in a batch as long as the MS passes the LCS acceptance criteria. When this happens, full documentation must be made available to the data user. If this is not allowed by a customer or regulatory body, the associated samples must be rerun with a compliant LCS when possible or reported with appropriate data qualifiers.

3.3.6. Please reference method-specific SOPs for acceptance criteria and associated corrective actions for LCSs.

3.4. Matrix Spike/Matrix Spike Duplicate (MS/MSD)

3.4.1. A matrix spike (MS) is a positive control used to determine the effect of the sample matrix on compound recovery for a particular method. A matrix spike/matrix spike duplicate (MS/MSD) set or matrix spike/sample duplicate set is processed at a frequency specified in a particular method or as determined by a specific customer request. The MS and MSD consist of the sample matrix that is spiked with known concentrations of target analytes.

3.4.2. The MS and MSD contain all analytes required by a specific method or by the customer or regulatory agency. In the absence of specified components, the laboratory will spike the MS/MSD with the same number of compounds as previously discussed in the LCS section.

3.4.3. A matrix spike and sample duplicate will be performed instead of a matrix spike and matrix spike duplicate when specified by the customer or method or when limited sample volume or weight prohibits the analysis of an MS/MSD set.

3.4.4. The MS and MSD are evaluated against the method or laboratory derived limits. Any compound that is outside of these limits is considered to be 'out of control' and must be qualified appropriately. Batch acceptance; however, is based on method blank and LCS performance, not on

MS/MSD recoveries. The spike recoveries give the data user a better understanding of the final results based on their site-specific information.

3.4.5. Please reference method-specific SOPs for acceptance criteria and associated corrective actions for MS/MSDs.

3.5. Sample Duplicate

3.5.1. A sample duplicate is a second portion of sample that is prepared and analyzed in the laboratory along with the first portion. It is used to measure the precision associated with preparation and analysis. A sample duplicate is processed at a frequency specified by the particular method or as determined by a specific customer.

3.5.2. The sample and duplicate are evaluated against the method or laboratory limits for relative percent difference (RPD). Any duplicate that is outside of these limits is considered to be 'out of control' and must be qualified appropriately.

3.5.3. Please reference method-specific SOPs for acceptance criteria and associated corrective actions for sample duplicates.

3.6. Surrogates

3.6.1. Surrogates are compounds that reflect the chemistry of target analytes and are added to samples for most organic analyses to measure the extraction efficiency or purge efficiency and to monitor the effect of the sample matrix on surrogate compound recovery.

3.6.2. The surrogates are evaluated against the method or laboratory derived acceptance limits. Any surrogate compound that is outside of these limits is considered to be 'out of control' and must be qualified appropriately. Samples with surrogate failures are typically 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 systemic error. An exception to this would be samples that have surrogate recoveries that exceed the upper control limit but have no reportable hits for target compounds. These samples would be reported and qualified to indicate the implied high bias would not affect the final results.

3.6.3. Please reference method-specific SOPs for acceptance criteria and associated corrective actions for surrogates.

3.7. Internal Standards

3.7.1. Internal Standards are method-specific analytes that are added, as applicable, to every standard, QC sample, and client sample at a known concentration, prior to analysis for the purpose of adjusting the response factor used in quantifying target analytes.

3.7.2. Please reference method-specific SOPs for acceptance criteria and associated corrective actions for internal standards.

3.8. Limit of Detection (LOD)

3.8.1. Pace laboratories use a documented procedure to determine a limit of detection (LOD) for each analyte of concern in each matrix reported. Unless otherwise noted in a published method, the procedure used by Pace laboratories to determine LODs is based on the Method Detection Limit (MDL) procedure outlined in 40 CFR Part 136, Appendix B, August 28, 2017. All sample

processing steps of the preparation and analytical methods are included in the LOD determination including any clean ups.

3.8.2. Additional information can be found in the *Determination of Detection and Quantitation Limits* SOP or its equivalent replacement.

3.9. Limit of Quantitation (LOQ)

3.9.1. A limit of quantitation (LOQ) for every analyte of concern must be determined. For Pace laboratories, this LOQ is referred to as the RL, or Reporting Limit. The RL may or may not be based on the lowest calibration standard concentration used in the initial calibration. Results below the lowest calibration level may not be reported without qualification since the results would not be substantiated by a calibration standard. For methods with a determined LOD, results can be reported below the LOQ but above the LOD if they are properly qualified (e.g., J flag).

3.9.2. Additional information can be found in the *Determination of Detection and Quantitation Limits* SOP or its equivalent replacement.

3.10. Estimate of Analytical Uncertainty

3.10.1. Pace can provide an estimation of uncertainty for results generated by the laboratory. The estimate quantifies the error associated with any given result at a 95% confidence interval. This estimate does not include bias that may be associated with sampling or sample matrix. The laboratory has a procedure in place for making this estimation. In the absence of a regulatory or customer-specific procedure, Pace laboratories base this estimation on the recovery data obtained from the Laboratory Control Samples (LCS). The uncertainty is a function of the standard deviation of the recoveries multiplied by the appropriate Student's t Factor at 95% confidence. Additional information pertaining to the estimation of uncertainty and the exact manner in which it is derived are contained in the *Estimation of Measurement Uncertainty* SOP or its equivalent replacement.

3.10.2. The measurement of uncertainty is provided only on request by the customer, as required by specification or regulation and when the result is used to determine conformance within a specification limit.

3.11. Proficiency Testing (PT) Studies

3.11.1. Pace laboratories participate in a defined proficiency testing (PT) program. PT samples are obtained from NIST-approved providers and analyzed and reported a minimum of two times per year for the relevant fields of testing per matrix.

3.11.2. The laboratory initiates an investigation whenever PT results are determined to be "Not Acceptable" by the PT provider. All findings and corrective actions taken are reported to the SQM/QM or their designee. A corrective action plan is initiated and, when required, this report is sent to the appropriate state accreditation agencies for their review. Additional PTs will be analyzed and reported as needed for certification purposes.

3.11.3. Additional information can be found in the *Proficiency Testing Program* SOP or its equivalent replacement.

3.12. Rounding and Significant Figures

3.12.1. In general, Pace laboratories report data to no more than three significant figures. The rounding rules listed below are descriptive of the LIMS and not necessarily of any supporting program such as Excel.

3.12.2. **Rounding:** Pace - Indianapolis follows the odd / even guidelines for rounding numbers:

- If the figure following the one to be retained is less than five, that figure is dropped and the retained ones are not changed (with three significant figures, 2.544 is rounded to 2.54).
- If the figure following the ones to be retained is greater than five, that figure is dropped and the last retained one is rounded up (with three significant figures, 2.546 is rounded to 2.55).
- If the figure following the ones to be retained is five and if there are no figures other than zeros beyond that five, then the five is dropped and the last figure retained is unchanged if it is even and rounded up if it is odd (with three significant figures, 2.525 is rounded to 2.52 and 2.535 is rounded to 2.54).

3.12.3. **Significant Figures**

3.12.3.1. Pace - Indianapolis observes the following convention for reporting to a specified number of significant figures. Unless specified by federal, state, or local requirements or on specific request by a customer, the laboratory reports:

Values > 10 – Reported to 3 significant figures
Values ≤ 10 – Reported to 2 significant figures

3.13. Retention Time Windows

3.13.1. When chromatographic conditions are changed, retention times and analytical separations are often affected. As a result, two critical aspects of any chromatographic method are the determination and verification of retention times and analyte separation. Retention time windows must be established for the identification of target analytes. The retention times of all target analytes in all calibration verification standards must fall within appropriately determined retention time windows. If an analyte falls outside the retention time window in an ICV or CCV, new absolute retention time windows must be calculated, unless instrument maintenance fixes the problem. New retention time windows must be established when column geometry is affected by maintenance.

3.13.2. Please reference method-specific SOPs for the proper procedure for establishing retention time windows.

3.14. Analytical Method Validation and Instrument Validation

3.14.1. In some situations, Pace develops and validates methodologies that may be more applicable to a specific problem or objective. When non-standard methods are required for specific projects or analytes of interest, when the laboratory develops or modifies a method, or when the laboratory brings new instrumentation online, the laboratory validates the method and/or instrument prior to applying it to customer samples. Method validity is established by meeting criteria for precision and accuracy as established by the data quality objectives specified by the end user of the data. The laboratory records the validation procedure, the results obtained and a statement as to the usability of the method. The

minimum requirements for method or instrument validation include evaluation of sensitivity, quantitation, precision, bias, and selectivity of each analyte of interest.

3.15. Regulatory and Method Compliance

3.15.1. It is Pace policy to disclose in a forthright manner any detected noncompliance affecting the usability of data produced by our laboratories. The laboratory will notify customers within 30 days of fully characterizing the nature of the nonconformance, the scope of the nonconformance and the impact it may have on data usability.

4.0. DOCUMENT MANAGEMENT AND CHANGE CONTROL

4.1. Document Management

4.1.1. Additional information can be found in the *Document Control and Management* SOP or its equivalent replacement. Information on Pace's policy for electronic signatures can also be found in this SOP.

4.1.2. Pace has an established procedure for managing documents that are part of the quality system.

4.1.3. A master list of managed documents is maintained at each facility identifying the current revision status and distribution of any controlled documents.

4.1.4. Each managed document is uniquely identified to include the date of issue, the revision identification, page numbers, the total number of pages and the issuing authorities. For complete information on document numbering, refer to the *Document Numbering* SOP or its equivalent replacement.

4.1.5. **Quality Assurance Manual (QAM):** The Quality Assurance Manual is the company-wide document that describes all aspects of the quality system for Pace. The base QAM template is distributed by the Corporate Environmental Quality Department to each of the SQMs/QMs. The local management personnel modify the necessary and permissible sections of the base template then applicable lab staff will sign the Quality Assurance Manual. Each SQM/QM is then in charge of distribution to employees, external customers or regulatory agencies and maintaining a distribution list of controlled document copies. The Quality Assurance Manual template is reviewed on an annual basis and revised accordingly by the Corporate Quality office.

4.1.6. **Standard Operating Procedures (SOPs)**

4.1.6.1. SOPs are reviewed every two years at a minimum; although, a more frequent review may be required by some state or federal agencies, programs, or customers. If no revisions are made based on this review, documentation of the review itself is made by the addition of new signatures on the cover page. If revisions are made, documentation of the revisions is made in the revisions section of each SOP and a new revision number is applied to the SOP. This provides a historical record of all revisions.

4.1.6.2. All copies of superseded SOPs are removed from general use and the original copy of each SOP is archived for audit or knowledge preservation purposes. This ensures that all Pace employees use the most current version of each SOP and provides the SQM/QM with a historical record of each SOP.

4.1.6.3. Additional information can be found in the *Preparation of SOPs* SOP or its equivalent replacement.

4.2. Document Change Control

4.2.1. Additional information can be found in the *Document Control and Management* SOP or its equivalent replacement.

4.2.2. Changes to managed documents are reviewed and approved in the same manner as the original review. Any revision to a document requires the approval of the applicable signatories. After revisions are approved, a revision number is assigned and the previous version of the document is officially retired.

4.2.3. All copies of the previous document are replaced with copies of the revised document and the superseded copies are destroyed or archived. All affected personnel are advised that there has been a revision and any necessary training is scheduled.

5.0. EQUIPMENT AND MEASUREMENT TRACEABILITY

5.1. Standards and Traceability

5.1.1. Each Pace facility retains pertinent information for standards, reagents, and chemicals to assure traceability to a national standard. This includes documentation of purchase, receipt, preparation, and use.

5.1.2. Upon receipt, all purchased standard reference materials are recorded into a standard logbook or database and assigned a unique identification number. The entries include the facility's unique identification number, the chemical name, manufacturer name, manufacturer's identification numbers, receipt date, and expiration date. Vendor's certificates of analysis for all standards, reagents, or chemicals are retained for future reference.

5.1.3. Subsequent preparations of intermediate or working solutions are also documented in a standard logbook or database. These entries include the stock standard name and lot number, the manufacturer name, the solvents used for preparation, the solvent lot number and manufacturer, the preparation steps, preparation date, expiration dates, preparer's initials, and a unique Pace identification number. This number is used in any applicable sample preparation or analysis logs so the standard can be traced back to the standard preparation record. This process ensures traceability back to the national standard.

5.1.4. Prepared standard or reagent containers include the Pace identification number, the standard or chemical name, and expiration date. The date of preparation, concentration with units, and the preparer's initials can be determined by tracing the standard or reagent ID through the standard log database.

5.1.5. Initial calibrations must be verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer, unless client-specific QAPP requirements state otherwise.

5.1.6. Reference standards and reference materials must be handled, stored, and maintained in a manner that prevents contamination and/or deterioration. Reference standards and reference materials must be stored per manufacturer's recommendations to avoid degradation and stored away from other materials that could contaminate them. Handle reference standards and reference materials with care to avoid evaporation, contamination, degradation or concentration of the material. If it is necessary to package and transport or ship any reference standard or reference material, consult with the manufacturer for proper packaging, labeling and shipping instructions to prevent damage, contamination or deterioration.

5.1.7. Additional information concerning the procurement of standards and reagent and their traceability can be found in the *Standard and Reagent Management and Traceability* SOP or its equivalent replacement.

5.2. General Analytical Instrument Calibration Procedures

5.2.1. Applicable instrumentation are calibrated or checked before use to ensure proper functioning and verify that laboratory, client and regulatory requirements are met. All calibrations are performed by, or under the supervision of, an experienced analyst at scheduled intervals against either certified standards traceable to recognized national standards or reference standards whose values have been statistically validated.

5.2.2. Calibration standards for each parameter are chosen to establish the linear range of the instrument and must bracket the concentrations of those parameters measured in the samples. The lowest

calibration standard is the lowest concentration for which quantitative data may be reported. Data reported below this level is considered to have less certainty and must be reported using appropriate data qualifiers or explained in a narrative. The highest calibration standard is the highest concentration for which quantitative data may be reported. Data reported above this level is considered to have less certainty and must be reported using appropriate data qualifiers or explained in the narrative.

5.2.3. Instrumentation or support equipment that cannot be calibrated to specification or is otherwise defective is clearly labeled as out-of-service until it has been repaired and tested to demonstrate it meets the laboratory's specifications. All repair and maintenance activities including service calls are documented in the maintenance log. Equipment sent off-site for calibration testing is packed and transported to prevent breakage and is in accordance with the vendor's recommendations.

5.2.4. In the event that recalibration of a piece of test equipment indicates the equipment may have been malfunctioning during the course of sample analysis, an investigation is performed. The results of the investigation along with a summary of the information reviewed are documented and maintained by the quality manager. Customers must be notified within 30 days after the data investigation is completed and the impact to final results is assessed. This allows for sufficient investigation and review of documentation to determine the impact on the analytical results. Instrumentation found to be consistently out of calibration is either repaired and positively verified or taken out of service and replaced.

5.2.5. Raw data records are retained to document equipment performance. Sufficient raw data is retained to reconstruct the instrument calibration and explicitly connect the continuing calibration verification to the initial calibration.

5.2.6. Please reference the *Calibration Procedures* SOP or its equivalent replacement and SOPs for specific methods for more detailed calibration information.

5.3. Support Equipment Calibration and Verification Procedures

5.3.1. All support equipment is calibrated or verified at least annually using NIST traceable references over the entire range of use, as applicable. The results of calibrations or verifications must be within the specifications required or the equipment will be removed from service until brought back into control. Additional information regarding calibration and maintenance of support equipment can be found in the *Support Equipment* SOP or its equivalent replacement.

5.3.2. On each day of use, balances, ovens, refrigerators, incubators, freezers and water baths are checked in the expected range of use with NIST traceable references in order to ensure the equipment meets laboratory specifications. These checks are documented appropriately.

5.3.3. **Analytical Balances**

5.3.3.1. Each analytical balance is calibrated or verified annually by a qualified service technician. The calibration of each balance is verified each day of use with weights traceable to NIST bracketing the range of use. Working calibration weights are ASTM Class 1 or other class weights that have been calibrated against a reference weight set that is re-certified every 5 years, at a minimum, by the manufacturer or other qualified vendor, against a NIST traceable reference. If balances are calibrated by an external vendor, verification of their weights must be available upon request. All information pertaining to balance maintenance and calibration is recorded on the balance's monitoring log and/or is maintained on file in the local Quality department.

5.3.4. **Thermometers**

5.3.4.1. Certified, or reference, thermometers are maintained for checking calibration of working thermometers. Reference thermometers are provided with NIST traceability for initial calibration and are re-certified every 3 years, at a minimum by the manufacturer or other qualified vendor with equipment directly traceable to NIST.

5.3.4.2. Working thermometers and temperature sensors that are electronic, digital or mechanical are verified against the reference thermometer annually, or more frequently if required by program, regulation or client, according to established metrology procedures. Working thermometers that are liquid-in-glass are verified against the reference thermometer annually according to established metrology procedures. Alternatively, working thermometers may be replaced with new thermometers in lieu of verification against the reference thermometer or may be verified by the manufacturer or other qualified vendor. Each working thermometer is individually numbered and assigned a correction factor, when applicable, based on comparison with the NIST reference source. In addition, working thermometers are visually inspected by laboratory personnel prior to use and when temperatures are documented.

5.3.4.3. Laboratory thermometer inventory and calibration data are maintained in the local Quality department.

5.3.5. **pH/Electrometers**

5.3.5.1. The meter is calibrated before use each day, at a minimum, using fresh buffer solutions.

5.3.5.2. The pH electrode is inspected daily and cleaned, filled or replaced as needed.

5.3.6. **Spectrophotometers**

5.3.6.1. During use, spectrophotometer performance is checked at established frequencies in analysis sequences against initial calibration verification (ICV) and continuing calibration verification (CCV) standards.

5.3.7. **Mechanical Volumetric Dispensing Devices**

5.3.7.1. Mechanical volumetric dispensing devices including bottle top dispensers dispensing critical volumes used to determine quantitative results, pipettes, and burettes, excluding Class A volumetric glassware, are checked for accuracy on a quarterly basis, at a minimum.

5.4. Instrument/Equipment Maintenance

5.4.1. The objectives of the Pace Analytical maintenance program are twofold: to establish a system of instrument care that maintains instrumentation and equipment at required levels of calibration and sensitivity, and to minimize loss of productivity due to repairs.

5.4.2. Department managers are responsible for providing technical leadership to evaluate new equipment, solve equipment problems, and coordinate instrument repair and maintenance. Analysts have the primary responsibility to perform routine maintenance.

5.4.3. To minimize downtime and interruption of analytical work, preventative maintenance may routinely performed on each analytical instrument. Up-to-date instructions on the use and maintenance of equipment are available to staff in the department where the equipment is used.

5.4.4. Department managers are responsible for maintaining an adequate inventory of spare parts required to minimize equipment downtime. This inventory includes parts and supplies that are subject to frequent failure, have limited lifetimes, or cannot be obtained in a timely manner should a failure occur.

5.4.5. All major equipment and instrumentation items are uniquely identified to allow for traceability. Equipment/instrumentation is, unless otherwise stated, identified as a system and not as individual pieces. The laboratory maintains equipment records that include the following:

- The name of the equipment and its software
- The manufacturer's name, type, and serial number
- Approximate date received and date placed into service
- Current location in the laboratory
- Copy of any manufacturer's manuals or instructions, if available
- Dates and results of calibrations and next scheduled calibration (as applicable)
- Details of past maintenance activities, both routine and non-routine
- Details of any damage, modification or major repairs

5.4.6. All instrument maintenance is documented in maintenance logbooks that are assigned to each particular instrument or system.

5.4.7. The maintenance log entry must include a summary of the problem encountered, the maintenance performed, and an indication that the instrument has been returned to an in-control status. In addition, each entry must include the initials of the analyst making the entry, the dates the maintenance actions were performed, and the date the entry was made in the maintenance logbook, if different from the date(s) of the maintenance.

5.4.8. Any equipment that has been subjected to overloading or mishandling, or that gives suspect results, or has been shown to be defective, is taken out of service and clearly identified. The equipment shall not be used to analyze customer samples until it has been repaired and shown to perform satisfactorily. In the event of instrumentation failure, to avoid hold time issues, the lab may subcontract the necessary samples to another Pace lab or to an outside subcontract lab if possible.

5.5. General Handling, Storage, Maintenance and Transport of Equipment

5.5.1. All support, measurement, and reference equipment must be handled, stored, and maintained in a manner that prevents contamination and/or deterioration. Balances, refrigerators, freezers, incubators, ovens, and hot blocks should be kept clean and free from debris inside and outside. Reference thermometers and reference weight sets must be controlled by the Quality Department, kept in pristine condition and inspected before each use. Working thermometers, weight sets, mechanical pipettes, and bottle top dispensers should be kept clean, inspected for damage before use, and handled properly. When it is necessary to package and transport or ship any support, measurement, or reference equipment to an external vendor for repair, maintenance, calibration, or certification, consult with the external vendor for proper packing, labeling and shipping to prevent damage, contamination, or deterioration.

6.0. CONTROL OF DATA

Analytical results processing, verification, and reporting are procedures employed that result in the delivery of defensible data. These processes include, but are not limited to, calculation of raw data into final concentration values, review of results for accuracy, evaluation of quality control criteria and assembly of technical reports for delivery to the data user.

All analytical data undergo a documented multi-tier review process prior to being reported to the customer. This section describes procedures used for translating raw analytical data into accurate final sample reports as well as Pace data storage policies.

When analytical data or field data is generated, it is documented appropriately. The resulting logbooks and other laboratory records are kept in accordance with each facility's SOP for documentation storage and archival. The laboratory must ensure that there are sufficient redundant copies of electronic data so that no data is lost due to unforeseen computer issues

6.1. Primary Data Review

6.1.1. The primary analyst is responsible for initial data reduction and data review. This includes confirming compliance with required methodology, verifying calculations, evaluating quality control data, noting observations or non-conformances in logbooks or as footnotes or narratives, and uploading analytical results into the LIMS. Data review checklists, either hardcopy or electronic, are used to document the primary data review process. The primary analyst must be clearly identified in all applicable logbooks, spreadsheets, LIMS fields, and data review checklists.

6.1.2. The primary analyst compiles the initial data for secondary data review. This compilation must include sufficient documentation for secondary data review.

6.1.3. Additional information regarding data review procedures can be found in the *Data Review Process* SOP or its equivalent replacement, as well as in the *Manual Integration* SOP or its equivalent replacement.

6.2. Secondary Data Review

6.2.1. Secondary data review is the process of examining data and accepting or rejecting it based on pre-defined criteria. This review step is designed to ensure that reported data are free from calculation and transcription errors, that quality control parameters are evaluated, and that any non-conformances are properly documented.

6.2.2. The completed data from the primary analyst is sent to a designated qualified secondary data reviewer, which must be someone other than the primary analyst. The secondary data reviewer provides an independent technical assessment of the data package and technical review for accuracy according to methods employed and laboratory protocols. This assessment involves a quality control review for use of the proper methodology and detection limits, compliance to quality control protocol and criteria, presence and completeness of required deliverables, and accuracy of calculations, data quantitation and applicable data qualifiers. The reviewer validates the data entered into the LIMS and documents review and approval of manual integrations. Data review checklists, either hardcopy or electronic, are used to document the secondary data review process.

6.2.3. Additional information regarding data review procedures can be found in the *Data Review Process* SOP or its equivalent replacement, as well as in the *Manual Integration* SOP or its equivalent replacement.

6.3. Data Reporting

6.3.1. Data for each analytical fraction pertaining to a particular Pace project number are released in the LIMS upon validation for assembly into the final report. Anomalies encountered during technical and QC reviews are included in data qualifiers on the final report or in a separate case narrative if there is potential for data to be impacted.

6.3.2. Final reports are prepared according to the level of reporting required by the customer and can be transmitted to the customer via hardcopy or electronic deliverable. A standard Pace final report consists of the following components:

6.3.2.1. A title which designates the report as "Report of Laboratory Analysis";

6.3.2.2. Name and address of laboratory and/or subcontractor laboratories, if used;

6.3.2.3. Phone number and name of laboratory contact to whom questions can be referred;

6.3.2.4. A unique identification number for the report. The pages of the report are numbered and a total number of pages is indicated;

6.3.2.5. Name and address of customer and name of project;

6.3.2.6. Unique laboratory identification of samples analyzed as well as customer sample IDs;

6.3.2.7. Date and time of sample collection, sample receipt and sample analysis;

6.3.2.8. Identification of the test methods used;

6.3.2.9. Qualifiers to the analytical data, if applicable;

6.3.2.10. Identification of whether results are reported on a dry-weight or wet-weight basis;

6.3.2.11. Reporting limits;

6.3.2.12. Final results or measurements;

6.3.2.13. A signature and title, electronic or otherwise, of person accepting responsibility for the content of the report;

6.3.2.14. Date report was issued;

6.3.2.15. A statement clarifying that the results of the report relate only to the samples tested or to the samples as they were received by the laboratory;

6.3.2.16. A statement indicating that the report must not be reproduced except in full, without the written approval of the laboratory;

6.3.3. Any changes made to a final report shall be designated as "Revised" or equivalent wording. The laboratory must keep sufficient archived records of all laboratory reports and revisions. For higher levels of data deliverables, a copy of all supporting raw data is sent to the customer along with a final report of results. Pace will provide electronic data deliverables (EDD) as required by contracts or upon customer request.

6.3.4. Customer data that requires transmission by telephone, telex, facsimile or other electronic means undergoes appropriate steps to preserve confidentiality.

6.3.5. The following positions are the only approved signatories for Pace final reports:

- Senior General Manager
- General Manager
- Quality Manager

- Client Services Manager
- Project Manager
- Project Coordinator

6.3.6. Additional information regarding final reports and data deliverables can be found in the *Final Report and Data Deliverable Contents* SOP or its equivalent replacement.

6.4. Data Security

6.4.1. All data including electronic files, logbooks, extraction/digestion/distillation worksheets, calculations, project files and reports, and any other information used to produce the technical report are maintained secured and retrievable by the Pace facility.

6.5. Data Archiving

6.5.1. All records compiled by Pace are archived in a suitable, limited-access environment to prevent loss, damage, or deterioration by fire, flood, vermin, theft, and/or environmental deterioration. Records are retained for a minimum of five years unless superseded by federal, state, contractual, and/or accreditation requirements. TNI-related records will be made readily available to accrediting authorities. Access to archived data is controlled by the Quality Department.

6.5.2. Records that are computer-generated have either a hard copy or electronic backup copy. Hardware and software necessary for the retrieval of electronic data is maintained with the applicable records. Archived electronic records are stored protected against electronic and/or magnetic sources.

6.5.3. In the event of a change in ownership, accountability or liability, reports of analyses performed pertaining to accreditation will be maintained per the purchase agreement. In the event of bankruptcy, laboratory reports and/or records will be transferred to the customer and/or the appropriate regulatory entity upon request.

6.6. Data Disposal

6.6.1. Data that has been archived for the facility's required storage time may be disposed of in a secure manner by shredding, returning to customer, or utilizing some other means that does not jeopardize data confidentiality. Records of data disposal will be archived for a minimum of five years unless superseded by federal, contractual, and/or accreditation requirements. Data disposal includes any preliminary or final reports, raw analytical data, logs or logbooks, and electronic files.

7.0. QUALITY SYSTEM AUDITS AND REVIEWS

7.1. Internal Audits

7.1.1. Responsibilities

7.1.1.1. The SQM/QM is responsible for managing, assigning and/or conducting internal audits in accordance with a predetermined schedule and procedure. Since internal audits represent an independent assessment of laboratory functions, the auditor must be independent from laboratory operations to ensure objectivity. 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 SQM/QM evaluates audit observations and verifies the completion of corrective actions. In addition, a periodic corporate audit will be conducted. The corporate audits will focus on the effectiveness of the Quality System as outlined in this manual but may also include other quality programs applicable to an individual laboratory.

7.1.1.2. Additional information can be found in the *Internal and External Audits* SOP or its equivalent replacement.

7.1.2. Scope and Frequency of Internal Audits

7.1.2.1. The complete internal audit process consists of the following four sections, at a minimum:

- Raw Data Review audits- conducted according to a schedule per local SQM/QM. A certain number of these data review audits may be conducted per quarter to accomplish this yearly schedule;
- Quality System audits- considered the traditional internal audit function and includes analyst interviews to help determine whether practice matches method requirements and SOP language;
- Final Report reviews;
- Corrective Action Effectiveness Follow-up

7.1.2.2. Internal systems audits are conducted annually at a minimum. The scope of these audits includes evaluation of specific analytical departments or a specific quality related system as applied throughout the laboratory.

7.1.2.3. Where the identification of non-conformities or departures cast doubt on the laboratory's compliance with its own policies and procedures, the lab must ensure that the appropriate areas of activity are audited as soon as possible.

7.1.2.4. Certain projects may require an internal audit to ensure laboratory conformance to site work plans, sampling and analysis plans, QAPPs, etc.

7.1.2.5. The laboratory, as part of their overall internal audit program, ensures that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Discovery and reporting of potential data integrity issues are handled in a confidential manner. All investigations that result in findings of inappropriate activity are fully documented, including the source of the problem, the samples and customers affected the impact on the data, the corrective actions taken by the laboratory, and identification of final reports that were re-issued. Customers must be notified within 30 days after the data investigation is completed and the impact to final results is assessed.

7.1.3. Internal Audit Reports and Corrective Action Plans

7.1.3.1. A full description of the audit, including the identification of the operation audited, the date(s) on which the audit was conducted, the specific systems examined, and the observations noted are summarized in an internal audit report. The Quality Department auditor writes and issues the internal audit report identifying which audit observations are deficiencies that require corrective action.

7.1.3.2. When audit findings cast doubt on the effectiveness of the operations or on the correctness of validity of the laboratory's environmental test results, the laboratory will take timely corrective action and notify the customer in writing within three business days, if investigations show that the laboratory results may have been affected.

7.1.3.3. Additional information can be found in the *Internal and External Audits* SOP or its equivalent replacement.

7.2. External Audits

7.2.1. Pace laboratories are audited routinely by regulatory agencies to maintain laboratory certifications and by customers to maintain appropriate specific protocols.

7.2.2. External audit teams review the laboratory to assess the effectiveness of quality systems. The SQM/QM host the external audit team and assist in facilitation of the audit process. After the audit, the external auditors will prepare a formalized audit report listing deficiencies observed and follow-up requirements for the laboratory. The laboratory staff and supervisors develop corrective action plans to address any deficiencies with the guidance of the SQM/QM, who provides a written response to the external audit team. The SQM/QM follows-up with the laboratory staff to ensure corrective actions are implemented and that the corrective action was effective.

7.3. Annual Managerial Review

7.3.1. A managerial review of Management and Quality Systems is performed on an annual basis at a minimum. This allows for assessing program effectiveness and introducing changes and/or improvements. Additional information can be found in the *Review of Laboratory Management Systems* SOP or its equivalent replacement.

7.3.2. The managerial review must include the following topics of discussion:

- Suitability of policies and procedures
- Reports from managerial personnel
- Internal audit results
- Corrective and preventive actions
- External assessment results
- Proficiency testing studies
- Sample capacity and scope of work changes
- Customer feedback, including complaints
- Recommendations for improvement,
- Other relevant factors, such as quality control activities, resources, staffing, and safety/waste.

7.3.3. This managerial review must be documented for future reference by the SQM/QM and copies of the report are distributed to management. Report must include goals, objectives, and action plans for the coming year. The laboratory shall ensure that actions identified during the review are carried out within an appropriate and agreed upon timeframe, whenever possible.

8.0. CORRECTIVE ACTION

Additional information can be found in the *Corrective and Preventive Actions* SOP or its equivalent replacement.

During the process of sample handling, preparation, and analysis, during review of quality control records, or during reviews of non-technical portions of the lab, certain occurrences may warrant corrective actions. These occurrences may take the form of analyst errors, deficiencies in quality control, method deviations, or other unusual circumstances. The Quality System of Pace provides systematic procedures for the documentation, monitoring, completion of corrective actions, and follow-up verification of the effectiveness of these corrective actions. This can be done using Pace's LabTrack system or other system that lists at a minimum, the deficiency by issue number, the deficiency source, responsible party, root cause, resolution, due date, and date resolved.

8.1. Corrective and Preventive Action Documentation

8.1.1. The following items are examples of sources of laboratory deviations or non-conformances that may warrant some form of documented corrective action:

- Internal Laboratory Non-Conformance Trends
- Proficiency Testing Sample Results
- Internal and External Audits
- Data or Records Review
- Client Complaints
- Client Inquiries
- Holding Time violations

8.1.2. Documentation of corrective actions may be in the form of a comment or footnote on the final report that explains the deficiency or it may be a more formal documentation. This depends on the extent of the deficiency, the impact on the data, and the method or customer requirements for documentation.

8.1.3. The person who discovers the deficiency or non-conformance initiates the corrective action documentation within LabTrack. The documentation must include the affected projects and sample numbers, the name of the applicable Project Manager, the customer name, and any other pertinent information. The person initiating the corrective action documentation must also list the known causes of the deficiency or non-conformance as well as any corrective/preventative actions that they have taken. Preventive actions must be taken in order to prevent or minimize the occurrence of the situation.

8.1.4. **Root Cause Analysis**: Laboratory personnel and management staff will start a root cause analysis by going through an investigative process. During this process, the following general steps must be taken into account: defining the non-conformance, assigning responsibilities, determining if the condition is significant, and investigating the root cause of the nonconformance. General non-conformance investigative techniques follow the path of the sample through the process looking at each individual step in detail. The root cause must be documented within LabTrack.

8.1.5. Based on the determined root cause(s), the lab implements applicable corrective actions and verifies their effectiveness. In the event that analytical testing or results do not conform to documented laboratory policies or procedures Project Management will notify the customer of the situation and will advise of any affect to data quality, if applicable.

8.2. Corrective Action Completion

8.2.1. Internal Laboratory Non-Conformance Trends

8.2.1.1. There are several types of non-conformance trends that may occur in the laboratory that would require the initiation of a corrective action report. Laboratories may choose to initiate a corrective action for all instances of one or more of these categories; however, the intent is that each of these would be handled according to its severity; one time instances could be handled with a footnote or qualifier whereas a systemic problem with any of these categories may require an official corrective action process. These categories, as defined in the Corrective Action SOP are as follows:

- Login error
- Preparation Error
- Contamination
- Calibration Failure
- LCS Failure
- Calculation error
- Laboratory accident
- Instrument Failure
- Final Reporting/Data Entry error

8.2.2. PE/PT Sample Results

8.2.2.1. Any PT result assessed as "not acceptable" requires an investigation and applicable corrective actions. The operational staff is made aware of the PT failures and they are responsible for reviewing the applicable raw data and calibrations and list possible causes for error. The SQM/QM reviews their findings and initiates a replacement PT sample if required. Replacement PT results must be monitored by the SQM/QM and reported to the applicable regulatory authorities.

8.2.2.2. Additional information, such as requirements regarding time frames for reporting failures to states, makeup PTs, and notifications of investigations, can be found in the *Proficiency Testing Program* SOP or its equivalent replacement.

8.2.3. Internal and External Audits

8.2.3.1. The SQM/QM or designee is responsible for documenting all audit findings and their corrective actions. This documentation must include the initial finding, the persons responsible for the corrective action, the due date for responding to the auditing body, the root cause of the finding, and the corrective actions needed for resolution. The SQM/QM or designee is also responsible for providing any back-up documentation used to demonstrate that a corrective action has been completed.

8.2.4. Data Review

8.2.4.1. In the course of performing primary and secondary review of data or in the case of raw data review, errors may be found which require corrective actions. Any finding that affects the quality of the data requires some form of corrective action, which may include revising and re-issuing of final reports.

8.2.5. Client Complaints

8.2.5.1. Project Managers are responsible for issuing corrective action requests, when warranted, for customer complaints. As with other corrective actions, the appropriate analyst or supervisor begin an investigation to determine possible causes and corrective actions. After potential corrective actions have been determined, the Project Manager reviews the corrective action to ensure all customer needs or concerns are being adequately addressed.

8.2.6. Client Inquiries

8.2.6.1. When an error on the customer's final report is discovered, the Project Manager is responsible for initiating a formal corrective action form that describes the failure (e.g., incorrect analysis reported, reporting units are incorrect, or reporting limits do not meet objectives). The Project Manager is also responsible for revising the final report if necessary and submitting it to the customer.

8.2.7. Holding Time Violations

8.2.7.1. In the event that a holding time has been exceeded due to laboratory error, the analyst or supervisor must complete formal corrective action. The Project Manager and the SQM/QM must be made aware of all holding time violations due to laboratory error.

8.2.7.2. The Project Manager must contact the customer in order that appropriate decisions are made regarding the out-of-hold sample and the ultimate resolution is then documented and included in the customer project file.

9.0. GLOSSARY

The source of some of the definitions is indicated previous to the actual definition (e.g., TNI, DoD).

Terms and Definitions	
3P Program	The Pace continuous improvement program that focuses on Process, Productivity, and Performance. Best Practices are identified that can be used by all Pace labs.
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.
Accreditation Body (AB)	TNI- The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.
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	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	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.
Analytical Method	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.
Annual (or Annually)	Defined by Pace as every 12 months ± 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).
Atomic Absorption Spectrometer	Instrument used to measure concentration in metals samples.
Atomization	A process in which a sample is converted to free atoms.
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. 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 - 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).
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	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.
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: % Completeness = (Valid Data Points/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.
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	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	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	Action taken to eliminate a detected non-conformity.
Corrective Action	The action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence. 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.
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	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	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.
Detection Limit (DL)	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)	Deuterated compounds used as surrogates for GC/MS 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	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	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 (absorbed material) from an absorbent 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	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.
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: • 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	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	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 space 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.
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).
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.
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.
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)	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.
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.
Internal Standard	TNI - 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 (C6H14) 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)	The entirety of an electronic data system (including hardware and software) that collects, analyzes, stores, and archives electronic records and documents.
LabTrack	Database used by Pace to store and track corrective actions and other laboratory issues.
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.
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.
Linear Dynamic Range	Concentration range where the instrument provides a linear response.
Liquid chromatography/ tandem mass spectrometry (LC/MS/MS)	Instrumentation that combines the physical separation techniques of liquid chromatography with the mass analysis capabilities of mass spectrometry.
Lot	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.
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.
May	EPA – The word "may" is used to provide guidance on aspects of the method that are useful but not essential.
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).
Measurement Uncertainty	An estimate of the error in a measurement often stated as a range of values that contain the true value within a certain confidence level. 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.
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 – β, 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 Pace 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.
Must	EPA – The word "must" is used to indicate aspects of the method that are considered essential to its performance, based on sound analytical practices.
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.

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.
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	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 - A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control activities.
Quantitation Range	The range of values (concentrations) in a calibration curve between the LOQ and the highest 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	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	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)	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. 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.
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.
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	EPA – The word "shall" is used to indicate aspects of the method that are considered essential to its performance, based on sound analytical practices.

Should	EPA – The word "should" is used to provide guidance on aspects of the method that are useful but not essential.
Signal-to-Noise Ratio (S/N)	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.
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	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	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	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	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.

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	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	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).

10.0. REFERENCES

10.1. "Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act." Federal Register, 40 CFR Part 136, most current version.

10.2. "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods." SW-846.

10.3. "Methods for Chemical Analysis of Water and Wastes", EPA 600-4-79-020, 1979 Revised 1983, U.S. EPA.

10.4. U.S. EPA Contract Laboratory Program Statement of Work for Organic Analysis.

10.5. U.S. EPA Contract Laboratory Program Statement of Work for Inorganic Analysis.

10.6. "Standard Methods for the Examination of Water and Wastewater." Current Edition APHA-AWWA-WPCF.

10.7. "Annual Book of ASTM Standards", Section 4: Construction, Volume 04.04: Soil and Rock; Building Stones, American Society of Testing and Materials.

10.8. "Annual Book of ASTM Standards", Section 11: Water and Environmental Technology, American Society of Testing and Materials.

10.9. "NIOSH Manual of Analytical Methods", U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, most current version.

10.10. "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).

10.11. Quality Assurance of Chemical Measurements, Taylor, John K.; Lewis Publishers, Inc. 1987.

10.12. Methods for Non-conventional Pesticides Chemicals Analysis of Industrial and Municipal Wastewater, Test Methods, EPA-440/1-83/079C.

10.13. Environmental Measurements Laboratory (EML) Procedures Manual, HASL-300, US DOE, February, 1992.

10.14. Requirements for Quality Control of Analytical Data, HAZWRAP, DOE/HWP-65/R1, July, 1990.

10.15. Requirements for Quality Control of Analytical Data for the Environmental Restoration Program, Martin Marietta, ES/ER/TM-16, December, 1992.

10.16. Quality Assurance Manual for Industrial Hygiene Chemistry, AIHA, most current version.

10.17. National Environmental Laboratory Accreditation Conference (NELAC) Standard- most current version.

10.18. ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories- most current version.

10.19. Department of Defense Quality Systems Manual (QSM), most current version.

10.20. TNI (The NELAC Institute) Standard- 2003 and 2009.

10.21. UCMR Laboratory Approval Requirements and Information Document, most current version.

10.22. US EPA Drinking Water Manual, most current version.

11.0. REVISIONS

The Pace Corporate Environmental Quality Office files an electronic version of a Microsoft Word document with tracked changes detailing all revisions made to previous versions of the Quality Assurance Manual. This document is available upon request. All current revisions are summarized in the table below.

Document Number	Reason for Change	Date
Quality Assurance Manual 19.0	General: made administrative edits that do not affect the policies or procedures within the document (including revising company name to Pace Analytical Services, LLC). Cover page: removed corporate approval signature lines and revised document control format. Table of Contents: added Attachment VII – Pace COC Old Section 3: moved to other sections of the QAM as applicable and deleted entire section (All section references below reflect the new section numbers). Section 1.1.2: replaced with section 3.1.1. Sections 1.3, 1.4, 1.11: removed extraneous language. Sections 1.5: added language from old section 1.6. Section 1.6: revised anonymous reporting information. Section 1.8: removed job descriptions for non-applicable personnel. Section 1.8.4: added tasks to QM job description. Section 1.8.8: added tasks to PM job description. Section 1.11.1: added keyless entry using key fobs detail. Section 2: rearranged existing sections. Section 2.4: reworded to match existing Sample Acceptance policy document. Section 2.6.3.2: added some detail regarding temperature monitoring corrective action. Section 2.6.5.1: added by-products of USDA soils. Section 3.2.2: added basic evaluation criteria. Section 3.4.3: added MS and Dup as optional alternative to MS/MSD. Section 3.5.2: added basic evaluation criteria. Section 3.9.1: added that RL may be based on calibration standard. Section 3.14: added new instrumentation as requiring validation. Section 4: in general, for each QC type, removed language regarding frequency and corrective actions and referenced lab-specific SOPs. Section 5: in general, removed extraneous language and Management of Change section. Section 5.1, 5.2: reorganized into Primary and Secondary Review sections and removed extraneous language. Section 5.3.2: specified types of support equipment to be monitored daily. Section 5.3.3.1: specified “working” weights. Section 5.3.4.2: added temperature sensors and added alternatives to annual in-house verification. Section 5.3.5: added pH electrode inspection/maintenance. Section 6: removed extraneous language including Quarterly Report section. Section 8.2.3.1: added “or designee”. Section 9 (glossary): revised and added definitions based on 2016 TNI Standard. Added “may, must, shall and should” based on SW-846 definition. Section 10: Added EPA DW Manual and revised references as applicable. Attachment III: updated corporate organizational chart. Old Attachment IV: removed floor plan attachment. Old Attachment VII: removed COC (available in SOPs). Indy added back in.	22Mar2017
Quality Assurance Manual 19.1	Throughout the document, references to SOP numbers were removed leaving only SOP titles. Section 1.8.9: added for Project Coordinator position. Section 2.4.3: changed “drinking water” to “drinking water compliance” for clarity. Section 2.6.4.1: clarified hazardous sample labeling. Section 3.8.1: updated the 40 CFR Part 136 reference. Section 3.12.1: removed language that limits the use of 3 sig figs. Section 5.1.6: added section to generally cover handling, storage, and transport of reference	14Jun2018

Document Number	Reason for Change	Date
	standards and reference materials. Section 5.2: removed details and added reference to Calibration Procedures SOP. Section 5.3.4: updated to reflect quarterly digital/mechanical thermometer calibration. Section 5.5: added section to generally cover handling, storage, maintenance and transport of measurement equipment. Section 6.3.1: clarified data review anomalies will be qualified or narrated. Section 6.3.2.1: updated to include the actual name of the final report. Section 8.2.2.1: added "calculation error" as a possible type of non-conformance. Glossary: updated definition of Deuterated Monitoring Compounds, removed DoD references, and updated the definition of Reporting Limit (RL). Attachment II: updated Attachment III: updated Attachment VI: updated Attachment V: updated Attachment VI: updated	
ENV-MAN-IND1-0001-rev.01 ENV-MAN-GRAP-0001-rev.01	Removed cover page and headers for use in Master Control. Table of Contents: added Grand Rapids address to header. Section 5.3.4.2: revised verification timeframe for thermometers to apply to both labs. Section 5.3.7: added clarification of the term critical volume. Attachment IIB: added Grand Rapids organizational chart. Attachment IV: updated and added Grand Rapids equipment. Attachment VI: updated and added Grand Rapids certifications. Attachment VII: updated to current form. Attachment VIII: added OIA 1677 and corrected soil holding time for OP Pest by 8141.	18Apr2019

ATTACHMENT I- QUALITY CONTROL CALCULATIONS

PERCENT RECOVERY (%REC)

$$\%REC = \frac{(MSConc - SampleConc)}{TrueValue} * 100$$

NOTE: The SampleConc is zero (0) for the LCS and Surrogate Calculations

PERCENT DIFFERENCE (%D)

$$\%D = \frac{MeasuredValue - TrueValue}{TrueValue} * 100$$

where:
TrueValue = Amount spiked (can also be the $\overline{CF}$ or $\overline{RF}$ of the ICAL Standards)
Measured Value = Amount measured (can also be the CF or RF of the CCV)

PERCENT DRIFT

$$\%Drift = \frac{CalculatedConcentration - TheoreticalConcentration}{TheoreticalConcentrtion} * 100$$

RELATIVE PERCENT DIFFERENCE (RPD)

$$RPD = \frac{|(R1 - R2)|}{(R1 + R2)/2} * 100$$

where:
R1 = Result Sample 1
R2 = Result Sample 2

CORRELATION COEFFICIENT (R)

$$CorrCoeff = \frac{\sum_{i=1}^{N} W_i * (X_i - \overline{X}) * (Y_i - \overline{Y})}{\sqrt{\left(\sum_{i=1}^{N} W_i * (X_i - \overline{X})^2\right) * \left(\sum_{i=1}^{N} W_i * (Y_i - \overline{Y})^2\right)}}$$

With:	N	Number of standard samples involved in the calibration
	i	Index for standard samples
	Wi	Weight factor of the standard sample no. i
	Xi	X-value of the standard sample no. i
	X(bar)	Average value of all x-values
	Yi	Y-value of the standard sample no. i
	Y(bar)	Average value of all y-values

ATTACHMENT I- QUALITY CONTROL CALCULATIONS (CONTINUED)

STANDARD DEVIATION (S)

$$S = \sqrt{\sum_{i=1}^{n} \frac{(X_i - \overline{X})^2}{(n-1)}}$$

where:
n = number of data points
X_i = individual data point
$\overline{X}$ = average of all data points

AVERAGE ($\overline{X}$)

$$\overline{X} = \frac{\sum_{n=1}^{i} X_i}{n}$$

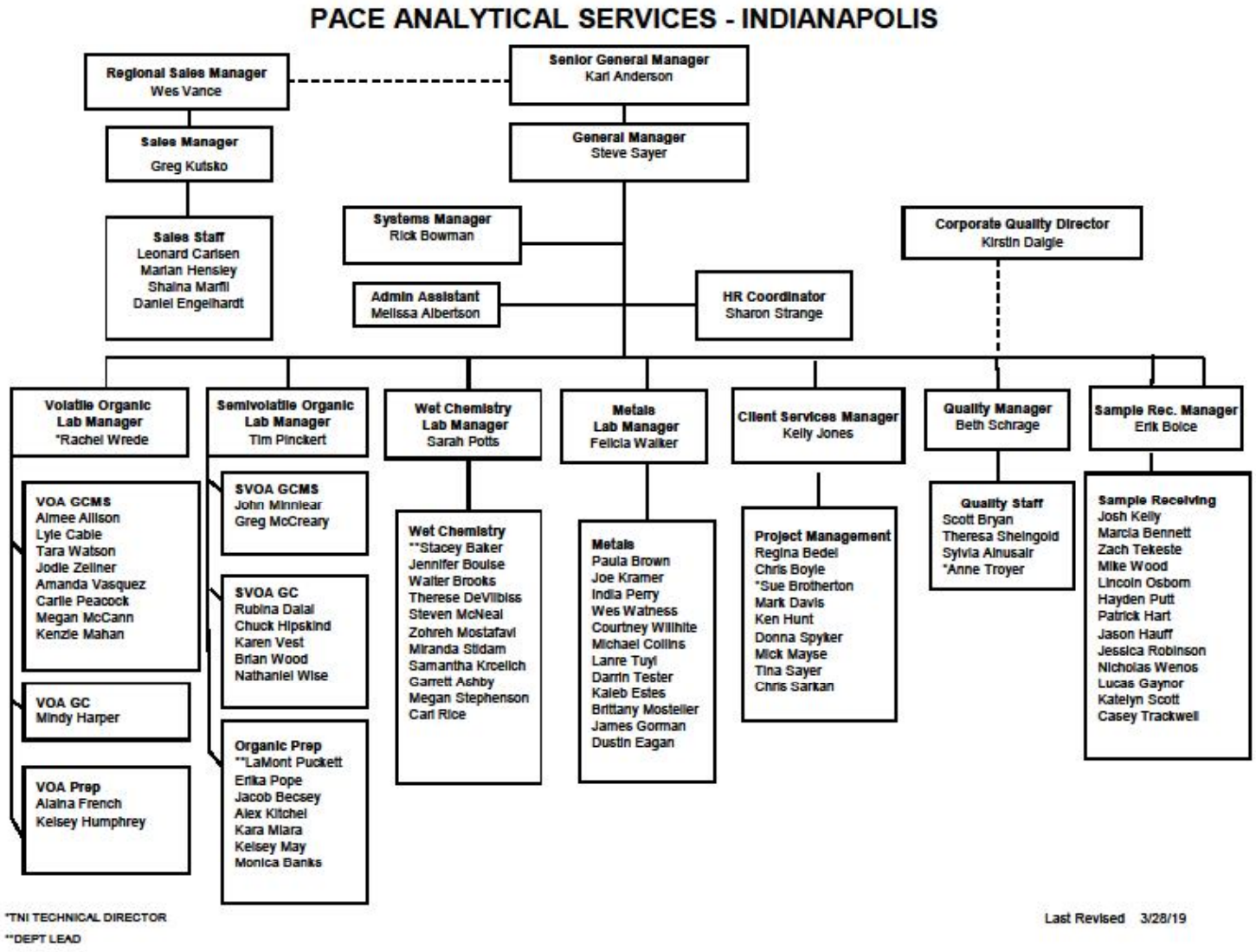
where:
n = number of data points
X_i = individual data point

RELATIVE STANDARD DEVIATION (RSD)

$$RSD = \frac{S}{\overline{X}} * 100$$

where:
S = Standard Deviation of the data points
$\overline{X}$ = average of all data points

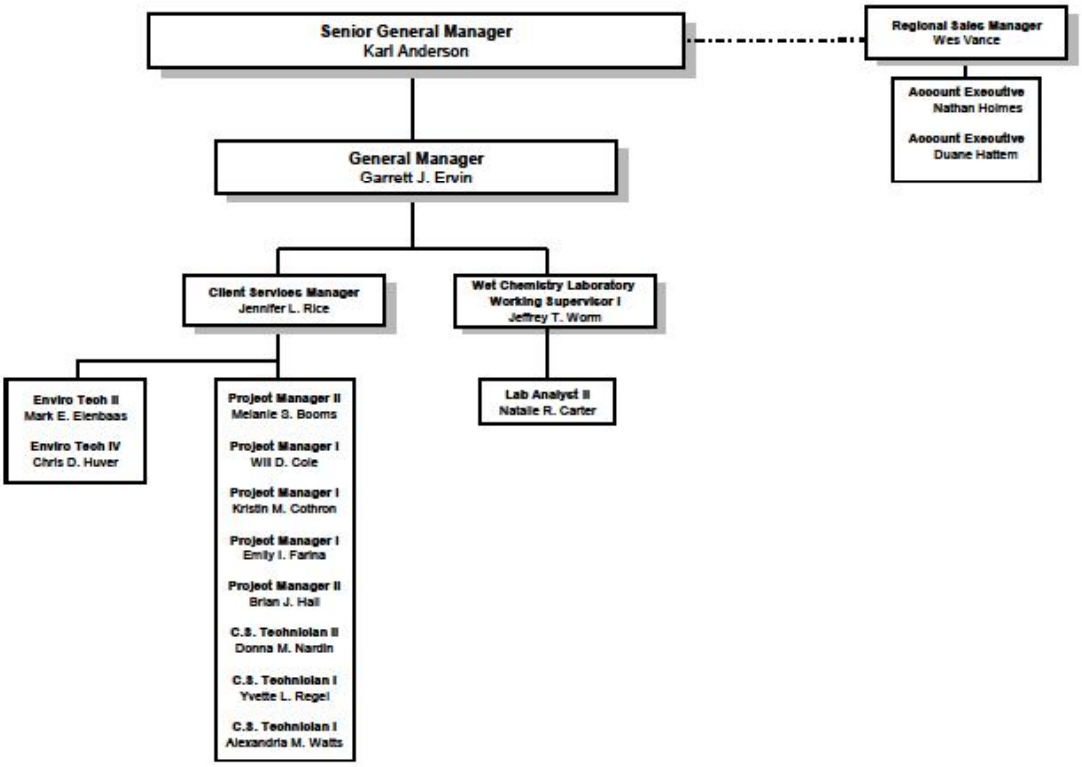
ATTACHMENT IIA- LABORATORY ORGANIZATIONAL CHARTS (CURRENT AS OF ISSUE DATE)



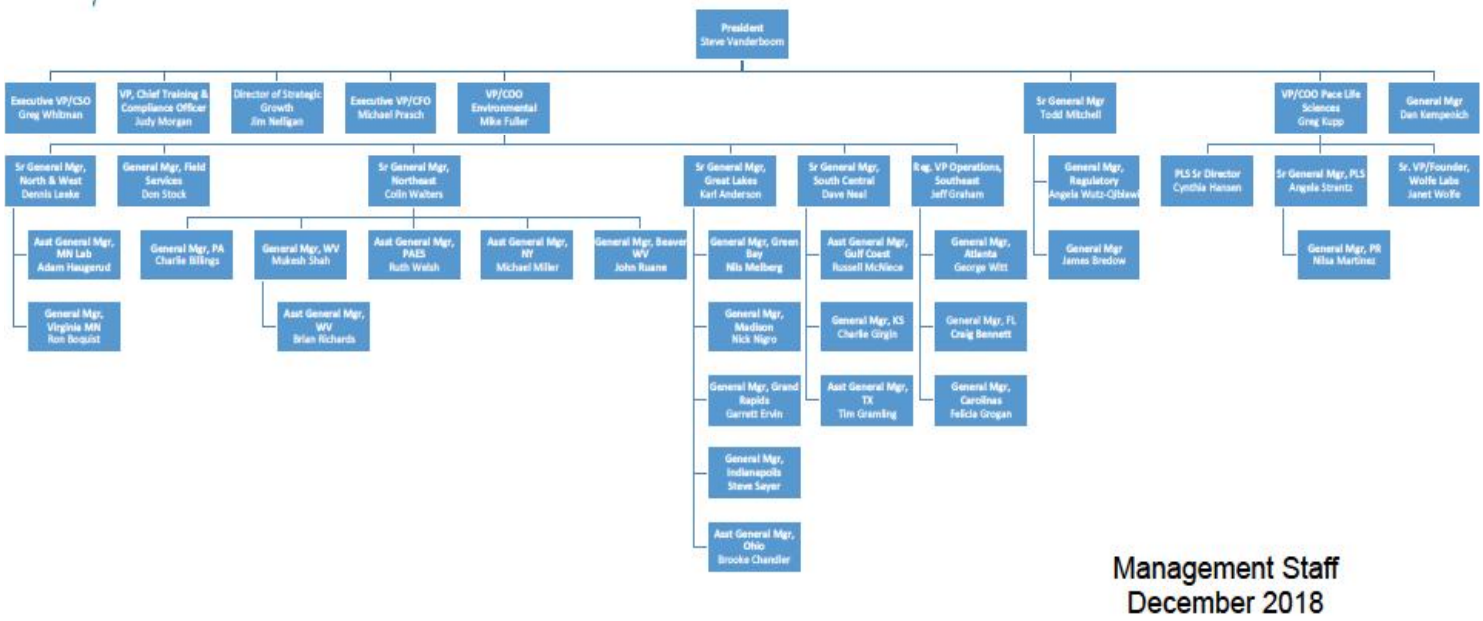
ATTACHMENT IIB- LABORATORY ORGANIZATIONAL CHARTS (CURRENT AS OF ISSUE DATE)

Pace Analytical

Pace Analytical Services, LLC. Grand Rapids, MI Service Center
January 2019



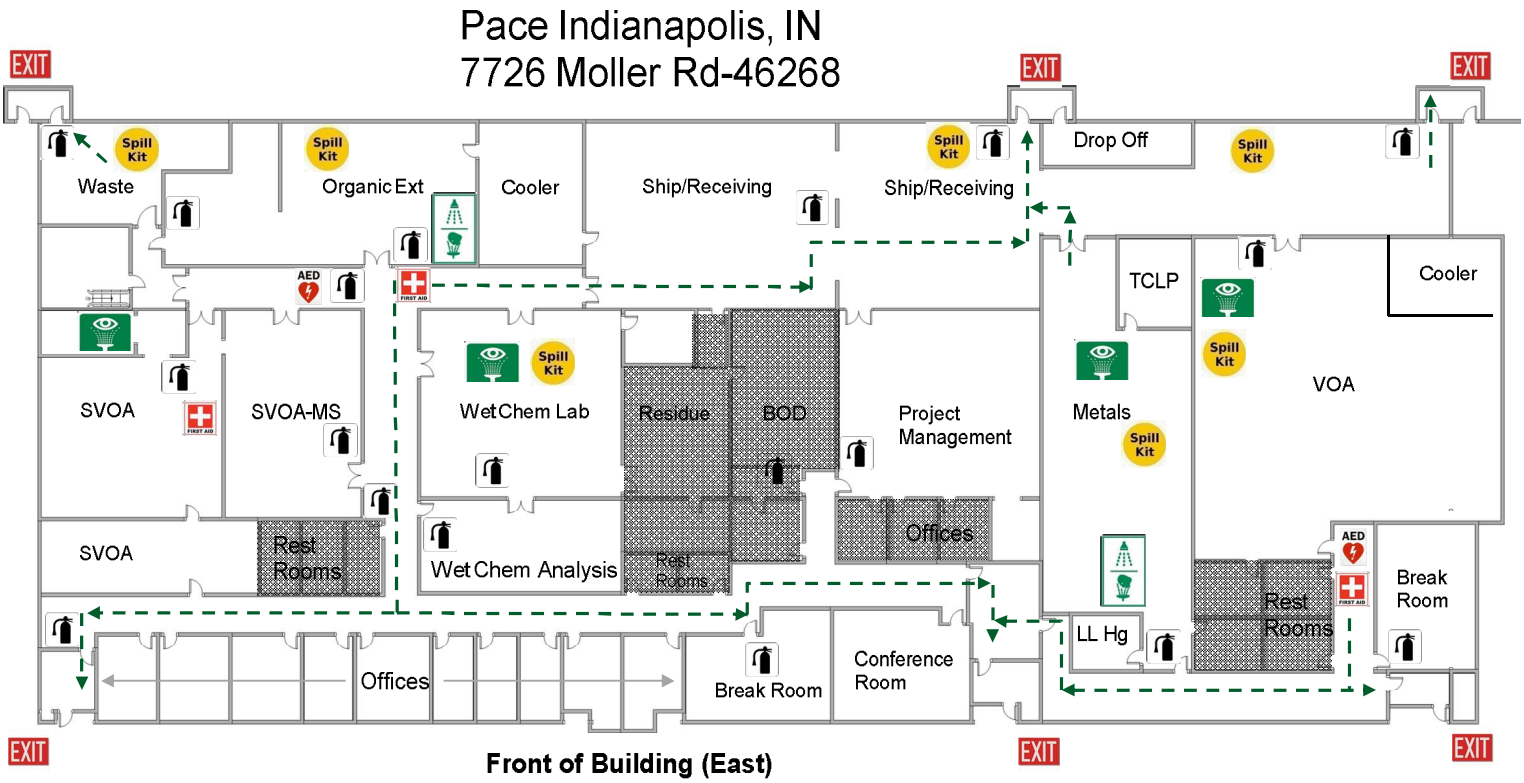
ATTACHMENT III- CORPORATE ORGANIZATIONAL CHART (CURRENT AS OF ISSUE DATE)



ATTACHMENT IV- EQUIPMENT LIST (CURRENT AS OF ISSUE DATE)

Pace Analytical - Indianapolis Equipment/Instrumentation List						
INSTRUMENT	MANUFACTURER	MODEL NUMBER	DETECTOR	AUTOSAMPLER	SERVICE ANALYSIS	YEAR
GC/MS	Agilent	6890	MS 5973	Centurion W/S	8260/624 VOC	2003
GC/MS	Agilent	6890	MS 5973	Centurion	8260/624/524.2 VOC	2007
GC/MS	Agilent	6890	MS 5973	Centurion W/S	8260/624 VOC	2003
GC/MS	Agilent	6850N	MS 5975	Centurion	8260/624/524.2 VOC	2007
GC/MS	Agilent	6890	MS 5973	Centurion W/S	8260/624 VOC	2004
GC/MS	Agilent	6850N	MS 5975	Centurion	8260/624 VOC	2010
GC/MS	Agilent	6890	MS 5973	Archon	8260/624 VOC	2010
GC/MS	Agilent	6890N	MS 5975	Centurion	8260/624/524.2 VOC	2010
GC/MS	Hewlett-Packard	6890	MS 5973	7683	8270 PAH SIM	2000
GC/MS (2)	Agilent	7890	MS 5975	7683	8270/625 BNA	2008
GC/MS (2)	Agilent	6890	MS 5975	7683	8270 PAH SIM	2009
GC/MS (3)	Agilent	6890	MS 5973	7683	8270/625 BNA	2008
GC/MS	Agilent	7890	MS 5975	7683	8270 PAH SIM	2009
GC/MS (2)	Hewlett-Packard	5890	MS 5971	7673	Solvent Screen	2007
GC/MS	Agilent	7890B	MS 5977	7693	8270/PAH SIM	2017
GC/MS	Agilent	7890B	MS 5977	7693	8270/PAH SIM	2018
Gas Chromatograph	Agilent	6890	FID	7683	8015 Alcohols	2006
Gas Chromatograph	Hewlett-Packard	6890	FID	6890	8015 Glycols	2008
Gas Chromatograph	Agilent	7890A	FID	7693	8015 DRO/ERO	2009
Gas Chromatograph	Agilent	7890A	Dual ECD	7693	8082/608 PCBs/8011 EDB/DBCP	2009/2013
Gas Chromatograph	Hewlett-Packard	5890	FID	6890	Benzene	2006
Gas Chromatograph	Hewlett-Packard	5890	FID	8100	8015 GRO	2011
Gas Chromatograph	Hewlett-Packard	5890	FID	EST LGX50	RSK175 Dissolved gases	2006
Gas Chromatograph	Agilent	6890N	FID	Archon	8015 GRO	2008
Gas Chromatograph	Agilent	6890	Dual NPD	7683	Pesticides	2008
Gas Chromatograph (2)	Agilent	6890	Dual ECD	7683	PCBs	2008
Gas Chromatograph	Hewlett-Packard	6890	Dual ECD	7683	Herbicides	2008
Gas Chromatograph	Agilent	7890	Dual ECD	7693	Pesticides	2010
Microwave Extractors (2)	CEM	230/60	n/a	n/a	soil extraction	2008/2011
Spe-Dex	Horizon	4790	n/a	n/a	1664A Oil & Grease	2008
Trace ICP (2)	Thermo Scientific	ICAP 6500	n/a	ASX520	6010/200.7 Metals	2008/2011
Trace ICP	Thermo Scientific	ICAP 6500	n/a	ESI SC-4 FAST	6010/200.7 Metals	2011
ICP/MS	Agilent	7700	n/a	ASX520	6020/200.8 Metals	2012
ICP/MS	Agilent	7800	n/a	ASX520	6020/200.8 Metals	2018
Mercury Analyzer	CETAC	M-6100	n/a	ASX520	7470/7471/245 Mercury	2012/2010
Mercury Analyzer	Teledyne Leeman	M-7600	n/a	ASX520	7470/7471/245 Mercury	2016
Low-Level Mercury Analyzer (2)	CETAC	M-8000	n/a	ASX520/ASX560	Low-Level Mercury	2015/2018
Auto Analyzer (2)	Lachat	Quick Chem	n/a	n/a	NO3,Cl,Phenol, NH3,TKN	2010/2012
Titrosampler	Metrohm	855	n/a	n/a	Alkalinity, Acidity	2014
Automated Flash Point	Tanaka	APM-8	n/a	n/a	flash point	2010
Spectrophotometer	Hach	DR5000	n/a	n/a	Sulfate,Cr6+,Fe2+, PO4	2007
Spectrophotometer	Thermo	AquaMatePlus	n/a	n/a	Surfactants, COD	2005
Turbidimeter	Hach	2100P	n/a	n/a	Turbidity	2006
pH/ISE Meter (2)	Accumet	AR25/XL25	n/a	n/a	pH, Fluoride, Redox	2003/2010
pH/ISE Meter	Thermo Orion Star	A214	n/a	n/a	pH, Fluoride, Redox	2013
Conductivity Meter	Oakton	CON 700	n/a	n/a	Conductivity	2016
Dissolved Oxygen/pH Meter	Hach	HQ440d	n/a	n/a	BOD, cBOD	2014
BOD Analyzer	Thermo	AutoEz	n/a	n/a	BOD, cBOD	2013
TOC Analyzer	Shimadzu	TOC-Vwp	n/a	n/a	TOC, DOC	2008
Discrete Analyzer	Smart Chem	200	n/a	n/a	Cyanide, Phosphorus	2006
Flow Analyzer	OIA	FS3100	n/a	n/a	Free and Available Cyanide	2018
Ion Chromatogram	Dionex	ICS2100	n/a	AS-AP	Cl-, F-, SO4-, Br-, NO3/NO2	2013
Pace Analytical - Grand Rapids Equipment/Instrumentation List						
pH/ISE Meter (2)	Accumet	AB150	n/a	n/a	pH	2017
BOD Meter and Probe	Hach	HQ40d	n/a	n/a	BOD, cBOD	2017
FIA Analyzer	OIA	FS-3100	n/a	n/a	Nitrate and Nitrite	2017
Spectrophotometer	Shimadzu	UV-1800	n/a	n/a	Cr6+,Fe2+, PO4, Color	2017
Turbidimeter	Hach	2100N	n/a	n/a	Turbidity	2017

ATTACHMENT V- LABORATORY FLOOR PLAN - INDIANAPOLIS (CURRENT AS OF ISSUE DATE)



= Automated External defibrillator

= First Aid Station

= Spill Kits

= Shower/Eyewash Combo

= Eyewash/Drench Hose Available

= ABC Extinguisher Location

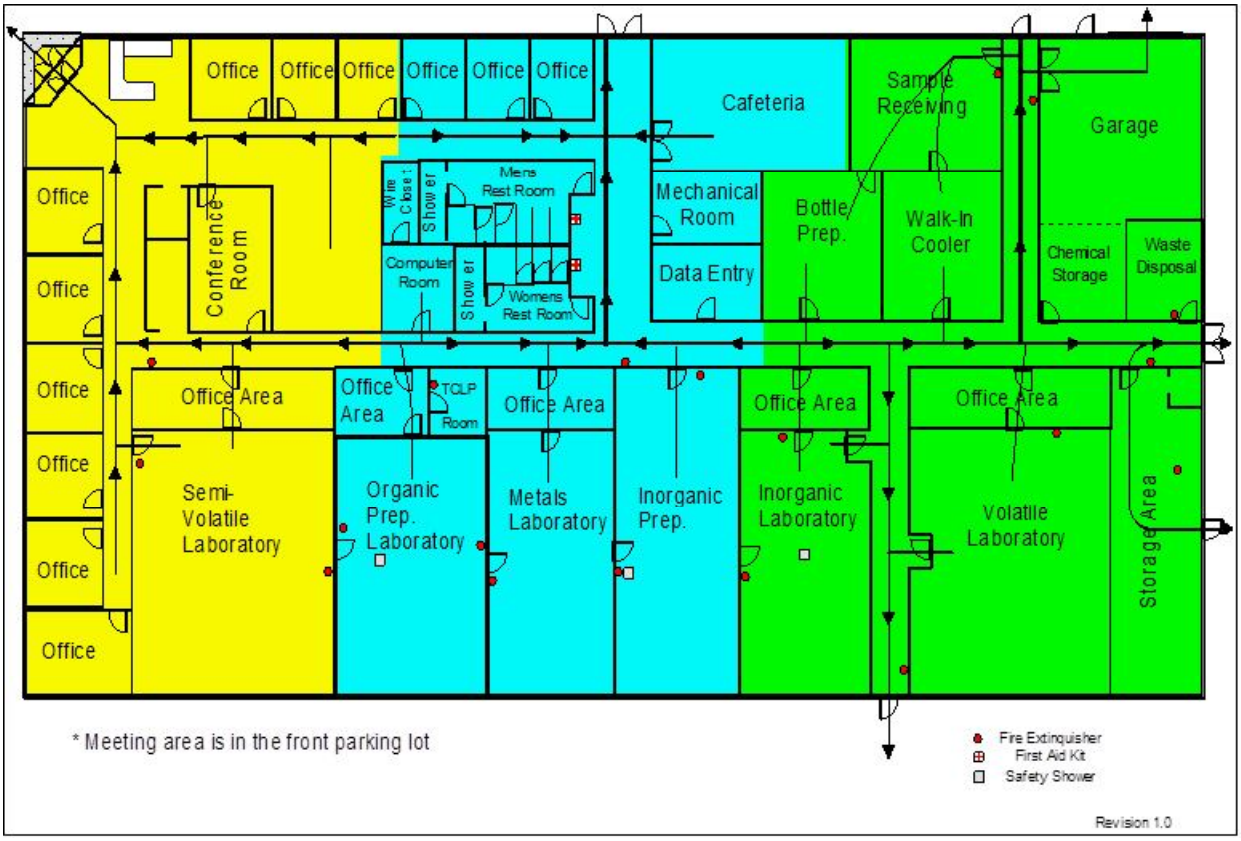
= Severe Weather Shelters

Fire Evacuation Meeting Place
(Front Parking lot. Greenway by road between main entrance and south entrance)

Effective:
3/26/18

ATTACHMENT VI- LABORATORY FLOOR PLAN – GRAND RAPIDS (CURRENT AS OF ISSUE DATE)

PACE GRAND RAPIDS
5560 Corporate Exchange Court SE



ATTACHMENT VII- LABORATORY CERTIFICATION LIST (CURRENT AS OF ISSUE DATE)

Pace Analytical Services, LLC

Indianapolis Laboratory Certifications

Accrediting Authority	Program Category	Accrediting Agency	Accreditation #	Expiration Date
Alaska	CSLAP	AK DEC	18-007	04/30/2019
Illinois (Secondary TNI)	Hazardous Waste	IL-EPA	200074	10/12/2019
Illinois (Secondary TNI)	Non-Potable Water	IL-EPA	200074	10/12/2019
Indiana	Drinking Water	ISDH	C-49-06	12/31/2021
Kansas (Primary TNI)	Hazardous Waste	KDHE	E-10177	04/30/2019
Kansas (Primary TNI)	Non-Potable Water	KDHE	E-10177	04/30/2019
Kentucky	UST	KDEP	80226	04/30/2019
Kentucky	Wastewater	KDEP	KY98019	12/31/2019
Michigan	Drinking Water	MDEQ	9050	12/31/2021
Ohio VAP	Hazardous Waste	OH-EPA	CL0065	01/10/2020
Ohio VAP	Non-Potable Water	OH-EPA	CL0065	01/10/2020
Oklahoma	Non-Potable Water	OK DEQ	9204	08/31/2019
Oklahoma	Solids	OK DEQ	9204	08/31/2019
Texas (Secondary TNI)	Non-Potable Water	TX CEQ	T104704355	01/31/2020
Texas (Secondary TNI)	Solid Chemical Mat.	TX CEQ	T104704355	01/31/2020
USDA	Compliance Agreement	USDA	IN-16-SL-FR-002	08/19/2019
USDA	Foreign Soil Permit	USDA	P330-16-00257	08/19/2019
West Virginia	Hazardous Waste	WV-DEP	330	10/31/2019
West Virginia	Non-Potable Water	WV-DEP	330	10/31/2019
Wisconsin	Non-Potable Water	WI DNR	999788130	08/31/2019
Wisconsin	Waste, Soil, Tissue	WI DNR	999788130	08/31/2019

Grand Rapids Laboratory Certifications

Accrediting Authority	Program Category	Accrediting Agency	Accreditation #	Expiration Date
Minnesota (Primary TNI)	Non-Potable Water	MDH	026-999-161	12/31/2019
Michigan	Drinking Water	MDEQ	0034	6/12/19

ATTACHMENT VIII- PACE CHAIN-OF-CUSTODY (CURRENT AS OF ISSUE DATE)

Pace Analytical

CHAIN-OF-CUSTODY Analytical Request Document

Chain-of-Custody is a LEGAL DOCUMENT - Complete all relevent fields

LAB USE ONLY- Affix Workorder/Login Label Here or List Pace Workorder Number or MTJL Log-in Number Here

ALL SHADED AREAS are for LAB USE ONLY

Company:	Billing Information:
Address:	
Report To:	Email To:
Copy To:	Site Collection Info/Address:
Customer Project Name/Number:	State: / County/City: Time Zone Collected: [ ]PT [ ]MT [ ]CT [ ]ET
Phone: Email:	Site/Facility ID #: Compliance Monitoring? [ ] Yes [ ] No
Collected By (print):	Purchase Order #: Quote #: DW PWS ID #: DW Location Code:
Collected By (signature):	Turnaround Date Required: Immediately Packed on Ice: [ ] Yes [ ] No
Sample Disposal: [ ] Dispose as appropriate [ ] Return [ ] Archive: _____ [ ] Hold: _____	Rush: [ ] Same Day [ ] Next Day [ ] 2 Day [ ] 3 Day [ ] 4 Day [ ] 5 Day (Expedite Charges Apply) Field Filtered (if applicable): [ ] Yes [ ] No Analysis: _____

Container Preservative Type **

Lab Project Manager:

** Preservative Types: (1) nitric acid, (2) sulfuric acid, (3) hydrochloric acid, (4) sodium hydroxide, (5) zinc acetate, (6) methanol, (7) sodium bisulfate, (8) sodium thiosulfate, (9) hexane, (A) ascorbic acid, (B) ammonium sulfate, (C) ammonium hydroxide, (D) TSP, (U) Unpreserved, (O) Other _____

Analyses

Lab Profile/Line:

Lab sample receipt checklist:

custody seals present/intact	Y N NA
custody signatures present	Y N NA
collector signature present	Y N NA
bottles intact	Y N NA
correct bottles	Y N NA
sufficient volume	Y N NA
samples received on ice	Y N NA
VOA - headspace Acceptable	Y N NA
USDA regulated soils	Y N NA
samples in holding time	Y N NA
residual chlorine present	Y N NA
Cl strips: _____	
sample pH Acceptable	Y N NA
pH strips: _____	
sulfide present	Y N NA
lead Acetate strips: _____	

LAB USE ONLY:
Lab sample # / comments:

* Matrix Codes (Insert in Matrix box below): Drinking Water (DW), Ground Water (GW), Wastewater (WW), Product (P), Soil/Solid (SL), Oil (OL), Wipe (WP), Air (AR), Tissue (TS), Bioassay (B), Vapor (V), Other (OT)

Customer Sample ID	Matrix *	Comp / Grab	Collected (or Composite Start) Date	Collected (or Composite Start) Time	Composite End Date	Composite End Time	Res Cl	# of Ctns

Customer Remarks / Special Conditions / Possible Hazards:

Type of Ice Used: Wet Blue Dry None

Packing Material Used:

Radchem sample(s) screened (<500 cpm): Y N NA

SHORT HOLDS PRESENT (<72 hours): Y N N/A

Lab Tracking #:

Samples received via: FEDEX UPS Client Courier Pace Courier

Lab Sample Temperature Info:
Temp Blank Received: Y N NA
Therm ID#: _____
Cooler 1 Temp Upon Receipt: _____oC
Cooler 1 Therm Corr. Factor: _____oC
Cooler 1 Corrected Temp: _____oC
Comments:

Trip Blank Received: Y N NA
HCL MeOH TSP Other

Non Conformance(s): YES / NO

Page: _____ of: _____

Relinquished by/Company: (Signature)	Date/Time:	Received by/Company: (Signature)	Date/Time:
Relinquished by/Company: (Signature)	Date/Time:	Received by/Company: (Signature)	Date/Time:
Relinquished by/Company: (Signature)	Date/Time:	Received by/Company: (Signature)	Date/Time:

MTJL LAB USE ONLY

Table #:
Acctnum:
Template:
Prelogin:
PM:
PB:

ATTACHMENT IX- METHOD HOLD TIME, CONTAINER AND PRESERVATION GUIDE (CURRENT AS OF ISSUE DATE)

THE HOLDING TIME INDICATED IN THE CHART BELOW IS THE MAXIMUM ALLOWABLE TIME FROM COLLECTION TO EXTRACTION AND/OR ANALYSIS PER THE ANALYTICAL METHOD. FOR METHODS THAT REQUIRE PROCESSING PRIOR TO ANALYSIS, THE HOLDING TIME IS DESIGNATED AS 'PREPARATION HOLDING TIME/ANALYSIS HOLDING TIME'.

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Acid Base Accounting	Sobek	Solid	Plastic/Glass	None	N/A
Acidity	SM2310B	Water	Plastic/Glass	$\leq 6^{o}C$	14 Days
Acid Volatile Sulfide	Draft EPA 1629	Solid	8oz Glass	$\leq 6^{o}C$	14 Days
Actinides	HASL-300	Water	Plastic/Glass	pH<2 HNO_3	180 Days
Actinides	HASL-300	Solid	Plastic/Glass	None	180 Days
Alkalinity	SM2320B/310.2	Water	Plastic/Glass (NY requires separate bottle filled to the exclusion of air)	$\leq 6^{o}C$	14 Days
Alkylated PAHs		Water	1L Amber Glass	$\leq 6^{o}C$; pH<2 1:1 HCl (optional)	14/40 Days preserved; 7/40 Days unpreserved
Alkylated PAHs		Solid	8oz Glass	$\leq 10^{o}C$	1 Year/40 Days
Anions (Br, Cl, F, NO_2, NO_3, o-Phos, SO_4, bromate, chlorite, chlorate)	300.0/300.1/SM4110B	Water	Plastic/Glass	$\leq 6^{o}C$; EDA if bromate or chlorite run	All analytes 28 days except: NO_2, NO_3, o-Phos (48 Hours); chlorite (immediately for 300.0; 14 Days for 300.1). NO_2/NO_3 combo 28 days.
Anions (Br, Cl, F, NO_2, NO_3, o-Phos, SO_4, bromate, chlorite, chlorate)	300.0	Solid	Plastic/Glass	$\leq 6^{o}C$	All analytes 28 days except: NO_2, NO_3, o-Phos (48 hours); chlorite (immediately). NO_2/NO_3 combo 28 days.
Anions (Br, Cl, F, NO_2, NO_3, o-Phos, SO_4	9056	Water/ Solid	Plastic/Glass	$\leq 6^{o}C$	48 hours

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Aromatic and Halogenated Volatiles (see note 1)	8021	Solid	5035 vial kit	See note 1	14 days
Aromatic and Halogenated Volatiles	602/8021	Water	40mL vials	pH<2 HCl; ≤ 6°C; $Na_2S_2O_3$ if Cl present	14 Days (7 Days for aromatics if unpreserved)
Asbestos	EPA 600/R-93/116	Solid	Plastic/Glass; bulk- 2" square; popcorn ceiling- 2tbsp; soil- 4oz	None (handling must be done in HEPA filtered fume hood; drying may be required)	N/A
Bacteria, Total Plate Count	SM9221D	Water	Plastic/WK	≤ 6°C; $Na_2S_2O_3$	24 Hours
Base/Neutrals and Acids	8270	Solid	8oz Glass	≤ 6°C	14/40 Days
Base/Neutrals and Acids	625/8270	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	7/40 Days
Base/Neutrals, Acids & Pesticides	525.2	Water	1L Amber Glass	pH<2 HCl; ≤ 6°C; Na sulfite if Cl present	14/30 Days
Biomarkers		Water	≤ 6°C; pH<2 1:1 HCl (optional)	14/40 Days preserved; 7/40 Days unpreserved	≤ 6°C; pH<2 1:1 HCl (optional)
Biomarkers		Solid	≤ 10°C	1 Year/40 Days	≤ 10°C
BOD/cBOD	SM5210B	Water	Plastic/Glass	≤ 6°C	48 hours
Boiling Range Distribution of Petroleum Fractions	ASTM D2887-98	Product	10mL glass vials	≤ 6°C	N/A
BTEX/Total Hydrocarbons	TO-3	Air	Summa Canister	None	28 Days
BTEX/Total Hydrocarbons	TO-3	Air	Tedlar Bag or equivalent	None	72 Hours
Carbamates	531.1	Water	Glass	$Na_2S_2O_3$, Monochloroacetic acid pH <3; ≤ 6°C	28 Days
Carbamates	8318	Water	Glass	Monochloroacetic acid pH 4-5; ≤ 6°C	7/40 Days
Carbamates	8318	Solid	Glass	≤ 6°C	7/40 Days
Carbon Specific Isoptope Analysis (CSIA)	AM24	Water	40mL clear VOA vial with TLS	≤ 6°C, trisodium phosphate or HCl	N/A
Cation/Anion Balance	SM1030E	Water	Plastic/Glass	None	None

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Cation Exchange	9081	Solid	8oz Glass	None	unknown
Cations (Ferrous Iron, Ferric Iron, Divalent Manganese)	7199 modified	Water	40mL clear VOA vials with mylar septum	≤ 6°C; HCl	48 Hours
Chloride	SM4500Cl-C,E	Water	Plastic/Glass	None	28 Days
Chlorinated Hydrocarbons in Vapor	AM4.02	Vapor	20cc vapor vial with flat septum	None	N/A
Chlorine, Residual	SM4500Cl-D,E,G/330.5/Hach 8167	Water	Plastic/Glass	None	15 minutes
Chlorophyll	SM10200H	Water	Opaque bottle or aluminum foil	≤ 6°C	48 Hours to filtration
COD	SM5220C, D/410.4/Hach 8000	Water	Plastic/Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Coliform, Fecal	SM9222D	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Coliform, Fecal	SM9222D	Solid	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	24 Hours
Coliform, Fecal	SM9221E	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Coliform, Fecal	SM9221E	Solid	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	24 Hours
Coliform, Total	SM9222B	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Coliform, Total	SM9221B	Solid	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Coliform, Total, Fecal and E. coli	Colilert/ Quanti-tray	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Coliform, Total and E. coli	SM9223B	Drinking Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	30 Hours
Color	SM2120B,E	Water	Covered Plastic/Acid Washed Amber Glass	≤ 6°C	48 Hours
Condensable Particulate Emissions	EPA 202	Air	Solutions	None	180 Days
Cyanide, Reactive	SW846 chap.7	Water	Plastic/Glass	None	28 Days
Cyanide, Reactive	SW846 chap.7	Solid	Plastic/Glass	None	28 Days
Cyanide, Total and Amenable	SM4500CN-A,B,C,D,E,G,I,N/9010/ 9012/335.4	Water	Plastic/Glass	pH≥12 NaOH; ≤ 6°C; ascorbic acid if Cl present	14 Days (24 Hours if sulfide present-applies to SM4500CN only)

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Cyanide, Available and Free	EPA OIA 1677-09	Water	250mL Amber Glass	pH 11-12 NaOH; ≤ 6°C	14 Days
Cyanide, Available and Free	9013A extraction / EPA OIA 1677-09	Solid	4oz Glass Jar	≤ 6°C	14/14 Days
Diesel Range Organics- Alaska DRO	AK102	Solid	8oz Glass	≤ 6°C	14/40 Days
Diesel Range Organics- Alaska DRO	AK102	Water	1L Glass	pH<2 HCl; ≤ 6°C	14/40 Days
Diesel Range Organics- TPH DRO	8015	Solid	8oz Glass Jar	≤ 6°C	14/40 Days
Diesel Range Organics- TPH DRO	8015	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	7/40 Days
Diesel Range Organics- TPH DRO	8015	Tissue	1L Amber Glass	≤ - 10°C	1 Year if frozen/40 Days
Diesel Range Organics- TPH DRO	TO-17	Air	Thermal desorption tubes via SKC Pocket Pumps or equivalent	≤ 6°C but above freezing	28 Days
Diesel Range Organics- NwTPH-Dx	Nw-TPH-Dx	Solid	8oz Glass Jar	≤ 6°C	14/40 Days
Diesel Range Organics- NwTPH-Dx	Nw-TPH-Dx	Water	1L Amber Glass	pH <2 HCl; ≤ 6°C	14/40 Days; 7 Days from collection to extraction if unpreserved
Diesel Range Organics- Wisconsin DRO	WI MOD DRO	Solid	Tared 4oz Glass Jar	≤ 6°C	10/47 Days
Diesel Range Organics- Wisconsin DRO	WI MOD DRO	Water	1L Amber Glass	≤ 6°C; pH <2 HCl	14/40 Days
Dioxins and Furans	1613B	Solid	8oz Glass	≤ 6°C	1 year
Dioxins and Furans	1613B	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	1 year
Dioxins and Furans	1613B	Fish/ Tissue	Aluminum foil	≤ 6°C	1 year
Dioxins and Furans	8290	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	30/45 Days
Dioxins and Furans	8290	Solid	8oz Glass	≤ 6°C	30/45 Days
Dioxins and Furans	8290	Fish/ Tissue	Not specified	< -10°C	30/45 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Dioxins and Furans	TO-9	Air	PUF	None	7/40 Days
Diquat/Paraquat	549.2	Water	Amber Plastic	≤ 6°C; $Na_2S_2O_3$	7/21 Days
EDB/DBCP (8011) EDB/DBCP/1,2,3-TCP (504.1)	504.1/8011	Water	40mL vials	≤ 6°C; $Na_2S_2O_3$ if Cl present	14 Days
Endothall	548.1	Water	Amber Glass	≤ 6°C; $Na_2S_2O_3$	7/14 Days
Enterococci	EPA 1600	Water	100mL Plastic	≤ 10°C	8 Hours
Enterococci	Enterolert	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Explosives	8330/8332	Water	1L Amber Glass	≤ 6°C	7/40 Days
Explosives	8330/8332	Solid	8oz Glass Jar	≤ 6°C	14/40 Days
Extractable Petroleum Hydrocarbons (aliphatic and aromatic)	NJ EPH	Water	1L Amber Glass	pH < 2 HCl; ≤ 6°C	14/40 Days
Extractable Petroleum Hydrocarbons (aliphatic and aromatic)	NJ EPH	Solid	4oz Glass Jar	≤ 6°C	14/40 Days
Extractable Petroleum Hydrocarbons (aliphatic and aromatic)	MA-EPH	Water	1L Amber Glass	pH<2 HCl; ≤ 6°C	14/40 Days
Extractable Petroleum Hydrocarbons (aliphatic and aromatic)	MA-EPH	Solid	4oz Glass Jar	≤ 6°C	7/40 Days
Fecal Streptococci	SM9230B	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Ferrous Iron	SN3500Fe-D; Hach 8146	Water	Glass	None	Immediate
Flashpoint/ Ignitability	1010	Liquid	Plastic/Glass	None	28 Days
Florida PRO	FL PRO DEP (11/1/95)	Liquid	Glass, PTFE lined cap	≤ 6°C; pH <2 H_2SO_4 or HCl	7/40 Days
Fluoride	SM4500Fl-C,D	Water	Plastic	None	28 Days
Gamma Emitting Radionuclides	901.1	Water	Plastic/Glass	pH<2 HNO_3	180 days
Gasoline Range Organics	8015	Water	40mL vials	pH<2 HCl	14 Days
Gasoline Range Organics	8015	Solid	5035 vial kit	See note 1	14 days
Gasoline Range Organics (C3-C10)	8260B modified	Water	40mL vials	≤ 6°C; HCl	14 Days
Gasoline Range Organics (C3-C10)	8260B modified	Solid	4oz Glass Jar	≤ 6°C	14 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Gasoline Range Organics- Alaska GRO	AK101	Solid	5035 vial kit	See 5035 note*	28 Days if GRO only (14 Days with BTEX)
Gasoline Range Organics- Alaska GRO	AK101	Water	40mL vials	pH<2 HCl; ≤ 6°C	14 Days
Gasoline Range Organics- NwTPH-Gx	Nw-TPH-Gx	Water	40mL vials	pH<2 HCl; ≤ 6°C	7 Days unpreserved; 14 Days preserved
Gasoline Range Organics- NwTPH-Gx	Nw-TPH-Gx	Solid	40mL vials	≤ 6°C; packed jars with no headspace	14 Days
Gasoline Range Organics- Wisconsin GRO	WI MOD GRO	Water	40mL vials	pH<2 HCl; ≤ 6°C	14 Days
Gasoline Range Organics- Wisconsin GRO	WI MOD GRO	Solid	40mL MeOH vials	≤ 6°C in MeOH	21 Days
Glyphosate	547	Water	Glass	≤ 6°C; $Na_2S_2O_3$	14 Days (18 Months frozen)
Grain Size	ASTM D422	Solid	Not specified	Ambient	N/A
Gross Alpha (NJ 48Hr Method)	NJAC 7:18-6	Water	Plastic/Glass	pH<2 HNO_3	48 Hrs
Gross Alpha and Gross Beta	9310/900.0	Water	Plastic/Glass	pH<2 HNO_3	180 Days
Gross Alpha and Gross Beta	9310	Solid	Glass	None	180 Days
Haloacetic Acids	552.1/552.2	Water	40mL Amber vials	NH_4Cl; ≤ 6°C	14/7 Days if extracts stored ≤ 6°C or 14/14 Days if extracts stored at ≤ -10°C
Hardness, Total ($CaCO_3$)	SM2340B,C/130.1	Water	Plastic/Glass	pH<2 HNO_3	180 Days
Heterotrophic Plate Count (SPC/HPC)	SM9215B	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Heterotrophic Plate Count (SPC/HPC)	SimPlate	Water	100mL Plastic	≤ 10°C; $Na_2S_2O_3$	8 Hours
Herbicides, Chlorinated	8151	Solid	8oz Glass Jar	≤ 6°C	14/40 Days
Herbicides, Chlorinated	8151	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	7/40 Days
Herbicides, Chlorinated	515.1/515.3	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	14/28 Days
Hexavalent Chromium	7196/218.6/ SM3500Cr-B, C	Water	Plastic/Glass	≤ 6°C	24 Hours (see note 4)
Hexavalent Chromium	218.6/SM3500Cr-B, C	Water	Plastic/Glass	Ammonium Buffer pH 9.3-9.7	28 Days (see note 4)
Hexavalent Chromium	218.6/218.7	Drinking Water	Plastic/Glass	Ammonium Buffer pH >8	14 Days (see note 4)

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Hexavalent Chromium	7196 (with 3060A)	Solid	Glass	≤ 6°C	30 Days from collection to extraction and 7 days from extraction to analysis
Hydrocarbons in Vapor	AM4.02	Vapor	20cc vapor vial with flat septum	None	N/A
Hydrogen by Bubble Strip	SM9/AM20GAx	Water	20cc vapor vial with stopper septum	None	14 Days
Hydrogen Halide and Halogen Emissions	EPA 26	Air	Solutions	None	6 Months
Ignitability of Solids	1030	Non-liquid Waste	Plastic/Glass	None	28 Days
Lead Emissions	EPA 12	Air	Filter/Solutions	None	6 Months
Light Hydrocarbons by Bubble Strip	SM9/AM20GAx	Water	20cc vapor vial with stopper septum	None	14 Days
Light Hydrocarbons in Vapor	AM20GAx	Vapor	20cc vapor vial with flat septum	None	14 Days
Lipids	Pace Lipids	Tissue	Plastic/Glass	≤ -10°C	1 Year if frozen
Mercury, Low-Level	1631E	Solid	Glass	None	28 Days
Mercury, Low-Level	1631E	Water	Fluoropolymer bottles (Glass if Hg is only analyte being tested)	12N HCl or BrCl	48 Hours for preservation or analysis; 28 Days to preservation if sample oxidized in bottle; 90 Days for analysis if preserved
Mercury, Low-Level	1631E	Tissue	Plastic/Glass	≤ - 10°C	28 Days if frozen
Mercury	7471	Solid	8oz Glass Jar	≤ 6°C	28 Days
Mercury	7470/245.1/245.2	Water	Plastic/Glass	pH<2 HNO_3	28 Days
Mercury	7471/245.6	Tissue	Plastic/Glass	≤ - 10°C	28 Days if frozen
Metals (GFAA)	7000/200.9	Water	Plastic/Glass	pH<2 HNO_3	180 Days
Metals (ICP)	NIOSH 7300A/7303	Air	Filters	None	180 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Metals (ICP/ICPMS)	6010/6020	Solid	8oz Glass Jar	None	180 Days
Metals (ICP/ICPMS)	6010/6020/200.7/200.8	Water	Plastic/Glass	pH<2 HNO_3	180 Days
Metals (ICP/ICPMS)	6020	Tissue	Plastic/Glass	≤ -10°C	180 Days if frozen
Methane, Ethane, Ethene	8015 modified	Water	40mL vials	HCl	14 Days
Methane, Ethane, Ethene	RSK-175; PM01/AM20GAx	Water	20mL vials	HCl; or trisodium phosphate or benzalkonium chloride and ≤ 6°C	14 Days; 7 Days unpreserved
Methane, Ethane, Ethene	EPA 3C	Air	Summa Canister	None	28 Days
Methane, Ethane, Ethene	EPA 3C	Air	Tedlar Bag or equivalent	None	5 Days
Methanol, Ethanol	8015 modified	Water	40mL vials	≤ 6°C	14 Days
Methanol, Ethanol	8015 modified	Solid	2oz Glass	≤ 6°C	14 Days
Methyl Mercury	1630	Water	Teflon/ fluoropolymer	Fresh water- 4mL/L HCl; Saline water- 2mL/L H_2SO_4 (must be preserved within 48 hours of collection)	6 months
Methyl Mercury	1630	Tissue	2-4oz glass jar	≤ 0°C	28 Days; ethylated distillate 48 hours
Nitrogen, Ammonia	SM4500NH3/350.1	Water	Plastic/Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Nitrogen, Total Kjeldahl (TKN)	351.2	Solid	Plastic/Glass	≤ 6°C	28 Days
Nitrogen, Total Kjeldahl (TKN)	SM4500-Norg/351.2	Water	Plastic/Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Nitrogen, Nitrate	SM4500-NO3/352.1	Water	Plastic/Glass	≤ 6°C	24 Hours preferred
Nitrogen, Nitrate & Nitrite combination	353.2	Solid	Plastic/Glass	≤ 6°C	28 Days
Nitrogen, Nitrate & Nitrite combination	SM4500-NO3/353.2	Water	Plastic/Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Nitrogen, Nitrite or Nitrate separately	SM4500-NO2/353.2	Water	Plastic/Glass	≤ 6°C	48 Hours
Nitrogen, Organic	SM4500-Norg/351.2	Water	Plastic/Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Non-Methane Organics	EPA 25C	Air	Summa Canister	None	28 Days
Non-Methane Organics	EPA 25C	Air	Tedlar Bag or equivalent	None	72 Hours

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Odor	SM2150B	Water	Glass	≤ 6°C	24 Hours
Oil and Grease/HEM	1664A/SM5520B/9070	Water	Glass	pH<2 H_2SO_4 or HCl; ≤ 6°C	28 Days
Oil and Grease/HEM	9071	Solid	Glass	≤ 6°C	28 Days
Oil Range Organics	8015	Solid	Glass	≤ 6°C	14/40 Days
Oil Range Organics	8015	Water	Glass	≤ 6°C	7/40 Days
Organic Matter	ASA 29-3.5.2	Solid	Plastic/Glass	None; samples air-dried and processed prior to analysis	N/A
Oxygen, Dissolved (Probe)	SM4500-O	Water	Glass	None	15 minutes
Oxygenates on Product (GCMS SIM)	1625 modified	Product	10mL glass vial	≤ 6°C	14 Days (7 Days from extraction)
PBDEs	1614	Water	1L Amber Glass	≤ 6°C	1 Year/1 Year
PBDEs	1614	Solid	Wide Mouth Jar	≤ 6°C	1 Year/1 Year
PBDEs	1614	Tissue	Aluminum Foil	≤ -10°C	1 Year/1 Year
PCBs and Pesticides, Organochlorine (OC)	TO-4/TO-10	Air	PUF	None	7/40 Days
PCBs and Pesticides, Organochlorine (OC)	608	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	Pest: 7/40 Days; PCB: 1 Year/1 Year
PCBs, Pesticides (OC), Herbicides	508.1	Water	Glass	Na2SO3; pH<2 HCl; ≤ 6°C	14/30 Days
PCBs, total as Decachlorobiphenyl	508A	Water	1L Glass, TFE lined cap	≤ 6°C	14/30 Days
Perchlorate	331	Water	Plastic/Glass	≥0-6°C, field filtered with headspace	28 Days
Permanent Gases (O2, N2, CO2)	RSK-175; PM01/AM20GAx	Water	40mL vials	benzalkonium chloride and ≤ 6°C	14 Days
Permanent Gases by Bubble Strip	SM9/AM20GAx	Water	20cc vapor vial with stopper septum	None	14 Days
Permanent Gases in Vapor	AM20GAx	Vapor	20cc vapor vial with flat septum	None	14 Days
Pesticides, Organochlorine (OC)	8081	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	7/40 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Pesticides, Organochlorine (OC)	8081	Solid	8oz Glass Jar	≤ 6°C	14/40 Days
Pesticides, Organochlorine (OC)	8081	Tissue	8oz Glass Jar	≤ -10°C	1 Year if frozen/40 Days
Pesticides, Organophosphorous (OP)	8141	Solid	8oz Glass Jar	≤ 6°C	7/40 Days
Pesticides, Organophosphorous (OP)	8141	Water	1L Amber Glass	pH 5-8 with NaOH or H_2SO_4; ≤ 6°C; $Na_2S_2O_3$ if Cl present	7/40 Days
PCBs (Aroclors)	8082	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	1 Year/1 Year
PCBs (Aroclors)	8082	Solid	8oz Glass Jar	≤ 6°C	1 Year/1 Year
PCBs (Aroclors)	8082	Tissue	Plastic/Glass	≤ -10°C	1 Year if frozen/1 Year
PCB Congeners	1668A	Water	1L Amber Glass	≤ 6°C but above freezing	1 Year/1 Year
PCB Congeners	1668A	Solid	4-8oz Glass Jar	≤ 6°C but above freezing	1 Year/1 Year
PCB Congeners	1668A	Tissue	4-8oz Glass Jar	≤ -10°C	1 Year/1 Year
Paint Filter Liquid Test	9095	Water	Plastic/Glass	None	N/A
Particle Size	ASA 15-5 modified	Solid	Plastic/Glass (100g sample)	None	N/A
Particulates	PM-10	Air	Filters	None	180 Days
Permanent Gases	EPA 3C	Air	Summa Canister	None	28 Days
Permanent Gases	EPA 3C	Air	Tedlar Bag or equivalent	None	5 Days
pH	SM4500H+B/9040	Water	Plastic/Glass	None	15 minutes
pH	9045	Solid	Plastic/Glass	None	7 Days
Phenol, Total	420.1/420.4/9065/9066	Water	Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Phosphorus, Orthophosphate	SM4500P/365.1/365.3	Water	Plastic	≤ 6°C	Filter within 15 minutes, Analyze within 48 Hours
Phosphorus, Total	SM4500P/ 365.1/365.3/365.4	Water	Plastic/Glass	pH<2 H_2SO_4; ≤ 6°C	28 Days
Phosphorus, Total	365.4	Solid	Plastic/Glass	≤ 6°C	28 Days
Polynuclear Aromatic Hydrocarbons (PAH)	TO-13	Air	PUF	None	7/40 Days
Polynuclear Aromatic Hydrocarbons (PAH)	TO-17	Air	Thermal desorption tubes via SKC Pocket Pumps or equivalent	≤ 6°C but above freezing	28 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Polynuclear Aromatic Hydrocarbons (PAH)	8270 SIM	Solid	8oz Glass Jar	≤ 6°C	14/40 Days
Polynuclear Aromatic Hydrocarbons (PAH)	8270 SIM	Water	1L Amber Glass	≤ 6°C; $Na_2S_2O_3$ if Cl present	7/40 Days
Polynuclear Aromatic Hydrocarbons (PAH)	8270 SIM	Tissue	Plastic/Glass	≤ -10°C	1 Year if frozen/40 Days
Purgeable Organic Halides (POX)	9021	Water	Glass; no headspace	≤ 6°C	14 Days
Radioactive Strontium	905.0	Water	Plastic/Glass	pH<2 HNO_3	180 days
Radium-226	903.0/903.1	Water	Plastic/Glass	pH<2 HNO_3	180 days
Radium-228 (see note 3)	9320/904.0	Water	Plastic/Glass	pH<2 HNO_3	180 days
Radium-228 (see note 3)	9320	Solid	Plastic/Glass		
Residual Range Organics- Alaska RRO	AK103	Solid	8oz Glass	≤ 6°C	14/40 Days
Saturated Hydrocarbons		Water	≤ 6°C; pH<2 1:1 HCl (optional)	14/40 Days preserved; 7/40 Days unpreserved	≤ 6°C; pH<2 1:1 HCl (optional)
Saturated Hydrocarbons		Solid	≤ 10°C	1 Year/40 Days	≤ 10°C
Silica, Dissolved	SM4500Si-D	Water	Plastic	≤ 6°C	28 Days
Solids, Settleable	SM2540F	Water	Glass	≤ 6°C	48 Hours
Solids, Total	SM2540B	Water	Plastic/Glass	≤ 6°C	7 Days
Solids, Total	SM2540G	Solid	Plastic/Glass	≤ 6°C	7 Days
Solids, Total (FOC, OM, Ash)	ASTM D2974	Solid	Plastic/Glass	≤ 6°C	7 Days
Solids, Total Dissolved	SM2540C	Water	Plastic/Glass	≤ 6°C	7 Days
Solids, Total Suspended	SM2540D/USGS I-3765-85	Water	Plastic/Glass	≤ 6°C	7 Days
Solids, Total Volatile	160.4/SM2540E	Water	Plastic/Glass	≤ 6°C	7 Days
Solids, Total Volatile	160.4	Solid	Plastic/Glass	≤ 6°C	7 Days
Specific Conductance	SM2510B/9050/120.1	Water	Plastic/Glass	≤ 6°C	28 Days
Stationary Source Dioxins and Furans	EPA 23	Air	XAD Trap	None	30/45 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Stationary Source Mercury	EPA 101	Air	Filters	None	180 Days, 28 Days for Hg
Stationary Source Metals	EPA 29	Air	Filters	None	180 Days, 28 Days for Hg
Stationary Source PM10	EPA 201A	Air	Filters	None	180 Days
Stationary Source Particulates	EPA 5	Air	Filter/Solutions	None	180 Days
Sulfate	SM4500SO4/9036/ 9038/375.2/ASTM D516	Water	Plastic/Glass	$\leq 6^{o}C$	28 Days
Sulfide, Reactive	SW-846 Chap.7	Water	Plastic/Glass	None	28 Days
Sulfide, Reactive	SW-846 Chap.7	Solid	Plastic/Glass	None	28 Days
Sulfide, Total	SM4500S/9030	Water	Plastic/Glass	pH>9 NaOH; ZnOAc; $\leq 6^{o}C$	7 Days
Sulfite	SM4500SO3	Water	Plastic/Glass	None	15 minutes
Surfactants (MBAS)	SM5540C	Water	Plastic/Glass	$\leq 6^{o}C$	48 Hours
Total Alpha Radium (see note 3)	9315/903.0	Water	Plastic/Glass	pH<2 HNO_3	180 days
Total Alpha Radium (see note 3)	9315	Solid	Plastic/Glass	None	180 days
Total Inorganic Carbon (TIC)	PM01/AM20GAx	Water	40mL VOA vial with mylar septum	$\leq 6^{o}C$	14 Days
Total Organic Carbon (TOC)	SM5310B,C,D/9060	Water	Glass	pH<2 H_2SO_4 or HCl; $\leq 6^{o}C$	28 Days
Total Organic Carbon (TOC)	9060/Walkley Black/Lloyd Kahn	Solid	Glass	$\leq 6^{o}C$	14 Days
Total Organic Halogen (TOX)	SM5320/9020	Water	Glass; no headspace	$\leq 6^{o}C$	14 Days
Total Petroleum Hydrocarbons (aliphatic and aromatic)	TPHCWG	Water	40mL vials	pH<2 HCl, no headspace, $\leq 6^{o}C$	7 Days
Total Petroleum Hydrocarbons (aliphatic and aromatic)	TPHCWG	Solid	Glass	$\leq 6^{o}C$	14 days
Tritium	906.0	Water	Glass	None	180 days
Turbidity	SM2130B/180.1	Water	Plastic/Glass	$\leq 6^{o}C$	48 Hours
Total Uranium	908.0/ASTM D5174-97	Water	Plastic/Glass	pH<2 HNO_3	180 days
UCMR Metals	200.8	Water	Plastic or glass	pH<2 HNO_3	28 Days
UCMR Hexavalent Chromium	218.7	Water	HDPE or propylene	Na_2CO_3/$NaHCO_3$/ $(NH_4)_2SO_4$; pH>8	14 Days
UCMR Chlorate	300.1	Water	Plastic or glass	EDA	28 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
UCMR Perfluorinated Compounds	537	Water	Polypropylene	Trizma	14 Days
UCMR 1, 4 Dioxane	522	Water	Glass	Na_2SO_3, $NaHSO_4$; pH<4	28 Days
UV254	SM5910B	Water	Glass	≤ 6°C	48 Hours
Vermiculite	EPA 600/R-93/116	Solid	Plastic/Glass	None (handling must be done in HEPA filtered fume hood; drying may be required)	N/A
Volatile Fatty Acids	AM21G	Water	40mL clear VOA vials	≤ 6°C	21 Days
Volatile Fatty Acids (low level)	AM23G	Water	40mL clear VOA vials	≤ 6°C with benzalkonium chloride	14 Days
Volatile Petroleum Hydrocarbons (aliphatic and aromatic)	MA-VPH	Water	40mL vials	pH<2 HCl; ≤ 6°C	14 Days preserved
Volatile Petroleum Hydrocarbons (aliphatic and aromatic)	MA-VPH	Solid	4-8oz Glass Jar	≤ 6°C; packed jars with no headspace	7/28 Days
Volatiles	TO-14	Air	Summa Canister	None	28 Days
Volatiles	TO-14	Air	Tedlar Bag or equivalent	None	72 Hours
Volatiles	TO-15	Air	Summa Canister or Tedlar Bag	None	28 Days
Volatiles	TO-17	Air	Thermal desorption tubes via SKC Pocket Pumps or equivalent	≤ 6°C but above freezing	28 Days
Volatiles	TO-18/8260	Air	Tedlar Bag or equivalent	None	72 Hours
Volatiles	8260	Solid	5035 vial kit	See note 1 (analyze for acrolein and acrylonitrile per local requirements)	14 days
Volatiles	8260	Water	40mL vials	pH<2 HCl; ≤ 6°C; $Na_2S_2O_3$ if Cl present (preserve and analyze for acrolein and acrylonitrile per local requirements)	14 Days

Parameter	Method	Matrix	Container	Preservative	Max Hold Time
Volatiles	8260	Conc. Waste	5035 vial kit or 40mL vials	≤ 6°C	14 Days
Volatiles	624	Water	40mL vials	pH<2 HCl; ≤ 6°C; $Na_2S_2O_3$ if Cl present (or unpreserved if run within 7 days of collection) (preserve and analyze for acrolein and acrylonitrile per local requirements)	14 Days (7 Days for aromatics if unpreserved)
Volatiles (see note 2)	524.2	Water	40mL vials (in duplicate)	pH<2 HCl; ≤ 6°C; Ascorbic acid or $Na_2S_2O_3$ if Cl present[2]	14 Days
Whole Oil	ASTM D3328 (prep); ASTM D5739	Product	10mL glass vials	≤ 6°C	N/A

[1] **5035/5035A Note**: 5035 vial kit typically contains 2 vials water, preserved by freezing **or**, 2 vials aqueous sodium bisulfate preserved at 4°C, **and** one vial methanol preserved at ≤6°C **and** one container of unpreserved sample stored at ≤6°C.

[2] Method 524.2 lists ascorbic acid as the preservative when residual chlorine is suspected, unless gases or Table 7 compounds are NOT compounds of interest and then sodium thiosulfate is the preservative recommended.

[3] Methods 9315 and 9320 both state that if samples are unpreserved, the samples should be brought to the lab within 5 days of collection, preserved in the lab, and then allowed to sit for a minimum of 16 hours before sample preparation/analysis.

[4] The holding time for hexavalent chromium may be extended by the addition of the ammonium buffer listed in EPA 218.6 per the 2012 EPA Method Update Rule. Although Method 218.6 stipulates a different pH range (9.0 to 9.5) for buffering, this method requirement was modified in the Method Update Rule to a pH range of 9.3 to 9.7. For non-potable waters, adjust the pH of the sample to 9.3 to 9.7 during collection with the method required ammonium sulfate buffer to extend the holding time to 28 days. For potable waters, addition of the buffer during collection will extend the holding time for 14 days per EPA 218.7 and the EPA UCMR program.

APPENDIX B-3:
Electronica Data Deliverable

120WaterAudit Electronic Data Deliverable (EDD)

Overview

The EDD is used to report sampling results to the 120WaterAudit Platform.

Results Submission

How to Submit your Results	Results Submitter Name	Results submitter Email
Complete the Results Tab of this ED and send the EDD to results@120wateraudit.com		

Submission Reference

Account ID
School Code
School Name
School ID
Sampling Event Name
Sampling Event ID

Results Fields Key

Column Alias	Description	Notes
SAMPLE_CODE	Sample Code	
SAMPLE_TYPE	Sample Type	Initial - initial draw Flush - 30 seconds
FIXTURE_CODE	Fixture Code	Optional
FIXTURE_TYPE	Fixture Type	Optional
FIXTURE_USE_TYPE	Fixture Use Type	Optional
FIXTURE_AREA_TYPE	Fixture Area Type	Optional
FIXTURE_LOCATION_DESC	Fixture Location Description	Optional
FIXTURE_DESC	Fixture Description	Optional
BUILDING_ID	Building ID	Optional
DATE_TIME_WATER_LAST_USED	Date and Time Water Last Used	Optional
DATE_TIME_COLLECTED	Date and Time Collected	
COLLECTED_BY	Collected By	
SAMPLER_TELEPHONE	Sampler Telephone	
LAB_SAMPLE_NUM	Lab Sample Number	
LAB_RECEIVE_DATE	Lab Receive Date	
PREP_DATE	Preparation Date	
ANALYSIS_DATE	Analysis Date	
ANALYTE_NAME	Analyte Name	Lead, total
LEAD_RESULT	Lead Result	
BELOW_DETECTION_LIMIT	Below Detection Limit	0 = above detection limit 1 = below detection limit
LAB_DETECTION_LIMIT	Lab Detection Limit	
UNIT_OF_MEASURE	Unit of Measure	ug/L
METHOD_CODE	Method Code	
MATRIX	Matrix	Drinking water

Building(s)

Building Name	Building ID
Note: additional rows added as necessary	

Electronic Data Deliverable Template			
SAMPLE_CODE			Note: additional columns added as necessary
SAMPLE_TYPE			
FIXTURE_CODE			
FIXTURE_TYPE			
FIXTURE_USE_TYPE			
FIXTURE_AREA_TYPE			
FIXTURE_LOCATION_DESC			
FIXTURE_DESC			
BUILDING_ID			
DATE_TIME_WATER_LAST_USED			
DATE_TIME_COLLECTED			
COLLECTED_BY			
SAMPLER_TELEPHONE			
LAB_SAMPLE_NUM			
LAB_RECEIVE_DATE			
PREP_DATE			
ANALYSIS_DATE			
ANALYTE_NAME			
LEAD_RESULT			
BELOW_DETECTION_LIMIT			
LAB_DETECTION_LIMIT			
UNIT_OF_MEASURE			
METHOD_CODE			
MATRIX			
LAB_ID_NO			

United States
Environmental Protection
Agency

Office of Environmental
Information
Washington, DC 20460

EPA/240/B-01/002
March 2001

EPA Requirements for Quality Management Plans

EPA QA/R-2

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Management Plan as a means of documenting how an organization will plan, implement, and assess the effectiveness of its quality assurance and quality control operations applied to environmental programs. The process of planning, implementing, and assessing these management systems is called *quality management* and the product of this process is called the *Quality System*. The Quality Management Plan is part of the mandatory Agency-wide Quality System that requires all organizations performing work for EPA to develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their desired use.

This document provides the development and content requirements for Quality Management Plans for organizations that conduct environmental data operations for EPA through contracts, assistance agreements, and interagency agreements; however, it may be used by EPA as well. It contains the same requirements as Chapter 3 of the EPA Order 5360 A1 (2000), *EPA Quality Manual for Environmental Programs*, for EPA organizations.

This document is one of the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. Questions regarding this document or other *Quality System Series* documents should be directed to the Quality Staff:

U.S. EPA
Quality Staff (2811R)
Washington, DC 20460
Phone: (202) 564-6830
FAX: (202) 565-2441
e-mail: quality@epa.gov

Copies of EPA *Quality System Series* documents may be obtained from the Quality Staff directly or by downloading them from its Home Page:

www.epa.gov/quality

ACKNOWLEDGMENTS

This document reflects the collaborative efforts of many quality management professionals who participate in the challenge for continual improvement in quality systems supporting environmental programs. These individuals, representing the EPA, other Federal agencies, State and local governments, and private industry, reflect a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews during the development of this document are greatly appreciated.

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

The U.S. Environmental Protection Agency (EPA) annually spends several hundred million dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. Furthermore, as EPA is increasingly involved in the use of environmental technology for pollution control and waste clean-up, the use of particular technologies is often specified in permits and regulations. If decision makers are to have the necessary confidence in the quality of environmental data used to support their decisions or that environmental technology successfully performed its intended role, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA organizations are required to document their quality system in a Quality Management Plan through EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (EPA 2000). Non-EPA organizations funded by EPA are required to document their quality system in a Quality Management Plan (or equivalent document)[1] through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

A Quality Management Plan documents how an organization structures its quality system and describes its quality policies and procedures, criteria for and areas of application, and roles, responsibilities, and authorities. It also describes an organization's policies and procedures for implementing and assessing the effectiveness of the quality system. This document describes the elements of a quality system that must be documented in a Quality Management Plan to comply with EPA requirements.

[1]An equivalent document may not be called a Quality Management Plan but still would document an organization's quality system and address the required quality management practices described in this document.

This requirements document presents specifications and instructions for the information that must be contained in a Quality Management Plan for organizations conducting environmental programs funded by EPA. The document also discusses the procedures for review, approval, implementation, and revision of Quality Management Plans. Users of this document should assume that all of the elements described herein are required in a Quality Management Plan unless otherwise directed by EPA.

1.2 QUALITY MANAGEMENT PLANS, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994

EPA Order 5360.1 A2 and the applicable Federal regulations (defined above) establish a mandatory Quality System that applies to all EPA organizations and organizations that are funded by EPA. Components of this system are illustrated in Figure 1. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. Quality system documentation (e.g., the Quality Management Plan) is a key component of the EPA Quality System as shown in Figure 1.

EPA policy is based on the national consensus standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*. The ANSI/ASQC E4-1994 standard describes the necessary management and technical elements for developing and implementing a quality system. This standard recommends using a tiered approach to a quality system. The standard recommends first documenting each organization-wide quality system in a Quality Management Plan or Quality Manual (to address requirements of *Part A: Management Systems* of the standard) and then documenting the applicability of the quality system to technical activity-specific efforts in a Quality Assurance Project Plan (QA Project Plan) or similar document (to address the requirements of *Part B: Collection and Evaluation of Environmental Data* of the standard). EPA has adopted this tiered approach for its mandatory Agency-wide Quality System. This document addresses Part A requirements of the standard.

The Quality Management Plan may be viewed as the 'umbrella' document under which individual projects are conducted. The Quality Management Plan is then supported by project-specific QA Project Plans. A QA Project Plan is the 'blueprint' by which individual projects involving environmental data are implemented and assessed and how specific quality assurance (QA) and quality control (QC) activities will be applied during a particular project. EPA requirements for QA Project Plans are defined in *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001). In some cases, a QA Project Plan and a Quality Management Plan may be combined into a single document that contains both organizational and project-specific elements. The QA Manager for the EPA organization sponsoring the work has the authority to determine when a single document is applicable and will define the content requirements of such a document.

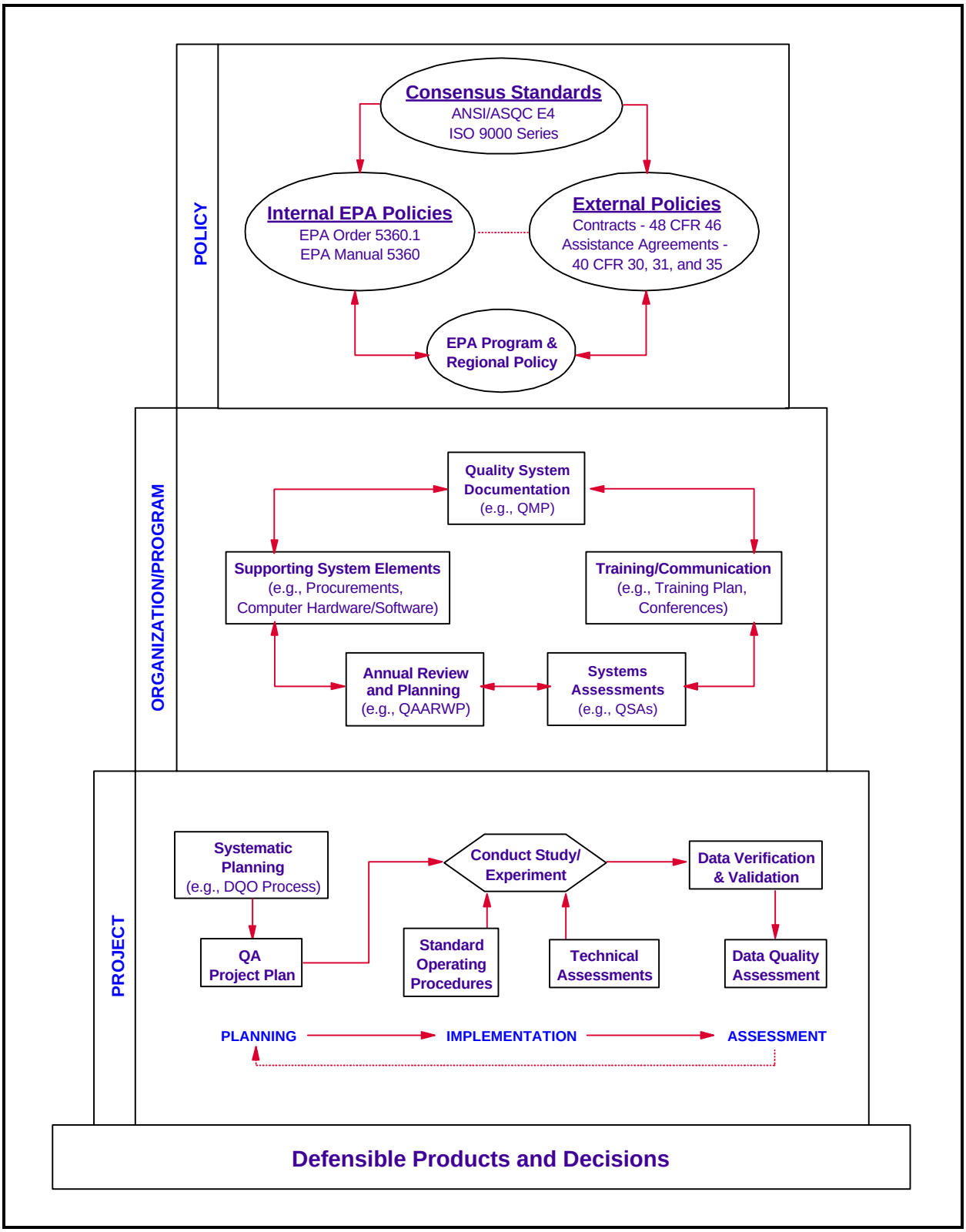

Figure 1. EPA Quality System Components and Tools

1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM

Implementation of the EPA Quality System is based on the principle of graded approach. This principle recognizes that a 'one size fits all' approach to quality requirements will not work in an organization as diverse as EPA so managerial controls are applied according to the scope of the program and/or the intended use of the outputs from a process. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. The specific application of the graded approach principle to Quality Management Plans is described in Section 2.4.2.

1.4 INTENDED AUDIENCE

This document specifies the requirements for developing a Quality Management Plan for organizations that conduct environmental data operations funded by EPA through contracts, financial assistance agreements, and interagency agreements. EPA organizations may also use this document to develop their Quality Management Plans since this document is clearer and more user-friendly than the equivalent requirements defined in Section 3.3 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs* (an internal policy document). However, the preparation, submission, review, and approval requirements for EPA organizations are still contained in Section 3.2 of EPA Order 5360 A1 as these represent internal EPA policy.

1.5 PERIOD OF APPLICABILITY

This document shall be valid for a period of up to five years from the official date of publication. After five years, it shall either be reissued without change, revised, or withdrawn from the EPA Quality System.

1.6 ADDITIONAL RESOURCES

EPA has issued a checklist for reviewing Quality Management Plans that can be used to verify if the requirements defined in this document are satisfied. This checklist is available on the Quality Staff website, www.epa.gov/quality/tools-org.html#qmp.

1.7 SUPERSESSION

This document replaces QAMS-004/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans* (EPA 1980) in its entirety.

CHAPTER 2

QUALITY MANAGEMENT PLAN REQUIREMENTS

2.1 POLICY

Quality systems supporting environmental programs involving environmental data or technology conducted by EPA organizations or by organizations funded by EPA shall be covered by an Agency-approved Quality Management Plan.

2.2 PURPOSE

A Quality Management Plan is a management tool that documents an organization's quality system for planning, implementing, documenting, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The Quality Management Plan is used to demonstrate conformance to Part A requirements of ANSI/ASQC E4-1994.

2.3 APPLICABILITY

These requirements apply to all organizations conducting environmental programs funded by EPA that acquire, generate, compile, or use environmental data and technology. These requirements apply to all work performed through contracts, cooperative agreements, interagency agreements, State-EPA agreements, State, local, and Tribal Financial Assistants/Grants (including Performance Partnership Grants and Agreements), Research Grants, and in response to statutory or regulatory requirements and consent agreements. These requirements shall be negotiated into interagency agreements, including sub-agreements, and, in some cases, included in enforcement consent agreements and orders. Where specific Federal regulations require the application of QA and QC activities (see Section 1.1), Quality Management Plans shall be prepared, reviewed, and approved in accordance with the specifications contained in this document unless explicitly superseded by regulation.

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

2.4.1 General Content

The Quality Management Plan documents the quality management practices which are critical to a quality system. Specific Quality Management Plan content requirements are described in Chapter 3. Each organization should evaluate these requirements for applicability to their quality system. Where a particular element is not relevant, an explanation of why it is not relevant must be provided in the Quality Management Plan. Also, if the Quality Management Plan preparer or EPA organization sponsoring the work determines that additional quality management

elements are useful or necessary for an adequate quality system, these elements should be discussed in the Quality Management Plan.

2.4.2 Level of Detail

The Quality Management Plan should describe a Quality System that is designed to support the objectives of the organization. The level of effort expended to develop a Quality Management Plan should be based on the scope of the program. For example, large grants to a State government may require a comprehensive quality system and Quality Management Plan, whereas smaller grants for programs with relatively less significant impacts may require less substantial documentation.

The Quality Management Plan must be sufficiently inclusive, explicit, and readable to enable both management and staff to understand the priority which management places on QA and QC activities, the established quality policies and procedures, and their respective quality-related roles and responsibilities. The Quality Management Plan must be written so that an assessment of the suitability and effectiveness of the organization's quality system can be accomplished. Such assessments will enable management to determine if the quality system meets the needs of the organization. The Quality Management Plan should be focused on the processes and procedures used to plan, implement, and assess the programs to which it is applied, and must include definitions of appropriate authorities and responsibilities for managers and staff.

2.5 QUALITY MANAGEMENT PLAN PREPARATION[2]

An organization's senior manager is responsible for assuring the preparation of a Quality Management Plan to cover all environmental programs supported or undertaken by the organization. Senior management, i.e., the executives and managers who are responsible and accountable for mission accomplishment and overall operations of the organization, is responsible for ensuring that the Quality Management Plan is prepared and that the quality system documented in the Quality Management Plan satisfies all EPA policy requirements and meets all statutory, contractual, and assistance agreement requirements for EPA work.

While senior management is responsible for the preparation of the Quality Management Plan, the actual preparation may be assigned to the organization's staff so long as it is assured that all managers support the effort; for example, the preparation of the Quality Management Plan may be directed by the QA Manager of the organization. However, it is essential that all management levels understand fully the content of the Quality Management Plan and concur with its implementation.

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[2]Specific preparation, submission, review, and approval requirements for EPA organizations are contained in Section 3.2 of EPA Order 5360 A1 (EPA 2000) as these represent internal EPA policy.

2.6 QUALITY MANAGEMENT PLAN SUBMISSION AND APPROVAL

The Quality Management Plan must be approved and signed by the senior management of the organization. This will certify that the organization has conducted an internal review of the Quality Management Plan and that management has concurred with its contents.

When a Quality Management Plan is required either by statute, contractual requirement, or assistance agreement condition, the Quality Management Plan must be submitted for review and approval to the EPA official responsible for the work. The EPA official may include the contracting officer's representative (such as the project officer, work assignment manager, or delivery order project office), the award official, and the EPA QA Manager. For example, the review and approval of a State Quality Management Plan that has been submitted as part of a request for an assistance agreement may be performed by the QA Manager of the office awarding the assistance agreement.

EPA approval of a Quality Management Plan will be valid for no more than five years for State, local, and Tribal governments or the length of the extramural agreement for all other extramural agreement holders. The period for which a Quality Management Plan is valid is defined in the Quality Management Plan of the EPA organization sponsoring the work.

2.7 QUALITY MANAGEMENT PLAN REVISIONS

Each organization shall review its Quality Management Plan at least annually to reconfirm the suitability and effectiveness of the approved quality management practices. The process of developing, annually reviewing, and revising (as needed) the Quality Management Plan provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and institutionalize improvements. Having an accurate Quality Management Plan at all times is an essential element in every quality system, thus changes in QA policy and procedures shall be documented in the Quality Management Plan in a timely fashion.

In general, a copy of any Quality Management Plan revision(s) made during the year should be submitted to EPA as a report when such changes occur. However, if significant changes have been made to the quality system that affect the performance of work for the Agency, it may be necessary to re-submit the entire Quality Management Plan to EPA for re-approval. Conditions requiring the revision of an approved Quality Management Plan include:

- expiration of the five-year life span of the Quality Management Plan;
- major changes in mission and responsibilities, such as changes in the delegation status of a program;
- re-organization of existing functions that affect programs covered by the Quality Management Plan; and
- assessment findings requiring corrective actions and response.

All appropriate personnel in the organization performing work covered by the scope of the Quality Management Plan shall be notified of changes to the quality system and the Quality Management Plan to keep them informed of the current requirements. This practice should also include active sub-contractors for relevant work.

CHAPTER 3

QUALITY MANAGEMENT PLAN ELEMENTS

3.1 CONTENT REQUIREMENTS

The Quality Management Plan documents management practices, including QA and QC activities, used to ensure that the results of technical work are of the type and quality needed for their intended use. Accordingly, the Quality Management Plan documents:

- the mission and quality policy of the organization;
- the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities;
- the means by which effective communications with personnel actually performing the work are assured;
- the processes used to plan, implement, and assess the work performed;
- the process by which measures of effectiveness for QA and QC activities will be established and how frequently effectiveness will be measured; and
- the continual improvement based on lessons learned from previous experience.

The Quality Management Plan reflects the organization's commitment to quality management principles and practices, tailored, when appropriate, by senior management to meet the organization's needs.

The elements to be addressed in a Quality Management Plan include: management and organization; quality system description; personnel qualifications and training; procurement of items and services; documentation and records; computer hardware and software; planning; implementation of work processes; assessment and response; and quality improvement. Specific requirements for each of these elements are described below in Sections 3.2 through 3.11. Items specific to Quality Management Plans developed by EPA organizations under EPA Order 5360.1 A2 (EPA 2000) are noted by "EPA Quality Management Plans." Organizations funded by EPA do not have to address these EPA-specific items.

It is preferable, but not necessary, that the Quality Management Plan address the specifications in the same order as presented below to ensure uniformity and a consistent and complete review. If an existing, approved Quality Management Plan adequately addresses each of these topics, it should not be rewritten simply to conform to the outline provided here.

3.2 MANAGEMENT AND ORGANIZATION

Purpose – To document the overall policy, scope, applicability, and management responsibilities of the organization's quality system.

Specifications – Provide the following:

- an approval page for the signatures of the organization's management and QA manager. The approval page may be part of a title page or a separate sheet following the title page. If EPA approval of the Quality Management Plan is required, the approval page shall include a section for the signature of the EPA official (see Section 2.6). For EPA Quality Management Plans[3], the approval page shall contain the signatures of the organization's senior manager, senior line management (as appropriate), the QA Manager, the Director of the Quality Staff, and the Assistant Administrator of the Office of Environmental Information;

- a statement of the organization's policy on quality assurance, including:

  - the importance of QA and QC activities to the organization and why,
  - the general objectives and goals of the quality system, and
  - the policy for resource allocation for the quality system (EPA Quality Management Plans must discuss personnel, intramural and extramural funding, and travel resources);

- an organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting for the QA Manager (or similar position such as a Quality Manager) and any QA staff;

- a discussion of the authorities of the QA Manager and any other QA staff that also:

  - documents the organizational independence of the QA Manager from groups generating, compiling, and evaluating environmental data, and
  - indicates how the organization will ensure that QA personnel will have access to the appropriate levels of management in order to plan, assess, and improve the organization's quality system;

- a discussion of the technical activities or programs that are supported by the quality system including:

  - the specific programs that require quality management controls,

[3]Organizations funded by EPA do not have to address these EPA-specific elements.

- where oversight of delegated, contracted, or other extramural programs is needed to assure data quality, and
- where and how internal coordination of QA and QC activities among the group's organizational units needs to occur;

- a discussion of how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs; and

- a discussion of the organization's process for resolving disputes regarding quality system requirements, QA and QC procedures, assessments, or corrective actions (requirement for EPA Quality Management Plans only).

3.3 QUALITY SYSTEM COMPONENTS

Purpose – To document how an organization manages its quality system and defines the primary responsibilities for managing and implementing each component of the system.

Specifications – Provide the following:

- a description of the organization's quality system that includes the principal components of the system and the roles and implementation responsibilities of management and staff with regards to these components. These components include, but are not limited to:

  - quality system documentation
  - annual reviews and planning
  - management assessments
  - training
  - systematic planning of projects
  - project-specific quality documentation
  - project and data assessments;

- a list of the tools for implementing each component of the quality system. These tools include, but are not limited to:

  - Quality Management Plans (quality system documentation),
  - Quality Systems Audits (management assessments),
  - Training Plans (training),
  - QA Project Plan (project-specific quality documentation),
  - Data Verification and Validation (data assessments);

- a list of any components of the organization that develop Quality Management Plans (or equivalent document) in support of the organization's Quality System and the review and approval procedures for such documentation; and

- a discussion of how roles and responsibilities for the principal components of the Quality System are incorporated into performance standards (requirement for EPA Quality Management Plans only).

3.4 PERSONNEL QUALIFICATION AND TRAINING

Purpose – To document the procedures for assuring that all personnel performing work for an organization have the necessary skills to effectively accomplish their work.

Specifications – Provide the following:

- a statement of the policy regarding training for management and staff;

- a description of the process(es), including the roles, responsibilities, and authorities of management and staff, for:

  - identifying, ensuring, and documenting that personnel have and maintain the appropriate knowledge, skill, and statutory, regulatory, professional or other certifications, accreditations, licenses, or other formal qualification necessary, and

  - identifying the need for retraining based on changing requirements.

3.5 PROCUREMENT OF ITEMS AND SERVICES

Purpose – To document the procedures for purchased items and services that directly affect the quality of environmental programs.

Specifications –

Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to all appropriate procurement documents or extramural agreements, including grants, cooperative agreements, and contracted and subcontracted activities, involving or affecting environmental programs, for:

- reviewing and approving procurement documents (and any changes to these documents) to ensure that procurement documents are accurate, complete, and clearly describe:

- the item or service needed,
- the associated technical and quality requirements,
- the quality system elements for which the supplier is responsible, and
- how the supplier's conformance to the customer's requirements will be verified;

- review and approval of all applicable responses to solicitations to ensure that these documents:
  - satisfy all technical and quality requirements, and
  - provide evidence of the supplier's capability to satisfy EPA quality system requirements as defined in the extramural agreement or applicable Federal Regulation (requirement for EPA Quality Management Plans only);

- ensuring that procured items and services are of acceptable quality, including the review of objective evidence of quality for applicable items and services furnished by suppliers and subcontractors, source selection, source inspections, supplier audits, and examination of deliverables;

- review and approval procedures for mandatory quality-related documentation (e.g., Quality Management Plans or QA Project Plans) from suppliers (requirement for EPA Quality Management Plans only);

- policies and criteria for delegations of EPA authority to review and approve mandatory quality-related documentation (e.g., Quality Management Plans or QA Project Plans) from suppliers consistent with Chapter 2.2 of EPA Order 5360 A1 (requirement for EPA Quality Management Plans only); and

- ensuring that EPA quality-related contracting policies, as defined by the Federal Acquisition Regulations, Office of Federal Procurement Policy, and the EPA Contracts Management Manual [EPA Order 1900 (EPA 1998)], are satisfied (requirement for EPA Quality Management Plans only).

3.6 DOCUMENTS AND RECORDS

Purpose – To document appropriate controls for quality-related documents and records determined to be important to the mission of the organization.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- identifying quality-related documents and records (both printed and electronic) requiring control;

- preparing, reviewing for conformance to technical and quality system requirements, approving, issuing, using, authenticating, and revising documents and records;

- ensuring that records and documents accurately reflect completed work;

- maintaining documents and records including transmittal, distribution, retention (including retention times), access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documentation, and disposition;

- ensuring compliance with all applicable statutory, regulatory, and EPA requirements for documents and records [EPA Quality Management Plans shall ensure compliance with EPA Order 2160 (EPA 1984) and EPA Directive 2100, Chapter 10 (EPA 1998)]; and

- establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records.

3.7 COMPUTER HARDWARE AND SOFTWARE

Purpose – To document how the organization will ensure that computer hardware and software satisfies the organization's requirements.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- developing, installing, testing (including verification and validation), using, maintaining, controlling, and documenting computer hardware and software used in environmental programs to ensure it meets technical and quality requirements and directives from management [EPA Quality Management Plan specifications must be consistent with EPA Directive 2100 (EPA 1998)];

- assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance;

- evaluating purchased hardware and software to ensure it meets user requirements and complies with applicable contractual requirements and standards;

- ensuring that data and information produced from, or collected by, computers meet applicable information resource management requirements and standards; and

- ensuring that applicable EPA requirements for information resources management are addressed [EPA Directive 2100 (EPA 1998)] including security and privacy requirements (requirement for EPA Quality Management Plans only).

Computer software covered by this requirement includes, but is not limited to, design, data handling, data analysis, modeling of environmental processes and conditions, operations, or process control of environmental technology system (including automated data acquisition and laboratory instrumentation), data bases containing environmental data.

3.8 PLANNING

Purpose – To document how individual data operations will be planned within the organization to ensure that data or information collected are of the needed and expected quality for their desired use.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- planning environmental data operations using a systematic planning process[4] which includes:
  - the identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers);
  - a description of the project goal, objectives, and questions and issues to be addressed;
  - the identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory and contractual requirements);
  - the identification of the type and quantity of data needed and how the data will be used to support the project's objectives;
  - the specification of performance criteria for measuring quality;

[4]EPA has developed a systematic planning process called the Data Quality Objectives (DQO) Process [See the *EPA Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000)]. While not mandatory, the DQO Process is the recommended planning approach for many EPA data collection activities.

- the specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);

- a description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection; and

- a description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, verification, validation), and assessed against its intended use and the quality performance criteria;

• developing, reviewing, approving, implementing, and revising a QA Project Plan or equivalent planning document [see *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001)]; and

• evaluating and qualifying data collected for other purposes or from other sources, including the application of any statistical methods, for a new use.

3.9 IMPLEMENTATION OF WORK PROCESSES

Purpose – To document how work processes will be implemented within the organization to ensure that data or information collected are of the needed and expected quality for their desired use.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff for:

• ensuring that work is performed according to approved planning and technical documents;

• identification of operations needing procedures (e.g., standardized, special, or critical operations), preparation (including form, content, and applicability), review, approval, revision, and withdrawal of these procedures; and policy for use; and

• controlling and documenting the release, change, and use of planned procedures, including any necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

3.10 ASSESSMENT AND RESPONSE

Purpose – To document how the organization will determine the suitability and effectiveness of the implemented quality system and the quality performance of the environmental programs to which the quality system applies.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to both management and technical assessments for:

- assessing the adequacy of the quality system at least annually;
- planning, implementing, and documenting assessments and reporting assessment results to management including how to select an assessment tool, the expected frequency of their application to environmental programs, and the roles and responsibilities of assessors;
- determining the level of competence, experience, and training necessary to ensure that personnel conducting assessments are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed;
- ensuring that personnel conducting assessments have sufficient authority, access to programs, managers, documents, and records, and organizational freedom to:
  - identify both quality problems and noteworthy practices,
  - propose recommendations for resolving quality problems, and
  - independently confirm implementation and effectiveness of solutions;
- management's review and response to findings;
- identifying how and when corrective actions are to be taken in response to the findings of the assessment, ensuring corrective actions are made promptly, confirming the implementation and effectiveness of any corrective action, and documenting (including the identification of root causes, the determination of whether the problem is unique or has more generic implications, and recommendation of procedures to prevent recurrence) such actions; and
- addressing any disputes encountered as a result of assessments.

Available assessment tools include quality systems audits, management systems reviews, peer reviews, technical reviews, performance evaluations, data quality assessments, readiness reviews, technical systems audits, and surveillance.

3.11 QUALITY IMPROVEMENT

Purpose – To document how the organization will improve the organization's quality system.

Specifications – Identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities and describe the process to ensure continuous quality improvement, including the roles and responsibilities of management and staff, for:

- ensuring that conditions adverse to quality are:
  - prevented,
  - identified promptly including a determination of the nature and extent of the problem,
  - corrected as soon as practical, including implementing appropriate corrective actions and actions to prevent reoccurrence,
  - documenting all corrective actions, and
  - tracking such actions to closure;

- encouraging staff at all levels to establish communications between customers and suppliers, identify process improvement opportunities, and identify and offer solutions to problems.

REFERENCES

40 CFR 30, Code of Federal Regulations, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

40 CFR 31, Code of Federal Regulations, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."

40 CFR 35, Code of Federal Regulations, "State and Local Assistance."

48 CFR 46, Code of Federal Regulations, "Federal Acquisition Regulations."

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs,* American National Standard, January 1995.

EPA Directive 2100 (1999), *Information Resources Management Policy Manual,* U.S. Environmental Protection Agency, Washington, DC.

EPA Order 1900 (February 1998), *Contracts Management Manual,* U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2160 (July 1984), *Records Management Manual,* U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360 A1 (May 2000), *EPA Quality Manual for Environmental Programs,* U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360.1 A2 (May 2000), *Policy and Program Requirements for the Mandatory Quality Assurance Program,* U.S. Environmental Protection Agency, Washington, DC.

U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Assurance Project Plans (QA/R-5),* EPA/240/B-01/003, Office of Environmental Information.

U.S. Environmental Protection Agency, 2000. *Guidance for the Data Quality Objectives Process (QA/G-4),* EPA/600/R-96/055, Office of Environmental Information.

U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans,* QAMS-004/80, Office of Research and Development.

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APPENDIX A

TERMS AND DEFINITIONS

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

data quality assessment - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

environmental conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

environmental data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental programs - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply

to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

independent assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

management system - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

management systems review - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

objective evidence - any documented statement of fact, other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

peer review - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

performance evaluation - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance (QA) - an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

quality assurance project plan - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

quality control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

quality improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

quality management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.

quality management plan - a document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

quality system - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

readiness review - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

record - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

self-assessment - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

specification - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

standard operating procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

surveillance (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

technical review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

technical systems audit - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

WV-10
Approved / Revised
06/08/18

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Vendor Preference, if applicable.

1. Application is made for 2.5% vendor preference for the reason checked:

☐ Bidder is an individual resident vendor and has resided continuously in West Virginia, or bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia, for four (4) years immediately preceding the date of this certification; **or,**

☐ Bidder is a resident vendor partnership, association, or corporation with at least eighty percent of ownership interest of bidder held by another entity that meets the applicable four year residency requirement; **or,**

☐ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. Application is made for 2.5% vendor preference for the reason checked:

☐ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. Application is made for 2.5% vendor preference for the reason checked:

☐ Bidder is a nonresident vendor that employs a minimum of one hundred state residents, or a nonresident vendor which has an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia and employs a minimum of one hundred state residents, and for purposes of producing or distributing the commodities or completing the project which is the subject of the bidder's bid and continuously over the entire term of the project, on average at least seventy-five percent of the bidder's employees or the bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years and the vendor's bid; **or,**

4. Application is made for 5% vendor preference for the reason checked:

☐ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. Application is made for 3.5% vendor preference who is a veteran for the reason checked:

☐ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. Application is made for 3.5% vendor preference who is a veteran for the reason checked:

☐ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

7. Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with *West Virginia Code* §5A-3-59 and *West Virginia Code of State Rules.*

☑ Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

8. Application is made for reciprocal preference.

☐ Bidder is a West Virginia resident and is requesting reciprocal preference to the extent that it applies.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) rescind the contract or purchase order; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: 120Water **Signed:** 

Date: 12/22/2020 **Title:** VP of Sales

**Check any combination of preference consideration(s) indicated above, which you are entitled to receive.*

Jennifer Whitson

Senior Program Manager

EDUCATION

Indiana University
BA in Political Science and German

Northwestern University
MA in Journalism

Certified Scrum Master

CORE SKILLS

Customer Service

Relationship Building

Software Product Management

120WATER

Senior Program Manager
May 2017–Present

PREVIOUS EXPERIENCE

Whitson Business Data
Owner
March 2011–Present

Evansville Courier
Statehouse Bureau Chief
August 2014–January 2016

Indianapolis Business Journal
Business Reporter
May 2006-August 2008

SUMMARY

Jennifer has more than 13 years of project management experience and has been leading programs at 120Water since May 2017. She knows how to brainstorm tailored solutions, build cohesion amongst diverse teams, define schedules and deliverables, and guide clients through all phases of a project.

ROLE AND RESPONSIBILITIES

Jennifer Whitson is solely responsible for managing water testing programs such as **[PROGRAM NAME]**. She will focus on the direct relationship between 120Water and **[CLIENT NAME]** and orchestrate all relevant conversations. She will work closely with the client, answering questions and

RELEVANT PROGRAM EXPERIENCE

Indiana Finance Authority
Statewide School Testing Program, Lead in Drinking Water
2017-2018

Led the program to test more than 900 public schools across Indiana for lead in drinking water. Walked the client through steps to define their software and program needs, set those expectations to a timeline, and tracked progress. Trained both the client and the field team on use of the software to use the software to map a school building. Managed lab relationships and tracked the shipment of sample kits and timeliness of lab analysis for more than 57,000 water samples. Worked with schools to order and track follow-up testing after remediation was performed. The client has since expanded the program to cover additional testing.

Maryland Department of the Environment
Statewide School Testing, Lead in Drinking Water
2018-Present

Currently leading this ongoing software-only program to track data for mandated lead in drinking water testing for all schools – public and private – in the state. Imported the state's historical data on testing, then helped train both client and school users on the software. Held training session and walked the client through software change and upgrade requests. Schools are required to test but can select any lab vendor, so also worked with state labs to import new results. To date, have imported and tracked nearly 67,000 sample results from nearly 2,300 facilities.