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March 01, 2023

Celine Wysgalla
United States Environmental Protection Agency
Region 5
77 West Jackson Boulevard
Chicago, Illinois 600604

Quality Assurance Project Plan – Wetland Excavation and Surface Debris Mitigation - Addendum No. 1
Penta Wood Products Superfund Site
Siren, Wisconsin
WDNR BRRTS Activity #02-07-000532

Dear Ms. Wysgalla:

GHD Services Inc. (GHD) has prepared this Addendum No. 1 associated with the Quality Assurance Project Plan (QAPP) – Wetland Excavation and Surface Debris Mitigation (GHD; February 1, 2023) for the Penta Wood Products Superfund Site located in Siren, Wisconsin. Attached are additional worksheets and appendices to document changes in laboratory and analytical methods necessary to achieve limits of detection/quantification that meet the pentachlorophenol cleanup criteria. Selected wetland excavation confirmation samples will be submitted for laboratory analysis of pentachlorophenol at the Eurofins Environment Testing Pittsburgh, Pennsylvania laboratory. All existing QAPP worksheets still apply.

Regards,

Tim Ree
Project Manager / Project Engineer

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GA/kg/LTR-93

Copy to: Phil Richard, WDNR

Worksheets

QAPP Worksheet #12-09: Laboratory Control Sample/Duplicate and Matrix Spike/Duplicate Recoveries

Matrix:	Soil
Analytical Method:	SW-846 Method 8270E Low Level
Concentration Level (if applicable):	Low

Analyte Description	LCS - Low	LCS - High	LCS - RPD %	MS - Low	MS - High	MS - RPD %
Pentachlorophenol	34	112	28	34	112	28

Note:
Control limits are updated by the laboratory on a regular basis and the most current control limits will be used for data review purposes.

QAPP Worksheet #15-09: Project Action Limits and Laboratory-Specific Detection/Quantitation Limits

Matrix: Soil
Analytical Method: SVOC SW-846 8270E Low Level
Concentration level (if applicable): Low

Analyte Description	CAS Number	Project Action Limit (RCL)[1]	Project Quantitation Limit Goal	RL	Units
Pentachlorophenol	87-86-5	1020	500	170	µg/kg

Notes:

[1] – Wisconsin Administrative Code NR 720 RR Soil RCL - Non-Industrial RCLs

RL – Reporting limit

QAPP Worksheets #19-01 & 30-01: Sample Containers, Preservation, and Hold Times

Laboratory (Pentachlorophenol):
Eurofins Environment Testing Northeast, LLC - Pittsburgh
RIDC Park
301 Alpha Drive
Pittsburgh, Pennsylvania 15238-2907
Donna Campbell (donna.campbell@et.eurofinsus.com)
708.534.5200

Back-up Laboratory: Various Eurofins Network Laboratories
Sample Delivery Method: FedEx (for Eurofins)
Laboratory Certifications: Laboratory certifications are provided in Appendix A

Analyte/ Analyte Group	Matrix	Method/ SOP	Container(s) (number, size & type per sample)	Preservation	Preparation Holding Time	Analytical Holding Time	Data Package Turnaround
Pentachlorophenol	Soil	SW-846 8270E Low Level	1 – 4 oz jar	0-6°C	14 days to extract	40 days from extraction to analysis	10 business day

Notes:
Extra sample volume is needed for MS/MSD samples.
Laboratory certifications can be found in Appendix A.

QAPP Worksheet #23-01: Analytical SOPs

Eurofins SOP #	**Title and Date**	**Definitive or Screening Data**	**Matrix/Analytical Group**	**Equipment Type**	**Modified for Project? Y/N**
PIT-ORG-GCMS- SOP45795, Rev 12	*SVOC Analysis by 8270E, 09/28/2022*	Definitive	Soil/PCP	GC/MS	N
PIT-QA-QM45117, Rev 7	*Quality Assurance Manual, Eurofins Pittsburgh, 07/08/2022*	NA	NA	NA	N

Note:
Laboratory SOP and QAM are provided in Appendix A

QAPP Worksheet #24-01: Analytical Instrument Calibration

Instrument	Calibration Procedure	Calibration Range	Frequency	Acceptance Criteria	Corrective Action (CA)	Title/Position Responsible for Corrective Action	SOP Reference
GC/MS Pentachlorophenol	Per SOP	Per SOP	Per SOP	Per SOP	Per SOP	Donna Campbell – Lab PM	PIT-ORG-GCMS-SOP45795, Rev 12

QAPP Worksheet #25-01: Analytical Instrument and Equipment Maintenance, Testing, and Inspection

Instrument / Equipment	Reference
GC/MS - Pentachlorophenol	PIT-ORG-GCMS-SOP45795, Rev 12 and Pittsburgh Quality Assurance Manual, PIT-QA-QM45117, Rev 7

QAPP Worksheet #28-09: Analytical Quality Control and Corrective Action

Matrix: Soil
Analytical Group: PCP
Analytical Method/SOP: SW-846 8270E Low Level/PIT-ORG-GCMS-SOP45795 Rev 12

QC Sample	Number/Frequency	Method/SOP Acceptance Criteria	Corrective Action	Title/position of person responsible for corrective action	Project-Specific MPC
Decafluorotriphenylphosphine (DFTPP) Tune	One every 12 hours	DFTPP Tune Criteria must be met per SW-846 Method 8270E	Re-tune and reanalyze DFTPP	Analyst / Laboratory Quality Assurance Officer	BFB Tune Criteria must be met per SW-846 Method 8270E
Continuing Calibration Check	One every 12 hours	%D and Minimum Mean Response Factors must be met per SW-846 Method 8270E	Re-calibrate and reanalyze.	Analyst / Laboratory Quality Assurance Officer	%D and Minimum Mean Response Factors must be met per SW-846 Method 8270E
Internal Standards (IS)	Every sample must be spiked with appropriate IS compounds	50-200% Recovery	Reanalyze samples with outlying recoveries. Qualify data as needed.	Analyst / Laboratory Quality Assurance Officer	50-200% Recovery
Surrogates	Every sample must be spiked with appropriate surrogate compounds	Must meet Laboratory Limits	None. Qualify data as needed.	Analyst / Laboratory Quality Assurance Officer	Must meet Laboratory Limits

QAPP Worksheet #28-02: Analytical Quality Control and Corrective Action

QC Sample	Number/Frequency	Method/SOP Acceptance Criteria	Corrective Action	Title/position of person responsible for corrective action	Project-Specific MPC
Laboratory Control Sample	One per preparatory batch of up to 20 samples.	Must meet Laboratory Limits	Reanalyze LCS and all samples in associated batch for failed analytes. Qualify data as needed.	Analyst / Laboratory Quality Assurance Officer	Must meet Laboratory Limits
Method Blank	1 per preparatory batch of up to 20 samples.	No target analyte concentrations > RL	Reanalyze the method blank and all samples processed with the contaminated blank. Qualify data as needed.	Analyst / Laboratory Quality Assurance Officer	No target analyte concentrations > RL
Matrix Spike/Matrix Spike Duplicate	One per preparatory batch of up to 20 samples	Must meet Laboratory Limits	None. Qualify data as needed	Analyst / Laboratory Quality Assurance Officer	Must meet Laboratory Limits

Appendix A

eurofins	Always check on-line for validity **GC/MS Analysis for Semivolatile Organics, Methods: SW-846 8270D & 8270E**	Level: **Standard Operating Procedure**
Document number: **PIT-ORG-GCMS-SOP45795**		
Old Reference: **PT-MS-008**		
Version: **12**		Organisation level: **4-Business Unit**
Approved by: **OA3Z, SBB9** Effective Date: **28-SEP-2022**	Document users: **6_EUUS79_PIT_Organics_GCMS BNA All**	Responsible: **5_EUUS79_PIT_Organics Department Manager**

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1) Scope and Application

1.1) This procedure is based upon SW846 methods 8270D and 8270E, utilizes best practices, and is applicable to the determination of the concentration of semivolatile organic compounds in extracts prepared from many types of solid matrices, soils and aqueous matrices.

1.1.1) Direct injection of a sample may be used in limited applications.

1.1.2) Refer to Table 1 for the list of compounds applicable for this method. Note that the compounds are listed in approximate retention time order. This method may be amenable to additional compounds. If non-standard analytes are required, they must be validated by the procedures described in section 12.2 before sample analysis.

- Benzidine can be subject to oxidative losses during solvent concentration and exhibits poor chromatography. Neutral extraction should be performed if this compound is expected.
- Hexachlorocyclopentadiene is subject to thermal decomposition in the inlet of the gas chromatograph, chemical reaction in acetone solution, and photochemical decomposition.
- N-Nitrosodiphenylamine decomposes in the gas chromatographic inlet and cannot be distinguished from diphenylamine.
- Pentachlorophenol, 2,4-dinitrophenol, 4-nitrophenol, 4,6-dinitro-2-methylphenol, 4-chloro-3-methylphenol, benzoic acid, 2-nitroaniline, 3-nitroaniline, 4-chloroaniline, benzidine, 7,12-dimethylbenz(a)anthracene, kepone, o-toluidine, 1,4-phenylene diamine, phthalic anhydride and benzyl alcohol are subject to erratic chromatographic behavior, especially if the GC system is contaminated with high boiling material.
- 3-Methylphenol cannot be separated from 4-methylphenol by the conditions specified in this method. They are reported as 3 and 4-methylphenol.
- Hexachlorophene and famphur analysis are not quantitatively reliable by this method.
- 1,2-diphenylhydrazine is unstable even at room temperature and readily decomposes to form azobenzene. Given the stability problems, it would be acceptable to calibrate for 1,2-diphenylhydrazine using azobenzene and the results for either of these compounds should be reported as a combined concentration.
- Pyridine may perform poorly at the GC injection port temperatures listed in this SOP. Lowering the injection port temperature may reduce the amount of degradation

1.3) The standard reporting limit (RL) of this method for determining an individual compound is approximately 330 µg/kg (wet weight) for soil/sediment/tissues samples, 33 µg/kg (wet weight) for low level soil/sediment/tissues samples, 2 - 400 mg/kg for wastes (dependent on matrix and method of preparation), 10 µg/L for groundwater samples and 1.0 µg/L for low level groundwater samples. Some compounds have higher reporting limits. Refer to Table 1 for specific RLs. Reporting limits will be proportionately higher for sample extracts that require dilution.

1.4) Certain clients may require specific project or program QC that may supersede the requirements presented in this section. Project specific QAPP’s should be developed to address these requirements

1.5) Any variation in procedure shall be completely documented using an NCM. The NCM is approved by the supervisor and then automatically sent to the laboratory Project Manager by e-mail so that the client can be notified as appropriate. The QA department also receives NCMs by e-mail for tracking and trending purposes. The NCM process is described in more detail in SOP PIT-QA-QAS-SOP45629 (formerly PT-QA-016). The

NCM shall be filed in the project file and addressed in the case narrative. Any unauthorized deviations from this procedure must also be documented as a nonconformance, with a cause and corrective action described.

1.6) On occasion clients may request slight modifications to this SOP. Any modification to this procedure must be approved by the QA department of the Laboratory or Technical Director, and documented fully in an NCM that accompanies the analytical batch.

2) Summary of Method

2.1) Aqueous samples are extracted with methylene chloride using either a continuous extractor (Method 3520C) or a separatory funnel (Method 3510C). TCLP samples are usually extracted by separatory funnel. Eurofins Pittsburgh performs both routine and low level water analyses with the final extract volume at 10 mL and 1.0 mL respectively.

2.2) Solid samples are extracted with methylene chloride / acetone using Soxhlet extraction. Eurofins Pittsburgh performs both routine and low level soil analyses with the final extract volume at 5.0 mL and 0.5 mL respectively

2.3) Waste dilution is used for samples that are miscible with the solvent.

2.4)
Extraction procedures are detailed in the following SOPs:

- PIT-ORG-ORGP-SOP45818 Extraction of Organic Compounds from Waters, Based on SW-846 3500 Series and 600 Series Methods
- PIT-ORG-ORGP-SOP45820 Extraction of Organic Compounds from Solids, Sediments, Tissue and Wipes Based on SW-846 3500 Series
- PIT-ORG-ORGP-SOP45822 Cleanup of Organic Compounds from Waters, Solids, Sediments, Tissue and Wipes Based on SW-846 3600 Series and CarboPrep90 Methods

2.5) Qualitative identification of the analytes in the extract is performed using the retention time and the relative abundance of characteristic ions. Quantitative analysis is performed using the internal standard technique with a single characteristic ion

3) Definitions

3.1) LIMS – Eurofins Laboratory Information Management System (TALS)

3.2) NCM – Non-Conformance Memo – a system within TALS for the lab to communicate to project management and others when there is an anomaly seen with the samples or batch, or a QC failure

3.3) Definitions of terms used in this SOP may be found in the glossary of the Pittsburgh Laboratory Quality Assurance Manual (*PIT-QA-QM45117*).

4) Interferences

4.1) Matrix interferences may be caused by contaminants that are co-extracted from the sample. The extent of matrix interferences will vary considerably from source to source, depending upon the nature of the sample. Cleanup procedures may help to eliminate select interferences, as follows:

- Method 3640A, Gel-Permeation Chromatography - Removes higher molecular weight hydrocarbons by size exclusion chromatography, which is most frequently used for biological samples
- Method 3660B, Sulfur Cleanup – If a sulfur peak is detected, copper or mercury can be used to treat the extract and remove the sulfur
- Other, more aggressive cleanup procedures listed in SW-846 may be used for select compounds listed in this procedure, but may cause degradation of some of the more reactive compounds. Consult with a technical expert in the laboratory for more difficult interference problems

Details concerning cleanup steps are described in the organic extraction SOP PIT-ORG-ORGP-SOP45822.

4.2) Contaminants in solvents, reagents, glassware, and other processing apparatus that lead to discrete artifacts may cause method interferences. All of these materials must be routinely demonstrated to be free from interferences under conditions of the analysis by running laboratory method blanks as described in the Quality Control section (Section 9.4). Raw GC/MS data from all blanks, samples, and spikes must be evaluated for interferences. If interference is detected, it is necessary to determine if the source of interference is in the preparation and/or cleanup of the samples; then take corrective action to eliminate the problem.

4.3) The use of high purity reagents, solvents, and gases helps to minimize interference problems.

4.4) Contamination by carryover can occur whenever high-level and low-level samples are sequentially analyzed. To reduce carryover, the sample syringe must be rinsed with solvent between samples. Whenever an unusually concentrated sample is encountered, it should be followed by the analysis of solvent to check for cross contamination

4.5) Phthalate contamination is commonly observed in this analysis and its occurrence should be carefully evaluated as an indicator of a contamination problem in the sample preparation step of the analysis

5) Safety

Employees must abide by the policies and procedures in the NDSC Environmental Health and Safety Manual (*NDSC-US EHS-QP46060*), the Pittsburgh Facility Addendum EH&S Manual (*PIT-EHS-HS-SOP45640*) and this document. This procedure may involve hazardous material, operations and equipment. This SOP does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of the method to follow appropriate safety, waste disposal and health practices under the assumption that all samples and reagents are potentially hazardous. Safety glasses, gloves, lab coats and closed-toe, nonabsorbent shoes are a minimum.

5.1) Specific Safety Concerns or Requirements

5.1.1) Eye protection with side-shields that protect against splash, laboratory coat, and nitrile gloves must be worn while handling samples, standards, solvents, and reagents. Disposable gloves that have been contaminated must be removed and discarded; non-disposable gloves must be cleaned immediately.

NOTE: Latex and vinyl gloves provide no protection against the organic solvents used in this method. Nitrile or similar gloves must be used.

5.1.2) The gas chromatograph and mass spectrometer contain zones that have elevated temperatures. The analyst needs to be aware of the locations of those zones, and must cool them to room temperature prior to working on them.

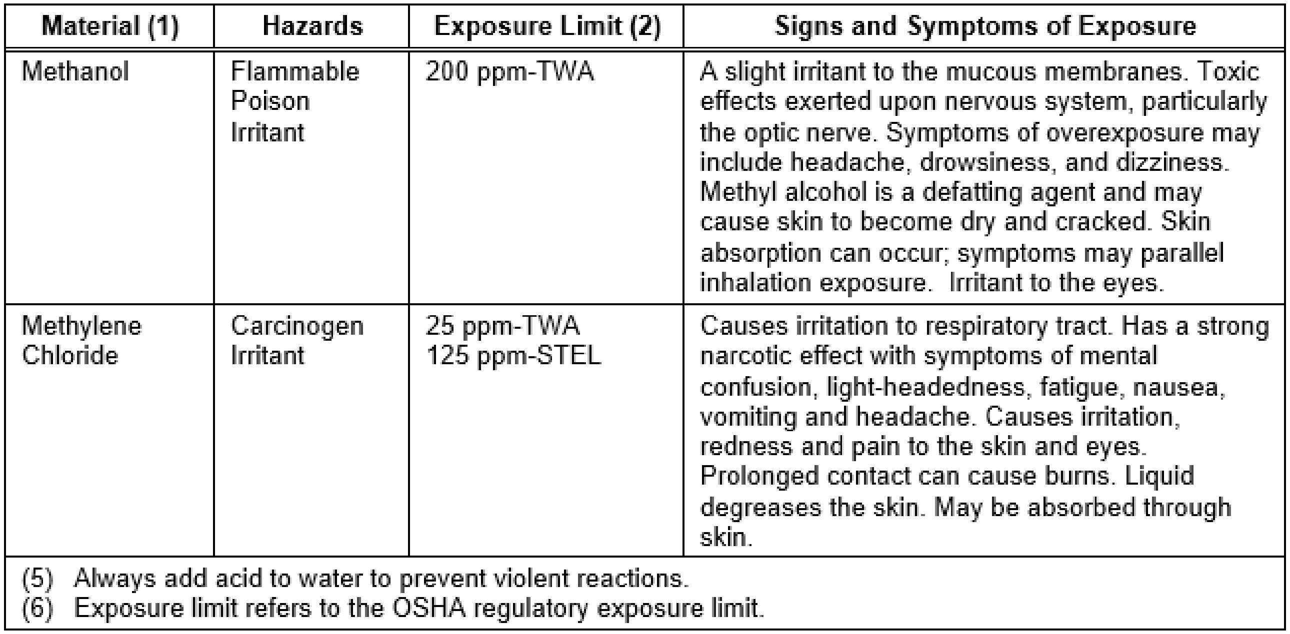
5.1.3) The mass spectrometer is under deep vacuum. The mass spectrometer must be brought to atmospheric pressure prior to working on the source.

5.1.4) There are areas of high voltage in both the gas chromatograph and the mass spectrometer. Depending on the type of work involved, either turn the power to the instrument off, or disconnect it from its source of power before performing any maintenance.

5.2) Primary Materials Used

The following is a list of the materials used in this method, which have a serious or significant hazard rating. This list does not include all materials used in the method. The table contains a summary of the primary hazards listed in the SDS for each of the materials listed in the table. A complete list of materials used in the method can be found in the reagents and materials section. Employees must review the information in the SDS for each material before using it for the first time or when there are major changes to the SDS.

Materials with Significant or Serious Hazard Rating



Material (1)	Hazards	Exposure Limit (2)	Signs and Symptoms of Exposure
Methanol	Flammable Poison Irritant	200 ppm-TWA	A slight irritant to the mucous membranes. Toxic effects exerted upon nervous system, particularly the optic nerve. Symptoms of overexposure may include headache, drowsiness, and dizziness. Methyl alcohol is a defatting agent and may cause skin to become dry and cracked. Skin absorption can occur; symptoms may parallel inhalation exposure. Irritant to the eyes.
Methylene Chloride	Carcinogen Irritant	25 ppm-TWA 125 ppm-STEL	Causes irritation to respiratory tract. Has a strong narcotic effect with symptoms of mental confusion, light-headedness, fatigue, nausea, vomiting and headache. Causes irritation, redness and pain to the skin and eyes. Prolonged contact can cause burns. Liquid degreases the skin. May be absorbed through skin.

(5) Always add acid to water to prevent violent reactions.
(6) Exposure limit refers to the OSHA regulatory exposure limit.

6) Equipment and Supplies

The following items are recommended for performing this procedure. Equivalent items should only be used when they result in an improvement in quality, efficiency, productivity, or cost. An item can be considered equivalent if with its use, the analytical and QA/QC requirements in this SOP can be met.

6.1) Gas chromatograph/mass spectrometer system: an analytical system complete with a temperature-programmable gas chromatograph suitable for split/splitless injection and all required accessories, including syringes, analytical columns, and gases. The capillary column should be directly coupled to the source.

6.2) Column: 30 m x 0.32 mm I.D. x 0.50-µm film thickness fused-silica capillary column coated with 5% diphenyl/95% dimethyl polysiloxane(Restek Rtx -5MS or equivalent). Alternate columns are acceptable if they provide acceptable performance.

6.3) Mass Spectrometer: Capable of scanning from 35 to 500 u (previously “amu”) every one second or less*, using 70 volts (nominal) electron energy in the electron impact ionization mode. The mass spectrometer must be capable of producing a mass spectrum for decafluorotriphenylphosphine (DFTPP) that meets all of the criteria in Table 4 when 50 ng of the GC/MS tuning standard is injected through the GC/MS.

- *The scan rate must be fast enough to acquire at least five (but preferably ten or more) mass spectra across each peak of interest.

6.4) Autosampler: HP7683 Autosampler or equivalent.

6.5) GC/MS Interface: Any GC-to-MS interface that gives acceptable calibration points and achieves acceptable tuning performance criteria may be used.

6.6)
Data System: A computer system must be interfaced to the mass spectrometer. The system must allow the continuous acquisition and storage on machine-readable media of all mass spectra obtained throughout the duration of the chromatographic program. The computer must have software that can search any GC/MS data file for ions of a specific mass and that can plot such ion abundances versus time or scan number. This type of plot is defined as the Extracted Ion Current Profile (EICP). Software must also be available that allows integrating the abundances in any EICP between specified time or scan-number limits. The most recent version of the EPA/NIH Mass Spectral Library is recommended.

6.7) Syringe: 10 µL Hamilton Laboratory grade syringes or equivalent. The 10 µL syringe is used for the Agilent ALS to be able to inject 2.0 µL.

6.8) Carrier gas: Ultra high-purity helium

6.9)
Injection Port Liners - Sylonized following this procedure, as needed:
a) Remove old glass wool plug
b) Using a Q-tip dipped in Toluene, swab the inside of liner
c) Replace old glass wool plug with new glass wool
d) Place liner in a 40 mL containing Sylon-CT solution until ready to use
e) Remove from Sylon-CT, rinse first with Methanol and then with Methylene Chloride (repeat this process once)
f) Place the clean liner into a VOA vial or onto a piece of foil and bake the liner in a GC oven until dry (approximately 2 minutes)
NOTE: Replace the Sylon-CT solution every two weeks or sooner if floating particulates are visible.

7) Reagents and Standards

The following items are recommended for performing this procedure. Equivalent items should only be used when they result in an improvement in quality, efficiency, productivity, or cost. An item can be considered equivalent if with its use, the analytical and QA/QC requirements in this SOP can be met. Please refer to the SDS prior to the use of any reagent or standard.

The preparation of standards, surrogates and spiking solutions is documented in the TALS Reagent Module. Formulary reports can be generated upon request.

7.1) Calibration Standard

7.1.1) Stock Solutions: Stock solutions may be purchased as certi¬fied solutions in sealed ampules from commercial sources or prepared from pure standard materials as appropriate. These standards are prepared in methanol and stored in Teflon-sealed screw-cap bottles with minimal headspace at -10° to -20°C. Purchased stock solutions in sealed ampules use the manufacturer's documented expiration date and storage requirements. Once the ampule is opened, the standard is assigned an expiration date of 1-year from the opened date, not to exceed the manufacturer's assigned date.

7.1.2)

Stock standards from a second source are required for verification of the primary stock standards. These standards must follow all requirements for the primary stocks. Verification standards (ICV) are prepared at the mid-range of the initial calibration in methylene chloride.

- Second source standards may be from the same manufacturer if certified that it was prepared independently from the batch used for calibration.

7.2) An eight-point calibration curve is prepared (a minimum of five is required) when average response factors or linear regression curve fitting is used. Six calibration points are required for second-order curve fits. The low point should be at or below the reporting limit. Calibration standards are prepared in methylene chloride. Refer to Table 9 for typical calibration levels for all analytes. Other calibration levels may be used, depending on instrument capability, but the low standard must support the reporting limit and the high standard defines the range of the calibration.

7.3) An internal standard (IS) solution is prepared. Compounds in the IS Mix are acenaphthene-d10, chrysene-d12, 1,4-dichlorobenzene-d4, naphthalene-d8, perylene-d12, and phenanthrene-d10.

7.3.1) Internal standards are added to all calibration standards and extracts to result in a final concentration of 4 µg/mL. For example, if the volume of an extract aliquot used was 100 µL, 1 µL of a 40 µg/mL internal standard solution would be added to the aliquot

7.4)

Surrogate Standard Spiking Solution: Prepare as indicated in the extraction SOPs. Typically a mix of surrogate solutions is purchased. Surrogate compound levels are listed in Table 8.

Acid Surrogates	**Base Surrogates**
2-Fluorophenol	2-Fluorobiphenyl
2,4,6-Tribromophenol	Terphenyl-d4
Phenol-d5	Nitrobenzene-d5

7.5) GC/MS Tuning Standard: A methylene chloride solution containing 25 ng/ul of decafluorotriphenylphosphine (DFTPP) is prepared and injected on to the column. Pentachlorophenol, benzidine, and DDT should also be included in the Tuning Standard at 25 ng/ul.

7.6) Laboratory Control / Matrix Spiking Solution: Prepare as indicated in the extraction SOPs. The spike solution is purchased with a certificate of analysis and contains all routinely analyzed target analytes. Appendix IX compounds and other specially requested compounds are included in the LCS/MS/MSD as requested by the client, and at least biannually.

7.7) All standards are stored away from any light source at >0.0°C but ≤6.0 °C (-10 °C recommended). The standard stock solutions expire after one year from preparation date or at the earliest expiration date assigned by the vendor to any parent standard, whichever is earlier. The working standards prepared from the stock standards are replaced every 6 months. The continuing calibration standard should be replaced every week, when there are visible signs of degradation, or when the standard fails to meet QC criteria

8) Sample Collection, Preservation, Shipment and Storage

8.2) Samples and extracts are stored at >0.0°C but ≤ 6.0ºC. Samples and extracts should be stored in suitable glass containers with Teflon lined caps. Extracts will be kept for at least 30 days after invoicing.

Matrix	Sample Container	Min. Sample Size	Preservation	Extraction Holding Time	Analysis Holding Time
Waters	1 liter amber	1 Liter	Cool, >0.0°C but ≤ 6.0ºC	7 Days	40 Days from extraction
Soils[1]	4oz Jar	15 grams	Cool, >0.0°C but ≤ 6.0ºC	14 Days	40 Days from extraction

[1] Includes solids, sludges, sediments, and organic liquid wastes

9) Quality Control

9.1) **Control Limits**

9.2.1) In-house statistical control limits, based on historical analytical data, must be determined for surrogates, matrix spikes, and laboratory control samples (LCS). These limits must be reviewed at least annually. The recovery limits are set using the mean recovery +/- 3 standard deviations for surrogates, MS and LCS Precision limits for matrix spikes / matrix spike duplicates are mean relative percent difference +/- 3 standard deviations

9.2.2) Precision limits for the MS/MSD pair results are the absolute value of the mean relative percent difference (RPD) ±3 standard deviations.

9.2.3) All QC, even failing compounds, must be entered into TALS so that realistic statistical control limits can be generated.

9.2.4) Refer to the QC program SOP, PIT-QA-QAS-SOP45631 (formerly PT-QA-021), for further details of control limits.

9.3) The following QC are performed with each preparation batch. Spiking is done to the original sample volume prior to extraction.

Quality Controls	**Frequency**	**Acceptance Limits**
Method Blank (MB)	1 per preparation batch1	< 1/2 RL or ≤ 10X analyte concentration found in client samples
Laboratory Control Sample (LCS) 2	1 per preparation batch1	Statistical limits are maintained in TALS
Matrix Spike (MS)2,3	1 per preparation batch1	Statistical limits are maintained in TALS. MS is not used for batch control.
Matrix Spike Duplicate (MSD)2,3	1 per preparation batch1	Statistical limits are maintained in TALS. MSD is not used for batch control.
Surrogates2	All samples and QC	Statistical limits are maintained in TALS

[1] A preparation batch is a maximum of 20 samples plus the associated prepared QC

2Statistical control limits are developed and updated as per SOP PIT-QA-QAS-SOP45631. LCS for batches with samples from South Carolina must meet 70-130% recovery limits for all target compounds, 60-140% for poor performers.

[3] The parent sample used for MS/MSD is randomly selected, unless specifically requested by a client

9.4) The following QC are performed along with each analysis batch. Standards are prepared by the GCMS analyst. Internal standards are added to the extracts prior to analysis. NOTE: Initial Calibration is not performed with each analytical batch.

Analytical QC	**Frequency**	**Acceptance Limits[1]**
Tune check (DFTTP)	1 per 12 hr clock, prior to any standards or samples	See Table 4
Initial Calibration Curve (ICAL)	Annually or more often as needed, minimum 5 points	8270D/E: ≤ 20%RSD see section 10.2
Initial Calibration Verification	After each ICAL	8270D/E: ≤30%D, see section 10.2.8
Calibration Verification Standard	1 per 12 hr clock, prior to any samples	8270D/E ≤ 20%D, see section 10.2.9.3
Internal Standards	All samples and QC	50– 200% Response in mid-level of ICAL

[1] Refer to Table 2 for List 1 and List 2 compounds

9.5) One

Method Blank (MB) is analyzed along with each batch of 20 or fewer samples of the same matrix. MBs are spiked with surrogates and internal standards.

9.5.1)
The MB must not contain any analyte of interest at or above ½ the reporting limit. For any analyte detected above the MDL in the MB, associated samples results will be reported with a "B" qualifier. If the MB is contaminated above ½ the RL, reanalyze the blank once. If the failure repeats, re-extraction of the associated samples is required unless one of the following situations exists. Blank subtraction is not permitted.

- If the analyte is a common laboratory contaminant (phthalate esters) the data may be reported with B qualifiers if the concentration of the analyte is not more than 5x the reporting limit. Results are reported using the "Method Blank – Report, Common Lab Contaminant < 5x RL" NCM.
- If the affected compound is not detected above the RL in the samples associated with an unacceptable method blank, the data may be reported with qualifiers and using the "Method Blank – Report, ND" NCM.
- If the sample concentrations are greater than 10x the concentration seen in the MB, results may be reported with qualifiers and using the "Method Blank – Report, 10X" NCM.
- If reanalysis of the batch is not possible due to limited sample volume or other constraints, the PM should be contacted for direction on how to proceed. If the data must be reported, affected compounds are qualified with a "B" in the associated samples, and appropriate comments are made in the case narrative

9.5.2) The MB must have acceptable surrogate recoveries. If surrogate recoveries are not acceptable, the data must be evaluated to determine if the method blank has served the purpose of demonstrating that the sample analysis is free of contamination. All non-conforming blanks will be documented in an NCM and, if reported, the reasons for reporting the data will be summarized. For example, if surrogate recoveries are low, re-extraction and/or reanalysis of the blank and affected samples will normally be required. If the surrogate recoveries are high in the MB only, results for samples may be reported along with narration. The PM must be contacted and consultation with the client should take place for how to proceed

9.6) One Laboratory Control Samples (LCS) is analyzed along with each batch of 20 or fewer samples of the same matrix. The matrix of the LCS matches that of the MB. The compounds must be spiked at a concentration equivalent to 20 ng/mL, depending on the analyte, unless a special QAS states a specific level. The LCS contains all routine analytes of interest (See Table 2). Appendix IX or other specialty analytes are added as required by client project, and at least once every 2 years. If any target analyte or surrogate is outside established control limits, the system is out of control and corrective action must occur (see marginal exceedance allowance in section 9.5.3). Samples associated with a failed LCS must be reanalyzed unless one of the following situations exists:

9.6.1) If the LCS recovers above the control limits, and the affected compound is not detected above the RL in the associated samples, results may be reported with qualification and using the "LCS/LCSD - %R High" NCM.

9.6.2) If reanalysis of the batch is not possible due to limited sample volume or will be past the analytical holding time, the PM must be notified and the client input sought on how to proceed. If the data must be reported, all associated sample results are qualified, and appropriate comments are made in a narrative to document the situation.

9.6.3) For SW846 methods, when there are more than 11 target analytes in the LCS, NELAC allows a specified number of results to fall beyond the

LCS control limit (3 standard deviations), but within the marginal exceedance (ME) limits, which are set at 4 standard deviations around the mean of historical data. The number of marginal exceedances allowed is based on the number of analytes in the LCS, as shown in the following table.

Allowed Marginal Exceedance

# of Analytes in LCS	**# of Allowed MEs**
> 90	5
71 – 90	4
51 – 70	3
31 – 50	2
11 – 30	1
< 11	0

- If more analytes exceed the LCS control limits than is allowed, or if any analyte exceeds the ME limits, the LCS fails and corrective action is necessary. Marginal exceedances must be sporadic and random, which is defined as no more than 2 failures in 3 consecutive batches. If the same analyte repeatedly fails the LCS control limits, it is an indication of a systematic problem, and this is tracked through the review of LCS control charts. The source of the error must be identified and corrective action taken
- ME limits are determined using the same annual control charts as the LCS control limits
- Use of marginal exceedances is not permitted for South Carolina work. Control Limits for South Carolina projects are 70-130% with poor performers at 60-140%. See Table 11 for list of poor performers.

NOTE:
Due to the nature of Safety Kleen samples, an LCS/LCSD will always be analyzed for QC purposes, in accordance with client instructions

9.7) One Matrix Spike / Matrix Spike Duplicate (MS/MSD) pair is required to be analyzed with every batch of 20 or fewer samples. The sample used for MS/MSD analysis is chosen at random from the batch unless a client specifies a sample for QC. Spiked compounds and recovery limits are the same as those established for the LCS. Precision limits are calculated from control charts run on an annual basis.

NOTE: Method 8270E allows for a duplicate/matrix spike OR a matrix spike/matrix spike duplicate to be analyzed for QC purposes

9.7.1) Batch quality is not controlled on the MS/MSD acceptance alone because the sample matrix is being tested. The initial corrective action for MS/MSD failures will be to check the recovery of that analyte in the Laboratory Control Sample (LCS). If the recovery of the analyte in the LCS is within limits, then the laboratory operation is in control and analysis may proceed. Only parent sample results will be qualified associated with MS/MSD failures.

9.7.2) If the recovery for any control component is outside QC limits for both the MS/MSD and the LCS, the laboratory operation is out of control and corrective action must be taken according to the LCS section above.

9.7.3) If a MS/MSD is not possible due to limited sample, it is acceptable to run only an MS, or the LCS may be analyzed in duplicate. RPD of the LCS and LCSD are compared to the matrix spike limits. Document this situation using the “MS/MSD/DUP – Insufficient Volume” NCM.

9.7.4) The matrix spike/duplicate must be analyzed at the same dilution as the unspiked, or parent, sample, even if some matrix spike compounds will be diluted out.

9.8) Surrogates are spiked into all samples and QC to monitor both the analytical system and the effect of the sample matrix on it. Surrogate compounds and spiking levels are provided in Table 8. Surrogate recovery limits are statistically determined annually using historical data. If recovery of any surrogate is outside limits, corrective action is required.

9.8.1)
If surrogate recovery is above the control limits, and none of the associated compounds are detected above the RL, results may be reported using the "Surrogate – High, ND" NCM.

9.8.2) Samples that have major matrix interference, which is obvious from the chromatogram, will not be rerun for confirmation of matrix interference. Results will be reported using the "Surrogate – Matrix" NCM.

9.8.3) The decision to reanalyze or flag the data should be made in consultation with the PM and client if neither of the above applies. It is only necessary to reprepare/reanalyze a sample once to demonstrate that poor surrogate recovery is due to matrix effect

9.8.4) If the surrogates are out of control for the sample, matrix spike, and matrix spike duplicate, then matrix effect has been demonstrated for that sample and re-preparation is not necessary. If the sample is out of control and the MS and/or MSD is in control, then reanalysis or flagging of the data is required.

9.8.5) Surrogate evaluation for dilutions

9.8.5.1) Samples analyzed straight and up to a 5X should have a reportable value for the surrogates above 10%, unless an underlying matrix, obvious or not, is suspected in the technical judgement of the analyst. When technical judgment is applied, no re-extraction will be performed and an explanatory NCM will be written and included with the TALS job. No "D" qualifier will be applied in TALS.

9.8.5.2) Samples analyzed at 6X and up to and including a 20X may have a reportable value less than 10% for the surrogate results. If surrogates are outside QC limits, regardless of obvious matrix or not, these samples will NOT require re-extraction due to the dilution performed, because sample matrix in conjunction with the dilution may cause reportable surrogate results to be less than 10%. No "D" qualifier will be applied in TALS only the "DL" suffix is used.

9.8.5.3) Samples analyzed at 11X and up to including a 20X will have their surrogates considered not monitored. In these instances, the values for the surrogates will be reported and No "D" qualifier will be applied in TALS.

9.8.5.4) Samples analyzed at a 21X and above will have their surrogates considered diluted out. The surrogate values will be reported as "0" on the quantitation report and a “D” qualifier will be manually applied in TALS denoting that the surrogate value being reported is from a diluted analysis and the results will be considered diluted out or not calculated.

9.9) Internal standards (IS) are added to all QC and samples to monitor system performance and adjust for minor changes over time and from sample matrices. The response of the IS must be within 50 – 200% of the response seen in the mid-level standard of the Initial Calibration Curve. If IS response is outside this range, it indicates either a drift in instrument response, or an adverse effect of the sample matrix and corrective action is required.

9.9.1) Internal standards (IS) are added to all QC and samples to monitor system performance and adjust for minor changes over time and from sample matrices. The response of the IS must be within 50 – 200% of the response seen in the mid-level standard of the Initial Calibration Curve. If IS response is outside this range, it indicates either a drift in instrument response, or an adverse effect of the sample matrix and corrective action is required.

9.9.2) If IS response falls outside the acceptance range in a MB or LCS, this may indicate a drift in instrument response from the ICAL, and a new initial calibration curve must be analyzed if the failures repeats.

9.9.3) IS failure in a sample or MS/MSD may be caused by the matrix. If volume is available, the sample should be reanalyzed to confirm, unless the matrix interference is obvious. If the bad matrix is obvious, results for the associates compounds are considered as estimated and may be reported along with the “ISTD – Matrix” NCM.

9.9.4) If the sample matrix effect is not obvious, and the sample cannot be reanalyzed due to limited volume or holding time, results for the associates compounds are considered as estimated and may be reported along with the “ISTD – No RX/Rerun” NCM.

9.9.5) Internal standards are also used to monitor for retention time shifts. See section 10.5.2 for details.

9.10) Instrument Blank - Instruments must be evaluated for contamination during each 12-hour analytical run. This may be accomplished by analysis of a method blank. If a method blank is not available, an instrument blank must be analyzed. An instrument blank consists of methylene chloride with the internal standards added. It is evaluated in the same way as the method blank.

9.11) Project-specific requirements can override the requirements presented in this section when there is a written agreement between the laboratory and the client, and the source of those requirements should be described in the project documents and approved by a supervisor and QA Manager.

10) Procedure

10.1) Sample Preparation - Samples are prepared according to the following organic preparation SOPs, as applicable

- PIT-ORG-ORGP-SOP45818 Extraction of Organic Compounds from Waters, Based on SW-846 3500 Series and 600 Series Methods
- PIT-ORG-ORGP-SOP45820 Extraction of Organic Compounds from Solids, Sediments, Tissue and Wipes Based on SW-846 3500 Series
- PIT-ORG-ORGP-SOP45822 Cleanup of Organic Compounds from Waters, Solids, Sediments, Tissue and Wipes Based on SW-846 3600 Series and CarboPrep90 Methods

10.2) Calibration - The instrument is tuned for DFTPP, calibrated initially with an eight point calibration curve (minimum of a five levels required), and verified each 12-hour shift with one or more continuing calibration standard(s). Recommended instrument conditions are listed in Table 3.

10.2.1) All standards and extracts are allowed to warm to room temperature before injecting.

10.2.2) Instrument Tuning

10.2.2.1) Prior to any GCMS analytical sequence, including calibration, the instrument parameters for the tune and subsequent sample analyses within that sequence must be set. Prior to tuning/auto-tuning the mass spec, the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally do not need any adjustment but it may be required based on the current instrument performance. If the tune verification does not pass it may be necessary to clean the source or perform additional maintenance. Any maintenance is documented in the maintenance log.

10.2.2.2) At the beginning of every twelve-hour shift when analyses are to be performed, the GC/MS system must be checked to see if the acceptance criteria are achieved for DFTPP (decafluorotriphenylphosphine). See Table 4.

10.2.2.3) Inject 50 ng/ul of the GC/MS tuning standard (Section 7.5) into the GC/MS system. Part of the purpose of the tune is to demonstrate sensitivity and analyzing solutions at higher concentrations does not support this purpose. Tune failures may be due to saturation and a lower DFTPP concentration may be warranted. Obtain a background-corrected mass spectra of DFTPP and confirm that all the key m/z criteria in Table 4 are achieved.

10.2.2.4) Acceptable means of passing DFTPP are as follows:

- Tune evaluations usually utilize the "Autofind" function and are set up to look at the apex +/- 1 scan and average the three scans. Background correction is required prior to the start of the peak but no more than 20 scans before. Background correction cannot include any part of the target peak. The peak apex, or the scan immediately before the apex, or the scan immediately after the apex, or the average of these three scans may be used.

10.2.2.5) Options or if Auto Tune Fails:

- Sometimes the instrument does not always correctly identify the apex on some peaks when the peak is not perfectly shaped. In this case, manually identify and average the apex peak +/- 1 scan and background correct as in 10.2.2.4 above. This is consistent with EPA 8270D/E.

- A single scan at the Apex (only) may also be used for the evaluation of the tune. For SW 846 methods, background correction is still required.
- Adjustments such as adjustments to the repeller and ion focus lenses, adjusting the EM Voltage, etc. may be made prior to tune verification as long as all of the subsequent injections in the 12 hour tune cycle are analyzed under the same MS tune settings and it is documented in the run sequence log and/or maintenance log that an adjustment was made. Necessary maintenance is performed and documented in instrument log. If changes are made to EM Voltage or other parameters that can result in changes to response and/or instrument sensitivity, a new initial calibration curve must be run under the new conditions prior to sample analysis.
- Cleaning the source or other maintenance may be performed and then follow steps for tune evaluation above. Note: If significant maintenance was performed, see methods 8000D then the instrument may require recalibration prior to proceeding.
- Tune evaluation printouts must include the chromatogram and spectra as well as the Tune evaluation information. In addition, the verifications must be sent directly to the printer or pdf file (no screen prints for DFTPP tunes). This ability should be built into the instrument software.
- Since the limits are expressed in whole percentages, the results may be rounded to whole percentage before comparing to criteria when assessing the tune verification against the tune requirements. However, the comparison to the criteria is usually done automatically by the software and if the printout says “Fail” then there would have to be documentation of the hand calculation on the raw data and comparison to the criteria if the lab intends to still accept the tune. In most cases the analyst is better off performing an adjustment and rerunning the tune standard.
- All MS tune settings must remain constant between running the tune check and all other samples. It is recommended that a separate tune method not be used, however a separate method may be used as long as the MS conditions between the methods are the same as the sample analysis method and tracked so any changes that are made to the analysis method are also made to the tune method.
- If the instrument has a built in macro that checks the DFTPP, use of this macro with no manual manipulation is also acceptable and preferred (assuming, of course that the correct ion ratios are being checked).

10.2.2.6) If all the criteria are not achieved, the analyst must retune the mass spectrometer and repeat the test until all criteria are achieved. The performance criteria must be achieved before any samples, blanks, or standards are analyzed.

10.2.2.7) The GC/MS tuning standard should also be used to evaluate the inertness of the chromatographic system. The acceptance criteria for the peak tailing factor for benzidine is < 2.0 and pentachlorophenol is < 2.0. DDT breakdown must be <20%. Refer to section 11 for the appropriate calculations.

10.2.3) **Initial Calibration**

10.2.3.1) Internal Standard (IS) Calibration Procedure: Internal standards are listed in Table 6. Use the base peak m/z as the primary m/z for quantitation of the standards. If interferences are noted, use one of the next two most intense masses for quantitation.

10.2.3.2) Compounds are assigned to the IS with the closest retention time.

10.2.3.3) Prepare calibration standards at eight (a minimum of five required) concentration levels for each parameter of interest when average response factors or linear regression curve fits are used. Six standards must be used for a quadratic least-squares calibration. It may also be useful to analyze six calibration levels and use the lower five for most analytes and the upper five for analytes that have poor response.

10.2.3.4) Generally, it is not acceptable to remove points from a calibration. If calibration acceptance criteria are not met, the normal corrective action is to examine conditions such as instrument maintenance and accuracy of calibration standards. Any problems must be fixed and documented in the run log or maintenance log. Then the calibration standard(s) must be reanalyzed.

10.2.3.5) If no problems are found or there is documented evidence of a problem with a calibration point (e.g., obvious misinjection explained in the run log), then one point might be rejected, but only if all of the following conditions are met:

- The rejected point is the highest or lowest on the curve, i.e., the remaining points used for calibration must be contiguous; and
- The lowest remaining calibration point is still at or below the project reporting limit; and
- The highest remaining calibration point defines the upper concentration of the working range, and all samples producing results above this concentration are diluted and reanalyzed; and
- The calibration must still have the minimum number of calibration levels required by the method, i.e. five levels for calibrations modeled with average response factors or linear regressions, or six levels for second-order curve fits.

10.2.3.6) Add the internal standard mixture to result in a 4-ng/mL final concentration. (For example, if the volume of the calibration standard used is 1.0 mL, add 10 µL of the 400 µg/mL internal standard). The concentrations of all analytes are listed in Table 9.

10.2.3.7) Analyze each calibration standard and tabulate the area of the primary characteristic m/z against the concentration for each compound and internal standard. Standard concentrations are listed in Table 9. Calculate the response factors (RF), average response factors, and the percent RSD of the response factors for each compound using the equations in Section 11. No sample analysis may be performed unless these criteria are met.

10.2.4) **Selection of Calibration Curve Fit Type**

10.2.4.1) Average Response Factor

- If all analyte RSDs in the initial calibration are ≤20% for methods 8270D/E, then all analytes may use average response factor for calibration.
- If the software in use is capable of routinely reporting curve coefficients for data validation purposes, and the necessary calibration reports can be generated, then the analyst should evaluate analytes with RSD ≥20% for methods 8270D/E for calibration on a curve. If it appears that substantially better accuracy would be obtained using quantitation from a curve fit, then the appropriate curve should be used for quantitation.
- If analyte RSDs in the initial calibration are ≥20% for method 8270D/E, then calibration using an alternative curve fit, must be used for those analytes. Linear or quadratic curve fits may be used. Use of 1/Concentration2 weighting is recommended to improve the accuracy of quantitation at the low end of the curve. The analyst should consider instrument maintenance to improve the linearity of response.

10.2.4.2) Linear Regression

- A weighted linear regression may be used even if the average response factor curve is acceptable.
-
- If linear regression is used the calibration must employ weighting by 1/Amt or $1/(Amt)^2$. A minimum of 5 points are required. The coefficient of determination (r^2) must be > 0.990.
- See section 10.2.6 for ICAL readback acceptance criteria.
- If the readback criteria fails for any analyte, sample detects should be reanalyzed under passing critiera. If reanalysis is not possible, the result must be flagged as estimated, or described in the narrative.
- For non-detects, reanalysis is not required, and flagging is not required.

10.2.4.3) Quadratic Regression

- In some cases the response/concentration relationship may be non-linear. In these cases quadratic regression may be used.
- Quadratic fits must only be used where an average or weighted linear fit is clearly inappropriate. **Quadratic curve fits are not allowed for analysis of South Carolina samples.**
- Force through zero is allowed, but should be necessary only rarely.
- A minimum of 6 points are required for a quadratic curve, and the coefficient of determination (r^2) must be > to 0.990. Additional checks are required to ensure that a quadratic fit is appropriate:
- The calibration plot must be inspected to ensure that the curve does not flatten out (i.e., slope = 0) or become negative within the range of the calibration.
- Where a quadratic curve fit is applied- all chromatograms for all samples must be inspected for off scale peaks in the retention time range of the analyte.
- See section 10.2.6 for ICAL readback acceptance criteria.
- If the readback criteria fails for any analyte, sample detects should be reanalyzed under passing criteria. If reanalysis is not possible, the result must be flagged as estimate, or the situation described in the narrative.
- For non-detects, if the readback failed with high recovery, reanalysis is not required, and flagging is not required. If the readback failed low, samples should be reanalyzed. If reanalysis is not possible, the result must be flagged as estimate, or the situation described in the narrative.

10.2.4.4) Linear Regression (unweighted)

- Unweighted linear should be used only where other available fits are clearly inappropriate.
- If unweighted linear regression is used, a minimum of 5 points are required. The coefficient of determination (r^2) must be > 0.990.
- See section 10.2.6 for ICAL readback acceptance criteria.
- If this readback criteria fails for any analyte, sample detects should be reanalyzed under passing criteria. If reanalysis is not possible, the result must be flagged as estimate, or the situation described in the narrative.
- For non-detects, if the readback failed with high recovery, reanalysis is not required, and flagging is not required. If the readback failed low, samples should be reanalyzed. If reanalysis is not possible, the result must be flagged as estimate, or the situation described in the narrative.

10.2.4.5) For method 8270D and 8270E, if more than 10% of the compounds included with the initial calibration exceed the 20% RSD limit and do not meet the minimum correlation coefficient (0.990) for alternate curve fits, then the chromatographic system is considered too reactive for analysis to begin. Clean or replace the injector liner and/or column, then repeat the calibration procedure. Minimum response factors should be met, especially for the low level standard.

10.2.4.6) Any analyte that fails both the RSD and the correlation requirement must have any positive result flagged as estimated and the non-conformance must be explained in the case narrative.

10.2.4.7) Any individual analyte that fails the minimum response factor (see Table 10) must have a demonstration of sensitivity in the analytical batch to report non-detects. Detected results may be reported without qualification.

- The demonstration of sensitivity is analysis of a low level CCV (LODV) at or below the reporting limit. The criterion for passing a LODV is detection only and a passing LODV allows non-detects to be reported without flagging.
- The LODV would be analyzed immediately after the mid-level CCV.
- Table 10 is used as guidance for the minimum response factors, however the RFs may be modified if appropriate (for example, especially if low level analysis is performed).

10.2.4.8) Table 11 lists Eurofins Pittsburgh’s poor performing compounds and the criteria used to evaluate these compounds in the ICAL, ICV and CCV.

10.2.5) Weighting of Calibration Data Points

In a linear or quadratic calibration fit, the points at the lower end of the calibration curve have less weight in determining the curve generated than points at the high concentration end of the curve. However, in environmental analysis, accuracy at the low end of the curve is very important. For this reason, it is preferable to increase the weighting of the lower concentration points. 1/Concentration^2 weighting (often called $1/X^2$ weighting) will improve accuracy at the low end of the curve and should be used if the data system has this capability. Because the data system does not indicate the type of weighting used, the analyst must make a notation on the initial calibration form as to the weighting used (e.g. $1/x$ or $1/x^2$).

10.2.6) Calibration Point Read-back Criteria

Whichever calibration model above is selected, it should be subjected to an additional check to establish the representativeness of the data that were used to produce it. This check is the refitting of each calibration point response back to the calibration model, or the comparison of the calculated amount of the standard against the expected amount.

- CHROM software provides an Initial Calibration %Drift report which shows the % Error for each calibration point. This report must be reviewed in addition to the %RSD / Linear Response Factor.
- The absolute value of the % Error for each calibration point should be < 30%. For the lowest calibration point, the % Error may be < 50%.
- See section 11.8 for the Calculation of the %Error.

10.2.7) If time remains in the 12-hour period initiated by the DFTPP injection before the initial calibration, samples may be analyzed. Otherwise, proceed to continuing calibration, Section 10.2.9.

NOTE: Quantitation is always performed using the calibration curve or average response factor from the initial curve, not the continuing calibration.

10.2.8) Second Source Calibration Verification Requirements: An initial calibration verification containing all components from a second source (an alternate vendor or a unique lot from the same vendor) must be analyzed after the initial calibration. The measured concentrations for all analytes of the second source standard must be within + 30% of the expected value. Table 11 lists Eurofins Pittsburgh's poor performing compounds and the criteria used to evaluate these compounds for second source ICV purposes for method 8270D/E.

10.2.8.1) If the SOP limits are exceeded, a fresh ICV standard is prepared and analyzed. If failure repeats, the ICAL and ICV should be reanalyzed.

10.2.8.2) If sample results must be reported associated with a failed ICV due to holding time or sample volume limitations, inform the Project Manager to get directions from the client. If results must be reported, describe the issue in the narrative or flag as an estimate. For samples from Pennsylvania, sample results must be flagged.

10.2.8.2) If sample results must be reported associated with a failed ICV due to holding time or sample volume limitations, inform the Project Manager to get directions from the client. If results must be reported, describe the issue in the narrative or flag as an estimate. For samples from Pennsylvania, sample results must be flagged.

10.2.9) Continuing Calibration Verification (CCV)

10.2.9.1) At the start of each 12-hour period, the GC/MS tuning standard must be analyzed. A 25-ng/µL injection of DFTPP must result in a mass spectrum for DFTPP, which meets the criteria given in Table 4.

10.2.9.2) Following a successful DFTPP analysis, the continuing calibration verification (CCV) standard(s) are analyzed. The standard(s) must contain all semivolatile analytes, including all required surrogates. A mid-level calibration standard is used for the CCV.

10.2.9.3) The following criteria must be met for the CCV to be acceptable:

- For method 8270D/E, all routine compounds (CCC and non-CCC) must have percent difference or drift (%D) £ 20%. Appendix IX compounds may have %D up to 40%. See Table 11 for poor-performer and Appendix IX compound list.
- Due to the large numbers of compounds that may be analyzed by this method, it is expected that some compounds will fail to meet the criterion.

    - For method 8270D/E, up to 20% of the compounds in the standard are allowed to fail exceed 20%D. If the criterion is not met for more than 20% of the compounds included in the calibration, then corrective action must take place prior to the analysis for samples. Any compound with a %D or Drift >20% must be narrated using the "CCV – Outside Criteria; Estimated Value (EPA 8270D/8260C)" NCM.
    - In cases where compounds fail, they may still be reported as non-detects if recovery was high, or if it can be demonstrated that there was adequate sensitivity to detect the compound at the applicable quantitation limit. For situations where the failed compound is present, the concentrations must be reported as estimated values (J flagged).
- Each of the most common target analytes in the CCV must meet the minimum response factors listed in Table 10. If they are not met, the system is evaluated, and corrective action takes place before sample analysis begins. Possible problems include standard mixture degradation, injection port inlet contamination, contamination at the front end of the analytical column, and active sites in the column or chromatographic system. Table 10 is used as guidance for the minimum response factors, however the RFs may be modified if appropriate (for example, especially if low level analysis is performed). Any individual analyte that fails the minimum response factor (see Table 10) must have a demonstration of sensitivity in the analytical batch to report non-detects. The demonstration of sensitivity is analysis of a low level CCV (LODV) at or below the reporting limit. The LODV or LLCCV would be analyzed immediately after the mid-level CCV. The criterion for passing a LODV is detection only and a passing LODV allows non-detects to be reported without flagging. Currently, TALs does not allow for the upload of the LODVs, thus they will be monitored using the instrument runlog.

10.2.9.4) The internal standard response of the CCV must be within 50 - 200% of the response in the same level of the corresponding calibration. If any internal standard retention time in the CCV changes by more than 30 seconds from that of the same level of the corresponding initial calibration, the chromatographic system must be inspected for malfunctions and corrections made, as required.

10.2.9.5) Once the above criteria have been met, sample analysis may begin. Initial calibration average RFs (or the calibration curve) will be used for sample quantitation, not the continuing calibration RFs. Analysis may proceed until 12 hours from the injection of the DFTPP have passed. (A sample injected less than or equal to 12 hours after the DFTPP is acceptable.)

10.2.9.6) Table 11 lists Eurofins Pittsburgh's poor performing compounds and the criteria used to evaluate these compounds for ICAL, ICV and CCV purposes.

10.2.9.7) Any sample detects for an analyte that fails the SOP CCV criteria must be flagged as an estimated or described in the narrative. Sample results (both ND and detects) associated with a compound outside 20%D in the CCV must be flagged for samples from Pennsylvania.

10.3) Sample Analysis Procedure

10.3.1) QC standards and sample extracts are stored at >0.0°C but ≤ 6.0°C, protected from light in screw cap vials equipped with unpierced Teflon lined septa. Allow standards and sample extracts to warm to room temperature prior to injection.

10.3.2) Preventative maintenance performed daily includes clipping column and changing the gold seal and injection port liner. This daily maintenance is part of the routine procedure, and is not recorded in the instrument maintenance logs.

10.3.3) Calibrate the instrument as described in Section 10.2. Depending on the target compounds required by the client, it may be necessary to use more than one set of calibration standards.

10.3.4) All samples must be analyzed using the same instrument conditions as the preceding continuing calibration verification (CCV) standard.

10.3.5) Add internal standard to an aliquot of the extract to result in a 4-ng/mL concentration (for example, 1.0 µL of internal standard solution at, 400 µg/mL in 100 µL of extract). Mix thoroughly before injection into the instrument.

10.3.6) Inject the aliquot into the GC/MS system using the same injection technique as used for the standards.

10.3.6) Inject the aliquot into the GC/MS system using the same injection technique as used for the standards.

10.3.7) The data system will determine the concentration of each analyte in the extract using calculations in Section 11. Quantitation is based on the initial calibration, not the continuing calibration verification.

10.3.8) Identified compounds are reviewed for proper integration. Manual integrations are performed if necessary and are documented by the analyst (see NDSC-QA-SOP43862, Manual Integrations) or automatically by the data system. The minimum documentation required includes a hard copy of original data system peak integration and a similarly scaled hard copy showing the manual integration with analyst ‘s electronic initials/name, date and reason for manual integration.

10.3.9) Target compounds identified by the data system are evaluated using the criteria listed in Section 11.1.

10.3.10) Library searches of peaks present in the chromatogram that are not target compounds, i.e., Tentatively Identified Compounds (TIC), may be performed if required by the client. They are evaluated using the criteria in Section 11.2.

10.3.11) Analysis of extracts from tissue samples follows the same procedure as other samples as described in this SOP.

10.4) Dilutions

10.4.1) If the response for any compound exceeds the working range of the GC/MS system, a dilution of the extract is prepared and analyzed. An appropriate dilution should be between the 4 and 10 ng on column concentration. Samples may be screened to determine the appropriate dilution for the initial run. If the initial diluted run has no hits or hits below 20% of the calibration range and the matrix allows for analysis at a lesser dilution, the sample must be reanalyzed at a dilution targeted to bring the largest hit above 50% of the calibration range. See Table 12, which shows how dilutions are prepared.

10.4.2) Guidance for Dilutions Due to Matrix

If the sample is initially run at a dilution and the baseline rise is less than the height of the internal standards, or if individual non-target peaks are significantly less than two times the height of the internal standards, the sample should be reanalyzed at a more concentrated dilution. This requirement is approximate and subject to analyst judgment. For example, samples containing organic acids may need to be analyzed at a higher dilution to avoid destroying the column.

10.4.3) Reporting Dilutions

The most concentrated dilution with no target compounds above the calibration range will be reported. Other dilutions will be reported only at client request.

10.5) Retention Time Criteria for Samples

If the retention time for any internal standard changes by more than 0.5 minutes from the last continuing calibration standard, the chromatographic system must be inspected for malfunctions and corrected. Reanalysis of samples analyzed while the system was malfunctioning is required.

10.6) Percent Moisture

Analytical results may be reported as dry or wet weight, as required by the client. Percent moisture must be determined if results will be reported as dry weight. Refer to SOP *PIT-WC-SGRAV-SOP45403* (formerly PT-WC-020) for determination of percent moisture.

10.7) Troubleshooting Guide

10.7.1) Daily Instrument Maintenance

In addition to the checks listed in Appendix A, the following daily maintenance should be performed.

- Clip Column as necessary.

- Install new or cleaned injection port liner as necessary.
- Install new septum as necessary.
- Install new or cleaned gold seal and washer as necessary.
- Perform mass calibration as necessary.
- Refill rinse autosampler vials with clean methylene chloride.

10.7.2) Major Maintenance

10.7.2.1) A new initial calibration is necessary following certain maintenance procedures. These maintenance procedures include changing or reversing the column, cleaning or changing the repeller, cleaning the source, replacing the multiplier, and replacing the “top board” or RF-related electronics. Refer to the manufacturer's manual for specific guidance.

10.7.3) In contrast, some maintenance procedures should not automatically require recalibration of the instrument. These maintenance procedures include changing septa, compressed gas cylinders, autosampler syringes, moisture traps, PTFE transfer lines, column fittings or inlet liners, breaking off or changing the guard column, changing an injection port or filaments and cleaning the inlet.

10.7.3.1) Whenever such procedures are performed, the analyst must demonstrate that the results for a CCV meet the acceptance criteria in section 10.8.15.3 before the analysis of any samples. Otherwise, recalibration is required.

11) Calculations/Data Reduction

11) **Calculations / Data Reduction**

11.1) Qualitative Identification

An analyte is identified by retention time, the relative abundances of characteristic ions and by comparison of the sample mass spectrum with the mass spectrum of a standard of the suspected compound (standard reference spectrum). Mass spectra for standard reference may be obtained on the user's GC/MS by analysis of the calibration standards or from the NBS library. Two criteria must be satisfied to verify identification: (1) elution of sample component at the same GC retention time as the standard component; and (2) correspondence of the sample component and the standard component characteristic ions.

NOTE: Care must be taken to ensure that spectral distortion due to co-elution is evaluated.

11.1.1) The sample component relative retention time must compare to within ± 0.06 RRT units of the relative retention time of the standard component. For reference, the standard must be run within the same twelve hours as the sample.

11.1.2) All ions present in the standard mass spectra at a relative intensity greater than 10% (most abundant ion in the spectrum equals 100%) should be present in the sample spectrum.

11.1.3) The characteristic ions of a compound must maximize in the same scan or within one scan of each other.

11.1.4) The relative intensities of ions should agree to within ±30% between the standard and sample spectra. (Example: For an ion with an abundance of 50% in the standard spectra, the corresponding sample abundance must be between 20% and 80%.)

11.1.5) If a compound cannot be verified by all the above criteria, but in the technical judgment of the analyst the identification is correct, the analyst shall report that identification and proceed with quantitation.

11.1.6) Mass chromatogram searches:

Certain compounds are unstable in the calibration standard and cannot be calibrated in the normal way. In particular, the compound hexachlorophene (CAS 70-30-4) falls into this category, and is required for Appendix IX analysis. For this analyte a mass chromatogram search is made.

11.1.6.1) Hexachlorophene - Display the mass chromatograms for mass 196, mass 198 and mass 209 for the region of the chromatogram from at least 2 minutes before chrysene-d12 to at least 4 minutes after chrysene-d12. If peaks for both ions coincide then the analyst evaluates the spectrum for the presence of hexachlorophene. No quantitation is possible.

11.2) For samples containing components not associated with the calibration standards, a library search may be made for the purpose of tentative identification. The necessity to perform this type of identification will be determined by the type of analyses being conducted. Computer generated library search routines should not use normalization routines that would misrepresent the library or unknown spectra when compared to each other. Only after visual comparison of sample spectra with the nearest library searches shall the mass spectral interpretation specialist assign a tentative identification. Following are guidelines for making tentative identification:

11.2.1) Relative intensities of major ions in the reference spectrum (ions >10% of the most abundant ion) should be present in the sample spectrum.

11.2.2) The relative intensities of the major ions should agree to within ±20%. (Example: For an ion with an abundance of 50% in the standard spectrum, the corresponding sample ion abundance should be between 30% and 70%.)

11.2.3) Molecular ions present in the reference spectrum should be present in the sample spectrum.

11.2.4) Ions present in the sample spectrum, but not in the reference spectrum, should be reviewed for possible background contamination or the presence of co-eluting compounds.

11.2.5) Ions present in the reference spectrum, but not in the sample spectrum, should be reviewed for possible subtraction from the sample spectrum because of background contamination or co-eluting peaks. Data system library reduction programs can sometimes create these discrepancies.

11.2.6) Automatic background subtraction can severely distort spectra from samples with unresolved hydrocarbons.

11.3) Isomers with identical mass spectra and close elution times pose problems for definitive identification. The following compounds fall into this category:

Aniline and bis(2-chloroethyl) ether
Dichlorobenzenes
2- and 4-Methylphenol/Benzyl alcohol
Trichlorophenols
Phenanthrene, anthracene
Fluoranthene, pyrene
Benzo(b) and (k)fluoranthene
Chrysene, benzo(a)anthracene
1&2-Methylnaphthalene
Bis(2-Ethylhexyl)phthalate/Di-n-octyl-phthalate
Indeno(1,2,3-cd)pyrene/Benzo(g,h,i)perylene
Safrole/1-Chloronaphthalene
1&2-Naphthylamine
1&2-Chloronaphthalene
2,4,5 and 2,4,6-Tribromophenol

Identification of these compounds requires both experience and extra precautions on the part of the analyst. Specifically, the analyst must more closely scrutinize the comparison of retention times between the unknown and the calibration standard. The analyst must also check that all isomers have distinct retention times. Structural isomers are considered resolved if the peaks are at least 50% resolved using the mid-point of the ICAL as well as the daily CCV.

11.4)
A second category of problem compounds consist of the poor responders or compounds that chromatograph poorly. The integrations for these types of compounds should be checked manually. The following compounds are included in this category:
Benzoic acid
Chloroanilines
Nitroanilines
2,4-Dinitrophenol
4-Nitrophenol
Pentachlorophenol

3,3'-Dichlorobenzidine
Benzyl alcohol
4,6-Dinitro-2-methylphenol
Atrazine
Famphur
Benzidine
2,2’- Oxybis (1-Chloropropane)
Kepone

11.5) Calculating the Percent Relative Standard Deviation for Initial Calibration

$$\%RSD = \frac{SD}{RF} \times 100\%$$

Where:

RF = Mean of RFs from the initial calibration for a compound
SD = Standard deviation for the mean RF from the initial calibration for a compound

$$SD = \sqrt{\frac{\sum_{i=1}^{n}\left(RF_i - \overline{RF}\right)^2}{n-1}}$$

RFi = RF for each of the calibration levels
n = Number of RF values

11.6) Calculating the Continuing Calibration Percent Drift

$$\%Drift = \frac{C_{actual} - C_{found}}{C_{actual}} \times 100\%$$

Where:

C actual = Known concentration in standard
C found = Measured concentration using selected quantitation method

11.7)
Calculating the Concentration in the Extract

The concentration of each identified analyte and surrogate in the extract is calculated from the linear or quadratic curve fitted to the initial calibration points, or from the average RF of the initial calibration

11.7.1)
Average Response Factor Calibration

If the average of all the RSDs of the response factors in the initial calibration is £20%, the average response factor from the initial calibration may be used for quantitation.

$$C_{ex} = \frac{R_x C_{is}}{R_{is} \overline{RF}}$$

Where:
Cex = Concentration in the extract, µg/mL
Rx = Response for the analyte
Ris = Response for the internal standard
Cis = Concentration of the internal standard
$\overline{RF}$ = Average response factor

11.7.2) Linear Fit Calibration

$$C_{ex} = A + B\frac{(R_x C_{is})}{R_{is}}$$

Where:
Cex = Concentration in the extract, µg/mL
Rx = Response for the analyte
Ris = Response for the internal standard
Cis = Concentration of the internal standard
A = Intercept of linear calibration line
B = Slope of linear calibration line

11.7.3) Quadratic Fit Calibration

$$C_{ex} = A + B\left(\frac{R_x C_{is}}{R_{is}}\right) + C\left(\frac{R_x C_{is}}{R_{is}}\right)$$

Where:
Cex = Concentration in the extract, µg/mL
Rx = Response for the analyte
Ris = Response for the internal standard

Cis = Concentration of the internal standard
A = Intercept
B = Factor for the linear term of the quadratic calibration function
C = Factor for the curvature term of the quadratic calibration function

11.8) Calculation of the %Error

$$\%Error = \frac{x_i - x_i'}{x_i} \text{x} \, 100$$

Where:

xi' = Measured amount of analyte at calibration level *i*, in mass or concentration unitsxi = True amount of analyte at calibration level *i*, in mass or concentration units

11.9) Calculating the Concentration in the Sample

$$\text{Concentration, } \mu\text{g / L} = \frac{C_{ex}V_t}{V_o}$$

Where:
Cex = Concentration in the extract
Vt = Volume of total extract in µL, taking into account dilutions (i.e., a 1-to-10 dilution of a 1-mL extract will mean that Vt = 10,000 µL. If half of the base/neutral extract and half of the acid extract are combined, then Vt = 2,000.)
Vo = Volume of the sample that was extracted (mL)

11.9.2) Calculation for Sediment, Soil, Sludge, and Waste Samples

Results for sediments, sludges, and soils are usually calculated on a dry-weight basis, and for waste, on a wet-weight basis.

$$\text{Concentration, } \mu\text{g / kg} = \frac{C_{ex}V_t}{W_sD}$$

Where:
Cex = Concentration in the extract
Vt = Volume of total extract in µL, taking into account dilutions (i.e., a 1-to-10 dilution of a 1-mL extract will mean that Vt = 10,000 µL. If half of the base/neutral extract and half of the acid extract are combined, then Vt = 2,000.)
Ws = Weight of sample extracted or diluted in grams
D = (100 - % moisture in sample)/100, for a dry-weight basis or 1 for a wet-weight basis

11.10) MS/MSD Percent Recovery Calculation

$$\text{Matrix Spike Recovery} = \frac{S_{SR} - S_R}{S_A} \times 100\%$$

Where:
SSR = Spike sample result
SR = Sample result
SA = Spike added

11.11) Calculating the Relative Percent Difference (RPD) MS/MSD Pair

$$RPD = \frac{|MS_R - MSD_R|}{(MS_R + MSD_R)/2} \times 100$$

Where:
RPD = Relative percent difference
MSR = Matrix spike result
MSDR = Matrix spike duplicate result

11.12) Relative Response Factor Calculation

$$RF = \frac{A_x C_{is}}{A_{is} C_x}$$

Where:
Ax = Area of the characteristic ion for the compound being measured
Ais = Area of the characteristic ion for the specific internal standard
Cx = Concentration of the compound being measured (µg/L)
Cis = Concentration of the specific internal standard (µg/L)

11.13) Calculation of TICs

The calculation of TICs (tentatively identified compounds) is identical to the above calculation (11.12) with the following exceptions:
Ax = Area of the total ion chromatogram for the compound being measured
Ais = Area of the total ion chromatogram for the nearest internal standard without interference
RF = 1

11.14) Calculating Percent DDT Breakdown

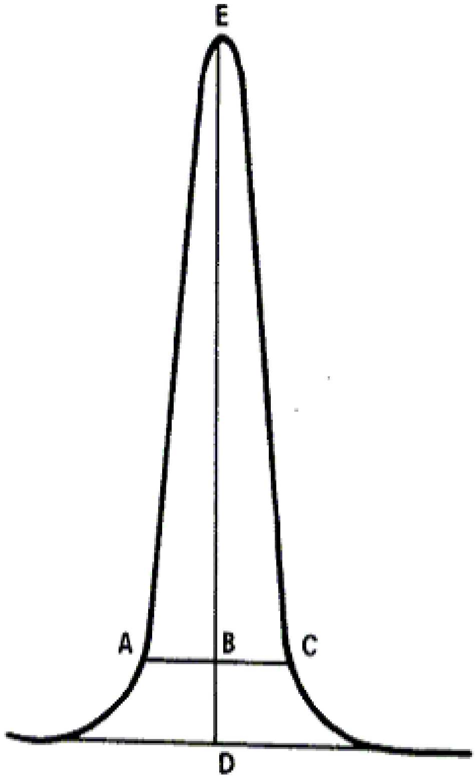
$$\%\,\text{DDT breakdown} = \frac{\text{DDEarea} + \text{DDDarea}}{\text{DDTarea} + \text{DDEarea} + \text{DDDarea}}$$

The areas for the 235 ion are used for this calculation.

11.15) Calculating the Peak Tailing Factor

$$TailingFactor = \frac{BC}{AB}$$

Where:
Peak width (AC) is measured at 10% peak height, and divided into two line segments at the peak centroid, so that.
AC = AB + BC, with
AB = left-hand segment
BC = right-hand segment



$$\text{TAILING FACTOR} = \frac{BC}{AB}$$

Example calculation: Peak Height = DE = 100 mm
10% Peak Height = BD = 10 mm
Peak Width at 10% Peak Height = AC = 23 mm
AB = 11 mm
BC = 12 mm

$$\text{Therefore: Tailing Factor} = \frac{12}{11} = 1.1$$

12) Method Performance

12.1) The supervisor has responsibility to ensure that an analyst who performs this procedure is properly trained in its use and has the required experience. Performance is monitored through internal QC and outside performance evaluation samples. Please refer to the QA Manual for additional information concerning Precision and Accuracy.

12.2) Demonstration of Capabilities – Prior to the analysis of samples, a Demonstration of Capabilities (DOC) as described in the QA Manual and SOP PIT-QA-TR-SOP45633 (formerly PT-QA-001), must be performed initially, annually and any time a significant change is made to the analytical system.

12.3) Method Detection Limit Study – A Method Detection Limit (MDL) study, as described in the NDSC Detection and Quantitation Limits SOP, *NDSC-QA-SOP42091*, must be performed initially and whenever a significant change is made to the analytical system. The MDL must be re-evaluated from quarterly MDL points at least every 12 months.

12.4) Lower Limit of Quantitation Verification – The lowest calibration standard analyzed establishes the LLOQ or Reporting Limit. The capability to reliably detect this concentration through the preparation, clean-up and analytical procedure is verified through the annual analysis of a standard at the LLOQ/RL. The LLOQ verification shall also be performed whenever significant changes are made to the preparation and/or analytical procedure.

12.4.1) The LLOQ verification standard shall be prepared at a concentration 0.5-2 times the LLOQ/RL, and be taken through all preparation and clean-up methods which samples would be.

12.4.2) The LLOQ verification standard for aqueous matrix shall be prepared using laboratory deionized water and for the solid matrix using clean Ottawa sand. Other clean matrices may be used in addition, for project specific requirements.

12.4.3) See *PIT-QA-DR-SOP45621* for further discussion on the LLOQ process and criteria.

13) Pollution Control

13.1) It is Eurofins' policy to evaluate each method and look for opportunities to minimize waste generated (i.e., examine recycling options, ordering chemicals based on quantity needed, preparation of reagents based on anticipated usage and reagent stability). Employees must abide by the policies in Section 13 of the NDSC Environmental Health and Safety Manual (*NDSC-US EHS-QP46060*) for "Waste Management and Pollution Prevention" and the Pittsburgh Facility Addendum EH&S Manual (*PIT-EHS-HS-SOP45640*).

14) Waste Management

14.1) Waste management practices are conducted consistent with all applicable rules and regulations. Excess reagents, samples and method process wastes are disposed of in accordance with all federal and state laws and regulations. Waste description rules and land disposal restrictions are followed. Waste disposal procedures are incorporated by reference to PIT-EHS-HS-SOP45640 (note a Waste Disposal SOP or manual). The following waste streams are produced when this method is carried out.

14.1.1) Solvent waste generated from cleaning operations and out of specification standards. This waste is placed in a waste container identified as “Methylene Chloride Waste”, Waste #2 or “Mixed Flammable Solvent Waste”, Waste #3.

14.1.2) Sample extracts in vials - This waste is placed in containers identified as “Vials & Extracts”, Waste #7.

14.1.3) Sylon Waste - This waste is collected in a container identified as “Sylon (5%) / Toluene Waste”, Waste #20.

15) References/Cross-References

15.1) Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846, 3rd Edition, Final Update V, Revision 5, July 2014, Method 8270D

15.2) Test Methods for Evaluating Solid Waste, Update VI, Gas Chroma-tography/Mass Spectrometry for Semivolatile Organic Compounds, Method 8270E, Revision 6, June 2018

15.3) SW 846, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, Update V, Method 8000D, Determinative Chromatographic Separations, Revision 4, October 2012

15.4) USEPA Contract Laboratory Program National Functional Guidelines for Organic Data Review, OSWER 9240.1-05A-P, PG99-963-506, EPA540/R-99/008, October 1999

15.5)
PIT-ORG-ORGP-SOP458158 Extraction of Organic Compounds from Waters, Based on SW-846 3500 Series and 600 Series Methods.

15.6)
PIT-ORG-ORGP-SOP45820 Extraction of Organic Compounds from Solids, Sediments, Tissue and Wipes Based on SW-846 3500 Series

15.7) PIT-ORG-ORGP-SOP45822 Cleanup of Organic Compounds from Waters, Solids, Sediments, Tissue and Wipes Based on SW-846 3600 Series and CarboPrep90 Methods

15.8) *NDSC-QA-SOP43862*, Manual Integrations

15.9) *NDSC-QA-SOP42091*, Detection and Quantitation Limits

15.10) PIT-QA-TR-SOP45633, Employee Orientation and Training

15.11) PIT-QA-QAS-SOP45629, Nonconformance and Corrective Action System

15.12)
PIT-QA-AUD-SOP45620, Technical Data Review Requirements

15.13)
PIT-QA-QAS-SOP45631, Quality Control Program

15.14) Pittsburgh Laboratory Quality Assurance Manual (PIT-QA-QM45117)

15.15) *PIT-EHS-HS-SOP45640*, Pittsburgh Facility Addendum EH&S Manual to the Corporate Environmental Health and Safety Manual (*NDSC-US EHS-QP46060*) for "Waste Management and Pollution Prevention"

15.16) *PIT-SM-RCT-SOP45637*, Internal Chain of Custody

15.17) *PIT-QA-DR-SOP45621*, Detection Limits

16) Method Modifications

16.1) The quantitation and qualifier ions for some compounds have been added to the list of those, which are recommended in SW-846 in order to improve the reliability of qualitative identification.

16.2) Method 8270E requires the DFTPP tune standard to be analyzed once prior to an ICAL and not daily after that prior to sample analysis. The laboratory will analyzed the DFTPP tune daily, prior to QC and sample analysis. The laboratory will use the tighter criteria from Method 8270D for tune evaluation, rather than the criteria suggested in Table 3 of Method 8270E.

17) Attachments

17.1)
Table 1 - Eurofins Pittsburgh Routine and Low Level Standard Reporting Limits (RLs)
Table 2 - Reportable Compounds for EurofinsPittsburgh Standard Tests
Table 3 - Suggested Instrument Conditions
Table 4 - DFTPP Key Ions and Ion Abundance Criteria
Table 5 - Characteristic Ions for Routine and Appendix IX Compounds
Table 6 - Semivolatile Internal Standards with Corresponding Analytes assigned for Quantitation
Table 7 - 8270 TCLP LCS Compounds
Table 8 - 8270 Surrogate Compounds
Table 9 - Routine and Appendix IX Standard Calibration Levels, µg/mL
Table 10 - Minimum Response Factor Criteria for Initial and Continuing Calibration Verification
Table 11 - Method 8270 Poor Performers and Laboratory Acceptance Criteria
Table 12 - Eurofins Pittsburgh GCMS Semivolatile Dilution Calculation Table
Appendix A - Instrument Maintenance Schedules - Mass Spectrometer & Gas Chromatograph

18) Revision History

18.1) Revision 0, 1/31/2009

18.2) Revision 1, 7/27/2009

18.3) Revision 2, 5/15/2012

18.4) Revision 3, 9/27/2013

18.5) Revision 4, 1/26/2016

18.6) Revision 5, 4/20/2016

18.7) Revision 6, 7/19/2016

18.8) Revision 7, 12/12/2016

18.9) Revision 8, 3/10/2017

18.10) Revision 9, 1/31/2019

18.11) Revision 10, 5/17/2019

18.12) Revision 11, 07/06/2021

18.13)
Changes to current revision

SOP section	**Change from**	**Change to**	**Reason**
Entire SOP	TestAmerica PT-QA-016 TALS Corporate PT-QA-M-001 PT-OP-028 CW-E-M-001 PT-HS-001 PT-QA-021 PT-OP-001 PT-OP-026 PT-OP-028 CA-Q-S-002 PT-WC-020 PT-QA-001 PT-QA-007 CA-Q-S-006 PT-QA-016 PT-QA-018 PT-QA-031	Eurofins PIT-QA-QAS-SOP45629 LIMS NDSC PIT-QA-QM452117 PIT-ORG-ORGP-SOP45822 NDSC-US-EHS-QP46060 PIT-EHS-HS-SOP45640 PIT-QA-QAS-SOP45631 PIT-ORG-ORGP-SOP45818 PIT-ORG-ORGP-SOP45820 PIT-ORG-ORGP-SOP45822 NDSC-QA-SOP43862 *PIT-WC-SGRAV-SOP45403* PIT-QA-TR-SOP45633 *PIT-QA-DR-SOP45621* *NDSC-QA-SOP42091* PIT-QA-QAS-SOP45629 PIT-QA-AUD-SOP45620 PIT-SR-RCT-SOP45637	Naming change
Entire SOP	Removed all references to Method 8270C since we no longer support this method		Dropped Method 8270C
1.6		Added ‘that accompanies the analytical batch.” After NCM in the 2nd sentence	SOP Checklist format

6.9		Added this section for sylonizing liners as needed to be consistent with 625.1 SOP	Clarification
9.8.5.3		Added this section for dilutions between 11X and up to and including 20X to be consistent with 625.1 SOP	Clarification
9.8.5.4		Added "manually" in front of "applied"	Clarification
10.2.2.3	"Inject 25 ng/uL"	"Inject 50 ng/uL"	Correction
10.2.2.5	Removed reference to 8000C	Added "/E" after "EPA 8270D"	Correction
11.4		Added Kepone to the poor performers list	Correction
Table 1	LLW RL 0.20 ug/L	LLW RL 0.19 ug/L	Correction
Table 9	Level 1 0.20 ug/L Level 1 0.40 ug/L	Level 1 0.19 ug/L Level 1 0.38 ug/L	Correction

19) Appendix

19.1)

Table 1

Eurofins Pittsburgh Standard and Low Level Reporting Limits (RLs)[1]

Compound	CAS #	Standard RL Aqueous (µg/L)	Standard RL Soil (µg/kg)	Low Level RL Aqueous (µg/L)	Low Level RL Soil (µg/kg)
1,1'-Biphenyl	92-52-4	10	330	1.0	33
1,2,4,5-Tetrachlorobenzene	95-94-3	10	330	1.0	33
1,2,4-Trichlorobenzene	120-82-1	10	330	1.0	33
1,2-Dichlorobenzene	95-50-1	10	330	1.0	33
1,2-Diphenylhydrazine	122-66-7	10	330	1.0	33
1,3,5-Trinitrobenzene	99-35-4	10	330	1.0	33
1,3-Dichlorobenzene	541-73-1	10	330	1.0	33
1,3-Dinitrobenzene	99-65-0	10	330	1.0	33
1,4-Dichlorobenzene	106-46-7	10	330	1.0	33
1,4-Dinitrobenzene	100-25-4	10	330	1.0	33
1,4-Dioxane	123-91-1	20	660	2.0	66
1,4-Naphthoquinone	130-15-4	10	330	1.0	33

1-Chloronaphthalene	90-13-1	10	330	1.0	33
1-Methylnaphthalene	90-12-0	2	66	0.19	6.6
1-Naphthylamine	134-32-7	10	330	1.0	33
2,2'-oxybis[1-chloropropane] [2]	108-60-1	10	330	1.0	33
2,3,4,6-Tetrachlorophenol	58-90-2	10	330	1.0	33
2,3,5,6-Tetrachlorophenol	935-95-5	10	330	1.0	33
2,4,5-Trichlorophenol	95-95-4	10	330	1.0	33
2,4,6-Trichlorophenol	88-06-2	10	330	1.0	33
2,4-Dichlorophenol	120-83-2	10	330	1.0	33
2,4-Dimethylphenol	105-67-9	10	330	1.0	33
2,4-Dinitrophenol	51-28-5	50	1650	5.0	165
2,4-Dinitrotoluene	121-14-2	10	330	1.0	33
2,6-Dichlorophenol	87-65-0	10	330	1.0	33
2,6-Dinitrotoluene	606-20-2	10	330	1.0	33
2-Acetylaminofluorene	53-96-3	10	330	1.0	33
2-Chloronaphthalene	91-58-7	2	66	0.19	6.6
2-Chlorophenol	95-57-8	10	330	1.0	33
2-Methylnaphthalene	91-57-6	2	66	0.19	6.6
2-Methylphenol	95-48-7	10	330	1.0	33
2-Naphthylamine	91-59-8	10	330	1.0	33
2-Nitroaniline	88-74-4	50	1650	5.0	165
2-Nitrophenol	88-75-5	10	330	1.0	33
2-Picoline	109-06-8	10	330	1.0	33
2-Toluidine	95-53-4	10	330	1.0	33
3,3'-Dichlorobenzidine	91-94-1	10	330	1.0	33
3,3'-Dimethylbenzidine	119-93-7	50	1650	5.0	165
3-Methylcholanthrene	56-49-5	10	330	1.0	33
3-Nitroaniline	99-09-2	50	1650	5.0	165
4,4'-Methylene bis(2-chloroaniline)	101-14-4	10	330	1.0	33
4,6-Dinitro-2-methylphenol	534-52-1	50	1650	5.0	165
4-Aminobiphenyl	92-67-1	10	330	1.0	33
4-Bromophenyl phenyl ether	101-55-3	10	330	1.0	33
4-Chloro-3-methylphenol	59-50-7	10	330	1.0	33
4-Chloroaniline	106-47-8	10	330	1.0	33
4-Chlorophenyl phenyl ether	7005-72-3	10	330	1.0	33
4-Methylphenol	106-44-5	10	330	1.0	33
4-Nitroaniline	100-01-6	50	1650	5.0	165
4-Nitrophenol	100-02-7	50	1650	5.0	165
4-Nitroquinoline-1-oxide	56-57-5	50	1650	5.0	165
6-Methylchrysene	1705-85-7	10	330	1.0	33
7,12-Dimethylbenz(a)anthracene	57-97-6	10	330	1.0	33
Acenaphthene	83-32-9	2	66	0.19	6.6

Acenaphthylene	208-96-8	2	66	0.19	6.6
Acetophenone	98-86-2	20	660	2.0	66
Acrylamide	79-06-1	10	330	1.0	33
Aniline	62-53-3	10	330	1.0	33
Anthracene	120-12-7	2	66	0.19	6.6
Aramite, Total	140-57-8	10	330	1.0	33
Atrazine	1912-24-9	20	660	2.0	66
Benzaldehyde	100-52-7	20	660	2.0	66
Benzidine	92-87-5	200	6600	20.0	660
Benzo[a]anthracene	56-55-3	2	66	0.19	6.6
Benzo[a]pyrene	50-32-8	2	66	0.19	6.6
Benzo[b]fluoranthene	205-99-2	2	66	0.19	6.6
Benzo[g,h,i]perylene	191-24-2	2	66	0.19	6.6
Benzo[k]fluoranthene	207-08-9	2	66	0.19	6.6
Benzoic acid	65-85-0	50	1650	5.0	165
Benzyl alcohol	100-51-6	10	330	1.0	33
Bis(2-chloroethoxy)methane	111-91-1	10	330	1.0	33
Bis(2-chloroethyl)ether	111-44-4	10	330	1.0	33
Bis(2-ethylhexyl) phthalate	117-81-7	20	660	2.0	66
Butyl benzyl phthalate	85-68-7	10	330	1.0	33
Caprolactam	105-60-2	50	1650	5.0	165
Carbazole	86-74-8	10	330	1.0	33
Chlorobenzilate	510-15-6	10	330	1.0	33
Chrysene	218-01-9	2	66	0.19	6.6
Diallate	2303-16-4	10	330	1.0	33
Dibenz(a,h)anthracene	53-70-3	2	66	0.19	6.6
Dibenz[a,h]acridine	226-36-8	10	330	1.0	33
Dibenzofuran	132-64-9	10	330	1.0	33
Diethyl phthalate	84-66-2	10	330	1.0	33
Dimethoate	60-51-5	10	330	1.0	33
Dimethyl phthalate	131-11-3	10	330	1.0	33
Di-n-butyl phthalate	84-74-2	10	330	1.0	33
Di-n-octyl phthalate	117-84-0	10	330	1.0	33
Dinoseb	88-85-7	10	330	1.0	33
Diphenylamine [3]	122-39-4	10	330	1.0	33
Disulfoton	298-04-4	10	330	1.0	33
Ethyl methanesulfonate	62-50-0	10	330	1.0	33
Ethyl Parathion	56-38-2	10	330	1.0	33
Famphur	52-85-7	100	3300	10.0	330
Fluoranthene	206-44-0	2	66	0.19	6.6
Fluorene	86-73-7	2	66	0.19	6.6

Hexachlorobenzene	118-74-1	10	330	1.0	33
Hexachlorobutadiene	87-68-3	10	330	1.0	33
Hexachlorocyclopentadiene	77-47-4	10	330	1.0	33
Hexachloroethane	67-72-1	10	330	1.0	33
Hexachloropropene	1888-71-7	10	330	1.0	33
Hexadecane	544-76-3	10	330	1.0	33
Indene	95-13-6	2	66	0.19	6.6
Indeno[1,2,3-cd]pyrene	193-39-5	2	66	0.19	6.6
Isodrin	465-73-6	10	330	1.0	33
Isophorone	78-59-1	10	330	1.0	33
Isosafrole	120-58-1	10	330	1.0	33
Kepone	143-50-0	40	1320	4.0	132
Methapyrilene	91-80-5	10	330	1.0	33
Methyl methanesulfonate	66-27-3	10	330	1.0	33
Methyl parathion	298-00-0	10	330	1.0	33
Methyl Phenols,Total	1319-77-3	20	660	2.0	66
Naphthalene	91-20-3	2	66	0.19	6.6
n-Decane	124-18-5	10	330	1.0	33
Nitrobenzene	98-95-3	20	660	2.0	66
N-Nitro-o-toluidine	99-55-8	10	330	1.0	33
N-Nitrosodiethylamine	55-18-5	10	330	1.0	33
N-Nitrosodimethylamine	62-75-9	10	330	1.0	33
N-Nitrosodi-n-butylamine	924-16-3	10	330	1.0	33
N-Nitrosodi-n-propylamine	621-64-7	10	330	1.0	33
N-Nitrosodiphenylamine	86-30-6	10	330	1.0	33
N-Nitrosomethylethylamine	10595-95-6	10	330	1.0	33
N-Nitrosomorpholine	59-89-2	10	330	1.0	33
N-Nitrosopiperidine	100-75-4	10	330	1.0	33
N-Nitrosopyrrolidine	930-55-2	10	330	1.0	33
n-Octadecane	593-45-3	10	330	1.0	33
o,o',o''-Triethylphosphorothioate	126-68-1	10	330	1.0	33
p-Dimethylamino azobenzene	60-11-7	10	330	1.0	33
Pentachlorobenzene	608-93-5	10	330	1.0	33
Pentachloroethane	76-01-7	10	330	1.0	33
Pentachloronitrobenzene	82-68-8	10	330	1.0	33
Pentachlorophenol	87-86-5	10	330	1.0	33
Phenacetin	62-44-2	10	330	1.0	33
Phenanthrene	85-01-8	2	66	0.19	6.6
Phenol	108-95-2	10	330	1.0	33
Phorate	298-02-2	10	330	1.0	33
p-Phenylene diamine	106-50-3	200	6600	20.0	660

Pronamide	23950-58-5	10	330	1.0	33
Pyrene	129-00-0	2	66	0.19	6.6
Pyridine	110-86-1	10	330	1.0	33
Quinoline	91-22-5	10	330	1.0	33
Safrole, Total	94-59-7	10	330	1.0	33
Sulfotepp	3689-24-5	10	330	1.0	33
Thionazin	297-97-2	10	330	1.0	33

[1] The Eurofins Pittsburgh Standard of standards are the standards normally used at Eurofins Pittsburgh. These standards include normal TCL compounds and Appendix IX compounds necessary to accommodate the majority of client compound requests.

[2] 2,2'oxybis(1-chloropropane) was formally known as bis(2-chloroisopropyl)ether.

[3] Diphenylamine can't be separated from N-Nitrosodiphenylamine. Hits for the compound will be reported as N- Nitrosodiphenylamine.

19.2)

Table 2
Reportable Compounds for Eurofins Pittsburgh Standard Tests

Analytes	CAS #	Routine Standard of Standards Compounds	APPIX Standard of Standards Compounds	TCLP
1,1'-Biphenyl	92-52-4	List 2		
1,2,4,5-Tetrachlorobenzene	95-94-3	List 2		
1,2,4-Trichlorobenzene	120-82-1	List 1		
1,2-Dichlorobenzene	95-50-1	List 2		
1,2-Diphenylhydrazine	122-66-7	List 2		
1,3,5-Trinitrobenzene	99-35-4		X	
1,3-Dichlorobenzene	541-73-1	List 1		
1,3-Dinitrobenzene	99-65-0	List 2		
1,4-Dichlorobenzene	106-46-7	CCC		X
1,4-Dinitrobenzene	100-25-4		X	
1,4-Dioxane	123-91-1	List 2		
1,4-Naphthoquinone	130-15-4	List 2		
1-Chloronaphthalene	90-13-1		X	
1-Methylnaphthalene	90-12-0	List 2		
1-Naphthylamine	134-32-7		X	

2,2'-oxybis[1-chloropropane]	108-60-1	List 2		
2,3,4,6-Tetrachlorophenol	58-90-2	List 2		
2,3,5,6-Tetrachlorophenol	935-95-5	List 2		
2,4,5-Trichlorophenol	95-95-4	List 1		X
2,4,6-Trichlorophenol	88-06-2	CCC		X
2,4-Dichlorophenol	120-83-2	CCC		
2,4-Dimethylphenol	105-67-9	List 1		
2,4-Dinitrophenol	51-28-5	List 2		
2,4-Dinitrotoluene	121-14-2	List 1		X
2,6-Dichlorophenol	87-65-0	List 2		
2,6-Dinitrotoluene	606-20-2	List 1		
2-Acetylaminofluorene	53-96-3		X	
2-Chloronaphthalene	91-58-7	List 1		
2-Chlorophenol	95-57-8	List 1		
2-Methylnaphthalene	91-57-6	List 1		
2-Methylphenol	95-48-7	List 1		X
2-Naphthylamine	91-59-8	List 2		
2-Nitroaniline	88-74-4	List 2		
2-Nitrophenol	88-75-5	CCC		
2-Picoline	109-06-8		X	
2-Toluidine	95-53-4		X	
3,3'-Dichlorobenzidine	91-94-1	List 2		
3,3'-Dimethylbenzidine	119-93-7		X	
3-Methylcholanthrene	56-49-5		X	
3-Nitroaniline	99-09-2	List 2		
4,4'-Methylene bis(2-chloroaniline)	101-14-4		X	
4,6-Dinitro-2-methylphenol	534-52-1	List 2		
4-Aminobiphenyl	92-67-1		X	
4-Bromophenyl phenyl ether	101-55-3	List 1		
4-Chloro-3-methylphenol	59-50-7	CCC		
4-Chloroaniline	106-47-8	List 2		
4-Chlorophenyl phenyl ether	7005-72-3	List 1		
4-Methylphenol	106-44-5	List 1		X

4-Nitroaniline	100-01-6	List 2		
4-Nitrophenol	100-02-7	List 2		
4-Nitroquinoline-1-oxide	56-57-5		X	
6-Methylchrysene	1705-85-7		X	
7,12-Dimethylbenz(a)anthracene	57-97-6	List 2		
Acenaphthene	83-32-9	CCC		
Acenaphthylene	208-96-8	List 1		
Acetophenone	98-86-2	List 2		
Acrylamide	79-06-1		X	
Aniline	62-53-3	List 2		
Anthracene	120-12-7	List 1		
Aramite, Total	140-57-8		X	
Atrazine	1912-24-9	List 2		
Benzaldehyde	100-52-7	List 2		
Benzidine	92-87-5	List 2		
Benzo[a]anthracene	56-55-3	List 1		
Benzo[a]pyrene	50-32-8	CCC		
Benzo[b]fluoranthene	205-99-2	List 1		
Benzo[g,h,i]perylene	191-24-2	List 1		
Benzo[k]fluoranthene	207-08-9	List 1		
Benzoic acid	65-85-0	List 2		
Benzyl alcohol	100-51-6	List 2		
Bis(2-chloroethoxy)methane	111-91-1	List 1		
Bis(2-chloroethyl)ether	111-44-4	List 1		
Bis(2-ethylhexyl) phthalate	117-81-7	List 2		
Butyl benzyl phthalate	85-68-7	List 2		
Caprolactam	105-60-2	List 2		
Carbazole	86-74-8	List 2		
Chlorobenzilate	510-15-6		X	
Chrysene	218-01-9	List 1		
Diallate	2303-16-4		X	
Dibenz(a,h)anthracene	53-70-3	List 1		

Dibenz[a,h]acridine	226-36-8		X	
Dibenzofuran	132-64-9	List 1		
Diethyl phthalate	84-66-2	List 2		
Dimethoate	60-51-5		X	
Dimethyl phthalate	131-11-3	List 2		
Di-n-butyl phthalate	84-74-2	List 2		
Di-n-octyl phthalate	117-84-0	CCC		
Dinoseb	88-85-7		X	
Diphenylamine[1]	122-39-4	CCC		
Disulfoton	298-04-4		X	
Ethyl methanesulfonate	62-50-0		X	
Ethyl Parathion	56-38-2		X	
Famphur	52-85-7		X	
Fluoranthene	206-44-0	CCC		
Fluorene	86-73-7	List 1		
Hexachlorobenzene	118-74-1	List 1		X
Hexachlorobutadiene	87-68-3	CCC		X
Hexachlorocyclopentadiene	77-47-4	List 2		
Hexachloroethane	67-72-1	List 1		X
Hexachloropropene	1888-71-7		X	
Hexadecane	544-76-3	List 2		
Indene	95-13-6	List 2		
Indeno[1,2,3-cd]pyrene	193-39-5	List 2		
Isodrin	465-73-6		X	
Isophorone	78-59-1	List 1		
Isosafrole	120-58-1		X	
Kepone	143-50-0		X	
Methapyrilene	91-80-5		X	
Methyl methanesulfonate	66-27-3		X	
Methyl parathion	298-00-0		X	
Methyl Phenols,Total	1319-77-3	List 1		
Naphthalene	91-20-3	List 1		
n-Decane	124-18-5	List 2		

Nitrobenzene	98-95-3	List 1		X
N-Nitro-o-toluidine	99-55-8		X	
N-Nitrosodiethylamine	55-18-5		X	
N-Nitrosodimethylamine	62-75-9	List 2		
N-Nitrosodi-n-butylamine	924-16-3		X	
N-Nitrosodi-n-propylamine	621-64-7	List 1		
N-Nitrosodiphenylamine	86-30-6	CCC		
N-Nitrosomethylethylamine	10595-95-6		X	
N-Nitrosomorpholine	59-89-2		X	
N-Nitrosopiperidine	100-75-4		X	
N-Nitrosopyrrolidine	930-55-2	List 2		
n-Octadecane	593-45-3	List 2		
o,o',o''-Triethylphosphorothioate	126-68-1		X	
p-Dimethylamino azobenzene	60-11-7		X	
Pentachlorobenzene	608-93-5		X	
Pentachloroethane	76-01-7		X	
Pentachloronitrobenzene	82-68-8		X	
Pentachlorophenol	87-86-5	CCC		X
Phenacetin	62-44-2		X	
Phenanthrene	85-01-8	List 1		
Phenol	108-95-2	CCC		
Phorate	298-02-2		X	
p-Phenylene diamine	106-50-3		X	
Pronamide	23950-58-5		X	
Pyrene	129-00-0	List 1		
Pyridine	110-86-1	List 2		X
Quinoline	91-22-5		X	
Safrole, Total	94-59-7		X	
Sulfotepp	3689-24-5		X	
Thionazin	297-97-2		X	

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[1] 2,2’oxybis(1-chloropropane) was formally known as bis(2-chloroisopropyl)ether

[2] Diphenylamine is a required compound for Appendix IX. N-nitrosodiphenylamine decomposes in the injection port to form diphenylamine. Therefore these two compounds cannot be distinguished. Diphenylamine is not included in the calibration standard.

[3] Hexachlorophene is a required analyte for Appendix IX. This compound is not stable, and therefore not included in the calibration standard. The characteristic ions for hexachlorophene are searched for in the chromatogram via a library search (TIC).

List 1 and List 2 designations are for ICAL and CCV evaluations.

19.3)

Table 3

Suggested Instrument Conditions

Mass Range:	35 - 500 amu
Scan Time:	≤ 1 second/scan
Initial Column Temperature/Hold Time:	40 °C for 1 minute
Column Temperature Program:	40 - 320 °C at 11.5 °C/min.
Final Column Temperature/Hold Time:	320 °C (until at least one minute after Benzo(g,h,i)perylene has eluted)
Total Run Time	0.5 min based on the last compound of CCAL
Injector Temperature:	250 - 300°C
Transfer Line Temperature:	250 - 300°C
Source Temperature:	According to manufacturer's specifications
Injector:	Grob-type, split / splitless
Sample Volume:	1 or 2 µl
Carrier Gas:	Helium at 30 cm /sec.

19.4)

Table 4

DFTPP Key Ions and Ion Abundance Criteria

Mass	Ion Abundance Criteria
51	30 - 60% of mass 198
68	<2% of mass 69
70	<2% of mass 69
127	40 - 60% of mass 198

197	<1% of mass 198
198	Base peak, 100% relative abundance
199	5 - 9% of mass 198
275	10 - 30% of mass 198
365	>1% of mass 198
441	Present, but less than mass 443
442	>40% of mass 198
443	17 - 23% of mass 442

19.5)

Table 5
Characteristic Ions for Routine and Appendix IX Compounds

Analytes	CAS #	Primary	Secondary	Tertiary
1,1'-Biphenyl	92-52-4	154	153	76
1,2,4,5-Tetrachlorobenzene	95-94-3	216	214	218
1,2,4-Trichlorobenzene	120-82-1	180	182	145
1,2-Dichlorobenzene	95-50-1	146	148	111
1,2-Diphenylhydrazine	122-66-7	77	182	105
1,3,5-Trinitrobenzene	99-35-4	213	75	120
1,3-Dichlorobenzene	541-73-1	146	148	111
1,3-Dinitrobenzene	99-65-0	168	75	76
1,4-Dichlorobenzene	106-46-7	146	148	111
1,4-Dinitrobenzene	100-25-4	168	75	122
1,4-Dioxane	123-91-1	88	58	57
1,4-Naphthoquinone	130-15-4	158	104	102
1-Chloronaphthalene	90-13-1	162	127	164
1-Methylnaphthalene	90-12-0	142	141	115
1-Naphthylamine	134-32-7	143	115	116
2,2'-oxybis[1-chloropropane]	108-60-1	45	77	121
2,3,4,6-Tetrachlorophenol	58-90-2	232	230	131
2,3,5,6-Tetrachlorophenol	935-95-5	237	230	131
2,4,5-Trichlorophenol	95-95-4	196	198	200
2,4,6-Trichlorophenol	88-06-2	196	198	200

2,4-Dichlorophenol	120-83-2	162	164	98
2,4-Dimethylphenol	105-67-9	107	121	122
2,4-Dinitrophenol	51-28-5	184	63	154
2,4-Dinitrotoluene	121-14-2	165	63	89
2,6-Dichlorophenol	87-65-0	162	164	63
2,6-Dinitrotoluene	606-20-2	165	89	63
2-Acetylaminofluorene	53-96-3	181	180	223
2-Chloronaphthalene	91-58-7	162	164	127
2-Chlorophenol	95-57-8	128	64	130
2-Methylnaphthalene	91-57-6	142	141	115
2-Methylphenol	95-48-7	108	107	79
2-Naphthylamine	91-59-8	143	115	116
2-Nitroaniline	88-74-4	65	92	138
2-Nitrophenol	88-75-5	139	65	109
2-Picoline	109-06-8	93	66	92
2-Toluidine	95-53-4	106	107	77
3,3'-Dichlorobenzidine	91-94-1	252	254	126
3,3'-Dimethylbenzidine	119-93-7	212	213	211
3-Methylcholanthrene	56-49-5	268	252	253
3-Nitroaniline	99-09-2	138	108	92
4,4'-Methylene bis(2-chloroaniline)	101-14-4	231	266	268
4,6-Dinitro-2-methylphenol	534-52-1	198	51	105
4-Aminobiphenyl	92-67-1	169	168	170
4-Bromophenyl phenyl ether	101-55-3	248	250	141
4-Chloro-3-methylphenol	59-50-7	107	144	142
4-Chloroaniline	106-47-8	127	129	65
4-Chlorophenyl phenyl ether	7005-72-3	204	206	141
4-Methylphenol	106-44-5	108	107	79
4-Nitroaniline	100-01-6	138	92	108
4-Nitrophenol	100-02-7	139	109	65
4-Nitroquinoline-1-oxide	56-57-5	190	128	160
6-Methylchrysene	1705-85-7	242	239	241
7,12-Dimethylbenz(a)anthracene	57-97-6	256	241	120

Acenaphthene	83-32-9	153	152	154
Acenaphthylene	208-96-8	152	151	153
Acetophenone	98-86-2	105	77	51
Acrylamide	79-06-1	71	55	44
Aniline	62-53-3	93	66	65
Anthracene	120-12-7	178	179	176
Aramite, Total	140-57-8	185	135	63
Atrazine	1912-24-9	200	173	215
Benzaldehyde	100-52-7	77	105	106
Benzidine	92-87-5	184	92	185
Benzo[a]anthracene	56-55-3	228	229	226
Benzo[a]pyrene	50-32-8	252	253	125
Benzo[b]fluoranthene	205-99-2	252	253	125
Benzo[g,h,i]perylene	191-24-2	276	138	277
Benzo[k]fluoranthene	207-08-9	252	253	125
Benzoic acid	65-85-0	122	105	77
Benzyl alcohol	100-51-6	108	79	77
Bis(2-chloroethoxy)methane	111-91-1	93	95	123
Bis(2-chloroethyl)ether	111-44-4	93	63	95
Bis(2-ethylhexyl) phthalate	117-81-7	149	167	279
Butyl benzyl phthalate	85-68-7	149	91	206
Caprolactam	105-60-2	113	55	56
Carbazole	86-74-8	167	166	168
Chlorobenzilate	510-15-6	251	139	253
Chrysene	218-01-9	228	226	229
Diallate	2303-16-4	86	43	234
Dibenz(a,h)anthracene	53-70-3	278	139	279
Dibenz[a,h]acridine	226-36-8	279	280	278
Dibenzofuran	132-64-9	168	139	84
Diethyl phthalate	84-66-2	149	177	150
Dimethoate	60-51-5	87	93	125
Dimethyl phthalate	131-11-3	163	194	164
Di-n-butyl phthalate	84-74-2	149	150	104

Di-n-octyl phthalate	117-84-0	149	167	43
Dinoseb	88-85-7	211	163	147
Diphenylamine[1]	122-39-4	169	168	167
Disulfoton	298-04-4	88	97	89
Ethyl methanesulfonate	62-50-0	79	109	97
Ethyl Parathion	56-38-2	109	97	291
Famphur	52-85-7	218	125	93
Fluoranthene	206-44-0	202	101	203
Fluorene	86-73-7	166	165	167
Hexachlorobenzene	118-74-1	284	142	249
Hexachlorobutadiene	87-68-3	225	223	227
Hexachlorocyclopentadiene	77-47-4	237	235	272
Hexachloroethane	67-72-1	117	201	199
Hexachloropropene	1888-71-7	213	215	211
Hexadecane	544-76-3	57	43	71
Indene	95-13-6	116	115	63
Indeno[1,2,3-cd]pyrene	193-39-5	276	138	277
Isodrin	465-73-6	193	66	195
Isophorone	78-59-1	82	95	138
Isosafrole	120-58-1	162	104	131
Kepone	143-50-0	272	274	237
Methapyrilene	91-80-5	58	97	72
Methyl methanesulfonate	66-27-3	80	79	65
Methyl parathion	298-00-0	109	125	263
Methyl Phenols,Total	1319-77-3	108	107	79
Naphthalene	91-20-3	128	129	127
n-Decane	124-18-5	43	57	71
Nitrobenzene	98-95-3	77	123	65
N-Nitro-o-toluidine	99-55-8	152	77	106
N-Nitrosodiethylamine	55-18-5	102	44	57
N-Nitrosodimethylamine	62-75-9	74	42	44
N-Nitrosodi-n-butylamine	924-16-3	84	57	41

N-Nitrosodi-n-propylamine	621-64-7	70	42	101
N-Nitrosodiphenylamine	86-30-6	169	168	167
N-Nitrosomethylethylamine	10595-95-6	88	42	43
N-Nitrosomorpholine	59-89-2	116	56	86
N-Nitrosopiperidine	100-75-4	114	42	55
N-Nitrosopyrrolidine	930-55-2	100	41	42
n-Octadecane	593-45-3	57	43	71
o,o',o''-Triethylphosphorothioate	126-68-1	198	121	93
p-Dimethylamino azobenzene	60-11-7	120	225	77
Pentachlorobenzene	608-93-5	250	248	252
Pentachloroethane	76-01-7	117	119	167
Pentachloronitrobenzene	82-68-8	237	142	214
Pentachlorophenol	87-86-5	266	264	268
Phenacetin	62-44-2	108	179	109
Phenanthrene	85-01-8	178	179	176
Phenol	108-95-2	94	65	66
Phorate	298-02-2	121	75	260
p-Phenylene diamine	106-50-3	108	80	107
Pronamide	23950-58-5	173	175	255
Pyrene	129-00-0	202	200	203
Pyridine	110-86-1	79	52	
Quinoline	91-22-5	129	102	128
Safrole, Total	94-59-7	162	104	77
Sulfotepp	3689-24-5	97	322	202
Thionazin	297-97-2	97	96	143
2-Fluorobiphenyl (Surrogate)	321-60-8	172	171	170
2-Fluorophenol (Surrogate)	367-12-4	112	64	63
2,4,6-Tribromophenol (Surrogate)	118-79-6	330	332	141
Nitrobenzene-d5 (Surrogate)	4165-60-0	82	128	54
Phenol-d5 (Surrogate)	4165-62-2	99	42	71
Terphenyl-d14 (Surrogate)	1718-51-0	244	122	212
1,4-Dichlorobenzene-d4 (Internal Standard)	3855-82-1	152	150	115
Naphthalene-d8 (Internal Standard)	1146-65-2	136	68	54
Acenapthene-d10 (Internal Standard)	15067-26-2	164	162	160

Phenanthrene-d10 (Internal Standard)	1517-22-2	188	94	80
Chrysene-d12 (Internal Standard)	1719-03-5	240	120	236
Perylene-d12 (Internal Standard)	1520-96-3	264	260	265

[1] Diphenylamine can’t be separated from N-Nitrosodiphenylamine. Hits for the compound will be reported as N- Nitrosodiphenylamine.

19.6)

Table 6

Semivolatile Internal Standards with Corresponding Analytes assigned for Quantitation

1,4-Dichlorobenzene-d$_4$	**Naphthalene-d$_8$**	**Acenaphthene-d$_{10}$**
1,2-Dichlorobenzene	1,2,4-Trichlorobenzene	1,1-Biphenyl
1,3-Dichlorobenzene	1-Methylnaphthalene	1,2,4,5-Tetrachlorobenzene
1,4-Dichlorobenzene	2,4-Dichlorophenol	1,3-Dinitrobenzene
1,4-Dioxane	2,4-Dimethylphenol	1,4-Dinitrobenzene
2,2’-oxybis[1-Chloropropane]	2,6-Dichlorophenol	1,4-Naphthoquinone
2-Chlorophenol	2-Methylnaphthalene	1-Chloronaphthalene
2-Fluorophenol (surrogate)	2-Nitrophenol	1-Naphthylamine
2-Methylphenol	4-Chloro-3-methylphenol	2,3,4,6-Tetrachlorophenol
2-Picoline	4-Chloroaniline	2,3,5,6-Tetrachlorophenol
2-Toluidine	4-Chlorophenol	2,4,5-Trichlorophenol
4-Methylphenol	Acetophenone	2,4,6-Trichlorophenol
Acetophenone	Benzoic acid	2,4-Dinitrophenol
Acrylamide	bis(2-Chloroethoxy)methane	2,4-Dinitrotoluene
Aniline	Caprolactam	2,6-Dinitrotoluene
Benzaldehyde	Hexachlorobutadiene	2-Chloronaphthalene
Benzyl alcohol	Hexachloropropene	2-Fluorobiphenyl (surrogate)
bis(2-Chloroethyl) ether	Hexadecane	2-Naphthylamine
Ethyl methanesulfonate	Isophorone	2-Nitroaniline
Hexachloroethane	Naphthalene	3-Nitroaniline
Indene	Nitrobenzene	4-Chlorophenyl phenyl ether
Methyl methanesulfonate	Nitrobenzene-d$_5$ (surrogate)	4-Nitroaniline
Methyl Phenols, Total	n-Nitrosodi-butylamine	4-Nitrophenol
n-Decane	n-Nitrosopiperidine	Acenaphthene
n-Nitrosodiethylamine	o,o’,o”-Triethylphosphorothioate	Acenaphthylene
n-Nitrosodimethylamine	p-Phenylene diamine	Dibenzofuran
n-Nitroso-di-n-propylamine	Quinoline	Diethyl phthalate
n-Nitrosomethylethylamine	Safrole	Dimethyl phthalate
n-Nitrosomorpholine	Thionazin	Fluorene

Table 6

Semivolatile Internal Standards with Corresponding Analytes assigned for Quantitation

n-Nitrosopyrrolidine		Hexachlorocyclopentadiene
n-Octadecane		Isosafrole
Pentachloroethane		n-Nitro-o-toluidine
Phenol		Pentachlorobenzene
Phenol-d_5		
Pyridine		
Phenanthrene-d_{10}	**Chrysene-d_{12}**	**Perylene-d_{12}**
4-Aminobiphenyl	1-Methylnaphthalene	3-Methylcholanthrene
1,2-Diphenylhydrazine	2-Acetylaminofluorene	7,12-Dimethylbenz(a)anthracene
1,3,5-Trinitrobenzene	3,3’-Dichlorobenzidine	Benzo(a)pyrene
2,4,6-Tribromphenol (surrogate)	3,3’-Dimethylbenzidine	Benzo(b)fluoranthene
4,6-Dinitro-2-methylphenol	4,4’-Methylene bis(2-chloroaniline)	Benzo(g,h,i)perylene
4-Bromophenyl phenyl ether	6-Methylchrysene	Benzo(k)fluoranthene
4-Nitroquinoline oxide	Aramite, Total	Dibenz(a,h)anthracene
Anthracene	Benzidine	Dibenz[a,h]acridine
Atrazine	Benzo(a)anthracene	Di-n-octyl phthalate
Carbazole	Butyl benzyl phthalate	Indeno(1,2,3-cd)pyrene
Diallate	Chlorobenzilate	
Dimethoate	Chrysene	
Di-n-butyl phthalate	Famphur	
Dinoseb	Kepone	
Diphenylamine	p-Dimethyl aminoazobenzene	
Disulfoton	Pyrene	
Ethyl Parathion	Terphenyl-d_{14} (surrogate)	
Fluoranthene		
Hexachlorobenzene		
Isodrin		
Methapyrilene		
Methyl Parathion		
n-Nitrosodiphenylamine		
Pentachloronitrobenzene		
Pentachlorophenol		
Phenacetin		
Phenanthrene		
Phenol		
Phenol-d_5		

19.7)

Table 7
8270 TCLP LCS Compounds

LCS Compounds[1]	Spiking Level, µg/mL, added to extract[2]
1,4-Dichlorobenzene	50
2,4-Dinitrotoluene	50
Hexachlorobenzene	50
Hexachlorobutadiene	50
Hexachloroethane	50
2-Methylphenol	50
3&4-Methylphenol	100
Nitrobenzene	50
Pentachlorophenol	50
Pyridine	50
2,4,5-Trichlorophenol	50
2,4,6-Trichlorophenol	50

[1] Recovery limits for the LCS and for matrix spikes are generated from historical data and are maintained by the QA group.

[2] TCLP's are either extracted via Separatory Funnel at a 200 mL initial volume and concentrated to a final volume of 10 mL or at a 1000 mL initial volume and concentrated to a final volume of 10 mL.

19.8)

Table 8
8270 Surrogate Compounds

Surrogate Compounds	Routine 8270D Spiking Concentration µg/mL	Low Level 8270D Spiking Concentration µg/mL
Nitrobenzene-d5	200	20
2-Fluorobiphenyl	200	20
Terphenyl-d14	200	20

Phenol-d5	200	20
2-Fluorophenol	200	20
2,4,6-Tribromophenol	200	20

[1] Recovery limits for surrogates are generated from historical data and are maintained by the QA department.

19.9)

Table 9

Routine and APPIX Standard Calibration Levels, µg/mL (for 2 µl injection)

Analyte	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6	Level 7	Level 8
1,2,4,5-Tetrachlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,2,4-Trichlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,2-Dichlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,2-Diphenylhydrazine (as Azobenzene)	0.19	1.0	2.0	5.0	10	20	30	40
1,3,5-Trinitrobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,3-Dichlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,3-Dinitrobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,4-Dichlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,4-Dinitrobenzene	0.19	1.0	2.0	5.0	10	20	30	40
1,4-Naphthoquinone	0.19	1.0	2.0	5.0	10	20	30	40
1-Naphthylamine	0.19	1.0	2.0	5.0	10	20	30	40
2,2′-oxybis(1-chloropropane)[1]	0.19	1.0	2.0	5.0	10	20	30	40
2,3,4,6-Tetrachlorophenol	0.19	1.0	2.0	5.0	10	20	30	40
2,4,5-Trichlorophenol	0.19	1.0	2.0	5.0	10	20	30	40
2,4,6-Trichlorophenol	0.19	1.0	2.0	5.0	10	20	30	40
2,4-Dichlorophenol	0.19	1.0	2.0	5.0	10	20	30	40
2,4-Dimethylphenol	0.19	1.0	2.0	5.0	10	20	30	40
2,4-Dinitrophenol	0.38	2.0	4.0	10	20	40	60	80
2,4-Dinitrotoluene	0.19	1.0	2.0	5.0	10	20	30	40
2,6-Dichlorophenol	0.19	1.0	2.0	5.0	10	20	30	40
2,6-Dinitrotoluene	0.19	1.0	2.0	5.0	10	20	30	40
2-Acetylaminofluorene	0.19	1.0	2.0	5.0	10	20	30	40
2-Chloronaphthalene	0.19	1.0	2.0	5.0	10	20	30	40
2-Chlorophenol	0.19	1.0	2.0	5.0	10	20	30	40
2-Methylnaphthalene	0.19	1.0	2.0	5.0	10	20	30	40
2-Methylphenol	0.19	1.0	2.0	5.0	10	20	30	40
2-Naphthylamine	0.19	1.0	2.0	5.0	10	20	30	40
2-Nitroaniline	0.19	1.0	2.0	5.0	10	20	30	40

2-Nitrophenol	0.19	1.0	2.0	5.0	10	20	30	40
2-Picoline	0.19	1.0	2.0	5.0	10	20	30	40
3,3'-Dichlorobenzidine	0.19	1.0	2.0	5.0	10	20	30	40
3,3'-Dimethylbenzidine	0.19	1.0	2.0	5.0	10	20	30	40
3-Methylcholanthrene	0.19	1.0	2.0	5.0	10	20	30	40
3-Nitroaniline	0.19	1.0	2.0	5.0	10	20	30	40
4,6-Dinitro-2-methylphenol	0.38	2.0	4.0	10	20	40	60	80
4-Aminobiphenyl	0.19	1.0	2.0	5.0	10	20	30	40
4-Bromophenyl phenyl ether	0.19	1.0	2.0	5.0	10	20	30	40
4-Chloro-3-methylphenol	0.19	1.0	2.0	5.0	10	20	30	40
4-Chloroaniline	0.38	2.0	4.0	10	20	40	60	80
4-Chlorophenyl phenyl ether	0.19	1.0	2.0	5.0	10	20	30	40
4-Methylphenol	0.19	1.0	2.0	5.0	10	20	30	40
4-Nitroaniline	0.19	1.0	2.0	5.0	10	20	30	40
4-Nitrophenol	0.38	2.0	4.0	10	20	40	60	80
4-Nitroquinoline-1-oxide	0.19	1.0	2.0	5.0	10	20	30	40
5-Nitro-o-toluidine	0.19	1.0	2.0	5.0	10	20	30	40
6-Methylchrysrene	0.19	1.0	2.0	5.0	10	20	30	40
7,12-Dimethylbenz(a) anthracene	0.19	1.0	2.0	5.0	10	20	30	40
Acenaphthene	0.19	1.0	2.0	5.0	10	20	30	40
Acenaphthylene	0.19	1.0	2.0	5.0	10	20	30	40
Acetophenone	0.19	1.0	2.0	5.0	10	20	30	40
Aniline	0.19	1.0	2.0	5.0	10	20	30	40
Anthracene	0.19	1.0	2.0	5.0	10	20	30	40
Aramite 1 & 2	0.19	1.0	2.0	5.0	10	20	30	40
Benzidine	0.19	1.0	2.0	5.0	10	20	30	40
Benzo(a)anthracene	0.19	1.0	2.0	5.0	10	20	30	40
Benzo(a)pyrene	0.19	1.0	2.0	5.0	10	20	30	40
Benzo(b)fluoranthene	0.19	1.0	2.0	5.0	10	20	30	40
Benzo(g,h,i)perylene	0.19	1.0	2.0	5.0	10	20	30	40
Benzo(k)fluoranthene	0.19	1.0	2.0	5.0	10	20	30	40
Benzoic Acid	0.38	2.0	4.0	10	20	40	60	80
Benzyl alcohol	0.19	1.0	2.0	5.0	10	20	30	40
Bis(2-chloroethoxy)methane	0.19	1.0	2.0	5.0	10	20	30	40
Bis(2-chloroethyl)ether	0.19	1.0	2.0	5.0	10	20	30	40
Bis(2-ethylhexyl)phthalate	0.19	1.0	2.0	5.0	10	20	30	40
Butyl benzyl phthalate	0.19	1.0	2.0	5.0	10	20	30	40
Carbazole	0.19	1.0	2.0	5.0	10	20	30	40
Chrysene	0.19	1.0	2.0	5.0	10	20	30	40
Diallate 1 & 2	0.19	1.0	2.0	5.0	10	20	30	40
Dibenz(a,h)anthracene	0.19	1.0	2.0	5.0	10	20	30	40
Dibenzofuran	0.19	1.0	2.0	5.0	10	20	30	40
Diethylphthalate	0.19	1.0	2.0	5.0	10	20	30	40

Dimethoate	0.19	1.0	2.0	5.0	10	20	30	40
Dimethyl phthalate	0.19	1.0	2.0	5.0	10	20	30	40
Di-n-butyl phthalate	0.19	1.0	2.0	5.0	10	20	30	40
Di-n-octylphthalate	0.19	1.0	2.0	5.0	10	20	30	40
Dinoseb	0.19	1.0	2.0	5.0	10	20	30	40
Disulfoton	0.19	1.0	2.0	5.0	10	20	30	40
Ethyl methanesulfonate	0.19	1.0	2.0	5.0	10	20	30	40
Famphur	0.3	1.5	3.0	7.5	15	30	45	60
Fluoranthene	0.19	1.0	2.0	5.0	10	20	30	40
Fluorene	0.19	1.0	2.0	5.0	10	20	30	40
Hexachlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40
Hexachlorobutadiene	0.19	1.0	2.0	5.0	10	20	30	40
Hexachlorocyclopentadiene	0.19	1.0	2.0	5.0	10	20	30	40
Hexachloroethane	0.19	1.0	2.0	5.0	10	20	30	40
Hexachloropropene	0.19	1.0	2.0	5.0	10	20	30	40
Indeno(1,2,3-cd)pyrene	0.19	1.0	2.0	5.0	10	20	30	40
Isodrin	0.19	1.0	2.0	5.0	10	20	30	40
Isophorone	0.19	1.0	2.0	5.0	10	20	30	40
Isosafrole 1 + 2	0.19	1.0	2.0	5.0	10	20	30	40
Kepone	0.8	4.0	8.0	20.0	40	80	120	160
Methapyrilene	0.19	1.0	2.0	5.0	10	20	30	40
Methyl methanesulfonate	0.19	1.0	2.0	5.0	10	20	30	40
Methyl parathion	0.19	1.0	2.0	5.0	10	20	30	40
Naphthalene	0.19	1.0	2.0	5.0	10	20	30	40
Nitrobenzene	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitrosodiethylamine	0.19	1.0	2.0	5.0	10	20	30	40
N-nitrosodimethylamine	0.19	1.0	2.0	5.0	10	20	30	40
n-Nitrosodi-n-butylamine	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitroso-di-n-propylamine	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitrosodiphenylamine	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitrosomethylethylamine	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitrosomorpholine	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitrosopiperidine	0.19	1.0	2.0	5.0	10	20	30	40
N-Nitrosopyrrolidine	0.19	1.0	2.0	5.0	10	20	30	40
o,o,o-Triethyl-Phosphorothioate	0.19	1.0	2.0	5.0	10	20	30	40
o-Toluidine	0.19	1.0	2.0	5.0	10	20	30	40
p-(Dimethylamino) azobenzene	0.19	1.0	2.0	5.0	10	20	30	40
Parathion, Ethyl	0.19	1.0	2.0	5.0	10	20	30	40
p-Chlorobenzilate	0.19	1.0	2.0	5.0	10	20	30	40
Pentachlorobenzene	0.19	1.0	2.0	5.0	10	20	30	40

Pentachloroethane	0.19	1.0	2.0	5.0	10	20	30	40
Pentachloronitrobenzene	0.19	1.0	2.0	5.0	10	20	30	40
Pentachlorophenol	0.38	2.0	4.0	10	20	40	60	80
Phenacetin	0.19	1.0	2.0	5.0	10	20	30	40
Phenanthrene	0.19	1.0	2.0	5.0	10	20	30	40
Phenol	0.19	1.0	2.0	5.0	10	20	30	40
Phorate	0.19	1.0	2.0	5.0	10	20	30	40
p-Phenylenediamine	0.19	1.0	2.0	5.0	10	20	30	40
Pronamide	0.19	1.0	2.0	5.0	10	20	30	40
Pyrene	0.19	1.0	2.0	5.0	10	20	30	40
Pyridine	0.19	1.0	2.0	5.0	10	20	30	40
Safrole	0.19	1.0	2.0	5.0	10	20	30	40
Sulfotepp	0.19	1.0	2.0	5.0	10	20	30	40
Thionazin	0.19	1.0	2.0	5.0	10	20	30	40

[1] 2,2'oxybis(1-chloropropane) was formally known as bis(2-chloroisopropyl)ether.

19.10)

Table 10

Minimum Response Factor Criteria for Initial and Continuing Calibration Verification

Analyte	**Minimum Response Factor (RF)**
Benzaldehyde	0.010
Phenol	0.800
Bis(2-chloroethyl)ether	0.700
2-Chlorophenol	0.800
2-Methylphenol	0.700
2,2'-oxybis(1-chloropropane)[1]	0.010
Acetophenone	0.010
4-Methylphenol	0.600
N-Nitroso-di-n-propylamine	0.500
Hexachloroethane	0.300
Nitrobenzene	0.200
Isophorone	0.400
2-Nitrophenol	0.100
2,4-Dimethylphenol	0.200
Bis(2-chloroethoxy)methane	0.300
2,4-Dichlorophenol	0.200
Naphthalene	0.700

Table 10

Minimum Response Factor Criteria for Initial and Continuing Calibration Verification

Analyte	Minimum Response Factor (RF)
4-Chloroaniline	0.010
Hexachlorobutadiene	0.010
Caprolactam	0.010
4-Chloro-3-methylphenol	0.200
2-Methylnaphthalene	0.400
Hexachlorocyclopentadiene	0.050
2,4,6-Trichlorophenol	0.200
2,4,5-Trichlorophenol	0.200
1,1′-Biphenyl	0.010
2-Chloronaphthalene	0.800
2-Nitroaniline	0.010
Dimethylphthalate	0.010
Acenaphthylene	0.900
2,6-Dinitrotoluene	0.200
3-Nitroaniline	0.010
Acenaphthene	0.900
2,4-Dinitrophenol	0.010
Dibenzofuran	0.800
4-Nitrophenol	0.010
2,4-Dinitrotoluene	0.200
Diethylphthalate	0.010
Fluorene	0.900
4-Chlorophenylphenylether	0.400
4-Nitroaniline	0.010
4,6-Dinitro-2-methylphenol	0.010
N-Nitrosodiphenylamine	0.010
4-Bromophenylphenylether	0.100
Hexachlorobenzene	0.100
Atrazine	0.010
Pentachlorophenol	0.050
Phenanthrene	0.700
Anthracene	0.700
Carbazole	0.010
Di-n-butylphthalate	0.010
Fluoranthene	0.600
Pyrene	0.600
Butylbenzylphthalate	0.010

Table 10

Minimum Response Factor Criteria for Initial and Continuing Calibration Verification

Analyte	**Minimum Response Factor (RF)**
Benzo(a)Anthracene	0.800
3,3'-Dichlorobenzidine	0.010
Chrysene	0.700
Bis(2-ethylhexyl)phthalate	0.010
Di-n-octylphthalate	0.010
Benzo(b)fluoranthene	0.700
Benzo(k)fluoranthene	0.700
Benzo(a)pyrene	0.700
Indeno(1,2,3-cd)pyrene	0.500
Dibenz(a,h)anthracene	0.400
Benzo(g,h,i)perylene	0.500
2,3,4,6-Tetrachlorophenol	0.010

19.11)

Table 11: Poor Performers and Laboratory Acceptance Criteria

Routine Poor Performers	**ICAL %RSD**	**ICV %D**	**CCAL %D**
1,4-Dioxane	50%	50%	**40%**
2,2 oxybis 1-Chloropropane	50%	50%	20%
2,4-Dinitrophenol	50%	50%	**40%**
2-Naphthylamine	50%	50%	**40%**
3,3'-Dichlorobenzidine	50%	50%	**40%**
4,6-Dinitro-2-methylphenol	50%	50%	20%
4-Nitrophenol	50%	50%	20%
Atrazine	50%	50%	**40%**
Benzaldehyde	50%	50%	**40%**
Benzidine	50%	50%	**40%**
Benzoic acid	50%	50%	**40%**
Benzyl alcohol	50%	50%	20%
Caprolactam	50%	50%	20%
Di-n-octylphthalate	50%	50%	20%
Hexachlorocyclopentadiene	50%	50%	20%
N-nitrosopyrrolidine	50%	50%	20%
Pentachlorophenol	50%	50%	20%

Pyridine	50%	50%	20%
Methylmethane sulfonate	50%	50%	**40%**
2,4 Dimethylphenol	50%	50%	20%

South Carolina Poor Performers	**ICAL %RSD**	**ICV %D**	**CCAL %D**	**LCS Limits %Recovery**
1,4-Dioxane	50%	50%	**40%**	60-140%
2,2 oxybis 1-Chloropropane	50%	50%	20%	60-140%
2,4-Dinitrophenol	50%	50%	**40%**	60-140%
2-Naphthylamine	50%	50%	**40%**	60-140%
3,3'-Dichlorobenzidine	50%	50%	**40%**	60-140%
4,6-Dinitro-2-methylphenol	50%	50%	20%	60-140%
4-Nitrophenol	50%	50%	20%	60-140%
Atrazine	50%	50%	**40%**	60-140%
Benzaldehyde	50%	50%	**40%**	60-140%
Benzidine	50%	50%	**40%**	60-140%
Benzoic acid	50%	50%	**40%**	60-140%
Benzyl alcohol	50%	50%	20%	60-140%
Caprolactam	50%	50%	20%	60-140%
Di-n-octylphthalate	50%	50%	20%	60-140%
Hexachlorocyclopentadiene	50%	50%	20%	60-140%
N-nitrosopyrrolidine	50%	50%	20%	60-140%
Pentachlorophenol	50%	50%	20%	60-140%
Pyridine	50%	50%	20%	60-140%
Methylmethane sulfonate	50%	50%	**40%**	50-150%
2,4 Dimethylphenol	50%	50%	20%	50-150%

Table 11: Poor Performers and Laboratory Acceptance Criteria (cont.)

Appendix IX Poor Performers	**ICAL %RSD**	**ICV %D**	**CCAL %D**
1,3,5-Trinitrobenzene	50%	50%	**40%**
1,4-Naphthoquinone	50%	50%	**40%**
1-Naphthylamine	50%	50%	**40%**
2-Acetylaminofluorene	50%	50%	**40%**
2-Picoline	50%	50%	**40%**
3,3'-Dimethylbenzidine	50%	50%	**40%**
3-Methylcholanthrene	50%	50%	**40%**
4,4'-Methylene bis(2-chloroaniline)	50%	50%	**40%**
4-Aminobiphenyl	50%	50%	**40%**

4-Nitroquinoline 1-oxide	50%	50%	**40%**
5-Nitro-o-toluidine	50%	50%	**40%**
6-methylchrysene	50%	50%	**40%**
Aramite 1	50%	50%	**40%**
Aramite 2	50%	50%	**40%**
Diallate 1	50%	50%	**40%**
Diallate 2	50%	50%	**40%**
Dibenz(a,h)acridine	50%	50%	**40%**
Dimethoate	50%	50%	**40%**
Dinoseb	50%	50%	**40%**
Disulfoton	50%	50%	**40%**
Ethyl methanesulfonate	50%	50%	**40%**
Famphur	50%	50%	**40%**
Hexachloropropene	50%	50%	**40%**
Isodrin	50%	50%	**40%**
Isosafrole 1	50%	50%	**40%**
Kepone	50%	50%	**40%**
m-Dinitrobenzene	50%	50%	**40%**
Methapyrilene	50%	50%	**40%**
Methyl parathion	50%	50%	**40%**
N-Nitrosodiethylamine	50%	50%	**40%**
N-Nitrosodi-n-butylamine	50%	50%	**40%**
N-Nitrosomethylethylamine	50%	50%	**40%**
N-Nitrosomorpholine	50%	50%	**40%**
N-Nitrosopiperidine	50%	50%	**40%**
O,O,O-Triethyl phosphorothioa	50%	50%	**40%**
o-Toluidine	50%	50%	**40%**
Parathion	50%	50%	**40%**
p-Chlorobenzilate	50%	50%	**40%**
p-Dimethylamino azobenzene	50%	50%	**40%**
Pentachlorobenzene	50%	50%	**40%**
Pentachloroethane	50%	50%	**40%**
Pentachloronitrobenzene	50%	50%	**40%**
Phenacetin	50%	50%	**40%**
Phorate	50%	50%	**40%**
p-Phenylene diamine	50%	50%	**40%**
Pronamide	50%	50%	**40%**
Safrole	50%	50%	**40%**
Sulfotepp	50%	50%	**40%**
Thionazin	50%	50%	**40%**

Appendix 9 compounds allowed outliers on ICAL %RSD. Outliers will be noted in an NCM.
Appendix 9 compounds allowed outliers on ICV %D. Outliers will be noted in an NCM.

19.12)

Table 12: Eurofins Pittsburgh GCMS Semivolatile Dilution Calculation Table

Dilution Required 100 uL F.V.	Amount of Sample uL	Amount of $MeCl_2$ uL	Amount of IS (if none added) uL	Amount of IS uL (if added)	Final Volume uL
1.5	66.7	33.3	1	0.33	100
2	50	50	1	0.5	100
3	33.3	66.7	1	0.67	100
4	25	75	1	0.75	100
5	20	80	1	0.8	100
6	16.7	83.3	1	0.83	100
7	14.3	85.7	1	0.86	100
8	12.5	87.5	1	0.88	100
9	11.1	88.9	1	0.89	100
10	10	90	1	0.9	100
11	9.1	90.9	1	0.91	100
12	8.3	91.7	1	0.92	100
13	7.7	92.3	1	0.92	100
14	7.1	92.9	1	0.93	100
15	6.7	93.3	1	0.93	100
20	5	95	1	0.95	100
25	4	96	1	0.96	100
30	3.3	96.7	1	1	100
35	2.85	97.15	1	1	100
40	2.5	97.5	1	1	100
45	2.2	97.8	1	1	100
50	2	98	1	1	100
55	1.8	98.2	1	1	100
60	1.7	98.3	1	1	100
65	1.5	98.5	1	1	100
70	1.4	98.6	1	1	100
75	1.3	98.7	1	1	100
80	1.25	98.75	1	1	100
85	1.18	98.82	1	1	100
90	1.11	98.89	1	1	100
95	1.05	98.95	1	1	100
100	1	99	1	1	100
150	0.67	99.33	1	1	100
200	0.5	99.5	1	1	100
250	0.4	99.6	1	1	100
300	0.33	99.67	1	1	100
350	0.29	99.71	1	1	100

400	0.25	99.75	1	1	100
500	0.2	99.8	1	1	100

19.13)

APPENDIX A

Instrument Maintenance Schedules - Mass Spectrometer & Gas Chromatograph

MASS SPECTROMETER Instrument Maintenance Schedule

Daily	Weekly	As Needed	Quarterly	Annually
Check for sufficient gas supply. Check for correct column flow and/or inlet pressure	Check mass calibration (PFTBA or FC-43).	Check level of oil in mechanical pumps and diffusion pump if vacuum is insufficient. Add oil if needed between service contract maintenance.	Check vacuum, relays, gas pressures, and flows.	Replace the exhaust filters on the mechanical rough pump every 1 to 2 years.
Check temperatures of injector, detector. Verify temperature programs.		Replace electron multiplier when the tuning voltage approaches the maximum and/or when sensitivity falls below required levels.	Check vacuum, relays, gas pressures and flows	Change the oil in the mechanical rough pump.
Check inlets, septa.		Clean source, including all ceramics and lenses. Source cleaning is indicated by a variety of symptoms, including inability of the analyst to tune the instrument to specifications, poor response, and high background contamination.		
Check baseline level.		Repair/replace jet separator.		

Check values of lens voltages, electron multiplier, and relative abundance and mass assignments of the calibration compounds.		Replace filaments when both filaments burn out or performance indicates the need for replacement.		

Attachment:
11, GC/MS Analysis for Semivolatile Organics, Methods: SW-846 8270C & 8270D (.pdf)

42091 Detection and Quantitation Limits
45117 Pittsburgh QA Manual
45403 Percent Moisture, Solids, Ash, Organic Matter in Soil Samples, Methods SM 2540G and ASTM D297-84
45621 Detection Limits

End of document

Version history

Version	Approval	Revision information	
11	29.AUG.2022	D4 Template for Analytical SOPs -	
12	28.SEP.2022		

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3) INTRODUCTION, SCOPE AND APPLICABILITY

3.1) INTRODUCTION, SCOPE AND APPLICABILITY

Eurofins Pittsburgh's Quality Assurance Manual (QAM) is a document prepared to define the overall policies, organization objectives and functional responsibilities for achieving the laboratory's QA Program.

The laboratory maintains a local perspective in its scope of services and client relations and maintains a national perspective in terms of quality.

This QAM has been prepared to assure compliance with The NELAC Institute (TNI) Standard, dated 2009 and 2016, Volume 1 Modules 2 and 4, and ISO/IEC Guide 17025:2017(E). In addition, the policies and procedures outlined in this manual are compliant with various accreditation and certification programs listed in Appendix 3.

This QAM has been prepared to be consistent with requirements of the following documents:

- EPA Requirements for Quality Management Programs (QA/R-2),
- EPA/240/B-01/002, May 31, 2006
- EPA 600/4-88/039, Methods for the Determination of Organic Compounds in Drinking Water, EPA, Revised July 1991
- EPA 600/R-95/131, Methods for the Determination of Organic Compounds in Drinking Water, Supplement III, EPA, August 1995
- EPA 600/4-79-019, Handbook for Analytical Quality Control in Water and Wastewater Laboratories, EPA, March 1979
- Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846), Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008, Final Update V, August 2015
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261
- Statement of Work for Inorganics & Organics Analysis, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration
- APHA, Standard Methods for the Examination of Water and Wastewater, 18th Edition, 19th, 20th, 21st, 22nd and on-line Editions
- U.S. Department of Energy Order 414.1D, Quality Assurance, April 25, 2011
- Nuclear Regulatory Commission (NRC) quality assurance requirements
- Marine Protection, Research, and Sanctuaries Act (MPRSA)
- Toxic Substances Control Act (TSCA)

3.2) TERMS AND DEFINITIONS

A Quality Assurance Program is a system designed to ensure that data produced by the laboratory conforms to the standards set by state and/or federal regulations. The program functions at the local management level through company goals and management policies, from guidance at the executive management level, and at the analytical level through Standard Operating Procedures (SOPs) and quality control. Our program is designed to minimize systematic error, encourage constructive, documented problem solving, and provide a framework for continuous improvement within the organization.

Refer to Appendix 2 for the Glossary/Acronyms

3.3) SCOPE / FIELDS OF TESTING

The laboratory analyzes a broad range of environmental and industrial samples. Sample matrices vary among effluent water, surface water, groundwater, hazardous waste, sludge, soils, sediments, and tissue. The Quality Assurance Program contains specific procedures and methods to test samples of differing matrices for chemical, physical and biological parameters. The Program also contains guidelines on maintaining documentation of analytical processes, reviewing results, servicing clients and tracking samples through the laboratory. The technical and service requirements of all analytical requests are thoroughly evaluated before commitments are made to accept the work. Measurements are made using published reference methods or methods developed and validated by the laboratory.

The methods covered by this manual include the most frequently requested methodologies needed to provide analytical services in the United States and its territories. The specific list of test methods used by the laboratory can be found in the Statement of Qualifications (SOQ). The current list of accredited methods is maintained in MyEOL. The approach of this manual is to define the minimum level of quality assurance and quality control necessary to meet these requirements. All methods performed by the laboratory shall meet these criteria as appropriate. In some instances, quality assurance project plans (QAPPs), project specific data quality objectives (DQOs) or local regulations may require criteria other than those contained in this manual. In these cases, the laboratory will abide by the requested criteria following review and acceptance of the requirements by the Laboratory Director and the Quality Assurance (QA) Manager. In some cases, QAPPs and DQOs may specify less stringent requirements. The Laboratory Director and the QA Manager must determine if it is in the lab's best interest to follow the less stringent requirements.

3.3.1) Specialty Analyses

3.3.1.1) Dredged Material Evaluations

Eurofins Pittsburgh offers trace level testing of waters (site-waters and elutriates), sediments, and tissues in support of Dredged Material Evaluations for in-water (ocean and inland waters) and upland (Confined Disposal Facilities (CDFs), beneficial use, etc.) disposal options. In-house capabilities for commonly requested sediment program parameters include:

- Organochlorine Pesticides
- Organophosphorus Pesticides
- PCBs (as Aroclors and Congeners)
- Volatile Organics
- Semivolatile Organics

- Metals
- Cyanide
- Total Sulfides
- Acid Volatile Sulfide (AVS) and Simultaneously Extracted Metals (SEM)
- Nitrogen, Ammonia
- Nitrogen, Nitrate + Nitrite
- Biochemical Oxygen Demand (BOD)
- Chemical Oxygen Demand (COD)
- Total Organic Carbon (combustion procedure for sediments)
- Total Solids/Moisture Content
- Total Volatile Solids
- Lipids
- With teaming arrangements with other Eurofins Environment Testing facilities, additional sediment program capabilities include:
- Polychlorinated Dibenzo-Dioxins and Furans (PCDDs/PCDFs)
- Butyl Tins (mono – tetra)
- Total Kjeldahl Nitrogen
- Total Phosphorus
- Grain Size
- Specific Gravity
- Atterberg Limits

Eurofins Pittsburgh also generates elutriate samples following appropriate U.S. Army Corps of Engineers procedures. These include:

- Standard Elutriate Test (SET) for in-water disposal evaluations, and
- Modified Elutriate Test (MET) or Effluent Elutriate Test (EET) for CDF disposal evaluations.
- Illinois Resuspension Tests (Supernatant and Elutriate Tests).
- Dredge Elutriate Test (DRET)

Eurofins Pittsburgh currently supports dredge material evaluation projects following several state specific programs, as well as, under the following guidance documents:

- Ocean Testing Manual or OTM (USACE, 1991).
- New Jersey’s Tidal Waters Technical Manual (NJDEP, 1997).
- Inland Testing Manual or ITM (USACE, 1998).
- Upland Testing Manual or UTM (USACE, 2003)

3.3.1.2) Tissue Analyses

Eurofins Pittsburgh has extensive experience in supporting projects requiring tissue analyses. These include analyses of laboratory cultured reference species from bioaccumulation tests associated with dredged material evaluations to a variety of field collected species (aquatic and terrestrial). Eurofins Pittsburgh has developed modifications to the standard solid methodologies (where possible) to allow for the use of smaller sample weights and achieve lower quantitation limits. In-house capabilities for commonly requested tissue parameters include:

- Organochlorine Pesticides
- PCBs (as Aroclors and Congeners)
- Semivolatile Organics
- Metals
- Lipids
- Moisture Content
- With teaming arrangements with other Eurofins Environment Testing facilities, additional tissue capabilities include:
- Polychlorinated Dibenzo-Dioxins and Furans (PCDDs/PCDFs)
- Butyl Tins (mono – tetra)

3.4) MANAGEMENT OF THE MANUAL

3.4.1) Review Process

This manual is reviewed every two years by senior laboratory management to assure that it reflects current practices and meets the requirements of the laboratory’s clients and regulators. Occasionally, the manual may need changes in order to meet new or changing regulations and operations. The QA Manager will review the changes in the normal course of business and incorporate changes into revised sections of the document. All updates will be reviewed by the senior laboratory management staff. The laboratory updates and approves such changes according to Pittsburgh laboratory SOP No. PT-QA-010, Document Development and Control.

4) MANAGEMENT REQUIREMENTS

4.1) Overview

Eurofins Pittsburgh is a local operating unit of Eurofins Environment Testing America. The laboratory's operational and support staff have the day-to-day independent operational authority under the direction of the direction of the Laboratory Director and is supported by the NDSC QA team. The laboratory management staff includes directors, managers and group leaders. The organizational chart for Eurofins Pittsburgh is presented in *PIT-GI-ORG-FRM47902*.

4.2) Roles And Responsibilities

In order for the Quality Assurance Program to function properly, all members of the staff must clearly understand and meet their individual responsibilities as they relate to the quality program. The following descriptions briefly define each role in its relationship to the Quality Assurance Program.

4.2.1) Additional Requirements for Laboratories

The responsibility for quality resides with every employee of the laboratory. All employees have access to the QAM, are trained to this manual, and are responsible for upholding the standards therein. Each person carries out his/her daily tasks impartially and in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory’s SOPs. This manual is specific to the operations of the Eurofins Pittsburgh laboratory.

4.2.2) Vice President of Quality and Environmental Health and Safety (VP-QA/EHS)

The Vice President (VP) of QA/EHS reports directly to the Eurofins Environment Testing America Chief Operating Officer (COO). With the aid of the NDSC Quality Team Members, Business Unit Managers, Laboratory Directors, the VP-QA/EHS has the responsibility for the establishment, general overview and maintenance of the Quality Assurance and EH&S Programs within Eurofins Environment Testing America. Additional responsibilities include:

- Review of QA/QC and EHS aspects of Corporate SOPs & Policies, national projects and expansions or changes in services.
- Work with various organizations outside of the laboratory to further the development of quality standards and represent the laboratory at various trade meetings.
- Prepare monthly reports for quality and EH&S metrics across the analytical laboratories and a summary of any quality related initiatives and issues.
- With the assistance of the Executive Management and the EHS Managers, development and implementation of the Eurofins Environment Testing America Environmental, Health and Safety Program.

4.2.3) Quality Directors

There are three (3) Quality Directors within NDSC that report directly to the VP-QA/EHS. These Quality Directors have oversight of the general overview and maintenance of the QA Program within the Eurofins Environment Testing America laboratories. Supported tasks include:

- Monitors laboratory internal audit findings;
- Identifies common laboratory weaknesses and monitors corrective action closures.
- Develops NDSC quality guidance documents and management tools for ensuring and improving compliance;
- Monitors and communicates DoD/DoE requirements;
- Monitors and communicates regulatory and certification requirements;
- Training and OnBoarding
- Laboratory assessments, mentoring, and interventions
- Track/drive root cause investigations and corrective action plans
- Builds knowledge base for preventive actions

4.2.3.1) Quality Assessment Director

The Quality Assessment Director reports to the VP-QA/EHS. The Quality Assessment Director has QA oversight of laboratories; is responsible for the internal audit system, schedule and procedure; monitors laboratory internal audit findings; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Compliance Director, the Quality Systems Director, and the VP-QA/EHS, the Quality Assessment Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within Eurofins Environment Testing America.

4.2.3.2) Quality Compliance Director

The Quality Compliance Director reports to the VP-QA/EHS. The Quality Compliance Director has QA oversight of laboratories; monitors and communicates DoD / DoE requirements; develops Corporate tools for ensuring and improving compliance; develops Corporate assessment tools; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Assessment Director, Quality Systems Director and the VP-QA/EHS, the Quality Compliance Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within Eurofins Environment Testing America.

4.2.3.3) Quality Systems Director

The Quality Systems Director reports to the VP-QA/EHS. The Quality Systems Director has QA oversight of laboratories; develops quality policies, procedures and management tools; monitors and communicates regulatory and certification requirements; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Assessment Director, Quality Compliance Director and the VP-QA/EHS, the Quality Systems Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within Eurofins Environment Testing America.

4.2.4) Quality Information Manager

The Quality Information Manager is responsible for managing all NDSC official documents (e.g., Policies, Procedures, Work Instructions), the company's accreditation database, intranet websites, external laboratory subcontracting, regulatory limits for clients on the company's MyEOL website; internal and external client support for various company groups (e.g., Client Services, EH&S, Legal, IT, Sales) for both quality and operational functions and communicating regulatory information and lists. The Quality Information Manager reports to the VP-QA/EHS; and works alongside the Quality Assessment, Quality Compliance and Quality System Directors and EHS Managers to support both the Analytical Quality Assurance and EHS Programs within Eurofins Environment Testing America.

4.2.5) Ethics and Compliance Officers (ECOs)

The NDSC VP-QA/EHS and Corporate Counsel are designated Ethics and Compliance Officer (ECO). Each ECO acts as a back-up to the other ECO and both are involved when data investigations occur. Each ECO has a direct line of communication to the entire senior Corporate and lab management staff.

The ECOs ensure that the organization distributes the data integrity and ethical practices policies to all employees and ensures annual trainings and orientation of new hires to the ethics program and its policies. The ECO is responsible for establishing a mechanism to foster employee reporting of incidents of illegal, unethical, or improper practices in a safe and confidential environment.

The ECOs monitor and audit procedures to determine compliance with policies and to make recommendations for policy enhancements to the President and CEO, VPOs, Laboratory Director or other appropriate individuals within the laboratory. The ECO will assist the laboratory QA Manager in the coordination of internal auditing of ethical policy related activities and processes within the laboratory, in conjunction with the laboratory's regular internal auditing function.

The ECOs will also participate in investigations of alleged violations of policies and work with the appropriate internal departments to investigate misconduct, remedy the situation, and prevent recurrence of any such activity.

4.2.6) Environmental Health and Safety Managers

The EHS Managers report directly to the VP-QA/EHS. The EHS Managers are responsible for the development and implementation of the Eurofins Environment Testing America Environmental, Health and Safety program. Responsibilities include:

- Consolidation and tracking all safety and health-related information and reports for the company, and managing compliance activities for Eurofins Environment Testing America locations
- Coordination/preparation of the Environmental, Health and Safety Manual Template that is used by each laboratory to prepare its own laboratory-specific Safety Manual/ CHP
- Preparation of information and training materials for laboratory EHS Coordinators
- Assistance in the coordination of employee exposure and medical monitoring programs to insure compliance with applicable safety and health regulations

- Serving as Department of Transportation (D.O.T.) focal point and providing technical assistance to location management
- Serving as Hazardous Waste Management main contact and providing technical assistance to location management

4.2.7) Laboratory Director (Business Unit Manager or BUMA)

Pittsburgh's Laboratory Director is responsible for the overall quality, safety, financial, technical, human resource and service performance of the whole laboratory and reports to their business unit President. The Laboratory Director is also responsible for any service centers connected with their laboratory that perform any tests, such as short holding time analysis for pH. The Laboratory Director provides the resources necessary to implement and maintain an effective and comprehensive Quality Assurance and Data Integrity Program. The Laboratory Director can also serve as the Technical Manager.

Specific responsibilities include, but are not limited to:

- Providing one or more technical managers for the appropriate fields of testing. If the Technical Manager is absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director must designate another full time staff member meeting the qualifications of the Technical Manager to temporarily perform this function. If the absence exceeds 30 consecutive calendar days, the primary accrediting authority must be notified in writing.
- Ensuring that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented. Working with Eurofins Environmental Testing Human Resources for hiring of new personnel.
- Ensuring that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- Ensuring Eurofins Environment Testing America's human resource policies are adhered to and maintained.
- Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory. Assessing laboratory capacity and workload.
- Ensuring that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs may be temporarily suspended by the Laboratory Director.
- Reviewing and approving all SOPs prior to their implementation and ensures all approved SOPs are implemented and adhered to.
- Pursuing and maintaining appropriate laboratory certification and contract approvals. Supports ISO 17025 requirements.
- Ensuring client specific reporting and quality control requirements are met
- Captaining the management team, consisting of the QA Manager, the Technical Managers and the Department Managers.
- Monitoring the validity of the analyses performed and data generated in the laboratory.
- Providing training and development programs to applicable laboratory staff as new hires and, on a scheduled basis. Training includes instruction on calculations, instrumentation management to include troubleshooting and preventive maintenance.
- Contributes to the continuous improvement of the laboratory operations.
- Maintains an awareness of technical developments and regulatory requirements.
- The Technical Manager meets the requirements specified in the Section 5.2.6.1 of the TNI standards

4.2.8) Quality Assurance (QA) Manager or Designee

The QA Manager has responsibility and authority to ensure the continuous implementation of the quality system at the laboratory where they work. The QA Manager is also responsible for any service centers connected with their laboratory that perform any tests, such as short holding time analysis for pH. The QA Manager reports directly to the Laboratory Director and their NDSC Quality Director. This position is able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence. The NDSC QA Team may be used as a resource in dealing with regulatory requirements, certifications and other quality assurance related items. The QA Manager directs the activities of the QA Specialists to accomplish specific responsibilities, which include, but are not limited to:

- Serving as the focal point for QA/QC in the laboratory.
- Having functions independent from laboratory operations for which he/she has quality assurance oversight.
- Maintaining and updating the QAM.
- Monitoring and evaluating laboratory certifications; scheduling proficiency testing samples.
- Monitoring and communicating regulatory changes that may affect the laboratory to management.
- Training and advising the laboratory staff on quality assurance/quality control procedures that are pertinent to their daily activities.
- Having documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Having a general knowledge of the analytical test methods for which data audit/review is performed (and/or having the means of getting this information when needed).
- Arranging for or conducting internal audits on quality systems and the technical operation.
- Maintaining records of all ethics-related training, including the type and proof of attendance.
- Maintaining, improving, and evaluating the corrective action database and the corrective and preventive action systems.
- Notifying laboratory management of deficiencies in the quality system and ensuring corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs shall be investigated following procedures outlined in Section 12 and if deemed necessary may be temporarily suspended during the investigation.
- Objectively monitoring standards of performance in quality control and quality assurance without outside (e.g., managerial) influence.
- Having the responsibility and final authority to accept or reject data and to stop work in progress in the event that procedures and practices compromise the validity and integrity of analytical data.
- Coordinating of document control of SOPs, MDLs, control limits, and miscellaneous forms and information. Controlling distribution of controlled documents.
- Reviewing a percentage of all final data reports for internal consistency, including Chain of Custody (COC), correspondence with the analytical request, batch QC status, completeness of any corrective action statements, 5% of calculations, format, holding time, sensibility and completeness of the project file contents.
- Reviewing of external audit reports and data validation requests.
- Following-up with audits to ensure client QAPP requirements are met.
- Establishing reporting schedule and preparation of various quality reports for the Laboratory Director, clients and/or NDSC QA Team.
- Developing suggestions and recommendations to improve quality systems.
- Researching current state and federal requirements and guidelines.
- Captaining the QA team to enable communication and to distribute duties and responsibilities.
- Ensuring Communication & monitoring standards of performance to ensure that systems are in place to produce the level of quality as defined in this document.
- Evaluating the thoroughness and effectiveness of training.
- Ensuring Compliance with ISO 17025, and other national and state programs, as applicable.
- Notifying the accrediting authorities within 30 days of a change in the legal name of the laboratory or a change in any information provided on the application submitted for accreditation.
- Notifying the primary accrediting authority of any change in the laboratories ability to produce valid analytical results that persists for more than 90 calendar days for any analyte/method/matrix combination for which the laboratory holds accreditation.
- Performing technical data audits and method audits to ensure consistency and compliance with regulatory requirements.
- Participate in the vendor and supplier approval process, including subcontractors.

4.2.9) Quality Assurance Specialist
The QA Specialist is responsible for QA documentation and involvement in the following activities:

- Assisting the QA Manager in performing the annual internal laboratory audits, compiling the evaluation, and coordinating the development of an action plan to address any deficiency identified.
- Facilitating external audits, coordinating with the QA Manager and Laboratory Staff to address any deficiencies noted at the time of the audit and subsequently presented in the final audit report.
- Assisting the QA Manager in the preparation of new SOPs and in the maintenance of existing SOPs, coordinating annual reviews and updates.
- Managing the performance testing (PT) studies, coordinates follow up studies for failed analytes and works with QA Manager and Laboratory Staff to complete needed corrective action reports.
- Assisting with review and maintenance of training records.
- Assisting the Quality Manager and Project Management Group in the review of program plans for consistency with organizational and contractual requirements. Summarize and convey to appropriate personnel anomalies or inconsistencies observed in the review process.
- Assisting with management of and applications for certifications and accreditations.
- Monitoring for compliance the following QA Metrics: temperature monitoring of refrigeration units and incubators; thermometer calibrations; balance calibrations; Eppendorf/pipette calibrations; and proper standard/reagent storage.
- Performing Technical Data Audits and the Audit Miner data file review process for organic instrumentation. Maintain tracking of reviews.
- Assisting with technical review of data packages which require QA review.

4.2.10) Technical Director
The Technical Director reports directly to the Laboratory Director. He/she is accountable for all analyses and analysts under their experienced supervision and for compliance with the ISO 17025:2017 standard. The scope of responsibility ranges from the new-hire process and existing technology through on-going training and development programs for existing analysts and new instrumentation, Specific responsibilities include, but are not limited to:

- Managing technical projects and evaluating technologies, reviewing technical data
- Solving technical problems in the laboratory including troubleshooting instruments and developing or modifying methods as needed to meet customer requirements.
- Maintaining and repairing analytical instruments to reduce downtime.
- Consulting with clients, regulators, and others regarding technical aspects of analyses.
- Suggesting and implementing process improvements to maximize productivity, save costs, and decrease turn-around time.
- Participating in Eurofins Environment Testing America's best practice process to spread best technical practices and developing Eurofins Environment Testing America Standard Operating Procedures (SOPs). Leads the implementation and follow-up of the best practices and SOPs in the laboratory.
- Evaluating and adapting new technologies and methodologies. Performs non-routine analysis as required to meet the needs of current long-term clients or as a means to capture new clients in support of business development efforts.
- Training analysts and technicians in area of expertise.
- Assisting with the development of health and safety protocols
- Consulting with Project Managers and sales staff regarding analytical techniques and capabilities.
- Investigating issues raised by clients, QA, sales, and other departments to find root cause and implement corrective action and proper response.
- Contributing technical information and evaluation for deciding major new equipment purchases and capital expenditures.
- Ensuring compliance with ISO 17025, and other national and state programs.

4.2.11) Technical Manager / Department Manager
The Technical Manager reports directly to the Laboratory Director. The scope of responsibility ranges from the new-hire training and existing technology through the ongoing training and development programs for existing analysts and new instrumentation and for compliance with the ISO 17025 Standard. Specific responsibilities include, but are not limited to:

- Exercising day-to-day supervision of laboratory operations for the appropriate field of accreditation and reporting of results. Coordinating, writing, and reviewing preparation of all test methods, i. e., SOPs, with regard to quality, integrity, regulatory and optimum and efficient production techniques, and subsequent analyst training and interpretation of the SOPs for implementation and unusual project samples. He/she insures that the SOPs are properly managed and adhered to at the bench. He/she develops standard costing of SOPs to include supplies, labor, overhead, and capacity (design vs. demonstrated versus first-run yield) utilization.
- Reviewing and approving, with input from the QA Manager, proposals from marketing, in accordance with an established procedure for the review of requests and contracts. This procedure addresses the adequate definition of methods to be used for analysis and any limitations, the laboratory's capability and resources, the client's expectations. Differences are resolved before the contract is signed and work begins. A system documenting any significant changes is maintained, as well as pertinent discussions with the client regarding their requirements or the results of the analyses during the performance of the contract. All work subcontracted by the laboratory must be approved by the client. Any deviations from the contract must be disclosed to the client. Once the work has begun, any amendments to the contract must be discussed with the client and so documented.
- Monitoring the validity of the analyses performed and data generated in the laboratory. This activity begins with reviewing and supporting all new business contracts, insuring data quality, analyzing internal and external non-conformances to identify root cause issues and implementing the resulting corrective and preventive actions, facilitating the data review process (training, development, and accountability at the bench), and providing technical and troubleshooting expertise on routine and unusual or complex problems.
- Providing training and development programs to applicable laboratory staff as new hires and, subsequently, on a scheduled basis. Training includes instruction on calculations, instrumentation management to include troubleshooting and preventive maintenance.
- Enhancing efficiency and improving quality through technical advances and improved LIMS utilization. Capital forecasting and instrument life cycle planning for second generation methods and instruments as well as asset inventory management.
- Coordinating sample management from "cradle to grave," insuring that no time is lost in locating samples.
- Scheduling all QA/QC-related requirements for compliance, e.g., MDLs, etc..
- Captaining department personnel to communicate quality, technical, personnel, and instrumental issues for a consistent team approach.
- Coordinating audit responses with the QA Manager.
- Ensuring compliance with ISO 17025, and other national and state programs.

4.2.12) Manger of Project Management
The Manager of Project Management reports directly to the Laboratory Director. There is an entire staff of Project Managers that makes up the Project Management team. With the overall goal of total client satisfaction. In addition to the responsibilities of the Project Manager, listed in section 4.2.13, the MPM's responsibilities include, but are not limited to:

- Training project managers in technical procedures and promoting the growth of the Project Management Team.
- Acting as liaison between laboratory management and the Project Management Team.
- Managing human resources for the Project Management Team.

4.2.13) Project Manager
The PM reports to the Manager of Project Management and serves as the interface between the laboratory's technical departments and the laboratory's clients. The responsibilities of this position include, but are not limited to:

- Ensuring that clients receive the proper sampling supplies
- Responding to client inquiries concerning sample status
- Assisting clients with the resolution of problems concerning COC
- Ensuring that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory
- Notifying the supervisors of incoming projects and sample delivery schedules
- Maintaining communication with clients on sample progress from daily status meeting with agreed-upon due dates
- Discussing with client any project-related problems, resolving service issues, and coordinating technical details with the laboratory staff
- Familiarizing laboratory staff with specific quotes, sample log-in review, and final report completeness
- Informing QA Manager of special client requests that are outside of standard operating procedure
- Monitoring the status of all data package projects in-house to ensure timely and accurate delivery of reports
- Informing clients of data package-related problems and resolve service issues
- Coordinating requests for sample containers and other services
- Verifying that subcontract laboratories hold the required certification for all analytes, methods, and matrices to be sent

4.2.14) Project Manager Assistant (PMA)
The PMA reports to the Manager of Project Management and serves as the interface between the laboratory's technical departments and the laboratory's clients. The responsibilities of this position include, but are not limited to:

- Collating data reports, expanded deliverables and CLP data packages for delivery to clients and reviews for accuracy
- Assisting the CSMs and PMs in the reporting process
- Printing reports as needed for Project Managers
- Monitoring report due dates for timely delivery
- Providing clerical support to the CSMs, PMs and other laboratory staff as needed
- Generating credit or debit invoices to ensure proper payment in compliance with client requirements as established and communicated
- Sending final data to clients via email or courier

4.2.15) Team Leader/Supervisor
The Team Leader/Supervisor reports directly to the Organics or Inorganics Manager and/or Laboratory Director or designee. The responsibilities of this position include, but are not limited to:

- Ensuring that analysts in their department adhere to applicable SOPs and the QA Manual. He/she performs frequent SOP review to determine if analysts are in compliance and if new, modified, and optimized measures are feasible and should be added to these documents.
- Overseeing training, development of performance objectives and standards of performance, appraisal (measurement of objectives), scheduling, counseling, discipline, and motivation of analysts and documents these activities in accordance with systems developed by the QA and Personnel Departments.
- Providing guidance to analysts in resolving problems encountered daily during sample prep/analysis in conjunction with the Technical Manager(s) and/or QA Manager. Each is responsible ensuring 100% implementation of the data review and documentation, non-conformance and corrective action issues, the timely and accurate completion of performance evaluation samples and MDLs, for his/her department.
- Ensuring that all logbooks are maintained, current, and properly labeled or archived.
- Ensuring that all data is properly entered into the LIMS system and is reviewed and approved as required by laboratory documentation policy.
- Reporting all non-conformance conditions to the QA Manager and Department Manager.
- Ensuring that preventive maintenance is performed on instrumentation as detailed in the QA Manual or SOPs. He/she is responsible for developing and implementing a system for preventive maintenance, troubleshooting, and repairing or arranging for repair of instruments.
- Maintaining adequate and valid inventory of reagents, standards, spare parts, and other relevant resources required to perform daily analysis.
- Achieving optimum turnaround time on analyses and compliance with holding times.
- Assisting QA department with root cause investigations and corrective action proposals for responses to external and internal audit issues, system failures and client complaints.

4.2.16) Laboratory Analyst
Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the team leader or supervisor. The responsibilities of the analysts include, but are not limited to:

- Performing analyses by adhering to analytical and quality control protocols prescribed by current SOPs, this QA Manual, and project-specific plans honestly, accurately, timely, safely, and in the most cost-effective manner.
- Ensuring sample and data integrity by adhering to internal chain-of-custody procedures.
- Documenting standard and sample preparation, instrument calibration and maintenance, data calculations, sample matrix effects, and any observed non-conformance on bench sheets, lab notebooks, run logs, and/or the Non-Conformance Database.
- Reporting all non-conformance situations, instrument problems, matrix problems and QC failures, which might affect the reliability of the data, to their supervisor, Department Manager, and/or the QA Manager or member of QA staff.
- Performing 100% review of the data generated prior to entering and submitting for secondary level review. Performs data processing using available tools/software.
- Suggesting method improvements to their supervisor, the Technical Manager (s), and the QA Manager. These improvements, if approved, will be incorporated. Ideas for the optimum performance of their assigned area, for example, through the proper cleaning and maintenance of the assigned instruments and equipment, are encouraged.
- Working cohesively as a team in their department to achieve the goals of accurate results, optimum turnaround time, cost effectiveness, cleanliness, complete documentation, and personal knowledge of environmental analysis.
  - A "work cell" is considered to be all those individuals who see a sample through the complete process of preparation, extraction, and analysis. To ensure that the entire preparation, extraction, and analysis process is completed by a group of capable individuals, the laboratory shall ensure that each member of the work cell (including a new member entering an already existing work cell) demonstrates capability in his/her area of responsibility in the sequence. Even though the work cell operates as a "team," the demonstration of capability at each individual step in the sequence, as performed by each individual analyst/team member, remains of utmost importance. A work cell may NOT be defined as a group of analysts who perform the same step in the same process (for example, extractions for Method 8270), represented by one analyst who has demonstrated capability for that step.

4.2.17) Sample Management Manager
The Sample Receiving Manager reports to the Laboratory Director and Client Services Manager. The responsibilities of this position include, but are not limited to:

- Ensuring implementation of proper sample receipt procedures, including maintenance of chain-of-custody.

- Reporting nonconformances associated with condition-upon-receipt of samples.
- Ensuring accurate login of samples into TALS.
- Ensuring that all samples are stored in the proper environment.
- Assisting Environmental Health and Safety staff with sample disposal.

4.2.18) Field Service Technician

The Field Service Technicians report to the Sample Management Department Manager. The responsibilities of the Field Service Technician include, but are not limited to:

- Performing sample collection and sample pick-up
- Ensuring sample containers are prepared for sampling
- Performing field tests and measurements and operating and maintaining equipment used for those purposes

4.2.19) Environmental Health and Safety Coordinator

The Health and Safety Coordinator reports to the Laboratory Director and ensures that systems are maintained for the safe operation of the laboratory. The EH&S Coordinator will:

- Conduct ongoing, necessary safety training and conduct new employee safety orientation
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Administer dispersal of all Safety Data Sheet (SDS) information.
- Perform regular chemical hygiene and housekeeping instruction.
- Give instruction on proper labeling and practice.
- Serve as chairman of the laboratory safety committee.
- Provide and train personnel on protective equipment.
- Oversee the inspection and maintenance of general safety equipment – fire extinguishers, safety showers, eyewash fountains, etc. and ensure prompt repairs as needed.
- Supervise and schedule fire drills and emergency evacuation drills.
- Determine what initial and subsequent exposure monitoring, if necessary to determine potential employee exposure to chemicals used in the laboratory.
- When determined necessary, conduct exposure monitoring assessments.
- Determine when a complaint of possible over-exposure is “reasonable” and should be referred for medical consultation.
- Assist in the internal and external coordination of the medical consultation/monitoring program conducted by Eurofins Environment Testing America’s medical consultants.

4.2.20) Hazardous Waste Coordinator

The Hazardous Waste Coordinator reports directly to the Laboratory Director. The duties include, but are not limited to:

- Staying current with the hazardous waste regulations
- Continuing training on hazardous waste issues
- Reviewing and updating annually the Hazardous Waste Contingency Plan in the Environmental Health & Safety Manual
- Auditing the staff with regard to compliance with the Hazardous Waste Contingency Plan
- Contacting the hazardous waste subcontractors for review of procedures and opportunities for minimization of waste

4.3) Business Continuity and Contingency Plans

Various policies and practices are in place to address continuity of business and contingency plans to ensure continued operations or minimal disruption in operations should unplanned events (natural disasters, unexpected management changes, etc.) occur. Deputies are identified for all key management personnel. Deputies would temporarily fill a role if the primary is absent for more than 15 consecutive calendar days. The deputies must meet the same qualifications as the primary person should they be required to take on the responsibilities. The QA Manager communicates to the relevant regulatory authorities when there are management or facility changes that impact the laboratory. Changes in the technical director must be communicated within a period of time and in the manner dictated by each regulatory authority.

The following table defines who assumes the responsibilities of key personnel in their absence:

Key Personnel	Deputy	Comment
Laboratory Director: Deborah Lowe	Project Technical Manager – Dave Dunlap	NELAP Technical Manager (entire laboratory)
Quality Assurance Manager: Amanda Grilli	Quality Assurance Specialist: Pam Dudeck	
Technical Director: Larry Matko	Laboratory Director: Deborah Lowe	NELAP Technical Manager (Lipids & 8141)
Organics Department Manager: Sharon Bacha	Designated Senior GC and GCMS Analyst	NELAP Technical Manager (Organics)
Inorganics Department Manager: Roseann Ruyechan	Designated Metals and Wet Chemistry Supervisors / Senior Analyst	NELAP Technical Manager (Organics)
Organic Prep Team Leader: Sharon Bacha/Larry Matko	Designated Senior Organic Prep Analyst	
Sample Management Department Manager: Christina Kovitch	Lab Director or Designated person in the Sample Management group	

If the NELAP Technical Manager is absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director must designate another full time staff member meeting the qualifications of the Technical Manager to temporarily perform this function. If the absence exceeds 30 consecutive calendar days, the primary accrediting authority must be notified in writing.

Note: Organization Charts are subject to change - the most recent version can be found here: *PIT-GI-ORG-FRM47902*

5) QUALITY SYSTEM

5.1) Quality Policy Statement

The Quality Policy statement gives employees clear requirements for the production of analytical data. As an organization, all personnel are committed to high quality professional practice, testing and data, and service to our clients.
We strive to provide the highest quality data achievable by:

- Reading and understanding all of the quality documents applicable to each position and implementing the process in our work.
- Following all recordkeeping requirements; describing clearly and accurately all activities performed; recording "real time" as the task is carried out; understanding that it is never acceptable to "back date" entries and should additional information be required at a later date, the actual date and by whom the notation is made must be documented.
- Ensuring data integrity through the completeness, consistency, impartiality and accuracy of the data generated. Data is attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). This applies to manual paper documentation and electronic records.
- Providing accountability and traceability for each sample analyzed through proper sample handling, labeling, preparation, instrument calibration/qualification/validation, analysis, and reporting; establishing an audit trail (the who, what, when, and why) that identifies date, time, analyst, instrument used, instrument conditions, quality control samples (where appropriate and/or required by the method), and associated standard material.
- Emphasizing a total quality management process which provides impartiality, accuracy, and strict compliance with agency regulations and client requirements, giving the highest degree of confidence; understanding that meeting the requirements of the next employee in the work flow process is just as important as meeting the needs of the external client.
- Providing thorough documentation and explanation to qualify reported data that may not meet all requirements and specifications, but is still of use to the client; understanding this occurs only after discussion with the client on the data limitations and acceptability of this approach.
- Responding immediately to indications of questionable data, out-of-specification occurrences, equipment malfunctions, and other types of laboratory problems, with investigation and applicable corrective action; documenting these activities completely, including the reasons for the decisions made.
- Providing a work environment that ensures accessibility to all levels of management and encourages questions and expression of concerns on quality issues to management. Eurofins recognizes that the implementation of a quality assurance program requires management's commitment and support as well as the involvement of the entire staff.
- Continually improve systems and manage risk to support quality improvement efforts in laboratory, administrative and managerial activities.
- We each take personal responsibility to provide this quality product while meeting the company's high standards of integrity and ethics, understanding that improprieties, such as failure to conduct the required test, manipulation of test procedures or data, or inaccurate documentation will not be tolerated. Intentional misrepresentation of the activities performed is considered fraud and is grounds for termination.
- Provide data of known quality to its clients by adhering to approved methodologies, regulatory requirements and the QA/QC protocols.
- To comply with the ISO/IEC 17025:2017(E) International Standard, the 2009 and 2016 TNI Standards and to continually improve the effectiveness of the management system.

Every staff member at the laboratory plays an integral part in quality assurance and is held responsible and accountable for the quality of their work. It is, therefore, required that all laboratory personnel are trained and agree to comply with applicable procedures and requirements established by this document.

5.2) Ethics And Data Integrity

Eurofins Environment Testing America is committed to ensuring the integrity of its data and meeting the quality needs of its clients. The laboratory operates our Ethics and Data Integrity program under the guidance of Eurofin's Key Guidance Document (KGD). The elements of our program include:

- An Ethics Policy (NDSC Policy No. SOP01-QA-QP5252) and Employee Ethics Statements
- Ethics and Compliance Officers (ECOs)
- A Training Program
- Self-governance through disciplinary action for violations
- A Confidential mechanism for anonymously reporting alleged misconduct and a means for conducting internal investigations of all alleged misconduct. (NDSC SOP No. QA-QP38228)
- Procedures and guidance for recalling data if necessary (NDSC SOP No. QA-QP38229)
- Effective external and internal monitoring system that includes procedures for internal audits (Section 15 and laboratory SOP PT-QA-002 on Internal Auditing)
- Produce results, which are accurate and include QA/QC information that meets client pre-defined Data Quality Objectives (DQOs)
- Present services in a confidential, honest and forthright manner
- Provide employees with guidelines and an understanding of the Ethical and Quality Standards of our Industry
- Provide procedures and guidance to ensure the impartiality and confidentiality of all data and customer information
- Operate our facilities in a manner that protects the environment and the health and safety of employees and the public
- Obey all pertinent federal, state and local laws and regulations and encourage other members of our industry to do the same
- Educate clients as to the extent and kinds of services available
- Assert competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made
- Promote the status of environmental laboratories, their employees, and the value of services rendered by them

5.3) Quality System Documentation

The laboratory's Quality System is communicated through a variety of documents.

- Quality Assurance Manual – Each laboratory has a lab specific quality assurance manual.
- NDSC Official Documents - Each laboratory may use the Guidance (instructional use) documents at their discretion. Template documents are process documents that the laboratory's need to implement locally by using the document as is or as an outline to define their internal practices that meet the minimum requirements of the template. Required documents need to be implemented as is and listed in the laboratory's document control list.
- Key Guidance Documents (KGDs) - Documents compiled at the Group Service Centre (GSC) level by Functional Leaders (document owners) aimed at providing specific Eurofins groups of employees with guidelines necessary for the good conduct of their respective work.
- Laboratory SOPs and Policies – General and Technical
- Work Instructions - A subset of procedural steps, tasks or forms associated with an operation of a management system (e.g., checklists, preformatted bench sheets, forms).
- Laboratory QA/QC Policy Memorandums

5.3.1) Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows:

- NDSC Guidance Documents
- KGDs
- Laboratory QA/QC Policy Memorandum
- Laboratory Quality Assurance Manual (QAM)
- Laboratory SOPs and Policies
- Other (Work Instructions (WI), memos, flow charts, etc.)

Note: The laboratory has the responsibility and authority to operate in compliance with regulatory requirements of the jurisdiction in which the work is performed.

5.4) QA/QC Objectives For The Measurement Of Data

Quality Assurance (QA) is responsible for developing planned activities whose purpose is to provide assurance to all levels of management that a quality program is in place within the laboratory, and that it is functioning in an effective manner that is consistent with the requirements of NELAP, ISO 17025, and any other regulatory agencies (i.e., states) in which the laboratory maintains accreditation.

Quality Assurance (QA) and Quality Control (QC) are activities undertaken to achieve the goal of producing data that accurately characterize the sites or materials that have been sampled. Quality Assurance is generally understood to be more comprehensive than Quality Control. Quality Assurance can be defined as the integrated system of activities that ensures that a product or service meets defined standards.

Quality Control is generally understood to be limited to the analyses of samples and to be synonymous with the term “analytical quality control”. QC refers to the routine application of statistically based procedures to evaluate and control the accuracy of results from analytical measurements. The QC program includes procedures for estimating and controlling precision and bias and for determining reporting limits.

Request for Proposals (RFPs) and Quality Assurance Project Plans (QAPP) provide a mechanism for the client and the laboratory to discuss the data quality objectives in order to ensure that analytical services closely correspond to client needs. In order to ensure the ability of the laboratory to meet the Data Quality Objectives (DQOs) specified in the QAPP, clients are advised to allow time for the laboratory to review the QAPP before being finalized. The client is responsible for developing the QAPP, however, the laboratory will provide support to the client for developing the sections of the QAPP that concern laboratory activities.

Historically, laboratories have described their QC objectives in terms of precision, accuracy, representativeness, comparability, completeness, selectivity and sensitivity (PARCCSS). Each laboratory SOP defines the required QC indicators.

5.4.1) Precision

The laboratory objective for precision is to meet the performance for precision demonstrated for the methods on similar samples and to meet data quality objectives of the EPA and/or other regulatory programs. Precision is defined as the degree of reproducibility of measurements under a given set of analytical conditions (exclusive of field sampling variability). Precision is documented on the basis of replicate analysis, usually duplicate or matrix spike (MS) duplicate samples.

5.4.2) Accuracy

The laboratory objective for accuracy is to meet the performance for accuracy demonstrated for the methods on similar samples and to meet data quality objectives of the EPA and/or other regulatory programs. Accuracy is defined as the degree of bias in a measurement system. Accuracy may be documented through the use of laboratory control samples (LCS) and/or MS. A statement of accuracy is expressed as an interval of acceptance recovery about the mean recovery

5.4.3) Representativeness

The laboratory objective for representativeness is to provide data which is representative of the sampled medium. Representativeness is defined as the degree to which data represent a characteristic of a population or set of samples and is a measurement of both analytical and field sampling precision. The representativeness of the analytical data is a function of the procedures used in procuring and processing the samples. The representativeness can be documented by the relative percent difference between separately procured, but otherwise identical samples or sample aliquots.

The representativeness of the data from the sampling sites depends on both the sampling procedures and the analytical procedures. The laboratory may provide guidance to the client regarding proper sampling and handling methods in order to assure the integrity of the samples. Refer to laboratory SOPs for subsampling and homogenization techniques appropriate to the analytical method.

5.4.4) Comparability

The comparability objective is to provide analytical data for which the accuracy, precision, representativeness and reporting limit statistics are similar to these quality indicators generated by other laboratories for similar samples, and data generated by the laboratory over time.

The comparability objective is documented by inter-laboratory studies carried out by regulatory agencies or carried out for specific projects or contracts, by comparison of periodically generated statements of accuracy, precision and reporting limits with those of other laboratories.

5.4.5) Completeness

The completeness objective for data is 90% (or as specified by a particular project), expressed as the ratio of the valid data to the total data over the course of the project. Data will be considered valid if they are adequate for their intended use. Data usability will be defined in a QAPP, project scope or regulatory requirement. Data validation is the process for reviewing data to determine its usability and completeness. If the completeness objective is not met, actions will be taken internally and with the data user to improve performance. This may take the form of an audit to evaluate the methodology and procedures as possible sources for the difficulty or may result in a recommendation to use a different method.

5.4.6) Selectivity

Selectivity is defined as the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. Target analytes are separated from non-target constituents and subsequently identified/detected through one or more of the following, depending on the analytical method: extractions (separation), digestions (separation), interelement corrections (separation), use of matrix modifiers (separation), specific retention times (separation and identification), confirmations with different columns or detectors (separation and identification), specific wavelengths (identification), specific mass spectra (identification), specific electrodes (separation and identification), etc.

5.4.7) Sensitivity

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected (above the Method Detection Limit) or quantified (above the Reporting Limit).

5.5) Criteria For Quality Indicators

The laboratory maintains tables, housed in TALS, that summarizes the precision and accuracy acceptability limits for analyses performed at Eurofins Pittsburgh. This summary includes an effective date, is updated each time new limits are generated and is managed by the laboratory’s QA department. Limits are archived within the LIMS when replaced. Unless otherwise noted, limits within these tables are laboratory generated. Some acceptability limits are derived from US EPA methods when they are required. Where US EPA method limits are not required, the laboratory has developed limits from evaluation of data from similar matrices. Criteria for development of control limits are contained in laboratory SOP PT-QA-021, Laboratory Quality Control Program.

5.6) Statistical Quality Control

Statistically-derived precision and accuracy limits are required by selected methods (such as SW-846) and other programs. The laboratory routinely utilizes statistically-derived limits to evaluate method performance and determine when corrective action is appropriate. Analysts are restricted to using only the current limits within TALS, controlled as discussed above. The Quality Assurance department maintains an archive of all limits used within the laboratory. These limits are maintained in TALS as part of the analytical historical record. If a method defines the QC limits, the method limits are used. For further details refer to laboratory SOP PT-QA-021.

If a method, or program, defines the QC limits, the required limits are used, unless laboratory developed limits are tighter.

If a method requires the generation of historical limits, the lab develops such limits from recent data in the QC database of TALS following the guidelines described in Section 24 and laboratory SOP PT-QA-021. All calculations and limits are documented and dated when approved and effective. On occasion, a client may request contract-specified limits for a specific project.

Current QC limits are entered and maintained in TALS analyte database. As sample results and the related QC are entered into TALS the sample QC values are compared with the limits in TALS to determine if they are within the acceptable range. The analyst then evaluates if the sample needs to be rerun or re-extracted/rerun or if a comment should be added to the report explaining the reason for the QC outlier.

5.6.1) QC Charts

The generation and use of QC Charts (Control Charts) are described in laboratory SOP PT-QA-021. The QA department evaluates control charts to determine if adjustments need to be made to existing limits or corrective actions are necessary. All findings are documented and kept on file.

5.7) Quality System Metrics

In addition to the QC parameters discussed above, the entire Quality System is evaluated on a monthly basis through the use of specific metrics (refer to Section 16). These metrics are used to drive continuous improvement in the laboratory’s Quality System.

5.8) Laboratory Certification/Accreditation

The Laboratory Quality System is designed to meet the requirements of all governing bodies through which it holds certification / accreditation.

- A list of certifications and accredited scopes is maintained by the QA Department, and current certificates are posted in the laboratory lobby. Expired certificates are maintained in the QA archive.
- Certification renewal is completed on an annual basis, or within the time frame required by each accrediting agency.
- The laboratory shall read and follow all accrediting agencies’ accreditation requirements before applying and when renewing accreditations.
- The laboratory indicates clearly in its reports which certifications it holds.
- The laboratory does not use their NELAP or any state certificate of accreditation, accreditation status, or accrediting agency logo to imply endorsement by any accrediting body.
- The laboratory distinguishes on data reports between testing for which the laboratory is accredited and testing for which the laboratory is not accredited. The laboratory’s primary AB accreditation number is also included on all data reports.
- Upon expiration, suspension, revocation or voluntary relinquishment of accreditation, a laboratory shall:
  - Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to the laboratory’s past accreditation status.
  - Discontinue use or display of the Department’s logo.
  - Return unexpired certificates of accreditation to the Department within 48 hours.
  - Discontinuing all testing for the affected fields of accreditation.
  - Notify all customers affected by the loss or suspension in writing within 72 hours of receiving notice of the change in accreditation status.
- If there is a change in laboratory ownership, the laboratory must notify all accreditors within 10 days. Some accrediting agencies require additional change applications be submitted within 30 days.

6) DOCUMENT CONTROL

6.1) Overview

The QA Department is responsible for the control of documents used in the laboratory to ensure that approved, up-to-date documents are in circulation and out-of-date (obsolete) documents are archived or destroyed. The following documents, at a minimum, must be controlled:

- Laboratory Quality Assurance Manual
- Laboratory Standard Operating Procedures (SOP)
- Laboratory Policies
- Work Instructions and Forms
- Logbooks and Calculation Spreadsheets
- External documents that are used as part of the laboratory’s Quality System
- NDSC Documents[1]
- KGDs[1]

[1] Includes locally implemented documents that are document controlled within the laboratory’s document control system or on D4. The NDSC and/or KGD documents are only considered controlled when they are read on the intranet site or on D4. Printed copies are considered uncontrolled unless the laboratory physically distributes them as controlled documents. The laboratory’s internal document control procedure is defined in SOP PT-QA-010, Document Development and Control.

The laboratory QA Department also maintains access to various references and document sources integral to the operation of the laboratory. This includes reference methods and regulations. Instrument manuals (hard or electronic copies) are also maintained by the laboratory.

The laboratory maintains control of records for raw analytical data and supporting records such as audit reports and responses, logbooks, standard logs, training files, MDL studies, Proficiency Testing (PT) studies, certifications and related correspondence, and corrective action reports and Nonconformance Memos (NCMs). Raw analytical data consists of bound logbooks, instrument printouts, any other notes, magnetic media, electronic data and final reports.

6.2) Document Approval And Issue

The pertinent elements of a document control system for each document include a unique document title and number, pagination, the total number of pages of the item or an 'end of document' page, the effective date, revision number and the laboratory's name. The QA personnel are responsible for the maintenance of this system.

Controlled documents are authorized by the QA Department. In order to develop a new document, a responsible manager submits an electronic or paper draft to the QA Department for suggestions and approval before use. Upon approval, QA personnel add the identifying version information to the document and retain that document as the official document on file. That document is then provided to all applicable operational units. Controlled documents are identified as such and records of their distribution are kept by the QA Department. Document control may be achieved by either electronic or hardcopy distribution.

The QA Department maintains a list of the official versions of controlled documents.

Quality System Policies and Procedures will be reviewed at a minimum of every two years, or more often as required, and revised as appropriate. Changes to documents occur when a procedural change warrants.

6.3) Procedures For Document Control Policy

For creation of or changes to SOPs and QA manual, refer to laboratory SOP No. PT-QA-010, Document Development and Control.

Uncontrolled copies must not be used within the laboratory. Controlled documents are marked as such, and posted to a controlled laboratory access drive by the QA department or on D4. Controlled distribution is achieved electronically. Controlled hardcopies must be obtained through the QA Department. Previous revisions and back-up data are stored on a restricted access drive by the QA department. Details of the numbering system, required format, and controlled distribution of documents are described in laboratory SOP No. PT-QA-010. Editable copies are stored on a restricted access drive.

Forms, worksheets, work instructions and information are organized by department by the QA office. Controlled electronic versions are distributed through the intranet or on D4 and hard copies can be printed out as needed. Editable versions are stored on a restricted access drive. All forms used in the laboratory are tracked in the controlled documents database which can be accessed by the QA department and the IT group. The procedure for the care of these documents is in laboratory SOP No. PT-QA-010.

6.4) Obsolete Documents

All invalid or obsolete documents are removed from general laboratory access, or otherwise prevented from unintended use. The laboratory has specific procedures as described above to accomplish this. Obsolete hardcopy documents are collected from employees according to distribution lists and are destroyed. At least one electronic copy of the obsolete document is archived according to laboratory SOP No. PT-QA-019, Records Information Management.

7) SERVICE TO THE CLIENT

7.1) Overview

The laboratory has established procedures for the review of work requests and contracts, oral or written. The procedures include evaluation of the laboratory's capability and resources to meet the contract's requirements within the requested time period. All requirements, including the methods to be used, must be adequately defined, documented and understood. For many environmental sampling and analysis programs, testing design is site or program specific and does not necessarily fit into a standard laboratory service or product. It is the laboratory's intent to provide both standard and customized environmental laboratory services to our clients.

A thorough review of technical and QC requirements contained in contracts is performed to ensure project success. The appropriateness of requested methods, and the lab's capability to perform them must be established. Projects, proposals and contracts are reviewed for adequately defined requirements and the laboratory's capability to meet those requirements. Alternate test methods that are capable of meeting the clients' requirements may be proposed by the lab. A review of the lab's capability to analyze non-routine analytes is also part of this review process.

All projects, proposals and contracts are reviewed for the client's requirements in terms of compound lists, test methodology requested, sensitivity (detection and reporting levels), accuracy, and precision requirements (%Recovery and RPD). The reviewer ensures that the laboratory's test methods are suitable to achieve these requirements and that the laboratory holds the appropriate certifications and approvals to perform the work. The laboratory and any potential subcontract laboratories must be certified, as required, for all proposed tests.

The laboratory must determine if it has the necessary physical, personnel and information resources to meet the contract, and if the personnel have the expertise needed to perform the testing requested. Each proposal is checked for its impact on the capacity of the laboratory's equipment and personnel. As part of the review, the proposed turnaround time will be checked for feasibility.

Electronic or hard copy deliverable requirements are evaluated against the laboratory's capacity for production of the documentation.

If the laboratory cannot provide all services but intends to subcontract such services, whether to another Eurofins Environment Testing America facility or to an outside firm, this will be documented and discussed with the client prior to contract approval. (Refer to Section 8 for Subcontracting Procedures.)

The laboratory informs the client of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the lab to complete the work satisfactorily. Any discrepancy between the client's requirements and the laboratory's capability to meet those requirements is resolved in writing before acceptance of the contract. It is necessary that the contract be acceptable to both the laboratory and the client. Amendments initiated by the client and/or Eurofins Pittsburgh, are documented in writing.

All contracts, QAPPs, Sampling and Analysis Plans (SAPs), contract amendments, and documented communications become part of the project record.

The same contract review process used for the initial review is repeated when there are amendments to the original contract by the client, and the participating personnel are informed of the changes.

7.2) Review Sequence And Key Personnel

Appropriate personnel will review the work request at each stage of evaluation.

For routine projects and other simple tasks, a review by the Project Manager (PM) is considered adequate. The PM confirms that the laboratory has any required certifications, that it can meet the clients' data quality and reporting requirements and that the lab has the capacity to meet the clients turn around needs. It is recommended that, where there is a sales person assigned to the account, an attempt should be made to contact that sales person to inform them of the incoming samples.

For new, complex or large projects, the proposed contract is given to the Client Relationship Manager or Proposal Team, who will decide which lab will receive the work based on the scope of work and other requirements, including certification, testing methodology, and available capacity to perform the work.

This review encompasses all facets of the operation. The scope of work is distributed to the appropriate personnel, as needed based on scope of contract, to evaluate all of the requirements shown above (not necessarily in the order below):

- Contract Administrator
- Laboratory Project Management
- Laboratory Director / Technical Manager
- Quality Managers
- Account Executives
- Laboratory EH&S Managers/Directors

The laboratory Director reviews the formal laboratory quote and makes final acceptance for their facility.

The Sales Director, Contract Administrator, Account Executive or Proposal Coordinator then submits the final proposal to the client.

In the event that one of the above personnel is not available to review the contract, his or her back-up will fulfill the review requirements

7.3) Balancing Laboratory Capacity and Workload

Evaluating laboratory capacity to perform specific projects is the responsibility of the Vice-President, Laboratory Directors and Managers, and the Client Services director and manager. Many analysts are cross-trained to perform a variety of tests, and there is redundant equipment available in case of malfunctions. This minimizes the need to evaluate small and medium size projects against capacity available to complete them. Large and complex projects are reviewed against capacity estimates before bids are submitted to ensure that the client's analysis schedule is met. Laboratory capacity and backlog is tracked on a continuous basis using information from the Laboratory Sample Information System (LIMS) including turnaround time, and work in-house.

7.4) Documentation

The Contracts Department maintains copies of all signed contracts. In the Pittsburgh laboratory, copies of contracts are maintained in the laboratory network public drive by the sales/marketing personnel.

Appropriate records are maintained for every contract or work request. All stages of the contract review process are documented and include records of any significant changes. Contracts review documentation and is maintained in the network public drive.

The contract will be distributed to and maintained by the appropriate sales/marketing personnel and the Account Manager. A copy of the contract and formal quote will be filed with the laboratory PM and the Lab Director.

Records are maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. The PM keeps a phone log or an electronic record of conversations with the client.

7.4.1) Project-Specific Quality Planning

Communication of contract specific technical and QC criteria is an essential activity in ensuring the success of site specific testing programs. To achieve this goal, a PM is assigned to each client. It is the PM's responsibility to ensure that project-specific technical and QC requirements are effectively evaluated and communicated to the laboratory personnel before and during the project. QA department involvement may be needed to assist in the evaluation of custom QC requirements.

PM's are the primary client contact and they ensure resources are available to meet project requirements. Although PM's do not have direct reports or staff in production, they coordinate opportunities and work with laboratory management and supervisory staff to ensure available resources are sufficient to perform work for the client's project. Project management is positioned between the client and laboratory resources.

Prior to work on a new project, the dissemination of project information and/or project opening meetings may occur to discuss schedules and unique aspects of the project. Items to be discussed may include the project technical profile, turnaround times, holding times, methods, analyte lists, reporting limits, deliverables, sample hazards, or other special requirements. The PM introduces new projects to the laboratory staff through project kick-off meetings or to the supervisory staff during production meetings. These meetings provide direction to the laboratory staff in order to maximize production and client satisfaction, while maintaining quality. In addition, project notes may be associated with each sample batch as a reminder upon sample receipt and analytical processing.

During the project, any change that may occur within an active project is agreed upon between the client/regulatory agency and the PM/laboratory. These changes (e.g., use of a non-standard method or modification of a method) and approvals must be documented prior to implementation. Documentation pertains to any document, e.g., letter, e-mail, variance, contract addendum, which has been signed by both parties.

Such changes are also communicated to the laboratory during production and operations meetings. Such changes are updated to the project notes and are introduced to the managers at these meetings. The laboratory staff is then introduced to the modified requirements via the PM or the individual laboratory Technical Manager. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s).

The laboratory strongly encourages client visits to the laboratory and for formal/informal information sharing session with employees in order to effectively communicate ongoing client needs as well as project specific details for customized testing programs

7.5) Special Services

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. It is the laboratory's goal to meet all client requirements in addition to statutory and regulatory requirements. The laboratory has procedures to ensure confidentiality to clients (Section 25).

The laboratory's standard procedures for reporting data are described in Section 25. Special services are also available and provided upon request. These services include:

- Reasonable access for our clients or their representatives to the relevant areas of the laboratory for the witnessing of tests performed for the client
- Assist client-specified third party data validators as specified in the client's contract
- Supplemental information pertaining to the analysis of their samples. Note: An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

When the client requests a statement of conformity to a specification or standard based on the analysis performed by the laboratory (e.g., pass/fail, in-tolerance/out-of-tolerance), the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to the client. Associated reporting requirements are addressed in Section 25.2.18

7.6) Client Communication

Project managers are the primary communication link to the clients. They shall inform their clients of any delays in project completion as well as any non-conformances in either sample receipt or sample analysis. Project management will maintain ongoing client communication throughout the entire client project.

Technical Managers, or their designees, are available to discuss any technical questions or concerns that the client may have.

7.7) Reporting

The laboratory works with our clients to produce any special communication reports required by the contract.

To the extent possible, results of testing or analysis of environmental samples shall be reported only if all quality control, analytical testing and sample acceptance measures are acceptable. If a quality control, analytical testing or sample acceptance measure is found to be out of control and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the failed quality control measure shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

7.8) Client Feedback and Surveys

The laboratory assesses both positive and negative client feedback. The results are used to improve overall laboratory quality and client service. Eurofins Sales and Marketing teams periodically develops lab and client specific surveys to assess client satisfaction. Survey results and both complaints and compliments are tracked in the monthly quality metrics report.

When a complaint is received, we determine, to the best of our ability, the extent of the issue and what data is in question. The person receiving the complaint documents this information and promptly forwards it to the appropriate management personnel where the work in question was performed. If a data reporting error is discovered, the final report and/or data must be regenerated with the correct value(s).

The laboratory QA personnel are responsible for entering client concerns into iCAT. In some cases, an ICAT / ICAR (Investigation and Corrective Action Report) is initiated to address and document the situation. While an individual issue may not warrant a formal investigation, QA monitors these issues for potential trends and will issue an ICAR/ICAT if a trend is evident.

8) SUBCONTRACTING OF TESTS

8.1) Overview

For the purpose of this quality manual, the phrase subcontract laboratory refers to a laboratory external to the Eurofins Environment Testing America laboratories. To distinguish between an external laboratory and a Eurofins Environment Testing America laboratory at a different location, the phrase "work sharing" or "work share lab" refers to internal subcontracting between Eurofins Environment Testing America laboratories. The term outsourcing refers to the act of subcontracting tests.

When contracting with our clients, the laboratory makes commitments regarding the services to be performed and the data quality for the results to be generated. When the need arises to outsource testing for our clients because project scope, changes in laboratory capabilities, capacity or unforeseen circumstances, we must be assured that the subcontractors or work sharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to the NDSC Document on Subcontracting, NDSC-US-LEG-SOP44936.

When outsourcing analytical services, the laboratory will assure, that the subcontract or work sharing laboratory maintains a program consistent with the requirements of this document, the requirements specified in TNI/ISO 17025 and/or the client's Quality Assurance Project Plan (QAPP). All QC guidelines specific to the client's analytical program are transmitted to the subcontractor or work share lab and agreed upon before sending the samples to the subcontract facility. Additionally, work requiring accreditation will be placed with an appropriately accredited laboratory. The laboratory performing the subcontracted work will be identified in the final report, as will non-TNI accredited work where required.

Project Managers (PMs) and other responsible Client Service members for the Export Lab (i.e. the Eurofins Environment Testing America laboratory that transfers samples to another laboratory) are responsible for obtaining client approval prior to subcontracting or work sharing any samples. The laboratory will advise the client of a subcontract arrangement in writing and when possible approval from the client shall be obtained and retained in the project folder. These approvals may be granted by the client in written contractual agreements between the client and Eurofins Environment Testing America.

Note: In addition to the client, some regulating agencies, (e.g, USDA) or contracts may require notification prior to placing such work. Client notification and approval must be documented.

8.2) Qualifying And Monitoring Subcontractors

Whenever a PM, Account Executive (AE) or Customer Service Manager (CSM) becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory(s) shall be selected based on the following:

- <u>Subcontractors specified by the client</u> – In these circumstances, the client assumes responsibility for the quality of the data generated from the use of a subcontractor.
- <u>Subcontractors reviewed by Eurofins Environment Testing America</u> – Firms which have been reviewed by the company and are known to meet standards for accreditations (e.g. State, TNI); technical specifications; legal and financial information.

A list of approved vendors is available on the Eurofins Environment Testing America intranet site. Approved vendors' capabilities and certifications are found in the individual folders maintained on that site.

All Eurofins Environment Testing America laboratories are pre-qualified for work sharing provided they hold the appropriate accreditations and can adhere to the project/program requirements. The originating laboratory is responsible for communicating all technical, quality, and deliverable requirements as well as other contract needs.

8.2.1)
When the potential sub-contract laboratory has not been previously approved, Account Executives or PMs may nominate a laboratory as a subcontractor based on need. The decision to nominate a laboratory must be approved by the Client Relations Manager (CRM) or Laboratory Director. The CRM or Laboratory Director requests that the QA Manager or Project Manager begin the process of approving the subcontract laboratory. Refer to NDSC Document NDSC-US-LEG-SOP44936, Subcontracting. The client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented).

Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability and forwarded to the NDSC Quality Information Manager (QIM) for review. After the NDSC QIM reviews the documents for completeness, the information is forwarded to the Finance Department for formal signature and contracting with the laboratory. The approved vendor will be added to the approved subcontractor list on the intranet site and the finance group is concurrently notified.

The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the lab to use. The qualified subcontractors on the intranet site are known to meet minimal standards. Eurofins Environment Testing America does not certify laboratories. The subcontractor is on our approved list and can only be recommended to the extent that we would use them.

8.3) Oversight and Reporting

The status and performance of qualified subcontractors will be monitored periodically by the NDSC Quality department and includes an annual review process. Refer to the NDSC Document No. NDSC-US-LEG-SOP44936 on Subcontracting. Any problems identified will be brought to the attention of Eurofins Environment Testing America’s Corporate Finance, Legal or NDSC Quality personnel.

- Complaints shall be investigated. Documentation of the complaint, investigation and corrective action will be maintained in the subcontractor’s file on the intranet site. Complaints are posted using the Vendor Performance Report.
- Information shall be updated on the intranet when new information is received from the subcontracted laboratories.
- Subcontractors in good standing will be retained on the intranet listing. CSO personnel will notify all Eurofins Environment Testing America laboratories, NDSC Quality and Corporate Contracts if any laboratory requires removal from the intranet site. This notification will be posted on the intranet site and e-mailed to all CSO personnel, Laboratory Directors, QA Managers, and Sales Personnel.

Prior to initially sending samples to the subcontracted laboratory, the PM confirms their certification status to determine if it’s current and scope-inclusive. The information is documented within the project records.

8.3.1) For continued use of an approved external subcontractor, current certifications are viewed by the responsible Project Manager on the intranet site. For Eurofins Environment Testing America laboratories, certifications can be viewed through TALS.

8.3.2)
All subcontracted samples must be accompanied by a Eurofins Environment Testing America Chain of Custody (COC). A copy of the original COC sent by the client must be available in TALS for all samples workshared within Eurofins Environment Testing America. Client COCs are only forwarded to external subcontractors when samples are shipped directly from the project site to the subcontractor lab. Under routine circumstances, client COCs are not provided to external subcontractors.

Through communication with the subcontracted laboratory, the PM monitors the status of the subcontracted analyses, facilitates successful execution of the work, and ensures the timeliness and completeness of the analytical report.

Non-TNI accredited work must be identified in the subcontractor’s report as appropriate. If TNI accreditation is not required, the report does not need to include this information.

Reports submitted from subcontractor laboratories are not altered and are included in their original form in the final project report. This clearly identifies the data as being produced by a subcontractor facility. If subcontract laboratory data is incorporated into the laboratories EDD (i.e., imported), the report must explicitly indicate which lab produced the data for which methods and samples.

Note: The results submitted by a Eurofins Environment Testing America work sharing laboratory may be transferred electronically and the results reported by the Eurofins Environment Testing America work sharing lab are identified on the final report. The report must explicitly indicate which lab produced the data for which methods and samples. The final report must include a copy of the completed COC for all work sharing reports.
Note: If a report including workshare data is sent to West Virginia clients, then individual reports per laboratory must be generated.
Note: If samples are subcontracted for SDWA compliance testing, the following information must be provided to the subcontract laboratory along with all other required chain-of-custody information: Public Water System ID Number and name of the system providing the sample, sample location ID number, and name and contact number of the Public Water System.

8.4) Contingency Planning

The full qualification of a subcontractor may be waived to meet emergency needs. This decision & justification must be documented in the project files, and the ‘Purchase Order Terms And Conditions For Subcontracted Laboratory Services’ must be sent with the samples and COC.

In the event this provision is utilized, the laboratory (e.g., PM) will be required to verify and document the applicable accreditations of the subcontractor. All other quality and accreditation requirements will still be applicable, but the subcontractor need not have signed a subcontract agreement with Eurofins Environment Testing America at this time.

The use of any emergency subcontractor will require the PM to complete a New Vendor Add Form in order to process payment to the vendor and add them to TALS. This form requires the user to define the subcontractor’s category/s of testing and the reason for testing.

8.5) Use of NELAP and A2LA Logo

It is not laboratory policy to use these logos on any company letterhead, including analytical reports.

9) PURCHASING SERVICES AND SUPPLIES

9.1) Overview

Evaluation and selection of suppliers and vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products on a continuous and short term basis, the overall quality of their services, their past history, and competitive pricing. This is achieved through evaluation of objective evidence of quality furnished by the supplier, which can include certificates of analysis, recommendations, and proof of historical compliance with similar programs for other clients. To ensure that quality critical consumables and equipment conform to specified requirements, which may affect quality, all purchases from specific vendors are approved by a member of the supervisory or management staff.

Request for Proposals (RFP's) will be issued where more information is required from the potential vendors than just price. RFP's allow Eurofins Environment Testing America to determine if a vendor is capable of meeting requirements such as supplying all of the Eurofins Environment Testing America facilities, meeting required quality standards and adhering to necessary ethical and environmental standards. The RFP process also allows potential vendors to outline any additional capabilities they may offer.

9.2) Glassware

Glassware used for volumetric measurements must be Class A or verified for accuracy according to laboratory procedure. Pyrex (or equivalent) glass should be used where possible. For safety purposes, thick-wall glassware should be used where available.

9.3) Reagents, Standards & Supplies

Purchasing guidelines for equipment and reagents must meet the requirements of the specific method and testing procedures for which they are being purchased. Solvents and acids are pre-tested in accordance with NDSC Document No. NDSC-QA-SOP46704, Acid and Solvent Lot Testing and Approval Program. Approval information for the solvents and acids tested under NDSC Document No. NDSC-QA-SOP46704 is stored on the Eurofins Environment Testing America intranet SharePoint, under Solvent Approvals. A master list of all tested materials, as well as the certificates of analysis for the materials, is stored in the same location. Additional approval and traceability instructions are found in laboratory SOP PT-QA-006, Procurement of Standards and Materials; Labeling and Traceability.

9.3.1)

Chemical reagents, solvents, glassware, and general supplies are ordered as needed to maintain sufficient quantities on hand. Materials used in the analytical process must be of a known quality. The wide variety of materials and reagents available makes it advisable to specify recommendations for the name, brand, and grade of materials to be used in any determination. This information is contained in the method SOP. The analyst completes the Material Request Sheet when requesting reagents, standards, or supplies, or they may check the item out of the on-site consignment system that contains items approved for laboratory use.

If an item is not in the consignment system, the analyst must obtain approval from the area team leader/supervisor and Laboratory Director prior to the order being placed by the purchasing department. The responsible analyst places the order.

9.3.2) Receiving

It is the responsibility of the Sample Receiving department to receive the shipment. It is the responsibility of the analyst or manager who ordered the materials to document the date the materials were received. Once the ordered reagents or materials are received, the analyst or designee compares the information on the label or packaging to the original order to ensure that the purchase meets the quality level specified. This is documented through the addition of the received date and reviewers initials to the packing slip.

Lot numbers of solvents and acids are checked against the approved solvent/acid list. If the material is listed as unapproved, or is not listed, it is sequestered and returned to the vendor. Alternatively, the laboratory may test the material for the intended use, and if it is acceptable, document the approval on the approval list. Records of any testing performed locally are maintained by the QA department, and lots approvals and certificates of analysis are stored on the Eurofins Environment Testing America intranet Pittsburgh SharePoint site.

Materials may not be released for use in the laboratory until they have been inspected, verified as suitable for use, and the inspection/verification has been documented.

Safety Data Sheets (SDSs) are available online through the Company's intranet website. Anyone may review these for relevant information on the safe handling and emergency precautions of on-site chemicals.

9.3.3) Specifications

Methods in use in the laboratory specify the grade of reagent that must be used in the procedure. If the quality of the reagent is not specified, analytical reagent grade will be used. It is the responsibility of the analyst to check the procedure carefully for the suitability of grade of reagent.

Chemicals must not be used past the manufacturer's expiration date and must not be used past the expiration time noted in a method SOP. If expiration dates are not provided, the laboratory may contact the manufacturer to determine an expiration date.

The laboratory assumes a five year expiration date on inorganic dry chemicals and solvents unless noted otherwise by the manufacturer or by the reference source method. Chemicals/solvents should not be used past the manufacturer's or SOPs expiration date unless verified as outlined below.

- An expiration date **cannot** be extended if the dry chemical/solvent is discolored or appears otherwise physically degraded. In this case, the dry chemical/solvent must be discarded.
- Expiration dates can be extended if the dry chemical/solvent is found to be satisfactory based on acceptable performance of quality control samples (Continuing Calibration Verification (CCV), Blanks, Laboratory Control Sample (LCS), etc.).
- If the dry chemical/solvent is used for the preparation of standards, the expiration dates can be extended 6 months if the dry chemical/solvent is compared to an unexpired independent source in performing the method and the performance of the dry chemical/solvent is found to be satisfactory. The comparison must show that the dry chemical/solvent meets CCV limits. The comparison studies are maintained on-file and available for review with each lab department and copy forwarded to QA department. Recertification is documented in TALS.

Wherever possible, standards must be traceable to national or international standards of measurement or to national or international reference materials. Records to that effect are available to the user.

Compressed gases in use are checked for pressure and secure positioning daily. To prevent a tank from going to dryness, or introducing potential impurities, the pressure should be closely watched as it decreases to approximately 15% of the original reading, at which point it should be replaced. For example, a standard sized laboratory gas cylinder containing 3,000 psig of gas should be replaced when it drops to approximately 500 psig. The quality of the gases must meet method or manufacturer specifications or be of a grade that does not cause any analytical interference.

Water used in the preparation of samples, standards or reagents must have a specific conductivity of less than 1- µmho /cm (or specific resistivity of greater than 1.0 megohm-cm) at 25oC. The specific conductivity is checked and recorded daily. If the water's specific conductivity is greater than the specified limit, the Facility Manager and appropriate Technical Managers/Supervisors must be notified immediately in order to notify all departments, decide on cessation (based on intended use) of activities, and make arrangements for correction.

The laboratory may purchase reagent grade (or other similar quality) water for use in the laboratory. This water must be certified clean by the supplier for all target analytes or otherwise verified by the laboratory prior to use. This verification is documented.

Standard lots are verified before first time use if the laboratory switches manufacturers or has historically had a problem with the type of standard.

Purchased bottleware used for sampling must be certified clean and the certificates must be maintained. If uncertified sampling bottleware is purchased, all lots must be verified clean prior to use. This verification must be maintained.

NOTE: Each bottleware type must be documented as clean down to the laboratory MDL for all target analytes for use with samples from Wisconsin.

Records of manufacturer's certification and traceability statements are maintained in files or binders in each laboratory section. These records include date of receipt, lot number (when applicable), and expiration date (when applicable). Incorporation of the item into the record indicates that the analyst has compared the new certificate with the previous one for the same purpose and that no difference is noted, unless approved and so documented by the Department Manager or QA Manager.

9.3.4) Storage

Reagent and chemical storage is important from the aspects of both integrity and safety. Light-sensitive reagents may be stored in brown-glass containers. Storage conditions are per the NDSC Environmental Health & Safety Manual (Doc. No. NDSC-US-EHS-QP46060), method SOPs, or manufacturer instructions.

9.4) Purchase Of Equipment / Instruments / Software

When a new piece of equipment is needed, either for additional capacity or for replacing inoperable equipment, the analyst or supervisor makes a supply request to the Department Manager and/or the Laboratory Director. A decision is made as to which piece of equipment can best satisfy the requirements. The appropriate written requests are completed and purchasing places the order.

Upon receipt of a new or used piece of equipment, an identification name is assigned and added to the equipment list. IT must also be notified so that they can synchronize the instrument for back-ups. Its capability is assessed to determine if it is adequate or not for the specific application. For instruments, a calibration curve is generated, followed by MDLs, Demonstration of Capabilities (DOCs), and other relevant criteria (refer to Section 19). For software, its operation must be deemed reliable and evidence of instrument verification must be retained by the IT Department or QA Department. Software certificates supplied by the vendors are filed with the LIMS Administrator. The manufacturer's operation manual is retained in the laboratory in a designated area or near the instrument.

9.5) Services

Service to analytical instruments (except analytical balances) is performed on an as needed basis. Routine preventative maintenance is discussed in Section 20. The need for service is determined by analysts and/or Technical Managers. The service providers that perform the services are approved by the Laboratory or Technical Director.

Analytical balances are serviced and calibrated annually in accordance with laboratory SOP No. PT-QA-012, Selection and Calibration of Balances and Weights. The calibration and maintenance services are performed on-site, and the balances are returned to use immediately following successful calibration. When the calibration certificates are received (usually within 24 hours of the service), they are reviewed, and documentation of the review is filed with the certificates. If the calibration was unsuccessful, the balance is immediately removed from service and segregated pending either further maintenance or disposal.

Calibration services for support equipment such as thermometers, weight sets, autopipettors, etc, are obtained from vendors with current and valid ISO 17025 accreditation for calibration of the specific piece of equipment. Prior to utilizing the vendor's services, the vendor's accreditation status is verified. Once the equipment has been calibrated, the calibration certificates are reviewed by the QA department, and documentation of the review is filed with the calibration certificates. The equipment is then returned to service within the laboratory.

9.6) Suppliers

Eurofins Environment Testing America selects vendors through a competitive proposal / bid process, strategic business alliances or negotiated vendor partnerships (contracts). The level of control used in the selection process is dependent on the anticipated spending amount and the potential impact on Eurofins Environment Testing America business. Vendors that provide test and measuring equipment, solvents, standards, certified containers, instrument related service contracts or subcontract laboratory services shall be subject to more rigorous controls than vendors that provide off-the-shelf items of defined quality that meet the end use requirements. The purchasing system includes all suppliers/vendors that have been approved for use.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality. This is documented by signing off on packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered.

Any issues of vendor performance are to be reported immediately by the laboratory staff to the Corporate Purchasing Group and laboratory QA.

The Purchasing Group will work through the appropriate channels to gather the information required to clearly identify the problem and will contact the vendor to report the problem and to make any necessary arrangements for exchange, return authorization, credit, etc.

Suppliers are subject to re-evaluation, as deemed appropriate, through a review of complaints the laboratory had against the vendor in the previous 12 months.

The laboratory has access to a listing of all approved suppliers of critical consumables, supplies and services. This information is provided through the Coupa purchasing system.

9.6.1) New Vendor Procedure

Laboratory employees who wish to request the addition of a new vendor must complete a Vendor Add Request Form.

New vendors are evaluated based upon criteria appropriate to the products or services provided as well as their ability to provide those products and services at a competitive cost. Vendors are also evaluated to determine if there are ethical reasons or potential conflicts of interest with Eurofins Environment Testing America employees that would make it prohibitive to do business with them as well as their financial stability. The QA Department and/or the Technical Services Director are consulted with vendor and product selection that have an impact on quality.

Vendors of critical supplies and services must be evaluated to ensure that their required ISO certification(s) are current and they meet any other laboratory specific criteria. Laboratory QA will add vendors who meet criteria to the Approved Vendors List for their site.

10) COMPLAINTS

10.1) Overview

The laboratory considers an effective client complaint handling processes to be of significant business and strategic value. Listening to and documenting client concerns captures client knowledge that enables our operations to continually improve processes and client satisfaction. An effective client complaint handling process also provides assurance to the data user that the laboratory will stand behind its data, service obligations and products.

A client complaint is any expression of dissatisfaction with any aspect of our business services (e.g., communications, responsiveness, data, reports, invoicing and other functions) expressed by any party, whether received verbally or in written form. Client inquiries, complaints or noted discrepancies are documented, communicated to management, and addressed promptly and thoroughly.

The laboratory has procedures for addressing both external and internal complaints with the goal of providing satisfactory resolution to complaints in a timely and professional manner.

The nature of the complaint is identified, documented and investigated, and an appropriate action is determined and taken. In cases where a client complaint indicates that an established policy or procedure was not followed, the QA Department must evaluate whether a special audit must be conducted to assist in resolving the issue. A written confirmation or letter to the client, outlining the issue and response taken is recommended as part of the overall action taken.

The process of complaint resolution and documentation utilizes the procedures outlined in Section 12 (Corrective Actions) and is documented following laboratory SOP PT-QA-016, Non-Conformance and Corrective Action System. A copy of this procedure will be made available to any interested party on request.

10.2) External Complaints

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint in the database, according to laboratory SOP PT-QA-016.

Complaints fall into two categories: correctable and non-correctable. An example of a correctable complaint would be one where a report re-issue would resolve the complaint. An example of a non-correctable complaint would be one where a client complains that their data was repeatedly late. Non-correctable complaints should be reviewed for preventive action measures to reduce the likelihood of future occurrence and mitigation of client impact.

The general steps in the complaint handling process are:

- Receiving and Documenting Complaints
- Acknowledge receipt of complaint, whenever possible
- Complaint Investigation and Service Recovery
- Process Improvement

The laboratory shall inform the initiator of the complaint of the results of the investigation and the corrective action taken, if any.

10.3) Internal Complaints

Internal complaints include, but are not limited to: errors and non-conformances, training issues, internal audit findings, and deviations from methods. Corrective actions may be initiated by any staff member who observes a nonconformance and shall follow the procedures outlined in Section 12. In addition, Executive Management, Sales and Marketing and IT may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 12.

10.4) Management Review

The number and nature of client complaints is reported by the QA Manager to the Laboratory Director and Quality Director in the QA Monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the Annual Management Systems Review (Section 16).

11) CONTROL OF NON-CONFORMING WORK

11.1) Overview

When data discrepancies are discovered or deviations and departures from laboratory SOPs, policies and/or client requests have occurred, corrective action is taken immediately. First, the laboratory evaluates the significance of the nonconforming work. Then, a corrective action plan is initiated based on the outcome of the evaluation. If it is determined that the nonconforming work is an isolated incident, the plan could be as simple as adding a qualifier to the final results and/or making a notation in the case narrative. If it is determined that the nonconforming work is a systematic or improper practices issue, the corrective action plan could include a more in depth investigation and a possible suspension of an analytical method. In all cases, the actions taken are documented using the laboratory’s corrective action system (refer to Section 12).

Due to the frequently unique nature of environmental samples, sometimes departures from documented policies and procedures are needed. When an analyst encounters such a situation, the problem is presented to their manager for advice. The manager may elect to discuss it with the Laboratory Director or QA Manager or have a PM contact the client to decide on a logical course of action. Once an approach is agreed upon, the analyst documents it using the laboratories non-conformance/corrective action system described in Section 12. This information can then be supplied to the client in the form of a case narrative with the report.

Project Management may encounter situations where a client may request that a special procedure be applied to a sample that is not standard lab practice. Based on a technical evaluation, the lab may accept or opt to reject the request based on technical or ethical merit. An example might be the need to report a compound that the lab does not normally report. The lab would not have validated the method for this compound following the procedures in

Section 19. The client may request that the compound be reported based only on the calibration. Such a request would need to be approved by the Laboratory Director and QA Manager, documented and included in the project folder. Deviations **must** also be noted on the final report with a statement that the compound is not reported in compliance with TNI (or the analytical method) requirements and the reason. Data being reported to a non-TNI state would need to note the change made to how the method is normally run.

11.2) Responsibilities And Authorities

Under certain circumstances, the Laboratory Director, a Technical Manager, or a member of the QA team may authorize departures from documented procedures or policies. The departures may be a result of procedural changes due to the nature of the sample; a one-time procedure for a client; QC failures with insufficient sample to reanalyze, etc. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures. This information is documented on a Nonconformance Memo (NCM) and may also be documented in logbooks and/or data review checklists as appropriate. Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility Senior Management within 24-hours. The Senior Management staff is comprised of the Laboratory Director, the QA Manager, and the Technical Managers. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an ECO (e.g., the VP-QA/EHS) and the laboratory's Quality Director within 24 hours of discovery.

Whether an inaccurate result was reported due to calculation or quantitation errors, data entry errors, improper practices, or failure to follow SOPs, the data must be evaluated to determine the possible effect.

The Laboratory Director, QA Manager, ECOs, VP of Operations, and the Quality Directors have the authority and responsibility to halt work, withhold final reports, or suspend an analysis for due cause as well as authorize the resumption of work.

11.3) Evaluation Of Significance And Actions Taken

For each nonconforming issue reported, an evaluation of its significance and the level of management involvement needed is made. This includes reviewing its impact on the final data, whether or not it is an isolated or systematic issue, and how it relates to any special client requirements.

The NDSC Document entitled Nonconforming Work (QA-QP38229) is the procedure to be followed when it is discovered that erroneous or biased data may have been reported to clients or regulatory agencies.

The NDSC Document entitled Internal Ethics and Data Integrity Investigations (QA-QP38228) is the procedure to be followed for investigation and correction of situations involving alleged incidents of misconduct or violation of the company's ethics policy.

Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting in lieu of the data recall determination form contained in the NDSC Document No. QA-QP38229.

11.4) Prevention Of Nonconforming Work

If it is determined that the nonconforming work could recur, further corrective actions must be made following the laboratory's corrective action system. On at least a monthly basis, the QA Department evaluates non-conformances to determine if any nonconforming work has been repeated multiple times. If so, the laboratory's corrective action process must be followed.

11.5) Method Suspension/Restriction (Stop Work Procedures)

In some cases, it may be necessary to suspend/restrict the use of a method or target analyte which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the persons noted in Section 11.2, Paragraph 4.

Prior to suspension/restriction, confidentiality will be respected, and the problem with the required corrective and preventive action will be stated in writing and presented to the Laboratory Director.

The Laboratory Director shall arrange for the appropriate personnel to meet with the QA Manager as needed. This meeting shall be held to confirm that there is a problem, that suspension/restriction of the method is required and will be concluded with a discussion of the steps necessary to bring the method/target or test fully back on line. In some cases, that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the method, target or test fully back on line. The QA Manager will also initiate a corrective action report as described in Section 12 if one has not already been started. A copy of any meeting notes and agreed upon steps should be e-mailed by the laboratory to their Business Unit President and VP-QA & EHS. This e-mail acts as notification of the incident.

After suspension/restriction, the lab will hold all reports to clients pending review. No faxing, mailing or distributing through electronic means may occur. The report must not be posted for viewing on the internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (e.g., Project Management, Log-in, etc.). Clients will NOT generally be notified at this time. Analysis may proceed in some instances depending on the non-conformance issue.

Within 72 hours, the QA Manager will determine if compliance is now met and reports can be released, OR determine the plan of action to bring work into compliance, and release work. A team, with all principals involved (e.g., Laboratory Director, Technical Manager, QA Manager) can devise a start-up plan to cover all steps from client notification through compliance and release of reports. Project Management and the Directors of Client Services and Sales and Marketing must be notified if clients must be notified or if the suspension/restriction affects the laboratory's ability to accept work. The QA Manager must approve start-up or elimination of any restrictions after all corrective action is complete.

12) CORRECTIVE ACTION

12.1) Overview

A major component of the laboratory's Quality Assurance (QA) Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent reoccurrence. The laboratory employs two systems to manage non-conformances. Issues suspected of being systematic in nature and for which root cause analysis and a formal Corrective Action Report (CAR) are needed are documented in the Incident Corrective Action Tracking (ICAT) database. Routine batch non-conformances, events that are understood to be isolated in nature, are documented in the TALS non-conformance memo (NCM) system. See Figure 12-1 for an example CAR.

12.2) General

Problems within the quality system or within analytical operations may be discovered in a variety of ways, such as QC sample failures, internal or external audits, proficiency testing (PT) performance, client complaints, staff observation, etc.

The purpose of a corrective action system is to:
- Identify non-conformance events and assign responsibility(s) for investigating.
- Resolve non-conformance events and assign responsibility for any required corrective action.
- Identify systematic problems before they become serious.
- Identify and track client complaints and provide resolution.

12.2.1) Non-Conformance Memo (NCM)

NCMs are used to document the following types of corrective actions:
- Deviations from an established procedure or SOP
- QC outside of limits
- Isolated reporting / calculation errors
- Client Complaints
- Discrepancies in materials / goods received vs. manufacturer packing slips (Forms of documentation other than NCMs in TALS are also acceptable.)
- Anomalies that occur during sample receipt, preparation or analysis

12.2.2) Corrective Action Documented in the ICAT Database

- Internal and external audit findings
- Failed or Unacceptable PT results
- Identified poor process or method performance trends
- Systematic reporting / calculation errors.
- Data recall investigations
- Questionable trends that are found in the review of NCMs
- Client complaints
- Excessive revised reports

The ICAT database is used to document background information, track the results of corrective action investigations and root cause analysis, and to provide reports of corrective action plans.

12.3) Closed Loop Corrective Action Process

Any employee in the company can initiate a corrective action. There are four main components to a closed-loop corrective action process once an issue has been identified: Cause Analysis, Selection and Implementation of Corrective Actions (both short and long term), Monitoring of the Corrective Actions, and Follow-up.

12.3.1) Cause Analysis

- Upon discovery of a non-conformance event, the event must be defined and documented. An entry into the ICAT system must be initiated. Someone is assigned to investigate the issue and the event is investigated for root cause. Table 12-1 provides some general guidelines on determining responsibility for assessment.
- The cause analysis step is the key to the process as a long term corrective action cannot be determined until the cause is determined.
- If the root cause is not readily obvious, the Technical Director, Laboratory Director, Technical Manager, or QA Manager (or QA designee) is consulted.

12.3.2) Selection and Implementation of Corrective Actions

- Where corrective action is needed, the laboratory shall identify potential corrective actions. The action(s) most likely to eliminate the problem and prevent recurrence are selected and implemented. Responsibility for implementation is assigned.
- Corrective actions shall be to a degree appropriate to the magnitude of the problem identified through the cause analysis.
- Whatever corrective action is determined to be appropriate, the laboratory shall document and implement the changes. The ICAT record is used for this documentation.

12.3.3) Root Cause Analysis

Root Cause Analysis is a class of problem solving (investigative) methods aimed at identifying the basic or causal factor(s) that underlie variation in performance or the occurrence of a significant failure. The root cause may be buried under seemingly innocuous events, many steps preceding the perceived failure. At first glance, the immediate response is typically directed at a symptom and not the cause. Typically, root cause analysis would be best with three or more incidents to triangulate a weakness. NDSC Document No. NDSC-QA-SOP43847, Root Cause Analysis, describes this procedure.

Systematically analyze and document the root causes of the more significant problems that are reported. Identify, track, and implement the corrective actions required to reduce the likelihood of recurrence of significant incidents. Trend the root cause data from these incidents to identify root causes that, when corrected, can lead to dramatic improvements in performance by eliminating entire classes of problems.

Identify the one event associated with problem and ask why this event occurred. Brainstorm the root causes of failures; for example, by asking why events occurred or conditions existed; and then why the cause occurred 5 consecutive times until you get to the root cause. For each of these sub events or causes, ask why it occurred. Repeat the process for the other events associated with the incident.

Root cause analysis does not mean the investigation is over. Look at technique, or other systems outside the normal indicators. Often creative thinking will find root causes that ordinarily would be missed, and continue to plague the laboratory or operation.

12.3.4) Monitoring of the Corrective Actions

- The Technical Manager and QA Manager are responsible to ensure that the corrective action taken was effective.

- Ineffective actions are documented and re-evaluated until acceptable resolution is achieved. Technical Managers are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- The QA Manager reviews monthly NCMs and ICAT records for trends. Highlights are included in the QA monthly report (refer to Section 16). If a significant trend develops that adversely affects quality, an audit of the area is performed and corrective action implemented.
- Any out-of-control situations that are not addressed acceptably at the laboratory level may be reported to the NDSC Quality Director by the QA Manager, indicating the nature of the out-of-control situation and problems encountered in solving the situation.

12.3.5) Follow-up Audits

- Follow-up audits may be initiated by the QA Manager and shall be performed as soon as possible when the identification of a nonconformance casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with state or federal requirements.
- These audits often follow the implementation of the corrective actions to verify effectiveness. An additional audit would only be necessary when a critical issue or risk to business is discovered.

(Also refer to Section 15.1.4, Special Audits.)

12.4) Technical Corrective Actions

In addition to providing acceptance criteria and specific protocols for technical corrective actions in the method SOPs, the laboratory has general procedures to be followed to determine when departures from the documented policies and procedures and quality control have occurred (refer to Section 11). The documentation of these procedures is through the use of an NCM or record in the ICAT system.

Table 12-1 includes examples of general technical corrective actions. For specific criteria and corrective actions, refer to the analytical methods or specific method SOPs. The laboratory may also maintain Work Instructions on these items that are available upon request.

Table 12-1 provides some general guidelines for identifying the individual(s) responsible for assessing each QC type and initiating corrective action. The table also provides general guidance on how a data set should be treated if associated QC measurements are unacceptable. Specific procedures are included in Method SOPs, Work Instructions, QAM Sections 19 and 20. All corrective actions are reviewed monthly, at a minimum, by the QA Manager and highlights are included in the QA monthly report.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If the deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the Project Manager is notified by an NCM and appropriate corrective action (e.g., reanalysis) is taken and documented.

12.5) Basic Corrections

When mistakes occur in records, each mistake shall be crossed-out, [not obliterated (e.g. no white-out)], and the correct value entered alongside. All such corrections shall be initialed (or signed) and dated by the person making the correction. In the case of records stored electronically, the original uncorrected file must be maintained intact and a second corrected file is created. This same process applies to adding additional information to a record. All additions made later than the initial must also be initialed (or signed) and dated. When corrections are due to reasons other than obvious transcription errors, the reason for the corrections (or additions) shall also be documented.

QC Activity ***(Individual Responsible for Initiation/Assessment)***	**Acceptance Criteria**	**Recommended Corrective Action**
Initial Instrument Blank *(Analyst)*	- Instrument response < MDL	- Prepare another blank. - If same response, determine cause of contamination: reagents, environment, instrument equipment failure, etc..
Initial Calibration Standards *(Analyst, Technical Manager(s))*	- Correlation coefficient > 0.99 or standard concentration value - Read-back errors within acceptance range - % Recovery within acceptance range - See details in Method SOP	- Reanalyze standards. - If still unacceptable, remake standards and recalibrate instrument.
Independent Calibration Verification (Second Source) *(Analyst, Technical Manager(s))*	- % Recovery within control limits	- Remake and reanalyze standard. - If still unacceptable, then remake calibration standards or use new primary standards and recalibrate instrument.
Continuing Calibration Standards *(Analyst, Data Reviewer)*	% Recovery within control limits	- Reanalyze standard. - If still unacceptable, then recalibrate and rerun affected samples.
Matrix Spike / Matrix Spike Duplicate (MS/MSD) *(Analyst, Data Reviewer)*	- % Recovery within limits documented in LIMS	- If the acceptance criteria for duplicates or matrix spikes are not met because of matrix interferences, the acceptance of the analytical batch is determined by the validity of the LCS. - If the LCS is within acceptable limits the batch is acceptable. - The results of the duplicates, matrix spikes and the LCS are reported with the data set. - For matrix spike or duplicate results outside criteria the data for that sample shall be reported with qualifiers.

QC Activity ***(Individual Responsible for Initiation/Assessment)***	**Acceptance Criteria**	**Recommended Corrective Action**
Laboratory Control Sample (LCS) *(Analyst, Data Reviewer)*	- % Recovery within limits specified in LIMS	- Batch must be re-prepared and re-analyzed. This includes any allowable marginal exceedance. When not using marginal exceedances, the following exceptions apply: 1) when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported with data qualifying codes; 2) when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level with data qualifying codes. **Note:** If there is insufficient sample or the holding time cannot be met, contact client and report with flags.
Surrogates *(Analyst, Data Reviewer)*	- % Recovery within limits of method or within three standard deviations of the historical mean	- Individual sample must be repeated. Place comment in TALS. - Surrogate results outside criteria shall be reported with qualifiers.
Method Blank (MB) *(Analyst, Data Reviewer)*	< Reporting Limit [1]	- Reanalyze blank. - If still positive, determine source of contamination. If necessary, reprocess (i.e. digest or extract) entire sample batch. Report blank results. - Qualify the result(s) if the concentration of a targeted analyte in the MB is at or above the reporting limit and is > 1/10 of the amount measured in the sample.
Proficiency Testing (PT) Samples *(QA Manager, Technical Manager(s))*	- Criteria supplied by PT Supplier	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.
Internal / External Audits *(QA Manager, Technical Manager(s), Laboratory Director)*	- Defined in Quality System documentation such as SOPs, QAM, etc.	- Non-conformances must be investigated through ICAT system and necessary corrections must be made.
Reporting / Calculation Errors (Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, *Technical Manager(s)*, QA Manager, NDSC QA, Executive Management)	- NDSC Document No. QA-QP38229, Nonconforming Work	- Corrective action is determined by type of error. Follow the procedures in NDSC Document No. QA-SOP38228, Internal Ethics and Data Integrity Investigations, or laboratory SOP PT-QA-016.
Client Complaints *(Project Managers, Lab Director, Sales and Marketing)*		- Corrective action is determined by the type of complaint. For example, a complaint regarding an incorrect address on a report will result in the report being corrected and then follow-up must be performed on the reasons the address was incorrect (e.g., database needs to be updated).
QA Monthly Report (Refer to Section 16 for an example) (QA Manager, Lab Director, *Technical Manager(s)*)	- QAM, SOPs	- Corrective action is determined by the type of issue. For example, NCMs and ICAT records for the month are reviewed and possible trends are investigated.
Health and Safety Violation (Safety Officer, Lab Director, *Technical Manager(s)*)	- Environmental Health and Safety (EHS) Manual	- Non-conformance is investigated and corrected through ICAT system.

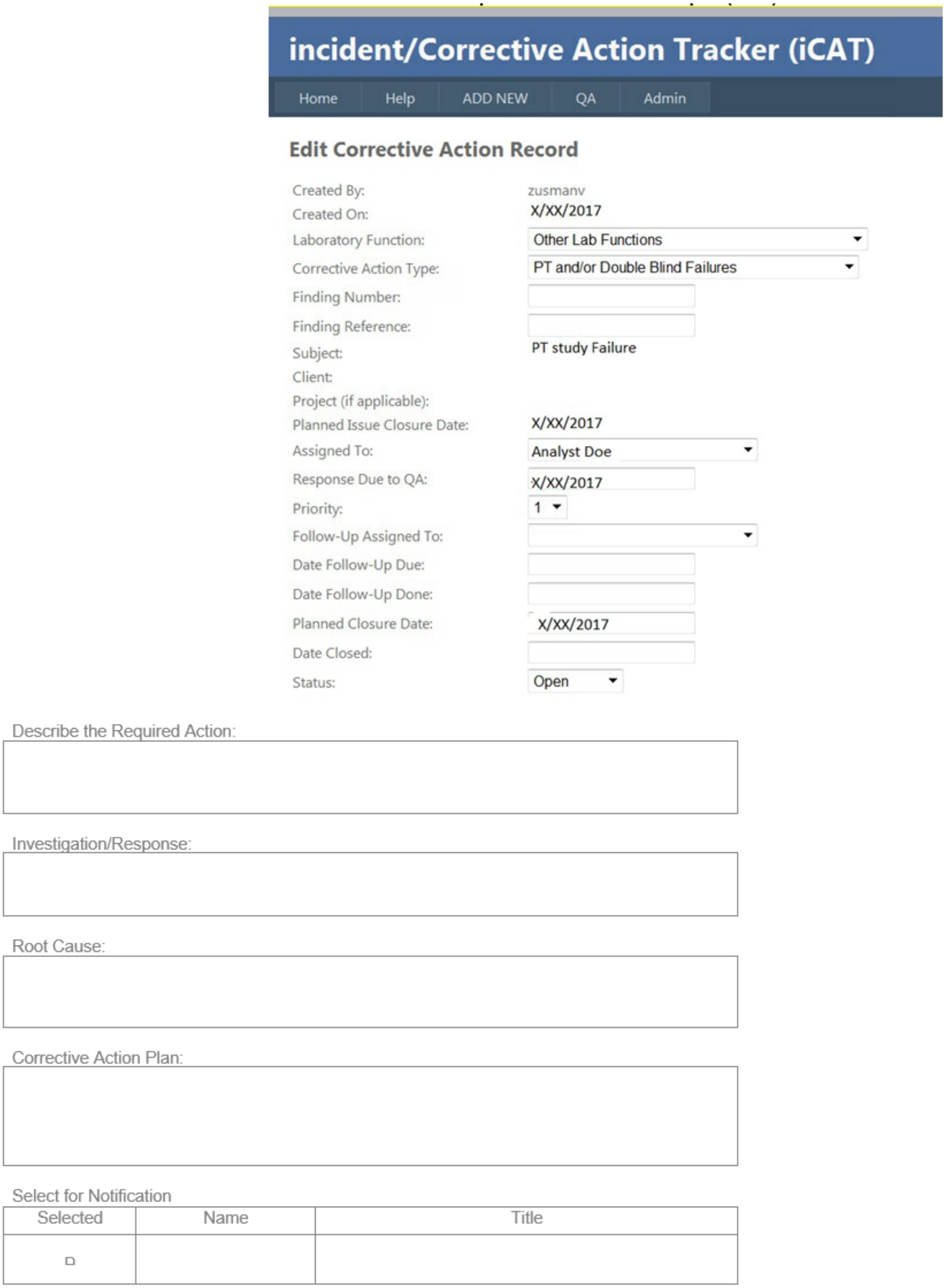
Note:

1. Except as noted below for certain compounds, the method blank should be below the reporting limit unless there is a client specific requirement or method requirement to be evaluated to a lower level. Concentrations up to five times the reporting limit will be allowed for the ubiquitous laboratory and reagent contaminants: methylene chloride, toluene, acetone, 2-butanone and phthalates provided that they appear in similar levels in the reagent blank and samples. This allowance presumes that the detection limit is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For benzene and ethylene dibromide (EDB) and other analytes for which regulatory limits are extremely close to the detection limit, the method blank must be below the method detection limit.

12.5.1)

Figure 12-1

Example – Corrective Action Report (iCAT)



Edit Corrective Action Record

Created By: zusmanv
Created On: X/XX/2017
Laboratory Function: Other Lab Functions
Corrective Action Type: PT and/or Double Blind Failures
Finding Number:
Finding Reference:
Subject: PT study Failure
Client:
Project (if applicable):
Planned Issue Closure Date: X/XX/2017
Assigned To: Analyst Doe
Response Due to QA: X/XX/2017
Priority: 1
Follow-Up Assigned To:
Date Follow-Up Due:
Date Follow-Up Done:
Planned Closure Date: X/XX/2017
Date Closed:
Status: Open

Describe the Required Action:

Investigation/Response:

Root Cause:

Corrective Action Plan:

Select for Notification

Selected	Name	Title
☐		

13) PREVENTIVE ACTION / IMPROVEMENT

13.1) Overview

The laboratory's preventive action programs improve or eliminate potential causes of nonconforming product and/or nonconformance to the quality system. This preventive action process is a proactive and continuous process if improvement activities that can be initiated through feedback from clients, employees, business providers, and affiliates. The QA Department has the overall responsibility to ensure that the preventive action process is in place, and that relevant information on actions is submitted for management review.

Dedicating resources to an effective preventive action system emphasizes the laboratory's commitment to its Quality Program. It is beneficial to identify and address negative trends before they develop into complaints, problems and corrective actions. Additionally, the laboratory continually strives to improve customer service and client satisfaction through continuous improvements to laboratory systems.

Opportunities for improvement may be discovered through any of the following on the Preventative Action Schedule:

Preventative Action	Frequency
Management System Review	Annually
Review of QA Metrics	Monthly
Trending NCMs	Monthly
Review of Control Charts of QC Results	At least annually
Trending PT Results	Semi-annually
Trending Client Complaints	Monthly
Review of Revised Reports and Invoices	Monthly
Review of Process Operations	At least annually
Staff Observations and Suggestions	As they arise

The monthly Management Systems Metrics Report shows performance indicators in all areas of the laboratory and quality system. These areas include revised reports, corrective actions, audit findings, internal auditing and data authenticity audits, client complaints, PT samples, holding time violations, SOPs, ethics training, etc. The metrics report is reviewed monthly by laboratory management, the NDSC QA Team and Local and Executive Management. These metrics are used in evaluating the management and quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

Items identified as continuous improvement opportunities to the management system may be issued as goals from the annual management systems review, recommendations from internal audits, white papers, Lesson Learned, Technical Services audit report, Technical Best Practices, or as Executive or management initiatives.

The laboratory's corrective action process is integral to implementation of preventive actions. A critical piece of the corrective action process is the implementation of actions to prevent further occurrence of a non-compliance event. Historical review of corrective action and non-conformances provides a valuable mechanism for identifying preventive action opportunities.

13.1.1)

The following elements are part of a preventive action/process improvement system:

- Identification of an opportunity for preventive action or process improvement
- Process for the preventive action or improvement
- Define the measurements of the effectiveness of the process once undertake
- Execution of the preventive action or improvement
- Evaluation of the plan using the defined measurements
- Verification of the effectiveness of the preventive action or improvement
- Close-Out by documenting any permanent changes to the Quality System as a result of the Preventive Action or Process Improvement. Documentation of Preventive Action/ Process Improvement is incorporated into the monthly QA reports, corrective action process and management review.

13.1.2)

Any Preventive Actions/ Process Improvements undertaken or attempted shall be taken into account during the Annual Management Systems Review (Section 16). A highly detailed report is not required; however a summary of success and failure within the preventive action program is sufficient to provide management with a measurement for evaluation.

13.2) Management of Change

The Management of Change process is designed to manage significant events and changes that occur within the laboratory. Through these procedures, the potential risks inherent with a new event or change are identified and evaluated. The risks are minimized or eliminated through pre-planning and the development of preventive measures. The types of indicators monitored under this collective system include:

Change Type	Examples
Facility Changes	-movement of prep or instrument groups to a new location in the laboratory -introduction of significant changes in air handling or gas and solvent delivery systems -significant room additions or renovations -significant electrical or network upgrades or changes
Major Accreditation Changes	-voluntary surrender of accreditations no longer deemed necessary to the laboratory -loss of accreditation -addition of new accreditation programs
Reagents and Waste Streams	- new chemicals/reagents not previously used in the laboratory -deletion of chemicals/reagents that will mean they are no longer used at all in the laboratory -major changes to the volume of chemicals/reagents being used - a new waste stream must be developed Note: See EHS for changes in waste streams
Addition or Deletion of Laboratory Capabilities	-implementation of new regulated methods -"retiring" of active methods -method development for "in-house" methods Note: New regulatory methods and method development require specific processes and documentation before the process can begin or the method can enter production. See QA and EHS for requirements.
LIMS changes	-large system upgrades -additions of new capabilities Note: These changes are handled on a Company-wide level
Key Personnel Changes	-key personnel promotions and their effect on that individuals group (experience, productivity, leadership, manpower) -key personnel losses -impact of new personnel that may add new experience or capabilities to the laboratory
New Types of Instrumentation	-addition of a new instrument class/technology

	-significant instrument upgrades that impact sensitivity, productivity or capability Note: New instrumentation requires collection and submission of instrument IDOC information before entering production. See QA for requirements.
Changes in Quality Systems and Policies	-implementation of a new Corrective Action System -changes to the Internal Audit program -implementation of uploads for Proficiency Testing samples

14) CONTROL OF RECORDS

The laboratory maintains a records management system appropriate to its needs and that complies with applicable standards or regulations as required. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the analytical report for a minimum of five years after it has been issued. Exceptions for programs with longer retention requirements are discussed in section 14.1.2.

14.1) Overview

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. A record index is listed in Table 14-1. Quality records are maintained by the Quality Assurance (QA) department electronically on the corporate designated QA network drive which is backed up as part of the regular network backup. Records are of two types; either electronic or hard copy paper formats, depending on whether the record is computer or hand generated (some records may be in both formats). Technical records are maintained by the CSO group, HR, and the QA department and as outlined in laboratory SOP PT-QA-019.

Table 14-1 Record Index[1]

	Record Types [1]:	**Retention Time:**
Technical Records	- Raw Data - Logbooks[2] - Standards - Certificates - Analytical Records - MDLs/IDLs/DOCs - Lab Reports	5 Years from analytical report issue*
Official Documents	- Quality Assurance Manual (QAM) - Work Instructions - Policies - SOPs - Policy Memorandums - Manuals - Published Methods	Indefinitely
QA Records	- Certifications - Method and Software Validation / Verification Data	Indefinitely
QA Records	- Internal & External Audits/Responses - Corrective/Preventive Actions - Management Reviews - Data Investigation	5 Years from archival* **Data Investigation:** 5 years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)
Project Records	- Sample Receipt & COC Documents - Contracts and Amendments - Correspondence - QAPP - SAP - Telephone Logbooks - Lab Reports	5 Years from analytical report issue*
Administrative Records	Financial and Business Operations	Refer to NDSC Doc. No. CW-L-WI-001 or lab SOP PT-QA-019
	EH&S Manual, Permits	Indefinitely
	Disposal Records	Indefinitely
	Employee Handbook	Indefinitely
	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	Refer to HR Manual
	Administrative Policies	Indefinitely
	Technical Training Records	7 years
	Legal Records	Indefinitely
	HR Records	Refer to NDSC Doc. No. CW-L-WI-001 or lab SOP PT-QA-019
	IT Records	Refer to NDSC Doc. No. CW-L-WI-001 or lab SOP PT-QA-019
	Corporate Governance Records	Refer to NDSC Doc. No. CW-L-WI-001 or lab SOP PT-QA-019
	Sales & Marketing	5 years
	Real Estate	Indefinitely

[1] Record Types encompass hardcopy and electronic records.

[2] Examples of Logbook types: Maintenance, Instrument Run, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Balance Calibration, Temperature (hardcopy or electronic records).

* Exceptions listed in Table 14-2.

14.1.1)

All records are stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or at the the Iron Mountain data storage facility that provides a suitable environment to prevent damage or deterioration and to prevent loss. All records shall be protected against fire, theft, loss, environmental deterioration, and vermin. In the case of electronic records, electronic or magnetic sources, storage media are protected from deterioration caused by magnetic fields and/or electronic deterioration.

Access to the data is limited to laboratory and company employees and shall be documented with an access log. Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Whether on-site or off-site storage is used, logs are maintained in each storage box to note removal and return of records. Retention of records are maintained on-site at the laboratory for at least 1 year after their generation and moved offsite for the remainder of the required storage time. Records are maintained for a minimum of five years unless otherwise specified by a client or regulatory requirement.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as NDSC and/or KGD Documents, QA, or Administrative Records, the retention time is calculated from the date the record is formally retired. Records related to the programs listed in Table 14-2 have lengthier retention requirements and are subject to the requirements in Section 14.1.3.

14.2) Programs with Longer Retention Requirements

Some regulatory programs have longer record retention requirements than the standard record retention time. These are detailed in Table 14-2 with their retention requirements. In these cases, the longer retention requirement is enacted. If special instructions exist such that client data cannot be destroyed prior to notification of the client, the container or box containing that data is marked as to who to contact for authorization prior to destroying the data.

Table 14-2 Special Record Retention Requirements

Program	[1]**Retention Requirement**
Drinking Water – All States	10 years (lab reports and raw data)
Drinking Water Lead and Copper Rule	12 years (project records)
Commonwealth of MA – All environmental data 310 CMR 42.14	10 years
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years
Michigan Department of Environmental Quality – all environmental data	10 years
Ohio VAP	10 years and State contact prior to disposal
OSHA	30 years

[1] Note: Extended retention requirements must be noted with the archive documents or addressed in facility-specific records retention procedures.

14.2.1) The laboratory has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data is maintained as hard copy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, refer to Section 19.15.1 and laboratory SOP PT-QA-019, Records Management, Retention, and Archive, for more information.

14.2.2) The record keeping system allows for historical reconstruction of all laboratory activities that produced the analytical data, as well as rapid recovery of historical data (Records stored off site should be accessible within 2 days of a request for such records). The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples and/or extracts.

- The records include the identity of personnel involved in sampling, sample receipt, preparation, or testing. All analytical work contains the initials (at least) of the personnel involved. The laboratory's copy of the chain of custody is stored with the invoice and the work order sheets generated by TALS. Details of the COC linking procedure are described in SOP PT-SR-001. The chain of custody would indicate the name of the sampler. Any sampling notes provided with the chain of custody are also scanned into TALS.
- All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.
- The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files, set format for what is included with a given analytical data set are described in SOP PT-QA-019. Instrument data is stored sequentially by instrument. Run logs are maintained for each instrument; a copy of each day's run long is stored in the electronic files along with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench sheets are used to record and file data or the data is entered directly into TALS as the analysis is done. Standard and reagent information is recorded in electronic standard log in TALS, and is associated with each preparation and analytical batch for which they are used.
- Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in TALS or instrument data are recorded in audit trails.
- The reason for a signature or initials on a document is clearly indicated in the records such as "sampled by," "prepared by," "reviewed by", or "analyzed by".
- All generated data, except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent dark ink.
- Hard copy data may be scanned into PDF format for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the laboratory's ability to retrieve the information prior to the destruction of the hard copy that was scanned. The procedure for this verification can be found in SOP PT-QA-019.
- Also refer to Section 19.15.1 'Computer and Electronic Data Related Requirements'

14.3) Technical And Analytical Records

14.3.1) The laboratory retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each analytical report issued, for a minimum of five years unless otherwise specified by a client or regulatory requirement. The records for each analysis shall contain sufficient information to enable the analysis to be repeated under conditions as close as possible to the original. The records shall include the identity of laboratory personnel responsible for the sampling, performance of each analysis and reviewing results.

14.3.1) Sample Handling Records

Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include but are not limited to records pertaining to:

- sample preservation including appropriateness of sample container and compliance with holding time requirement;
- sample identification, receipt, acceptance or rejection and login;
- sample storage and tracking including shipping receipts, sample transmittal / COC forms; and
- procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples

14.3.2) Observations, data and calculations are recorded real-time and are identifiable to the specific task

14.3.3) Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in TALS or instrument data are recorded in audit trails.

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, include:

- Laboratory sample ID code;
- Date of analysis; Time of Analysis is also required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times, incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook, on a benchsheet or in TALS;
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in method specific SOPs or in instrument maintenance logs where available;
- analysis type;
- all manual calculations and manual integrations;
- analyst's or operator's initials/signature;
- sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
- test results;
- standard and reagent origin, receipt, preparation, and use;
- calibration criteria, frequency and acceptance criteria;
- data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- quality control protocols and assessment;
- electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and
- Method performance criteria including expected quality control requirements. These are indicated both in the TALS and on specific analytical report formats.

14.3.4) All logbooks used during receipt, preparation, storage, analysis, and reporting of samples or monitoring of support equipment shall undergo a periodic, documented supervisory or peer review.

14.4) Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following are retained QA records and project records (previous discussions in this section relate where and how these data are stored):

- all original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);
- a written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;
- copies of final reports;
- archived SOPs;
- correspondence relating to laboratory activities for a specific project;
- all corrective action reports, audits and audit responses;
- proficiency test results and raw data; and
- results of data review, verification, and crosschecking procedures

14.4.1) Sample Handling Records

Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include but are not limited to records pertaining to:

- sample preservation including appropriateness of sample container and compliance with holding time requirement;
- sample identification, receipt, acceptance or rejection and login;
- sample storage and tracking including shipping receipts, sample transmittal / COC forms; and
- procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

14.5) Administrative Records

The laboratory also maintains the administrative records in either electronic or hard copy form. Refer to Table 14-1.

14.6) Records Management, Storage, and Disposal

All records (including those pertaining to test equipment), certificates and reports are safely stored, held secure and in confidence to the client. Certification related records are available upon request.

All information necessary for the historical reconstruction of data is maintained by the laboratory. Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

Records that are stored or generated by computers or personal computers have hard copy, write-protected backup copies, or an electronic audit trail controlling access.

The laboratory has a record management system (a.k.a., document control) for control of laboratory notebooks/benchsheets, instrument/equipment logbooks, and records for data reduction, validation and reporting. Laboratory notebooks are issued on a per analysis basis, as needed, and are numbered sequentially. All sample data are recorded in TALS. Bench sheets are filed sequentially. Standards are maintained in the electronic standards in TALS. Records are considered archived when noted as such in the records management system (a.k.a., document control).

14.6.1) Transfer of Ownership

In the event that the laboratory transfers ownership or goes out of business, the laboratory shall ensure that the records are maintained or transferred according to client's instructions. Upon ownership transfer, record retention requirements shall be addressed in the ownership transfer agreement and the responsibility for maintaining archives is clearly established. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed. In the event of the closure of the laboratory, all records will revert to the control of the NDSC. Should the entire company cease to exist, as much notice as possible will be given to clients and the accrediting bodies who have worked with the laboratory during the previous 5 years of such action.

14.6.2) Records Disposal

Records are removed from the archive and destroyed after 5 years, unless otherwise specified by a client or regulatory requirement. On a project specific or program basis, clients may need to be notified prior to record destruction. Records are destroyed in a manner that ensures their confidentiality such as shredding, mutilation or incineration. (Refer to Tables 14-1 and 14-2).

Electronic copies of records must be destroyed by erasure or physically damaging off-line storage media so no records can be read.

If a third party records management company is hired to dispose of records, a “Certificate of Destruction” is required.

15) AUDITS

15.1) Internal Audits

Internal audits are performed to verify that laboratory operations comply with the requirements of the lab's quality system and with the external quality programs under which the laboratory operates. Audits are planned and organized by the QA staff. Personnel conducting the audits should be independent of the area being evaluated. Auditors will have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the assessments to laboratory management and when requested to Executive Management.

Audits are conducted and documented as described in the NDSC Document No. SOP02-QA-QP5260, *Internal Auditing*. More detail on the specific elements for internal audits and data audit is described in Pittsburgh Laboratory SOP No. PT-QA-002, *Internal Auditing*. The types and frequency of routine internal audits are shown in Table 15-1. Special or ad hoc assessments may be conducted as needed under the direction of the QA staff.

Table 15-1 Types of Internal Audits and Frequency

Description	Performed by	Frequency
Quality Systems Audits	QA Department, QA approved designee, or Corporate QA	All areas of the laboratory annually
Method Audits QA Technical Data Audits*	Joint responsibility: a) QA Manager or designee b) Technical Manager or Designee (Refer to NDSC Doc. SOP02-QA-QP5260)	50% of methods annually
SOP Method Compliance*	Joint responsibility: c) QA Manager or designee d) Technical Manager or Designee (Refer to NDSC Doc. SOP02-QA-QP5260)	Every 2 years
Special	QA Department or Designee	Surveillance or spot checks performed as needed, e.g., to confirm corrective actions from other audits.
Performance Testing	Analysts with QA oversight	Two successful per year for each TNI field of testing or as dictated by regulatory requirements

*Technical Data and Method Compliance audits are in addition to the annual Quality Systems Audit

15.1.1) Annual Quality System Audit

An annual quality systems audit is required to ensure compliance to analytical methods and SOPs, Eurofins Data Integrity and Ethics Policies, TNI quality systems, client and state requirements, and the effectiveness of the internal controls of the analytical process, including, but not limited to, data review, quality controls, preventive action and corrective action. The completeness of earlier corrective actions is assessed for effectiveness & sustainability. The audit is divided into sections for each operating or support area of the lab, and each section is comprehensive for a given area. The area audits may be performed on a rotating schedule throughout the year to ensure adequate coverage of all areas. This schedule may change as situations in the laboratory warrant. See SOP PT-QA-002 for auditing area details.

Effectiveness of training will be determined during our annual QA systems evaluation. Evidence of successful training includes:

- Audit and surveillance results, control charts, proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends and continually improve the quality system:
- Adequate documentation of training within operational areas, including one-on-one technical training for individual technologies, and for people cross-trained.
- Analysts knowledge of QA Manual and SOPs. Analysts following SOPs, i.e., practice matches SOPs.
- .Analysts regularly communicate to supervisors and QA if SOPs need revision.

15.1.2) QA Technical Data Audits

QA technical audits assess data authenticity and analyst integrity. These audits are based on client projects, associated sample delivery groups, and the methods performed. Reported results are compared to raw data to verify the authenticity of results. The validity of calibrations and QC results are compared to data qualifiers, footnotes, and case narratives. Documentation is assessed by examining run logs and records of manual integrations. Manual calculations are checked. Where possible, electronic audit miner programs (e.g., Chrom AuditMiner) are used to identify unusual manipulations of the data deserving closer scrutiny. QA technical audits will include all methods within a two-year period. All analysts and data reviewers should be reviewed over the course of a two year period through at least one QA Technical Audit.

15.1.3) SOP Method Compliance

Compliance of all SOPs with the source methods and compliance of the operational groups with the SOPs will be assessed by the QA department, Technical Manager, or qualified designee at least every two years. It is also recommended that the work of each newly hired analyst is assessed within 3 months of working independently, (e.g., completion of method IDOC). In addition, as analysts add methods to their capabilities, (new IDOC) reviews of the analyst work products will be performed within 3 months of completing the documented training.

15.1.4) Special Audits

Special audits are conducted on an as needed basis, generally as a follow up to specific issues such as client complaints, corrective actions, PT results, data audits, system audits, validation comments, regulatory audits or suspected ethical improprieties. Special audits are focused on a specific issue, and report format, distribution, and timeframes are designed to address the nature of the issue.

15.1.5) Performance Testing

The laboratory participates semi-annually in performance audits conducted through the analysis of PT samples provided by a third party. The laboratory generally participates in the following types of PT studies: Water Pollution Program, Water Supply Program, Hazardous Waste Program, client supplied PTs and Lab internal PTs.

It is Eurofin's policy that PT samples be treated as typical samples in the production process. Furthermore, where PT samples present special or unique problems, in the regular production process they may need to be treated differently, as would any special or unique request submitted by any client. The QA Manager must be consulted and in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

Unacceptable PT results are required to be entered into the ICAT system for investigation. In some cases it may be necessary for blind QC samples to be submitted to the laboratory to show a return to control.

15.2) External Audits

External audits are performed when certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is Eurofins Environment Testing America's policy to cooperate fully with regulatory authorities and clients. The laboratory makes every effort to provide the auditors with access to personnel, documentation, and assistance. Laboratory supervisors are responsible for providing corrective actions to the QA Manager who coordinates the response. Audit responses are due in the time allotted by the client or agency performing the audit. When requested, a copy of the audit report and the labs corrective action plan will be forwarded to NDSC QA.

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. The client may only view data and systems related directly to the client's work. All efforts are made to keep other client information confidential.

15.2.1) Confidential Business Information (CBI) Considerations

During on-site audits, auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. Additional information regarding CBI can be found in within the 2009 TNI standards.

15.3) Audit Findings

Audit findings are documented using the ICAT system (see Section 12). The laboratory's corrective action responses may include action plans that could not be completed within a predefined timeframe. In these instances, a completion date must be set and agreed to by operations management and the QA Manager.

Developing and implementing corrective actions to findings is the responsibility of the Technical Manager where the finding originated. Findings that are not corrected by specified due dates are reported monthly to management in the QA monthly report. When requested a copy of the audit report and the labs corrective action plan will be forwarded to NDSC QA.

If any audit finding casts doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action, and shall notify clients in writing if the investigations show that the laboratory results have been affected. Once corrective action is implemented, a follow-up audit is scheduled to ensure that the problem has been corrected.

Clients must be notified promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a test report. The investigation must begin within 24-hours of discovery of the problem and all efforts are made to notify the client within two weeks after completion of the investigation.

16) Management Reviews

16.1) Quality Assurance Report

A comprehensive QA Report shall be prepared each month by the laboratory's QA Department and forwarded to Management to keep them apprised of current quality issues. This report fosters communication, review, and refinement of the QA system to evaluate the suitability of policies and procedures to meet both regulatory and laboratory quality objectives. During the course of the year, the Laboratory Director, or NDSC QA may request that additional information be added to the report.

The NDSC QA team compiles information from all the monthly laboratory reports for the Executive Management Team. The NDSC Quality Directors prepare a report that includes a compilation of all metrics and notable information and concerns regarding the QA programs within the laboratories. The report also includes a listing of new regulations that may potentially impact the laboratories.

16.2) Annual Management Review

The Laboratory Management team (Laboratory Director, QA Manager, and Technical Managers) conducts a review annually of its quality systems and TALS to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. It will also provide a platform for defining goals & objectives and action items that feed into the laboratory planning system. NDSC personnel is to be included in this meeting at the discretion of the Laboratory Director. The TALS review consists of examining any audits, complaints or concerns that have been raised through the year that are related to the TALS. The laboratory will summarize any critical findings that cannot be solved by the lab and report them to Corporate IT.

The Management System Review (see NDSC Document No. QA-QP38702, *Management System Review*, and Work Instruction No. NDSC-QA-FRM43453) uses information generated during the preceding year to assess the "big picture" by ensuring that routine actions taken and reviewed on a monthly basis are not components of larger systematic concerns. The monthly review should keep the quality systems current and effective, therefore, the annual review is a formal senior management process to review specific existing documentation. Significant issues from the following documentation are compiled or summarized by the QA Manager prior to the review meeting:

- Matters arising from the previous annual review
- Prior Monthly QA Reports issues
- Laboratory QA Metrics
- Review of report reissue requests
- Review of client feedback and complaints
- Issues arising from any prior management or staff meetings
- Minutes from prior senior lab management meetings - Issues that may be raised from these meetings include:

    - Adequacy of staff, equipment and facility resources.
    - Adequacy of policies and procedures.
    - Future plans for resources and testing capability and capacity.

- The annual internal double blind PT program sample performance
- Compliance to the Ethics Policy and Data Integrity Plan, including any evidence/incidents of inappropriate actions or vulnerabilities related to data integrity
- Review of Corrective and Preventative Actions, assessments by external bodies and recommendations for improvement
- Evaluation of overall risk, including risks to impartiality, confidentiality, reporting statements of conformity, and nonconforming work.

A report is generated by the QA Manager and management. The report is distributed to the Laboratory Manager, President of the Business Unit and the Quality Director. The report includes, but is not limited to:

- The date of the review and the names and titles of participants
- A reference to the existing data quality related documents and topics that were reviewed
- Quality system or operational changes or improvements that will be made as a result of the review [e.g., an implementation schedule including assigned responsibilities for the changes (Action Table)]

Changes to the quality systems requiring update to the laboratory QA Manual shall be included in the next revision of the QA Manual.

16.3) Potential Integrity Related Managerial Reviews

Potential integrity issues (data or business related) must be handled and reviewed in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and issues clarified. Eurofins NDSC Internal Investigation and Nonconforming Work SOPs shall be followed (Doc Nos. QA-SOP38228 and QA-QP38229). All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

Eurofins Environment Testing America Presidents, Business Unit Managers, Laboratory Directors, and NDSC Team are informed of any current data integrity or data recall investigations via the monthly metrics report.

17) Personnel

17.1) Overview

The laboratory's management believes that its highly qualified and professional staff is the single most important aspect in assuring a high level of data quality and service. The staff consists of professionals and support personnel as outlined in the organization chart *PIT-GI-ORG-FRM47902*.

All personnel must demonstrate competence in the areas where they have responsibility. Any staff that is undergoing training shall have appropriate supervision until they have demonstrated their ability to perform their job function on their own. Staff shall be qualified for their tasks based on appropriate education, training, experience and/or demonstrated skills as required.

The laboratory employs sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned responsibilities.

All personnel are responsible for complying with all QA/QC requirements that pertain to the laboratory and their area of responsibility. Each staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular area of responsibility. Technical staff must also have a general knowledge of lab operations, test methods, QA/QC procedures and records management.

Laboratory management is responsible for formulating goals for lab staff with respect to education, training and skills and ensuring that the laboratory has a policy and procedures for identifying training needs and providing training of personnel. The training shall be relevant to the present and anticipated responsibilities of the lab staff.

The laboratory only uses personnel that are employed by or under contract to, the laboratory. Contracted personnel, when used, must meet competency standards of the laboratory and work in accordance to the laboratory's quality system.

17.2) Education And Experience Requirements For Technical Personnel

The laboratory makes every effort to hire analytical staffs that possess a college degree (AA, BA, BS) in an applied science with some chemistry in the curriculum. Exceptions can be made based upon the individual's experience and ability to learn. For supervisory positions, the Pennsylvania DEP has education and experience requirements that must be met by the Pittsburgh laboratory personnel, and these are reflected in Table 17-1 below. Selection of qualified candidates for laboratory employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Minimum education and training requirements for Eurofins Environment Testing America employees are outlined in job descriptions and are generally summarized for analytical staff in the table below.

The laboratory maintains job descriptions for all personnel who manage, perform or verify work affecting the quality of the environmental testing the laboratory performs. Job Descriptions are located on the Eurofins Environment Testing America intranet site's Human Resources web-page (Also see Section 4 for position descriptions/responsibilities).

Experience and specialized training are occasionally accepted in lieu of a college degree (basic lab skills such as using a balance, pipette or quantitation techniques, etc., are also considered).

Table 17-1 General Requirements for Analytical Staff

Specialty	Education	Experience
Extractions, Digestions, some electrode methods (pH, DO, Redox, etc.), or Titrimetric and Gravimetric Analyses	H.S. Diploma	On the job training (OJT)
GFAA, CVAA, FLAA, Single component or short list Chromatography (e.g., Fuels, BTEX-GC, IC	A college degree in an applied science or 2 years of college and at least 1 year of college chemistry	Or 2 years prior analytical experience is required
ICP, ICPMS, Long List or complex chromatography (e.g., Pesticides, PCB, Herbicides, HPLC, etc.), GCMS	A college degree in an applied science or 2 years of college chemistry	or 5 years of prior analytical experience
Spectra Interpretation	A college degree in an applied science or 2 years of college chemistry	And 2 years relevant experience Or 5 years of prior analytical experience
Technical Manager (s) – **General**	Bachelors Degree in an applied science or engineering with 24 semester hours in chemistry An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years' experience in environmental analysis of representative analytes for which they will oversee
Technical Manager (s) – **Wet Chem** only (no advanced instrumentation)	Associates degree in an applied science or engineering or 2 years of college with 16 semester hours in chemistry	And 2 years relevant experience
Technical Managers - **Microbiology**	Bachelors degree in applied science with at least 16 semester hours in general microbiology and biology An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years of relevant experience (1 year if laboratory analysis is limited to coliforms and heterotrophic plate count)
Technical Managers – **Microbiology** limited to analysis of fecal coliforms, total coliforms or heterotrophic bacteria	Associates degree in an applied science or engineering and at least 4 credit hours in biology	And 2 years of relevant experience

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Technical Manager, and are considered an analyst in training. The person supervising an analyst in training is accountable for the quality of the analytical data and must review and approve data and associated corrective actions.

17.3) Training

The laboratory is committed to furthering the professional and technical development of employees at all levels.

Orientation to the laboratory's policies and procedures, in-house method training, and employee attendance at outside training courses and conferences all contribute toward employee proficiency. Below are examples of various areas of required employee training.

Table 17-2 Employee Training Examples

Required Training	Time Frame	Employee Type
Environmental Health & Safety	Prior to lab work	All
Ethics –New Hire	1 week of hire	All
Ethics – Comprehensive	60 days of hire	All
Data Integrity	60 days of hire	Technical and PMs
Quality Assurance	90 days of hire	All
Ethics – Comprehensive Refresher	Annually (within 14 months of previous)	All
Initial Demonstration of Capability (DOC)	Prior to unsupervised method performance	Technical

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills and experience of technical personnel (including contracted personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Also refer to "Demonstration of Capability" in Section 19.

The training of technical staff is kept up to date by:

- Each employee must have documentation in their training file that they have read, understood and agreed to follow the most recent version of the laboratory QA Manual and SOPs in their area of responsibility. This documentation is updated as SOPs are updated.
- Documentation from any training courses or workshops on specific equipment, analytical techniques or other relevant topics.
- Documentation of proficiency (refer to Section 19).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of annual ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment.
- Human Resources maintains documentation and attestation forms on employment status & records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics violations). This information is maintained in the employee's secured personnel file.

Evidence of successful training could include such items as:

- Adequate documentation of training within operational areas, including one-on-one technical training for individual technologies, and particularly for people cross-trained.
- Analysts knowledge to refer to QA Manual for quality issues.
- Analysts following SOPs, i.e., practice matches SOPs.
- Analysts regularly communicate to supervisors and QA if SOPs need revision, rather than waiting for auditors to find problems.

Further details of the laboratory's training program are described in the Pittsburgh Laboratory SOP No. PT-QA-001, *Employee Orientation and Training*.

17.4) Data Integrity and Ethics Training Program

Establishing and maintaining a high ethical standard is an important element of a Quality System. Ethics and data integrity training is integral to the success of Eurofins Environment Testing America and is provided for each employee at Eurofins Environment Testing America. It is a formal part of the initial employee comprehensive ethics and data integrity training within 30 days of their start date, and an annual (within at most 14 months of the previous training) refresher for all employees. Senior management at each facility performs the ethics training for their staff.

In order to ensure that all personnel understand the importance Eurofins Environment Testing America places on maintaining high ethical standards at all times; NDSC Eurofins Environment Testing America has established Policy No. SOP-01-QA-QP5252, *Ethics and Data Integrity Policy*, and an Ethics Statement. All initial and annual training is documented by signature on the signed Ethics Statement demonstrating that the employee has participated in the training and understands their obligations related to ethical behavior and data integrity.

Violations of this Ethics Policy will not be tolerated. Employees who violate this policy will be subject to disciplinary actions up to and including termination. Criminal violations may also be referred to the Government for prosecution. In addition, such actions could jeopardize Eurofins Environment Testing America's ability to do work on Government contracts, and for that reason, Eurofins Environment Testing America has a Zero Tolerance approach to such violations.

Employees are trained as to the legal and environmental repercussions that result from data misrepresentation. Key topics covered in the presentation include:

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting
- Ethics Policy
- How and when to report ethical/data integrity issues and confidential reporting
- Record keeping
- Discussion regarding data integrity procedures
- Specific examples of breaches of ethical behavior (e.g. peak shaving, altering data or computer clocks, improper macros, etc., accepting/offering kickbacks, illegal accounting practices, unfair competition/collusion)
- Internal monitoring, investigations, and data recalls
- Consequences for infractions, including potential for immediate termination, debarment, or criminal prosecution
- Importance of proper written narration / data qualification by the analyst and project manager with respect to those cases where the data may still be usable but are in one sense or another partially deficient

Additionally, a data integrity hotline (1-800-736-9407) is maintained by the NDSC.

18) ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

18.1) Overview

The laboratory is a 33,000 ft^2 secure laboratory facility with controlled access and designed to accommodate an efficient workflow and to provide a safe and comfortable work environment for employees. All visitors sign in and are escorted by laboratory personnel. Access is controlled by various measures.

The laboratory is equipped with structural safety features. Each employee is familiar with the location, use, and capabilities of general and specialized safety features associated with their workplace. The laboratory provides and requires the use of protective equipment including safety glasses, protective clothing, gloves, etc., OSHA and other regulatory agency guidelines regarding required amounts of bench and fume hood space, lighting, ventilation (temperature and humidity controlled), access, and safety equipment are met or exceeded.

Traffic flow through sample preparation and analysis areas is minimized to reduce the likelihood of contamination. Adequate floor space and bench top area is provided to allow unencumbered sample preparation and analysis space. Sufficient space is also provided for storage of reagents and media, glassware, and portable equipment. Ample space is also provided for refrigerated sample storage before analysis and archival storage of samples after analysis. Laboratory HVAC and deionized water systems are designed to minimize potential trace contaminants.

The laboratory is separated into specific areas for sample receiving, sample preparation, volatile organic sample analysis, non-volatile organic sample analysis, inorganic sample analysis, microbiological sample analysis, and administrative functions.

18.2) Environment

Laboratory accommodation, test areas, energy sources, lighting are adequate to facilitate proper performance of tests. The facility is equipped with heating, ventilation, and air conditioning (HVAC) systems appropriate to the needs of environmental testing performed at this laboratory.

The environment in which these activities are undertaken does not invalidate the results or adversely affect the required accuracy of any measurements.

The laboratory provides for the effective monitoring, control and recording of environmental conditions that may affect the results of environmental tests as required by the relevant specifications, methods, and procedures. Such environmental conditions include humidity, voltage, temperature, and vibration levels in the laboratory. Systems are controlled and monitored to assure constant and consistent test conditions.

When any of the method or regulatory required environmental conditions change to a point where they may adversely affect test results, analytical testing will be discontinued until the environmental conditions are returned to the required levels.

Environmental conditions of the facility housing the computer network and TALS are regulated to protect against raw data loss.

When the laboratory performs laboratory activities at sites of facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

Specific requirements for facility and environmental conditions, as well as periodic monitoring of conditions, are given in the Environmental Health & Safety Manual plus each laboratory's Facility Addendum.

18.3) Work Areas

There is effective separation between neighboring areas when the activities therein are incompatible with each other. Examples include:

- Microbiological culture handling and sample incubation areas
- Volatile organic chemical handling areas, including sample preparation and waste disposal, and volatile organic chemical analysis areas

Access to and use of all areas affecting the quality of analytical testing is defined and controlled by secure access to the laboratory building as described below in the Building Security section.

Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality. These measures include regular cleaning to control dirt and dust within the laboratory. Work areas are available to ensure an unencumbered work area. Work areas include:

- Access and entryways to the laboratory
- Sample receipt areas
- Sample storage areas
- Chemical and waste storage areas
- Data handling and storage areas
- Sample processing areas
- Sample analysis areas

Refer to the following documents and procedures for specific requirements for microbiological laboratory facilities:

- Standard Methods, 9020B, Sec. 2
- TNI V1M5, 1.7.3.7.a

18.4) Responding to Emergencies

Employees must be aware of procedures to respond to all emergencies that might occur in the workplace. Employees must be familiar with the location and proper operation of all emergency equipment, evacuation routes and designated assembly areas for all areas where they work. Refer to the NDSC EH&S Manual Document No. NDSC-US-EHS-QP46060, Sec. 7 and the laboratory's local EH&S addendum for complete details. These documents provide direction for situations where normal operations of the laboratory are not possible (e.g., electrical failures, heating/air conditioning failures, fire/building evacuation, computer failures, hazardous material spills, injury to employees, pandemic flu, disruption of phone service, etc.).

In the event that the building or information technology (IT) systems would be severely challenged, a designated disaster recovery team, which includes Facility Management, Maintenance, Safety, Laboratory/Executive Management, Public Relations, IT, QA and other applicable personnel depending on the scope of the disaster, would assemble at a designated area to assess the situation and formulate a plan.

18.5) Building Security

The laboratory is considered a secure facility. All outside doors (except the main lobby entrance) are locked during normal business hours to prevent unauthorized entry. (An attendant monitors this entrance at all times.) Building keys and alarm codes are distributed to employees as necessary.

Visitors to the laboratory sign in and out in a visitor's logbook. A visitor is defined as any person who visits the laboratory who is not an employee of the laboratory. In addition to signing into the laboratory, the Environmental, Health and Safety Manual contains requirements for visitors and vendors. There are specific safety forms that must be reviewed and signed. Visitors (with the exception of company employees) are escorted by laboratory personnel at all times, or the location of the visitor is noted in the visitor's logbook.

18.6) Floor Plan

A floor plan can be found in Appendix 1.

19) TEST METHODS AND METHOD VALIDATION

19.1) Overview

The laboratory uses methods that are appropriate to meet our clients' requirements and that are within the scope of the laboratory's capabilities. These include sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement of uncertainty as well as statistical techniques for analysis of environmental data.

Instructions are available in the laboratory for the operation of equipment as well as for the handling and preparation of samples. All instructions, Standard Operating Procedures (SOPs), reference methods and manuals relevant to the working of the laboratory are readily available to all staff. Deviations from published methods are documented (with justification) in the laboratory's approved SOPs. SOPs are submitted to clients for review at their request. Significant deviations from published methods require client approval and regulatory approval where applicable.

19.2) 19.2 Standard Operating Procedures (SOPs)

The laboratory maintains SOPs that accurately reflect all phases of the laboratory such as assessing data integrity, corrective actions, handling customer complaints as well as all analytical methods and sampling procedures. The method SOPs are derived from the most recently promulgated/approved, published methods and are specifically adapted to the laboratory facility. Modifications or clarifications to published methods are clearly noted in the SOPs. All SOPs are controlled in the laboratory. A SOP list is included in Appendix 4. The most current list of SOPs is maintained in the QA SOP directory, Work Instruction PT-QA-WI-002.

- All SOPs contain a revision number, effective date, and appropriate approval signatures. Controlled copies are available to all staff.
- Procedures for writing an SOP are incorporated by reference to Eurofins Pittsburgh's SOP PT-QA-010, *Document Development and Control*.
- SOPs are reviewed at a minimum of every 2 years, and where necessary, revised to ensure continuing suitability and compliance with applicable requirements. SOPs related to drinking water testing are reviewed every year.

19.3) Laboratory Methods Manual

For each test method, the laboratory shall have available the published referenced method as well as the laboratory developed SOP.

Note: If more stringent standards or requirements are included in a mandated test method or regulation than those specified in this manual, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. Any exceptions or deviations from the referenced methods or regulations are noted in the specific analytical SOP.

The laboratory maintains an SOP Index (PT-QA-WI-002) for both technical and non-technical SOPs. Technical SOPs are maintained to describe a specific test method. Non-technical SOPs are maintained to describe functions and processes not related to a specific test method.

19.4) Selection of Methods

Since numerous methods and analytical techniques are available, continued communication between the client and laboratory is imperative to assure the correct methods are utilized. Once client methodology requirements are established, this and other pertinent information is summarized by the Project Manager. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for log-in. For non-routine analytical services (e.g., special matrices, non-routine compound lists), the method of choice is selected based on client needs and available technology. The methods selected should be capable of measuring the specific parameter of interest, in the concentration range of interest, and with the required precision and accuracy.

19.4.1) Sources of Methods

Routine analytical services are performed using standard EPA-approved methodology. In some cases, modification of standard approved methods may be necessary to provide accurate analyses of particularly complex matrices. When the use of specific methods for sample analysis is mandated through project or regulatory requirements, only those methods shall be used.

When clients do not specify the method to be used or methods are not required, the methods used will be clearly validated and documented in an SOP and available to clients and/or the end user of the data.

The analytical methods used by the laboratory are those currently accepted and approved by the U. S. EPA and the state or territory from which the samples were collected. Reference methods include:

- *Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; 40CFR Part 136 as amended by Method Update Rule, August 28, 2017*
- *Methods for Chemical Analysis of Water and Wastes, EPA 600 (4-79-020), 1983*
- *Methods for the Determination of Inorganic Substances in Environmental Samples, EPA-600/R-93/100, August 1993*
- *Methods for the Determination of Metals in Environmental Samples, EPA/600/4-91/010, June 1991. Supplement I: EPA-600/R-94/111, May 1994*
- *Standard Methods for the Examination of Water and Wastewater, 18th/19th /20th /on-line edition; Eaton, A.D. Clesceri, L.S. Greenberg, A.E. Eds; American Water Works Association, Water Pollution Control Federation, American Public Health Association: Washington, D.C.*
- *Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846), Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008, Final Update V, August 2015*
- *Annual Book of ASTM Standards, American Society for Testing & Materials (ASTM), Philadelphia, PA.*
- *Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261*
- *Evaluation of Dredged Material Proposed for Disposal at Island, Nearshore, or Upland Confined Disposal Facilities – Testing Manual, U.S. Army Corps of Engineers, January, 2003*

The laboratory reviews updated versions to all the aforementioned references for adaptation based upon capabilities, instrumentation, etc., and implements them as appropriate. As such, the laboratory strives to perform only the latest versions of each approved method as regulations allow or require.

Other reference procedures for non-routine analyses may include methods established by specific states (e.g., Underground Storage Tank methods), ASTM or equipment manufacturers. Sample type, source, and the governing regulatory agency requiring the analysis will determine the method utilized.

The laboratory shall inform the client when a method proposed by the client may be inappropriate or out of date. After the client has been informed, and they wish to proceed contrary to the laboratory's recommendation, it will be documented.

19.4.1.1) Client Supplied Methods

Most of the client-supplied method requirements presented to us involve achieving specific quality control criteria, limits of quantitation (LOQ), and/or method detection limits (MDL) using standard EPA methods. These requirements are communicated to the appropriate technical groups prior to the project start up. Each technical group evaluates the scope of work and the requirements to ensure the criteria can be met using the standard EPA method. The data is monitored to ensure the criteria are met throughout the project. The PM notifies the client if there is a more appropriate method available or if the client's criteria cannot be achieved on a certain sample matrix (i.e., due to matrix or dilutions).

Occasionally, we are asked to transfer a non-standardized method from a client into our lab or to develop a new method, when one is not available. In the case of a method transfer, we set up the client's method and perform some initial evaluation. After the initial evaluation, we may make recommendations on how to improve method performance. If the method appears to be adequate, we determine linearity, specificity, precision, accuracy, MDL, and LOQ by performing calibrations, analyzing method blanks, and carrying out method detection limit and IDOC studies.

In the case of method development, we work with the client and/or data user to determine the level of validation required ensuring that the method meets its intended purpose. In addition to the elements above, we also determine standard and sample stability and robustness depending on the scope of the project. Typically, a standard operating procedure is written and submitted to the client with the results of the validation. These steps are completed prior to analysis of field samples. Data related to the setup of the method are archived.

19.4.1.2) Procedural Deviations

Analysts are required to follow a documented method for all tests performed; and any deviations from analytical methods must be documented, approved, and justified in an appropriate and consistent manner. We classify method deviations as either being a planned deviation or an unplanned deviation. In general, the following information is captured to document both types of situations:

- Description of the situation
- Reason or justification for the deviation
- Impact the deviation had on the testing
- Signature/date of analyst performing the test
- Signature/date of QA and Laboratory management approving the deviation
- Signature/date of client approval, if necessary

Deviations to written procedures are documented in raw data records, ICAT or through the ICAR (Investigation and Corrective Action Report) system. Both types of documentation require management and QA review and approval.

19.4.2) Demonstration of Capability

Before the laboratory may institute a new method and begin reporting results, the laboratory shall confirm that it can properly operate the method. In general, this demonstration does not test the performance of the method in real world samples, but in an applicable and available clean matrix sample. If the method is for the testing of analytes that are not conducive to spiking, demonstration of capability may be performed on quality control samples.

A demonstration of capability (DOC) is performed whenever there is a change in instrument type (e.g., new instrumentation), matrix, method or personnel (e.g., analyst hasn't performed the test within the last 12 months). The IDOC must meet the control limits specified in the reference method, if any, or meet method LCS criteria if no IDOC specific controls are provided. (See laboratory SOP No. PT-QA-001, *Employee Orientation and Training*, for details.)

Note: The laboratory shall have a DOC for all analytes included in the methods that the laboratory performs, and proficiency DOCs for each analyst shall include all analytes that the laboratory routinely performs. Addition of non-routine analytes does not require new DOCs for all analysts if those analysts are already qualified for routine analytes tested using identical chemistry and instrument conditions.

The initial demonstration of capability must be thoroughly documented and approved by the Technical Manager and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratories archiving procedures.

The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct an MDL study (when applicable). There may be other requirements as stated within the published method or regulations (i.e., retention time window study).

Note: In some instances, a situation may arise where a client requests that an unusual analyte be reported using a method where this analyte is not normally reported. If the analyte is being reported for regulatory purposes, the method must meet all procedures outlined within this QA Manual (SOP, MDL, and DOC). If the client states that the information is not for regulatory purposes, the result may be reported as long as the following criteria are met:

- The instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method or criteria are per project DQOs).
- The laboratory's nominal or default reporting limit (RL) is equal to the quantitation limit (QL), must be at or above the lowest non-zero standard in the calibration curve and must be reliably determined. Project RLs are client specified reporting levels which may be higher than the QL. Results reported below the QL must be qualified as estimated values. Also see Section 19.6.1.3, Relationship of Limit of Detection (LOD) to Quantitation Limit (QL).
- The client request is documented and the lab informs the client of its procedure for working with unusual compounds. The final report must be footnoted: *Reporting Limit based on the low standard of the calibration curve.*

19.4.3) Initial Demonstration of Capability (IDOC) Procedures

Initial Demonstration and Capability (IDOC) procedure is described in laboratory SOP No. PT-QA-001.

19.4.3.1) The spiking standard used to prepare IDOCs must be prepared independently from those used in instrument calibration.

19.4.3.2) The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified by a method or the laboratory SOP.

19.4.3.3) At least four aliquots shall be prepared (including any applicable clean-up procedures) and analyzed according to the test method (either concurrently or over a period of days).

19.4.3.4) Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest.

19.4.3.5) When it is not possible to determine the mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory will assess performance against criteria described in the method SOP.

19.4.3.6) Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in the laboratory generated acceptance criteria (LCS or interim criteria) if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

19.4.3.7) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either option below:

- Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with 19.4.3.3 above.
- Beginning with 19.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all parameters beginning with 19.4.3.1 above.

Note: Results of successive LCS analyses can be used to fulfill the DOC requirement.

A certification statement (Figure 19-1) shall be used to document the completion of each initial and continuing demonstration of capability. A copy of the certification is archived in the analyst's training file.

Methods on line prior to the effective date of this Section shall be updated to the procedures outlined above as new analysts perform their demonstration of capability. A copy of the new record will replace that which was used for documentation in the past. At a minimum, the precision and accuracy of four mid-level laboratory control samples must have been compared to the laboratory's quality control acceptance limits for methods for which standards exist.

19.5) Laboratory Developed Mthods and Non-Standard Methods

Any new method developed by the laboratory must be fully defined in an SOP and validated by qualified personnel with adequate resources to perform the method. Method specifications and the relation to client requirements must be clearly conveyed to the client if the method is a non-standard method (not a published or routinely accepted method). The client must also be in agreement to the use of the non-standard method.

19.6) Validation of Methods

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Validation of a method is a planned activity. A coordinator is designated for the process, who's responsibility it is to communicate the process and progress to all involved personnel.

All non-standard methods, laboratory designed/developed methods, standard methods used outside of their scope, and major modifications to published methods must be validated to confirm they are fit for their intended use. The validation will be as extensive as necessary to meet the needs of the given application. The results are documented with the validation procedure used and contain a statement as to the fitness for use.

19.6.1) Method Validation and Verification Activities for All New Methods

While method validation can take various courses, the following activities can be required as part of method validation. Method validation records are designated QC records and are archived accordingly.

When changes are made to any validated methods, the influence of such changes shall be documented and, if appropriate, a new validation shall be performed.

19.6.1.1) Determination of Method Selectivity

Method selectivity is the demonstrated ability to discriminate the analyte(s) of interest from other compounds in the specific matrix or matrices from other analytes or interference. In some cases to achieve the required selectivity for an analyte, a confirmation analysis is required as part of the method.

19.6.1.2) Determination of Method Sensitivity

Sensitivity can be both estimated and demonstrated. Whether a study is required to estimate sensitivity depends on the level of method development required when applying a particular measurement system to a specific set of samples. Detection limit studies are conducted as described in Section 19.7 below. Where other protocols for estimations and/or demonstrations of sensitivity are required by regulation or client agreement, these shall be followed.

19.6.1.3) Relationship of Limit of Detection (LOD) to the Limit of Quantitation (LOQ)

An important characteristic of expression of sensitivity is the distinction between the LOD and the LOQ. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The LOQ is the minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias, equivalent to the laboratory's routine reporting limit (RL). For most instrumental measurement systems, there is a region where semi-quantitative data is generated around the LOD (both above and below the estimated MDL or LOD) and below the LOQ. In this region, detection of an analyte may be confirmed but quantification of the analyte is unreliable within the accuracy and precision guidelines of the measurement system. When an analyte is detected below the LOQ, and the presence of the analyte is confirmed by meeting the qualitative identification criteria for the analyte, the analyte can be reliably reported, but the amount of the analyte can only be estimated. If data is to be reported in this region, it must be done so with a qualification that denotes the semi-quantitative nature of the result.

19.6.1.4) Determination of Interferences

A determination that the method is free from interferences in a blank matrix is performed.

19.6.1.5) Determination of Range

Where appropriate to the method, the quantitation range is determined by comparison of the response of an analyte in a curve to established or targeted criteria. Generally the upper quantitation limit is defined by highest acceptable calibration concentration. The lower quantitation limit or QL cannot be lower than the lowest non-zero calibration level, and can be constrained by required levels of bias and precision.

19.6.1.6) Determination of Accuracy and Precision

Accuracy and precision studies are generally performed using replicate analyses, with a resulting percent recovery and measure of reproducibility (standard deviation, relative standard deviation) calculated and measured against a set of target criteria.

19.6.1.7) Documentation of Method

The method is formally documented in an SOP. If the method is a minor modification of a standard laboratory method that is already documented in an SOP, an SOP Attachment describing the specific differences in the new method is acceptable in place of a separate SOP.

19.6.1.8) Continued Demonstration of Method Performance

Continued demonstration of Method Performance is addressed in the SOP. Continued demonstration of method performance is generally accomplished by batch specific QC samples such as LCS, method blanks or PT samples.

19.7) Method Detection Limits (MDL)/ Limits Of Detection (LOD)

The MDL is the minimum measured quantity of a substance that can be reported with 99% confidence that the concentration is distinguishable from method blank results, consistent with 40CFR Part 136 Appendix B, August, 2017. The MDL is equivalent to the TNI LOD. The working or final MDL is the higher of the MDL value determined from spikes (MDLs) and the MDL value determined from blanks (MDLb). An initial MDL study shall be performed during the method validation process and when the method Is altered in a way that can reasonably be expected to change the sensitivity. On-going data are collected during each quarter in which samples are being analyzed. At least once every 13 months, the MDLs and MDLb are re-calculated and re-evaluated using data collected during the preceding period. Details of Eurofins Environment Testing America's procedure for conducting MDL studies are given in NDSC Document No. NDSC-QA-SOP42091 and Pittsburgh' s SOP PT-QA-007.

19.8) Verification of Detection Limits

If it is found during the re-evaluation of detection limit results that more than 5% of the spiked samples do not return numeric results that meet the method qualitative identification criteria, then the spiking level shall be increased and the initial MDL study re-performed at the new spiking concentration.

19.9) Instrument Detection Limits (IDL)

The IDL is sometimes used to assess the reasonableness of the MDLs or in some cases required by the analytical method or program requirements. IDLs are most used in metals analyses but may be useful in demonstration of instrument performance in other areas.

IDLs are calculated to determine an instrument's sensitivity independent of any preparation method. IDLs are calculated either using 7 replicate spike analyses, like MDL but without sample preparation, or by the analysis of 10 instrument blanks and calculating 3 x the absolute value of the standard deviation.

19.10) Limit of Quantitation

The LOQ shall be at a concentration equivalent to the lowest calibration standard concentration, with the exception of methods using a single-point calibration, and shall be greater than the MDL. The LOQ is verified by preparing and analyzing spikes at or below the LOQ concentration, employing the complete analytical process.

When the laboratory establishes a quantitation limit, it must be initially verified by the analysis of a low level standard or QC sample at 1-2 times the reporting limit or by a DL check samples at or below the LOQ. The LOQ is verified annually thereafter. The annual requirement is waived for methods that have an annually verified MDL. The laboratory will comply with any additional regulatory requirements.

19.11) Retention Time Windows

Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis or as specific in the reference method, each analyte will have a specific time of elution from the column to the detector. This is known as the analyte's retention time. The variance in the expected time of elution is defined as the retention time window. As the key to analyte identification in chromatography, retention time windows must be established on every column for every analyte used for that method. These records are kept on-file and available for review. Complete details are available in the laboratory SOPs.

19.12) Evaluation Of Selectivity

The laboratory evaluates selectivity by following the checks within the applicable analytical methods, which include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, spectrochemical, atomic absorption or fluorescence profiles, co-precipitation evaluations and specific electrode response factors.

19.13) Estimation Of Uncertainty Of Measurement

19.13.1) Uncertainty is "a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result's validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty" defined as the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.

19.13.2) Uncertainty is not error. Error is a single value (i.e. the difference between the true result and the measured result). On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.

19.13.3) The minimum uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling and the variability due to matrix effects). The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.

19.13.4) To calculate the uncertainty for the specific result reported, multiply the result by the decimal of the lower end of the LCS range percent value for the lower end of the uncertainty range, and multiply the result by the decimal of the upper end of the LCS range percent value for the upper end of the uncertainty range. These calculated values represent uncertainties at approximately the 99% confidence level with a coverage factor of k =3. As an example, for a reported result of 1.0 mg/L with an LCS recovery range of 50 to 150%, the estimated uncertainty in the result would be 1.0 +/- 0.5 mg/L. Uncertainty determination is further described in laboratory SOP PT-QA-005, *Measurement Uncertainty.*

19.13.5) In the case where a well recognized test method specifies limits to the values of major sources of uncertainty of measurement and specifies the form of presentation of calculated results, no further discussion of uncertainty is required.

19.14) Sample Reanalysis Guidelines

Because there is a certain level of uncertainty with any analytical measurement, a sample re-preparation (where appropriate) and subsequent analysis (hereafter referred to as 'reanalysis') may result in either a higher or lower value from an initial sample analysis. There are also variables that may be present (e.g., sample homogeneity, analyte precipitation over time, etc.) that may affect the results of a reanalysis. Based on the above comments, the laboratory will reanalyze samples at a client's request with the following caveats. **Client specific Contractual Terms & Conditions for reanalysis protocols may supersede the following items.**

Homogenous samples: If a reanalysis agrees with the original result to within the RPD limits for MS/MSD or Duplicate analyses, or within ± 1 reporting limit for samples ≤ 5x the reporting limit, the original analysis will be reported. At the client's request, both results may be reported.

- If the reanalysis does not agree (as defined above) with the original result, then the laboratory will investigate the discrepancy and reanalyze the sample a third time for confirmation if sufficient sample is available.
- Any potential charges related to reanalysis are discussed in the contract terms and conditions or discussed at the time of the request. The client will typically be charged for reanalysis unless it is determined that the lab was in error.
- Due to the potential for increased variability, reanalysis may not be applicable to Non-homogenous, Encore, and Sodium Bisulfate preserved samples. See the Area Technical Manager/Supervisor or Laboratory Director if unsure.

19.15) Control Of Data

The laboratory has policies and procedures in place to ensure the authenticity, integrity, and accuracy of the analytical data generated by the laboratory.

19.15.1) Computer and Electronic Data Related Requirements

The three basic objectives of our computer security procedures and policies are shown below. The laboratory is currently using the Eurofins Environment Testing America TALS LIMS system, which has been highly customized to meet the needs of the laboratory. It is referred to as TALS throughout this document. More detailed descriptions of computer systems and associated controls are given in the IT Change Control Procedure Manual (NDSC-US-IT-QP46202) and policies and procedures posted on EETANet and D4.

19.15.1.1) Maintain the Database Integrity: Assurance that data is reliable and accurate through data verification (review) procedures, password-protecting access, anti-virus protection, data change requirements, as well as an internal LIMS permissions procedure.

- LIMS Database Integrity is achieved through data input validation, internal user controls, documentation of system failures and corrective actions taken, and data change requirements.
- Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use. Cells containing calculations must be lock-protected and controlled.
- Instrument hardware and software adjustments are safeguarded through maintenance logs, audit trails and controlled access.

19.15.1.2) Ensure Information Availability: Protection against loss of information or service is ensured through scheduled back-ups, stable file server network architecture, secure storage of media, line filter, Uninterruptible Power Supply (UPS), and maintaining older versions of software as revisions are implemented.

19.15.1.3) Maintain Confidentiality: Ensure data confidentiality through physical access controls such as password protection or website access approval, when electronically transmitting data.

19.15.2) Data Reduction

The complexity of the data reduction depends on the analytical method and the number of discrete operations involved (e.g., extractions, dilutions, instrument readings and concentrations). The analyst calculates the final results from the raw data or uses appropriate computer programs to assist in the calculation of final reportable values.

For manual data entry, e.g., Wet Chemistry, the data is reduced by the analyst and then verified by the Department Manager or alternate analyst prior to updating the data in TALS. The spreadsheets, or any other type of applicable documents, are signed by both the analyst and alternate reviewer to confirm the accuracy of the manual entry(s). The applicable data/spreadsheet is scanned in TALS with the batch.

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with the NDSC Document No. NDSC-QA-SOP43862, *Manual Integrations*.

Analytical results are reduced to appropriate concentration units specified by the analytical method, taking into account factors such as dilution, sample weight or volume, etc. Blank correction will be applied only when required by the method or per manufacturer's indication; otherwise, it should not be performed. Calculations are independently verified by appropriate laboratory staff. Calculations and data reduction steps for various methods are summarized in the respective analytical SOPs or program requirements.

19.15.2.1)
All raw data must be retained in the worklist folder, computer file (if appropriate), and/or run log. All criteria pertinent to the method must be recorded. The documentation is recorded at the time observations or calculations are made and must be signed or initialed/dated (month/day/year). It must be easily identifiable who performed which tasks if multiple people were involved.

19.15.2.2)
In general, concentration results are reported in milligrams per liter (mg/l) or micrograms per liter (µg/l) for liquids and milligrams per kilogram (mg/kg) or micrograms per kilogram (µg/kg) for solids. For values greater than 10,000 mg/l, results can be reported in percent, i.e., 10,000 mg/l = 1%. Units are defined in each lab SOP.

19.15.2.3)
In reporting, the analyst or the instrument output records the raw data result using values of known certainty plus one uncertain digit. If final calculations are performed external to TALS, the results should be entered in LIMS with at least three significant figures. In general, results are reported to 2 significant figures on the final report.

19.15.2.4)
For those methods that do not have an instrument printout or an instrumental output compatible with TALS, the raw results and dilution factors are entered directly into TALS by the analyst, and the software calculates the final result for the analytical report. TALS has a defined significant figure criterion for each analyte.

19.15.2.5)
The laboratory strives to import data directly from instruments or calculation spreadsheets to ensure that the reported data are free from transcription and calculation errors. For those analyses with an instrumental output compatible with the TALS, the raw results and dilution factors are transferred into TALS electronically after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst prints a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations, retention times, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored on the server and every night backed up to a tape file.

19.15.3) Logbook / Worksheet Use Guidelines

Logbooks and worksheets are filled out 'real time' and have enough information on them to trace the events of the applicable analysis/task. (e.g. calibrations, standards, analyst, sample ID, date, time on short holding time tests, temperatures when applicable, calculations are traceable, etc.).

- Corrections are made following the procedures outlined in Section 12.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the lab.
- Unused portions of pages must be "Z"d out, signed and dated.
- Worksheets are created with the approval of the Technical Manager / QA Manager at the facility.
  - Any cells that perform calculations must have the calculation verified and the cell locked so that the formula cannot be changed.
  - The QA Manager controls all worksheets following the procedures in Section 6.

19.15.4) Review / Verification Procedures

Review procedures are outlined in several SOPs (e.g. laboratory SOPs PT-QA-013, *Independent QA Data Review*; PT-QA-018, *Technical Data Review*; and PT-SR-001, *Sample Receipt and Login*) to ensure that reported date are free from calculation and transcription errors, and that QC parameters have been reviewed and evaluated before data is reported. The laboratory also has an SOP discussing Manual Integrations to ensure the authenticity of the data (NDSC-QA-SOP43862). The general review concepts are discussed below. More specific information can be found in the SOPs.

19.15.4.1) Log-In Review - The data review process starts at the sample receipt stage. Sample control personnel review chain-of-custody forms and project instructions from the project management group. This is the basis of the sample information and analytical instructions entered into TALS. The log-in instructions are reviewed by the personnel entering the information, and a second level review is conducted by the project management staff.

19.15.4.2) First Level Data Review - The next level of data review occurs with the analysts. As data are generated, analysts review their work to ensure that the results meet project and SOP requirements. First level reviews include inspection of all raw data (e.g., instrument output for continuous analyzers, chromatograms, spectra, and manual integrations), evaluation of calibration/calibration verification data in the day's analytical run, evaluation of QC data, and reliability of sample results. The analyst transfers data into TALS, data qualifiers are added as needed. All first level reviews are documented.

19.15.4.3)
Second Level Data Review – All analytical data are subject to review by a second qualified analyst or supervisor. Second level reviews include inspection of all raw data (e.g., instrument output, chromatograms, and spectra) including 100% of data associated with any changes made by the primary analyst, such as manual integrations or reassignment of peaks to different analytes, or elimination of false negative analytes. The second review also includes evaluation of initial calibration/calibration verification data in the day's analytical run, evaluation of QC data, reliability of sample results, qualifiers and NCM narratives. Manual calculations are checked in second level review. All second level reviews are documented.

Issues that deem further review include the following:

- QC data are outside the specified control limits for accuracy and precision
- Reviewed sample data does not match with reported results
- Unusual detection limit changes are observed
- Samples having unusually high results
- Samples exceeding a known regulatory limit
- Raw data indicating some type of contamination or poor technique
- Inconsistent peak integration
- Transcription errors
- Results outside of calibration range

19.15.4.4) Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Assurance Manager, Technical Director, Department Manager, or section Supervisor for further investigation. Corrective action is initiated whenever necessary.

19.15.4.5)
The results are then entered or directly transferred into the computer database and a .pdf is printed for the client.

19.15.4.6) As a final review prior to the release of the report, the Project Manager (or designee) reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly completed. The process includes, but is not limited to, verifying that the COC is followed, cover letters / narratives are present, flags are appropriate, and project specific requirements are met. The Project Manager may also evaluate the validity of results for different test methods given expected chemical relationships.

19.15.4.7) Any project that requires a data package is subject to a tertiary data review for transcription errors and acceptable quality control requirements. The Project Manager (or designee) then signs the final report. The accounting personnel also check the report for any clerical or invoicing errors. When complete, the report is sent out to the client.

19.15.4.8) As a further check of the system, the QA department reviews both selected and random batches and final reports.

19.15.4.9) A visual summary of the flow of samples and information through the laboratory, as well as data review and validation, is presented in Figure 19-2.

19.15.5) Manual Integrations

Computerized data systems provide the analyst with the ability to re-integrate raw instrument data in order to optimize the interpretation of the data. Though manual integration of data is an invaluable tool for resolving variations in instrument performance and some sample matrix problems, when used improperly, this technique would make unacceptable data appear to meet quality control acceptance limits. Improper re-integrations lead to legally indefensible data, a poor reputation, or possible laboratory decertification. Because guidelines for re-integration of data are not provided in the methods and most methods were written prior to widespread implementation of computerized data systems, the laboratory trains all analytical staff on proper manual integration techniques using NDSC Document No. NDSC-QA-SOP43862.

19.15.5.1) The analyst must adjust baseline or the area of a peak in some situations, for example when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest. The analyst must use professional judgment to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.

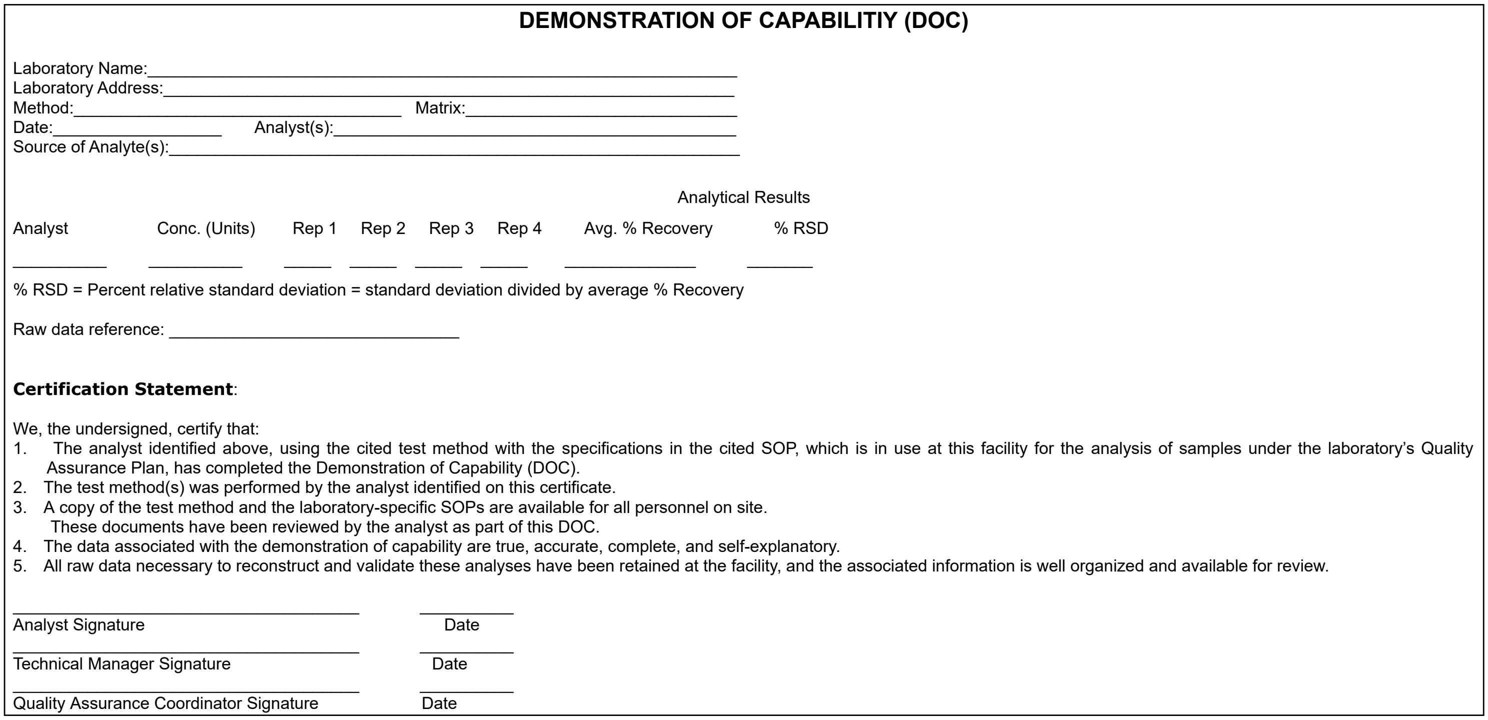
19.15.5.2) Analysts shall not increase or decrease peak areas for the sole purpose of achieving acceptable QC recoveries that would have otherwise been unacceptable. The intentional recording or reporting of incorrect information (or the intentional omission of correct information) is against company principles and policy and is grounds for immediate termination.

19.15.5.3) Client samples, performance evaluation samples, and quality control samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.

19.15.5.4)
All manual integrations receive a second level review. Manual integrations must be indicated on an expanded scale "before" and "after" chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale "before" chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, laboratory control samples, internal standards, surrogates, etc.) unless the laboratory has another documented NDSC approved procedure in place that can demonstrate an active process for detection and deterrence of improper integration practices.

Figure 19-1

Example - Demonstration of Capability Documentation



DEMONSTRATION OF CAPABILITIY (DOC)

Laboratory Name:____
Laboratory Address:______________________________________
Method:______________________ Matrix:____________________
Date:____________ Analyst(s):____________________________
Source of Analyte(s):______________________________________

Analytical Results

Analyst	Conc. (Units)	Rep 1	Rep 2	Rep 3	Rep 4	Avg. % Recovery	% RSD

% RSD = Percent relative standard deviation = standard deviation divided by average % Recovery

Raw data reference: __________________________

Certification Statement:

We, the undersigned, certify that:

1. The analyst identified above, using the cited test method with the specifications in the cited SOP, which is in use at this facility for the analysis of samples under the laboratory's Quality Assurance Plan, has completed the Demonstration of Capability (DOC).
2. The test method(s) was performed by the analyst identified on this certificate.
3. A copy of the test method and the laboratory-specific SOPs are available for all personnel on site. These documents have been reviewed by the analyst as part of this DOC.
4. The data associated with the demonstration of capability are true, accurate, complete, and self-explanatory.
5. All raw data necessary to reconstruct and validate these analyses have been retained at the facility, and the associated information is well organized and available for review.

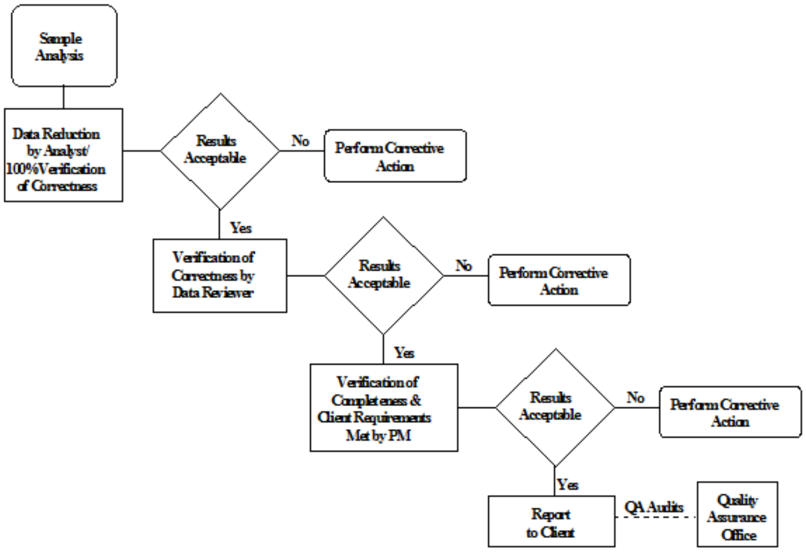
____________________________ ________
Analyst Signature Date

____________________________ ________
Technical Manager Signature Date

____________________________ ________
Quality Assurance Coordinator Signature Date

Figure 19-2

Example Work Flow



20) EQUIPMENT AND CALIBRATIONS

20.1) Overview

The laboratory purchases the most technically advanced analytical instrumentation for sample analyses. Instrumentation is purchased on the basis of accuracy, dependability, efficiency and sensitivity. Each laboratory is furnished with all items of sampling, preparation, analytical testing and measurement equipment necessary to correctly perform the tests for which the laboratory has capabilities. Each piece of equipment is capable of achieving the required accuracy and complies with specifications relevant to the method being performed. Before being placed into use, the equipment (including sampling equipment) is calibrated and checked to establish that it meets its intended specification. The calibration routines for analytical instruments establish the range of quantitation. Calibration procedures are specified laboratory analytical SOPs. Also see NDSC Document No. NDSC-QA-QP44940, *Calibration Curves and Selection of Calibration Points*.

A list of laboratory instrumentation types is presented in Table 20-1.

Equipment is only operated by authorized and trained personnel. Manufacturer's instructions for equipment use are readily accessible to all appropriate laboratory personnel.

20.2) Preventive Maintenance

The laboratory follows a well-defined maintenance program to ensure proper equipment operation and to prevent the failure of laboratory equipment or instrumentation during use. This program of preventive maintenance helps to avoid delays due to instrument failure.

Routine preventive maintenance procedures and frequency, such as cleaning and replacements, should be performed according to the procedures outlined in the manufacturer's manual. Qualified personnel must also perform maintenance when there is evidence of degradation of peak resolution, a shift in the calibration curve, loss of sensitivity, or failure to continually meet one of the quality control criteria.

Table 20-2 lists examples of scheduled routine maintenance. It is the responsibility of each Technical Manager to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures are outlined in analytical SOPs or instrument manuals. Further detail for equipment maintenance is included in SOP No. PT-QA-022 and individual analytical SOPs. (Note: for some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

Instrument maintenance logs are controlled and are used to document instrument problems, instrument repair and maintenance activities. Maintenance logs shall be kept for all major pieces of equipment. Instrument maintenance logs may also be used to specify instrument parameters.

- Documentation must include all major maintenance activities such as contracted preventive maintenance and service and in-house activities such as the replacement of electrical components, lamps, tubing, valves, columns, detectors, cleaning and adjustments.
- Each entry in the instrument log includes the Analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control. e.g. CCV run on *'date'* was acceptable, or instrument recalibrated on 'date' with acceptable verification, etc.) must also be documented in the instrument records.
- When maintenance or repair is performed by an outside agency, service receipts detailing the service performed can be affixed into the logbooks adjacent to pages describing the maintenance performed. This attached document must be signed across the page entered and the logbook so that it is clear that a page is missing if only half a signature is found in the logbook.

If an instrument requires repair (subjected to overloading or mishandling, gives suspect results, or otherwise has shown to be defective or outside of specified limits) it shall be taken out of operation and tagged as out-of-service or otherwise isolated until such a time as the repairs have been made and the instrument can be demonstrated as operational by calibration and/or verification or other test to demonstrate acceptable performance. The laboratory shall examine the effect of this defect on previous analyses.

In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Back-up instruments, which have been approved, for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the back-up is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be subcontracted.

If an instrument is sent out for service or transferred to another facility, it must be recalibrated and the laboratory MDL verified (using an MDLV) prior to return to lab operations following the requirements in SOP PT-QA-007.

20.3) Support Equipment

This section applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, field sampling devices, temperature measuring devices, thermal/pressure sample preparation devices and volumetric dispensing devices if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All raw data records associated with the support equipment are retained to document instrument performance.

Support equipment that provides quantitative results are calibrated or calibration verified to a recognized national metrology standard, such as NIST, where available, over the expected range of use. The acceptability for use shall be according to the needs of the analysis or application for which the equipment is being used.

Calibration and calibration verification scheduling and documentation for support equipment is maintained by the QA department. All equipment is labeled with the most recent calibration information and the next verification due date.

20.3.1) Weights and Balances

The accuracy of the balances used in the laboratory is checked every working day, before use. All balances are placed on stable counter tops.

Each balance is checked prior to initial serviceable use with at least three certified ASTM type 1 weights spanning its range of use (weights that have been calibrated to ASTM type 1 weights may also be used for daily verification). ASTM type 1 weights used only for calibration of other weights (and no other purpose) are inspected for corrosion, damage or nicks at least annually and if no damage is observed, they are calibrated at least every 5 years by an outside calibration laboratory. Any weights (including ASTM Type 1) used for daily balance checks or other purposes are recalibrated/recertified annually to NIST standards (this may be done internally if laboratory maintains “calibration only” ASTM type 1 weights).

All balances are serviced annually by a qualified service representative, who supplies the laboratory with a certificate that identifies traceability of the calibration to the NIST standards.

All of this information is recorded in logs, and the recalibration/recertification certificates are kept on file. Refer to Pittsburgh Laboratory SOP No. PT-QA-012, *Selection and Calibration of Balances and Weights*, for details.

20.3.2) pH, Conductivity, and Turbidity Meters

The pH meters used in the laboratory are accurate to ± 0.1 pH units, and have a scale readability of at least 0.05 pH units. The meters automatically compensate for the temperature, and are calibrated with at least two working range buffer solutions before each use.

Conductivity meters used in the laboratory are capable of measuring conductivity with an error not exceeding 1% or one umhos/cm, whichever is greater. The meters are also calibrated before each use with a known standard.

Turbidity meters are also calibrated before each use. All of this information is documented in logs.

Consult pH and Conductivity, and Turbidity laboratory analytical SOPs for further information.

20.3.3) Thermometers

All thermometers are calibrated on an annual basis with a NIST-traceable thermometer. IR thermometers, digital probes and thermocouples are calibrated quarterly. IR thermometers are checked daily for calibration accuracy against an NIST thermometer daily before use.

- If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;
- If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.

IR thermometers, digital probes and thermocouples are calibrated quarterly.

Mercury or digital NIST thermometers are recalibrated every five years (unless thermometer has been exposed to temperature extremes or apparent separation of internal liquid) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometer(s) have increments of at least 1 degree (0.5 degree or less increments are required for drinking water microbiological laboratories), and have ranges applicable to method and certification requirements. The NIST traceable thermometers are used for no other purpose than to calibrate other thermometers.

All of this information is documented in logbooks. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in method or device-specific logbooks. More information on this subject can be found in Pittsburgh Laboratory SOP No. PT-QA-008, *Thermometer and Barometer Verification and Temperature Monitoring.*

20.3.4) Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators

The temperatures of all refrigerator units and freezers used for sample and standard storage are monitored each working day. Sample storage temperatures are monitored continuous (24/7).

Ovens, waterbaths and incubators are monitored on days of use.

All of this equipment has a unique identification number, and is assigned a thermometer for monitoring.

Sample storage refrigerator temperatures are kept between > 0ºC and ≤ 6 ºC.

Specific temperature settings/ranges for other refrigerators, ovens waterbaths, and incubators can be found in method specific SOPs.

All of this information is documented in Daily Temperature Logbooks or electronically. Refer to laboratory SOP PT-QA-008.

20.3.5) Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices, including burettes, (except Class A Glassware and glass microliter syringes) are given unique identification numbers and the delivery volumes are verified gravimetrically, at a minimum, on a quarterly basis. Glass micro-syringes are considered the same as Class A glassware.

For those dispensers that are not used for analytical measurements, a label shall be applied to the device stating that it is not calibrated. Any device not regularly verified cannot be used for any quantitative measurements. Pipette calibration is described in Pittsburgh Laboratory SOP No. PT-QA-017, *Aqueous Pipette Calibration*.

Micro-syringes are purchased from Hamilton Company. Each syringe is traceable to NIST. The laboratory keeps on file an “Accuracy and Precision Statement of Conformance” from Hamilton attesting established accuracy.

20.3.6) Field Sampling Devices (Isco Auto Samplers)

Each Auto Sampler (ISCO) is assigned a unique identification number in order to keep track of the calibration. This number is also recorded on the sampling documentation.

The Auto Sampler is calibrated quarterly by setting the sample volume to 100ml and recording the volume received. The results are filed in a logbook/binder. The Auto Sampler is programmed to run three (3) cycles and each of the three cycles is measured into a graduated cylinder to verify 100ml are received.

If the RSD (Relative Standard Deviation) between the 3 cycles is greater than 10%, the procedure is repeated and if the result is still greater than 10%, then the Auto Sampler is taken out of service until it is repaired and calibration verification criteria can be met. The results of this check are kept in a logbook/binder.

20.4) Instrument Calibrations

Calibration of analytical instrumentation is essential to the production of quality data. Strict calibration procedures are followed for each method. These procedures are designed to determine and document the method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

Sufficient raw data records are retained to allow an outside party to reconstruct all facets of the initial calibration. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration, response, type of calibration (Avg RF, curve, or other calculations that may be used to reduce instrument responses to concentration.)

Sample results must be quantitated from the initial calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method or program.

If the initial calibration results are outside of the acceptance criteria, corrective action is performed and any affected samples are reanalyzed if possible. If the reanalysis is not possible, any data associated with an unacceptable initial calibration will be reported with appropriate data qualifiers (refer to Section 12).

Note: Instruments are calibrated initially and as needed after that and at least annually.

20.4.1) Calibration Standards

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative method SOP. If a reference method does not specify the number of calibration standards, a minimum of 3 calibration points (exception being ICP and ICP/MS methods) will be used.

Standards for instrument calibration are obtained from a variety of sources. All standards are traceable to national or international standards of measurement, or to national or international standard reference materials.

The lowest concentration calibration standard that is analyzed during an initial calibration must be at or below the stated reporting limit for the method based on the final volume of extract (or sample).

The other concentrations define the working range of the instrument/method or correspond to the expected range of concentrations found in actual samples that are also within the working range of the instrument/method. Results of samples not bracketed by initial instrument calibration standards (within calibration range to at least the same number of significant figures used to report the data) must be reported as having less certainty, e.g., defined qualifiers or flags (additional information may be included in the case narrative). The exception to these rules is ICP and ICP-MS methods or other methods which define the working range with periodic linear dynamic range studies, rather than through the range of concentrations of daily calibration standards.

All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst at a different time or by a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.1.1) Calibration Verification

The calibration relationship established during the initial calibration must be verified at least daily as specified in the laboratory method SOPs in accordance with the referenced analytical methods and in the 2009 and 2016 TNI standard. The process of calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models. Initial calibration verification (ICV) is with a standard source secondary (second source standard) to the calibration standards, but continuing calibration verifications (CCV) may use the same source standards as the calibration curve.

Note: The process of calibration verification referred to is fundamentally different from the approach called "calibration" in some methods. As described in those methods, the calibration factors or response factors calculated during calibration are used to update the calibration factors or response factors used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration.

All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of retention time confirmation and to demonstrate that calibration verification criteria are being met, i. e., RPD, per 2009 TNI Std. EL-V1M4 Sec. 1.7.2.

All samples must be bracketed by periodic analyses of standards that meet the QC acceptance criteria (e.g., calibration and retention time). The frequency is found in the determinative methods or SOPs.

Generally, the initial calibrations must be verified by an ICV analyzed immediately following initial calibration and before sample analysis. The ICV may be used as the first bracketing CCV if criteria for both are met.

A continuing instrument calibration verification (CCV) is generally analyzed at the beginning of each 12-hour analytical shift during which samples are analyzed. (The 12-hour analytical shift begins with the injection of the calibration verification standard (or the MS tuning standard in MS methods). The shift ends after the completion of the analysis of the last sample, QC, or standard that can be injected within 12 hours of the beginning of the shift. For methods that have quantitation by external calibration models, a CCV is analyzed at the end of each analytical sequence. Some methods have more frequent CCV requirements. See specific SOPs. Most inorganic methods require the CCV to be analyzed after every 10 samples or injections, including matrix or batch QC samples.

Note: If an internal standard calibration is being used (e.g., GCMS and some GC methods) then bracketing standards are not required, only daily verifications are needed, except as specified by program or method requirements.

If the results of a CCV are outside the established acceptance criteria and analysis of a second consecutive (and immediate) CCV fails to produce results within acceptance criteria, corrective action shall be performed. Once corrective actions have been completed & documented, the laboratory shall demonstrate acceptable instrument / method performance by analyzing two consecutive CCVs, or a new initial instrument calibration shall be performed.

Sample analyses and reporting of data may not occur or continue until the analytical system is calibrated or calibration verified. However, data associated with a unacceptable calibration verification may be fully useable and may be reported, based upon discussion and approval of the client, under the following special conditions:

a) When the acceptance criteria for the CCV are exceeded high (i.e., high bias) and the associated samples within the batch are non-detects, then those non-detects may be reported with a footnote or case narrative comment explaining the high bias. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or

b) When the acceptance criteria for the CCV are exceeded low (i.e., low bias), samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

Samples reported under one of the conditions identified above will be appropriately flagged.

20.4.1.2) Verification of Linear and Non-Linear Calibrations

Calibration verification for calibrations involves the calculation of the percent drift or the percent difference of the instrument response between the initial calibration and each subsequent analysis of the verification standard. (These calculations are available in the laboratory method SOPs.) Verification standards are evaluated based on the % Difference from the average CF or RF of the initial calibration or based on %Drift or %Recovery if a linear or quadratic curve is used.

Regardless of whether a linear or non-linear calibration model is used, if initial verification criterion is not met, then no sample analyses may take place until the calibration has been verified or a new initial calibration is performed that meets the specifications listed in the method SOPs. If the calibration cannot be verified after the analysis of a single verification standard, then adjust the instrument operating conditions and/or perform instrument maintenance, and analyze another aliquot of the verification standard. If the calibration cannot be verified with the second standard, then a new initial calibration is performed.

- When the acceptance criteria for the calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise, the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.
- When the acceptance criteria for the calibration verification are exceeded low, i.e., low bias, those samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted. Alternatively, a reporting limit standard may be analyzed to demonstrate that the laboratory can still support non-detects at their reporting limit.

Note: Some programs require additional verification steps for linear and quadratic calibration – i.e. reading the lowest, or all, initial calibration level standard against the curve, or verification at a low and a high concentration. See analytical SOPs and project notes for details.

20.5) Tentatively Identified Compounds (TICs) – GC/MS Analysis

For samples containing components not associated with the calibration standards, a library search may be made for the purpose of tentative identification. The necessity to perform this type of identification will be determined by the purpose of the analyses being conducted. Data system library search routines should not use normalization routines that would misrepresent the library or unknown spectra when compared to each other. Additional details are provided in NDSC Document No. CA-Q-QM-001, Tentatively Identified Compounds (TICS) - GCMS Analysis.

Note: If the TIC compound is not part of the client target analyte list but is calibrated by the laboratory and is both qualitatively and/or quantitatively identifiable, it should not be reported as a TIC. If the compound is reported on the same form as true TICs, it should be qualified and/or narrated that the reported compound is qualitatively and quantitatively (if verification in control) reported compared to a known standard that is in control (where applicable).

20.6) GC/MS TUNING

Prior to any GCMS analytical sequence, including calibration, the instrument parameters for the tune and subsequent sample analyses within that sequence must be set.

Prior to tuning/auto-tuning the mass spectrometer the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally don't need any adjustment but it may be required based on the current instrument performance. If the tune verification does not pass it may be necessary to clean the source or perform additional maintenance. Any maintenance is documented in the maintenance log.

Table 20-1

Eurofins Pittsburgh Instrumentation Type List
(see PT-QA-WI-045 for the most current full listing of instrumentation and equipment)

GC	GC/MS	ICP	ICP/MS	IC	Carbon Analyzer	Auto-Analyzer	Variable Spectro-photometer	Electrode Meter
√	√	√	√	√	√	√	√	√

Tables 20-2

Example - Schedule of Routine Maintenance
(See SOP No. PT-QA-022 for more instrument specific information)

Daily	Weekly	Monthly	Quarterly	Annually	As Needed
Check sample waste container level.	Check peristaltic pump: proper roller pressure, sample introduction tubing, correct pump rotation, and condition of drain tubing.	Clean all filters and fans.	Replace oil in roughing pumps.	Replace oil in turbo-molecular pump.	Check electronic settings for optimum sensitivity: resolution, mass calibration, ion optics, CEM, deflector voltage.
Check quartz torch condition.	Check condition of sampler and skimmer cones.	Check recirculator water level.			
Measure quartz torch for proper alignment.	Check and drain oil mist eliminator on roughing pumps.				
Clean spray chamber and nebulizer.					
Check oil level of roughing pumps.					

21) Measurement Traceability

21) Overview

Traceability of measurements shall be assured using a system of documentation, calibration, and analysis of reference standards. Laboratory equipment that are peripheral to analysis and whose calibration is not necessarily documented in a test method analysis or by analysis of a reference standard shall be subject to ongoing certifications of accuracy. At a minimum, these must include procedures for checking specifications of ancillary equipment: balances, thermometers, temperature, Deionized (DI) and Reverse Osmosis (RO) water systems, automatic pipettes and other volumetric measuring devices. (Refer to Section 20.3). With the exception of Class A Glassware and Glass microliter syringes, quarterly accuracy checks are performed for all mechanical volumetric devices. Microsyringes can be verified at least semi-annually or disposed of after 6 months of use. Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. Class A Glassware and Glass microliter syringes should be routinely inspected for chips, acid etching or deformity (e.g., bent needle). If the Class A glassware or syringe is suspect, the accuracy of the glassware will be assessed prior to use.

21.2) NIST-Traceable Weights And Thermometers

Reference standards of measurement shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

For NIST-traceable weights and thermometers, the laboratory requires that all calibrations be conducted by a calibration laboratory accredited by A2LA, NVLAP (National Voluntary Laboratory Accreditation Program) or another accreditation organization that is a signatory to a MRA (Mutual Recognition Arrangement) of one or more of the following cooperations – ILAC (International Laboratory Accreditation Cooperation) or APLAC (Asia – Pacific Laboratory Accreditation Cooperation). A certificate and scope of accreditation is kept on file at the laboratory.

Additional details can be found in laboratory SOP No's. PT-QA-008 and PT-QA-012.

21.3) Reference Standards / Materials

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared reference standards, to the extent available, are purchased from vendors accredited to ISO Guide 34 and ISO/IEC Guide 17025. All reference standards from commercial vendors shall be accompanied by a certificate that includes at least the following information:

- Manufacturer
- Analytes or parameters calibrated
- Identification or lot number
- Calibration method
- Concentration with associated uncertainties
- Purity

If a standard cannot be purchased from a vendor that supplies a Certificate of Analysis, the purity of the standard is documented by analysis. The receipt of all reference standards must be documented in the LIMS. Reference standards are labeled with a unique Standard Identification Number and expiration date. All documentation received with the reference standard is retained as a QC record and references the Standard Identification Number.

All reference, primary and working standards/materials, whether commercially purchased or laboratory prepared, must be checked regularly to ensure that the variability of the standard or material from the true value does not exceed method requirements. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a vendor certified different lot is acceptable for use as a second source. For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst would be considered a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or LCS (where there is no sample preparation) is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g. calibration checks, laboratory control samples).

All standards and materials must be stored and handled according to method or manufacturer's requirements in order to prevent contamination or deterioration. Refer to the Corporate Environmental Health & Safety Manual or laboratory SOPs. For safety requirements, please refer to method SOPs and the laboratory Environmental Health and Safety Manual.

Standards and reference materials shall not be used after their expiration dates unless their reliability is verified by the laboratory and their use is approved by the Quality Assurance Manager. The laboratory has contingency procedures for re-verifying expired standards. See Pittsburgh Laboratory SOP No. PT-QA-006, *Procurement of Standards and Materials, Labeling and Traceability.*

21.4) Documentation And Labeling Of Standards, Reagents, And Reference Materials

Reagents must be at a minimum the purity required in the test method. The date of reagent receipt and the expiration date are documented. The lots for most of the common solvents and acids are tested for acceptability prior to company-wide purchase. (Refer to NDSC Document No. NDSC-QA-SOP46704, *Acid & Solvent Lot Testing and Approval*.)

All manufacturer or vendor supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained in the QA public drive and in the LIMS, scanned into Reagent log. Records must be kept of the date of receipt and date of expiration of standards, reagents and reference materials. In addition, records of preparation of laboratory standards, reagents, and reference materials must be retained, stored appropriately, and be readily available for use and inspection. For detailed information on documentation and labeling, please refer to laboratory analytical SOPs and SOP PT-QA-006.

Commercial materials purchased for preparation of calibration solutions, spike solutions, etc., are usually accompanied with an assay certificate or the purity is noted on the label. If the assay purity is 96% or better, the weight provided by the vendor may be used without correction. If the assay purity is less than 96% a correction will be made to concentrations applied to solutions prepared from the stock commercial material.

21.4.1)

All standards, reagents, and reference materials that may affect quality must be labeled in an unambiguous manner. Standards are logged into TALS, and are assigned a unique identification number. The following information is typically recorded within TALS.

- Standard ID
- Description of Standard
- Department
- Preparer's name
- Final volume and number of vials prepared
- Solvent type and lot number
- Preparation Date or Date opened
- Expiration Date
- Standard source type (stock or daughter)
- Standard type (spike, surrogate, other)
- Parent standard ID (if applicable)
- Parent Standard Analyte Concentration (if applicable)
- Parent Standard Amount used (if applicable)
- Component Analytes
- Final concentration of each analyte
- Comment box (text field)

Records are maintained electronically for standard and reference material preparation. These records show the traceability to purchased stocks or neat compounds. These records also include method of preparation, date of preparation, expiration date and preparer's name or initials. Preparation procedures are provided in the laboratory analytical SOPs.

21.4.2)

All standards, reagents, and reference materials must be clearly labeled with a minimum of the following information:

- Expiration Date (include prep date for reagents)
- Standard ID (from electronic standard log in TALS)
- Special Health/Safety warnings if applicable

Records must also be maintained of the date of receipt for commercially purchased items or date of preparation for laboratory prepared items. Special Health/Safety warnings must also be available to the analyst. This information is maintained in standard/reagent log. Health and safety warning are in the SDS (Safety Data Sheets) which is accessed through the company intranet site, EETANet.

21.4.3)

In addition, the following information may be included:

- Date opened (for multi-use containers, if applicable)
- Description of standard (if different from manufacturer's label or if standard was prepared in the laboratory)
- Recommended Storage Conditions
- Concentration (if applicable)
- Initials of analyst preparing standard or opening container

All containers of prepared reagents must include, expiration date and an ID number to trace back to preparation.

Procedures for preparation of reagents can be found in the Method SOPs.

Standard ID numbers must be traceable through associated logbooks, worksheets and raw data.

All reagents and standards must be stored in accordance to the following priority: 1) with the manufacturer's recommendations; 2) with requirements in the specific analytical methods as specified in the laboratory SOP.

22) SAMPLING

22.1) Overview

The laboratory provides sampling services for the following matrices:
Groundwater
Wastewater
Potable Water
Wastes
Soil and Sediment
The laboratory also offers the following services:
Flow Monitoring
Field Parameter Analysis
Field Analyses are address in Eurofins Pittsburgh SOP No.'s:
PT-FS-001 – Field Measurement of Dissolved Oxygen (DO)
PT-FS-003 – Field Measurement of pH
PT-FS-004 – General Sampling

22.2) Sampling Containers

The laboratory offers clean sampling containers for use by clients. These containers are obtained from reputable container manufacturers and meet EPA specifications as required. Certificates of cleanliness for bottles and preservatives are provided by the supplier and are maintained at the laboratory. Alternatively, the certificates may be maintained by the supplier and available to the laboratory on-line.
For detailed information regarding container/bottle order, refer to laboratory SOP No. PT-SR-002, *Bottle Order Preparation and Shipping*.

22.2.1) Preservatives

Upon request, preservatives are provided to the client in pre-cleaned sampling containers. In general, containers are purchased pre-preserved from the container supplier. Whether prepared by the laboratory or bought pre-preserved, the grades of the preservatives are at a minimum:

- Hydrochloric Acid – AR Select (ACS) or equivalent
- Methanol – Purge and Trap grade
- Nitric Acid – AR Select (ACS), Trace-Metals Grade or equivalent
- Sodium Hydroxide – AR Select (ACS) or equivalent
- Sulfuric Acid – AR Select (ACS) or equivalent
- Sodium Thiosulfate – ACS Grade or equivalent
- Sodium Bisulfate – ACS Grade or equivalent

22.3) Definition Of Holding Time

The date and time of sampling documented on the COC form establishes the day and time zero. As a general rule, when the maximum allowable holding time is expressed in days (e.g., 14 days, 28 days), the holding time is based on calendar day measured. Holding times expressed in hours (e.g., 6 hours, 24 hours, etc.) are measured from date and time zero. However, there are some programs that determine holding time compliance based on the date and specific time of analysis compared to the time of sampling regardless of how long the holding time is. Holding times for analysis include any necessary reanalysis.

22.4) Sampling Containers, Preservation Requirements, Holding Times

The container type, preservation, and holding time criteria specified in the SOPs are derived from the source documents for the methods. If method required holding times as specified in the SOPs or preservation requirements are not met, the reports will be qualified using a flag, footnote or case narrative. As soon as possible, or "ASAP", is an EPA designation for tests for which rapid analysis is advised, but for which neither EPA nor the laboratory have a basis for a holding time.

22.5) Sample Aliquots / Subsampling

Taking a representative sub-sample from a container is necessary to ensure that the analytical results are representative of the sample collected in the field. The size of the sample container, the quantity of sample fitted within the container, and the homogeneity of the sample need consideration when sub-sampling for sample preparation. It is the laboratory's responsibility to take a representative subsample or aliquot of the sample provided for analysis.

Analysts should handle each sample as if it is potentially dangerous. At a minimum, safety glasses, gloves, and lab coats must be worn when preparing aliquots for analysis.

Guidelines on taking sample aliquots and subsampling are located in laboratory SOP PT-QA-024, Subsampling.

23) HANDLING OF SAMPLES

It is the responsibility of the client to send us representative and/or homogeneous and properly preserved samples of the system from which they are drawn. The laboratory assumes that all multiple sample containers with the same designator/description and bottle type contain a homogeneous, representative sample.

The laboratory provides the appropriate sample containers, required preservative, chain-of-custody (COC) forms, shipping containers, labels, and custody seals. The laboratory also provides trip blanks and analyte-free water for field blanks. Preparation of methanol containers for field preservation of volatile soil samples is available.

Sample management procedures at the laboratory ensure that sample integrity and custody are maintained and documented from sampling/receipt through disposal. Details can be found in laboratory SOP No. PT-SR-001, *Sample Receipt and Login*, and PT-HS-001, *Pittsburgh Facility Addendum EH&S Manual.*

23.1) Chain Of Custody (COC)

The COC form is the written documented history of any sample and is initiated when bottles are sent to the field, or at the time of sampling. This form is completed by the sampling personnel and accompanies the samples to the laboratory where it is received and stored under the laboratory's custody. The purpose of the COC form is to provide a legal written record of the handling of samples from the time of collection until they are received at the laboratory. It also serves as the primary written request for analyses from the client to the laboratory. The COC form acts as a purchase order for analytical services when no other contractual agreement is in effect. An example of a COC form may be found in Figure 23-1.

23.1.1) Field Documentation

The information the sampler needs to provide at the time of sampling on the container label is:

- Sample identification
- Date and time
- Preservative

During the sampling process, the COC form is completed and must be legible (see Figure 23-1). This form includes information such as:

- Client name, address, phone number and fax number (if available)
- Project name and/or number
- The sample identification
- Date, time and location of sampling
- Sample collectors name
- The matrix description
- The container description
- The total number of each type of container
- Preservatives used
- Analysis requested
- Requested turnaround time (TAT)
- Any special instructions
- Purchase Order number or billing information (e.g. quote number) if available
- The date and time that each person received or relinquished the sample(s), including their signed name.

When the sampling personnel deliver the samples directly to the laboratory personnel, the samples are stored in a cooler with ice, as applicable, and remain solely in the possession of the client's field technician until the samples are delivered to the laboratory personnel. The sample collector must assure that each container is in his/her physical possession or in his/her view at all times, or stored in such a place and manner to preclude tampering. The field technician relinquishes the samples in writing on the COC form to the sample control personnel at the laboratory or to a laboratory courier. When sampling personnel deliver the samples through a common carrier (Fed-Ex, UPS), the CoC relinquished date/time is completed by the field personnel and samples are released to the carrier. Samples are only considered to be received by laboratory when personnel at the fixed laboratory facility have physical contact with the samples.

Note: Independent couriers are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. The receipt from the courier is stored in login by date; it lists all receipts for each date.

23.1.2) Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, login will complete the custody seal retain the shipping record with the COC, and initiate an internal COC for laboratory use by analysts and a sample disposal record.

23.2) Sample Receipt

Samples are received at the laboratory by designated sample receiving personnel and a unique laboratory project identification number is assigned. Each sample container shall be assigned a unique sample identification number that is cross-referenced to the client identification number such that traceability of test samples is unambiguous and documented. Each sample container is affixed with a durable sample identification label. Sample acceptance, receipt, tracking and storage procedures are detailed in the laboratory's SOP PT-SR-001, Sample Receipt & Login, and are summarized in the following sections.

23.2.1) Laboratory Receipt

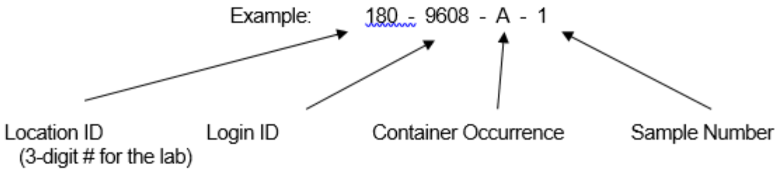
When samples arrive at the laboratory, sample receiving personnel inspect the coolers and samples. The integrity of each sample must be determined by comparing sample labels or tags with the COC and by visual checks of the container for possible damage. Samples and COC must meet the laboratory Sample Acceptance Policy (Figure 23-2). Any non-conformance, irregularity, or compromised sample receipt must be documented in TALS on the Sample Receipt checklist (Figure 23-3), and must be brought to the immediate attention of the client. The COC, shipping documents, documentation of any non-conformance, irregularity, or compromised sample receipt, record of client contact, and resulting instructions become part of the project record. This procedure is further described in laboratory SOP PT-SR-001.

Sample Registration personnel check and document preservation of non-volatile liquid samples after the samples have been entered into TALS and before they are released to the laboratory for testing or placed into storage. Any checks of volatile samples and samples for oil and grease are performed and documented at the time of analysis.

23.2.1.1) Unique Sample Identification

All samples that are processed through the laboratory receive a unique sample identification to ensure that there can be no confusion regarding the identity of such samples at anytime. This system includes identification for all samples, subsamples and subsequent extracts and/or digestates.

The laboratory assigns a unique identification (e.g., Sample ID) code to each sample container received at the laboratory. This Primary ID is made up of the following information (consisting of 4 components).



The above example states that Eurofins Pittsburgh Laboratory (Location 180). Login ID is 9608 (unique to a particular client/job occurrence). The container code indicates it is the first container ("A") of Sample #1.

If the primary container goes through a prep step that creates a "new" container, then the new container is considered secondary and gets another ID. An example of this being a client sample in a 1-Liter amber bottle is sent through a Liquid/Liquid Extraction and an extraction vial is created from this step. The vial would be a SECONDARY container. The secondary ID has 5 components.

Example: 180-9608-A-1-**A**, a Secondary Container Occurance would indicate the PRIMARY container listed above that went through a step that created the 1st occurrence of a Secondary container.

With this system, a client sample can literally be tracked throughout the laboratory in every step from receipt to disposal.

23.3) Sample Acceptance Policy

The laboratory has a written sample acceptance policy (Figure 23-2) that clearly outlines the circumstances under which samples shall be accepted or rejected. These include:

- a COC must filled out completely
- samples must be properly labeled
- proper sample containers with adequate volume for the analysis and necessary QC
- samples must be preserved according to the requirements of the requested analytical method
- sample holding times must be adhered to
- Samples that require chilling must be received proper temperature
- the project manager will be notified if any sample is received in damaged condition

Data from samples which do not meet these criteria are flagged and the nature of the variation from policy is defined.

23.3.1)
After inspecting the samples, the sample receiving personnel sign and date the COC form, make any necessary notes of the samples' conditions and store them in appropriate refrigerators or storage locations.

23.3.1)
Any deviations from these checks that question the suitability of the sample for analysis, or incomplete documentation on the chain-of-custody will be resolved by consultation with the client. If the sample acceptance policy criteria are not met, the laboratory shall either:

- Retain all correspondence and/or records of communications with the client regarding the disposition of rejected samples, or
- Fully document any decision to proceed with sample analysis that does not meet sample acceptance criteria. Include information for the case narrative of the report.
- If the conditions listed on the Acceptance Policy are not satisfactory and when lacking direction or agreement with the client, the sample may be rejected by the laboratory.
- Any deviation in that impacts sample results, such as temperature and preservation, shall be noted on sample results.

Note: North Carolina requires that they be notified when samples are processed that do not meet sample acceptance criteria.

Once sample acceptance is verified, the samples are logged into the TALS according to laboratory SOP PT-SR-001.

23.4) Sample Storage

In order to avoid deterioration, contamination or damage to a sample during storage and handling, from the time of receipt until all analyses are complete, samples are stored in refrigerators, freezers, or protected locations suitable for the sample matrix. In addition, samples to be analyzed for volatile organic parameters are stored in separate refrigerators designated for volatile organic parameters only. Samples are never to be stored with reagents, standards or materials that may create contamination.

To ensure the integrity of the samples during storage, refrigerator blanks are maintained in the volatile sample refrigerators and analyzed at least every two weeks. See laboratory SOP PT-MS-005, *Volatile Holding Blanks*.

Analysts and technicians retrieve the sample container allocated to their analysis from the designated storage location and place them on carts, analyze the sample, and return the remaining sample or empty container to the storage location from which it originally came. All unused portions of samples, including empty sample containers, are returned to the secure sample control area. Raw samples requiring cold storage are kept in the cold room for approximately 30 days after reported. Volatile samples are stored in the VOA refrigerator. All sample extracts are kept in the refrigerators for approximately two to four weeks after analysis, which meets or exceeds most sample holding times. After the cold storage time, the samples are moved to dry room-temperature sample archive area, where they are stored for an additional four weeks before they are disposed of. This holding period allows samples to be checked if a discrepancy or question arises. Special arrangements may be made to store samples for longer periods of time. This extended holding period allows additional metal analyses to be performed on the archived sample and assists clients in dealing with legal matters or regulatory issues.

Access to the laboratory is controlled such that sample storage need not be locked at all times unless a project specifically demands it. Samples are accessible to laboratory personnel only. Visitors to the laboratory are prohibited from entering the refrigerator and laboratory areas unless accompanied by an employee of Eurofins Pittsburgh.

23.5) Hazardous Samples And Foreign Soils

To minimize exposure to personnel and to avoid potential accidents, hazardous and foreign soil samples are stored in an isolated area designated for hazardous waste only. For any sample that is known to be hazardous at the time of receipt or, if after completion of analysis the result exceeds the acceptable regulatory levels, a Hazardous Sample Notice must be completed by the analyst. This form may be completed by Sample Control, Project Managers, or analysts and must be attached to the report. The sample itself is clearly marked with a red stamp, stamped on the sample label reading "HAZARDOUS" or "FOREIGN SOIL" and placed in a colored and/or marked bag to easily identify the sample. The date, log number, lab sample number, and the result or brief description of the hazard are all written on the Hazardous & Foreign Soil Sample Notice. A copy of the form must be included with the original COC and Work Order and the original must be given to the Sample Control Custodian. Analysts will notify Sample Control of any sample determined to be hazardous after completion of analysis by completing a Hazardous Sample Notice. All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm that lab-packs all hazardous samples and removes them from the laboratory. Foreign soil samples are sent out for incineration by a USDA-approved waste disposal facility.

23.6) Sample Shipping

In the event that the laboratory needs to ship samples, the samples are placed in a cooler with enough ice to ensure the samples remain just above freezing and at or below 6.0°C during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature). A trip blank is enclosed for those samples requiring water/solid volatile organic analyses. The chain-of-custody form is signed by the sample control technician and attached to the shipping paperwork. Samples are generally shipped overnight express or hand-delivered by a Eurofins Pittsburgh courier to maintain sample integrity. All personnel involved with shipping and receiving samples must be trained to maintain the proper chain-of-custody documentation and to keep the samples intact and on ice. The Environmental, Health and Safety Manual contains additional shipping requirements.

Note: If a client does not request trip blank analysis on the COC or other paperwork, the laboratory will not analyze the trip blanks that were supplied. However, in the interest of good client service, the laboratory will advise the client at the time of sample receipt that it was noted that they did not request analysis of the trip blank; and that the laboratory is providing the notification to verify that they are not inadvertently omitting a key part of regulatory compliance testing.

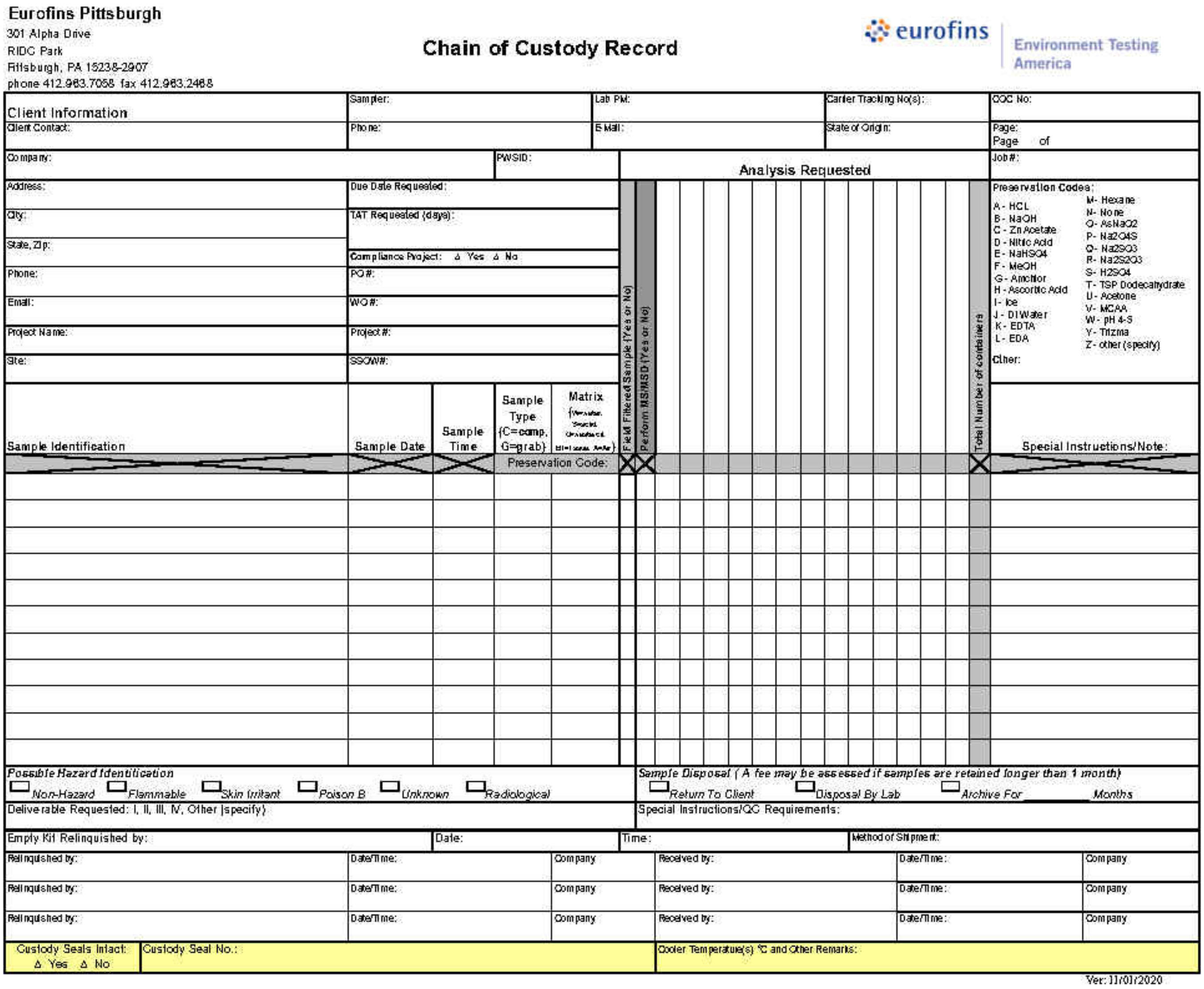
23.7) Sample Disposal

Samples should be retained for a minimum of 30 days after the project report is sent, however, provisions may be made for earlier disposal of samples once the holding time is exceeded. Some samples are required to be held for longer periods based on regulatory or client requirements (e.g., 60 days after project report is sent). The laboratory must follow the longer sample retention requirements where required by regulation or client agreement. Several possibilities for sample disposal exist: the sample may be consumed completely during analysis, the sample may be returned to the customer or location of sampling for disposal, or the sample may be disposed of in accordance with the laboratory's waste disposal procedures (SOP No. PT-HS-001). All procedures in the laboratory Environmental, Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than two months from receipt unless otherwise requested. Unused portions of samples found or suspected to be hazardous according to state or federal guidelines may be returned to the client upon completion of the analytical work.

If a sample is part of a known litigation, the affected legal authority, sample data user, and/or submitter of the sample must participate in the decision about the sample's disposal. All documentation and correspondence concerning the disposal decision process must be kept on file. Pertinent information includes the date of disposal, nature of disposal (such as sample depletion, hazardous waste facility disposal, return to client), names of individuals who conducted the arrangements and physically completed the task. The laboratory will remove or deface sample labels prior to disposal unless this is accomplished through the disposal method (e.g., samples are incinerated). A Waste Disposal Record should be completed.

Figure 23-1

Example: Chain of Custody (COC)



Eurofins Pittsburgh
301 Alpha Drive
RIDC Park
Pittsburgh, PA 15238-2907
phone 412.963.7058 fax 412.963.2468

Chain of Custody Record

Client Information
Sampler:
Lab PM:
Carrier Tracking No(s):
COC No:
Client Contact:
Phone:
E-Mail:
State of Origin:
Page:
Page of
Company:
PWSID:
Analysis Requested
Job #:
Address:
Due Date Requested:
City:
TAT Requested (days):
State, Zip:
Compliance Project: ∆ Yes ∆ No
Phone:
PO #:
Email:
WO #:
Project Name:
Project #:
Site:
SSOW#:

Preservation Codes:
A - HCL
B - NaOH
C - Zn Acetate
D - Nitric Acid
E - NaHSO4
F - MeOH
G - Amchlor
H - Ascorbic Acid
I - Ice
J - DI Water
K - EDTA
L - EDA
M - Hexane
N - None
O - AsNaO2
P - Na2O4S
Q - Na2SO3
R - Na2S2O3
S - H2SO4
T - TSP Dodecahydrate
U - Acetone
V - MCAA
W - pH 4-5
Y - Trizma
Z - other (specify)
Other:

Sample Identification	Sample Date	Sample Time	Sample Type (C=comp, G=grab)	Matrix	Field Filtered Sample (Yes or No)	Perform MS/MSD (Yes or No)														Total Number of containers	Special Instructions/Note:
			Preservation Code:																		

Possible Hazard Identification
☐ *Non-Hazard* ☐ *Flammable* ☐ *Skin Irritant* ☐ *Poison B* ☐ *Unknown* ☐ *Radiological*
Sample Disposal (A fee may be assessed if samples are retained longer than 1 month)
☐ *Return To Client* ☐ *Disposal By Lab* ☐ *Archive For* ________ *Months*
Deliverable Requested: I, II, III, IV, Other (specify)
Special Instructions/QC Requirements:
Empty Kit Relinquished by:
Date:
Time:
Method of Shipment:

Relinquished by:	Date/Time:	Company	Received by:	Date/Time:	Company
Relinquished by:	Date/Time:	Company	Received by:	Date/Time:	Company
Relinquished by:	Date/Time:	Company	Received by:	Date/Time:	Company

Custody Seals Intact: ∆ Yes ∆ No
Custody Seal No.:
Cooler Temperature(s) °C and Other Remarks:

Ver: 11/01/2020

Figure 23-2

Sample Acceptance Policy

All incoming work will be evaluated against the criteria listed below. Where applicable, data from any samples that do not meet the criteria listed below will be noted on the laboratory report defining the nature and substance of the variation. In addition the client will be notified either by telephone, fax or e-mail ASAP after the receipt of the samples.

1. Samples must arrive with labels intact with a Chain of Custody filled out completely. The following information must be recorded.
   - *Client name, address, phone number and fax number (if available)*
   - *Project name and/or number*
   - *Unique sample identification*
   - *Date, time and location of sampling*
   - *The collectors name*
   - *The matrix description*
   - *The container description*
   - *The total number of each type of container*
   - *Preservatives used*
   - *Analysis requested*
   - *Requested turnaround time (TAT)*
   - *Any special instructions*
   - *Purchase Order number or billing information (e.g. quote number) if available*
   - *The date and time that each person received or relinquished the sample(s), including their signed name.*
   - Information must be legible

2. Samples must be properly labeled.

   - Use durable labels (labels provided by Eurofins TestAmerica are preferred)
   - Include a unique identification number
   - Include sampling date and time & sampler ID
   - Include preservative used.
   - Use indelible ink
   - **Information must be legible**

3. Proper sample containers with adequate volume for the analysis and necessary QC are required for each analysis requested.
4. Samples must be preserved according to the requirements of the requested analytical method. (See Sampling Guide)
5. Most analytical methods require chilling samples to 4o C (other than water samples for metals analysis). For these methods, the criteria are met if the samples are chilled to below 6o C and above freezing (0oC). For methods with other temperature criteria (e.g. some bacteriological methods require < 10 oC), the samples must arrive within + 2o C of the required temperature or within the method specified range. **Note:** Samples that are hand delivered to the laboratory immediately after collection may not have had time to cool sufficiently. In this case the samples will be considered acceptable as long as there is evidence that the chilling process has begun (arrival on ice).

> 5i.) Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 5. In these cases, the samples shall be considered acceptable if the samples were received on ice.
>
> 5ii.) If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required.
>
> 5iii.)Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection.

- Chemical preservation (pH) will be verified prior to analysis and documented, either in sample control or at the analyst's level. The project manager will be notified immediately if there is a discrepancy. If analyses will still be performed, all affected results will be flagged to indicate improper preservation.
- **FOR WATER SAMPLES TESTED FOR AVAILABLE / FREE CYANIDE (Method OIA-1677)**
  - In the Field: Samples will be collected in pre-preserved bottles for both a regular sample collection and a 1:50 diluted sample in case of the presence of sulfide.
    - The lab will test the samples for sulfide using lead acetate paper at the time of analysis and if sulfide is present in the sample above 50mg/L, the diluted sample will be analyzed.
    - If the water being collected may contain residual chlorine or other oxidizer, the sample should be treated at time of collection with sodium arsenite.
    - Water samples that require ortho-phosphorus must be filtered in the field within 15 minutes of sampling. Samples received without indication of filtration in the field will have results flagged for improper preservation.
- Water samples being collected for dissolved metals analysis should be filtered in the field within 15 minutes of sampling and prior to preservation.

- Samples for coliform analysis must be in sterile containers and must be free of residual chlorine. The bottle must be filled to above the 100mL mark.

6. For the laboratory to meet method requirements for the analysis of *Duplicate, Matrix Spikes* and/ or *Matrix Spike Duplicates*, extra volume for at least 1 samples should be collected.
   - If *Matrix Spikes* are required on a specific sample for your project, separate sample volumes for the required QC must be collected for the requested analyses.

7. For Volatile Organic analyses: Efforts should be made to minimize any air bubbles in aqueous volatile samples. Air bubbles also the escape of volatile organics. This is especially important because air bubbles tend to form in iced samples. Volatile vials containing air bubbles larger than a pea will be treated as non-conformances.
8. All samples submitted for Volatile Organic analyses, including by method 8011, must have a Trip Blank submitted at the same time. Eurofins TestAmerica will supply a blank with the bottle order.
9. Sample Holding Times
   - Eurofins TestAmerica will make every effort to analyze samples within the regulatory holding time. Samples must be received in the laboratory with enough time to perform the sample analysis. Except for short holding time samples (< 48hr HT) sample must be received with at least 48 hrs (working days) remaining on the holding time for us to ensure analysis.

   - Analyses that are designated as "field" analyses (Odor, pH, Dissolved Oxygen, Disinfectant Residual; a.k.a. Residual Chlorine, and Redox Potential) should be analyzed ASAP by the field sampler prior to delivering to the lab (within 15 minutes). However, if the analyses are to be performed in the laboratory, Eurofins TestAmerica will make every effort to analyze the samples within 24 hours from receipt of the samples in the testing laboratory. Samples for "field" analyses received after 4:00 pm on Friday or on the weekend will be analyzed no later than the next business day after receipt (Monday unless a holiday). Samples will remain refrigerated and sealed until the time of analysis. Samples analyzed in the laboratory will be qualified on the final report to indicate holding time exceedance.

10. The project manager will be notified if any sample is received in damaged condition. Eurofins TestAmerica will request that a sample be resubmitted for analysis. The laboratory will notify the client upon sample receipt if the samples exhibit obvious signs of damage, contamination or inadequate preservation.

11. Recommendations for packing samples for shipment.
    - Pack samples in Ice rather than "Blue" ice packs.

    - Soil samples should be placed in plastic zip-lock bags. The containers often have dirt around the top and do not seal very well and are prone to intrusion from the water from melted ice.

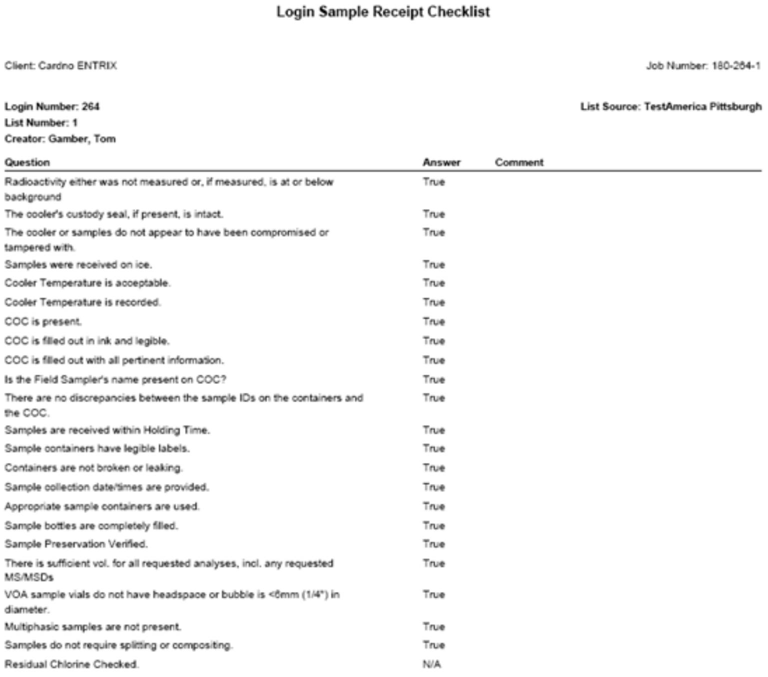
    - Water samples would be best if wrapped with bubble-wrap or paper (newspaper, or paper towels work) and then placed in plastic zip-lock bags.

    - Fill extra cooler space with bubble wrap.

12. If the conditions listed on the Acceptance Policy are not satisfactory and when lacking direction or agreement with the client, the sample will be rejected by the laboratory.

Figure 23-3

Example: Sample Receipt Checklist



Login Sample Receipt Checklist

Client: Cardno ENTRIX
Job Number: 180-264-1

Login Number: 264
List Number: 1
Creator: Gamber, Tom
List Source: TestAmerica Pittsburgh

Question	Answer	Comment
Radioactivity either was not measured or, if measured, is at or below background	True	
The cooler's custody seal, if present, is intact.	True	
The cooler or samples do not appear to have been compromised or tampered with.	True	
Samples were received on ice.	True	
Cooler Temperature is acceptable.	True	
Cooler Temperature is recorded.	True	
COC is present.	True	
COC is filled out in ink and legible.	True	
COC is filled out with all pertinent information.	True	
Is the Field Sampler's name present on COC?	True	
There are no discrepancies between the sample IDs on the containers and the COC.	True	
Samples are received within Holding Time.	True	
Sample containers have legible labels.	True	
Containers are not broken or leaking.	True	
Sample collection date/times are provided.	True	
Appropriate sample containers are used.	True	
Sample bottles are completely filled.	True	
Sample Preservation Verified.	True	
There is sufficient vol. for all requested analyses, incl. any requested MS/MSDs	True	
VOA sample vials do not have headspace or bubble is <6mm (1/4") in diameter.	True	
Multiphasic samples are not present.	True	
Samples do not require splitting or compositing.	True	
Residual Chlorine Checked.	N/A	

24) ASSURING THE QUALITY OF TEST RESULTS

24.1) Overview

In order to assure our clients of the validity of their data, the laboratory continuously evaluates the quality of the analytical process. The analytical process is controlled not only by instrument calibration as discussed in Section 20, but also by routine process quality control measurements (e.g. Blanks, Laboratory Control Samples (LCS), Matrix Spikes (MS), duplicates (DUP), surrogates, Internal Standards (IS)). These quality control checks are performed as required by the method or regulations to assess precision and accuracy. Quality control samples are to be treated in the exact same manner as the associated field samples being tested. In addition to the routine process quality control samples, Proficiency Testing (PT) Samples (concentrations unknown to laboratory) are analyzed to help ensure laboratory performance.

24.2) Controls

Sample preparation or pre-treatment is commonly required before analysis. Typical preparation steps include homogenization, solvent extraction, sonication, acid digestion, filtration, distillation, reflux, evaporation, drying and ashing. During these pre-treatment steps, samples are arranged into discreet manageable groups referred to as preparation (prep) batches. Prep batches provide a means to control variability in sample treatment. Control samples are added to each prep batch to monitor method performance and are processed through the entire analytical procedure with investigative/field samples.

24.3) Negative Controls

Table 24-1. Negative Controls

Control Type	Details
Method Blank (MB)	are used to assess preparation and analysis for possible contamination during the preparation and processing steps.
	The specific frequency of use for method blanks during the analytical sequence is defined in the specific standard operating procedure for each analysis. Generally it is 1 for each batch of samples; not to exceed 20 environmental samples.
	The method blank is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (e.g., Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).
	Reanalyze or qualify associated sample results when the concentration of a targeted analyte in the blank is at or above the reporting limit as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.
Calibration Blanks	are prepared and analyzed along with calibration standards where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses the calibration blank may be included in the calibration curve.
Instrument Blanks	are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample prep process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.

Table 24-1. Negative Controls

Control Type	Details
Trip Blank [1]	are required to be submitted by the client with each shipment of samples requiring aqueous and solid volatiles analyses (or as specified in the client's project plan). Additionally, trip blanks may be prepared and analyzed for volatile analysis of air samples, when required by the client. A trip blank may be purchased (certified clean) or is prepared by the laboratory by filling a clean container with pure deionized water that has been purged to remove any volatile compounds. Appropriate preservatives are also added to the container. The trip blank is sent with the bottle order and is intended to reflect the environment that the containers are subjected to throughout shipping and handling and help identify possible sources if contamination is found. The field sampler returns the trip blank in the cooler with the field samples.
Field Blanks [1]	are sometimes used for specific projects by the field samplers. A field blank prepared in the field by filling a clean container with pure reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)
Equipment Blanks [1]	are also sometimes created in the field for specific projects. An equipment blank is a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (TNI)
Holding Blanks	also referred to as refrigerator or freezer blanks, are used to monitor the sample storage units for volatile organic compounds during the storage of VOA samples in the laboratory.

[1] When known, these field QC samples should not be selected for matrix QC as it does not provide information on the behavior of the target compounds in the field samples. Usually, the client sample ID will provide information to identify the field blanks with labels such as "FB", "EB", or "TB."

Evaluation criteria and corrective action for these controls are defined in the specific standard operating procedure for each analysis. Also further detail is provided in SOP No. PT-QA-021.

24.3.1)
Negative Controls for Microbiological Methods – Microbiological Methods utilize a variety of negative controls throughout the process to ensure that false positive results are not obtained. These controls are critical to the validity of the microbiological analyses. Some of these negative controls are:

Table 24-2. Negative Controls for Microbiology

Control Type	Details
Sterility Checks (Media)	are analyzed for each lot of pre-prepared media, ready-to-use media and for each batch of medium prepared by the laboratory.
Filtration Blanks	blanks are run at the beginning and end for each sterilized filtration unit used in a filtration series. For pre-sterilized single use funnels a sterility check is performed on at least one funnel per lot.
Sterility checks (Sample Containers)	are performed on at least one container per lot of purchased, pre-sterilized containers. If containers are prepared and sterilized by the laboratory, one container per sterilization batch is checked. Container sterility checks are performed using non-selective growth media.
Sterility Checks (Dilution Water)	are performed on each batch of dilution water prepared by the laboratory and on each batch of pre-prepared dilution water. All checks are performed using non-selective growth media.
Sterility Checks (Filters)	are also performed on at least one filter from each new lot of membrane filters using non-selective growth media.

Negative culture controls demonstrate that a media does not support the growth of non-target organisms and ensures that there is not an atypical positive reaction from the target organisms. Prior to the first use of the media, each lot of pre-prepared selective media or batch of laboratory prepared selective media is analyzed with at least one known negative culture control as appropriate to the method.

24.4) Positive Controls

Control samples (e.g., QC indicators) are analyzed with each batch of samples to evaluate data based upon (1) Method Performance (Laboratory Control Sample (LCS) or Blank Spike (BS)), which entails both the preparation and measurement steps; and (2) Matrix Effects (Matrix Spike (MS) or Sample Duplicate (MD, DUP)), which evaluates field sampling accuracy, precision, representativeness, interferences, and the effect of the matrix on the method performed. Each regulatory program and each method within those programs specify the control samples that are prepared and/or analyzed with a specific batch.

Note that frequency of control samples vary with specific regulatory, methodology and project specific criteria. Complete details on method control samples are as listed in each analytical SOP.

24.4.1) Method Performance Control - Laboratory Control Sample (LCS)

The LCS measures the accuracy of the method in a blank matrix and assesses method performance independent of potential field sample matrix affects in a laboratory batch.

The LCS is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (for example: Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The LCS is spiked with verified known amounts of analytes or is made of a material containing known and verified amounts of analytes, taken through all preparation and analysis steps along with the field samples. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), a calibration verification standard may be reported as the LCS. In some instances where there is no practical clean solid matrix available, aqueous LCS's may be processed for solid matrices; final results may be calculated as mg/kg or ug/kg, assuming 100% solids and a weight equivalent to the aliquot used for the corresponding field samples, to facilitate comparison with the field samples.

Certified pre-made reference material purchased from a NIST/A2LA accredited vendor may also be used for the LCS when the material represents the sample matrix or the analyte is not easily spiked (e.g. solid matrix LCS for metals, TDS, etc.).

The specific frequency of use for LCS during the analytical sequence is defined in the specific standard operating procedure for each analysis. It is generally 1 for each batch of samples; not to exceed 20 environmental samples.

If the mandated or requested test method, or project requirements, do not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample (and Matrix Spike) where applicable (e.g. no spike of pH). However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, at a minimum, a representative number of the listed components (see below) shall be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

- For methods that have 1-10 target analytes, spike all components.
- For methods that include 11-20 target analytes, spike at least 10 or 80%, whichever is greater.
- For methods with more than 20 target analytes, spike at least 16 components.
- Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.
- Exception: Due to analyte incompatibility between the various PCB aroclors, aroclors 1016 and 1260 are used for spiking as they cover the range of all of the aroclors. Specific aroclors may be used by request on a project specific basis.

24.4.1.1) Positive Controls for Microbiological Methods

- Each lot of pre-prepared media (including chromofluorogenic reagent) and each batch of laboratory prepared media is tested with a pure culture of known positive reaction.
- In addition, every analytical batch also contains a pure culture of known positive reaction

A pure culture of known negative reaction is also tested with each analytical batch to ensure specificity of the procedure.

24.5) Sample Matrix Controls

Table 24-3 Sample Matrix Control

Control Type	Details	
Matrix Spikes (MS)	Use	used to assess the effect sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used;
	Typical Frequency [1]	At a minimum, with each matrix-specific batch of samples processed, an MS is carried through the complete analytical procedure. Unless specified by the client, samples used for spiking are randomly selected and rotated between different client projects. If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. Refer to the method SOP for complete details
	Description	essentially a sample fortified with a known amount of the test analyte(s).
Surrogate	Use	Measures method performance to sample matrix (organics only).
	Typical Frequency [1]	Are added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. The recovery of the surrogates is compared to the acceptance limits for the specific method. Poor surrogate recovery may indicate a problem with sample composition and shall be reported, with data qualifiers, to the client whose sample produced poor recovery.
	Description	Are similar to matrix spikes except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environment samples.
Duplicates[2]	Use	For a measure of analytical precision, with each matrix-specific batch of samples processed, a matrix duplicate (MD or DUP) sample, matrix spike duplicate (MSD), or LCS duplicate (LCSD) is carried through the complete analytical procedure.
	Typical Frequency [1]	Duplicate samples are usually analyzed with methods that do not require matrix spike analysis.
	Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.
Internal Standards	Use	Are spiked into all environmental and quality control samples (including the initial calibration standards) to monitor the qualitative aspect of organic and some inorganic analytical measurements.
	Typical Frequency [1]	All organic and ICP methods as required by the analytical method.
	Description	Used to correct for matrix effects and to help troubleshoot variability in analytical response and are assessed after data acquisition. Possible sources of poor internal standard response are sample matrix, poor analytical technique or instrument performance.

[1] See the specific analytical SOP for type and frequency of sample matrix control samples.

[2] LCSD's are normally not performed except when regulatory agencies or client specifications require them. The recoveries for the spiked duplicate samples must meet the same laboratory established recovery limits as the accuracy QC samples. If an LCSD is analyzed both the LCS and LCSD must meet the same recovery criteria and be included in the final report. The precision measurement is reported as "Relative Percent Difference" (RPD). Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

24.6) Acceptance Criteria (Control Limits)

As mandated by the test method and regulation, each individual analyte in the LCS, MS, or Surrogate Spike is evaluated against the control limits published in the test method. Where there are no established acceptance criteria, the laboratory calculates in-house control limits with the use of control charts or, in some cases, utilizes client project specific control limits. When this occurs, the regulatory or project limits will supersede the laboratory's in-house limits.

Note: For methods, analytes and matrices with very limited data (e.g., unusual matrices not analyzed often), interim limits are established using available data or by analogy to similar methods or matrices.

Once control limits have been established, they are verified, reviewed, and updated if necessary on an annual basis unless the method requires more frequent updating. Control limits are established per method (as opposed to per instrument) regardless of the number of instruments utilized.

Laboratory generated % Recovery acceptance (control) limits are generally established by taking ± 3 Standard Deviations (99% confidence level) from the average recovery of a minimum of 20-30 data points (more points are preferred).

- Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV) (Unless the analytical method specifies a tighter limit).
- In-house limits cannot be any wider than those mandated in a regulated analytical method. Client or contract required control limits are evaluated against the laboratory's statistically derived control limits to determine if the data quality objectives (DQOs) can be achieved. If laboratory control limits are not consistent with DQOs, then alternatives must be considered, such as method improvements or use of an alternate analytical method.

- The lowest acceptable recovery limit will be 10% (the analyte must be detectable and identifiable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable and identifiable.
- The maximum acceptable recovery limit will be 150%.
- The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit is 10%.
- If either the high or low end of the control limit changes by < 5% from previous, the control chart is visually inspected and, using professional judgment, they may be left unchanged if there is no effect on laboratory ability to meet the existing limits.

24.6.1)
The lab must be able to generate a current listing of their control limits and track when the updates are performed. Current and historical limits are maintained in TALS, along with the effective dates. In addition, the laboratory must be able to recreate historical control limits. Refer to laboratory SOP PT-QA-021, *Quality Control Program*, for details on the creation, evaluation and application of statistical control limits.

24.6.2)
A LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined as out of control and should be reanalyzed if possible. If reanalysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 12) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

- The analyte results are below the reporting limit and the LCS is above the upper control limit.
- If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit. For further detail refer to laboratory SOP PT-QA-021 and method specific SOPs.
- For TNI work, there are an allowable number of Marginal Exceedances (ME):

<11 analytes	0 marginal exceedances are allowed
11 – 30 Analytes	1 marginal exceedance is allowed
31-50 Analytes	2 marginal exceedances are allowed
51-70 Analytes	3 marginal exceedances are allowed
71-90 Analytes	4 marginal exceedances are allowed
> 90 Analytes	5 marginal exceedances are allowed

  - Marginal exceedances are recovery exceedances between 3 SD and 4 SD from the mean recovery limit (TNI).
  - Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systematic problem. The source of the error must be located and corrective action taken. The laboratory has a system to monitor marginal exceedances to ensure that they are random.

Though marginal exceedances may be allowed, the data must still be qualified to indicate it is outside of the normal limits.

24.6.3)
If the MS/MSDs do not meet acceptance limits, the MS/MSD and the associated parent sample are reported with a qualifier for those analytes that do not meet limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and reanalyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in SOP No. PT-QA-021 – Laboratory Quality Control Program, analytical method SOPs and in Section 12 of this document.

24.6.4)
If a surrogate standard falls outside the acceptance limits, and if there is not obvious chromatographic matrix interference, reanalyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious chromatographic interference, results are reported from the original analysis and a qualifier is added. If the reanalysis meets surrogate recovery criteria, the second run is reported (or both are reported if requested by the client). Under certain circumstances, where all of the samples are from the same location and share similar chromatography, the reanalysis may be performed on a single sample rather than all of the samples and if the surrogate meets the recovery criteria in the reanalysis, all of the affected samples would require reanalysis.

24.7) Additional Procedures to Assure Quality Control

The laboratory has written and approved method SOPs to assure the accuracy of the test method including calibration (see Section 20), use of certified reference materials (see Section 21) and use of PT samples (see Section 15).

A discussion regarding MDLs, Limit of Detection (LOD) and Limit of Quantitation (LOQ) can be found in Section 19.

Use of formulae to reduce data is discussed in the method SOPs and in Section 20.

Selection of appropriate reagents and standards is included in Section 9 and 21.

A discussion on selectivity of the test is included in Section 5.

Constant and consistent test conditions are discussed in Section 18.

The laboratories sample acceptance policy is included in Section 23.

25) Reporting Results

25.1) Overview

The results of each test are reported accurately, clearly, unambiguously, and objectively in accordance with State and Federal regulations as well as client requirements. Analytical results are issued in a format that is intended to satisfy customer and laboratory accreditation requirements as well as provide the end user with the information needed to properly evaluate the results. Where there is conflict between client requests and laboratory ethics or regulatory requirements, the laboratory's ethical and legal requirements are paramount, and the laboratory will work with the client during project set up to develop an acceptable solution. Refer to Section 7.

A variety of report formats are available to meet specific needs.

In cases where a client asks for simplified reports, there must be a written request from the client. There still must be enough information that would show any analyses that were out of conformance (QC out of limits) and there should be a reference to a full report that is made available to the client. Review of reported data is included in Section 19.

25.2) Test Reports

Analytical results are reported in a format that is satisfactory to the client and meets all requirements of applicable accrediting authorities and agencies. A variety of report formats are available to meet specific needs. The report is printed on laboratory letterhead, reviewed, and signed by the appropriate project manager. At a minimum, the standard laboratory report shall contain the following information:

25.2.1)
A report title (e.g. Analytical Report) on the cover page with a “Result” column header on the sample result page.

25.2.2)
The cover page shall include the laboratory name, address and telephone number.

25.2.3)
A unique identification of the report (e.g. Eurofins Environment Testing America Job ID#) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as page # of ## at the bottom of the page. Where the first number is the page number and the second is the total number of pages.

25.2.4)
A copy of the chain of custody (COC).

- Any COCs involved with Subcontracting are included.

25.2.5)
The name and address of client and a project name/number, if applicable.

25.2.6)
Client project manager or other contact.

25.2.7)
Description and unambiguous identification of the tested sample(s) including the client identification code.

25.2.8)
Date of receipt of sample, date and time of collection, and date(s) and time of test preparation and performance, and time of preparation or analysis if the required holding time for either activity is less than or equal to 72 hours.

25.2.9)
Date reported or date of revision, if applicable.

25.2.10)
Method of analysis including method code (EPA, Standard Methods, etc).

25.2.11)
Reporting Limit

25.2.12)
Method detection limits (if requested)

25.2.13)
Definition of Data qualifiers and reporting acronyms (e.g. ND).

25.2.14)
Sample results.

25.2.15)
QC data consisting of method blank, surrogate, LCS, and MS/MSD recoveries and control limits are included unless the client specifies they do not require reporting the QC.

25.2.16)
Condition of samples at receipt including temperature. This may be accomplished in the case narrative or by attaching sample login sheets. The temperature is documented on the sample receipt checklist and noted in the report case narrative.

25.2.17)
A statement expressing the validity of the results, that the source methodology was followed and all results were reviewed for error.

25.2.18)
A statement to the effect that the results relate only to the items tested and the sample as received by the laboratory, except when information is provided by the client. When data is provided by the client there shall be a clear indication of it, and a disclaimer shall be put in the report when the client supplied data can affect the validity of the test.

25.2.19)
A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory coordinator.

25.2.20)
A signature and title of the person(s) accepting responsibility for the content of the report and date of issue (Signatories are appointed by the Lab Director).

25.2.21)
When TNI accreditation is required, the lab shall certify that the test results meet all requirements of TNI or provide reasons and/or justification if they do not.

25.2.22)
If applicable, the laboratory includes a cover letter.

25.2.23)
Where applicable, a narrative to the report that explains the issue(s) and corrective action(s) taken in the event that a specific accreditation or certification requirement was not met.

25.2.24)
When soil samples are analyzed, a specific identification as to whether soils are reported on a “wet weight” or “dry weight” basis.

25.2.25)
Appropriate laboratory certification number for the state of origin of the sample, if applicable.

25.2.26)
If only part of the report is provided to the client (client requests some results before all of it is complete), it must be clearly indicated on the report (e.g., preliminary report). A complete report must be sent once all of the work has been completed.

25.2.27)
Any non-Eurofins Environment Testing America subcontracted analysis results are provided as a separate report on the official letterhead of the subcontractor. All Eurofins Environment Testing America subcontracting is clearly identified on the report as to which laboratory performed a specific analysis.

25.2.28)
A clear statement notifying the client that non-accredited tests were performed and directing the client to the laboratory’s accreditation certificates of approval shall be provided when non-accredited tests are included in the report.

25.2.29)
Where the laboratory is responsible for the sampling stage, in addition to the requirements listed above, reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

- The date of sampling
- Unambiguous identification of the material sampled
- The location of sampling
- A reference to the sampling plan and procedures, and deviations, additions to or exclusions from the sampling procedures
- Details of any environmental conditions during sampling that affect the interpretation of test results
- Information required to evaluate measurement uncertainty for subsequent testing

Note: It is required by the PA DEP that non-accredited parameters be clearly identified on the sample results.

Note: Refer to the NDSC Document on Electronic Reporting and Signature Policy (No. NDSC-US-IT-QP46227) for details on internally applying electronic signatures of approval.

25.3) Reporting Level Or Report Type

The laboratory offers four levels of quality control reporting. Each level, in addition to its own specific requirements, contains all the information provided in the preceding level. The packages provide the following information in addition to the information described above:

- Level I is a report with the features described in Section 25.2 above.
- Level II is a Level I report plus summary information, including results for the method blank reported to the laboratory MDL, percent recovery for laboratory control samples and matrix spike samples, and the RPD values for all MSD and sample duplicate analyses.
- Level III contains all the information supplied in Level II, but presented on the CLP-like summary forms, and relevant calibration information. A Level II report is not included, unless specifically requested. No raw data is provided.
- Level IV is the same as Level III with the addition of all raw supporting data.

In addition to the various levels of QC packaging, the laboratory also provides reports in diskette deliverable form. Initial reports may be provided to clients by facsimile. Procedures used to ensure client confidentiality are outlined in Section 25.6.

25.4) Electronic Data Deliverables (EDDs)

EDDs are routinely offered as part of Eurofins Pittsburgh's services in addition to the test report as described in section 25.2. When NELAP accreditation is required and both a test report and EDD are provided to the client, the official version of the test report will be the combined information of the report and the EDD. Data qualifiers appearing on the test report must be included in the EDD.

Eurofins Pittsburgh offers a variety of EDD formats including Environmental Restoration Information Management System (ERPIMS), Staged Electronic Data Deliverable (SEDD) Environmental Quality Information System (EQuIS), Electronic Deliverable Format (EDF), Excel and custom files as requested by the client.

EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. Once the facility has committed to providing data in a specific electronic format, the coding of the format may need to be performed. This coding is documented and validated. The validation of the code is retained by the IT staff coding the EDD.

EDDs shall be subject to a review to ensure their accuracy and completeness. If EDD generation is automated, review may be reduced to periodic screening if the laboratory can demonstrate that it can routinely generate that EDD without errors. Any revisions to the EDD format must be reviewed until it is demonstrated that it can routinely be generated without errors. If the EDD can be reproduced accurately and if all subsequent EDDs can be produced error-free, each EDD does not necessarily require a review.

25.5) Supplemental Information For Test

The lab identifies any unacceptable QC analyses or any other unusual circumstances or observations such as environmental conditions and any non-standard conditions that may have affected the quality of a result. This is typically in the form of a footnote or a qualifier and/or a narrative explaining the discrepancy in the front of the report.

Numeric results with values outside of the calibration range, either high or low are qualified as estimated.

Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications is required, including identification of test results derived from any sample that did not meet TNI sample acceptance requirements such as improper container, holding time, or temperature.

Where applicable, a statement on the estimated uncertainty of measurements; information on uncertainty is needed when a client's instructions so require.

When, as required by the client and agreed to by Eurofins Pittsburgh, the report includes a statement of conformity to specification or standard (see Special Services, Section 7.4), the report shall clearly identify:

- To which results the statement applies
- Which specifications, standard or parts thereof are met or no
- The decision rule that was applied unless the decision rule is inherent in the requested specification or standard, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule.

Opinions and Interpretations - The test report contains objective information, and generally does not contain subjective information such as opinions and interpretations. If such information is required by the client, the Laboratory Director will determine if a response can be prepared. If so, the Laboratory Director will designate the appropriate member of the management team to prepare a response. The response will be fully documented, and reviewed by the Laboratory Director, before release to the client. There may be additional fees charged to the client at this time, as this is a non-routine function of the laboratory.

Note: Review of data deliverable packages for submittal to regulatory authorities requires responses to non-conforming data concerning potential impact on data quality. This necessitates a limited scope of interpretation, and this work is performed by the Manager(s)/Team Leaders or as assigned by the lab Director. This is the only form of "interpretation" of data that is routinely performed by the laboratory.

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator.

25.6) Environmental Testing Obtained From Subcontractors

If the laboratory is not able to provide the client the requested analysis, the samples would be subcontracted following the procedures outlined in the NDSC Document on Subcontracting (NDSC-US-LEG-SOP44936).

Data reported from analyses performed by a subcontractor laboratory are clearly identified as such on the analytical report provided to the client. Results from a subcontract laboratory outside of Eurofins Environment Testing America are reported to the client on the subcontract laboratory's original report stationary and the report includes any accompanying documentation.

25.6.1)

Report deliverable formats are discussed with each new client. If a client requests that reports be faxed or e-mailed, the reports are to meet all requirements of this document, including a cover letter.

25.7) Client Confidentiality

The laboratory will ensure the highest standards of quality and integrity of the data and services provided to our clients.

The laboratory is responsible for maintaining in confidence all client information obtained or created. In situations involving the transmission of environmental test results by telephone, facsimile or other electronic means, client confidentiality must be maintained.

The laboratory will not intentionally divulge to any person (other than the Client or any other person designated by the Client in writing) any information regarding the services provided by the laboratory or any information disclosed to the laboratory by the Client. Furthermore, information <u>known</u> to be potentially endangering to national security or an entity's proprietary rights will not be released.

Information about the client obtained from sources other than the client (e.g, complaint, regulators) shall be confidential between client and laboratory. The source of this information shall be confidential to the laboratory and shall not be shared with the client, unless agreed to by the source.

Note: This shall not apply to the extent that the information is required to be disclosed by the laboratory under the compulsion of legal process. The laboratory will, to the extent feasible, provide reasonable notice to the client before disclosing the information.

Note: Authorized representatives of an accrediting authority are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.

25.7.1)
Report deliverable formats are discussed with each new client. If a client requests that reports be e-mailed, the reports are to meet all requirements of this document.

25.8) Format of Reports

The format of reports is designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse.

25.9) Amendments To Test Reports

Corrections, additions, or deletions to reports are only made when justification arises through supplemental documentation. Justification is documented using the laboratory’s corrective action system (refer to Section 12).

The revised report is retained on the data server, as is the original report. The revised report is stored in the data server under the job number followed by “Rev (n)” where ‘n’ is the revision number. The revised report will have the words “Revision (n)” on the report cover page beneath the report date.

When the report is re-issued, a notation of “report re-issue“ is placed on the cover/signature page of the report or at the top of the narrative page with a brief explanation of reason for the re-issue and a reference back to the last final report generated.

25.10) Policies On Client Requests For Amendments

25.10.1) Policy on Data Omissions or Reporting Limit Increases

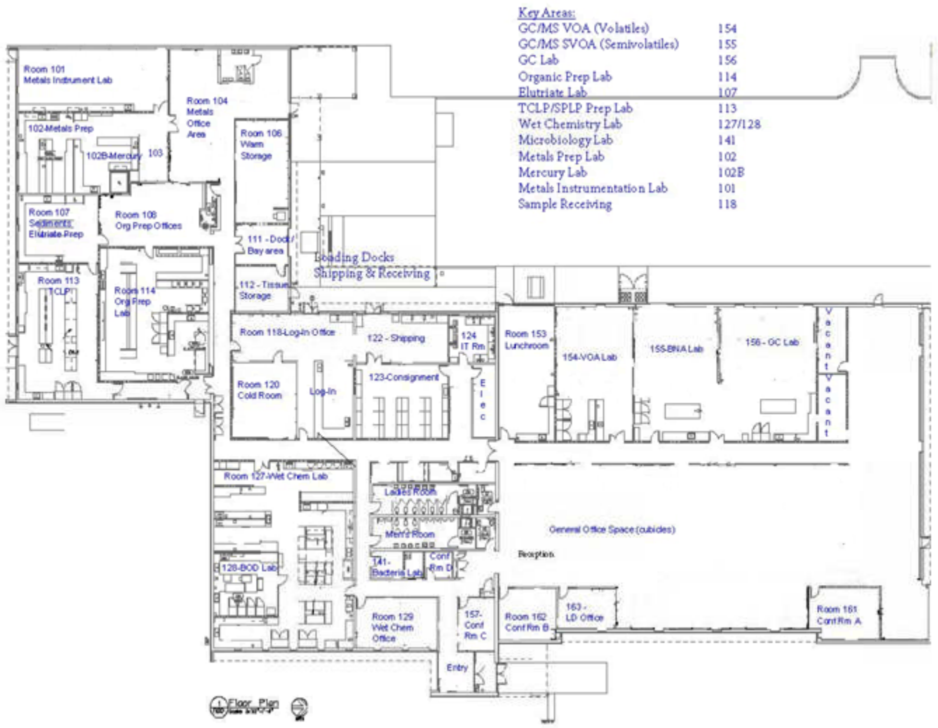
Fundamentally, our policy is simply to not omit previously reported results (including data qualifiers) or to not raise reporting limits and report sample results as ND. This policy has few exceptions. Exceptions are:

- Laboratory error
- Sample identification is indeterminate (confusion between COC and sample labels)
- An incorrect analysis (not analyte) was requested (e.g., COC lists 8315 but client wanted 8310). A written request for the change is required.
- Incorrect limits reported based on regulatory requirements
- The requested change has absolutely *no possible* impact on the interpretation of the analytical results and there is *no possibility* of the change being interpreted as misrepresentation by anyone inside or outside of our company.

25.10.2) Multiple Reports

The laboratory does not issue multiple reports for the same job number where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by QA.

Appendix 1
Laboratory Floor Plan



Appendix 2
Glossary/Acronyms

Glossary:

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Analyst: The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (TNI)

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis. (TNI)

Anomaly: A condition or event, other than a deficiency, that may affect the quality of the data, whether in the laboratory’s control or not.

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation). (TNI)

Audit: A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives. (TNI)

Batch: Environmental samples which 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 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 twenty (20) samples. (TNI)

Bias: The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample’s true value). (TNI)

Blank: A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC)

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. (TNI)

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 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: The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (TNI)

Calibration Standard: A substance or reference material used to calibrate an instrument (QAMS)

Certified Reference Material (CRM): A reference material, accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute. (TNI)

Chain of Custody (COC) Form**:** 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 types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. (TNI)

Compromised Samples: Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation require analysis, the results must be appropriately qualified.

Confidential Business Information (CBI): Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. TNI and its representatives agree to safeguarding identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation: 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. (TNI)

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. (ANSI/ASQC E4-1994)

Correction*:* Actions necessary to correct or repair analysis specific non-conformances. The acceptance criteria for method specific QC and protocols as well as the associated corrective actions. The analyst will most frequently be the one to identify the need for this action as a result of calibration checks and QC sample analysis**.** No significant action is taken to change behavior, process or procedure.

Corrective Action: The action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data re of acceptable quality (i.e., that they meet specified acceptance criteria). (TNI)

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collation into a more useable form. (TNI)

Data Review Checker: Automated data review feature in TALS that compares data entered to list of control and preventative review requirements and presents all findings to the first level data reviewer for response or correction.

Deficiency: An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC), whether in the laboratory’s control or not.

Demonstration of Capability: A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision. (TNI)

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 if performed. (ASQC)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

Equipment Blank: Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

External Standard Calibration: Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Field Blank: Blank prepared in the field by filing a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken (EPA OSWER)

Field of Accreditation: Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Holding Times : The maximum times that samples may be held prior to analyses and still be considered valid or not compromised. (40 CFR Part 136)

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical test method. (TNI)

Internal Standard Calibration: Calibrations for methods that utilize internal standards to compensate for changes in instrument conditions.

Instrument Blank: A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Instrument Detection Limit (IDL): The minimum amount of a substance that can be measured with a specified degree of confidence that the amount is greater than zero using a specific instrument. The IDL is associated with the instrumental portion of a specific method only, and sample preparation steps are not considered in its derivation. The IDL is a statistical estimation at a specified confidence interval of the concentration at which the relative uncertainty is ± 100%. The IDL represents a range where qualitative detection occurs on a specific instrument. Quantitative results are not produced in this range.

Laboratory Control Sample (however named, such as laboratory fortified blank, 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, taken through all preparation and analysis 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 assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method, or more frequently if so required by the reference method, except for analytes for which spiking solutions are not available such as, total volatile solids, odor, temperature, or dissolved oxygen. The results of these samples shall be used to determine batch acceptance.

Least Squares Regression (1st Order Curve): The least squares regression is a mathematical calculation of a straight line over two axes. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for organics and 0.995 for inorganics.

Limit of Detection (LOD): [a.k.a., Method Detection Limit (MDL]: The MDL is the minimum measured quantity of a substance that can be reported with 99% confidence that the concentration is distinguishable from method blank results, consistent with 40CFR Part 136 Appendix B, August, 2017.

Limit(s) of Quantitation (LOQ) [a.k.a., Reporting Limit]: The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. (TNI)

(QS) Matrix: The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated as a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges, and other matrices with >15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air *& Emissions*: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (TNI)

Matrix Spike (spiked sample or fortified sample): 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 (spiked sample or fortified sample duplicate): A replicate matrix spike prepared and analyzed to obtain a measure of the precision of the recovery for each analyte.
Method Blank: A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Method Detection Limit: See Limit of Detection (LOD)

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

Non-conformance**:** An indication, judgment, or state of not having met the requirements of the relevant specifications, contract, or regulation.

Observation: A record of phenomena that (1) may assist in evaluation of the sample data; (2) may be of importance to the project manager and/or the client, and yet not at the time of the observation have any known effect on quality.

Performance Audit: The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

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.

Precision: 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: Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis. (TNI)

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (TNI)

Proficiency Testing Program: 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. (TNI)

Proficiency Test Sample (PT): A sample, the composition of which is unknown to the laboratory and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (TNIS)

Quality Assurance: An integrated system of management activities involving planning, implementation, assessment, ~~,~~ reporting and quality improvement to ensure that a process, item, product or service is of the type of quality needed and expected by the client. (TNI)

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. (EAP-QAD)

Quality Control: 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. (TNI)

Quality Control Sample: 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. (TNI)

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (TNI)

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, and assessing work performed by the organization and for carrying out required QA and QC activities. (TNI)

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records. (TNI)

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions.

Reference Material: Material or substance one or more properties of which are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

Reference Standard: Standard used for the calibration of working measurement standards in a given organization or a given location. (TNI)

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Second Order Polynomial Curve (Quadratic): The 2nd order curves are a mathematical calculation of a slightly curved line over two axis. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The 2nd order regression will generate a coefficient of determination (COD or r^2) that is a measure of the "goodness of fit" of the quadratic curvature the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

Selectivity: 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. (TNI)

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (TNI)

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: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting NELAC and meets the approval requirements of standard adoption organizations procedures and policies. (TNI)

Standard Operating Procedures (SOPs): A written document which 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. (TNI)

Storage Blank: A blank matrix stored with field samples of a similar matrix (volatiles only) that measures storage contribution to any source of contamination.

Surrogate: A substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes.

Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with sample composition and shall be reported to the client whose sample produced poor recovery. (QAMS)

Systems Audit (also Technical Systems Audit): A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Manager: A member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results

Technology: A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. (TNI)

Trip Blank:
A blank matrix placed in a sealed container at the laboratory that is shipped, held unopened in the field, and returned to the laboratory in the shipping container with the field samples.

Uncertainty:
A parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measured value.

Acronyms:

CAR – Corrective Action Report
CCV – Continuing Calibration Verification
CF – Calibration Factor
CFR – Code of Federal Regulations
COC – Chain of Custody
DOC – Demonstration of Capability
DQO – Data Quality Objectives
DUP - Duplicate
EHS – Environment, Health and Safety
EPA – Environmental Protection Agency
GC - Gas Chromatography
GC/MS - Gas Chromatography/Mass Spectrometry
HPLC - High Performance Liquid Chromatography
ICP - Inductively Coupled Plasma Atomic Emission Spectroscopy
ICP/MS – ICP/Mass Spectrometry
ICV – Initial Calibration Verification
IDL – Instrument Detection Limit
IH – Industrial Hygiene
IS – Internal Standard
LCS – Laboratory Control Sample
LCSD – Laboratory Control Sample Duplicate
LIMS – Laboratory Information Management System
LOD – Limit of Detection
LOQ – Limit of Quantitation
MDL – Method Detection Limit
MDLCK – MDL Check Standard
MDLV – MDL Verification Check Standard
MRL – Method Reporting Limit Check Standard
MS – Matrix Spike
MSD – Matrix Spike Duplicate
MSDS - Material Safety Data Sheet
NELAP - National Environmental Laboratory Accreditation Program
PT – Performance Testing
TNI – The NELAC Institute
QAM – Quality Assurance Manual
QA/QC – Quality Assurance / Quality Control
QAPP – Quality Assurance Project Plan
RF – Response Factor
RPD – Relative Percent Difference
RSD – Relative Standard Deviation
SD – Standard Deviation
SOP: Standard Operating Procedure
TAT – Turn-Around-Time
VOA – Volatiles
VOC – Volatile Organic Compound

Appendix 3

Laboratory Certifications, Accreditations, Validations

Eurofins Pittsburgh maintains certifications, accreditations, certifications, and validations with numerous state and national entities. Programs vary but may include on-site audits, reciprocal agreements with another entity, performance testing evaluations, review of the QA Manual, Standard Operating Procedures, Method Detection Limits, training records, etc. At the time of this QA Manual revision, the laboratory has accreditation / certification / licensing with the following organizations:

Organization	Certificate Number Or Laboratory ID Number
Arkansas	88-0690
California ELAP	2891
Connecticut	PH-0688
Florida	E871008
Illinois	002602
Kansas	E-10350
Kentucky	KY98043
Louisiana	04041
Maine	2020007
Minnesota	042-999-482
Nevada	PA00164
New Hampshire	203010
New Jersey	PA005
New York	11182
North Carolina	434
North Dakota	R-227
Oregon	PA-2151
Pennsylvania	02-00416
Rhode Island	LAO00362

South Carolina	89014002
Texas	T104704528
Utah	STLP
USDA	P330-10-00139
USDA	P-Soil -01
Virginia VELAP	460189
West Virginia	142
Wisconsin	998027800

The certificates and parameter lists (which may differ) are available, upon request, from a laboratory representative. They may be found on the Corporate web site, the laboratory's public server and in the QA web page.

Appendix 4

Eurofins Pittsburgh Laboratory SOP List

Document No.	Title
PT-FS-001	Field Measurement of Dissolved Oxygen (DO) Method: SM 4500-O G
PT-FS-002	Field Measurement of Total Residual Chlorine Method: SM 4500-Cl G
PT-FS-003	Field Measurement of pH Method: SM 4500 H+B
PT-FS-004	General Sampling Instructions
PT-GC-001	Gas Chromatographic Analysis of Herbicides, SW-846 Method 8151A
PT-GC-002	Analysis of Organochlorine Pesticides and PCBs by Method 608
PT-GC-004	1,2-Dibromoethane(EDB) and 1,2-Dibromo-3-Chloropropane(DBCP) in Water by Microextraction and Gas Chromatography, Method 8011
PT-GC-005	Polychlorinated Biphenyls (PCBs) and PCBs as Congeners by GC/ECD - Method: SW-846 8082 and 8082A
PT-GC-006	Chlorinated Pesticides - Method: SW-846 8081A/B
PT-GC-007	Organophosphorus Pesticides by Gas Chromatography - Method: SW-846 8141A and 8141B
PT-GC-009	Determination of Inorganic Anions by Ion Chromatography EPA Method 300 SW-846 Method 9056A
PT-GC-010	TOC Analysis for Solids by Lloyd Kahn Method
PT-GC-013	Determination of Particulate Organic Carbon in Sediment and Estuarine / Coastal Water Matrices
PT-GC-014	Halogenated Organic Compounds by Direct Injection GC/ECD
PT-GC-015	Analysis of Organochlorine Pesticides and PCBs by EPA Method 608.3
PT-HS-001	Pittsburgh Facility Addendum to Eurofins TestAmerica Corporate Environmental Health & Safety Manual (CW-E-M-001)
PT-HS-002	Bloodborne Pathogen Exposure Control Path
PT-IP-002	Acid Digestion of Soils, SW-846 Method 3050B
PT-IP-003	Acid Digestion of Aqueous Samples by SW-846 Methods 3005A, 3010A and EPA Methods 200.7 and 200.8
PT-IT-001	Data Backup Procedures
PT-MI-001	Total Coliforms and E. coli – Presence/Absence Test Using Colilert
PT-MS-001	Semivolatile Organic Anaysis by GC/MS, Method 625
PT-MS-002	Volatile Organics by GC/MS Based on Method 624
PT-MS-005	VOA Holding Blanks
PT-MS-008	GC/MS Analysis for Semivolatile Organics, Methods: SW-846 8270C & D
PT-MS-010	Determination of Volatile Organics by GC/MS Methods: SW-846 8260B & C
PT-MS-011	Semivolatile Organic Analysis by GCMS, EPA Method 625.1
PT-MS-012	Volatile Organic Analysis by GCMS, EPA Method 624.1
PT-MT-001	Inductively Coupled Plasma-Atomic Emission Spectroscopy, Spectrometric Method for Trace Element Analyses, SW-846 Method 6010B, 6010C, 6010D and EPA Method 200.7
PT-MT-002	Analysis of Metals by Inductively Coupled Plasma/Mass Spectrometry (ICPMS) for Methods 200.8, 6020, 6020A
PT-MT-005	Preparation and Analysis of Mercury by Cold Vapor Atomic Absorption
PT-OP-001	Extraction and Cleanup of Organic Compounds from Waters and Solids, Based on SW-846 3500 and 600 Series Methods
PT-OP-002	Simplified Laboratory Runoff Procedure (SLRP)

Document No.	Title
PT-OP-003	Standard Elutriate Test (SET)
PT-OP-004	Toxicity Characteristic Leaching Procedure and Synthetic Precipitation Leaching Procedure
PT-OP-005	Modified and Effluent Elutriate Tests (MET and EET)
PT-OP-006	Long Tube Column Settling Test
PT-OP-007	Illinois Re-suspension Tests
PT-OP-008	Dredging Elutriate Test (DRET)
PT-OP-009	Sequential Batch Leach Test (SBLT) for Freshwater Sediments
PT-OP-011	Extractable Residue (Lipids) from Animal Tissue
PT-OP-015	Modified Multiple Extraction Procedure Method: SW-846 1320
PT-OP-016	Porewater Generation
PT-OP-017	Liquid-Solid Partitioning as a Function of Extract pH in Solid Materials using a Parallel Batch Procedure SW-846 Method 1313
PT-OP-018	Liquid-Solid Partitioning as a Function of Liquid-to-Solid Ratio in Solid Materials using a Parallel Batch Procedure SW-846 Method 1316
PT-OP-019	Mass Transfer Rates of Constituents in Monolithic or Compacted Granular Materials using a Semi-Dynamic Tank Leaching Procedure SW-846 Method 1315
PT-OP-020	Standard Test Method for 24-h Batch-Type Measurement of Contaminant Sorption by Soils and Sediments ASTM D4646-03
PT-OP-021	Liquid-Solid Partitioning as a Function of Liquid-to-Solid Ratio for Constituents in Solid Materials using an Up-Flow Percolation Column Procedure SW-846 Method 1314
PT-OP-022	Low Volume Extraction and Cleanup of Organic Compounds from Waters Method: SW846 3500 Series
PT-OP-023	Measurement of the Leachability of Solidified Wastes by a Short Term Test Procedure Modified ANSI/ANS-16.1-2003
PT-OP-025	Soil/Sediment Amendment Procedure
PT-OP-026	Extraction of Organic Compounds from Solids, Sediments, Tissues, and Wipes Based on SW-846 3500 Series Methods
PT-OP-027	Extraction of Herbicides by SW846 Method 8151A
PT-OP-028	Clean-up of Organic Extracts by SW-846 3600 Series Methods
PT-OP-030	Handling and Preparation of Biota and Tissue Samples
PT-OP-031	Australian Standard Leaching Procedure - AS 4439.3-1997
PT-QA-001	Employee Orientation & Training
PT-QA-002	Internal Auditing
PT-QA-003	Glassware Clean-up for Organic/Inorganic Procedures
PT-QA-004	Quarantine Soil Procedure
PT-QA-005	Measurement Uncertainty
PT-QA-006	Procurement of Standards and Materials; Labeling and Traceability
PT-QA-007	Detection Limits
PT-QA-008	Thermometer and Barometer Calibration and Temperature Monitoring
PT-QA-009	Rounding and Significant Figures
PT-QA-010	Document Development and Control
PT-QA-012	Selection and Calibration of Balances and Weights
PT-QA-013	Independent QA Data Review
PT-QA-014	Reporting Limits
PT-QA-016	Nonconformance & Corrective Action System
PT-QA-017	Aqueous Pipette Calibration – Gravimetric Method
PT-QA-018	Technical Data Review Requirements
PT-QA-019	Records Information Management
PT-QA-021	Laboratory Quality Control Program
PT-QA-022	Equipment Maintenance
PT-QA-024	Subsampling

Document No.	Title
PT-QA-026	Container Accuracy Verification – Gravimetric
PT-QA-031	Internal Chain of Custody
PT-SR-001	Sample Receipt & Login
PT-SR-002	Bottle Order Preparation and Shipping
PT-WC-001	Determination of Total and Total Volatile Solids in Waters and Wastes (Methods EPA160.4 and SM 2540B & 2540E)
PT-WC-002	Color, Method 110.2
PT-WC-003	Alkalinity, SM Method 2320B
PT-WC-004	Total Hardness (mg/L as CaCO3) by Method SM 2340C; and Hardness by Calculation SM 2340B
PT-WC-005	Turbidity by Method 180.1
PT-WC-007	Nitrate/Nitrite-N EPA Method 353.2
PT-WC-008	Acid Volatile Sulfides (AVS) and Simultaneously Extracted Metals (SEM) in Sediment
PT-WC-009	Performance Checks on Spectronic 21 and Model 1001 Spectro-Photometers
PT-WC-010	Total Sulfide as Acid Soluble Sulfide, Method 9030B/9034, Standard Method 20th Ed. 4500S-2-F
PT-WC-013	Specific Conductance by 120.1, 2510B, and 9050A
PT-WC-014	Nitrogen, Ammonia (Automated), Method 350.1
PT-WC-015	Chromium, Hexavalent (Colorimetric) by SM3500-Cr-B, SW846 3060A/7196
PT-WC-016	Biochemical Oxygen Demand (BOD) and Carbonaceous Biochemical Oxygen Demand (CBOD) by Dissolved Oxygen Probe - SM5210B
PT-WC-017	Total Organic Carbon (TOC) and Total Inorganic Carbon (TIC), Methods SM 5310C and SW-846 9060/9060A
PT-WC-018	Cyanide – Semi-Automated, Pyridine-Barbituric Acid For Total and Amenable, Cyanide in Water (Methods 335.4) and Soil Analyses (Method 9012A/9012B)
PT-WC-020	Percent Moisture, Ash, Organic Matter and Total Solids in Soil Samples - SM 2540G and ASTM D297-84
PT-WC-021	Flash Point by Pensky-Martens Closed Tester, SW-846 Method 1010A and ASTM D93-08
PT-WC-022	Ignitability of Solids for Waste Characterization EPA SW-846 Chapter 7, Section 7.1
PT-WC-023	Chemical Oxygen Demand, Low Level, Method 410.4
PT-WC-025	n-hexane extractable material (HEM) in Sludge, Sediment and Soil samples - 9071B
PT-WC-026	PH Electrometric by SM 4500 H+B and SW-846 Methods: 9045C/D and 9040B/C
PT-WC-027	Salinity by Calculation, Electrical Conductivity Method SM 2520B
PT-WC-028	Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated Hexane Extractable Material (SGT-HEM; TPH), Method 1664A/1664B and 9070A
PT-WC-029	Available Cyanide by Ligand Exchange and Flow Injection Analysis (FIA) Method 1677
PT-WC-031	Cyanide Extraction Procedure for Solids and Oils, SW-846 Method 9013
PT-WC-032	Total Organic Carbon Analysis for Solid Matrices by Walkley Black
PT-WC-033	DI-Leachate Procedure for Solids (1 Hour Routine DI Leachate Procedure)
PT-WC-034	Paint Filter Liquids Test, SW-846 Method 9095B
PT-WC-035	Acidity of Water and Waste Water, SM Method 2310B
PT-WC-036	Flash Point of Liquids by Setaflash (Small Scale) Closed-Cup Apparatus, SW-846 Method 1020B and ASTM Standard D 3278-96
PT-WC-037	Oxidation Reduction Potential, SM 2580B (20th Ed)
PT-WC-038	Phenolics (Automated), Method 420.1/420.2, SW-846 9065/9066
PT-WC-039	Screening Apparent Specific Gravity and Bulk Density of Waste - Method: ASTM D 5057-90
PT-WC-040	Anion Surfactants as MBAS, Standard Methods 5540C
PT-WC-041	Compatibility of Screening Analysis of Waste, Method: ASTM D5058 Test Method C – Water Compatibility
PT-WC-042	Acid Titration of Samples for Bechtel Bettis (NaOH Solution for Caustic and Na2CO3 Concentration), Bechtel-Bettis SOP - WAPD-MT(CAC)-2141, Revision 0
PT-WC-043	Determination of Total and Volatile Suspended Solids in Waters and Wastes - EPA 160.4 and SM 2540D & 2540E
PT-WC-044	Determination of Settleable Solids in Water SM 2540F
PT-WC-045	Determination of Total Dissolved and Volatile Dissolved Solids in Water and Wastes, SM 2540C & 2540E
PT-WC-046	ASTM 18-Hour Leaching Procedure

Note: The SOPs are subject to change, refer to PT-QA-WI-002 for current list of SOPs and revision numbers.

Attachment:
1, Pittsburgh QA Manual (.pdf)

PIT-GI-ORG-FRM47902 Organizational Chart

End of document

Version history

Version	Approval	Revision information	
7	08.JUL.2022		

The State of Wisconsin
Department of Natural Resources

has granted

Accreditation under NR 149

to

Eurofins Pittsburgh

FID: 998027800

The laboratory is accredited to perform environmental sample analysis in support of covered environmental programs per matrix for the combination of analyte and technology or analyte and method as specified in the attached Scopes of Accreditation.

Printed on: **August 13, 2022**

Expires on: **August 31, 2023**

Steven Geis

Steven Geis, Chief
Certification Services

Preston D. Cole Secretary
Department of Natural Resources

This certificate does not guarantee validity of data generated, but indicates the methodology, equipment, quality control practices, records, and proficiency of the laboratory have been reviewed and found to satisfy the requirements of chapter NR 149, Wisconsin Administrative Code.

State of Wisconsin
DEPARTMENT OF NATURAL RESOURCES
101 S Webster St
PO Box 7921
Madison, WI 53707-7921

Tony Evers, Governor
Preston D. Cole, Secretary
Telephone 608-266-2621
Toll Free 1-888-936-7463
TTY Access via relay - 711

WISCONSIN
DEPT. OF NATURAL RESOURCES

August 13, 2022

FID: 998027800

Amanda Grilli
Eurofins Pittsburgh
301 Alpha Drive RIDC Park
Pittsburgh, PA 15238

Dear Amanda:

Enclosed is your new laboratory accreditation certificate and scope of accreditation. These documents supersede all previous versions.

Your scope of accreditation is an important document because it identifies the parameters, by technology, for which your laboratory maintains accreditation in the aqueous and non-aqueous matrices. If your laboratory is certified in the drinking water matrix, the scope of accreditation also identifies the parameters and methods for which your laboratory is certified. It is critical that the scope of accreditation be reviewed carefully for errors. **It is your responsibility to make sure that the scope of accreditation agrees with your understanding of the matrices, technologies, parameters, and any drinking water methods for which your laboratory maintains accreditation in Wisconsin.**

If you believe that your Scope of Accreditation contains errors or you would like to discuss how to get reinstatement for any lost parameters, contact the Laboratory Accreditation Program Chemist immediately at 920-412-5970 or by email at Tom.Trainor@wisconsin.gov.

Sincerely,

Steve Geis

Steven Geis, Chief
Certification Services

Wisconsin Scope of Accreditation

Laboratory FID: 998027800
CERTIFICATION
Aqueous (Non-potable Water)

Eurofins Pittsburgh
301 Alpha Drive RIDC Park
Pittsburgh, PA 15238

Printed on: **8/13/2022**
Expires on: **8/31/2023**

Colorimetric or Turbidimetric	**Cyanide, Total**
Electrometric Assays (ISE)	**pH**
Cold Vapor Atomic Absorption Spectrophotometry (CVAA)	**Mercury**
Inductively Coupled Plasma-Mass Spectrometry (ICP/MS)	**Aluminum**
	Antimony
	Arsenic
	Barium
	Beryllium
	Boron
	Cadmium
	Calcium
	Chromium, Total
	Cobalt
	Copper
	Iron
	Lead
	Magnesium
	Manganese
	Molybdenum
	Nickel
	Potassium

Wisconsin Scope of Accreditation

Laboratory FID: 998027800
CERTIFICATION
Aqueous (Non-potable Water)

Inductively Coupled Plasma-Mass Spectrometry (ICP/MS)	**Selenium**
	Silicon
	Silver
	Sodium
	Strontium
	Thallium
	Tin
	Titanium
	Vanadium
	Zinc
Gas Chromatography (GC)	**## PCB as AROCLORS (group)**
	## PESTICIDES, ORGANOCHLORINE (group)
Gas Chromatography-Mass Spectrometry (GC/MS)	**## BNA - SEMIVOLATILE ORGANICS (group)**
Flow Injection - Gas Diffusion - Amperometry	**Cyanide, Available**

Wisconsin Scope of Accreditation

Laboratory FID: 998027800
CERTIFICATION
Non-Aqueous (Biosolids, Leachates, Soils, Tissues, & Wastes)

Eurofins Pittsburgh
301 Alpha Drive RIDC Park
Pittsburgh, PA 15238

Printed on: 8/13/2022
Expires on: 8/31/2023

Colorimetric or Turbidimetric	**Cyanide, Total**
Electrometric Assays (ISE)	**pH**
Cold Vapor Atomic Absorption Spectrophotometry (CVAA)	**Mercury**
Inductively Coupled Plasma-Mass Spectrometry (ICP/MS)	**Aluminum**
	Antimony
	Arsenic
	Barium
	Beryllium
	Boron
	Cadmium
	Calcium
	Chromium, Total
	Cobalt
	Copper
	Iron
	Lead
	Lithium
	Magnesium
	Manganese
	Molybdenum
	Nickel

This laboratory is accredited under NR 149 to perform environmental sample analysis in support of covered environmental programs for the combination of analyte or analyte group and technology in the aqueous and non-aqueous matrices and analyte or analyte group and method in the drinking water matrix as specified in this Scope of Accreditation.

Wisconsin Scope of Accreditation

Laboratory FID: 998027800
CERTIFICATION
Non-Aqueous (Biosolids, Leachates, Soils, Tissues, & Wastes)

Inductively Coupled Plasma-Mass Spectrometry (ICP/MS)	**Potassium**
	Selenium
	Silicon
	Silver
	Sodium
	Strontium
	Thallium
	Tin
	Titanium
	Vanadium
	Zinc
Gas Chromatography (GC)	**## PCB as AROCLORS (group)**
	## PESTICIDES, ORGANOCHLORINE (group)
Gas Chromatography-Mass Spectrometry (GC/MS)	**## BNA - SEMIVOLATILE ORGANICS (group)**
	## VOC - VOLATILE ORGANICS (group)
Hazardous Waste Characteristics	**Paint Filter Liquids Test**
	TCLP Extraction

This laboratory is accredited under NR 149 to perform environmental sample analysis in support of covered environmental programs for the combination of analyte or analyte group and technology in the aqueous and non-aqueous matrices and analyte or analyte group and method in the drinking water matrix as specified in this Scope of Accreditation.