QUALITY ASSURANCE PROJECT PLAN

FOR

THE DISTRICT OF COLUMBIA STORMWATER

COLLECTION & ANALYSIS PROJECT

Contract No. CW58584

29 June 2018

Prepared by
Apex Companies, LLC
9700 Capital Court Suite #100
Manassas, VA 20110

Prepared for
District Department of Energy and Environment
1200 First Street NE, 5th Floor
Washington, DC 20002

6/29/2018

_____ Date: _____
Project Manager

_____ Date: _____
QA Officer

_____ Date: _____
DOEE Representative

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A. PROJECT MANAGEMENT

A3. Distribution List

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Contact Information:
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Title: Quality Assurance/Quality Control Manager
Organization: Retaw Engineering
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Address: 2903 Sagecreek Circle
Midlothian, VA 23112
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Name: Melanie Duszynski
Title: Data Quality Reviewer
Organization: Microbac Laboratories, Inc
Contact Information:
Address: 2101 Van Deman Street
Baltimore, MD 21224
Telephone: (410) 633-1800
Email: melanie.duszynski@microbac.com

A4. Project/Task Organization

Key Corporate Quality Assurance (QA) /Quality Control (QC) personnel for each specific task are as follows:

- Project Manager, Andrea Heller; Apex Companies, LLC
- QA/QC Manager, Ignatius Mutoti; Retaw Engineering
- Health and Safety Manager, Gavin Kitchens; Apex Companies, LLC
- Task Manager/Key Personnel, Amanda Hren and Toni Sanders; Apex Companies, LLC
- Field Sampling Team, Apex and Microbac Team (Multiple Individuals)
- Data Quality Reviewer, Melanie Duszynski; Microbac Laboratories, Inc.

Project Manager (PM). The Project Manager is accountable for the organization, coordination, and implementation throughout the duration of the project and utilizes the Task Leaders/Key Personnel for any technical assistance. The Project Manager may delegate authority to expedite and facilitate the implementation of the project plan. The Project Manager is responsible for:

- Coordination with client
- Budget control
- Subcontractor performance
- Project coordination to implement work plan
- Allocation of resources and staffing to implement the QA/QC program
- Allocation of resources and staffing to implement the Health and Safety Plan (HASP)
- Review of engineering and interim reports

QA/QC Manager. The QA/QC Manager is accountable to the Project Manager throughout the duration of the project and is responsible for validation of analytical data reports on all sampling and analysis data conducted under the storm water sampling project. The QA/QC Manager is also responsible for project-specific supervision and monitoring of the QA/QC Program.

- Will ensure that field personnel use proper sample procedures, field measurement techniques, sample identification, and chain-of-custody procedures
- Coordinate with the analytical laboratory for the receipt of samples, the reporting of analytical results, and recommending corrective actions to correct deficiencies in the analytical or sampling protocol
- Will audit field activities
- Provide QA/QC reports to management
- Will provide QA/QC technical assistance to the field sampling team

Health and Safety Manager. The Health and Safety Manager serves as the administrator of the Apex Team's Corporate Health and Safety Program. He is accountable directly to the Project Manager for project health and safety concerns and is responsible for:

- Proper training for the Apex Team field personnel
- Medical clearance of the Apex Team field personnel
- Field personnel having adequate experience with personal protective equipment
- Providing guidance on Health and Safety Plan (HASP) data interpretation

- Determining levels of worker protection
- Evaluating compliance with the HASP through regular audits of field activities

Task Managers/Key Personnel. Task Managers/Key Personnel provide technical support to the Project Manager for implementation of the Work Plan relative to their respective tasks and have the following responsibilities:

- Prepare task reports and outlining field investigation requirements
- Review daily reports and field notebooks
- Task scheduling
- Task budget management
- Task work plan coordination
- Review of field and laboratory analysis data
- Coordinate field activities
- Schedule sampling and other field activities

Field Sampling Team. Project personnel are drawn from the Apex Team irrespective of group or geographic assignment. The project personnel are selected based on appropriate skills, experience, and availability. Tasks and subtasks are assigned to Task Managers. Personnel working on specific tasks report daily to their respective Task Managers. Task Managers, in turn, work under the daily direction of the Project Manager. Personnel follow the procedures described in the following sections to assure consistency in sample collection and handling. Other duties may include:

- Inspect and replace equipment
- Prepare daily and interim reports
- Prepare samples for shipment

Data Quality Reviewer. A qualified laboratory, which is responsible for performing chemical analyses of environmental samples collected at hazardous substance sites. The laboratory is local and is able to receive and prep samples 24/7. The laboratory is capable of providing complete environmental analytical services consistent with U.S. EPA protocols and site-related Daily Quality Objectives (DQOs). The Laboratory Quality Assurance Manual (LQAM), provided by the approved laboratory, will supply details on laboratory operations, certifications, and personnel qualifications. The Data Quality Reviewer reviews all laboratory reports for quality and completeness before sending them to Apex and Microbac.

Apex has selected Retaw Engineering (Retaw) to provide QA/QC Support, additional technical, sampling and laboratory support.

RETAW ENGINEERING

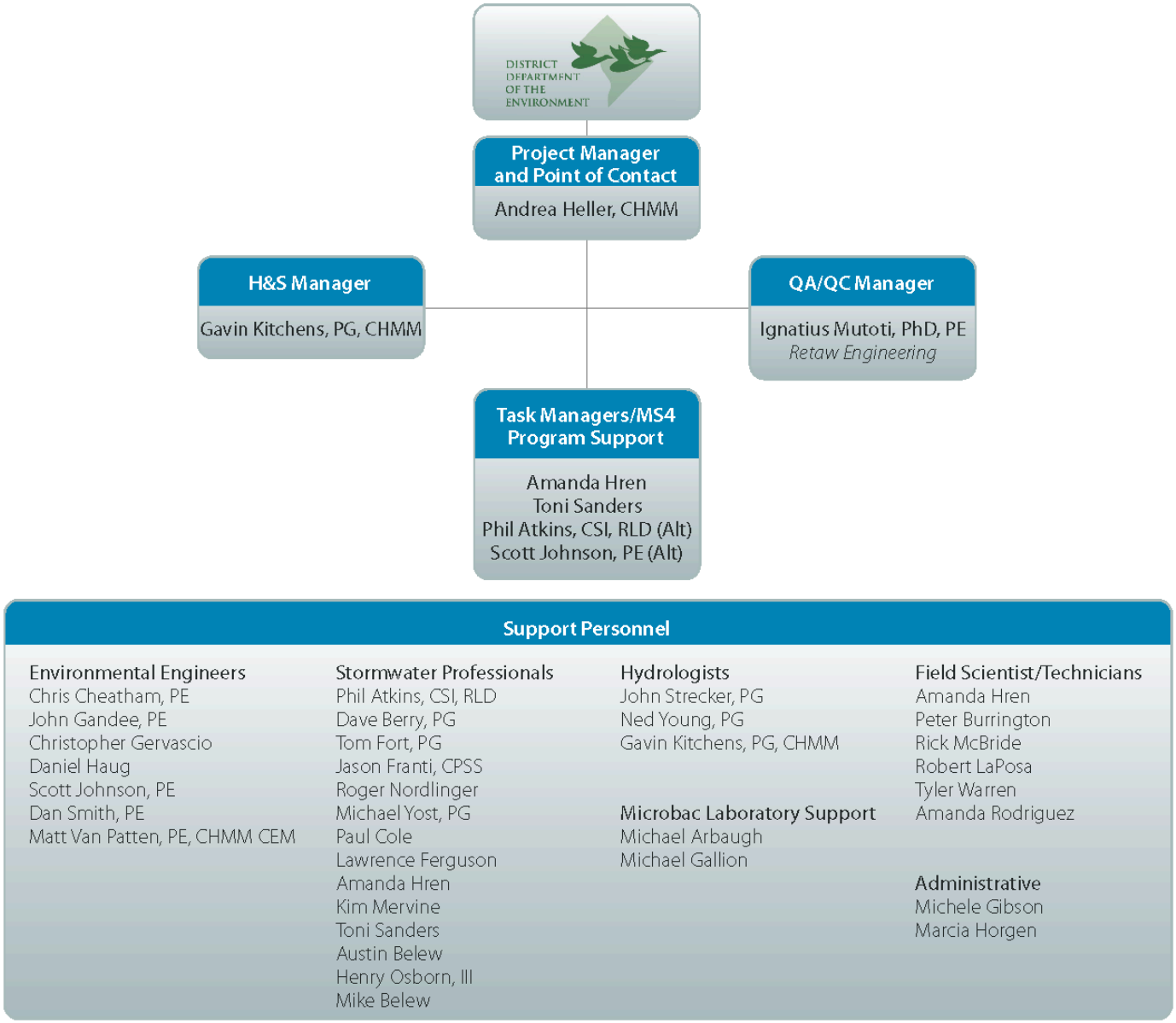
2903 Sagecreek Circle
Midlothian, Virginia 23112
(804) 245-2979
Ignatius.mutoti@retaweng.com

Retaw and Apex have selected Microbac Laboratories, Inc. (Microbac) which is responsible for performing chemical analyses of stormwater samples. The laboratory will be capable of providing complete environmental analytical services consistent with 40 CFR part 136 U.S. EPA protocols and site-related DQOs. The Laboratory Quality Assurance Manual (LQAM), provided by the approved laboratory, will supply details on laboratory operations, certifications, and personnel qualifications. The LQAM is attached in Appendix 1.

Microbac Laboratories, Inc.

Gascoyne Division
2101 Van Deman Street,
Holabird Business Park
Baltimore MD 21224
(410) 633-1800

Apex has worked extensively with both Retaw and Microbac on other projects and has assembled the Team to meet all of the anticipated projects outlined in the Solicitation. An organizational chart showing the relationships and the lines of communication among all project participants is presented below.



A5. Problem Definition/Background

The DC Office of Contracting and Procurement have contracted Apex Companies, LLC (Apex) to perform storm water sample collection for the District of Columbia Municipal Separate Storm Sewer System (MS4) permit DC0000221. The project is designed to supply the DC Department of Energy and Environment (DOEE) with the data necessary to show compliance with the National Pollutant Discharge Elimination System (NPDES) Permit issued in May of 2018.

In fulfillment of C.5.6 of the Storm Water Collection and Analysis contract number CW58584, the Quality Assurance Project Plan (QAPP) has been incorporated into this document. This document provides procedures for the sample collection, analysis, and evaluation of data. The DC stormwater

collection project will require close coordination with the client and the laboratory to ensure the viability of the samples and the integrity of the holding times.

Apex recognizes that analytical data quality management at all levels and phases of environmental work is critical to the ultimate success of any environmental project. Quality Assurance (QA) starts with the field crews taking the environmental samples in accordance with approved sampling methods, proper sample handling, preservation, sample shipment, clear and accurate chain-of-custody forms and documentation. The process continues to the laboratory, where the samples are analyzed in accordance with 40 CFR Part 136 - approved analytical methods following good laboratory practices to ensure the precision, accuracy, representativeness, comparability, and completeness of the chemical analytical results. To achieve these goals, the laboratory chemists must properly and routinely maintain analytical instruments, and non-laboratory chemists must periodically audit laboratory operations and procedures.

The following sections describe Apex's approach to ensure that these QA goals are met for any environmental program conducted or managed by Apex. This approach applies to all environmental media samples, i.e., air, soils, storm water, surface water, groundwater, and sediments, etc.

A6. Project/Task Description and Schedule

The objective for the storm water sampling is to determine if the Separate Storm Sewer System is compliant with the NPDES Permit. The DOEE has identified nine locations that storm water samples will be collected from by Apex. The nine locations consist of three locations within the Anacostia River Watershed, three locations within the Potomac River Watershed, and three locations within the Rock Creek Watershed. These locations are described in the table below:

Table 1-Watershed and Sampling Locations

Site	Sampling Location	Watershed	Type of Site
1	Tributary to Anacostia-Gallatin Street & 14th Street NE	Anacostia River	Continuous Record
2	Oxon Run-Mississippi Ave and 15th St. SE	Potomac River	Continuous Record
3	Soapstone Creek-Connecticut Avenue and Albemarle Street NW	Rock Creek	Continuous Record
4	TBD	Anacostia River	TBD
5	TBD	Anacostia River	TBD
6	Outfall 950-Tributary to Potomac	Potomac River	Stratified Random
7	Outfall 103-Oxon Run	Potomac River	Stratified Random

8	TBD	Rock Creek	TBD
9	Outfall 901-Tributary to Pinehurst Branch	Rock Creek	Stratified Random

The flow characteristics for each location will be defined in advance of a storm event. The geometry of the outfall or storm water structure will be evaluated and a method of determining flow will be determined in advance of the sampling event. The flow will be determined by the cross-sectional geometry of the outfall, depth of flow and the velocity of the water passing through the structure. The velocity of the flow will be estimated and recorded and the estimated flow rate will be recorded using a digital flow meter reading or other acceptable industry methods.

Sampling will occur during wet weather events. A wet weather sampling event will occur when rainfall amounts to 0.10 inches or more. A wet weather sampling event must occur 72 hours from previous 0.10 inches of recorded rain and the site must not have been previously sampled within a 30 day period. Samples will be collected using both grab and composite techniques. Samples will be collected at outfalls and manholes in each of the prospective watersheds as directed by the Permit.

Samples from wet weather events will be delivered under the Chains of Custody to Microbac. Sample event reports will be produced within 30 days of the sampling event.

A7. Quality Objectives and Criteria

A7.1. Data Quality Objectives

Data Quality Objectives (DQOs) are developed to achieve the level of data quality required for the anticipated data use and are implemented so that for each task, the data is legally and scientifically defensible. The development of DQOs for a specific site and measurement takes into account project needs, data uses and needs, and data collection. These factors help in determining the appropriate quality assurance objectives necessary to ensure the quality and quantity of data are adequate for the end use of the data.

DQOs are attained through sound chemical quality management and achieved through the implementation of this plan. This QAPP is in accordance with applicable U.S. EPA standards and regulations.

A7.2. Analytical Data Quality Assurance

The objective of the Analytical Quality Control Program is to provide sampling and analysis data of acceptable quality.

- Accuracy (Bias) is a measure of confidence that describes how close a measurement is to its “true” value. Accuracy for field and laboratory tests shall be determined using various approaches including: instrument calibrations, various types of QC checks – e.g. sample split measurements, sample spike recoveries, matrix spike duplicates, continuing

calibration verification checks, internal standards, sample blank measurements (field and lab blanks), external standards), and performance audit samples (DMRQA). Accuracy shall be assessed using the following formula:

$$Accuracy = \frac{MeasuredValue}{TrueValue} \times 100$$

Precision. Measure of mutual agreement among repeated measurements of the same parameter, and provides information about the consistency of methods usually under prescribed conditions. Precision is expressed in terms of the relative percent difference between two measurements (A and B). The objective for precision is to equal or exceed the precision demonstrated for similar samples, and should be within the established control limits for the methods. Precision shall be determined as follows:

For field measurements, precision shall be assessed by measuring duplicate samples at the same *locations* and as soon as possible to limit temporal variance in sample results. Field and laboratory precision shall be measured by collecting blind (to the laboratory) field duplicate samples. For paired and small data sets project precision is calculated using the following formula:

$$Precision = (A - B)/\left(\frac{(A + B)}{2}\right)x100$$

For larger sets of paired precision data sets (e.g. overall project precision) or multiple replicate precision data, use the following formula:

RSD = 100*(standard deviation/mean)

- Completeness. Measure of the amount of valid data obtained from a measurement system compared to the amount expected under normal conditions. The objective is to generate a sufficient database with which to make informed decisions with statistical confidence. Project completeness is determined for each pollutant parameter using the following formula:

  $$\frac{T - (I+NC)}{T} \times (100\%) = \text{Completeness}$$

  Where T = Total number of expected sample measurements.
  I = Number of invalid sample measured results.
  NC = Number of sample measurements not produced (e.g. spilled sample, etc.)

- Representativeness. Expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. Representativeness includes what parameters to sample for, where to sample, type of sample (grab, continuous, composite, etc.) and frequency of sample collection and shall be in accordance with the DC 0000221 NPDES Permit. To meet the objective of obtaining representativeness of samples, a Work Plan is developed.

- Comparability. The confidence with which one data set can be compared to another collected by using standardized methods of sampling and analysis. Comparability shall be shown by referencing the appropriate measurement method approved by as specified in 40 CRF Part 136 or other approved methods for the parameter(s) to be sampled and measured (e.g., ASTM, Standard Methods). For each parameter to be analyzed, the method to be used and the measurement quality objective shall be listed to meet the overall data quality objectives. This applies to both direct field measurements (e.g., field pH meters, DO meters, etc.) as well as samples collected for subsequent laboratory analyses. This objective is met by using 40 CFR Part 136 and standard methods for sampling procedures and analyses, and by following techniques and methods set forth in the Work Plan.

- Sensitivity. Measure of a method's detection limits and ability to distinguish between two values. The sensitivity and detection limits of a method will be reviewed to determine a method based on the method's detection limit (MDL) and practical quantification limit (PQL).

A8. Special Training/Certification

Apex team leaders and full-time staff are OSHA 40 Hour HAZWOPER trained. All staff members working on this project receive in house sampling and safety training. Microbac will be capable of providing complete environmental analytical services consistent with 40 CFR part 136 U.S. EPA protocols and site-related DQOs. The Laboratory Quality Assurance Manual (LQAM), provided by Microbac, will supply details on laboratory operations, certifications, and personnel qualifications. Laboratory certifications are presented in Appendix 1.

Under the National Pollutant Discharge Elimination System (NPDES) program, the laboratory is required to participate in the annual Discharge Monitoring Report–Quality Assurance (DMR-QA) study program. DMR-QA evaluates the analytical ability of the laboratories that routinely perform self-monitoring analyses required by the NPDES permit. Microbac will participate in this annual study.

The quality assurance (QA) laboratory will deliver the sample results and data package, which will be reviewed by the QA/QC Manager. The data reviewed will include all blank, sample, and internal quality control results such as spike and surrogate recoveries and replicate analyses. Any significant differences or problems discovered will be addressed; corrective action, such as reanalysis and/or resampling, may result at the Project Manager's discretion.

A9. Documents and Records

The records for this project will include field logs, field data worksheets, laboratory data reports, and sample event report. Field logs will include observations about weather conditions at the site when samples are collected and field analyses conducted. Any other pertinent observations or deviations from the procedures in this QAPP, deemed noteworthy by any member of the field team will also be recorded in the field log book. Field data worksheets (Appendix 2) will be used to record all field measurements. Each page of the field logs and field data worksheets will be dated and signed by the person making the entries.

The sample event report will be submitted within approximately 30 days of the actual sampling event and based on actual analytical results receipts from the Microbac laboratory. The results of the field parameters tested during the sampling event, field data collection sheet, site narrative report of the event and sampling locations where the actual storm water samples collected, site photographs and meteorological data predicting the storm-water event, flow monitoring, precipitation data including rainfall hydrograph, signed chain-of-custody forms and the laboratory analytical results of analyzed samples will be included in the sample event report. Two hard copies of the report and an electronic report copy will be submitted for each event report to the DOEE.

Data packages generated from analyses shall include the following:

1. Pertinent physical data presented in concise, easy to follow formats (i.e., sample number, client, date of sample preparation, date analyzed, percent moisture, etc.).

2. Data from each discrete sample reported using cross referencing between normal samples and quality control samples.

3. Reported data to include associated quality control samples such as blanks, spikes and spike duplicates, laboratory duplicates, field duplicates, and appropriate check standards.

4. Copies of chain of custody sheets.

Data reduction is the process that raw analytical data generated from laboratory instrument systems is converted into usable concentrations. The raw data, which may take the form of area counts, instrument responses or observations, is processed by the laboratory and converted into concentrations expressed in the part per million or part per billion range. Raw data from these systems include compound identifications, concentrations, retention times, and data system printouts. Raw data is usually reported in graphic form, bar-graph form or tabular form. Data reduction procedures will be discussed in greater detail in the LQAM (Appendix 1).

B. DATA GENERATION AND ACQUISITION

B1. Sampling Process Design (Experimental Design)

The storm water sample collection and analyses will supply the DOEE with the data necessary to show compliance with the Municipal Separate Storm Sewer System (MS4) Permit. The samples will be collected at the following locations (9 outfalls).

For each sampling location, the field sampling team will record estimated flow velocity, odor, pH, dissolved oxygen content, temperature, specific conductivity, and approximate water depth. The field sampling team will complete a sample data collection form to document the event. Digital photography will be collected if necessary to further document conditions during the event.

B1.1. Wet Weather Sampling

Mobilization and preparing the samplers starts with coordination and notification. Communication will come from the PM who then will notify the integral field sampling team. The field sampling team will begin by organizing and preparing all necessary sampling and sample transportation equipment for the event approximately 24 hours in advance, so the equipment is charged and available when the storm reaches the monitoring area. Any in-situ autosamplers being used for the rain event are reviewed to ensure required bottleware, power sources, and sample preservation materials are in place. For direct sampling of sites, the field sampling team will mobilize to sampling site locations approximately 1-2 hours prior to the predicted beginning of a storm event.

Once the sampling event (3 hours for composite samples) has been completed, the field sampling team will meet with the designated lab or courier to deliver the event samples with their respective Chains of Custodies.

B1.1.1. Collection Procedures, Sampling Handling, and Transportation of Samples for Wet Weather Sampling

Collection Methods for Wet Weather Sampling:

GRAB SAMPLES

- E. coli

COMPOSITE SAMPLES

- Total nitrogen
- Total phosphorus
- Total Suspended Solids
- Cadmium
- Copper
- Lead
- Zinc

FIELD ANALYSIS

- pH
- Temperature
- Dissolved oxygen
- Conductivity
- Hardness

1. The storm water samples shall be collected at the locations designated in the contract and at a minimum of four (4) sites for each wet weather event. Samples will be collected using both grab and composite techniques. Samples will be collected at outfalls and manholes in each of the prospective watersheds as directed by the Permit. When a qualifying event (storms with at least 0.1 inch of precipitation, 72 hours, and one month since the last collection at a specific site) is anticipated based on the available meteorology, the auto-samplers will be charged and set up in advance using all appropriate safety precautions. The suction stub of the auto-sampler will be positioned upstream of the grab sample locations and field parameter test points.

2. The auto-samplers will be equipped with a pre-cleaned 2 1/2 gallon lab supplied glass container to collect composite samples. The auto-sampler will be packed with ice to ensure the composite sample is kept adequately preserved during sample collection.

3. When it is determined that a qualifying event is highly likely to occur, the field teams will mobilize to the site, don any required Personal Protective Equipment (PPE), and exercise appropriate safety precautions. Apex is experienced in after-hours sampling and minimizes safety concerns by working in teams, using reflective clothing and equipment, utilizing flashlights and headlamps.

4. Data quality depends, in part, on proper collection and preservation to guarantee representativeness of the sample. Sample containers will be labeled in such a manner as shown in Section B3.2.2 and B3.2.3. Once collected, samples will be immediately placed in a cooler filled with ice and held at 4°C. Disposable gloves and other appropriate PPE will be worn by the sampling personnel and changed between sampling points to avoid cross contamination. Personnel will also be equipped with appropriate rain gear. The information collected in the field shall be recorded in a dedicated field logbook and on the sample collection form at the time of sampling.

5. The field sampling team will perform the required analytical field tests (Conductivity, Hardness, Dissolved Oxygen, pH, Temperature, and Flow) using direct reading equipment in accordance with manufacturers written procedures. These readings will be noted in the field data sheets.

6. It is the policy of Apex to calibrate required equipment, collect samples properly and to ensure that they maintain the characteristics of the sample source using appropriate sampling and preservation techniques. It is critical that the sampling be performed correctly and documented thoroughly,

following protocols. The techniques used are based on EPA-National Field Manual for the Collection of Water-Quality Data (USGS updated 2008), the NPDES Permit DC0000221, and the "NPDES Storm Water Sampling Guidance Document" (EPA 833-B-92-001).

7. When sampling an outfall, the field sampling team will stand downstream of the sampling location and work upstream to collect samples.

8. Grab samples will be collected for the required parameters and these will be placed in pre-cleaned containers prepared with the appropriate preservatives and properly labeled. The samples will be placed in a cooler charged with ice in preparation for delivery to the laboratory.

9. The auto-samplers will be checked and if they have completed the collection routine and the composite sampling is complete, the container will be removed from the unit and included in the shipment to the lab. The auto-samplers will be set to take samples as a time weighted average (TWA) at a minimum of every 15 minutes. The full composite sampling container will be transported to the laboratory for division into appropriate sample containers and will be preserved in accordance with the requirements of the specific analytical procedures.

10. The field sampling team will complete the sample collection data forms, chain of custody forms and field logbook prior to moving to next site. The team will perform a QC check to ensure that all required data has been captured prior to moving on to the next location.

11. The field sampling team will communicate via company supplied mobile phones to ensure that all scheduled sites can be completed within the 3 hour window for the event. These phones allow the sampling crews to check weather patterns and forecasts from the field as well as keep in contact with the PM via text messaging, emails, or phone. Sampling will be completed within the first three hours of a qualifying event.

12. The team will meet at a predetermined location and the coolers for each location will be inspected for quality control, completeness and then packaged for transport to the laboratory. The samples will be transferred under chain of custody to one vehicle or to a courier service for transportation to the laboratory. This effort is expected to take approximately 30 minutes.

13. The proposed laboratory for this project is located Baltimore, MD and is approximately one hour from Washington, DC. This laboratory is equipped to receive samples on a 24 hour seven day a week basis. Based on the above scenario and time frames, this will leave approximately 90 minutes at the lab to prepare the micro-biological samples and meet the six hour holding time for the micro-biological parameters.

14. All used field equipment will be properly decontaminated after each event.

B1.2. Field Documentation

The following information will be recorded in a field notebook and on the sample data collection form at the time of sampling:

- Sample location
- Name of field technicians present during sampling
- Method of sample collection utilized
- Time/date of sampling
- Type of sample
- Analyses required and sample container types
- Field measurements and calibration (if applicable)
- Observed conditions that may impact the chemistry of the sample
- Observations and remarks: A bound field logbook will be maintained in which to record the daily activities. All entries will be made in indelible ink. Incorrect entries will be corrected by a single stroke through the error and will be verified with the recorder's initials. Entries to the log book, in addition to the required sampling entries, will include:

    - Date
    - Start and finish times
    - Summary of work performed (including samples collected)
    - Names of personnel present
    - Weather observations
    - Calibration of equipment
    - Observations and remarks
    - Field measurements

B1.3. Meteorological Event Planning Procedures

Accurate prediction, evaluation and documentation of qualifying weather events are necessary to determine when to engage each sampling team to the necessary locations. Accuracy in these matters also ensures close coordination with the client and the laboratories to ensure the viability of the samples and the integrity of the holding times.

Although meteorological and storm events can be unpredictable, they can be forecasted using various resources including electronic and broadcast media, historical weather trends, newspapers, and visual observation. Tools such as thermometers, barometers, electronic weather stations, and rain gauges accessed with staff smartphones will also be on-hand to aid in predicting a qualifying storm event. The project manager will use this data to produce weekly in-house weather forecasts each week and to alert field managers and sampling teams of pending storm events.

B1.4. Qualifying Storm Event Criteria

According to the EPA's guidelines, the storm water discharge permit requires that each qualifying rain event have the following criteria:

- The depth of the storm must be greater than 0.10 inch accumulation;

- The storm must be preceded by at least 72 hours of dry weather;
- The depth of rain and duration should not vary by more than 50 percent from the average depth and duration for each location.
- The same site is not to sampled more than once in a 30 day period.

This specific criterion ensures that:

- Adequate flow would be discharged from each location;
- Some build-up of pollutants during dry weather intervals occurs;
- The storm would be typical for the area (i.e. intensity, depth, and duration).

Data on local weather patterns is provided by the National Weather Service's (NWS) website at www.weather.gov and includes historic, future, and current weather conditions. National Oceanic and Atmospheric Administration (NOAA) supplies average rain and duration figures for the immediate and surrounding areas based on normal data records collected since 1971. This information will be analyzed to determine if the range of the storm is within the duration, intensity, and depth typical of the representative area and time of year.

A variety of sources will be used retrieve and verify weather data. Numerous sources have been investigated and deemed acceptable meteorological sources to predict upcoming weather patterns. Electronic resources will be the primary source of weather prediction; however, secondary sources such as newsprint, radio, and television will assist in forecasting.

NOAA's National Weather Service (NWS) website will serve as Apex's principal daily forecast source. The National Weather Service (NWS) provides weather, hydrologic, and climate forecasts and warnings for the United States up to 10 days in advance. They also provide forecast maps that display anticipated amounts of precipitation to occur within the upcoming 72 hours. These interactive maps loop instantly in 6-hour increments to show expected depths of precipitation in this 72 hour window.

- National Oceanic and Atmospheric Administration's National Weather Service http://www.weather.gov/
- Reagan National Airport (Washington, DC) http://weather.noaa.gov/weather/current/KDCA.html
- Radio/Television
- FM radio channel: 88.5 WAMU or 103.5 WTOP
- The Weather Channel on various cable outlets

- Electronic Tools

- Smartphones to access specific online tools

B1.5. Daily Weather Logs

The Project Manager or qualified representative will maintain a daily weather log using information from NOAA.gov

1. Time & Date of report- as 24-hour day, as day month year (1730 01/11/2006)
2. High and Low Daily Temperature in degrees Fahrenheit (Hi-85° F/Lo-35° F)
3. High and Low Record Temperature in degrees Fahrenheit (1905-Hi-85°F/1945-Lo-35°F)
4. Conditions- Categorized as
   CLEAR- little to no clouds
   CLOUDY- fifty percent or greater sky cover
   NON-QUALIFYING EVENT- less than one tenth of an inch (<00.1")
   QUALIFYING EVENT- greater than one tenth of an inch (>00.1")
   SEVERE STORM- severe winds and storms that create unsafe work environments
5. Wind Speed & Direction- at the time log is written in miles per hour (15.0mph)

The field sampling team will maintain a weather log for every qualifying weather event. They will record the following information;

1. Time & Date of report
2. Author's name/source
3. Current Weather alerts and warnings
4. Temperature in degrees Fahrenheit
5. Site locations expected to be sampled
6. Site locations sampled
7. Time arrived on site
8. Number and size of samples taken
9. Time samples were taken
10. Time left site
11. Time Chain of Custody was completed

The QA/QC Manager will review these logs on a weekly basis.

B1.6. Coordination of Events for Storm Sampling

Apex's Project Manager will manage the notification of all involved parties in the event of a pending qualifying weather 24 hours in advance. Apex personnel are equipped with cell phones to facilitate efficient mobilization. The Project Manager will notify each member of the sampling teams to ensure proper dissemination of information regarding locations to be sampled and other vital information. Phone notifications will be made and a follow up email, after demobilization, will be sent stating the locations and quantity of samples, if any, were collected and sent to the laboratory.

B2. Sampling Methods Requirements

Samples will be collected using the containers and preservatives specified in Appendix 3. Unless otherwise stated, the order of sample collection will be:

1. In-situ measurements
2. Microbiological
3. Total metals, other parameters, etc.

Sample containers will be labeled with the following information: location identification, date, parameter(s) to be analyzed, and type of preservative. Samples will then be immediately placed in a cooler and held at 4°C. Disposable gloves will be worn by the sampling personnel and changed between sampling points. The field data collected shall be recorded in the field logbook and on the sample collection form at the time of sampling.

While performing any equipment decontamination, phthalate-free gloves (neoprene or natural rubber) will be worn in order to prevent phthalate contamination of the sampling equipment by interaction between the gloves and the organic solvent(s). To the greatest extent possible disposable sample collection equipment will be used and will be disposed of in accordance with applicable Federal, state and local regulation.

At the end of each sampling event, the sampling team shall report any problems requiring corrective action that were encountered during the event. Corrective action will be undertaken when a nonconforming condition is identified. A nonconforming condition occurs when QA/QC objectives for precision, accuracy, completeness, representativeness, or comparability are not met, or when procedural practices or other conditions are not acceptable. The report shall be filed with the Project Manager which documents the problems encountered and the corrective action implemented.

B2.1. Sampling Equipment

This project is specifically for the collection and analysis of storm water. A list of typical field equipment and devices used for sample collection are presented below.

Sampling Equipment:

- Personal Protective Equipment (Reflective Vests) & Rain Gear
- Mobile Phones
- Work, Safety and Traffic Control Plan
- Permits- DDOT, National Park Services (NPS), and DC Water.
- pH, dissolved oxygen, temperature, and specific conductivity meter
- Flow-meter
- Stainless Steel Buckets
- Auto-sampler
- Coolers
- Flashlights – Various Types
- Manhole Removal Tool
- Digital Camera

- Small Hand Tools
- Gloves

Field analytical equipment:

- Dissolved Oxygen Meter
- pH meter
- Specific Conductivity Meter
- Chlorine Meter/Test
- Temperature Probe - YSI 3510

Field Sample Collection Devices:

- Glass/plastic beaker or dipper for surface water samples
- Stainless steel buckets
- ISCO auto samplers

B2.2. Decontamination of Sampling Equipment

To avoid cross-contamination of samples, equipment used in sampling must be clean and free from the residue of previous samples. To the greatest extent possible, Apex will utilize dedicated pre-cleaned and disposable equipment to minimize the potential for cross contamination. Non-dedicated sampling equipment must be cleaned initially and prior to being reused and will be appropriately packaged to prevent contamination. The following is the procedure for decontamination and does not apply to heavy equipment or drilling equipment.

- Wash and scrub with low phosphate, laboratory grade detergent (bucket 1)
- Tap water rinse
- Wash and scrub with low phosphate, laboratory grade detergent (bucket 2)
- Thorough rinse with distilled water
- Wash and scrub with low phosphate, laboratory grade detergent (bucket 3)
- Thorough rinse with distilled water
- Air dry
- Wrap appropriate equipment in aluminum foil, plastic sheets, plastic bags or place in clean ziplock bag

  Note: A variation of the above decontamination procedure may be used depending on the DQO level and parameters to be sampled.

  Field instrumentation shall be cleaned and calibrated per manufacturer's instructions. Probes, such as those used in pH and conductivity meters, and thermometers must be decontaminated and rinsed prior to and after use with deionized water and shall be properly calibrated.

B2.3. Decontamination Solutions

- Deionized demonstrated analyte-free water

- Low phosphate laboratory grade detergent
- Concentrated nitric acid (HNO_3)
- Concentrated hydrochloric acid (HCl)
- Distilled Water

Note: Decontamination fluids are highly specific to the type of sample being collected and the analysis being performed. To the greatest extent possible Apex will use dedicated disposable equipment to minimize equipment decontamination.

A table of parameters, holdings times and methods are listed in Table 2.

Table 2 – Wet Weather Parameters

Parameter	Container Type	Preservation	Sample Type	Method	Holding Times
E. coli	4 oz. sterile polypropylene	Sodium Thiosulfate	Grab	SM 9221 F	6 hours
Total nitrogen	500 ml plastic	HNO3	Composite	SM 4500N-org/NH3G	28 days
Total phosphorus	500 ml plastic	HNO3	Composite	SM 4500-P	28 days
Total Suspended Solids	1000 ml plastic	Neat	Composite	SM 2540 D	7 days
Cadmium	1000 ml plastic	H2SO4	Composite	EPA 200.8	180 days
Copper	500 ml plastic	HNO3	Composite	EPA 200.8	180 days
Lead	500 ml plastic	HNO3	Composite	EPA 200.8	180 days
Zinc	500 ml plastic	HNO3	Composite	EPA 200.8	180 days
pH	N/A	N/A	In Field	SM 4500 H B	15 minutes
Dissolved Oxygen	N/A	N/A	In Field	N/A	N/A
Hardness	N/A	N/A	In Field	N/A	N/A
Temperature	N/A	N/A	In Field	N/A	N/A
Conductivity	N/A	N/A	In Field	N/A	N/A

B3. Sample Handling and Custody Requirements

The samples will be packaged, preserved and handled in a manner to ensure the integrity of the sample. The laboratory may preserve sample containers before sending them to the field sampling team or they may be preserved in the field before or after sample collection depending on the analytical parameter and project specifications. All required preservatives would be specified by the analytical method to be used. The samples will be packaged and shipped in a manner to minimize the potential for breakage and ensure the holding time for all parameters is not exceeded.

1. Samples requiring pH adjustment in the sample jar shall be obtained with the appropriate preservative pre-measured in the sample container by the laboratory. If preservation of the sample causes effervescence, the sample will be submitted without pH adjustment and all samples will be cooled to +/- 4°C. Appropriate safety precautions when handling sample containers preserved with acids, or caustics.

2. Each cooler shall be prepared to contain the exact number and type of sample containers required for one suite of parameters for each outfall/location. The sample containers will be

pre-labeled and preserved and all required sample packaging material will be prepared and included in the cooler.

3. After collection the samples will be placed in lined cooler using a large plastic bag. Each cooler will have the correct number of sample containers inside and the containers will be pre-labeled. Waterproof labels will be used.

4. The field sampling team will double check to ensure that all sample containers have been filled properly and are properly protected against breakage and will then secure the bag.

5. The field sampling team will complete the chain of custody for each cooler and will seal it in a ziplock bag. Chain of custody will filled-out to the greatest extent possible prior to mobilizing to the field and will be completed in the field. The bag will be taped to the interior lid of the cooler. The cooler will then be sealed with clear packaging tape and equipped with tamper proof seals and labeled for shipment to the Lab.

6. The sample coolers will be shipped to the lab using the most expedient method. This may include courier, commercial transporter or hand delivery.

B3.1. Overview

Sample custody during the field investigations will be performed in three phases. The first phase encompasses sample collection, pre-laboratory treatment procedures (preservation), packaging, and field custody shipping procedures. The second custody phase involves sample shipment, where mode of shipment, airbill numbers, dates, and times are documented. The third phase involves the custody procedures employed by the laboratory.

All three phases of sample custody will be performed to provide that:

- All samples are uniquely identified
- The correct samples are tested and are traceable to their source
- Important sample characteristics are preserved
- Samples are protected from loss or damage
- A record of sample integrity is established and maintained through the entire custody process

Custody and shipping procedures are modeled after standard U.S. EPA procedures.

B3.2. Field Custody Procedures

B3.2.1 Sample Identification

All samples collected must be identified with a sample label in addition to an entry on a chain-of-custody record. Indelible ink will be used to complete sample labels, then labels will be covered with clear plastic waterproof tape.

B3.2.2. Sample Labels

Sample labels will require the field team to complete the following information for each sample bottle:

1. Site Name
2. Sample Number
3. Sample Matrix
4. Parameters to be analyzed
5. Date of Collection
6. Time of Collection
7. Preservation Technique Employed
8. Sampler's Name

Sample labels will be attached to the sample bottles and covered with clear plastic waterproof tape.

B3.2.3. Sample Numbering

Samples shall be numbered in such a manner that the site, location, type of sample, and depth of sample or date of sample is evident. Below are suggested examples of sample numbering.

Stormwater samples will be labeled as follows:

SWXX – Composite
SWXX – Grab

SW:	Storm-water sample
XX:	Identifies site location (Per Table 1)
Composite:	Composite sampling
Grab:	Grab sampling

Trip blanks will be labeled by adding TB to the end of the sample number.

B3.3. Chain-of-Custody-Record

The chain-of-custody guidelines create an accurate written record that can be used to trace the possession and handling of the sample from the moment of its collection through analysis. Chain-of-custody forms will be completed for each sample at the time of collection and will be maintained while shipping the sample to the laboratory. A person is in custody of a sample if the sample is:

- Sample is in that person's physical possession.
- Sample is visible after being in that person's physical possession.
- Sample placed in a locked repository by that person.
- Placed in a secure restricted area by that person.

Prior to the sampling event or soon as practical after sample collection, preferably after decontamination, the following information must be entered on the chain-of-custody form. All information is to be recorded in ink.

1. Project number. Enter the alphanumeric designation that uniquely identifies the project site.

2. Project name. Enter the site name.

3. Samplers. Sign the name(s) of the sampler(s).

4. Sample number(s). Enter the sample number for each sample in the shipment. This number appears on the sample identification label.

5. Date. Enter a 6-digit number indicating the day, month, and year (MMDDYY) that each sample was collected.

6. Time. Enter a 4-digit number indicating the time of collection of each sample based on the 24-hour clock: for example, 1354.

7. Sample matrix. Enter the matrix (e.g., soil, aqueous, drum waste, etc.) of the sample.

8. Parameters for analysis. Enter the analyses to be performed for each sample.

9. Number of containers. For each sample number, enter the number of sample bottles that are contained in the shipment by parameter for analysis.

10. Remarks. Enter any appropriate remarks.

B3.4. Sample Shipment

Custody of samples must be maintained through the shipment of samples to the selected laboratory. All samples will be packaged and delivered so that the samples are not held at the site more than 6 hours. Samples will be delivered directly to the laboratory by sampling personnel or courier to ensure the 6-hour holding time for micro-biological samples is complied with. The samples will be packaged using the following procedures.

- Use waterproof high-strength plastic ice chests or coolers only.

- After filling out the pertinent information on the sample label and tag, put the sample in the bottle or vial and screw on the lid.

- Tape cooler drain shut.

- Place inert cushioning material such as bubble wrap will be placed in the bottom of the cooler. Styrofoam packing cannot be used when sampling for volatile organics.

- Enclose the bottles in clear plastic bags through which sample labels are visible, and seal the bag. Bottles are to be placed upright in the cooler in such a way that they

do not touch and will not touch during shipment. Place cushioning material around the bottles.

- Enclose temperature blank in each cooler.
- Additional inert packing material will be put in to partially cover sample bottles (more than halfway). Place bags of ice or ice-gel packs around, among, and on top of the sample bottles in a separate plastic bag
- Custody seals will be applied to the front and back of the cooler.
- Tape will be used to secure lids. Wrap the cooler completely with strapping tape at a minimum of two locations. Do not cover any labels.
- Attach completed shipping label to top of the cooler. The shipping label shall have a return address.
- The cooler will be delivered/shipped via courier or directly delivered by Apex personnel to the respective laboratory or laboratory personnel.

Custody forms will be placed in a "ziplock" bag and taped to the inside cover of the shipping cooler.

B3.5. Laboratory Custody Procedures

When the sample arrives at the laboratory following shipment, the custodian receives the sample. The label will be identified upon receipt by the laboratory and cross-referenced to the -chain-of-custody record. Any inconsistencies will be noted on the custody record. Laboratory personnel will notify the Project Manager immediately if any inconsistencies exist in the paper work associated with the samples.

Laboratory personnel, following laboratory protocols, will maintain custody of the samples throughout analysis. The laboratory custody procedures are detailed in the LQAM.

B3.6. Documentation and Tracking Deficiencies

Complete documentation of sample custody and shipment will be performed. Copies of chain-of-custody forms and field documentation notes are to be kept on file by the Project Manager. Mode of shipment, air-bill numbers, dates and times of all sample shipments will also be documented. Any deficiencies (including coolers lost by the shipper) requiring corrective actions will be reported to the Project Manager, who will document the problem and respond with corrective action after consultation with the QA/QC Manager. Corrective action may include resampling where the tracking deficiency resulted in exceeding sample holding times, etc. Additional information regarding nonconformance is presented in Section C2.1. Laboratory procedures for responding to deficiencies and the resultant corrective actions are discussed in further detail in the LQAM.

B4. Analytical Methods

Retaw and Apex have selected Microbac Laboratories, Inc. to be responsible for sample analysis. Analytical methods and parameters will be determined on a project-specific basis. A copy of the laboratory's standard operating procedures (SOPs) for common analytical methods will be included in the LQAM. The SOPs will include target analytes, practical quantitation limits, spiking conditions, and precision and accuracy criteria for all matrices.

The contract requires a specific set of analysis be performed on a highly specific schedule.

B5. Quality Control

Apex will ensure that Microbac participates in the annual U.S. Environmental Protection Agency's Discharge Monitoring Report-Quality Assurance Study Program and submit testing results for all parameters. All analytical laboratory instruments should have initial and subsequent daily calibration verified after every set of samples. Quantitative limits should be defined for individual parameters and should be expressed as the lowest calibration standard employed. Values below the quantitative limit should be reported as estimated values. Values below the laboratory method detection limit should be reported as less than the method detection limit. The method detection limit studies, analytical data and results should be on file at the laboratory.

Table 3 – Quality Control

QC Parameter	QC Limit	Frequency
Initial Calibration	(Intentionally blank)	A minimum of 3 concentration levels (or a specified by the method) and after the laboratory control sample, continuing calibration verification or method blank failure
Method blank	Method detection limit	One per set of samples
Lab control sample	85-115%	1 per batch
Continuing Calibration Verification	85-115%	at daily start up, 1 after each 10 determinations, and at the end of the batch
Laboratory Duplicate	20% relative percent difference	One per set of samples
Matrix Spike	75-125%	One per set of samples

Definitions:

- Initial calibration curve: calibration is needed for all analytes for example, calibration standards for ion chromatography, turbidimetric and spectrophotometric tests (correlation coefficient. ≥ .995). Initial calibration criteria must be met prior to analysis of samples.

- Continuing calibration verification (CCV): a verification of calibration is to be performed at the beginning of each analytical batch using a mid-range reference/ standard (as appropriate for method) from a source different from the initial calibration. If CCV is outside of QC limits, recalibrate instrument and rerun samples analyzed since the last compliant continuing calibration check.

- Laboratory control sample (LCS); a mid-level standard/reference (as appropriate for method) carried through the entire analytical procedure as for a sample. If QC criteria are not met for the LCS, determine the source of contamination, and repeat the analysis of the samples, method blank and LCS. The limits must be set for analysis to be acceptable.

- Method Blank: if the method blank is outside of QC limits, determine the source of contamination, and prepare a new blank and re-prepare all samples. Repeat until criteria are met.

- Duplicate: if the relative percent difference is outside of QC limits, flag the data results and report results in the narrative.

- Matrix Spike: If the percent recovery is outside of QC limits, flag the results and report. Spike levels are based on 2 x CRQL

B5.1. Laboratory Quality Control

The analyses shall include the following QC procedures, when applicable:

Table 4 – Laboratory Quality Control

Procedure	Frequency
Calibration	As required
Standards	Daily
Method Blanks	Daily
Duplicates	5 percent
Matrix Spikes	5 percent
Surrogates	Each sample

Duplicate samples, rinsate blanks, and trip blanks will be collected in the field at the rate required for each particular project. Laboratory blanks, standards, and check samples will be run at the rate specified in the appropriate analytical method. Matrix spikes and matrix spike

duplicates will be run at the rate of one per 20 samples or one per batch, whichever is more frequent. Performance evaluation samples will be run at a rate of once per calendar quarter or at a frequency determined by the Project Manager. Internal performance evaluation samples will be run at a frequency determined by the internal laboratory QC staff.

The analytical method performance will be evaluated by an examination of precision, accuracy, and completeness. Analytical data quality assurance objectives are presented in Section A7.2.

Precision is the ability to replicate a value. Precision is determined by measuring the agreement among individual measurements of the same property, under similar conditions. The degree of agreement, expressed as the relative percent difference (RPD), is calculated using the formula below.

Precision:

$$RPD = \frac{|V_1 - V_2| \times 100}{\frac{(V_1 + V_2)}{2}}$$

Where:

V_1=value 1
V_2=value 2

Accuracy is a measure of the closeness of an individual measurement to the true or expected value. To determine accuracy, a reference material of known concentration is analyzed or a sample that has been spiked with a known concentration is reanalyzed. Accuracy is expressed as a percent recovery and is calculated using the following formula.

Accuracy:

$$\%recovery = \frac{measured\ value}{true\ value} \times 100$$

Completeness is a measure of the quantity of valid data acquired from a measurement process compared to the amount expected under the measurement conditions. Completeness is usually expressed as a percentage.

Data reduction is the process by which raw analytical data generated from laboratory instrument systems is converted into usable concentrations. The raw data, which may take the form of area counts, instrument responses or observations, is processed by the laboratory and converted into concentrations expressed in the part per million or part per billion range. Raw data from these systems include compound identifications, concentrations, retention times, and data system printouts. Raw data is usually reported in

graphic form, bar-graph form or tabular form. Data reduction procedures will be explained in greater detail in the LQAM.

Laboratory audit procedures are presented in the LQAM.

B5.3. Field Audits

Field audits are performed by the QA/QC Manager or his designate on a periodic basis (based on project-specific needs) throughout the duration of the field program. The field audits will include an evaluation of sampling methods; sample handling and packaging; equipment use; equipment decontamination, maintenance, and calibration procedures; and -chain-of-custody (COC) procedures. In addition, all records and documentation procedures will be reviewed to ensure compliance with the project requirements. Any deviations from the Work Plan (WP) or Quality Assurance Project Plan (QAPP) will be recorded in the field notebook by the person conducting the audit, which will then inform the personnel involved in the activity of the problem and notify the Project Manager for initiation of any necessary corrective action procedures.

B6. Instrument/Equipment Testing, Inspection, & Maintenance

B6.1. Preventive Maintenance

A preventive maintenance program is necessary to help prevent delays in project schedules, poor output performance, or erroneous results in investigative and/or remedial operations. Qualified personnel will perform preventive maintenance on laboratory analytical equipment used in this program. Maintenance of field equipment will be performed routinely for sampling events. More extensive maintenance will be performed, based on hours of use, by a qualified servicing organization. Repairs, adjustments, and calibrations will be recorded. Records will be available for inspection by the Project Manager on request.

B6.2. Field Equipment

The three elements of the field equipment maintenance program include normal upkeep of equipment, service and repair (when required), and formalized recordkeeping of all work performed on each piece of equipment. This section addresses the normal equipment upkeep element of the maintenance program. For most of the equipment, normal maintenance will consist of cleaning outside surfaces, lubrication of all moving parts, and, if applicable, a battery level check and recharge or replacement as necessary. This program will include the maintenance of all monitoring, measuring, and test equipment returning from field use or any equipment used on a daily basis. The frequency of maintenance checks will be dependent on the individual needs and use of each piece of equipment. Details regarding the required maintenance and operational procedures for the field equipment can be found in the associated manufacturer's handbook or instruction manual. Maintenance procedures will be only those necessary for keeping an instrument in service or to prepare for everyday use. Repair problems will be referred to the manufacturer or other qualified servicing organizations.

The Project Manager or the designated task leader will be responsible for keeping all maintenance records, making sure all equipment used is maintained properly, informing field

team members of any specific maintenance requirements for equipment used at the site, and shipping any instrument in need of repair to the correct source.

The field personnel responsibilities include maintaining each piece of equipment located at the site and the maintenance of equipment after use. A record of equipment maintenance and repair will be kept in the field logbook.

B6.3. Rental Equipment

Rental equipment used on the project will be obtained only from a reliable rental supplier. The equipment will require an equipment test sheet to verify accuracy, maintenance, and upkeep of the equipment. A receipt indicating that the equipment has been checked upon return will be required as well.

B6.4. Laboratory Equipment

An important factor in maintaining accuracy and precision, achieving required holding times, and addressing contract schedule is preventive maintenance. As part of the laboratory's standard operating procedures, service contracts will be held on critical analytical instruments.

B7. Instrument/Equipment Calibration and Frequency

B7.1. Field Calibration Procedures

Measuring and test equipment shall have an initial calibration and shall be recalibrated at scheduled intervals against certified standards that have known and valid traceability to recognized national standards. Calibration intervals for each item shall be, at a minimum, in accordance with manufacturer's recommendations as defined in the equipment manual. Test equipment used for calibration of sensors shall be recalibrated at least once a year or when maintenance or damage indicates a need for recalibration.

Calibration standards shall be maintained and used in an environment with temperature, humidity, and cleanliness controls that are compatible with the accuracy and operating characteristics of the standards. An inspection will be made during the equipment calibration to evaluate the physical condition of the equipment. The purpose of the inspection is to detect any abnormal wear or damage that may affect the operation of the equipment before the next calibration. Equipment found to be out of calibration or in need of maintenance or repair will be identified and removed from service.

The QA/QC Manager shall be notified if the test equipment is found to be out of tolerance during inspection and calibration. The corrective actions to be taken include evaluating the validity of previous inspection or test results; evaluating the acceptability of the items inspected or tested since the last calibration check; and repeating the original inspections or tests using calibrated equipment when it is necessary to establish the acceptability of previous inspections or tests.

Each item of measuring or testing equipment in the calibration program shall be identified in such a way as to show its calibration status and calibration expiration date. Equipment history

records for measurement and test equipment shall be used to indicate calibration status and conditions, corrections to be applied, results of in-service checks, and repair history. This will provide a basis for establishing calibration frequencies and for remedial action if the instrument is found to be out of calibration.

Calibration frequency and procedures for each piece of equipment can be found in the manufacturer's manual.

B7.2. Laboratory Calibration Procedures

Laboratory instrumentation calibration procedures, frequency, and standards will be consistent with the requirements of the applicable analytical method. Additional information on instrumentation calibration procedures and frequency are presented in the LQAM.

B8. Inspection/Acceptance of Supplies and Consumables

The task manager will be responsible for inspecting sample containers before leaving for a dry or wet weather sampling event. The sample containers will be supplied by Microbac and will be inspected for cracks, ill-fitting lids, and other obvious defects before use and will be discarded if defects are found to be present.

The Microbac laboratory analyst assigned to conduct the analysis will be responsible for inspecting equipment and supplies upon receipt.

B9. Non-direct Measurements

No existing data was obtained or provided for this project.

B10. Data Management

B10.1. Data Management Locations

Data for this project will be produced in two locations: in the field and in the laboratory. The field data collection will be recorded on the field data sheets and in the field notebooks. The field data sheets and field notebooks will be submitted to the task manager when field activities are complete and will become part of the project file.

Field book entries will be completed for each day of field activities by the field sampling team and forwarded to the Project Manager. The report includes the weather during sampling, samples taken, instrument maintenance and calibration, and any field changes, problems, or corrective actions. The field books will document the enforcement of the Quality Control program through the field audit program.

All field books, laboratory data reports, and reports will be stored in one central location at Apex's office in Manassas, VA.

C. ASSESSMENT AND OVERSIGHT

C1. Assessment and Response Actions

Planned assessments include routine monitoring of field activities and the verification and validation of all reported data (conducted in accordance with sections D1 and D2). The monitoring of field activities will be conducted by the Project Manager or QA/QC Manager, on-site, at the time(s) when samples are being collected for both field and laboratory analysis and when field analyses are conducted. The purpose of this audit will be to identify any performance deficiencies and to verify conformance with the procedures discussed and referenced in this QAPP. The findings from this audit will be used to plan any follow-up actions needed to ensure resolution of performance deficiencies. The Project Manager or QA/QC Manager will have the authority to stop work on-site if he/she deems the findings from the audit to justify such actions. The Task Manager/Key Personnel, in consultation with the Project Manager, will be responsible for corrective actions relating to field activities.

The narrative report included with each laboratory data report will include a discussion of the quality of the reported laboratory data, which will result from the Microbac Laboratory Director's audit of data quality according to SOP No. QM-001-020 Issue No. 001, "Quality Assurance Manual- Baltimore Division". The Microbac Laboratory Director will be responsible for corrective actions at the laboratory. The Project Manager or QA/QC Manager will review the results from all reported data to verify that it is useable for the purposes of this project, and that it is reasonable when taken with other facts known about the site. Sections D1 and D2 of this QAPP discuss the verification and validation process in detail.

If a particular analysis is deemed "out-of control," corrective action will be taken to ensure continued data quality. Actions that may be taken include, but are not limited to:

- Rechecking calculations
- Checking QC data on other samples
- Auditing laboratory procedures
- Reanalyzing the sample if the holding time requirements have not been exceeded
- Accepting data with the acknowledged level of uncertainty
- Discarding data

The coordinator of the laboratory's analytical section will be responsible for initiating laboratory corrective action when necessary. The laboratory Data Quality Reviewer will make recommendations for corrective actions outside the laboratory to the Apex Project Manager or QA/QC Manager.

C2. Reports to Management

Reports to management will include a DOEE Notifications and a Sampling Report following each successfully sampled qualifying rain event (greater than 0.1" of rain).

Apex will notify the DOEE by email of all attempts (successful or not successful) within 48-hours of the first business day following each attempt to collect samples.

Following successfully sampled rain events, Sampling Reports will be generated by the Project Manager for inclusion in DOEE's project file upon receipt of analytical results. Reports will be submitted no later than 30 days following each sampling event. These reports will include a summary description of sampling activities, field analysis results, a summary of analytical data, and a discussion of any problems encountered and associated corrective actions. Attachments will include field data sheets, Chain-of-Custody documents, precipitation data including hydrographs, and a full copy of the laboratory analytical report.

Field activity reports will be generated by Project Manager within thirty days of the sampling event. Laboratory analytical reports will be generated by Microbac laboratory staff and submitted to the Project Manager after receipt of the samples. Apex will then include the analytical information, in conjunction with the field information, in a Sampling Report to DOEE. Any significant QA problems encountered in the laboratory or in the field, as deemed by Microbac or the QA/QC Manager will be reported immediately to the Project Manager via telephone.

C2.1. Nonconformance Reporting

A nonconformance is defined as an identified or suspected deficiency in an approved document (e.g., technical report, analysis, calculation, computer program); or a deficiency in an item where the quality of the end item itself or subsequent activities using the document or item would be affected by the deficiency; or an activity that is not conducted in accordance with the established plans or procedures.

Any team member (including laboratory team members) engaged in project work that discovers or suspects a nonconformance is responsible for initiating a nonconformance report. This team member shall obtain a nonconformance report number from the QA/QC Manager. The QA/QC Manager shall evaluate each nonconformance report and shall provide a disposition that describes the actions to be taken.

The Project Manager shall ensure that no further project work dependent on the nonconforming item or activity is performed until approval is obtained and the nonconformance report is closed out. If the nonconformance is related to material, the Project Manager shall be responsible for marking or identifying, with the nonconformance report number, the nonconforming item (if practical), and indicating that it is nonconforming and is not to be used.

A copy of each closed nonconformance report shall be included in the quality assurance file. The QA/QC Manager shall maintain copies of all nonconformances.

D. DATA REVIEW AND USABILITY

D1. Data Review, Verification, and Validation

Data will be accepted if they meet the following criteria:

1. Field data sheets are complete and signed.
2. Field data and laboratory data were validated.
3. Actual sample locations and collection procedures match the proposed sample locations and collection procedures identified in sections A6 and B1.1.1, respectively.
4. Sample handling procedures are documented on COC forms.
5. Field book narrative matches the proposed sample handling procedures identified in sections B2 and B3 (e.g., samples properly preserved, microbiological holding time of six hours not exceeded).
6. Field QC was conducted as outlined and meets the acceptance criteria in section B5 (field equipment was calibrated daily, field duplicate sample results within 5%, field rinsate blank indicated no cross-contamination).

Any deviations from the QAPP must be reported in the field book or analytical data report. The analytical data report will include the information described in section A9. The DOEE Water Quality Division Contract Administrator will verify the content of these reports.

If the data fails to meet the criteria, they will be flagged by the Project Manager as estimated values. Any flagged data will be discussed with the project team and DOEE Water Quality Division to determine if the data point will be rejected and re-sampling done.

D2. Verification and Validation Methods

The Project Manager will validate the field data and any problems identified during this process will be reported to the Project Manager in field book activity reports.

The Microbac Laboratory Director will validate the laboratory data according to SOP No. QM-001-020 Issue No. 001, “Quality Assurance Manual- Baltimore Division”. Any problems identified during this process will be reported to Apex Companies, LLC Project Manager in the analytical data report.

The Project Manager or QA/QC Manager will review and verify the field sheets, field book activity reports, and the analytical data report. Any problems or deviations identified will be discussed with the project team.

D3. Reconciliation with User Requirements

The laboratory shall review data prior to its release. Objectives for review are in accordance with the QA/QC objectives stated earlier in this document. The laboratory is required to evaluate their ability to meet these objectives. Outlying data shall be flagged in accordance with laboratory SOPs and

corrective action shall take place to rectify the problem. Laboratory review SOPs will be found in the LQAM.

Under the National Pollutant Discharge Elimination System (NPDES) program, the laboratory is required to participate in the annual Discharge Monitoring Report–Quality Assurance (DMR-QA) study program. DMR-QA evaluates the analytical ability of the laboratories that routinely perform self-monitoring analyses required by their NPDES permit. Microbac Laboratory will participate in this annual study.

The quality assurance (QA) laboratory will deliver the sample results and data package, which will be reviewed by the QA/QC Manager. The data reviewed will include all blank, sample, and internal quality control results such as spike and surrogate recoveries and replicate analyses. Any significant differences or problems discovered will be addressed; corrective action, such as reanalysis and/or resampling, may result at the Project Manager's discretion.

The sample event report will be submitted within 30 days of the actual sampling event and based on actual analytical results receipts from the Microbac laboratory. The results of the field parameters tested during the sampling event, field data collection sheet, site narrative report of the event and sampling locations where the actual storm water samples collected, site photographs and meteorological data predicting the storm-water event, signed chain-of-custody forms and the laboratory analytical results of analyzed samples will be included in the sample event report. Two hard copies of the report and an electronic report copy will be submitted for each event report to DC DOEE. The electronic environmental measurement data will be submitted in a format specified by the Contract Administrator.

Appendix 1

(Laboratory Quality Assurance Manual)

MICROBAC®

Quality Manual

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Table of Contents

Section 2: References

2.1 References

The following is a list of primary sources for obtaining analytical methods. This list is not all-inclusive.

Guidelines Establishing Test Procedures for the Analysis of Pollutants, 40 CFR Part 136 (Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977) as most recently published in the Federal Register.

Methods for Chemical Analysis of Water and Wastes, EPA-600/4-79-020, USEPA, Revised March 1983.

Methods for the Organic Chemical Analysis of Municipal and Industrial Wastewater, EPA-600/4-82-057, USEPA, Office of Research and Development, Environmental Monitoring and Support Laboratory, July 1982.

Methods for the Determination of Organic Compounds in Drinking Water, EPA-600/4-88/039, USEPA, Office of Research and Development, Environmental Monitoring Systems Laboratory, Revised July 1991 and supplements.

Test Methods for Evaluating Solid Wastes, SW-846, Fifth Edition and earlier editions, USEPA, Office of Solid Waste and Emergency Response, November 1986 and updates.

Standard Methods for the Examination of Water and Wastewater, on-line version and earlier editions.

Annual Book of ASTM Standards, current editions, American Society for Testing and Materials (ASTM), Philadelphia, PA.

Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, EPA-600/4-89-017, ORD, Atmospheric Research and Exposure Assessment Laboratory, June 1988.

Methods for the Determination of Metals in Environmental Samples, Supplement I, EPA-600/R-94/111, USEPA, Office of Research and Development, May 1994.

Methods for the Determination of Inorganic Substances in Environmental Samples, EPA-600/R-93/100, USEPA, Office of Research and Development, August 1993.

Official Methods of Analysis, AOAC, 18th edition and earlier editions.

Compendium of Methods for the Microbiological Examination of Foods, APHA, current edition.

Standard Methods for the Examination of Dairy Products, APHA, current edition.

Bacteriological Analytical Manual, FDA, online version.

Microbiology Laboratory Guidebook, USDA/FSIS, 3rd ed., online version.

The United States Pharmacopoeia/The National Formulary, United States Pharmacopoeia Convention, Inc., Rockville, MD.

2.2 Other Documents Used in QA Manual Preparation

ISO/IEC 17025: 2005, General requirements for the competence of testing and calibration laboratories.

2009 TNI Environmental Laboratory Sector Standard – Vol 1 - Management and Technical Requirements for Laboratories Performing Environmental Analysis.

Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals, an Aid to Interpretation of ISO/IEC 17025, AOAC International, 2015.

Manual for the Certification of Laboratories Analyzing Drinking Water, 5th edition, EPA 815-B-97-001, USEPA Office of Groundwater and Drinking Water, March 2005.

Handbook for Analytical Quality Control in Water and Wastewater Laboratories, EPA-600/4-79-01, March 1979.

Quality Assurance Principles for Analytical Laboratories, 3rd ed., AOAC International, 2000.

Consolidated Quality Systems Manual (QSM) for Environmental Laboratories, Version 5.1 Department of Defense (DoD), 2016.

Good Laboratory Practice for Non-Clinical Laboratory Studies, 21 CFR Part 58

Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food, 21 CFR Part 110

Current Good Manufacturing Practices in Manufacturing, Packing or Holding Operations for Dietary Supplements, 21 CFR Part 111

Good Laboratory Practice Standards for FIFRA, 40 CFR Part 160

Current Good Manufacturing Practices., 21 CFR Parts 210. 211 and 820.

Section 3: Introduction

3.1 General

Microbac laboratories are located across many states which often differ in both regulatory and laboratory accreditation requirements. This Quality Manual is not intended to supersede regulatory requirements. Where state regulatory and/or laboratory accreditation bodies provide additional requirements, those will be followed and/or contained either in a laboratory work instruction or in an appendix to this Quality Manual.

Quality control terms are generally defined within the Section that describes the activity. Other definitions can be found in Q-024, Quality Glossary and Acronyms

3.2 Purpose

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

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

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

In addition, this Quality Manual outlines how we meet:

- ISO/IEC 17025:2005
- AOAC INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals.
- TNI Standard and/or Department of Defense, QSM
- State certification and accreditation standards
- GxP Regulations

It is the responsibility of each laboratory identified in Appendix A to carry out its testing and calibration activities in accordance with the requirements and this Quality Manual. All personnel take an active role in establishing, implementing and maintaining our quality management program. We do not separate quality from our daily business. Quality cannot be something that we do just to pass audits. Quality is integrated into every facet of the decision-making process in the management of our laboratories and the science we practice.

3.3 Distribution

This Quality Manual is maintained on the Company SharePoint site.

Revision History

Section 3, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

Section 4: Management Requirements

4.1 Organization

4.1.1 Legal Identification/Registration

Microbac Laboratories, Inc.
One Allegheny Square, Suite 400
Pittsburgh, PA 15212
Phone: 412.459.1060
Fax: 866.515.4668
Web: www.microbac.com

Location specific information is listed in Appendix A.

4.1.2 Laboratory Requirements

The Divisions of Microbac Laboratories, Inc. have been organized to satisfy the needs of the client and regulatory authorities (as shown in Appendix B by laboratory location) and to also meet the standards and regulations listed in Section 3.2 of this manual.

4.1.3 Scope of Management System

The management system covers activities in the laboratory's permanent facilities, satellite facilities, and temporary mobile facilities. The fields of activities include:

Potable and Non-Potable Water
Solid and Hazardous Waste
Food Microbiological and Chemical Analysis
Pharmaceutical Products
Tobacco Testing
Dietary Supplements Analysis
Sanitizer Efficacy Studies
Mechanical Testing
Fuel Analysis
Air Testing
Product Testing
Clinical Testing
Viral Clearance

4.1.4 Potential Conflicts of Interest

Not applicable. Each laboratory is a standalone testing entity that provides independent testing services. All laboratories are wholly owned by a corporation based in Pennsylvania.

4.1.5 Organization

A. Management and Technical Personnel

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

Details:
Responsibilities are detailed in 4.1.5 (F).

Departures from the organizational and management policies in this manual can only be approved by the Microbac senior management and Quality Manager.

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

Departures from test methods or technical standard operating procedures (SOPs) can only be approved by the Technical Manager and Quality Manager. (See also section 4.9.1).

Departures from protocols can only be approved by the GLP study director.

Departures from clinical protocols are approved by Principle Investigator, Sponsor and Institutional Review Board (IRB) and regulatory authorities.

B. Undue Pressure

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

Details:
Microbac's Ethics and Data Integrity program includes:

- documented data integrity procedures authorized by Microbac senior management and reviewed annually
- an Ethics and Data Integrity Policy signed by all management and staff on hire. This policy is approved, dated and distributed by the Chief Executive Officer.
- annual ethics and data integrity training for all staff
- procedures for confidential reporting of alleged data integrity issues
- an audit program that monitors data integrity and procedures for handling data integrity investigations and client notifications

The following topics and activities are covered in initial training:

- organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting
- how and when to report data integrity issues

- record keeping
- training, including discussion regarding all data integrity procedures
- data integrity training documentation
- in-depth data monitoring and data integrity procedure documentation
- specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal. Annually all employees are required to sign conflict of interest statements. For additional information, please see HR-011, Conflict of Interest.

Confidential reporting of data integrity issues is provided through Microbac's Open Door Policy where employees can report possible violations of the Ethics and Data Integrity Policy, anonymously, without the fear of reprisal. Employees can email their concern to opendoor@microbac.com which goes only to the Company's Ethics Compliance Officer.

All investigations resulting from data integrity issues are conducted confidentially. Documentation of the investigation is maintained by Corporate Quality. If the investigation identifies an ethical concern, corporate quality advises the laboratory management of the need for any further detailed investigation.

C. Client Confidentiality

Policy:

It is the policy of our laboratory to protect the confidential information and proprietary rights of our client including the electronic storage and transmission of results.

Details and Procedures:

All employees sign an Employee Confidentiality Agreement. The signed agreement is retained in each employee's personnel file.

Test results are only released to the client. Release to someone other than the client requires the express permission of the client, except when the situation contravenes State or Federal Legislation and the results must be provided to the appropriate agency. The release of test results to anyone other than the client requires the permission of Corporate Counsel. Refer to SOP# Q-009 Confidentiality of Client Data.

D. Operational Integrity

Policy:

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

Details and Procedures:

To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through check sample programs. Impartiality is assessed through audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving his or her skills. Operational

integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through corrective action procedures.

E. Organizational Structure

Policy:

The organization and management structure of the Microbac Laboratories, Inc. and the relationships between management, technical operations, support services, and the quality management system is presented in the current Microbac Laboratories, Inc. Organization Chart. Refer to Appendix C

Details

Both corporate and laboratory organizational charts are available with this manual as a reference record and is considered the official record on the date it is marked.

F. Responsibility and Authority

Depending on the size, complexity, and needs of individual laboratories, some personnel may perform multiple functions. In addition, certain roles may be split among multiple people. The laboratory must define these circumstances. All personnel have the responsibility to inform laboratory management of any departures from the management system and test procedures in addition to any actions that can be taken to prevent or minimize such departures.

President

- Develops primary goals, operating plans, policies, and short and long range objectives for the Company.
- Directs and coordinates activities to achieve profit and return on capital.
- Establishes organizational structure; delegates authority to subordinates.
- Leads the Company towards objectives, meets with and advises other executives, and reviews results of business operations.
- Determines action plans to meet the needs of stakeholders.
- Represents organization to major clients, government agencies, shareholders, and the public.

Corporate Quality

- Develops and maintains corporate policies and procedures for the Company.
- Maintains Company Master Document List
- Supports implementation of management system companywide.
- Provides training tools for laboratories related to management system.
- Facilitates internal audit system.
- Assists laboratories with accreditation efforts.
- Develops and facilitates tabulation of company quality benchmarks.
- Reviews quality manual annually to maintain its currency.

Managing Director/Division Manager

- Responsible for the quality, safety, financial, technical, human resource and service performance of the laboratory
- Interface with Corporate management regarding administrative policy, capital expenditures and business planning.

- Ensures that personnel are free from any commercial, financial and other undue pressures that might adversely affect the quality of their work
- Develops primary goals, operating plans, policies, and short and long range objectives for the laboratory.
- Directs and coordinates activities to achieve profit and return on capital.
- Establishes organizational structure and delegates authority to subordinates within the Guidelines established by Corporate and this document.
- Provides the necessary resources (personnel, equipment) to implement and maintain an effective quality and data integrity program.
- Leads the laboratory towards objectives, meets with and advises other executives, and reviews results of business operations
- Determines action plans to meet the needs of stakeholders
- Represents organization to major clients, government agencies, shareholders, and the public

Technical Manager

- Ensures that the laboratory complies with ISO 17025, TNI Standard, AOAC Guidelines, and/or DoD QSM as appropriate for their location.
- Is/are knowledgeable of the scope of all processes under their supervision
- Makes recommendations to management related to required resources necessary to ensure confidence in the laboratory's results
- Ensures equipment is maintained and calibrated, reporting all deficiencies (e.g., equipment malfunctions) in the appropriate manner
- Ensures personnel are trained for the duties they perform - includes substitutes when regular personnel are absent
- Ensures appropriate corrective actions are taken to address analyses identified as requiring such actions by external, internal or procedural audits
- Maintains current employee job descriptions for their area of responsibility
- Maintains records and manages all aspects of testing activities

Quality Manager

- Ensures that the Quality Management System is established, implemented and maintained in accordance with the ISO 17025, TNI Standard, AOAC Guidelines, GxP, and/or DoD QSM as appropriate for their location.
- Serves as the focal point for QA/QC; has a general knowledge of the analytical methods for which data review is performed and is responsible for the oversight and/or review of quality control data.
- Functions independently from laboratory operations for which they have oversight being able to evaluate data objectively and perform assessments without outside influence
- Manages the internal audit program including in-depth data monitoring.
- Coordinates laboratory accreditation activities
- Maintains a master list of current versions of local quality documentation; handles the distribution locally maintained documents.
- Trains personnel on Quality Management System activities
- Monitors the Quality Management System
- Reports on the performance of the Quality Management System to senior management for review and as a basis for improvement of the Quality Management System
- Supervises the laboratory's proficiency testing program
- Notifies laboratory management of deficiencies in the quality system
- Monitors corrective actions
- For GxP laboratories:

- Maintains a Master Schedule
- Monitors and inspects GLP studies
- Monitors laboratory for compliance with regulations
- Issues QA Report
- Reviews Final Report
- Record retention

Supervisors and Group Leaders

- Implements company policies, procedures and practices within their respective groups.
- Responds to client inquiries and provides professional advice
- Provides technical leadership within their discipline.
- Recommends need for personnel; approves new hires
- Orientates new personnel
- Determines technical training needs of personnel
- Conducts employee performance reviews
- Schedules vacation and coverage
- Ensures that all health and safety regulations are followed
- Prioritizes workload
- Facilitates operational concerns in their area
- Ensures accurate and consistent testing procedures through the validation of all current procedures and by developing, validating and implementing new procedures
- Coordinates purchasing requests
- Ensures that the operational needs are within budget and advising management of any discrepancies
- Controls and improves work group processes.

Analysts and Technicians

- Maintains records of all quality activities as required in SOPs and test methods
- Handles samples and perform analyses according to SOPs and test methods
- Writes SOPs and test methods
- Signs reports when designated with signing authority
- Maintains and calibrates equipment
- Reports deficiencies or malfunctions to the supervisor
- Identifies and records nonconformities in the Conformance Management System (CMS)
- Identifies and records potential nonconformities in the CMS.
- Corrects nonconformities and potential nonconformities
- Improves laboratory and/or quality activities on a continuous basis

Sample Administration and Project Managers

- Performs work functions and keeps records as per approved SOPs and/or laboratory policies
- Determines scope and schedule for each job in new work review, as assigned
- Accepts work with a typical scope (i.e., standard turnaround, testing, matrices and reporting).
- Reviews sample log-in.
- Prepares, reviews and signs reports, as assigned; approves client invoices
- Coordinates technical needs of the client
- Identifies and records nonconformities in the Conformance Management System (CMS)
- Corrects nonconformities and potential nonconformities
- Improves laboratory and/or quality activities on a continuous basis
- Represents the laboratory to the client

Logistics Support Personnel

- Fill bottle orders for sample containers.
- Pick-up samples from local clients and pick-up locations.
- Process sample receipt and log-in accurately and in a timely manner
- Store samples and maintain sample storage areas
- Coordinate the receipt of materials with the laboratory staff

G. Laboratory Supervision

Policy:

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

Details:

Adequate supervision is ensured through designated supervisors as well as through documentation such as this Quality Manual, test methods and SOPs. A thorough orientation and training program is adhered to for all new employees. Ongoing training for regular personnel is required.

H. Technical Management

Policy:

A Technical Manager is assigned for each major department of the laboratory. They have overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.

Details:

Technical Managers monitor standards of performance in quality control and quality assurance, as well as the validity of the analyses performed and the reporting of results. While the Technical Manager may at times delegate duties to other personnel, the Technical Manager is accountable for any nonconforming activities.

I. Quality Manager

Policy:

The Quality Manager is approved through Corporate Quality and appointed by the Managing Director. The Quality Manager has documented training and/or experience in QA/QC procedures and in the laboratory's quality management system. The Quality Manager, who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed. The Quality Manager reports directly to corporate quality and has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

Note: Where staffing is limited, the quality manager may also be the technical manager.

Details:

This statement notifies all laboratory personnel that the following personnel in Appendix D are the Quality Managers as assigned by the table and authorized below by the Vice President of Quality. Any change in this position requires the reissue of this appendix to all holders of controlled copies of the Quality Manual. The following signature also serves as approval for this Quality Manual

and affirms senior management's commitment to the policies and procedures set forth in this manual.

Bradley A. Stawick
Vice President, Quality

J. Managerial Substitutions

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

Details:
Each laboratory must define their key roles and assign deputies. This information will be approved by the local senior management and local Quality Manager and filed on SharePoint in the laboratory's "Deputy" folder maintained in the laboratory's Quality Manual Appendix Training and qualifications for deputies shall be documented and filed in the training files.

Laboratory management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments due to employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent. If sufficient human resources are not available, management will identify the best possible solution to meet operational and quality requirements.

Accrediting bodies require notification of changes in personnel for key roles. The Quality Manager is responsible for complying with the schedule for these notifications to meet the laboratory's accreditation requirements.

K. Awareness

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

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

4.1.6 Communication Processes

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

Revision History:
Section 4.1, Rev 0: Effective 03.31.16
Section 4.1, Rev 1: Effective 04.01.17
Changed corporate office address; 4.1.5 -A-added authorities for departures for protocols and clinical protocols; B-authority for EDI policy is now CEO; C-Corporate Counsel permission required for release of test results to someone without client authorization; E- added corporate organization chart, removed reference to Microbac Leadership structure memo; F- added responsibility to implement appropriate quality standards including ISO17025 to Technical Manager; added responsibility of implementing company policies and practices within their departments and to provide technical leadership to Supervisors; removed reference to Study Directors and Principle Investigators for GxP from sample administration section; updated samples administrative responsibilities and added section on logistics personnel; J- state that Deputy folder is kept in laboratories' Quality Manual appendix.

Approved by:

Bradley A. Stawick
Vice President, Quality

4.2 Management Systems

4.2.1 Policies and Procedures

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

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

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

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

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

- standard operating procedures
- quality control plans in test methods
- organizational charts
- proposals
- project management schemes
- protocols
- sampling plans

4.2.2 Quality Policy Statement

Policy:
The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement, and endorsed by all management, and reviewed during management review.

Quality Policy Statement:
To ensure accurate and timely testing services and to continuously meet or exceed the stated or implied expectations of our clients through day-to-day interactions.

a) ***Management commitment to good professional and ethical practice and quality of services provided to the client***: tests and calibrations are always carried out in accordance with stated standardized methods and clients' requirements. Requests to perform tests that may jeopardize an objective result or have a low validity are rejected.

b) ***Standards of service** include*:
- client satisfaction
- accuracy
- timeliness

Excellence in the workplace is promoted by providing all employees with the knowledge, training, and tools necessary to allow for the completion of accurate and timely work.

c) ***Purpose of management system related to quality***: to manage our business by meeting the needs of our clients.

d) ***Personnel***: familiarize themselves with quality documentation and implement the policies and procedures in their work.

e) ***Management is committed to complying with ISO 17025, TNI Standard, GxP, DoD QMS, and AOAC Food Program requirements as defined in Appendix B and to continually improve the effectiveness of the management system***: the objective of this Quality Manual is to document the compliant policies and associated procedures that are integrated into our daily activities. Continual improvements are established, implemented, and locked into the management system.

Additional objectives include:
- to establish the level of the laboratory's performance
- to make test method changes to improve performance
- to participate in proficiency testing or quality evaluation programs with peer laboratories
- to ensure that all personnel are trained to a level of familiarity with the quality management system appropriate to the individual's degree of responsibility
- to improve and validate laboratory methodologies by participation in method validation collaborative tests

4.2.3 Commitment to the Management System

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

Details**:**
The results of the management system are regularly reviewed during management review (section 4.15) and continual improvements are made as outlined in section 4.10.

4.2.4 Communication of Requirements

Policy**:**
Microbac management communicates to the organization the importance of meeting client requirements as well as statutory and regulatory requirements.

Details:
In general, the underlying message in all oral and written management communications involves meeting requirements. Meeting client requirements ensures that ongoing business relationships secure the contracts that keep everyone employed. Meeting statutory and regulatory

requirements ensures that laboratory operations will not be disrupted and the organization can continue to meet client needs.

4.2.5 Quality Manual

Policy:
This Quality Manual outlines the structure of the documentation used in the quality management system. This Quality Manual references supporting procedures including technical procedures and is maintained up to date.

Details:
This quality management system is structured in three tiers of documentation. The tiers are as follows:

I. Quality Manual
II. Standard Operating Procedures and Test Methods
III. Records

Sections of this manual are updated by making a change to the section and then increasing the section revision number by one. The Table of Contents and the company master document list are also updated.

Laboratory specific appendices to this manual are approved by the laboratory's Managing Director and Vice President, Quality. These appendices include documents that supplement the Quality Manual to address additional requirements and information that are facility-specific.

Quality Project Plans may be prepared on a client specific basis. These Quality plans supplement the general requirements as stated in this Manual and associated documents as necessary to comply with client project requirements.

The documents referenced above written in English and are controlled documents.

The following records and directive documents are referenced in the Quality Manual, but maintained separately:

- laboratory's scope of tests (section 4.1.3)
- confidentiality agreements (section 4.1.5 C)
- organizational chart(s) (section 4.1.5.E)
- copies of the Quality Policy Statement posted in the laboratory (section 4.2.2)
- master document list (section 4.3.2)
- contract review (section 4.4.2)
- procurement and subcontracting records (sections 4.6 and 4.5.4)
- client complaint records (section 4.8.1)
- corrective action records (section 4.11)
- preventive action records (section 4.12)
- audit schedule and records (section 4.14.3)
- identification of resources and management review (section 4.15.1)
- job descriptions (section 5.2.4)
- training records (section 5.2.5)
- facility floor plan (section 5.3.1)
- quality control plan / criteria for workmanship (section 5.4.1)
- validation of test methods (section 5.4.5)

- equipment inventory and records (sections 5.5.4 and 5.5.5)
- calibration status indicators (section 5.5.8)
- reference standards inventory (section 5.6.3)
- verification records (section 5.9)
- statistical techniques (section 5.9)
- test reports (section 4.13.2 and 5.10)
- identification of the laboratory's approved signatures (section 5.10.2)
- concurrence statement (environmental laboratories only, see appendix L)

4.2.6 Technical Management and the Quality Manager

The roles and responsibilities for technical management and the Quality Manager are outlined in section 4.1.5 (F) of this manual.

Technical management ensures that section 5 of this manual is implemented and maintained. The Quality Manager ensures that section 4 of this manual is implemented and maintained.

4.2.7 Maintenance

Policy and Details:

Corporate Quality ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

Revision History

Section 4.2, Rev 0: Effective 03.31.16
Section 4.2, Rev 1: Effective 04.01.17
Section(s): 4.2.1: added protocols to details section; 4.2.5: added approval of laboratory appendices; replaced "modify" with "supplement" in discussion of quality project plans; added location of quality manual concurrence statements in Appendix L.

Approved By:

Bradley A. Stawick
Vice President, Quality

4.3 Document Control

4.3.1 Policies and Procedures

Policy:
SOP# Q-010 describes the process used to control quality management system documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, specifications, instructions, and manuals.

Details:
Document means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled by Corporate Quality include:

- Quality Manual
- Standard Operating Procedures and corporate issued test methods
- Standards (See 3.2)

Note: Laboratory issued SOPs approved prior to January 1, 2017 are controlled locally until they are revised.

The control of data related to testing and calibration is covered in section 5.4.7. The control of records is covered in section 4.13.

4.3.2 Document Approval and Issue

A. Review / Approval / Master List

Policy and Details:
All documents issued to personnel in the laboratory as part of the quality management system are reviewed and approved for use by authorized personnel prior to issue (i.e., reviewed by personnel knowledgeable in the documented activity and then approved by management). A master list identifying the current revision status and distribution of documents in the quality management system is readily available to preclude the use of invalid and/or obsolete documents (see SOP# Q-010). A revision history of documents is also maintained.

Documents, except for the Quality Manual, are formally reviewed to ensure their continuing suitability on a biennial basis except where programs or regulations dictate a more frequent review. The Quality Manual is reviewed annually. Refer to Q-010 for examples of programs that require more frequent review.

B. Availability and Obsolete Documents

Policy and Details:
The master list shows the status of all controlled documents. The master list document is organized with the following information:

- Document #

- Title
- Revision #
- Effective Date
- Date of last review
- Locations

Controlled documents are approved before issue.

SOP# Q-010 for document control ensures that:

- authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed
- documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements
- invalid or obsolete documents are promptly removed from all points of issue or use to assure against unintended use
- obsolete documents retained for either legal or knowledge preservation purposes are either suitably marked (i.e., stamped "OBSOLETE" and dated) or moved to an archived directory.

Where applicable, obsolete documents will be stored in an archive as historical documents according to 21 CFR Part 58, Retention of Records.

C. Identification

Policy and Details:

All quality management system documentation is identified by:

- date of issue and/or revision number
- page numbering
- total number of pages (e.g., page 5 of 5)
- issuing authority (i.e., approval signature)

4.3.3 Document Changes

A. Review / Approval

Policy:

Changes to documents are reviewed and approved by the same function (i.e., personnel or position) that performed the original review. The designated personnel have access to pertinent background information upon which to base their review and approval.

Details:

Developments in policies and procedures require documents to be changed from time to time. Changes to documents receive the same level of review and approval as the originals.

The Quality Manual is reviewed annually by Corporate Quality. Records are kept of this review.

Unless otherwise required by a specific program or regulation, test methods and SOPs are reviewed on a biennial basis. Procedures for this are outlined in SOP# Q-010.

Obsolete documents are withdrawn, but a copy is retained for archive purposes and clearly labeled as “obsolete” and archived.

B. Identification of Changes

Policy:
The nature of document changes is identified in the document.

Details:
As outlined in SOP# Q-010. In general, changes are identified in the document revision history section.

C. Amendments by Hand

Policy and Details:
Hand-written amendments to documents are not permitted.

D. Computerized Documents

Policy and Details:
SOP# Q-010 details how changes in documents maintained in computerized systems are made and controlled.

Revision History
Section 4.3, Rev 0: Effective 03.31.16
Section 4.3, Rev 1: Effective 04.01.17
Sections: 4.3.1: Added laboratory-issued SOPs approved prior to 01.01.17 are controlled locally until they are revised; 4.3.2.A: Added reference to Q-010 for example of programs where document review requirements supersede the biennial review; deleted specific program references from this section. 4.3.2.B: Added reference to 21 CFR, Part 58 for storage of obsolete documents in archive; will mark documents “obsolete” instead of “archived”; 4.3.3.A: Annual Quality Manual review is corporate responsibility.

Approved By:

Bradley A. Stawick
Vice President, Quality

4.4 Review of Requests, Tenders, and Contracts

4.4.1 Policies and Procedures

Policy:

SOP# Q-011 is used to review requests, tenders, or contracts. This procedure ensures that:

a) the client requirements including the methods to be used are adequately defined, documented and understood (see section 5.4.2)
b) the laboratory has the capability and resources to meet the requirements
c) the appropriate test method is selected and capable of meeting the client's requirements (see section 5.4.2)

Any differences between the request or tender and the contract are resolved before any work commences. Each contract must be acceptable by both the laboratory and the client.

Details:

The request, tender and contract review is conducted in a practical and efficient manner, and the effect of financial, legal, and time schedule aspects are considered. Internal client review of requests, tenders, and contracts are performed in a simplified manner.

The review of capability establishes that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial test using samples or items of known value to determine uncertainties of measurement, limits of detection, and confidence limits.

The contract review ensures that each client's requirements are adequately defined and documented before the services are provided. This should ensure that any order, once accepted, can be completed without delay, and that the client's requirements including delivery date, technical specification, and cost can be met.

If the contract review highlights any ambiguities or uncertainties, then the client will be contacted and the problem resolved before the order is accepted.

SOP# Q-011 also describes the activities that take place should there be a subsequent amendment to a client's order.

Typical types of contracts include:

- Approved service quotations
- Confidentiality agreements
- Non-disclosure agreements
- Sample submission requests or chains of custody
- Memorandum of agreement
- Memorandum of understanding
- Research proposals and contracts
- Verbal orders (oral agreements)
- Activity plans
- Client specific quality assurance project plans

4.4.2 Records of Review

Policy:
Records of request, tender and contract review, including significant changes, are maintained. Records of pertinent discussions with a client relating to the client's requirements or the work during the period of execution of the contract are also maintained.

Details:
For review of routine and other simple tasks, the date and the identification (e.g., initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on grant of the contract for on-going routine work performed under a general agreement with the client, if the client's requirements remain unchanged. For new, complex or advanced testing tasks, a more comprehensive record is maintained.

4.4.3 Review of Subcontracted Work

Policy:
Request, tender, and contract review also includes work that is to be subcontracted by the laboratory.

Details:
Subcontractor laboratories are reviewed as described in section 4.5.

4.4.4 Notification of Client

Policy and Details:
Clients are informed of deviations from the contract. This is typically communicated to the client prior to the performing the deviation.

4.4.5 Contract Amendment

Policy and Details:
If a contract needs to be amended after the work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel.

Revision History
Section 4.4, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

4.5 Subcontracting Tests and Calibrations

4.5.1 Subcontractor Competence

Policy:
Work that must be subcontracted for any reason is subcontracted to a technically competent laboratory. For environmental testing, certain states require certification from the same state when subcontracting occurs.

Details:
The subcontracted laboratory demonstrates technical competence by possession or receipt of one or more of the following:

- recognized technical accreditation
- satisfactory performance of appropriate quality control check samples, certified reference material, in-house reference material or replicate analysis
- audit of the subcontractor's quality management system by our auditors

It is the responsibility of the Quality Manager to assess and approve the competence level of subcontractor laboratories.

4.5.2 Client Approval

Policy:
Clients are advised of work (or any portion thereof) that is being subcontracted to another laboratory and their approval is obtained (preferably in writing).

Details:
Clients are advised of subcontracted work through fee schedules or any type of contract listed in section 4.4.1.

Subcontracted work is identified on the final report.

4.5.3 Assurance of Subcontractor Competence

Policy:
The laboratory is responsible to the client for the subcontractor's work. Technical competence of subcontractor laboratories is demonstrated through various records.

> **Note** – there may be circumstances where the client specifies which subcontractor is to be used. In such cases, we may not be able to demonstrate the competence of the subcontractor and therefore are not responsible for the results.

Details:
Records of subcontractor competence may include, but are not limited to, the following:

- accreditation certificates or documentation
- registration certificates
- check sample results
- audit results
- approval by the Quality Manager

4.5.4 Subcontractor Register

Policy:
A register of all subcontractors performing tests and calibrations is maintained.

Details:
The approved register of subcontractors and all assessment records are maintained by the Quality Manager.

Revision History
Section 4.5, Rev 0: Effective 03.31.16
Approved By:

Bradley A Stawick
Vice President, Quality

4.6 Purchasing Services and Supplies

4.6.1 Policies and Procedures

Policy:
The laboratory ensures that purchased supplies and services that affect the quality of tests are of the required or specified quality, by using approved suppliers and products.

Details:
SOP# Q-012 is used for purchasing, receiving, and storage of supplies that affect the quality of testing. Consumable materials are stored according to the appropriate test method, SOP, work instruction or manufacturer's specifications.

4.6.2 Specifications

Policy:
Only services and supplies of the required quality are used. These quality requirements are detailed in laboratory SOPs and will identify the appropriate minimum specifications when necessary.

Details:
Packing slips are checked against package content labels and matched with the purchase order and/or ordering database if accepted. Once accepted, the packing slip is dated and initialed as evidence of compliance. Certificates of analysis (COA) are maintained on file after the COA is checked to ensure the received item meets minimum specifications.

Chemicals are purchased with manufacturer's certificates where needed. Uncertified chemicals are purchased from ISO 9000 registered companies. Whatever the source, the laboratory verifies the quality of the standards by comparing the new batch of standards to the old. Due regard is paid to the manufacturer's recommendations on storage and shelf life.

Reagents are generally purchased from manufacturers who have a quality management system based on ISO 9000. The grade of any reagent used (including water) is stated in the method together with guidance on any precautions to be observed in its preparation or use.

Suppliers of calibration services and reference standards must be ISO 17025 accredited. Suppliers of reference materials must be ISO 17034 and/or Guide 34 accredited, if available and practical for A2LA accreditation only.

Where no independent assurance of the quality of procured goods or services is available or the supplier's evidence is insufficient the laboratory ensures that purchased goods and services comply with specified requirements. Where possible and practical the laboratory ensures that goods are inspected, calibrated, or are otherwise in compliance with any standard specification relevant to the calibrations or tests concerned.

4.6.3 Purchasing Documents

Policy:
Purchasing requests are recorded on the purchase order or in an ordering database containing data describing the product ordered and/or requested services. The purchase order is reviewed and approved for technical content prior to release.

Details:
The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, quality required and quality management system standard under which they were produced.

The completion of the purchase order is the responsibility of the purchasing individual. They review the purchase order for accuracy and approve the technical content prior to release with their signature and the date.

4.6.4 Approved Suppliers

Policy:
Suppliers of critical services and supplies are evaluated and approved before use. An approved supplier list is maintained.

Details:
Audits or tender evaluation is conducted to qualify suppliers of critical services and supplies prior to use. The criteria for evaluation may include, but is not limited to the following:

- references
- accreditation
- formal recognition

The records are maintained by the laboratory.

Once a supplier is approved, it is reevaluated biennially per the criteria listed above along with service and performance to the laboratory. This review is recorded and the approved supplier list updated.

Revision History
Section 4.6, Rev 0: Effective 03.31.16
Section 4.6, Rev 1: Effective 04.01.17
Section(s): 4.6.2 & 4.6.3: Added reference to ordering databases; 4.6.4: Added supplies to the policy and details; changed review of approved suppliers from “biannually” to “biennially.”

Approved by:

Bradley A. Stawick
Vice President, Quality

4.7 Service to the Client

4.7.1 Service

Policy:

Client requests are clarified for the clients or their representatives. Furthermore, the client or their representative will be afforded the right to monitor the performance of the laboratory in relation to the work performed, if the laboratory ensures confidentiality to other clients.

Details and Procedures:

Service to the client includes:

- Affording the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of work performed for the client; it is understood that such access should not conflict with rules of confidentiality of work for other clients or with safety.
- Preparing, packaging, and dispatching of test items needed by the client for verification purposes.
- Maintaining of open contacts. The client values advice and guidance in technical matters, and opinions and interpretations based on results. Contact with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests.
- GxP laboratories permit an authorized employee or duly designated representative of EPA or FDA, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies. The records inspection and copying requirements should not apply to quality assurance unit records of findings and problems, or to the action recommended and taken, except that EPA or FDA may seek production of these records in litigation or formal adjudicatory hearings.

4.7.2 Feedback

Policy and Details:

The laboratory seeks feedback from the client. Positive and negative feedback can be obtained passively through ongoing communications with the client (e.g., review of test reports with clients) or actively through client satisfaction surveys. The corporate office requests feedback from clients annually by way of an online survey. The feedback is used to improve the quality management system, testing activities, and client service.

Revision History

Section 4.7, Rev 0: Effective 03.31.16
Section 4.7, Rev 1: Effective 04.01.17
Section(s): 4.7.1: Added discussion of GxP; 4.7.2: Added annual corporate survey.

Approved By:

Bradley A. Stawick
Vice President, Quality

4.8 Complaints

Policy:

SOP# Q-017 describes the process used to handle and resolve complaints received from clients or other parties. Records are maintained of all complaints and follow-up.

Details:

Records of complaints include the following information:

- details of the complaint
- investigation
- corrective action
- follow-up verification

See also section 4.11.

All personnel are responsible for recording and responding to complaints.

Revision History

Section 4.8, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

4.9 Control of Nonconforming Testing

4.9.1 Procedures to Control Nonconforming Work

Policy:
SOP# Q-016 is used to control any aspect of testing and/or calibration work, or the results of this work, when they do not conform to the test methods or the agreed requirements of the client.

Details:
The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports) are defined and taken into consideration when nonconforming work is identified
- an evaluation of the significance of the nonconforming work is made
- correction is taken immediately, together with any decision about the acceptability of the nonconforming work
- where necessary, the client is notified and the work is recalled
- the responsibility for authorizing the resumption of work is defined

Identification of nonconforming work or problems with the quality management system or with testing activities can occur at various locations within the quality management system and technical operations such as:

- client complaints
- quality control
- instrument calibration
- checking of consumable materials
- staff observations or supervision
- test report checking
- management reviews
- internal or external audits

Planned departures will be fully documented by the laboratory Quality Manager and include the reason for the departure, the affected standard operating procedures, the intended results of the departure and the actual results. Planned departures do not require audits or investigations. The corrective action procedure is used for documenting this process. Refer to 4.1.5.A.

4.9.2 Root Cause Analysis

Policy:
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 are followed to identify the root cause(s) of the problem and to eliminate this (these) cause(s).

Details:
SOP# Q-008 outlines the recording of the root cause analysis for investigating nonconforming work.

Situations warranting corrective action investigation include:

- failure to comply with test method including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- failures related to compliance with support procedures such as sample receipt, procurement or information management necessary to ensure the integrity and representative nature of the sample
- failures or suspected failures in method performance as demonstrated by unacceptable quality control sample and proficiency test sample results
- deficiencies identified by quality audit(s) and client complaints
- deficiencies identified through data validation
- neglect to check the inherent property of the sample that compromises the testing

Revision History

Section 4.9, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

4.10 Improvements

Policy:
The laboratory continually improves the effectiveness of its management system using the quality policy, quality objectives, audit results, analysis of data, corrective actions, and management review.

Details:
The laboratory has implemented a continual improvement philosophy within the management system. Every employee in the laboratory is encouraged to suggest new ideas for improving services, processes, systems, productivity, and the working environment.

Opportunities for improvement of operations and processes are identified by managers on a continual basis from ongoing feedback on operations and through management reviews. Opportunities for improvement of services are identified by anyone within the organization.

Inputs for improvement opportunities can be obtained but are not limited to the following sources:

- client satisfaction surveys and any other client feedback
- employees, suppliers, and other interested parties
- internal and external audits of the management system
- records of service nonconformities
- data from process and service characteristics and their trends
- market research and analysis

Opportunities for improvement may also be identified on a special project basis. The following are listed only as examples:

- improving usefulness of bench space
- reducing excessive handling and storage
- reducing test/calibration failures
- reducing instrument downtime
- eliminating rework

Opportunities for improvement from daily feedback on operational performance (i.e., internal audits, client feedback, and test failures) are evaluated by the Technical or Quality Manager. Typically, they are implemented through the corrective and preventive action system.

Opportunities for improvement from analysis of longer-term data and trends are evaluated and implemented through the management review process. They are prioritized with respect to their relevance for achieving quality objectives. When opportunities for improvement are no longer supported by the current policy and objectives, management will establish new quality objectives, and possibly change the policy. The process for this evaluation is described in Section 4.15. Longer-term improvement projects are initiated through the management review process, as well as the corrective and preventive action system.

Service improvement opportunities are evaluated by management. They are implemented through the supervisor of the laboratory who ensures that the improvements are validated as outlined in Section 5.4 of this manual and appropriate level of quality control is performed on an ongoing basis.

Revision History

Section 4.10, Rev 0: Effective 03.31.16

Bradley A. Stawick
Vice President, Quality

4.11 Corrective Action

4.11.1 General

Policy**:**
The SOP# Q-008 is utilized for implementing corrective action when nonconforming work or departures from policies and procedures in the quality management system or technical operations have been identified. The procedure requires that appropriate authority be designated for the implementation of corrective actions. The procedure includes root cause analysis, selection and implementation of corrective action, and monitoring of actions for effectiveness

Details:
Problems with the quality management system or technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feed-back from clients, or staff observations.

Corrective action investigations are documented and required changes to operational procedures are implemented. The corrective action request (CAR), investigation and resolution are recorded in the CMS system.

4.11.2 Cause Analysis

Policy:
Corrective action always begins with an investigation to determine root cause(s) of the problem.

Details:
Potential causes of the problem could include client requirements, the samples, sample specifications, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration.

4.11.3 Selection and Implementation of Corrective Actions

Policy and Details:
After determining the cause(s) of the problem, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the problem and to prevent recurrence. It should be noted that any corrective actions taken to eliminate the cause(s) of nonconformities or other departures are to a degree appropriate to address the magnitude of the problem and commensurate with the risks encountered. Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Action

Policy:
After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

Details:
Monitoring is assigned to an appropriate individual such as the originator of the CAR, the originator's manager or the Quality Manager. Changes resulting from corrective action are documented. If corrective actions are shown to be ineffective, the investigation is reopened; additional root causes proposed and corrective action implemented.

4.11.5 Additional Audits

Policy:
Where the identification of nonconformities or departures casts doubts on compliance of policies, procedures, regulations, international quality standards, the appropriate areas of activity are promptly audited in accordance with section 4.14.

Details:
Special audits follow the implementation of corrective actions to confirm their effectiveness. A special audit is only necessary when a serious issue or risk to the business is identified. Special audits are carried out by trained and qualified personnel who are, whenever resources permit, independent of the activity to be audited. See section 4.14 for more details.

Revision History
Section 4.11, Rev 0: Effective 03.31.16
Section 4.11, Rev 1: Effective 04.01.17
Section 4.11.4: Added proposed corrective actions are found to be ineffective, the investigation is reopened.

Approved By:

Bradley A. Stawick
Vice President, Quality

4.12 Preventive Action

4.12.1 Preventive Action Identification

Policy:
Opportunities for needed improvement and potential sources of nonconformities, either technical or with the quality management system shall be identified. If action is required, action plans are developed, implemented and monitored, to reduce the likelihood of occurrence of such nonconformities and to take advantage of the improvement opportunities.

Details:
Records of preventive action include the following information:

- details of potential nonconformities
- action plan
- preventive action
- follow-up verification

These records are maintained in the CMS system.

4.12.2 Preventive Action Plans

Policy:
The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective.

Details:
Preventive action may result from the review of operational procedures and analysis of data. Analysis of data includes trend analysis, analysis of proficiency testing results, and risk analysis.

SOP# Q-008 is utilized to implement opportunities for needed improvement and prevent potential sources of nonconformities.

Revision History
Section 4.12, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

4.13 Control of Records

4.13.1. Procedures

Policy:
The laboratory maintains a record system appropriate to its needs, records all laboratory activities, and complies with applicable standards or regulations as required. The SOP# Q-013 is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose of quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective and preventive action records.

Details:
Records are available to demonstrate conformance to requirements and effective operation of the Quality Management System. Quality records from suppliers are also maintained.

All records, including test reports, are safely stored in secured areas in confidence to the client, restricted from unauthorized access and locked when appropriate. Records that are stored only on electronic media are supported by the hardware and software necessary for their retrieval.

GxP laboratories maintain a master index of records.

The dating format for records is MM/DD/YYYY.

4.13.1.2 Record Integrity

Policy:
All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Details:
The retention times for records are generally set at five years. Exceptions to this are client and program specific requirements.

Records may be in the form of any type of media, such as hard copy or electronic media.

4.13.1.3 Record Security

Policy**:**
All records are held secure and in confidence.

Details:
Access to stored records is controlled and documented. An access log is kept for records taken from and returned to the storage area. Access to electronic records is secured through password control. Refer to IT-100-1, Password Security Policy.

Access to protected records in our GxP laboratories is secured (locked). The Managing Director assigns a record archivist who monitors day-to-day activities. Only persons authorized by the

record archivist may enter the archive. A log is kept of the material taken and replaced from the archive.

4.13.1.4 Record Backup

Policy:
SOP# Q-013 is followed to protect and backup data/records held on computers at all times and to prevent unauthorized access to or amendment of data/records on computers.

Details:
Data is password protected.

Electronic backups of records ensure integrity and availability of data / information in the event of a system / power failure.

4.13.2 Technical Records

4.13.2.1 Record Information

Policy:
Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records, personnel records and a copy of each test report issued are retained for five years or for a period specified in program or client requirements.

The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the test uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for sampling, performing of each test and/or calibration and checking of results.

Details:
Technical records are accumulations of data (see 5.4.7) and information that result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, note books, instrument printouts, magnetic media, check sheets, work notes, control graphs, test reports, calibration certificates, client's notes, papers and feedback, and test reports to clients.

The records for each test contain sufficient information to permit its repetition. Records may include:

- sampling records (environmental)
- sample receipt
- sample handling, storage, and disposal
- sample preparation
- sample analysis (raw data)
- identification of personnel for all steps of the analysis
- analyst proficiency
- equipment identification and performance
- calibration records
- media and reagent performance, where appropriate
- standards batch # or lot #, where appropriate

- results
- reviews
- reports (including transmissions)

Note - the above records may be stored in separate locations. They are cross-referenced for easy retrieval.

A record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record is maintained.

4.13.2.2 Recording

Policy:
Observations, data, and calculations are clearly and permanently recorded in the designated record and identifiable to the specific job at the time they are made.

Details:
Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected and/or after calculations are made.

4.13.2.3 Corrections to Records

Policy:
Changes to test data are made so as not to obscure or delete the previous data entry.

Details**:**
Mistakes are crossed out using a single line and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records include a reason for the change and are signed or initialed and dated by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.

Revision History
Section 4.13, Rev 0: Effective 03.31.16
Section 4.13, Rev 1: Effective 04.01.17
Section 4.13.1: Deleted detail for Master List of Records; relocated the information to SOP Q-013; 4.13.1.3: Revised "safely stored and held in secured locked areas" to "restricted from unauthorized access and locked when appropriate."; added use of storage access log; added section on GxP archive; 4.13.2.3: Added need to document reason for all error correction; removed allowance for not recording a reason for transcription errors in non-GxP laboratories.

Approved By:

Bradley A. Stawick
Vice President, Quality

4.14 Internal Audits

4.14.1 Internal Audit Program

Policy:
The internal audit program involves periodic audits conducted according to a predetermined schedule for each year. This program is defined on an annual basis and conducted as outlined in this section with further details found in SOP# Q-014. All elements of this Quality Manual will be audited each year and all relevant laboratory records are available to personnel conducting the audit. These audits are performed to verify operations continue to comply with the requirements of this Quality Manual and are effective.

Details:
The Quality Manual, test procedures, and laboratory results are verified for compliance. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.11.5). Audits may be performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit.

Generally, the types of audits include:

- quality management system
- processes and procedures
- method, services, and reports
- regulatory compliance

GLP, GCP and cGMP require that the Quality Assurance Unit (QAU) inspect each study at intervals adequate to ensure the integrity of the study. The QAU must maintain written records of each periodic inspection showing the date, the study inspected, the phase or segment, the person performing the inspection, findings and problems, recommended actions and any scheduled re-inspection date. Results from audits (status reports) are reported to test facility management and study director.

4.14.2 Corrective Action

Policy:
When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken and clients are notified if investigations show that laboratory results may have been affected. For environmental work, if audit findings cast doubt on the validity of test results, clients shall be notified within 72 hours of completing the investigation of the finding and any actions are discharged within the agreed timeframe.

Details:
Nonconformities that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformities that require a more involved resolution are recorded on a CAR and resolved as described in section 4.11.

Corrective actions and client modifications must be kept on record for each audit deviation that casts doubt as described in this section.

4.14.3 Records and Management

Policy:
Records are made of the activity being audited, the audit findings, and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.

Details:
A report is prepared by the auditors and distributed to those audited and/or the area manager/supervisor within an appropriate and agreed timeline. The audit report may include the following sections, as appropriate:

- audit objective and scope
- area or section audited
- personnel involved – auditors and auditees
- date of audit
- reference documents
- observations including nonconformities and commendations
- opening and closing meetings
- recommendations
- audit report distribution

The appropriate manager is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are maintained.

4.14.4 Follow-up Audits

Policy:
Follow-up audits are performed to verify and record the implementation and effectiveness of the corrective action taken.

Details:
The follow-up audit is performed at a mutually acceptable time between the area implementing corrective action and the auditor. This time is determined when the CAR is issued.

Revision History
Section 4.14, Rev 0: Effective 03.31.16
Section 4.14, Rev 1: Effective 04.01.17
4.14.1: Added paragraph related to QAU inspections performed in GxP laboratories.

Approved By:

Bradley A. Stawick
Vice President, Quality

4.15 Management Reviews

4.15.1 Review of Quality Management System and Testing

Policy:

Senior management periodically (at least annually) and in accordance with a predetermined schedule and SOP# Q-015, conduct a review of the laboratory's quality management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

Details:

The review takes account of:

- suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal audits
- corrective and preventive actions
- assessments by external bodies
- results of inter-laboratory comparisons or proficiency tests
- changes in the volume and type of work undertaken
- feedback from clients, including complaints and client satisfaction surveys
- recommendations for improvement
- other relevant factors, such as quality control activities, resources and personnel training

Results of the review feed into the laboratory planning system and include goals, objectives and action plans for the coming year.

A management review can be supplemented by consideration of related subjects at regular management meetings.

4.15.2 Findings, Actions, and Records

Policy and Details:

Findings from management reviews and the actions that arise are recorded in the minutes of the meeting. Management will ensure that the actions are discharged within an appropriate and agreed upon timeline.

Revision History

Section 4.15, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

Chapter 5: Technical Requirements

5.1. General

5.1.1 Correctness and Reliability

Policy and Details:
Correctness and reliability of the tests and/or calibrations performed have many contributing factors including:

- human factors (see section 5.2)
- accommodation and environmental conditions (see section 5.3)
- test and calibration methods and method validation (see section 5.4)
- equipment (see section 5.5)
- measurement traceability (see section 5.6)
- sampling (see section 5.7)
- handling of test and calibration items (see section 5.8)

5.1.2 Measurement Uncertainty

Policy:
When developing test and calibration methods and procedures, total measurement uncertainty must be accounted for in the training and qualification of personnel, and in the selection and calibration of equipment.

Details:
The extent to which the factors contribute to total measurement uncertainty differs between (types of) tests and between (types of) calibrations.

See section 5.4.6 for more details.

Revision History
Section 5.1, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

5.2. Personnel

5.2.1 Competence and Qualification

Policy:
Management ensures the competency of all specific equipment operators, those performing tests and/or calibrations, those evaluating results and signing test reports. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified based on appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in test reports also have:

- relevant knowledge of the technology used for the manufacturing of the items, materials, products tested, or the way they are used or intended to be used and of the defects or degradation that may occur during or in service
- knowledge of the general requirements expressed in the legislation and standards
- an understanding of the significance of deviations found regarding the normal use of the items, materials, or products concerned

Details:
Management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. In some technical areas, it may be required that the personnel performing certain tasks be certified. The laboratory is responsible for fulfilling specified certification requirements of personnel. The requirements for personnel certification might be regulatory, might be included in the standards for the specific technical field, or required by the client. (NELAP accredited laboratories to reference TNI V1M2 5.2.6)

New employees or employees new to a given task must successfully complete initial demonstration of competence on the portion of the method that they are responsible for prior to working on client samples.

Continued competence is monitored and where this is not achieved, the need to retrain personnel is considered. Where a method or technique is not in regular use, the verification of personnel performance before they undertake tests may be necessary.

5.2.2 Training Policies and Procedures

Policy:
Management will formulate the goals with respect to the education and the skills of the laboratory personnel. The training program is relevant to the present and anticipated tasks of the laboratory. SOP# Q-018 is utilized to identify training needs and providing the necessary training for personnel. The effectiveness of the training actions taken is evaluated.

Details:
The skills and knowledge are defined in the job description for each job function as described in section 5.2.4. Management compares the job description to the skills and knowledge of the new incumbent to determine the training needs.

Training in the laboratory must include all methods or parts of methods and techniques that personnel are asked to perform. Minimally, the analyst must demonstrate competency through

observation by trainer and verification using replicate and/or check samples. For technicians who perform only parts of the method, confirmation of competency may be verified by observation only. Re-verification of all personnel must be performed annually on all methods or techniques pertinent to their job description.

In some cases, it may be appropriate to define competence related to a technique or instrument rather than methods. If so, it will be necessary to define for each method, the necessary technique-based competence required together with any additional requirements.

5.2.3 Employees

Policy:
Competent permanent or contractual employees are employed in the laboratory. The technical manager ensures that contractual, additional technical employees, and key support personnel are supervised and work in accordance to the policies and procedures of this Quality Manual.

Details:
Laboratory duties must be either performed or supervised by an appropriately experienced person qualified to perform the task. Personnel must demonstrate competence and have authorization for the task prior to working on client samples.

5.2.4 Job Descriptions

Policy:
Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained. See section 4.1.5.f. Further detail may be maintained by local management.

Details:
Minimum contents of job descriptions may include:

- the duties required of the position
- the act of planning tests and/or calibrations and evaluation of results
- the responsibility of developing and validating new methods as / when requested
- expertise and experience
- qualifications and training programs
- managerial duties

5.2.5 Authorized Personnel

Policy:
Management authorizes specific personnel to perform sampling, test and/or calibration, to issue test reports, to give opinions and interpretations and to operate equipment. Records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel and contracted personnel are maintained. This information is readily available and includes the date on which authorization and/or competence was confirmed and the criteria on which the authorization is based and the confirming authority.

Details:

The purpose of these records is to provide evidence that personnel have been adequately trained and their competence to perform tests has been assessed. In some cases, it may be pertinent to state any specific limitations to competence. The records are maintained in the training file and include:

- academic and professional qualifications
- external and internal courses attended
- relevant on-the-job training and retraining as necessary (i.e., demonstration of competence)
- skills and experience (i.e., resume)
- relevant authorizations

Revision History

Section 5.2, Rev 0: Effective 03.31.16
Section 5.2, Rev 1: Effective 04.01.17
Section(s): 5.2.1: Details: Added employees new to a given task must demonstrate competence prior to working on client samples; 5.5.2: replaced “management” with “trainer” when observing analyst competency; 5.2.3: clarified authorization to work on client samples is required; 5.2.4: Added reference to 4.1.5.f and added further detail may be maintained by local management.

Approved By:

Bradley A. Stawick
Vice President, Quality

5.3. Accommodations and Environmental Conditions

5.3.1 Facility

Policy:
Laboratory facilities are appropriate to attain correct performance of tests and/or calibrations. This may include, but not limited to, energy sources, lighting, HVAC and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. Care is taken when sampling, tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented.

Details:
This section deals with the test areas in the laboratory and premises for support such as sample receipt and storage. Central laboratory supplies and services, such as water purification systems, HVAC, and sample storage, are appropriate to facilitate proper performance of tests.

5.3.2 Monitoring

Policy:
Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Due attention is paid, for example, to biological sterility, dust, air quality, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Testing is stopped when the environmental conditions jeopardize the results of the tests.

Details:
Laboratories are ventilated to reduce the levels of contamination, lower humidity, and control temperature. Laboratories' test areas are climate controlled. Airborne microorganisms are controlled by air systems with filters. Verification is done using air sampling devices or air settling plates and surface swabs.

Bench tops and floors are made of impervious, smooth easily cleaned materials. There is adequate workspace per analyst while working. Walls and ceilings are made of materials that are smooth and easily cleaned. Critical work surfaces are monitored for pathogens where pertinent to the scope of the laboratory.

5.3.3 Separation of Incompatible Activities

Policy:
Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

Details:
Reference materials and certified reference materials must be kept separated from samples (log-in and storage). Sample log-in and storage must be segregated, ideally in a separate area from the testing laboratory, and include proper sanitation to exclude the possibility of cross-contamination. Segregation of activities is achieved through time and space allocations.

An example of space segregation would be for ultra-trace analysis. Physical separation of the ultra-trace analysis from high-level analysis is achieved by separate rooms.

An example of time segregation would be the coordination of activities at different times. It may be appropriate to perform work on "cleaner" samples first before starting "dirtier" type samples.

5.3.4 Controlled Access

Policy:
Access to and use of areas affecting quality of the tests and/or calibrations is defined and controlled.

Details:
Access to the laboratory is restricted to authorized personnel. The authorized personnel are made aware of the following items:

- the intended use of the area
- the restrictions imposed on working within such areas
- the reasons for imposing the restrictions

5.3.5 Good Housekeeping

Policy:
Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary.

Details:
Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements. The laboratory must maintain a master cleaning schedule of its facilities.

Revision History
Section 5.3, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick,
Vice President, Quality

5.4. Tests and Calibration Methods and Method Validation

5.4.1 General

Policy:
Methods and procedures used for all tests and/or calibrations are appropriate not only for the tests and or/calibrations, but also support activities such as:

- sampling, handling, transport, storage, and preparation of items to be tested and/or calibrated
- an estimation of the measurement of uncertainty as well as statistical techniques for analysis of test and/or calibration data where appropriate

Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing and/or calibration are available. All instructions, standards, manuals and reference data relevant to the work of the laboratory are maintained current and readily available to personnel. Deviation from test and calibration methods must be documented, technically justified, authorized, and accepted by the client.

Details:
There are SOPs for sampling, sample handling, transport, storage, preparation of test items, QA/QC procedures (media QC, incubation times and temperatures, equipment calibration and maintenance, process control QC), and standards for approving / rejecting results. These may be combined with or separate from the method. See SOP Q-010, Document Control for details.

International, national, or regional standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations are not necessarily supplemented or rewritten as an internal procedure when they are written in a way that can be used as published by laboratory staff. Consideration may need to be given to providing additional documentation for optional steps in the method.

5.4.2 Selection of Methods

Policy:
Test and/or calibration methods, including methods for sampling, meet the needs of the client and are appropriate for the tests and/or calibrations it undertakes. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

Details:
Methods that have been published either in international, national, or regional standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer are selected when the client does not specify the method to be used. These methods may be adopted from the EPA, SMEWW, ASTM, AOAC, FDA, USDA, SMEDP, and Compendium of Methods for the Microbiological Examination of Foods, USP, etc. Methods used for regulatory compliance monitoring can only be modified to the extent that the program allows.

The ability of the laboratory to achieve satisfactory performance against documented performance characteristics is verified before samples are analyzed.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client is informed as to the method chosen. The laboratory confirms that it can properly operate standardized methods before introducing the tests or calibrations. If the standardized method changes the confirmation is repeated.

The client is informed when the method proposed by the client is inappropriate or out of date.

5.4.3 Laboratory-Developed Methods

Policy:
Introduction of test and calibration methods developed internally is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and ensure effective communication amongst all personnel involved.

Details:
Methods developed in-house are validated and authorized before use. Where available, Certified Reference Materials (CRMs) are used to determine any systemic bias, or where possible results are compared with other techniques, preferably based on different principles of analysis. Determination of uncertainty must be part of this validation process and is essential for ongoing quality control.

5.4.4 Non-Standard Methods

Policy:
Utilization of non-standard methods is subject to agreement with the client and includes a clear specification of the client's requirements and the purpose of the test. The developed method is validated appropriately before use.

Details:
Discussion and agreement for the use of non-standard methods is recorded as part of contract review procedures (see section 4.4).

All non-standard and new tests are validated for their intended purpose. Qualitative test methods must be validated to demonstrate estimated sensitivity and specificity, relative accuracy to official methods (if appropriate), positive and negative deviation, limit of detection, matrix effect, repeatability, and reproducibility.

Quantitative test methods are validated to demonstrate specificity, sensitivity, relative accuracy, positive and negative deviation, repeatability, reproducibility, and limit of determination.

For new methods where procedures are developing rapidly, especially for emergency situations, it may be necessary to circumvent normal validation procedures. The client will be notified of this situation.

New test and/or calibration methods are documented prior to providing test and/or calibration results to clients and contain at least the following information:

- appropriate identification
- scope
- description of the type of item to be tested or calibrated

- parameters or quantities to be determined
- apparatus and equipment, including technical performance requirements
- reference standards and reference materials required
- environmental conditions required and any stabilization period needed
- description of the procedure, including:
- affixing identification marks, handling, transporting, storing and preparing of items
- ensuring checks are made before the work is started
- checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use
- listing method of recording the observations and results
- indicating any safety measures to be observed
- criteria and/or requirements for approval/rejection (quality control plan)
- data to be recorded and method of analysis and presentation
- uncertainty or procedure for estimating uncertainty

5.4.5 Validation of Methods

A. Performance Characteristics

Policy**:**
Validation of a method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the test results.

Details:
The performance characteristics of a validation plan includes, as applicable:

- selectivity and specificity
- range
- linearity
- sensitivity
- limit of detection
- limit of quantitation
- ruggedness
- accuracy
- precision
- reporting limit
- repeatability
- reproducibility
- recovery
- confirmation techniques
- criteria for the number of samples tested to validate method as per defined scope of method
- action levels where defined by regulation
- quality control incorporating statistics as applicable
- interpretation of population results as applicable

Performance characteristics that are selected consider the intended use of the method, whether for screening, confirmatory analysis, or quantitation.

The design, verification of the method and documentation procedures for validation are planned and conducted by qualified personnel, equipped with adequate resources.

This section lists a few acceptable validation procedures. The choice of the procedure depends on the extent of the deviation from the published method.

Validation of methodology is a value judgment in which the performance parameters of the method are compared with the requirements for the test data. A prerequisite for a valid method is that data produced by the method must attain a state of statistical control. Such a state is obtained when the mean value of a large number of individual values tends to approach a limiting value called the limiting mean.

Methods may be validated by one or more alternative procedures. Some of these procedures are described below. Apparent differences can be analyzed statistically to confirm their significance. In all cases, the reasons for choosing one or more alternatives must be documented.

- analysis of standard reference materials (SRM) that are identical or almost identical to the test samples
- in the absence of suitable SRMs, analysis of reference materials that are similar in all respect to the test samples; the use and validity of this reference material must be documented
- using an alternative method to measure the same parameter provides a very high level of confidence if results are confirmed
- recovery studies by the addition of a known concentration of the parameter of interest to some of the replicates being measured
- proficiency testing programs as appropriate

The parameters to be determined include:

- the scope of the method and any known interference
- detection limit
- the range of concentration where the method is valid
- precision and bias
- intra-laboratory variations
- inter-laboratory variations

Judgment is required to determine if some or all of the above is required. Requirements will depend largely on the extent of deviation from the original method.

Developments in methodology and techniques require methods to be changed from time to time. The difference in performance between revised and obsolete methods is established so that it is possible to compare old and new data.

Where a change in method involves only minor adjustments, such as sample size, or glassware, the amended method is verified as fit for use. If proposed change involves technology or methodology, the laboratory seeks the approval of the accreditation body and follows regulatory guideline

Records are kept on all validation activities. The records include any of the performance characteristics chosen, reference procedures or guidance documents followed to validate the method or custom validation procedure, and a final confirmation (memo to file) that the method validation results are acceptable for continued use of the method. An example statement would be “This memo serves as record that the validation of the XYZ Test Method has been approved for use by [name and title of approver] along with the approval date.

B. Fit for Use

Policy:
The laboratory validates non-standardized methods, laboratory-designed/developed methods; standardized methods used outside their intended range, and amplifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs in the given application or field of application (may include procedures for sampling, handling, and transportation). The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

Details and Procedure:
Validation records are kept as in section 5.4.5.A. Included in these records is the validation procedure. The procedure used for the validation is likely to vary between different methods. Therefore, the procedures included in the laboratory records are not as detailed as a typical SOP, but are enough to re-create how the method was validated.

The techniques used for the determination of the performance of a method, are one of, or a combination of, the following:

- calibration using reference standards or reference materials
- comparison of results achieved with other methods
- inter-laboratory comparisons
- systematic assessment of the factors influencing the result
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When changes are made in the validated non-standard method, the influence of such changes carried out is documented and if appropriate a new validation is performed.

C. Client's Needs

Policy:
The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use is relevant to the client's needs.

Details:
Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

As method development proceeds, regular review is required to verify that the needs of the client are still being fulfilled. Changing requirements requiring modifications to the development plan are approved and authorized.

Validation is always a balance between costs, risks, and technical possibilities.

5.4.6 Uncertainty of Measurement

A. Calibration

Policy:
Physical, chemical, and biological standards are calibrated or characterized by qualified suppliers.

Details and Procedures:
Repeatability and reproducibility data are components of measurement uncertainty and are determined as a first step towards producing estimates of this parameter. The uncertainty of measurement is available on the supplier's certificate of analysis or calibration certificate.

Note – in-house calibrations include procedures for uncertainty of measurement estimates where this is common practice.

Note – certain accreditation program requirements (e.g. TNI) allow a laboratory to have a procedure but not calculate uncertainty for methods in that testing market. The way methods are defined and performed makes laboratory error very consistent batch to batch. Other testing markets, such as food and life sciences require measurement uncertainty determination.

B. Testing

Policy:
The SOP# Q-019 is utilized to estimate uncertainties of measurement in testing, except when the test methods preclude such rigorous calculations. In certain cases, it is not possible to undertake metrologically and statistically valid estimations of uncertainty of measurement. In these cases, the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope and makes use of previous experience and validation data.

Details:
The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- requirement of the test method
- requirement by the client
- if there are narrow limits on which decisions on conformity to a specification are based

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the reporting instructions (see section 5.10).

C. Uncertainty Components

Policy**:**
When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

Details:
Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested or calibrated and the operator.

The effects of sampling and the long-term behavior of the sample is normally not accounted for when estimating the measurement uncertainty.

5.4.7 Control of Data

A. Calculations and Data Transfers

Policy:
Calculations and data transfers are subject to appropriate checks in a systematic manner.

Details:
Test data are validated through the following arrangements by the Technical Manager

- checks to determine accuracy of calculations, conversions, and data transfers
- checks for transcription errors, omissions, and mistakes
- checks to determine consistency with normal or expected values

For those analyses where manual data reduction is required, it is performed according to the instructions provided in the test method or SOP.

Test data is reviewed and accepted or rejected based on a set of quality assurance and control criteria defined in the test method or program. Data review occurs at several levels: by the analyst through evaluation of quality control checks; by a peer or technical supervisor and finally by a project manager before the report is sent to the client.

B. Computers and Automated Equipment

Policy:
When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

- computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use
- procedures are established and implemented for protecting the integrity of data; such procedures include, but are not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing (see section 4.13.1.4)
- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data
- data is securely maintained by preventing unauthorized access to, and unauthorized amendment of, computer records
- manual manipulation of chromatographic software is done in accordance with SOP# Q-004, Manual Integration Policy.
- all electronic tracking and audit functions must be enabled where available in the instrument software

Details and Procedures:

Data generated using computer software programs that are interfaced directly to instruments often incorporates all dilutions and calculations, thereby eliminating the need for manual data reduction. Whenever possible instruments are interfaced directly into LIMS eliminating the need for manual data reduction.

Commercially developed software in general use within its designed application range may be considered sufficiently validated. Laboratory-developed spreadsheets using features such as calculations and conditional formatting must be validated prior to use and protected to prevent accidental changes Laboratory software configuration / modifications are validated as outlined in SOP# Q-020 Equipment.

If a digital signature is applied to a record, it must be equivalent to the handwritten signature on paper.

Revision History

Section 5.4, Rev 0: Effective 03.31.16
Section 5.4, Rev 1: Effective 04.01.17
Section 5.4.2: Added that method use for regulatory compliance monitoring can only be modified to the extent the program allows; 5.4.5.A: Added need for approval date to method performance validation; 5.4.7: added spreadsheets are to be protected to prevent accidental changes.

Approved By:

Bradley A. Stawick
Vice President, Quality

5.5. Equipment

5.5.1 Required Equipment

Policy:
The laboratory is furnished with all items for sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). When equipment is used outside the laboratory's permanent control, it ensures that the requirements of this Quality Manual are met.

Details:
Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method, including the equipment's range and specifications of operation.

5.5.2 Required Accuracy

Policy:
Equipment and software used for testing, calibration and sampling can achieve the accuracy required and comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. When received, equipment, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with section 5.6 before use.

Details:
The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

5.5.3 Authorized Personnel

Policy:
Equipment is operated by authorized personnel.

Details:
Access to laboratory equipment is controlled to ensure that only authorized personnel use equipment.

5.5.4 Unique Identification

Policy:
Each item of equipment used for testing and calibration is uniquely identified as appropriate.

Details:
Measuring and testing equipment is uniquely identified using any system that provides an identifier for each piece of equipment, such as serial numbers, asset numbers, or laboratory IDs. Measuring and testing equipment includes any instrument that could affect the quality of test

results. Components that can be interchanged between various instruments such as autosamplers are typically assigned individual asset numbers as well.

5.5.5 Inventory and Maintenance Records

Policy:
Records are maintained for each item of equipment significant to the tests and/or calibrations performed.

Details:
A database is used to capture the inventory information. The information below related to service and maintenance is kept in individual equipment files and/or binders. The records include the following:

- identity of the item of equipment (and its software)
- manufacturer's name, type identification, and serial number, company asset number and/or other unique identification
- date received and date placed in service
- operation status
- current location, where appropriate
- checks that equipment complies with the specification (see section 5.5.2)
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)
- damage, malfunction, modification or repair to the equipment
- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification (IQ/OQ)
- performance history (PQ), where appropriate (e.g., response time, drift, noise level)

5.5.6 Equipment Procedures

Policy:
SOP# Q-020 is utilized as an established plan for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and to prevent contamination or deterioration.

Note – additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations, or sampling.

Details and Procedures**:**
The procedures for each piece of measuring equipment are handled according to the Document Control SOP (Q-010). These procedures detail any information for safe handling, transport, storage, use, and maintenance of measuring equipment.

5.5.7 Out of Service Equipment

Policy:
Equipment that has either been subjected to overloading or mishandling, gives suspect results, has shown not to function to specifications, or has been shown to be defective or outside specified limits, is taken out of service, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly.

Details:
Testing work is discontinued on equipment that shows repeated nonconformance or failures. Not only do we do this for ethical reasons in support of our client, but minor repeated nonconformance may be indicative of more serious issues or pending malfunction.

Out of service equipment is clearly identified, initialed and dated by the person pulling the unit out of service.

The laboratory examines the effect of the defect or departure from specified limits on previous test and/or calibrations and institutes the “Control of Nonconforming Work” procedure as outlined in section 4.9.

5.5.8 Calibration Status

Policy**:**
Where practicable, equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate.

Details**:**
Calibration labels have a write-on surface and a pressure sensitive adhesive. The areas that are filled out include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, the equipment’s identification number, and any correction factors.

Where the use of pressure sensitive adhesive labels is not possible, other methods of identification may be used; e.g., metal tags or placards.

Measuring equipment that has failed calibration is taken out of service and labeled (see 5.5.7).

5.5.9 Return to Service

Policy:
When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

Details and Procedures:
Before equipment is returned to service the equipment is checked to ensure that the function and calibration status of the equipment are satisfactory per the governing SOP for that piece of equipment.

5.5.10 Periodic Checks

Policy:
When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to a defined procedure.

Details and Procedures:
As stated in section 5.5.6, the procedures for each piece of measuring equipment are available. SOP# Q-020 outlines a general maintenance plan for equipment and includes various checks. Internal quality control checks are specified in individual test methods.

5.5.11 Correction Factors

Policy:
Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software).

Details and Procedures:
The updating of correction factors, including all copies, is assured by following the appropriate test method or SOP. It is the responsibility of the Quality Manager to ensure that all copies are updated.

5.5.12 Safeguards against Adjustments

Policy:
Test and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate test and/or calibration results/status.

Details:
Safeguards against adjustment for laboratory equipment include:

- detailed SOPs and manufacturer's manuals on the operation of the equipment
- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel

Safeguards against adjustment for software include:

- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel

Revision History
Section 5.5, Rev 0: Effective 03.31.16
Section 5.5, Rev 1: Effective 04.01.17
Section(s): 5.5.7: Added language to the Detail section related to repeated equipment nonconformance; 5.5.8: allow use of metal tags or placards to indicate calibration status; 5.5.10: removed need to keep a copy of the SOP in the same room with the equipment.

Approved By:

Bradley A. Stawick
Vice President, Quality

5.6. Measurement Traceability

5.6.1 General

Policy:
Test equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling are calibrated before being put into service. All measurement and test equipment influencing the accuracy or validity of tests is calibrated and/or verified before being put into service. As mentioned in section 5.5, SOP# Q-020 outlines an established program for the maintenance of equipment and includes calibration.

Details:
The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform analyses

Procedures are documented where appropriate. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained for each standard. These records include, as applicable:

- laboratory identification#
- supplier, grade, batch#
- dates of preparation or verification
- measurement of weights, volumes, time intervals, temperatures, and pressures and related calculations
- relevant processes (e.g., pH adjustment, sterilization)
- identification of personnel involved

Records are maintained for each lot of test organisms. These records include, as applicable:

- laboratory identification #
- source, including age, species, and lot#
- date of arrival
- arrival condition
- culture and/or holding conditions

Reagents prepared in the laboratory are labelled to identify substance, strength, solvent (where not water), and date of preparation and/or expiry. The person responsible for the preparation of the reagent is identified both the label and records.

5.6.2 Specific Requirements

A. Calibration

Policy:
The program for calibration equipment is designed and operated to ensure that calibration measurements are traceable to the Système International (SI) units of measurement.

Details:
Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard or by reference to a natural constant the value of which, in terms of the relevant SI unit, is known.

The term “identified metrological specification” means that it must be clear from the calibration certificate against which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

When the terms “international standard” or “national standard” are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

Maintain certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability. Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

Reference standards, such as thermometers and weights, are traceable to a national or international standard (e.g., NIST).

B.1 Testing - Traceability to SI Units

Policy:
The requirements given in section 5.6.2.A apply to measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that equipment used can provide the accuracy of measurement needed.

Details:
The extent to which the requirements in section 5.6.2.A are followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements are strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in section 5.6.2. B.2.

B.2 Testing - Traceability to SI Units Not Possible

Policy:
Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:

- the use of suitable reference materials certified to give a reliable characterization of the material
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned
- participation in a suitable program of inter-laboratory comparisons or proficiency testing

Details:
Reliable characterization involves an estimate of recovery.

The laboratory participates in proficiency testing and/or check sample programs. The list of programs is maintained by the Quality Manager.

5.6.3 Reference Standards and Reference Materials

A. Reference Standards

Policy:
SOP# Q-021 outlines the program for the calibration of reference standards. Reference standards are obtained or calibrated by a body that can provide traceability as described in section 5.6.2.A. Such reference standards of measurement held by the laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

Details:
Reference standards are calibrated from ISO 17025 accredited providers. If an accredited provider is not available, the laboratory must consult with Corporate QA before proceeding.

B. Reference Materials

Policy:
Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

Details:
Reference materials, including calibration standards, used in chemical measurement are prepared so that the point of measurement is similar or equivalent to that of the samples. The matrix, prior to the addition of the analyte does not have a detectable concentration of the analyte. Reference materials cannot be used past their expiry. Reagents used in the preparation of reference materials, including calibration standards are of certified purity. Reference materials for methods listed on A2LA Scopes of Accreditation are obtained from ISO 17034 and/or Guide 34 accredited providers. If an accredited provider is not available, the laboratory must consult with Corporate QA before proceeding.

Certified reference cultures are traceable to a national or internationally recognized type culture collection. Reference cultures from laboratory sources must be identified to standard reference sources. These reference cultures must be handled to maintain their biochemical reaction and physiological characteristic integrity. All Reference Cultures and Certified Reference Cultures are not transferred more than five times from a type culture collection. Alternatively, re-identify the culture for key biochemical and physiological characteristics using national or internationally recognized

reference sources. Another alternative is to grow the type culture, then freeze it (or freeze-dry it), and use periodically. Thus, extending the length of time required before repurchase or re-identification. These may also be commercially available and purchased for use. Companies selling Certified Reference Cultures must comply with the requirements of ISO 17025 for a calibration laboratory.

C. Intermediate Checks

Policy:
Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

Details and Procedures:
The control check standards used to verify the accuracy of all the other standards are prepared independently from all the other standards used to establish the original calibration. These control check standards are preferably prepared from a separate lot # or source.

D. Transport and Storage

Policy:
SOP# Q-021 outlines safe handling, transport, storage and use of reference standards and reference materials to prevent contamination or deterioration and to protect their integrity.

Details:
Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations, or sampling.

Proper conditions are established for housing, handling, and care of reference standards, reference materials and test organisms. All information needed to properly identify references appears on their housing or containers.

Revision History:
Section 5.6, Rev 0: Effective 03.31.16
Section 5.6, Rev 1: Effective 04.01.17
Section(s): 5.6.1: Added laboratory identification to records maintained for standards and test organisms; 5.6.2: Added clarification to headers B.1 and B.2; 5.6.3.B: added reference materials cannot be used past their expiry.

Approved By:

Bradley A. Stawick
Vice President, Quality

5.7. Sampling

5.7.1 Sampling Plan and Procedures

Policy**:**
The laboratory uses sampling plans provided by clients or prepared in consultation with the client. The sampling plan and procedures are available at the location where sampling is performed. Sampling plans are based on appropriate statistical methods whenever reasonable. The sampling process addresses the factors to be controlled to ensure validity of the test and calibration results, including representative subsampling. SOP# Q-022 outlines the sampling plan and procedures for sampling substances, matrices, materials for subsequent testing.

Details:
Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide for testing or calibration as a representative sample of the whole. Sampling can also be required by the appropriate specification for which the substance, matrix, material or product is to be tested or calibrated. In certain cases, (e.g., forensic analysis), the sample may not be representative, but determined by availability.

The sampling plan describes the allocation, withdrawal and preparation of a sample. All samples are collected and placed in sealed containers except for unit packages of products which may be submitted in their entirety.

5.7.2 Deviations, Additions or Exclusions

Policy:
Where the client requires deviations, additions or exclusions from the sampling procedure, these are recorded in detail with the appropriate sampling data and included in all documents containing test and/or calibration results, and communicated to the appropriate personnel.

Details:
The physical appearance and temperature of all test items is observed and recorded upon receipt. Any deviations from specifications or observations are discussed with the client as to the suitability of the sample. Cross-contamination is the most critical issue from broken, leaking samples for both qualitative and quantitative tests.

5.7.3 Records

Policy:
SOP# Q-021 outlines the procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records include reference to the sampling plan, the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and any diagrams or other equivalent means to identify the sampling location as necessary, and, if appropriate, the statistics upon which the sampling procedures are based.

Details:
Adequate sample identification upon receipt in the laboratory includes:

- unique and unambiguous sample identification, usually a number or alphanumeric identification, retained throughout the testing life of the test item
- client name and person(s) the report will be sent to
- identification number or description from (client) if any
- sample source
- tests desired and/or methods requested
- containers provided, as applicable
- date of receipt
- delivery carrier
- Additional for environmental laboratories
  - sample collector
  - sample condition at receipt, including temperature and/or the presence of ice.
  - date and time of sampling
  - type of sample: composite or grab
  - sample preservation type
  - matrix

Revision History
Section 5.7, Rev 0: Effective 03.31.16
Section 5.7, Rev 1: Effective 04.01.17
Section(s): 5.7.1: allows exception for unit packages of products when placing samples in sealed containers; 5.7.3: added sample preservation type and matrix to environmental laboratories record keeping.

Approved By:

Bradley A. Stawick
Vice President, Quality

5.8. Handling of Test Items

5.8.1 Procedures

Policy:
SOP# Q-023 outlines the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and the interests of the laboratory and the client.

Details:
Test samples are stored to ensure their integrity by preventing against deterioration, contamination, and loss of identity. It is recognized that this is a general statement, but details are elaborated upon in SOP# Q-023.

5.8.2 Identification of Test and/or Calibration Items

Policy:
Test and/or calibration items are systematically identified as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated to ensure that items cannot be confused physically, or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

Details:
Sample labelling indicates the unique identification and conforms to applicable legal requirements. Where conformity of possession of a test sample must be maintained for forensic or evidentiary purposes, the laboratory establishes and documents a system for appropriate chain-of-custody.

5.8.3 Receipt

Policy:
Upon receipt of the test item, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, are recorded. When there is any doubt as to the suitability of an item for testing, or when an item does not conform to the description provided, or the test required is not specified in sufficient detail, the laboratory consults the client for further instructions before proceeding and keeps a record of the discussion. Environmental laboratories maintain a record of rejected samples.

Details:
Conform to applicable regulations or contractual arrangements. The condition of sample may include or relate to damage, quantity, preparation, packaging, or temperature. Preparation may include addition of chemical preservative, removal of moisture, isolation of portion of sample to be tested, homogenization, or subsampling.

Arrangements are in place to ensure that elapsed time between sampling and testing does not exceed test method specifications (holding time).

5.8.4 Protection

Policy:

SOP# Q-023 outlines the procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation and testing; instructions provided with the item are followed. When items must be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded. Where a test item is to be held secure (e.g., for reasons of record, safety or value, or to enable complementary tests to be performed later), the laboratory has arrangements for storage and security that protect the condition and integrity of the secured item concerned.

Details:

A sampling procedure and information on storage and transport of test items including all information that may influence the test or calibration result, is provided to those responsible for taking and/or transporting these items.

The laboratory establishes whether the sample has received all necessary preparation or whether the client requires preparation to be undertaken or arranged by the laboratory. Proper requirements for packaging, environmental conditions, and separation from incompatible materials are observed. Where test items must be stored or conditioned under specific conditions, these conditions are maintained, monitored, and recorded, where necessary.

Where a sample, or portion of a sample, is to be held secure (e.g., for reasons of record, safety, or value, or to enable check tests to be performed later), the laboratory has storage and security arrangements that protect the condition and integrity of the sample.

Where test items are to be returned into service after testing (e.g., for non-destructive testing or human subjects in clinical trials), special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

Revision History

Section 5.8, Rev 0: Effective 03.31.16
Section 5.8, Rev 1: Effective 04.01.17
Section 5.8.3: added requirement for environmental laboratories to maintain a record of rejected samples.

Approved By:

Bradley A. Stawick
Vice President, Quality

5.9 Assuring the Quality of Test and Calibration Results

5.9.1 Quality Control / Quality Assurance

Policy:

Quality control procedures are utilized to monitor the validity of test results. These procedures are for each test method utilized in the laboratory. The resulting data are recorded so that trends are detectable (and where practicable, statistical techniques are applied to the reviewing of the results). This monitoring is planned and reviewed and may include, but not limited to, the following:

- regular use of certified reference materials and/or internal quality control using secondary reference materials
- participation in inter-laboratory comparisons or proficiency testing programs
- replicate tests or calibrations using the same or different methods
- re-testing or re-calibration of retained items
- correlation of results for different characteristics of an item

Details:

The methods utilized from the above list will be appropriate for the type and volume of the work undertaken. Records are maintained of assurance activities and any actions taken.

As a guide, for routine analyses the level of internal quality control is typically 5% of the sample throughput. For more complex procedures, 20% is not unusual and on occasions even 50% may be required. For analyses performed infrequently, a full system validation is performed on each occasion. This may typically involve the use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the sample and spiked sample. For analyses undertaken more frequently, systematic quality control procedures incorporating the use of control charts and check samples are implemented. These procedures are documented in the "Quality Control" section" of each test method and/or in laboratory quality control standard operating procedures.

Internal quality control schemes using statistics may include:

- design of experimental/factorial analysis
- variation/regression analysis
- safety evaluation/risk analysis
- tests of significance
- quality control charts
- statistical sampling inspection

Proficiency testing helps to highlight not only repeatability and reproducibility performance between laboratories, but also systematic errors such as bias. It is important to monitor proficiency testing results as a means of checking quality assurance and to take action as necessary.

The Quality Manager maintains a list of all the current proficiency testing programs the laboratory participates in, monitors the results, and notifies the appropriate personnel of both problematic and successful results. Refer to SOP# Q-007, PT Plan.

Technical personnel use both certified reference materials and reference materials to evaluate test performance and include daily process control checks. These data are used to evaluate the validity of the test results.

Replicate tests may be used if suitable reference material is available. These materials and proficiency test materials are available for improving repeatability.

Re-testing of test items is sometimes performed when quality control checks fail; when test results seem anomalous; or as a result of an out-of-spec investigation. Retests are allowed as long as sample integrity has not been compromised.

5.9.2 Correction and Prevention

Policy and Details:

Quality control checks are analyzed and, where they are found to be outside pre-defined criteria, planned action is taken to correct and to prevent incorrect results from being reported.

Revision History

Section 5.9, Rev 0: Effective 03.31.16
Approved By:

Bradley A. Stawick
Vice President, Quality

5.10 Reporting of Results

5.10.1 General

Policy:
The results of each test, or series of tests are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.

The results are reported, normally in a test report and include all the information requested by the client and necessary for the interpretation of the test results and all information required by the method used. This information may include what is outlined in section 5.10.2, 5.10.3 and 5.10.4.

In the case of tests performed for internal clients, and in the case of a written agreement with the client, the results may be reported in a simplified way. The information listed in section 5.10.2 to 5.10.4, and not reported, is kept readily available.

Details:
Test reports are issued as either hard copy or by electronic data transfer.

5.10.2 Test reports

Policy:
Test reports include the following information, as appropriate:

- a title (e.g., “Test Report”)
- name and address of laboratory, and location where tests and/or calibrations were carried out if different from the address of the laboratory
- unique identification of the test report (such as a serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report, and a clear identification of the end of the test report
- name and address of the client
- identification of the preparation method used
- identification of the method used
- description, condition, and unambiguous identification of the item(s) tested date of receipt of test items (where this is critical to the validity and application of the results) and date(s) of performance of the test
- reference to sampling procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results
- test results with, where appropriate, units of measurement
- date of analysis
- the name(s), function(s) and signature(s) or equivalent of person(s) authorizing the test report
- where relevant, a statement to the effect that the results relate only to the items tested
- if accredited and non-accredited tests are on the same report, a notation of which are not accredited tests
- identification of subcontracted testing
- environmental test reports also require:
  - time of sample preparation and/or analysis if the required holding time for either is less than or equal to 72 hours
  - results that are reported on a basis other than as received (e.g. dry weight)
    - clear identification of numerical results outside of the calibration range

- GLP, GCP laboratories test reports also include:
  - The statement prepared and signed by the Quality Assurance Unit;
  - Location of all raw data and location of the final report;
  - Initiation and termination of the study; and
  - Names of the Study Director and other technical personnel involved in the study.

Details**:**
Signing authority for test reports is the responsibility of the person authorizing release of the data, typically the Project Manager or Managing Director; the Study Director or Principle Investigator. Records for individuals with signing authority for test reports are approved by the Managing Director and maintained by the Quality Manager.

Hard copies of test reports include the page number and total number of pages.

A statement is included specifying that the test report is not to be reproduced except in full, without written approval of the laboratory.

5.10.3 Test Reports

A. Additional Reporting Requirements for Interpretation of Results

Policy and Details**:**
In addition to the requirements listed in section 5.10.2, test reports include the following, where necessary for the interpretation of results:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when uncertainty affects compliance to a specification limit
- where appropriate and needed opinions and interpretations (see section 5.10.5)
- additional information required by specific methods, clients, or groups of clients

B. Additional Reporting Requirements Related to Sampling

Policy and Details:
In addition to the requirements listed in sections 5.10.2 and 5.10.3.1, test reports containing the results of sampling include the following, where necessary for the interpretation of test results:

- date of sampling
- unambiguous identification of substance, matrix, material or product sampled (including name of manufacturer, model or type of designation and serial numbers as appropriate)
- location of sampling, including any diagrams, sketches or photographs
- reference to sampling plan and procedures used
- details of any environmental condition during sampling that may affect the interpretation of the test results
- any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned

C. Additional Reporting Requirements Related to SDWA MCL Exceedances

Policy and Details:
Laboratories certified to analyze drinking water compliance samples for public water suppliers must report compliance data to the public water system and/or regulatory agency when there is a Maximum Contaminant Limit (MCL) exceedance in a timely manner. The notification period is defined in states' regulation.

5.10.4 Calibration Certificates

Policy**:** This section is not applicable as the testing laboratory does not issue calibration certificates.

5.10.5 Opinions and Interpretations

Policy**:**
When opinions and interpretations are included in the test report, the basis upon which the opinions and interpretations have been made is documented. Opinions and interpretations are clearly marked as such in the test report generally in a narrative.

Note - Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

Details**:**
Opinions and interpretations are provided by trained individuals designated by laboratory management and included in a test report may comprise, but not be limited to, the following:

- opinion on conformity of the results with requirements
- fulfilment of contractual requirements
- recommendations on how to use the results
- guidance to be used for improvements

In many cases, it is appropriate to communicate the opinions and interpretations by direct dialogue with the client. This dialogue is written down.

5.10.6 Testing and Calibration Results Obtained from Subcontractors

Policy and Details**:**
Test reports containing the results of tests performed by subcontractors are clearly identified for the subcontracted results. The subcontractor reports the results either in writing or electronically to our laboratory. The laboratory shall make a copy of the subcontractor's report available to the client when requested.

5.10.7 Electronic Transmission of Results

Policy**:**
In the case of transmission of test results by telephone, telex, facsimile or other electronic means, the requirements of the policies and procedures of this Quality Manual continue to apply (see also 5.4.7).

Details:
Reports that are “published” electronically contain the image of the signature of the person approving the report.

5.10.8 Format of Reports

Policy:
The format of reports is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

Details:
The layout of the test report is such that the presentation of the test data facilitates ease of assimilation by the reader.

The headings are standardized as far as possible.

5.10.9 Amendments to Reports

Policy**:**
Material amendments to a test report after issue are made only in the form of a further document, or data transfer, which includes the statement “Supplement to Test Report”, or equivalent wording. Such amendments meet all the requirements in this Quality Manual.

Details:
When it is necessary to issue a complete new test report, it is uniquely identified and contains a reference to the original that it replaces. The reason for the amendment will be noted.

Revision History
Section 5.10, Rev 0: Effective 03.31.16
Section 5.10, Rev 1: Effective 04.01.17
Section(s) 5.10.1: removed reference to calibration reports; 5.10.2: added preparation method to contents of environmental test reports; 5.10.3: added C: Additional Reporting Requirements Related to SDWA MCL Exceedances

Approved By:

Bradley A. Stawick
Vice President, Quality

Appendix A: Microbac Laboratory Directory

FACILITY	CODE	LABORATORY MANAGEMENT	
BALTIMORE	(007)G	James Williams James.williams@microbac.com	
		Baltimore James Williams james.williams@microbac.com 2101 Van Deman St Baltimore, MD 21224 410.633.1800 p 410.633.6553 f	Richmond Curtis Read curtis.read@microbac.com 2028 Dabney Rd. Suite E-17 Richmond, VA 23230 804.353.1999 p
BOULDER	(025)Y	TBD	
		Boulder 4750 Nautilus Court South Unit A Boulder, CO 80301 720.406.4800 p 303.581.0195 f	
MERRILLVILLE	(012)L	Ron Misiunas ron.misiunas@microbac.com	
		Merrillville Ron Misiunas ron.misiunas@microbac.com 250 West 84th Drive Merrillville, IN 46410 219.769.8378 p 219.769.1664 f	Indianapolis (service center) Kristin Gehlbach Kristin.gehlbach@microbac.com 5713 West 85th Street Indianapolis, IN 46278 317.872.1375 p 317.872.1379 f
CORTLAND	(040)	Christine Pechacek Christine.pechacek@microbac.com	
		Cortland 3821 Buck Drive Cortland, NY 13045 607.753.3403 p 607.753.3415 f	Scranton 1620 N. Main Avenue Scranton, PA 18508 571.348.0775 p

FACILITY	CODE	LABORATORY MANAGEMENT	
CORTLAND (CONT)		Sayre (service center) 2369 Elmira Street, Suite C Sayre, PA 18840 570.888.0169 p	Harrisburg (service center) 4359 Linglestown Rd Harrisburg, PA 17112 717.651.9700 p 717.657.0752 f
ERIE	(003)C	Jeffrey Ogle jeffrey.ogle@microbac.com Erie 1962 Wager Rd. Erie, PA 16509 814.825.8533 p 814.825.9524 f	
FAIRWATER	(029)	Sarah Muellenbach Sarah.muellenbach@microbac.com c/o Bonduelle 101 Kennedy Street Fairwater, WI 53931 855.962.2105 p	
FAYETTEVILLE	(011)K	James Williams james.williams@microbac.com 2592 Hope Mills Rd Fayetteville, NC 28306 910.864.1920 p 910.864.8774 f	
LOUISVILLE	(005)E	Jeffrey Ogle jeffrey.ogle@microbac.com Louisville Jeffrey Ogle jeffrey.ogle@microbac.com 3323 Gilmore Industrial Blvd. Louisville, KY 40213 502.962.6400 p 502.962.6411 f Hazard 100 Grand Vue Plaza, Suite 22 Hazard, KY 41701 606.487.0511 p 606.910.0086 f	Lexington Lisa Martin Lisa.martin@microbac.com 2520 Regency Rd. Lexington, KY 40503 859.276.3506 p 859.278.5665 f Evansville 3119 North First Avenue Evansville, IN 47710 812.464.9000 p 812.424.0667 f

FACILITY	CODE	LABORATORY MANAGEMENT	
LOUISVILLE (CONT)		Paducah Ted Meriwether Ted.meriwether@microbac.com 5309 Reidland Rd. Paducah, KY 42003 270.898.3637 p 270.898.3666 f	
DAYVILLE	(033)	Ron Warila Ron.warila@microbac.com Dayville Ron Warila Ron.warila@microbac.com 61 Louisa Viens Drive Dayville, CT 06241 860.774.6814 p	Lee (034) Christine Furcinite-Reynolds Christine.furcinite-reynolds@microbac.com 8080 Run Way Lee, MA 01238 413.776.5025p
WESTBOROUGH	(006) F	Westborough Trevor Craig Trevor.craig@microbac.com 117 Flanders Road, Suite 101 Westborough, MA 01581 508.329.7927 p	
MARIETTA	(015)O	Leslie Bucina Leslie.bucina@microbac.com Marietta 158 Starlite Drive Marietta, OH 45750 800.373.4071 p 740.373.4835 f	
PITTSBURGH	(001)A	Robert Dempsey robert.demsey@microbac.com Warrendale 100 Marshall Drive Warrendale, PA 15086 724.772.0610 p 724.373.1686 f	

FACILITY	CODE	LABORATORY MANAGEMENT
MARYVILLE	(018)F	Joe Sloan Joe.sloan@microbac.com Knoxville 505 E. Broadway Ave. Maryville, TN 37804 865.977.1200 p 865.984.8618 f Nashville 2631 Grandview Ave. Nashville, TN 37211 615.242.1480 p 615.242.5522 f Johnson City Kim Storey Kimberly.storey@microbac.com 2109 W. Market St. Suite 177 Johnson City, TN 37604 423.926.6385 p 423.926.6997 f
WILSON – F&N		Jateisha Lowe Jateisha.lowe@microbac.com Wilson Food & Nutrition 3809 Airport Drive Wilson, NC 27896 910.864.1921 p 910.864.8774 f

Revised: 06.18.2018

Appendix B: Accreditation, Approvals and Certifications

Laboratory	Accrediting Body	Matrix	Type	Certification
COLORADO				
Boulder	US Consumer Product Safety Commission	Toys, Jewelry, Textiles	Registered	ID 1130
	American Assoc. for Laboratory Accreditation	Chemical	Accredited	Cert 0018.01
	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 0018.03
	American Assoc. for Laboratory Accreditation	Mechanical	Accredited	Cert 0018.04
CONNECTICUT				
Dayville	Connecticut Dept. of Public Health	DW, WW, SW	Certified	ID PH-0465
	Kentucky Energy and Env Cabinet	DW	Certified	ID 90151
	Massachusetts DEP	DW, WW	Certified	ID M-CT008
	Maryland Department of Env.	DW	Certified	ID 349
	New Hampshire ELAP	DW, WW, SW	Accredited	ID 2020
	New York Department of Health	DW, WW, SW	NELAP Accredited	ID 11549
	Pennsylvania DEP	DW, WW, SW	Accredited	ID 68-04413
	Rhode Island Dept. of Public Health	DW, WW, SW	Certified	ID PH-0465
	Tennessee Dept. of Env. & Cons.	DW	Certified	ID 04903
	UCMR4 Laboratory Approval	DW	Approved	ID CT00008
	Virginia Dept. of General Services	DW	Certified	ID 460279
	Vermont Department of Health	DW	Certified	ID VT 11549
INDIANA				
Merrillville	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 3045.01
	American Assoc. for Laboratory Accreditation	Environmental-DoD	Accredited DoD ELAP	Cert 3045.02
	US Center for Disease Control	Legionella	Proficient	
	US Coast Guard	WW-Cruise Vessels	Recognized	
	Illinois EPA	DW, WW, SW	Accredited	ID 200064
	Illinois Dept. of Public Health	DW	Approved	
	Indiana Board of Animal Health	Dairy	Certified	
	Indiana Dept. of Environ Mgt	WW, SW	Approved	
	Indiana State Dept. of Health	DW	Approved	ID C-45-03
	Indiana State Dept. of Health	DW	Approved	ID M-45-08
	Kansas Dept. of Health and Env.	WW, SW	NELAP Accredited	Cert E-10397
	Kentucky Energy and Env. Cabinet	WW, SW-UST	Approved	ID 90147
	North Carolina DENR	WW	Certified	Cert 597

Merrillville (cont.)	New York Department of Health	DW, WW - LL Hg; Legionella	Approved	ID 12006
	Pennsylvania DEP	DW, WW - LL Hg	Accredited	ID 68-04863
	Virginia Dept. of General Services	DW, WW	Accredited	ID 460280
Evansville	Kentucky Energy and Env. Cabinet	WW	Certified	ID 98021
KENTUCKY				
Louisville	American Assoc. for Laboratory Accreditation	Chemical	Accredited	Cert 0085.04
	Kentucky Energy and Env. Cabinet	DW, WW	Certified	ID 00074
	US Coast Guard	WW-Cruise Vessels	Recognized	
	Indiana State Dept. of Health	DW	Approved	ID C-KY-05
	Indiana State Dept. of Health	DW	Approved	ID M-KY-02
Lexington	Kentucky Energy and Env. Cabinet	DW, WW-WET	Certified	ID 00040
	West Virginia DEP	WETT	Certified	Cert 404
Paducah	Kentucky Energy and Env. Cabinet	DW, WW	Certified	ID 00089
MARYLAND				
Baltimore	American Assoc. for Laboratory Accreditation	Environmental	Accredited	Cert 0410.01
	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 0410.02
	Maryland Dept. of Environment	DW	Certified	ID 109
	US Consumer Product Safety Commission	Lead	Registered	
	Virginia Dept. of General Services	DW, WW, SW	Accredited	ID 8574
	West Virginia DEP	WW - Available CN	Certified	Cert 054
	Florida DOH	DW, WW, SW	NELAP	E871126
MASSACHUSETTS				
Lee	Massachusetts DEP	DW, WW	Certified	ID M-MA1146
	New Hampshire ELAP	DW, WW	Accredited	ID 2067
Westborough	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 3302.01
	MA Health and Human Services	Dairy	Approved	ID 0056
NEW YORK				
Cortland	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 3881.01
	NY Ag and Markets	Dairy	License	ID 158650
	New York Department of Health	DW, WW	NELAP Accredited	ID 10795
	Pennsylvania DEP	DW, WW	Accredited	ID 68-01385

N. CAROLINA

Fayetteville	NC Dept. of Health and Human Service	DW	Certified	ID 37714
	North Carolina DENR	WW	Certified	Cert 11
Wilson F&N	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 3275.01
	USDA Meat & Poultry Export Program	Microbiology	Approved	

OHIO

Marietta	American Assoc. for Laboratory Accreditation	Environmental-DoD	Accredited	Cert 2936.01
	Arizona Department of Health Services	WW, SW	Licensed	ID AZ0723
	California ELAP	WW, SW	Approved	Cert 2730
	Connecticut Dept. of Public Health	DW, WW, SW	Certified	ID PH-0304
	Florida DOH	DW, WW, SW	Accredited	ID E87551
	Georgia Dept. of Natural Resources	WW, SW	Reciprocal	
	Illinois EPA	WW, SW	Accredited	ID 200019
	Indiana State Dept. of Health	DW-Radiochemistry	Recognized	
	Kansas Dept. of Health and Environment	WW, SW	Accredited	Cert E-10290
	Kentucky Energy and Env. Cabinet	WW	Certified	ID 460187
	Kentucky UST	SW	Approved	Cert 72
	Louisiana Dept. of Env. Quality	WW, SW	Accredited	Cert 01976
	North Carolina DENR	WW	Certified	Cert 583
	New Jersey DEP	WW, SW	Accredited	ID OH004
	New York Department of Health	WW, SW	Approved	ID 10861
	Ohio EPA	SW	Certified	ID CL0012
	Ohio EPA	DW	Certified	ID 4125
	Oklahoma Department of Env. Quality	WW, SW	Accredited	ID 9611
	Pennsylvania DEP	WW, SW	Accredited	ID 68-01670
	Rhode Island Department of Health	WW	Certified	ID E87551
	Texas Commission on Env Quality	WW, SW	Accredited	Cert T104704254-14-7
	UCMR4 Laboratory Approval	DW	Approved	ID OH00218
	Virginia Department of General Services	WW, SW	Accredited	ID 460187
	West Virginia DEP	WW, SW	Certified	Cert 361

PENNSYLVANIA

Erie	New York Department of Health	DW, WW, SW	Approved	ID 10121
	Pennsylvania DEP	DW, WW, SW	NELAP Accredited	ID 25-00067
Pittsburgh	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 2413.01
	American Assoc. for Laboratory Accreditation	Chemistry	Accredited	Cert 2413.02
	PA Department of Agriculture	Dairy	Approved	

Pittsburgh	Pennsylvania DEP	DW, WW	Accredited	ID 02-00257
Scranton	Pennsylvania DEP	DW, WW	Accredited	ID 35-05082
	PA Department of Agriculture	Dairy	Approved	

TENNESSEE

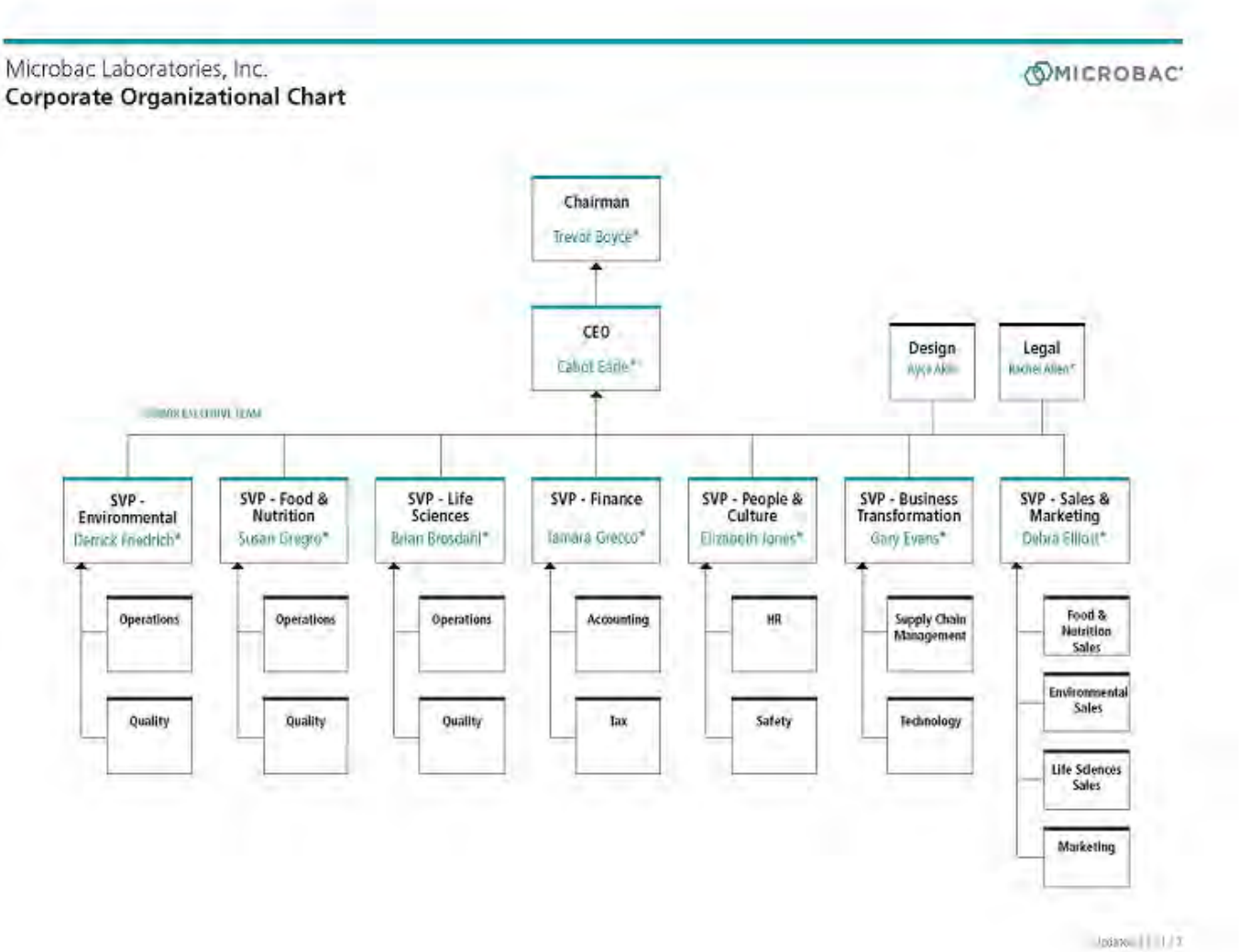
Knoxville	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 3131.01
	American Assoc. for Laboratory Accreditation	Environmental	Accredited	Cert 3131.03
	Georgia Dept. of Natural Resources	DW	Certified	ID 980
	USDA Meat & Poultry Export Program	Microbiology	Approved	
Nashville	American Assoc. for Laboratory Accreditation	Biological	Accredited	Cert 3131.02
TN Operations	Tennessee Dept. of Env. & Conservation	DW	Certified	ID 02017

VIRGINIA

Richmond	Virginia Dept. of General Services	DW, WW - Micro	Accredited	ID 460022

Current as of 06.18.18

Appendix C: Corporate Organization Chart



Appendix D: Quality Managers by Laboratory

Facility	Quality Manager	Contact Information
Baltimore, MD Richmond, VA	Env TBD Christina Urban, QA Specialist Dave Danis (F&N)	christina.urban@microbac.com david.danis@microbac.com
Boulder, CO	Whitney Griebel	whitney.griebel@microbac.com
Merrillville, IN	Teresa Dyson	teresa.dyson@microbac.com
Scranton, PA Harrisburg, PA	Tiffany Barnes	tiffany.barnes@microbac.com
Cortland, NY Sayre, PA	Jennifer Walker	jennifer.walker@microbac.com
Erie, PA	Interim: Chuck Piano	chuck.piano@microbac.com
Fayetteville, NC	Janice Reyes	janice.reyes@microbac.com
Fairwater, WI	Whitney Griebel	whitney.griebel@microbac.com
Louisville, KY Evansville, IN Paducah, KY Hazard, KY Lexington, KY	Megan Rothgerber	megan.rothgerber@microbac.com
Dayville, CT Lee, MA	Melisa Montgomery	melisa.montgomery@microbac.com
Worcester, MA	Elizabeth DiBonaventura	elizabeth.dibonaventura@microbac.com
Marietta, OH	Maren Beery	maren.beery@microbac.com
Pittsburgh, PA	Lauren Zeleny	lauren.zeleny@microbac.com
Knoxville, TN Nashville, TN Johnson City, TN	LeAnne Burns	leanne.burns@microbac.com
Wilson, NC (F&N)	David Danis	dave.danis@microbac.com

Revised: 06.18.2018

Appendix 2

(Sample Field Collection Sheet)

8854 Rixlew Lane
Manassas, VA 20109
Phone: 703-396-6730
Fax: 703-396-6743

Watershed: **Outfall ID#/Name:** Soapstone Creek	**Samplers:**	**Date:**
	Signature	**Time of Arrival:**
Outfall Address: Albemarle and 32nd Street, NW	x	**Time of Departure:**
Outfall Weather: Temperature (F˚) (C˚): General Conditions:	**Sampling Methods:** Composite Sampling grabs directly from flow	**Composite Sample Time Started:** **Composite Sample Time Ended:** **Grab Sample Time:**
Field Measurements: Temperature of Water (F˚): Conductivity Hardness pH Level: Dissolved Oxygen (mg/L) Depth of Discharge : Width of Discharge : Velocity of Discharge: **Flow Rate at Outfall (GPM):**	**Comments/Remarks:** Measurements of depth and width taken with tape measure	

Appendix 3

(Sample Chain of Custody Form)

MICROBAC® **Microbac Laboratories, Inc., Baltimore Division**
2101 Van Deman Street • Baltimore, MD 21224
Phone: 410-633-1800
Fax: 410-633-6553
www.microbac.com

17C0320

Tentatively Scheduled Date: **3/6/2017**

Client: **Retaw Engineering**
Project: **DC DOE-Wet Weather - Apex Sampled**
Project Number: **DC DOE-Wet Weather**

Report To:
Andrea Owen Heller
P.O. Box 5881
Midlothian, VA 23112
Phone: (804) 744-1792

Invoice To:
Ignatius Mutoti, PhD, PE
P.O. Box 5881
Midlothian, VA 23112
Phone :(804) 744-1792

TAT 7 days

Sample ID: A2-SW2 - Composite

Lab Sample ID: 17C0320-01
Matrix: Stormwater
Type: Composite

Sample Start Date & Time: 3/18/17 2115
Sampled Date & Time: 3/18/17 2415
Volume: 13L

Analysis	Method	Container	Hold
Nitrogen, Total HL	varies		28
Hard_Titration	SM 2340 C-11		28
M_Cd_ICPMS	EPA 200.8		180
M_Cu_ICPMS	EPA 200.8		180
M_Pb_ICPMS	EPA 200.8		180
M_Zn_ICPMS	EPA 200.8		180
		A- 500ml Plastic HNO3 to pH <2	
P_T_Seal	SM 4500-P B5+E-11		28
		B-1000ml Plastic H2SO4 to pH <2	
TSS	SM 2540 D-11		7
		B-1000ml Plastic Neat	

Total Containers: 3

Sample ID: A2-SW2 - Grab

Lab Sample ID: 17C0320-02
Matrix: Stormwater
Type: Grab

Sampled Date & Time: 3/18/17 2415

Analysis	Method	Container	Hold
Chlorophyll	SM 10200 H 1 plus 2		2
		E-4oz Amber Glass NM Neat	
E. coli_MPN_W	SM 9221 F-06		0.333
Fecal_Col_MPN_W	SM 9221 E-06		0.333
		S-4oz Sterile Plastic w/Thiosulfate	

Total Containers: 2

Sampled by:	Date/Time: 3/17/17 0115	Received by:	3/19/17 15
Printed Name: Toni Sanders / Alvin Ferguson		Printed Name: V. STATION	
Relinquished by:	Date/Time:	Received by:	
Printed Name:		Printed Name:	
Relinquished by:	Date/Time:	Received by:	
Printed Name:		Printed Name:	

As Received at Laboratory: On Ice: Yes / No Cooler Temp _____ Rad Scan Acceptable: Yes / No Total Bottles 5

Notes:

Temp 1.7

MICROBAC® **Microbac Laboratories, Inc., Baltimore Division**
2101 Van Deman Street • Baltimore, MD 21224
Phone: 410-633-1800
Fax: 410-633-6553
www.microbac.com

17C0320

Tenatively Scheduled Date: **3/6/2017**

Client: **Retaw Engineering**
Project: **DC DOE-Wet Weather - Apex Sampled**
Project Number: **DC DOE-Wet Weather**

Ship bottle order back to below with clean pickle jar for next event.

Andrea Owen
Apex Companies, LLC
8854 Rixlew Lane
Manassas, VA 20109
O) 703-396-6730 x103 M) 703-675-7055

Cooler Receipt Form / Sample Acceptance & Noncompliance Form	Microbac Laboratories, Inc., Baltimore Division **Control #** 606-03 **Effective Date**: 11/30/2016 **Page** 1 of 1

Number of Coolers Received: 1
Client: Retail Engineering
Form Completed By: [illegible]
Shipper: [illegible]

Receipt Date / Time: 03/19/17 0115
Work Order # 17C0320 | 0321

☒ Microbac ☐ Client ☐ UPS ☐ FedEx
Custody Tape Intact: YES / NO / NA
Containers Intact: YES / NO
Sample Received on Ice or refrigerated: YES / NO / NA
Infrared (IR) Temperature: 1.7 °C

Chain of Custody Present with shipment: YES / NO
Sample Bottle IDs agree with COC: YES / NO
Preservation requirements met: YES / NO / Not Checked
Correct Number of Containers / Sample Volume: YES / NO (If No, contact client immediately)
Headspace in container: YES / NO / NA
Type of Sample: Water Soil Wipes Oil Filter Solid Sludge Food Swab Other

***Container Type / Quantity*:**

A -	___ Unpreserved	___ H2SO4	2 HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid:	If preserved pH <2 2H, pH >10___
B -	2 Unpreserved	2 H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2 2H, pH >10___
C -	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
D -	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
E -	2 Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
H -	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
K -	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
L -	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
M-	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
P -	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
W-	___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___

V - ___ Unpreserved ___ HCl ___ HCl / Ascorbic Acid ___ HCl / NaTHIO **(Checked at time of Analysis)**
F - ___ Unpreserved ___ NaTHIO **(Checked at time of Analysis)**
S - ___ Unpreserved 2 NaTHIO **(Checked at time of Analysis)**
SN- ___ Unpreserved ___ NaTHIO ___ NaTHIO/EDTA **(Checked at time of Analysis)**

___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___
___ Unpreserved	___ H2SO4	___ HNO3	___ HCl	___ NaOH	___ NaOH/Ascorbic Acid	If preserved pH <2___, pH >10___

Describe preservation requirements not met:
All Acid preserved <2 pH *NaOH preserved >12 pH* *All others >2 and <10 (usually 4-8)*
Sample ID:_____ H_2SO_4 HNO_3 NaOH _____ mls added
Sample ID:_____ H_2SO_4 HNO_3 NaOH _____ mls added
Sample ID:_____ H_2SO_4 HNO_3 NaOH _____ mls added
Sample ID:_____ H_2SO_4 HNO_3 NaOH _____ mls added
H_2SO_4 – Sulfuric Acid, HNO_3 – Nitric Acid, NaOH – Sodium Hydroxide, ASC – Ascorbic Acid, NaTHIO – Sodium Thiosulfate

Describe Anomalies:
17C0320-01B & 17C0321-01B both split into a P10 1L for subcontract out for NO_2/NO_3 & Total Phos. PMW 03/20/17

Contact information / Summary of Actions:
Date / Time:_____ Contact:_____ Contact By:_____
Comments:_____