

# **Quality Assurance Project Plan**

# City of Columbia Water Quality Monitoring as Required for Supplemental Environmental Projects (SEP)

Prepared by City of Columbia Department of Utilities & Engineering

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Project Location:	Station 1 – C-001 – Gills Creek @ Garners Ferry Road
	Station 2 – B-280 – Smith Branch @ North Main Street
	Station 3 – C-017 – Gills Creek @ Bluff Road

# A1. SIGNATORY PAGE:

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City QA Manager:	Tracy Mitchell, EIT, CFM	Date:
City of Columbia U&E Director:	Joseph D. Jaco, PE	Date:
SCDHEC Bureau of Water WQ Manager:	David Graves	Date:
SCDHEC QA Office:	Nydia Burdick, Manager	Date:

# A2. Table of Contents

Α.	Proje	ct Management5
	A1.	Title and Approval Sheet2
	A2.	Table of Contents
	A3.	Distribution List
	A4.	Project/Task Organization
	A5.	Problem Definition / Background
	A6.	Project / Task Description / Schedule7
	A6.1	Map of Monitoring Sites8
	A7.	Data Quality Objective (DQOs) and Data Quality Indicators (DQIs)9
	A7.1	The DQO Process9
	A7.2	Representativeness
	A7.3	Accuracy10
	A7.4	Precision
	A7.5	Detectability11
	A7.6	Completeness11
	A7.7	Comparability11
	A7.8	Project DQIs11
	A8.	Special Training Requirements and Certifications12
	A9	Documentation and Records13
	A9.1	Data Reporting14
в.	Mea	surement/Data Acquisition14
	B1. Sa	mpling Process Design (Experimental Design)14
	B2.	Sampling Methods14
	B2.1.	Sample Collection15
	B3.	Sampling Handling and Custody Requirements16
	B3.1.	Sample Receiving and Storage17
	B3.2.	Sample Distribution and Handling18
	B3.3.	Sample Disposal
	B4.	Analytical Methods
	B4.1.	Control of Analytical Processes
	B5.	Quality Control Requirements (QC)19
	B5.1.	Dissemination of Quality Requirements19

	B6.	Instrument/Equipment Testing, Inspection and Maintenance	. 24
	B6.1	Preventative Maintenance	. 24
	B7.	Instrument Calibration and Frequency	. 24
	B8.	Inspection/Acceptance Requirements for Supplies and Consumables	. 25
	B9.	Data Acquisition Requirements (Non-Direct Measurement)	. 26
	B10.	Data Management	. 26
C.	Asse	ssment and Oversight	. 27
	C1.	Assessment and Response Actions	. 27
	C2.	Reports to Management	. 28
D.	Data	Validation and Usability	. 28
	D1.	Data Review, Verification & Validation	. 28
	D2.	Verification and Validation Methods	. 29
	D3.	Reconciliation with User Requirements	. 29

# Appendices

#### Appendix A – Forms

Chain of Custody

#### Appendix B – Standard Operating Procedures (SOPs)

E.Coli (Bacteria)

Dissolved Oxygen (DO)

Temperature

Total Suspended Solids (TSS)

## **Project Management**

## A3. Distribution List

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Nydia Burdick	SCDHEC – Office of Quality Assurance – Columbia	Burdicnf@dhec.sc.gov
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Tracy Mitchell	City of Columbia –Project and QA Manager	temitchell@columbiasc.net
David Graves	SCDHEC – Bureau of Water – WQ Monitoring and Modeling Manager	gravesda@dhec.sc.gov

## A4. Project/Task Organization

The tasks of the City of Columbia's QAPP will be to monitoring 4 parameters at 3 different S.C. DHEC established water quality monitoring stations for a period of 6 years. Concurrently, there will be Supplemental Environmental Projects occurring at various stages of completion and activity. The goal is to compare the water quality monitoring data collected during these improvement projects to the historical DHEC data at these stations. This will help determine the overall success of the projects efforts as well as indicate the current level of water quality in these areas. The following is a breakdown in general responsibility:

Project Manager / City of Columbia Staff (City of Columbia) - Will manage the project including developing and maintaining the QAPP and submitting reports to hand off to DHEC and CDM Smith/EPA, per the Consent Decree Schedule.

City of Columbia QA Manager – Will oversee any potential issues and adherence to the QAPP for the duration of the project.

Access Analytical – Will perform field analysis / sampling and confirm / compile data for City reports.

Nydia Burdick (SCDHEC QA/QC) – Will review and approve the QAPP.

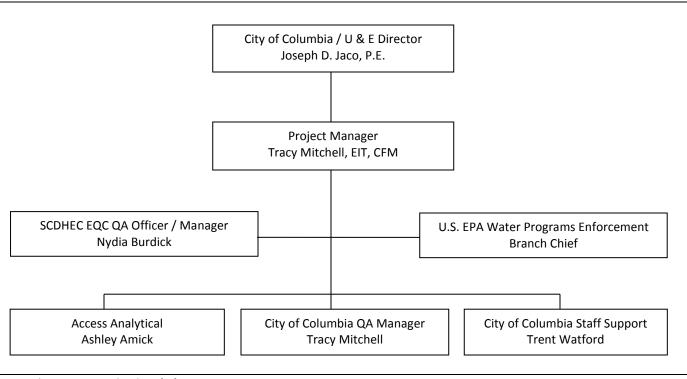


Figure 1: Organizational Chart

## A5. Problem Definition / Background

Effective May 21, 2014, the City of Columbia (Columbia) entered into a Consent Decree (CD) as a result of violations of the Clean Water Act through the City's Wastewater Program. Among the objectives of this CD, the City agreed to implement a program for ambient monitoring of four different parameters at the three existing monitoring stations, as requested by DHEC and EPA that correspond to Supplemental Environmental Projects (SEP). This information is being collected to comply with the Water Quality Monitoring Component of Revised Appendix I of the CD.

## A6. Project / Task Description / Schedule

#### I. Monitoring

The City of Columbia will implement a program for ambient monitoring of dissolved oxygen (DO), total suspended solids (TSS), temperature (temp) and *E. coli*<sub>1</sub> at the monitoring sites listed below. Columbia will conduct the monitoring in accordance with an approved South Carolina Department of Health and Environmental Control (DHEC) quality assurance project plan (QAPP). Columbia will have the TSS and *E. coli* data analyzed at a DHEC certified lab.<sup>2</sup> By using established monitoring sites, water quality data collected by Columbia will be available for comparison to historic water quality data taken by DHEC for assessment purposes.

Within sixty (60) days of entry of the Consent Decree (May 21, 2014), Columbia is required to submit this QAPP to DHEC for review and approval. Columbia will begin monitoring within thirty (30) days of DHEC's approval of the QAPP. As indicated below, Columbia will monitor quarterly for the first 3 years under the Consent Decree and monthly (or every other month at Site C-17) from years 4 through 6 under the Consent Decree.

Site	Description	Impairment	TMDL	Monitoring	Frequency
				Parameters	
C-001	Gills Creek @	Fecal	Yes	DO	Quarterly during years
	Garners Ferry	Coliform		E. Coli	1-3; Monthly during
	Road			Temp	years 4-6
				TSS	
B-280	Smith Branch @	Fecal	Yes	DO	Quarterly during years
	North Main Street	Coliform		E. Coli	1-3; Monthly during
				Temp	years 4-6
				TSS	
C-017	Gills Creek @	Fecal	Yes	DO	Quarterly during years
	Bluff Road	Coliform;		E. Coli	1-3; Monthly during
		Dissolved		Temp	years 4-6
		Oxygen		TSS	

**II.** Water Quality Stations (see attached map):

1 *E. coli* standard replaces the existing fecal coliform standard.

2 The temp and DO parameters measured in the field with a probe are not subject to the certified laboratory requirement

#### Table 1: Water Quality Monitoring Stations/Sites

NOTE: By extension of utilizing a DHEC-certified lab for the collection and analyzation of all parameters required of this QAPP, it should be known that all parameters listed throughout this document will have been collected and analyzed by a DHEC-certified laboratory, whether or not that is a requirement.

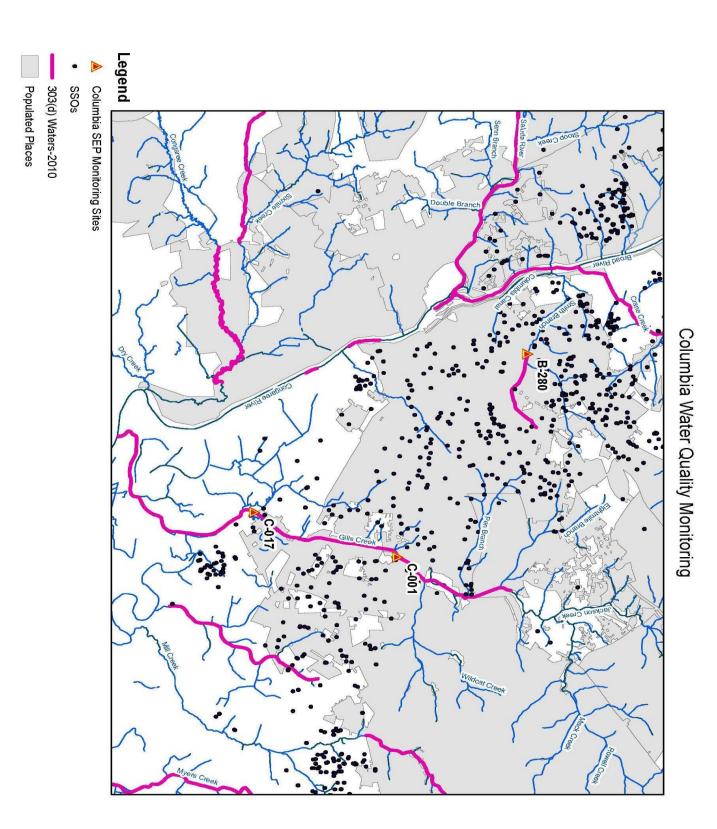


Figure 2: Map of DHEC Monitoring Stations / Sampling Sites

## A7. Data Quality Objective (DQOs) and Data Quality Indicators (DQIs)

#### A7.1 The DQO Process

- a. State the Problem: The objective of this project is to monitor four specific parameters at three established DHEC water quality monitoring stations within the Gills Creek (Gills Creek) and Broad River Watersheds (Smith Branch) for 6 years. This monitoring will be performed quarterly during years 1-3 and monthly from years 4-6.
- **b.** Identify the Decision- No pre-determined decisions are to be made due to the proposed monitoring. All data collected under this plan is a requirement mandated by SEP projects and will be collected to ensure environmental compliance. By using established monitoring sites, water quality data collected by Columbia will be available to DHEC for comparison to historic water quality data taken by DHEC for assessment purposes.
- **c.** Inputs to the Decision- Lab and field data, in addition to historical data from DHEC monitoring
- **d.** Define the Study Boundaries- The study boundaries are noted and discussed in Section 1.4 and Figure 2. At each sampling site within the study boundaries, water samples will be collected at a depth of 6-12 inches.
- e. Develop an analytical approach and a decision rule- All data collected under this plan is collected to ensure environmental compliance with the SEP. No future efforts or decisions are planned based on the outline of this plan.
- **f. Specify Limits on Decision Error** See Section 0 for information on errorminimization strategies used in this study.

**g.** Optimize the design for obtaining the data- The quality of measurements made for the plan by the laboratory is determined by the following data quality indicators (DQIs), or characteristics: representativeness, accuracy, precision, detectability, completeness, and comparability. Specific criteria for each characteristic were established to assist in the selection of appropriate sampling and analytical protocols and to identify applicable documentation, sample handling procedures, and measurement system procedures. These DQI criteria were established based on site conditions, requirements of the project, and knowledge of available measurement systems, and were addressed whenever appropriate for the data generated.

#### A7.2 Representativeness

Representativeness is a qualitative measure of the extent to which a sample acquired from a matrix describes the chemical or physical characteristics of that matrix. Sample collection, handling (e.g., splitting, preservation, storage), and measurements are all conducted according to protocols allowing for the highest degree of representativeness possible for the sample media (air, soil, water, etc.). Recording procedures are utilized which document adherence to proper protocols and maintain sample identification and integrity.

#### A7.3 Accuracy

Accuracy describes the degree of agreement between an observed value and an accepted reference (true) value. It includes a combination of random error (precision) and systematic error (bias) components which are introduced in sampling and analytical operations. DQI criteria for accuracy are established through quality control limits for each parameter measured and for each analytical technique, per matrix where applicable. These objectives are assessed through the analysis of sterility checks, positive and negative culture checks, blanks, matrix spike (MS)/matrix spike duplicates (MSDs), and laboratory control samples (LCSs), as specified by the analytical method, required by the project, or generated and updated from data acquired through required quality control measurements. Nominal quality control limits for each parameter and analytical technique are specified in the analytical methods.

#### A7.4 Precision

Precision is a measure of the reproducibility of an analysis under a given set of conditions, regardless of the true value of the target analyte in a sample. The overall precision of a sampling event has both a sampling and an analytical component. DQI criteria for

precision are established through quality control limits for each parameter measured and for each analytical technique, per matrix where applicable. These objectives are assessed through the analysis of MSDs (if practical), LCS duplicates (if available), field duplicates, laboratory replicates, and split laboratory samples, as specified by the analytical method, required by the project, or generated and updated from data acquired through required quality control measurements. Nominal quality control limits are specified for each parameter and analytical technique in the analytical methods.

#### A7.5 Detectability

Method detectability objectives define the lowest concentration or quantities required of the measurement system for each analyte or parameter. The laboratory has established reporting limits (RLs) which are the minimum concentrations to be reported without qualification for routine laboratory conditions. Data quality indicator criteria for detectability (i.e., RLs) are established for each parameter measured and for each analytical technique. These criteria are specified by the analytical method, required by the project, or determined and updated from data acquired through required quality control measurements (e.g., the replicate analyses of samples or standards containing low concentrations of the analyte of concern).

The RL for an analyte is a function of the specific analytical procedures and can vary substantially as a result of dilutions and similar procedure modifications. In all cases, the RL necessary to fulfill data quality objectives is confirmed by laboratory measurements. Nominal RLs for each parameter and analytical technique are listed in the analytical methods and on the report of analysis.

#### A7.6 Completeness

The characteristic of completeness is a measure of the amount of valid data obtained compared to the amount that was expected to be obtained under normal conditions. The amount of valid data expected is based on the measurements required to accomplish project objectives.

#### A7.7 Comparability

The characteristic of comparability reflects both internal consistency of measurements and expression of results in units consistent with other organizations reporting similar data. The generation of comparable data requires operating within the calibrated range of an instrument and utilizing analytical methodologies which produce comparable results. Appropriate standard units for measurement values are utilized for each measurement system, which yields internally and externally comparable results assuming other comparability criteria are met.

#### A7.8 Project DQIs

Because of the intended data uses, the general philosophy for determining the project's DQI criteria was that data quality should meet current industry standards for such measurement data. In general, measurement DQI criteria are based on the published analytical method for each parameter. Specific criteria for measurement DQIs for the analyses to be performed are summarized below.

Parameter	Units	Accuracy <sup>a</sup> (LCS)	Accuracy <sup>a</sup> (Matrix Spike)	Precision <sup>a</sup> (RSD or RPD)	MDL <sup>b</sup>	RL <sup>c</sup>	Complete- ness (%)
E. coli	CFU/100ml	NA	NA	RPD≤ 200% for <150 CFU/100 ml RPD≤ 100% for ≥ 150 CFU/100 ml	1 C1 CFU/100 mL FU	1 CFU/100 mL if sample is not diluted	95
Total Suspended Solids (TSS)	mg/L	90-110%	NA	≤5%	≥2.5 mg to ≤200 mg	≥2.5 mg to ≤200 mg	100
Dissolved Oxygen	mg/L	90-110%	NA	<u>&lt;</u> 25%	<0.3	<0.3	95
Water Temperature	°C	± 0.5°C	NA	± 0.5°C	NA	NA	95

LCS = laboratory control sample MDL = method detection limit % R = percent recovery

RL = reporting limit

MS = matrix spike

NA = not applicable

RPD = relative percent difference

% RSD = percent relative standard deviation

<sup>a</sup> Criteria apply to concentrations <u>></u> RL.

<sup>b</sup> For undiluted samples.

<sup>c</sup> For undiluted samples. If sample is diluted, RL is proportionally higher.

Table 2: Criteria for Measurement DQIs

## A8. Special Training Requirements and Certifications

The Certificate issued by the SC DHEC Office of Environmental Laboratory Certification for Access Analytical, Inc. is 32575001.

The generation of reliable data by a laboratory requires that all operations are conducted by knowledgeable and trained personnel. The laboratory requires the accomplishment of a prescribed sequence of training objectives by a staff member before that individual is designated as qualified and permitted to independently conduct any assignment or analyses. The indoctrination and qualification process includes as a minimum:

- Reading and understanding applicable laboratory SOP,
- Reading and understanding applicable reference documents,
- Hands-on training under the supervision of an experienced and qualified individual, and
- For analytical methods used for measurements, a successful initial demonstration of analytical capability (i.e., IDC) by performing four replicate measurements which satisfy precision and accuracy criteria for the method as well as an MDL study.

Training records for staff are maintained by the Laboratory Director or Supervisor of the lab contracted to perform the work, and training files are kept for each staff member in the training and qualification files. Lab analysts shall also collect samples and perform field measurements. A summary of training accomplishments is recorded on file on the contracted lab's premises. Otherwise, no additional, specialized training will be needed for this project.

## **A9. Documentation and Records**

The QAPP will be maintained, revised, managed and facilitated by City of Columbia Staff, as listed in the Organizational Chart with the Project Manager as primary lead. S.C. DHEC's Quality Assurance Manager will review modifications pertaining to the QAPP and grant approval. Updates or changes regarding the QAPP will be e-mailed to individuals on the distribution list, unless otherwise specified. Sample collection times, field observations, and etc. will be recorded within a separate logbook by laboratory staff, as appropriate. Maps, GPS coordinates, photos, and etc. may be utilized to track progress, if necessary.

Data will be provided to the Project Manager by the lab on a quarterly basis for the first 3 years and on a monthly basis for the last three years of the project's duration. Any summaries or comments associated with the data will be drafted and finalized by the Project Manager and provided to appropriate personnel as defined in the organizational chart for distribution to all those required to receive notification pursuant to the SEP. All those required to receive notice are listed in the distribution list at the front of this document.

All raw data and/or data reports received form the lab along with summaries and commentary will be backed up, when received, to a shared folder for staff and management to access, when appropriate. Annually, electronic records will be backed up onto an external hard drive and kept for a minimum of 10 years or as defined in the Consent Decree. Hardcopies will be bound

and stored for a minimum of 10 years or as defined in the Consent Decree. All records are kept onsite.

#### A9.1 Data Reporting

After completion of analyses, analysts enter results for both samples and QC measurements into the laboratory's computer-based report templates. After peer review of the data is completed and the results are acceptable, the Laboratory Director reviews the preliminary report and works with necessary laboratory personnel to make any needed corrections. A final report is then produced and submitted to the City, either electronically or by mail depending on the contract. For this project, the laboratory will forward final reports containing completed, reviewed, and approved project results to the Program Manager pursuant to the project schedule. DHEC will receive the data on a quarterly basis for years 1-3 and monthly years 4-6.

The copy of the data package provided to the City and all associated raw data are typically kept for a period of at least 10 years or as defined in the Consent Decree. These records are stored in the laboratory for approximately two years, and then transferred to a storage room for secure, long term storage. For electronic data deliverables in Microsoft Excel or similar formats, files are maintained on the laboratory's desk top computers. Backup copies of the electronic files are prepared at least annually and stored in a secure area.

Laboratory and field data for the four required parameters are the only items being collected and evaluated through this QAPP. All reports, records and electronic files from the laboratory will be supplied by the City and DHEC on the quarterly or monthly basis, as described previously.

## A. Measurement/Data Acquisition

## **B1.** Sampling Process Design (Experimental Design)

The DHEC water quality monitoring stations listed in the Project Schedule table will be the focus of where sampling takes place. These locations were outlined in the SEP language of the City's Consent Decree and, therefore, mandated to be the sites of collection. No explanation was given as to why these sites were chosen, although it is assumed that since DHEC already had sites set up at these locations, it was more likely that they would be able to compare the data collected through this QAPP to the historical data on file. All samples that require analysis will be taken at the outfall of the station, with the exception of those that can be taken in the field by handheld devices and are not subject to the standards of a DHEC certified lab method.

It is not predicted that the sampling sites will ever be inaccessible for data collection. This is primarily due to the fact that these sites were originally set up to be a long-term monitoring site

for DHEC and should not only have proper flow through and position in the watershed, but is easy to access for maintenance and collection.

While the set schedule has yet to be determined, the samples will be collected at the same time and day each month or quarter, depending on which year the project is in and is independent of weather. Every sample will follow the EPA method and laboratory protocol for handling and hold times in which it should be analyzed. If a sample is destroyed anywhere in the process of collection, transport or analysis, the sample will need to be recollected and the occurrence should be noted with reason given. For more information on this procedure, please see Section D.

## **B2.** Sampling Methods

As mentioned before, four parameters will be measured on a quarterly basis for Years 1-3 and on a monthly basis for Years 4-6.

Sampling efforts will involve the collection of water samples for the following analytes: total suspended solids (TSS), *E. coli*. At the time of sample collection, <u>in situ</u> measurements will also be made for temperature and dissolved oxygen (DO) at each sampling location through the use of calibrated field probes (YSI).

Field measurement procedures and sample collection, handling, receiving, storage, and associated record keeping procedures are integral parts of the laboratory's QA program. The policies are designed to ensure that each measurement result and each sample are accounted for at all times. The primary objectives of measurement and sample control procedures are as follows:

- Each field measurement is recorded and uniquely identified at the time of measurement,
- Each sample received for analysis is uniquely identified,
- The correct samples are analyzed and are traceable to the applicable data records,
- Important and necessary sample characteristics are preserved,
- Samples are protected from loss, damage, or tampering,
- Any alteration of samples during collection or transport (e.g., filtration, preservation, breakage) is documented,
- Records of field measurements and sample custody (i.e., chain of custody) and integrity are established which will satisfy legal scrutiny, and

• A record of ultimate sample disposition (i.e., disposal or release from laboratory) is established.

#### **B2.1 Sample Collection**

A summary of sample collection, handling, and preservation activities is provided in Table 3.

Sample Type	Parameter Measured	Sample Container	Minimum Sample Size	Preservation Method/ Storage
Urban stream/ditch water, collected via grab samples	E. coli	Sterile plastic with sodium thiosulfate	100 mL	Field: store in cooler at 1-6 °C Lab: store in refrigerator at 1-6 °C and start analysis within 8 hours
Urban stream/ditch water, collected via grab samples	Total Suspended Solids (TSS)	plastic	500 mL	Field: store in cooler at 1-6 °C Lab: store in refrigerator at 1-6 °C and start analysis within 7 days

Table 3: Sample Collection Criteria

Samples collected by laboratory personnel are placed in appropriate containers, having the required preservatives or additives, and labeled with site-specific information to uniquely identify each container at the time of collection. Conditions of sampling sites, sample IDs, number of samples, dates/times of collection, equipment calibrations, etc., are recorded on site in field logbooks or on laboratory chain of custody forms as appropriate. Unless otherwise specified, samples are stored on ice in coolers at 1-6 °C until their receipt at the laboratory. Samplers may be the Laboratory Director, Laboratory Master Technician and/or Laboratory Technicians trained in sampling. In general, samples collected are grab samples (i.e., sample collected at a specific time and place) and collected manually. For bacteria analysis, samples are collected using sterile glass or sterile plastic sample bottles and collected carefully at just below the outfall/station so as to not contaminate by touching the inside of either the bottle or its lid. The bottle is filled with sample to approximately one-inch from the top, and then the lid is replaced. The bottle is then placed in a snap and seal plastic bag and a cooler with ice for storage and transport to laboratory. For analyses other than bacteria, samples are collected in plastic bottles. Bottles collecting samples for TSS only, are rinsed with river water at the site three times (due to lack of preservative), carefully filled with river, capped, and then placed in a cooler for storage and transport to the laboratory.

If issues occur in the field, the sample collector will handle these and record the issue and the corrective action in field books and/or logs. If the sample collector cannot fix the situation, then the Project Manager and Laboratory Director will be contacted.

All SOPs are provided in Appendix B, which provides more specifics on both in-situ and laboratory analyzed equipment, procedure, disposal and troubleshooting.

## **B3.** Sampling Handling and Custody Requirements

For laboratory samplers at the time of sampling, a chain of custody (COC) form must be filled out. The following information must be recorded by samplers:

- Date sample was collected
- Time sample was collected
- Location of sample: city, general location, and specific location.
- Example for a river sample: \_\_\_\_\_\_
- Name of sampler
- ID of sampling bottle is the site name and the date collected.
- Analysis (e.g., bacteria) to be conducted, which must also be written in indelible ink on the sample bottle
- Environmental conditions (e.g., waves, currents, tide, wind, sky, rain, runoff)
- Describe in comments section any problems encountered during sampling and corrective actions taken

The sample collector is considered to have custody of the sample until relinquishing the sample. This sample is properly in the custody of the sampler as long as the sample is in possession of the sampler, within sight of the sampler, or locked in a secure place. When the sampler relinquishes custody he/she should sign, date, and write the time the sample was relinquished on the COC form. The person receiving the sample should then sign, date, and write the time the sample was received on the same line. The sample can be relinquished to other qualified individuals in the same manner. Sample receipt in the laboratory is indicated by the Laboratory Director, Laboratory Master Technician or a Laboratory Technician accepting the sample and documenting it on the COC form. If the same individual transports the sample to the lab and processes that sample in the laboratory, then that person will record both accepting and relinquishing the sample on the COC form. A copy of the COC form is provided in Appendix A.

#### **B3.1** Sample Receiving and Storage

Samples must be delivered to the laboratory in coolers packed in ice less than six hours after sample collection. Analysis of the samples must begin within the stated hold times for each parameter from the time of sample collection with the exception of DO and temperature which

are in-situ and read immediately after stabilization. At the beginning of sampling, a sample bottle containing water should be placed in the cooler with ice, and then upon delivery of the cooler to the laboratory, the water in this bottle is measured to determine the sample receipt temperature.

Prior to accepting custody and signing for the samples, the laboratory representative verifies that all samples submitted are listed on the COC and that the COC documentation is complete. Received samples and corresponding documentation are carefully reviewed for compliance with regard to condition of containers, sample preservation and temperature (i.e., reading temperature of water blank in cooler), holding times (collection date/time), and accurate identification on the COC.

Once the COC has been verified against the delivered samples, sample information is entered into the laboratory receipt log. The receipt log for samples is kept as a Microsoft Excel spreadsheet. The file is password protected.

Samples received by the laboratory are identified by unique laboratory identification numbers. The sample's laboratory number is transcribed to each container associated with that sample using an indelible marker. Numbered samples are stored in secured areas according to aliquot preservation requirements.

At the end of the day or as soon as practical, the receipt log for all samples received on a day is printed and placed in a logbook in chronological order. The printed sheet(s) must be reviewed for correctness and then initialed at the bottom of the sheet. In the event an error is later found in the receipt log, the change must be made on all recording documents, electronic and hard copy, as applicable. Hard copy corrections must be made by drawing a single line through the error, writing the correct data above or to the side, and initialing and dating the entry.

#### **B3.2** Sample Distribution and Handling

Samples retrieved from their designated storage areas must be documented internally. Personnel removing samples from the storage areas are required to record the sample numbers removed, date, time, and their initials on the form. Staff must also document on that form the date and time samples are returned to storage. Several coolers and a refrigerator in the laboratory are for temporary storage of samples requiring refrigeration and awaiting preparation or analysis.

Notification of samples with parameters with critically short hold times (i.e., less than 48 hours) is provided verbally or in writing to the laboratory analytical staff on the day of receipt of such samples. Once notified, it is the responsibility of the analyst to perform the requested analysis within the appropriate hold time.

#### **B3.3 Sample Disposal**

In general, samples are disposed of approx. 14 days after results have been reported to the client. Arrangements for shorter or longer storage times are made with client approval based on specific project requirements. All sample container labels are removed or obliterated prior to disposal. Destruction of samples are noted on internal COC forms.

All samples suspected to be bacterially hazardous, incubated samples, used media, and bacteria control samples are sterilized by autoclaving for 30 minutes at 121 °C. In general, other samples found to be hazardous, or RCRA "D" listed, is returned to the client for disposal. Other hazardous wastes are disposed of by the science building staff by sending directly to an in-state permitted landfill.

Sterilized and non-hazardous aqueous samples are disposed of by pouring the sterilized, neutralized, or non-hazardous sample into a conventional drain to the municipal sewage treatment system. Non-hazardous solid wastes (including emptied disposable containers from aqueous samples) are disposed of by placing in a dumpster for municipal landfill disposal. The date of sample disposal is recorded internally.

## **B4.** Analytical Methods

#### **B4.1 Control of Analytical Processes**

All aspects of laboratory operations are controlled by key documents: quality assurance manual(s) and standard operating procedures (SOPs). The SOPs detail and document the procedures which implement the activities and requirements specified in the quality assurance manual.

To perform the tasks described in this QAPP, the laboratory uses 2 field and 2 laboratory analysis procedures:

- E. coli by IDEXX Colilert-24<sup>™</sup> QuantiTray<sup>™</sup> method , based on IDEXX 06-02027-24
- Total Suspended Solids (TSS) by gravimetric measurement, based on Method 2540 D of *Standard Methods*
- Dissolved oxygen by membrane electrode method, based on Method 4500-O G of *Standard Methods*
- Water temperature by thermometer or thermistor, based on Method 2550 B of *Standard Methods*

The step-by-step procedures of these techniques are provided in laboratory SOPs:

• SM 9223B (E. coli)

- SM 2540-D-2011 (Total Suspended Solids)
- SM 4500-0 G-2011 (field measurement of DO)

All laboratory SOPs referenced in this QAPP can be found on-site of the contracted laboratory at all times. Protocols are also in place, should issues occur in the laboratory. Appropriate corrective actions are outlined within each individual SOP, where applicable.

When samples are completely used or destroyed, a notation is made on the internal chain of custody.

Laboratory turnaround time is generally associated with meeting holding times for samples.

Data reports will go through the QA/QC process and then be sent to the City's project manager immediately after validation. The City's project manager will process the report information and submit to DHEC on a quarterly (years 1-3) or monthly (years 4-6) basis.

## **B5.** Quality Control (QC)

#### **B5.1 Dissemination of Quality Requirements**

The laboratory uses several means of communication to ensure staff is informed of all quality requirements. Routine operational requirements are communicated to applicable staff through distribution of the QAPP and laboratory SOPs. All these documents are controlled internally and are issued to selected laboratory staff on an individual basis, depending on staff assignment, task responsibilities, and work location. The QAPP and all SOPs are available to all laboratory staff on the laboratory's computer network. Changes in requirements are communicated to laboratory staff by distribution of revisions to this QAPP and applicable SOPs.

Any laboratory staff member observing any occurrence (e.g., equipment failure) that impacts laboratory capabilities or schedule of deliverables (i.e., analysis results are to be reported to SC DHEC and clients within 24 hours of completion of analysis) must immediately bring that observation to the attention of the Laboratory Director. The Laboratory Director shall immediately communicate the situation to the affected customer. A copy of this communication should be placed in the project file and the laboratory director can determine if any corrective actions are necessary.

Quality control (QC) procedures for laboratory measurements in this project are summarized in Tables 4-6. When recording results of QC measurements on samples (e.g., duplicate analysis), an acronym suffix is added to the sample number; the suffixes are as follows:

duplicate = D or DUP	replicates = R# or REP#
matrix spike = MS	matrix spike duplicate = MSD

Acronyms for recording other QC measurements are as follows:

blank = B or BLK	method blank = MB
calibration standard = CAL or CALIB	calibration verification standard = CV
initial calibration verification standard = ICV	primary standard = PS
working standard = WS	laboratory control sample = LCS

Temperature is measured with a thermometer in-situ conditions. For each cooler of samples that is transported to the analytical laboratory, a 100ml plastic container (prepared by the laboratory) will be included that is marked "temperature blank." This blank will be used by the laboratory's sample custodian to check the temperature of samples upon receipt to ensure that samples were maintained at the temperature appropriate for the particular analysis. Typically, a sample is collected in a 250 mL bottle with no preservative and the hold time is considered immediate. Temperature should be taken by a calibrated NIST thermometer.

#### Accuracy

Accuracy (bias) is a measurement of the extent to which a measured value of a quantity (parameter or analyte) agrees with the accepted value of that quantity. It is assessed by the analysis of samples of known concentration for the analytes of concern.

For LCSs, calibration standards, field reference standards, or additional QC samples of known concentration, accuracy is quantified by calculating the *percent recovery* (%R) of analyte from a known quantity of analyte as follows:

$$\%R = \frac{V_m}{V_t} x 100$$

where:

V<sub>m</sub> = measured value (concentration determined by analysis)

Vt = true value (concentration or quantity as calculated or certified by the manufacturer)

A matrix spike (MS) sample or a matrix spike duplicate (MSD) sample is designed to provide information about the effect of the sample matrix on the digestion and measurement methodology. A known amount of the analyte of interest is added to a sample prior to sample

preparation and instrumental analysis. To assess the effect of sample matrix on accuracy, the %R for the analyte of interest in the spiked sample is calculated as follows:

$$\%\mathbf{R} = \frac{(\mathbf{SSR} - \mathbf{SR})}{\mathbf{SA}} x \mathbf{100}$$

where:

- SSR = spiked sample result
- SR = sample result

SA = spike added

#### Precision

Precision is a measurement of the random error in an analytical measurement process. It reflects the degree of agreement between independent measurements determined by the analysis of replicate samples. When calculated for duplicate sample analyses, precision is expressed as the *relative percent difference* (RPD), which is calculated as:

$$\operatorname{RPD}(\%) = \frac{(S-D)}{\frac{S+D}{2}} \times 100$$

where:

- S = first sample value (original result)
- D = second sample value (duplicate result)

When precision is calculated for three or more replicate determinations, the *relative standard deviation* (RSD), also known as the coefficient of variation, expressed in units of percentage, is used. This is an expression of the spread of the data relative to the mean value of the determinations. The specific formulas used for calculating the RSD are:

$$\bar{\mathbf{x}} = \frac{\sum_{i=0}^{n} \left( \mathbf{x}_{i} \right)}{n}$$

Water Quality Monitoring QAPP for Columbia SEP Projects Rev. 1, August 2014

$$s = \sqrt{\frac{\sum_{i=0}^{n} (\mathbf{x}_{i} - \bar{\mathbf{x}})}{n-1}}$$

$$RSD(\%) = \frac{s}{\bar{\mathbf{x}}} \times 100$$

where:

- x = mean of n measurements
- x<sub>i</sub> = result value for the i<sup>th</sup> measurement
- n = total number of measurements
- s = standard deviation

#### **Method Detection Limits**

Method detection limits (MDLs) are determined for each analyte for each method used. These MDLs are determined by (a) conducting replicate analyses of standards at quantities approximately one to five times the estimated MDL, (b) determining the standard deviation, s, of the replicate measurements, and then (c) calculating the MDL from:

 $MDL = t (n-1, 1 - \infty = 0.99) \times S$ 

where:

n = number of replicate analyses

 $t_{(n-1,1-\infty=0.99)} = t$  distribution value appropriate to a 99% confidence level (one-tailed) and standard deviation estimate with n - 1 degrees of freedom

s = standard deviation of the data set

The MDL calculated in this manner represents the minimum amount of a substance that can be measured and reported, with 99% confidence that the analyte quantity is greater than zero.

The MDL does *not* represent the analyte quantity for which there is a 99% probability that the analyte will be detected; there is a 50% probability of detection and reporting of the analyte whose actual amount is at the MDL. The analyte quantity at which there is a 99% probability that the analyte will be detected and reported is twice the MDL.

Because MDLs are usually determined using standards in a clean matrix, they represent optimum obtainable performance. MDLs for actual sample matrices are likely to be higher than those determined using clean matrices.

#### **Quantitation/Reporting Limits**

Because of significant uncertainty (about 33% RSD) associated with MDLs determined in a "clean" matrix, plus possible additional variability due to actual sample matrix, EQL uses higher levels, referred to as "limits of quantitation" or "reporting limits", down to which it routinely reports measured values.

The *limit of quantitation* (LOQ) is defined as 10 times the standard deviation (s) from the MDL determination. Therefore, the LOQ is roughly 3.33 times the MDL, since the MDL is usually about three times s.

The *reporting limit* (RL) is not as rigidly, and usually not as conservatively, defined as the LOQ. It is usually chosen at a level two to 10 times higher than the MDL. As much as possible, it is also chosen at a level which is below applicable regulatory action levels and which simplifies data review and reporting (e.g., RL of 1.0  $\mu$ g/L for numerous parameters of similar chemical behavior, MDLs, and regulatory action levels).

#### Completeness

The characteristic of completeness is a measure of the amount of valid analytical data obtained compared to the total number of analyses performed. Valid analytical data are those for which all QC specifications are met. Completeness of the reported data (expressed as a percentage) is calculated as:

$$\%C = \frac{M_v}{M_t} x 100$$

where:

 $M_v$  = number of measurements judged to be valid (meets all QC specifications)

 $M_t$  = total number of measurements performed (based upon number of samples submitted)

#### Comparability

Comparability of analysis results is evaluated by at a minimum checking the following against project requirements:

• Analysis method utilized

- Analysis QC measurement results •
- Units utilized for reporting measurement values

#### **Rejection of Data**

Rejection of an analytical result for a sample may be required if established quality control acceptance criteria are not satisfied at any point during the course of analysis. Nominal quality control decision criteria are provided in analytical method SOPs and the corresponding data review checklists.

Additionally, outliers are determined using a statistical outlier test (Standard Methods, 1010 B. Statistics, 17<sup>th</sup> through 21<sup>st</sup> Editions) for evaluation of a questionable value from a group of replicate readings, measurements, results, etc., for an individual sample or standard. Briefly, the test involves dividing the difference between the questionable value and the replicates' mean value by the standard deviation for all replicate values, to calculate a quotient, T. The questionable value is rejected if the calculated T is greater than an established rejection T. The outlier test is conducted at the 99% confidence level, which means if the calculated T exceeds the rejection  $T_{0.99}$ , then the questionable value may be rejected with 99% probability that it is significantly different from the other values (Table 4).

		Rej	ection
Questionable Value <sup>a</sup>	Formula for Calculating T <sup>b</sup>	Number of Values	Quotient T <sub>0.99</sub>
Smallest value (X <sub>1</sub> )	X <sub>ave</sub> – X <sub>1</sub> T =	3	1.1
	S	4	1.49
		5	1.7
	X <sub>n</sub> – X <sub>ave</sub>	6	1.94
Largest value (X <sub>n</sub> )	T = S	7	2.10
		8	2.22
nge values in order of incre	asing magnitude.	9	2.32
T <sub>0.99</sub> reject questionable va	alue.	10	2.4
average value for all replica	ites.		
standard deviation for all r - $X_{ave}$ ) <sup>2</sup> /(n - 1)] <sup>1/2</sup>	eplicates, where s =		

#### Table 4. Outlier test for evaluation of a questionable group from a group of replicate values

Water Quality Monitoring QAPP for Columbia SEP Projects Rev. 1, August 2014

12 2.55

14 2.66

16 2.75

QC Sample or Activity	Minimum Frequency	Acceptance Criteria	Corrective Action
Capability demonstration	Four (4) prepared samples analyzed prior to any customer sample analyses	Criteria for LCS recovery and duplicate precision	Repeat until acceptable
Media sterility check	Prior to use of new lot of Colilert-24 and weekly	No fluorescence	Investigate problem. Eliminate contaminations. Obtain new lot of Colilert- 24,if necessary. Repeat until successful before using Colilert-18 lot.
Media positive check with control culture	Prior to use of new lot of Colilert-24 and weekly	Fluorescence	Investigate problem. Obtain new lot of Colilert-24 if necessary. Repeat until successful before using Colilert-18 lot.
Media negative checks with control cultures (gram+ and gram-)	Prior to use of new lot of Colilert-24	No fluorescence	Investigate problem. Eliminate contaminations. Obtain new lot of Colilert- 24_if necessary. Repeat until successful before using Colilert-18 lot.
Method blank	At least weekly, prior to sample analysis	≤ 20 CFU/100 mL	Clean analytical system and repeat MB analysis. Identify and eliminate source of contamination.
Sample duplicate or matrix spike duplicate	At least one (1) weekly, and one with all large sample batches (~20 samples)	RPD ≤ 200% for <150 CFU/100 mL RPD ≤ 100% for ≥ 150 CFU/100 mL	Investigate problem. If system precision is in control, qualify results. If system precision is out of control, reanalyze entire batch.
Internal PE sample	Samples and frequency determined by Lab QA Officer	Criteria for LCS recovery and duplicate precision	Investigate all unacceptable results.
Blind PE sample	Samples and frequency determined by accrediting agencies and projects	Determined by PE provider	Investigate all unacceptable results.
LCS = laboratory control sample		QC = quality cont	trol
MB = method b	MB = method blank		covery
MDL = method dete	ection limit	RL = reporting li	mit
PE = performar	nce evaluation	RPD = relative per	rcent difference

Table 5. Summary of QC requirements for E. coli analysis by Colilert-24
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QC Sample or Activity	Minimum Frequency	Acceptance Criteria	Corrective Action
Capability demonstration	Four (4) prepared samples analyzed prior to any customer sample analyses	90 – 110% R < 10% RSD	Repeat until acceptable
Balance Calibration Check	Prior to weighing any sample filters	Weight of certified 200 mg weight: 0.1998 – 0.2002 g	Investigate problem including cleaning weight and balance. If balance is out of calibration attempt recalibration or use another balance until obtain acceptable calibration check.
Method Blank	At least one (1) per analysis batch of up to 10 samples	For 1.0 L blank filtered: < 1.0 mg/L	Investigate, identify, and correct the problem. If system accuracy is in control, qualify results. If system accuracy is out of control, correct problem before analyzing samples
Sample analysis	For all sample analyses	Total residue on filter: ≥2.5 mg to ≤ 200 mg	If total residue on filter < 2.5 mg report result as < RL If total residue on filter > 200 mg filter a smaller volume of sample.
Laboratory Control Sample	At least one (1) per year	90 – 110% R	Investigate, identify, and correct problem. If system accuracy is in control, qualify results. If system accuracy is out of control, correct problem before analyzing samples.
Sample duplicate	One (1) per preparation batch of up to 10 samples	RPD ≤ 5%	Investigate problem. If system precision is in control, qualify results. If system precision is out of control, reanalyze entire batch.
Internal PE sample	Samples and frequency determined by Lab QA Officer	Criteria for LCS recovery and duplicate precision	Investigate all unacceptable results.
Blind PE sample	Samples and frequency determined by accrediting agencies and projects	Determined by PE provider	Investigate all unacceptable results.
LCS = laboratory contro MB = method blank MDL = method detection MS = matrix spike PE = performance eva	n limit F	QC = quality control R = percent recovery RL = reporting limit where RL = (2.5 m RPD = relative percent difference SD = relative standard deviation	ng /mL filtered) x 1000 mL

Table 6. Summary of QC requirements for TSS

## Table 7. Summary of QC requirements for YSI Pro Plus probes

QC Sample or Activity	Minimum Frequency	Acceptance Criteria	Corrective Action
Capability demonstration	Four (4) prepared samples analyzed prior to any customer sample analyses	DO 97-104% of theoretical DO Others 75-125% R Others RPD <u>&lt;</u> 25%	Repeat until acceptable.
Calibration stability monitoring	Immediately before calibration measure standards	Not applicable.	Not applicable. Results are used to monitor stability of probes and evaluate need for maintenance.
Calibration	Daily prior to sample analysis and after every 8 hours	After calibration, measure calibration standards (conductivity, pH, DO % saturation of water saturated air) as sample pH ± 0.1 of expected, others 99-101% R	Investigate and fix any obvious problems. Repeat until acceptable.
Calibration check	Immediately following calibration	Measurement of calibration standards or LCS (conductivity, pH, DO % saturation of LCS or of water saturated air) Cond. 90-110% R, pH ± 0.1 of expected, DO 97-104% sat **DO method requires LCS to be read in duplicate with each calib. event**	Investigate and fix any obvious problems. Recalibrate and repeat until acceptable.
Field duplicate (duplicate sample collected at one of sampling sites	One (1) per sampling event	RPD ≤ 25%	Investigate problem. If system precision is in control, qualify results. If system precision is out of control, reanalyze all sampling sites if possible.
Internal PE sample	Samples and frequency determined by Lab QA Officer	75-125% R RPD ≤ 25%	Investigate all unacceptable results.
Blind PE sample	Samples and frequency determined by accrediting agencies and projects	Determined by PE provider	Investigate all unacceptable results.

## **B6.** Instrument/Equipment Testing, Inspection and Maintenance

Equipment, as used in this QAPP, refers to and includes equipment or instrumentation used in the areas of sample collection, preparation, or analysis. The laboratory utilizes all equipment (Table 7) as appropriate and necessary for a given technique, as specified in a referenced method, or as required by regulatory programs. The equipment investment and subsequent capabilities are sufficient for the laboratory's field and laboratory tasks for this project. Except for the autoclave and Quanti-Tray sealer, there is a backup instrument for every critical instrument. There is a rapid response maintenance contract for the autoclave.

#### Table 8. Equipment list

Instrument	Number of Units
Analytical Balance	
Autoclave	
Conductivity/Dissolved Oxygen/pH Field Meter	
Incubator	
Oven	
Refrigerator/Freezer	
Water deionizing system	
Quanti-Tray sealer	
Water Bath	

#### **B6.1** Preventative Maintenance

Manufacturer recommended preventative maintenance schedules are performed internally for all equipment, in all lab areas. Additionally, some equipment, such as autoclave and analytical balances, require service checks by the commercial vendor. Service calls of this nature are scheduled by the Quality Assurance Officer or science building staff according to the maintenance schedule.

Maintenance logs are used to document any procedures performed either internally, or by vendor service technicians. These logs also document maintenance or repair which may be necessary as a part of corrective action resulting from QC failures. Documentation in the logs is the responsibility of the analyst or technician operating the instrument or equipment.

## **B7.** Instrument Calibration and Frequency

Equipment requiring calibration must be calibrated according to manufacturer's instructions or the analytical method. General guidelines for analytical instrument calibrations are covered in the corresponding analytical SOPs. A summary of instrument calibration procedures for this task's measurements is provided in Table 8. For equipment where documentation of the calibration can be obtained in the form of hardcopy printouts, the calibration data must be filed with the analytical run data. Where printouts are not possible, the following minimum information must be recorded in a calibration log or on the raw data sheet: equipment identification, calibration date, analyst initials, standard(s) used, certified concentration(s), equipment reading(s) per standard, calibration verification standard(s) results, due date for next calibration. It is the responsibility of the analyst performing calibration to record this information in the calibration log. If repair work or service has been done to any equipment, the analyst shall record the details of this work performed, and obtain any applicable certificates from the vendor.

	alibration procedures			
Instrument	Calibration Procedure	<b>Frequency</b>	Acceptance Criteria	Corrective Action if Unaccepatable
Incubators and Water Bath	One-point or two-point calibration of thermometer with NIST traceable thermometer	Annual	<u>+</u> 0.5 °C	Replace thermometer
Refrigerators and pH Meters	One-point or two-point calibration of thermometer with NIST traceable thermometer	Annual	<u>+</u> 2.0 °C	Replace thermometer
Freezers and Ovens	One-point or two-point calibration of thermometer with NIST traceable thermometer	<mark>Annual</mark>	<u>+</u> 2.0 °C	Replace thermometer
Analytical Balance	Calibration verification using NIST traceable weights	Daily	<u>+</u> 0.1%	<mark>Clean and autocal</mark> or repair
Quanti-Tray sealer	NA	NA	NA	NA
<mark>рН meter</mark>	Two-point calibration with standard buffers	<mark>Every</mark> session	<mark>Slope 90-102%</mark> рН <u>+</u> 0.1	Clean probe, replace electrolyte, or replace probe as needed. Repeat calibration until acceptable.

#### Table 9. Instrument calibration procedures

## B8. Inspection/Acceptance Requirements for Supplies and Consumables

Upon receipt, buffer solutions, standards and reagents used in the field kit will be inspected by the laboratory receiving team for leaks or broken seals and to compare the age of each reagent to the manufacturer's recommended shelf-life. Field personnel will also assure that all supplies and consumables have not expired, have not been tampered with and are appropriate for the work being performed prior to use in the field.

Reagents are replaced before they exceed manufacturer's recommended shelf life. These shelf lives are typically one to two years. However, specific replacement dates can be determined by providing the reagent lot number to the manufacturer. Reagent replacement dates are noted in the maintenance log.

Sample containers will be received by the contracted laboratory. The containers will be examined upon receipt to ensure that the appropriate number and type of containers have been provided to meet sampling needs. The containers will be checked to ensure that preservative has been added, if required. Any discrepancies will require additional containers to be obtained and re-checked. If any sampling problems or abnormalities occur during sampling in the field, the laboratory and the QA Manager for the City shall be notified.

#### **B9.** Data Acquisition Requirements (Non-direct Measurement)

This is not applicable.

#### B10. Data Management

A lab staff member collects the sample and preserves it according to the SOPs. The samples are brought to the laboratory. If they are performing the analysis they relinquish them to themselves. If not, they relinquish them to sample custodian who logs and disseminates the samples. The samples are analyzed. The analyst verifies the sample calculations and then they make a hard copy of the data and submit it to the laboratory supervisor. The laboratory supervisor performs a second verification. After which, the data is given to a lead technician who also reviews the QC, provides verification and then enters the data into a data archive spreadsheet. A preliminary report is submitted to the Laboratory Director for validation. If issues occur, the Laboratory Director will act as an assistant validator and will review any anomalies found to determine if the anomaly is valid. Once validation is complete, the data are released to the City's QA/Project Manager for review and reporting use.

Data integrity is ensured by the amount of verification that is performed. Hardware and software issues are also avoided by verification at several levels.

# C. Assessment and Oversight

## **C1.** Assessments and Response Actions

Table 10. Assessments a	_		
Assessment .	Frequency	Description	Information reported to
Initial demonstration of	Initially, prior to	The analyst must prepare four	<mark>Analyst, Laboratory</mark>
<mark>capability (IDC)</mark>	reporting client	aliquots of a known level of the	Director, Program
	<mark>data</mark>	analyte of interest, analyze them	Director, SCDHEC, EPA
	<mark>independently</mark>	according to the appropriate method,	Region 4
		and demonstrate the ability to	
		recover the analyte within established	
		acceptance criteria.	
Data generator review	<mark>Every time data is</mark>	Conduct real-time review and	Laboratory Director
	<mark>generated</mark>	verification of 100% of the data	
		resulting from their activities.	
<mark>Peer review</mark>	<mark>Every time data is</mark>	The peer reviewer(s) must be a	Laboratory Director
	generated	qualified individual other than the	
		data generator and must meet the	
		minimum training and qualifications	
		requirements for analysts. Data is	
		reviewed for technical correctness for	
		a minimum of the method, proper	
		units/significant digits, calculation	
		verifications, variations documented,	
		transcription errors, complete data	
		package, QC measurements within	
		limits or qualified, and hold times	
		were met or exceptions documented.	
Analysis of internal	Once per year or as	Analysis of a blind sample for the	Laboratory Director, PE
and/or external	required by	analyte(s) of interest. Results are	provider, clients,
performance evaluation	specific client	evaluated for accuracy by a third	Program Director,
(PE) samples	contract	party.	SCDHEC, EPA Region 4
	requirements.		
Internal audits	Quarterly	Review of SOPs for referenced	Analysts, Lab Director,
		method, review of procedure, review	Program Director
		of data files, review of logbooks,	
		review of compliance with QA policies	
External audits	Per request	Review of entire scope of	Lab Director, Program
		accreditation and project tasks by	Director
		state, agency, or affiliations through	
		whom EQL holds some form of	
		certification or contract.	
Lab Certification	Minimum of three	Review of entire scope of	Laboratory Director,
Evaluations	years	accreditation and project tasks by	Program Director,
	<mark>,</mark>	SCDHEC's Office of Laboratory	SCDHEC, EPA Region 4
		Certification	

#### Table 10. Assessments and response actions

#### **C2.** Reports to Management

By mid-June of each year, the Laboratory Director prepares an annual activity report summarizing the following:

- Goals
- Financial summary and projections
- Measures and comparisons
- Major activities and accomplishments for year
- Needs

## **D.** Data Validation and Usability

D1. Data Review, Verification and Validation

ltem	Criteria	If not met sample is accepted, flagged or rejected?	Flag	Comments
Sample not analyzed within hold time	Sample received in the lab within 6 hours of collection and analyzed within 2 hours of receipt appropriate hold time	Rejected	H	Out of holding time
Lost sample	Proper COC documentation not followed and sample is misplaced	<mark>(Unable to analyze)</mark>	LS	N/A
<mark>Unable to Collect</mark> <mark>Sample</mark>	Various circumstances (i.e., weather, lost sampling container) cause sample to not be collected	<mark>(Unable to analyze)</mark>	NS	<mark>N/A</mark>
Sample not held within required temperature range	Temperature blank within cooler indicates temperature above 6° C or proper storage equipment failed to read within range (refrigerator/freezer)	Rejected	T	Out of required temperature range
Temperature blank not placed within cooler during sample transport	Unknown receipt temperature	Flagged	UT	Noted
Incorrect sampling container used for sample collection	Incorrect sampling container used for sample collection	Flagged	<mark>SC</mark>	Noted
Improper preservation	Improper preservation (i.e., acidification, filtering)	Flagged	IP	Noted

Table 11: Criteria for accepting, rejecting, or flagging data

#### D2. Validation and Verification Methods

All data receive analyst review and independent analyst or peer review. The Laboratory Director and/or quality assurance personnel will review the data to varying degrees at different points in the review process. These review processes are appropriately documented before data are released from the laboratory.

Data review ensures that raw data are properly collected, reduced, and reported. Data verification confirms by examination of the measurement process and provision of evidence, that specified method, procedural, or contractual requirements have been met. For example, QC measurements must indicate that deviations between measured values and known values are smaller than the maximum allowable error (i.e., DQIs).

Data validation is the process of substantiating that specified performance criteria were achieved for an entire data set or data reporting group, including comparisons between analytes and samples to see if relationships are scientifically reasonable.

#### D3. Reconciliation with User Requirements

Reconciliation of data with DQI criteria to determine data usability is performed primarily by the Laboratory Program Director working in direct communication with the clients.