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QUALITY ASSURANCE MANUAL
FOR
[CITY OR AUTHORITY NAME]
WASTEWATER TREATMENT PLANT LABORATORY
[Street Address
City, State Zip Code]

Responsible Official – [Name]
[Phone No. Incl. Area Code]

Date

Quality Assurance Officer – [Name]
[Phone No. Incl. Area Code]

Date

Laboratory Manager – [Name]
[Phone No. Incl. Area Code]

Date

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Quality Manual Review for the [City or Authority Name] WWTP					
Date					
Reviewer					

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1.0 Quality Policy Statement

1 VAC 30-45 Requirements: 1 VAC 30-45-610 A and -610 B 3 and B 6.

Instructions: This section should contain the quality policy statement and the scope of the laboratory's operations. This section should provide a statement of the laboratory's commitment to its quality system and to good laboratory practices. The statement should describe what the quality system covers and set out the goals and objectives of the quality system. The statement should address how the goals and objectives of the quality policy are achieved. It should also address how the goals and objectives are communicated to and carried out by laboratory staff.

Example:

The quality manual is intended for the laboratory operations of the [name of the laboratory]. This laboratory provides analysis of samples as required by the Virginia Pollutant Discharge Elimination System (VPDES) permit issued to [the laboratory's owner] and analysis of process samples to ensure proper operation of the [WWT facility]. Only the samples required to be analyzed under the VPDES permit are covered by this quality system.

Quality Policy Statement

The laboratory management is committed to providing the necessary resources and to defining acceptable laboratory practices in the quality documentation to ensure compliance with the Virginia laboratory certification requirements. Management's policy is to ensure the information in quality documentation is communicated to, implemented and understood by all the laboratory staff performing work in the laboratory.

The quality manual documents the policies and references the procedures to ensure test data generated for submittal to the Virginia Department of Environmental Quality (VA DEQ) are scientifically acceptable as defined by the method performance criteria.

The objectives of the laboratory are to produce data of known and documented quality in order to demonstrate conformance to the permit and laboratory accreditation requirements. The objectives are measured with internal audits and evaluated as part of the management review.

The goal of the [name of the laboratory] is to produce data that is in compliance with permit # [redacted], pertinent regulations under the Virginia State Water Control law (9 VAC 25), and the Virginia laboratory certification requirements for noncommercial laboratories (1 VAC 30-45).

2.0 Organization and Management Structure

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 4, B5, and - B7; 1 VAC 30-45-200 through -230, 1 VAC 30-45-610 C, and 1 VAC 30-45-620.

Instructions: This section should contain a description of the organization and management of the laboratory. A relevant organization chart should be provided and can be appended to the QA Manual.

This section should --

- describe the organization and management structure of the laboratory,
- indicate its place in any parent organization, and
- describe the functional responsibility, level of authority, and interrelationship or lines of communication of all personnel who manage, perform or verify work affecting the quality of testing and analysis.

Each manager and employee of the laboratory shall have a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the overall work of the laboratory.

An outline of how this section might be organized is provided in the text below. This example lists brief job descriptions for the laboratory staff. Detailed job descriptions could be attached.

2.1 Organizational Chart

Include, attach, or refer to location of organizational chart. (See Attachment 1.)

Example:

2.2 Management Responsibilities

Management has the overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management includes the Laboratory Manager and the Quality Assurance Officer.

2.3 Job Descriptions of Staff Positions

The Laboratory Manager is responsible for:

- ensuring the supervision of all personnel employed by the laboratory.
- ensuring the quality of data produced by the laboratory.
- training and keeping personnel up to date on laboratory procedures, operation of instrumentation, and laboratory support equipment.
- appointing personnel in the absence of laboratory staff.
- reviewing and approving any changes to the quality manual and associated quality documentation.

The Quality Assurance Officer is responsible for:

- implementing and overseeing the quality system.
- reviewing and approving any changes to the quality manual and associated quality documentation.

The Laboratory Technician is responsible for:

- performing technical laboratory tests and procedures.
- adhering to the quality assurance plan.
- reporting deviations from the quality assurance plan and taking necessary action to bring the quality management system back into compliance.

2.4 Personnel Qualifications

Laboratory Manager: (Define as appropriate according to 1 VAC 30-45-200 B)

Quality Assurance Officer: Documented training or experience in quality assurance and quality control procedures and knowledgeable in the quality system.

Laboratory Technician: Documented demonstration of capability for each method. (List any other requirements)

2.5 Identification of Approved Signatories

The following individuals are authorized to sign laboratory reports:

[Insert Name of Individual], Title (i.e. Lab Manager)

[Insert Name of Individual], Title (Quality Assurance Officer)

See Attachment 2 for signature identifications.

3.0 Ethics Policy and Data Integrity

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 9 and 1 VAC 30-45-730 B 1.

Instructions: This section should contain the laboratory's policy statement with regards to ethics and data integrity. This statement should define the laboratory's commitment to ensuring data integrity and ethical conduct. It should include the laboratory's procedures for educating and training personnel in their ethical and legal responsibilities, including the potential penalties for improper, unethical or illegal actions. This section should address what topics are covered in the training, how often the training is done, how the training for individuals is documented and what records are kept.

See www.epa.gov/quality/bestlabs.html for quality management tools related to data integrity and ethics. The link provided there to the American Council of Independent Laboratories Environmental Sciences Publications page includes a representative code of ethics and an ethics and data integrity agreement. In the example below, training is discussed. No policy statement material is provided.

Example:

The laboratory has developed an ethics policy and established procedures to educate and train personnel in their ethical and legal responsibilities. The laboratory performs routine data review to ensure the records are complete and that they demonstrate ethical conduct. Data integrity procedures are part of this quality manual.

The ethics agreement defines the employees' ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

4.0 Document Control

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 11 and 1 VAC 30-45-630 through -660.

Instructions: This section should contain a description of the laboratory's system for control and maintenance of documentation through a document control system. This section should indicate how the system works and who is responsible for the system. This section should define what documents are covered and how they are authorized, identified, and accessed.

Example:

The purpose of the document control system is to ensure that only the most recent revisions of SOPs, worksheets, forms, logs, etc. are available to the appropriate personnel, are timely, and receive the required approvals. All internal regulatory documentation, standard operating procedures, work instructions, service manuals, and product instructions are under document control. The Quality Assurance Officer is responsible for the document control system and keeps a master list of the location of all documents and their current revision. The Laboratory Manager and the Quality Assurance Officer approve all newly released documents and revised documents. Worksheets, forms, and logbooks are designed to include all information pertinent to the analysis or task performed. Each worksheet, form, and logbook includes a unique identifier. Worksheets and forms have a revision number and effective date. Attachment 3 lists documents in use at [Laboratory Name].

5.0 Subcontracting Sample Analysis and Review of New Work

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 10 and 1 VAC 30-45-680.

Instructions: This section should contain a description of the procedures used for subcontracting the analysis of samples (5.1) and the review of any new work (5.2). Section 5.1 should describe the procedures for subcontracting analytical samples to another laboratory. The section should include a description of how the results of the subcontractor's analysis are reported and how records of the subcontracted work are kept. Section 5.2 should describe the procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work. For VPDES permittees, any new work would come in as requirements to monitor and report analytes or parameters in addition to those currently monitored.

Example:

5.1 Subcontracting of Sample Analysis

Any subcontracting of work for regulatory reporting shall be subcontracted to laboratories accredited under 1 VAC 30-46. A chain of custody form is used to track samples from wastewater sampling activities to the subcontract laboratory. The chain of custody lists the tests requested for analysis.

5.2 Review of New Work

All new work is initiated by the Laboratory Manager who delegates responsibilities for the new work according to available resources. Staff will meet prior to initiation of new work in order to determine if appropriate facilities and resources are available. The plan for any new testing shall be reviewed and approved by the Laboratory Manager before commencing such work. After agreement is reached, facilities and resources are organized to efficiently perform the work. For any new testing requirements, the designated employee shall write a standard operating procedure and demonstrate capability to perform those tests prior to reporting results. The SOP(s) shall be under document control, and a Demonstration of Capability Statement(s) shall be on file.

6.0 Purchasing

1 VAC 30-45 Requirement: 1 VAC 30-45-690.

Instructions: This section should contain a description of the laboratory's procedures for selecting and purchasing services and supplies used for testing.

Example:

Purchasing procedures follow the procurement requirements defined by the [city or authority]. The technical specifications for equipment and supplies for the laboratory are defined in the laboratory SOPs. The laboratory technician documents the materials or equipment to be ordered. The order is reviewed by the Quality Assurance Officer and approved by the [title of authorizing person].

7.0 Complaints

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 12, 1 VAC 30-45-670 A and D, and 1 VAC 30-45-700.

Instructions: This section should contain a description of the laboratory's procedures for the resolution of complaints about the laboratory's activities. Complaints may be concerns

expressed by clients, laboratory personnel, assessors or any person or organization regarding work performed by the laboratory or problems that have been detected. The laboratory should handle complaints in the same manner that it handles corrective actions.

Example:

All complaints about the laboratory's activities are documented in a complaint file maintained in the laboratory. The file contains the date and name of the person receiving the complaint, a description of the complaint, source of the complaint, the resolution, and any written material accompanying the complaint. A corrective action form is used to document the complaint.

The Quality Assurance Officer investigates complaints and promptly investigates all areas of activity and responsibility involved. The written results of the investigation including actions taken by the laboratory are reviewed by the Laboratory Manager. The results of the investigation are signed and dated by the Laboratory Manager and the Quality Assurance Officer.

8.0 Departures from documented policies and procedures or from standard specifications

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 16 and 1 VAC 30-45-670 D.

Instructions: This section should contain a description of the laboratory management's arrangements for permitting departures from documented policies and procedures or from standard specifications when the departures are planned and controlled.

Example:

The Laboratory Manager has responsibility for ensuring adherence to the laboratory's policies and procedures. Arrangements for known and controlled departures from documented policies and procedures are allowed. Planned departures do not require audits; however, the departure will be fully documented and include the reason for the departure, the affected SOP(s), the intended results of the departure and the actual results. If the data reported to DEQ are affected adversely, the DEQ will be notified in writing. The procedure used to document any specific departure affecting DEQ data is the same as the corrective action procedure.

9.0 Corrective Action

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 15, 1 VAC 30-45-390, 1 VAC 30-45-670 D and 1 VAC 30-45-730 C 2 s.

(Attachment 5 provides a sample Corrective Action Form that can be used to document corrective actions.)

Instructions: This section should contain a description of the laboratory's procedures for corrective action. Corrective action needs to be taken to identify and implement measures to handle unexpected departures from documented policies and procedures or out of control QC performance that can affect data quality. Corrective actions should be established for each test method in the test method SOP (1 VAC 30-45-730 C 2 s). Corrective action reports are required of the laboratory in response to deficiencies identified during on-site assessments (1 VAC 30-45-390). The laboratory also should establish general procedures to follow whenever testing discrepancies are detected (1 VAC 30-45-670 D). This section should describe the procedures to be followed for feedback and corrective action. The test method SOPs can be referred to. General procedures should be defined fully in this section. The procedures for corrective action should provide the following at a minimum:

- identify who is responsible for assessing each QC data type
- identify who is responsible for initiating or recommending corrective action
- define how the analyst treats a data set if associated QC is unacceptable
- define what is unacceptable QC
- specify how out-of-control situations and subsequent corrective actions are to be documented
- specify procedures for the QA officer and management to review corrective action reports

Example:

Corrective actions are the result of concerns regarding work performed by the laboratory, detected problems, or nonconformance and may be from clients, laboratory personnel, assessors or any person or organization with concerns. Records of the concern, nonconformance or complaint and subsequent actions are maintained.

The laboratory takes corrective action whenever unacceptable conditions exist or departures from policies and procedures occur. The following indicators are used to determine unacceptable conditions:

- *QC samples outside of the established acceptance criteria*
- *Calibrations outside acceptable criteria*
- *Equipment failure*
- *PT studies outside acceptable limits*
- *Non-conformance identified during internal reviews*
- *Non-conformance identified during DCLS on-site assessments*
- *Non-conformance or problems identified after receiving a question or complaint*

Once an unacceptable condition is identified, the laboratory investigates the problem and outlines a corrective action plan.

Corrective action may include, but is not limited to, one or all of the following:

- *Re-analysis of samples*
- *Re-calculation of results*
- *Re-calibration of instrument*
- *Preparation of new standards*
- *Re-analysis of blanks*
- *Dilution of samples*
- *Additional analyst training*
- *Replace equipment or supplies*
- *Re-sampling*
- *Recalled analysis results or amended reports*

SPECIFIC CORRECTIVE ACTION <i>(The following are examples and should be modified/expanded to fit your organization.)</i>		
TYPE	RECOMMENDED ACTION	DOCUMENTATION
Contaminated Method Blank (Chemistry)	<ol style="list-style-type: none"> 1. Determine source of contamination. 2. Eliminate source of contamination. 3. Re-analyze blank. 	Work sheet/log book
LCS outside acceptance limit (Chemistry)	<ol style="list-style-type: none"> 1. Check preparation log for errors 2. Check analysis for errors 3. Check calculations 4. Remake standard or use a different standard 5. Re-analyze standard and all affected samples 6. Run a matrix spike 	Work sheet/log book
Positive/Negative controls (Microbiology)	<ol style="list-style-type: none"> 1. Check expiration date of the media 2. Check media preparation 3. Confirm incubator temperatures 4. Prepare new media from same lot. If still not acceptable, prepare new media from different lot 5. Examine analytical technique 	Work sheet/log book
Analyst not following the SOP (All methods)	<ol style="list-style-type: none"> 1. Provide additional training 2. Do demonstration of performance 3. Analyze a PT sample 	Analyst training file Work sheet/log book

All corrective actions are documented. A corrective action form may be used for issues that warrant more detailed documentation.

10.0 Records Management

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 11, 1 VAC 30-45-630 through -660, and 1 VAC 30-45-730 K.

Instructions: This section should contain a description of the procedures to ensure all records required by 1 VAC 30-45 are retained. This section should also describe the procedures for managing records which allow the historical reconstruction of all laboratory activities. This section should describe what records are kept including those required to be kept by 1 VAC 30-45-630 through -660. This section should describe how records are stored. This section should describe how corrections are made to records.

Example:

The laboratory has implemented a record management system that allows the historical reconstruction of all laboratory activities. The laboratory keeps a record of each environmental analysis for at least three years as required by environmental regulation.

The laboratory maintains the following records: [provide a list, such as: personnel records, sample preservation, sample tracking, raw data, maintenance records, copies of reports of analysis, internal audit reports, etc.]

11.0 Internal Quality System Audits

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 13 and 1 VAC 30-45-670 A and C.

Instructions: This section should contain a description of the laboratory's procedures for annual internal audits. The audits should be done by someone independent of the activity to be

audited and trained and qualified to do the audit. No one should audit their own work. Describe what happens if an audit finding casts doubt on the laboratory's test results.

Example:

The Quality Assurance Officer arranges for an internal quality system review annually. The audit is carried out by trained personnel who are independent (if possible) of the activity being audited. The review assesses the requirements of the quality assurance manual against laboratory operations, and laboratory operations against the laboratory's quality assurance manual and SOPs.

The results of the audits are documented in writing. Where audit findings cast doubt on the validity or correctness of the data, the laboratory will take immediate corrective action. Any corrective actions are documented. The Laboratory Manager ensures that the corrective actions are discharged within the agreed upon time frame. Any authority whose work was possibly adversely affected shall be notified in writing.

12.0 Management Review

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 13 and 1 VAC 30-45-670 B.

Instructions: This section should contain a description of the laboratory's procedures for management review. The section should describe what is specifically to be reviewed (PTs, internal audits, certification on-site assessments, complaints, corrective actions, etc.) and who is to participate in the review. The section should indicate how the review is to be conducted, documented and communicated to others.

Example:

The laboratory management reviews the laboratory quality system and its testing and calibration activities annually to introduce any necessary changes or improvements. The review takes into account the outcome of recent internal audits, assessments by external bodies (DCLS or DEQ), the results of interlaboratory comparisons, the results of proficiency tests, any changes in the volume and type of work undertaken, feedback from authorities or others, and corrective actions. The findings and any corrective actions from this review are documented.

13.0 Personnel Training

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 8, 1 VAC 30-45-210 and -220, and 1 VAC 30-45-730 E, F and G.

Instructions: This section should contain a description of the laboratory's procedures for establishing that personnel have adequate training and experience in the duties they are expected to carry out and are receiving any needed training. Discuss how laboratory management determines whether a laboratory applicant is qualified. How does laboratory management define adequate training and experience? Describe initial and continuing demonstration of method capability for the analyst. What training records does laboratory management keep with regard to their employees?

Example:

Before conducting any analysis, each analyst receives training by another analyst or supervisor who has completed training. An analyst in training is supervised by an experienced individual.

In addition to in-house training, additional training may be provided to the analyst in the form of educational courses, professional seminars, and continuing proficiency testing.

Analyst training and performance is considered complete after the analyst has produced a successful initial demonstration of method capability for the analysis for which he/she is responsible. In addition, acceptable results from a proficiency testing sample or internal blind quality control sample are documented for the analyst.

All training is documented and kept on file. At a minimum, documentation includes the name of the analyst, the reference method/SOP, the dates of training, the person providing training, initial demonstration of method capability (if appropriate), and PT results (if appropriate). To document the training, the [Name] Laboratory uses a training form for each analytical procedure. After successful training and demonstration, the Laboratory Manager and Quality Assurance Officer sign the Demonstration of Capability Form as certification of the analyst's performance.

14.0 Facilities and Environmental Conditions

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 17, 1 VAC 30-45-710, and 1 VAC 30-45-850 (8).

Instructions: This section should contain a description of the physical facility and environment used by the laboratory in conducting tests. Describe how the laboratory conditions are controlled so as not to adversely affect testing. Describe how the laboratory meets any environmental conditions required by test methods or sample preservation. Describe the housekeeping procedures. Discuss how samples are stored in order to preserve the samples.

Example:

Testing occurs only within the laboratory. Laboratory space is maintained and monitored to the specifications required. Electronic balances are located away from drafts and doorways and mounted on marble slabs in areas where their use is affected by vibrations.

The laboratory is kept clean. Attention is given to good housekeeping at all times. The laboratory is designed, and activities are conducted, so sample contamination is avoided. The laboratory has adequate lights and ventilation. When required, laboratory temperature and barometric pressure are monitored; the acceptable range is defined in the test method to ensure the proper operation of instrumentation. Appropriate data corrections are made using these monitored values (such as in the BOD method) as defined in Standard Operating Procedures. If environmental conditions are outside the defined method limits, results are qualified.

15.0 Test Methods and Validation

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 19, 1 VAC 30-45-730 A-E, and 1 VAC 30-45-760 B.

Instructions: This section should contain a description of the test methods the laboratory uses. The laboratory maintains an in-house method manual for each certified analyte or test method. The manual may consist of copies of published or referenced methods or standard operating procedures that have been written by the laboratory. Attachment 4 provides an SOP format which includes the sections or references for a test method. The description should include references to the specific method and technology used, the detection limit, and the reporting limits. The section should contain a discussion of the demonstration of initial method performance or validation.

Example:

15.1 List of Analytical Tests, Parameters, Method Reference, MDL, and Reporting Limits

ANALYTICAL METHODS <i>(The following are examples and should be modified to fit your organization.)</i>				
Analytical test	Analytical Method	REFERENCE METHOD	METHOD DETECTION LIMIT	REPORTING LIMITS
5-day BOD	D.O. Probe	SM 18 Ed. 5210 B	Depletion of @ least 2.0 mg/L	20 mg/L
pH	Ion Selective Electrode	SM 18 th Ed. 4500 H ⁺	1.0 SU	6.0 – 9.0 SU

ANALYTICAL METHODS <i>(The following are examples and should be modified to fit your organization.)</i>				
Analytical test	Analytical Method	REFERENCE METHOD	METHOD DETECTION LIMIT	REPORTING LIMITS
Total Suspended Solids	Gravimetric	SM 18 th Ed. 2540 D	2.0 mg/L	30mg/L
Fecal Coliform	Membrane Filter	SM 18 th Ed. 9222 D	1.0 cfu/100ml	April /October 200c/100ml November - March 2000c/100ml

15.2 Conducting Demonstration of Method Performance

Prior to implementation of a method, the laboratory prepares an initial demonstration of method performance in accordance with method specifications. When the approved method does not specify initial demonstration of performance, the laboratory uses the following guidelines as described in 1VAC30-45-760 B :

- Determination of Limit of Detection (LOD)
- Determination of Limit of Quantitation (LOQ)
- Evaluation of Precision and Bias
- Evaluation of Selectivity

Initial demonstration of method performance must be repeated each time significant changes are made to instrumentation, personnel, or the method. Initial demonstration of performance is documented in Demonstration of Capability records. The process for conducting method validation and/or initial demonstration of performance is included in the *[Laboratory SOPs or other location]*.

16.0 Equipment, Reagents, Supplies, and Reference Materials

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 17-18 and B 20, 1 VAC 30-45-690, 1 VAC 30-45-720, 1 VAC 30-45-730 J, and 1 VAC 30-45-740.

Instructions: This section should contain information about the following aspects of the laboratory's operation:

- the major equipment and the reference materials
- the procedures used to
 - calibrate analytical support equipment and instruments
 - maintain equipment
 - receive, label and store standards, reagents, and other consumables
- the approach used to provide traceability of calibration or verification to appropriate standards
- the process for documenting the activities addressed in this section and how these records are kept

One approach to providing some of the information in this section is to provide tables or lists of laboratory equipment and reference materials, including information about the model and date the equipment was put into service.

Example:

All equipment, reagents, supplies, and reference materials necessary for analyses are kept on hand for the specific analysis for which the *[Name]* Laboratory performs.

For calibrations of analytical instrumentation, the laboratory uses standards that assure that measurements made by the laboratory are traceable to national standards of measurement, such as NIST traceable standards (when

available) or certified reference materials. To achieve traceability of measurements, the laboratory maintains detailed records identifying the analyst(s) responsible for each step of the analytical processes, the origin of all consumables, standards, and reagents used, unique identification of analytical instruments used, calibration records for all equipment used, dates and times of analyses conducted, procedures used for preparing reagents and for analyzing samples, and unique identification of each sample analyzed. [The laboratory may want to be specific here regarding where this information is documented, e.g., bench sheets, log books, etc..]
 Calibration procedures are established for all applicable tests. These procedures are detailed in the SOP for the analysis.

16.1 Laboratory equipment

- All equipment is properly maintained. Procedures for maintenance of equipment are documented in SOPs and equipment manuals.
- Any defective equipment or part is removed from service and labeled until repaired. Equipment or parts are not put back in service until the laboratory demonstrates that it is functioning correctly.
- All routine and non-routine maintenance and repairs are documented in laboratory records. [The laboratory may want to be specific here regarding where this information is documented, e.g., bench sheets, log books, etc..]
- Calibration records are maintained for all measuring equipment. See laboratory bench sheets and logs.
- Laboratory Support Equipment. All laboratory support equipment is calibrated, or verified, or both, before being put into service, and on a continuing basis. The procedures for the calibration and verification of the laboratory support equipment are found in the SOPs and equipment manuals.

16.2 Reagents and supplies

- Glassware is properly cleaned and maintained as specified in the SOPs. Any cleaning or maintenance requirements specified in the approved test procedure are followed.
- Analytical reagent grade materials, if available, are used by the laboratory.
- The laboratory does not use prepared reagents, standards, or purchased chemicals outside the expiration date of the material.
- All stock and standard solution containers are labeled with content, preparation date, expiration date, concentration, and initials of analyst preparing the solution. For the preparation of reagents, standards, and rinsing glassware, the laboratory uses water of the purity and quality specified by the Standard Operating Procedure, published method, or regulation. [Describe this purity/quality of water here or in individual SOPs.]

16.3 Reference materials

- To ensure accurate and precise measurements, the laboratory uses reference materials traceable to a national standard of measurement where commercially available, such as NIST, or are traceable to certified reference materials.
- The laboratory retains the Calibration Certificates of Reference Materials to demonstrate the traceability.
- The laboratory has a program and procedure for the calibration or re-certification of its reference standards (e.g., Class 1 or 2 weights or equivalent, thermometers). [Describe the laboratory's program/procedure.]
- The original containers are labeled with an expiration date.

16.4 Listing of Laboratory Equipment and Reference Materials

LABORATORY EQUIPMENT AND REFERENCE MATERIALS (The following are examples and should be modified to fit your organization.)			
Name	Brand	Model	Date Placed in Service

LABORATORY EQUIPMENT AND REFERENCE MATERIALS <i>(The following are examples and should be modified to fit your organization.)</i>			
Name	Brand	Model	Date Placed in Service
Balance	Mettler	AE1000C	1995
Vacuum Pump	Fisher Scientific	5KH36KN906X	1996
BOD Incubator	Precision Scientific	815	2005
DO Meter	Hach	HQ 10	2005
Refrigerator	G E Select	TBX21GIDARWW	2004
Laboratory Oven	Precision	14EG	2004

16.5 Calibration and Maintenance Procedures and Frequency

CALIBRATION AND MAINTENANCE <i>(The following are examples and should be modified to fit your organization.)</i>			
INSTRUMENT	ACTIVITY	FREQUENCY	DOCUMENTATION
Balance	1. Clean 2. Check alignment 3. Service Contract	1. before use 2. before use 3. annual	Work sheet/log book Post annual service date on balance
Class "2" Weights	1. Only use for the intended purpose 2. Use plastic forceps to handle	5 year or if damaged	Calibration: certificate to NIST
Reference Thermometers	To calibrate working Thermometers	5 year or if damaged	Calibration: certificate to NIST
Working Thermometers: 1. Glass and electronic 2. dial thermometers	Check at the temperature used, against a reference NIST certified thermometer	1. Annual for glass and electronic 2. Quarterly for dial thermometers	Calibration factor and date of calibration on thermometer and work sheet/log book

17.0 Samples

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 21, 1 VAC 30-45-730 H, and 1 VAC 30-45-850.

Instructions: This section should contain information concerning the laboratory's sample acceptance policy, and how samples are identified, tracked, and stored. This section should also address the disposal of samples. (Note: Although not required by 1 VAC 30-45, the laboratory may want to include the requirements for sample collection, handling, preservation, and holding times here. The laboratory may want to include a table specific to its required monitoring.)

Example:

Each sample is uniquely identified from collection to disposal. All samples are identified on the outside of the sample bottle. Each sample is recorded in the sample log.

17.1 Sample Acceptance Policy

After sample collection and transportation to the facility, the laboratory will verify the integrity of the sample by checking for the following items:

- Leakage or breakage.
- Completeness of sample collection logs.
- Correct sample identification.
- Appropriate use of sample labels (such as water resistant) and use of permanent ink.
- Use of appropriate sample containers, adequate volume, preservation, and holding time as required by specific test methods and 40 CFR Part 136. [The laboratory should specify these requirements here for the methods the lab performs unless stated in SOPs.]
- Temperature of samples requiring thermal preservation (checked and recorded at time of sampling).

When the sample received does not meet the acceptance requirements, the condition of the sample is documented and the sample is rejected and re-collected in accordance with the laboratory's written sample acceptance policy. [The laboratory should specify here or in a separate document the circumstances under which samples will be accepted, rejected, or run with qualified results. The policy shall ensure that only properly obtained samples with appropriate sampling records are analyzed and that the samples are handled properly per 1VAC30-45-850.]

All samples are logged into the sample log book. [Here the laboratory should describe its own system for uniquely identifying, tracking and labeling samples.]

17.2 Storage of Samples in the Laboratory

The laboratory will store samples, sub-samples, and/or other preparation products such as extracts or digestates according to the specified conditions in the approved methodology. All samples, sub-samples, etc. will be protected from all potential sources of contamination, deterioration, or damage.

17.3 Sample Disposal

The laboratory follows its waste management plan or chemical safety program for sample disposal appropriate for the samples handled and wastes generated. Wastewater samples are disposed in the laboratory drain. Any material determined to be hazardous for disposal in a sanitary sewer will be taken to a hazardous disposal site.

[State the plan here or in a separate policy.]

18.0 Assuring the Quality of Test Results

1 VAC 30-45 Requirements: 1 VAC 30-45, Article 3; 1 VAC 30-45-610 B 14; 1 VAC 30-45-730 I; and 1 VAC 30-45-750 and -760. The specific quality control requirements of the test methods performed by the laboratory or the specific quality control requirements of 1 VAC 30-45-770 et seq.

Instructions: This section should contain a description of or references to the laboratory's quality control procedures used in running its test methods. The laboratory must follow the specific quality control procedures that are required by the test methods run by the laboratory. Laboratories using test methods that do not have quality control procedures associated with them must use the quality controls specified in 1 VAC 30-45-770 et seq. Laboratories using the test methods published by *Standard Methods* must use the quality controls published in the separate pertinent section of *Standard Methods* if the method does not specify the quality controls required. The laboratory should set out in detail in this section of the manual the specific quality controls for the method or provide a reference to the test method SOP that includes the required quality controls for the method. This section should also contain a description of the proficiency testing that the laboratory is performing for its test methods. NOTE: Detailed examples are not given in this section. The laboratory should go to the applicable section of 1 VAC 30-45 (e.g., 1 VAC 30-45-770 through -775 for chemistry) for guidance in outlining the quality control requirements for each test method. Information stated in

SOPs does not have to be re-stated in the Quality Manual.

Example:

The laboratory demonstrates the quality of analytical results through the implementation of a quality control plan.

18.1 Quality Control Samples

[Describe the types of quality control samples run in the laboratory or refer to SOPs where information is found.]

18.2 Proficiency Testing (PT) Samples

The laboratory obtains PT studies from [name of approved PT provider]. PT studies are performed twice per year. The following parameters are tested: [list parameters or reference where list is found]

PT studies are analyzed in the same manner as regular samples. The same test method procedures and the same internal QC protocol are used when analyzing PT studies.

If the laboratory fails a PT study, an investigation of the cause is conducted. When problems are identified, a corrective action plan is outlined on the corrective action form and actions are completed in a timely manner.

19.0 Reporting the Results

1 VAC 30-45 Requirements: 1 VAC 30-45-610 B 13 and B 22, 1 VAC 30-45-670 A - C, 1 VAC 30-45-730 I, and 1 VAC 30-45-860.

Instructions: This section should contain a description of the laboratory's procedures for reporting analytical results. This description should describe the procedures to ensure that data are free from errors.

Example:

19.1 Procedures to Ensure Reported Data are Free from Errors

Data Validation:

The analyst performing the analysis verifies all data. The data review is to include the following items:

- Calibration of the instrumentation. (Confirm the calibration criteria are met.)
- Quality control data. (Confirm QC meets the acceptance criteria.)
- Calculations. (Check for calculation errors.)
- Documentation. (Check worksheets, logbooks and printouts for accuracy and completeness.)

Before final reporting is done, data are validated by the [Define the responsible staff person] to verify that all quality control measures are reviewed and evaluated and to ensure the reported data are free from transcription and calculation errors. [When a second person is not available for data review before report release, describe the schedule for data review of an analyst's work.]

19.2 Procedures for Data Qualifiers

Data qualifiers are added to all data not meeting collection, analytical, or internal QC acceptance criteria.

19.3 Procedures for Reporting Analytical Results

[Describe the procedure DEQ requires your laboratory/facility to use to report the results of analytical testing.]

20.0 Glossary

Most of the definitions presented here are selected definitions from 1 VAC 30-45, *Certification for Noncommercial Environmental Laboratories*, the provisions of the Virginia Administrative Code under which noncommercial environmental laboratories are certified in Virginia. Other definitions are included and their source is noted in parentheses at the end of the definition and the full source provided at the end of the glossary.

"Acceptance criteria" means specified limits placed on characteristics of an item, process, or service defined in requirement documents.

"Accuracy" means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. Accuracy is an indicator of data quality.

"Aliquot" means a portion of a sample taken for analysis.

"Analyst" or "laboratory technician" means the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

"Analyte" means the substance or physical property to be determined in samples examined.

"Analytical method" means a technical procedure for providing analysis of a sample, defined by a body such as the Environmental Protection Agency or the American Society for Testing and Materials, which may not include the sample preparation method.

"Assessment" means the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and its systems or both to defined criteria.

"Assessor" means the person who performs on-site assessments of laboratories' capability and capacity for meeting the requirements under this chapter by examining the records and other physical evidence for each one of the tests for which certification has been requested.

"Audit" means a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

"Batch" means environmental samples that are prepared together or analyzed together or both with the same process and personnel, using the same lot or lots of reagents. "Analytical batch" means a batch composed of prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. "Preparation batch" means a batch composed of one to 20 environmental samples of the same matrix that meets the criteria in this definition for "batch" and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

"Blank" means a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the

usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include the following types:

1. Field blank. A blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken.
2. Method blank. A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

"Calibration" means to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

"Calibration curve" means the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

"Calibration standard" means a substance or reference material used to calibrate an instrument.

"Certified reference material" means a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

"Commercial environmental laboratory" means an environmental laboratory where environmental analysis is performed for another person.

"Corrective action" means the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

"DEQ" or "VA DEQ" means the Department of Environmental Quality.

"DGS-DCLS" or "DCLS" means the Division of Consolidated Laboratory Services of the Department of General Services.

"Demonstration of capability" means the procedure to establish the ability of the analyst to generate data of acceptable accuracy and precision.

"Detection limit" means the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence.

"Document control" means the act of ensuring that documents, and revisions to the documents, are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (AQSC)

"Environmental analysis" or "environmental analyses" means any test, analysis, measurement, or monitoring used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the Code of Virginia). For the purposes of these regulations, any test, analysis, measurement, or monitoring required pursuant to the regulations promulgated under these three laws, or by any permit or order issued under the authority of any of these laws or regulations is "used for the purposes" of these laws. The term shall not include the following:

1. Sampling of water, solid and chemical materials, biological tissue, or air and emissions.
2. Field testing and measurement of water, solid and chemical materials, biological tissue, or air and emissions, except when performed in an environmental laboratory rather than at the site where the sample was taken.
3. Taxonomic identification of samples for which there is no national accreditation standard such as algae, benthic macroinvertebrates, macrophytes, vertebrates and zooplankton.

"Environmental laboratory" or "laboratory" means a facility or a defined area within a facility where environmental analysis is performed. A structure built solely to shelter field personnel and equipment from inclement weather shall not be considered an environmental laboratory.

"Establishment date" means the date set for the accreditation program under 1VAC30-46 and the certification program to be established under this chapter.

"Establishment of certification program" or "established program" means that DGS-DCLS has completed the initial accreditation of environmental laboratories covered by 1VAC30-46 and the initial certification of environmental laboratories covered by 1VAC30-45.

"Facility" means something that is built or installed to serve a particular function.

"Field of certification" means an approach to certifying laboratories by matrix, technology/method and analyte/analyte group.

"Field testing and measurement" means any of the following:

1. Any test for parameters under 40 CFR Part 136 for which the holding time indicated for the sample requires immediate analysis; or
2. Any test defined as a field test in federal regulation.

The following is a limited list of currently recognized field tests or measures that is not intended to be inclusive: continuous emissions monitoring; on-line monitoring; flow monitoring; tests for pH, residual chlorine, temperature and dissolved oxygen; and field analysis for soil gas.

"Finding" means an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition.

"Holding time (or maximum allowable holding time)" means the maximum time that a sample may be held prior to analysis and still be considered valid or not compromised.

"Initial certification period" means the period during which DGS-DCLS is accepting and processing applications for the first time under this chapter as specified in 1VAC30-45-60.

"Internal standard" means a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

"International System of Units (SI)" means the coherent system of units adopted and recommended by the General Conference on Weights and Measures.

"Laboratory control sample" or "LCS" means a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

"Laboratory control sample" or "LCS" may also be named laboratory fortified blank, spiked blank, or QC check sample.

"Laboratory duplicate" means aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

"Laboratory manager" means the person who has overall responsibility for the technical operation of the environmental laboratory and who exercises actual day-to-day supervision of laboratory operation for the appropriate fields of testing and reporting of results. The title of this person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager.

"Legal entity" means an entity, other than a natural person, who has sufficient existence in legal contemplation that it can function legally, be sued or sue and make decisions through agents as in the case of corporations.

"Limit of detection" or "LOD" means an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte and matrix specific and may be laboratory dependent.

"Limit of quantitation" or "LOQ" means the minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

"Matrix" means the component or substrate that may contain the analyte of interest. A matrix can be a field of certification matrix or a quality system matrix.

1. Field of certification matrix. These matrix definitions shall be used when certifying a laboratory.

- a. Non-potable water. Any aqueous sample that has not been designated a potable or potential potable water source. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.
 - b. Solid and chemical materials. Includes soils, sediments, sludges, products and byproducts of an industrial process that results in a matrix not previously defined.
 - c. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origins.
 - d. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.
2. Quality system matrix. For purposes of batch and quality control requirement determinations, the following matrix types shall be used:
- a. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.
 - b. Aqueous. Any aqueous sample excluded from the definition of drinking water matrix or saline/estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.
 - c. Saline/estuarine. Any aqueous sample from an ocean or estuary, or other salt water source.
 - d. Nonaqueous liquid. Any organic liquid with less than 15% settleable solids.
 - e. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
 - f. Solids. Includes soils, sediments, sludges and other matrices with more than 15% settleable solids.
 - g. Chemical waste. A product or by-product of an industrial process that results in a matrix not previously defined.
 - h. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

"Matrix spike (spiked sample or fortified sample)" means a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

"Matrix spike duplicate (spiked sample or fortified sample duplicate)" means a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

"Method detection limit" means one way to establish a limit of detection, defined as the minimum concentration of a substance (an analyte) that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (NELAC)

"National Environmental Laboratory Accreditation Conference (NELAC)" means a voluntary organization of state and federal environmental officials and interest groups with the primary purpose to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP.

"National Environmental Laboratory Accreditation Program (NELAP)" means the overall National Environmental Laboratory Accreditation Program of which NELAC is a part.

"National Institute of Standards and Technology" or "NIST" means an agency of the U.S. Department of Commerce's Technology Administration that is working with EPA, states, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested states can be certified by NIST to provide NIST-traceable proficiency testing (PT) samples.

"Negative control" means measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

"Noncommercial environmental laboratory" means either of the following:

1. An environmental laboratory where environmental analysis is performed solely for the owner of the laboratory.
2. An environmental laboratory where the only performance of environmental analysis for another person is one of the following:
 - a. Environmental analysis performed by an environmental laboratory owned by a local government for an owner of a small wastewater treatment system treating domestic sewage at a flow rate of less than or equal to 1,000 gallons per day.
 - b. Environmental analysis performed by an environmental laboratory operated by a corporation as part of a general contract issued by a local government to operate and maintain a wastewater treatment system or a waterworks.
 - c. Environmental analysis performed by an environmental laboratory owned by a corporation as part of the prequalification process or to confirm the identity or characteristics of material supplied by a potential or existing customer or generator as required by a hazardous waste management permit under 9VAC20-60.
 - d. Environmental analysis performed by an environmental laboratory owned by a Publicly Owned Treatment Works (POTW) for an industrial source of wastewater

under a permit issued by the POTW to the industrial source as part of the requirements of a pretreatment program under Part VII (9VAC25-31-730 et seq.) of 9VAC25-31.

e. Environmental analysis performed by an environmental laboratory owned by a county authority for any municipality within the county's geographic jurisdiction when the environmental analysis pertains solely to the purpose for which the authority was created.

f. Environmental analysis performed by an environmental laboratory owned by an authority or a sanitation district for any participating local government of the authority or sanitation district when the environmental analysis pertains solely to the purpose for which the authority or sanitation district was created.

"Owner" means any person who owns, operates, leases or controls an environmental laboratory.

"Preservation" means refrigeration and/or reagents added at the time of sample collection, or later, to maintain the chemical and/or biological integrity of the sample. (NELAC)

"Person" means an individual, corporation, partnership, association, company, business, trust, joint venture or other legal entity.

"Physical," for the purposes of fee test categories, means the tests to determine the physical properties of a sample. Tests for solids, turbidity and color are examples of physical tests.

"Positive control" means measures taken to ensure that a test or its components are working properly and producing correct or expected results from positive test subjects.

"Precision" means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is an indicator of data quality. Precision is expressed usually as standard deviation, variance or range, in either absolute or relative terms.

"Primary accrediting authority" means the agency or department designated at the territory, state or federal level as the recognized authority with the responsibility and accountability for granting NELAC accreditation to a specific laboratory for a specific field of accreditation.

"Proficiency test or testing (PT)" means evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

"Proficiency test (PT) field of testing" means the approach to offer proficiency testing by matrix, technology/method, and analyte/analyte group.

"Proficiency test (PT) sample" means a sample, the composition of which is unknown to both the analyst and the laboratory provided to test whether the analyst or laboratory or both can produce analytical results within specified acceptance criteria.

"Proficiency testing (PT) program" means the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

"Program," in the context of a regulatory program, means the relevant U.S. Environmental Protection Agency program such as the water program under the Clean Water Act (CWA), the air program under the Clean Air Act (CAA), the waste program under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund) or the waste program under the Resource Conservation and Recovery Act (RCRA).

"Publicly Owned Treatment Works (POTW)" means a treatment works as defined by § 212 of the CWA, which is owned by a state or municipality (as defined by § 502(4) of the CWA). This definition includes any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes, and other conveyances only if they convey wastewater to a POTW treatment plant. The term also means the municipality as defined in § 502(4) of the CWA, which has jurisdiction over the indirect discharges to and the discharges from such a treatment works.

"Quality assurance" means an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

"Quality assurance officer" means the person who has responsibility for the quality system and its implementation. Where staffing is limited, the quality assurance officer may also be the laboratory manager.

"Quality control" means the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

"Quality control sample" or "QC sample" means a sample used to assess the performance of all or a portion of the measurement system. QC samples may be certified reference materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking. (NELAC)

"Quality manual" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

"Quality system" means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control.

"Range" means the difference between the minimum and maximum of a set of values.

"Reference material" means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement test method, or for assigning values to materials.

"Reference standard" means a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

"Responsible official" means one of the following, as appropriate:

1. If the laboratory is owned or operated by a private corporation, "responsible official" means (i) a president, secretary, treasurer, or a vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy-making or decision-making functions for the corporation or (ii) the manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding \$25 million (in second-quarter 1980 dollars), if authority to sign documents has been assigned or delegated in accordance with corporate procedures.
2. If the laboratory is owned or operated by a partnership, association, or a sole proprietor, "responsible official" means a general partner, officer of the association, or the proprietor, respectively.
3. If the laboratory is owned or operated by a governmental body, "responsible official" means a director or highest official appointed or designated to oversee the operation and performance of the activities of the environmental laboratory.
4. Any person designated as the responsible official by an individual described in subdivision 1, 2 or 3 of this definition, provided the designation is in writing, the designation specifies an individual or position with responsibility for the overall operation of the environmental laboratory, and the designation is submitted to DGS-DCLS.

"Sample tracking" means procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (NELAC)

"Sampling" means the act of collection for the purpose of analysis.

"Sanitation district" means a sanitation district created under the provisions of Chapters 3 (§ 21-141 et seq.) through 5 (§ 21-291 et seq.) of Title 21 of the Code of Virginia.

"Sewage" means the water-carried human wastes from residences, buildings, industrial establishments or other places together with such industrial wastes and underground, surface, storm, or other water as may be present.

"Simple test procedures" means any of the following:

1. Field testing and measurement performed in an environmental laboratory.

2. The test procedures to determine:
 - a. Biochemical oxygen demand (BOD);
 - b. Fecal coliform;
 - c. Total coliform;
 - d. Fecal streptococci;
 - e. E. coli;
 - f. Enterococci;
 - g. Settleable solids (SS);
 - h. Total dissolved solids (TDS);
 - i. Total solids (TS);
 - j. Total suspended solids (TSS);
 - k. Total volatile solids (TVS); and
 - l. Total volatile suspended solids (TVSS).

"Spike" means a known mass of target analyte added to a blank sample or sub-sample, used to determine recovery efficiency or for other quality control purposes. (NELAC)

"Standard operating procedure (SOP)" means a written document that details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

"Standardized reference material (SRM)" means a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method.

"Statistical Minimum Significant Difference (SMSD)" means the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased. (NELAC)

"System laboratory" means a noncommercial laboratory that analyzes samples from multiple facilities having the same owner.

"TCLP" or "toxicity characteristic leachate procedure" means Test Method 1311 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in 40 CFR 260.11. This method is used to determine whether a solid waste exhibits the characteristic of toxicity (see 40 CFR 261.24).

"Test" means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Air Pollution Control Law" means any method of analysis required by the Virginia Air Pollution Control Law (§ 10.1-1300 et seq.); by the regulations promulgated under this law (9VAC5) including any method of analysis listed either in the definition of "reference method" in 9VAC5-10-20, or listed or adopted by reference in 9VAC5; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Waste Management Act" means any method of analysis required by the Virginia Waste Management Act (§ 10.1-1400 et seq.); by the regulations promulgated under this law (9VAC20), including any method of analysis listed or adopted by reference in 9VAC20; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Water Control Law" means any method of analysis required by the Virginia Water Control Law (§ 62.1-44.2 et seq.); by the regulations promulgated under this law (9VAC25), including any method of analysis listed or adopted by reference in 9VAC25; or by any permit or order issued under and in accordance with this law and these regulations.

"Test method" means an adoption of a scientific technique for performing a specific measurement as documented in a laboratory standard operating procedure or as published by a recognized authority.

"Test sensitivity/Power" means the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis. (NELAC)

"Traceability" means the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

"U.S. Environmental Protection Agency" means the federal government agency with responsibility for protecting, safeguarding and improving the natural environment (i.e., air, water and land) upon which human life depends.

"Validation" means the confirmation by examination and provision of objective evidence that the particular requirements of a specific intended use are fulfilled. (NELAC)

"Verification" means the confirmation by examination and provision of evidence that specified requirements have been met. (NELAC) NOTE: In connection with the management of

measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

"Virginia Air Pollution Control Law" means Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 of the Code of Virginia, which is titled "Air Pollution Control Board."

"Wastewater" means liquid and water-carried industrial wastes and domestic sewage from residential dwellings, commercial buildings, industrial and manufacturing facilities and institutions.

"Waterworks" means each system of structures and appliances used in connection with the collection, storage, purification, and treatment of water for drinking or domestic use and the distribution thereof to the public, except distribution piping.

"Working range" means the difference between the limit of quantitation and the upper limit of measurement system calibration. (NELAC)

Definition Sources

American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance Terms, 1996

National Environmental Laboratory Accreditation Conference (NELAC), 2003 Standards.

Document No.:

Effective Date:

Revision No.:

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Attachment 1

Organization Chart

Document No.:

Effective Date:

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Attachment 2

Signature Page

(List as appropriate)

Laboratory Manager

[Name]

Signature

Initials

Date

Quality Assurance Officer

[Name]

Signature

Initials

Date

Attachment 3**Example: Document Listing**

(The following are examples and should be modified/expanded to fit your organization.)

Document Number	Document Name	Revision Number
SOP 001	Biochemical Oxygen Demand	1
SOP 002	Total Suspended Solids	3
SOP 003	Ph	1
SOP 004	Fecal Coliform	2
		1
WS001	Biochemical Oxygen Demand Worksheet	1
WS002	Total Suspended Solids Worksheet	1
WS003	pH Work Sheet	1
WS004	Fecal Coliform	2
		1
TR001	Analyst Training Form	1
TR002	Demonstration of Capability	1
MR001	Management Review Format	1
IA001	Internal Audit Form	1
CA001	Corrective Action Form	1

Attachment 4**Test Method SOP Format****HEADER**

SOP #

Effective Date:

Revision #:

Laboratory Manager Approval: _____ Date: _____

Quality Assurance Officer Approval : _____ Date: _____

SOP NAME**1. Identification of test method**

Indicate the title of the method or alternative names for the method as used by the laboratory or found in the laboratory records.

2. Applicable matrix or matrices

List the applicable matrix for the method. Review the 1VAC30-45, 1VAC30-46, or NELAC definitions of matrix, specifically the quality system matrix section, for defining the matrix.

3. Method detection limit

List the method detection limit or reference the location where this information is found. Also include the quantitation limit listing for each analyte or define the relationship between the MDL and QL to allow personnel to determine these and document in the record or report format rather than the SOP. Define the location of the information if referenced and not presented in the SOP.

4. Scope and application, including components to be analyzed

This section outlines the purpose, range, limitations, and intended use of the method and identifies the analytes or compounds measured with the method.

5. Summary of the test method

This section provides an overview of the method procedure and quality assurance.

6. Definitions

This section includes definitions of terms, acronyms, and abbreviations used in the method. If preferred, definitions may be provided in a glossary at the end of the method or quality manual. In this case, the definitions section appears in the method, with a notation that definitions are provided in a glossary in the specified location.

7. Interferences

This section identifies known or potential interferences that may occur during use of the method, and describes ways to reduce or eliminate interferences. If there are no interferences as part of the test method, then state "No interferences known or identified for this method." Do not leave this section blank. Do not remove the section.

8. Safety

This section describes special precautions needed to ensure personnel safety during the performance of the method. Procedures described here should be limited to those which are above and beyond good laboratory practices. The section contains information regarding specific toxicity of analytes or reagents.

9. Equipment and supplies

This section lists and describes all non-consumable supplies and equipment needed to perform the method.

10. Reagents and standards

This section lists and describes all reagents and standards required to perform the method and provides preparation instructions and/or suggested suppliers as appropriate. Indicate the quality of the reagents and standards. This section is used to ensure the purchase of the appropriate quality of materials.

11. Sample collection, preservation, shipment and storage

This section provides requirements and instructions for collecting, preserving, shipping, and storing samples.

12. Quality control

This section cites the procedures and analyses required to fully document the quality of data generated by the method. The required components of the laboratory's quality assurance (QA) program and specific quality control (QC) analyses are described in this section. For each QC analysis, the complete analytical procedure, the frequency of required analyses, and interpretation of results are specified.

Note: Some test methods may contain specific QC elements and may specify QC acceptance criteria for each of those elements.

13. Calibration and standardization

This section describes the method/instrument calibration and standardization process, and required calibration verification. Corrective actions are described for cases when performance specifications are not met.

14. Procedure

This section describes the sample processing and instrumental analysis steps of the method, and it provides detailed instructions to analysts.

15. Calculations

This section provides instructions for analyzing data, and equations and definitions of constants used to calculate final sample analysis results.

16. Method performance

This section provides method performance criteria for the method, including precision/bias statements regarding detection limits and source and/or limitations of data produced using the method. This section provides the information for the analyst or data reviewer to ensure the method is being performed consistently with a defined and measured performance specification.

17. Pollution prevention

This section describes aspects of the method that minimize or prevent pollution known to be or potentially attributable to the method. Reference may be made to a separate document where this is located, if found in a waste management or other document.

18. Data assessment and acceptance criteria for quality control measures

This section defines the specific quality control acceptance criteria for the method. This may be presented in a table or other format. Describe how the data is assessed, who is responsible, and the documentation required. If the information is referenced in another SOP or document, place the reference here.

19. Corrective actions for out of control data

Describe some possible solutions for correcting the problem to ensure the data is returned to control or the person to contact if the method is out of control. Possible maintenance options to try before running samples may be placed in this section.

20. Contingencies for handling out of control or unacceptable data

Describe how to handle the data when it is not acceptable, such as the process for reporting and qualifying (or flagging) data.

21. Waste management

This section describes minimization and proper disposal of waste and samples. Refer to the document where this is located, if found in a waste management or other document.

22. References

This section lists references for source documents and publications that contain ancillary information. Note: Each SOP should be a free-standing document, providing all information necessary for the method user to perform the method.

23. Any tables, diagrams, flowcharts, and validation data

This section contains all method tables and figures (diagrams and flowcharts), and may contain or reference the location of method validation data.

ADDITIONAL NOTES:

In accordance with the requirement to produce unequivocal, accurate records that document all laboratory activities (1VAC30-45-630, NELAC 2003 5.4.12), changes to SOPs should be documented with a Change Log that accompanies the current version and captures the timeline and content of changes. A sample format is below:

Date:	Revision #:	Summary of Changes:	Submitted By:	Approved By/Date:	Effective Date:

Document No.:

Effective Date:

Revision No.:

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Attachment 5

CORRECTIVE ACTION (CA) FORM

LABORATORY NAME: _____ EPA ID: _____

DEPARTMENT OR ANALYSIS TYPE: _____

EVENT NAME / CATEGORY _____ LOG # _____

Example names / categories: QC failure; PT failure; customer complaint; sample mishandled by lab; instrument malfunction; reporting error, etc. THE LOG NUMBER IS A UNIQUE IDENTIFIER ASSIGNED BY THE LABORATORY.

RESPONSIBLE SUPERVISOR / MANAGER: _____

PERSON COMPLETING CA FORM (NAME, TITLE): _____ DATE: _____

The QA Manager retains all Corrective Action reports in an organized system. The Log # is used to ensure all CAs are uniquely identified. Filing records by Log # is recommended; complete records will account for all Log #s. The Event Name/Category is used to track CAs for trends/patterns.

**RECORD INFORMATION BELOW OR ATTACH ADDITIONAL SHEETS.
PROVIDE DOCUMENTATION WHENEVER POSSIBLE.**

EVENT DESCRIPTION:

Describe the nonconforming event or analysis result. Include details of staff member notified, date and time of notification, customer or outside involvement, analysis data, etc., as applicable. Attach any documentation that supports and/or supplements this description. If PT Failure, attach copy of PT report.

EVENT RESPONSE / INVESTIGATION STEPS:

Indicate the response(s) to the nonconformance, including all processes or raw data reviewed, QA or Management staff notified, analysis repeated, analysis halted, etc.

ROOT CAUSE DETERMINATION:

State the root cause (reason) for the nonconformance with the analysis or process.

CORRECTIVE ACTION (CA) FORM (cont'd)

ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: *Include SOP revision, staff training, purchase of standards or equipment, document/form revision, etc.*

<u>Corrective Action(s)</u>	<u>Contact Person Responsible</u>	<u>Proposed Implementation Date</u>	<u>Date Completed</u>	<u>Evidence Of Completion</u>

Additional Comments/Supplemental Information:

Submitted By:		Date:
Reviewed By:	Responsible Supervisor or Manager	Date:

By signature and comments below, the QA Manager and Laboratory Director or Technical Manager approve this corrective action plan and the proposed implementation date(s) given. The QA Manager or designee will provide follow-up until the corrective action is closed with documentation/evidence of completion as noted above.

Approved By:	Quality Assurance Manager	Date:
Approved By:	Laboratory Director or Technical Manager	Date:

Reviewer Comments or Additional Actions Recommended:

Closing the Corrective Action: The QA Manager is responsible for effectiveness review. The CA should stay OPEN for a sufficient time to ensure all stated actions were taken and address/solve the initial issue.

Corrective Action Closed By QA Manager: Signature: _____ Date: _____