

# **ENVIRONMENTAL LABORATORY QUALITY ASSURANCE MANUAL**

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## Attachments

Standard Operating Procedures (SOP's) and Bench Sheets:

SOP001	E. coli
SOP002	BOD <sub>5</sub>
SOP003	TSS
SOP004	COD
SOP005	Ammonia-N

## 1.0 Quality Policy Statement

This quality manual is intended for the laboratory operations of EMS, Inc. This laboratory provides analysis of environmental samples as required by clients' Virginia Pollutant Discharge Elimination System (VPDES) permits, as well as process control samples and samples required to demonstrate compliance with pretreatment permits. Only samples required by VPDES or pretreatment permits are covered by this quality system.

### Quality Policy Statement

EMS, Inc. laboratory management and personnel are committed to providing the necessary resources and to defining acceptable laboratory procedures in the quality documentation to ensure compliance with the Virginia environmental laboratory certification requirements. The information contained in laboratory quality documentation is communicated to, implemented, and understood by all laboratory personnel.

The quality manual documents laboratory policies and references proper procedures to ensure analytical data generated for submittal to the Virginia Department of Environmental Quality (VA DEQ) is scientifically acceptable as defined by the method performance criteria. The objectives of the EMS, Inc. laboratory are to produce data of known and documented quality in order to demonstrate conformation to clients' permits and laboratory accreditation requirements. The objectives are measured with internal audits and management review. The goal of the EMS, Inc. laboratory is to produce data that is in compliance with clients' permits, pertinent regulations under the Virginia State Water Control Law (9 VAC 25), and the Virginia laboratory certification requirements for commercial laboratories (1 VAC 30-46.)

## 2.0 Organization and Management Structure

EMS, Inc. is owned and managed by Gary L. Johnson and Gary Mychel Johnson.

### 2.1 Organizational Chart

Gary L. Johnson  
Laboratory Manager, Quality Assurance Officer, Laboratory Analyst

Gary Mychel Johnson  
Laboratory Manager, Quality Assurance Officer, Laboratory Analyst

### 2.2 Management Responsibilities

Laboratory 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 laboratory personnel,
- Ensuring the quality of the data produced by the laboratory,
- Training and keeping personnel up to date on laboratory procedures and proper operation of laboratory instrumentation and 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 Analyst is responsible for:

- Performing technical laboratory tests and procedures, including analyzing environmental and PT samples,
- 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,
- Performing quality control checks,
- Thermometer and instrument calibration,
- Instrument and equipment maintenance.

### 2.4 Personnel Qualifications

Laboratory Manager: Documented training or experience in all aspects of laboratory operation.

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

Laboratory Analyst: Documented demonstration of capability for each method performed and the ability to produce acceptable results for PT studies.

## 2.5 Identification of Approved Signatories

The following individuals are authorized to sign laboratory reports:

Gary L. Johnson  
Gary Mychel Johnson

## 3.0 Ethics Policy and Data Integrity

EMS, Inc. has developed an ethics policy and established procedures to train personnel in their ethical and legal responsibilities. All EMS, Inc. laboratory staff members are required to read, understand, and abide by the ethics policy. Laboratory management performs routine data audits to ensure completeness and that they demonstrate proper ethical conduct. Data integrity is protected by the procedures in the quality assurance manual and by the laboratory ethics policy.

### Ethics Policy

It is the policy of EMS, Inc. to promote the highest standard of quality into all services provided by adhering to the following practices:

- EMS, Inc. will only offer environmental analysis for which it can consistently demonstrate compliance with high quality, traceable and legally defensible performance standards.
- EMS, Inc. is committed to complete honesty in the production and reporting of data and will present our services in a confidential and forthright manner.
- EMS, Inc. employees who are aware of misrepresentation of facts regarding analytical data, or the improper manipulation of data, are required to immediately inform the Quality Assurance Officer.
- The Quality Officer will promptly investigate any reports of suspected violations and will respond in a timely manner to all employee concerns regarding data quality and ethical behavior. The Laboratory Manager and Quality Assurance Officer have the authority to resolve all known or potential violations of this policy and will determine if the circumstances warrant client and/or regulatory agency notification.
- Willful disregard or failure to comply with this policy will result in immediate and unconditional termination of employment.

## 4.0 Document Control

The purpose of the document control system is to ensure that only the most recent revisions of SOP's, bench sheets, forms, etc. are available to the appropriate personnel, are timely, and receive the required approvals. All internal regulatory documentation, SOP's, 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. Bench sheets, log books, and forms are designed to include all information pertinent to the analysis or task performed. SOP's and Quality Assurance Manuals reflect their respective effective dates.

## 5.0 Subcontracting of Sample Analysis and Review of New Work

### 5.1 Subcontracting of Sample Analysis

Any subcontracting of work for regulatory reporting shall be subcontracted to laboratories accredited under 1VAC 30-46 for the parameters requested. A chain of custody form is used to track samples from the time they are collected until they arrive at the subcontracted laboratory. This chain of custody form includes the client's facility name, the date and time of collection, preservatives used, and the analysis requested.

### 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. Laboratory 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. If a new test or procedure is required, the laboratory shall develop an appropriate SOP and demonstrate capability to perform the new test or procedure prior to reporting results. The SOP(s) shall be under document control and the demonstration(s) of capability shall be kept on file.

## 6.0 Purchasing

The technical specifications for laboratory equipment and supplies are defined in the laboratory's SOP's. The Laboratory Manager shall verify that all equipment and supplies used meet the requirements of the SOP's and of the appropriate regulatory agencies.

## 7.0 Complaints

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.

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

The Laboratory Manager has the 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 shall be fully documented to 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 is adversely affected, DEQ will be notified in writing. The laboratory's corrective action procedure is used to document any departure affecting data submitted to DEQ.

#### 9.0 Corrective Action

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 actions whenever unacceptable conditions exist or departure 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
- Nonconformance identified during internal reviews or audits
- Nonconformance identified during DCLS on site assessments
- Nonconformance 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 actions may include, but are not limited to, one or all of the following:

- Re-analysis of samples
- Re-calculation of results
- Re-calibration of instrument(s)
- Preparation of new standards
- Re-analysis of blanks
- Dilution of samples
- Additional analyst training
- Replacing equipment or supplies
- Re-sampling
- Recalling analysis results or amended reports

Specific Recommended Corrective Actions:

Contaminated Method Blank (Chemistry)

1. Determine source of contamination
2. Eliminate source of contamination
3. Re-analyze blank
4. Fully document in work sheet or log book

LCS Outside Acceptance Limits (Chemistry)

1. Check preparation bench sheet for errors
2. Check analysis bench sheet for errors
3. Check calculations for errors
4. Remake standard or use a different standard
5. Re-analyze standard and all affected samples
6. Run a matrix spike
7. Fully document in work sheet or log book

Positive/Negative Controls (Microbiology)

1. Check expiration date of media
2. Check media QC documentation
3. Repeat media QC checks
4. Confirm incubator temperatures
5. Use media from a different lot
6. Examine analytical technique
7. Fully document in work sheet or log book

Analyst Not Following the SOP (All Methods)

1. Provide additional training
2. Do demonstration of performance
3. Analyze PT samples

4. Fully document in analyst training file and in work sheet or log book

## 10.0 Records Management

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 regulations. The laboratory maintains the following records:

- Demonstrations of capability
- PT sample evaluations and raw data
- Sample log book, including collection and preservation information
- Bench sheets, including raw data
- Chain of custody forms for subcontracted samples
- Copies of signed laboratory reports
- Laboratory inspection reports
- Internal audit reports
- Corrective action documentation
- QC checks
- Instrument calibrations
- Equipment maintenance records

## 11.0 Internal Quality System Audits

The Quality Assurance Officer arranges for an internal quality system review annually. When possible, the audit is carried out by personnel who are independent of the activity being audited. Audits are conducted by personnel who are trained and experienced in the activity being audited. This review assesses the laboratory's adherence to the quality assurance manual and SOP's. The results of the audit are documented in writing. When audit results cast doubt on the validity or correctness of analytical data, the laboratory will take immediate corrective action, which is fully documented. The Laboratory Manager ensures that the corrective actions are completed in a reasonable amount of time. Any client or regulatory authority whose work was adversely affected shall be notified in writing.

## 12.0 Management Review

The Laboratory Manager reviews the 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 DCLS and DEQ, the results of PT studies, any changes in the volume or type of work undertaken, feedback from authorities or others, and any corrective actions taken. The findings and any corrective actions needed from this review are documented.

## 13.0 Personnel Training

Before conducting any analysis, each analyst receives training by an experienced analyst, who has completed training and a demonstration of capability. An analyst in training is supervised by an experienced analyst. In addition to in-house training, additional training may be provided in the form of educational courses, professional seminars, and continuing proficiency testing.

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

All training is documented and kept on file. Documentation includes, but is not limited to, the name of the analyst, the method/SOP, the dates of training, the person providing training, the initial demonstration of capability, and PT sample results. After successful training, the Laboratory Manager and Quality Assurance Officer sign the analyst's demonstration of capability form as certification of the analyst's performance.

## 14.0 Facilities and Environmental Conditions

Sample analysis occurs only within the laboratory. Laboratory space is maintained and monitored to required specifications. The electronic balance is located away from doorways and ventilation systems.

The laboratory is kept clean and attention is given to good housekeeping practices at all times. The laboratory is designed and activities are conducted so that sample contamination is avoided. The laboratory has adequate bench space, lighting, and ventilation. A reasonably constant temperature is maintained by the building's central heating and cooling system and by separate air conditioners as required.

## 15.0 Test Methods and Validation

### 15.1 List of Analytical Tests Performed

<u>Parameter</u>	<u>Analytical Technique</u>	<u>Reference Method</u>	<u>Method Detection Limit</u>
E. coli	Chromogenic/ Fluorogenic Substrate	19 <sup>th</sup> SM 9223B	1.0 MPN/100ml
TSS	Gravimetric	18 <sup>th</sup> SM 2540D	1.0 mg/L

<u>Parameter</u>	<u>Analytical Technique</u>	<u>Reference Method</u>	<u>Method Detection Limit</u>
BOD <sub>5</sub>	D.O. Electrode/ Oxygen Depletion	18 <sup>th</sup> SM 5210B	2.0 mg/L
COD	Colorimetric	Hach 8000	10 mg/L
Ammonia-N	Ion Selective Electrode	18 <sup>th</sup> SM 4500-NH <sub>3</sub> F	0.10 mg/L

## 15.2 Conducting Demonstrations of Method Performance

Prior to implementation of an analytical method, the laboratory prepares an initial demonstration of method performance in accordance with method specifications. Initial demonstration of method performance must be repeated each time there is a significant change in instrumentation, personnel, or test method. Initial demonstrations of method performance are conducted using the same procedures as initial demonstrations of capability, which are required of each analyst performing testing in the laboratory. For chemistry methods, this process consists of analyzing a known QC sample (from an outside source) in quadruplicate. All four results obtained must be within ten percent of the known value (twenty percent for BOD<sub>5</sub>.) For microbiological methods, this process consists of successfully analyzing a PT sample specific for the method's target organism(s).

## 16.0 Equipment, Reagents, Supplies, and Reference Materials

All equipment, reagents, supplies, and reference materials necessary for analyses are kept on hand for the specific methods used. Calibration procedures are established for all tests and are detailed in the standard operating procedure for the analysis.

### 16.1 Laboratory Equipment

- All equipment is properly maintained. Equipment maintenance procedures are documented in SOP's and equipment manuals.
- Any defective equipment or part is removed from service and labeled until repaired. Equipment or parts are not put back into service until the laboratory demonstrates that it is functioning properly.
- All routine and non-routine maintenance and repairs are documented in laboratory records.
- Calibration records are maintained for all measuring equipment.
- All laboratory support equipment is calibrated or verified, or both, before being put into service, and on a continuing basis.

## 16.2 Laboratory Reagents and Supplies

- Glassware is properly cleaned and maintained as specified in each method's SOP. Any specific cleaning or maintenance requirements specified in the test procedure are followed.
- Analytical reagent grade materials, if available, are used in the laboratory.
- Reagents, standards, and chemicals are not used outside their expiration dates.
- All stock and standard solution containers are labeled with content, preparation date, expiration date, concentration, and the analyst's initials. For the preparation of reagents, standards, stock solutions, and rinsing glassware, the laboratory uses water that has been distilled and passed through a deionization cartridge.

## 16.3 Laboratory 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 traceable to certified reference materials.
- The laboratory retains manufacturer's documentation of traceability, when available.
- The laboratory has a program and procedure for the calibration or re-certification of its reference standards. All thermometers in use (incubator thermometers, pH meters, etc.) are calibrated every six months against the laboratory's NIST thermometer. The laboratory's NIST thermometer is calibrated annually by a qualified metrology laboratory. The laboratory's electronic balance and reference weights are calibrated annually by a qualified technician.
- Method specific calibrations are described in each method's SOP.

## 16.4 Listing of Major Laboratory Equipment

<u>Name</u>	<u>Brand</u>	<u>Model</u>
Laboratory Refrigerator	Kelvinator	MRT1SCSEW0
Quanti-Tray Sealer	Idexx	2X
Ultraviolet Lamp	Spectroline	EA-160
Ultraviolet Viewing Cabinet	Spectroline	CM-10

<u>Name</u>	<u>Brand</u>	<u>Model</u>
Coliform/E. coli Incubator	Fisher	IsoTemp 655D
Vacuum Pump	Gast	1HAB-25-M100X
Laboratory Oven	Quincy Lab	30GC
Electronic Balance	Sartorius	BA110S
BOD Incubator	Fisher	307
Dissolved Oxygen Meter	Hach	HQ40d
LDO Probe	Hach	LBOD101
pH Meter	LaMotte	DHA-3000
COD Reactor	Hach	16500-10
Colorimeter	Hach	DR-850
ISE Meter	Thermo Orion	Four Star
Ammonia Electrode	Thermo Orion	9512HPBNWP
Autoclave	Napco	8000-DSE

### 16.5 Calibration and Maintenance Procedures and Frequency

All calibrations and maintenance performed are documented in the laboratory's equipment maintenance log, bench sheets, or on instrument specific forms.

<u>Name</u>	<u>Activity</u>	<u>Frequency</u>
Electronic Balance	Check Level Check with Ref. Weights Service/Calibration	Before Use Before Use Annually
Reference Weights	Re-certification	Annually
Working Thermometers	Calibrate at Use Temp.	Bi-annually

Reference Thermometer	Calibrate	Annually
pH Meter	Calibrate	Before Use
ISE Meter/Ammonia Electrode	Calibrate	Before Use
D.O. Meter/LDO Probe	Calibrate	Before Use

## 17.0 Samples

Each sample submitted for analysis is identified by a unique sample number, which is assigned at the time of log-in, and is identified on the outside of the sample container. Each sample is recorded in the sample log book.

### 17.1 Sample Acceptance Policy

The laboratory will verify the integrity of all samples submitted for analysis by checking for the following:

- Leakage or breakage
- Completeness of sample collection information
- Correct sample identification
- Use of appropriate sample containers and preservatives
- Adequate sample volume
- Holding time as required by specific test methods
- Temperature requirements

When a sample received does not meet the acceptance requirements, the condition of the sample is documented and the sample is rejected for analysis. Laboratory personnel will notify the client of the sample rejection and ask the client how they wish to proceed. If the client wants to proceed with the analysis, the laboratory will analyze the sample and flag the results on the laboratory report with an explanation of the violation of the laboratory's sample acceptance policy. It is the client's responsibility to ensure that only data meeting all acceptance criteria is reported to DEQ.

All samples are logged into the sample log book, where they are assigned a unique sample number. The following information is recorded for all samples:

- Sample number
- Client's name
- Sample location
- Date and time of receipt at the laboratory
- Person receiving the sample

- Date and time of sample collection
- Sample collector
- Person who delivered the sample to the laboratory
- Analysis requested
- Preservatives used, including sample temperature when required
- Type of sample container(s) used
- Date the final laboratory report is sent to the client

## 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 specific conditions required in the test method or procedure in a manner which protects them from potential sources of contamination, deterioration, or damage.

## 17.3 Sample Disposal

Upon completion of all required analysis and quality control procedures, wastewater samples are disposed in the laboratory drain. Any sample, waste product, or other material determined to be hazardous for disposal in the sanitary sewer will be taken to an appropriate hazardous disposal site. Tests performed which generate hazardous waste as a part of the routine analysis procedure have a specific plan for disposal of such wastes in the test's approved SOP.

## 18.0 Assuring the Quality of Test Results

The laboratory demonstrates the quality of analytical results through the implementation of a quality control plan. This quality control plan includes analysis of blanks, quality control samples, and PT samples.

### 18.1 Quality Control Samples

Quality control samples are analyzed as specified in each SOP.

### 18.2 Proficiency Testing (PT) Samples

The laboratory obtains PT studies from an approved PT provider. PT studies are performed twice per year for the following parameters: E. coli, BOD<sub>5</sub>, COD, TSS, and Ammonia-N. PT samples are analyzed in the same manner as regular samples, using the same test methods, procedures, and QC protocol. If the laboratory fails a PT study, an investigation of the cause is conducted by appropriate laboratory personnel. When problems are identified, a corrective action plan is outlined and actions are completed in a timely manner.

## 19.0 Reporting the Results

The laboratory follows procedures to ensure reported data is complete and free from errors.

### 19.1 Procedures to Ensure Reported Data is Free from Errors

The analyst performing the analysis verifies all data. The data review includes, but is not limited to the following items:

- Calibration of the instrumentation used (Confirm all calibration criteria are met.)
- Quality control data (Confirm QC meets the acceptance criteria.)
- Calculations (Check for calculation errors.)
- Documentation (Check bench sheets, log books, and printouts for accuracy and completeness.)

Before final reporting is done, the data is reviewed by the Laboratory Manager and/or the Quality Assurance Officer to verify that all quality control measures are reviewed and evaluated and to ensure the reported data is free from transcription and calculation errors.

### 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

Once all criteria in sections 19.1 and 19.2 are satisfied, a final laboratory report (certificate of analysis) is issued, approved, and submitted to the client. Reports may be submitted to the client by fax or e-mail if requested; however, the original report is hand delivered or mailed to the client. The responsibility of reporting the results to any regulatory agency, including DEQ, remains with the client.

## 20.0 Glossary

The following definitions are provided by the 2003 NELAC Standard and by 1VAC 30-46-40. These definitions are applicable to the entire quality assurance manual and any supporting documentation, including SOP's, bench sheets, and log books.

"Accreditation" means the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. "Accreditation" is the term used as a substitute for the

term "certification" under this chapter.

"Accrediting authority" means the territorial, state, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

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

"Algae" means simple single-celled, colonial, or multicelled, mostly aquatic plants, containing chlorophyll and lacking roots, stems and leaves that are either suspended in water (phytoplankton) or attached to rocks and other substrates (periphyton).

"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, that 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 accreditation has been requested.

"Authority" means, in the context of a governmental body or local government, an authority created under the provisions of the Virginia Water and Waste Authorities Act, Chapter 51 (§ 15.2-5100 et seq.) of Title 15.2 of the Code of Virginia.

"Benthic macroinvertebrates" means bottom dwelling animals without backbones that live at least part of their life cycles within or upon available substrates within a body of water.

"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.

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

"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 this chapter and the certification program under 1VAC30-45 to be established.

"Establishment of accreditation program" or "established program" means that DGSDCLS has completed the initial accreditation of environmental laboratories covered by this chapter 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 accreditation" means an approach to accrediting laboratories by matrix, technology/method and analyte/analyte group.

"Field of accreditation matrix" means the following when accrediting a laboratory:

1. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.
2. Nonpotable water. Any aqueous sample excluded from the definition of drinking water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.
3. Solid and chemical materials. Includes soils, sediments, sludges, products and byproducts of an industrial process that results in a matrix not previously defined.
4. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin, i.e., by species.
5. 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.

"Field of proficiency testing" means an approach to offer proficiency testing 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 a conclusion reached during an on-site assessment 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.

"Governmental body" means any department, agency, bureau, authority, or district of the United States government, of the government of the Commonwealth of Virginia, or of any local government within the Commonwealth of Virginia.

"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 accreditation period" means the period during which DGS-DCLS is accepting and processing applications for the first time under this chapter as specified in 1VAC30-46-70.

"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.

"Local government" means a municipality (city or town), county, sanitation district, or authority.

"Macrophytes" means any aquatic or terrestrial plant species that can be identified and observed with the eye, unaided by magnification.

"Matrix" means the component or substrate that contains the analyte of interest.

"National accreditation database" means the publicly accessible database listing the accreditation status of all laboratories participating in NELAP.

"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.

"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.

"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.

"Pretreatment requirements" means any requirements arising under Part VII (9VAC25-31-730 et seq.) of 9VAC25-31 including the duty to allow or carry out inspections, entry or monitoring activities; any rules, regulations, or orders issued by the owner of a POTW; or

any reporting requirements imposed by the owner of a POTW or by the regulations of the State Water Control Board. Pretreatment requirements do not include the requirements of a national pretreatment standard.

"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) 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.

"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 technical director.

"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 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.

"Quality system matrix," for purposes of batch and quality control requirements, means the following:

1. Aqueous. Any aqueous sample excluded from the definition of drinking water matrix or saline/estuarine source. Includes surface water, groundwater, effluents, 8 and TCLP or other extracts.
2. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.
3. Saline/estuarine. Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.
4. Non-aqueous liquid. Any organic liquid with less than 15% settleable solids.
5. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
6. Solids. Includes soils, sediments, sludges and other matrices with more than 15% settleable solids.
7. Chemical waste. A product or byproduct of an industrial process that results in a matrix not previously defined.
8. 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.

"Recognition" means the mutual agreement of two or more accrediting authorities to accept each other's findings regarding the ability of environmental laboratories to meet NELAC standards.

"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 governmental 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 laboratory, and the designation is submitted to DGS-DCLS.

"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.

"Standard operating procedure (SOP)" means a written document which 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.

"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).

"Technical director (however named)" 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.

"Technology" means a specific arrangement of analytical instruments, detection systems, or preparation techniques, or any combination of these elements.

"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 (§ 10.62.1-44.2 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.

"U.S. Environmental Protection Agency (U.S. EPA or EPA)" 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.

"Virginia Air Pollution Control Law" means Chapter 13 § 10.1-1300 et seq. 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.

"Zooplankton" means microscopic animals that float freely with voluntary movement in a body of water.

## Signature Page

Gary L. Johnson  
Laboratory Manager  
Quality Assurance Officer

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Signature

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Initials

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Date

Gary Mychel Johnson  
Laboratory Manager  
Quality Assurance Officer

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Signature

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Initials

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Date