Public Health and Environmental Laboratories 3 Schwarzkopf Drive, Ewing, NJ 08628 POLICIES AND PROCEDURES				
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CHAPTER ONE
DATA QUALITY POLICIES, OBJECTIVES AND DEFINITIONS

1.1 MANAGEMENT POLICY

The policy of the Environmental and Chemical Laboratory Services (ECLS) is to generate environmental laboratory data of known and documented quality and to maintain the quality systems necessary to generate this data. This is accomplished through two separate actions. The first is the verification that management and the analysts are free from any undue influences that could possibly affect the objectivity of their actions. This is documented by the completion of the employee Attestation Form, **Appendix 15**. The second is by adopting and implementing the standards and quality systems, as delineated in this manual, as the operating procedures for ECLS. Management and the Quality Assurance Officer (QAO) have developed the requisite standards and quality systems and have communicated these systems to the analysts. This is documented by the employee's acknowledgement that s/he has received this version of the Quality Manual (QM), **Appendix 5.** Management has also provided the analysts with all the tools necessary to successfully fulfill the requirements contained in this document.

Furthermore, ECLS will maintain the appropriate certifications and/or accreditations necessary to demonstrate compliance with all the rules and regulations applicable to the types of analytical analyses being conducted. These certifications and/or accreditations are prominently displayed in the lobby of the Public Health, Environmental and Agricultural (PHEAL) building, with a binder at the Security desk with lists of analytes and certified methods.

1.2 DATA QUALITY OBJECTIVES

The objective of this manual is to define the quality systems and standard operating procedures that are employed in the generation of environmental laboratory data. This manual establishes the minimum quality standards that the resultant data must meet. Through the establishment of the quality systems and operating procedures, it is ECLS's goal to produce data that are accurate and precise, as well as comparable to data generated by other nationally accredited laboratories. ECLS ensures the quality of all reported data through the strict adherence to the policies and procedures contained in this manual.

The laboratory's procedures and Quality Assurance (QA)/Quality Control (QC) practices listed in the subsequent chapters are based on NJ Department of Environmental Protection (DEP)and US Environmental Protection Agency (EPA) standards.

The implementation and management of all the quality systems and procedures contained in this manual are the responsibility of the QAO. To that end, the QAO performs proactive and preventive actions such as conducting internal system and performance audits; participating in regularly scheduled management staff meetings or conducting QAO staff meetings (see section 2.5) to explain the QA/QC requirements to the analysts; by providing senior management with written reports, as needed, on the status of the QA Program.

Since the quality of the data reported by ECLS is only as good as the samples provided to ECLS, copies of this manual are made available to the clients providing samples to ECLS so that they are fully aware of ECLS's current policies regarding the collection, submission, acceptance, and rejection of samples.

ECLS Management is committed to making whatever changes are necessary to the quality systems to maintain the quality of the data generated and provide sufficient documentation in support of those data. There will be a yearly review of the QM. There may be a separate meeting with the QAO to discuss the current state of the QA Program; or it will be discussed at a monthly QA/QC meeting. The agenda of the meeting will be to review QA activities, to discuss issues affecting the QA Program, and to resolve potential problems in the QA Program. The QAO will present to management proposed changes that are necessary to keep ECLS certification status current with DEP and EPA protocols along with explanations of why they are necessary and how to implement those changes. Pertinent outcomes of the meeting will be included in the next revised SOP.

The minutes of all meetings will be documented and posted on the shared Q drive.

1.3 QUALITY ASSURANCE PROJECT PLAN

ECLS strives to meet any additional data quality requirements that our clients may want associated with a specific set of samples. The client informs ECLS of the changes from the ECLS routine data quality practices that they want to institute, prior to the submittal of samples. In those instances, the specifics may be detailed in a Quality Assurance Project Plan (QAPP) and conveyed to the analysts.

If a client desires ECLS to perform analytical work that is outside ECLS's normal analytical capabilities, a QAPP must be prepared prior to initiating sampling, with the following information:

1) Type of samples being submitted e.g., potable water, waste-water, etc.
2) The suggested method to be used along with an acknowledgement as to the deficiencies/shortcomings of the method. If the client has a specific analytical method in mind, it should be made available to ECLS to shorten the time needed by ECLS to validate the method.
3) Requested Reporting Level values.
4) Maximum Contaminant (MCL) or other action levels. If the MCL is too close to the achievable MDL, the method may be inappropriate for the expressed purpose.
5) Intended data usage to determine the level of QC that is necessary for the analyses.
6) Types of QC required.
7) Whether Chain of Custody is requested.
8) Turnaround time.
9) Sampling frequency.
10) Date of sampling event initiation.
11) Extent of the event.
12) Sampling dates if scheduled.
13) Projected number of samples.
14) Data reporting format.
15) Listing of any other ECLS and/or submitting agency requirements.
16) Agency submitting QAPP.
17) Contact person.
18) Billing information.
19) Sign off by the contact person the ECLS Laboratory Manager or their designee and the QAO.
20) The QAO will maintain a copy and post copies of all QAPPs to the Q drive.

The most common information referred to the analysts pertains to sample scheduling and the preparation specifics of the various projects. Informing the analysts of sampling schedules allows for the sampling events and to determine if those events would overwhelm the analytical capacity of the laboratory.

Informing the analysts of project requirements makes them aware of any additional information may need to know.

1.4 PROCEDURE

1. When ECLS Management has been informed of the specifics of a planned project or has signed off on a QAPP the information is forwarded by the ECLS Director or their designee, to the ECLS Program Managers for them to inform their staff.
2. This notification consists of a copy of the QAPP, a copy of the correspondence describing the project, or a summary of the project specifics. If a project is already underway, then a re-construction of the project specifics must be prepared and distributed.
3. The analysts keep this information for subsequent referrals.
4. When Sample Receiving reviews the collector's paperwork during the sample acceptance process, they must make sure that when samples are submitted under a defined project, that the project name is specified on the submittal forms. All requested analyses must be documented on each of the sample submittal forms and in accordance with the procedures described in the ECLS sample receiving sop.
5. Sample Receiving must then inform the analysts that samples have been received under a specific project. This notification can be accomplished by posting the information in Sample Receiving, emailing the analytical supervisors, verbally informing the affected analysts, and/or clearly defining certain batch numbers as specific to a project.

The majority of ECLS clients do not require any additional QC information beyond that which is routinely generated by ECLS. In the absence of any notification to the contrary, ECLS will perform its routine QC practices on all the samples submitted.

CHAPTER TWO
LABORATORY ORGANIZATION AND MANAGEMENT

2.1. PLACEMENT OF THE ENVIRONMENTAL AND CHEMICAL LABORATORY SERVICES WITHIN THE NEW JERSEY DEPARTMENT OF HEALTH

NJDOH is the parent organization in which ECLS operates. ECLS is a Service Area located within PHEL, a part of the NJDOH Division of Public Health Infrastructure, Laboratories and Emergency Preparedness (PHILEP). The ECLS Service Director reports directly to the PHEL Director. See **Appendix 2.**

ECLS is autonomous in its day to day operation as a laboratory in that it follows its own protocols, policies, and standard procedures without any interference from senior DOH management. ECLS performs the types of testing that it is certified to perform, using the requisite analytical methodologies, and reporting its results according to established protocols without any attempted interference from senior management. That is, senior management does not try to force ECLS to use non-approved methods, lessen QC testing, or in any way subvert the policies and procedures contained in this manual. Due to public health concerns, certain samples may receive emergency analysis at the temporary expense of routinely submitted samples; however, all analyses, data validation, and data reporting activities are still performed according to established standard procedures contained in this manual.

NOTE: Some titles listed below are not the official NJ Civil Service Commission (CSC) position titles. These titles have been adopted / modified from the DEP/EPA guidelines and are used to indicate job function. There are several CSC position titles that are qualified to fill these titles listed below. See the New Jersey CSC website for job titles and specifications for positions listed on the Table of Organization.

2.2.1 ORGANIZATIONAL AND MANAGEMENT STRUCTURE OF ENVIRONMENTAL and CHEMICAL LABORATORY SERVICES (ECLS)

There is a PHEL Director who reports to the Assistant Commissioner for PHILEP. The PHEL Director has four Service areas, each headed by a Service Director. These Service Directors also function as a substitute PHEL Director when the Director is away.

ECLS is divided into five programs each headed by a Program Manager who reports directly to the ECLS Service Director. These Program Managers also function as the substitute Service Director when the ECLS Director is away from the laboratory. These assignments are made on a rotating basis. The ECLS Director informs the Program Managers, designates who is in charge during their absence, and the managers inform the staff. There is also a Quality Assurance Officer from the PHEL Policy Planning and Regulatory Compliance (PPRC), who works closely with the ECLS Director, but reports directly to PPRC Service Director. See **Appendix 3**. The ECLS programs are listed below.

CHEMICAL TERRORISM, BIOMONITORING, MEDICINAL MARIJUANA, and FOOD SAFETY (CT): This program is primarily responsible for the shipment and analysis of clinical specimens following the Laboratory Response Network (LRN) provided protocols from the CDC. This Program can detect exposure to a limited number of toxic chemicals, such as cyanide or toxic metals, in human specimens such as blood or urine.
The CT program also analyzes medical marijuana, food and environmental samples potentially associated with acts of terrorism, and Biomonitoring analyses which are the ability to test for environmental

contaminants to which NJ residents could potentially be exposed. CT has its own QM and therefore, CT operations are not detailed in this QM.

DATA MANAGEMENT: This program is responsible for the preparation and collation of final sample reports, and the implementation and maintenance of the Laboratory Information Management System (LIMS).

INORGANIC TESTING: This program is subdivided into three sections: General Analytical Chemistry Testing, Automated Chemistry and Nutrient Analyses, and Metals Laboratory. The General Analytical Chemistry Section performs the traditional "wet" chemical analyses using techniques such as gravimetry, titrimetry, and colorimetry. The Automated Chemistry and Nutrient Analyses Section performs more sophisticated automated techniques such as continuous flow analysis, Ultraviolet and Visible spectroscopy (UV/VIS), and ion chromatography (IS). The Metals Laboratory analyzes aqueous and other sample matrices for the presence of trace metals by cold vapor and graphite furnace atomic absorption spectroscopy, inductively coupled plasma optical emission spectroscopy (ICP-OES), fluorescence spectroscopy and inductively coupled plasma-mass spectrometry (ICP/MS).

This program is also responsible for the shipment and analysis of clinical specimens (urine and blood), medicinal marijuana and foods. These analyses are covered in the CT Quality Manual and therefore are not detailed in this QM.

SAMPLE MANAGEMENT and ORGANIC TESTING: This program is subdivided into four sections: Sample Receiving, Gas Chromatography/Mass Spectrometry (GC/MS), Gas Chromatography (GC) and High-Performance Liquid Chromatography (HPLC), and Sample Preparation. Sample Receiving is responsible for the receipt, logging in and sample custody of samples submitted to ECLS. The GC and HPLC section analyze environmental and other samples for toxic organic contaminants. The Sample Preparation section is responsible for carrying out the various sample preparation and clean-up protocols necessary to make samples ready for GC/MS, GC, or HPLC techniques.

RADIOANALYTICAL SERVICES: This program is subdivided into two sections: Sample Preparation and Instrumental Analysis. The Sample Preparation Section utilizes US EPA approved and other nationally recognized procedures for the preparation of water samples for analysis. The Instrumental Analysis section selects the appropriate instrumentation to measure the requested type of radiological activity in the sample.

The Radioanalytical Services program has its own QM and therefore, Radiochemical operations are not detailed in this QM.

SANITARY BACTERIOLOGY SECTION: This section is subdivided into two programs: water testing and dairy testing.

Sanitary Bacteriology has its own QM and therefore, its operation is not detailed in this QM. Sanitary Bacteriology is a unit under the Public Health Laboratory Services Microbiology Program.

OFFICE OF QUALITY ASSURANCE (OQA): OQA is responsible for implementing, reviewing and maintaining all procedures, protocols and policies contained in this Quality Assurance Manual. OQA is also responsible for providing sufficient documentation to verify that these activities have been successfully completed. OQA reviews data packages for accuracy and completeness prior to those packages being forwarded to the sample submitters. The QAO: serves as the focal point for QA/QC oversight and review; functions

independently from laboratory operations for which s/he has QA oversight; evaluates data objectively; and has general knowledge of the analytical test methods for which data review is performed. The QAO, working with the ECLS Service Director, will notify its certification authorities (EPA Region 2 and NJDEP) regarding changes in management, supervisory, and technical changes in personnel within 30 days of the change.

2.3 RELATIONSHIP BETWEEN MANAGEMENT, TECHNICAL OPERATIONS, SUPPORT SYSTEMS AND QUALITY SYSTEMS

The ECLS management consists of the PHEL Director, ECLS Service Director, the various ECLS Program Managers, and the Quality Assurance Officer. All laboratory personnel must comply with all the QA/QC procedures contained in this manual. All professional and technical staff are full time employees of ECLS or contracted with PHEL through Rutgers or the Department's staffing agency.

Selective individual responsibilities of the laboratory staff are listed below. This includes, and is not limited to:

- Determining the operational priorities of ECLS.
- Deciding how resources will be allocated.
- Having the final say on all personnel decisions such as hiring, firing, and promotions.
- Providing fiscal and administrative support such as maintaining a purchasing program to facilitate the acquisition of supplies and equipment and maintaining a central service program that assists in the cleaning and maintenance of laboratory glassware.
- Providing and maintaining adequate facilities for proper laboratory operation.

The PHEL Director is the final authority on ECLS policy and operations. Although the PHEL Director sets the ECLS priorities, s/he may not be directly involved in all day-to-day operations of ECLS.

The ECLS Service Director is a position that is under the direction of the PHEL Director. S/He is responsible for the day-to-day operation of ECLS, including and not limited to:

- Providing the analytical methods and SOPs for the analysts to employ to generate accurate and reliable results.
- Adhering to the educational and experience requirements for each type of employee working in ECLS formulated by the State of New Jersey's Civil Service Commission (CSC).
- Providing adequate training to all employees to allow them to successfully complete their assigned duties.
- Delegating the Program Manager's responsibilities to qualified analysts, where appropriate.
- Assuming ultimate responsibility for the accuracy and reliability of the results that are reported.
- If absent for a period exceeding fifteen (15) consecutive calendar days shall designate another full-time staff member meeting the qualifications of the program manager to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing.

Quality Assurance Officer (QAO) is a person meeting all the requirements as stated in the NJDEP environmental laboratory personnel regulations. The QAO responsibilities include, but are not limited to:

- Maintaining, revising, and implementing as appropriate the quality systems contained in this Quality Manual.

- Developing and implementing the requisite documentation protocols necessary to verify that all the procedures contained in this manual are, in fact, being adhered to.
- Performing the requisite number of system and performance audits called for in the documentation protocols.
- Providing reports to management detailing the functioning of the quality systems.
- Serving as focal point for all QA/QC activities.
- Having responsibility for the oversight and/or review of QC data.

A more detailed account of the QAO responsibilities and practices are contained throughout the QM and in Chapter 10. The QAO reports directly to the PPRC Service Director.

- The ECLS Program Managers oversee the five ECLS programs mentioned above who meet all the requirements contained in the CSC job listings. The responsibilities for these program managers include, but are not limited to:
- Providing day-to-day supervision and technical guidance to the analysts in their analytical section.
- Reviewing selected analytical QC data to verify that they meet all the specifications of this manual, they have been interpreted correctly by the analysts, and that they are complete.
- Reviewing selected raw data for correctness.
- Performing the secondary data validation of the LIMS data, when necessary.
- Troubleshooting analytical problems.
- Bringing QC problems to the attention of the QAO.
- Certifying the analyst's capability to perform the requisite analyses.
- Performing analyses, when required.
- Monitoring standards of performance in QC and QA
- The ECLS Director and Quality Assurance must be informed of any changes to the program's: personnel, instrumentation, equipment, methods, and matrices

The program managers report directly to the Service Director of ECLS who reports to the laboratory director of PHEL.

Analysts are staff who meet the requirements contained in the CSC job listings for the professional titles of Research Scientist series, Chemist series and Laboratory Technician series or their equivalents in any contract agency. The responsibilities of the analysts include, but are not limited to:

- Conducting analyses using only approved methodologies as they are written.
- Reviewing the generated QC data of the analytical run to determine the validity of the sample data.
- Verifying that they analyze the proper samples for the analytes requested.
- Reporting data through their Program Manager.
- Maintaining their instruments in proper working condition and documenting those activities.
- Demonstrating, on a continuous basis, their capability to perform their assigned analytical tests.
- Identifying and reporting any QA/QC issue.

Analysts report directly to their respective program managers or their designees.

2.4 PROPER TRAINING AND EDUCATION

It is the responsibility of the ECLS Service Director to verify that the analysts within their respective titles meet the education and experience requirements of those titles and to provide analysts with the training

necessary to fulfill the requirements of their assigned duties. A personnel file is maintained in the QAO's office that contains the following information:

- A copy of their resumes to document the years and type of experience that they have accumulated. Resumes must be updated for each change in title and/or duties.
- A copy of the certificate or summary of training/continuing education classes taken either on- or off-site. These may include: computer classes, vendor training on operating an instrument, management classes, continuing education sessions, seminars, conferences, and the like.
- A copy of signed Analyst Receipt of Method for new hires or staff assigned to a new method. See **Appendix 4.**
- A copy of the Receipt and agreement that they have read and understood the ECLS Quality Manual. See **Appendix 5**. Appendix 5 is completed annually and on an as needed basis for new hires and changes in duties.
- A copy of the Demonstration(s) of Capability (DOC) Analyst Certification Statement. See **Appendix 6.** A DOC is performed prior to the initial use of new analytical procedures and after every significant change to instrument type, personnel, matrix or test method and/or yearly thereafter. If an analyst originally failed a DOC, the additional training given to the analyst to correct their shortcomings is documented and included in their personnel file.
- A copy of the DOC Summary Report. See **Appendix 7.**
- A copy of ECLS Training Document, with backup documentation. See **Appendix 8.**

Analysts are to maintain a copy of all the information forwarded to the QAO.

It is the responsibility of the supervisor and Program Manager to have training documents prepared and ready for issue to any new employee or newly assigned employee on their start date. The training documents are to include: General PHEL orientations, the location or copies of SOPs, reference method SOP, what the method training will encompass, the time frame of the method training, the expectations of the employee in learning the SOP, , documentation of that performance with a written test/quiz, proficiency or blind samples, standard curves and calibrations interpretation, and attestation to having achieved competency. See **Appendix 8** – ECLS Training Documents.

2.5 DATA INTEGRITY POLICY

The Data Integrity (DI) System adopted by ECLS consists of a four-step approach: DI training; signed DI documentation; periodic monitoring of DI activities; and defining the DI procedures that are followed.

DI Training is conducted annually and includes but is not limited to:

- Discussion of the organizational mission and the critical need for honesty.
- Discussion of the DI procedures.
- Discussion of DI record keeping.
- Discussion of how to report DI issues.
- Discussion of the emphasis on the importance of proper narration, on the part of the analysts, to explain circumstances that could impact the quality of the data.

DI Training Documentation: Attendees sign an attendance sheet indicating that they have taken the DI training and if they have any subsequent questions regarding the DI system, they are to inform the QAO in writing, through their Program Manager within 30 days of attending the DI training. The response will be

submitted back to the person raising the question as well as all the section Program Manager and supervisor. See **Appendix 9**.

Periodic DI Monitoring: DI monitoring is conducted as an integral part of the internal system audits. DI is contained in the total of all QA/QC activities in this manual. Everyone who is following all these items will comply with the DI program outlined below.

DI PROCEDURES:
It is the responsibility of every ECLS employee to follow the DI policy discussed above. The intent of the DI policy can be summarized as follows:

- No one shall knowingly circumvent the required procedures contained in their Method Manuals.
- No one shall knowingly circumvent the policies and procedures contained in the Quality Manual.
- No one shall knowingly refuse to adhere to other policies and procedures as they become available and are explained to the employees.
- No one shall knowingly falsify any records that must be generated during the performance of their assigned duties, such as: analytical raw data, final data, reports, etc.
- No one shall knowingly discuss the business of ECLS with persons who do not have a legitimate need to know (e.g. print or media reporters, the public at large, other agencies of State Government, etc.). When receiving a request to discuss ECLS business, employees are required to say nothing until they have had an opportunity to ascertain, by discussing the situation with their Program Managers, Service Director, or QAO whether this request is being made by a party with a legitimate right to know. In some cases, it may be necessary to refer the request to the Commissioner's Office for final resolution. NOTE: ECLS frequently receives requests from the various programs within NJ DEP for interim verbal reports for results on samples that they submitted. The employees can respond to these requests without going through upper management provided that the employee categorically knows to whom they are speaking and that they do in fact work for the program that originally submitted the samples. If there is any question in the employee's mind, proceed as listed above.
- No one shall knowingly provide false information on any document that they are required to prepare.

An employee found to be in violation of the DI policy shall be subject to appropriate disciplinary or counseling actions. These actions are contained in the NJDOH Corrective and Disciplinary Action Handbook. Any action undertaken will comply with the existing CSC rules and regulations in force at the time of the violation. Documenting that the employee understands their DI responsibilities is made by using **Appendix 10**.

Appendices 10, 11, 12, and 15 are signed by the analysts at the end of the DI training session.

Any employee may bring to the attention of the PPRC Service Director and or the QAO any matter pertaining to data integrity or issue of ethical concern. These issues and concerns are kept confidential to the extent of DOH policy and federal/state laws allow. All issues/concerns are investigated and reported. Refer to SOP *Confidential Reporting.*

2.6 LEGAL POLICY

Due to the nature of the analytical work that is performed within ECLS, ECLS data can be used in court proceedings. As such actions take place, law firms forward subpoenas and/or requests to ECLS to make available certain information and/or records. Whenever an employee receives such a request for

information and records, s/he is to immediately notify the Program Manager and the QAO. The QAO will proceed as follows:

1.) Send the subpoena for records to PHEL's Record Custodian who will in turn provide a copy to the Department's Legal and Regulatory Compliance Division and receive authorization from Legal to provide the records.
2.) Notify any other requestor of records to go through the State's Open Public Records (OPRA) process.
3.) At the request of the PHEL Records Custodian, work with the Program Managers to obtain the requested records.
4.) The Records Custodian completes the history, timeline, and records request OPRA database information and either provides the records or declines the request.

If anyone is found to have knowingly circumvented this policy, disciplinary action like that discussed above in the DI Policy will be undertaken. **See Appendix 11**.

2.7 CONFIDENTIALITY POLICY

Confidentiality policy addresses the proprietary nature of certain products and their formulations. ECLS does not generally receive samples with such proprietary considerations; however, the possibility does exist. At the time of sample submittal, ECLS must be provided written notification detailing the exact proprietary nature of the sample; ECLS will not release that information with the reported data. Legal considerations may supersede this policy.

The routine application of the confidentiality policy within ECLS takes the form of assuring that analytical results are reported only to those agencies that submitted the sample. This data reporting, as well as the disciplinary action, is addressed in the DI Policy. See **Appendix 12**.

2.8 COMPLAINTS/OBSERVATIONS

A complaint is an official expression of dissatisfaction, by a client, with the way ECLS has conducted itself while providing analytical services to that client. The dissatisfaction may stem from the analytical results, the way they were reported, the QC results associated with the client's results, the timeliness in receiving the report, or anything else that causes, in the opinion of the client, dissatisfaction. In effect, a complaint is a serious accusation against the credibility of ECLS. Whenever anyone receives a complaint, whether it is through the mail, over the phone, or in person, the complaint is forwarded to the QAO for resolution. The analyst is not to respond to the complaint. S/he should mention that the issue is being referred to the ECLS QAO for resolution. The QAO will follow the steps outlined in the PHEL SOP Complaint Procedure effective 01/03/18, **Appendix 13**.

2.9 ATTESTATION STATEMENT

Each ECLS employee must sign an attestation statement indicating that they are free from any commercial, financial, or other undue pressures that could interfere with the quality of their work. See **Appendix 15**. It is impossible to list all the different types of interference that could affect a person's ability to do quality work. However, the type of "potential conflicts" that we are looking to avoid are those where somebody, that the analyst knows, would unduly benefit from a specific type of laboratory result and the analyst is able to generate that result, or influence some other analyst to generate that result. **Appendix 15** will be maintained in the analyst's personnel file in the QAO's office.

It is certainly understandable that an analyst could sign this statement when they clearly were not experiencing any undue pressures of any kind. However, at some later date the situation could change. It shall be understood that the intent of this attestation is that whenever a situation as described above is encountered; it must be brought to the attention of management immediately. Failure to do so will be considered a violation of the Data Integrity Policy and will be handled accordingly.

2.10 POLICY VIOLATION

If it is determined that an employee deliberately violates any of these policies, disciplinary action like that discussed in section 2.5 will be undertaken. Because of the policy violation, OQA will determine whether client data has been adversely affected and what steps are necessary to rectify the situation.

2.11 LIST OF EMPLOYEES

Appendix 16 contains the names of all ECLS employees that contribute to the generation or review of analytical results. This list also serves as the means of relating a set of initials to an employee. It is still necessary for analysts to enter their initials and signatures in work records.

Any changes in staff, from supervisory and above, must be reported to EPA Region 2 and the New Jersey Department of Environmental Protection (NJDEP) office of Quality Assurance (OQA), in writing, within 30 days of its occurrence. Credentials and resumes will be sent upon request.

Refer to **Appendix 1** for the definitions of all terms used within this Quality Manual.

CHAPTER THREE
PHYSICAL FACILITIES

3.1 FACILITY OPERATIONS

The Public Health and Environmental Laboratories' Environmental and Chemical Laboratory Service (ECLS) is located on the State Police Complex in Ewing Township. The physical address of the Public Health Environmental and Agricultural Laboratory (PHEAL) is 3 Schwarzkopf Drive, West Trenton, NJ 08628. ECLS' normal hours of operation are from 7:30 am to 5:30 pm, Monday through Friday. These hours may be extended if prior arrangements are made through ECLS Management.

ECLS is utilized as the NJ Department of Environmental Protection's Principal Drinking Water Laboratory for the enforcement of State and Federal regulations. Therefore, the data generated must be demonstrably valid and capable of withstanding court challenges. ECLS has expanded its test capabilities to analyze blood and urine samples for metabolites, chemical agents, and trace metals that may be indicators of a chemical terrorism event or an exposure to an environmental contaminant. ECLS does not store or utilize any chemical warfare agents or other unique chemical materials that would pose a special health risk to laboratory staff or would be of unique interest to a terrorist.

3.2 SECURITY STRATEGY

I. **Purpose:** To inform all employees of the security provisions and requirements incorporated at PHEAL. The PHEAL is a consolidated State testing facility. The work conducted here includes State Public Health, Environmental and Agricultural testing services.
In addition, the BioThreat Response Laboratory, BTRL is in this facility. This laboratory Program handle select agents which are regulated by CDC/USDA. These agents have the potential to cause illness and even death when used inappropriately. This policy will address the facility security issues that must be in place to use these agents in addition to addressing the general access issues to ensure all work conducted at this facility is protected and secure.

II. **Policy*:*** Security of/for/at the PHEAL must be exercised by all employees, occupants, or visitors of the facility. Security Officer(s) will be present at this facility on a 24/7 basis and may be expected to require verification of your identification at any time.

a. Upon completion of the PHEAL Access Card/Employee ID Request form, all employees, new-hires, consultants and other individuals as deemed applicable, will be issued a separate access/photo ID card for the PHEAL indicating their level of operations.
b. ***Occupancy*** – All employees, consultants, and visitors will access the PHEAL through the doors located at the front of the building and must utilize the turnstiles for passage beyond the security desk.
c. Photographing the facility is prohibited, unless otherwise provided by the Employer for business reasons. Employees discovered taking pictures without permission may be subject to discipline.
d. Vendors needing access to the PHEAL laboratory areas to repair equipment must be accompanied by an authorized PHEAL employee for the duration of his/her repair visit.
e. ***Campus Access*** – Employees may access the campus via the State Police Drive or Cozy Road entrance and proceed to the employee parking lot.

f. All non-employees of the PHEAL must access the campus via the State Police Drive and present their identification for inspection as required. All visitors accessing the State Police campus must have a SP-306 form e-mailed to two State Police email addresses: C430_RJH@gw.NJSP.org and hqsecurity@gw.njsp.org and to the PHEAL Security Guards at pheal.guards@doh.nj.gov . The form is to be completed by the visitor's point of contact (NJDOH employee) and sent no later than 5:00 PM the day before the visit. Note: the form must be filled out in alphabetical order when providing more than one name.

g. All delivery personnel will be required to follow signs to the delivery entrance and present their identification at the swing gate via the camera to the PHEAL building security staff. Upon acceptance, Security will lift the gate for access. The driver will proceed to the correct loading dock (Agriculture or Health), call the applicable laboratory, show his/her identification via the camera and enter the proper accessioning area.

h. ***Parking*** – Upon completion of PHEAL Parking Request form, employees will receive access to the campus gates through their ID card.
   i. Reserved parking is limited.
   ii. There is no permanent parking behind the building. Service contractors who require a service vehicle to perform their duties may park vehicles in designated areas behind the building. Employees may park temporarily (approximately 30 minutes) at the AHRF, Greenhouse, supply sheds, loading docks, etc., to drop off product or supplies.
   iii. All employees will be expected to park in front of the building in the spaces provided by PHEAL Management.

III. **Procedures:**

a. Criminal Background Reviews:
   i. Cost of the fingerprint check will be borne by the PHEAL agency(ies) however, all other associated costs such as travel, tolls, etc., must be borne by the candidate for employment or employee.
   ii. The results of the review by the New Jersey State Police will be forwarded to the Criminal Background Investigation Unit (CBI) and such information will be forwarded to the PHEAL Administration. This information is considered highly confidential and will not be faxed.
   iii. If a criminal history is revealed which places the PHEAL in a vulnerable position (conviction of a crime of the first, second, third degree and selected crimes of the fourth degree), the candidate for employment or employee will be so advised and given an opportunity to review, refute, and/or clarify the information obtained before any final determination regarding their PHEAL employment status is issued.
   iv. All questionable results and candidate or employee appeals will be forwarded to the respective departments' Human Resource division for review and final determination.
   v. An individual may address Human Resource orally or in writing, at the individual's discretion.
   vi. Human Resource's determination is considered final in the matter and will be conveyed to the affected individual via the PHEAL Administration.
   vii. All individuals' records indicating no convictions will be shredded upon notification to the appropriate parties.
   viii. Individual's records indicating a relevant criminal conviction will be forwarded to Human Resource. Unless the claim is subject to litigation (Administrative, Civil, Criminal), the information will be shredded after two years. This information will NOT be transmitted to another employer (even if State Agency) or prospective employer.

ix. Individuals who do not wish to comply with the required criminal background review will not be considered for employment, or if already employed, will be subject to appropriate administrative action.

x. Confidentiality: The information received regarding an individual's criminal arrest/convictions is considered highly confidential. The improper dissemination of such information may cause severe repercussions and/or may be addressed via administrative measures levied against the responsible party.

b. Visitor Policy

i. This policy describes the requirements that must be followed that will allow visitors and other non-employees (VNE) access to PHEAL. The requirements outlined are designed to protect VNEs from injury or incident while ensuring the facility is not exposed to potential liabilities and breaches of security arising out of their access.

c. Responsibilities

i. Safety Office is responsible for the development and periodic revision of this policy.

ii. Senior leadership is responsible for providing input on the development of this policy and ensuring it is supported and enforced across the organization. Directors and managers are responsible for ensuring the use of this policy within their groups. Supervisors and their staff are responsible for the implementation and compliance of this policy. Employees who are coordinating the access and escort of VNEs are responsible for reading and following the requirements documented herein.

iii. At PHEAL, Security is responsible for checking the identification of all VNE's, signing them in, providing those with a temporary photo ID. All employees, consultants, and visitors are required to use their ID cards to gain entrance into the building. Employees, consultants, vendors or visitors attempting to gain access to non-authorized areas will be addressed via proper administrative or legal responses.

iv. Operating area escorts are responsible for ensuring all VNE's comply with the safety and operating area requirements always.

v. Categories of VNE include but not limited to, graduate students, consultants, vendors, clients and sponsors, contractors, regulatory inspectors, consultants/subject matter experts (SME), visiting scientists/collaborators, visiting grammar, high school, or college students, and job candidates.

vi. In general, facility access for individuals under the age of 18 years is limited to the lobby of any PHEAL facility. Children should not be left unattended in any PHEAL lobby or non-work area. Security personnel will not be responsible for watching children. Tours may be permitted for students and children under 18 years of age that have been pre-approved by the appropriate senior leadership and safety office. Tour groups will be prohibited from entering any high-hazard area. This will include any chemical or biological laboratory where work is being conducted. Tour groups are permitted at PHEAL facilities with prior approval.

d. Procedures to be followed

i. Operating area escorts are responsible for identifying which areas of the facility the VNE will need to access.

ii. Upon arrival, the VNE will register with security and will receive a temporary photo ID. All VNEs must sign in with the guards daily if they are here.

iii. All personal protective equipment (PPE) will be provided to the VNE by the employee coordinating the visit prior to entering laboratory areas.

iv. For VNE's requiring access to the facility's BSL-3 for our Biothreat Response Laboratory, please refer to the separate Select Agent protocols for Biosafety and Biosecurity.

v. Service contractors hired by Facilities may be allowed to do work unsupervised for periods of time if they are not working in a functioning laboratory or other high hazard area.

vi. VNEs are prohibited from carrying cameras or portable electronic devices into any BSL-2 or 3 laboratory or high security area of our facilities without the express permission of senior leadership.

vii. VNE's are prohibited from entering the PHEAL facility after hours without the approval of senior leadership responsible for that area.

e. Training

If the VNE will be working in a functioning laboratory, or other high hazard area; training on area-specific hazards (physical, chemical, and biological) must be provided by the supervisor or designee. This would include identifying hazardous chemicals, biological agents, radiation, confined spaces, electrical hazards, etc., that the VNE may encounter. In addition to this information the VNE must be instructed on actions to take in an emergency, and the location of emergency eye washes, showers and exits. Safety office should be contacted to assist with this training

3.3 LABORATORY ENVIRONMENT

a. Lighting: The lighting system in PHEAL is a state-of-the art automatic occupancy detection system.

b. Ventilation: The contracted facilities maintenance vendor conducts routine maintenance on all the PHEAL HVAC system equipment, monthly, quarterly, and semi-annually. All this equipment is monitored by the building automation system which alarms if problems detected. There is an annual recertification of the BSL-3 laboratory space which includes measurement and testing of airflow in the high containment laboratory space, as well as testing the supply and exhaust fans under different failure scenarios (including complete power failure). In the event of any unplanned power outages, a series of checks are performed to ensure that the HVAC system returns to normal operation.

c. Temperature and Humidity: Temperature is controlled by the facility's automated HVAC system between 70^{o} and 74^{o} F. There are times of day automatic setbacks in some of the laboratory rooms, while others necessitate constant temperature. The thermostats are controlled from a central location. The building is designed to maintain a humidity level between 30% - 35%.

CHAPTER FOUR
INSTRUMENTATION and REFERENCE MATERIAL

4.1 MAJOR PIECES of INSTRUMENTATION

Appendix 17 contains the instrumentation in use by ECLS staff along with:

- Manufacturer.
- Serial number.
- Location.
- Methods analyzed.
- Model number.
- Instrument.
- Date acquired (if known).

Appendix 17 information must be updated annually by each program manager or designee. All the instruments are operated according to the manufacturer's instructions and/or according to specific criteria contained in the reference method for any analysis. The instrument's manufacturer provides technical manuals which are kept close to the instrument for easy access. The specific protocols for operating these major pieces of instrumentation, e.g., calibration, QC requirements, operating specifications, etc., are contained in the Method Manuals for the individual analyses.

4.2 SUPPORT EQUIPMENT

Support equipment consists of instruments and equipment that are used in conjunction with other instrumentation to perform a specific analysis and report a result. Support equipment are usually items that an analyst is expected to know how to operate correctly and accurately. Therefore, the manufacturer operating instructions may be very limited or not provided at all. Below are operating instructions, and where appropriate, calibration and QC activities for ECLS support equipment not covered by manufacturer's operating instructions.

ANALYTICAL BALANCE-MECHANICAL: mounted on a heavy shockproof table or a heavy slab support, located away from laboratory traffic, and operated when in equilibrium with room temperature. This type of analytical balance is operated as follows:

- Make sure that the pan and the inside of the weighing chamber are clean. Use a brush to remove dust or particulate matter that could adhere to the weighing vessel and adversely affect the weighing.
- With the sliding doors closed, zero the balance by SLOWLY releasing the balance from its fully arrested position. By releasing the balance slowly, a minimum of vibration is introduced to the system thereby preventing an extended period being required to allow the balance to come to a resting position. If too much vibration is introduced, fully arrest the balance again, wait a minute, and then fully release. Zero the balance by turning the ZERO KNOB until the zero line of the balance readout is located between the two fixed reference gap indicators. If this does not zero the balance, it may be necessary to check the balance level (a circular "bulls-eye" configuration containing an air bubble) to verify that the balance is level (the air bubble is in the center of the circular array). To level the balance, adjust the height of the appropriate balance leg to bring the bubble to the center of the array by turning the knob on the balance leg. Zero the balance. In extreme cases, it may be necessary to adjust the

weights inside of the balance before a zero can be achieved. This adjustment must be performed only by individuals familiar with the adjustment procedure.
- Place the weighing dish on the balance pan. With the doors closed, partially release the balance. Slowly add weights to the balance by turning the appropriate weight knobs until an approximate weight is obtained.
- Bring the balance slowly back to the fully arrested position. Then fully release the balance and add or subtract weights to arrive at a final weight of the weighing dish. Record the weight.
- Add the material to be weighed and repeat the weighing process described above.

Quality control measures:

- Each time of use, the balance is checked with a set of two class 1 weights that bracket the anticipated weight range that the balance will be operating in for that analysis. If a second analysis requires the use of that balance, another set of weight measurement are entered on **Appendix 18**. **Appendix 18** forms are contained in a bound logbook (CHEM 17) associated with each balance. The balance reading must agree to ± 1 in the decimal place to the left of the decimal place that the balance is capable of reading. For example, if a balance reads to 5 decimal places, 0.00000g, the acceptable limit for that balance is 0.00010g. The acceptance limits for other balances are similarly determined until a balance is capable of reading to only one decimal place. Then the acceptance limit is ± 0.3g. If this acceptance limit is exceeded, the balance is "removed from service" until corrective actions produce acceptable results.
- Monthly, balances are checked with OQA's NIST traceable weight set. This set is reserved strictly for monthly balance checks. The checks are documented on **Appendix 19** and each program maintains their own Monthly Balance Check Logbook (LAB-6).
- Yearly, under a service contract, the balances are serviced by a qualified repair technician.
- An analytical Balance Logbook is kept for each balance documenting all the information required by section 4.3 3 of this manual.
- If a balance does not achieve the desired degree of accuracy, a sign is placed on the balance by OQA indicating that the balance is "Out-of-Service". The balance remains out of service until maintenance is performed and it has been verified by OQA to be working properly again.

ANALYTICAL BALANCE-ELECTRONIC: mounted on a heavy shockproof table or a heavy slab support, located away from laboratory traffic, and operated when in equilibrium with room temperature. This type of balance is operated as follows:

- Make sure that the pan and the inside of the weighing chamber are clean. Use a brush to remove dust or particulate matter that could adhere to the weighing vessel and adversely affect the weighing.
- With the sliding doors closed, zero the balance by pressing the on/off button. Wait until a constant reading is displayed. If it is not zero, press the TARE button and wait until a constant reading is displayed.
- If a zero reading is not obtained, see the remedial steps listed above.
- Place the weighing dish on the balance and press the TARE button.
- Add the material to be weighed and record the weight.

Quality control measures are the same as listed above for Analytical Balance: Mechanical.

pH METER: the electrodes are immersed in a buffer solution or saturated potassium chloride solution when not in use. The pH meters must have a scale readability of ± 0.05 pH unit. The pH meter is operated as follows:

- The electrodes are removed from the preservative solution and rinsed with de-ionized water to remove the solution adhering to the electrodes.
- The electrodes are standardized against three buffers (pH 4.0, 7.0, and 10.0) and the standardization checked against two buffers from a different source (pH 4.0 and 10.0) prior to analyzing samples. The standardization is performed by pressing the standardization button on the meter and following the displayed instructions.
- Calibration and sample values are obtained using automatic temperature compensation while the sample is being stirred at a constant rate using a magnetic stirrer and stir bar.

Quality control measures:

- Electrodes are rinsed with de-ionized water after each reading.
- Electrodes are blotted dry, not wiped.
- Samples are stirred during analysis.
- The electrode solution is checked weekly by the analyst and the level is maintained at three-quarters capacity or greater. This is documented in the instrument maintenance log.
- The electrode bulb is cleaned as needed, with a 10% pepsin solution and/or a 50% solution of acetone and water. This is documented in the instrument maintenance log.
- Electrodes are conditioned by soaking in a pH 7.0 buffer solution for several hours following any of the stated QC measures and/or maintenance steps.
- The junction, if required, is replaced, as needed.
- A maintenance log is maintained for each pH meter documenting all the information required above and by section 4.3 of this manual.
- If a pH meter stays in operation for an extended time, it must be recalibrated after every three (3) hours of continuous operation.
- If the pH meter cannot be calibrated accurately, it is taken “Out-of-Service” as described above.

DISSOLVED OXYGEN METER: located in the Biochemical Oxygen Demand (BOD) laboratory. The DO meter is operated as follows:

- The DO probe is removed from the water bottle, in which it has been maintained, and placed in a BOD bottle that is half filled with water. The probe is not in contact with the water.
- The probe and the DO meter must achieve thermal equilibrium with the ambient air temperature.
- If the air temperature is 20^{o} C, the probe should read 9.2 ppm. If a reading other than this is obtained, the meter is calibrated to read 9.2 ppm. There is a temperature chart that correlates the various temperature readings to the appropriate ppm value, so a proper calibration can be achieved.
- A sample reading is obtained by immersing the probe in the sample, so that there are no air spaces in the sample and turning the probe on.

Quality control measures:

- The probe membrane is changed as needed or every two weeks, whichever is more frequent.
- All other maintenance is performed by the vendor at the vendor's workstation.
- A maintenance log is kept for documenting all the information required by section 4.3 of this manual.

BOD INCUBATOR: there is one large, walk-in incubator located in L466. The incubator is maintained by the laboratory staff. The staff makes daily temperature checks to verify that the incubator is maintaining a temperature of 20 ± 1 Celsius degree. Those temperature readings are recorded in a bound logbook

kept inside the incubator. If the incubators cannot maintain the required temperatures, they are taken "Out-of-Service" as described above.

OVENS, REFRIGERATORS, AND FREEZERS: are located throughout ECLS. These items require no operating instructions and do not require any preventive maintenance by ECLS. The only control measure that is required is for the temperatures of these items to be monitored each day. The temperatures are recorded on the bound logbooks (CHEM 5) attached to each item. The acceptable refrigerator temperature range is between 2.0°C and 6.0°C, as per DEP and EPA Regulation. Ovens are to maintain the desired temperature within a ± 1.0°C range. Presently, there is no freezer temperature requirement listed in any of the reference methods. Therefore, when an analyst stores something in the freezer, s/he may establish the temperature and acceptance range. Generally, the temperature range for freezers is between -15°C to -25°C. When a method states a specific temperature range for a piece of equipment that range is to be followed. Entries into the temperature logbook are made each working day. If the equipment is outside of the acceptance limits, adjustment to the unit should be made. If the unit shows continuous out of range readings an "Out of Order" notation is entered. "Out-of-Order" is defined as temperatures that are less than or greater than 2°C outside of the acceptable temperature range that are observed for 2 consecutive days or for 2 days of the last 5 recording days. Any temperature observed that is outside of the acceptance range by more than 2^0C, is automatically considered Out of Service. If the equipment is not being used on a day, then a "Not-in-Use" notation must be entered in the temperature book. When listed as Out of Order, the corrective actions taken to return the equipment to service must be recorded on the temperature log. If the equipment is not being used that day, a "Not in Use" notation is to be entered. These logbooks are maintained by OQA for a five-year period and then discarded.

NOTE: The calibrated thermometers used to take these temperature readings have a correction factor associated with that thermometer. That correction factor must be used when recording the actual temperature of the unit in the temperature log. If a thermometer has a correction factor of +0.5 degrees and the reading that is obtained from the thermometer is 4.0°C, the temperature that is to be recorded in the temperature logbook is 4.5° C.

THERMOMETERS: Thermometers are used throughout the laboratory. All liquid-in-glass thermometers are calibrated annually near the temperature of its intended use. **All Digital thermometers require quarterly calibration.** All thermometer calibrations are recorded in the LAB 11 logbook kept by the QA Officer. See **Appendix 20**. This is accomplished by comparing the temperature readings of the in-house thermometers against a NIST thermometer that is re-calibrated ever 5 years. It is sent out for recertification and the "corrected" temperatures are used to calibrate the in-house thermometers. Each thermometer is then labeled to include the following information: date of calibration, person performing the calibration, the thermometer's in-house ID number and the correction factor necessary to achieve the equivalent NBS reading. The record of these calibrations is maintained by the QAO for a period of at least 5 years and then discarded. Thermometers are graduated in at least 0.5°C increments.

When an infrared detection device is used to measure the temperature of samples, the device should be verified at least every six months using a NIST certified thermometer over the full temperature range that the IR thermometer will be used. Each day of use a single check of the IR should be made and recorded by checking the temperature of a bottle of water at the temperature of interest that contains a calibrated thermometer. Agreement between the two should be within 0.5^0 C, or the device should be recalibrated.

BURETTES: are used to perform titrations in the laboratory and are used as follows:

- The burette is washed with three 5 to 10 ml portions of the titrant solution. These washings consist of partially inverting the burette to make sure that the titrant contacts all the surface area of the burette. The wash solutions are discarded by allowing it to flow through the tip of the burette.
- The burette is filled with titrant. The titration is performed by slowly adding the titrant, by means of manipulating the stopcock at the bottom of the burette, until the endpoint is achieved. As the endpoint is approached, the titrant is added dropwise to prevent overshooting the endpoint.
- The reading is obtained by looking at the BOTTOM of the meniscus of the titrant.
- The burette is then washed with several times with the appropriate solvent (usually water) to remove the titrant.
- The burette is then stored either right side up, with water in the burette and a beaker over the top to prevent the accumulation of dust particles that would clog the stopcock assembly, or upside down.
- The only maintenance to be performed is to make sure that the grease used on the glass stopcock assembly does not dry out and thereby freeze the assembly. The stopcock is re-greased as needed. If Teflon stopcocks are used, this maintenance step does not need to be performed.

Quality control measures:

- If burettes are not designated as “Class A” the accuracy is validated as per Automatic Pipettes listed below. If they are designated as “Class A”, no validation is necessary.

PIPETTES: are used in the preparation of reagents, standards, and quality control samples. Pipettes are used as follows:

- There are two general types of volumetric pipettes: those identified as “To Deliver” (TD) or the "traditional" volumetric pipette and those identified as To Contain (TC) or serological pipettes. The pipettes are rinsed with the solution to be transferred two or three times before use. For the TD pipettes, the actual transfer is performed by placing the pipette in contact with the receiving vessel and emptying the pipette while the pipette is in an upright position. Pipette and receiving vessel contact are maintained for two to three seconds after transfer to ensure that the proper volume of solution is transferred. Since all volumetric pipettes are certified class "A", no checks of these pipettes are required. For the TC pipettes, the transfer is accomplished as above except that instead of allowing the pipette to remain in contact with the receiving vessel to complete the transfer, the remaining solution in the pipette is blown-out to ensure complete transfer.

  Before use, inspect pipettes for chips or cracks in the tip, inspect for cleanliness, and rinse with the solution to be transferred. Pipetting by mouth is strictly forbidden.

AUTOMATIC PIPETTES (ELECTRONIC OR MANUAL TYPES): are used to transfer small amounts of solutions that cannot be easily transferred by normal glass pipettes. They are composed of a hand-held pipette assembly, manufactured to deliver a specific volume, and have disposable plastic pipette tips. These pipettes are used as follows:

- The pipette tip is placed on the end of the assembly.
- Holding the pipette tip in the solution to be transferred, squeeze the "trigger" to uptake solution into the pipette.
- Empty the pipette by squeezing the "trigger" again. These are emptied as in the TD pipettes above.

Quality control measures:

- These pipettes have their accuracy validated before they are placed in service and quarterly thereafter.
- Both gravimetric and photometric methods are acceptable techniques for calibrating pipettes.

GRAVIMETIC CALIBRATION

- Ten water aliquots are transferred to weighing dishes and the weights of the transferred water are determined.
- These actual weights are compared to the theoretical weights of the transferred water.
- The readings are recorded and entered into an Excel spreadsheet to generate a report.
- All reports are signed by the analyst and reviewed by a supervisor.
- The accuracy acceptance limits are ± 2.5% of the true value.
  The precision acceptance limits are ± 1.5%
- Each automatic pipette is assigned an ID number by the supervisor through which one can relate a specific validation event to a specific pipette. Examples of both calibration documentations are listed in **Appendix 21.** A copy is maintained by the supervisor and a copy kept by OQA for filing for a period of at least 5 years and then discarded.

INSTRUMENT MAINTENANCE: consists of two basic types: routine and non-routine. The routine maintenance is that which is required by the manufacturer to keep the instrument in working condition. The specific maintenance procedures, frequency for each procedure, and the responsible party for that procedure (laboratory or manufacturer personnel), are established by the manufacturer. Non-routine maintenance is required when an instrument can no longer function according to the manufacturer and/or quality control required specifications. This may require the attention of a service technician. At this time, the instrument is removed from service before it can adversely affect client data. Clients will be notified when there is a significant delay in results reporting due to instrument malfunction.

4.3 INSTRUMENT MAINTENANCE

The instrument will remain out of service until the methods run on that instrument have been re-validated. Much of the instrumentation in **Appendix 17** is covered under service contracts with the vendors. The procurement and maintenance of these contracts is the responsibility of the Program Technical Directors. All maintenance performed is documented in the INSTRUMENT MAINTENANCE LOG. This log consists of the following information:

- Instrument name, manufacturer, model number, serial number and the NJDOH ID number.
- Dates that the instrument was received and placed into service. For those instruments previously in-use, the following notation will be made: "Previously in service but date not recorded." For new instruments, this information will be recorded.
- Condition of the instrument when received. Since all the instrumentation received by ECLS is purchased new, NEW will be the entry for this requirement. If a used instrument is ever obtained by ECLS, the condition of that instrument will be described using descriptions such as: received in working order, needed service to repair (list particulars), etc.
- Dates, results, and retention of hard copy data for any calibrations or verifications performed by the contract service technician during the initial instrument set-up or non-routine service maintenance.
- Routine maintenance and documentation consist of the following: description of each item of maintenance, as indicated by the manufacturer that is to be performed, the frequency of its

performance, when it was performed, by whom, and when it is to be performed next. Also included are any extra maintenance steps taken by the analyst.

- Non-routine maintenance and documentation consist of the following items: description of the instrumental problem, date(s) the service was performed, who performed the service, and a listing the items serviced and/or replaced.
- A history of the damage, malfunction, etc. of the instrument not covered by the above-mentioned items.
- If there is space in a workbook for documenting the completion of a maintenance item, then an entry must be made for every day that the items appears in the workbook. Of course, if the maintenance item was performed, that is documented. If no maintenance was performed, enter the reason why. For example, if no maintenance was required, you can place a "NA," or some similar entry in the space. If the instrument was not in use, state as such.
- If maintenance is documented in the daily run logs, etc., highlight the entries so that they are readily observable to auditors.

It is ECLS policy that if a piece of equipment has no notice to the contrary, it is properly functioning. Only in the instance that the instrument is malfunctioning will an "Out of Service" notice be affixed to the instrument.

4.4 TRACEABILITY OF REFERENCE STANDARDS

ECLS can trace back to a primary reference or measurement standard, all the reference material used within the laboratory. The reference materials presently in-use are weight sets used to check the balances, the thermometers used in temperature measurements, and the reagents and standards used in analyses. The traceability of these reference materials is as follows:

- WEIGHTS (ASTM Type I): weights are used to check the accuracy of the balances on each day of use by recording the results of the weighing's in the bound book consisting of **Appendix 18**. The Inorganic Technical Director or the Organic Technical Director, or their designees, maintain possession of these weights. The accuracy of these weights is verified by comparing them to another "made to class S specifications" weights maintained by the QAO. This verification is performed prior to placing the weights in-use and annually thereafter. The results of these verifications are maintained by the QAO on **Appendix 22**. The NIST traceable QAO weights are sent every five years as per EPA regulations for re-certification. The NJ Office of Weights and Measures has been used in the past as the re-certification vendor. All certification documentation is maintained by the QAO. In this manner, every weighing that is made in ECLS is traceable back to a nationally recognized standard weight; namely, the NJ Office of Weights and Measures or the equipment manufacturer.
- THERMOMETERS: thermometers are used to check the temperature accuracy of ovens, refrigerators, freezers, etc. on each day of use. This check is documented by recording the temperature in the bound book that is maintained on that piece of equipment. The thermometers are dedicated to the instrument that they are functioning within. The accuracy of these thermometers is verified by comparing them to the "traceable to NIST" thermometer maintained by the QAO. This verification is performed prior to placing the thermometer in-use and annually thereafter. The results of these verifications are maintained by the QAO on **Appendix 20.** The QAO thermometers are sent every five years for recalibration according to the calibration date, to be calibrated against a NIST certified thermometer. In this manner,

every temperature reading that is made in ECLS is traceable back to a nationally recognized temperature standard; namely, NIST.

- REAGENTS AND STANDARDS: at a minimum, all reagents used in ECLS are of analytical reagent grade. In those instances where analytical reagent grade chemicals are not available, the highest purity reagent available is used. Special high purity reagents are used in the trace metal and trace organic analytical laboratories; e.g. trace metal grade acids and pesticide residue free solvents. Standards purchased are of the highest purity available and come with a Certificate of Analysis that is maintained in the analytical unit using the material.

  Reagents and standard solutions are all labeled with unique identifiers. The unique identifier is assigned to the individual solution by the analysts. For those analysts, or analytical units, that employ workbooks in which they document how they prepare each solution, those workbooks have an ID number that was assigned to them by the QAO. The unique solution identifiers are generated by the analyst by combining the workbook ID number with the page number on which the formulation is documented and, in the case that there is more than one formulation on a page, adding a suffix (a, b, c etc.) to indicate the formulation on that page. For example, if the preparation of the total phosphorous color reagent was documented in workbook 1729 on page 73 and was the second reagent documented, the unique identifier would be 1729-73b. Additionally, each reagent or standard solution is assigned a unique identifier by the ECLS LIMS system. This number is used in conjunction with the unique identifier assigned by the analyst to identify the reagent or standard. The solution bottle is then labeled, as a minimum, with these unique identifiers along with the name of the solution and its expiration date. If no expiration dates are provided by the manufacturer or the reference method, ECLS will assign a tentative expiration date. For example, most of the VO standards have an expiration date of two years. Therefore, this will be assigned as the expiration date. ECLS is in the process of adopting one label that will be used by the Inorganic and Metal units which provides spaces for recording the pertinent information.

  Reagents that are used as titrants must be standardized or replaced by a new lot at the schedule listed in the appropriate reference method. All titrants that are purchased must have a lot specific C of A. In the absence of any such specification, the titrants are to be re-standardized quarterly.

  Those analysts that perform analyses that require that reagents and standards be made daily and used only on that day, may document the preparation and ID of the materials in the daily run log.

  When a solution is prepared, the type of information documented in the workbook depends on the source material that is used. For the preparation of a solution from a solid source, liquid source or solution from a previously prepared in-house solution, see the information below.

PREPARATION OF A SOLUTION FROM A SOLID SOURCE

FOR THE SOLUTION BEING PREPARED, DOCUMENT THE FOLLOWING:

Solution ID number: as per section 4.4.
Solution name: Name that will appear on the solution container e.g., standard mix #1.
Name of analyst preparing the solution:
Preparation date:
Expiration date:

FROM THE SOLID SOURCE, DOCUMENT THE FOLLOWING:

Name of the chemical supplier:
Lot number:
Bottle number: 1 of X, 2 of X,
Date received in the laboratory:
Purity:
Expiration date:

PREPARATION DOCUMENTATION:

Weight of the weighing dish and the chemical:
Weight of the weighing dish:
Weight of the chemical:
Dilution volume:
Solvent:
Analyte(s) concentration(s):
Description of the preparation process: Any specific detail that is necessary for the correct preparation of the solution. This may be a reference back to the Method Manual.
Calculations:
Analyst Signature:

PREPARATION OF A SOLUTION FROM A LIQUID SOURCE

FOR THE SOLUTION BEING PREPARED, DOCUMENT THE FOLLOWING:

Solution ID number: as per section 4.4.
Solution name: Name that will appear on the solution container e.g., standard mix #1.
Name of the analyst preparing the solution:
Preparation date:
Expiration date:

FROM THE LIQUID SOURCE, DOCUMENT THE FOLLOWING:

Name of the chemical supplier:
Lot number:
Bottle number: 1 of X, 2 of X,
Purity:
Analyte(s) concentration(s):
Date received in the laboratory:
Expiration date:

PREPARATION DOCUMENTATION:

Volume transferred:
Dilution volume:
Solvent:
Analyte(s) concentration(s):
Description of the preparation process: Any specific detail that is necessary for the correct preparation of the solution. This may be a reference back to the Method Manual.
Calculations:
Analyst signature:

PREPARATION OF A SOLUTION FROM A PREVIOUSLY PREPARED IN-HOUSE SOLUTION

FOR THE SOLUTION BEING PREPARED, DOCUMENT THE FOLLOWING:

Solution ID number: as per section 4.4.
Solution name: Name that will appear on the solution container e.g., standard mix #1.
Name of the analyst preparing the solution:
Preparation date:
Expiration date:

FROM THE IN-HOUSE SOLUTION BEING DILUTED, DOCUMENT THE FOLLOWING:

Solution ID number:
Analyte(s) concentration(s):
Expiration date:

PREPARATION DOCUMENTATION

Volume transferred:
Dilution volume:
Solvent:
Analyte(s) concentration(s):
Description of the preparation process: Any specific detail that is necessary for the correct preparation of the solution. This may be a reference back to the Method Manual.
Calculations:
Analyst signature:

If an analyst determines that he would like to develop a form that would make the preparation and documentation of his reagents, standards, etc. easier, he may do so provided that all of the information requested in the preparations described above are documented. However, these forms must be compiled into a bound book, like the temperature and balance books; pages numbered, and have a book number assigned by the QAO. This will allow the analysts to assign a unique identifier to the reagents, etc. in an analogous manner as the other analysts.

4.5 ORDERING REAGENTS, STANDARDS and OFFICE SUPPLIES

IN-HOUSE OFFICE/LABORATORY SUPPLY INVENTORY:

The Office of the Service Director maintains an in-house inventory of office supplies. In addition to these supplies, the Office of the Service Director maintains an in-house inventory for laboratory gloves, plastic sample bottle, Kim wipes, and plastic gloves. Staff may go to the storage location and obtain the necessary office supplies on an as needed basis. For all items, excluding plastic sample bottles, staff must submit a completed LAB-22 form approved by the respective Technical Supervisor, then forward to the Office of the Service Director. The supply request will be processed and given to the requestor. The Office of the Service Director is responsible for tracking the in-house supply inventory and assuring that adequate quantities of supplies are available.

When necessary to restock the in-house office supply inventory, The Office of the Service Director will complete a LAB-22 form and enter the request into the purchase tracking records. The request will be forwarded to the, Divisional Warehouse Coordinator, for processing. Upon delivery the order is verified for completeness by comparing the LAB-22 with the items received against the original order. All items will be received, verified, and placed in storage area by the close of the business day.

WAREHOUSE OFFICE SUPPLY REQUESTS:

When requesting office supplies not covered in the in-house Office Supply Inventory, staff must submit a completed LAB-22 form approved by the Technical Supervisor, and then forward it the director's secretary for processing. All requests will then be submitted for review and approval by the Director. Upon approval, the request will be entered into the purchase tracking records. The request will then be forwarded to Divisional Warehouse for processing. To track completed orders, orders will no longer be combined. They will be submitted to the Divisional Warehouse as originally received by The Office of the Director.

LABORATORY SUPPLY REQUESTS:

Requests for purchase of laboratory supplies will be made using the DOH ReqTrack app available on the intranet, which includes several approval levels. A LAB-14 Purchase Request form may be uploaded to ReqTrack to assist the PHEL Purchasing group obtain the material or item. The service director's secretary tracks all purchase orders and will initiate follow-up action on those unfilled orders by checking the Purchase Order Log and identifying all orders that have not been received within 2 months of submittal to the purchasing unit. This follow-up action and feedback from the purchasing unit will be forwarded back to the respective Technical Supervisor in writing.

4.6 RECEIVING SUPPLIES

Upon delivery of office supplies, verification that the order is complete is confirmed by comparing the LAB-22 with the items received against the original order. The respective Technical Supervisors are then notified that the ordered items have been received.

Upon delivery of laboratory supplies, the employee receiving the delivery will sign for the delivery of the supplies and perform an immediate review of the items to see if anything being delivered is hazardous or requires refrigeration or freezing.

All packing slips must be given to the director's assistant to be kept in a file. The copy of the packing slip will be given to the respective Technical Supervisor for supply receipt verification. Once the laboratory program staff has verified the receipt of the supplies, the director's assistant will forward the original packing slip to purchasing processing. If there are any outstanding items on the LAB-14, this must be brought to, the director's secretary's attention.

GLASSWARE: are of the Pyrex-Kimax or borosilicate type with all the volumetric glassware being Class-A. All new glassware must be initially washed as per Chapter 3 in the Central Service unit or by the analyst using the glassware. ECLS has switched to using pre-washed, one time use plastic bottles for sample collection, wherever appropriate. Some glassware requires additional cleaning prior to their use in the laboratory. Those additional cleaning steps are as follows:

METAL ANALYSIS: The additional cleaning steps consist of:

- Placing in an acid bath containing 1:4 (v/v) nitric acid/water and allowed to soak for three hours.
- This is followed by a tap water rinse.
- Rinsing with de-ionized water three times.
- Inverting and placing in plastic storage containers or storage cabinets to prevent contamination.

ORGANIC ANALYSIS: The additional cleaning steps outlined below are described as beginning immediately after analysis. Any or all steps may be necessary to clean depending upon the nature of the sample and the concentration of the analysis.

- Removals of surface residues as soon as possible after use by using acetone (or other suitable solvent) prior to being placed in the hot detergent soak.
- The hot detergent soak consists of a bath of a suitable detergent (Alconox or Sparkleen) in water at 50^0 C or warmer. These detergents are entirely synthetic and not of fatty acid base since that would cause a film to develop on the glassware which would have an affinity for organic residues.
- Hot water rinse.
- Soak in an oxidizing agent or deep penetrating agent which usually consists of a warm chromic acid solution. Potential substitutes are Chem Solve 2157 and Detex.
- Several hot tap water rinses.
- Distilled water rinse.
- Acetone rinse.
- A preliminary flush before use with the solvent to be employed in the analysis.
- An additional "cleaning" step adhered to is to discard all glassware that encounters highly contaminated samples rather than risk contaminating other glassware through incomplete cleaning.

4.7 SAMPLE BOTTLES

May be purchased pre-cleaned to USEPA specifications or may be cleaned in-house by the Central Services Unit. Bottles cleaned in-house are cleaned according to the listed procedure for Central Service. These bottles may require additional cleaning prior to distribution to the sample collectors. The finished sample bottles are stored in the bottle supply cabinet inside of the Sample Receiving room. The additional cleaning steps for bottles are as follows:

GENERAL CHEMISTRY: bottles used for collection of samples for general analyses such as, cyanide, color turbidity; BOD, COD, etc. require no additional cleaning.

TRACE METAL: bottles are rinsed with 10% nitric acid, double distilled water rinsed, and then air dried.

ORGANICS: bottles are acetone rinsed, hexane rinsed, air-dried and capped.

CHAPTER FIVE
SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES

5.1 SAMPLE REQUIREMENTS

The list below provides the parameter groupings, volume of sample, preservation, and holding time requirements for the various routine analyses performed on aqueous samples by ECLS. The volumes listed in the tables will suffice for all samples requiring routine data reporting (I.E., a report produced in the Tier 2 format). Should the sample batch require a full deliverables data package (I.E., a report produced in the Tier 1 format), ECLS requests that one of the samples in the batch be submitted at a volume three times that requested in the tables. For example, if the sample batch submitted contains 5 samples to be analyzed for a combination of ICP and GFAA metals, one of the five samples should be submitted with three 500ml bottles for ICP and three 500ml bottles for GFAA. Sample batches containing more than 20 samples should include this additional volume for one sample out of every 20. Lists for non-aqueous matrices (soils, air samples and biological tissues) are also provided. Sample preservation is usually conducted in the field at the time of sample collection. Exceptions may include trace metals, addition of dechlorinating agents to sample containers, and EPA 531 preservative added to the sample bottles prior to bottle distribution. The container, preservation, and holding times must meet the requirements: established by the US EPA, as listed in 40CFR136 and 40CFR141; established by the State of New Jersey, as listed in NJSA58:10A-1 and NJAC7:10-1.1; and recommended by the National Institute of Occupational Safety and Health, as listed in its third edition methods manual.

SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES FOR AQUEOUS SAMPLES

Parameter	Parameter Grouping	Required Volume, ml	Container	Preservative	Holding Times (2)
Microbiology					
Total Coliform	I	100 Colilert 100 (MPN)	Sterilized P	Sodium thiosulfate	30 hours (PW) 8 hours (NPW)
Fecal Coliform	I	100 (MPN)	Sterilized P	Sodium thiosulfate	8 hours (NPW)
Fecal Streptococci	I	100 (MPN)	Sterilized P	Sodium thiosulfate	8 hours (NPW)
Fecal Coliform (Recreation Public Bathing)	I	100 (MPN)	Sterilized P or G	Sodium thiosulfate	6 hours (NPW)
Enterococci	I	100 (MPN)	Sterilized P	Sodium thiosulfate	8 hours (NPW)
E. Coli	I	100 Colilert	Sterilized P	Sodium thiosulfate	30 hours (PW)
E. Coli	I	100 (MPN)	Sterilized P	Sodium thiosulfate	30 hours (PW)
E. Coli	I	Colilert	Sterilized P	Sodium thiosulfate	8 hours (NPW)
HPC	I	pour plate 100 ml	Sterilized P	Sodium thiosulfate	8 hours (PW&NPW)
INORGANIC TESTS					

Parameter	Parameter Grouping	Required Volume, ml	Container	Preservative	Holding Times (2)
ABS/LAS (MBAS)	B	500	P or G	P-1	48 Hours
Alkalinity	E	500	P or G	P-1	14 Days
BOD5	A	1000 (3)	P or G	P-1	48 Hours
BOD20	A	1000 (3)	P or G	P-1	48 Hours
Ultimate BOD 90	A	1000 (3)	P or G	P-1	48 Hours
CBOD5	A	1000 (3)	P or G	P-1	48 Hours
CBOD20	A	1000 (3)	P or G	P-1	48 Hours
COD	L	500 (10)	P or G	P-2	28 Days
Bromide by IC	B	100	P or G	None Required	28 Days
Chloride by IC	B	100	P or G	None Required	28 Days
Chloride	B	100	P or G	None Required	28 Days
Color	B or J	100	P or G	P-1	48 Hours
Cyanide	A	1000 (23)	P or G	P-25	14 days (9)
Dissolved Oxygen	A	300	G	P-4	8 Hours
Fluoride (PW)	B	300	P or G	None Required	28 days
Fluoride (SS)	B	500	P or G	None Required	28 Days
Fluoride by IC	B	100	P or G	None Required	28 Days
Hardness	C	100	P or G	P-5	6 Months
METALS TOTAL					
Aluminum	C or D	500 (7)	P (12)	P-5	6 Months
Antimony	C or F	500 (7)	P (12)	P-5	6 Months
Arsenic	C or F	500 (7)	P (12)	P-5	6 Months
Barium	C or D	500 (7)	P (12)	P-5	6 Months
Beryllium	C or D	500 (7)	P (12)	P-5	6 Months
Boron	C or D	500 (7)	P (12)	P-5	6 Months
Cadmium	C or D	500 (7)	P (12)	P-5	6 Months
Chromium, Hexavalent Ion Chromatographic Method Non-chlorinated	A	250 (7)	P	P-26	28 Days
Chromium, Hexavalent Ion Chromatographic Method Chlorinated (PW)	A	250 (7)	P	P-1	24 Hours
Chromium Total	C or D	500 (7)	P (12)	P-5	6 Months
Cobalt	C or D	500 (7)	P (12)	P-5	6 Months
Copper	C or D	500 (7)	P (12)	P-5	6 Months
Iron	C or D	500 (7)	P (12)	P-5	6 Months
Lead	C or F	500 (7)	P (12)	P-5	6 Months
Manganese	C or D	500 (7)	P (12)	P-5	6 Months
Mercury (SS)	C or K	250 (7)	G (12)	P-5	28 Days
Mercury (PW)	C or K	250 (7)	G (12)	P-5	28 Days
Low Level Mercury	C or K	1000 (7)	G (12)	P-27	3 Months
Molybdenum	C or D	500 (7)	P (12)	P-5	6 Months
Nickel	C or D	500 (7)	P (12)	P-5	6 Months
Selenium	C or F	500 (7)	P (12)	P-5	6 Months
Silver	C or D	500 (7)	P (12)	P-5	6 Months
Strontium	C or K	250 (7)	P (12)	P-5	6 Months
Thallium	C or F	500 (7)	P (12)	P-5	6 Months
Titanium	C or K	250 (7)	P (12)	P-5	6 Months
Vanadium	C or D	500 (7)	P (12)	P-5	6 Months

Parameter	Parameter Grouping	Required Volume, ml	Container	Preservative	Holding Times (2)
Zinc	C or D	500 (7)	P (12)	P-5	6 Months
METALS DISSOLVED (13)					
MINERALS TOTAL					
Calcium	C or G	500	P (12)	P-5	6 Months
Magnesium	C or G	500	P (12)	P-5	6 Months
Potassium	C or G	500	P (12)	P-5	6 Months
Sodium	C or G	500	P (12)	P-5	6 Months
MINERALS DISSOLVED (13)					
NITROGEN					
Ammonia	H	200	P or G	P-6	28 Days
Nitrite	B	100	P or G	P-1	48 Hours
Nitrite + Nitrate (SS)	H	100	P or G	P-6	28 Days
Nitrite + Nitrate (PW) chlorinated	B	100	P or G	P-1	28 Days
Nitrite + Nitrate (PW) non-chlorinated	H	100	P or G	P-6	14 Days
TKN	H	250	P or G	P-6	28 Days
Odor	A	1000	G	P-1	24 Hours
pH	E	250	P or G	P-1	Analyze Immediately
Phenolics	A	500	G	P-6	28 Days
Phosphorus Hydrolyzable	H	100	P or G	P-6	7 Days
Phosphorus Ortho	B	100	P or G	P-1	48 Hours
Phosphorus Total	H	100	P or G	P-6	28 Days
Residue Filterable (TDS)	B	250	P or G	P-1	7 Days
Residue Non-filterable (SS)	B	250	P or G	P-1	7 Days
Residue, Volatile (TVS)	B	250	P	P-1	7 Days
Residue Total (TS)	B	250	P or G	P-1	7 Days
Settleable Matter	A	1000	P or G	P-1	48 Hours
Conductance	B	250	P or G	P-1	28 Days
Silica	C or D	250	P	P-5	6 months
Sulfate	B	500	P or G	P-1	28 Days
Sulfate IC	B	100	P or G	P-1	28 Days
TOC	L	500 (3,10)	P or G	P-2	28 Days
Turbidity	B or J	100	P or G	P-1	48 Hours
ORGANIC TESTS					
Methylcarbamates EPA 531.1 Chlorinated	A	125	G (31)	P-21	28 Days
Methylcarbamates EPA 531.1 Nonchlorinated	A	125	G (31)	P-23	28 Days

Parameter	Parameter Grouping	Required Volume, ml	Container	Preservative	Holding Times (2)
Chlorinated Acids EPA 515.3 Chlorinated	A	1000	G (28)	P-22	14 Days (30)
Chlorinated Acids EPA 515.3 Nonchlorinated	A	1000	G (28)	P-1	14 Days (30)
EDB, DBPC EPA 504.1 Chlorinated	A	5 X 40	G (25)	P-20	14 Days (27)
EDB, DBPC EPA 504.1 Nonchlorinated	A	5 x 40	G (25)	P-1	14 Days (27)
ABN EPA 525.2 Chlorinated	N	1000 (15)	G (5))	P-13	14 Days (11)
ABN EPA 525.2 Nonchlorinated	N	1000 (15)	G (5))	P-15	14 Days (11)
VOs EPA 524.2 Chlorinated	A	6 x 40	G, Screwcapped septum vials (3, 6, 24)	P-14	14 Days
VOs EPA 524.2 Nonchlorinated	A	6 x 40	G, Screwcapped septum vials (3, 6, 24)	P-14	14 Days
VOs EPA 624 Chlorinated	A	8 x 40	G, Screwcapped septum vials (3, 6, 24)	P-14	14 Days
VOs EPA 624 Nonchlorinated	A	8 x 40	G, Screwcapped septum vials (3, 6, 24)	P-14	14 Days
Perfluorinated Alkyl Acids (PFAS) EPA 537	A	250 ml	polypropylene	Trizma 5 g/L	14 Days extraction Analyze within 28 days of extraction
RADIOLOGICAL TESTS					
Gross Alpha/Beta	O	1000	P, 1-Gallon	P-5	24 hours
Ra-224 (and/or Pb 212)	O	6000	P, 2-Gallon	P-5	(32)
Ra-226	O	6000	P, 2-Gallon	P-5	6 months
Ra-228	O	6000	P, 2-Gallon	P-5	6 months
Isotopic Uranium	O	1000	P, 1-Gallon	P-5	6 months
Tritium	P	100	G, 100ml	P-24	6 months
Rn-222	P (34)	20	G, 20ml vials	P-24	(32) & (33)
Gamma	O	4000	P, 2-Gallon	P-5	6 months
I-131	O	4000	P, 2-Gallon	P-24	8 days
Sr-89/90	O	1000	P, 1-Gallon	P-5	6 months

PARAMETER GROUPINGS

A. These parameters must be bottled separately and preserved if required.

B. These parameters may be collected within the same bottle provided that the required sample volumes are supplied. These require NO CHEMICAL PRESERVATION but should be cooled to less than or equal to 6° C as soon as possible after collection.

C. These parameters may be collected within the same bottle provided that the required sample volumes are supplied.

D. Any combination of ICP metals (pretreated to a pH of less than 2 with nitric acid) may be analyzed in a single 500ml sample.

E. These parameters must be bottled together. They may be analyzed from a single 500ml sample. No preservative should be added but the bottle should be iced as soon as possible.

F. A combination analysis may be made for furnace metals (antimony, arsenic, lead, selenium, tin, and thallium) with a 500ml sample (pretreated to a pH of less than 2 with nitric acid.

G. Any combination of these minerals (pretreated to a pH of less than 2 with nitric acid) may be analyzed from a single 500ml sample.

H. These parameters may be collected within the same bottle provided that the required sample volumes are supplied.

I. Most Probable Number (MPN) procedure is utilized for stream, lake, estuarine, municipal and industrial discharge samples. When sampling for fecal strep., fecal coliform, and total coliform singularly or in combination of all three, the 150 ml sterilized (aluminum foil covered) sodium thiosulfate treated bottle will contain sufficient sample for all three analyses in any dilution combinations except requests for fecal strep., fecal coliform, and total coliform at dilutions of 10, 1, and 0.1, for example. When these three parameters are to be requested at the above specified dilutions, the 290 ml sterilized (aluminum foil covered) sodium thiosulfate treated bottle is to be used. The bottle will hold enough sample for the requested analyses. These bottles are obtainable from the ECLS Receiving Laboratory (L-176).

When sampling for bacteriological parameters, be sure to leave ample air space within the bottle to allow for adequate sample mixing by the laboratory.

J. Any combination of these parameters (color and turbidity) can be made from a 100ml sample.

K. Mercury may be analyzed from a 250 ml glass bottle, preserved to a pH of less than 2 with nitric acid.

L. Any combination of these parameters can be made from a single, separately bottled, properly preserved 500ml sample.

M. Reserved.

N. These parameters must be bottled separately in acetone rinsed containers.

O. These parameters may be collected within the same bottle provided that the required sample volumes are supplied.

P. These parameters must be bottled separately.

PRESERVATIVES

P-1 Cool to less than or equal to 6^{o} C in an ice chest.

P-2 Preserve with concentrated sulfuric acid to a pH of less than 2. Do not add an excessive amount of sulfuric acid as this may inadvertently affect the analytical results.

P-3 Test the sample for the presence of residual chlorine. If present, add 0.6g of ascorbic acid prior to preserving the sample with 10N sodium hydroxide to a pH of greater than 12. After preserving the sample, cool to 4° C in an ice chest.

P-4 Collect the sample using a Dissolved Oxygen Sampler and a 300ml BOD bottle. Remove the filled 300ml sample bottle from the sampler. Add 2ml of manganous sulfate solution followed by 2ml of alkaline iodide/azide solution well below the surface of the liquid. Stopper the bottle with care to exclude air bubbles and mix well by inverting the bottle several times. When the precipitate settles, leaving a clear supernatant above the manganous hydroxide floc, shake again. Place a layer of distilled water on top of the glass stopper and cover this opening with the plastic cap provided with the bottle. This produces a water seal that prevents any entrance of air into the sample. This method (Winkler) is not applicable for the determination of dissolved oxygen in chlorinated wastewater effluents.

NOTE: Hach's manganous sulfate powder pillows and alkaline-iodine-azide reagent powder pillows may be substituted for the respective liquid reagents.

When using the Hach Powder Pillow reagents, the sequence is as follows:

- Fill the BOD bottle with sample.
- Add the contents of the manganous sulfate powder pillow to the BOD bottle.
- Add the contents of the alkaline-iodide-azide powder pillow to the BOD bottle.
- Stopper the bottle taking care to exclude air bubbles.
- Mix well by inverting the bottle several times.
- After the precipitate settles, mix well again.
- Stopper the bottle and mix well.
- Without removing the stopper, fill the neck of the bottle with distilled water and place the plastic cap with the foam insert over the flared neck to ensure that the water seal remains intact in the bottle neck.

P-5 Acidify the sample with concentrated nitric acid to a pH of less than 2.

P-6 Preserve the sample with concentrated sulfuric acid to a pH of 2 and cool to 4° C in an ice chest**. Do not add an excessive amount of acid, as this will results in analytical interference.**

P-7 Preserve the sample with concentrated sulfuric or hydrochloric acid to a pH of less than 2.

P-8 Preserve the sample with concentrated sulfuric or hydrochloric acid to a pH of less than 2 and cool to 4° C in an ice chest.

P-9 To 500ml of sample, add 2ml of zinc acetate solution and sodium hydroxide to a pH of greater than 9.

P-10 Approximately 80mg/l sodium thiosulfate is added to the bottle in the laboratory prior to being brought into the field. After collection, the sample is cooled to 4° C in an ice chest.

P-11 Use pre-sterilized containers with sodium thiosulfate. The bottles should not be rinsed prior to sampling. Once collected, the sample should be cooled to less than 10° C in an ice chest, as per the federal register, Monday, March 12, 2007, Table II.

P-12 Preserve samples with concentrated nitric acid to a pH of less than 2. Do not add an excessive amount of acid. Leave no air spaces. Cool to 4° C. If residual chlorine is present, add 5mg of sodium sulfite crystals at the time of collection.

P-13 Approximately 40 to50mg of sodium sulfite is added to the bottle in the laboratory prior to being brought into the field. After collection, the sample is acidified to a pH of less than 2 with 1:1 hydrochloric acid. The sample is then cooled to 4° C.

P-14 Samples should be preserved with 1:1 hydrochloric acid to a pH of less than 2 and then cooled to 4° C. For samples containing residual chlorine, the appropriate dechlorinating agent (25mg ascorbic acid for EPA 524.2 or 10mg sodium thiosulfate for EPA 624) is added in the laboratory prior to the bottles being taken into the field.

P-15 The sample is acidified to a pH of less than 2 with 1:1hydrochloric acid and cooled to 4° C.

P-16 Adjust the pH of the sample to a range of 2 to 7 with sulfuric acid. Cool to 4° C and protect from light.

P-17 Adjust the pH of the sample to between 4.5 and 5.0 using a combination of 1.0N, 0.2N, and 0.04N hydrochloric acid.

P-18 25mg of ammonium chloride must be added to the sample bottle, either in the laboratory prior to sending the bottle into the field or in the field, and then cooled to 4° C.

P-19 80mg of sodium thiosulfate must be added to the sample bottle, either in the laboratory prior to sending the bottle into the field or in the field, and then cooled to 4° C.

P-20 3mg of sodium thiosulfate must be added to the sample bottle, either in the laboratory prior to sending the bottle into the field or in the field, and then cooled to 4° C.

P-21 10 mg of sodium thiosulfate and 3.6 ml of monochloroacetic acid buffer must be added to the sample bottle, either in the laboratory prior to sending the bottle into the field or in the field. If the test request includes the compounds oxamly, 3-hydroxycarbofuran, aldicarb sulfoxide, or carbaryl, the sample must be preserved to pH 3 with hydrochloric acid and the cooled to 4° C.

P-22 80mg of sodium thiosulfate must be added to the sample bottle, either in the laboratory prior to sending the bottle into the field or in the field, and then cooled to 4° C.

P-23 3.6 ml of monochloroacetic acid buffer must be added to the sample bottle. If the compounds oxamly, 3-hydroxycarbofuran, aldicarb sulfoxide, or carbaryl are requested, the sample must be preserved to pH 3 with hydrochloric acid and then cooled to 4° C.

P-24 No preservation should be performed.

P-25 See requirements listed in Table II of 40CFR136.

P-26 The sample is preserved in the field by adjusting the pH to between 9.3 and 9.7 by addition of the laboratory supplied ammonium sulfate / ammonium hydroxide buffer solution to the sample after filtration. Chlorinated samples must have a free chlorine value of less than 0.1 mg/L.

PRESERVATION PROCEDURE

NOTE: When fixing sample (with an acid or base) to specific pH, add the appropriate preservative and check the sample pH as follows:

- Add the preservative to the sample one or two drops at a time.
- Replace the stopper on the sample bottle and mix thoroughly by inverting the bottle several times.
- Remove the bottle stopper and place a drop of sample from the stopper onto pH test paper.
- If the proper pH has not been obtained, repeat the above steps as necessary.
- Do not add excessive amounts of acid. Only add sufficient acid to reach the required pH. Excessive acid may result in inaccurate results or inability to analyze the sample.

FOOTNOTES

(1) If samples cannot be returned to the laboratory in less than 6 hours and the holding time exceeds this limit, the final report will indicate the actual holding time.

(2) Holding time is defined as the length of time between the collection of the sample and the initiation of the analysis. For composite samples (i.e., 4 hours or 24 hour), the holding time begins at the end of the collection of the last sample to be composited. It is the responsibility of the analyst to analyze samples within the prescribed holding times and/or inform their supervisor of any potential problems regarding holding time considerations.

(3) Fill bottle or vial to the top, leaving no air bubbles.

(4) When filling a 1-liter glass bottle for oil and grease analysis, approximately one inch of air space should remain inside the bottle. Do not overflow the bottle with sample because in doing this, the oil and grease phase, being lighter than water, may flow out of the bottle and be lost.

(5) Glass, one-liter bottles, rinsed with acetone and hexane prior to sample collection.

(6) Each sampler will also receive 2 dated and numbered trip blanks, filled with organic free water, for each day of sampling. These blanks are always kept with the sample vials and turned in to the laboratory with the filled sample vials. These blanks are to show if there is any contamination of the vials while they are in the field. The identification number on the trip blank should be placed on each analysis request form for every sample associated with that travel blank. Samples will be rejected when the date on the blank is more than 14 days old.

(7) Metal analyses require an additional amount of sample for quality control measures mandated US EPA and NJ DEP laboratory certification regulations. To correct for this additional volume, determine the volume of sample needed for the metals being requested using the amounts cited in Table 5-1 and the Charts 1 and 2 below and calculate a corrected sample volume as follows:

a. If the sample is less than one liter, multiply by 2 and submit this volume as the corrected volume. However, a minimum sample volume of 500ml of sample is required.
b. If the sample volume is equal to or greater than one liter, add one liter (for quality control) to the sample volume and submit this as the corrected sample volume.

Chart 5-1
Metal Parameter Groupings

Parameter Grouping	Metal(s)
F	As, Pb, Sb, Se, Sn, Tl
D	Al, B, Ba, Be, Cd, Cu, Cr, Co, Fe, Mn, Mo, Ni, Ag, V, Zn
K	Hg
G	Ca, Na, K, Mg

Chart 5-2
Volume of Sample Required for Metals Analyses

Groups	Volume, ml
F	500
D	500
K	250
G	500
F&D, F&G, D&G	1000

NOTES: These volumes apply if the analysis of one or all the metals in the group is requested.
For any full regulatory (Tier I) data package, double the volumes listed above.

(8) Air spaces within the sample must be kept at one inch.

(9) See Table II in 40CFR136 for the new specific requirements that samplers are responsible for conducting in the field.

(10) When requesting the analysis of this parameter, field personnel must also request a chloride analysis and provide the necessary additional sample. ECLS will analyze this additional sample to compensate for a possible chloride interference with these analytes.

(11) Sample extracts may be held for 30 days after extraction.

(12) Plastic and glass bottles used for metal analyses are pre-rinsed in the laboratory with nitric acid followed by double distilled water.

(13) Dissolved metals and dissolved minerals have the same sampling and preservation requirements as total metals and total minerals except that the sample must be filtered immediately after sample collection and prior to the addition of the preservative.

(14) Each vial is preserved in the laboratory with 4 mg of ammonium chloride.

(15) When collecting aqueous semi-volatile samples (pesticides, PCBs, BNAs, and benzidines), three times the required sample volume (three 1000ml containers) must be submitted for one sample per case per day. The additional sample volume is utilized by ECLS for matrix spike and matrix spike duplicate analyses.

(16) Base/neutral and acid extractable organics may be analyzed from a single 1000ml sample.

(17) Samples may be held for 40 days after extraction.

(18) Glass, 250ml amber bottle with Teflon lined cap to which 23mg of ammonium chloride has been added.

(19) Glass, one-liter amber bottle with Teflon lined screw cap, rinsed with acetone. After cleaning and acetone rinse, approximately 80mg of sodium thiosulfate is added prior to field use.

(20) Glass, one-liter bottle with Teflon lined screw cap, acetone rinsed.

(21) Glass, 250 or 500ml, amber bottle, with Teflon lined screw cap.

(22) Although there is no regulated maximum holding time for this parameter, whenever possible, ECLS will hold these samples no longer than 28 days. Samples analyzed after 28 days will be so noted.

(23) When collecting water samples for cyanide, 2000ml of sample must be submitted for one of the samples collected with each daily sampling episode. This additional volume is necessary to carry out quality control measures required by US EPA and NJ DEP laboratory certification regulations.

(24) A dechlorinating agent must be added to the volatile organic sample vials when the water to be sampled is from a chlorinated source. It is not recommended when sampling water from a non-chlorinated source. Accordingly, ECLS maintains a supply of treated and untreated vials. Field sampling personnel should request the appropriately pretreated vials depending on the method of analysis that they are requesting. For US EPA 524.2, the dechlorinating agent is 25mg ascorbic acid. For US EPA 624, the dechlorinating agent is 10mg of sodium thiosulfate

(25) The holding time for US EPA method 608 analysis is 7 days if the pH is between 5.0 and 9.0. If not, the holding time is 3 days.

(26) 40 ml amber glass vial with Teflon lined septum and screw cap. A dechlorinating agent must be added to the vials if the water to be sampled is from a chlorinated source. The appropriate amount for US EPA method 504 is 3mg sodium thiosulfate per 40ml vial.

(27) Sample should be extracted and analyzed within 14 days of collection. The extract may only be held for 24 hours from the time of extraction to the time of analysis.

(28) One-liter, amber glass, screw-capped bottle with silicone-Teflon lined cap. If the water to be sampled is from a chlorinated source, sodium thiosulfate must be added at a rate of 80mg per liter.

(29) The extract must be analyzed within 14 days of extraction.

(30) Sample must be extracted within 14 days of collection. The extract must be analyzed within 14 days of extraction.

(31) 250 ml, amber glass, screw-capped bottle with silicone-Teflon lined cap. If the water to be sampled is from a chlorinated source, sodium thiosulfate must be added at a rate of 20 mg per 250ml bottle.

(32) Sample should be counted during the 2-4 day "counting window" from the time of sample collection.

(33) Sample should be counted after 3 hours and no later than 7 days from the time of sample collection.

(34) Sample should be collected in accordance with the specific Rn-222 in water collection procedures.

(35) One sample from every group of samples submitted to ECLS for oil and grease and petroleum hydrocarbons shall be submitted in triplicate to allow for the completion of precision and accuracy measurements required as part of the quality control measures for this analysis.

SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES FOR SOILS

Measurement	Groupings	Req. Wt., g	Container	Preservative	Holding Time
Fecal Coliform		50	soil jar (1,7)	4° C	6 hours
ABN Extract.		40	Soil jar (2)	4° C	14 days (9)
Aluminum	C	1 (3,4)	Soil jar (5)	none	6 months
Antimony	C	1	Soil jar	none	6 months
Arsenic	C	1	Soil jar	none	6 months
Barium	C	1	Soil jar	none	6 months
Beryllium	C	1	Soil jar	none	6 months
Cadmium	C	1	Soil jar	none	6 months
Chromium-hex	A	1 (3,4)	Soil jar	none	6 months
Chromium-tot	C	1	Soil jar	none	6 months
Cobalt	C	1	Soil jar	none	6 months
Copper	C	1	Soil jar	none	6 months
Iron	C	1	Soil jar	none	6 months
Lead	C	1	Soil jar	none	6 months
Manganese	C	1	Soil jar	none	6 months
Mercury	B	0.2	Soil jar (5)	none	6 months
Nickel	C	1	Soil jar	none	6 months
Selenium	C	1	Soil jar	none	6 months
Silver	C	1	Soil jar	none	6 months
Tin	C	1	Soil jar	none	6 months
Zinc	C	1	Soil jar	none	6 months
TKN		50	Soil jar	none	28 days
Total Phosphorous		50	Soil jar	4° C 7 days	28 days

FOOTNOTES

1. Not filled.
2. Acetone rinsed.
3. Dry weight.
4. At least one sample per group must contain a minimum of 5 g, dry weight.
5. Rinsed with 50% nitric acid.
6. Rinsed with acetone, followed by hexane.
7. A soil jar is a 4 ounce, straight sided glass jar with a Teflon lined cap.
8. At least on sample per case must contain a minimum of 30 g, dry weight.
9. Samples may be held 40 days after extraction. These holding times are from SW 846, 3rd edition.

SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES FOR AIR SAMPLES

Parameter	Grouping	Collection Media	Preservative	Holding Time
Aluminum	D	Cellulose ester	none	6 months
Antimony	D	Cellulose ester	none	6 months

Arsenic	D	Cellulose ester	none	6 months
Barium	D	Cellulose ester	none	6 months
Beryllium	D	Cellulose ester	none	6 months
Cadmium	D	Cellulose ester	none	6 months
Calcium	D	Cellulose ester	none	6 months
Chromium-hexavalent	A	PVC membrane	none	6 months
Chromium-total	D	Cellulose ester	none	6 months
Cobalt	D	Cellulose ester	none	6 months
Copper	D	Cellulose ester	none	6 months
Iron	D	Cellulose ester	none	6 months
Lead	D	Cellulose ester	none	6 months
Manganese	D	Cellulose ester	none	6 months
Mercury	B	Hopcalite	none	6 months
Nickel	D	Cellulose ester	none	6 months
Selenium	D	Cellulose ester	none	6 months
Silver	D	Cellulose ester	none	6 months
Tin	D	Cellulose ester	none	6 months
Titanium	C	Cellulose ester	none	6 months
Zinc	D	Cellulose ester	none	6 months
Silica		PVC filter	none	14 days

FOOTNOTES

1. A maximum of 8 compatible metals may be analyzed from one filter. Sample collectors should consult ECLS to verify that all the requested metals can be analyzed from one filter sample.
2. Three blanks are required with each set of samples submitted.
3. For TEM analysis, one blank filter from each new box of filters must be submitted for analysis prior to field usage. In addition, field blanks are to be submitted with samples at a frequency of one blank per week of samples per inspector. Field blanks are required to ensure that the cassettes have not been contaminated prior to reaching the lab as well as that no cross-contamination has occurred within the lab. Therefore, all field blanks must be labeled "Field Blank".

SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMESFOR BIOLOGICAL TISSUES

Measurement	Grouping	Req. Wt., g	Container	Preservative	Holding Time
Aluminum	D (1)	15	Plastic bag	Freeze	6 months
Antimony	A (1)	15	Plastic bag	Freeze	6 months
Arsenic	A	15	Plastic bag	Freeze	6 months
Barium	D	15	Plastic bag	Freeze	6 months
Beryllium	D	15	Plastic bag	Freeze	6 months
Cadmium	D	15	Plastic bag	Freeze	6 months
Chromium-tot	D	15	Plastic bag	Freeze	6 months
Cobalt	D	15	Plastic bag	Freeze	6 months
Copper	D	15	Plastic bag	Freeze	6 months
Iron	D	15	Plastic bag	Freeze	6 months
Lead	D	15	Plastic bag	Freeze	6 months
Manganese	D	15	Plastic bag	Freeze	6 months
Nickel	D	15	Plastic bag	Freeze	6 months
Mercury	C (1)	15	Plastic bag	Freeze	6 months
Selenium	D	15	Plastic bag	Freeze	6 months
Silver	D	15	Plastic bag	Freeze	6 months

Tin	D	15	Plastic bag	Freeze	6 months
Zinc	D	15	Plastic bag	Freeze	6 months

FOOTNOTES

1. At least one sample per group must contain a minimum of 50 grams.

ECLS also conducts other analyses on samples that do not have regulatory requirements similar to those listed above. In those instances, it is recommended that samples be collected in accordance with the most recent, scientifically accepted procedure. Whenever possible, analyses performed on these samples will be initiated within the corresponding aqueous sample holding time. However, exceeding the aqueous holding times will not invalidate any of the analytical data produced.

ECLS does not collect samples. Samples are collected by field personnel employed by the submitting agency or by a contractor of the submitting agency and delivered to ECLS. The samples are collected according to the procedures contained in the NJ DEP Field Sampling Manual. Other State and Federal agencies also collect samples and deliver them to ECLS. These submitted samples also meet the acceptance criteria contained in this manual unless otherwise specified in **the table below:**

SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES FOR MISCELLANEOUS MATRICES

Measurement	Grouping	Req. Wt., g	Container	Preservative	Holding Time
Lead	Paint chips	1	Zip lock plastic bag	None	6 months
Metals (2)	Wipes		Soil jar or zip lock plastic bag	None	6 months
Metals	Food		As available	Freeze	1 month
Pesticides (1, 4, 6) and PCBs	Milk	10	As available (6)	Refrigerate	1 month (5)
Silica	Bulk		Soil jar	None	14 days

FOOTNOTES

1. As specifically requested.
2. Three field blanks are required with each set of samples submitted.
3. Small (20 ml) or large (4 oz.).
4. Because food samples may be submitted in non-pesticide/PCB clean containers and/or their original container may be made of phthalate containing plastic, analytical problems may occur.
5. This holding time is not a regulated requirement.
6. For scheduled milk sampling, a glass bottle rinsed with acetone then hexane is required. Other containers may cause analytical problems.

The ECLS Manager, or his designated appointee, is available for advice or comments pertaining to the selection and/or modification of sampling methodologies that are required to meet non-routine analytical requests. Upon delivery of the samples to ECLS, ECLS does check the samples to verify that the requirements listed above are adhered to. See section 6-2.

See the description below on how the laboratory staff are informed of specific client information regarding certain specific samples:

INFORMING ANALYSTS OF SPECIFIC CLIENT INFORMATION

There are instances when ECLS is asked to perform an analysis that would constitute a departure from our documented policies or to evaluate whether it is feasible to conduct a new analysis. For each of these instances, it is necessary for both parties to have a clear understanding of each party's desires and what the consequences of any subsequent action would be. Therefore, it is necessary to develop a QAPP to memorialize the decisions reached by the parties.

Sometimes a client may desire to prepare a QAPP for specialized projects and, sometimes, even for routine sampling events. When a client desires ECLS to perform analytical work that is outside ECLS's normal analytical capabilities, a QAPP must be prepared prior to initiating sampling. The following items are addressed by ECLS and the Client when preparing a QAPP:

- Type of samples being submitted e.g., potable water, waste-water, etc.
- The suggested method to be used along with an acknowledgement as to the deficiencies/shortcomings of the method. If the client has a specific analytical method in mind, this should be made available to ECLS since this could shorten the time needed by ECLS to validate the method.
- Requested MDL values. These values will be a driving force to see if ECLS can validate the method at the level of recovery that is being sought.
- MCL or other action levels. If the MCL is too close to the achievable MDL, the method may be inappropriate for the expressed purpose.
- Intended data usage. This is necessary to determine the level of QC that is necessary to be run during the analyses. If enforcement is the objective, then one type of QC would be required. If preliminary information gathering is the objective, then perhaps a less strenuous QC protocol could be used. This determination would influence the type of method validation that would have to be performed.
- Types of QC required. The requested QC may be inappropriate for the intended data usage.
- Whether chain of Custody is requested.
- Turnaround time. This turnaround time is for responding back to the client with data from analytical runs performed on field samples.
- Sampling frequency.
- Date of sampling event initiation. Again, this would play into determining the amount of method validation that is necessary.
- Extent of the event.
- Sampling dates.
- Projected number of samples. If the projected number of samples is too low, it may not be economically feasible to pursue the project.
- Data reporting format. If a format is requested that ECLS currently does not have available, that could have a large impact on the possibility of going forward in a short period of time.
- Listing of any other ECLS and/or submitting agency requirements.
- Agency submitting QAPP.
- Contact person.
- Billing information.
- Sign off by the contact person and the ECLS Laboratory Manager or his designee.

This will allow for no misunderstanding between parties as to what is expected of each party when the uses of non-mandated methods are used to generate analytical data. The QAO will maintain a copy of all the QAPPs.

However, the most likely information that is referred to the analysts deals with sample scheduling and the specifics of the various projects being run by DEP. Informing the analysts of sampling schedules

allows them to prepare for the sampling events and to determine if those events would overwhelm the analytical capacity of the laboratory. Informing the analysts of project requirements makes them aware of any additional information that the analysts would need to be able to handle the project, e.g., knowing that a certain project is scheduled to come in next week and that it will consist of 20 samples that will have to be analyzed according to total and dissolved procedures. This means that 40 analyses would have to be conducted instead of 20, something the analysts should be in the position to prepare for.

PROCEDURE

1. When ECLS Management has been informed of the specifics of a planned project or has signed off on a QAPP, that information is forwarded, by the ECLS Director or his designee, to the section supervisors so they can inform their staff of such.
2. This notification is to consist of a copy of the QAPP or a copy of the correspondence describing the project or a summary of the project specifics. If a project is already underway, then a re-construction of the project specifics must be prepared and distributed.
3. The analysts keep this information for subsequent referrals.
4. When Sample Receiving reviews the collector's paperwork during the sample acceptance process, they must make sure that when samples are submitted under a defined project, that the project is specified on the submittal forms. *ALL REQUESTED ANALYSES MUST BE DOCUMENTED ON EACH OF THE SAMPLE SUBMITTAL FORMS*.

Sample Receiving must then inform the analysts that samples have been received under a specific project. This notification can be accomplished by placing the information on the white board by the receptionist or by emailing the analytical supervisors or by verbally informing the affected analysts, or, if possible, by clearly defining certain Batch Numbers as specific to a project.

5.2 SAMPLE CONTAINERS AND PRESERVATIVES

ECLS changed to single use pre-cleaned plastic polyethylene bottles for most inorganic analyses in early 2004. These bottles meet the preservation requirements for metals, general chemistry and nutrient analyses. These containers may be ordered in case lots or smaller in 1 liter, 500 ml and 250 ml sizes. Client field personnel and laboratory staff may request them from the ECLS sample receiving area located in room L176. Sampling agencies wishing to obtain sample containers and/or preservatives should obtain these items from the sample custodian. If the sample custodian is not present, assistance may be obtained by asking the receptionist to page a staff member that can assist them. The sample custodian will obtain the containers from the bottle storage cabinets. Field sampling personnel are not permitted in laboratory areas other than the sample receiving area. Therefore, if items are not readily available from the storage cabinets, the items will be obtained from other areas of the laboratory by the sample custodian. For a comprehensive description of the sample receiving procedures see the ECLS Sample Receiving SOP (ECLS-SR-1).

5.3 SAMPLE COLLECTION

At the time of sample collection, the appropriate sample submittal form must be completed**.** ECLS has developed three distinctive sample submittal forms with instructions for the three different sample types received by the ECLS Sample Receiving Section. They include bacteriological testing (BACT-44), the inorganic and organic testing (CHEM-44) and radiological testing (RAD-4). These forms are available at www.nj.gov/health or, alternatively, through the department intranet and selecting the nj.gov/health link. Then, tab on "topics A-Z" and pick the letter "F". Click on "Forms" and select the appropriate form.

It is ECLS policy that all samples submitted to the laboratory must be handled on a chain of custody basis, and the submittal of each sample shall be documented on, and accompanied by, its own separate submittal form. Each of these forms includes a chain of custody section which must be completed as discussed below.

Each of the above cited submittal forms (BACT-44, CHEM-44 and RAD-4) include a chain of custody record located on the bottom portion the document. As with all chain of custody documents, these forms must clearly indicate every person who had custody of the sample. This is done by recording the full names (printed) and signatures of each person who took possession of the sample. The names must be legible, and signatures must be present. Failure to meet these criteria would break the chain, and the form would be useless in any court proceeding. ECLS reserves the right to reject any sample for which chain of custody has been compromised and/ or the documentation is incomplete.

At the time of sample collection, the sample bottles are numbered and labeled with the appropriate colored ECLS bottle labels according to the following:

- Light blue: for BOD analyses. The sample collector must note the dilutions required for analysis on the tag.
- Sand: for bacteriology analyses. The sample collector must note the dilutions required for analysis on the tag.
- Lilac: for volatile organic analyses by US EPA Method 524.2.
- Pink: for volatile organic analyses by US EPA Method 624.
- Red: for pesticide and PCB analyses by US EPA Methods 505 and 508A.
- White: for any other analyses.
- White label with green lettering: for trace metal analyses.
- White label with black lettering: for general chemistry analyses.
- White label with orange lettering: for preserved nutrient analyses such as total phosphorous, ammonia, and Kjeldahl nitrogen.
- White label with brown lettering: for semi-volatile organic analyses by US EPA Method 525.2.
- White label with red lettering: for pesticide and PCB analyses by US EPA Method 608.
- White label with pink lettering: for semi-volatile analyses by US EPA Method 625.
- White label with burgundy lettering: Chromium Hexavalent
- White label with rust lettering: EPA Method 507
- White label with brown lettering: EPA Method 531
- White label with brown lettering: EPA Method 515
- White label with red lettering: Cyanide

The sample collector must specify the analyses requested on the tag.
The sample collector also indicates on each label the preservation steps, if any, that have been taken for that container. This is documented in the laboratory by the sample custodian, at the time of receipt. This form is maintained in the batch file folder. The labels are water resistant and completed with indelible ink.

5.4 ALIQUOTS

In taking an aliquot of a submitted sample, the analyst makes sure that the sample is well-mixed, and then uses the appropriate means to obtain a sub-sample, including filtering the sample if required by the method. Regardless of the manner chosen, the transferring agent should be rinsed with the sample prior to taking the aliquot.

5.5 FIELD and TRIP BLANKS

TRIP BLANKS: The trip blank is used to assess the sample transportation mechanism for possible contamination. It contains organic free water that has been sealed in a bottle in the laboratory. It accompanies the sample bottles from the laboratory to the sampling site and back again unopened. It is then analyzed as a "routine" environmental sample.

FIELD and TRIP BLANKS are not required to determine the acceptability of an analytical run. They are used by the data user to determine whether the samples possibly could have been subjected to a contamination source prior to analysis. It is the clients' prerogative to submit, or not, field and trip blanks. It should be clearly understood by the client that these blanks are highly recommended to be supplied with VO samples. They can also be submitted with other types of samples as well. ONLY THE METHOD BLANK IS USED TO DETERMINE THE ACCEPTABILITY OF AN ANALYTICAL RUN.

5.6 FIELD DUPLICATES and "SEQUENTIAL SAMPLES"

In the past, there has been some confusion as to what constitutes a field duplicate. A field duplicate is a sample that has been collected in sufficient volume, in a single container and preserved, and then split between the 2 sample containers prior to their being submitted to the laboratory for analysis. Care must be taken in splitting the sample into 2 separate containers. Each separate sample must be equivalent to each other. As an example, if some sediment is collected into the original sampling container, then that sediment must be included in each of the duplicate samples. If the sediment is only included in one of the submitted samples, they are not true field duplicates. What has been submitted erroneously as field duplicate samples really can be classified as sequential samples. Some sample collectors have described the procedure they use for collecting their "field duplicates." They collect a sample and preserve it and then place that sample in the appropriate sample container. They then collect another sample from the same spot at the sampling location and preserve it and transfer it to the appropriate sample container. They then call these 2 separate samples duplicates.

If the purpose behind submitting field duplicate samples is to place a check on the laboratory's precision in analyzing samples, then true field duplicates, as define above, must be submitted. If the purpose of submitting field duplicates is to test the precision of the sampler's technique, then that cannot be accomplished with the true field duplicate since the sampler is only collecting one sample. It also cannot be accomplished with the sequential samples since two completely different samples have been collected.

CHAPTER SIX
LABORATORY SAMPLE HANDLING PROCEDURES

6.1 SAMPLE SCHEDULING

Routine samples are samples whose analytical requests are based on the "**SAMPLE COLLECTION, PRESERVATION, AND HOLDING TIMES FOR AQUEOUS SAMPLES"** found in Chapter 5. ECLS has specific maximum capacities for certain routine analyses due to limitations in resources, time required to complete certain analyses, quality control requirements and holding time restrictions. The organic methods are most likely to be affected by these concerns. However, other methods may also be affected during periods when sampling loads are heavy. Whenever ECLS approaches the limits of its analytical capabilities, ECLS informs the appropriate clients so they can adjust their sampling schedules. To prevent an over submittal situation from developing, routine sampling projects are scheduled through ECLS Sample Receiving (609-530-2773 or 609-530-2753) at least 48 to 72 hours before the anticipated sampling collection to verify that the capacity exists for the normal completion of the project. As these projects are scheduled, the staff is informed of such so they can be prepared to analyze them in as an expedient manner as possible. Requests for sample bottles, preservatives, etc., used in the collection of routine samples can also be made through the Sample Receiving.

INFORMING ANALYSTS OF SPECIFIC CLIENT INFORMATION

There are instances when ECLS is asked to perform an analysis that would constitute a departure from our documented policies or to evaluate whether it is feasible to conduct a new analysis. For each of these instances, it is necessary for both parties to have a clear understanding of each party's desires and what the consequences of any subsequent action would be. Therefore, it is necessary to develop a QAPP to memorialize the decisions reached by the parties (see Chapter 1).

However, the most likely information that is referred to the analysts deals with sample scheduling and the specifics of the various projects being run by DEP. Informing the analysts of sampling schedules allows them to prepare for the sampling events and to determine if those events would overwhelm the analytical capacity of the laboratory. Informing the analysts of project requirements makes them aware of any additional information that the analysts would need to be able to handle the project, e.g., knowing that a certain project is scheduled to come in next week and that it will consist of 20 samples that will have to be analyzed according to total and dissolved procedures. This means that 40 analyses would have to be conducted instead of 20, something the analysts should be in the position to prepare for.

PROCEDURE

1. When ECLS Management has been informed of the specifics of a planned project or has signed off on a QAPP, that information is forwarded, by the ECLS Service Director or his designee, to the Program Managers so they can inform their staff of such.
2. This notification is to consist of a copy of the QAPP or a copy of the correspondence describing the project or a summary of the project specifics. If a project is already underway, then a re-construction of the project specifics must be prepared and distributed.
3. The analysts keep this information for subsequent referrals.
4. When Sample Receiving reviews the collector's paperwork during the sample acceptance process, they must make sure that when samples are submitted under a defined project, that the project is specified on the submittal forms. *ALL REQUESTED ANALYSES MUST BE DOCUMENTED ON EACH OF THE SAMPLE SUBMITTAL FORMS*.
5. Sample Receiving must then inform the analysts that samples have been received under a specific project. This notification can be accomplished by emailing the analytical supervisors or by verbally

informing the affected analysts, or, if possible, by clearly defining certain Batch Numbers as specific to a project.

All non-routine samples, samples whose analytical requests are not based on Chapter 5 collection criteria or are intended to be submitted under priority or emergency turnaround times, must be scheduled through the ECLS Sample Receiving Supervisor (609-530-8728), or Laboratory Director (609-530-2803), at least 48 to 72 hours before the anticipated sample collection.

As sampling events are scheduled, the number and types of bottles that will have to be distributed for each event and the date of bottle pick-up are entered into the ECLS laboratory information management system (LIMS), referred to as Element, by the person scheduling the event.

Sample submitters should be aware of ECLS analytical capabilities and submit only samples that ECLS can analyze completely. If questions arise regarding ECLS capabilities, those questions are discussed with the ECLS Service Director prior to submittal. If ECLS cannot meet the analytical needs of the submitter, the submitter should make other arrangements to meet their needs. In some case ECLS may sub-contracts with other laboratories.

6.2 SAMPLE ACCEPTANCE CRITERIA AND ROUTINE SAMPLE RECEIVING

All samples submitted to ECLS for analysis are logged-in at the sample receiving area, located on the first floor Room L176. The sampler accesses the sample receiving area in the rear of the laboratory. S/He is then met by the receiving staff and the samples are processed. ECLS's sample custodians are available from 8:00 AM to 4:00 PM Monday through Friday. However, samples may be submitted outside of the sample submission hours listed above. Special arrangements should be made through the Sample Management Office as early as possible prior to sample submittal so that a sample custodian may be scheduled to receive the samples. At No Time Are Non-Laboratory Personnel Permitted in the Laboratory Beyond Room L176, Unless Approved by the ECLS Service Director and Accompanied by ECLS Staff.

SAMPLE ACCEPTANCE CRITERIA AND ROUTINE SAMPLE RECEIVING

ECLS has trained personnel whose primary function is receiving samples. Only those people who are trained in the specific functions that they are performing are authorized to receive samples. The sample custodians perform a review of the sample acceptance criteria and, if all the criteria are fulfilled, will take possession of the samples and log the samples into the Element. Refer to ECLS Sample Receiving SOP (ECLS-SR-1) for a more detailed description of sample log-in procedure.

6.3 CHAIN OF CUSTODY LOG-IN

The analytical results of some samples submitted to ECLS for analysis have the potential of being submitted as evidence in a court of law. These samples are considered physical evidence and, as such, their possession must be traceable from the time the samples are collected until they are introduced as evidence in legal proceedings.

A sample is considered under an individual's custody if:

a. It is in their possession.
b. It is in their view after being in his possession.

c. It is in their possession and then is locked up to prevent tampering, or
d. It is in a secure area. A secure area is one where access to a sample can only be achieved by a representative of ECLS.

CHAIN OF CUSTODY LOG-IN

The chain of custody documents the movement and possession of samples from the time they are received by ECLS until all analyses are completed. All samples are maintained using a chain of custody protocol. However, the chain is assembled and reviewed for only those samples that ECLS is legally or contractually required to do so. Routine sample chain of custody documentation can be provided if requested by the client. The bottom portion of each sample submittal form functions as the External Chain of Custody. Upon receipt of the sample the sample custodian signs the COC section of the sample submittal sheet signifying that the sample custodian has taken custody of the designated samples on behalf of ECLS. The samples are transferred immediately by the sample custodian to the designated COC refrigerator(s). However, in the case of COC samples requiring pH, or other analyses with limited holding times, the sample custodian may immediately distribute the sample bottle(s) for the parameters to the appropriate analyst and have the analyst sign the Internal COC form generated by element and signed by both to document the transfer of the sample. The COC forms are maintained in A465.

There are several ECLS Sample Receiving personnel who function as sample custodians. Receipt of samples by one custodian is equivalent to receivership by all the custodians. This is considered the sample receiving work cell.

INTERNAL CHAIN OF CUSTODY

Internal Chain of Custody forms document the movement and possession of samples from the time that are received by the ECLS testing program staff until all analyses are completed. The internal chain of custody is documented in Element and a copy is printed out and signed by both the sample receiving staff and the analyst during the sample transfer process.

The date and time of transfer are documented by the element generated internal chain of custody.

6.4 SAMPLE REJECTION

As stated above, samples and their corresponding paperwork are checked and reviewed during the sample receivership process. Errors that are found that adversely affect the quality of the analytical data will result in the sample custodian "rejecting" the sample and therefore, the sample will not be analyzed.
The sample custodian will reject samples and fill out a sample rejection form when samples are submitted under the following instances:

a. Sample was not properly preserved (stamped "NPP"). This includes those instances when:
   - The preservative was not added at the time of collection.
   - Insufficient preservative was added.
   - Too much preservative was added.
   - The preservative used was not indicated on the sample bottle, or
   - An improper preservative was used.
b. The sample was not properly labeled (stamped "NPL"). This includes those instances when:
   - The wrong sample ID number is affixed to the sample bottle.
   - The wrong sample bottle tag is affixed to the sample bottle.
   - The sample ID numbers on the sample analysis request form and sample bottle tag (also COC form, if used) do not match, or
   - No sample ID number and/or sample bottle tag is affixed to the sample bottle.

c. Samples were submitted in an improper container (stamped "IPC"). This includes those instances when:
   - Samples are submitted in plastic containers when glass bottles are required, or vice versa.
   - Sample bottles were not properly prepared before sample collection, or
   - Sample bottles with screw cap lids do not have the required Teflon inserts.

d. Sample exceeds holding time. This is used on samples that are submitted to ECLS for the analysis of a parameter whose holding time has already been exceeded.

e. Sample will exceed holding time (stamped "Sample will exceed the recommended holding time for the parameter before the analysis can be performed by the ECLS laboratory"). This is used when samples are submitted to ECLS within the holding time for the analysis of a parameter but whose holding time will be exceeded before ECLS can initiate the analysis. Sometimes samples are submitted that possibly may not be analyzed before the holding time requirements are exceeded. These samples/analytes will not be rejected since ECLS will do whatever it can to analyze these samples within holding time considerations. However, if the analyses cannot be analyzed in a timely enough manner, the resultant data will be qualified as questionable. A notation will be made on the sample submittal form at the time of submittal as to which analyses may be in jeopardy. Only in those instances where it is a fact that the analyses cannot be completed in time will this rejection citation be used. For example, an unpreserved VO sample has a 24 hour holding time. Since ECLS has to honor its prior commitments for the analysis of scheduled VO analyses and since these commitments are on a tight time line and scheduled sometimes months in advance, ECLS could not analyze the unpreserved sample before the holding time will expire. That sample would be rejected.

f. Samples submitted for bacteriological analysis that are received after 3:45 PM cutoff time (stamped "Sample delivered to ECLS laboratory after the 3:45 cutoff time").

g. Samples will also be rejected for other reasons affecting analyst safety, data quality and/or reliability, such as:
   - Date and time of sample collection and/or name of sample collector are not indicated on the sample analysis request form.
   - Sample bottle not submitted for the requested analysis.
   - Sterile bacteriological sample bottles exceed the expiration date indicated on the sample bottle.
   - Samples submitted for VO analysis contain air bubbles in all vials of a sample set. If only some of the vials contain air bubbles, the sample is accepted and the presence of air bubbles in some of the sample is so noted in the comment section of the sample analysis request form and the COC form, if present.
   - Air and wipe samples submitted for metal analyses without the required blanks.
   - Samples submitted in chipped or cracked bottles that pose a safety risk.

6.5 SAMPLE REJECTION OVERRIDE

Samples rejected under the procedures described above should not be analyzed due to the resultant data being of questionable quality. However, in some instances the requesting agency may feel that the resultant data may still be of value even though it may be of questionable quality.

a. At the time of sample rejection, a sample rejection form is completed by the sample custodian.

b. The sample collector must then indicate to the sample custodian that they are requesting that the rejection be overridden and that the sample analysis can proceed.

c. The sample collector must confirm this request by signing in the appropriate place on the sample rejection form.

d. This signature authorizes ECLS to proceed with the requested analysis, report the results when available, and qualify the data where necessary.
e. Samples analyzed under the rejection override process will be billed to the sample submitting agency following normal billing practices. The resultant data will be qualified as appropriate and reported. The rejection override form is maintained in the batch file folder.

6.6 ROUTINE SAMPLE HANDLING

Analysts can determine what samples have been received and which tests have been scheduled by querying the Element database and creating a work list. Analysts should perform this function every day to ensure they keep themselves abreast of the current work queue.

Analysts generate work lists (lists of samples that are available for testing) using the *"Query Analysis Status"* module. This module is opened via a drop-down menu by clicking on *"Laboratory"* on the main Element menu. The analyst then clicks on *"Query Analysis Status"* which opens the *"Query Analysis Status"* window. This module allows the user to query the database in several ways.

One of the more common queries is to search by analysis. The analyst selects the analysis of interest, sets the date range for the query and selects the statuses ("received" or "available") to be searched. When selecting the date range the analyst needs to make sure he spans an appropriate range so as not to miss any samples.

Once the analysis, date range and status have been selected the analyst clicks on the query button and a list of samples that meets the search criteria is generated. Samples listed in the "received" status have been received but have not yet been cleared by sample receiving staff for analysis; those that are in the "available" status have been cleared and need to be tested at the analyst's earliest convenience.

The results of the query can be sorted by selecting the various criteria in the three selection boxes displayed under "Order Results By." Element provides three sort levels. The results of the search will be displayed in the display area at the bottom of the window.

The results may now be printed in the form of a work list by clicking on the "Print" button.

Once the daily analytical workload has been determined, the analyst draws an aliquot of that sample from the appropriate sample container, or in cases where the analysis requires a separately prepared or preserved bottle, the analyst takes the bottle with them to the workstation. If the analysts note any abnormalities with the sample, like those listed in the **SAMPLE ACCEPTANCE CRITERIA AND ROUTINE SAMPLE RECEIVING See Chapter 5**, they list the abnormality in their analytical documentation. These observations may or may not be used to qualify the resultant data. However, this information would be invaluable to help determine the reason for any results that may be questioned in the future. The aliquot, or bottle, remains with the analyst, or the analyst's cell, until the analysis is completed. If a digestate etc. is produced during the analysis and must be kept overnight, the analyst follows the storage recommendations listed in the method. If no recommendations are provided, the analyst will store the digestate etc. in a manner that will not adversely affect the analysis.

As the analytical results are produced, they are reviewed by the analyst and uploaded to Element. The supervisor then reviews the raw data and approves the results in Element.

Prior to the preparation of the final report packages, the general chemistry and metal results undergo a final review by their respective section supervisor or designee. In the general chemistry section, a printout of the results, that were entered the previous week, is reviewed by the supervisor and any discrepancies are corrected. For the metals section, Data Management prints a listing of the sample results entered since the last time the

program was run. This listing is then checked against the analytical instrument output records to ensure that no transcription or other errors were made.

Organic reports are reviewed by the technical supervisor prior to their being turned over to Data Management.

Once the laboratory supervisor is satisfied, the final reports are printed out by the data management section. When all requested analyses are completed, and the final reports are received by data management, the data management staff assembles the reports into a complete package which is logged out and forwarded to the requesting agency. At this time, the remaining portions of sample are discarded, and the bottles are sent to Central Services area for cleaning, unless *long term storage of the samples has been requested at the time of sample submission.*

6.7 CHAIN OF CUSTODY SAMPLE HANDLING

COC samples are received and logged-in by the sample custodian in room L176 with the appropriate internal COC forms being generated from Element to document sample transfer when an analyst needs an aliquot or sample container, a sample custodian witnesses the analyst drawing his aliquot or taking the sample container. The custodian then documents the transfer of custody by signing into Element and generating the internal COC (ICOC) form. The ICOC is signed by both the analyst and sample custodian. The internal COC stays in sample receiving and is transferred to a permanent file in data management. After the Sample is in the custody of the analyst the ICOC is maintained by the following mechanisms:

- The analyst signing the COC form will keep the samples in his possession, as per section 6.5, until another analyst in his work cell (see definition below) takes possession of the sample.
- This change can be for digestion, distillation, sample analysis, etc. and is documented by completing the forms for the specific process (digestion log, extraction log, Bench Sheet, Sequence Analysis) in the particular analytical unit by the person taking possession of the sample.
- Data entry into the laboratory information system and subsequent review is automatically recorded in element when the individual logs in and performs the process.
- All the above changes in possessions are dated when they occur.

WORK CELLS
Work cells are analytical units that perform the same types of analyses on submitted samples. There are 5 separate work cells. (Sample Receiving, Organics, Inorganics, RADs and Sanitary Bacteriology.) that do not share their bottles with any other operational unit within ECLS. The sample bottles remain in the possession of the work cell until disposal.

6.8 SAMPLE STORAGE

Samples are stored away from standards, reagents, food, and other potentially contaminating sources to prevent any type of cross-contamination. Samples are stored according to their preservation protocols until such time that a final report has been sent to the sample submitter. If special sample storage conditions were arranged for at the time of sample submittal, or within one week of submittal, such as, long term storage for up to one year, the requested storage will be implemented. If no prior arrangements were made for storage, the samples are when the final reports are mailed.

Sample extracts, distillates, etc. are stored as per method requirements until the analyses are completed.

6.9 PROCEDURES FOR SAMPLE DISPOSAL

When analyses are completed, the analysts return their sample bottles/containers to their designated storage areas. Each analytical group is responsible for managing and discarding its own sample containers. Once it has been determined that the results for a sample have been reported and there is no longer a need to retain the sample, it can be disposed. As soon as the sample is disposed, a record documenting the disposal must be created.

This record of disposal is created using barcode scanners that are strategically located throughout the laboratory facility. The barcode scanners are interfaced to the laboratory information management system (LIMS). When a sample is disposed, the empty container is immediately scanned by the personnel performing the disposal. Each sample container that ECLS receives is labeled with a barcode upon its submittal. When the container is scanned, the sample information encoded within the barcode is automatically read into the laboratory's information management system (LIMS). This updates the container's status to "disposed" within the LIMS. Additionally, the LIMS database is updated and can be queried at any time to determine who disposed the container and when it was disposed. The LIMS can also be used to generate printed lists of disposed sample containers for purposes of documentation.

Digestates are discarded down the drain. Extracts are discarded as organic waste. Inorganic distillates, except for cyanide, are discarded down the drain. Cyanide is discarded as hazardous waste only if the sample tested positive for cyanide. Organic distillates are discarded as organic waste. More detailed analyte specific instructions for sample and waste disposal are available in the individual method SOP.

6.10 NON-ROUTINE PRE-LOGIN SAMPLES

Pre-login samples are non-chain of custody samples that are electronically logged in usually prior to the samples arrive as this is a spreadsheet driven process. This process is described an appendix in SR-1 SOP and is currently under development.

CHAPTER SEVEN
ANALYTICAL METHODS

7.1 LABORATORY METHOD MANUALS

ECLS has in-house method manuals detailing the exact procedures employed for each accredited analyte or test procedure. Each analyst has access to the electronic versions of the Standard Operating Procedures (SOPs) and reference methods for which they conduct analyses, in addition to the current Quality Manual. Each analyst may print a copy.

Each method manual is arranged according to the following chapter sections:

1. Identification of the test method.
2. Applicable matrix or matrices.
3. Detection limit.
4. Scope and application, including components to be analyzed.
5. Summary of the test method.
6. Definitions.
7. Interferences.
8. Safety.
9. Equipment and supplies and maintenance.
10. Reagents and standards.
11. Sample collection, preservation, shipment, and storage.
12. Quality control.
13. Calibration and standardization.
14. Procedure.
15. Calculations.
16. Method performance.
17. Pollution prevention.
18. Data assessment and acceptance criteria for quality control measures.
19. Corrective actions for out of control data.
20. Contingencies for handling out of control or unacceptable data.
21. Waste management.
22. References.
23. Any tables, diagrams, flowcharts and validation data.
24. Appendices

REQUIRED ELEMENTS FOR STANDARD OPERATINGPROCEDURE MANUALS

The following items must be addressed in all ECLS method SOPs. This list of required elements is presented so that each ECLS SOP contains the same type of information located in the same section of the SOP. This list is not meant to represent the entire gamut of information that may be necessary to accurately describe the "exact procedure" that is being delineated in each specific SOP. Only the combination of the analysts and section supervisors can make the final determination as to what additional information is necessary. The finished SOP must contain all the pertinent information necessary to completely and accurately describe the entire analytical procedure and the responsibilities of the analysts and supervisors. Sufficient detail must be included so that an auditor is able to read the method, be able to follow what is written, and verify that the method is being executed correctly without further explanation from the analyst.

Some information that must be included in the SOP may change over the time that the current revision is in effect, e.g. the DOC, MDL values, and RL values. By placing this type of information in the method appendix,

only that appendix would need to be updated. If a change is made to the Appendix information during the period that the SOP is in effect, keep both old and new appendices with the SOP. The new information should contain a statement that this information is replacing the previous information along with the date that the change took place. When the SOP is next revised, only a copy of the newest information is incorporated in that version, the Appendix revision number is updated.

The designation of the in-house method must include the assigned in-house name and the revision number. Whenever a request is made for the method that is used to perform an analysis, both pieces must be provided.

Some of the following sections require the presentation of information that may be more easily listed as an Appendix to the method rather than in the body of the method. When situations like this arise, a reference to that Appendix is to be listed in the appropriate section.

The header information for each page of the SOP must include:

- The name of in-house method.
- The date that the in-house method was first prepared.
- The revision number of the SOP.
- The revision date for the most recent version of the SOP. The revision date is the date that the method updating was completed and forwarded to management.
- In either the header or footer of every page, including the cover page, that this page is "page x of the total number of pages."
- The physical address of laboratory where the analyses/calibrations are being performed. A brief definition of the method, for example, determination of metals by ICP-AES, determination of volatile organics by GC/MS, etc.
- A space for recording the effective date of the current revision.

Section 1 Identification of the Test Method must include:

- The types of analyses that the method is used to conduct.
- The in-house method name which includes the ECLS designation and the current revision number of the method.
- A listing of the reference method(s) that the in-house method is based upon and where those reference methods can be found in the laboratory either the hard copy or electronic version of that method.
- If all the acceptance limits listed in the in-house method are obtained from the reference method, a statement to that affect can be made in this section. If all the acceptance limits are not obtained from the reference method, it must be indicated as to where or how that limit was obtained or generated then whenever an acceptance limit is listed.

Section 2 Applicable Matrix or Matrices must include:

- All the matrices for which ECLS is currently employing this method. The only matrices that can be listed are those for which the method has been approved for use by USEPA, NJDEP, or some other nationally recognized compendium of analytical methods.

Section 3 Method Detection Limits must include:

- A listing of the current MDL values and the MDL completion date. A reference can be made that the completion date is listed on the summary report and listed in an Appendix.

- The procedure used to determine the MDL values. This section must be written out to document the exact procedure that was used to generate the values and must include: decision rationale used during this process, including the decision used to terminate the process, the formulas used to perform the calculations, the number of replicates used, and the Student t value employed. The Student t values are listed in Appendix B of 40CFR136.
- The raw data used to make the MDL determinations. Raw data is all the chart recordings, instrument printouts, or data generated for determining MDL. A Summary Report of this information can be listed in an Appendix along with a statement indicating where all the raw data is located that was used to generate that information.
- When using a previous MDL value as the starting point for the generation of a new MDL, the evaluation criteria used to determine if the new calculated MDL is acceptable, must be included in the SOP. This could be statement such as, "If the new MDL value is +/-20% of the previous value, it is acceptable."
- List the RL value for the method along with calibration range employed for typical routine analyses.

Section 4 Scope and Application must include:

- A listing of the symbol or abbreviation used to identify the parameter in the raw data. Each such abbreviation must be defined as it is used in-house.
- Some form of designation indicating which of the parameters, that are currently being analyzed for by ECLS, were not listed in the reference method as being a parameter that was initially included in the reference validation of the method by the method developer. This would include those parameters that were explicitly requested by DEP to be added to the analytical process as well as any parameters that were requested by other clients and parameters that were added by ECLS to provide "analytical capability" for the clients. If ECLS is only analyzing parameters that were originally contained in the reference method, a statement to that effect must be made here.
- A listing of the Maximum Contaminant Levels (MCL) for the compounds that have an established MCL. It is necessary to list these MCL since obtaining analytical values that exceed the MCL requires that ECLS take appropriate steps to notify the client of such an incident.

Section 5 Summary of Method must include:

- A summary of the process, both manual and instrumental, used to conduct the analysis.

Section 6 Definitions must include:

- Only those definitions used to explain the terms used in that SOP should be included. Terms used by outside agencies need not be included.
- The terms being defined in this section must be correlated with the proper unit nomenclature**.**

Section 7 Interferences must include:

- A listing of the potential sources of interference that could affect the analytical accuracy of the generated data along with the steps that are/could be taken to eliminate/lessen the effects of that interference. If a previously defined data qualifier does not exist for the situation, documentation can be made using a "custom qualifier."
- A statement is to be made indicating that the definitions of the previously defined, routine qualifiers are in the QM.

Section 8 Safety must include:

- A listing of the general safety precautions taken by the analysts along with any safety precautions specific to the analysis.
- Location of the Safety Data Sheets (SDS).

- A listing of the hazardous chemicals used along with a listing of the "Health Effects", "Target Organ", "Incompatibilities", and any special safety precautions that must be employed when handling a particular chemical.

Section 9 Equipment, Supplies, and Maintenance must include:

- A listing of the specific equipment and supplies used to perform the analyses along with their instrument identification numbers. The instrument identification numbers are those numbers that are assigned to the instruments based upon the naming system contained in the QM. A statement should be made indicating that the identification of the various components that comprise the instrument are listed in Appendix 17, separate documents associated with the QM. Appendix 17 is kept updated by the Program Manager.
- A listing of the manufacturer's required preventive maintenance and frequency. If this information is not contained in the instrument manual, it must be obtained from the manufacturer in writing. List all the maintenance activities and the frequencies at which these activities are performed by the analysts that are separate from those that are required by the manufacturer. If there are no manufacturer required routine maintenance activities necessary for the upkeep of the instrument, this should be so indicated. A listing of the "as needed" maintenance activities should also be included along with the observations that would be seen that would indicate that these "as needed" activities would have to be performed.
- A reference to where these maintenance activities are documented such as the run logs, instrument maintenance logbooks, in Element. If these activities are documented within the body of a run log, the activities should be highlighted to make them easy to recognize when an audit takes place.
- A reference to where the manufacturer's instrument manuals are kept.

Section 10 Reagents and Standards must include:

- A listing of the reagents used in the preparation of the samples for analysis including their quality grade and vendor. Since it is possible that the vendor may change during the time that the current version of the SOP is in effect, the term "or equivalent" may be added. The next SOP revision may include the name of the new vendor with or equivalent
- A listing of all the stock standards purchased along with the name of the vendor and the initial parameter concentrations. As in the item immediately above, the term "or equivalent" can be added.
- A listing of any intermediate standard solutions, the parameter concentrations, the procedure used to prepare the solution, and the "equipment type" used to perform the preparation, such as, syringe, pipette, etc.
- A listing of the final standard solutions, the parameter concentrations, the procedure used to prepare the solution, and the "equipment type" used to perform the preparation. To provide sufficient information to verify that the preparation and calculations associated with those preparations are correct. This documentation will also show traceability back to a nationally recognized standard.
- The use of the prepared standard solutions, e.g. initial calibration, continuing calibration, internal standard, control samples, interference check, reporting level check, etc.
- A reference to where to where the manufacturers' Certificates of Analysis are maintained.
- A listing of the length of time that the item can be used while maintaining its viability is to be made for all the prepared solutions and standards. If this information is not contained in the reference method or by the manufacturer**,** the specifics of assigning a usage time to material are addressed in the QM.

Section 11 Sample Collection, Preservation, Shipment and Storage must include:

- The type of container that must be used for sample submittal.
- The volume of sample that is necessary to perform the initial analysis, dilution analysis, if needed, and the requisite quality control analyses.
- The type of preservation that is required.

- Where are samples stored when they are picked up from Sample Receiving.
- How and when unused samples are discarded along with the disposal of the sample bottle.
- Holding times: before the analysis is initiated, after initiation; e.g., the analyst may have a 7-day period in which to extract a sample but after the extraction is completed there may be another 28-day window in which to complete the analysis.

Section 12 Quality Control must include:

- A listing of all QA/QC checks, e.g. blanks, performance check solutions, quality control solutions, laboratory duplicates, LFM and LFMD, spectral interference checks, reporting level checks, internal standards, check sources, background checks, etc. along with their intended uses, acceptance ranges, the frequency of their inclusion within the daily run, and designations as to which of these items are used to determine whether the analytical sequence can begin or not. A listing of the analytical sequence that is employed during the batch analysis.
- A listing of the data that is recorded on control charts along with the frequency of chart updating and supervisor review.
- A listing of the steps used to determine if peak tailing is a problem and how is the tailing problem overcome and documented. There may be certain instances that occur more frequently during a specific analysis that would necessitate this determination.
- A listing of reasons why a manual integration may be performed and how such manual integrations are conducted and documented.

Section 13 Calibration and Standardization must include:

- Describe the process for the initial calibration: the number of standards analyzed, the minimum number of standards that are necessary for completing the calibration process, the acceptance criteria for a valid calibration, the source for the acceptance criteria (reference method, DEP requirement, in-house limits, etc.) and the time for which the calibration is valid.
- Describe the conditions under which a calibration point that is determined to be an outlier, may be dropped to achieve the required R^2 value. Dropping a point just to achieve an acceptable correlation coefficient is unacceptable. The basis for determining how the point was determined to be an outlier must be included in the SOP. Describe the continuing calibration check (CCC) process (for those methods that require one), the acceptance criteria for the specific compounds, and the number of CCC that may fail before the method is determined to be "out of compliance."
- A listing of the parameters that are being analyzed by the method along with the concentration range over which the analysis of each parameter is being conducted; i.e. concentration range over which the calibration curve is constructed.

Section 14 Analytical Procedure must include:

- The process for picking up your samples from Sample Receiving.
- The process for preparing the samples for analysis.
- The process for preparing the instrument to conduct the analysis.
- The conditions that the instrument adheres to during the analytical run.
- A listing of the analytical sequence showing the order in which the calibration standards, QC samples, blanks, and samples are analyzed during a normal analytical run. This may be entered in an Appendix.
- A listing of the items that must be checked during the run to verify that the instrument is still operating normally. A statement can be made indicating that this information is contained in sections 12 and 18 of the QM.
- A description of the process used to report results to the Data Management for entry into Element.
- For those methods that rely entirely or partially on the use of Retention Time (RT) windows for the identification of analytes, the source of the RT must be specified as well as whether the RT are strictly

adhered to all times, whether the RT are recalculated at certain specified periods, or whether they are adjusted from run to run.

- A breakdown of the analytical responsibilities for those analysts associated with the production of the analytical results

Section 15 Calculations must include:

- Describe how the calibration curve is prepared (i.e. by the instrument software, linear or quadratic equations, by analyst, etc.).
- List the formulas used to prepare the standard curves and to calculate the sample and QC sample results. For methods established prior to January 2008 for which the instrument performs these calculations, the inclusion of this information is not required.
- List the formulas used to calculate percent recovery, relative percent difference, and percent difference for serial dilutions along with any other calculations that must be performed as part of the analytical process.
- Describe the process used to calculate the error associated with radiochemical analyses.

Section 16 Method Performance must include:

- List the type of sample that the analyst analyzes to document their DOC and the acceptance limits that are used to show this capability. When using a PT result for a procedure that has multiple analytes to show continuing DOC, list what will constitute an acceptable demonstration, e.g. 80% correct.
- List the frequency at which the DOC is performed, annually and after there is a change to the instrumentation or when the instrument is moved.
- The analyst certification statement (obtained from OQA), and the summary statements for the DOC can be listed as an Appendix to the SOP.
- A listing of the accuracy and precision statements for the method.

Section 17 Pollution Prevention must include:

- Describe the process used to discard non-hazardous digestates, extracts, samples, and/or byproducts. Discarding of hazardous waste is addressed in Section 21.
- Describe the process used in the laboratory for cleaning up spills that occur in the laboratory.

Section 18 Data Assessment and Acceptance Criteria for Quality Control Measures must include:

- List the analyst and supervisor responsibilities for determining whether the “in-control” status is achieved, for: initial calibration, CCC, surrogate analysis, instrumental check analyses, blank analyses, duplicate analysis, control sample analysis, Lab Fortified Matrix/LFM Duplicate analyses, and RL check analyses if the results fall outside of the acceptance limits listed in Section 12.
- List the data qualifiers that can be used for the analysis and conditions under which they are used.
- Describe the process used to determine the acceptance of the entire analytical run or portions of the run, based on the results of the QC information generated during the run.
- Describe the responsibilities of the analyst and supervisor in the data assessment process.

Section 19 Corrective Action for Out of Control Analyses must include:

- List the analyst and supervisor responsibilities for determining the cause of the isolated failure of the analyses to achieve “in-control” status.

Section 20 Contingencies for Handling Continuing, Persistent Out of Control Analyses must include:

- A statement can be made indicating that this process is defined in the QM**.**

Section 21 Waste Management must include:

- Describe the process used by the analyst to discard those materials that are designated as hazardous waste from the laboratory work area.
- List the items that are used in the analysis or generated by the analysis that are deemed to be "hazardous waste." To make this determination, consult the PHEAL Safety Officer.

Section 22 References must include:

- A listing of where the reference method can be found or from whom it was obtained.
- A listing of other sources of material used in the preparation of the SOP.

Section 23 Tables, Diagrams, and Flowcharts must include:

- Any materials that fit the heading.

Section 24 Appendices must include:

- A listing of the different appendices and the type of information that is contained in each one.

7.2 CHEMISTRY METHODS

SOPs are to be maintained on the Qualtrax Document Management System beginning January 2019.

7.3 DEPARTURES FROM DOCUMENTED POLICIES AND PROCEDURES

Occurrences that have an immediate and profound effect on the health of the citizens of New Jersey have resulted in samples being delivered to ECLS for analyses. Similar incidents may arise again where ECLS will be required to conduct analyses that fall outside of its established and documented policies and procedures, i.e. test a matrix not ordinarily analyzed, test a matrix that is ordinarily analyzed but for compounds not routinely tested for, or use methods for which ECLS has no practical experience. The Agency requesting these emergency analyses of samples must bring this request to the attention of the both the Laboratory Director and the Service Director of ECLS; and be able to provide the following: nature of the emergency, suspected cause, nature of the injuries caused, matrix, type of testing requested, and data quality objectives. ECLS Management will determine if the service can assist the Agency in any manner. If ECLS can not accommodate the request, the ECLS Service Director will prepare a document indicating the specifics of the request and the reasons for ECLS's decision not to accept the samples in question.

If ECLS can accommodate the request, the analyses will be performed under the supervision of the appropriate Technical Supervisor. The Program Manager will prepare a document listing: the specifics of the request, steps taken by ECLS to perform the analysis including the quality control measures used, how well the data met the data quality objectives, and providing an indication as to the quality of the data provided. This document will accommodate the reported data or, if it is not practical to do so, will be forwarded to the Agency as soon as possible after the reporting of the data.

NOTE: data may have ECLS's normal data qualifiers, however on the report and in the case narrative it must noted that this is not a certified method.

Another way ECLS may conduct analyses that are outside of its currently established policies and procedures is if a request is made to go strictly to a Performance Based Methodology. If this type of request is made, the requesting Agency must submit a QAPP. This will allow ECLS to determine if it can accommodate the request and to select the method that will give the Agency the type of data for which they are asking. After establishing a specific QAPP, this can then be incorporated into the routine analytical capabilities of ECLS.

NOTE: data may have ECLS's normal data qualifiers, however on the report and in the case narrative it must indicated that this data is not from a certified method.

7.4 NEW METHOD EVALUATION

There are times when analyses are requested that require the use of methodologies not usually performed by ECLS. The requested analytical turnaround time determines the amount of methodology validation that can be performed prior to sample analysis. Since it is impossible to say for certain how much lead time ECLS will have to verify a methodology, one cannot list a definitive methodology verification sequence. Listed below are the two "extremes" of methodology verification. The actual steps employed by ECLS most likely will fall between these extremes.

a. When the immediate analysis is requested, the following samples will be included in the analytical scheme: Standards, a set of duplicate spiked blanks, a set of duplicate spiked natural samples, a set of duplicate natural samples, and an OQA control sample, when available. The results will be forwarded without being qualified, to the requesting agency along with all the results of the QC samples. The method will be identified as experimental or non-certified. The requesting agency must make its own judgement as to how much confidence can be placed in the results.

b. When sufficient lead-time is supplied, QC data will be generated before sample analysis begins that will establish: an accuracy statement for percent recovery, a precision statement for duplicate analyses, a target acceptance range for control sample analyses and the analyst's DOC. Data reported under these circumstances will be validated in the manner addressed below. The method validation data will be maintained by ECLS.

New Method Validation Checklist

Method Name
Instrumentation
Method ECLS-X-YY-1

- **SOP** □
- **Accuracy** □
- **Precision** □
- **Interference** □
- **Concentration Range** □
- **Limit of detection** □
- **Quality Control** □

When the use of Performance Based Methods (PBMS) is allowed, each client will be required to submit a Quality Assurance Project Plan (QAPP). See **Chapter 1**.

CHAPTER EIGHT
QUALITY CONTROL

8.1 ROUTINE INSTRUMENT MAINTENANCE AND QUALITY CONTROL

The following is a list of the routine maintenance and QC measures performed by the ECLS staff. For those analyses that require more detailed instrumental QC, those QC measures are contained within the various analytical method manuals.

CONDUCTIVITY METER
Maintenance:

- The cell is cleaned, as needed, with a solution of isopropyl alcohol, ethyl ether, concentrated hydrochloric acid and distilled water.
- The cell is re-platinized as needed.
- The cell is immersed in distilled water when not in use.

Quality Control:

- The conductivity meter is calibrated monthly using a NIST traceable conductivity standard.
- The cell constant is checked monthly using a 0.01M potassium chloride solution.
- The meter is checked daily against two levels of quality control solutions.
- The cell is rinsed several times in distilled water before and after every determination.
- The cell is immersed in the sample several times before the final reading is made.
- A temperature compensating probe is employed during the analysis with the compensated value being digitally displayed.

TURBIDITY METER
Maintenance:

- The light source is changed as needed.

Quality Control:

- The instrument is calibrated quarterly against sealed stabilized formazin standards.
- Sample cuvettes are protected from scratches.
- A constant orientation of the cuvette in the holder is maintained for all the analyses.
- There are no air bubbles in solution during the analysis.
- Samples with turbidity readings of greater than 40 NTU are diluted and re-analyzed.

CONTINUOUS FLOW ANALYZERS (FLOW INJECTION AND BUBBLE SEGMENTED)
Maintenance:

- The pump tubes are changed as needed.
- The pump tubes and coils are cleaned approximately twice per month.
- The pump motor is oiled as needed.
- The light source is changed as needed.
- Back flush the flow cell as needed.
- Check the roller alignment semiannually, if required by the manufacturer.
- Replace the platen annually, if required by the manufacturer.

Quality Control:

- There are no specific quality control procedures for this instrument other than those analytical requirements listed below.

UV/VIS SPECTROPHOTOMETER
Maintenance:

- Change the light source as needed.

- Change the photocell as needed.

Quality Control:

- Absorption cells are kept clean and free from scratches.
- Matched cells are employed where necessary.
- Wavelength alignment is checked annually by the manufacturer under the service contract.
- The instrument is checked annually under a maintenance contract with the manufacturer.

GRAPHITE FURNACE ATOMIC ABSORPTION SPECTROMETER

Maintenance:

- The graphite furnace tube is changed approximately every 3-4 days or as needed. The graphite tube must also be replaced whenever a significant change in sensitivity or replicate precision is observed.
- The quartz lenses are cleaned daily with methanol.
- The graphite contact rings are replaced every 6 months or when a significant change in precision or sensitivity is observed.
- Auto-sampler rinse water is replaced as needed.
- Argon or Ar-H_2 gas is changed as needed.

Quality Control:

- Daily, prior to calibration, a precision test is performed to verify auto-sampler function and instrument reproducibility. If the percent relative standard deviation is ≤ 5, calibration can be performed.
- For daily verification of the calibration standards and instrument performance, a quality control sample (QCS) is analyzed. The QCS is prepared at two concentration levels, SSL (low) and SSH (high). The acceptance limits are ± 10%. If either QCS does not meet the acceptance criteria, the analysis is stopped and the instrument re-calibrated. The SS in this instance stands for Second Standard.

TOTAL ORGANIC CARBON ANALYZER

Maintenance:

- Pump tubing is changed as needed.
- The lithium hydroxide scrubber is checked for moisture and replaced as necessary.

Quality Control:

- Gas flow rate @200cc/min is checked for each day of use.
- IR zero and span adjustment is checked for each day of use.

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

Maintenance:

- The rubber diaphragms are changed as needed.
- The pump oil is changed, and seals replaced as needed.
- Tubing is changed periodically.

Quality Control:

- Instrumental QC is highly dependent upon the analysis undertaken at any time and, as such, is addressed in the method manuals.

GAS CHROMATOGRAPH

Maintenance:

- Change the glass wool at the injection port as needed.
- Change the glass inserts as required.
- Clean the air filters and vacuum dust in and around the GC as required.
- Change the septa as required.

- Change or clean the detectors as required.
- Serviced under a maintenance contract at least once per year.

Quality Control:

- Instrumental QC is highly dependent upon the analysis undertaken at any time and, as such, is addressed in the method manuals.

GAS CHROMATOGRAPH/MASS SPECTROMETER

Maintenance:

- In addition to the maintenance steps listed above for GC, change the pump oil as needed.
- Clean the source as needed.
- Change the air filter on the computer system as needed.
- Checked under a service contract once per year.

Quality Control:

- Instrumental QC is highly dependent upon the analysis undertaken at any time and, as such, is addressed in the method manual.

INDUCTIVELY COUPLED PLASMA SPECTROMETER

Maintenance:

- All peristaltic pump tubing is changed before each use of the instrument.
- The sampling probe is cleaned before each use.
- The sample introduction is rinsed thoroughly before and after each use of the instrument.
- The peristaltic pump rollers are inspected before each use, to make sure they are clean and move freely.
- The purge extension window is checked monthly for fogging and cleaned or replaced if necessary.
- The ceramic interface cone is checked monthly for fogging and cleaned or replaced if necessary.
- Daily cleaning of the low-flow Gem Cone ® nebulizer and cross-flow nebulizer is performed as part of the sample introduction system cleaning.
- Daily inspection of the torch is performed.

Quality Control:

- For daily verification of the calibration standards and instrument performance, a quality control sample (QCS) is analyzed. The QCS is prepared at two concentration levels, SSL (low) and SSH (high). The acceptance limits are ± 5% for SSH and 10% for SSL. If either QCS does not meet the acceptance criteria, the analysis is stopped and the instrument re-calibrated.

COLOR TEST APPARATUS (HELLIGE AQUA TESTER)

Maintenance:

- Light source is replaced as needed.
- Sample tubes and sample chamber are kept clean.
- Light diffusing base plate is cleaned regularly.

Quality Control:

- The color wheel is standardized against platinum-cobalt standard solutions as per directions in Standard Methods. This is performed quarterly.

8.2 NEGATIVE CONTROLS

Negative controls are used to determine whether the samples in question could have been exposed to contaminants or other interferences during their collection, transportation, preparation, and/or analysis. The negative controls consist of travel, field and method blanks.

METHOD BLANK: also referred to as Laboratory Reagent Blank (LRB): The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. It consists of a matrix that is like the associated samples and is known to be free of the analytes of interest. It is processed along with, and under the same conditions as the associated samples, to include all steps of the analytical procedure. Any affected samples associated with a contaminated method blank shall be re-analyzed or the results reported with the appropriate data qualifying codes. The blank is contaminated if the concentration of the targeted analyte in the blank is at or above the reporting limit, as established by the test method or by regulation, AND is greater than 1/10 of the amount measured in any sample. The blank is also contaminated if the results otherwise affects the sample results, as per the test method requirements, or the individual project data quality objectives. If contamination is observed, every effort will be made to locate and eliminate the source of the contamination. If ECLS can not eliminate the contamination, the reported data will be so qualified.

The method blank is analyzed at a minimum of 1 per 20 samples. In those instances, for which no separate preparation method is used (VOs), the batch is defined as the environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, and consists of approximately 20 environmental samples. In those instances, when more than 20 samples are analyzed, the method blank will be re-analyzed, as a minimum, after every additional 20 samples.

FIELD BLANKS: The field blank is used to assess the sample collection process for possible contamination. It is usually submitted for samples that are requesting various organic analyses and, as such, contains organic free water that has been sealed in a bottle in the laboratory. If field blanks are submitted for metal or other determinations, the water supplied by the laboratory is free of contaminants for that specific analysis requested. At the collection site, it is subjected to the same sampling procedure that the environmental samples are subjected. Preservatives are added, if necessary, and submitted for analysis.

TRIP BLANKS: The trip blank is used to assess the sample transportation mechanism for possible contamination. It contains organic free water that has been sealed in a bottle in the laboratory. It accompanies the sample bottles from the laboratory to the sampling site and back again unopened. It is then analyzed as a "routine" environmental sample.

FIELD and TRIP BLANKS are not required to determine the acceptability of an analytical run. They are used by the data user to determine whether the samples possibly could have been subjected to a contamination source prior to analysis. It is the clients' prerogative to submit, or not, field and trip blanks. It should be clearly understood by the client that these blanks are highly recommended to be supplied with VO samples. They can also be submitted with other types of samples as well. Only the method blank is used to determine the acceptability of an analytical run.

8.3 POSITIVE CONTROL-METHOD PERFORMANCE

The positive control used to assess method performance is the Laboratory Control Sample (LCS). The standards used to prepare the LCS and the specific controls are all a second source, or at least of a second lot number, then the standards used in the calibration process.

LABORATORY CONTROL SAMPLE (LCS), also referred to as Laboratory Fortified Blank (LFB), or Spiked Blank (BS): the LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. The results of the LCS are compared to the established analytical criteria (see section 8.7) and, if found to be outside of these criteria, indicates that the analytical system is "out-of-control". Any affected

samples associated with an out of control LCS are re-analyzed or the results are reported with the proper data qualifiers. The LCS is analyzed at a minimum of 1 per every 20 samples except for those parameters for which no spiking solutions are available. The LCS is prepared in a controlled matrix known to be free of the analytes of interest. For those test methods that have a long list of analytes, a representative number may be chosen according to these criteria. For methods that include 1-10 targets, spike all components. For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater. For methods that have more than 20 targets, spike at least 16 compounds. Over a two-year period, all the target compounds shall have been included in the LCS. ECLS is attempting to incorporate all compounds of interest in the spiking solution. If feasible, that will become ECLS routine practice. If not, then the percentages outlined above will be followed.

8.4 SAMPLE SPECIFIC CONTROLS

Sample specific controls are used to determine the effect of the sample matrix on method performance and consist of matrix spike, matrix spike duplicates, matrix duplicates, and surrogate spikes. If situations arise where ECLS has the option to decide if matrix spiked duplicates or matrix duplicates are to be analyzed, preference will be given to analyzing the spiked duplicates. These controls are not used to judge laboratory performance as to the acceptability of the analytical run.

MATRIX SPIKES, MS (also referred to as Laboratory Fortified Matrix, LFM) and MATRIX SPIKE DUPLICATES: Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch. The frequency of analysis is specified by the required mandated test method. If not so specified, then analysis will occur at a frequency of at least one per every 20 samples. Since ECLS does not collect their own samples but accepts them primarily from DEP, it is not possible to rotate choosing client samples to spike. If DEP notifies ECLS that they wish a specific sample used for this purpose, ECLS makes every effort to do so. If no such designation is made, a sample is randomly chosen by ECLS. The components to be spiked are specified by the mandated method. For those test methods that have long lists of analytes, a representative number may be chosen according to the schedule listed in section 8.3. The results of the matrix spike are expressed as percent recovery and relative percent difference and are compared to the acceptance criteria as published in the mandated method or to in-house developed acceptance limits. For matrix spike results outside established criteria, the data is reported with the appropriate data qualifying codes (section 9.5) for the sample in question if a MRRF or SRRF package is requested.

MATRIX DUPLICATES: are replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the specific method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample. The frequency of the analysis of matrix duplicates is specified in the mandated methods. If not so specified, then analysis will occur at a frequency of at least one per every 20 samples. Since ECLS does not collect their own samples, but primarily accepts them from NJDEP, it is not possible to rotate choosing client samples to run in duplicate. If DEP notifies ECLS that they wish a specific sample analyzed in duplicate, then it is so analyzed. If no such designation is made, a sample is chosen at random by ECLS. The results are primarily designed to assess the precision of the analytical results in a given matrix and are usually expressed as relative percent difference. Results are compared to the acceptance criteria in the mandated method or to in-house developed acceptance limits. For results that are outside established criteria, the data is reported with appropriate data qualifying codes for the sample in question if a MRRF or SRRF data package is requested.

SURROGATE SPIKES: Surrogates are compounds (usually organic) chosen to reflect the chemistries of the targeted components of the method and for their unlikely occurrence as an environmental contaminant. They are added prior to sample preparation/extraction and provide a measure of the recovery for every sample

matrix. Except where the matrix precludes its use or when surrogates are not available, surrogates are added to all the samples, standards, and blanks for all the appropriate test methods. The results are compared to the acceptance criteria published in the mandated method. Surrogates results outside the acceptance criteria are reported with the appropriate data qualifiers for the sample in question if a MRRF or SRRF data package is requested. The specific surrogates used by the individual methods are contained in the method.

EXAMPLES OF QUALITY CONTROL SAMPLES INCORPORATED WITHIN AN ANALYSIS SEQUENCE

As an example of how these quality control samples are incorporated into a routine run, below is the NORMAL RUN ORDER FOLLOWED BY THE TRACE METAL LABORATORY for a batch of 20 samples. The inorganic general analytical laboratory follows a similar QC scheme.

- Standards
- IPC (+/- 5%)
- Blank
- Reporting limit check
- C
- D
- LRB
- LFB
- Sample
- Sample duplicate
- Sample spike (LFM)
- Up to 3 samples
- IPC (+/- 10%)
- Blank
- Sample spike duplicate (LFM DUP)
- Up to 9 samples
- IPC (+/- 10%)
- Blank
- Up to 7 samples
- IPC (+/- 10%)
- Blank
- End of run
- If there are more than 20 samples, another LRB, LFB, duplicate, LFM and LFM DUP must be run.

IPC: is a control sample made up from the same stock solution as the standards at a concentration of one-half the concentration of the high standard.

Blank: is a control made up of the same water used to make the reagents.
C: is a control made up from a separate stock solution at the concentration of the second standard after the blank. This can be identified as Second Source Low (SSL) in the general analytical laboratory documentation.

D: is a control from a separate stock solution at the concentration of the next to the highest standard. This can be identified as Second Source High (SSH) in the general analytical laboratory documentation.

Spike Sample: is a sample spiked at the level of the IPC. This is designated as the laboratory fortified matrix (LFM).

Duplicate Sample: is a separate aliquot of a sample taken through the entire preparation and analysis procedure.

LRB: is an aliquot of reagent water taken through the entire preparation and analysis procedure.

LFB: is an aliquot of reagent water spiked at the level of the IPC and taken through the entire preparation and analysis procedure.

An example of the QC samples involved in a VO run is as follows:

- BFB tune
- QC Check Sample (Continuing Calibration Check)
- Reagent Water Blank
- Trip Blank (if one is provided) or sample
- Samples analyzed through the next 9 analytical spots
- Matrix Spike
- Matrix Spike Duplicate

NOTE: Whenever a RPD is calculated, it is always expressed as a positive number. When the RPD calculation is listed in the method SOP, place the calculation within absolute value signs.

8.5 INITIAL and CONTINUING CALIBRATIONS

Prior to analysis, calibrations are performed on the instrumentation that is used to conduct the specific analysis. These calibrations are of two different types: initial and continuing. The INITIAL CALIBRATION is a more thorough calibration process that establishes the working range of the specified analysis. Standards are analyzed throughout the expected working range and a standard curve is constructed.

For inorganic analyses, the correlation coefficient for the curve is calculated and compared to previously established acceptance criteria. If the correlation coefficient is acceptable, the analytical run proceeds. If not, the calibration process is repeated. The initial calibration is directly used for quantitation since a new calibration curve is prepared daily.

For organic analysis, an average response factor is calculated, as per the method, for the individual analytes and compared against the acceptance criteria contained in the mandated method. If the factors are acceptable, the analytical runs can begin. If not, the calibration process is repeated. The initial calibration is directly used for quantitation. CONTINUING CALIBRATION is a daily check of the initial calibration responses. All inorganic analyses, for those parameters for which an initial calibration can be performed, have an initial calibration performed daily. The initial calibration for the organic test methods take an excessively long time to complete and would allow no time for any analyses of actual samples to be performed if an initial calibration were performed daily. The continuing calibration addresses this situation. A spiked blank is analyzed and the response factors for the individual parameters are compared to the initial calibration response factors. If the continuing response factors fall within the acceptance ranges, the instrument is considered to still be calibrated and the initial calibration response factors are used to calculate any positive results generated during that day's analytical run.

Manual manipulation of the raw data is permissible under certain method specific reasons. These reasons are listed in the individual method manuals.

INORGANIC INITIAL CALIBRATION

INORGANIC INITIAL CALIBRATION: The process for performing the initial calibrations for Graphite Furnace Atomic Absorption (GFAA) Analyses, Cold Vapor Atomic Absorption (CVAA) Analyses, Inductively Coupled Plasma (ICP) Emission Analyses, and Colorimetric and Continuous Flow Analyses are addressed below:

- GFAA: A calibration blank and 6 standards are analyzed for each element. The absorbance reading for each standard is the average of 3 replicate readings of the separate aliquots pipetted by the instrument's auto-sampler. The instrument software takes the absorbance readings and does a least squares regression analysis giving a plot of the standards, correlation coefficient (R), slope and intercept. The correlation coefficient, a measure of the strength of the linear relationship, must be 0.999 or greater ($R^2 \geq 0.998$) the analysis can proceed. If a value less than 0.999 is obtained, the analyst may drop one of the standards (one that may have yielded a spurious result in relation to the other standard results) and recalculate the correlation coefficient. Additionally, the intercept of the calculated standard line must be below 0.005 absorbance units. If not, one of the standards may be dropped and the intercept recalculated. However, every final correlation coefficient must be calculated, and every acceptable intercept generated with the blank result and the results from 5 standards. If these situations cannot be achieved after dropping one standard, the calibration process is repeated in its entirety. If repeated calibration runs fail to yield an acceptable standard curve, operation ceases and troubleshooting is undertaken.
- CVAA for Mercury: A calibration blank and 5 standards are analyzed. The instrument performs 3 replicate analyses of the blank and standards and uses the average as the absorbance reading. The software performs a regression analysis giving a plot of the standard curve, correlation coefficient, slope and intercept. The correlation coefficient must be ≥ 0.999 before proceeding ($R^2 \geq 0.998$) with the analysis. Like above, a standard may be dropped to recalculate the correlation coefficient. However, every final correlation coefficient must be calculated using the blank result and the results from 4 standards. If an acceptable correlation coefficient cannot be achieved after dropping a standard, the calibration process is repeated in its entirety. If repeated calibrations fail to yield an acceptable result, operation ceases and troubleshooting is undertaken.
- ICP: Like the above citations. A calibration blank and 4 to 6 standards are analyzed depending on the element. If the required correlation coefficient of 0.995 is not achieved ($R^2 \geq 0.990$), a standard can be dropped, and the correlation coefficient recalculated. Every final correlation coefficient must be calculated from the blank result and 6 standard results. If an acceptable result is not obtained, the calibration process is repeated in its entirety. If continued calibrations fail to yield acceptable results, operations cease, and troubleshooting is undertaken.
- COLORIMETRIC and CONTINUOUS FLOW: The calibrations for these analyses are addressed in the same manner as listed above for GFAA with the exceptions that the results are not a composite of 3 replicate readings but a single reading and the coefficient of determination (R^2) must obtain a value of 0.995 ($R \geq 0.9975$). Also, the number of calibration standards required by each method are defined in that method.

Each calibration has the following information recorded:

- Calibration date.
- Test method.
- Instrument identification.
- The identification of all analytes.
- Concentrations.
- Responses.
- Calibration curve and correlation coefficient.

Whenever the limitations of the analytical procedures and or the ability to purchase standards of the appropriate concentrations permit it, at least one standard will be at the regulatory limit for the specified analytes.

INORGANIC CONTINUING CALIBRATION: ECLS does not perform any inorganic continuing calibrations. All inorganic results generated are because of using daily initial calibrations.

REPORTING LIMIT CHECK: as part of the calibration or continuing calibration check, a reporting limit check (RLC) is analyzed.

REPORTING LIMIT CHECK

Reporting Limit Checks (RLC) are performed after a calibration curve has been established. The RLC is a sample prepared at the same concentration as the low standard used to generate the calibration curve. The acceptance limit that EPA stated should be used as a first approximation to the laboratory's ability to obtain reproducible results at that concentration level is +/-50% of the standard concentration. As data points are produced over a year's period, ECLS will review that data and decide as to whether the acceptance limits should be modified. This modification should hopefully be toward lessening the limits. However, this may not be the case for all the organic compounds since the listed compound recoveries obtained by EPA during the method validation process indicate that these compounds can have a wide variability of reproducibility in the analysis.

The RLC is analyzed near the beginning of the analytical sequence and serves as a go/no go indicator for the rest of the sequence. If the RLC fails, the analyst can re-analyze the RLC. If acceptable results are obtained on the second analysis, the sequence can continue. If the RLC fails the second time, analysis cannot proceed until the cause of the failures can be identified and corrected. The analyst is to document what the cause was for the failures and the corrective action that was taken. This process can be addressed by the analyst and the section supervisor and does not need to have OQA as part of the process. OQA will have to be notified only if the corrective actions fail to resolve to situation.

Altering any of the RLC acceptance limits can only be accomplished through ECLS OQA.

INITIAL AND CONTINUING ORGANIC CALIBRATIONS

ORGANIC INITIAL and CONTINUING CALIBRATIONS: Due to the number of organic analyses and the complexity of their respective initial and continuing calibration processes, these items are not addressed here but are addressed in depth in the respective Method Manuals along with their respective acceptance criteria. However, each initial calibration will consist of at least a blank and four standards if the reference method does not indicate otherwise.

Given the excessive number of compounds in these methods, it is extremely unrealistic to expect that all the compounds will yield acceptable response factors on the continuing calibration check (CCC) analysis. This fact has been recognized by both DEP and EPA. When a compound fails the CCC, analysis for that compound will continue. However, when data packages are prepared, the compounds failing the CCC are identified to the data user. This allows the data user to interpret the results and assign a certain level of significance to the analytical data.

DROPPING A CALIBRATION POINT: the occurrence of an unacceptable instrument response(s) from the analysis of calibration standards, e. g., unacceptable coefficient of determination, RSD, etc., is an indication of an analytical problem with the selected calibration range for the analysis and must be corrected before sample analyses are conducted. Sample analyses may not proceed until the resulting calibration curve is fully acceptable according to the established criteria identified in the QM.

DROPPING A CALIBRATION POINT

Sometimes, it is apparent by looking at the calibration data that one of the standards is an outlier as compared to the other standards and that by eliminating that one calibration point would yield an acceptable Coefficient of Determination (R^2) value. A calibration point may be dropped provided that the remaining number of calibration points is at least equal to the minimum number of calibration points necessary to produce a valid calibration curve. For example, if a method states that 5 calibration points are necessary for the calibration process, then after dropping a calibration point there must still exist 5 calibration points.

Elimination of a calibration point is an acceptable practice under the following special conditions:

- In multi-analyte tests in which the calibration solutions are prepared from mixtures, analyzed concentrations that are outside the established calibration range for a given analyte should not be included in the calibration situation because the stock solutions are mixtures.
- The lowest calibration point may be eliminated from the calibration curve, but this action should take place only as a last resort. If the low calibration point is eliminated, that does not change or affect the calculated MDL that was derived for that test.
- The highest calibration point may be eliminated if all sample concentrations and all associated QC data are bracketed by the remaining calibration standards. This action should take place only as a last resort.
- An outlier calibration point may be eliminated if that point can be shown to be an outlier and not done solely to improve performance relative to calibration curve acceptance criteria.
- In all cases, when a calibration point has been eliminated from the instrument calibration curve, to assure that this is not a continuing problem, the section supervisor must be notified. Additionally, the reasons for the elimination and all the data associated with that elimination must be included in the laboratory records that document the affected analyses.

MANUAL INTEGRATION

MANUAL INTEGRATION POLICY: Manual integration may be required because the compound identification and integration results produced by the quantitation software may not always be accurate for the following reasons:

- The automated integration routine may not find the target analyte because of retention time shift, co-eluting interference, or inappropriate (too high or too low) peak intensity.
- A peak area may be incorrectly integrated by the automated integration routine because of poor peak shape, co-elution with other peaks, peak tailing, or a significant baseline drift.
- If one or more peaks elute within the retention time window, the automated integration routine may not select the peak with the retention time that best matches the retention time established by the calibration.

It is the analyst's responsibility to review the integration report generated by the computer software for every sample and calibration analysis. When errors are detected in the compound identification and peak integration, the analyst must conduct manual integration to correct the errors.

The manual integration must be reasonable, scientifically valid, and logically sound. The manual integration must meet the following criteria:

- The manual integration must be performed for one or more of the reasons listed above.
- The entire area and only the area of the peak is to be integrated for that peak. This integration shall not extend past the point where the sides of the peak intersect with the baseline. Conducting peak-shaving to eliminate part of the subject peak or including peaks not belonging to

the subject peak is prohibited. Excluding peaks not part of the subject peak is allowed. Manual integration performed solely to meet QC criteria is unacceptable.

Manual integration must be documented in the following manner:

- The reason for performing the Manual Integration must be listed in the documentation.
- The Manual Integration is signed and dated by the person performing the integration if that person is not the analyst who originally generated the raw data associated with file number for that sample.

Just by the nature of the testing, organic analyses generate a large amount of paper work that is necessary to document the generation of the analytical result. There is a certification requirement that states that the analyst performing the analytical work must be identified in the work records. The way the ECLS LIMS systems, associated with the organic instrumentation, are set up, they assign a file number for the analysis. Under that file number, all the raw data associated with that analysis is stored. This file number is printed on every page of the printout of that raw data that the analyst reviews during the normal completion of the analysis.

It is unrealistic to expect the analyst to sign every page for every sample analyzed especially given the fact that the file number appears on every page. Therefore, ECLS has taken the approach that when the analyst signs next to the file number on the first page of the printout, that signature indicates that all the raw data, and any notations made during the evaluation of the data, were made by the signing analyst. Therefore, notations indicating 'manual integrations', 'computer match is incorrect', etc. do not require the analyst signature. Only in those instances where the person who performs such evaluations is not the analyst who generated the raw data, would require that person's signature next to those evaluations.

There are instances when entries must be initialed and dated by whoever makes the entries. Examples of these are: whenever a cross out or correction is made to the printed data and who prepares the finished final report.

8.6 DEMONSTRATION OF CAPABILITY (DOC)

This evaluation is performed to verify that the analysts have the capability to perform an analysis within the requisite method accuracy and precision. At a minimum, this demonstration is performed yearly. An additional demonstration will be performed whenever there is a significant change in instrumentation type, personnel, or test method. Work cells are employed in two areas of ECLS: metals and certain organic analyses. In each instance there are personnel dedicated to the preparation of samples and personnel dedicated to the instrumental analyses of those samples. In these instances, the sample preparation and analysis personnel have their names associated with that DOC which reflects that analyst's involvement with the analytical process. There is no one specific cell DOC, only DOCs for the individual analysts. However, it is true that more than one analyst name can appear on a DOC. When a new member is added to the work cell, that person receives training from a competent analyst until such time that the new analyst can handle the activity by his or herself. This is documented by the preparation of a new DOC. Additionally, the type and length of training received is documented in the personnel files maintained by OQA. If the analyst produces an unacceptable DOC, he receives additional training until he can pass the DOC. This also becomes part of his training record.

The DOC is usually performed by correctly analyzing at least four consecutive LCS at a concentration of about 10 times the MDL or the low LCS, completing the appropriate forms, and placing the raw data in the appropriate Method Manual. However, the DOC can also be achieved by successfully analyzing an internal performance audit sample. Forms are maintained by OQA. The yearly continuing DOC can be accomplished by the same conditions as the initial DOC.

8.7 ESTABLISHING ACCEPTANCE LIMITS

To determine LCS acceptance limits, a minimum of seven and a maximum of twenty determinations are made. The average value and standard deviation are calculated. The acceptance limit is set at +/- 3 SD or +/- 15% of the true value or +/- 10% where required by the method. Regardless of the calculated limits, if acceptance limits are listed in the methods, those limits are used. If it is determined that the calculated limits are excessively tight and could lead to too frequent re-analyze, the acceptance limits can be adjusted through consultation with OQA. Acceptance limits for matrix and surrogate spikes are established in an analogous manner. Acceptance limits for duplicate analyses are established by calculating the relative percent difference (RPD) based on between seven and twenty duplicate analyses. If the calculated RPD is less than +/- 20%, the acceptance limit will be set at +/-20%. If the calculated RPD is > +/- 20%, the acceptance limit is set at that value, provided that this value is allowed by the method.

In those instances, where no officially recognized methods exist, as a first approximation, limits derived from similar methods will be applied until limits can be established for that method.

Acceptance limits for newly prepared LCS etc. must be derived before the old solution has been depleted. This allows for the continuous coverage of the analysis by fully documented check samples. Calculations for developing all acceptance limits are performed by the analysts.

8.8 METHOD DETECTION LIMIT (MDL)

MDLs are determined using the procedures outlined in the individual methods or according to the procedure outlined in 40CFR141 appendix B. These are performed at least yearly, as required by EPA, or when there is a significant change in personnel, instrumentation, or analytical procedure. MDLs are determined for the individual matrices that are analyzed in the laboratory. The raw data used in these calculations are generated over a period of at least 3 days. This method of determining MDLs can yield some MDLs that are below the concentration value of the blank analysis for that method. This occurs in some colorimetric analyses where a certain threshold concentration must be achieved before the reaction can take place. Until the regulatory agencies guide us on how to handle this situation, ECLS will continue to calculate MDLs as currently required.

See **Attachment # 12** - **Part 136 Method Update Rule Revisions to Appendix B – MDL Procedure as Applied to Drinking Water**

ECLS does not relate the MDL data to quantitation levels (QL). Some laboratories establish a QL by defining it as 5 times the MDL. ECLS has defined its reporting level as the concentration of the lowest standard on the calibration curve. This concentration may be approximately 5 times the MDL, but it may not. There are instances where the calculated MDL is so low that the instrumentation is not able to detect a concentration of 5 times the MDL. ECLS does relate the MDL to reporting levels as follows:

- Data reported at concentrations greater than the lowest standard are reported normally.
- Data reported at concentrations below the lowest standard are reported with a numerical value plus the data qualifier "JR" meaning an estimated value below the reporting level.
- Data seen at levels below the MDL are reported the numerical value of the MDL plus the qualifying code "K" meaning less than.

8.9 MANUAL CALCULATIONS

There are still occasions where results must be calculated manually and not read off a computer printout. In those instances, randomly selected examples of the manual calculation performed by the analyst are checked by the technical supervisor during their data review process to verify their accuracy.

8.10 VERIFICATION OF SOFTWARE CALCULATIONS

Verification of the software calculations must be performed when a new instrument has been installed; when new software has been implemented; when an analyst's Demonstration of Capability is being performed; and once at least annually. The analysts determine the equations used by their computer system to perform the various calculations, either from the information supplied with the system or by directly requesting this information from the company. The analyst then checks the instrument generated results by manually calculating results using the provided equations and verifying that the results match. These results are then verified by the technical supervisor. For those analyses that consist of multiple analytes, it is only necessary to check the results for a few of the analytes. The equations and the documentation of the manual check then becomes part of the Method Manual by incorporating this information into the Calculations Section of the Method Manual. The records of the manual verifications are kept by the analysts at the appropriate laboratories and a copy with OQA.

The internal transfer of data is checked indirectly every day when the analysts and technical supervisors verify that collected or entered data has been received correctly. This process entails the entry of data, transfer of data to the LIMS, and the transfer back to the workstation. To date, the only mistakes encountered during this process have been manual entry mistakes.

Some analytical data is transferred electronically via the LAN into our LIMS System. The accuracy of the transfer of this data is checked by the technical supervisor of the Data Management section by comparing the copied data to the original data that is being reported. A record of this check is maintained by the technical supervisor.

CHAPTER NINE
DATA HANDLING

9.1 ANALYSIS WORKBOOKS/PRINTOUTS: INORGANIC TESTING

Raw data, calculations, analytical results, and control data are either recorded in bound workbooks or computer printouts. Any computer printouts are then placed in loose-leaf binders that document the analytical runs undertaken. Any handwritten entries are made in ink. Pencil is never used on analytical documentation. Erasures and the use of whiteout or correction tape are also forbidden. The workbooks fall into three categories: reagent and standard workbooks, instrument logbooks, and analysis workbooks.

REAGENT AND STANDARD WORKBOOKS contain the following information:

- Method reference.
- A listing of preparation procedures that are followed. This could be a copy of the preparation procedures copied from the analytical method or a reference to the procedure in the write-up.
- The unique identifier assigned to each of the solutions. This identifier is based on the workbook number, page number, and the position on the page on which the preparation is documented. For example, if the preparation is documented in workbook 2121, page 45, in the second position on the page, the unique identifier for that solution is 2121-45b. The first position on the page is designated "a", the second "b", etc. If the reagent/standard has been assigned a number in Element, the Element ID for this reagent/standard is recorded as well.
- The date of the solution preparation along with the analyst's initials.
- Any readings and/or calculations employed during the standardization of the solution along with the appropriate units of measure.
- A reference to the stock standard material that was used to produce the standard solution. This reference is to the bottle ID assigned to it at the time of receipt in the laboratory and to its certificate of analysis that the manufacturer supplied with the shipment.

In some cases, the reagent workbook may be "combined" with the analytical workbook to closely monitor the preparation of the critical reagents and standard solutions.

INSTRUMENT LOGBOOKS are maintained for each major piece of instrumentation. The log lists:

- The type of instrument along with the make, model, and serial number.
- Each day that the instrument is used, an entry is made to indicate the analyses performed on that instrument.
- Any maintenance performed on the instrument.
- If a problem is observed, the nature of the problem is listed along with the corrective action steps undertaken.
- All entries are accompanied by the initials of the analyst.

ANALYSIS WORKBOOKS can be divided into two categories: those resulting from tests and analyses that are carried out using manual techniques, and those resulting from analyses carried out using instrumental techniques. The Manual Analysis Workbooks are permanently bound and paginated books that contain the following information:

- A reference to the analytical method and analytical SOP being used.
- Date the sample was prepared or analyzed.
- Laboratory identification number that was assigned to the sample during the sample receivership process.
- Volume of sample taken for the analysis.

- A listing of any subsequent dilutions undertaken during analysis. These are listed serially until an on-scale reading is obtained. In some cases, it is not practical to perform the required sample dilutions during the initial analytical run. In these cases, any required dilutions are performed in subsequent analytical runs.
- Value of the reading obtained during analysis.
- The analyte concentration corresponding to the value of the reading obtained from the standard curve.
  The results.
- The concentration of the standards and their respective readings that were analyzed to generate the standard curve for the analysis. The inorganic laboratory prepares a standard curve with each day's analyses. No "continuing calibration check" is required.
- The laboratory ID numbers of the samples that were analyzed in duplicate (if required).
- The calculated Relative Percent Difference (RPD) of the duplicate analyses along with the acceptable RPD range.
- The laboratory ID numbers of the samples that were analyzed as Matrix Spiked Samples (if required).
- The calculated Percent Recovery for the matrix spike analysis along with the acceptable percent recovery range.
- A listing of all the in-house Quality Control Samples analyzed along with their target values and acceptable ranges.
- A listing of the analyst's initials and the section supervisor's initials.

The INSTRUMENT "WORKBOOKS" are in many cases loose-leaf binders that contain the instrumental printouts generated during the analytical run. These printouts are generated by the instrument's software and they contain:

- The name of the analysis and a method reference.
- The name of the analyst.
- The date and time of analysis.
- Instrument ID and/or serial number.
- A tabular representation of the calibration standards and their raw measurement values.
- A graphical representation of the calibration curve including the calculated correlation coefficient (R) or the coefficient of determination (R^2).
- A tabular representation of the sample and quality control results (as listed above).
- Where applicable (ion chromatography, continuous flow analysis), the strip chart of the analytical run showing the peaks for all the samples analyzed.
- The analyst's initials.

9.2 ANALYSIS WORKBOOKS/PRINTOUTS: ORGANIC TESTING.

ORGANIC WORKBOOKS AND PRINTOUTS

An INSTRUMENTAL LOGBOOK is maintained for each GC, GC/MS and HPLC. This log lists the type of instrument along with its make, model and serial number and functions as the record for the daily analyses performed by the instrument. The analysis of each sample is documented by entering into the log the laboratory ID number of the sample, the injection size, the time of the analysis (if the data is being acquired by a system that does not automatically record the analysis time), and the data file number (if, as is usually the case, the data is being

acquired by a laboratory data system). Any maintenance performed on the instrument is also entered on the log. For each instrument that has not been formally taken out of service, at least one entry must be made each day in its log even when the instrument is not in operation even if it is to note that the instrument was not in use. If an instrument is to be formally removed from service, an entry to this effect, including the removal date, will be placed in the log. When the instrument is restored to service, a dated entry indicating restoration must be made in the log. If maintenance is performed on the out of service instrument, entries covering the maintenance must be placed in the log even though the instrument is out of service. All entries are initialed by the analyst.

STANDARD PREPARATION WORKBOOK documentation includes: the unique ID number of the solution (generated as above), date of preparation, name of the compound(s), lot number of the primary standard, final weight, tare weight (unless automatic tare is employed on a digital balance), correction for purity of the primary standard, dilution volume, solvent(s), and final concentration. When a new working standard is prepared, its chromatographic behavior is carefully compared with the latest chromatograms of the previous standards so that any response irregularities can be noted before incorporating the standard into routine use. The response characteristics of the future analyses may be compared against the initial chromatographic data to determine whether the standard is decomposing during use.

CHROMATOGRAM DOCUMENTATION (ALL ORGANIC CHROMATOGRAPHIC INSTRUMENTS ARE INTERFACED WITH THE LABORATORY DATA SYSTEM): The instrument's computer system assigns a unique data file name to each run. The analyst records this data file name in the Instrument Log. The data system then stamps this name on all subsequent copies of that chromatogram. The data file name can be used to determine the operating conditions under which the chromatographic run was made by referring to the data file name in the instrument log.

QUALITY CONTROL DOCUMENTATION: The results of all the QC procedures associated with an instrument and analysis are documented as the information is generated. Items documented in this manner include: initial instrument calibration, continuing calibration checks, MDL determinations, MS tune results, blank analyses, surrogate spike recoveries, matrix spike recoveries, duplicate sample analyses and/or duplicate matrix spike recoveries. All these results are compared against the acceptance criteria contained in the specific methods.

9.3 DATA REVIEW

There are several reviews of the raw and final data that generated by the laboratory prior to reporting the data out of the laboratory. These reviews are conducted by the analysts and the analytical section supervisors.

DATA REVIEW

ANALYST REVIEW: The analysts are the first people to review the raw data of the analytical run. They review all the QC data associated with the runs to verify that the QC data is within the stated acceptance limits. If all QC associated with the run is found to be acceptable, the analyst initials and dates the workbook or printout and enters the results into Element changing the status of all affected samples to "Analyzed". If the QC data is not within the acceptance limits, the analyst must re-analyze the run from the spot of the last acceptable QC values if there is sufficient sample volume to do so, and the sample has not exceeded the required holding time. If this corrects the situation, the data can be addressed as above. If the re-analysis does not correct the situation, the sample data generated between the points of acceptable QC results can be forwarded as above but the rest of the data is to be rejected and new analyses performed after the analyst corrects the situation that led to unacceptable results. If the unacceptable results are still being generated, the analyst shuts-down the analytical system and notifies the section supervisor and OQA. The supervisor and the QAO investigate the problem and the QAO documents the solution and what steps were taken to correct the problem.

SUPERVISOR REVIEW: The section supervisor verifies that the analyst correctly evaluated the QC data, and correctly entered the analytical results into Element. He or she also checks for certain parameter correlations, e.g., TKN>ammonia; and TP>hydrolysable phosphate>orthophosphate.

During the data review process, it may be necessary for the analyst or supervisor to make certain markings on the pages containing the raw data. These markings are for internal references for the ECLS staff and are not meant to convey any relevant information to any client. Therefore, those markings are not defined on the raw data that is reported to the clients. Any markings that appear on the report forms are identified to the clients. The supervisor then signs the applicable workbook and changes the status of the affected samples to "Reviewed" in Element. See **Attachment # 9** The Promium Element Laboratory Information Management System, for more detailed information. After all results for a given work order are entered and reviewed in Element, the data management section generates a laboratory report

9.4 DATA DELIVERY

ECLS provides sample analysis reports, data feeds and billing information to our clients and Billing Unit. All data is stored in the Element LIMS LTDB SQL Server 2005 database. Both reports and data feeds are customized based on agency specifications and requirements. Billing information is generated on a monthly schedule and produces monthly invoicing data along with summary information used by client to reconcile billing.

DATA REPORTING

ECLS generates two types of reports the TIER 2 report which contains qualified results data and the TIER 1 report that requires extensive amount of supporting data. The client specifies what type of report they need by checking the proper box on the COC form. If it becomes necessary to change to a report, this is handled as a "Supplement to Test Report." This supplement would be necessary if the laboratory ascertained that some aspect of the laboratory operation caused questionable data to be reported. The QAO prepares the supplement report and retains a copy for a period of 5 years.

TIER 2

This is the routine data report generated for most of the regular sample analyses testing performed by ECLS. The Data Administration production report team reports all final reviewed reports every day at 2:00 pm. They also generate reports on demand at any time during the working day. TIER 2 reports are created using Crystal Report software submitted in Element from the Project Management\Reports menu. These are custom reports created as PDF files. Reports are then delivered to the client and provided to ECLS program manager for review. Clients have the choice of having reports sent to them by email, hard copy regular mail or moved into a shared drive using Citrix. All reports along with all scanned source and supporting documents are saved on the Shared V drive in the ALLREPORTS folder in pdf files. These files are accessible to the entire lab for data review and the shared folder provides a data store of all reports sent to clients. When a client requires more supportive information they are required to request this through the ECLS Laboratory Manager in charge of the project.

TIER 1

A Standard Regulatory Report Format (SRRF), or Tier 1 data package, includes: the analytical results along with all the QC data produced during the analysis, all raw analytical data, a laboratory chronicle, and a case narrative. The requisite information is produced, compiled, and reviewed by the analytical sections and given to the Data Administration Section for processing. The Data Admin group compiles then scans all documents creating the Tier 1 data package into a PDF format file. A final review is made by and signed by the QAO and

Director. This file is then used to create a CD-ROM or DVD along with the data feed file if required and then distributed to the clients as required.

SRRF REPORTS (TIER 1 DATA PACKAGES): SRRF reports vary slightly, depending on the type of analysis conducted, and the instrumentation used to do so. All pages beyond the Table of Contents in this report are numbered. All tables and X - Y graphs are set broad side, i. e., the open edge of the paper toward the reader. The package includes all the following sections:

- Title page containing the case name, field sample numbers, laboratory batch number, laboratory sample numbers, sample location, date, time of sample collection, laboratory manager and quality assurance officer signatures.
- Table of contents listing all major sections of the document with referenced pages.
- Sample analysis request forms that list the type of analyses that were requested for the sample and all pertinent field information.
- Chain of custody forms detailing the change of possession of the samples from the time of collection to delivery to the laboratory and the internal laboratory forms detailing the change of possession of the samples in the laboratory.
- Laboratory chronicle contains a dated sequence of the sample analysis and re-analysis. This is provided as a summary in addition to the chain of custody forms. It addresses sample receipt, refrigeration, and storage; preparation by fraction; extractions; and section supervisor's review and approval with signatures.
- Methodology review contains a brief narrative outlining the essential points of each method used.
- Case-Narrative/Non-conformance summary that presents in appropriate narrative or tabular form, such that all data falling outside the QC criteria specified in the individual methods and/or this manual is highlighted so the data user can evaluate the data and determine the significance it wishes to place on the impact to that data.
- Quality control summary listing the surrogate recovery summary, matrix spike/matrix spike duplicate summary, reagent blank summary, laboratory fortified blank summary, and GC/MS tuning and mass calibration summary.
- Sample data package includes the sample result summary with detection limits, sample chromatograms and mass spectral data, quantitation reports, and library searches.
- Standard data package includes the initial calibration data, continuing calibration data, and the standard chromatograms, quantitation reports and summaries.
- Raw QC data package includes the DFPTT and BFB spectra, and the reagent blank data.

In addition to all the above, there are additional reporting requirements under SRRF for certain analyses e. g., GC/MS analysis of volatile and semi-volatile organic compounds, pesticides by GC/ECD, and metals by ICP and PFAA. The additional reporting requirements for GC/MS are as follows:

- Targeted analyte summary consists of the quantitation results (uncorrected for blank); MDLs, method blank, and spiked blank results. The following data reporting qualifiers are used: "J" indicates an estimated value. It may also be used to indicate an estimated value resulting from factors, such as, questionable QC results, exceeding holding times, etc. "JR" indicates an estimated value that is below the reporting level but above the MDL. “K” indicates a compound was analyzed for but not detected. When using the "U" qualifier, report the minimum detection limit also (e.g., 100U). "B" indicates that the analyte was found in the laboratory reagent blank and, as such, alerts the data end user that a possible contamination has occurred. The targeted analytes are reported as a minimum. Results are reported to two significant figures. For rounding rules, the USEPA handbook of Analytical Quality Control in Water and Wastewater Laboratories, USEPA-600/4-79-019 is followed.

- Matrix spike/matrix spike duplicate analyses have their percent recoveries (%R) and relative percent difference (RPD) are calculated. Alternately, duplicate analyses may be performed on unspiked samples and the matrix spike run separately. The RPD and % R are reported.
- GC/MS tune summary data is reported.
- Calibration curve validation data consists of the initial calibration curve data and the continuing calibration curve check data.
- Surrogate compound recovery summary data.
- Non-targeted analyte summary consists of searching a NIST spectra library (1998 version with approximately 130,000 spectra) and presenting the following: scan number, analyte, CAS number, absolute retention time, molecular weight, and the estimated concentration.
- Supportive confirmation spectra used for comparison for positive targeted compounds is presented.
- Extracted ion current profile for characteristic and secondary ions versus RIC or TIC showing maximum +/- 1 scan is reported. Presentation is within a limited window near the expected RT of the analyte.
- NBS library search presentation of non-targeted compound spectra with the 3 best matches. If possible, additional classification of the unknown compounds is presented, e. g., unknown aromatic, unknown chlorinated compound, etc.
- Actual data output is submitted for all runs.
- Quantitation report includes the following: summary of all the analytes, comparison of compounds found v. the library entry, and the method of quantitation.
- Handwritten decision by the mass spectroscopist indicating negation or confirmation of the software's tentatively identified compounds values is reported.
- Chromatograms, either RICs or TICs, and a m/z tabular listing are included for all the tune compounds.
- Chromatograms for method blanks, spiked blanks, calibration standards, field samples, matrix spike, and matrix spike duplicate are included. Each internal standard and surrogate compound is clearly labeled on the chromatograms.

The special reporting requirements for pesticides and PCBs by GC/ECD are as follows:

- Targeted analyte summary consists of the following: quantitative results (either the primary or confirmatory result), MDLs, method blank, and spiked blank results. The external standard quantitation method is used to quantitate all pesticides/PCBs. Quantitative results are on a dry weight basis for soil and sediment samples. Every identifiable peak is quantified unless interference with individual peaks persists after cleanup.
- Matrix spike/matrix spike duplicate results.
- Surrogate compound recovery data.
- Chromatograms are submitted for field samples, method blanks (both primary and confirmatory), calibration standards, matrix spike, and matrix spike duplicates. The chromatograms are labeled with the following: sample ID, volume injected, date and time of injection, GC column identification, GC instrument ID, and positively identified analytes have their retention times printed over the peak or on a printout of retention times.
- If using manual data reduction, retention times and peak areas are provided.
- If using data reduction by using software retention time windows for each analyte, documentation is furnished.

Special reporting requirements for metals analyses include the following:

- For ICP: analytical results, method blank data, spiked duplicate data, initial calibration, calibration verification data (quality control samples), blank data, matrix spike data, and the ICP interference check sample data. The ICP check is used to verify inter-element and background correction

factors. This is analyzed at the beginning and end of every run. This sample contains all the elements analyzed by ICP and functions as the control sample analysis listed above. Results must fall within the established control limits of +/- 20% of the mean value. If not, the analysis is terminated, the problem is corrected, the instrument is re-calibrated, and the samples re-analyzed.

- For platform furnace: the items listed above are reported. If the Method of Standard Additions (MSA) is required, the following is also included: the absorbance and concentrations for zero, first, second, and third additions; and the slope, intercept and correlation coefficient data.

9.5 DATA PACKAGE REVIEW

The SRRF packages are compiled by the manager of the section in which the analyses were performed. They verify that all the requested analyses have been completed and then obtain all the necessary data and supporting documentation. The data is collated, placed in a binder, the pages consecutively numbered, and the signature page added. The package is given to the QAO who reviews it for completeness and spot checks the data to verify that no mistakes have been made during the analysis and collation of the data. See **Appendix 25**. The QAO and the laboratory manager sign the package. It is returned to the Data Management section for copying and distribution. A record of the QAO package review is maintained by the QAO.

9.6 DATA QUALIFYING CODES

Sometimes it is necessary to qualify the reported data to indicate to the data user specific information that could be relevant to the user's interpretation of that data. The codes employed by the Inorganics laboratory are based on the US EPA STORET data qualifiers. However, when the codes are used to qualify BOD results, they have a slightly different meaning. This is due to the uniqueness of the BOD test. The definitions of the BOD codes were supplied to ECLS by an US EPA Region II Laboratory Certification Officer. The codes used in the Organics laboratory are modeled on the CLP format. The meanings of all the ECLS codes have been forwarded to NJ DEP, our primary contractor. However, when compiling a data package, the meanings of all these codes appear at the end of the analytical report. The ECLS and Sanitary Bacteriology laboratories data qualifying codes are presented in **Attachment 10.**

9.7 RECORD STORAGE

Analytical results and the supporting documentation are maintained by ECLS for a period established by the State Archives Commission. All the hard copy material is kept at ECLS for a period of about one year, depending on the storage capacity available at any given time. This includes the final reports, workbooks, instrument printouts, etc. After the initial in-house retention of the records, the records are transferred to a secondary holding facility operated by a contract vendor. The transfer of all these records is handled through the ECLS Management Assistant. The analyst informs the Supervisor of the need to transfer records and is given the appropriate forms to complete. The records are boxed and inventoried and the contents so noted on the forms. The boxes are given an ID number, and that number is entered on the form. The records are then transferred to the other facility where they are stored until permission is given to discard the records. The storage forms are maintained by the ECLS Management Assistant.

If the need arises, the records can be retrieved from storage. Again, this operation is handled through the ECLS Management Assistant. The ECLS Management Assistant informs the DHSS Forms Control and Records Management Office of the ID numbers of the boxes that contain the required material. The boxes are delivered to ECLS and the material is subsequently returned to the storage facility. Again, the documentation of the retrieval and return of documents is maintained by the ECLS Management Assistant.

The records will remain in storage until ECLS provides written permission to discard the records. The permission document is prepared by the NJDOH Forms Control and Records Management Office and then reviewed by ECLS Management Assistant and the QAO before being forwarded to the facility for disposition.

Recent Organic data that is stored electronically is kept in the instrument data systems for an unspecified period. The data is backed up and is also forwarded to a Department's Server where it is maintained. The Server's contents are then additionally backed up to another server. Some of the GC data will be backed-up to stand alone hard drives rather than the server. Once the data is deleted from the instrument's system, it has already been saved to at least two different sites. The Inorganic data is stored in the instrument data system for a period of up to 6 months before it is backed up in a similar fashion.

However, all laboratory data is also stored as hard copy. This precludes the need of having to maintain an antiquated computer system to retrieve stored data.

9.8 REQUESTS FOR DATA VERIFICATION

Sometimes ECLS receives requests to verify that the data that was reported was reported correctly. Requests are sometimes made because the reported data does not agree with some historical data that the client has for a specific site. Sometimes requests are made simply because the data "does not look right". Requests for data verification are considered by ECLS to be a form of a complaint and, as such, requests are made through the QAO.

REQUESTS FOR DATA VERIFICATION

Requests for data verification are sometimes requested of ECLS. Sometimes these requests are made directly to the analysts and sometime through management. These requests usually take the form of wanting ECLS to verify that the results reported were not the result of some transcription error or the result of faulty quality control data associated with that analysis. These requests are made because the data user has received results that do not meet their expectations of what the data should look like.

Sometime ECLS is requested to forward partial analytical results to the sampling agency. The data associated with this type of partial reporting is preliminary data. If a request is made for data verification on these preliminary results, the analyst may perform an examination of the raw data to determine if the test was performed correctly and accurately and so inform the requesting agency verbally provided the analyst absolutely knows for sure the identity of the person to whom s/he is providing the information. If there is any doubt, refer the matter to management.
When a request is received for data verification of data that has already been reported to the submitting agency, those requests are forwarded to QAO for handling. See **Appendix 23** for the information that must be supplied with the data request.

The QAO starts a Complaint/Observation form and obtains the following information from the person making the request: name, agency, telephone number, basis for the request, and the laboratory ID numbers of the affected samples. This information is used to investigate the complaint with the section supervisor. Although not specifically stated as a complaint, any request made by an outside agency to check the work produced by ECLS is considered by ECLS to be a complaint since they are calling into question the operation of the laboratory. The result of the investigation, any corrective actions taken by ECLS, a copy of the written response and the date of the response entered or attached to the Corrective Action form. The final report of the findings is reported by the QAO back to requester. These forms are maintained by the QAO for a period of five years.

9.9 RECORD CORRECTIONS.

If a correction must be made to a hard copy entry, it is made by placing a single line through the incorrect entry, in such a way, so the incorrect entry is still legible, and the correct entry is placed next to it. The person making the correction initials the cross out, dates when the correction was made, and cites the reason for the correction when the correction is not obvious. Under no circumstance is "white out" to be used in this process. Before a correction is made, permission must be obtained from at least the Technical Supervisor of that unit.

After data has been entered into the laboratory information management system, it can still be changed prior to printing the final report. These changes are made by members of the Data Management staff. However, it can also be changed by the technical supervisors. Data Management prints out, by analyte, a report listing the data that has been entered since the last report and forwards it to the supervisors. These printed results are compared to the actual analytical results. If an error is noted, the correction is noted on the printout. The supervisor initials the printout and returns it Data Management where the change is affected. A "user profile" has been established for each analyst that sets limits to what they can perform on the data system. It is these profiles that provide the ability of certain personnel to make data changes. When a change is made, the computer creates an "audit trail". This audit trail records who made the changes, the type of change, and when the change was made.

If an error is observed after the data has been reported, a written correction is prepared by the QAO within 2 days of the observation and forwarded to the client as a "Supplement to Test Report".

9.10 SIGNIFICANT FIGURES AND ROUNDING OFF

At the current time, it is ECLS policy to report analytical results to 3 significant figures. For radiochemistry results, the number of significant figures used will be based on the error calculation for that analysis. If there is reason for the analyst to believe that some data should be reported to more than 3 significant figures, the analyst should consult the QAO to affirm this decision.

The following are the rounding off rules that are in effect in ECLS:

- Increase the last retained digit by one if the leftmost dropped digit is greater than 5 or is 5 followed by other numbers.
- Leave the last retained digit unchanged if the leftmost dropped digit is less than 5.
- If the leftmost dropped digit is exactly 5, increase the last retained digit by 1 if it is odd and leave it unchanged if it is even.

The example below is for rounding off to the third decimal place for results produced to 5 decimal places. If these numbers had to be rounded to 3 significant figures, all the results would be 1.24. This is presented for illustrative purposes.

1.23742	1.237
1.23751	1.238
1.23750	1.238
1.23650	1.236
1.23749	1.237

In addition, and subtraction, retain only the number of decimal places in the result as are in the component with the fewest number of decimals.

32.7	
3.62	
10.008	
46.328	46.3

CHAPTER TEN
QUALITY ASSURANCE

10.1 QUALITY ASSURANCE PROGRAM (QAP)

Implementing and maintaining the QAP is the responsibility of the Quality Assurance Officer (QAO). Activities performed by the QAO are listed in the sections that follow immediately below.

10.2 DEVELOPING THE QUALITY SYSTEMS CONTAINED IN THIS QUALITY MANUAL (QM).

The QAO, together with input from the ECLS and PPRC Service Directors and the ECLS Program Managers, developed the quality systems that appear in the QM. QA continues to be an evolving field and it is anticipated that future additions and/or refinements will have to be made to the existing quality systems. Any such modifications to those quality systems contained in this QM can only be affected by the QAO. The QAO will affect these changes by: informing management of the type of change that is necessary, informing management of the reason for that change, informing management of the affect that it may have on laboratory operations, providing a listing of what will be required to affect that change, developing any forms or a listing of the documentation steps that will have to be implemented as a result of the change, and providing an anticipated date for the change.

It is anticipated that as changes to the quality systems become necessary because of regulatory requirements, those changes will be implemented as soon as possible after being informed of the changes in the requirements. Service Area staff are notified when changes are made to the QM. The Quality Manual will be reviewed biannually and made available electronically to the ECLS staff. The QAO will retain copies of all previous versions of the QM as a historical record for a minimum of five years.

10.3 IMPLEMENTING AND MAINTAINING THOSE QUALITY SYSTEMS

It is the QAO's responsibility for implementing and maintaining the quality systems. The first step in the implementation process is holding training sessions for the Program Managers, supervisors, and analysts. See section 2.5 of the QM. The sessions detail the nature of the changes that are taking place in the existing laboratory quality systems and the responsibilities that these changes would place on everyone working in the laboratory. As additional changes are made to the quality systems, other informational sessions will also be scheduled. When the Quality Manual is revised and finalized, all analysts must document that they have read and understood the contents.

Quality systems are maintained through periodic, independent, and documented examination and verification of activities, records, processes, and other elements of a quality system to determine their conformity with the requirements of the established quality standards. An auditing checklist will be completed for each section for each auditing event. These will be maintained by the QAO for a period of at least five years. The audits are posted on the shared Q drive. They are a regular part of the Monthly QA/QC Meeting agenda reviewed, and discussed

10.4 DEVELOPING AND IMPLEMENTING THE REQUISITE DOCUMENTATION PROTOCOLS NECESSARY TO VERIFY COMPLIANCE WITH ALL THE PROCEDURES CONTAINED IN THE QM.

The forms used in the documentation of the use of the established quality systems are contained in the QM. This allows the laboratory personnel to know specifically what documentation they must make and

the types that will be made by the supervisors and the QAO. As additional forms are added or as forms are modified, they will replace the forms in the QM, but the old forms will be kept for a period of at least five years. Where appropriate, changes to pertinent sections of the QM will also be affected.

10.5 PERFORMING THE REQUISITE NUMBER OF SYSTEM AND PERFORMANCE AUDITS CALLED FOR IN THE QUALITY SYSTEMS

INTERNAL SYSTEM AUDITS:

Internal system audits are conducted in each analytical section of ECLS at least once per calendar year to verify compliance with the requirements of this manual, including looking for any evidence of improper, unethical, and illegal activities. The audits cover the following areas of laboratory operation on a rotating basis: Inorganics (Metals and General Chemistry), Organics (VO, Pesticides and BNA), Radiochemistry, Sample Receiving and Data Management. Not all the methods performed in each area will be audited during every auditing event. Prior to conducting the audits, the QAO reviews the appropriate SOP to familiarize him/herself with the methods to be audited, to verify that the SOP is in the ECLS accepted format, and that it contains all the requisite information. A checklist (**Appendix 24**) will be completed for each method/section. Besides covering the material contained in the QM, the checklist also contains a section for adding auditing items based on the material contained in the SOP. This allows making each auditing checklist to be specific to the method being audited. An audit report is then issued detailing the findings of the audit. If any deficiencies are noted, a statement will detail the reasons for citing that deficiency along with references to the appropriate sections in the QM and/or SOP from which the deficiency was derived. An e-mail is sent by the QAO to the ECLS Director, the Program Manager, the analyst, the analyst's supervisor, and the Director of PPRC notifying them that deficiency summary is available on the shared Q drive for review and a response is required within 30 calendar days. The Program Manager/Technical Supervisor will then respond to the audit findings by a written report to the QAO and it will be added to the monthly QA/QC Meeting agenda for review, discussion and determination of acceptability. The response should provide an implementation date, set by the Program Manager for the completion of the corrective actions that are detailed in his response. Upon learning of the implementation date, the QAO will conduct a follow-up to verify that the corrections have been implemented. Once completed it will be noted and attached to the original audit report. The QAO maintains copies of all audit reports.

If a deficiency is of such a nature that reported analytical data is compromised, the QAO:

- Determines all samples so compromised.
- Informs the Service Director of the need for potential client notification
- Make recommendations following course of action
- If possible, have ECLS re-analyze samples and submit a Supplement to Test response.
- If necessary, have clients submit new samples.
- Document causes for the deficiency and the corrective actions undertaken by initiating the Non-Conforming Event process. **Appendix 14.**
- Change any necessary quality system that failed to detect the deficiency.

Regularly scheduled system audits are conducted at least 10/12 months/ year. Additional audits will be necessary to verify that corrective actions have been implemented and, of course, management may request additional audits at any time.

EXTERNAL SYSTEM AUDITS

These audits are conducted by NJDEP and USEPA, the ECLS certifying authorities, on a schedule of approximately every 2 to 3 years. Making the arrangements for the audit, providing pre-audit information to the auditing agencies, corrective action responses back to the auditing agency and implementing the corrective actions within the time frames mentioned in the corrective action response are the responsibility of the QAO. The findings made during these audits then form the basis of revising the QM to make sure that these corrective actions are contained in that document. Depending on the timing of the audit, this revision can be made during the yearly review of the QM or it may entail making an immediate change and distributing the amended sections of the QM to the analysts. Whichever process is taken, the corrective actions are implemented immediately.

EXTERNAL PERFORMANCE AUDITS: PROFICIENCY TESTING SAMPLES.

At least two sets of WPs PT and two sets of WS PT samples are analyzed during each calendar year. These PT samples are obtained from approved PT vendors. The PT samples are delivered to the QAO who verifies the completeness of the order. S/he also checks to see that the lot numbers on the PT samples match the lot numbers on the report form. Any discrepancies are reported to the vendor. The PT samples are logged and distributed to the analysts. The PT samples are incorporated into the routine analytical schedules of the laboratory. **PT samples are tested the same number of times as a client sample.** PT results, after having been checked by the analyst and the technical supervisor, are entered on-line by the Program staff or automatically uploaded from Promium to the PT Provider's result website. (NJDEP and US EPA, Region II, receive copies of the PT results directly from the PT provider.)

Upon receipt of the PT event summary evaluation report, the QAO reviews and starts a Corrective Action/Preventive Action (CAPA) form for any unacceptable results. The CAPA is sent to the Program Manager who works with the analytical staff to determine the cause of the unacceptable result. The raw data used to produce any unacceptable results are reviewed along with search for clerical errors, integration errors, interfering analytes, etc. The completed, signed External PT CAPA form (**Attachment 11)** is given to the QAO within 28 calendar days to the QAO. It is required by both the EPA and NJDEP, for ECLS to maintain an evaluation of at least two 'Acceptable' determinations in the last three testing events for each certified testing parameter. Acquiring and performing additional 'Quick Response' PT samples may be necessary to prevent decertification if there are two out of three unacceptable results. If necessary, the additional PT samples are obtained by the QAO from a vendor accredited to provide such samples. The vendor forwards the results of these supplemental PT samples directly to the EPA or DEP. EPA has stated that the use of these make-up PT samples is an appropriate course of action. DEP may decertify the method when this performance standard has not been met for a period of six months.

Additional PT samples are also received from: The Centers for Disease Control for CT; USGS for nutrients; MAPEP for radiochemistry analytes, and Wadsworth Center of the NYSDOH for trace elements in clinical samples.

The results of PT samples are used as part of each analyst's annual demonstration of capability documentation. As such, PT samples must be rotated among the method qualified analysts each time they are received.

10.6 PROVIDING REGULAR REPORTS TO MANAGEMENT DETAILING THE FUNCTIONING OF THE QUALITY SYSTEMS.

There are regularly scheduled reports or data to management by the QAO. The first is a copy of the monthly audit report; the second involves monthly proficiency testing results and copies of all External PT CAPA submissions. Acceptable PT % is reported through PHEL Monthly Key Performance Indicators report.
In addition, the QAO can make available to both the ECLS and PPRC Service Directors any Complaint, Non-Conforming Event, and Correction Action Forms; External PT CAPA forms; legal requests for analytical data; and any client notifications of amended or corrected analytical reports.

10.7 CONDUCTING A REVIEW OF THE QUALITY SYSTEMS WITH MANAGEMENT.

ECLS Management is committed to making whatever changes are necessary to the quality systems to maintain the quality of the data generated and provide enough documentation in support of that data. The QA and Performance Improvement Program are reviewed by the PPRC Service Director. The QAO meets regularly with the PPRC Service Director to discuss the current state of the QA Program. This will allow for anticipated changes to the QA manual to be worked out well in advance of being updated. The ECLS Director and Program Managers also participate in the annual updating of the QA manual.

10.8 NOTIFICATION TO CLIENTS.

ECLS Providing Client Notifications

Whenever it becomes necessary to inform ECLS clients of pertinent information regarding the laboratory, this notification will be provided by the Service Director or his/her designee. Those notifications that do not require immediate attention/action on behalf of either the laboratory or the clients will be in writing. This notification will be used to convey the specifics of impending actions giving ample time for both the clients and ECLS to plan for its implementation. It could be used for notifying clients of upcoming changes: in methodology, in certification status, to sampling requirements, etc.

Those notifications that require immediate attention/action on behalf of either the laboratory or the client will be made verbally first and followed-up in writing. It could be used for notifying clients: of an instrument break down so the client could stop sampling for that testing procedure, or of laboratory analytical capacity being exceeded, etc.

ECLS Providing Information to Client Inquiries

There are instances when clients request: follow-up information on reported results, a check of QC data associated with certain analytical results, replacement copies of lost data, etc. *ALL INQUIRIES ARE TO BE MADE THROUGH THE ECLS QAO BY FORWARDING THE COMPLETED FORM CONTAINED IN* ***appendix 23****.* The form is to be completed and electronically emailed to sharon.robinson@doh.nj.gov . All fields listed on the form are required fields and must be completed before the request can be addressed by ECLS. When the information has been assembled, the response back to the requesting personnel will also be made by the ECLS QAO.

NOTE: Please be cognizant of the fact that any request for follow-up information may require the pulling of records from secondary storage. This process may still take several days for retrieval and, consequently, the response may not be immediately available.

10.9 OTHER OQA RESPONSIBILITIES

There are other miscellaneous responsibilities that the QAO must perform to document compliance with the quality systems. These are regularly scheduled activities that are of a more intermittent nature than the ones listed above. These activities are:

- Handling legal requests for information. Section 2.6.
- Handling complaints. Section 2.8.
- As needed, send the OQA standard weights out for re-calibration and maintain records indicating the results of those calibrations. (NIST traceable calibration is good for five years). This re-calibration is performed by the State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, Office of Weights and Measures, Avenel NJ 07001-1647, 732-815-4840, or some other equally qualified vendor. These weights are used to perform the monthly balance checks and for rechecking the other in-house weights.
- As needed, send the OQA thermometers out for re-calibration and maintain records indicating the results of those calibrations. (NIST traceable calibration is good for five years). This re-calibration is performed a by qualified vendor. Section 4.4.
- Retain records for automatic pipet calibrations. Section 4.2.
- Assign workbook identification numbers. Section 4.4.
- Annually, check the in-house weights against the re-calibrated OQA weights and maintain a record of those checks. Section 4.4.

CHAPTER ELEVEN
HEALTH and SAFETY

11.1 OBJECTIVE

It is ECLS's goal to provide a safe and healthful workplace for all employees. This goal can be met only through the cooperation of all parties involved. The very nature of laboratory work requires that employees utilize materials, equipment, and procedures not commonly found in other areas of employment. Reagents, chemicals, compressed gases, electrical equipment, etc. are all potentially hazardous when used carelessly or without taking proper precautions. All employees, technical, professional, and supervisors alike must constantly be aware of these potential hazards and must take all necessary precautions to reduce or eliminate the risks involved.

Accordingly, employees are expected to comply with established safety standards and policies. Managers and Supervisors are responsible for the enforcement of these standards and policies. Supervisors and employees alike should be diligent in identifying potential safety hazards and in ensuring that these hazards are reported to management and corrected expeditiously.

Above all other work objectives, safety is the number one priority. No work operation should be initiated unless the employee is certain that the procedure can be carried out and completed in a safe manner.

The rest of this chapter details the ECLS Policies concerning various safety practices. The Department maintains a fulltime Safety Officer on the premises should a situation arise that is not covered by the existing policies.

11.2 GENERAL SAFETY RULES

- Eating or drinking in laboratory areas is PROHIBITED along with eating or drinking from laboratory glassware. Food and beverages are not to be stored in laboratory areas, or in refrigerators that contain, or have contained, specimens, chemicals/reagents.
- Always wash hands thoroughly before exiting the laboratory area.
- Wear prescribed personal protective equipment:
  - Lab coats or lab gowns are mandatory for all personnel in laboratory areas. Lab coats are not to be worn outside the laboratory building and are PROHIBITED in administrative areas or rest rooms.
  - Gloves must be worn when handling samples/specimens or chemicals/reagents.
  - Safety glasses must be worn when opening or working with samples/specimens or chemicals/reagents.
- Assume that all specimens are potentially infectious. Use universal precautions when handling them.
- Report all accidents, potential hazards, and occurrences to your supervisor immediately, and to the Human Resources Leave Unit and to the Safety Officer. (Refer to “DOH Incident/Accident-Procedures”.)
- Mouth pipetting is not permitted under any circumstances. Always use a pipetting aid.
- Use a biosafety cabinet when there is a potential to inhale infectious aerosols or agents.
- Use a fume hoods when working with volatile, noxious or toxic chemicals/reagents. Refer to SDS for guidance on chemicals/reagents.
- No more than one gallon (4 liters) of flammable liquids per 100 square feet may be stored outside of an approved flammable storage cabinet within a laboratory.
- Never proceed with an analysis if you are unsure of its safety.
- Never bypass a safety device on any piece of equipment, for any reason.
- Do not obstruct or block doorways, hallways, emergency equipment, or exits. Storage of records, supplies, equipment, or chemicals in the hallway is prohibited.

- Keep work area as clean and uncluttered as possible. A disorderly work area is both a safety and a fire hazard.
- Clean spills immediately, according to established written protocol.
- Laboratory work surfaces must be decontaminated with a 1:10 solution of household bleach with water following any spill and at the end of work activities when working with clinical or biological specimens. This solution must be prepared daily.
- Do not bend, re-sheath, cut, or remove needles from syringes. Syringes and needles should be discarded in a heavy plastic or metal "sharps container", containing an appropriate antiseptic solution.
- All Hazardous/Radioactive waste for disposal must be placed in closed, labeled containers.

11.3 EYE AND FACE PROTECTION POLICY

ECLS requires that every employee and visitor wear eye and face protective equipment as indicated in this policy. **INDUSTRIAL QUALITY EYE AND FACE PROTECTIVE DEVICES SHALL BE WORN WHEN THE POSSIBILTY EXISTS THAT AN INJURY CAN BE PREVENTED BY SUCH DEVICES**.

The areas at risk and potentially hazardous procedures may include, but not limited to:

- Locations where chemicals are stored or handled.
- Working with hazardous biomedical material, cultures, and specimens.
- Handling explosives and flammables.
- Working with or near systems under vacuum or pressure.
- Areas and activities that present the hazard of flying objects such as glass cutting, preparation of capillary gas chromatographic columns, etc.
- During field operations or visiting a site where eye protection is required by the host institution.
- Pouring a corrosive or irritating liquid.
- Carrying out distillations or liquid-liquid extraction procedures.
- Any task that may result in a splash of a hazardous material.
- Any other area or task where eye/face safety is in question.

Laboratory management, with the assistance of the Employee Health and Safety Program (EHSP), shall identify potentially hazardous areas, procedures, and tasks. It is the responsibility of a program supervisor to assure that all employees under his/her supervision, including those temporarily assigned to the program, wear the required eye/face protection always in the areas at risk.

Entrance to all areas that require eye protection shall be posted with a sign indicating the eye protection requirement. In addition, equipment or processes that require an operator to wear eye/face protection shall be posted with appropriate warning signs.

Within PHEL, it is permissible not to wear eye protection in the break and conference rooms, administrative offices, and other rooms and hallways where chemical and biomedical materials are not in use. However, if at any time there is a hazardous operation being carried out in these areas, signs will be posted and all personnel entering the area shall be warned that eye protection and/or other personal protective equipment, if any, is temporarily required.

Industrial quality eye protection devices must comply with the Z87.1 Standard. This standard specifies the following requirements:

- Impact resistance.
- Passage of a flammability test.
- A 3 mm minimum of lens thickness.
- Lens retaining frames.

When selecting appropriate eye protection, consideration should be given to the employee's safety and personal comfort. Selection of an appropriate eye and face protective device is the responsibility of both the employee and supervisor. EHSP should be consulted in all cases where there is uncertainty as to what protection is necessary.

SAFETY GLASSES AND SPECTACLES PROVIDE ONLY A MINIMUM OF EYE PROTECTION WITH REGULAR USE. ADDITIONAL PROTECTION SUCH AS GOGGLES AND FACE SHIELDS SHALL BE REQUIRED WHEN CARRYING OUT MORE HAZARDOUS OPERATIONS.

DOH shall provide eye and face protection devices at no cost to all employees whose work requires such protection. Where appropriate, DOH shall provide prescription spectacles at no cost to the employee upon submission of prescription from their physician. Both glass and plastic lenses are available through EHSP. Plastic lenses are not resistant to some chemicals and get easily scratched. Glass lenses are heavier, but they are chemical resistant and last longer. Based upon the potential for exposure, both the supervisor and the employee should determine which type of prescription lenses is the most appropriate. Plain safety spectacles are available through EHSP for employees awaiting prescription safety glasses.

Other forms of eye protection that may be required for an operation include goggles and face shield. Goggles should be worn when there is a potential danger of splashing chemicals, irritating vapors, or flying particles, e. g., working with glassware under vacuum or pressure, or when glass apparatus is used in high temperature operation. Goggles offer no protection to the face and neck, and do not offer protection against chemical splashes. Full-face shields over safety glasses should always be worn when maximum protection to the face and throat is needed.

EXAMPLES OF OPERATIONS REQUIRING MAXIMUM PROTECTION ARE:
- Handling corrosive, irritating materials or those which can absorbed through the skin.
- Conducting a reaction that has a potential for explosion or working with a vacuum system that may implode.

CONTACT LENSES SHALL NEVER BE WORN WITH A QUARTER OR HALF-MASK RESPIRATOR.

CONTACT LENSES SHALL NOT BE WORN IN THE LABORATORY. Gases and vapors can be concentrated under the lens and cause permanent damage to the eyes. In the event of a chemical splash into the eyes, it is often impossible to remove the contact lens to irrigate the eye because of involuntary spasm of the eyelid. Soft lenses can absorb solvent vapors even through face shields and, as a result, adhere to the eye.

11.4

(a) **IN CASE OF EXPOSURE**

ACCIDENTS INVOLVING EXPOSURE TO HARMFUL MATERIAL REQUIRE PROMPT ATTENTION.
THE IMMEDIATE TIME OF 0-15 MINUTES FOLLOWING AN EXPOSURE IS CRITICAL.
WASH THE AREA IMMEDIATELY.

- **Eye Contact**: Promptly flush eyes with water for no less than 15 minutes and seek medical attention.
- **Ingestion**: Encourage the victim to drink large amounts of water, call Poison Control, and seek medical attention.
- **Skin Contact**: Promptly flush the affected area with water and remove any contaminated clothing. If symptoms persist after washing, seek medical attention.

(b) **FIRST AID POLICY**

First aid is referred to as that aid given at the first instance following the injury. First aid assistants (Medical Emergency First Responder) are located on every floor. Their names are posted on the Employee Health & Safety bulletin boards. In the event of a MINOR INJURY:

- Contact the nearest Medical Emergency First Responder.
- Contact the supervisor and the Safety Officer to report the injury.
- Complete an Injury/Illness Form, RM-2 Risk MGMT (available at: http://dhss). Submit the form to the Human Resource representative.
- If the person must be taken for additional medical assistance, call The Human Resources Leave Unit (633-0074 or 0022) to schedule a medical appointment.

If an employee is unable to walk, disoriented, in pain, bleeding profusely, etc., these would be considered a serious injury:

- Call 9-911 for ambulance assistance.
- Contact the nearest Medical Emergency First Responder.
- Call the call The Human Resources Leave Unit (633-0141 or 439-2842).
- Contact the supervisor to report the injury.

Never move an accident victim unless they are in danger of further injury. Seriously injured employees will be taken to the nearest hospital for treatment. A volunteer should collect the injured employee's belongings and meet the emergency vehicle/employee at the hospital.
Note: The First Responder or other individual helping the injured employee should not follow behind or try to keep up with the ambulance.

11.5 CHEMICAL FUME HOOD POLICY

Laboratory fume hoods are important safety devices. They provide the employee and the general laboratory area protection from exposure to chemical fumes that might be injurious to health and safety. However, the hood must be used properly to provide maximum protection. The following guidelines will be adhered to when using the chemical fume hood:

- The average face velocity of the chemical fume hood should be maintained between 80-120 L.F.M. for maximum efficiency.
- Do not clutter the hood area with unnecessary equipment. Do not use the hood as a ventilated storage cabinet.
- If an apparatus must be housed in a hood, it should be equipped with legs that will allow air to flow beneath it. Any apparatus, such as an oven, large hot plate, or water bath that does not have legs should be placed up on blocks. Prior to performing work, the user should be satisfied that the hood is in proper working order.
- Keep all work at least 8 inches inside the hood face but not against the back wall of the hood.
- The worker should keep their face out of the hood, i. e., outside of the plane of the sash.
- The sash should always be closed as much as practical to work with, but never more than 18 inches high.
- A hood should be thoroughly checked following installation. Maintenance activities should be carried out at least once a year.

11.6 GLASSWARE POLICY

To minimize or eliminate the frequency of injuries from broken glassware, the following is the ECLS glassware policy:

- Glass will be chemically attacked by hydrofluoric acid, hot phosphoric acid, and strong alkalis so glassware is never used to contain or process these materials.

- Do not use broken, chipped, cracked, or badly scratched glassware since it is prone to breakage. Instead, see that it is properly disposed of by placing it in "Broken Glass" containers.
- Never pick up broken glass with bare hands. Instead: use gloves; sweep up with hand broom and dustpan; fine glass particles may be picked up with a wet paper towel; place broken glass in "Broken Glass" containers; and do not mix broken glassware with other trash.
- Always wear safety glasses and gloves while cutting or breaking glass tubing.
- Use tongs or zetex gloves to remove all glassware from heat. Hot glass can cause severe burns.
- When clamping glassware, do not permit glass to metal contact or use excessive force to tighten.
- Do not attempt to catch falling glassware.
- Laboratory glassware is never to be used for holding food or drink for human consumption. It may contain toxic chemicals or biological residues.
- Carry long tubing or burets in an upright position, close to the body.
- Never carry glassware and/or samples on the stairwells. Always use the elevators.

11.7 FIRE PREVENTION POLICY

FLAMMABLE CHEMICALS are handled as follows:

- If the area has only one exit, flammable materials should never be stored near or adjacent to the exit. Such material should be stored at the end of the room farthest from the exit. Room exits should always be kept clear of obstructions.
- Handle all solvents in an exhaust hood, using the smallest amount practical.
- Store flammable liquids in a flammable liquid storage cabinet or in flammable materials storage (FMS) refrigerator.
- Always keep the supply of solvents in a laboratory to a minimum. No more than one gallon (or 4 liters) of flammable liquids per 100 square feet may be stored outside of an approved flammable storage cabinet within a laboratory.
- Extinguish all flames in the area when using flammables. Always be aware of nearby electrical equipment such as hot plates and ovens.
- No flammables are to be stored in refrigerators that are not rated "flammable materials storage" or "explosion proof".

Smoking is banned in all NJ State buildings. Smoking is permitted only in designated areas outside of each building.

REACTIVE CHEMICALS are handled as follows:

- Understand possible dangers before using and be aware of special storage requirements. See Safety Data Sheets (SDS) or Hazardous Substance Fact Sheets (HSFS) available in the service corridors or the RTK Central File.
- Keep the supply in the laboratory at a minimum, ordering the smallest amount practical to work with.
- When using these chemicals, co-workers in the area are to be notified when the work is started and completed. If no else is in the area in which you are working, your immediate supervisor is to be notified when work is started and completed.
- Segregate chemicals that are capable of explosive reaction with each other.
- It is your responsibility to know the properties of the chemicals you work with. If in doubt, always refer to SDS and HSFS and your supervisor.

TOXIC AND CORROSIVE CHEMICALS are handled as follows:

- Understand the possible dangers before using and be aware of special storage requirements. See SDS or HSFS.
- Keep the supply in the laboratory to a minimum, ordering the smallest amount practical to work with.
- Always store in the proper container.

- Follow all rules pertaining to good laboratory housekeeping; labeling, handling, and disposal (see PHEAL Laboratory Waste Disposal Guidelines).
- Use only in hooded or well-ventilated areas. Keep sealed when not in-use.
- Use appropriate protective equipment. Always refer to your supervisor for the proper equipment.

ELECTRICAL EQUIPMENT

- Do not use electrical equipment if power cords are frayed or control switches are not in good working order. Label "DO NOT USE" and see that arrangements are made through your supervisor for disconnection, repair, and/or replacement.
- Do not use electrical equipment, such as hot plates, around flammable liquids.
- Never try to bypass any safety device on a piece of equipment.
- In any emergency involving electrical equipment, including fire: Shut off power immediately; alert those in your immediate area; follow the PHEAL Emergency Response Plan; and fire extinguishers shall be used only by those who have been trained, and for small fires only.

LABORATORY HOUSEKEEPING

- Each employee is responsible for keeping his or her area neat and orderly. A disorderly work area is both a fire and a safety hazard.
- Laboratory benches should not be used as storage areas but should be cleared upon completion of each analysis.
- Aisles and hallways must never be blocked for any reason. Furniture and equipment in laboratory work areas shall be arranged so that means of access to any exit may be reached easily from any point.
- Laboratory apparatus should be assembled in a stable, orderly manner.
- Safety equipment such as fire extinguishers, eyewashes, and showers are to be kept clean and their access should never be blocked.
- All spills and leakages should be cleaned up immediately. Refer to Spill Policy.
- Keep all cabinet doors and drawers closed.

TRAINING AND EDUCATION

Emergency Response training and education will be presented to all new employees by, the PHEL Safety Officer, and the Emergency Evacuation Coordinator. The training includes:

- Review of Fire Prevention Program and Special Policies.
- Explaining the use of the Emergency shower and the Stop, Drop, and Roll technique.
- Review of Emergency Evacuation Plan.

11.8 COMPRESSED GAS CYLINDER POLICY

STORAGE is handled as follows:

- When cylinders are delivered, they are to be separated and secured immediately in the cylinder cages on the loading dock.
- Chains must be refastened once the tank has been placed into or removed from a slot.
- Do not store full and empty cylinders together. Serious "suck-back" can occur when an empty cylinder is attached to a pressurized system.
- All cylinders should be stored and attached to a firm support with a chain or strap at or above the mid-point to prevent them from falling over. If not in use, their valves should be closed completely, and the original shipping cap should be in-place.
- Always leave positive pressure in a gas cylinder. Label it "MT" (empty).
- Store empty cylinders in the designated locations in the gas cages.

TRANSPORTATION is handled as follows:

- Safety glasses are required whenever and wherever cylinders are handled.

- Before using or removing cylinders, read all label information and data sheets concerning the gas.
- Never drop gas cylinders or permit them to strike each other.
- Cylinders should be handled carefully and properly. They are never to be dragged, rolled or slid but moved on a hand truck designed for moving gas cylinders. Always be sure that the cylinder is secured to the truck.
- Never move a used gas cylinder until the valve is closed, the line is bled, the regulator is removed, the shipping cap is on, and the cylinder is labeled "MT".
- Cryogenic gases are extremely cold. Liquid nitrogen is stored at -320 degrees F and will cause burns and frostbite. Therefore, these tanks should only be transported by two or more workers wearing safety glasses, insulated gloves and a lab coat.

USAGE is handled as follows:

- Never lubricate, modify, or tamper with a safety valve or its safety devices.
- No part of a gas cylinder should be subject to a temperature higher than 125 degrees F. A flame should never be permitted to encounter any part of a gas cylinder.
- Know the contents of the gas cylinder before making any connections. The properties of a compressed gas that represent hazards should be well known to the user before the gas is put into use.
- Use compressed gases in a well-ventilated area. Toxic, flammable, and corrosive gases should be handled in a hood. Only small cylinders of toxic gases should be used.
- Always use a reducing valve or a pre-set pressure control.
- Tools and gas wrenches should always be readily available to shut off or adjust cylinders and regulators.
- Never hammer or tighten a compressed gas line while it is under pressure. The extra stress may cause the line to rupture.
- Copper tubing is not to be used for acetylene.

11.9 GUIDELINES FOR HANDLING AND TESTING BIOHAZARDOUS MATERIALS

The following practices shall be followed when handling or testing any "biological specimen":

- Assume that all specimens are potentially infectious.
- All specimens received broken shall be rejected and not tested.
- Gloves should be worn to avoid skin contact with all body fluids, work surfaces, materials, and other objects exposed to biological agents. After use, gloves must be discarded in biohazard disposal bags.
- Disposable gowns and masks should be worn in designated areas and should be placed in biohazard disposal bags before you leave the laboratory.
- All personnel should wash their hands following completion of laboratory activities, after removal of protective clothing, before leaving the laboratory and before eating or smoking.
- Laboratory work surfaces should be decontaminated with a 1:10 solution of household bleach with water following any spill and at the end of work activities. This solution should be prepared daily.
- Do not bend, re-sheath, cut, or remove needles from syringes. Syringes and needles should be placed in a heavy plastic or metal discard pan containing an appropriate antiseptic solution. Discard pans should be located as close as practical to the area in which the syringes are used. Autoclaved needles and syringes should be double boxed and taped securely for disposal.
- Mechanical or electronic pipetting devices should be used for the manipulation of all liquids in the laboratory. Mouth pipetting is prohibited.
- All procedures and manipulations of potentially infectious material should be performed carefully to minimize the creation of droplets and aerosols. These procedures include centrifuging, blending, and vigorous mixing.
- When the potential for aerosolizing, splashing, or spillage of biohazardous material is present, all manipulations should be done in Class II biological safety cabinets. Centrifuge safety caps should be utilized.
- Specimens are not to be transported via stairwells under any circumstances.

- All contaminated materials will be decontaminated by autoclaving before disposal or reprocessing.
- **Note: biological specimens can be, but are not limited to, the following: fish tissue, bird tissue, human secretions, excretions, and blood**.

References:

- US Department of Health and Human Services. US Public Health Service. Acquired Immunodeficiency Syndrome (AIDS). Precautions for Clinical Laboratory Staff: 1982, 5;31:577-80.
- US Department of Health and Human Services, Public Health Service. CDC Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2009.

11.10 GUIDELINES FOR REPORTING SAFETY AND HEALTH CONCERNS

- Employees should report any safety or health concerns to their immediate supervisor.
- Supervisors should take whatever action is necessary to correct or resolve the problem within the Program, Service Area, or Division and inform the Safety Officer.
- When it is not feasible to resolve the problem within the Division, staff should forward their concerns through their respective Director to the EHSP Chief.
- Dependent upon the nature and level of the complaints and concerns, the coordinator will take appropriate action as soon as possible.
- If at any time an employee feels that their concerns are not being addressed within a reasonable time frame, they are encouraged to contact the EHSP Chief at (609)633-0361.
- All calls will be confidential. Identification will be required if a direct response is requested.

11.11 WASTE CHEMICAL REMOVAL POLICY

- **Disposal of hazardous chemicals into the sewer system or trash collectors is prohibited.**
- All hazardous outdated and waste chemicals must be removed from laboratories and properly disposed through the Laboratory Safety Office (LSO). See the PHEAL Laboratory Disposal Guidelines for details.

Containers:

- Must be labeled with the appropriate **label obtained from the LSO.**
- Must be compatible with chemicals they contain.
- Must be leak proof and have tightly closed lids.
- Must be kept closed, except when in the process of being filled.

Accumulation and Storage:

- **Liquid wastes** are to be **collected in one-gallon (or 4-liter) containers** and stored in an appropriate hazardous waste cabinet in the laboratory.
- Each **cabinet** for storing chemical waste must be **labeled** with the words "HAZARDOUS WASTE".
- Quantities of chemical waste accumulated in the laboratory, at any time, **shall not exceed five (5) gallons** of liquid or ten (**10) pounds** of solids.

Disposal:

- Laboratories which regularly generate chemical waste:
  - At 2:00 PM, on Thursdays, and beginning on the fourth floor, Central Services (CS) staff will be checking with these laboratories.
  - If you have full bottles of chemicals to dispose of, you (not CS staff) are to place the chemicals on the chemical waste cart (provided by CS staff).
- Laboratories which are not regular generators of chemical waste are to contact the LSO for instructions on disposal.
- **In case of an emergency**, if you need waste disposed of; it must be taken to the Hazardous Waste Storage Room (L192) for storage, at the appointed time. Appointments can be made by contacting the LSO.

Within 180 days from the accumulation start date, all hazardous waste will be shipped to an off-site facility, for final disposal.

NOTE: The chemical waste removal company cannot accept unidentified chemicals.

11.12 CHEMICAL STORAGE POLICY

- Reagents straight from the manufacturer must have the date received written clearly on the label.
- Incompatible chemicals shall be segregated in storage to prevent accidental contact with other chemicals.

  CORROSIVE CHEMICALS are: stored in a cool, dry well-ventilated area away from sunlight; stored with acids segregated from bases (hydrofluoric acid); stored segregated from toxic materials, organics, and flammables.

  REACTIVE CHEMICALS are: stored in a cool, dry area protected from shock, elevated temperatures or rapid temperature changes (aluminum alkalis); store segregated from corrosives, fire, and/or heat sources.

  OXIDIZING CHEMICALS are: stored in a cool, well-ventilated area out of direct sunlight (potassium chromate); segregated from organics, flammables, corrosives, toxicants, heat and/or strong sunlight.

  WATER SENSITIVE CHEMICALS are: not stored where automatic sprinkler or shower is installed; segregated from other reactive chemicals; stored in a room that has no water service and that is cool and water resistant; segregated from moist air, water and water solutions, aqueous acids and bases, flammables, and reactive chemicals.

11.13 SPILL POLICY

Spills of samples, acids, bases, solvents, and other substances found in the laboratory are to be handled in the following manner:

- Alert the immediate supervisor and workers in the area of any type of spill.
- Attempt to prevent further spillage and contamination. The worker must be wearing safety glasses, gloves, and a lab coat.
- If the spill cannot be contained and constitutes a life-threatening situation, evacuate the affected laboratory area.
- To contain liquid spills, use copious amounts of paper towels, spill pillows, or absorbent to encircle the substance.
- For solid spills, block off the area and see that no one walks through it or spreads it.
- To clean up liquid spills, use large amounts of towels or absorbent. For solvents, place towels in a hood and allow them to dry. For other liquids, use appropriate absorbent and place it in a suitable container (determined by the nature of the substance) for proper disposal.
- To clean up a solid material, sweep it up and place it in a suitable container for proper disposal.

11.14 REFERENCES

SAFETY DATA SHEETS (SDS) are available from the chemical manufacturer and suppliers. They provide comprehensive information about individual chemicals and reagents. Information contained in the sheets includes:

- Identification information such as chemical formula, CAS number, chemical name, and synonyms, etc.
- Labeling information.
- Physical data.
- Fire and explosion hazard data.
- Health hazard data.
- Reactivity data.
- Spill and disposal procedures.
- Recommended protective equipment.
- Storage and handling precautions.
- Transportation information.
- SDS are in the RTK Central File (outside L-365).

HAZARD SUBSTANCE FACT SHEETS (HSFS) are published by the NJ DOH Right to Know Program and contain information like that provided by the SDS. However, these are not available for all chemicals. The HSFS are also located in the RTK Central File.

A copy of the "CHEMICAL HYGIENE PLAN which includes the EMPLOYEE GUIDE TO WORKING SAFELY WITH HAZARDOUS MATERIALS" is available in the RTK Central File and is also accessible at the Department's intranet website. Employees are encouraged to review this material as often as possible. These documents are updated annually by the Laboratory Safety Officer and the PHEAL Safety Committee.

APPENDIX 1: Definitions

ACCEPTANCE CRITERIA: specified limits on the characteristics of an item, process, or service defined in requirement documents.

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

AMERICAN PUBLIC HEALTH ASSOCIATION (APHA): publisher of "Standard Methods for the Examination of Water and Wastewater."

ANALYST: the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality control measures designed to meet the required level of quality.

ANALYTE: any compound or element, which can be detected and quantified by an analytical method.

APPROVED ANALYTICAL METHODS: methods, where applicable, which are mandated by State and/or Federal regulations for use during analyses conducted for compliance with State and/or Federal laws.

ASSESSMENT: the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria.

ATOMIC ABSORPTION SPECTROSCOPY: term applied to one of the instrumental methods generally used to analyze environmental samples for metals. The prepared sample is introduced via cold vapor, flame, or furnace techniques and atomized. A light beam from a hollow cathode lamp, whose cathode is made of the element to be determined, or an electrodeless discharge lamp, is directed through the vapor onto a monochromator, and into a detector that measures the amount of light absorbed. Absorption depends upon the presence of free unexcited ground state atoms in the vapor. Since the wavelength of the light beam is characteristic of only the metal being determined, the light energy absorbed is a measure of the concentration of that metal in the sample.

AUDIT: a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

BATCH: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A "preparation batch" is usually, but not always, composed of 1 to 20 samples of the same defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. A “submission batch” is composed of the samples that a sampler delivers to ECLS. It can consist of as few as one sample and is open ended on the other side. An "analytical batch" is composed of prepared 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 submission batches.

BLANK: an aliquot of laboratory grade water, free of the analytes of interest 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 background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

EQUIPMENT BLANK: a sample of analyte free matrix, which has been used to rinse common sampling equipment to check the effectiveness of decontamination procedures.
FIELD BLANK: blank prepared in the field by filling a clean container with pure distilled/de-ionized water and the appropriate preservative, if any, for the specific sampling activity being undertaken.
INSTRUMENT BLANK: a clean sample (e.g. distilled or deionized water) processed through the instrumental steps of the measurement process; used to determine instrument contamination.
METHOD BLANK: a sample of a matrix similar to a 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. Since it is usually not possible to obtain a "matrix similar to the batch matrix," an in-house matrix is substituted for the batch matrix. This results in the method blank, being equivalent to the reagent blank.
LABORATORY REAGENT BLANK (LRB): a sample consisting of laboratory de-ionized water and reagents, without the target analyte or sample matrix, subjected to the same processes as the samples and used to determine the contribution of the reagents to the instrument readings.
TRIP BLANK: a container of laboratory pure water that is taken into the field to experience the conditions that samples undergo during sampling and transportation back to the laboratory. This serves as an indicator of potential sample contamination.

BLIND SAMPLE: a sample submitted for analysis with a composition known only to the submitter, usually the QAO. The analyst/laboratory may know the identity of the sample but not its concentration. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement and reporting processes. See also Performance Audit.

CALIBRATION: 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 bracket the range of planned or expected sample measurements.

CALIBRATION CURVE: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument responses.

CALIBRATION METHOD: a defined technical procedure for performing a calibration.

CALIBRATION STANDARD: a substance or reference material used to calibrate an instrument.

CERTIFIED REFERENCE MATERIAL (CRM): 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 issued by a certifying body.

COEFFICIENT of DETERMINATION: a measure of the amount of variation in the dependent variable that is accounted for by the independent variable and is designated as R^2.

COMPLAINT: statement made by a client that expresses, directly or indirectly, dissatisfaction with the services provided by ECLS. Examples of a complaint could be: a request to "validate" reported results; reported results do not match historical data; a request for a partial list of results after the expected reporting timeline has been exceeded; etc. Further determinations as to what constitutes a complaint will be made by the QAO.

CONFIRMATION: verification of the identity of a component using an approach employing a different scientific principle from the original method. These may include, but are not limited to: second column confirmation,

alternative wavelength, derivatization, mass spectral interpretation, alternative detectors, or additional cleanup procedures.

CONFORMANCE: an affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also, the state of meeting the requirements.

CONTINUING CALIBRATION CHECK (CCC): a term generally used in organic analyses. It is not practical to daily perform an initial calibration of the instruments used in these analyses due to the length of the calibration process. The initial calibration establishes a response factor for the individual parameters. The parameter values generated by the CCC are compared against those response factors and, if they are within acceptable limits, the instrument is judged to still be calibrated.

CONTINUOUS FLOW ANALYSIS: a colorimetric method of analysis performed by pumping samples through a closed system and having the reagents added and the analysis conducted automatically. (See Flow Injection Analysis and Segmented Flow Analysis).

CONTROL LIMITS: a range that delineates acceptable performance for the analysis of a given analyte. The term applies to calibration check, surrogate, duplicate, control samples, and matrix spike results.

CORRECTIVE ACTION: the action taken to eliminate the causes of an existing nonconformity, defect or other situation to prevent recurrence.

CORRELATION COEFFICIENT: a measure of the linear relationship between 2 variables and is designated as R.

DATA AUDIT: a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria or that conformance has been achieved).

DATA PACKAGE REVIEW: the process of verifying data packages for completeness of required analytical information and spot checking the accuracy of the reported analytical results.

DATA REDUCTION: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc. and collating it into a more useable form.

DEFICIENCY: an unauthorized deviation from acceptable procedures or practices, or a defect in an item.

DEMONSTRATION OF CAPABILITY: a procedure used to establish the ability of an analyst to generate acceptable accuracy and precision for a specific analysis.

DETECTION LIMIT: the lowest concentration or amount of the target analyte that can be identified, measured, and reported with 99% confidence that the analyte concentration is not a false positive value.

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

ELEMENT: The ECLS Laboratory Information Management System (LIMS).

EXTERNAL CHAIN OF CUSTODY FORM: a record that documents the possession of the samples from the time of collection to receipt in the laboratory, including the transfer of samples from the sample collector to a courier

for delivery to the laboratory. This record generally recorded in a Sample Submittal Form and includes: the number and types of containers; the mode of collection; collector; time of collection; and requested analyses.

FIELD DUPLICATE: an individual environmental sample that is collected at a sampling point and is then aliquoted into two different containers at the time of sample collection. The two samples are generally not identified to the laboratory as duplicates and therefore the laboratory cannot calculate the relative percent difference (RPD). The data user may calculate the RPD as a measure of sampling technique consistency or matrix homogeneity. The laboratory analyzes and handles field duplicates as routine samples.

FLOW INJECTION ANALYSIS: a technique whereby a small, fixed volume of a liquid sample is injected as a discrete zone using an injection device into a liquid carrier which flows through a narrow bore tube or conduit. The sample zone is progressively dispersed into the carrier, initially by convection and later by axial and radial diffusion, as it is transported along the conduit under laminar flow conditions. Reagents may be added at various confluence points and these mix with the sample zone under the influence of radial dispersion, to produce reactive or detectable species which can be sensed by any one of a variety of flow-through detection devices. The height or area of the peak-shaped signal thus obtained can be used to quantify the analyte after comparison with peaks obtained for solutions containing know concentrations of the analyte.

FLUORESCENCE SPECTROSCOPY: analytical technique that measures the emitted radiation of a target analyte. The analyte is subjected to a radiation source causing the analyte to absorb the radiation. The analyte then emits radiation usually at a longer wavelength than the absorbed radiation. The measure of this emitted radiation indicates the amount of the analyte present in the sample. This technique is used to analyze for low levels of mercury.

GAS CHROMATOGRAPHY: an analytical technique for separating organic substances by percolating an inert gas stream over an inert, adsorptive stationary phase contained in a column.

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC): an analytical technique for separating organic compounds by passing an active mobile liquid over an inert stationary phase that has bound to it an active liquid phase. The varying affinities of the compounds in the sample for the active liquid phase, causes the desired compound separations.

HOLDING TIMES: These are the maximum allowable times, as defined by State and/or Federal regulations that samples may be held prior to the initiation of the analysis and still be considered valid or not compromised.

INDUCTIVELY COUPLED PLASMA ATOMIC EMISSION SPECTROMETRY (ICP-AES): a term applied to the process which can analyze for more than one metallic element by measuring the emission spectra produced by the sample when introduced into an argon plasma.

INDUCTIVELY COUPLED PLASMA/MASS SPECTROMETRY (ICP/MS): an analytical technique used to determine low level metal concentrations. The ICP is the means through which the sample is introduced into the system. The MS functions as the separator and the detector of the system.

INSPECTION (Also see: Audit): an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements to establish whether conformance is achieved for each characteristic.

INTERNAL CHAIN OF CUSTODY FORM: records that document which laboratory personnel took possession of a sample to initiate analysis. This record does not consist solely of one form that accompanies the sample

through analysis but is comprised of several different documents, that taken together, establishes internal chain of custody.

INTERNAL STANDARD: a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. It is used to calculate the concentrations of the analytes of interest in the sample.

ION CHROMATOGRAPHY: an analytical technique used to separate the ionic components of a sample by passing a liquid phase containing the sample over an ion exchanger. The strength of the affinity of the sample ions for the ionic sites of the exchanger effects the separation.

ION SELECTIVE ELECTRODE METER: an apparatus used to assay samples, directly or indirectly, containing the species for which the electrode is selective.

INSTRUMENT PERFORMANCE CHECK SAMPLE (IPC): solutions of known concentrations of one or more constituents prepared from the same stock standard solutions that are used to prepare the calibration curve and subjected to the same processes that those standards are subjected, which are analyzed prior to and/or throughout the analysis of environmental samples and are used to check for line drift of the calibration curve throughout the analysis.

LABORATORY FORTIFIED BLANK (LFB), also referred to as LABORATORY CONTROL SAMPLE (LCS), or SPIKED BLANK (SP), or QC check sample: a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes prepared from a different set of standard material that are used to prepare the calibration standards and subjected to the same processes as the calibration standards. It is used to check on the continuing validity of the calibration curve throughout the analyses and to establish intra-laboratory or analyst specific precision or bias.

LABORATORY DUPLICATE: aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently in the same analytical batch which are used to determine the precision of the analyses.

LEGAL CHAIN OF CUSTODY PROTOCOLS: procedures employed to record the possession of samples from the time of sampling through analysis that are performed at the special request of the client. These protocols include the use of a Sample Submittal Form that documents the collection, transport, and receipt of compliance samples by the laboratory. **In addition, these protocols document all handling of the samples within the laboratory via the internal chain of custody records.**

MANAGER: LABORATORY (however named): the individual designated as being responsible for the overall operation, personnel, and the physical plant of the environmental laboratory. This presently is the Director of PHEL. A Technical Director may report directly to the Laboratory Manager.

MANAGER: SERVICE: the individual designated as being responsible for the day-to-day operation of the Environmental and Chemical Laboratory Services. This person can also be referred to as a TECHNICAL DIRECTOR.

MATRIX: the component or substance that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following distinctions shall be used, provided the sample submitter does not specifically designate the sample as a certain type:

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.

DRINKING WATER: any aqueous sample that has been designated as potable or potential potable water source.
SALINE/ESTUARINE: any aqueous sample from an ocean or estuary, or other salt-water source such as the Great Salt Lake.
NON-AQUEOUS LIQUID: any organic liquid with <15% settleable solids.
BIOLOGICAL TISSUE: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
SOLIDS: includes soils, sediments, sludges and other matrices with >15% settable solids.
CHEMICAL WASTE: a product or by-product of an industrial process that results in a matrix not previously defined.
AIR: 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 another device.
SURFACE WIPES: a solids sample generated by using an appropriate wipe material to collect dust samples for metals analyses.
BODY FLUIDS: blood or urine samples collected from a person.

MATRIX SPIKE (MS) also referred to as SPIKED SAMPLE or LABORATORY FORTIFIED MATRIX (LFM): a sample prepared by adding a known amount 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: a replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

MAXIMUM CONTAMINANT LEVEL (MCL): the highest level of a contaminant that is permitted in Drinking Water under Federal and/or State regulations.

METHOD DETECTION LIMIT (MDL) (Also see: DETECTION LIMIT): the minimum concentration of a substance that can be measured and reported with 99% confidence that the concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40CFR Part 136, Appendix B).

MODIFIED REGULATORY REPORT PACKAGE (MRRP): see Tier 2 Report.

MS TUNING DATA: refers to the data generated and reviewed by the analyst to ensure that the mass spectrometer (MS) is operating within the required performance criteria. This is accomplished by running one of two compounds through the GC/MS: bromofluorobenzene (BFB) for volatile organics and decafluorotriphenylphosphine (DFTPP) for non-volatile extractable organics. A spectrum of the appropriate compound is acquired, and it must meet the specific criteria listed in the methodology. The tuning solution for the ICP/MS consists of the elements: beryllium, magnesium, cobalt, indium, and lead. The spectrum of this solution must meet the acceptance criteria listed in the method.

NEGATIVE CONTROL: measures taken to ensure that a test, its components, or the environment have not been exposed to method analytes or other interferences during the collection, transportation, preparation and/or analysis. This consists of method blanks, field blanks, and trip blanks.

NELAP: (National Environmental Laboratory Accreditation Program) The purpose of this program is to establish and implement a program for the accreditation of environmental laboratories.

NIST: National Institute of Standards and Technology. This agency was previously known as the National Bureau of Standards (NBS).

NJDEP: New Jersey Department of Environmental Protection.

NJDOH: New Jersey Department of Health.

PERFORMANCE AUDIT: the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data to evaluate the proficiency of an analyst or laboratory. This consists of external proficiency and internal blind samples.

PERFORMANCE BASED MEASUREMENT SYSTEM (PBMS): a set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified and serve as criteria for selecting test methods to meet those needs in a cost-effective manner.

POSITIVE CONTROL: measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. This is shown through the analyses of LCSs.

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

PRESERVATION: refrigeration and/or reagents added, usually at the time of sample collection, to maintain the chemical and/or biological integrity of the sample.

PROFICIENCY TESTING: a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an outside source.

PROFICIENCY TESTING PROGRAM: the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

PROFICIENCY TEST SAMPLE (PT): a sample, the composition of which is unknown to the analyst, which is provided by external, certified PT providers, to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria.

PROMIUM™ Element: ECLS' Laboratory Information Management System (LIMS).

PROTOCOL: a detailed written procedure for field and/or laboratory operation that must be strictly followed.

QUALITY ASSURANCE: 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 PROJECT PLAN (QAPP): a formal document describing the detailed quality control procedures by which the quality requirements, defined for the data and decisions pertaining to a specific project, are to be achieved.

QUALITY CONTROL: 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: 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 the users.

QUALITY SYSTEM: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products, and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

QUANTITATION LIMITS: levels, concentrations, or quantities of a target variable that can be reported at a specified degree of confidence.

RANGE: the difference between the minimum and the maximum of a set of values.

RAW DATA: any original information from a measurement activity or study recorded in laboratory notebooks, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted.

RECOMMENDED METHODS: methods recommended by State and/or Federal agencies for use during certain analyses. However, these methods are not currently mandated for use by State and/or Federal Regulations.

REFERENCE MATERIAL: a material or substance, one or more properties of which are sufficiently well established, used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

REFERENCE METHOD: a method of known and documented accuracy and precision issued by an organization recognized as competent to do so.

REFERENCE STANDARD: a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

REPLICATE ANALYSES (See also: LABORATORY DUPLICATE): the measurements of the variable of interest performed identically on one or more sub-samples of the same sample within a short time interval.

REPORTING LEVEL: the lowest concentration of an analyte that can be reported with a specified level of certainty, and without any special data qualifying codes. Defined by ECLS as the concentration of the lowest calibration standard.

REQUIREMENT: denotes a mandatory specification.

SAMPLE TRACKING: procedures employed to record the possession of a sample from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory along with the Internal Chain of Custody records. Access to the laboratory is limited and controlled to protect the integrity of

the samples. Therefore, once a sample is received in the laboratory, only ECLS personnel have access to the submitted samples.

SEGMENTED FLOW ANALYSIS (SFA): or segmented continuous flow analysis (SCFA) is a technique which involves the introduction of sample into a flowing stream of reagents that react with the sample to produce a measurable product. Samples are separated by the introduction of gas bubbles and a wash solution to avoid cross contamination between samples. In SCFA, turbulent flow conditions apply, complete sample dispersion occurs, and a steady-state condition is attained prior to analyte detection. The means of detection are like those used in flow injection analysis.

SELECTIVITY: the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances.

SENSITIVITY: the capability of a method or instrument to discriminate between measurement responses representing different concentrations of a variable of interest.

SPIKE: a known concentration of target analyte, or a substance which responds similarly to the analyte, added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

STANDARD: the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies.

"STANDARD METHODS FOR THE EXAMINATION OF WATER AND WASTEWATER": a compendium of approved analytical methods issued by the American Public Health Association (APHA).

STANDARD OPERATING PROCEDURES (SOPs or METHOD MANUALS): 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. ECLS SOPs list the actual procedures that are used in the laboratory and are not just a rewriting of the reference method.

STANDARD REGULATORY REPORT PACKAGE (SRRP): See Tier 1 Report.

STANDARDIZED REFERENCE MATERIAL (SRM): 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. SUPERVISOR: Within each functional unit in ECLS, there are analytical areas of specialization each of which is led by an individual who has responsibility for the proper functioning of that area. These individuals are designated as Supervisors. These Supervisors also meet the requirements of a Technical Director and are used as substitute Technical Supervisors when the Technical Supervisor is absent from work.

SURROGATE: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes.

TECHNICAL DIRECTOR: individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties, and training of personnel so that those employees have the required balance of education, training, and experience to perform the required analyses. The Technical Director must possess the qualifications contained in revision 15 of the NELAC document (July 12, 2002) in section 4.1.1.1.

TECHNICAL SUPERVISOR: The ECLS staff here designated as Technical Supervisors, also meet the requirements of this section in NELAC for Technical Director. However, Technical Supervisor will be used to reference the 4 individuals that are the supervisors of the Inorganic, Organic, Sample Receiving and Data Management, and Radiochemistry Units within ECLS.

TEST: 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 specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

TEST METHOD: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOPS.

TIER 1 REPORT: this is the full data deliverables analytical report package produced by ECLS upon request of the client. It is also referred to as a Standard Regulatory Report Package (SRRP). Although it is referred to as a "Standard" package, it is not the style of report routinely generated by ECLS. This style of report is produced only if a client requests it. The report comprises a very large data package that fully documents every aspect of each analytical procedure used to produce the results. It includes copies of the analytical results as well as raw instrument output, raw QC data, summary QC data, extraction logs, submittal and chain of custody forms, a laboratory chronicle, a case narrative, etc.

TIER 2 REPORT: this is the analytical report package ECLS routinely produces for its clients.

TOLERANCE CHART: a chart in which the plotted quality control data is assessed via a tolerance level (e.g., +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/data use requirements instead of statistical acceptance criteria (e.g., +/- 3 sigma).

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

USEPA: refers to the United States Environmental Protection Agency.

USGS: refers to the United States Geological Survey.

UV-VIS SPECTROMETER: an apparatus used as the detector in colorimetric analyses. The instrument functions by passing light of a specific wavelength through the sample that has been treated with reagents to form a colored end product with the analyte of interest. The colored end product absorbs light of the specific wavelength. The absorbance is proportional to the concentration of the end product in the sample.

VALIDATION: the process of substantiating specified performance criteria.

VERIFICATION: confirmation by examination and provision of evidence that specified requirements have been met. 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 to 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.

WORK CELL: a defined group of analysts that work together to perform a specific analysis. The members of the group and their specific functions within the work cell are documented through the DOC process.

APPENDIX 4: Analyst Receipt of Methods

This form is to be completed by newly hired personnel and existing personnel whenever they are assigned new analytical responsibilities. When entering the method numbers below, make sure that the revision number of the in-house method is included.

ANALYST (PRINT): _____

This is to certify that I have received a personal copy of all the analytical SOPs for the tests that I am required to conduct. It also indicates that I will review these SOPs within 30 days of receipt and that I will address any requests for clarifications to the appropriate Technical Supervisor. In the absence of any such requests, it will be Management's understanding that I fully understand the SOP requirements and that I will strictly adhere to the protocols contained therein.

ECLS METHOD: _____ REVISION: _____

SIGNATURE: _____ DATE: _____

ECLS METHOD: _____ REVISION: _____

SIGNATURE: _____ DATE: _____

ECLS METHOD: _____ REVISION: _____

SIGNATURE: _____ DATE: _____

ECLS METHOD: _____ REVISION: _____

SIGNATURE: _____ DATE: _____

ECLS METHOD: _____ REVISION: _____

SIGNATURE: _____ DATE: _____

SUPERVISORY REVIEW: _____ DATE: _____

APPENDIX 5: Analyst Receipt of ECLS QM

This form will be replaced with a Qualtrax acknowledgement test, issued with every published revision of the QM. Expected to start February 2019.

This form is required to be completed at the time the analyst receives his/her copy of the latest version of the Quality Manual.

ANALYST (PRINT): _____

This is to certify that I have received my personal copy of the QM and that I realize that I am to adhere to the policies and requirements contained therein. It also indicates that I will review the QM within 10 working days of receipt of the QM and that I will address any requests, in writing, for clarification to the QAO through the Technical Supervisor. As part of my education concerning the QM and the changes that exist in this version of the QM when compared to the last version, there will be a set of 3 meetings, one of which I am required to attend, that will be scheduled for approximately 2 weeks after distribution, so that the changes in requirements can be brought to the analyst's attention. This will also allow me the opportunity to seek clarification on the requirements contained in the QM. In the absence of any written requests it is understood that I fully understand the QM requirements and that I will strictly adhere to the protocols contained therein.

EFFECTIVE DATE OF QM RECEIVED: _____

DATE RECEIVED: _____

Location of ECLS QM Q: > PHL SOPs> 317 ECLS GENERAL> QUALITY MANUALS> ECLS QM 2018/2019

SIGNATURE: _____

APPENDIX 6: DOC Certification Statement

Each analyst is required to obtain this DOC Certification for each analysis, on a yearly basis, that s/he is responsible for performing.

NJ Department of Health
Public Health and Environmental Laboratories
Environmental and Chemical Laboratory Service
3 Schwarzkopf Drive,
West Trenton NJ 08628

Certification Statement Date:
ECLS Method No. and Revision No.:
Analyst(s): **Matrix:**
Parameter(s):

We, the undersigned, CERTIFY that:

1. The analyst(s) identified above, using the cited test method, which is in use at this facility for the analysis of samples under the USEPA and NJDEP Laboratory Certification Regulations, have met the Demonstration of Capability (DOC).
2. The test method was performed by the analyst(s) identified on this certification.
3. A copy of the test method and the laboratory specific Quality Manual is available for all personnel on-site.
4. The data associated with the DOC are true, accurate, complete, and self-explanatory.
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility by the analyst, and that the associated information is well organized and available for review by authorized assessors.

Technical Supervisor of The Appropriate Analytical Unit	Signature	Date
Quality Assurance Officer	Signature	Date

Appendix 8

ECLS Laboratory Training Form

Analyst:

Method:

Training Start Date: **Training Completion Date:**

Supervisor Signature:

Goal training period: example: 3 days, 1 week, 4 weeks, 2 months, etc.

I certify for the method listed above that 1) I have read and understand the original method and the standard operating procedure for this method, 2) I have been properly trained to perform this method, and 3) that I am competent to perform this method:

Signature

Date

Required Activity	Sub-activity	Trainer	Date Completed
PHEL Safety Training	Emergency Response Plan		
	Chemical and Right to Know		
	Biosafety & Blood-borne Pathogens		
	Compressed Gas Cylinder		
	Biosafety Cabinet		
Laboratory Safety Training	Eye Washes and Emergency Showers		
	Personal Protective Equipment, Spill Kits, and First Aid Kits		

	Incident/Accident Procedure Instructions		
	Chemical/Hazards/Waste handling & SDS Locations		
Test Method/SOP	Read Original Method		
	Read Standard Operating Procedure		
Quality Assurance	Quality Assurance Training through QA Office		
	Quality Manual		
	Laboratory QA/QC Overview (QC, Verifications, Other Logs, etc.)		
Reagents & Supplies	Overview of Reagent Locations/Safety/Inventory/Logs		
	Overview of Supplies/Inventory		
Samples	Sample Receiving and Integrity		
	Holding Time & Turn Around Time		
	Sample Storage		
	Sample Preparation (Turbidity, Digestion, etc.)		
	Sample Preparation Logs		
Required Activity	**Sub-activity**	**Trainer**	**Date Completed**
Standards & Controls	Calibration Standards Preparation		

	Quality Control Standards Preparation		
	Standard and Control Logs		
	Standards and Controls Expiration		
Instrument	Overview of Instrument Operation		
	Instrument Logs		
	Instrument Daily/Periodic/Annual Maintenance		
	Instrument Startup		
	Instrument Optimization		
Required Activity	**Sub-activity**	**Trainer**	**Date Completed**
Instrument Continued	Instrument Calibration		
	Analytical Procedure		
	Quality Control		
	Troubleshooting		
	Data Capture		
	Instrument Shutdown		

Laboratory Information Management System (LIMS)	Overview of Element		
	Checking Sample Backlog		
	Generating Batch		
	Datatool and Data Import		
	Data Review		
	Advanced Features (QC Tables, Test Selection, Sample Disposal)		
Waste Handling	Sample Retention and Disposal		
	Reagent and Waste Disposal		
Required Activity	**Sub-activity**	**Trainer**	**Date Completed**
Data Review/Reporting	Calibration Requirements (curve coefficient, continuous checks)		
	Blank Requirements		
	Control Standard Requirements		
	Duplicate and Spike Requirements		
	Peer Data Review		
	Tier 1 Package Requirements		

	Data Backup & Data Storage		
Demonstration of Capability	Passing Calibration Curve		
	Passing Continuous Calibration and Blank Checks		
	Passing Quality Control Samples		
	Passing Reporting Level Checks		
	Passing Lab Reagent Blanks and Blank Spikes		
	Sample Properly Prepared		
	4 Low QC samples (or PT), Correct Analysis of Unknown Sample		

Analyst's Comments:

Trainer(s)'s Comments:

Attach required documents: MDLs, PT/blinded sample results), written quiz, DOC examples.

APPENDIX 9: DI Meeting Attendance

NAME	DI Training Date AM	DI Training Date PM	Make up New Hire
Environmental Chemistry Laboratory Services			
Apollon, Valine			
Argenti, Anthony			
Bind, Eric			
Blue, Latasha			
Camacho, Sandra			
Chu, Christopher			
Compagnucci, Lynne			
Du, Songyan			
French-Mesch, Rebecca			
Gleason, Diana			
Haltmeier, Douglas			
Hargrave, Deborah			
Henitz, James			
Khalil, Nermine			
Kidd, Alana			
Krasley, Andrew			
Lawson, Bill			
Lettiere, Lauren			
Madon, Maria			
Mukherjee, Jhindan			

NAME	DI Training Date AM	DI Training Date PM	Make up New Hire
Nemeth, William			
Obed, Reynaldo			
Patel, Bhupendra			
Patel, Vaishali			
Patterson, Norman			
Pierzhanowski, Sandra			
Riker, Collin (Dave)			
Robinson, Sharon			
Saad, Mounir			
Servis, Robert			
Shah, Jayshree			
Steffens, Andrew			
Tanner-Banks, Keisha			
Thomas, Katherine			
Voronin, Erick			
Wene, Daniel			
Yu, Chang Ho			
Zhong, Linbin			
Microbiology			
Arcieri, Donna			
Dimalaluan, Ana Liza			

NAME	DI Training Date AM	DI Training Date PM	Make up New Hire
Hayduk-Kramer, Joann			
Lazdins, Ann Marie			
MacMillan, Alyssa			
Management			
Fan, Zhihua (Tina)			
Smith, Martha			

Appendix 10 Employee DI Policy Statement

This form is to be completed at the time of the analyst's DI training.

This is to certify that I will read the Data Integrity Policy contained in the QM. It also indicates that if I have any questions regarding this policy, a written notification can be sent to the appropriate Technical Supervisor and forwarded to the OQA for clarification. If there are no written requests for clarification within 30 days of receiving DI training, it will be Management's understanding that I fully understand the requirements of this policy and that I will strictly adhere to the protocols contained therein.

The Data Integrity Policy consists of the following:

- I shall not knowingly circumvent the required procedures contained in my Method Manual(s).
- I shall not knowingly circumvent the policies and procedures contained in the ECLS Quality Manual.
- I shall not knowingly refuse to adhere to other policies and procedures as they become available and explained to the employees.
- I shall not knowingly falsify any records generated during the performance of my assigned duties, such as: raw data, final data, reports, time sheets, etc.
- I shall not knowingly discuss the business of ECLS with persons who do not have a legitimate right to know.
- I shall not knowingly falsify time sheets or any other records that I am required to prepare as part of my employment.
- I know that if I am found to be in violation of this Data Integrity Policy I am subject to the disciplinary actions contained in section 2.5 of the Quality Manual.

ANALYST (Print): _____

SIGNATURE: _____

SIGNING DATE: _____

Appendix 11 Employee Legal Policy

This form is to be completed at the time of the analyst's DI training.

Due to the nature of the work that is performed within ECLS, there is a strong chance that ECLS data will be used in court proceedings. I understand that if I were to receive a subpoena, a request for data from someone who does not have a right to that information, a request for information from someone who I do not know is an employee of a client in an unit that submitted the samples for analyses, or a request to explain the workings of ECLS, I will immediately inform either my Technical Supervisor or the QAO. I understand that I will not respond to these types of requests until I have been instructed to do so by either the Technical Supervisor or the QAO. I also understand that if I am ever in a position in which I do not absolutely know for sure how to proceed that I will contact the Technical Supervisor or the QAO for direction. I also understand that I have 10 working days from the date of DI training in which to have any questions regarding this Policy explained. In the absence of any such requests, it will be Management understanding that I fully understand, and will conduct myself in accordance, with this Policy.

ANALYST (Print): _____

SIGNATURE: _____

SIGNING DATE: _____

Appendix 12 Employee Confidentiality Statement

This form is to be completed at the time of the analyst's DI training.

I understand that ECLS may be required to analyze certain products, formulations, etc. that have proprietary components. I understand that it is ECLS's duty not to disclose any proprietary information in the reporting of analytical data, subject to the overriding legal considerations. I understand that as an employee of ECLS I will only report data, information, etc. that I am specifically told to do so by the Technical Supervisor, QAO, or Service Manager. In the absence of any written requests for explanation of this Policy, within 10 working days of receipting DI training, it is Management's understanding that I fully understand this Policy and will strictly adhere to this Policy.

ANALYST (Print): _____

SIGNATURE: _____

SIGNING DATE: _____

Appendix 13

NJ Health	Public Health and Environmental Laboratories 3 Schwarzkopf Drive, Ewing, NJ 08628 POLICIES AND PROCEDURES		
Program: ALL	Subject: Complaint Procedure		
Version: 1 Replaces Version:	Author: Patricia Jackman	Date: 10/12/2016	Effective Date: 01/03/2018

1. Purpose

The purpose of this document is to establish a uniform process for investigating complaints. This Standard Operating Procedure (SOP) is applicable to and can be modified for all programs within Public Health and Environmental Laboratories (PHEL).

A complaint is an allegation that could result in citing noncompliance with any licensing agency. A complaint may be substantiated or unsubstantiated as a result of an investigation or survey. A substantiated complaint is one resulting in a finding of noncompliance at the time of the investigation, or a finding that noncompliance was proven to exist, but corrected prior to the investigation. An unsubstantiated complaint is an allegation where sufficient evidence could not be found to conclude that noncompliance with regulations existed during the investigation or at the time of the alleged violation.

a. Obtain the following information for every complaint:

- Complainant's name, address and phone number, unless the complainant requests anonymity;
- Facility's/program's/individual's name and address; and
- Description of the problem, (e.g., personnel, places, and dates of occurrence).

b. Establish a file for the complaint and logs the action in a control system. The system is a manual logbook that is kept in a binder labelled "Complaints" in the program manager's office. The control system facilitates tracking, control and follow-up by the program of the complaint and includes the following:

- Control # which consists of a letter designation for the program (B=Blood Bank, C=CLIS, E=ECLS, N=Newborn Screening, P=PHL), the number in order of the complaint within a

Approvals

Program Manager	Martha M Smith Print/ Sign	Laboratory Director	Thomas Kirchhoff MD FACP Print/ Sign 1/3/18
Annual Review: (initials & date) :		Annual Review: (initials & date) :	
Annual Review: (initials & date) :		Annual Review: (initials & date) :	
Annual Review: (initials & date) :		Retired on:	

year (1, 2, 3, etc.) and hyphen the last two digits of the year. For example, the first two complaints of the year 2016 for CLIS would be C1-16 and C2-16.

- Name of facility/program/individual
- Date complaint received
- Date acknowledged
- Investigation/survey date
- Plan of correction due date
- Date completed

c. Each program enters the following tracking information on their programs (Blood Bank, CLIS, ECLS, NBS and PHL) Complaint Tracking spreadsheet for the current year found on the PHEL Shared Drive→PHLS SOPs→Working Folder-Drafts→Complaint Tracking-All Programs→Complaint Tracking 20XX: Control #, Received date, Nature of complaint, Acknowledgment date, Date completed and Turnaround Time (TAT).

2. Acknowledgement

If the complainant is known, promptly issue a written acknowledgement that the complaint is being investigated. The program does not delay acknowledgement pending an investigation unless the investigation will take place within three working days. The program must take appropriate precautions to protect the complainant's anonymity and privacy. Maintain a copy or record of notification of the complaint documentation.

3. Evaluation

a. The program evaluates any complaint to determine whether it should be investigated by the program directly or referred to the appropriate authority (e.g., Medicaid or OSHA).

b. The program assesses the complaint to determine if an immediate investigation/survey of the facility/program/individual is necessary as part of the investigation.

c. If a complaint is especially significant, sensitive, or attracting broad public or media attention, the program informs their director immediately.

4. Scheduling Investigations/Surveys

Each program follows their individual priority system for scheduling of complaint investigations/surveys.

5. Conducting Investigations/Surveys

a. The program investigates complaints by means of an onsite survey, by phone, by electronic communication, by letter, or by documentary review. Onsite complaint surveys are unannounced.

b. For onsite complaint surveys, the program performs a full or partial survey based on the complaint. If a complaint alleges generalized inappropriate practices, evaluate compliance with

Subject Complaint Procedure

applicable requirements or conducts a full survey, as needed. If the complaint is of a specific nature, perform a survey focused on areas relevant to the complaint.

6. Post Investigation Actions

Each program follows their individual policy.

7. Documentation/Closeout

a. Each program maintains paper and/or electronic documentation of the complaint, acknowledgement, investigation/survey and notification as required by their individual policy.

b. Complainants will be notified that an investigation was completed.

Appendix 14 Non-Conforming Event Documentation

NJ Health — Public Health and Environmental Laboratories

POLICIES AND PROCEDURES

Program: QA

Subject: Nonconforming Event Documentation

Version: 1.0

Author: A. Dimaiuta, M. Smith

Date: 2/8/2018

Effective Date: 2/20/18

Purpose:

The purpose of this procedure is to provide a guideline to standardized Non-Conforming Event (NCE) reporting within the NJ Public Health and Environmental Laboratories. NCEs may pertain to and are not limited to Quality Controls, Temperature monitoring, Inventory, Specimen Collection, Data Entry, Test Performance and Result Reporting.

Scope:

This procedure is intended to enhance overall laboratory operations by improving the NCE process of reporting and implementation of corrective actions and preventive measures. The purpose of non-conforming event management is to identify and characterize problem-prone processes so that investigations can be carried out through a Root Cause Analysis (RCA) or other assessment tool and improvement projects initiated, with the goal of eliminating recurrence.

Definitions

Corrective Action – an action to eliminate the cause of a detected nonconformity or other undesirable situation.

Immediate action / Remedial Action – act or deed performed without hesitation upon recognition or awareness of a nonconforming event.

Approvals

Program Manager	Martha M Smith 2/16/18	Service Director	Thomas Kuo MD PhD 2/20/18
Annual Review: (initials & date):		Annual Review: (initials & date):	
Annual Review: (initials & date):		Annual Review: (initials & date):	
Annual Review: (initials & date):		Retired on:	

Page 1 of 8

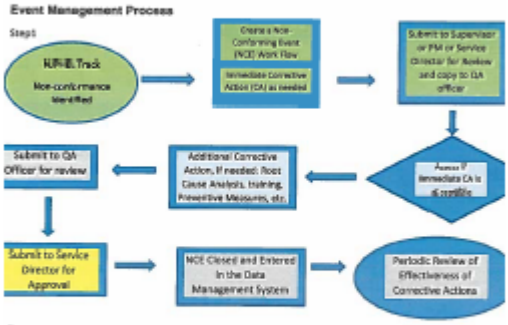
Nonconforming Event (NCE)-is defined as an occurrence that does not conform to the laboratory's policies, processes and/or procedures; does not conform with regulatory or accreditation requirements; or has the potential to affect (or has affected) patients.

Preventive Action – action to eliminate the cause of a potential nonconformity or any other undesirable potential situation.

Root Cause Analysis (RCA)- process of identifying basic or casual factors that underlie vari in performance, including the occurrence or possible occurrence of a nonconforming event.

SOP – Standard Operating Procedure

Event Management Process



Procedure:

1. Event Documentation: The event is created electronically using NCE workflow through NJ Health Sharepoint Server. When the event is created an email is sent to the Unit Supervisor/Program Manager or Service Director (if the Unit Supervisor and Program Manager are both absent) and copied to the QA officer. Listed below are some of the common situations that warrant a NCE. This list is not all inclusive, when in doubt, complete one. If it is determined that the event created was not necessary, it can be cancelled by the QAO or the Service Director.
   - SOP not followed as written
   - Temperature monitoring of refrigerators, freezers, water baths, incubators, hea blocks, room, etc. is missing or out of range

Page 2 of 8

- Expired reagents are used for testing or reagents improperly stored
- Required daily instrument maintenance/function checks are not performed/documented on day of use
- Quality Control (QC) not performed/documented for a particular test/reagent/media, etc.
- QC fails or is out of range for a test/reagent/media, etc.
- Instrument/equipment calibrations, e.g. pipette, thermometer, etc. are not performed on time. This also includes any calibrations which need to be performed for instrument/equipment before/during testing samples/specime
- If test results or corrected test results are not documented according to poli
- Issuance of corrected reports due to test result or patient demographic entr
- Delay in reporting of test results
- Proficiency Testing materials stored/handled/processed incorrectly
- Any employee on-premises injury
- Recurrent Safety Practice violations – defined as identical violation within tl same unit identified during a routine or random inspection in a 12-month pe

2. Access NCE through the Intranet NJ Health Sharepoint Server. From the NJ Healtl Sharepoint Server, click "Apps" then "PHEL Track". On the NCE Home screen, clic here".
   - **Type:** This will be pre-filled as Non-Conforming Event.
   - **Title:** Date and a short description, example: 12/17/17 Temperature not Ta
   - **Division:** Public Health and Environmental Laboratories (PHEL)
   - **Program:** Select the Program or Unit
   - **Additional Requestor:** If any, only applies when the event is being createc someone other than the person who identified the nonconformance.
   - **Click on "Create"**

3. Initiator
   - **Date Initiated:** Click the calendar icon to select the date.
   - **Laboratory:** Select either PHLS or ECLS. This will determine the correspor QAO or Service Director to whom the event will be sent.
   - **Event Date:** This is the date when the NCE occurred, this can be different f the date the NCE form was initiated.
   - **Unit:** Select the Program or Unit
   - **Enter Email Address of Supervisor or Program Manager or Service Dir who will conduct the investigation.**
   - **Sample ID# or Equipment ID#:** If the NCE involves a Specimen Identificati number it needs to be written here. If the NCE pertains to an instrument/equipment, write the type of instrument/equipment, e.g. freezer, incubator, water bath, pH meter, etc. and the instrument/equipment identific number.
   - **Description of the Nonconforming Event:** The description of the NCE mu include as much information as possible about the event, including when, w

and how the event occurred or was discovered with dates and time, if possible. Describe any initial investigation conducted and the people involved.

- **Immediate Action Taken:** Describe in detail the immediate action that was take Include the following information in this section: The date the action was taken, i different from the date the NCE form as the date initiated. Include who was contacted, if anyone, to rectify the situation, e.g. manufacturer, building maintenance, etc. Include the date of contact, if different from the date the NCE form was initiated.

4. Report events that have adversely affected patients and continue to have a negative outcome for patients to the Program Manager / Unit Supervisor immediately, i.e. incorre results, no results, delayed results, etc. The Service Director or designee must also be notified.

5. One NCE form may be submitted for multiple events if the events were all discovered or the same date and pertain to the same occurrence, e.g. upon monthly review, several temperature readings were out of range. Additional notes may be added to the space provided. Click "Save" then "Start Work Flow" button located on top right corner of the screen or,

6. Attach documents as necessary by selecting the DOCUMENT Tab from the top of the page. Select the document type from the dropdown menu. Click on "Browse" to select th file then "Attach". Go back to the FORM tab, click "Save" then "Start Work Flow" button located on top right corner of the screen.

7. The Unit Supervisor/Program Manager or Service Director (in the absence of both Unit Supervisor and Program Manager) Approval: Review the NCE form created by the initiat to determine if the immediate corrective action implemented was acceptable and if client or patients were negatively impacted by the NCE. If the Immediate Corrective Action is r acceptable, additional corrective actions will be required.

8. Corrective Action(s): Describe the corrective action(s) taken to resolve the situation, including the date the corrective action(s) was completed or will be completed and by whom. In addition, **include measures taken to prevent reoccurrence of the event.** Some examples of corrective action(s) that can be taken to resolve the situation or prevent recurrence of the event are revising/reviewing procedures, providing training, monitoring in place, repairing equipment, writing or revising an SOP, etc.

9. Conduct RCA for the following reasons:
   - The hazard or harm associated with the NCE is of moderate to **high risk severit**
   - The NCE has a moderate to **high probability** of occurrence or has occurred in th past.
   - Aggregate data have reached or exceeded acceptable threshold criteria for the NCE type (trend analysis).

   Examples of Tools used in RCA: For more examples, refer to Public Health Quality Improvement Encyclopedia or consult with your QAO.

- Process mapping- It is useful to break down the testing process into steps, such as pre-analytical, analytical and post-analytical, to facilitate identification of weak points and allow the laboratory to recognize potential failure modes that could present significant risks to patients and to identify opportunities in the process to control them. Refer to Appendix 1 for an example of a root cause analysis by process mapping. For more relevant information, refer to the CLSI EP-23-A document.
- Repeated whys (5 Whys) - a tool designed to explore the cause and effect relationships underlying a problem and determine the problem's root cause. Refer to Public Health Quality Improvement Encyclopedia.
- Cause and Effect- a tool that displays multiple potential causes for a problem, assists in gaining better understanding of the problem and in finding meaningful solutions.

Root Causes can most often be attributed to a small number of recurring issues but may not be limited to the following:

- Equipment problem
- Supply problem
- Software problem
- Outdated or lack of policy, process or procedure
- Lack of or ineffective training
- Lack of or ineffective communication
- Human factor issues (human capabilities and limitations as they influence performance of tasks, decision making, use of tools and equipment, work area and environment, etc.)
- Human behavior types (unintended, at-risk, reckless)
- Random events

When the Supervisor or Program Manager review is complete, click "Approve". This action will automatically send an approval request to the corresponding QAO (ECLS or PHLS).

10. The Quality Assurance Officer (QAO) will review the appropriateness of the corrective actions implemented, determine if follow-up action is required, and that adequate documentation was provided. The QAO may assign task(s), request additional documentation, or approve the NCE which is then automatically submitted to the Service Director for final review and approval. The NCE are grouped into the following categories:

a. Data Entry Error
b. Delay in Reporting
c. Documentation
d. Equipment Malfunction
e. Incorrect Reporting
f. Laboratory Accident
g. QC Not Acceptable
h. Reagent Issue

i. Safety Issue
j. SOP Not Followed
k. Specimen/Sample Issue
l. Temperature Out of Range
m. Miscellaneous

11. Service Director Review: The Service Director may assign task(s), request additional documentation, or determine that the NCE has been addressed and resolutions or actions taken were acceptable, and approve or reassign

12. All NCEs are reviewed and analyzed periodically to identify trends and discussed in the QA meetings.

References:

CLSI. Nonconforming Event Management, 2nd ed. CLSI Guideline QMS11. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.

CLSI. Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A. Wayne, PA: Clinical Laboratory Standards Institute; 2011.

Moran, John W, and Grace L Duffy. *Public Health Quality Improvement Encyclopedia*. Edited by Emily E Reinoso and Margaret L Beaudry, Public Health Foundation, Washington DC, 2012.

Appendix 15
Employee Attestation Statement

This form is to be completed at the time of the analyst's Data Integrity (DI) training.

This is to certify that I am free from any commercial, financial, interdepartmental, or other undue pressures that could interfere with the quality of my work. I also understand that should my status change in regard to this matter, I will immediately inform management of such a change. I also understand that if I purposely am not truthful in signing this statement, or I purposely withhold from management any subsequent change in my status, that I am in violation of the Environmental and Chemical Laboratory Service Data Integrity Policy. In the absence of any written requests for an explanation of this Policy, within 10 working days of receipting DI training it is understood that I fully understand this Policy and I will strictly adhere to this Policy.

ANALYST (Print): _____

SIGNATURE: _____

SIGNING DATE: _____

Appendix 16
Employee Signatures

APPENDIX 16

EMPLOYEE SIGNATURES

NAME	SIGNATURE	INITIALS
Apollon, Valine	Valine Apollon	VA
Arcieri, Donna	Donna Arcieri	DA
Argenti, Anthony	Anthony Argenti	AA
Bind, Eric		EB
Blue, Latasha	Latasha Blue	LB
Camacho, Sandra	Sandra Camacho	SC
Chu, Christopher		
Compagnucci, Lynne	Lynne Compagnucci	
Dimalabuan, Ana Liza		
Du, Songyan	Songyan Du	SD
Fan, Zhihua (Tina)		ZF
French-Mesch, Rebecca		RF
Gleason, Diana	Diana S. Gleason	DG
Haltmeier, Douglas		
Hargrave, Deborah	Deborah Hargrave	DH
Hayduk-Kramer, Joann		
Henitz, James		JH
~~Khalil, Nermine~~	see below SHR	
Kidd, Alana		AK
Khalil, Nermine	Nermine Khalil	NK
Krasley, Andrew		AK
Lawson, Bill		BL
Lazdins, Ann Marie	Anne Marie Lazdins	AML
Lettiere, Lauren		

EMPLOYEE SIGNATURES

NAME	SIGNATURE	INITIALS
Madon, Maria	Maria Madon	MM
MacMillan, Alyssa	Alyssa MacMillan	AM
Mukherjee, Jhindan		JM
Nemeth, William	William K Nemeth	WKN
Obed, Reynaldo	Reynaldo Ng Obed	RNO
Patel, Bhupendra	Bhupendra Patel	BP
Patel, Vaishali	Vaishali R Patel	VRP
Patterson, Norman	Norman Patterson	NEP
Pierzhanowski, Sandra	Sandra Pierzhanowski	
Riker, Collin (Dave)		
Robinson, Sharon	Sharon Y. Robinson	SYR
Saad, Mounir	Mounir Saad	MS
Shah, Jayshree	Jayshree Shah	JS
Servis, Robert		
Steffens, Andrew		AS
Tanner-Banks, Keisha	Keisha Tanner-Banks	KAB
Thomas, Katherine	Katherine Thomas	KT
Voronin, Erick		EV
Wene, Daniel	Daniel J Wene	DJW
Yu, Chang Ho		CHY
Zhong, Linbin		LZ
Poku, Kwaku		KOP

Appendix 18
Daily Balance Check

Make: _____ Model Number: _____
Serial Number: _____ Location: _____

Date	Zero	Serial No. of Weight Set	Value Listed on Wt. (g)	Reading (g)	Correction Factor (g)	Corrected Reading (g)	Analyst Signature

LOGBOOK # CHEM 17

Appendix 19

Monthly Balance Check

BALANCE ID NO.: _____ ROOM: _____ DATE: _____

CHECKED BY: _____ NBS WT. SET SERIAL NO.: 82051

Listed NBS Wt. (g)	Correction (g) (1)	True Wt. Of NBS Wt. (g)	Weighing (g)	Difference (g)	Difference Within +/- 5% of True Wt.

(1) Obtained mm/dd/yy from: NIST Certification Source

LOGBOOK # LAB 6

Appendix 20
Annual Thermometer Check

DATE	CHECKED BY	NBS SERIAL NO.	NBS CORRECTION FACTOR (^{O}C)	NBS READING (^{O}C)	TRUE NBS TEMP. (^{O}C)	THERMO-METER SERIAL NO.	THERMO-METER READING (^{O}C)	CORRECTION FACTOR (^{O}C) TO ACHIEVE TRUE NBS TEMP.

LOGBOOK # LAB 11

Appendix 21

Public Health and Environmental Laboratories
3 Schwarzkopf Drive, Ewing, NJ 08628

Single Channel Pipette Calibration - Gravimetric Test

Pipette Range: 100-1000 uL **Pipette #** _____

Date _____ **Analyst** _____ **Balance** _____

Temp. (C) 21 **Water Density** 0.99802213 **Serial #** _____

100 uL	
VOLUME (ml)	WEIGHT (g)
0.1000	
0.1000	
0.1000	
0.1000	
0.1000	
0.1000	
0.1000	
0.1000	
0.1000	
0.1000	
MEAN WEIGHT	#DIV/0!
MEAN VOLUME	#DIV/0!
STD DEV	#DIV/0!
% CV (Precision)	#DIV/0!
% INACC. (Error)	#DIV/0!
PASS / FAIL ?	#DIV/0!

500 uL	
VOLUME (ml)	WEIGHT (g)
0.5000	
0.5000	
0.5000	
0.5000	
0.5000	
0.5000	
0.5000	
0.5000	
0.5000	
0.5000	
MEAN WEIGHT	#DIV/0!
MEAN VOLUME	#DIV/0!
STD DEV	#DIV/0!
% CV	#DIV/0!
% INACC.	#DIV/0!
PASS / FAIL ?	#DIV/0!

1000 uL	
VOLUME (ml)	WEIGHT (g)
1.0000	
1.0000	
1.0000	
1.0000	
1.0000	
1.0000	
1.0000	
1.0000	
1.0000	
1.0000	
MEAN WEIGHT	#DIV/0!
MEAN VOLUME	#DIV/0!
STD DEV	#DIV/0!
% CV	#DIV/0!
% INACC.	#DIV/0!
PASS / FAIL ?	#DIV/0!

Supervisor Review _____ QA Review _____

Date _____ Date _____

Corrective Action Due To Failures? _____

_____

Acceptance Criteria
% Inaccuracy and % CV taken from ISO 8655 guidelines

ISO 8655 Guidelines:

Range	Volume (uL)		Max Permis systemic error (ACC)			Max Permis random error (CV)	
			+/- uL	+/- %		+/- uL	+/- %
100-1000 uL	1000		8.000	0.80		3.000	0.30
	500		8.000	1.60		3.000	0.60
	100		8.000	8.00		3.000	3.00

Appendix 22

Annual Check of In-House Weights vs. NIST Weights

Checked by: _____ Date: _____

ID of Weight Set Checked: _____ NIST Weight Set Serial #: _____

Listed NIST Wt. (g)	NIST Weighing (g)	Correction Factor (g)[1]	True Balance Wt. (g)	Set Wt. (g)	Weighing (g)	Correction to Achieve Eq. Bal. Wt. (g)

(1) Obtained mm/dd/yyyy from: National Institute of Standards and Technology (NIST) Certification Source

Appendix 23

FORM FOR REQUESTING FOLLOW-UP INFORMATION FROM ECLS

NAME OF PERSON REQUESTING INFORMATION:

PHONE NUMBER:

REQUESTING AGENCY/PROGRAM:

FIELD AND/OR LABORATORY SAMPLE NUMBERS OF THE SAMPLES FOR WHICH THE INFORMATION IS BEING REQUESTED:

TYPE OF INFORMATION REQUESTED:

REASON FOR THE REQUEST:

APPENDIX 24

SYSTEM AUDIT CHECKLIST - METHODS

AUDITOR:
AUDITED METHOD:
ANALYST:

AUDIT DATES:
REFERENCE METHOD:
ANALYST SUPERVISOR:

QUALITY MANUAL ITEMS TO BE CHECKED

No.	Audit Checklist	Yes	No	NA	Comments
1	Has the analyst attended a Data Integrity meeting within the last year (S2.5)?				
2	Has the analyst signed their Legal Policy (S2.6); Confidentiality Policy (S2.7), and Attestation Statement (S2.9)?				
3	Are the pieces of equipment that the analyst uses contained in Appendix 17 (S4.1)?				
4	Check to verify that the information contained in Appendix 17 is complete and accurate.				
5	Do the analyst assigned unique ID numbers for the equipment appear on or near the equipment?				
6	Have the analyst describe the support equipment that is used and the Quality Control procedures that are in effect. [Balances, pH Meter, DO meter, Ovens, Refrigerators, Freezers, Burettes, and Pipettes] Are these procedures adequate (S4.2)?				
7	Are the pipette calibrations performed quarterly and documented, including pipette ID numbers (S4.2)?				
8	Where are calibration records maintained and who performed the pipette calibrations?				
9	Are pipette calibrations performed according to Appendix?				
10	Have copies of the pipette calibrations been forwarded to OQA for filing (S4.2)?				
11	What maintenance is being performed on the instruments and the frequency (S4.3)?				
12	Verify the accuracy of the maintenance schedule against the manufacturer's instructions.				
13	Where are the maintenance activities documented by the analyst (S4.3)?				

14	If maintenance activities are documented in a workbook, are all the scheduled activities listed along with their frequency?				
15	Are the manufacturer's required maintenance procedures available for review (S4.3)?				
16	Are the manufacturer's requirements being performed (S4.3)?				
17	If maintenance activities are documented in a maintenance log book, are all required entries being made and non-used entry sites being indicated as "not required" or some other appropriate designation (S4.3)?				
18	If maintenance is documented in the daily run logs, are they highlighted for easy identification by auditors (S4.3)?				
19	If a balance is required to perform the analysis or prepare reagents or standards, is a set of calibrated weights available to check the balance prior to use including their correction factors (S4.4)? Are the correction factors being employed to obtain the correct weighing?				
20	Verify that the balance is checked, and the checks bracket the weights of interest, by reviewing the balance logbook for the appropriate entries (S4.4)				
21	If the use of thermometers is required, are calibrated thermometers, with correction factors, available (S4.4)?				
22	Are the correction factors used when recording the temperatures in the temperature logbook (S4.4)?				
23	What is the process used by the analyst to prepare reagents and standards?				
25	Are the preparations labeled with unique identification numbers and what constitutes those identification numbers (S4.4)?				
26	Has the analyst received written information from management concerning the specifics of any current or upcoming special project?				
27	Do the analysts prepare daily "new arrivals" printouts to determine if samples requiring their analyses have been received (S6.8)?				
28	When, during the day, is the "new arrivals" form printed and is it a single printout or a printout that is made a couple times a day (S6.8)?				
29	Does the analyst run a backlog list every Monday to verify that they have not missed the submission of samples or any amendments to previously listed samples whose changes were made during the week (S6.8)?				

No.	Audit Checklist	Yes	No	NA	Comments
30	Does Sample Receiving notify the analyst regarding any changes to previously logged-in information, and if so, how?				
31	Have the analysts been given copies of any QAPPs that have been developed for certain projects?				
32	From where does the analyst receive COC samples (S6.5)?				
33	Has all the required information been entered onto Appendix 35a at the time of sample transfer?				
34	Is the analyst part of a work cell? If so, how is the work cell "defined" as to the delineation of their duties?				
35	Is this delineation part of the method SOP?				
36	How does the analyst obtain their sample container or aliquot?				
37	Are abnormalities with the sample documented in the work records? Where is this information documented?				
38	Are the observations of abnormalities reported / documented in the case narrative?				
39	Who enters the data into the data system and who verifies that the data entry was correct?				
40	How is this entry and verification documented?				
41	Where does the analyst place the sample container when the analyses are completed?				
42	Are routine metal and organic sample containers disposed of by the analyst and documented?				
43	Is Appendix 40a used to document the disposal of samples?				
44	Review OQA method SOP before beginning the audit. Does OQA copy of the SOP contain all the headings (S7.1) and content that it should contain?				
45	Is the QM required instrument maintenance being performed (S8.1)? Conductivity Meter? Turbidity Meter? Continuous Flow Analyzers? UV/VIS Spectrophotometer? GFAA? TOC Analyzer? HPLC? GC? GC/MS? ICP? Color Test Apparatus?				
46	Observe at least 3 separate analytical runs to determine the frequency at which each of the various QC samples are analyzed?				
No.	**Audit Checklist**	**Yes**	**No**	**NA**	**Comments**

47	Are the negative controls analyzed at the correct frequency (S8.2)? Method Blank? Field Blank? Trip Blank?				
48	Are the positive controls analyzed at the correct frequency (S8.3)? Laboratory Control Sample? Laboratory Fortified Blank?				
49	Are the Sample Specific Controls analyzed at the correct frequency (S8.4)? MS/MSD? Sample Duplicates? Surrogate Spikes?				
50	Has the equivalent QC outline described in Appendix 45 been incorporated into the analytical scheme?				
51	Review the raw data used to construct the most recent Initial Calibration Curve and the latest Continuing Calibration Check.				
52	Have in initial inorganic calibrations been developed with the criteria stated in (S8.5)?				
53	Have calibration points been dropped to achieve acceptable calibration? If so, what rationale was used to drop the calibration point?				
54	Have Reporting Limit checks been analyzed?				
55	Have Manual Integrations been performed? If so, were they performed according to the criteria in A49? If manual integration was not necessary during the analyses observed during the audit, have the analyst go back in the records until one is observed by the auditor.				
56	How has the analyst documented producing the raw data and the reported results?				
57	Is the analyst's latest Demonstration of Capability (DOC) attached to the method SOP (S8.6)? [Not specifically mentioned at this site.]				
58	How have the various QC acceptance limits been established for this method (S8.7)?				
59	Is the latest determination of the method MDLs attached to the method SOP (S8.8)? [Not specifically mentioned at this site.]				
60	How were the MDLs determined (S8.8)? Was the determination spread over a several days?				
61	Have the software calculations been verified by hand?				
62	How is inorganic raw data documented (S9.1)?				
63	How is organic raw data documented (S9.2)?				
No.	**Audit Checklist**	**Yes**	**No**	**NA**	**Comments**

64	How is data reviewed prior to reporting data to Data Management (S9.3)?				
65	What data is forwarded to Data management when providing results for routine, MRRF, and SRRF reports?				
66	How is the use of data qualifying codes determined? Who determines which ones to use and are the codes checked prior to reporting to Data Management?				
67	How are the records stored for long term storage (S9.6)?				
68	Are the analysts aware of the fact that requests for data verification must be referred to OQA?				

GENERAL SOP ITEMS TO BE CHECKED

Some of the items below were determined by reviewing the specific method SOP prior to initiating the audit. Those items for review are specific for this method SOP and probably, but not necessarily, fall outside the items contained in the QM. The rest of the review items are applicable to all SOP.

No.	Audit Checklist	Yes	No	NA	Comments
1	Is the current revision of the method SOP and QM available to each analyst?				
2	Does each page of the SOP contain a page number and the total number of pages in the SOP?				
3	Section 1: Identification of the Test Method • Types of analyses? • In-house method name? • Reference methods? • Are all acceptance limits derived from the reference method?				
4	Section 2: Matrix • Matrices for which method can be used?				
5	Section 3: MDL • Listing of the current MDL and completion date? • Procedure used to generate MDL? • If using a previous MDL, is evaluation criteria for the new MDL listed? • Raw data? • Listing of Reporting Limits?				
6	Section 4: Scope and Application				

	• Listing of parameters and the concentration range over which the calibration curve is constructed? • MCL? • Listing of symbols, abbreviations used to identify the parameters? • Designation of parameters not originally covered by the reference method?				
7	Section 5: Summary of Method • Summary of manual and instrumental processes?				
8	Section 6: Definitions • Only terms used in the SOP?				
9	Section 7: Interferences • Potential interferences? • Potential corrective actions?				
10	Section 8: Safety • List of general safety precautions? • Location of MSDS? • Hazardous chemical listings with health effects, target organ, and incompatibilities?				
11	Section 9: Equipment, Supplies, and Maintenance • Equipment serial numbers and in-house instrument ID numbers? • Manufacturer's preventive maintenance and frequency? • Where are the maintenance activities documented? • Where are the manufacturer's manuals located?				
12	Section 10: Reagents and Standards • Listing of reagents, quality grade, and vendor. Qualifying with a statement such as "Or equivalent" is acceptable. • A listing of the stock standards, vendor, and initial concentrations. "Or equivalent." • Procedure for preparing stock, intermediate, and working standards, concentrations, and equipment used (pipettes, syringe)? • The intended use of the standards? • Expiration dates for prepared solutions and standards? • Reference to where the Certificates of Assay are maintained?				
No.	**Audit Checklist**	**Yes**	**No**	**NA**	**Comments**
13	Section 11: Collection, Preservation, Shipment and Storage • Type of container? • Total volume of sample necessary for analysis and QC? • Preservation requirements?				

	• Color of labels on sample containers? • Storage of sample when picked up from Sample Receiving? • Holding times? • How and when discarded?				
14	Section 12: Quality Control. List: intended uses, acceptance ranges, which items are used to determine if an analytical sequence can begin, and which ones are used to determine if data must be qualified, for each of the following: • Blanks? • Surrogates? • Performance check samples? • QC samples? • Duplicate samples? • LFM/LFMD? • Reporting level checks? • Internal standards? • Check sources? • Background checks? • Listing of the data recorded on Control Charts? • Determining if peak tailing is a problem and what to do about it? • Manual Integration: reasons for using and how to document?				
15	Section 13: Calibration and Standardization • Initial calibration: number of standards used, minimum number of standards required for acceptable calibration, acceptance criteria, source of acceptance criteria, duration for which the calibration is valid? • When can a calibration point be dropped in order to achieve a valid calibration? • Basis for determining if a point is an outlier? • Continuing calibration check: acceptance criteria, number of compounds that can fail and still achieve acceptable compliance?				
No.	**Audit Checklist**	**Yes**	**No**	**NA**	**Comments**
16	Section 14: Analytical Procedure • Process for obtaining samples? • Process for preparing samples? • Instruments settings? • Instrument conditions during analysis; e.g., ramping temperatures, types and number of washings, etc.?				

	• Analytical sequence? • Retention Time windows: reference method, in-house, constant use, recalculating RT? • Procedure for reporting results? • Sequence in which the QC samples are evaluated to determine run acceptance? • Work Cell and delineation of analytical responsibilities?				
17	Section 15: Calculations • How is the calibration curve prepared; e.g., instrument, analyst? • List the formula used to prepare the curve for methods placed on-line after January 2008? • How are results calculated by the software? • List formulas used to calculate: percent recovery, relative percent difference, and percent difference for serial dilutions? • Reasons for performing manual integrations and how they are done?				
18	Section 16: Method Performance • List the type of sample that is used to determine the initial DOC and the continuing DOC and the frequency for performing the DOC? • Acceptance limits for DOC especially for multiple analyte methods? • DOC certification and summary statements? • Listing of the accuracy and precision statements that the method must meet?				
19	Section 17: Pollution Prevention • Process used to discard samples, digestates, extracts, etc? • How are spills cleaned up?				
20	Section 18: Data assessment • List the analyst and supervisor's responsibilities for determining the cause of an isolated analytical failure? • List data qualifiers and the conditions under which they can be used? • Process for determining the acceptance of the entire run, portions of the run?				
No.	**Audit Checklist**	**Yes**	**No**	**NA**	**Comments**
21	Section 19: Corrective Action for Out-of-Control Analyses. • List the analyst and supervisor's responsibilities for determining the cause of the persistent failure to achieve in-control status? • Document corrective actions and forward a summary report to OQA? • Circumstances at which point OQA is notified, in writing, of unsuccessful resolution of the persistent problem?				

22	Section 20: Contingencies for Handling Continuing, Persistent Out-of-Control Analyses. • Informing QA? • Instrument shut down? • Process for bring the instrument back on-line? • Notification to clients? • Process for re-establishing analytical capabilities?				
23	Section 21: Waste Management • • How are hazardous wastes discarded from the laboratory area? • List of items that are deemed to be hazardous waste?				
24	Section 22: References • Listing of where the reference method can be found? • Listing of other source material used in the preparation of the SOP?				
25	Section 23: Tables, Diagrams, Flowcharts, and Validation Data • Raw data used to determine the MDL and DOC or a reference to where it can be found?				
26	Section 24: Appendices Collection of appendices mentioned in the body of the SOP?				

Appendix 25
Data Package Review Form

DATA PACKAGE: **REVIEWER:**

LABORATORY RECEIPT DATE: **BATCH NO.:**

DATE REVIEWED: **SUBMITTING AGENCY:**

SAMPLE COLLECTOR: **METHODS REVIEWED:**

A. SAMPLE IDENTIFICATION	**Y,N,NA**
A. 1. Analysis request form for each sample; field sample numbers; laboratory sample numbers; date and time of sample collection.	
B. EXTERNAL CHAIN OF CUSTODY FORMS FOR EACH SAMPLE	
B. 1. Analyses requested.	
B. 2. Names, dates, and times of change in sample custody.	
B. 3. Field sample numbers.	
C. INTERNAL CHAIN OF CUSTODY FORMS	
C. 1. Names, dates, and times of transfer of custody between the sample receiving custodian and the analysts.	
C. 2. Bench Sheets	
D. LABORATORY CHRONICLE	
D. 1. Dates of sample receipt and refrigeration.	
D. 2. Dates of sample extractions, digestions, and analyses.	
E. CASE NARRATIVE	
E. 1. Condition of submitted forms and samples at time of receipt in the laboratory.	
E. 2. Details of any observed sample/paperwork deficiencies.	
E. 3. Laboratory personnel performing the analyses.	
E. 4. Analytical and reporting protocols including the definitions of the data qualifiers used.	
E. 5. ORGANICS: Internal standards data.	
E. 6. ORGANICS: Surrogate spike recoveries.	
E. 7. ORGANICS: Matrix spike/matrix spike duplicate results.	
E. 8. INORGANICS: Method blanks.	
E. 9. INORGANICS: Laboratory fortified blank results.	
E. 10. INORGANICS: Control sample data.	
E. 11. INORGANICS: Duplicate sample data.	

E. 12. INORGANICS: Spiked sample results.	
E. 13. INORGANICS: Instrument check results.	

ORGANICS	504	505	507	SIM	515.3	524.2	525.2	531.1	537	608	624	625
F. QUALITY CONTROL SUMMARY												
F. 1. Method blank data.												
F. 2. Spiked blank data.												
F. 3. Tuning and mass calibration data.												
F. 4. Internal standard data.												
F. 5. Matrix spike/matrix spike duplicate data.												
F. 6. Surrogate Recoveries.												
G. ANALYTICAL RESULTS												
G. 1. Results for target and non-target compounds.												
G. 2. Quantitation reports.												
H. STANDARD RESULTS												
H. 1. Initial calibration data.												
H. 2. Continuing calibration data.												
H. 3. Internal standard data.												
H. 4. Raw data reports for calibration standards.												

TRACE METALS	200.7	200.8	200.9	245.2	1631
I. QUALITY CONTROL SUMMARY					
I. 1. Method blank data.					
I. 2. Laboratory fortified blank data.					
I. 3. Quality control sample data.					
I. 4. Duplicate sample data.					
I. 5. Matrix spike/matrix spike duplicate data.					
I. 6. IPC interference check sample data.					
I. 7. SIC instrument check sample data.					
I. 8. Reporting Level Check Standard.					
J. ANALYTICAL RESULTS					
J. 1. Analysis report forms.					
K. STANDARD RESULTS					
K. 1. Initial calibration data.					
K. 2. Standard curve and coefficients of determination (R^2)					

L. RAW DATA RESULTS					
L. 1. Digestion logs.					
L. 2. Run logs.					
L. 3. Analytical chromatograms.					
L. 4. Analytical printouts.					

GENERAL CHEMISTRY	Y, N, NA
M. QUALITY CONTROL SUMMARY	
M. 1. Method blank data.	
M. 2. Spiked blank data.	
M. 3. Quality control sample data.	
M. 4. Duplicate analysis data.	
M. 5. Matrix spike/matrix spike duplicate data.	
M. 6. IPC interference check sample data.	
M. 7. Reporting level check.	
N. ANALYTICAL RESULTS	
N. 1. Analysis report forms.	
O. RAW DATA RESULTS	
O. 1. Digestion/distillation logs.	
O. 2. Run logs.	
O. 3. Analytical chromatograms.	
O. 4. Analytical printouts.	
O. 5. Workbook pages.	

RADIOANALYTICAL SERVICES	
P. QUALITY CONTROL SUMMARY	
P. 1. Method blank data.	
P. 2 Spike blank data.	
P. 3 Spiked sample data.	
P. 4. Duplicate analysis data.	
Q. ANALYTICAL RESULTS	
Q. 1. Analysis report forms.	
R. RAW DATA RESULTS	
R. 1. Preparation Bench Sheet.	

R. 2. Assignment summary.	
R. 3. Unknown Batch report.	
R. 4. Analytical printouts.	
R. 5. Workbook pages.	

ANALYTICAL FAILURES MENTIONED IN PACKAGE:

PROBLEMS OBSERVED WITH PREPARATION OF DATA PACKAGE:

Appendix 26
Entering Calibration Standards into Element

Metals
Purpose: Entering calibration standards into Element will allow tracking of calibration standards and will further integrate all aspects of an analysis into the Element database. This will assist any audits and will reduce paper use.

Initial Standard Preparation

Step 1: Log into Element and under Laboratory, select Standards.
Step 2: Select Add then select box 1, "Specify each analyte and its concentration".
Step 3: Write the description of the standards including method and matrix (e.g. Cal Standards ECLS-I-ICP-1, Aqueous 200.7 Minerals).
Step 4: Ensure Department is correct.
Step 5: Input the preparation date, reference date (same as preparation date), and expiration date (e.g. 1 month from preparation date for 200.7 Minerals).
Step 6: Input user name under Prepared By and fill the correct solvent and units (2 % HNO_3, 1 % HCl and ug/mL for 200.7 Minerals).
Step 7: Under vendor, select None if the analyst is the preparer and under vendor lot input "-".
Step 8: Input the number of standards prepared under vials and input the volume of each standard in mL.
Step 8: If analyst prepared the standards, ensure "Prepared" and not "Purchased" is selected.
Step 9: In the empty comments box, input the stock standards and solvents used. (e.g. for 200.7 Minerals: HNO_3 – Element ID, HCl – Element ID, H_2O – Water ID, Standard Stock – Element ID, QCS Stock ID – Element ID, CRL Stock – Element ID, S6 Stock – Ce and Co Element IDs.)
Step 10: Under Standard Type, select Reagent.
Step 11: Click the box next to Standard Type for User-Defined Fields. Input each standard under Variable Items including the standard name and concentration or volume where appropriate.
e.g. for 200.7 Minerals

Standard Info (1)	S0 – Cal Blank
Standard Info (2)	S1 – CRL 0.5 ppm Na, Ca, K, Mg
Standard Info (3)	S2 – 8 ppm Na, Ca, K, Mg
Standard Info (4)	S3 – 40 ppm Na, Ca, K, Mg
Standard Info (5)	S4 – 80 ppm Na, Ca, K, Mg
Standard Info (6)	S5 – 100 ppm Na, Ca, K, Mg
Standard Info (7)	S6 – 50 ppm Ce, Co
Standard Info (8)	ICV/CCV – 50 ppm Na, Ca, K, Mg
Standard Info (9)	LCV – 10 ppm Na, Ca, K, Mg
Standard Info (10)	HCV – 80 ppm Na, Ca, K, Mg

Step 12: Click Save to finish.

Copy Procedure

After completing the initial standard preparation, subsequent preparations can be performed by copying the initial standard preparation into a new standard (after expiration of old standards or simply needing to remake standards).
Step 1: Log into Element and under Laboratory, select Standards.
Step 2: Find the old calibration standard list, select it, and click Copy. Most relevant information will be copied over though the user should ensure that everything copied correctly and all standards are current.
Step 3: User will have to change the Preparation, Reference, and Expiration dates and will have to fill in the Solvent/Solvent Lot box and the Vendor Lot box.
Step 4: Click Save to finish.
Step 5: Find and select the old calibration standard and click Edit. Under Department change to EXPIRED_STD and select the box for Disposed.
Step 6: Click save to finish.

Adding Standards to Batches

One major benefit to having standards logged into Element is that Element will not allow a batch to be created with expired standards. To take advantage of this feature, all standards should be added to relevant batches.
Step 1: Log into Element and under Laboratory, select Batch.
Step 2: Make batch as usual but right click the box on the left under “Reagent” and click “Add Reagent”
Step 3: Find the Element number for the standards prepared above and double click that ID.
Step 4: Under “Comments” in the box on the right type “Calibration standards: ‘Element ID’”
Step 5: Finish batch preparation as usual.

Attachment # 9

Laboratory Information Management System(LIMS)

OVERVIEW

ECLS uses the **Promium® ELEMENT®** LIMS product to improve the process flow of its Laboratory work. The system was entered into production service in September of 2009. ELEMENT is a client server system built on Microsoft Windows-based platform that utilizes Microsoft SQL SERVER for the back end data base. The ELEMENT LIMS system is supported by the ECLS Data Administration group. SOP's are developed by each of the ECLS laboratory program groups detailing how they manage analytical data using the ELEMENT LIMS. Promium ELEMENT includes the following components:

ECLS FACILITIES

The ECLS Laboratory uses the ELEMENT multiple facilities feature to separate LAB groups analytical data processing within ELEMENT. Each Lab groups sample data is logically partitioned within the labs database (LTDB) based on facility code while sharing the same Client information. This provides the ability to customize and default different features for processing like different report formats based on LAB group requirements. Every LAB group has its own set of users defined to their facility code. Below chart maps the LAB group to facility code.

LAB Facility and Reference Chart

LAB Group	*Facility Code*	*Citations*
Inorganics LAB	*A*	All Method SOPs, Appendix B
Organics LAB	*A*	All Method SOPs, Appendix A
Radioanalytical LAB	*B*	All Method SOPs sections 13,14,15,20 Radioanalytical Services Element Guidelines
Bacteriology LAB	*C*	Sanitary Bacteria Water SOP Promium Section Ver. 1
CT – Medical Marijuana Lab	*D*	*Under Development*
Data Administration IT	*A,B,C,D*	Data Handling Section 9.4
Sample Receiving	*A,B,C,D*	SOP ECLS-SR-1 Section 3.2.2 and Attachments 5-8

ACCESS SECURITY

LIMS access is protected through system logins and user restrictions. A user needs valid credentials to be able to access the NJDOH server. It's important to note that all desktops using Element attached to an instrument gain access thru a VLAN for security reasons. Next a valid copy of ELEMENT needs to be loaded onto client computer. Finally when the user launches ELEMENT from their desktop they need an ELEMENT userid and password. The ELEMENT userid is administered by the Data Admin group that

grants specific permissions controlling user functionality and access to ECLS facility codes. User rights are determined by each ECLS Program Manager.

ANALYTICAL DATA PROCESS

The ELEMENT LIMS fundamental design is to control the ECLS analytical data process by changing status based on the state of the data within the LIMS. Using this status change the data is moved through the LIMS controlled by the ELEMENT programming logic. The following are the major status types used by ELEMENT.

- Received - sample analysis have been entered into ELEMENT by the ECSL Sample Receiving group.
- Available - samples have been released to the different lab groups for analysis.
- Reviewable - sample analysis is complete and results are ready for the review process.
- Reportable – after the final review process is finished, analysis result data is released for data delivery and billing.

ELEMENT FUNCTIONALITY

- SAP Crystal Reports application is used to create both the standard and the custom reports.
- In depth User guide is used for both help information and the main point of reference for the laboratories SOP's.
- Utilizes a bar code reader for sample COC and final bottle disposal disposition.
- Manages Clients conveniently through the ability to customize Projects.
- Ability to maintain and control different Lab Facilities.

REFERENCE

USER MANUAL – ELEMENT LIMS Version 6
from PROMIUM®

Attachment 10
Qualifiers

Qualifier	TextBody
TNTC with	TNTC W/Positives
#LA	Lab Accident
*	Analysis was performed by EPA-approved method ECLS-R-Ra 226/228, which is documented in SM 7500-Ra E, 21st Ed.
**	Radium-224 analysis was performed by NJDEP-approved NJDHSS Method, which is documented in SM 7500-Ra E.
***	This analysis is not an approved method for the determination of radium-226 and radium-228 in wastewater.
_<1est	<1 CFU/mL EST
_>16000	>16000
_A	Absence
_P	Presence
< 18	<18
< 180	<180
< 1800	<1800
<1	< 1
<1.1	< 1.1
<1.8	<1.8
<10	< 10
<100	<100
<18	
> 160000	>160000
> 23	>23
>10%	>10%
>1600	Value above the quantitation Limit
>16000	>16000
>241,960	>241,960
>2419.6	>2419.6
>59,000	>59,000
>5900	>5900
A-01	[Custom Value]
B	Analyte is found in the associated blank as well as in the sample.
BW	Bottled water sample. Holding times were not exceeded, because the bottle was not opened until just before analysis.
C	Presence of compound may be due to contamination of samples during laboratory processing
CN	Refer to the Case Narrative located at the end of the sample results page.
Confluent+	Confluent with Positives
CP	Contaminated Plates
D	Result obtained from a Dilution of the sample

DLF	Failed to meet NJDEP, BSDW detection limit (DL). NJ, BSDW adopted the DL as the miniumun detectable concentration (MDC) . This differs from the SDWA DL,asdefinedin10CFR40 141.25 (c).
DUP	Sample and duplicate analyses failed acceptance criteria.
E	Result exceeded calibrated range.
F	Exceeded holding time in the field
G	Equipment failure
H	Holding time exceeded due to laboratory causes
H-01	Your sample exceeded holding time for the gross alpha 48-hour, double-count procedure.
I	Insufficient quantity
IS	Internal standard area response failed acceptance criteria.
J	Approximate Value
JR	Approximate value. Result is below the reporting level but greater than the method detection limit.
K	Value below the method detection limit
L	Value above the quantitation Limit. For BOD: the residual remaining after 5 days is less than 1.0 ppm (reported as a greater than value).
LFB	The laboratory fortified blank (LFB) failed acceptance criteria.
LFM	Matrix spike (MS) or laboratory fortified matrix (LFM) failed acceptance criteria.
LRB	The laboratory reagent blank (LRB) failed acceptance critieria.
M	Matrix Interference
MI-Color	Matrix interference - sample contained elevated chloride levels
MI-Elev CL	Matrix interference - sample contained elevated chloride levels
MI-HiColor	Matrix interference - sample was highly colored
N	Not requested
ND	The activity concentration was less than the calculated MDC
NE1	RPD not evaluated - the difference between the sample and duplicate was </= the MDL
NE2	MS/MSD not evaluated - the concentration of the spiking material added was less than 30 percent of the sample background concentration
NE3	RPD not evaluated - the concentrations of one or both replicates were below the reporting limit.
P	Results obtained from primary and confirmatory columns differ by more than the method allows
Presence	Presence
Q	Approximate value. Compound failed continuing calibration check (CC) or QC check criteria.

RN	Result is qualified due to either 1) cap not properly tightened and/or 2) did not exactly contain the required 10mL water volume.
S	Surrogate recovery failed acceptance criteria.
T	Hardness by calculation method
UFL	The planchtted sample was NOT flamed.
Z-01	[Custom Value]

Attachment # 11

Environmental and Chemical Laboratory Services

Proficiency Testing Exception Report
Corrective Action/Preventive Action Report Form

Program: ECLS: Category: Due Date:

Analyte	Units	Reported Value	Assigned Value	Acceptance Limits	Performance Evaluation	Method Description	Survey/Date

Error:

Root Cause: A. Methodology Problem B. Technical Problem: C. Clerical Error D. Survey Sample Problem E. Other (describe) **See key for more specific problem list**

First Time Occurrence **Repeat** Occurrence (Within the last 24 months)

Impact on Client Testing:

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Corrective Action(s)*

Effective Date: Supervisor Signature / Date:

Recommended Preventive Action(s)*

Effective Date: Supervisor Signature Date:

Verification of Implementation of Corrective & Preventive Action(s) by Program Manager (Within 7 days)

Program Manager Signature / Date:

Verification of Effectiveness of Corrective & Preventive Action(s) by QA (30-45 Days)

QA Signature / Date:

Laboratory Director Review

Service Director / Designee Signature / Date:

***** Attach separate sheet(s) if necessary

ERROR/FAILURE KEY

A. Methodology Problem

1. Instrument problem
2. Standard or reagent problem
    a. Expired standard or reagent
    b. Contaminated standard or reagent
3. Incorrect calculation
4. Method problem
5. Lack of stain or growth medium
6. Sensitivity
7. Error/problem in sample preparation

B. Technical Problem

1. Misinterpretation or misidentification
2. Incorrectly reconstituted
3. Time delay between reconstitution and analysis
4. Pipeting error (other than reconstitution)
5. Calculations(s) performed incorrectly
6. Linearity
7. Incorrect incubation temperature
8. Incorrect standard or calibrator used
9. Samples lost or delayed
10. Carryover
11. QC not acceptable
    a. Blank contamination
    b. Poor duplicate reproducibility
    c. Continuing calibration check failed criteria
    d. Calibration did not meet criteria

C. Clerical Error

1. Results transcribed on to questionnaire incorrectly
2. Incorrect peer group code used
3. Incorrect master file code used
4. Incorrect units reported
5. Decimal point error
6. Results transcribed incorrectly
    a. into LIMS
    b. onto PT provider forms
    c. onto PT provider website

D. Problem With Survey

1. Hemolyzed specimen
2. Contaminated specimen
3. Instability of survey
4. Survey shipment arrived too late
5. Survey shipment did not arrive

E. Other (attach explanation)

Attachment # 12
Part 136 Method Update Rule
Revisions to Appendix B – MDL Procedure as Applied to Drinking Water

Office of Ground Water and Drinking Water, Technical Support Center
October 2017

In the revised Part 136, Appendix B procedure, method detection limits (MDLs) are determined by analyzing seven method blanks (i.e. laboratory reagent blanks, LRBs) along with seven low-level laboratory fortified blanks (LFBs). Laboratories then use the higher MDL calculation derived from either the LRB or LFB replicates. ***From a drinking water perspective, if a laboratory practices good hygiene by keeping their laboratory clean (i.e. sample prep areas, glassware, instrumentation, etc.), the method blanks should never indicate a recurring background as nearly all blank failures would invalidate analytical results. Consequently, the revised procedure should have little to no impact, and MDLs will be calculated in the same way as described in the original MDL procedure used over the last thirty years.*** The question then becomes whether the revised MDL procedure has any significance for the drinking water program. The short answer is "yes," with careful consideration for the following:

1. Specific citations to Part 136, Appendix B in the drinking water regulations. Such citations will require a laboratory to follow the new procedure. There are three such regulatory citations related to the analysis of VOCs and laboratory certification:
   a. For all VOCs, except vinyl chloride. 40 CFR 141.24(f)(17)(i)(E) – "Achieve a method detection limit of 0.0005 mg/L, according to the *procedures in appendix B of part 136."*
   b. For vinyl chloride. 40 CFR 141.24(f)(17)(ii)(C) – "Achieve a method detection limit of 0.0005 mg/L, according to the *procedures in appendix B of part 136."*
   c. For all VOCs. 40 CFR 141.24(f)(20) – "Each certified laboratory must determine the method detection limit (MDL), as defined in *procedures in appendix B to part 136*, at which it is capable of detecting VOCs. The detectable MDL is 0.0005 mg/L. This concentration is the detection concentration for purposes of this section."

   There is also such a citation in the lead and copper rule:
   d. 40 CFR 141.89(a)(1)(iii) – "To obtain certification to conduct analyses for lead and copper…Achieve the method detection limit for lead of 0.001 mg/L according to *procedures in appendix B of part 136* of this title." There is not a similar explicit specification for copper, but it is implied: 40 CFR 141.89(a)(3) – "All lead and copper levels measured between the PQL and MDL must be either reported as measured or they can be reported as one-half the PQL specified for lead and copper in paragraph (a)(1)(ii) of this section. All levels below the lead and copper MDLs must be reported as zero."

2. EPA methods and MDL procedure. A few of the older EPA methods (e.g. 515.1, 548.1, 555) and various methods evaluated through the alternate test procedure (ATP) program and approved for drinking water analysis (e.g. OIA-1677 OW cyanide method) specifically cite the Part 136, Appendix B MDL procedure. Labs using those methods will need to follow the new procedure. Many of the newer EPA drinking water methods, however, either describe the specific steps for the 'old' MDL procedure without referencing Part 136, Appendix B or they reference the 1981 Glaser/Budde paper that was the basis for development of the old MDL procedure. Options for dealing with these methods are:
   a. Apply the new MDL procedure across all methods. From the standpoint of consistency, this would be a logical choice. Laboratories that analyze wastewater samples will be required to follow the new

procedure and it may be simpler to revise all their SOPs to specify the new procedure for both drinking water and wastewater methods. *Do not* penalize a lab if they choose to implement the new MDL procedure even if the drinking water method only describes the old procedure for determining MDLs (provided of course that their method blanks meet the method criteria).

b. Follow methods as written. If Part 136, Appendix B is not cited in a regulation and its associated methods, and a method contains the steps for determining MDL following the old procedure, it becomes a judgement call. Just be consistent in applying such judgement across the region.

3. Standard Methods. Similar issue as the EPA methods discussed above. Rather than incorporating QC within each method which would result in a massive unwieldy book, Standard Methods consolidates the common QC requirements within specific sections (e.g., Sect. 4020 contains the QC that pertains to the Part 4000 methods). ***The separate QC section is considered an intrinsic part of each method***. In the 22nd edition of *Standard Methods for the Examination of Water and Wastewater*, the QC section references the MDL Revision 1.11 in Part 136. That's the 'old' MDL determination. But the recently published 23rd edition incorporates the requirements of the 'new' MDL procedure (the editors apparently had anticipated publication of the CWA methods update rule prior to publication of the 23rd edition). We will be reviewing the methods within the 23rd edition for subsequent approval in a *Federal Register* notice at a later time. So, again, a laboratory may choose to apply the new MDL procedure across all methods or use the old procedure as described in the older editions.

The following represent some highlights from the new procedure:

1. Read the revised procedure and especially the frequently asked questions (FAQs) on the CWA webpage at: https://www.epa.gov/cwa-methods/method-detection-limit-frequent-questions.

2. The value calculated from the seven low-level LFBs is called the MDL_s. The MDL_s is the same as the 'old' MDL. The seven method blanks are used to calculate the MDL_b, which involves a similar evaluation of contamination/noise associated with the measurement. The final MDL is the higher of the two values. ***From the standpoint of conducting drinking water analyses, the MDL_b should not be the higher value***. If it is, that's a sure sign the lab needs to take corrective action.

3. The new procedure requires that the LFBs used to calculate the MDL are representative of laboratory performance throughout the year, rather than determined from a single analysis batch. Thus, the laboratory needs to analyze at least seven low-level LFBs and seven LRBs for an instrument in a two-year period (spread over at least three batches), but there is also a requirement to analyze two LFBs per quarter in separate batches for any quarter in which samples are analyzed. There are several nuances to this; read the FAQs.

Under Part 136, laboratories have the option to pool data from multiple instruments to calculate one MDL that represents multiple similar instruments. That is not considered a reasonable option for drinking water:

1. Chapter IV, Sect. 7.2.9 (Initial Demonstration of Capability) in the Laboratory Certification Manual states: "Before beginning the analysis of compliance samples, an initial demonstration of capability (IDC) must be performed for each method as required by the method. The IDC includes a demonstration of the ability to achieve a low background, the precision and accuracy required by the method, and determination of the method detection limit (MDL). ***An IDC should be performed for each instrument***." This specification of determining the MDL per method and per instrument precludes the option of determining a multi-instrument MDL for instruments that will be used to analyze drinking water compliance samples.

2. For some drinking water contaminants, e.g. the SOCs identified in 40 CFR 141.24(h)(18), qualification for reduced monitoring is based on specified low threshold levels. In order for a laboratory to meet those low levels, they will need to optimize *lower* detection levels. Pooling data from multiple instruments will have the net effect of increasing variability, resulting in *higher* calculated MDL values.

As discussed in the FAQs on the CWA web page, while the rule becomes effective 30 days after publication in the *Federal Register*, "EPA recognizes that it is not possible for any laboratory to make this change instantaneously. The laboratory should comply with the requirements of its control authority or permitting authority to implement Revision 2 of the MDL procedure." No one needs to start from scratch, cease operations and conduct new MDL studies. The revised procedure is structured to allow labs to use existing batch LRBs and low-level LFBs to calculate their initial MDL under the new procedure.