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Agency

Environmental Response Laboratory Network (ERLN) Laboratory Requirements Document

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1.0 BACKGROUND

The United States Environmental Protection Agency (EPA) has the responsibility of enhancing national capabilities for decontamination and disposal as a result of terrorist events and environmental sampling and analysis of all environmental matrices in response to nationally significant incidents (NSI). To protect the nation from the potential threats posed by terrorism or environmental emergencies, the EPA implemented the Environmental Response Laboratory Network (ERLN). The ERLN is one of five laboratory response networks under the Integrated Consortium of Laboratory Networks (ICLN). The ICLN is a Department of Homeland Security program designed to coordinate federal response networks to provide timely, high quality and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response. The mission of the ERLN is to provide known laboratory capabilities, capacities, and quality data in a scalable, systematic, and coordinated response to environmental emergencies providing preparedness, response, remediation and recovery analytical support. The Water Laboratory Alliance (WLA) is an integral part of the ERLN and focuses solely on water. ERLN laboratories include federal, state, local and commercial laboratories capable of analyzing environmental sample matrices contaminated by toxic industrial chemicals (TICs), chemical warfare agents (CWAs), biological agents, and radiological agents as a result of acts of terrorism or an environmental emergency. The WLA is composed of drinking water, public health, environmental and select commercial laboratories with analytical capabilities and capacity in the event of natural, intentional and unintentional water contamination.

EPA's Office of Solid Waste and Emergency Response (OSWER), Office of Emergency Response (OEM), is responsible for managing the ERLN and EPA's Water Security Division (WSD), Office of Water (OW) is responsible for managing the WLA. OEM's responsibilities include integrating and coordinating ERLN operations as well as providing the technical support infrastructure necessary to build and maintain the required capability and capacity. OEM is the lead in this coordination responsibility, while the EPA Regions and the other EPA program offices provide assistance and support for developing the ERLN's infrastructure, and when required, managing individual ERLN projects.

2.0 PURPOSE

The laboratory shall provide reliable, dependable laboratory analytical services and support to EPA in conducting Agency missions under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Superfund Amendments and Reauthorization Act (SARA), Oil Pollution Act (OPA), Resource Conservation and Recovery Act (RCRA), Safe Drinking Water Act (SDWA), Toxic Substances Control Act (TSCA), Clean Water Act (CWA), Clean Air Act (CAA), National Oil and Hazardous Substances Pollution Contingency Plan (NCP), Presidential Decision Directives (PDD) 39, 62, and 63, Homeland Security Presidential Directives (HSPDs) 5, 7, 8, 9, 10 and 22 as well as the National Response Framework (NRF), Robert T. Stafford Natural Disaster Act and other legislative acts.

The requirements in this document are designed to ensure consistent analytical data of known and documented quality across the ERLN. These requirements also apply to WLA laboratories. The laboratory shall strictly adhere to the requirements specified in this document and the project-specifications issued with each individual Analytical Services Request (ASR) for receiving, tracking, storing, preparing, analyzing and reporting data for

environmental samples contaminated by toxic industrial chemicals (TICs), chemical warfare agents (CWAs), biological agents, and/or radiological agents.

3.0 ERLN OPERATIONAL FRAMEWORK

The ERLN is faced with many unique challenges. It must be able to provide a wide variety of laboratory analytical capabilities including the analysis of toxic industrial chemicals, chemical warfare agents, biological agents and radiological agents. It must be able to provide these analytical capabilities for a wide variety of environmental matrices including drinking water, surface water, soil, air, surfaces (wipes), and other environmental matrices. It must be able to provide these analytical capabilities to support a wide variety of capacity needs including an individual short term response involving a few dozen samples to multiple long term responses that require the analyses of tens of thousands of samples. It must be able to provide these analytical capabilities to support a wide variety of data needs including determining:

- Priorities for response based on risks to human health and the environment;
- The nature and extent of contamination from the release of a hazardous material;
- Appropriate cleanup action levels; and
- Whether or not contaminated areas can be returned to their intended use.

ERLN data must also include the necessary content so that it can be shared and used by other networks and federal agencies.

In order to meet these challenges, the ERLN has established an operational framework that enables it to reliably access laboratory assets on an as-needed basis with sufficient capacity and analytical capability to perform analytical services on the targeted environmental matrices to meet project-specific data quality objectives by producing data of known and documented quality. The key components of the ERLN operational framework include:

- A comprehensive quality system, based on industry-accepted standards, designed to ensure that ERLN data meet their intended use;
- A stable sample management system designed to maintain the integrity of samples at the laboratory;
- An analytical services system designed to identify the laboratories best able to meet a project's analytical, capacity and data needs; and
- A data reporting requirement designed to provide consistent, reliable data of known and documented quality to its ERLN customers.

3.1 ERLN Quality Systems

The ERLN quality system's flexibility enables it to address various analytical services while maintaining the integrity of the data used to make major decisions regarding public health and environmental welfare. The ERLN's quality system is designed to:

- Ensure that ERLN laboratory analytical measurement systems are maintained in an acceptable state of stability and reproducibility;
- Detect problems through data assessment and establish corrective action procedures that keep the analytical process reliable;
- Document all aspects of the measurement process to improve inter-laboratory data

comparison; and

- To provide data that are technically sound and legally defensible.

3.1.1 Laboratory Quality Systems

The first and most integral component of this system relies on each ERLN laboratory managing the quality aspects of its laboratory operations in a systematic and organized manner. All ERLN laboratories must establish and maintain a documented quality system that provides an internal framework for planning, implementing, and assessing work performed and for carrying out required quality assurance and quality control activities necessary to ensure the integrity of the data they generate. A key feature of each laboratory's quality system is a set of standard operating procedures (SOPs) that facilitates consistency in the quality and integrity of data through the consistent implementation of processes or procedures within each ERLN laboratory. Finally, because of the hazards inherent in processing and analyzing environmental samples, each laboratory's quality system must operate in a safe and secure environment.

3.1.2 External Quality System

The second component of the ERLN quality system is an EPA-managed external quality system. External review of data and procedures is accomplished by monitoring the processes followed and data generated by each ERLN laboratory. Each external review is designed to address a different component of the quality system. Features of the external quality system include external third party laboratory accreditation, proficiency testing, on-site laboratory evaluations, data assessments, and electronic instrument data audits.

As with external laboratory accreditation, the ERLN external quality system is designed to verify the status of a laboratory's quality system. Many features of the ERLN's external quality system such as, proficiency testing samples and on-site evaluations are also features of external laboratory accreditation programs. For this reason, ERLN laboratories are strongly encouraged to participate in these programs.

3.1.2.1 Proficiency Testing

ERLN proficiency testing samples demonstrate the laboratory's continuing ability to produce acceptable analytical data. ERLN proficiency testing samples are provided either as single-blinds (recognizable as a proficiency testing sample but of unknown composition), or as double-blinds (not recognizable as a proficiency testing sample and of unknown composition). In either instance, the laboratory is not informed in advance of either the substances or the concentrations in the proficiency testing samples.

3.1.2.2 On-Site Evaluations

ERLN on-site laboratory evaluations are carried out to monitor the laboratory's ability to meet the terms and conditions of the ERLN agreement. The evaluation process is composed of two elements: analytical system evaluation and evidentiary system evaluation. ERLN on-site evaluations may consist of either one or both of these elements.

An analytical systems evaluation consists of an inspection of the laboratory's facilities to verify the adequacy and maintenance of instrumentation, the continuity, experience and education of personnel, and the acceptable performance of analytical and quality control procedures for adherence to ERLN requirements.

Aspects of the laboratory's facility, equipment, procedures, and operations are evaluated including, but not limited to the:

- Size, cleanliness, and organization of the facility;
- Quantity, age, availability, scheduled maintenance, and performance of instrumentation;
- Availability, appropriateness, and use of the QAP and SOPs;
- Staff qualifications and experience, and personnel training programs;
- Analysis of proficiency testing sample(s);
- Reagents, standards, and sample storage facilities;
- Standard preparation logbooks and raw data;
- Bench sheets and analytical logbook maintenance and review; and
- Review of the laboratory's sample analysis, data package inspection and data management procedures.

An evidentiary system evaluation is comprised of three parts: a procedural audit, written SOP audit, and an analytical project file audit. These evaluations are conducted in order to determine if laboratory policies and procedures are in place to satisfy evidence-handling requirements.

The procedural audit covers all aspects of sample handling and analysis from sample receipt to data assembly. During a procedural audit, the laboratory may be requested to perform the analysis of proficiency testing sample(s) in the presence of the authorized ERLN Representative(s).

The written SOPs audit includes reviewing and examining SOPs for specific laboratory operations to determine if the SOPs are accurate and complete. The laboratory operations covered in the written SOPs audit includes, but not limited to: sample receiving; sample storage; sample identification; sample security; sample tracking (from receipt to completion of analysis); and analytical project file organization and assembly.

The analytical project file evidence audit consists of reviewing and examining the laboratory's analytical project file documentation to determine the accuracy of the document inventory; the completeness of the file; the adequacy and accuracy of the document numbering system; the traceability of sample activity; identification of activity recorded on the documents; and error correction methods.

3.1.2.3 Upon completion of an on-site evaluation, the evaluators present their observations, findings and recommendations for necessary corrective actions to the laboratory. A report which discusses deficiencies found during the on-site evaluation is sent to the laboratory to provide further clarification of findings. Data Audits

Data audits are used to assess the technical quality of the data and evaluate overall laboratory and method performance. These audits are not the same as project-specific data assessments performed to ensure that laboratory data meet the project-specific measurement quality objectives. Data audits are performed by the ERLN program periodically, using data packages selected from recently received projects.

Data audits consist of a thorough review of the raw data, including: all instrument/equipment readouts used for the sample results; instrument/equipment printouts; quantitation reports; chromatograms; spectra; library searches and other documentation for deviations from the requirements; a check for transcription and calculation errors; a review of the qualifications

of the laboratory personnel involved with the project; and a review of the latest version of all SOPs on file. Feedback is provided to the laboratory when the audit is completed.

3.1.2.4 Electronic Data Audits

Electronic data audits provide a mechanism to assess adherence to requirements and to ensure consistent data are reported in the electronic data submissions generated from analytical instruments. This function provides external monitoring and checks the laboratory's adherence to its' internal procedures. In addition, electronic data audits enable the ERLN program to evaluate the utility, precision, and accuracy of analytical methods.

Electronic data audits review and assess many of the same components of the hardcopy data audits, but focus on the electronic data management and data processing. The laboratory is provided feedback when the audit is completed.

3.2 Sample Management System

ERLN samples are received and maintained under chain of custody. Each sample can potentially be considered physical evidence whose control and tracking is an essential part of an investigative effort. It is essential that that all ERLN samples be maintained under custody from the time of collection through disposal or return to the data user.

Sample custody is when a sample is

- in the possession of an individual; or
- in the view of an individual after being in his/her possession; or
- locked in a secure area by an individual after being in his/her possession; or
- in a designated secure area that is only accessible by authorized personnel.

Sample tracking data and records supporting sample-related activities can have weight as evidence in future litigation. Once a laboratory has possession of a sample, it must be carefully tracked to maintain the integrity of the sample data. In addition to evidentiary requirement, data are used to support decisions associated with public health and environmental welfare. It is vital that these data can be appropriately related to its sampling location to avoid costly errors that can potentially occur if the sample is incorrectly identified. All associated document control and inventory procedures must be documented and followed.

All ERLN laboratories must establish and maintain a sample management system that ensures

- Traceability of samples while in possession of the laboratory;
- Custody of samples while in possession of the laboratory;
- The integrity of sample identity while in possession of the laboratory;
- Sample-related activities (i.e., sample receipt, storage, preparation, analysis, and disposal) are recorded on documents or in other formats;
- All laboratory records for each sample received by the laboratory are accounted for when the project is completed; and
- All laboratory records directly related to samples are assembled and delivered or made available upon request to the data user upon request.

Each ERLN laboratory has the discretion to employ a variety of tools as part of its sample management system. These tools may include automated tracking tools such as laboratory information management systems (LIMS), manual tools, such as handwritten tracking forms, or a combination of the two. However, the core of each laboratory sample management system is a set of written SOPs that address internal laboratory procedures for sample receiving, sample identification, sample security, sample storage, sample tracking and document control, data management, and report organization and assembly.

3.2.1 Sample Receiving

Sample receiving SOPs describe procedures for documenting sample log-in information, inspecting shipping containers (i.e., coolers), inspecting sample containers, inspecting chain of custody documentation, documenting the condition of samples (e.g., temperature, pH, etc.), and communicating discrepancies to the customer. Procedures for safe handling of samples in the sample receiving and log in areas are also addressed in these SOPs.

3.2.2 Sample Identification

Sample identification SOPs describe procedures for maintaining the identity of samples and prepared samples throughout the laboratory. Procedures for assigning unique laboratory sample identifiers, labeling each sample and sample preparation container and properly assigning samples to the appropriate analytical methods/parameter groups and matrix types, as appropriate.

3.2.3 Sample Security

Sample security SOPs describe how the laboratory maintains security of designated secure areas, defines secure areas, identifies authorized personnel who have access to locked storage areas, and details how the laboratory maintains the capability to track sample location and transfers within the laboratory. These SOPs describe both the laboratory facility's physical security and personnel security at the laboratory.

3.2.4 Sample Storage

Sample storage SOPs designate storage areas for samples and prepared samples. The SOPs describe the locations, characteristics, contents, and identities of all sample storage areas in the laboratory. Laboratory procedures for sample disposal and the disposal of unused extracts, bottle and containers are also addressed in these SOPs.

3.2.5 Sample Tracking and Document Control

Sample tracking and document control SOPs describe procedures for tracking and documenting the status of a sample as it is processed by the laboratory and include inventory procedures documenting sample location and transfer within the laboratory. Process activities include sample receipt; sample storage; sample preparation; sample analysis; and sample disposal. These SOPs also address the laboratory's logbook policy, all hard copy forms used to document sample tracking and how this documentation is maintained by the laboratory.

3.2.6 Data Management

Data management SOPs describe procedures for maintaining the accuracy, integrity and security of electronic and hardcopy data. These SOPs describe procedures for verifying the accuracy of manually entered data, electronically entered data, and data acquired from instruments, as well as access to data by laboratory personnel and protecting data from malicious attacks (e.g., virus protection).

3.2.7 Report Organization and Assembly

Report organization and assembly SOPs describe procedures for maintaining project files at the laboratory, data review and verification, submitting electronic data, compiling and submitting original hardcopy data, when required and tracking data submissions. These SOPs address both original data submissions and resubmissions.

3.3 Analytical Services

ERLN laboratories do not have to possess the analytical capability to perform all ERLN analyses; but each laboratory must be proficient in the ones that they can perform. This proficiency is demonstrated through a laboratory's quality system and can be verified and tracked through their sample management system. Each laboratory must maintain their proficiencies so that they can respond to the project-specific needs of the ERLN.

The ERLN laboratories are considered valuable assets that enable EPA to respond to all types of environmental incidents. Managing these assets is essential to ensure that their technical capability and analytical capacities can be appropriately directed to support the data needs of response personnel. EPA has established an ERLN program office to oversee access to these laboratories; implement the external quality system; monitor method and laboratory performance; and manage daily operations.

The ERLN program office is located in OEM's Homeland Security Laboratory Response Center. The ERLN program office consists of technical and administrative staff members who act as contracting officer's representatives (COR). These CORs are supported by staff located in other EPA program offices and the Regions, who perform a variety of roles including acting as analytical and laboratory coordinators. The CORs, analytical coordinators and laboratory coordinators act as the authorized ERLN Representatives. These individuals are authorized to broker project-specific ASRs with ERLN laboratories and act as the primary conduit for communicating between project staff, the ERLN program office and ERLN laboratories. Similar functions as the above are performed by the Water Security Division in EPA's Office of Water for the management of the WLA, an important component of the ERLN. As such, for purposes of the WLA, the WLA Representative is an ERLN Representative.

The project-specific ASR is the most essential part of the ERLN operations. Within these ASRs, the data user specifies their data needs. Each ASR contains project-specific requirements including:

- The project identifier;
- The names and contact information of the project's authorized ERLN (and where appropriate WLA) Representative(s) and data recipient;
- An estimated project period of performance;
- An estimated shipping schedule;
- The number and environmental matrix of the samples;
- Any known or suspected hazards associated with the samples;
- Reporting requirements including data turnaround, data submission type and format;
- The required analytical services including method references and their associated measurement quality criteria, indicators and objectives; and

- Any special requirements for the project (e.g., providing sample collection media, sample containers, special sample handling, etc.)

The analytical services requirements typically reference analytical protocols identified in the *"Standard Analytical Methods (SAM) for Environmental Restoration following Homeland Security Events"* for the isolation, detection, and quantitative measurement of biological, chemical, and/or radiological agents in samples collected in support of environmental responses.

The project's authorized ERLN Representative selects a community of ERLN laboratories who have the necessary capability and capacity to fulfill the project-specific requirements. Laboratories are selected based on the information that they provide to the "EPA's Compendium of Environmental Testing Laboratories". Each ERLN laboratory maintains a profile in this system which includes the laboratory location; contact information; analytical capabilities; number and type of instruments; participation in external quality assurance programs; and ability to meet ERLN reporting requirements.

The project-specific ASR is sent to the selected ERLN laboratories that assess the requirements and respond. The authorized ERLN Representative evaluates all of the responses, selects the appropriate laboratory, obtains all necessary ERLN approvals, registers the project with the ERLN program office; and assigns the project to the selected laboratory. The project's field personnel are informed of the laboratory assignment and sample shipment begins.

The samples are received at the laboratory and entered into the laboratory's sample management system. As samples are received, a project file is initiated and they are assigned to data reporting groups by the laboratory. The data reporting group is the basis for all data reporting. The standard ERLN data reporting group is created for every 20 field samples received by the laboratory during a calendar week (Sunday-Saturday). Field blanks, trip blanks and project-specific performance evaluation samples associated with the field samples are also included in a data reporting group but are not considered field samples. It is important that the laboratory completes its data reporting group upon receipt of the 20th field samples because all data turnarounds are calculated from the date the data reporting group is closed. Once a data reporting group is created, the laboratory provides the authorized ERLN Representative with documentation that includes the project identifier, the data package identifier and the samples included in the data reporting group. This information enables the authorized ERLN Representative to track the laboratory's progress and to determine a data delivery schedule.

The ERLN laboratory processes the samples ensuring that their preparation and analysis are performed in accordance with project-specification. The laboratory documents all specified measurement quality indicators and whether or not measurement quality criteria are achieved for all positive and negative controls associated with the analysis of samples. In instances where the criteria are not met, the laboratory takes appropriate corrective action as specified by their quality system and the project-specific requirements. Corrective action may include reanalysis of affected samples. The laboratory assigns appropriate data qualifiers to affected results, and prepares the data for reporting.

It is important that the laboratory not deviate from project-specifications without prior approval from the ERLN personnel specified in the laboratory's ERLN agreement or within the project-specific ASR. All problems, deviations and their resolutions are documented and reported in the appropriate data package narrative.

3.4 Data Reporting

ERLN data reporting business processes, specifications and formats are designed to support the various ERLN project's data needs by enabling laboratories to provide data submissions with rapid turnarounds, while having sufficient data to support decisions made for each project. ERLN data are reported in both electronic and hardcopy format. ERLN electronic data are provided in a computer-readable format and PDF. The computer-readable format consists of data whose content is provided in unformatted spreadsheet, comma separated value (CSV) or extensible markup language (XML) format that facilitates importing data into project-level or enterprise-level relational databases and its processing by automated electronic data review and assessment software. Word processed documents and e-mails are not considered computer-readable electronic data in this context. The supplemental portable document format (PDF) file is submitted containing a laboratory narrative, summary forms, and chain of custody documentation. The PDF is an electronic, bookmarked version of the hardcopy data package. Electronic data in computer-readable and PDF are required for each ERLN data submission, while hardcopy submissions are optional.

ERLN data submissions are separated into three types. The data submission type is determined by the data user for each individual project. These types correlate to the data required to support decisions made for the various intended uses of response personnel. Each type builds on the previous type in order to limit a proliferation of formats. They are also designed recognizing the various capabilities of ERLN laboratories to produce electronic data. Like analytical capabilities, ERLN laboratories do not have to possess the capability to submit all electronic data format types; but each laboratory must be proficient in the ones that they can perform. A complete description of the ERLN data requirements can be found in *"Requirements for ERLN Data Submissions"*.

3.4.1 ERLN Type One Data Submissions

Type One data submissions primarily support emergency response projects where time is of the essence. It acts as the cornerstone of the ERLN data reports because it includes the minimum requirements which are included throughout all of the data submission types.

The Type One format for computer-readable data is either a spreadsheet or CSV that contains column headers for the 18 required ERLN data elements. These data elements are:

- Project Identifier - A designator used to uniquely identify the project to organizations generating and sharing ERLN data.
- Organization Identifier - A designator used to uniquely identify an ERLN laboratory.
- Organization Type - The name that describes the capacity or function that an organization or individual serves, or the relationship between an individual or organization and a project or action.
- Agreement Number – Number assigned by EPA to identify a laboratory's ERLN agreement.
- Data Package Identifier - A laboratory-defined identifier for data package. This identifier applies uniquely to a single data submission.
- Field Sample Identifier - A designator used by sample collection personnel to uniquely identify a sample within a context.

- Matrix - Sub-medium or matrix that is sampled and analyzed.
- Method Identifier - The identification number assigned by the ERLN that relates to the analytical procedures and the measurement quality criteria, indicators and objectives for a method.
- Analysis End Date - The date and time of the end of the analysis period.
- CAS Registry Number - The unique number assigned by Chemical Abstracts Service (CAS) to a chemical substance (required for chemical analyses only).
- Substance Name - The name assigned to a chemical, biological or radiological substance or feature that describes it in terms of its molecular composition, taxonomic nomenclature or other characteristic.
- Result - The reportable measure of the result for the chemical, microbiological or other characteristic being analyzed.
- Result Units - The code that represents the unit for measuring the item.
- Result Uncertainty - A value or set of values that characterizes the dispersion of the values that could reasonably be attributed to the measured result value.
- Reporting Limits - The number or value below which data are typically reported as 'not detected' for the substance being measured.
- Reporting Limit Units - Units associated with reporting limit as determined by the lab.
- Reporting Limit Type - Client, regulation, or organization defined acronyms or statistical methodologies that specify the type of reporting limit.
- Laboratory Result Qualifiers - A laboratory-assigned string of result qualifiers (usually a single character for each qualifier), based on client -defined rules and values.

The Type One format for computer-readable data is limited to the final results of an analytical process for the substances of concern as determined by the laboratory for samples received by the laboratory for a project (e.g., field samples, field blanks and performance evaluation samples). Results for calibrations; instrument performance checks; laboratory generated positive and negative control samples (e.g., LCS, blanks, etc); and non-target substances (e.g., surrogates, internal standards, tentatively identified compounds, etc.) are not reported. This format relies most heavily on the laboratory's ability to meet measurement quality objectives as the only quality indicator provided by the laboratory is a data qualifier.

The Type One hardcopy format requires the laboratory to include a laboratory narrative, chain of custody documentation, sample login information, sample tags (if used) and data summary forms for the final sample results for the substances measured. Summary data forms are separated for each analytical method used. All hardcopy data submitted by the laboratory are originals, not copies.

3.4.1.1 Type One Transitional Format

The Type One Transitional format is a variation of the Type One format that is requested when a data user only needs results but wishes to spot check some of the measurement quality indicators associated with sample analysis. The Type One Transitional Format applies only to computer-readable data. It is either a spreadsheet or CSV that contains column headers for the required ERLN data elements with additional column headers that identify the type of sample, the type of substance and expected result for spiked

compounds. A complete description of the Type One Transitional format data elements and requirements can be found in *"Requirements for ERLN Data Submissions"*.

3.4.2 ERLN Type Two Data Submissions

Type Two data submissions includes all of the elements included in the Type One and Type One Transitional formats; however additional elements are included to enable the data user to perform a more extensive data assessment. It also includes additional metadata associated with the project, laboratory and methods used. Results are reported for each analysis performed on a sample and all associated calibrations, instrument performance checks, and laboratory generated positive and negative control samples (e.g., LCS, duplicates, blanks, etc). Data are also reported for non-target substances (e.g., surrogates, internal standards, tentatively identified compounds, etc.) with the results of the sample.

The Type Two computer-readable format for submitting data is XML. This format is used in order to maintain the data relationships between the project, samples and their analysis by grouping these data together. This data grouping helps to limit redundant data in a laboratory's data submission. This format also accommodates reporting additional data associated with sample characteristics (e.g., pH, temperature, % moisture, etc.); sample handling; sample preparation; laboratory batching; and sample analysis. These data, along with data associated with the substance measured, sample type, and the expected result for spiked compounds, enables the laboratory to report data for a project's measurement quality indicators that can be independently verified by the data user. By providing these data in an electronic XML format, the majority of these assessments can be performed electronically by web-based electronic data assessment and review software. Data from these reviews not only provides the data user with a project-level data assessment, but can also provide the ERLN program office with important laboratory and method performance information.

The Type Two hardcopy format includes all Type One contents. It also follows the same structure and organization as a Type One submission. However, additional summary forms for each measurement quality indicator identified in the analytical method used to analyze the samples are also included. These forms include the measurement quality criteria for each indicator and the results of the laboratory's quality control analysis.

3.4.3 ERLN Type Three Data Submissions

The Type Three format is considered the most extensive ERLN data submission format. It includes all of the elements included in Type Two; however additional elements are included to enable the data user to perform a more extensive data assessment by recreating the analysis as it was performed in the laboratory. Data associate with the instrument responses and other measurements used to generate the results included in a Type Two data submission are submitted by the laboratory in a Type Three submission.

The Type Three computer-readable format for submitting data is XML. This format is identical to the Type Two format with the exception of additional data groups that associate various types of instrument responses with their associated analyses. These data are used to recalculate a laboratory's reported result for each analysis in order to verify its correctness. Data submitted in a Type Three format are also amenable to electronic processing by web-based electronic data assessment and review software.

The Type Three hardcopy format includes all Type Two contents. It also follows the same structure and organization as a Type Two submission. However, each summary form is accompanied by the instrument output used to calculate the result. Type Three hardcopy data submissions include all data associated with its receipt, storage, tracking, preparation,

and analysis of samples included in the data submission. This includes tracking forms, logbook analyst entries and any other documents or artifacts associated with the analysis.

4.0 REQUIREMENTS

In order for the laboratory to operate within the ERLN framework, the laboratory shall comply with the following requirements. These requirements apply to all ASRs performed by the laboratory and shall remain in effect for the period of performance of this agreement unless specifically modified by the appropriate ERLN Representative.

4.1 General Requirements

4.1.1 The laboratory shall provide analytical services for the isolation, detection, and quantitative measurement of biological, chemical, and/or radiological agents in samples collected in support of environmental responses.

4.1.2 The laboratory shall adhere to the methods and technical requirements specified in the project-specific ASR when testing ERLN samples and reporting results. The laboratory shall immediately report positive or suspect test results to authorized ERLN personnel only.

4.1.3 The laboratory shall possess and have operational all necessary measurement and testing equipment/instrumentation required to perform the applicable test as specified in the methods reference in the project-specific ASR, prior to receipt of samples.

4.1.4 The laboratory shall submit a unique data package for each data reporting group received for a project at the data submission type, in the appropriate medium (computer-readable, PDF, hardcopy), and within the timeframe specified in the project-specific ASR. The laboratory shall submit these data to the authorized ERLN Representative specified in the project-specific ASR.

4.1.5 The laboratory shall have sufficient personnel with necessary education, training, technical knowledge and experience to perform their assigned functions.

4.1.6 The laboratory shall provide all necessary standards, reagents, glassware and other consumable products necessary to perform the applicable test as specified in the methods reference in a project-specific ASR, prior to receipt of samples. **Exception:** Standards for chemical warfare agents and reagents for biological select agents will be provided to the laboratory, as necessary.

4.1.7 The laboratory shall possess and have operational all necessary computer hardware, software and data acquisition systems required to report electronic data as specified in the project-specific ASR, prior to receipt of samples.

4.1.8 The laboratory shall provide clean sample collection media, sample containers (e.g. jars, bottles, vials, etc.), preservatives and shipping containers as requested in the project-specific ASR.

4.1.9 The laboratory shall have a documented sample management system that addresses sample receiving; sample identification; sample security; sample storage; sample tracking and document control; data management; and report organization and assembly.

4.1.10 The laboratory shall be responsible for any handling of sample shipments. This includes sample pick-up and being available to receive and process sample shipments at any

time the delivery service is operating, including Saturdays and Sundays, as required, to ensure that sample preparation and analysis time requirements can be met.

4.1.11 The laboratory shall use the project identifier, data package identifier, and field sample identifiers when identifying samples received under this ERLN agreement both verbally and in reports/correspondence.

4.1.12 The laboratory shall accept responsibility for all risks associated with handling materials and agents associated with analyzing ERLN samples. ERLN samples received and processed by the laboratory may contain levels of chemical, biological, and/or radiological materials of a potentially hazardous nature and of unknown structure and concentration. All samples should be handled throughout the analysis with appropriate caution. It is the laboratory's responsibility to take all necessary measures to ensure safety.

4.1.13 The laboratory shall ensure no unauthorized transfer of any ERLN materials or data to any third party. The laboratory shall ensure sufficient internal security to control access to ERLN materials.

4.1.14 The laboratory shall have a system in place to limit copying, and control distribution and access of any method systems or procedures identified by ERLN as secure to those individuals who are actively engaged in analysis of environmental samples in the ERLN.

4.1.15 The laboratory shall ensure data and information system security is in place to protect clients' confidential information and proprietary rights.

4.1.16 The laboratory shall have the ability to share or exchange its data with authorized ERLN Representatives via an approved, secure data system, as required.

4.1.17 The laboratory shall be responsible for sample disposal and disposal of unused sample bottles/containers and extracts. All disposals must be done in accordance with all applicable laws and regulations governing disposal of such materials.

4.1.18 The laboratory may be required to appear and testify to the accuracy and/or validity of the data generated.

4.2 Laboratory Quality Systems

4.2.1 The laboratory shall establish and maintain a documented quality system consistent with the *"Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs." (ANSI/ASQC E4)*", American National Standard ANSI/ASQC E4-1994.

4.2.2 The laboratory shall have a written Quality Management Plan (QMP) that describes their structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and its processes for planning, implementing, documenting, and assessing all activities conducted under the organization's quality system. The laboratory shall ensure that its QMP includes all elements specified in *"EPA Requirements for Quality Management Plans (QA/R-2) - EPA/240/B-01/002"*, March 2001 (Reissued May 2006)."

4.2.3 The laboratory shall have a written Quality Assurance Project Plan (QAPP) that describes the quality assurance procedures, quality control specifications, and other technical activities that must be implemented to ensure that the results of ERLN projects meet project-specifications with the objective of providing sound analytical measurements. The laboratory shall ensure that its QAPP includes all elements

specified in "*EPA Requirements for Quality Assurance Project Plans (QA/R-5) - EPA/240/B-01/003"*, March 2001 (Reissued May 2006).

4.2.4 The laboratory shall have written SOPs that consist of a set of instructions documenting routine or repetitive activities undertaken by the laboratory under the ERLN agreement. These SOPs shall describe both technical and administrative operational elements managed under the laboratory's QMP and QAPP. The laboratory shall ensure that its SOPs include all appropriate elements listed in *"Guidance for Preparing Standard Operating Procedures (SOPs) (QA/G-6) - EPA/600/B-07/001"*, April 2007.

4.2.4.1 The laboratory shall document that all laboratory personnel performing actions identified in an SOP are trained and understand the contents of that SOP at least annually.

4.2.4.2 The laboratory shall have document control procedures that preclude using outdated or inappropriate SOPs.

4.2.4.3 The laboratory shall have SOPs available at specific workstations as appropriate.

4.2.5 The laboratory shall have a written Health and Safety (H&S) Plan that addresses laboratory management and administration; hazard identification and evaluation; laboratory safety and health; engineering controls; protective clothing and equipment; work practice controls; laboratory emergency situations; and designates an emergency medical treatment center. The laboratory shall ensure that its H&S Plan includes all appropriate elements specified in, *''Occupational Exposure to Hazardous Chemicals in Laboratories''*, 29 CFR part 1910.1450, *"Hazard Communication''* 29 CFR part 1910.1200 and/or EPA's *"Safety, Health, and Environmental Management Program (SHEMP) Operations Manual for Laboratories, Release 1, - EPA-202-B-98-001",* July 1998.

4.2.5.1 The laboratory shall supplement its H&S Plan with elements from appropriate sources to address hazards other than toxic industrial chemicals (e.g. Chemical Hygiene Plan for CWA, Biosafety Plan and a Radiation Protection Plan), as appropriate.

4.2.5.2 The laboratory shall have radioactive materials licensing and radiation safety plans and procedures as appropriate. This requirement applies to only those laboratories with radiological capabilities.

4.2.6 The laboratory shall amend its QMP, QAPP, SOPs and H&S Plan when conditions warrant a change, such as organizational, personnel, facility, equipment, policy, or procedural changes, or if the laboratory identifies deficiencies resulting from internal review procedures and documentation. The laboratory shall archive all previous versions of its QMP, QAPP, SOPs and H&S Plan identifying the date and reason for amendment and submit an electronic copy(ies) of its QMP, QAPP, SOPs and H&S Plan in PDF format to the appropriate COR within 14 days of written request.

4.3 External Quality System

4.3.1 The laboratory shall maintain any existing accreditation through the NELAC Institute (TNI) or an ISO 17025 equivalent accreditation program throughout the period of performance of this agreement. State certification and reciprocity agreements can also be referenced. If the laboratory is not currently accredited, it shall take all reasonable steps to obtain accreditation. Failure to obtain or maintain accreditation may affect the laboratory's continued participation in the ERLN.

4.3.2 The laboratory shall prepare and analyze proficiency testing samples using the procedure described in the sample preparation and method analysis sections of the method specified in the ASR, as well as any special instructions arriving with the proficiency testing sample concerning any unique preparation procedures required to reconstitute the proficiency testing samples (i.e., the required dilution of the proficiency testing sample concentrate).

4.3.2.1 The laboratory shall be responsible for correctly identifying and quantifying the substances included in a proficiency testing sample. When proficiency testing sample results are received by the COR, the proficiency testing sample results are evaluated for correct analytical identification and quantitation. The proficiency testing sample evaluations are provided to the laboratory via coded evaluation sheets, by substance.

4.3.3 The laboratory shall agree to on-site evaluations by ERLN Representatives for the purposes of assessing qualifications for membership, capabilities, capacity, competency, and quality.

4.3.3.1 The laboratory shall have a complete set of SOPs that are bound together available for inspection by ERLN Representatives prior to and during on-site evaluations. The laboratory shall also provide any additional ERLN project documentation as requested by ERLN Representatives during an audit.

4.3.3.2 The laboratory shall complete and return the self-inspection checklist prior to on-site evaluation, as appropriate.

4.3.3.3 The laboratory shall perform the analysis of proficiency testing sample(s) in the presence of authorized ERLN Representatives during a procedural audit, as requested.

4.3.4 The laboratory shall provide data in the appropriate hardcopy and electronic format to ERLN Representatives for specified ERLN projects in response to electronic data audits.

4.3.4.1 The laboratory shall provide all associated raw data files for all analytical samples, all quality control samples, standards, and blanks. The laboratory shall provide all processed data files and quantitation output files associated with the raw data files. In addition, the laboratory shall supply raw data for the demonstration of capabilities studies and values for the year in which the samples were analyzed.

4.3.4.2 The laboratory shall provide all associated identifications and calculation files (method files) used to generate the data submitted in the data package. This includes, but is not limited to, results files, acquisition files, calibration files, method files, and all laboratory-generated library files. True values used to calculate statistical quality control objectives (e.g., %RSD, acceptable % recoveries, etc) for all surrogates, spikes, calibration analytes must be stored and dated.

4.3.4.3 The laboratory shall provide a copy of the laboratory's reference logbook relating data files to field sample identifiers, calibration data, standards, and blanks. The logbook shall include laboratory file identifiers for all samples, blanks, and standards, identified by project and data package.

4.3.4.4 The laboratory shall provide a printout of all files in each directory, including all subdirectories and files.

4.3.4.5 The laboratory shall provide a statement attesting to the completeness of the electronic instrument data, and that attests that these data reported have not been

altered in any way. The statement will be signed and dated by the Laboratory Manager.

4.3.4.6 The laboratory shall provide the following information with the data in electronic format relevant to a data tape submission: instrument make and model number; instrument operating software name and version; data software name and version used for acquisition, re-quantitation, and hardcopy/ report generation; data system computer; system operating software; data system network; data backup software; data backup hardware; data analysis software; media type and volume of data [in Megabytes (MB)] backed up; and names and telephone numbers of two laboratory contacts for further information regarding the submission.

4.4 Sample Receiving

4.4.1 The laboratory shall sign and date the airbill received with a sample shipment. If an airbill is not received, the laboratory shall include a hardcopy receipt requested from the shipping company or a printout of the shipping company's electronic tracking information.

4.4.2 The laboratory shall examine the shipping containers and record their condition (e.g., intact, broken, leaking). The laboratory shall note the presence/absence of custody seals on the shipping containers and record the custody seal numbers.

4.4.3 The laboratory shall open each shipping container, remove the enclosed sample documentation, and record the presence/absence of a signed chain of custody and airbills or airbill stickers. The laboratory shall record the chain of custody number and the airbill number, if present.

4.4.4 The laboratory shall measure and record the temperature of the shipping container immediately upon opening the shipping container. The laboratory shall document the technique used to determine shipping container temperature. Under no circumstances shall a thermometer or any other device be inserted into a sample container for the purpose of determining container temperature.

4.4.5 The laboratory shall remove the samples from each shipping container, examine the sample bottles and the sample tags (if present), record the condition of the sample bottles (e.g., intact, broken, leaking) and presence/absence of sample tags.

4.4.6 The laboratory shall review the sample shipping documents, compare the information recorded on all the documents and samples and indicate whether information on the samples and documentation agree.

4.4.7 The laboratory shall record date and time of sample receipt at the laboratory.

4.4.8 The laboratory shall sign and date (include the time) the chain of custody, and record the field sample identifiers, if there are no problems observed during sample receipt.

4.4.9 The laboratory shall return a copy of the chain of custody record to the authorized ERLN Representative within 24 hours of receiving the last sample in the data reporting group.

4.4.10 The laboratory shall record the appropriate sample tag numbers and assigned laboratory numbers, if applicable.

4.4.11 The laboratory shall record the analytical methods requested and the specific area designation where samples are stored (e.g., refrigerator number).

4.4.12 The laboratory shall return clean sample shipping containers (e.g., coolers) to the appropriate sampling office within 14 calendar days following shipment receipt.

4.4.13 The laboratory shall immediately contact the project-specified authorized ERLN Representative to resolve problems and discrepancies including but not limited to: absent documents; conflicting information; absent or broken custody seals; insufficient sample volume; elevated cooler temperature; unsatisfactory sample condition (e.g., leaking sample container); samples not preserved to the proper pH (if applicable); and missing samples or sample documentation and paperwork. The laboratory shall sign and date the document and note the resolution of the problem.

4.4.14 The laboratory shall have written SOPs describing sample receiving procedures. These SOPs shall detail all procedures associated with documenting sample log-in information; inspecting shipping containers (i.e., coolers); inspecting sample containers; inspecting chain of custody documentation; documenting the condition of samples (e.g., temperature, pH, etc.); and communicating discrepancies to the customer. Descriptions of any automated systems used to document these procedures should also be included in these SOPs.

4.4.15 The laboratory shall have written SOPs describing procedures for safe handling of samples in the sample receiving and log in areas. These SOPs shall detail all procedures associated with identifying and processing potentially hazardous samples including use of a hood or biosafety cabinet.

4.5 Sample Identification

4.5.1 The laboratory shall have written SOPs describing sample identification procedures. These SOPs shall detail all procedures associated with maintaining the identity of samples and prepared samples throughout the laboratory; assigning unique laboratory sample identifiers; labeling each sample and sample preparation container; and properly assigning samples to the appropriate analytical methods/parameter groups and matrix types, as appropriate.

4.6 Sample Security

4.6.1 The laboratory shall have written SOPs describing sample security. These SOPs shall detail all procedures associated with how the laboratory maintains security of designated secure areas; defines secure areas; identifies authorized personnel who have access to locked storage areas; and details how the laboratory maintains the capability to track sample location and transfers within the laboratory.

4.6.2 The laboratory shall have written SOPs describing physical security of the laboratory facility including but not limited to security alarms, security personnel, and procedures for reporting breaches in security.

4.6.3 The laboratory shall have written SOPs describing measures for ensuring personnel security at the laboratory, including background checks.

4.7 Sample Storage

4.7.1 The laboratory shall retain unused sample volume in the original containers for a period of 60 days after data submission. The laboratory shall maintain all samples under appropriate conditions.

4.7.2 The laboratory shall dispose of unused sample volume and used sample bottles/containers no earlier than 60 days after data submission, unless specified otherwise within the project-specific ASR.

4.7.3 The laboratory shall dispose of sample extracts no earlier than 365 days from data submission, unless specified otherwise within the project-specific ASR.

4.7.4 The laboratory shall submit extracts and associated logbook pages within 7 days following receipt of a written request from an authorized ERLN Representative.

4.7.5 The laboratory shall maintain a logbook of stored extracts, listing field sample identifiers, project identifier, and data package identifier.

4.7.6 The laboratory shall document the disposal or retention of samples, remaining portions of samples, and prepared samples.

4.7.7 The laboratory shall have written SOPs describing sample storage procedures for samples and prepared samples. These SOPs shall detail all procedures associated with describing the locations, characteristics, contents, and identities of all sample storage areas in the laboratory.

4.7.8 The laboratory shall have written SOPs describing procedures for sample disposal and the disposal of unused extracts, bottle and containers

4.8 Sample Tracking and Document Control

4.8.1 The laboratory shall print the identity of the activity being performed on each page of all laboratory documents. The laboratory name shall be identified on preprinted laboratory documents. Activities include but are not limited to sample receipt; sample storage; sample preparation and analysis; sample retention or disposal; and report preparation. When a document is a record of analysis, the analysis/instrument type shall be included in the title.

4.8.2 The laboratory shall identify reviewers' signatures on laboratory documents when reviews are conducted. Individuals recording review comments on computer-generated raw data are not required to be identified unless the written comments address data validity.

4.8.3 The laboratory shall date laboratory document entry and shall be signed by the individual(s) responsible for performing the recorded activity at the time the activity is recorded.

4.8.4 The laboratory shall ensure that all documentation is legible (i.e., information reported must be either typewritten or computer-generated. Handwritten corrections of the information must be legible, signed, and dated).

4.8.5 The laboratory shall record all notations on laboratory documents in ink.

4.8.6 The laboratory shall draw single lines through the errors for corrections to laboratory data reporting forms and raw data. Original information shall not be obliterated or rendered unreadable. Corrections and additions to information shall be signed (or initialed) and dated.

4.8.7 The laboratory shall line-out, sign (or initial) and date unused portions of laboratory documents.

4.8.8 The laboratory shall sequentially number pages in bound and unbound logbooks.

4.8.9 The laboratory shall maintain instrument-specific run logs to enable the reconstruction of run sequences.

4.8.10 The laboratory shall chronologically order logbook entries. Each page in bound and unbound logbooks shall be dated and signed (no initials) at the bottom by the individual

recording the activity (if a single entry is made on a page) or by the last individual recording information on the page (if multiple entries are on the same page).

4.8.11 The laboratory shall permanently affix information inserted into laboratory documents. The individual responsible for inserting information shall sign and date across the edge of the insert and logbook page at the time information is inserted.

4.8.12 The laboratory shall have written SOPs describing sample tracking and document control through all laboratory processes. Process activities include sample receipt; sample storage; sample preparation; sample analysis; and sample disposal. These SOPs shall detail all procedures associated with tracking and documenting the status of a sample as it is processed by the laboratory, and inventory procedures documenting sample location and transfer within the laboratory.

4.8.13 The laboratory shall have written SOPs describing all documentation policies and procedures. These SOPs shall detail all procedures associated with laboratory/analysts' notebook policy, including review policy; determining data package contents; organizing and assembling data package, including review policy; and document inventory procedures, including review policy.

4.8.14 The laboratory shall have written SOPs describing all hard copy forms used to document sample tracking and how this documentation is maintained by the laboratory.

4.9 Data Management

4.9.1 The laboratory shall make changes to electronic data in a manner which ensures that the original data entry is preserved; the editor is identified; the revision date is recorded; and the reason for the change is documented.

4.9.2 The laboratory shall routinely verify the accuracy of manually entered data, electronically entered data, and data acquired from instruments.

4.9.3 The laboratory shall routinely verify documents produced by the electronic data collection system to ensure accuracy of the information reported.

4.9.4 The laboratory shall ensure that the electronic data collection system is secure by maintaining it in a secure location, limiting data collection system functions to authorized personnel through use of software security techniques (e.g., log-ins or restricted passwords), and protecting it from the introduction of external programs or software (e.g., viruses).

4.9.5 The laboratory shall designate archive storage areas (including off-site backup) for electronic data and the software required to access the data including LIMS and instrument files.

4.9.6 The laboratory shall maintain the archives of electronic data and necessary software in a secure location (secure areas shall be accessible only to authorized personnel).

4.9.7 The laboratory shall maintain a record of changes, corrections and updates to data originally generated, submitted, and/or resubmitted to allow traceability of updates. Documentation shall include the justification or rationale for the change; the initials of the person making the change(s); data changes were implemented and reviewed by a person or group independent of the source generating the data submission; and the Laboratory Manager approved changes to original data submissions.

4.9.8 The laboratory shall identify individual(s) responsible for the data management functions such as system operation and maintenance, including documentation and training;

database integrity, including data entry, data updating, and data review; and data and system security, backup, and archiving.

4.9.9 The laboratory shall store all raw and processed electronic analytical data in appropriate instrument manufacturer's format, uncompressed, and with no security codes. The data shall include all necessary data files for a complete reconstruction of the previously submitted hardcopy and electronic data package. All associated raw data files in the instrument manufacturer proprietary software format must be submitted if those files contain data or instrumental parameters regarding any analysis and/or correction applied to an instrument or analytical result. This instrument electronic data shall include data for all samples, including but not limited to: field samples, blanks; matrix spike and matrix spike duplicates (MS/MSDs); laboratory control samples (LCSs); initial calibrations; continuing calibrations; calibration verification standards; as well as all laboratory-generated spectral libraries and quantitation reports required to generate the data package.

4.9.10 The laboratory shall maintain a written reference logbook of data files of the laboratory field sample identifiers, calibration data, standards, blanks, and MS/MSDs. The logbook shall include standard and blank identifiers, identified by project and data package.

4.9.11 The laboratory shall have procedures for controlling and estimating data entry errors.

4.9.12 The laboratory shall have procedures for reviewing changes to data and data submissions and ensuring traceability of updates.

4.9.13 The laboratory shall have life cycle management (LCM) procedures for testing, modifying, and implementing changes to existing computing systems including hardware, software, and documentation or installing new systems.

4.9.14 The laboratory shall have database security, backup, and archival procedures including recovery from system failures.

4.9.15 The laboratory shall have system maintenance and response time procedures.

4.9.16 The laboratory shall have storage, retrieval, and verification of the completeness and readability of instrument files transferred to electronic media.

4.9.17 The laboratory shall have virus protection procedures for software and electronic data.

4.9.18 The laboratory shall retain all hardcopy and electronic data associated with an ERLN project for a period of five years after data submission. After this time, the laboratory may dispose of the data.

4.9.19 The laboratory shall have written SOPs describing data management procedures. These SOPs shall detail all procedures associated with specifying the acquisition or entry, update, correction, deletion, storage, and security of computer-readable data and files. The laboratory shall ensure that the procedures contain clear definitions for all databases and files the laboratory used to generate or submit data under the ERLN agreement.

4.9.20 The laboratory shall have written SOPs describing procedures for maintaining the accuracy, integrity and security of electronic data. These SOPs shall detail all procedures associated with verifying the accuracy of manually entered data, electronically entered data, and data acquired from instruments, as well as access to data by laboratory personnel and protecting data from malicious attacks (e.g., virus protection).

4.9.21 The laboratory shall have written SOPs describing all data reduction procedures. These SOPS shall detail all procedures associated with data processing systems operation; outlier identification methods; identification of data requiring corrective action; and procedures for format and/or forms for each operation.

4.10 Report Organization and Assembly

4.10.1 The laboratory shall assign a unique data package identifier to each data reporting group received at the laboratory. Samples may be assigned to data packages by matrix (i.e., all soil/sediment samples in one data package, all aqueous/water samples in another), at the discretion of the laboratory. Such assignment is made at the time the samples are received, and shall not be made retroactively.

4.10.2 The laboratory shall maintain all documents relating to the hardcopy data submission in a secure location.

4.10.3 The laboratory shall include all original laboratory forms and documents in the hardcopy data submission. No photocopies of original documents shall be placed in the hardcopy data submissions unless the original data were initially written in a bound notebook maintained by the laboratory, or the original data were previously submitted with another project or hardcopy data submission. Copies of laboratory documents shall be photocopied in a manner to provide complete and legible replicates.

4.10.4 The laboratory shall include documents in the hardcopy data submission relevant to the data submission that include, but not limited to, logbook pages; storage temperature records; bench sheets; analytical records; receiving records; re-analysis records; airbill receipts; records of failed or attempted analysis; sample condition at receipt (pH, temperature, physical); custody records; screening records; sample tracking records; pre-preparation records; raw data summaries; re-preparation records; computer printouts; sample storage records and logbooks; correspondence; FAX originals; library search results; and other pertinent documents or artifacts associated with the receipt, storage, tracking, preparation and analysis of samples included in the data submission

4.10.5 The laboratory shall ensure that sample tags are encased in clear plastic bags before placing them in the hardcopy data submission.

4.10.6 The laboratory shall stamp each page of the hardcopy data submission with a sequential number. Page number ranges and intentional gaps in the page numbering sequence shall be recorded. When inserting new or inadvertently omitted documents, the laboratory shall identify them with unique accountable numbers.

4.10.7 The laboratory shall verify that the information included in the PDF file is of the appropriate data submission type, the contents are the same as the hardcopy data package and the file is complete.

4.10.8 The laboratory shall document the data package shipments, including what was sent, to whom, the date, and the carrier used.

4.10.9 The laboratory shall seal all hardcopy data submissions with custody seals in a manner such that opening the packages would break the seals. Custody seals shall be signed and dated by the by the individual sealing hardcopy data submission.

4.10.10 The laboratory shall resubmit electronic and hardcopy data, and associated documentation, that does not conform to the ERLN or project-specific ASR requirements or the criteria, as necessary. These data shall be resubmitted with deficiencies corrected within the timeframe specified by the ERLN Representative, at no additional

cost to the government. The data shall be clearly marked as ADDITIONAL DATA and shall be sent to the authorized ERLN Representative. The laboratory shall include a cover letter that describes which data are being delivered and who requested the data (i.e., data reviewer's name).

4.10.11 The laboratory shall have written SOPs describing report organization and assembly. These SOPs shall detail all procedures associated with maintaining project files at the laboratory, data review and verification, submitting electronic data, compiling and submitting original hardcopy data, when required and tracking data submissions.

4.10.12 The laboratory shall have written SOPs describing all procedures for inspecting and validating data prior to submission. These SOPs shall detail all procedures for defining data flow and chain of command for data review; measuring precision, accuracy and uncertainty; identifying systematic errors; ensuring that hardcopy and electronic data submissions are complete and compliant with the terms of the ERLN agreement and this requirements document; ensuring that hardcopy data submissions are in agreement with their comparable electronic data submissions; demonstrating internal inspection procedure (demonstrated by supervisory sign-off on personal notebooks, internal proficiency testing samples, etc.); defining the frequency and type of internal audits (i.e., random, quarterly, spot checks, perceived trouble areas); and documenting audit reports (internal and external), audit response, and corrective actions.

4.11 Analytical Services

4.11.1 The laboratory shall prepare and analyze samples according the methods included in the project-specific ASR. Sample preparation methods shall remain consistent for all samples analyzed within a project. The laboratory shall strictly adhere to all requirements specified in this document and the project-specific ASR.

4.11.2 The laboratory shall perform a demonstration of capability for methods included in a project-specific ASR prior to analysis of any ERLN project samples. The laboratory shall perform additional demonstrations of capability at least annually or more frequently as conditions require.

4.11.3 The laboratory shall review the sample chain of custody prior to sample analysis for any special sample analysis instructions.

4.11.3.1 The laboratory shall not follow any special sample analysis instructions on the chain of custody record if they contradict the technical requirements included in the project-specific ASR without authorization from the appropriate ERLN Representative.

4.11.3.2 The laboratory shall follow the instructions on the sample chain of custody in choosing the spike and duplicate samples when such information is provided. If no sample is designated, the laboratory shall select a sample that is most representative of the other associated samples and document the selection in the data package narrative.

4.11.3.3 The laboratory shall not perform matrix spike or duplicate analyses on samples marked as field-generated blanks or proficiency samples.

4.11.4 The laboratory shall review all analytical results associated with a sample, including undiluted, diluted, serial dilution, and interference results. Anomalies that occur during sample analysis shall be reported to the authorized ERLN Representative immediately.

4.11.5 The laboratory shall report the concentrations for positively identified target substances as uncorrected for blank contaminants.

4.11.6 The laboratory shall report all analytical results and other measurements to at least two significant figures.

4.11.7 The laboratory shall report any significant anomalies indicating possible matrix interferences in the narrative.

4.11.8 The laboratory shall contact the appropriate ERLN Representative if insufficient sample volume (less than the required amount) is received to perform the requested analysis, in order to obtain direction on how to proceed. The laboratory shall document the ERLN Representative's decision in the data package narrative.

4.11.9 The laboratory shall have written SOPs describing sample preparation. These SOPs shall detail all procedures associated with reagent purity check procedures and documentation; extraction procedures; maintaining extraction bench sheets; and logbook maintenance.

4.11.10 The laboratory shall have written SOPs describing glassware cleaning procedures.

4.11.11 The laboratory shall have written SOPs describing calibration procedures for all equipment. These SOPs shall detail all procedures associated with frequency requirements; preventative maintenance schedule and procedures; acceptance criteria and corrective actions; and logbook maintenance.

4.11.12 The laboratory shall have written SOPs, consistent with instrument manufacturers' specific instruction manuals where appropriate, describing all analytical procedures performed by the laboratory. These SOPs shall detail all procedures associated with instrument performance specifications; instrumental operating procedures; data acquisition system operation; procedures when automatic quantitation algorithms are overridden; required quality control measurement indicators; maintaining analytical run/injection logbooks; and instrumental error and editing flag descriptions and resulting corrective actions.

4.11.13 The laboratory shall have written SOPs describing all maintenance activities for each of the laboratory's analytical systems. These SOPs shall detail all procedures associated with scheduling and performing preventative maintenance, determining when corrective maintenance should be performed and how they are performed; and authorizing maintenance activities.

4.11.14 The laboratory shall have written SOPs describing all activities associated with handling, storage and traceability of reagents and analytical standards. These SOPs shall detail all procedures associated with standard coding/identification; maintaining inventory system; maintaining standards preparation logbook(s); standards preparation; determining equivalency/traceability analyses and maintaining documentation; maintaining purity logbook (primary standards and solvents); storage, replacement, and labeling requirements; and corrective action measures.

4.11.14.1 The laboratory shall have written SOPs describing how it maintains all necessary documentation to demonstrate that its standards conform to the requirements specified in the project-specific ASR.

4.11.14.2 The laboratory shall maintain weighing logbooks, calculations, chromatograms, mass spectra, etc., whether produced by the laboratory or purchased from standards supply houses. These documents shall be maintained by the laboratory and may be subject to review during on-site laboratory evaluations. In those cases where the documentation supports the analytical results in the ERLN data packages, it shall be kept on file by the laboratory.

4.11.14.3 The laboratory shall submit the previous year's (i.e., last 12 months) documentation for the verification and preparation of standards upon request by an ERLN Representative.

4.11.14.4 The laboratory shall address the deficiencies in the laboratory's documentation for the verification and preparation of standards identified through internal or external reviews and document the subsequent corrective action implemented to resolve the deficiencies as directed by an ERLN Representative.

4.12 ERLN Type One Format Data Submissions

4.12.1 The laboratory shall submit the final results for the substances of concern as determined by the laboratory for samples received at the laboratory. (e.g., field samples, field blanks and performance evaluation samples). Data associated with calibrations, instrument performance checks, laboratory generated positive and negative control samples (e.g., LCS, blanks, etc) and non-target substances (e.g., surrogates, internal standards, tentatively identified compounds, etc.) shall NOT be reported in Type One data submissions.

4.12.2 The laboratory shall include in its hardcopy data submissions a table of contents; a laboratory narrative; correspondences associated with samples included in the data package; all original sample receiving documentation; and data summary forms for the final sample results for the substances measured. Summary data forms shall be grouped by analytical method.

4.12.2.1 The laboratory shall include in its narrative the laboratory's name; ERLN agreement number; project identifier; field sample identifiers for samples included in the data submission; data package identifier; and detailed documentation of any sample, shipment, and/or analytical problems encountered in processing the samples reported in the data submission.

4.12.2.2 The laboratory shall include in its narrative the following statement verbatim: "I certify that this sample data submission is in compliance with the terms and conditions of the ERLN agreement, both technically and for completeness, for other than the conditions detailed above. Release of the data contained in this data package and in the associate electronic submission has been authorized by the Laboratory Manager or the Manager's designee, as verified by the following signature." This statement shall be directly followed by an original signature of the Laboratory Manager or designee with typed lines below it containing the signer's name and title, and the date of signature.

4.12.2.3 The laboratory shall include in its hardcopy data submissions all email correspondences or documentation of telephone conversations with ERLN Representatives regarding problems encountered with samples included in the data submission.

4.12.2.4 The laboratory shall include in its hardcopy data submissions all original receiving documents including but not limited to the following documents: sample log-in sheet; other receiving forms or copies of receiving logbooks; airbills (if an airbill is not received, include a hardcopy receipt requested from the shipping company or a printout of the shipping company's electronic tracking information); sample chain of custody records; and sample tags (if present) sealed in plastic bags.

4.12.2.5 The laboratory shall include in its hardcopy data submissions the following minimum information in the data summary forms. Form headers should include the ERLN

organization identifier for the laboratory; project identifier; data package identifier; field sample identifier and matrix. The body of the form should be a tabular representation of the results and should include the name of the substance measured; CAS number (if applicable); the measured result; the units associated with the result; laboratory data qualifiers; the substance's reporting limit; and the measurement uncertainty.

4.12.3 The laboratory shall include in its PDF data submission an exact copy of the hardcopy data package. The PDF file shall be bookmarked using a hierarchal bookmark structure (i.e., an overview or "parent" bookmark, and a subordinate or "child" bookmark nested underneath the "parent" bookmark) based on the table of contents. Data shall be grouped by laboratory narrative, project correspondences, sample receiving documentation and summary data forms for sample data (grouped by analytical method).

4.12.4 The laboratory shall include only the required ERLN data elements computer-readable data submission.

4.12.4.1 The laboratory shall submit computer-readable data in spreadsheet, CSV or XML format.

4.12.5 The laboratory shall comply with the Type One specifications included in "*Requirements for ERLN Data Submissions*" regarding formatting content, data exchange template structures, order of data and instructions for submitting ERLN data.

4.13 ERLN Type One Transitional Format Data Submissions

4.13.1 The laboratory shall submit the final results for the substances of concern as determined by the laboratory for samples received at the laboratory. (e.g., field samples, field blanks and performance evaluation samples) and laboratory generated positive and negative control samples (e.g., LCS, blanks, etc) and non-target substances (e.g., surrogates, etc.) Data associated with calibrations, instrument performance checks, internal standards and tentatively identified compounds shall NOT be reported in Type One Transitional data submissions.

4.13.1.1 The laboratory shall submit computer-readable data in spreadsheet, CSV or XML format.

4.13.2 The laboratory shall include all of the Type One elements in its hardcopy data submissions.

4.13.3 The laboratory shall include in its PDF data submission an exact copy of the hardcopy data package. The PDF file shall be bookmarked using a hierarchal bookmark structure (i.e., an overview or "parent" bookmark, and a subordinate or "child" bookmark nested underneath the "parent" bookmark) based on the table of contents. Data shall be grouped by laboratory narrative, project correspondences, sample receiving documentation and summary data forms for sample data (grouped by analytical method).

4.13.4 The laboratory shall comply with the Type One Transitional Format specifications included in "*Requirements for ERLN Data Submissions*" regarding formatting content, data exchange template structures, order of data and instructions for submitting ERLN data.

4.14 ERLN Type Two Format Data Submissions

4.14.1 The laboratory shall submit the results of the analysis of samples received at the laboratory. (e.g., field samples, field blanks and performance evaluation samples), and all associated calibrations, instrument performance checks, and laboratory generated positive and negative control samples (e.g., LCS, blanks, etc) used as measurement quality indicators. Non-target substances such as those used to indicate measurement quality, and tentatively identified compounds shall also be reported in Type Two data submissions.

4.14.2 The laboratory shall include all of the Type One elements in its hardcopy data submissions with the following additions.

4.14.2.1 The laboratory shall include in its hardcopy data submissions additional summary forms for all appropriate measurement quality indicators. These forms precede associated sample data and will be grouped with the sample data by method.

4.14.2.2 The laboratory shall include in its hardcopy data submissions the following minimum information in the additional summary forms for all appropriate measurement quality indicators. Form headers should include the ERLN organization identifier for the laboratory; project identifier; data package identifier; and the name of the measurement quality indicator. The body of the form should include any measurements associated with the indicator and the indicator's acceptance criteria.

4.14.2.3 The laboratory shall include in its narrative information differentiating between initial sample analyses and re-analyses and any calculations used by the laboratory when calculating measurement uncertainty.

4.14.3 The laboratory shall verify that the information included in the PDF file is the same as the hardcopy package and includes the summary forms for all appropriate measurement quality indicators.

4.14.4 The laboratory shall include in its computer-readable data submission: the required ERLN data elements; metadata associated with the project, laboratory and methods used; data associated with sample characteristics, sample handling, preparation, laboratory batching and sample analysis; data associated with the substance measured and sample type; and measurements associated with the expected result for spiked compounds.

4.14.4.1 The laboratory shall include only the data elements associated with the measurement quality indicators specified in the project-specific ASR.

4.14.4.2 The laboratory shall submit its computer-readable electronic data in XML format that is amenable to electronic processing by web-based electronic data assessment and review software.

4.14.5 The laboratory shall comply with the Type Two format specifications included in *"Requirements for ERLN Data Submissions"* regarding formatting content, data exchange template structures, order of data and instructions for submitting ERLN data.

4.15 ERLN Type Three Data Submissions

4.15.1 The laboratory shall submit the results of all analysis performed on samples received at the laboratory. (e.g., field samples, field blanks and performance evaluation samples); all associated calibrations, instrument performance checks, and laboratory generated positive and negative control samples (e.g., LCS, blanks, etc) used as measurement

quality indicators; and data associated with the instrument responses, output and other measurements used to calculate these results. Non-target substances such as those used to indicate measurement quality, and tentatively identified compounds shall also be reported in Type Three data submissions.

4.15.2 The laboratory shall include all of the Type Two elements in its hardcopy data submissions plus the instrument output used to calculate the result and all original data associated with its receipt, storage, tracking, preparation, and analysis of samples included in the data submission.

4.15.2.1 The laboratory shall submit all original laboratory records of sample transfer, preparation, and analysis including but not limited to the following documents: log book preparation entries documenting the steps and calculations of diluted and working standards; receipt of stock standards showing the lot number and date of receipt or date of preparation for all standards and spiking solutions; original preparation and analysis forms or copies of preparation and analysis logbook pages; internal sample and sample extract transfer chain of custody records; and screening records.

4.15.2.2 The laboratory shall submit all other original data package-specific documents in the possession of the laboratory including but not limited to the following documents: telephone contact logs; copies of personal logbook pages; and all handwritten data package-specific notes.

4.15.2.3 The laboratory shall include in its narrative sufficient information to allow for the recalculation of sample results from raw instrument output. This includes equations or curves (at least one equation or curve per method), Additionally, the laboratory shall identify and explain any differences that exist between the analytical data reported and supporting documentation provided in the data submission.

4.15.3 The laboratory shall include in its PDF data submission an exact copy of the hardcopy data package. The PDF file shall be bookmarked using a hierarchal bookmark structure (i.e., an overview or "parent" bookmark, and a subordinate or "child" bookmark nested underneath the "parent" bookmark) based on the table of contents. Data shall be grouped laboratory narrative, project correspondences, sample receiving documentation and summary data forms for sample data (grouped by analytical method).

4.15.3.1 The laboratory shall insert a parent bookmark within each method group book mark for summary of measurement quality indicators, sample data, standards data, and raw data for measurement quality indicators.

4.15.4 The laboratory shall verify that the information included in the PDF file is the same as the hardcopy package and includes the summary forms for all appropriate measurement quality indicators.

4.15.5 The laboratory shall include in its computer-readable data submission all of the Type Two elements plus additional data elements associated with the instrument responses and other measurements used to generate results. These additional data may be used to recalculate a laboratory’s reported result for each analysis in order to verify its correctness.

4.15.5.1 The laboratory shall submit its computer-readable electronic data in XML format that is amenable to electronic processing by web-based electronic data assessment and review software.

4.15.6 The laboratory shall comply with the Type Three format specifications included in *"Requirements for ERLN Data Submissions"* regarding formatting content, data exchange template structures, order of data and instructions for submitting ERLN data.

5.0 GLOSSARY OF TERMS

AGENT - Any physical, chemical, or biological entity that can be prepared and analyzed, as specified by the authorized ERLN Representative, for the use of Incidents of National Significance.

ANALYTICAL COORDINATOR – Representative responsible for scheduling all ERLN environmental sample analyses. The Analytical Coordinator ensures laboratories have the capability to meet data delivery requirements; coordinates with regional representatives for the ERLN; maintains a list of laboratory contacts available to assist with analyses of environmental samples during an emergency; ensures chain of custody for samples and data throughout project; and receives analytical data and monitoring data.

ANALYTICAL SERVICE REQUEST – Project specific requirements sent to an ERLN laboratory, by the authorized ERLN Representative, when requesting services. An ASR is typically provided as a form and includes the following elements: date of request, project identifier, point(s) of contact information, sampling/shipping information, analytical request information, criteria for analytical method, special requirements, and a section to document any known contaminants.

METHOD - A body of procedures and techniques for performing an activity (e.g., sample preparation, instrument calibration, sample analysis, and result calculations) systematically presented in the order in which they are to be executed.

BLANK - An analytical sample designed to assess specific sources of field or laboratory contamination.

CALIBRATION - The establishment of an analytical curve based on the absorbance, emission intensity, or other measured characteristics of known standards. The calibration standards must be prepared using the same type of reagents or concentration of acids as used in the sample preparation.

CHAIN OF CUSTODY - A form completed by the sampler, which accompanies the sample during shipment to the laboratory and is used to document the field sample identifier, sample chain-of-custody, sample condition, and sample receipt by the laboratory.

CONTRACTING OFFICER'S REPRESENTATIVE (COR) - An official appointed in writing by the contracting officer who provides technical direction, clarification and guidance with respect to the contract specifications and statement of work. The COR is the technical liaison between the contractor and the contracting officer and is responsible for ensuring satisfactory performance and timely delivery as set forth in the contract.

CONTINUING CALIBRATION - A solution of method analyte(s) analyzed at the beginning, ending and at regular intervals throughout an analytical batch to verify whether the initial calibration response is still valid.

DATA REPORTING GROUP – A group of samples assigned to a unique data package identifier that acts as the basis for all ERLN data reporting. The standard ERLN data reporting group is created for every 20 field samples received by the laboratory during a calendar week (Sunday-Saturday). Field blanks, trip blanks and project-specific performance evaluation samples associated with the field samples are also included in a data reporting group but are not considered field samples. It is important that the laboratory completes its data reporting group

upon receipt of the 20th field samples because all data turnarounds are calculated from the date the data reporting group is closed.

DEMONSTRATION OF CAPABILITY – A procedure that establishes an analyst's ability to measure samples using a documented analytical process that meet the that processes measurement quality criteria.

DUPLICATE - A second aliquot of a sample that is treated the same as the original sample in order to determine the precision of the method.

ENVIRONMENTAL RESPONSE LABORATORY NETWORK (ERLN) - One of five response networks within the Integrated Consortium of Laboratory Networks (ICLN) that is managed by the EPA's Office of Solid Waste and Emergency Response (OSWER). The ERLN provides a readily available source of reliable analytical data of known and documented quality to identify contaminants in environmental sample matrices collected during investigation and remediation activities following a nationally significant incident (NSI).

ERLN REPRESENTATIVE - Individual responsible for the administration of a project related to a nationally significant incident using the ERLN.

FIELD SAMPLE - A portion of material that is contained in single or multiple containers and identified by a unique Sample Number for the purposes of analysis.

FIELD SAMPLE IDENTIFIER - A unique identification number designated by the authorized ERLN Representative for each sample. The Field sample identifier appears on the sample Chain of Custody (COC) Record which documents information on that sample.

INTEGRATED CONSORTIUM OF LABORATORY NETWORKS (ICLN) – Develops and maintains a U.S. homeland security infrastructure with a coordinated and operational system of laboratory networks that provides timely, high-quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response. The ICLN is composed of five networks and managing agencies.

INITIAL CALIBRATION - Analysis of analytical standards for a series of different specified concentrations; used to define the quantitative response, linearity, and dynamic range of the response of the instrument to the target analyte/agent.

INTERFERENCES - Spectral, physical, or chemical effects that interfere with the detection and quantitation of target agents by a specific analytical technique.

INTERNAL STANDARDS - Compounds added to every sample, standard, or blank at a known concentration, prior to analysis. Instrument responses to internal standards can be used as the basis for quantitation of the target compounds

LABORATORY - Location where scientific procedures are performed including but not limited to: sampling, pretreatment and treatment, measurement, calculation, presentation of results.

LABORATORY CONTROL SAMPLE (LCS) - An internal laboratory QC sample used to monitor the capability of the laboratory to perform the analytical method.

LABORATORY COORDINATOR – Representative responsible for coordinating with region representatives for the ERLN and assists in brokering laboratory services. The Laboratory Coordinator provides outreach to available laboratory resources; sets priorities for laboratory

analysis; coordinates laboratory resources with other agencies and organizations; works with laboratory resources to facilitate sample processing; and assists in identifying laboratory resources to meet the needs of the incident.

MATRIX - The predominant material of which the sample to be analyzed is composed.

MATRIX SPIKE (MS) - Aliquot of a sample taken from one of the field samples to be analyzed within a data reporting group, fortified (spiked) with known quantities of specific compounds, and subjected to the entire analytical procedure in order to indicate the appropriateness of the method for the matrix by measuring recovery.

MATRIX SPIKE DUPLICATE (MSD) - A second aliquot of the same sample as the Matrix Spike (above) that is spiked in order to determine the precision of the method.

MEASUREMENT QUALITY CRITERIA - Acceptance limits selected for project-specific sampling and analytical systems that will be used to judge whether project quality objectives are met.

MEASUREMENT QUALITY INDICATOR – The parameters that indicate the qualitative and quantitative degree of quality associated with measurement data, used to evaluate the different components of the measurement system including precision, accuracy/bias, representativeness, comparability, completeness, and sensitivity.

METHOD DETECTION LIMIT (MDL) - The concentration of a target parameter that, when a sample is processed through the complete method, produces a signal with 99 percent probability that it is different from the blank. For 7 replicates of the sample, the mean value must be 3.14s above the blank, where "s" is the standard deviation of the 7 replicates.

NATIONALLY SIGNIFICANT INCIDENT (NSI) - High impact events that require an extensive and well-coordinated multi-agency response and provide the basis for long-term recovery.

PROFICIENCY TESTING SAMPLE - A sample, the composition of which is unknown to the laboratory or analyst, which is provided to that laboratory or analyst to assess capability to produce results within acceptable criteria.

PREPARATION LOGBOOK - An official record of the sample preparation steps maintained by the laboratory.

PROJECT - An environmental data collection effort that has a stated purpose and puts a series of samples/results into a meaningful context.

QUALITY ASSURANCE (QA) - An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality expected by the client to achieve a stated level of confidence.

QUALITY CONTROL (QC) – The overall system of technical activities and checks that measure the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements within prescribed limits established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

RESPONSE (Instrumental Response) - A measurement of the output within an instrument in which the intensity of the signal is proportionate to the amount (or concentration) detected.

RUN - A continuous analytical sequence consisting of prepared samples and all associated QA measurements as required by the method.

SAMPLE - A portion of material to be analyzed that is contained in single or multiple containers and identified by a unique sample number.

SAMPLE CUSTODY - When a sample is in the possession of an individual; or in the view of an individual after being in his/her possession; or locked in a secure area by an individual after being in his/her possession; or in a designated secure area that is only accessible by authorized personnel.

SAMPLE EXTRACT - Portion of the sample that remains after the sample preparation process has been completed.

SELF-INSPECTION CHECKLIST - A form that includes the items to be reviewed by ERLN auditors sent to a laboratory prior to an audit in order to assist audit preparations.

STANDARD OPERATING PROCEDURE (SOP) - a set of instructions documenting routine or repetitive activities undertaken by the laboratory.

THE NELAC INSTITUTE (TNI) - An organization that fosters the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. This organization manages the National Environmental Laboratory Accreditation Conference (NELAC) accreditation program.

WATER LABORATORY ALLIANCE (WLA) - An integral part of the ERLN and focuses solely on water. The WLA provides the Water Sector with an integrated, nationwide network of laboratories. These laboratories provide the analytical capabilities and capacity in the event of natural, intentional, or unintentional water contamination involving chemical, biological, or radiochemical contaminants. The WLA is composed of drinking water, public health and environmental laboratories and commercial laboratories.