Environmental LIMS
Request for Proposals:
A Guide

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Introduction
Public Health Laboratory Business Processes
Laboratory Informatics
Data Exchange
An RFP Template

Appendix 1: Requirements for Public Health Laboratory Information Management Systems
Appendix 2: Relevance of Laboratory Informatics in the RFP Process
MOU Provisions
Appendix 3: Standardized Electronic Data Deliverable
Type 1 Data Submission
Type 2 Data Submission
Appendix 4: Example of RFP Language for System Procurement

4.1 Summary
4.2 Expected Benefits
4.3 Proposed Schedule
4.3.1 LIMS Installation
4.3.2 System Testing/LIMS Verification
4.3.3 System Training
4.4 Contractor Staffing
4.5 Role of State Technical Staff and Knowledge Transfer
4.6 Business Requirements
4.7 Contractor Requirements
4.8 LIMS Warranty
4.9 Sample Tracking
4.10 Sample Scheduling
4.11 Data Entry and Storage of Quality Control/Quality Assurance Information
4.12 Electronic Data transfer from instrument to LIMS
4.13 Storage of instrument calibration data, analyst training certificates, and instrument repair records
4.14 Electronic data transfer to user clients
4.15 Maintaining of chemical inventories
4.16 System Security Features
4.17 Generation of Client Billings
4.18 Customized hardcopy report generation
4.19 Additional Technical Requirements
4.20 Detailed Specifications
4.20.1 Project Initiation
4.20.2 Project Management
4.20.3 Quality Management
4.20.4 Data Considerations
4.20.5 User Acceptance
Introduction

The Association of Public Health Laboratories (APHL) works in support of national and global health objectives, and to shape policies and programs which assure continuous improvement in the quality of laboratory practice. As part of this mission, APHL seeks to improve laboratory information management systems (LIMS) implementation, data exchange and interoperability. This document provides a high-level “holistic” guide that environmental laboratories can use when developing a request for proposals (RFP) for a LIMS purchase or implementation.

Informatics allows the modern laboratory to move from paper-based systems to electronic test orders and results. A LIMS serves as a key component to modern laboratory informatics, but it is not the sole component. While this guide provides an RFP template for an environmental LIMS, the reader is encouraged to consider laboratory informatics holistically. Other components critical to successful LIMS implementations include governance, policies and practices necessary to support the LIMS infrastructure.

A LIMS not only manages laboratory business processes, it can also help create electronic messages to be sent to a data user or network. For public health laboratories, the ability to create electronic messages is key to data exchange and to interoperability. LIMS implementations benefit when electronic messaging is considered early in the design process. This messaging should include the ability to securely transfer result messages between data systems via national standard messaging formats, codes and terms.

As laboratories advance toward this vision of interoperability, several considerations must be addressed:

• standards (including vocabulary and data formats),
• flexibility to accommodate ever-changing transport mechanisms, and
• validating the content and ensuring the security of electronic data exchange.

This document provides information that may be considered before, during and after a LIMS RFP is developed. This guide contains four areas, each of which is complemented with a more granular appendix:

1. **Public Health Laboratory Business Processes**: the business processes essential for an environmental LIMS to manage.

2. **Informatics**: how a particular LIMS fits within the broader informatics needs of the laboratory and entire laboratory enterprise, which may include multiple components in addition to the LIMS.

3. **Data Exchange**: a LIMS should be able to provide a standardized electronic data deliverable, capable of being exchanged with multiple data consumers.

4. **An RFP Template**: modeled after a recent state RFP process. (*Environmental ONLY*)
Public Health Laboratory Business Processes

Once thought of as a support function, the delivery of laboratory information technology (IT) services has now evolved to the point where electronic record-keeping and automated data management are mission-critical components of public laboratory operations. However, it is unlikely that any two environmental laboratories will share the exact same laboratory information management needs. This section serves as an informational guide to the many business processes that an environmental laboratory may need to manage (and thus should consider when developing an RFP).

There are eight primary business needs that justify LIMS implementation. These include the ability to:

1. Meet multiple customer data needs.
2. Meet rapid response times associated with emergency response.
3. Achieve better efficiency in storing and retrieving large amounts of analytical data.
4. Standardize laboratory data collection, including the ability to collect and report quality control data associated with measurement quality objectives.
5. Better manage laboratory fiscal and business needs.
6. Manage the increased complexity associated with laboratory deliverables.
7. Integrate complex analytical instrumentation and automation into data collection and reporting.
8. Provide sample tracking and legal audit trails for data.

Fortunately, APHL already developed a document that summarizes the likely universe of business processes as well as an approach for considering appropriate use in a particular laboratory. Readers are encouraged to review the September 2003 publication: “Requirements for Public Health Laboratory Information Management Systems: A Collaboration of State Public Health Laboratories, the Association of Public Health Laboratories and the Public Health Informatics Institute.”

Sixteen public health laboratories (PHLs) contributed their laboratory experience and expertise to the Institute’s knowledge of the professional IT environment; this joint effort by many parties is referenced here as “the Collaborative.” The resulting document brought together the strategic priorities of APHL along with public health informatics expertise using a collaborative approach. It also served as the basis for many RFPs for public health laboratories over the past eight years.

The Collaborative demonstrated the feasibility of a common set of laboratory information management system (LIMS) requirements and its applicability to the individual needs of public health laboratories. Defining system requirements serves as the most important step in developing or acquiring any information system. With incorrectly-defined requirements, the system will not meet user needs, and there will be serious financial consequences. With correct system requirements, PHLs should be able to match their needs with commercial software products.

The Collaborative’s document serves as both a roadmap and a tool. This document does not propose a physical solution for a LIMS that would support these business processes; rather, it delineates the appropriate requirements specifications, which can be used as a basis for determining systems support. Users are encouraged to package the requirements into modules or any other physical implementation scheme desired. Appendix 1 summarizes the 16 business processes which will help in writing an RFP.

LIMS user groups have also been championed by APHL to aid in the standardization and implementation of LIMS (ultimately reducing the need for expensive customization). A real benefit for PHLs working together in user groups with a common vendor is the ability to share development business processes.

1 http://www.aphl.org/aphlprograms/informatics/Pages/requirementslims.aspx
An example of a process to share development, but still allow individual implementations to be unique, is the use of “configuration.” Configuration provides an extensive administrative interface, allowing end users to configure the application as much as possible without programming or direct database intervention. The user interface should also be evaluated for the ability to add, remove and change design and form elements on the screen to create productive forms and workflows with minimal programming.

Another useful and newly developed reference is the ASTM Laboratory Informatics Standard Guide. Much of this guide concentrates on the business processes of a laboratory information management system. This guide describes the laboratory informatics landscape and covers issues commonly encountered at all stages in the life cycle of laboratory information management, from inception to retirement. The guide:

1. Helps educate new users of LIMS tools.
2. Provides a standard terminology that can be used by different vendors and end users.
3. Establishes minimum requirements for all LIMS tools’ functions.
4. Provides guidance for the specification, evaluation, cost justification, implementation, project management, training and documentation.
5. Provides function checklist examples for each of the LIMS tools adopted within the laboratory and integrated with the existing systems.

Interestingly, ASTM changed the acronym LIMS for this publication from Laboratory Information Management System to Laboratory Informatics Management System. Readers are encouraged to follow this document through the ASTM website. This offers an excellent segue to the need to expand any LIMS (in this case “Laboratory Information Management System”) implementation to include informatics that are necessary to support your LIMS.

**Laboratory Informatics**

For a LIMS implementation to be successful, the PHL must take into account the broader IT infrastructure that will support the LIMS. LIMS implementations may go well beyond the vendor and supplied software and hardware. The RFP addresses the vendor-supplied products; however, this is not the complete picture. Issues of training, help desk, server and network maintenance, and financial support after the purchase are but a few examples of the broader needs that the PHL must take into account.

In practice, the LIMS itself is only the most visible component of the laboratory’s IT infrastructure; the proverbial ‘tip of the iceberg.’ Laboratory informatics takes into account this complete IT infrastructure. The LIMS, its associated hardware and software are critical assets; however, the larger IT infrastructure (e.g., informatics) also includes:

- **Governance functions**, such as contract oversight, budgeting for IT products and services, policymaking and other management activities. Another important consideration is the movement of many government jurisdictions, state governments in particular, to consolidated/centralized services or shared services models for IT provision. Many public laboratories do not have direct access to data servers and to laboratory-specialized IT resources.

- **Technical support**, including software customization, staff training, trouble-shooting and other activities to implement commercial technologies and otherwise assist end users. An example of technical support is specification of vendor management and technical interfacing – who in the organization will provide the necessary technical support and who will be the contact with the vendor.

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2 This guide is written under the jurisdiction of ASTM Committee E13 on Molecular Spectroscopy and Separation Science and is the direct responsibility of Subcommittee E13.15 on Analytical Data. At the time of this writing the edition was approved Sept. 1, 2006. Published September 2006. Readers should download the updated version (designation E1578), which is expected to be released in 2013.
A successful RFP takes into account these components along with associated costs, risks, metrics, significant milestones and implementation strategies. Appendix 2 provides additional information on informatics as well as information on the new model of consolidated IT and factors to consider for laboratory leaders to negotiate with IT leaders to provide infrastructure support for a LIMS.

**Data Exchange**

In this age of increased electronic communication, it is common for data users to request data from laboratories in a standardized electronic format also known as an electronic data deliverable (EDD). Reporting EDDs saves laboratories time by sending data directly from a LIMS, thereby reducing transcription errors, speeding up data delivery and minimizing and possibly eliminating manual data entry. EDDs also facilitate the use of automated data review software to approve and share data.

Local, state and federal agencies possess different reporting requirements and systems, including unique EDDs with unique data elements and inter-relationships. The existence of multiple EDDs places a large burden on laboratories and reduces the overall ability of public laboratories to network and integrate information. Even within agencies there can also be multiple technical implementations of a data standard.³

APHL’s Environmental Health Committee, Environmental Laboratory Subcommittee and Informatics Committee are working together to improve environmental LIMS implementation, data exchange and interoperability.⁴ One outcome is a proposed standard environmental EDD, the APHL EDD, with a defined list of data elements, comprehensive enough to support multiple specific programmatic and data user needs, and their associated data structures and components.⁵ Note, this APHL EDD focuses on the analysis data elements that the PHL generates, not demographic data and pass-through data. This APHL EDD is very comprehensive and should provide a large universe of data elements that supports multiple partner EDD needs.

Standardization by multiple agencies on a single EDD to meet all environmental data needs is not likely soon. APHL hopes that as laboratories develop and update their LIMS, they will plan for the ability to efficiently produce multiple EDDs. Within the RFP process, PHLs should consider the APHL EDD as one option for a standard template to output laboratory generated data. The APHL EDD can serve both as a template for reporting data directly to data consumers (as in the case of the EPA ERLN where the APHL EDD maps directly to this EDD) or can be used as a source of data to support other individual data consumer EDDs. For these other individual data consumer EDDs the PHL should consider integrating 3rd party mapping software available to map from the APHL EDD to individual program formats (e.g., multiple agencies within EPA, CDC, FDA and others).

The RFP development process should include discussions on meeting multiple EDD requirements. Appendix 3 provides additional information on the APHL EDD standard and how this can be used as a template for building multiple EDDs. The APHL EDD is published and available for download:


³ For example EPA uses: SCRIBE, eDWR, SDWIS, SEDD, ERLN, et al.


⁵ This APHL requirements document is modeled after the EPA’s draft “Requirements for Environmental Response Laboratory Network (Type 2) Data Submissions” for use by environmental public health laboratories to use to in LIMS implementations. After reviewing multiple EDDs used to represent environmental data, APHL believes this particular model is the most modern and comprehensive. No preference for program or agency was considered in this review.
Whether the APHL EDD is used, or the LIMS developer provides another EDD, the following components should be considered:

- Focus on a set of discrete data elements and their relationship to each other, i.e., how they relate to the collection of analytical measurements (e.g., the analytical sequence).

- The EDD must not negate the ability of multiple agencies to receive data in their individual, unique reporting formats. The EDD may serve as a middle layer between the LIMS and the multiple client formats.

- The use of XML allows the creation of relationships between data elements, however a spreadsheet option can be used if XML is not available.

- Focus on those data elements generated by the laboratory. While associated demographic and pass-through data is important, this data is very program-specific and does not lend itself to standardization. However, this data can be linked to the laboratory data via reference numbers. For example, many environmental agencies manage pass-through data through a separate data delivery. This pass-through data is often referred to as “auxiliary data.”

- An EDD should comprehensively include quality control data and measurement quality objectives (MQOs) that are associated with target analysis and performance criteria, as included in the laboratory analytical sequence. Collection of quality control data allows results to be validated against measurement quality objectives and promotes accountability with each analytical result.

- An EDD can be used for automated data review (ADR) and validation. Many data consumers may not wish to see quality control data but need to know that the data was validated. An example is EPA’s WebEDR that provides a web service to upload and perform ADR review both within the laboratory and by a reviewer.

While the APHL EDD is recommended, other options exist. Some vendors provide their own unique standardized EDD output that contains all measurement data. This unique EDD is then combined with an integration broker to map data to different client requirements—managing vocabulary, format and transport. As an example one vendor creates a simple XML message that contains all LIMS measurements using the simple hierarchy of:

![Diagram of ORDER, SAMPLE, TEST, RESULT]

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6 MQOs are defined as specified performance criteria used in a sampling and analysis plan for indicators such as precision, bias and completeness. Fortunately, laboratories typically use a fairly universal approach to collect sample data and associated quality control data. The process for collecting this inclusive set of data is referred to as the “analytical sequence.”

7 Already federal agencies seek increased data elements that include quality control data with EDD submittals. Most recent examples include the LRN-C (LIMSi), ERLN and the NextGen of SDWIS State to EPA.

An RFP Template

PHLs share common business processes; however differences among PHLs certainly exist. These differences may be due to many factors such as: laboratory size, number of employees, volume of specimens/samples processed, sample sources and differences in funding streams.

The procurement process also differs by governmental authority and has ramifications of legal concerns (e.g., force majeure) and unique legislative criteria for entering contractual agreements. As an approach to providing a template, a recent RFP is provided in Appendix 3 to use as a reference template. The source of this RFP is kept anonymous; however the successful bidder did produce a LIMS with:

- a relatively low cost (~$250,000 for a medium-sized environmental laboratory)
- a rapid implementation (<6 months)
- an ability to provide data exchange with multiple partners.

This is a high-level template only and the requester should use the subsections as placeholders for additional information relevant to their laboratory. Other sources for RFPs (e.g., The ASTM LIMS Guide E1578) are recommended.

The ability to meet client needs for electronic management of your laboratory services/ deliverables depends on having a LIMS capable of managing information electronically, the technical infrastructure necessary to package and transmit the results securely and, most important of all, the skills to implement and manage that process. Environmental laboratories are encouraged to consider necessary business processes from Appendix 1, the unique informatics interdependencies associated with the environmental laboratory, and data exchange delivery standards from Appendix 4.

Appendix 1: Requirements for Environmental & Public Health Laboratory Information Management Systems

There is a critical need for efficient laboratory information management systems (LIMS) in the nation’s public health laboratories. To address this need, APHL collaborated with the Public Health Informatics Institute (PHII) and with state and local public health laboratories to develop universal requirements that encompass a common set of needs for LIMS at public health laboratories. The “Requirements for Public Health Laboratory Information Management Systems” document, published by APHL in 2003, details the processes and requirements identified through the collaboration.

The collaboration identified 16 business processes that provide the framework for defining workflows and outputs of a LIMS (see Table 1). The resulting document provides the specifics for future implementations of LIMS that public health labs and commercial vendors alike require. Using the document as a guide will:

- Ensure that public health LIMS are highly interoperable, enabling better data flow among public health labs as well as federal and local agencies.
- Improving PHL capacity for mutual assistance in a crisis situation.
- Provide a framework for LIMS implementations that are either independent or part of a collaborative development process.

TABLE 1: The 16 Business Processes

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Laboratory Test Processing (Clinical and Environmental)</td>
</tr>
<tr>
<td>2.</td>
<td>Test Scheduling</td>
</tr>
<tr>
<td>3.</td>
<td>Proactive Specimen/Sample Collection (Prescheduled Tests)</td>
</tr>
<tr>
<td>4.</td>
<td>Specimen and Sample Tracking/Chain of Custody</td>
</tr>
<tr>
<td>5.</td>
<td>Media, Reagent, Stains, Controls, etc. Manufacturing</td>
</tr>
<tr>
<td>6.</td>
<td>Inventory Control Including Kits &amp; Forms Management</td>
</tr>
<tr>
<td>7.</td>
<td>General Laboratory Reporting</td>
</tr>
<tr>
<td>8.</td>
<td>Statistical Analysis and Surveillance</td>
</tr>
<tr>
<td>9.</td>
<td>Billing for Laboratory Services</td>
</tr>
<tr>
<td>10.</td>
<td>Contract and Grant Management</td>
</tr>
<tr>
<td>11.</td>
<td>Training, Education and Resource Management</td>
</tr>
<tr>
<td>12.</td>
<td>Lab Certifications/Licensing</td>
</tr>
<tr>
<td>13.</td>
<td>Customer Concerns/Suggestions</td>
</tr>
<tr>
<td>14.</td>
<td>Quality Control (QC) and Quality Assurance (QA) Management</td>
</tr>
<tr>
<td>15.</td>
<td>Laboratory Safety and Accident Investigation</td>
</tr>
<tr>
<td>16.</td>
<td>Laboratory Mutual Assistance/Disaster Recovery</td>
</tr>
</tbody>
</table>

The logical design document is based on the natural flow of the laboratory testing business processes, beginning with test requests and sample receiving workflow, and continuing through test results reporting. There is also a section that includes eight workgroup discussion papers on complex and cross-cutting issues that informed the resulting design.

Appendix 2: Relevance of Laboratory Informatics in the RFP Process

The white paper “The Brave New World of Consolidated and Shared IT Services: A Guide for Laboratories” provides much more than a guidance to identify, distinguish and negotiate components of operational agreements to successfully employ consolidated IT services. In fact, there is a particular focus on describing the totality of the laboratory IT infrastructure and how best to approach negotiations involving the two major tools for consolidated/shared services management: the memorandum of understanding (MOU) and service level agreement (SLA).

Successful LIMS implementations may ultimately depend upon how laboratory leaders serve as effective advocates for their organization in a sometimes foreign world of IT, with its own vocabulary and culture. Laboratory leaders may also have to address current trends in IT centralization by maximizing the up-side and minimizing the down-side.

One noteworthy tool presented in the white paper, data governance, relies on continuous business analysis to improve IT operations. Just as assays change more quickly than testing platforms, data systems analysis models change more quickly than installed software.

Another tool, shared IT services arrangements, can take many forms; however, there are some common approaches that laboratory leaders can use to negotiate with IT leaders. One approach involves focusing first on the totality of the laboratory IT infrastructure (not just the LIMS). Then before any IT negotiations begin, the following activities should occur:

11 An emerging discipline focused on the formal management of data assets throughout an organization.
• Identify IT leaders and their priorities.
• Plan to explain the work of the laboratory.
• Document the laboratory business case.
• Identify costs.
• Segregate services that must be managed locally.
• Identify risks.
• Plan for handoffs.
• Participate in IT governance.

Memoranda of understanding (MOUs) and service level agreements (SLAs) serve the two major forms of shared service arrangements. They document the IT activities necessary for successful laboratory operations. IT and laboratory leaders use these to communicate and document the costs, risks and metrics of laboratory IT services. Such documents must convey the importance and functions of laboratory services, and be written in the language of the IT professional, with clear business case models.

The MOU, discussed further below, is the more general of the two and defines the role of each of the governmental partners. The SLA, which is not addressed in depth here, is more granular and presents the details of IT delivery, including a funding model for laboratory technology initiatives and infrastructure. The SLA also generally includes metrics to define acceptable outcomes, as well as the risks associated with failure to comply with the terms of the agreement. A critical component of both the MOU and SLA remains the approval page, which must be signed by high-ranking organization representatives.

Modern governmental laboratories require a variety of IT technologies. Some of these, such as laptop computers and budgeting software, will be familiar to IT leaders outside the laboratory. Others, such as computerized analytical instruments and instrument interfaces, are specific to the laboratory and will be unfamiliar to most IT professionals. Needs associated with these technologies and services must be explicitly discussed. Figure 1 provides a summary of essential laboratory IT technologies.

![Diagram of laboratory's multi-tiered IT infrastructure]

*Figure 1: The Laboratory’s Multi-tiered, Physical IT Infrastructure*
Once the MOU and SLA are in place, continued dialogue and negotiation are essential to provide feedback on implementation, to maintain a close working relationship with IT managers, and to offer guidance for the future.

**MOU Provisions**

Although each laboratory operates within a unique political and business environment, there exist some vital, common needs that every laboratory leader should consider incorporating into a MOU:

1. Prioritizing the LIMS as a critical adjunct to laboratory instruments, and a core component of the laboratory infrastructure.
2. Prioritizing the need for dedicated application-level LIMS support.
3. Assuring 24/7 on-site IT support.
4. Assuring authority for the laboratory to manage instrument vendors.
5. Addressing security clearances and protection of personal identifiers in laboratory data.
6. Defining partnerships with high visibility agencies that have a governance role in IT affairs.
7. Prioritizing IT support for emergency response activities.
8. Assuring oversight and project management at the laboratory level.

**Appendix 3: Standardized Electronic Data Deliverable**

One way to meet the multiple demands of PHL clients is to create an electronic output directly from the LIMS, containing all the possible laboratory measurements that clients may request. The data exchange template for this electronic output can take multiple forms.

APHL offers the “APHL EDD” as one example of such an output. Figure 2 illustrates the relationship of the APHL EDD to a LIMS and multiple electronic data output options. Basically, the LIMS collects data generated by the laboratory (e.g., the raw and quality control data from the analytical instruments and metadata associated with testing) and also data that is not generated by the laboratory (e.g., “pass-through” data or “auxiliary data”). This data is stored in an electronic data deliverable. Mapping software facilitates standardized EDD delivery to multiple data consumers, each with unique reporting requirements.

Figure 2 highlights the fact that the “APHL Standardized EDD” need NOT be the final EDD for the clients; rather it can be the basis for creating these other EDDs.

The APHL EDD can be formatted in one of two submission types: Type 1t or Type 2. The type 1t stands for transition; Type 2 is a more inclusive XML EDD.

- The Type 1t provides a high-level picture of the result information, including target and non-target substances as well as field and lab-generated samples, using a spreadsheet as the required electronic format.
- The Type 2 provides more-detailed information in order to perform an automated assessment on field and laboratory-generated samples. The Type 2 uses an XML electronic format which also relates the data fields into groups.

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13 Modern environmental LIMS can typically collect and store significant amounts of data, which exist in two forms. One, analytical measurements and data to support those measurements (e.g., quality control data). The second is what is referred to as “pass-through data” which is data that the laboratory does not generate, but needs to enter in “side-tables” available to pass through to laboratory reports.
A detailed summary of the data elements is provided below, broken down by the two types.

**Type 1t Data Submission**

The Type 1t spreadsheet requires that each column name represent a required data element. A single substance for a sample will constitute a new row within the spreadsheet. Additionally, several fields will be repeated in each row in order to ensure the project information can be identified for each substance when processing the data. As an example, every unique analyte must be reported in a new row, but the sample ID is repeated for each row.

Table 2 provides a short summary of the data elements used in the Type 1t EDD. A complete listing is provided in the referenced document.

<table>
<thead>
<tr>
<th>Table 2: Type 1t Examples of Required Data Elements*</th>
</tr>
</thead>
<tbody>
<tr>
<td>• SubstanceName</td>
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<tr>
<td>• SampleMatrix</td>
</tr>
<tr>
<td>• MethodIdentifier</td>
</tr>
<tr>
<td>• SampleIdentifier</td>
</tr>
<tr>
<td>• SampleCollectionEndDate</td>
</tr>
<tr>
<td>• AnalysisEndDate</td>
</tr>
<tr>
<td>• Result</td>
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<tr>
<td>• ResultUnits</td>
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<tr>
<td>• ReportingLimit</td>
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<td>• ProjectIdentifier*</td>
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<td>• DataPackageIdentifier*</td>
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</tr>
<tr>
<td>• SampleType</td>
</tr>
<tr>
<td>• AnalysisStartDate</td>
</tr>
</tbody>
</table>

* Data must be provided for all elements for each substance provided.
Type 2 Data Submission

Type 2 data provides data users with the ability to perform an automated data assessment based on defined quality objectives, by requiring data to be submitted using extensible markup language (XML). XML allows establishment of the necessary relationships for data validation. Type 2 data includes all of the elements included in Type 1; however, additional elements are included to enable more extensive data assessment. Results are reported for each analysis performed on a sample as well as laboratory-generated positive and negative control samples (e.g., laboratory control samples [LCS], duplicates, blanks, etc.). Data are also reported for non-target substances (e.g., surrogates, internal standards, tentatively identified compounds, etc.), batching information, instrument performance & general calibration information, and tentatively-identified compounds.

The use of 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. Importantly, the Type 2 also allows other measurements to be included on the fly and is not restricted to a limited formal set of measurements.

The Type 2 data exchange template (DET) defines the specific data elements applicable to each submission type and data must be reported using an XML file meeting (data type definition) DTD requirements. Table 3 summarizes the individual data elements. Figure 2 highlights the fact that the “APHL Standardized EDD” need NOT be the final EDD for the clients; rather it can be the basis for creating these other EDDs.

<table>
<thead>
<tr>
<th>Datapackageidentifier</th>
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<th>Substanceidentificationdetails</th>
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<tbody>
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<td>Exclusionindicator</td>
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<td>Samplematrix</td>
<td>Reportinglimit</td>
</tr>
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<td>Laboratoryqualifiersdefinition</td>
<td>Sampletype</td>
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<tr>
<td>Projectidentifier</td>
<td>Analysisdetails</td>
<td>Reportinglimitunits</td>
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<td>Organizationdetails</td>
<td>Analysisbatchidentifier</td>
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<td>Resultunits</td>
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<td>Runbatchidentifier</td>
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<tr>
<td>Sampleidentifier</td>
<td>Laboratoryanalysisidentifier</td>
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</tbody>
</table>

Table 3: Required Data Elements for Type 2

14 Type 2 focuses on arranging information into groupings. These groupings allow relationships to exist between the different data elements; they represent key components of the analytical process. Groupings allow the analytical process to be re-created during data review. Data required from Type 1 is still required in Type 2 but data are now organized under objects that define the relationships between the data.
Appendix 4: Example of RFP Language for System Procurement

The contractor shall provide an “off-the-shelf” LIMS software package that is designed, installed and verified by the contractor and is capable of being customized by the State to meet the changing needs of the laboratory clients. The system shall have a one-year warranty, with ongoing technical assistance and maintenance for the duration of the contract term. The contractor shall provide guidance with regard to customization.

4.1 Summary

The proposed LIMS shall be designed for use in an environmental laboratory and shall be capable of managing the laboratory’s data, including but not limited to:

- Sample tracking;
- Sample scheduling;
- Data entry and storage of quality control/quality assurance information;
- Electronic data transfer from instrument to LIMS;
- Storage of instrument calibration data, analyst training certificates, and instrument repair records;
- Electronic data transfer to user clients;
- Maintaining of chemical inventories;
- System security features;
- Generalization of client billings; and
- Customized hardcopy and softcopy report generation.

4.2 Expected Benefits

The proposed system shall provide improved accuracy, user interface, and timeliness to the laboratory’s internal data handling, client data reporting and client billing activities. The system shall include enhanced electronic capabilities such as LIMS/instrument interfaces, electronic data reporting, test scheduling, electronic client billing and maintaining chemical reagent inventories. Internal electronic data handling and sample tracking are minimum activities required for the daily operation of an environmental laboratory.

4.3 Proposed Schedule

The contractor shall complete this project in three (3) stages: LIMS installation and configuration; system verification (validation and parallel test); and staff training on LIMS operation and maintenance.

4.3.1 LIMS Installation

Within three (3) months of contract award, the contractor shall set up, install, and configure the LIMS software.
4.3.2 System Testing/LIMS Verification

System testing shall be conducted after the system has been installed and customized. Within three (3) months of contract award, the contractor shall demonstrate and verify the system operation to the State Contract Manager. The contractor shall work with the Laboratory IT Team to demonstrate and verify functionality of the LIMS package, as well as any custom features that are incorporated.

The contractor shall provide a system validation package which includes a test plan that is reviewed with the client. System verification shall be conducted in two (2) phases. Phase one shall test the system functionality using the validation package provided by the contractor. The second phase shall consist of a parallel test. This test shall compare the results of the new custom application against the existing LIMS.

The new LIMS shall run in a parallel test with the existing system for a minimum of five (5) business days without errors. The new LIMS system shall be monitored with Microsoft Operations Manager running on the server to access the system performance.

4.3.3 System Training

Within four (4) months of contract award, the contractor shall provide on-site training to the Laboratory IT Team in proper installation, configuration, system administration and maintenance of the system. Training shall consist of three (3) days on-site training. The contractor shall provide a copy of the LIMS training manual on a CD along with appropriate end user/administrator training guides.

The system shall include context sensitive on-line help throughout the application.

4.4 Contractor Staffing

The contractor shall provide the appropriate number of qualified staff to install, verify and provide training to staff.

4.5 Role of State Technical Staff and Knowledge Transfer

All questions concerning the installation, verification and training on the LIMS shall be directed to the State Contract Manager who is responsible for the laboratory’s sample accessioning and IT functions. The State Contract Manager is responsible for approving the final installation of the LIMS and coordinating the transfer of the laboratory’s testing operations from the old system to the new system. This effort shall also be coordinated with the laboratory’s data reporting activities with other State agencies and data systems.

4.6 Business Requirements

The system shall continue the business processes associated with the current LIMS – receiving, recording, scheduling, tracking and reporting results on environmental samples for clients. The system shall also store quality control and quality assurance information and electronically transfer data from the instrumentation to the LIMS.

The system shall be a stand-alone system and not impact any other system.

Users of the system may include employees of laboratories and IT and stakeholders which are primarily employees of Departments of Environmental Protection, Transportation, Military and Veteran’s Affairs, the United States Geological Survey, Consumer Health Services and public health programs.
4.7 Contractor Requirements

The contractor shall be experienced in LIMS with a minimum of 12 environmental laboratory LIMS installations.

The contractor shall secure a website where service packs can be downloaded 24 hours per day, provide free upgrades, and a dedicated account manager with active maintenance. The contractor shall also be ISO 9001:2000 certified.

The contractor shall provide unlimited technical phone support on a toll-free number from 8:00 AM to 5:00 PM eastern standard time, Monday through Friday and shall coordinate and disseminate all technical and programmatic issues with the State Contract Manager.

4.8 LIMS Warranty

The contractor shall provide a one-year warranty on the LIMS at no additional cost to the State.

4.9 Sample Tracking

The LIMS shall:

- Provide a laboratory sample numbering format which is user configurable instead of by selecting from a fixed list of formats.
- Store unique field sample identification numbers that are configurable by the user and linked to the LIMS sample number.
- Integrate with portable field collection devices that utilize Windows Mobile Technology, allowing field collectors to collect field data and upload that data from any location that provides Internet access.
- Automatically calculate the sample hold times associated with the minimum time available for initiation of sample analysis based upon user input.
- Be capable of following the progress of samples throughout the analytical process and include integrated barcoding, sample login, chain of custody, price quoting and billing.
- Group samples into work lists, preparation batches, and QC batches by user definable selection criteria such as by batch, sample number, client, project, test, method, department, etc.
- Provide a query function to retrieve sample information by work order, sample number, client, analysis, project test, department, date range, site, or other information for many functions throughout the LIMS.
- Have the ability to read a variety of bar code fonts and generate bar code labels representing laboratory and field sample identification numbers.
- Provide sample log-in and sample tracking capabilities capable of distinguishing samples being analyzed in-house versus those submitted to other governmental and/or contract laboratories. In-house analyses, as well as samples submitted to other laboratories, shall be tracked separately. The LIMS shall also enable the user to change the status of a sample from “in-house” to “contractual.”
- Generate sample backlog reports identifying current sample workloads.
- Identify samples with completed client requested analysis and designate for sample disposal.
4.10 Sample Scheduling

The LIMS shall automatically log-in and schedule samples for a client/project in advance of the sample collection event. This feature shall address a variety of scheduling frequencies, including hourly, daily, weekly, biweekly, monthly, semi-annually and annually or via a special study.

4.11 Data Entry and Storage of Quality Control/Quality Assurance Information

The user shall have the ability to retrieve test results, both manually and directly from the analytical instrumentation.

The system shall provide integration of simple calculations for the generation of sample analytical results.

Data shall be transferred to an “archive” location. The end user shall have the ability to view this data without restoring the data into the “active” location.

The system shall track quality control, including sample replicates, matrix spikes, quality control check standards and blanks.

The user shall have the ability to create quality charts based upon quality control data that has been entered into the system.

The system shall link all quality control data to the associated sample, test data and batch run.

The system shall calculate quality control results and automatically flag all quality control data which is not within user defined quality control limits.

4.12 Electronic Data transfer from instrument to LIMS

Electronic data shall be imported directly from the analytical instrumentation, both manually and automatically by scanning directories. Instrument interfacing is required for the following instruments. Include instruments that will be interfaced here.

4.13 Storage of instrument calibration data, analyst training certificates, and instrument repair records

The system shall store and maintain records pertaining to the instrument’s calibration data, as well as historical records on all instrumental repairs. Records pertaining to formal and informal training obtained by analysts shall be stored and maintained.

4.14 Electronic data transfer to user clients

The LIMS shall include data import and export capabilities. Electronic Data Deliverables should support the APHL EDD Requirements document attached to this document. A Type 2 XML EDD is preferred over the 1t spreadsheet option. A summary of the data elements is included in Appendix A.

4.15 Maintaining of chemical inventories

The system shall maintain an inventory of all chemicals used in the environmental laboratory, including but not limited to chemical name, expiration date, location of storage and vendor used for procurement.
4.16 System Security Features

A system for supervisory data review and approval of all analytical results shall be included.

The network administrator shall have the ability to control user access to data.

Changes made to any data field shall be audited and tracked by the system. Audit information shall include the name of the individual that made the change, date/time changed, original value, new value and reason the data was changed.

Web reporting software shall support SSL (secure socket layer) to ensure data security and shall generate canned XML preliminary and final reports, provide a news editor, and provide one click capability to inactivate user accounts. PHL State IT will be responsible for obtaining SSL certification and installing it on the server.

The application shall support a single sign-on process that includes the user’s log-on id and password.

4.17 Generation of Client Billings

The system shall provide automatic reporting and client billings for completed work orders that includes, at a minimum: client agency, sample number, test performed, charge per test and final charge.

4.18 Customized hardcopy report generation

The LIMS shall:

- Contain fully configurable reports.
- Automatically report numeric results to the number of significant figures and decimal places as specified by the user.
- Have the ability to enter text values into the result field.
- Automatically report as “less than” any numerical data value which is less than the method detection limit specified by the user.

4.19 Additional Technical Requirements

The proposed software shall be capable of operating on the laboratory’s existing platform (provide example here).

The LIMS client operating system shall be (provide an example here).

Client portions of the application shall be created solely with (provide an example here e.g., Microsoft Access) and shall allow additions of tables, queries, forms, reports, macros, and modules to the LIMS and the database engine, Structured Query Language (SQL) server.

The system shall have the ability to add functions to the program main menu and all other screens allowing the database administrator to keep the LIMS current with user needs.

The software shall be licensed to accommodate an unlimited number of users at two (2) separate locations without user fees, additional fees for on-line instrumentation or any new users.

The system shall include a cost tracking capability which tracks analyst time and workloads.

All software updates shall be compatible with user definable configuration, as long as user definable configuration is done in accordance with contractor recommendations.
The system shall utilize a SQL database, such as Oracle or Microsoft SQL server, to store information in tables. Any proposed LIMS with a proprietary database engine will not be considered.

The system shall use a comprehensive statistical process control (SPC) software package for charting and analysis used in routine process management and continuous process improvement. Such software may be a supplied but integrated 3rd party vendor.

The contractor shall articulate minimum system requirements for the server. Existing LIMS server specifications – (Each state must supply these values).

4.20 Detailed Specifications

4.20.1 Project Initiation

Within five (5) days of contract award, the contractor shall conduct a meeting with laboratory staff that will be involved with overseeing the project. The meeting shall be held at the laboratory. The purpose of the meeting is to discuss the contractor’s next steps for installation and verification of the LIMS, including the projected dates for project initiation.

4.20.2 Project Management

During the first month of the project, the contractor shall meet with the State Contract Manager on a weekly basis to discuss the project’s status and progress. The contractor shall provide the State Contract Manager with a written progress report. A revised mutually agreed upon meeting frequency will be developed after the first month and will continue until conclusion of the project.

4.20.3 Quality Management

Standards for the contractor’s installation and verification of the LIMS include demonstrating and verifying the functionality of the LIMS package, as well as any custom features that are incorporated.

4.20.4 Data Considerations

Specify any requirement needs for Data Warehouses or Data Marts.

The contractor shall provide instrumentation interfaces for web access.

Ten (10) percent of samples shall have parallel testing on the new system and the current system for one month to assure accuracy and precision of results.

4.20.5 User Acceptance

Once the parallel test is complete and the server is within acceptable performance measures, the State will sign off on the system as being complete.

Acceptable performance on the server is defined as CPU utilization below 80% and system response time under two (2) seconds. Response time is considered the time to navigate from one screen to the next and/or the amount of time the system takes to update a transaction.