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

September 2003

ACKNOWLEDGEMENTS

This publication is the product of an unprecedented collaboration between state and local public health laboratories, a professional association representing public health labs (the Association of Public Health Laboratories), and a nonprofit organization promoting the development of information technology among public health organizations (The Public Health Informatics Institute).

The following public health laboratories contributed significant time and materials to the initiative: Arkansas Department of Health; Connecticut Division of Laboratories; University of Iowa Hygienic Laboratory; Public Health Laboratory, Marion County Health Department, Indianapolis, Indiana; Kansas Division of Health and Environmental Laboratories; Maine Laboratory Operations – Health & Environmental Testing; Massachusetts State Laboratory Institute; New York Wadsworth Center; Utah Division of Epidemiology and Laboratory Services; and the Virginia Division of Consolidated Laboratory Services.

Six other laboratories offered valuable input: Florida Bureau of Laboratories, Kentucky Division of Laboratory Services, Mississippi State Public Health Laboratory, Missouri State Public Health Laboratory, New Jersey Public Health Laboratories and Environmental Laboratories, and Washington Public Health Laboratories. The following laboratory leaders put it extra hours as workgroup participants: Dariush Shirazi (IA), Bob Bostrom (KS), Wanda Andrews (VA), Tom York (VA), Richard Jenny (NY), and Jay Lewis (WA).

Special thanks are due to Helen L. Regnery of the Association of Public Health Laboratories (APHL) staff who served as project coordinator and to Doug Drabkowski for project supervision. The staff of the Public Health Informatics Institute – Dave Ross, Director; Anita Renahan-White, Project Manager; Pete Kitch, Informatics Consultant; Robert Sokolow, Laboratory Consultant; and Terry Hastings, Communications Director – worked tirelessly to provide conceptual, technical and managerial support.

APHL's Management and Information Systems Committee provided oversight for the project: Steve Hinrichs, Chair; Bonna Cunningham, Subcommittee Chair; Robert Rej, Andrei Kisselev, and Larry Scanlan, Subcommittee members for oversight of the initiative. The Information Resources Management Office of the Centers for Disease Control and Prevention reviewed the manuscript and added information on PHIN standards and requirements.

APHL welcomes comments on this document and related issues. Please address correspondence to Patina Zarcone, Informatics and LIM Systems Manager, pzarcone@aphl.org or Doug Drabkowski, Director of Program Development, ddrabkowski@aphl.org, telephone 202.822.5227.

This project was funded by the Public Health Informatics Institute with support from the Robert Wood Johnson Foundation.

Published by
Association of Public Health Laboratories
2025 M Street, NW, Suite 550
Washington, DC 20036

TABLES AND FIGURES

EXECUTIVE SUMMARY

The Association of Public Health Laboratories (APHL), the APHL Management Information Systems (MIS) Committee, designated state and local public health labs (PHLs), and the Public Health Informatics Institute (the Institute) joined together in October 2002 in an effort to determine commonalities among PHLs' requirements specifications. Their objective was to determine a more efficient and economically viable manner to address information technology needs.

The critical need for PHLs to have efficient electronic laboratory information management (LIM) systems became evident after the bioterrorism events of fall 2001. APHL's 2002-2005 strategic plan subsequently called for the development and use of effective laboratory information plans and the development of consensus on the essential elements of laboratory information systems. The Robert Wood Johnson Foundation (RWJF) funded the Institute in September 2002 to develop collaborative approaches for state and local public health agency use of information tools to respond to bioterrorism and other public health threats. The APHL-Institute partnership brought together the strategic priorities of APHL and the collaborative approach and public health informatics expertise of the Institute. It has proven to be a highly effective model for collaboration.

Sixteen PHLs contributed their laboratory experience and expertise to the Institute's knowledge of the professional IT environment. APHL and its MIS Committee provided coordination and oversight. This requirements specifications document is thus the result of a joint effort by many parties, referenced here as "the Collaborative."

The Collaborative succeeded in demonstrating the feasibility of a common set of LIM system requirements and its applicability to the individual needs of public health laboratories.

Defining system requirements is the most important step in developing or acquiring any information system. If the requirements are not correctly defined, the system will not meet the needs of its users. With correct LIM system requirements, PHLs will be able to match their needs with commercial software products.

This document is designed to be both a roadmap and a tool. It is a roadmap for moving PHLs toward the vision articulated here. At the same time, it is a tool for structuring specific implementation projects and creating comprehensive vendor requests for proposals (RFPs).

The text describes the roles of Collaborative partners, the methodology, and key lessons learned, notably the importance of engaging system users from the beginning of the development process. It also details the business processes that underlie the system requirements.

Separate from this document, but integral to the effort, the LIM system project will develop a business case with cost-benefit analysis and a commercial vendor analysis.

Sections III through VIII present LIM requirements specifications as follows:

1) Development of a conceptual framework for the work performed in a PHL (**Section III***).*

2) An explanation of how the business processes relate to each other (**Section IV**).

3) Delineation of requirements specifications for each business process that takes relationships between the processes into account (**Section V**).

4) A statement of LIM system requirements specifications that span all 16 business processes (Section VI).

5) An explanation of the database interfaces between the LIM system and other relevant system databases (**Section VII**).

6) Delineation of vendor-related requirements specifications commonly found in requests for proposals (**Section VIII**).

This publication outlines a common set of laboratory information management (LIM) system requirements specific to public health laboratories (PHLs) that can be used to purchase, enhance, or develop LIM systems with the capability to electronically exchange information with laboratory customers.

For the purposes of this document, a LIM system is defined to mean more than a specimen "tracking system." Here a LIM system encompasses 16 business processes associated with core business functions such as the standard collection of specimen information.

Background

The Critical Need. Due to years of under-funding, PHLs have not been able to capitalize on advances in information technology. The consequences of inadequate IT capacity became evident during the anthrax crisis as states scrambled to create Access® databases or worked with ancient Wang® systems that lacked system interfaces. Had electronic systems been in place, the management of data would have been more efficient, accurate and timely. More recently, the spread of West Nile virus has confirmed the need for efficient electronic laboratory information management systems. Implementation of standards that will allow laboratory results data to be linked with patient information, case studies, and other epidemiological data represents a major challenge to public health.

The Institute and APHL began discussions in July 2002 on developing standards for PHL LIM systems. APHL's Board of Directors, based on recommendations from the MIS Committee, approved the undertaking during its September 2002 meeting. In October, APHL began collaborating with the Institute to advance the initiative.

The Collaborative Partners

The term "the Collaborative" is used in this document to refer to the partners involved in the LIM system requirements project. Profiles of these partners follow.

Public Health Informatics Institute (the Institute). The Institute is an independent, nonprofit organization dedicated to advancing public health practitioners' ability to strategically apply and manage information systems. The Institute is a program of the Center for Innovation in Health Information Systems, which operates under the umbrella of The Task Force for Child Survival and Development whose mission is to improve human health and development around the world.

Funded by The Robert Wood Johnson Foundation (the RWJF), the Institute began operations in September 2002. In its initial phase, the Institute was asked by RWJF to address the urgent needs for state and local public health preparedness and response to bioterrorism. It is now involved in several projects aimed at improving the public health information technology infrastructure.

Association of Public Health Laboratories (APHL). APHL works to safeguard the public's health by strengthening public health laboratories in the United States and across the world. In collaboration with members, APHL advances laboratory systems and practices, and promotes policies that support healthy communities. The association's founding members are directors of state and territorial public health laboratories. Others include city, county, environmental health, and environmental quality laboratory directors, international representatives and other laboratory professionals. APHL is a non-profit, 501(C3) organization with a history of over fifty years.

The Management and Information Systems (MIS) Committee. The MIS Committee advises APHL on information systems development. The MIS Committee has the responsibility of addressing two key sections of the Third Goal of APHL's Strategic Plan 2002 - 2005[1]: "Develop and promote the use of effective laboratory information systems," and "Develop consensus on the essential elements of effective Laboratory Information Management (LIM) Systems." Given this charge, the Committee was asked to assume oversight for the LIM system requirements project.

State and Local Public Health Laboratory Partners. State and local PHLs are at the core of the United States public health delivery system, linking almost every facet of public health infrastructure – disease control and prevention, maternal and child health, environmental health, epidemiology, and emergency preparedness and response. As a result, PHLs interact with a wide range of local/state/federal agencies and individuals, including local hospitals/laboratories/clinics, environmental/agricultural/ wildlife institutions, academic institutions/health sciences centers, and law enforcement agencies.

PHLs applied to participate in the LIM system requirements project. Nine state PHLs and one local PHL were chosen as fully participating partners (committing time and materials.) Six other states were selected as contributing members (committing experience and materials.) Participating partners included the Arkansas Department of Health; Connecticut Division of Laboratories; University of Iowa Hygienic Laboratory; Public Health Laboratory, Marion County Health Department, Indianapolis, Indiana; Kansas Division of Health and Environmental Laboratories; Maine Laboratory Operations – Health & Environmental Testing; Massachusetts State Laboratory Institute; New York Wadsworth Center; Utah Division of Epidemiology and Laboratory Services; and the Virginia Division of Consolidated Laboratory Services. Contributing members included the Florida Bureau of Laboratories, Kentucky Division of Laboratory Services, Mississippi State Public Health Laboratory, Missouri State Public Health Laboratory, New Jersey Public Health Laboratories and Environmental Laboratories, and Washington Public Health Laboratories.

Centers for Disease Control and Prevention. CDC is committed to collaboratively identifying and defining standards for the implementation of electronic reporting of laboratory results. It provides consultation, guidance, and direction in specimen accessioning, electronic laboratory reporting, results messaging, and secure transport of data. CDC reviewed this document in its final draft form and provided detailed requirements for electronic transmission of data **(Section VI. Public Health Information Network (PHIN) Requirements as Related to LIM Systems).**

[1] Strategic Plan 2002–2005. Association of Public Health Laboratories, June 2002.

Benefits of the Project

The benefits of the LIM system requirements project extend to all PHLs in that all will be able to access this information through its steward, APHL. In addition, the project demonstrates that PHLs can act collectively to define LIM system requirements, and then can use this information to select or develop a common LIM system for sharing costs, upgrades, etc. Such a collective approach likewise promotes participation in national informatics initiatives such as PHIN.

Methodology

The analogy of building a house without an architectural plan is often used to illustrate the information systems approach taken by many public health professionals – an approach that has led to the myriad of information systems and has resulted in redundant data entry, difficulties in sharing data, and complexities in maintaining systems. The LIM system requirements project provides PHLs the opportunity to apply the basic principles of public health informatics to acquiring or developing a LIM system that will satisfy the laboratory's business processes, reduce re-entry of data, enhance data exchange, increase robustness of public health databases, and streamline systems maintenance.

Defining system requirements is the most important step in developing or acquiring any information system and is basically an analytical process with the business processes forming the framework for the analysis **(Section IV. Business Process Interdependencies).** If the requirements are not correctly defined, the system will not meet the needs. Defining the LIM system requirements correctly will allow PHLs to match requirements to vendors' software products. As is often the case when requirements are not completed first, the result is a vendor comparison based on arbitrary likes or dislikes, as opposed to one based on a product's appropriateness.

Emphasizing business processes instead of specific laboratory services and programs is a key principle of public health informatics. Consequently, the LIM system requirements project began with a high-level review of the PHL business – its goals, procedures, customers, and organizational structure. Workgroups identified 16 business processes that provided the framework for defining workflows and outputs that could logically be provided by a LIM system. During this business process phase, it became apparent that PHLs play an integral role in the broader public health data flow.

A chronology of project workgroup and team activities is outlined in **Table 1**. System users were engaged from the inception to completion of the project, an important element of success in public health informatics. A larger group reviewed workgroup products to ensure accuracy and completeness. The broader impact of the document will be determined by recipients, which include APHL members, CDC leaders, and other public health stakeholders.

Lessons Learned

Insights and "lessons learned" emerged at each milestone of the project. The most significant are listed below:

PHLs share common business processes. Workgroup members from clinical, environmental, and IT backgrounds agreed that PHLs share common business processes. Differences among PHLs were found to relate more closely to laboratory size, number of employees, volume of specimens/samples processed, and differences in funding streams than to core business processes. (Milestone 1)

TABLE 1. LIM SYSTEM REQUIREMENTS PROJECT METHODOLOGY

DATE	WORKGROUPS	ACTIVITY	OUTCOME
Milestone 1			
Workshop (Nov 13-15, 2002)	IA, KS and VA Institute/APHL staff	Identify the business processes of a PHL	Draft of the 16 Business Processes prepared. Reviewed by all Project Partners and Contributing Members (completed 12-12-2002).
Milestone 2			
Workshop (Jan 13-14, 2003)	IA, KS, VA adding NY and WA Institute/ APHL staff	Refine business processes and establish workflows	Context diagrams, workflows, and inputs/ outputs drafted by Institute staff and reviewed by workgroup.
Milestone 3			
Site Visits (Feb 3-6, Feb 19-21, Mar 3-5, 2003)	Site Visit Team: Institute/APHL staff and KS	Site visits – VA, NY and Marion County, IN	Verification of Business Processes, context diagrams inputs/outputs, and work flows.
Milestone 4			
(Mar 31- Apr 1, 2003)	10 Project Partners (2 representatives each) and 4 Contributing Members (1 representative each), MIS Subcommittee, Institute/APHL staff	Consensus on draft LIM system requirements specifications	Discussed all requirements specifications sections of the document. Provided all comments for synthesis into requirements specifications document
Milestone 5			
Apr 15, 2003	Institute/APHL staff	Final document APHL assumes stewardship	APHL released a draft of the requirements specifications to member directors in May. CDC reviewed and finalized end of August. Final edits completed, document released and posted on APHL website in September.

PHLs play a significant role in processing public health data. PHLs are positioned centrally in relation to broad data flows. They receive clinical specimens and environmental samples, process the data, generate additional data, and send the resulting data to public health agencies. (Milestone 1)

PHLs are dependent on specimen providers, and customers on PHLs. Another working group grasped the interdependency among phls and both specimen providers and customers. Accurate testing depends on quality specimens; effective treatment depends on accurate testing. Understanding the unique position of PHLs within public health data flow makes it possible to address issues, limitations, and improvements related to receiving and sharing data in a more meaningful way. (Milestone 2)

PHLs share basic business practices and workflows. Though each PHL visited for the project was unique in organizational structure and facilities, all shared basic business processes and workflows. This finding confirmed that a common set of LIM system requirements was feasible, and that all PHLs would be able to use them. (Milestone 3)

II. HOW TO USE THIS DOCUMENT

This document is designed to be both a roadmap and a tool. It serves as a roadmap for helping PHLs move toward the vision expressed in this document. At the same time, it is a tool for structuring specific implementation projects and the basis for the creation of comprehensive vendor requests for proposals (RFPs). It does not provide an information system requirements definition in the sense that the term is used in informatics.

PHLs are invited to customize this document to meet individual needs and can modify the business process sections, adding specific or unique requirements, and deleting business processes not under their jurisdiction.

General organizational support processes normally supported by separate information systems, such as payroll and general accounting, are not included in these requirements. Purchasing, which can be a companion to inventory control, has been omitted as a business process at this point.

The document has been organized to lead the reader from a "macro" to a "micro" view of a LIM system and its functionality. Individual requirements specifications can only be communicated within the context of an overall LIM system structure. The progression is as follows:

1) Development of a conceptual framework for the work performed in a PHL (**Section III**).

2) Explanation of how the business processes relate to each other (**Section IV**).

3) Delineation of requirements specifications for each business process that takes the relationships between the processes into account (**Section IV**).

4) Statement of LIM system requirements specifications that span all 16 business processes (**Section V**).

5) Explanation of the database interfaces between the LIM system and other relevant system databases (**Section VIII**).

6) Delineation of vendor related requirements specifications commonly found in Request for Proposals (**Section IX**).

III. BUSINESS PROCESS DESCRIPTIONS

This section briefly describes 16 business processes and associated objectives relevant to the operation of public health laboratories. Not all business processes are represented at all PHLs, but each is relevant to a number of laboratories. These descriptions serve as the basis for delineation of requirements specifications in **Section V**.

This document does not propose a physical solution for a LIM system 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.

BP #1. Laboratory Test Processing (Clinical and Environmental)

OBJECTIVE: Securely deliver correct and complete test result reports to the submitting customer and other mandated recipients.

This business process encompasses the core of a PHL's work: receiving, initial processing, analytical laboratory testing, and test result reporting for both clinical and environmental specimens and samples. Receiving includes verifying the completeness of the test request information, ensuring the adequacy/appropriateness of the specimens/samples for testing, initial processing, and prioritizing the tests for the various internal laboratories. Test requests can be received by phone, FAX, hard copy, or electronic transmission using an HL7 order message. The testing task includes all analytical activities associated with the requested tests (and any further tests, if needed as a result of initial test results) and recording of results. Test result reporting includes verification and secure transmission of reports via hard copy, phone, FAX, electronic copy, HL7 result message, etc., to the customer and other mandated recipients, as well as posting results where they can be retrieved by authorized parties.

BP #2. Test Scheduling

OBJECTIVE: Optimize the use of laboratory personnel and instruments in order to maximize the use of resources available to the laboratory and be able to adapt to sudden surges in a specific test request volume.

In addition to the prioritization performed in receiving, each internal lab within a PHL schedules its workload by specific instrument or bench. Scheduling factors include "rush" test requests, the length of time a test takes, and holding/storage time requirements. In general, test requests are processed in the order in which they are received except during an event prioritization.

BP #3. Proactive Specimen/Sample Collection (Prescheduled Tests)

OBJECTIVE: Receive prescheduled specimens/samples in an efficient and timely manner.

Tests can be prescheduled in some instances. This business process includes the identification and scheduling of either single (one-time) requests, or recurring tests over some period of time. In either case, the PHL ideally should capture the test schedule in the computer system and track each requested test, starting with the distribution of the kits and forms and ending with the receipt of the individual specimen/samples and completed forms. This process is a front end to the standard test processing described in Business Process #1.

BP #4. Specimen and Sample Tracking/Chain of Custody

OBJECTIVE: Create accurate and timely specimen and sample tracking and chain of custody documentation.

Specimens and samples must be tracked from the time of receipt until disposal. Unique identification of the sample and all of its aliquots is required so that results can be matched back to the originating sample. Besides the sequential processing from receiving through testing, specimens and samples may spend time in intermediate storage, as well as be stored for subsequent testing following the initial testing or stored as evidence. Long-term specimen and sample storage may also be required, including products/organisms grown from them. Additionally, samples may be sent to third parties for confirmatory testing or as overflow. In instances where chain of custody documentation is required, the lab must be able to document custody of the specimen or sample from receipt through disposal or return to the submitter or other agency. In many instances this requires a written signature or a digital signature from the custodian of the sample/specimen.

BP #5. Media, Reagent, Stains, Controls, etc. Manufacturing

OBJECTIVE: Efficiently prepare media and other materials for use in the PHL or for sale to other laboratories and ensure they will work as intended.

A PHL may manufacture media, reagents, stains, and other materials required for support of the individual laboratory analytical testing activity from a variety of components. These components all have expiration dates and the final manufactured items carry expiration dates determined by the laboratory. All new lots are quality controlled, and the manufacture may involve multiple steps. Some items may require instrument “recalibration” in the lab when first used. This business process covers all activities associated with the manufacture and introduction of these items in a PHL’s individual laboratories, except for Quality Control (QC), which is included under Business Process #14.

BP #6. Inventory Control Including Kits & Forms Management

OBJECTIVE: Manage appropriately all items inventoried by a PHL.

This business process covers all aspects of inventory control (ordering, tracking, and distribution) for all items inventoried by a PHL. Examples include specimen and sample collection kits, testing kits, lab supplies, chemicals, equipment, and forms. Collection kit management includes order processing, component and kit assembly tracking, and assembled kit inventory tracking activities including lot number and expiration date tracking for QC purposes. Forms management encompasses version control, printing, and distribution.

BP #7. General Laboratory Reporting

OBJECTIVE: Create timely and efficient general laboratory reports addressing all PHL external obligations and internal management needs.

A PHL may have a wide variety of external reporting requirements dictated by a wide variety of organizations (CDC, EPA, epidemiology, local health departments, etc.), as well as internal reporting requirements that include both management reporting and records management. An example of an external reporting requirement would be reporting on laboratory capacity and critical personnel changes. This business process includes all aspects of reporting other than the direct test reporting to the customer and other mandated recipients as described in Business Process #1.

BP #8. Statistical Analysis and Surveillance

OBJECTIVE: Create appropriate statistical analysis, surveillance outputs, and reports needed internally and supplied to external partners for statistical and surveillance purposes.

Because of the unique PHL role in infectious diseases and PHLs' special relationship with epidemiology (for example, helping identify, understand and control disease outbreaks), PHLs must be able to perform statistical analysis and surveillance activities. This business process covers serving the data needs of a variety of organizations, including state epidemiologists and other public health agencies, other laboratories, practitioners, CDC, etc., in order to identify trends and sentinel events indicating emerging health problems, as well as actively participating in mitigation of adverse health events once they have been identified.

BP #9. Billing for Laboratory Services

OBJECTIVE: Collect and record billing revenue.

APHL may engage in a wide variety of billing activities associated with the provision of lab services. These include collecting fees prior to, as well as after, the performance of lab tests, withholding lab test results until fees have been paid in certain instances, provision of indirect billing services for the PHL, collecting licensing fees from other laboratories in the PHL jurisdiction, billing customers under contract arrangements for testing and training services, and billing Medicaid and other health care plans for services rendered to their clients.

BP #10. Contract and Grant Management

OBJECTIVE: Accurately manage contracts and grants per agreement requirements.

Contracts are normally used as a part of the definition of the business relationship between a PHL and a regular customer. A given customer may have multiple contracts with the laboratory at the same time or over a period of time. In addition, a PHL may perform testing services under a grant mechanism in which there is an agreed amount of testing to be performed. Once the limit is reached, no further testing is done. This business process is defined as the way in which the contracts and grants are managed within the PHL.

BP #11. Training, Education and Resource Management

OBJECTIVE: Provide appropriate staff and customer training and education, and manage overall personnel resources.

This business process includes staff and customer training and education activities, as well as the overall management of the PHL's personnel resources (including skills, education, certifications, etc.). Training and education includes course preparation, scheduling, attendance and follow up. Resource management includes tracking employee certifications and competency testing for each test they perform, as well as the instruments they use in testing. This business process also includes the training, documentation, and reporting necessary to maintain a PHL's certification.

BP #12. Lab Certifications/Licensing

OBJECTIVE: Fulfill state and other regulatory certification/licensing and oversight responsibilities assigned to the PHL.

A PHL is generally charged with the responsibility for certifying and providing oversight of other laboratories in their respective states. This function includes the regular certification process, inspections to identify deficiencies, tracking of proficiency testing, and complaint investigation. In addition, the PHL provides inspection and oversight data and reports to other government agencies and maintains the reciprocal agreements with laboratories in other states.

BP #13. Customer Concerns/Suggestions

OBJECTIVE: Provide appropriate follow up, reporting and resolution of concerns and suggestions received from customers and employees.

Complaints and other input from both employees and customers must be received, recorded, investigated, and reported. This business process covers all aspects of this activity.

BP #14. Quality Control (QC) and Quality Assurance (QA) Management

OBJECTIVE: Provide appropriate QC and QA services.

Although many of these activities are woven into the performance of the laboratory testing process, the determination of the QC and QA activities to be performed, the performance tracking, and the subsequent reporting requirements are management responsibilities and, consequently, are defined as a separate business process under this heading. QA not only includes internal performance, but also relates to customer performance in meeting the requirements for proper test submittal and customer satisfaction with the PHL's performance.

BP #15. Laboratory Safety and Accident Investigation

OBJECTIVE: Creation of a safe and accident free laboratory environment.

The very nature of PHL work mandates that safety is a key consideration. It involves elements of several of the other business processes discussed above but has been broken out separately to emphasize its importance. Safety involves training, follow up, monitoring and investigation of safety violations and safety related injuries and accidents. All tasks associated with these activities are included in this business process.

BP #16. Laboratory Mutual Assistance/Disaster Recovery

OBJECTIVE: Process test request surges without compromising turnaround times and quality.

The ability to identify other laboratories with available capacity in an emergency in order to create surge capacity and the capability to transfer existing test backlogs as well as divert a portion of new tests requests to alternate surge capacity laboratory locations.

IV. BUSINESS PROCESS INTERDEPENDENCIES

As noted above, the 16 business processes are interdependent, linked to laboratory test processing (Business Process #1) and other business processes through tasks performed and outputs produced.

For example, inventory is directly linked to test processing and supports this function. Without reagents and media, the laboratory could not perform testing. In this case, it would not be reasonable to implement the inventory business process without first implementing test processing. Integrating inventory business process support into the LIM system produces efficiencies in laboratory operations that would not be possible if the inventory function was supported by a separate information system or performed manually.

This section describes the intersections between the business processes and the associated dependencies. The description creates the framework for the LIM system business process interfaces and impacts on the critical work activities to be supported within each of the dependent business processes. Each of these critical work activities is converted into requirements specifications in **Section V**.

Moreover, the dependency relationships define a logical phased implementation strategy for use where a given PHL can only implement a subset of the business processes in each stage of the overall LIM system development. By the same token, it also suggests the logical sequence for module implementation if the user decides to support all or a large number of the business processes at the same time using a phased implementation strategy.

Relationship of Inputs, Outputs, and Business Processes

From an information system perspective, each business process can be described in terms of an Input-Process-Output model. That is, certain **Inputs** are required to enable the user to perform the **Business Process** to produce **Outputs** that represent the completion of the work tasks performed within the business process that achieve the objective of the process. In its most simple form, it can be represented as follows:

FIGURE 1. RELATIONSHIPS OF INPUTS, OUTPUTS, AND BUSINESS PROCESSES

This model can be modified to further define inputs and outputs. In this case, the inputs and outputs are categorized as follows:

FIGURE 2. MODEL FOR BUSINESS PROCESS INTERDEPENDENCIES IN PHLS

The outputs associated with each business process are categorized in the business process interdependency descriptions that follow. Inputs to a laboratory business process are categorized under the business process from which the input was received in order to avoid duplication. Inputs from external sources in Figure 2 can come from three different entities: test request submitters (BP #1A), results users (BP #1F), and mutual assistance laboratories (BP #16).

Note that in the business process interdependency descriptions, outputs between these external entities are listed, but are not subsequently reflected in the requirements specifications since they are outside of the LIM system scope or involvement[2]. Outputs from these entities to the internal business processes are accounted for in the requirements specifications associated with the receiving processes.

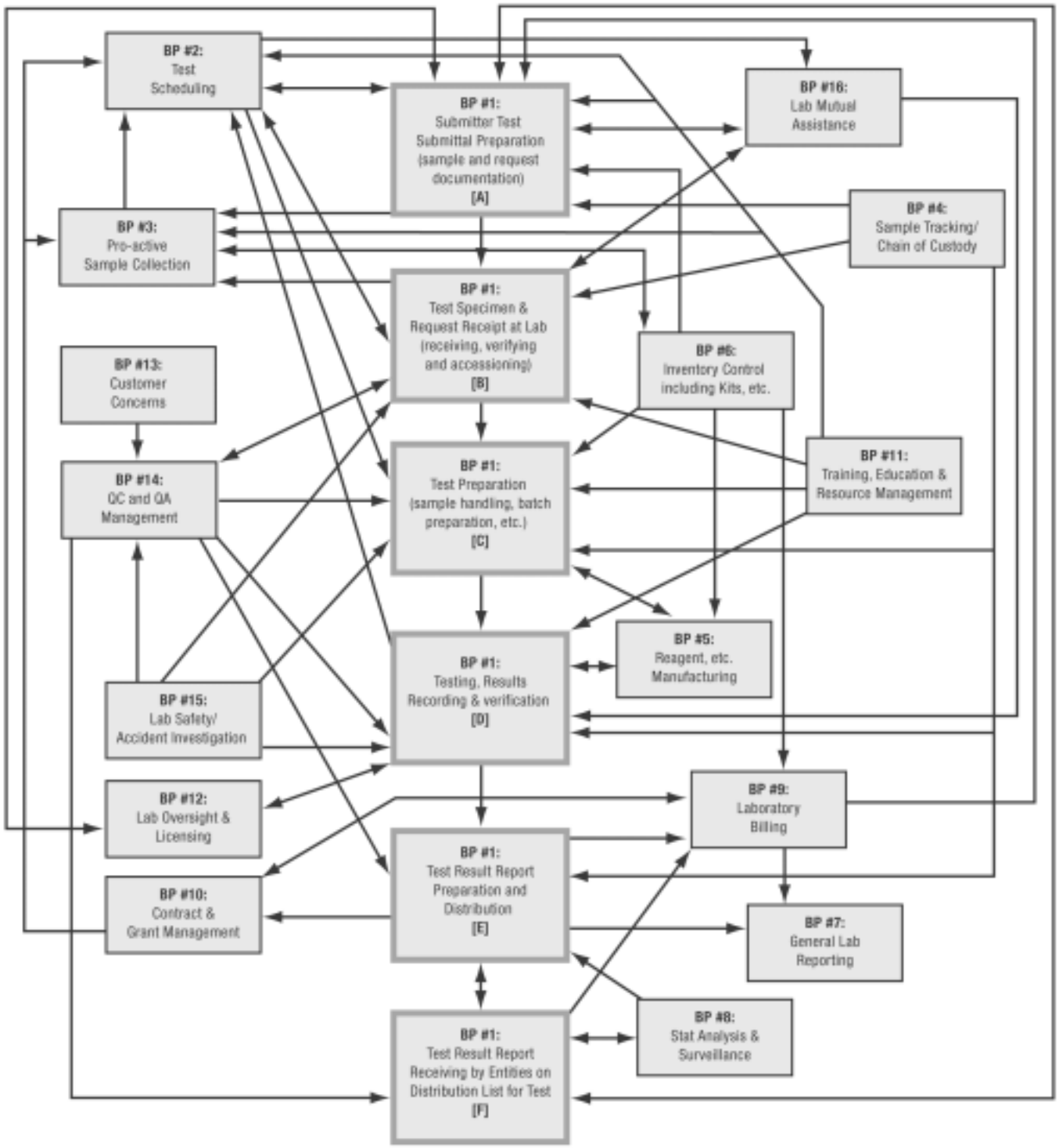
Business Process Interdependency Descriptions

The business process interdependencies represent exchanges of data sets between two business processes. **Figure 3** describes the relationships between the various business processes. This description is further defined for each business process later in this section, and the section is closed with a suggested prioritization scheme for phased implementation.

The arrows (→) in **Figure 3** represent the interdependencies with the head of the arrow pointing in the direction of the interaction. Two headed arrows («) indicate that a two-way exchange of data occurs in the interface. Theoretically, one could show the input and output interdependencies associated with each business process, but that would simply duplicate each interdependency as an input to the receiving business process and an output from the sending business process. In the following discussion, the interdependency has been stated on the *output side only, that is, in association with the originating business process that performed the work task that created the output.* To state it again as an input would only repeat the statement of the same transaction.

[2] They have been noted as "Out of Scope" in this document.

FIGURE 3. LABORATORY TEST PROCESSING SUMMARY WORK FLOW (BUSINESS PROCESS #1) AND INTERFACES WITH OTHER BUSINESS PROCESSES



For example, in the first interdependency description below dealing with the submitter's relationship to the laboratory, the test submitter (BP #1A) sends test specimens/samples and test requests to the Test Specimen/Sample & Request Receipt area of the laboratory (BP #1B). These requests and specimens/samples originated as a result of work activities within the submitter organization that produced them as an output. By the same token, the submitter creates the "Request for accelerated testing/rush requests" sent to Test Scheduling (BP #2) based on some work activity within their organization (an output of BP# 1B).

Interdependencies Explanations

BP #1A: Submitter Test Submittal to:

- Test Specimen/Sample & Request Receipt (BP #1B)
  1) Test specimens/samples & Requests for processing
  2) Additional epidemiology-related data as needed that is incorporated into the request form
- Test Scheduling (BP #2)
  1) Request for accelerated testing/ "rush requests"
  2) Test Request advance notification
- Lab Oversight & Licensing (BP #12)
  1) Submitter name and address records and associated information for other laboratories, particularly those referring tests to the PHL for confirmation or further testing [i.e., creation of a single identification
  (name & address) laboratory master file for all laboratories under the PHL jurisdiction]
  2) Test volume patterns by instrument/method
  3) Instrument and personnel capabilities
- Lab Mutual Assistance (BP #16)
  1) "Diverted" test requests and specimens/samples in response to the need for surge capacity [Out of Scope]

BP #1B: Test Specimen/sample & Request Receipt to:

- Test Preparation (BP #1C)
  1) Request information in electronic form
  2) Accession ID for use in processing test
  3) Properly labeled specimens/samples
- Test Scheduling (BP #2)
  1) Information on test requests received
  2) "Rush" request information
- Proactive Specimen/Sample Collection (BP #3)
  1) Information on prescheduled test requests received
- Inventory Control (BP #6)
  1) Request for glassware and other items needed in the receiving process (splitting out specimens samples, etc.)
- QC/QA (BP #14)
  1) QA information on completeness of request form information received from each source
  2) QA information on adequacy./completeness/usability of specimens/samples received from each source

- Laboratory Mutual Assistance (BP #16)
  1) Notification of need for assistance and test load status
  2) Request diversion information for specimens/samples to be shipped from the PHL receiving area
  3) Electronic request information for specimens/samples to be diverted from PHL receiving
  4) Notification of anticipated test requests expected to be diverted directly from submitter(s)

BP #1C: Test Preparation to:

- Testing & Results Recording (BP #1D)
  1) Batched test requests
  2) Specimens/samples or preprocessed specimens/samples (aliquots, etc)
  3) Batch worksheets
- Media, Reagent Mfg (BP #5)
  1) Request for new media or reagent (reorder) for situations where preprocessing requirements dictate the need for these items

BP #1D: Testing, Results Recording & Verification to:

- Test Result Report Preparation & Distribution (BP #1E)
  1) Test results and associated submitter test request information
  2) Data sets on additional tests needed as a result of the initial testing
  3) Associated information to determine if “preliminary” report should be issued
- Test Scheduling (BP #2)
  1) Data sets on additional tests needed as a result of the initial testing
- Media, Reagent Mfg (BP #5)
  1) Request for new Media or Reagent (reorder)
- Laboratory Oversight and Licensing (BP #12)
  1) Proficiency tests for distribution to other laboratories

BP #1E: Test Result Report Preparation and Distribution to:

- Test Report Receiving (BP #1F)
  1) Preliminary and/or final test reports
  2) Status reports on current outstanding tests
  3) Responses to request for historical data on specific test submittals including chain of custody
- General Laboratory Reporting (BP #7)
  1) Data sets on tests performed, results, and other associated information
- Statistical Analysis & Surveillance (BP #8)
  1) Data sets on tests performed and results
  2) EPI data sets associated with test submittals

- Laboratory Billing (BP #9)
  1) Data sets on tests performed for each submitter where a charge is billed
- Contract & Grant Management (BP #10)
  1) Data on the number of tests performed under each contract and grant at periodic intervals
  2) Projections of contract and grant fulfillment (time when the agreed upon testing will be completed based on testing rates)

BP #1F: Test Result Receiving by Entities on Distribution List to:

- Test Result Report Preparation and Distribution (BP #1E)
  1) Inquiries on test report status and delivery
  1) Inquiries on historical tests; chain of custody, etc.
- Statistical Analysis & Surveillance (BP #8)
  1) Inquiries for statistical analysis information

BP #2: Test Scheduling to:

- Submitters (BP #1A):
  1) Updates of test schedule
  2) Confirmation of test scheduling requests
- Lab Receiving (BP #1B):
  1) Current Test Schedule Information (Rush orders, etc.)
- Test Preparation (BP #1C)
  1) Current test schedule information (rush orders, etc.)
- Lab Mutual Assistance (BP #16)
  1) Notification of tests being diverted from specific submitters
  2) Estimates of test volume anticipated to be diverted by timeframe

BP #3: Proactive Specimen/Sample Collection to:

- Submitters (BP #1A)
  1) Current specimen/sample collection schedule
- Test Scheduling (BP #2)
  1) Specimen/sample collection schedules
  2) Specimen/sample collection schedule modifications/status
- Inventory Control (BP #6)
  1) Schedule for kit distribution
  2) Information on payment due for kits

BP #4: Specimen/Sample Tracking/Chain of Custody to:

- Submitters (BP #1A):
  1) Chain of custody requirements and form recommendations
- Lab Receiving (BP #1B)
  1) Specimen/sample tracking/chain of custody information
- Test Preparation (BP #1C)
  1) Specimen/sample tracking/chain of custody information
- Testing, Results Recording & Verification (BP #1D)
  1) Specimen/sample tracking/chain of custody information
- Test Result Report Preparation & Distribution (BP #1E)
  1) Specimen/sample tracking/chain of custody information

BP #5: Media/Reagent Manufacturing to:

- Test Preparation (BP #1C)
  1) Media or reagent batch delivery
  2) QC documentation
- Testing, Results Recording & Verification (BP #1D)
  1) Media or reagent batch delivery
  2) QC documentation

BP #6: Inventory Control to:

- Submitters (BP #1A):
  1) Shipment of specimen/sample collection kits to selected submitters at specified times for prescheduled specimen/sample collection schedules
  2) Shipment of collection kits in response to submitter request
- Lab Receiving (BP #1B)
  1) Delivery of requested glassware and other inventory items needed for processing incoming specimens samples.
  2) Order fulfillment documentation and associated QC (if any applicable)
- Test Preparation (BP #1C)
  1) Delivery of requested glassware, media, reagents, etc
  2) Order fulfillment documentation and associated QC (if any applicable)
- Proactive Specimen/Sample Collection (BP #3)
  1) Kit delivery capability/status
  2) Kit shipping documentation (shipped to whom/where/when)
- Reagent, etc. manufacturing (BP #5)
  1) Orders for manufactured item replenishment and estimated quantity needed
  2) Manufactured item inventory status and usage rates
- Lab Billing (BP #9)
  1) Billing information for items shipped to submitters and others (such as media used by other laboratories)

BP #7: General Laboratory Reporting to:

- (No outputs to other specific business processes. However, report distribution to all management and external entities.)

BP #8: Statistical Analysis & Surveillance to:

- Test Result Report Preparation & Distribution (BP #1E)
  1) Provision of test statistical information for test reporting (comparison data)
- Test Result Report Receiving (BP #1F)
  1) Statistical analysis reports as requested
  2) Standard statistical analysis, trends, observations on test loads, etc.

BP #9: Lab Services Billing to:

- Submitters (BP #1A)
  1) Invoices for kits and other materials
- Test Result users (BP #1F)
  1) Billings for testing services provided
- Inventory Control (BP #6)
  1) Payment status on kits, etc. if payment required prior to shipments to submitters
- General Laboratory Reporting (BP #7)
  1) Billing reports
- Contract & Grant Management (BP #10)
  1) Grant & contract testing services provided
  2) Dollar value by grant/contract based on standard costs if needed

BP #10: Contract and Grant Management to:

- Test Scheduling (BP #2)
  1) Information on contract/grant testing schedule requirements
- Proactive Specimen/Sample Collection (BP #3)
  1) Information on contract/grant test sampling schedules
- Lab Billing (BP #9)
  1) Contract/Grant billing information
  2) Test volumes allowed under Contract/Grant

BP #11: Training, Education & Resource Management (including instruments) to:

- Submitters (BP #1A)
  1) Training schedule
  2) Special education (as needed depending on QA related findings)
- Test Specimen/Sample and Request Receipt (BP #1B)
  1) Training schedule
  2) Special education (as needed depending on QA problems)
- Test Preparation (BP #1C)
  1) Training schedule
  2) Special education (as needed depending on QA problems)

- Testing (BP #1D)
  1) Training schedule
  2) Special education (as needed depending on QA problems)
- Test Scheduling (BP #2)
  1) Available qualified personnel counts by instrument
  2) Instrument availability schedule
- Proactive Specimen/Sample Collection (BP #3)
  1) Available qualified personnel counts by instrument
  2) Instrument availability schedule

BP #12: Laboratory Oversight and Licensing to:

- Test Submitter (BP #1A)
  1) Proficiency tests and instructions
- Oversight inspection schedules
  1) Testing, Results Reporting, & Verification (BP #1D)
  2) Requests for proficiency tests

BP #13: Customer Concerns to:

- QC/QA (BP #14)
  1) Summaries of complaints and problems for use in QA measures

BP #14: Quality Control (QC) and Quality Assurance (QA) Management to.[3]

- Test Submitter (BP #1A)
  1) QA concerns and recommendations
- Test Specimen/Sample and Request Receipt (BP #1B)
  1) QC/QA concerns and recommendations relating to specimens/samples
- Test Preparation (BP #1C)
  1) QC/QA concerns and recommendations
- Testing, Test Recording & Verification (BP #1D)
  1) QC/QA concerns and recommendations
- Test Result Report Preparation and Distribution (BP #1E)
  1) –QC/QA concerns and recommendations
- Test Result Report Recipients (BP #1F)
  1) QC documentation on specific tests when requested

[3] Exhibit 3 only shows the QC relationships with the elements of Business Process #1, the QC/QA business process in reality touches on every other internal laboratory business process. To emphasize this point, a separate QC/QA heading has been included in the Chapter V specific requirements for every business process.

BP #15: Laboratory Safety/Accident Investigation to:

- Test Specimen/Sample and Request Receipt (BP #1B)
  1) Safety materials and status reports
  2) Accident investigation reports
- Test Preparation (BP #1C)
  1) Safety materials and status reports
  2) Accident investigation reports
- Testing, Test Recording & Verification (BP #1D)
  1) Safety materials and status reports
  2) Accident investigation reports
- QC & QA (BP #14)
  1) QA data on safety and accidents

BP #16: Laboratory Mutual Assistance to:

- Submitter (BP #1A)
  1) Information on test requests to be diverted [Out of Scope]
- Test Specimen/Sample and Request Receipt (BP #1B)
  1) Test load status and backlogs
- Testing, Results Recording, & Verification (BP #1D)
  1) Diverted test request test reports

Each of these interdependencies will be translated into LIM system requirements specifications in **Section V**.

Implementation Prioritization

Some laboratories inevitably will be forced to stagger implementation of a new LIM system. This section has been included to assist them in categorizing (or prioritizing) business processes.

A LIM system supports the laboratory's core business process, testing. Prioritization begins with the assumption that test processing is the lab's primary objective. Priorities for the remaining business processes are set according to their relative importance in test processing.

This analysis is based on the degree to which the LIM system database required for support of test processing contains data sets relevant to one of the other business processes. For example, Quality Control (QC) and Quality Assurance (QA) (BP #14) are tightly linked to test processing, because the associated QC must be identified in any test, and the user must be able to reference the LIM system historically to determine whether QC sets for the instrument and other test items such as media were relevant at the time the test was performed. QC results also determine whether or not the test result was reliable and ready for verification and reporting.

*Priorities are stated in groups, with no internal prioritization. [*Note that General Laboratory Reporting (BP #7) is not included in the priority groups below since reporting spans all of the specific business processes.*] The priority groups and business processes within each group are as follows:*

First Priority Group:

- QC and QA (BP #14)
- Test Scheduling (BP #2)
- Proactive Specimen/Sample Collection (BP #3)
- Inventory Control (BP #6)

Second Priority Group:

- Reagent, etc. Manufacturing (BP #5)
- Lab Billing (BP #9)
- Statistical Analysis & Surveillance (BP #8)
- Lab Mutual Assistance (BP #16)

Third Priority Group:

- Sample Tracking/chain of custody (BP #4)
- Contract and Grant Management (BP #10)
- Training and Resource Management (BP #11)
- Lab Oversight & Licensing (BP #12)
- Customer Concerns (BP #13)
- Lab Safety/Accident Investigation (BP #15)

V. BUSINESS PROCESS REQUIREMENTS SPECIFICATIONS

The mix of initial versus confirmatory testing varies from state-to-state and location-to-location based on the operating philosophy and business model of that PHL. Moreover, the way in which a test is processed through a laboratory varies from one PHL to another (for example, the difference between central receiving and accessioning versus individual laboratory accessioning). The most important factor is how a PHL views the differences in the information processing support needs of its internal laboratories. The difference most commonly cited relates to the distinction between clinical and environmental testing. Nonetheless, in each instance, testing is initiated by the receipt of a specimen/sample, some form of scheduling is required, and test results have to be recorded and reported.

This observation has been characterized as *diversity within commonality* for the purpose of laboratory testing requirements specification. It is this commonality that creates the framework within which diversity is expressed. Thus, the requirements specifications call for the ability to create user-defined, laboratory-specific worksheets for batch processing as well as laboratory-specific request forms and associated data sets.

The requirements specifications reflect the unique requirements associated with PHL activities. Of primary importance is the population-based orientation of PHLs relative to the focus on individual testing common in commercial laboratories. This perspective has numerous impacts on PHL LIM system requirements, reflected in requirements specifications relating to multiple users of test result information, the importance of geographic data, and the need for patient name and address along with expanded demographic and epidemiological data.

The requirements specifications are intended to be "forward looking" rather than mimicking current practice. A PHL may not be able or need to implement certain segments of the requirements at this time. However, all of the requirements are feasible and practical in the next five years if the PHL is doing or expecting to do all or most of the business processes.

The specifications for each business process are not intended to suggest any physical implementation strategy. A PHL could choose to interface the LIM system with other packages or commercial off-the-shelf (COTS) solutions. These are decisions to be made by each PHL based on its own needs and the broader organizational structure in which it operates (for example, a state may provide adequate centralized inventory support that could be interfaced with the LIM system).

This section sets forth business process requirements specifications and contains information in the following categories for each of the 16 business processes:

- Overview: A summary of the business process
- Workflow summary: A brief description of the key workflow elements associated with the business process
- Business process specific requirements for each workflow area: Presentation of the key requirements specifications associated with the workflow elements
- Selected QC/QA specifications relevant to each business process
- Selected system output requirements: Examples of relevant outputs/reports not included in business process specific requirements above

This section begins with the core PHL business process, Business Process #1: processing of laboratory test requests. This process has been broken into four internal segments as reflected in **Figure 3** of the previous section:

B – Test Request and Samples Receiving

C – Test Preparation

D – Testing, Results Recording and Verification

E – Test Result Report Preparation and Distribution

The other 15 business processes are each treated as single segments.

References to "specimens" and "samples" should be interpreted as referring to the entire spectrum of clinical, environmental, and other types of testing performed by public health laboratories.

Specifications For BP #1: Laboratory Test Processing

BP #1-B: Laboratory Test Processing (Clinical and Environmental)
Segment B – Test Request and Samples Receiving

Overview: This segment of test processing deals with test request and specimen/sample receipt and initial processing activities. Once this work is completed, the specimen/sample will have been routed to the specific laboratory and the test request entered in the LIM system. Any problems with test submittals will have been identified and the submitter notified.

Workflow summary: Receive and enter the test requests into the LIM system, check specimens/samples for completeness and acceptability, accession specimens/samples, and route to appropriate laboratories.[4]

BP# 1-B. Laboratory specific requirements for each workflow area:

1.1. Receive and log test requests received in PHIN standard HL7 message structure utilizing agreed upon coding standards

1.1.1. Ability to create test request records in the LIM system directly from the electronic test request records, (this refers to the ability to parse a test request record), including specimen package contents (e.g., group electronic test request submittals by physical specimen package where a package may contain multiple specimens for multiple subjects)

1.1.2. Ability to audit electronic test request records and return acknowledgement (ACK) me sages to submitter verifying receipt and processing of the transmission

1.1.3. Ability to manually enter test request if received on paper form and perform independent verification on selected data fields by re-entry of the data in a second pass

[4] The requirements specifications have been stated in relation to a central receiving operation. However, the same specifications would be valid if receiving is done in each individual laboratory.

1.1.4. Ability to handle different test request information content for clinical versus environmental versus othermiscellaneous specimen/samples and identify each request record as to whether it is a clinical, environmental or other test request in the LIM system

1.1.5. Ability to accept and process additional epidemiology data associated with test requests from selected submitters (e.g., supplemental data segments; also see 8-C, 8.1.2.)

1.1.6. Ability for the user to define and create supplemental data segments and specify usage byselected submitters (e.g., a stream water testing contract may call for the collection of additional specified data only relevant to the specific stream study under the contract)

1.1.7. Ability to enter request forms with multiple test requests

1.1.8 Ability to enter multiple request forms from the same submitter as a batch; without repeating entry of common data

1.1.9. Ability to record whether or not hazard screening for BT samples (explosive, chemical radiological, etc.) has been done before receipt by laboratory.

1.1.10. Ability to link multiple specimens from same individual at same time for same test from

1.2.1. Link specimens/samples to corresponding test requests and verify completeness

1.2.1. Ability to link specimens/samples to corresponding electronic test request records via a LIM system display of unprocessed test requests for a given submitter, submittal date, and package ID[5]

1.2.2. Ability to record any specimen/sample problems that prevent testing to proceed (may happen at any point in the testing process)

1.2.3. Ability to send PHIN compliant HL7 error messages to a submitter delineating which test request(s) have been rejected, and generate these messages automatically for all errors associated with a specific package once any problems have been recorded in the LIM system

1.2.4. Provide mechanism for name matching where LIM system "suggests" patient names in database that might be the same as that entered for current test request

1.2.5. Ability for user to establish link between current request name and database name (i.e., associate multiple separate test requests to same individual). For example, the linking of acute to convalescent specimens/samples when they are sent in separately.

1.2.6. Ability to monitor test requests that require subsequent submittals such as acute and convalescent specimens for the same patient

1.2.7. Ability to generate follow up letters and reports on outstanding subsequent test submittals (e.g., the notification of a submitter that a convalescent specimen/sample is required when the acute test was positive)

[5] The approach assumes that the submitter will send one or more packages of specimens/samples for a given date and that each package will contain the specimens/samples for one to many test requests and that the test requests are electronically submitted with the same date the package is sent by the submitter.

1.3. Accession specimens/samples

1.3.1. Ability to accession specimens/samples with PHL wide unique numbers or individual laboratory specific unique numbers using a common accessioning protocol that allows real-time tracking of specimen progeny and siblings

1.3.2. Ability to create specimen/sample labels

1.3.3. Ability to create specimen/sample barcode labels using PHL designated barcode format

1.3.4. Ability to create post script numbers for splits and aliquots of original specimen/samples

1.3.5. Ability to use accession number as a direct link to the corresponding LIM system test request record

1.3.6. Ability to create skeleton test request record (test ID, accessioning number, and other core data) when total data entry might preclude timely testing

1.3.7. Ability to flag skeleton record as incomplete and create queue of incomplete test request records needingremainder of data to be entered

1.4. Route specimens/samples to appropriate laboratories

1.4.1. Ability to update LIM system with routing information (laboratory to which a specimen sample is directed) and status code

1.4.2. Ability to route specimens/samples associated with a test request submittal to multiple laboratories

1.4.3. Ability to route test requests to a centralized aggregation point, such as the state health department, forspecial projects or when an event prioritization occurs.

1.4.4. Ability to route specimens/samples to CDC or other reference laboratories and create supporting docmentation and packaging/shipping labels

1.4.5. Ability to create electronic transactions utilizing CDC PHIN HL7 compliant standards for order messages.

1.4.6. Ability to utilize a directory or registry to hold message recipient contact and protocol information

1.4.7. Ability to modify or inactivate a test request

BP# 1-B: Selected QC/QA specifications:

1.5.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP# 1-B: Selected system output requirements:

1.6.1.Report of specimen/sample rejections by rejection code and submitter for user specified time period

1.6.2. Report on tests requests forwarded to other reference laboratories

1.6.3. Report on specimens/sample splits and aliquots

1.6.4. Reports on number of specimens accessioned by site, program, etc.

1.6.5.Report of overdue specimens, including the ability for an authorized user to define when a specimen is overdue

1.6.6. Reports on test requests by submitter and timeframe

BP # 1-C: Laboratory Test Processing (Clinical and Environmental)
Segment C – Test Preparation

Overview: Upon receipt in the laboratory, the specimen/sample will be prepared for testing. This work includes creating any desired aliquots, any preliminary processing completed, and batch runs created where appropriate.

Workflow summary: Test preparation preliminary processing, and batch run[6] creation

BP # 1-C: Laboratory specific requirements for each workflow area:

1.1. Test preparation and preliminary processing

1.1.1. Ability to create additional post scripted accessioning numbers for laboratory splits and aliquots

1.1.2. Ability to create and schedule a new test based on type of testing originally requested (a form of reflex testing)

1.1.3. Ability to update test request status and tracking record to track splits and aliquots

1.2. Batch run creation (Also see Section VII on database interfaces)

1.2.1 Ability for user to define test instrument specific uniquely defined batches based on the specific needs of the analytical area. Further:

a) Ability to determine position of each standard, control, and patient specimen in the batch and specify specimens/samples for duplicate testing.

b) Ability to track specimen/sample dilutions

c) Ability to specify whether test results are manually entered or will be "resulted" from an instrument. If test results are manually entered, the system should automatically call up all items on the list sequentially or the whole worksheet to be resulted at operator request.

d) Ability to select all pending tests for worksheet generation, select a range of pending specimen/samples, if desired, (by date range, for example) and "tag" specific tests for worksheet generation.

e) Ability to note specific safety concerns or hazards associated with the procedure's performance, reagents, on each worksheet

1.2.2. Ability to create and print batch worksheet and allow user to regenerate (modify) the worksheet and add tests up to the point when the batch run results are entered.

1.2.3. Ability to prioritize test requests from test queue for inclusion in a batch.

1.2.4. Ability to display and/or print batch map (specimen/sample location by well/position).

1.2.5. Ability to create additional numerical sequence numbers and labels for consecutive specimen/sample numbering within a batch.

[6] As used in this document the term "batch" refers to both individual testing (a batch of one) and multiple specimen/sample testing (a batch of more than one). Some of the batch functionality does not apply to individual testing.

BP # 1-C: Selected QC/QA specifications:

1.3.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP # 1-C: Selected system output requirements:

1.4.1. Report of reflux and other subsequent testing organized by source test and reason

1.4.2. Report of patient name matches accepted and contents of combined lab records

BP # 1-D: Laboratory Test Processing (Clinical and Environmental) – Segment D – Testing, Results Recording, and Verification

Overview: This segment of the test processing encompasses the testing, QC checks for validity of the results, the recording of the test results, and the generation of additional test requests where additional testing, based on the initial test results, is needed. In addition, in the case of QC failure, retesting requests are generated.

Workflow summary: Test results reading and recording, QC verification, and creation of additional test requests

BP# 1-D: Laboratory specific requirements for each workflow area:

1.1. Test result recording (Also see specifications in Section VII Database Interfaces)

1.1.1. Ability to present uniquely identified batch worksheet result entry screen in same sequence as batch

1.1.2. Ability to allow manual entry of positive entries only and then default remainder of tests in batch to negative description

1.1.3. Ability to select result description from user defined table for valid entries for each given test and apply the selected description to multiple tests in batch

1.1.4. Ability to utilize tables containing the Systematized Nomenclature for Human and Veterinary Medicine (SNOMED) for results descriptions where applicable or ability to map local codes used with the LIMS to SNOMED codes[7].

1.1.5. Ability to select coded comments for inclusion with test result

1.1.6. Ability to enter text field comments related to entire batch with the ability to code the comment as “internal lab use only” when appropriate so it doesn’t show on reports sent outside the lab

1.1.7. Ability to remove “obvious outliers” when applicable

1.1.8. Ability to support complex calculations (concentration calculations, etc.)

1.1.9. Ability to change the specimen condition in resulting (QNS, lab accident, etc.)

1.1.10. Ability to enter text field comments related to specific test result

1.1.11. Ability to highlight positive tests so they stand out on batch presentation

1.1.12. Ability to capture ID of laboratory technician performing the test and creating the result entries along with date and time of analysis. Methods would include biometrics, etc.

[7] There are situations where no appropriate SNOMED codes are available and available codes are often at too low a level for test result reporting.

1.1.13. Ability to allow easy recombination of individual determinations into multiple test suites (generally a tree type structure which may have multiple grouping levels)

1.1.14. Ability to average results on duplicate specimens/samples using the intra specimen sample variation as a QC parameter and store a record of all results

1.1.15. Ability to track specimen/sample dilution factors back to undiluted specimens/samples and select the most appropriate test result (based on per test preferred concentration ranges) and select a correction of the dilution and record a corrected result

1.1.16. Ability to monitor for and create alerts of "major" variations from normal

1.2. QC verification

1.2.1. Ability to define test (batch) specific control ranges

1.2.2. Ability to flag batch as suspect due to QC test values

1.2.3. Ability to reject the batch based on QC failure and create appropriate audit trail

1.2.4. Ability to tag each test in batch with QC failure reason

1.2.5. Ability to present peer (second reading entry or review) validation screen

1.2.6. Ability to enter peer validation edits and changes while keeping original recorded results with full audit trail for all changes/modifications

1.2.7. Ability to enter peer reviewer ID for each batch

1.2.8. Ability to create queue of batch test worksheets ready for peer or supervisory review

1.2.9. Ability to present supervisor review screen

1.2.10. Ability to enter supervisor validation edits and changes while keeping original and peer review recorded results

1.2.11. Ability to release test batch for result printing once all required reviews have been completed

1.2.12. Ability for a supervisor to over-ride a batch or individual test result tagged with a QC failure and to log a comment on why it was released despite the QC failure

1.3. Creation of additional test requests

1.3.1. Ability to trigger retest requirement and set up the tests in the test queue

1.3.2. Ability to arbitrarily repeat any individual test request in a batch

1.3.3. Ability to reuse same accessioning number for retest run

1.3.4.Ability to link rejected test run to subsequent rerun

1.3.5. Ability to create additional test requests associated with initial test results

1.3.6. Ability to link initial test information to subsequent/additional testing

1.3.7. Ability to reconcile current result with a previous result on same patient when result is different

BP# 1-D: Selected QC/QA specifications:

1.4.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

1.4.2. QC reports on what was changed, why, and by whom

BP# 1-D: Selected system output requirements:

1.5.1. Workload statistics based on provider, test result, and time frame

1.5.2. Ability to create report on pertinent run data for a specific batch including QC data associated with each test request

BP # 1-E: Laboratory Test Processing (Clinical and Environmental) – Segment E – Test Report Preparation and Distribution

Overview: The recorded test results are used as the basis for the preparation and delivery of the test results report to the submitter and the creation and delivery of test results reports to other designated users

Workflow summary: Create and deliver hard copy or electronic test reports to submitter and other qualified users and prepare test result tabulations for other qualified users

BP# 1-E: Laboratory-specific requirements for each workflow area:

1.1. Create and deliver test results to submitter

1.1.1. Ability to create PHIN-compliant HL7[8] electronic test report transactions utilizing SNOMED and LOINC[9] coding standards

1.1.2. Ability to transmit electronic test results either individually or by batch

1.1.3. Ability to control which results, detailed or summary, should be included in a report

1.1.4. Ability to transmit print image so that submitter can print out hard copy in PHL pre scribed form including letterhead image

1.1.5. Ability to send a test impression summary result that is an interpretation of multiple detailed test results

1.1.6. Ability to control which results, detailed or summary, should be included in a report

1.1.7. Ability to transmit electronic test reports in secure format (such as ebXML format utilizing Public Key Infrastructure (PKI) encryption) conforming to PHIN and HIPAA standards for privacy and security

1.1.8. Ability to attach electronic signature to each electronic record

1.1.9. Ability to print hard copy test report for mailing containing an electronic signature (one way is to attach the printed signature field onto the test record as the report is prepared for printing rather than having it as a standard text field in the print format)

1.1.10. Ability to indicate that the report is “preliminary,” “final,” “corrected,” or “amended (CAP and CLIA requirements) and track multiple revisions to the same report

1.1.11. Ability to sort printed hard copy test results by submitter prior to printing, and print a cover sheet for each submitter grouping

1.1.12. Ability to create mailing labels for each submitter test report package

1.1.13. Ability to update test request record to indicate report has been created

1.1.14. Ability to create duplicate or amended test reports in either electronic or hard copy with

[7] The HL7 transaction structure is not yet adequate for public health usage; particularly in the area of Epi data.

[8] PHIN references the use of LOINC standards that map to observations that may be too specific for the purpose of public health laboratory test reporting. For this reason, a “higher” level standard may be needed.

indication that they are “duplicate” or “amended”

1.1.15. Ability to flag list of user-defined results requiring immediate submitter notification, including creation of call lists (submitter table will carry contact information)

1.1.16. Ability to record notification contact information including date and time, person notified, PHL person making the contact, and the result(s) recorded

1.2. Prepare test result tabulations for other qualified users

1.2.1. Ability to qualify (i.e., grant permission to see) users by specific report

1.2.2. Ability to create and maintain authorized distribution list for each report (since some reports can contain HIPAA-defined personal health information for which the laboratory would have to have formal business associate agreements)

1.2.3. Ability to read a registry or directory to get contact and/or protocol information for report recipients

1.2.4. Ability to utilize a rules engine to determine the recipients for a message. The rules would dictate different recipients based on parameters ranging from: the type of test requested in the received test order; to the heightened urgency of the test as would be dictated during an event

1.2.5. Ability to tabulate test results by “positive” or total tests processed or a “rate positive” for a given geographic area by user over a specified time period through the use of a GIS tool

1.2.6. Ability to release individual test results to a submitter prior to the completion of other …. related testing or recording of other test results in the same batch

BP# 1-E: Selected QC/QA specifications:

1.3.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP# 1-E: Selected system output requirements: (Many of these are embedded in the above requirements specifications)

1.4.1. Communicable disease reports to CDC, state and county epidemiology, and others as necessary

1.4.2. Data exports to other reporting programs such as CDC’s Public Health Laboratory Information System (PHLIS), state on-line activity reporting (STELLAR, etc.) and Epi Info or its successor.

1.4.3. Reports of number of tests per instrument per time period

1.4.4. Reports of number of tests performed by work unit by time period

1.4.5. Reports of number of tests by method by time period

1.4.6. Ability to create reports of tests (last three entries) for client specimen/sample tests only (i.e., exclude QC and proficiency tests)

1.4.7. Data extracts to FDA (food quality, food alterations, etc.)

1.4.8. Lab test kit performance reporting (reagent failure, performance problems, etc.)

1.4.9. Reports and data extracts for environmental health to EPA and others (SDWIS, STORET, etc.)

1.4.10. Ability to create “overlays” of data from both clinical and environmental testing by geographic area

1.4.11. Reports on number of duplicate, amended, etc., reports issued

Specifications For BP #2: Test Scheduling

Overview: Long-term test workload projections are covered in the next business process. This business process deals with prioritizing and processing the test workload already received. Scheduling factors include request urgency, specimen/sample holding time, and other factors relating to the timely processing of the test requests. In addition, the test schedule, in combination with longer-term workload projections, provide the basis for activating mutual assistance agreements (See Business Process #16—Laboratory Mutual Assistance).

Workflow summary: Add requests received, prioritize requests, remove requests that have been completed, and publish real-time test schedule.

BP# 2: Specific requirements for each workflow area:

2.1. Add requests received or additional tests generated in-house

2.1.1. Ability to add test requests and specimens/samples received and accepted by PHL to specific test schedule

2.1.2. Ability to add in-house generated tests to schedule

2.2. Prioritize requests

2.2.1. Ability to assign a submitter priority to a specific test

2.2.2. Ability to assign priority by type of test

2.2.3. Ability to generate internal priority based on holding times, number of days since receipt, and other factors associated with specimen/sample

2.2.4. Ability to adjust priorities

2.2.5. Ability to organize test "queue" by priority

2.3. Remove completed requests/transfers from active queue

2.3.1. Ability to automatically delete tests from the schedule once the result has been entered in the LIM system (and restore if needed)

2.3.2. Ability to manually delete a test request from the schedule/batch (and restore if needed) or delete an entire batch

2.3.3. Ability to select tests for diversion to mutual assistance laboratory and create file of diverted tests

2.3.4. Ability to create packing lists and other documentation for diverted tests

2.3.5. Ability to adjust holding times based on extractions and other reasons

2.3.6. Ability to divert specimens/samples to another area in-house based on a trigger from a completed test for subsequent testing (e.g., isolation of *E coli* 0157 through PFGE)

2.4. Publish real-time test schedule

2.4.1. Ability to calculate daily processing capacity for each test; adjusted by instrument avail ability and personnel availability

2.4.2. Ability to translate workload into N-day "rolling schedule" based on capacity limits where N is the number of days ahead of current date the user wants to include in the display

2.4.3. Ability to track test loads in the schedule at the specific instrument level

2.4.4. Ability to indicate which tests have been passed through to another laboratory (mutual assistance situation, etc.)

2.4.5. Ability to record test results for tests performed by another laboratory and indicate name of person who performed the test

2.4.6. Ability to create subsequent test requests from a given test request

2.4.7. Ability to flag overdue test requests based on schedule and notify submitter

BP# 2: Selected QA specifications:

2.5.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 2: Selected system output requirements:

2.6.1. Reports of test processing time by priority

2.6.2. Test status reports

Specifications For BP #3: Proactive Specimen/Sample Collection (Prescheduled Tests) & Overall Workload Projections

Overview: Specimen/sample collection schedules may be received from submitters either as a part of a contract or grant agreement or independent of any formalized agreement. These specimen/sample collection schedules can involve kit distribution to multiple locations/ collectors over multiple time frames. The kit distribution process and timing constitutes a "leading indicator" for subsequent test submissions. Overall workload projections are derived from adding "regular" submittal projections to the collection schedule derived projections.

Workflow summary: Record collection distribution schedules, monitor corresponding test request submittals, and update anticipated future workload

BP# 3: Specific requirements for each workflow area:

3.1. Record collection kit distribution schedules in schedule system

3.1.1. Ability to manually enter specimen/sample collection schedules by submitter and collector kit delivery point

3.1.2. Ability to electronically receive and process submitter collection schedules

3.1.3. Ability to translate collection schedule into anticipated test request receipt dates with the capability for a separate routine for each submitter

3.1.4. Ability to create submitter collector specific kit delivery orders including volumes, shipping dates,and out dates

3.2. Record test requests received against collection schedule

3.2.1. Ability to identify receipt of test requests generated from the collection schedule

3.2.2. Ability to adjust workload projections by deducting the test requests received from the collection schedule

3.3. Update anticipated future workload projections

3.3.1. Ability to present adjusted workload projects as new collection schedules are added and tests received are deducted.

3.3.2. Ability to have "real-time" current schedule available online for selected users

3.3.3. Ability to create and add projections of "regular" workload by test for inclusion in the overall workload projections

BP# 3: Selected QA specifications:

3.4.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 3: Selected system output requirements:

3.5.1. Report of Current Specimen/Sample Collection Schedule by individual submitter or for all submitters

3.5.2. Report of Current Test Workload by date and specific test

3.5.3. Report of Current Kit Distribution orders by submitter, collector and time period

Specifications For BP #4: Specimen and Sample Tracking/Chain of Custody

Overview: In many instances, the chain of custody documentation originates outside the PHL and will arrive with the test specimen/sample. Once started, the chain of custody needs to be maintained so most PHLs simply continue using the manual form. However, as back up to the formal chain of custody, the LIM system contains a great deal of information about the routing of the specimen/sample through the testing process. It could also contain entries to track the specimen/sample into and out of primary storage and its ultimate disposition. Ideally, the LIM system would be able to identify the location of a specimen/sample at any step in the process, at least by storage location and device ID, if not also by the shelf and box location wherever it is stored. This would also facilitate the need to establish the link between specimen/samples and the QC documentation on storage temperature control, in that the temperature control sheets are date range-specific, and the date range for which the specimen/sample was in a given refrigerator would be captured as a part of the specimen/sample tracking transaction.[1]

Workflow summary: Tracking specimens/samples, control materials and media movement into and out of storage.

BP# 4: Specific requirements for each workflow area:

4.1. Record movement of specimens/samples

4.1.1. Ability to record storage refrigerator or container ID, date stored, date removed for a specific specimen/sample ID

4.1.2. Ability to record dates and location when a specific specimen/sample was out of storage for testing process (could be linked to the test batch start and end times if recorded as a part of batch processing)

4.1.3. Ability to record specimen/sample disposition date and disposition code

4.1.4. Ability to move entire contents of a given storage location to another location (freezer mechanical failure for example)

4.1.5. Ability to make a tracking stop mandatory (i.e., a specimen must end up in a specific freezer)

4.1.6. Ability to identify and track individuals with specimen/sample custody

4.1.7. Ability to support and modify “chain of custody routing rules” by type of specimen/sample and use the rules for alerts when the actual chain of custody deviates from the standard rule set

4.1.8. Ability to access threat assessment information for each specimen/sample

4.1.9. Ability to flag a specimen/sample with a user defined code for “legal” or other desired code

4.1.10. Ability to track specimen/sample to forwarded locations external to lab

4.2. Capture of temperature information

4.2.1 Ability to manually enter header record for specific temperature sheet for a specific refrigerator and sheet begin and end dates

[10] Although this paragraph deals with specimens/samples, it should also be noted it is equally or even more important to establish the relationship between temperature control sheets and media, reagents, antisera, and other important control materials.

BP# 4: Selected QA specifications:

4.3.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 4: Selected system output requirements:

4.4.1. Report on a given specimen/sample's location from receipt to disposition by location and date

4.4.2. Tracking reports of known specimens/samples (QC organisms, etc.)

4.4.3. Report on the contents of a given refrigerator/freezer on any given date

Specifications For BP #5: Media, Reagent, Stains, Controls, etc. Manufacturing

Overview: Based on manufacturer availability or cost a PHL may choose to manufacture media, reagents, stains, controls, or other items used by the laboratories for test processing. In some cases, the PHL may sell a portion of one or more manufactured items to another laboratory. External sales are covered in the inventory and kit business process.

Workflow summary: Receive and process orders, manufacture new lots as necessary, QC the lot, and replenish inventory

BP# 5: Specific requirements for each workflow area:

5.1. Receive and process orders from internal laboratories and replenishment orders from inventory control. The replenishment order may be for more plates, which would potentially cause a need for more media to be produced which would have a ripple effect back to the inventory business process.

5.1.1. Ability to record orders

5.1.2. Ability to schedule manufacturing run based on inventory counts and orders

5.1.3. Ability to flag minimum quantity levels for triggering of reorders

5.2. Manufacture new lot

5.2.1. Ability to create electronic recipe book with ingredients for each recipe

5.2.2. Ability to create raw ingredient needs for finished product lot, trigger appropriate orders from inventory, and record receipt from inventory

5.3. QC lot and replenish inventory with new lot

5.3.1. Ability to record QC and expiration date against each lot

5.3.2. Ability to increment inventory on hand quantity

5.3.3. Ability to track batch failures when QC failure in laboratory is associated with manufactured or purchased lot

5.3.4. Ability to create labels for marking incoming inventory as to date, time and hazard code (if any)

5.3.5. Ability to capture the internal QC result for QA purposes

BP# 5: Selected QC/QA specifications:

5.4.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP# 5: Selected system output requirements:

5.5.1. QC Documentation

5.5.2. Reports on manufactured items by time frame and use

5.5.3. Cost reports for each manufactured item

SpecificationsFor BP# 6: Inventory Control Including Kits & Forms Management

Overview: Of primary interest are inventory items needed for direct support of the testing process starting with kit order processing, assembly, and shipping. Other inventory items are ordered from the individual laboratories and delivered to the bench. In addition, the PHL may manufacture media and other items for sale to private laboratories and other PHL entities.

Workflow summary for kit management (a): Kit component ordering and receiving, kit assembly, submitter order receipt and processing, and shipping.

Workflow summary for inventory control (b): Monitor inventory quantities, create replenishment orders, receive inventory and add to balances, receive and fill orders from individual laboratories.

Workflow summary for forms management (c): The management of forms versions and distribution.

BP# 6: Specific requirements for each kit management workflow area:

6.1. (a) Kit component ordering and receiving

6.1.1. Ability to process proactive specimen/sample schedules and set delivery dates and quantities

6.1.2. Ability to track inventory status and create replenishment orders for kit components based on assembled kit shipping schedule

6.1.3. Receive component orders and increment stock inventories

6.2. Process submitter orders

6.2.1. Ability to create order packing slips for kit shipment to specific submitter locations based on proactive specimen/sample schedule delivery dates

6.2.2. Ability to receive and process kit orders directly from submitters either electronically or manually submitted

6.2.3. Ability to block order preparation based on submitter payment status or records indicate they have sufficient quantity on hand based on number of test requests received by the laboratory

6.2.4. Ability to create submitter kit invoice information for prepayment or payment subsequent to shipping for processing by billing function

6.2.5. Ability to decrease inventory counts for order items pulled for shipping

6.3. Ship submitter orders

6.3.1. Ability to create order package labels and change order status for each specific submitter ship to location

6.3.2. Ability to record shipping information for tracking purposes

BP# 6: Specific requirements for each inventory control workflow area:

6.4. (b) Monitor inventory levels and create replenishment orders

6.4.1. Ability to monitor inventory levels and anticipated usage

6.4.2. Ability to create replenishment orders

6.5. Receive orders and stock inventory

6.5.1. Ability to update stock on hand and decrease outstanding order quantities based on quantities received

6.6. Receive and fill internal and external laboratory and media kitchen orders

6.6.1. Receive and record orders (or receive them electronically from the individual laboratories or media kitchen)

6.6.2. Ability to decrease inventory counts for order items pulled for delivery to bench or shipped to other laboratories

6.6.3. Ability to create billing invoice for external sales

6.6.4. Ability to produce physical inventory worksheets and reconcile physical inventory counts with LIM system counts

6.6.5. Ability to create inventory labels to track date received, time put in use, etc.

BP# 6: Specific requirements for each inventory control workflow area.

6.7 (c) Forms management workflow:

6.7.1. Ability to electronically create and distribute new versions of forms and other documents necessary for the operation of the laboratory.

6.7.2. Ability to manage the acquisition and distribution of forms and documents obtained in hard copy from external sources.

6.7.3. Ability for users to create and modify on-line requisition form for use by the laboratories in ordering items from inventory

BP# 6: Selected QC/QA specifications:

6.8.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP# 6: Selected system output requirements:

6.9.1. Inventory item usage by item and cost (also person/section who used)

6.9.2. Projections of inventory item usage by user defined time period and current proactive specimen/sample collection schedule, including estimated submitter inventory levels

6.9.3. Cost history by item, cost center, and other factors

6.9.4. Documentation of manufacturer QC for applicable items

6.9.5. Report on sales to external laboratories by laboratory and item for user specified time period

6.9.6. Reports of kit shipments to submitters by submitter location and/or collector

6.9.7. Reports of test cost profiles for all items supplied to laboratories

6.9.8. Reports on kit outdating (kits in inventory that have expiration dates)

Specifications For BP# 7: General Laboratory Reporting

This business process is covered in the General System Requirements section since these outputs do not apply to the specific business processes.

Specifications For BP# 8: Statistical Analysis and Surveillance

Overview: PHLs are neither the originators nor the users of the testing process in which they are intimately involved. However, they are in a position to greatly "enrich" the test data that is passed on to a variety of critical users and back to the submitters. Obviously, the key delive able is accurate and timely test results. These results represent the major objective of a PHL's activity and the reason for its existence. This business process deals with several ways in which the PHL can contribute to the broader public health objective of assessment, policy development, and assurance in terms of identifying and responding to adverse health events caused by disease or environmental factors. These contributions can be broken out into two general categories: as a conduit for surveillance data and as a contributor to the understanding of the cause and impact of adverse test result patterns.

Workflow summary: Capture and pass along non-test specific information, perform additional testing for typing and understanding primary results, and perform statistical analysis activities intended to identify suspicious test request and result patterns

BP# 8: Specific requirements for each workflow area:

8.1. Provide a conduit for non test specific data associated with test request submittals

8.1.1. Ability to capture and store patient name, address and demographic data submitted in conjunction with test requests from specific submitters

8.1.2. Ability to capture and store risk factors, exposure information, and other patient characteristics associated with a test request from specific submitters

8.1.3. Ability to electronically transmit non-test data elements to specified users

8.1.4. Ability to electronically or manually capture and store the non test specific data

8.2. Perform additional testing for typing and understanding of primary results

8.2.1. Ability to flag test results for which subsequent testing would be appropriate and automatically add follow up test requests to testing schedule

8.2.2. Ability to link the subsequent test results to the primary test report

8.2.3. Ability to build business rule tables for use in flagging in 8-C., 8.2.1

8.3. Analyze test result patterns

8.3.1. Ability to create positive test results as rates (positives related to total submittals)

8.3.2. Ability to analyze positive test patterns by type of test

8.3.3. Ability to present combinations of clinic and environmental tests by geographic location for clustering analysis

8.3.4. Ability to create user defined extracts of test data for electronic transmittal to specified users utilizing a standard open file structure format such as comma delimited flat files

BP# 8: Selected QA specifications:

8.4.1.Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 8: Selected system output requirements:

8.5.1. Ability to enable the PHL to send certain specified test results to users (such as Epidemiology) other than the submitter before being sent to the submitter.

Specifications For BP# 9: Billing for Laboratory Services[11]

Overview: Public health laboratories engage in a wide variety of billing activities designed to help offset the testing costs. In general, the billing is associated with the following aspects of the lab's workflow: provision of collection kits and containers to submitters, testing and test reporting, provision of training services, manufactured products such as media and proficiency tests, and laboratory annual licensing fees and inspection services.

Workflow summary: The work involves obtaining the billing information from the submitter or other entities, tabulating the items to be billed, applying appropriate billing rates, and creating the invoices and supporting billing documentation. In some cases, the billing function is not performed by the laboratory. However, in this situation the laboratory still has to collect and prepare the billing information associated with each invoice.

BP# 9: Specific requirements for each workflow area:

9.1. Obtaining submitter and other entity billing information

9.1.1. Ability to capture and maintain submitter billing address and responsible party information

9.1.2. Ability to specify which services are included under a given contract agreement and tag each service with a active/inactive flag (or timestamp each unique set of services active under the agreement for any given service provision date)[12]

9.1.3. Ability to capture and maintain agreed upon charges for specific services if different than standard PHL billing rates

9.1.4. Ability to capture relevant patient billing information for a given service date. Key items currently are patient's name and Medicaid number, since in most states Medicaid requires the service provider (in this case the laboratory performing the test) to bill for the service. In the future, this could also be extended to private insurance and other third-party payment sources

9.2. Identification of services performed and qualifying for billing

9.2.1. Ability to match services provided against the submitter billing master for creation of billing ledger entries (i.e., selection of billable services from the LIM system records recording the provision of the services)

9.2.2. Ability to allow for costing and fee development at either the instrument test level or test/method level.

9.3. Preparation of invoices and billing documentation

9.3.1. Ability for user to select specific billing ledger entries and create submitter specific billing invoices

9.3.2. Ability to create hard copy invoices grouped by submitter

9.3.3. Ability to create electronic billing invoices in lieu of paper

9.3.4. Ability to track billing and payment status

9.3.5. Ability to create billing invoices for services requiring prepayment that are linked to a submitter's purchase order or request for the services

[11] Although we have not included the accounts payable portion of a billing system here, since most laboratories do not do their own receivables tracking, there are a couple of specification statements that rely on capturing data relating to invoice payment.

[12] The term "service" is used rather than "test" to include training fees, annual license fees, etc.

9.3.6. Ability to block shipment of kits and other items if prepayment is required

9.3.7. Ability to collect payments, print receipts, and account for miscellaneous prepaid service requests (walk-in business for well water testing from the public for example)

9.3.8. Ability to support CPT (service) and ICD-9 (diagnosis) coding and HIPAA compliant HL7 transactions for billing purposes

9.3.9. Ability to create preliminary bill with initial test results

BP# 9: Selected QA specifications:

9.4.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 9: Selected additional system output requirements:

9.5.1. Ability to create billing reports by submitter, timeframe, service and other key parameters

9.5.2. Ability to track grant & contract services and associated fees

9.5.3. Ability to create reports for non-billable services indicating dollar value by grant/contract based on standard costs

9.5.4. Ability to report on test billing – what tests have been billed and the amount billed by selected time period

Specifications For BP #10: Contract and Grant Management

Overview: Contracts and grants between a PHL and users of the laboratory services may specify specific services (generally clinical or environmental testing) by type and quantity. Contract/grant limits may be stated in either number of tests to be performed or total dollars. The key aspect of contract and grant management from the LIM system perspective is the tracking and reporting of the services provided to the users to ensure that the PHL has met the conditions of the agreement in terms of the services provided and the timeframe in which they were provided. Some agreements also contain schedules for the timing of test requests over the life of the agreement.

Workflow summary: The workflow includes creating the anticipated test request schedule, ensuring that all collection kits required are delivered in a timely manner to the submitter(s), tracking of tests performed under the agreement (both dollars and numbers), and providing periodic updates of services performed under the agreement.

BP# 10: Specific requirements for each workflow area:

10.1. Contract/grant set up

10.1.1. Ability to create tracking file containing grantor name and address information, time period, tests covered, and specimen/sample collection schedules

10.1.2. Ability to create collection/collector name and address information associated with each contract/grant and link to collection schedule

10.1.3. Ability to record and track contract/grant objectives and their achievement

10.2. Service Scheduling & collection kit distribution

10.2.1. Ability to electronically create scheduling records in proactive specimen/sample collection schedule file [See Business Process #3—Proactive Specimen/Sample Collection (Prescheduled Tests)]

10.2.2. Ability to update proactive specimen/sample collection schedule based on contract grant modifications

10.3. Tracking tests performed

10.3.1. Ability to track tests performed under each contract by collector within each grantee contract

10.4. Periodic reporting on contract/grant status

10.4.1. Ability to alert test scheduling when contract/grant service limits have been or are close to being reached.

10.4.2. Grant reporting tickler file (due dates and responsible party in PHL)

BP# 10: Selected QA specifications:

10.5.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP# 10: Selected system output requirements:

10.6.1. Reports by contract/grant showing testing schedule, tests performed to date, and dollar value

10.6.2. Summaries of contract/grant activity by grantee
Billing summaries by test and unit cost for situations where the contract/grant is disbursed on the basis of work performed

10.6.3. Billing summaries by test and unit cost for situation where the contract/grant is disbursed on the basis of work performed

Specifications For BP# 11: Training, Education and Resource Management

Overview: It is not the intent to create a human resources management system within the LIM system. In general, if a lab is using a human resources management system it is for a larger governmental unit, such as the state's overall health department operation or possibly for all the state's various departments and divisions. However, there are a number of critical data elements that pertain only to laboratory testing capabilities: primarily certification and proficiency on a given instrument and method. To capture instrument-specific information in a general human resources system would not be feasible from the standpoint of the particularity of the data. By the same token, the information must be readily available for use with other related LIM system data. Thus, the only logical conclusion is that the data sets required for the support of the LIM-system specific training, education, and resource management (data such as instrument preventive maintenance)[13] must be incorporated in the LIM system to effectively support the laboratory's data needs in this regard.

Workflow summary for Training (a): Create employee (primarily laboratory technicians) training record and populate it with relevant training and education experience, monitor records and testing trends to determine training needs, determine training opportunities and schedule training, and record training in employee record.

Workflow summary for Resource (Instrument) Management (b): Create records for each instrument and instrument method if multiple methods are used on a given instrument, track instrument preventive and emergency maintenance, track next preventive maintenance date, and monitor instrument usage.

BP# 11: Specific requirements for each training workflow area:

11.1. (a) Create and maintain laboratory technician training records

11.1.1. Ability to create and maintain employee records pertaining to specialized training

11.1.2. Ability to track employee immunization status

11.1.3. Ability to create and maintain code tables for training activities

11.2. Monitor records for training needs

11.2.1. Ability to create and maintain business rules associated with each training activity including time intervals between "refresher" sessions

11.2.2. Ability to flag employee training records when additional training is required and create reminders

11.2.3. Ability to forecast training needs for specified time period (for example, projections for next 12 months by type of training)

11.3. Determine training opportunities and schedule training

11.3.1. Create calendar for training offerings that can be accessed by employees and submitters (for example, instructions on specimen/sample packaging and shipping) for self enrollment

[13] The instrument availability is included in this business process only because of the need to track personnel proficiencies by instrument. Test capacity is determined both by the availability of instruments and qualified personnel to perform the given test (and in some cases test method). Thus, training needs are tightly coupled with test load projections from scheduling and instrument availability.

11.4. Record training and proficiency information

11.4.1. Ability to record training received in laboratory supported training as well as external training attended

11.4.2. Ability for employees to view their training records

11.5. Track QC/QA issues and institute training for problem correction (both laboratory personnel and submitters)

11.5.1. Create and schedule training specifically addressed to correct QC or QA problems

BP# 11: Specific requirements for each resource (instrument) management workflow area:

11.6. (b) Create records for each instrument and instrument method

11.6.1. Ability to create and maintain master records for each instrument and associated method and periodic verification of minimum detection limits (MDL)

11.6.2. Ability to analyze test /method volumes and create capacity/day for each instrument method

11.6.3. Ability to track preventive and emergency maintenance activity by instrument, including average "down time" for a preventive maintenance and average down time per month associated with emergency maintenance

11.6.4. Ability to schedule instrument preventative maintenance and associated down time.

11.7. Track instrument preventive and emergency maintenance

11.7.1. Ability to record actual down time for preventive and emergency maintenance.

11.8. Monitor instrument usage (tests by method)

11.8.1. Ability to report on test volumes and times by instrument and method

BP# 11: Selected QA specifications:

11.9.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 11: Selected system output requirements:

11.10.1. Current training schedule and associated information

11.10.2. Schedule of special education (as needed depending on QA problems) and intended audience

11.10.3. Reports of available qualified personnel counts by instrument

11.10.4. Electronic instrument availability schedule and utilize it in scheduling activities

11.10.5. Instrument maintenance schedules

Specifications For BP# 12: Lab Certifications/Licensing

Overview: The major emphasis is support of initial and ongoing annual licensing of other laboratories in the jurisdiction (normally a state) by the PHL. This activity includes inspections, obtaining and verifying proficiency test results, and re-inspection when deficiencies are noted.

Workflow summary: The inspection cycle consists of scheduling inspections, both initial and annual, tracking proficiencies, performing the inspections and re-inspections if deficiencies discovered, and issuing licenses.

BP# 12: Specific requirements for each workflow area:

12.1. Proficiency Testing

12.1.1. Ability to create and maintain records of each proficiency test provided by the PHL and the results reported from the using laboratories

12.1.2. Ability to record results from proficiency testing supplied by other vendors/laboratories

12.1.3. Ability to track records associated with "foreign" (out-of-state) laboratories performing testing work within the PHL jurisdiction

12.2. Initial laboratory licensing

12.2.1. Ability to create master file record for new applicant laboratory including specific capabilities the laboratory wants to be certified to perform.

12.2.2. Ability to track initial licensure requirement fulfillment

12.2.3. Ability to schedule initial inspection visit and record inspection findings

12.2.4. Ability to track initial inspection deficiencies, re-inspection scheduling, and re-inspection results.

12.2.5. Ability to support license issuance

12.3. Annual Licensing

12.3.1. Ability to support creation of annual inspection schedule

12.3.2. Ability to record annual inspection results including deficiencies

12.3.3. Ability to support re-inspection process and recording of deficiency resolution

12.3.4. Ability to support issuance of annual license

12.3.5. Ability to maintain master record of each laboratory's testing capability and qualifications

BP# 12: Selected QA specifications:

12.4.1.Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

BP# 12: Selected system output requirements:

12.5.1. Data sets for entry into ASPEN and other regulatory reporting systems

12.5.2. Variety of regulatory reports for CAP, CLIA, etc.

12.5.3. Proficiency test distribution schedule

12.5.4. Oversight inspection schedules

12.5.5. History reports by laboratory

12.5.6. Inspection and oversight reports for various government agencies

Specifications For BP #13: Customer Concerns/Suggestions

Overview: Customer and employee feedback in the form of suggestions, concerns, and complaints are a key source of information relating to the health of an organization. Generally, in mature organizations this feedback is encouraged and validated by a process of careful review, investigation and consideration, as well as feedback to the customer or employee on actions taken as a result.

Workflow summary: The feedback must be received and recorded, investigated, some action taken, and the action reported back to the source of the feedback.

BP# 13: Specific requirements for each workflow area:

13.1. Receiving and Recording

13.1.1. Ability to record and classify concerns and complaints including source and nature.

13.2. Investigation

13.2.1. Ability to assign and change person responsible for investigation

13.2.2. Ability to "escalate" problem status.

13.3. Action Recording

13.3.1. Ability to document the findings and recommendations

13.3.2. Ability to monitor success of any corrective action

13.3.3. Ability to escalate a problem to the supervisory level

13.4. Reporting

13.4.1. Ability to report findings and recommendations back to the source via letter or other means

BP# 13: Selected QA specifications:

13.5.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Business Process #14 for additional information)

BP# 13: Selected system output requirements:

13.6.1. Summaries of suggestions, complaints and feedback for use in QA measures[14]

[14] Over the past decade the linkage between complaints and suggestions and QA activities has been codified in theories of "Continuous Quality Improvement," "Quality Circles," and "Business Process Reengineering." Thus, the ability to classify and quantify complaints and suggestions provides a rich source of information related to QA evaluations and ongoing operational improvement. This is the reason for the linkage between this business process and QC/QA in this document.

Specifications For BP# 14: Quality Control (QC) and Quality Assurance (QA) Management [15]

Overview: The key element for QC and QA is the ability to support an integrated view of these business and quality measures. For QC this involves the ability to determine the applicable QC elements that were operative at the time any test was performed and to be able to retrieve the documentation references through the use of the LIM system if the information is stored on hard copy. Ultimately, the goal would be to have electronic documentation complete with electronic signature capability. For QA the goal is the ability to capture the data elements that define each QA measure and make it easier for the PHL to track and evaluate the QA measures.

This business process focuses on the overall management of the QC/QA function.

Workflow summary for QC (a): Establish QC parameters for each test/method including manufactured or purchased ingredient used in conjunction with the test/method as well as specimen/sample condition tracking, capture QC data for each test, and analyze trends in QC test results.

Workflow summary for QA (b): Establish and review each QA measure and determine data sources available for supporting each measure, capture QA measures, and analyze trends and institute corrective actions when necessary.

BP# 14: Specific requirements for each QC workflow area:

14.1. (a) Set up each QC parameter and associated data elements

14.1.1. Ability to create and maintain a master record for each QC test by instrument/method.

14.1.2. Ability to create and maintain a master instrument/test/method records for associated input QC parameters (media, reagents, etc.).

14.1.3. Ability to create and maintain a master instrument/test/method record for specimen sample condition tracking elements (temperature control, holding time, etc.)

14.1.4. Ability to link the QC records for QC test, associated input, and specimen/sample condition if not created in same database table

14.1.5. Ability to capture SOP on each instrument/test/method along with effective dates for each version

14.2. Capture QC measures

14.2.1. Ability to electronically capture all QC measure values as appropriate as a part of the testing business process

14.2.2. Ability to manually enter QC measure values in cases where the measures are not included in the testing business process support (media manufacturing, etc.)

14.2.3. Ability for user to define the placement of QC and proficiency tests within a batch

14.3. Analyze QC measures

14.3.1. Ability to track QC measures and create analyses by time period or individual tests. For example, analysis capabilities might include:

[15] Because QC and QA are embedded in each of the business processes, this description emphasizes the overall management of the process. The QC and QA references in each business process refer back to this section.

a) Ability to perform a variety of data reduction capabilities including linear regression (straight line fit), Log (Logit), Four Parameter Logistic and Cubic Spline.

b) Ability to produce Levy-Jennings QC plots, as needed.

c) Ability to use Westgard rules to evaluate whether analysis is in or out of control. The rules must be able to be turned on or off as needed for each test performed as well as specifying which rules to use for each test. The rules must be able to be used on a real time basis for problem identification.

14.3.2. Ability to analyze information on unknown specimens/samples, spiked specimens/samples and duplicate specimens/samples

14.3.3. Ability to create alerts when QC measures trend toward limits

14.3.4. Ability to warn users that QC for one or more elements for a instrument/test/method has failed under either batch or individual test circumstances

14.3.5. Ability to automatically reschedule all tests invalidated by a QC failure with manual over-ride by supervisory personnel

14.3.6. Ability to create a report of all QC measures associated with a specific specimen/sample submission

14.3.7. Ability to include electronic signatures for QC entries

BP# 14: Specific requirements for each QA workflow area:

14.4. (b) Set up and maintain each QA measure

14.4.1. Ability to create and maintain master records for each QA measure

14.5. Capture each incidence of each QA measure

14.5.1. Ability to electronically transfer QA data associated with other business process support files

14.5.2. Ability to manually enter QA data not captured in the LIM system as a part of other process support

14.6. Analyze each QA measure and institute corrective action where necessary

14.6.1. Ability to track QA measures and create analyses by time period

14.6.2. Ability to create alerts when QA measures trend toward limits

14.6.3. Ability to trigger special reports when QA measures have exceeded acceptable limits

BP# 14: Selected QC/QA specifications: Specified above

BP# 14: Selected system output requirements:

14.7.1. Reports of QC failures for specified timeframe by specific laboratory, instrument, test, and method

14.7.2. QC reports for support of audit activities (CLIA, CAP, etc)

14.7.3. QC analysis reports on duplicate testing

14.7.4.Reports/screen displays of standard operating procedures for each method with “read only” security controls

14.7.5. QA reports for management by QA parameter

Specifications For BP# 15: Laboratory Safety and Accident Investigation [16]

Overview: The core activity is support of investigation and reporting on all accident/safety violations and tracking laboratory items considered to be safety hazards.

Workflow summary: Create tracking record for each incidence, support the investigation process, and capture investigation findings.

BP# 15: Specific requirements for each workflow area:

15.1. Create incident tracking record and records for tracking chemical and biological waste handling and disposal (incidents would also involve personnel related safety violations and accidents)

15.1.1. Ability to create incident tracking records containing relevant data about the incident

15.1.2. Ability to create and maintain records on chemical inventory and biological waste where appropriate

15.2. Record pertinent investigation information

15.2.1. Ability to record predefined investigation data

15.3. Record findings summary

15.3.1. Ability to create incident finding summaries using user-defined codes for cataloguing the findings

15.3.2. Ability to record and follow up on recommendations for revisions to safety policies and procedures

BP# 15: Selected QA specifications:

15.4.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

15.4.2. Ability to reference MSDS sheets on-line

BP# 15: Selected system output requirements:

15.5.1. Safety & materials status reports

15.5.2. Accident investigation reports

15.5.3. Special reports on QA data related to safety and accidents

[16] This section could also contain security and access information if not incorporated into the laboratory's security system.

Specifications For BP #16: Laboratory Mutual Assistance/Disaster Recovery

Overview: Mutual assistance capability is essential for building surge capacity. Laboratories must be able to transfer work in emergency situations when a laboratory temporarily loses the capacity to process a specific test or is compromised or closed as a result of a disaster. The ability to transfer appropriate test requests and associated specimens/samples in a timely and efficient manner is key. The transfer may be from one laboratory to another or from a submitter directly to the mutual assistance laboratory.

Workflow summary: The need for assistance must first be recognized based on scheduling loads, lab capacities, and test submittal trends. Once identified, the laboratory must decide what tests from which submitters should be diverted or transferred to the mutual assistance laboratory. Finally, the test request results from the diverted tests must be transferred back to the originating laboratory LIM system.

BP# 16: Specific requirements for each workflow area:

16.1. Mutual Assistance need identification

16.1.1. Ability to monitor and evaluate test request patterns and workloads based on recent workload trends and estimates of new requests to be received in the immediate future

16.1.2. Ability to perform load-balancing analysis

16.1.3. Ability to document mutual assistant laboratory certification and qualifications for each test in mutual assistance agreement

16.2. Selection and transmittal of tests to be diverted/transferred to one or more mutual assistance sites

16.2.1. Ability to select submitted test requests for transfer based on hold limits, date received, and other factors such as the specific tests included in the mutual assistance agreement

16.2.2. Ability to evaluate and determine which submitter immediate future specific test loads to divert directly to the mutual assistance laboratory

16.2.3. Ability to create a standard format transfer file for test requests received

16.2.4. Ability to load test request/results data into LIMS in responsible PHL from which the tests were diverted

BP# 16: Selected QA specifications:

16.3.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

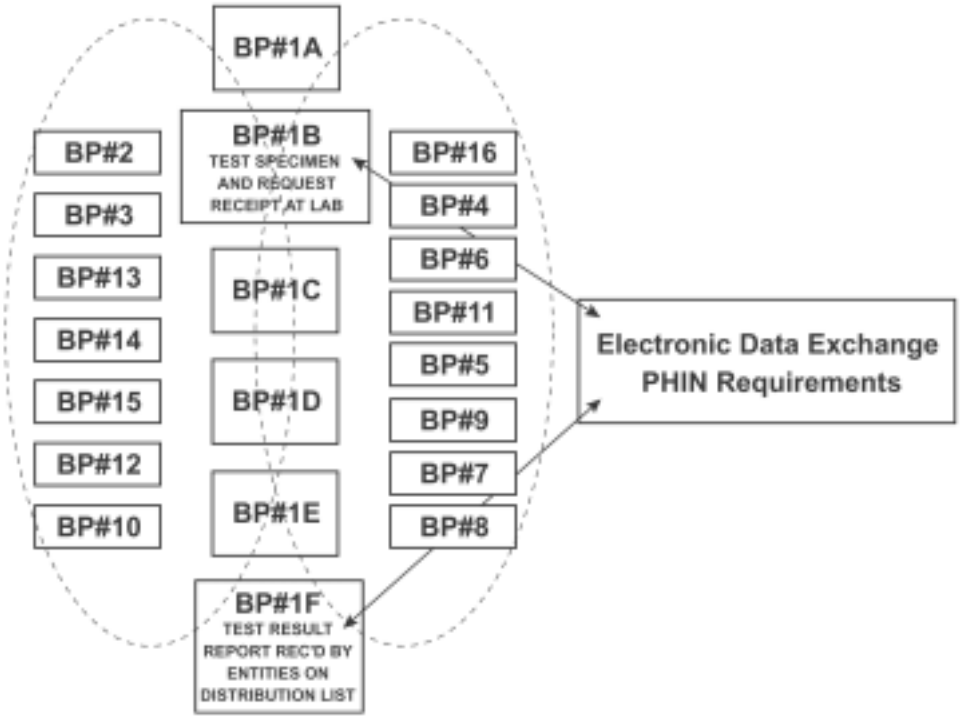
BP# 16: Selected system output requirements: Specified above

VI. PUBLIC HEALTH INFORMATION NETWORK (PHIN) REQUIREMENTS AS RELATED TO LIM SYSTEMS

CDC has made tremendous strides towards creating architectural and vocabulary standards as evidenced by the work performed in the clinical area (NEDSS) and more recently PHIN. CDC's vision to implement information technology standards in public health will enable partners to work together towards the common goal of improving public health. It is important to realize that work is ongoing and many standards are not in place in this evolutionary process. It is also important that standards be implemented as they evolve. PHLs should make every effort to implement or prepare to implement PHIN standards related to electronic transmission and exchange of data. It is appreciated that CDC provided the following guidance for PHL LIM systems to become PHIN compliant.

This section addresses the clinical aspects of LIM systems, since comparable environmental standards are not available though they are equally important to PHL functions. Figure 6 indicates the PHL business processes where PHIN standards apply.

FIGURE 4. RELATIONSHIP BETWEEN PHIN AND LIM SYSTEMS



PUBLIC HEALTH INFORMATION NETWORK (PHIN) REQUIREMENTS AS RELATED TO LIM SYSTEMS

A. Electronic Data Exchange

OBJECTIVE: To support data exchange between the lab and other associated public health entities.

Electronic Transmission of data refers to the laboratory's process of exchanging data with associated public health entities in a standardized manner. Communication is bi-directional and includes both receiving and sending information such as test orders and test results. To support interoperability between public health entities, data exchange refers to standard HL7 message receipt and message creation. Regardless of the transport protocol, interoperability requires that public health entities are able to interpret the data they receive and this is accomplished by adhering to message formatting standards, such as HL7 and terminology standards, such as SNOMED and LOINC. Adherence to standards may be accomplished either by mapping local codes to standard codes, or by directly implementing the standard codes within the LIMS.

Requirements specifications for electronic data exchange

Overview: Data exchange refers to the ability of the lab to interoperate with associated public health entities in a standardized manner. Several processes are required to support data exchange between the lab and external entities: the message must be transported using a secure transport protocol, the message payload must be constructed prior to transmission, a received message must be parsed, and business rules will need to be maintained to control distribution lists and prioritization of testing.

Secure Transport Protocol refers to the ability to transport a message or file in a mode that can only be interpreted by the intended party. Secure Transport protocol refers to HL7 messaging using ebXML and is typically handled by an application the LIMS invokes to manage the physical transmission of the message.

1. Message Receipt
   2.1 Ability to receive an HL7 message
   1.2 Ability to decrypt a received message
   1.3 Ability to send a receipt acknowledgment for successfully received messages
   1.4 Ability to send an error message for messages that were unsuccessful
2. Message Send
   2.1 Ability to package message content into an ebXML format
   2.2 Ability to transmit an HL7 message using ebXML
   2.3 Ability to encrypt a sent message, for example using PKI
   2.4 Ability to digitally sign a message
   2.5 Ability to determine Collaboration Protocol Agreement (CPA) between sender and recipient
   2.6 Ability to use CPA to Route Message
   2.7 Ability to use CPA to determine authentication credentials for the recipient (if certificate based, form based)
   2.8 Ability to re-queue Message at Transport Failure

3. Message Payload Constructor and Parser[17]

3.1 Message Construction

3.1.1 Ability to create the content for an HL7 message, where content creation includes mapping source data from the LIMS to HL7 content format for the appropriate message type

3.1.2 Ability to interface with an application that provides message transport

3.2 Message Parsing

3.2.1 Ability to parse received messages and store parsed content within the LIMS

3.2.2 Ability to assign unique identifies, such as OIDs, to parsed records prior to storage in the LIM system.

3.2.4 Ability to interface with an application that receives messages

3.2.5 Ability to provide an application error to the message transport application, in the event that parsing was unsuccessful

3.3 Business Rules Engine[18]

3.3.1 Ability to create new business rules

3.3.2 Ability to tie distribution to a test request type or test priority

B. Maintenance of system tables supporting electronic data exchange

OBJECTIVE: Support data maintenance of components necessary for electronic data exchange and PHIN interoperability.

Additional system tables may be developed to support electronic data exchange, including standard vocabulary reference tables, mapping from source data fields to electronic message content, directory services such as LDAP, and ebXML registries. Tables supporting electronic data exchange may be maintained via external packages that interface with the LIM system application software. Processes are needed to maintain components that support interoperability between the PHLs LIM systems and PHIN partner systems.

Requirements specifications for maintaining system tables

Overview: Electronic data exchange requires regular updating of reference codes/lookup tables, security related tables, and system parameter tables.

1. Table Maintenance

1.1 Ability to maintain reference tables and code tables used to populate drop down lists within the application

1.2 Ability to maintain security setup tables for users, roles and groups

1.3 Ability to maintain user and application parameter tables that establish defaults and operational preferences.

[17] Message payload constructor and Parser may be part of a LIM system or may be interfaced to a LIM system. The constructor transforms data from the LIM system into a standard content format to be transmitted to an external party. The parser transforms a received message into the appropriate records for storage in the LIM system database.

[18] In the context of messaging, the business rules engine is used to store rules that are applied to determine the distribution list for a message. For example, the business rules may dictate that all test results for a notifiable disease include the State Health Department in the distribution list, or that selected test orders/requests are forwarded to the State Health Department.

2. Maintenance of standard vocabularies[19]
   2.1 Ability to submit changes or additions to standards committees to update standards tables
   2.2 Ability to interface with an ontology service
   2.3 Ability to map local terms and concepts to standard vocabulary references[20]

Requirements specifications for maintaining components that support PHIN interoperability

Overview: Processes are required to routinely update the components supporting PHIN interoperability.

1. Directory or registry maintenance capability in typically handled using an interface between the LIM system application and directory or registry application.
   1.1 Ability to add, update, delete directory information
   1.2 Ability to add, update, delete information from an ebXML registry
   1.3 Ability to interface with an LDAP application to retrieve contract information

2. Unique identification of entities
   2.1 Ability to create or assign global unique identifiers to a subject to guarantee uniqueness across the PHIN namespace.
   2.2 Ability to link a domain name to an internal accession number to produce an identifier that will be unique throughout the PHIN namespace
   2.3 Ability to create or assign unique identifiers to sample/specimen, test and result records
   2.4 Ability to link specimen/sample with epidemiology data and test/results data
   2.5 Ability to link specimen/sample data with submitter
   2.6 Ability to link non-unique identifiers to a unique identifier

3. Mapping data source to message format[21]
   3.1 Ability to map single record data source fields to message format
   3.2 Ability to map multiple record data source fields to message format
   3.3 Ability to update mapping definition to accommodate format revisions
   3.4 Ability to update mapping for changed data sources to message format

[19] A process must be in place to maintain standard terminology that can be used to communicate with PHIN partners. The process will differ based on the implementation model: the PHL may maintain a local copy of standard vocabulary, interface with an ontology service to obtain standard vocabulary, or map local vocabulary to standard vocabulary.

[20] This requirement exists when the LIM system implements a non-standard code set that must be mapped to industry standard code sets before exchanging data with PHIN partners can occur.

[21] Mapping Data Source to Message Format supports the ability to extract data from LIMS and map it to the expected message payload element. The message payload is then included in an ebXML package for transmission to the recipient (see A.3 above)

VII. GENERAL SYSTEM REQUIREMENTS

There are a number of general requirements that are not business process specific, but are important from the perspective of overall system functioning ("consistent look and feel"). This section includes overall system capabilities to supplement the detailed requirements specifications in other sections. This section concentrates on the LIM system application and operating environment while **Section VIII** deals with vendor-related aspects of the application.

LIM System Access and Navigation

1.1. Security: Control for system access by authorized users. These specifications assume the PHL has appropriate security in place to authenticate users to access the information system environment that is separate from authorization to LIM system functions and data. Ability to create and maintain individual user specific security tables containing user ID and password information that is accessed only by administrator level security.

1.2. Ability to restrict user passwords to HIPAA-compliant combinations of characters of a standard minimum length

1.3. Ability to track user password revisions and force users to change their passwords at PHL determined intervals

1.4. Ability to terminate log-on screen after PHL determined number of unsuccessful tries by a user to log in

1.5. Ability to automatically log off idle workstations after a predetermined period of time

1.6. Ability to enable a user automatically logged off to log back in and have the system reset to the same screen the user was on when the automatic log off occurred

1.7. Ability to limit workstations from which a given user can log on and whether or not they can access system from a remote site

1.8. Ability to prevent a user from being logged on to multiple workstations at the same time

1.9. Ability to limit hours of access for individual users and lock them out of the system during non-authorized hours

1.10. Ability to create an audit trail of who, when, where, and what functions were accessed by a specific user

1.11. Ability to conform to any other HIPAA security conditions adopted by a particular PHL as a part of its privacy and security documentation

2. User Rights and Privileges: This section generally covers what users are authorized to do once they are granted access to the LIM system.

2.1. Ability to create rights and privilege groups by type of user

2.2. Ability to create unique user rights based on functions and screen displays

2.3. Ability to control which users have the right to update specified data sets and track the data updated

2.4. Ability to lock certain records at some specified point after creation (test results for example)

2.5. Ability to include add/delete/edit/read only limits on user rights

3. Screen Access and Navigation: User rights notwithstanding, this segment relates to requirements specifications regarding system screen access and navigation.

3.1. Ability to access any allowed function from any workstation on the system

3.2. Ability to access various screens through the use of menus and appropriate icons on various screens

3.3. Ability to move easily from one screen to another utilizing screen appropriate icons or function keys

3.4. Ability for off-site customers to access limited read-only fields or portions of the Web LIM system for data entry and barcode generation

4. General Query Capabilities:

4.1. Ability to query specific records based on record key data fields

4.2. Ability to perform name searches utilizing soundex approaches

4.3. Ability to access query function screens from screens where it would be logical to do so rather than having to return to a system menu

4.4. Ability to query for any specific test request test status

Field Entry and Editing and System Table Maintenance

1. Field Value Entry and Editing: Any field containing a coded value rather than text should include the following:

1.1. Ability to enter the value desired directly or from a drop down table of valid values through standard mouse selection procedure

1.2. Ability to require mandatory fields to be filled before user can exit the screen, along with prompts or highlights that enable the user to quickly see which fields need to be completed

1.3. Ability to define data entry fields for dual entry with separate verification pass prior to accepting the data set

2. Other Field Editing: Editing of non-table fields

2.1.Ability to apply alpha/numeric edits

2.2. Ability to test for valid numeric value range

2.3. Ability to perform selected correlation edits between fields

2.4. Ability to edit for valid dates and reasonable date ranges

2.5. Ability to insert default values for any code or non code field

2.6. Ability to default value for current date and time in all appropriate fields that are generated from the system clock, but allow user over-ride

3. System Maintenance: Maintenance of all LIM system tables for which the user has the responsibility for populating

3.1. Ability to control access to the system tables by authorized administrative personnel

3.2. Ability to update code tables directly from any screen where the field appears by authorized users only

3.3. Ability to maintain the value set for any table

3.4. Ability to time-stamp any table where changes are only valid starting on a specific date. Code set that will be presented to the user will correspond to the system date.

Reporting and Data Transfer

1. General Reporting: Standard reports embedded in the LIM system. Many of these reports support general "business management" activities. Examples include:

1.1. Ability to provide Workload Reports (periodic – weekly, monthly, yearly, etc. – workload reports that will indicate separate counts of specimen/samples received and tests performed for each analytical area)

1.2. Ability to provide reports that differentiate between client-ordered tests and tests done in-house as part of a testing protocol or study

1.3. Ability to provide Work Time Unit reports (reports that calculate the amount of labor it took to run the tests). The system should also be flexible enough so the laboratorians can add, delete, or change tests and work time units as needed.

1.4. Ability to provide Quality Assurance Reports. The system should produce reports based on any of data fields and the comment fields where additional QA information will be stored. Examples of QA reports include information about unsatisfactory specimens/samples, specimen/sample rejection, improperly labeled specimen/samples and/or request slips, etc.

1.5. Ability to provide Turn-around Time Reports (reports showing the turn-around times for specific tests or test groups, including the average turn-around times plus the number that meet, exceed, and are less than predetermined turn-around times)

1.6. Ability to provide Quality Control Reports (reports showing periodic summaries of QC results with detailed reports of exceptions including detailed listings of QC results for a particular date range, as well as tracking changes in QC measures and who made the changes)

1.7. Ability to provide Submitter Usage Reports (reports providing lists of submitters and the tests they requested for a specified period of time)

1.8. Ability to provide Reportable Disease Report (reports listing all reportable diseases based on the results of laboratory testing with flexibility to add, change, and/or delete tests as necessary)

1.9. Ability to provide Test Log Reports (reports on various test logs such as specimen/sample pending log, reportable disease log, specimen/sample send-out log, etc., as well as a list for a specific test(s) or series of results for a given time period/submitter/etc.)

2. Report Generation Strategy (Internal and Export): This general specification supplements the more specific specifications contained in other sections.

2.1. Ability to provide a reports menu from which the user can select and run standard system reports

2.2. Ability to schedule the production of reports for non-peak system usage or nighttime

2.3. Ability to create user query reports utilizing a standard query tool compatible with the LIM system data base architecture

2.4. Ability to limit scope of query reports

2.5. Ability to select and export data sets for more intensive analysis on a workstation in a format compatible with appropriate desktop database products and statistical analysis packages

3. Web Front End: More general specification than contained in Section VII relating to database interfaces.

3.1. Ability to provide secure Internet site for the exchange of laboratory data sets that comply with HIPAA and PHIN standards and recommended architecture

3.2. Ability to support user input screens for test request submission and specimen/sample collection

3.3. Ability for external users to pick up test reports and files as well as general purpose report data files

3.4. Ability to provide second-tier authentication for data access

Miscellaneous General Requirements Specifications

1. General Barcode Usage: Barcoding has been mentioned elsewhere in this document. This section pertains to the general use of barcodes in the LIM system environment.

1.1. Ability to support a variety of barcode labels for different uses that contain use-specific codes

1.2. Ability to print barcode labels on variety of printers

1.3. Ability to print user-defined number of copies

1.4. Ability to support multiple barcode standards

1.5. Ability to add additional standards and alert system as to which barcode standard is being scanned

2. Data Archiving: Although the cost of on-line storage has dropped dramatically there still may be a need to archive data sets from a system performance perspective or database size

2.1. Ability to construct logical parameters for selecting data sets to be archived

2.2. Ability to support multi-tiered archiving with a progression of movement from the system hard drive to other forms of data storage

2.3. Ability to find and retrieve specific archived data sets

2.4. Ability to delete archived data sets at end of specified holding periods

3. Standards and Regulatory Compliance: Many of the standards have been stated elsewhere. As a general rule, the following standards and requirements will apply to an individual PHLs based on its internal policies and procedures and functional activities performed.

3.1. Ability to comply wherever feasible with all data processing requirements of CLIA, the College of American Pathologists (CAP), NCCLS, EPA (water), FDA (shellfish, food, pharmaceutical requirements), and NELAC, as well as any other applicable standards.

3.2. Ability to comply with CDC PHIN standards and applicable HIPAA regulations pertaining to privacy/security and medical transactions containing personal health information.

VIII. LIM SYSTEM INTERFACES

This section contains specification requirements for four major interface categories:

Category 1. Interfaces with submitter database systems

Category 2. Interfaces with instruments

Category 3. Interfaces with submitter data sets and data users' databases (e.g., epidemiology, state government agencies and federal government entities)

Category 4. Interfaces via website with submitter and data users

These interfaces are critical from the standpoint of efficiency, data accuracy, timeliness (turn around time), and surge capacity. The underlying intent of interfaces is to eliminate wherever possible the manual *re-entry* of data at any point during the continuum from submitter database to the LIM system, from the LIM system to test instruments, from the instruments to the LIM system, and from the LIM system to the test result users. It is apparent that where data re-entry is required, the data entry process is a potential constraining factor impacting on the efficient, accurate, and timely processing of test requests. This point is illustrated in the following example.

If a test request must be entered manually together with the test receiving/accessioning process *without* delaying the start of testing, an initial "skeleton" record is often created to enable the LIM system to print batch worksheets and track the accessioning number and required name information. The remainder of the data is then added in a second data entry pass. The two-step data entry solution helps prevent the data entry process from holding up the test result processing. However, handling the request form twice increases the data entry workload. On the other hand, if the test request is received electronically, the processing time is shorter, not only for each individual test, but for creation of test batches as well. This relationship is described graphically in **Figure 5**.

For manual entry there is essentially a 1:1 relationship between the number of requests and the time it takes to enter them (i.e., there is no incremental gain or efficiency related to volume). Naturally time is involved in processing an electronic batch of test requests (shown as T-1 above). However, processing the second batch should take significantly less time (shown as T-2 above), and even if it doesn't, the total time for creating both batches is far less than for manual entry. Clearly from the perspective of data entry, electronic request submission greatly reduces the risk of data entry as the constraining factor in processing test requests. As will be seen below, the same logic can be applied to database interfaces (i.e., an electronic interface increases accuracy, helps ensure test processing in a timely fashion, and creates surge capacity, all of which increase overall PHL efficiency).

FIGURE 5. RELATIONSHIP OF TEST REQUEST ENTRY TO PROCESS TIME

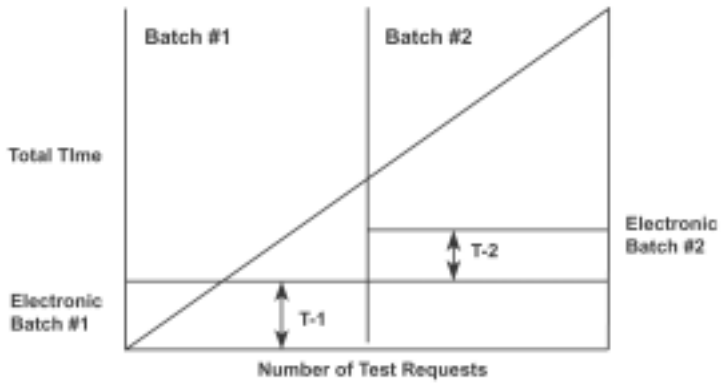
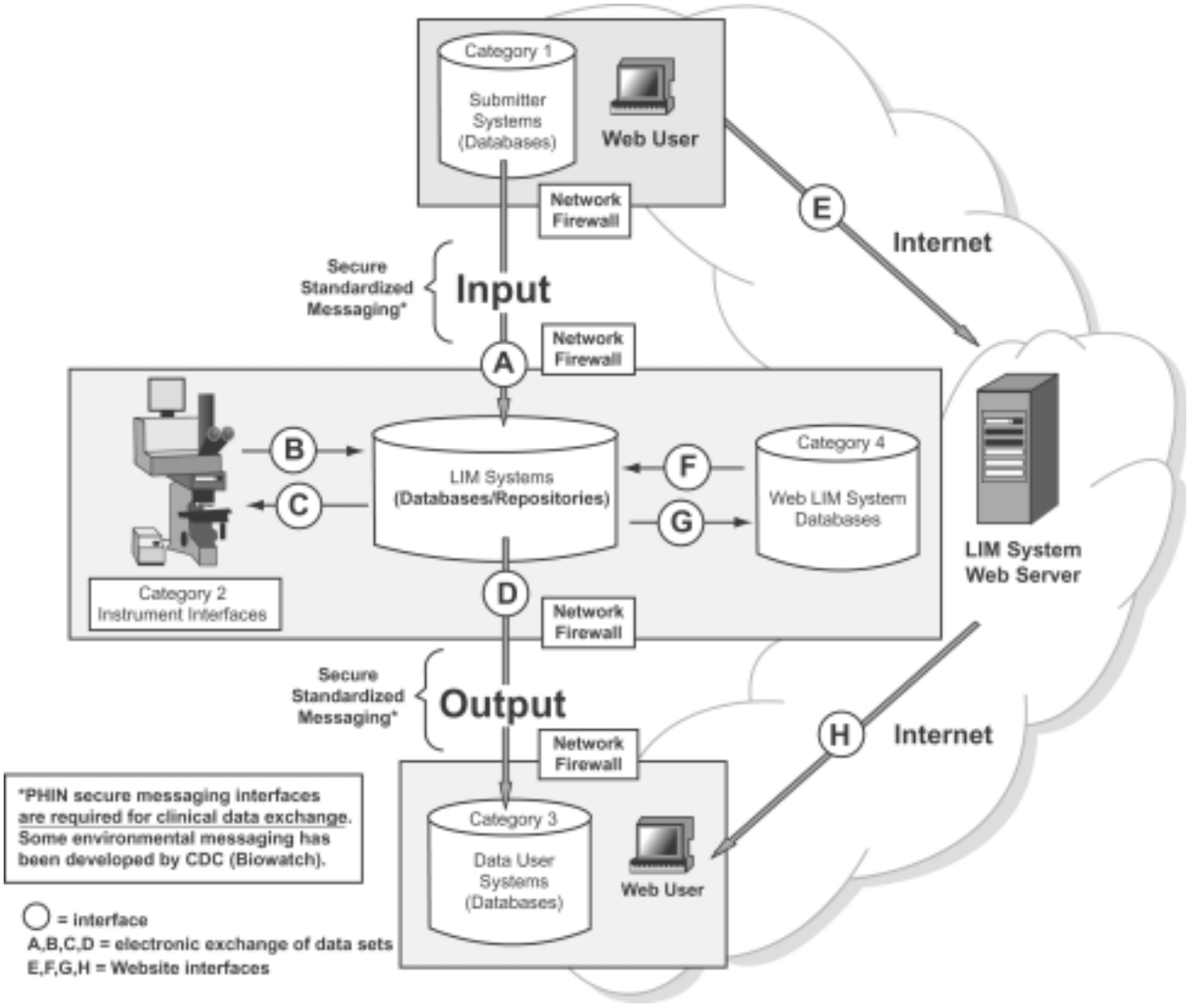


FIGURE 6. CATEGORIES OF MAJOR LIM SYSTEM DATABASE INTERFACES

This figure illustrates the 8 electronic interfaces (A-H) in four major interface categories (1-4). Four of the interfaces are associated with the exchange of electronic data sets (A, B, C, D), while the remaining four (E, F, G, H) deal with the use of a Web common user interface as an alternative to the electronic interfaces for submission of test requests and the subsequent reporting to users.[22]



[22] It is important that each interface is isolated for maintenance and data integrity-related issues.

Categories of Major LIM System Interfaces

Category 1. Interfaces with submitter database systems (See Figure 6.)

Interface A. Submitter System to the LIM system

In many cases, the submitter organization has an information system that contains much or all of the test request data. Still, for a variety of reasons the test request submission is made on paper (e.g., PHL request forms are often multi-copy). Many times, the request form is wrapped around the specimen/sample and secured by a rubber band.

Specifications for submitter system to LIM system:

1.1.Creation of a HL7 message or standard file format containing standard terminology for test submittals that submitters can map to/from their system databases

1.2. Ability to securely transmit standard message or file

1.3. Ability to parse and load electronic test submittals directly into the LIM system

1.4. Ability to link electronically submitted test requests to corresponding specimen/samples when they are delivered to the PHL

1.5. Ability to scan barcode labels on specimen/samples in order to establish link to associated electronic test submittal

Category 2. Interfaces with Instruments (See Figure 6.)

Interface B. Test data sets from the LIM system to the individual instruments

In this interface, it is important to be able to electronically load test requests for a given test batch per the given instrument's electronic interface specifications. This often will require instrument-specific batch file creation as a part of the LIM system software.

Specifications for test data sets to instrument:

2.1. Ability to create instrument specific data sets for loading test batches into the instrument for processing

2.2. Ability to scan barcode labels for machine loading in cases where the instrument only utilizes a unique ID for processing the tests.

2.3. Ability to print out a hard copy of the test batch data loaded for each instrument run as documentation of the contents of the run

Interface C. Instrument test results to the LIM system

Sometimes instrument output from test processing requires "interpretation" or subsequent calculations in order to arrive at a test result. Thus, this interface, in addition to performing the electronic test result loading to the LIM system, must have the ability to review and/or modify the data set extracted from the instrument prior to the transfer to the LIM system.[23] As an option, the "interpretation" could be performed within the LIM system if all the required data was appropriate for inclusion in the LIM system database.

[23] If a PHL is creating a vendor RFP, it should attach a spreadsheet listing instrument interfaces used in the laboratory and require respondents to indicate whether or not they support two-way data exchange with each instrument (Y/N) and describe how their product accomplishes the electronic interface.

Specifications for instrument test results to LIM system:

3.1. Ability to create instrument specific test result data sets for processing into the LIM system.

3.2. Ability to review and modify the test result data set prior to or following the release of the results to the LIM system

3.3. Ability to load the reviewed and/or modified test result data set into the LIM system

3.4. Ability to print out the extracted data set for hard copy record keeping

3.5. Ability to note modifications made to the original extract data set prior to loading into the LIM system

3.6. Ability to track who modified the result data set and the time the data set was modified.

3.7. Ability to load raw instrument data directly to the LIM system and have the "interpretation" performed within the LIM system.

Category 3. Interfaces with submitter data sets and data user's databases creating enriched data sets (See Figure 6.)

Interface D. Test results from the LIM system to the submitter data set and/or to authorized data users databases.

Test result reports sent from the laboratory to the submitter not only enriches submitter data sets but also submitters as well as others use the data user's databases, i.e., the data. The key to this interface is to create a test result report for authorized users that is an exact replica as generated by the LIM system for submitters.

Specifications for test results from LIM system to the submitter's data set and/or to authorized data users databases:

4.1. Ability of LIM system to create standard message or file

4.2. Creation of a print file format for the test report for the purpose of allowing the submitter to print out a PHL test report that would be identical to that which would be printed by the PHL for manual test reporting

4.3. Creation of a standard test report file for use by the submitter to capture the test result information in their information system (submitter would map the test result files to their databases for processing)

4.4. Ability to create and attach an electronic signature to each test report. An example approach would be to attach the "signature" (authorized person's name) to the test report file only upon completion of the test results verification process

4.5. Ability to create standard summary test report files by date range, test IDs, results, result status, and other selected parameters of importance to authorized users

4.6. Ability to securely transmit message or file and route to submitter system

4.7. Ability to control which users have access to which reports

Category 4. Interfaces via the web for submitters and data users[24] (See Figure 6.)

Interface E. Test request submittal via the Website.
This interface creates the ability for the submitter to directly enter test requests in lieu of electronic or paper submittal. In the future, this interface may be extended (particularly in environmental health) to direct field entry at the time the specimen/sample is collected.

Submitter to Web Site Interface Specifications:

5.1. Ability for the submitter to enter test requests through the Web interface.

5.2. Ability to assign a processing number to each test request submission

5.3. Ability for the submitter to enter multiple test requests at the same time without repeating submitter data and other repetitive data

5.4. Ability to audit test request data set for completeness and present error messages to the submitter if request is incomplete or inaccurate

Interface F. Transfer of test requests from the Website to the LIM system

This interface moves the test request data from the Web-entered test request to the LIM system.

Web-Entered Test Requests to LIM System Interface Specifications:

6.1. Ability to move test requests entered into the Web LIM system to the core LIM system database

6.2. Ability to audit/track the movement of the test requests

6.3. Ability to link submitted test requests to corresponding specimens/samples when they are delivered to the PHL

6.4. Ability to scan barcode labels on specimens/samples in order to establish link to associated test submittal

Interface G. Transfer of test results from the LIM system to the Website.

It is anticipated that for the purposes of security and confidentiality, the Web LIM system will contain a separate database in order to help guarantee that external users cannot access the LIM system database. Thus, this interface (G) and the next interface (H) deal with the exchange of data between the Web LIM system and the laboratory's core LIM system.

LIM System to Web Site Interface Specifications:

7.1. Ability to load specific submitter test results to the Web database from the LIM system

7.2. Ability to assure that the Web LIM system reflects the same corresponding data values as contained in the core LIM system

7.3. Ability to track whether or not a given lab test result has been "picked up" by the appropriate submitter

[24]The following four interfaces (E-H) relate to the creation of a Web-based common user interface as an alternative means of test request entry and transmission of test results to submitters and authorized test result users. Other Web interfaces are likely to arise in the near future created by governmental submitters such as EPA, which is undertaking a project known as the Central Data Exchange/Network Node. Environmental data should be able to be exchanged in compliance with standards and recommended architectures evolving from these efforts.

7.4. Ability to audit/track the movement of the test request data from the core LIM system to the Web LIM system

7.5. Ability to designate on the submitter files whether or not the test results should be moved to the Web LIM system for pick up by the submitter (i.e., the individual submitter has selected this means for retrieving test results)

7.6. Ability to move test results user reports to the Web LIM system for pick up by authorized users

Interface H. Test results reporting submitters and to the authorized results users via the Web site[25]

In general, this interface would create the capability to transmit user specific reports to submitter data set and authorized users databases (both individual test results as well as customized summary reports and statistical analyses).

Web Test Results to Authorized Users (including submitters) Interface

Specifications:

8.1. Same capabilities as delineated in **"Interface D. Test results from the LIM system to the submitter data set and to authorized data users databases"** except done via the Web LIM system.

Creation of PHL Surge Capacity

As noted at the beginning of this section, interfaces increase efficiency, data accuracy, and timeliness. Similarly, they also can increase surge capacity by eliminating the manual test request entry that often ties up a specific test instrument (i.e., the instrument is unable to process tests until the data is loaded). If the instrument-required data is loaded electronically, more batches can be run on the instrument during the course of the day.

The same logic applies to the ability to electronically move the test result information from the instrument to the LIM system instead of having to read the results off the instrument and record them on a manual worksheet and then enter them into the LIM system. If it takes as long to record the instrument test results on the worksheet, perform the validation process, and then enter the results in the LIM system as it does to run the batch, the electronic transfer from the instrument could theoretically, along with electronic entry, triple the surge capacity associated with the entry while eliminating manual data recording and entry as a critical surge restraining factor. Obviously, the relationship between data entry and result capture versus the test run time will vary from instrument to instrument. However, it is clear that electronic instrument interfaces will enhance efficiency, create surge capacity, and increase test result accuracy.

Finally, electronic submission and test reporting also significantly reduces the test turn-around time, which could be critical in a test surge related to a bioterrorism event or a major disease outbreak.

In summary, the electronic interfaces eliminate data entry as a limiting factor for surge capacity, and therefore, the surge capacity associated with each test instrument is significantly increased. In addition, the electronic interfaces result in greater accuracy and efficiency while decreasing test-processing costs by eliminating the manual data entry and handling.

[25] This capability would be particularly useful for users who do not have systems capable of receiving electronic test reports.

IX. VENDOR-RELATED REQUIREMENTS

This section contains vendor considerations that will be relevant if a PHL wants to convert this requirements specification into an RFP document.

Information about the Vendor

1. Organization History

1.1. Number of years in LIM system business

1.2. Number of staff in organization

1.3. Number of staff assigned to LIM system related operations

1.4. Number of staff in LIM system development

1.5. Number of staff in LIM system implementation and training

1.6. Number of staff in LIM system supporting current install base

1.7. Describe history of your LIM system development efforts

1.8. Date of original version/release

1.9. Date of current version/release

2. Current Installation Base

2.1. Total number of unique customer LIM system installations

2.2. Total number of LIM system customers on latest version

2.3. References for three LIM system customers on latest version with LIM system needs similar those stated in this RFP

2.4. References for three additional customers

2.5. Total number of concurrent user licenses or workstations on which LIM system software is installed

2.6. Last fiscal year LIM system total revenue

2.7. Number of new LIM system customer installations

3. Product Marketing

3.1. Describe primary LIM system market

3.2. Is product marketed as (indicate all that applies):

- Part of a “bundled “ product
- Part of multi-vendor suite
- A stand alone product offering

3.3. Describe ways in which the product can be demonstrated

3.4. Describe any warranty provided (length, coverage)

3.5. New version and release strategy (how often and to whom available and at what cost if any)

4. Implementation Support (installation, training, database conversion)

4.1. Describe application and database installation procedure

4.2. Describe the administrative and user training provided as a part of the implementation process

4.3. Describe customer database conversion services

4.4.Describe database conversion tools/programs used for converting a legacy database[26]

4.5. Describe implementation project management strategy including customer sign-offs

5. LIM System Technical Support

5.1. Describe Help Desk support and problem investigation including:
- Hours of operation
- Access method(s) (800 numbers, Internet, on site, on-line remote, etc.)
- Help desk operator training and LIM system experience
- Problem-logging mechanism
- Documentation of complaint history and resolution

5.2. Describe strategy for system patches and fixes including:
- Application method: individually or in groups
- How they are applied at user site (remote, by user, etc.)
- To whom are they distributed (entire base, version specific users only, etc.)?
- Describe bug-fix priority and average timeframe between report and installed fix

5.3. Describe continuing training opportunities and associated costs (if any)

5.4. Describe how new versions and releases are deployed

6. User Groups and Other Services

6.1. Name of user group and contact information (name, phone number, address and/or e-mail address)

6.2. Group organizational structure and membership requirements

6.3. Describe group purpose and objectives

6.4. Frequency of meetings and location(s)

6.5. Number of members (organizations and average attendance at last two meetings)

6.6. Describe other customer services and benefits

7. Vendor Risk Assessment.

7.1. Provide Dunn & Bradstreet rating if available

7.2. Percent personnel turn over last year

7.3. Provide last financial statement (balance sheet and income statement for last full year)

7.4. Provide banking reference (name, account officer, address, and telephone number)

8. Documentation

8.1. What level of detail does the documentation address? (e.g., general operation, low level configuration, report design, API access, etc.)

8.2. Describe on-line documentation that can be accessed by the user directly from the application screens

8.3. Describe the organization of the documentation and provide a hard copy version for inspection

[26] PHL would insert database name(s) for current LIM system that they desire to convert to the new system

Information about the LIM System Product

1. General System Characteristics

1.1. Describe the basic system architecture (host based, client server, multi-tiered, etc.) and operating architecture (ASP, server location, etc.)

1.2. Describe the operating systems supported on the client (if applicable) and the server.

1.3. Describe any database back-ends supported and do they use native drivers, ODBC, or another access technology.

1.4. Describe user interfaces supported (thin client, thick client, Web, PDA, API, ADO, DDE, etc.)

1.5. Describe how site synchronization is achieved in the event of network failure in multi-site implementations if separate site servers are utilized.

1.6. Describe other products with which the LIM system is designed to integrate[2]

1.7. Describe the user interfaces supported by the product that are used by two or more customers (include PDA, Web, GUI, etc.)

1.8. Can a customer install multiple non-interacting instances of the LIM system in order to support training and testing? If so, describe most common approach used by customers and give two supporting customer references.

1.9. Describe the system's audit trail capability

1.10. Describe the minimum requirements for workstations and associated peripherals such as printers and bar code readers

2. Database

2.1. Name of database product if one is used

2.2. Description of data model (flat file, relational, object-oriented, proprietary, etc.)

2.3. Size of largest customer installed LIM system database (Mbytes and number of test records)

2.4. Describe relationship of server size to database size and impact of server memory (all in relationship to system response time)

2.5. Describe impact of workstation sizing on response time (if any)

2.6. Describe relationship of response time to number of concurrent users

2.7. Is there a maximum number of concurrent users that can be efficiently supported? If so, how many?

2.8. Application development language

2.9. Does the database product support ODBC?

2.10. Does the design of the application database tables support the use of ODBC?

2.11. Describe the database tools supplied along with the application

2.12. Describe the archiving capability and approach utilized in your application

2.13. Describe the audit trail capability and approach utilized to address HIPAA requirements

[27] PHL can describe desired interfaces to other products here.

Bid Sheet

Bid sheet formats are generally dictated by governmental organizations. For a LIM system bid the following categories should be included:

- License costs and terms
- Implementation costs
- Warranty (if there is a cost)
- Annual Maintenance

Try to avoid incurring extra costs for documentation, user training following implementation and on-site travel.

EXPLANATION OF TERMINOLOGY

The following terms are included to clarify the meaning of words having multiple interpretations.

authentication Process by which a secure system verifies the identity of someone or something that is attempting to gain access. The use of digital certificates or secure token in conjunction with a challenge phrase or password are common examples.

Authorization Permission associated with accessing functions or subsets of data within an . Generally, an administrator will define the users who are authorized to access a application functions or data.

business process Collection of tasks that are performed for the purpose of achieving some specific set of business purposes or objectives.

clinical “Clinical,” as opposed to “health” or “human,” is used to indicate testing that isnon-environmental.

CPT codes Acronym for Current Procedural Terminology codes , refers to a set of terms and codes used by medical professionals for reporting medical services to healthinsurance organizations.

ebXML Acronym for Electronic Business using Extensible Markup Language, refers to a series of specifications that allows organizations to conduct business via an exchange of data over the Internet.

GUID Acronym for Globally Unique Identifier, refers to a globally unique string that is used to identify an object.

HL7 Acronym for Health Level Seven, refers to the effort to develop healthcare standards for clinical and administrative data. The goal of this effort is to create guidelines that will facilitate interoperability amongst disparate healthcare information systems.

ICD codes Acronym for International Classification of Diseases codes, refers to the system by which the World Health Organization (WHO) assigns diagnostic codes to illnesses, symptoms and medical procedures. ICD codes used in the United States are enacted by the United States government.

LDAP Acronym for Lightweight Directory Access Protocol, refers to a set of software protocols that enable access to network directories and, therefore, enable usersto locate resources on the network

LIMS Acronym for Laboratory Information Management System.

LOINC Acronym for Logical Observation Identifiers and Codes, refers to a series of terms and codes that identify laboratory and clinical results.

messaging	Ability to send secure messages utilizing HL7 message standards between public health labs, commercial labs, government agencies and other public health partners.
OID	Acronym for Object Identifier, refers to a globally unique character string that is used to unambiguously identify an object. OIDs have been identified by HL7 as the preferred method for coding systems.
PHIN	Acronym for Public Health Information Network, refers to a CDC initiative\ that uses information systems and technology to enable real-time data exchangebetween organizations for the promotion of interoperability, collaboration, rapid dissemination of critical information and computer assisted statistical analysis.
PKI	A PKI (public key infrastructure) enables users of a basically unsecured public network such as the Internet to securely and privately exchange data and money through the use of a public and a private cryptographic key pair that is obtained and shared through a trusted authority. The public key infrastructur provides for a digital certificate that can identify an individual or an organization and directory services that can store and, when necessary, revoke the certificates.
registry	Repository of information that identifies a computer's peripherals, software, settings, and policies. The computer initializes this information at startup to make these resources readily available to the operating system.
requirements definition	This term refers to information system development. This document is not a requirements definition in that sense. Nor is it a set of "standards," although standards such as HL7 and PHIN are mentioned. The term we finally agreed upon was "requirements specifications."
SNOMED	Acronym for Systematized Nomenclature of Medicine, refers to a universal terminology used to encode medical records.
specimen/sample	Term used instead of "specimen" or "sample" to describe something to a PHL for laboratory testing. This term is intended to cover everything from water samples to human specimens to animal heads to lottery tickets.
Sample ID	Unique identifier for the specimen/sample record.
Subject ID	Unique identifier for the subject, where it is the origination point for multiple specimen/samples. The unique identifier should be an OID.
XML	Acronym for Extensible Markup Language, refers to a standard for creating common information constructs so that data can be shared on the Internet, on intranets and on other networks.