PHIN Preparedness

(DRAFT for discussion)

CONNECTING LABORATORY SYSTEMS FUNCTIONAL REQUIREMENTS AND PROCESS FLOWS

Version 0.1 Draft

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1 INTRODUCTION

This document describes Public Health Information Network (PHIN) functional requirements and general workflow for systems managing and reporting the results of laboratory testing. Public health laboratories are a critical asset in safeguarding the public's health. Working in collaboration with other public health organizations and disciplines, public health laboratories ensure the rapid identification of disease agents and threats and inform an effective and timely response to contain and minimize their impact on the health of communities. Public health laboratories are leading-edge organizations, equipped to tackle the most advanced science available today in performing diagnostic testing, disease surveillance, and research. In some cases they may have even broader capabilities and may additionally perform chemical and environmental testing, food testing, and animal testing.

To ensure the nation's readiness in detecting and responding to both natural and man-made outbreaks of disease, the Laboratory Response Network (LRN) was formed in 1999 by a broad coalition of scientific partners including the Centers for Disease Control and Prevention, the Association of Public Health Laboratories, the Department of Defense, the Federal Bureau of Investigation, the Food and Drug Administration, United States Department of Agriculture and the Environmental Protection Agency.

During the anthrax events of 2001 the LRN laboratories tested over 125,000 samples representing over 1 million separate laboratory tests. The management of data and test results associated with this event was enormously complex and largely unsupported by any form of standardized electronic reporting between participating organizations. As successful as the laboratory testing activity was, the reporting, aggregation, and analysis of the results from the many labs performing the testing was anything but systematic.

What became apparent from this experience was the need to develop and broadly adopt common specifications and processes for information exchange among the nation's public health laboratories and their partner organizations. As clinical laboratories and healthcare organizations also come into play in these events this need for standard electronic interchange of laboratory results and service requests is ever more important.

The remainder of this document presents essential PHIN interoperability requirements to support coordinated laboratory services and response across local, state and federal public health jurisdictions. This document does not present requirements for Laboratory Information Systems (LIMS) themselves but rather focuses on the interface of these systems to other systems both internal and external to the public health laboratory.

2 REQUIREMENTS

The following requirements describe baseline functionality for the PHIN functional area of Connecting Laboratory Systems.

2.1 Structural Concepts: Laboratory data must be assigned unambiguous identifiers and support traceable linkages among related data.

2.2 Message Types and Content: Electronic messages must adhere to specific implementation guides and data structure to ensure data exchange consistency.

2.3 Data Exchange - Connecting with other Organizations: Public health laboratory data must be communicated reliably and securely between partner organizations. All public health organizations need be interconnected with the appropriate technology to support these secure, electronic communications.

2.4 Chain of Custody: A detailed record must be kept of the sample from the collection point through the testing and result reporting process.

2.5 Audit Trail: Logs must be captured to identify and trace attempts to access or modify laboratory records.

2.6 Vocabulary Standards: Standard vocabulary lists and data structures have been defined by various organizations. Where they exist, connected laboratory systems should utilize them. As additional standards are defined, they should be accepted and implemented.

2.7 Operations: Personnel, roles, and responsibilities necessary to support laboratory data exchange should be clearly defined.

2.8 System Security and Availability: Security of laboratory data includes the protection of data from corruption and access by unauthorized individuals, as well as the protection of a laboratory system itself from sabotage or other failure. There must be a backup plan for continuing activities when connected laboratory systems are unavailable.

2.9 Privacy: Patients and organizations must be protected from fraudulent and unauthorized use of their information.

2.1 STRUCTURAL CONCEPTS

Laboratory data is frequently communicated to other public health organizations, where it is aggregated and linked with data from other sources. To aggregate and link data, it must contain identifiers that are unique across organizations. This "global uniqueness" is only possible when all organizations consistently follow predefined strategies for identifying organizations, subjects and test specimens.

The PHIN has adopted Object Identifiers (OIDs), an ISO[1] standard, to promote global uniqueness. OIDs enable unambiguous identification of specimens and subjects, and support linkages among specimens/subjects, related epidemiological data, laboratory test results, and other data. To create global uniqueness, these identifiers can be combined with a globally unique ID for the entity or system assigning the identifier. This is the "namespace" ID. PHIN requirements for identification and linkages are described below.

2.1.1 Identifier Namespaces

An identifier namespace defines the scope of the assigning authority for identifiers. A namespace could exist for a specific software system, physical location, organizational unit or jurisdiction. For example, there might be two LIMS deployed at a given laboratory, each assigning specimen numbers requiring two identifier namespaces for that physical laboratory location. Conversely the lab could have a single namespace but would need to ensure global uniqueness of specimen IDs across both LIMS. OIDs are the standard for namespace identification.

2.1.1.1 OIDs must be used to identify namespaces in public health where Subject IDs, Specimen IDs, Organization IDs, etc. are assigned.

2.1.1.2 OIDs must be used to identify well known objects, such as Messaging Partners, Physical Locations, software instances etc.

2.1.1.3 PHIN requires a vocabulary structure reliant on OID(s) for identification of vocabulary items, including code systems, value sets, or SRT(s).

Example:

- 2.16.840.1.114222.4.3.2.1 - Laboratory Results Management and Messaging System
- 2.16.840.1.114222.4.3.2.2 - Public Health Information Network - The Messaging System (ebXML transport system)
- 2.16.840.1.113883 – Health Level Seven, Inc.
- 2.16.840.1.113883.6.6 – SNOMED-CT
- 2.16.840.1.113883.6.1 - LOINC
- 2.16.840.1.113883.6.12 - CPT
- 2.16.840.1.113883.6.2 – ICD9
- Subject Identifiers

2.1.1.4 Subjects of laboratory testing must be identified with a unique identifier within the namespace assigning the identifier. It will be assumed by external systems that subjects with the same identifier are indeed the same person.

Example

- Subject ID: 556-094560
  Uniquely identifies Martha Smith in the state public health lab LIMS system
  - OID: 2.16.840.1.11422.4.3.2.2.1.100.1
    identifies the specific LIMS system in the state laboratory in Columbus, Ohio that assigned the Specimen ID to the specimen.
- Globally Unique ID: 2.16.840.1.11422.4.1.100.1 556-094560
  Combined OID + Subject ID creates a globally unique ID for the Subject that will not collide with any other Subject ID assigned by any other system or organization world-wide.

2.1.1.5 To provide global uniqueness, subject identifiers must be combined with an OID for the assigning namespace whenever reported externally to public health partners. A namespace will generally refer to the system or entity assigning an identifier such as a specific LIMS system, a state's Master Person Index (MPI), a surveillance system, etc.

2.1.1.6 Laboratories must maintain the subject identifier assigned by an external requestor of laboratory services.

2.1.1.7 Laboratory results must be reported with the subject identifier assigned by the requestor of laboratory services.

2.1.2 Specimen Identifiers

2.1.2.1 Samples and specimens undergoing laboratory testing must be identified with a unique identifier within the namespace assigning the identifier.

2.1.2.2 It will be assumed by external systems that specimens with the same identifier are indeed the same specimen.

2.1.2.3 It will also be assumed that specimens with different identifiers are different specimens.

2.1.2.4 To provide global uniqueness, specimen identifiers must be combined with an OID whenever reported externally to public health partners.

Example

- Specimen ID: PQ8907
  The unique accession number assigned to a blood specimen collected by a public health worker and accessioned by a LIMS system in the state public health lab in Columbus, Ohio.
- OID: 2.16.840.1.11422.4.3.2.2.1.100.1
  Identifies the specific LIMS system in the state laboratory in Columbus, Ohio that assigned the Specimen ID to the specimen.
- Globally Unique ID: 2.16.840.1.11422.4.3.2.2.1.100.1 PQ8907
  Combined OID + Specimen ID creates a globally unique ID for the specimen that will not collide with any other specimen ID assigned by any other system or organization world-wide.

2.1.2.5 Laboratory systems must maintain the specimen identifier assigned by an external requestor of laboratory services.

2.1.2.6 Laboratory results must be reported with the specimen identifier assigned by the requestor of laboratory services.

2.1.3 Linkages

2.1.3.1 Laboratories must track specimens from receipt to result reporting.

2.1.3.2 Specimens common to a subject (person, place, animal or object) should be traceable back to that subject.

2.1.3.3 Field assigned specimen identifiers must be retained and linked to the lab assigned specimen identifier, if it is different. When possible, it is recommended that specimens collected in the field be accessioned using centrally accessioned numbers.

2.1.3.4 It should be possible to associate epidemiology data with samples and specimens, although laboratory data and epidemiological data may reside in separate information store.

2.1.3.5 Laboratories must retain use of the original subject and specimen identifiers throughout the course of testing and link them to any aliquots created from the specimen.

2.1.3.6 Where aliquots are created, the relationship between the aliquot and the original parent specimen must be maintained. If the aliquot is assigned a postscript ID, the parent-child linkage must be specifically captured.

Example

- Specimen ID: PQ8907
  The accession number assigned to a 5.0 ml blood sample
- Specimen ID: PQ8907-01
  The accession number assigned to a 1ml aliquot of the original blood specimen.
- The parent-child relationship is maintained in the LIMS system

  Parent: PQ8907

  ↓

  Child: PQ8907-01

2.1.3.7 The parent and child specimen IDs must be reported with all laboratory results returned to an external requestor. In this way all testing associated with an original (root) specimen can be easily aggregated for review and analysis.

2.2 MESSAGE TYPES AND CONTENT

Laboratory data is frequently communicated to other public health organizations, where it is aggregated and linked with data from other sources. For laboratories and partner organizations to understand information that is exchanged electronically, the information must be organized in a format that is understood by the sender and the receiver. Since laboratories handle a diversity of information, more than one message format must be available for use. Consistent formats provide the rules that laboratories and partner organizations can follow when constructing a message to be exchanged and when interpreting the contents of a message that has been received. For messages to be interpreted correctly, the information must be described using a consistent set of terminologies so that, for example, a specimen type of serum would consistently be called "serum", rather than "whole blood" or "plasma".

Moving laboratory requests and results electronically between software systems and partner organizations requires that all exchange partners adhere to standards. The PHIN standard for electronic messaging is Health Level Seven (HL7). In the laboratory area, a number of message specifications are already in place and others are in development to support a core set of interactions between public health LIMS systems and other applications. These PHIN specifications and their uses are identified in this section.

2.2.1 Message Content

2.2.1.1 Message content must comply with message implementation guides found at *http://www.cdc.gov/phin/messaging/index.htm*. Currently specified message formats are shown below:

Message Type	Reference	HL7 Version	Description	Status
BT Laboratory Result Message	ORU_R01	V2.4z	Unsolicited test result for LRN labs doing bioterrorism related testing including BioWatch	Available
ELR Laboratory Results	ORU_R01	V2.3.1	Unsolicited test result for reporting clinical laboratory findings to state, territorial, and federal public health agencies for purposes of disease surveillance	Available
Public Health Laboratory Results for	OUL_R22	V2.5	Unsolicited test result for wide range of public health testing of clinical and environmental samples	Fall 2004
Laboratory Order Request	OML_O21	V2.5	Laboratory request for testing, includes specimen information	Fall 2004
Laboratory Order Response	OMF_O22	V2.5	Confirmation to execute test request.	Fall 2004

2.2.2 Construction

The constructor transforms data from the laboratory data repository into a standard content format to be transmitted to an external party.

2.2.2.1 Laboratories must be able to construct messages for transmission.

2.2.2.2 Constructors may be developed internally or a service or interface may be used.

2.2.2.3 Message constructors must be able to interface with an application that provides message transport.

2.2.3 Parsing

The parser transforms a received message into the appropriate records for storage by the laboratory.

2.2.3.1 Laboratories must be able to parse received messages and store parsed content within a centralized laboratory data store.

2.2.3.2 Laboratories must be able to save unique identifiers (such as OIDs) when storing a record, and have the ability to assign unique identifiers, in the event that they are missing, to parsed records prior to storage in the laboratory data store.

2.2.3.3 Parsers must be able to interface with applications that receive and transmit messages, including error events and acknowledgements.

2.2.3.4 Laboratories must be able to acknowledge successful parsing of messages and send an error message for messages that were unsuccessful.

2.3 DATA EXCHANGE - CONNECTING WITH OTHER ORGANIZATIONS

Public health laboratory data must be communicated reliably and securely between partner organizations. Transported information can be secured by making sure it is only sent to a recipient who is allowed to see it, and by applying a code (encryption) to the information that can only be decoded by the intended recipient. To support these secure, electronic communications, all public health organizations need be interconnected with the appropriate technology.

The PHIN relies on the public internet to support inter-organizational information exchange. Security and privacy requirements necessitate that information generally be encrypted and that communications be performed in a way which ensures delivery to the intended recipient(s) and only the intended recipient(s). The CDC has developed PHIN Messaging Services (PHIN MS) to support secure message transport, and exchange partners must use a secure transport protocol that is compatible with PHIN MS.

> PHIN MS fully implements PHIN standards for secure messaging and is available from CDC. More information on PHIN MS is available at *http://www.cdc.gov/phin/messaging/index.htm*. PHIN MS, however, is not required so long as the laboratory can meet the PHIN data exchange requirements using a PHIN MS compatible solution.

Detailed data exchange requirements should be reviewed in the *PHIN Preparedness Cross Functional Components Requirements* document. (*www.cdc.gov/phin/CFC.pdf*)

2.3.1 Laboratory systems must be able to construct and send laboratory results messages. This functional requirement is identified as a key performance measure for assessing preparedness and described in the PHIN *Key Performance Measures* document (*www.cdc.gov/phin/KPM.pdf*).

2.3.2 Laboratory systems must be able to receive, parse and process laboratory results. This functional requirement is identified as a key performance measure for assessing preparedness and described in the PHIN *Key Performance Measures* document (*www.cdc.gov/phin/KPM.pdf*).

2.3.3 Laboratory systems must be able to create and send laboratory test order messages for tests that have been requested. This functional requirement is identified as a key performance measure for assessing preparedness and described in the PHIN *Key Performance Measures* document (*www.cdc.gov/phin/KPM.pdf*).

2.3.4 Laboratory systems must be able to receive, parse and process laboratory test order messages for tests that have been requested This functional requirement is identified as a key performance measure for assessing preparedness and described in the PHIN *Key Performance Measures* document (*www.cdc.gov/phin/KPM.pdf*).

2.3.5 Laboratory systems must be able to create and send to partner organizations laboratory request acknowledgements indicating acceptance of a laboratory test order in accordance with the specifications defined in the PHIN Laboratory Request Acknowledgement Implementation Guide located at www.cdc.gov/phin/messaging.

2.4 CHAIN OF CUSTODY

2.4.1 The laboratory should support chain of custody records for routine samples handled internal to the laboratory or redirected to external testing facilities.

2.4.2 The laboratory must support chain of custody records for select agent samples handled internal to the laboratory or redirected to external testing facilities

2.4.3 Chain of custody for forensic and select agent samples must document the chronological history of the sample and should include the following:

- Identifier for the individual handling the specimen/sample
- Name of each person or entity subsequently having custody of specimen/sample
- Dates the items were collected or transferred
- Unique identifier of the subject

2.5 AUDIT TRAIL

2.5.1 The laboratory must support an audit trail of data records.

2.5.2 The audit trail must record date created, created by, date modified, modified by, and the changes made to the record.

2.5.3 The laboratory must support an audit trail of access attempts (whether successful or unsuccessful) to electronic systems and system functions.

2.6 VOCABULARY STANDARDS

It is recommended that standards be used across laboratory systems; however, vocabulary standards must be used when exchanging data. Vocabulary requirements specific to systems supporting connecting laboratory systems are included in the section below. Vocabulary requirements that span PHIN functional areas are separately defined and should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.6.1 Test results produced and reported externally by public health laboratories must utilize the Logical Observation Identifiers, Names and Codes (LOINC) coding system for test names and codes (*http://www.loinc.org/*), where the codes for their assays are available.

2.6.2 Electronic test results reported externally to the public health laboratory must use the SNOMED CT coding system for encoding laboratory findings (See *http://www.snomed.org/*) where the codes are available.

2.6.3 Laboratory orders must use CPT codes.

2.6.4 There are occasions when a new assay method is recommended but does not have an assigned LOINC code, or an organism is reported but does not have a corresponding SNOMED code. In these cases the laboratory must be able to support creation of local test and results codes that are consistently identified. The local structure must contain the ability to map to a standard code as it becomes available.

2.7 OPERATIONS

Operational requirements, such as system backup policies and procedures, continuity of operations, system monitoring, and employee training ensure that public health partners can effectively support activities in connecting laboratory systems and other PHIN functional areas. Operational requirements specific to connecting laboratory systems are defined below. Operational requirements that span PHIN functional areas are separately defined and should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.7.1 Labs must be able to monitor test capacity, recognize when capacity has been exceeded and redirect test orders to partner labs that have capacity.

2.7.1.1 Redirection of specimens must be traceable, including when, why and where a specimen was redirected as described above in section *2.4 Chain of Custody*.

2.7.1.2 Laboratories should be able to communicate test capacity with partner organizations, and during public health emergencies, provide updates to allow national capacity to be assessed.

2.8 SYSTEM SECURITY AND AVAILABILITY

Systems supporting laboratory data exchange must be protected from sabotage or other system corruption. Security requirements that span PHIN functional areas should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

2.9 PRIVACY

Privacy requirements ensure that sensitive information is not accessible to unauthorized users. Privacy requirements are broadly defined because they span all PHIN functional areas. These requirements should be reviewed in the PHIN Preparedness Cross Functional Components Requirements document. (www.cdc.gov/phin/CFC.pdf)

3 ELECTRONIC INTERACTIONS

3.1 ELECTRONIC LABORATORY REPORTING

3.1.1 Public health laboratories must be able to report laboratory findings to CDC, their state or territorial department of health and other partner organizations appropriate to the situation.

3.1.2 Test result reporting should be implemented as shown in the diagram in Figure 3-1

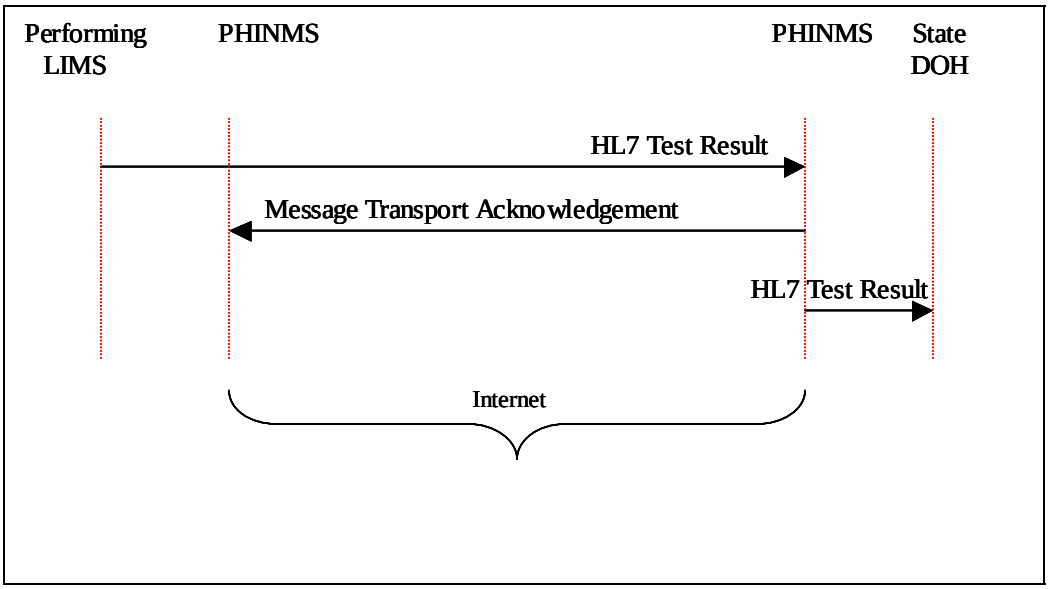

Figure 3- 1 Electronic Laboratory Reporting

3.2 MUTUAL ASSISTANCE - ELECTRONIC LABORATORY REQUESTS

3.2.1 In an emergency public health labs must be able to assist other labs that have reached or exceeded their testing capacity. To do so, PHIN compliant public health laboratories must be able to receive electronic requests for laboratory testing and electronically return results via PHIN standard HL7 messages.

3.2.2 Upon receipt of HL7 test request messages Public health laboratories must be able to validate, parse, and store this message for processing by a LIMS system.

3.2.3 Electronic laboratory requests must be acknowledged as received with an HL7 acknowledgement message.

3.2.4 Electronic laboratory requests must be acknowledged as accepted or denied for testing.

3.2.5 The requesting Laboratory must be able to validate, parse and store the message content reporting the acceptance or denial of the test request.

3.2.6 Public health laboratories must be able to perform the electronic interchange associated with laboratory requests diagrammed in Figure 3-2 and must be able to perform at various times as the requestor or the performing lab.

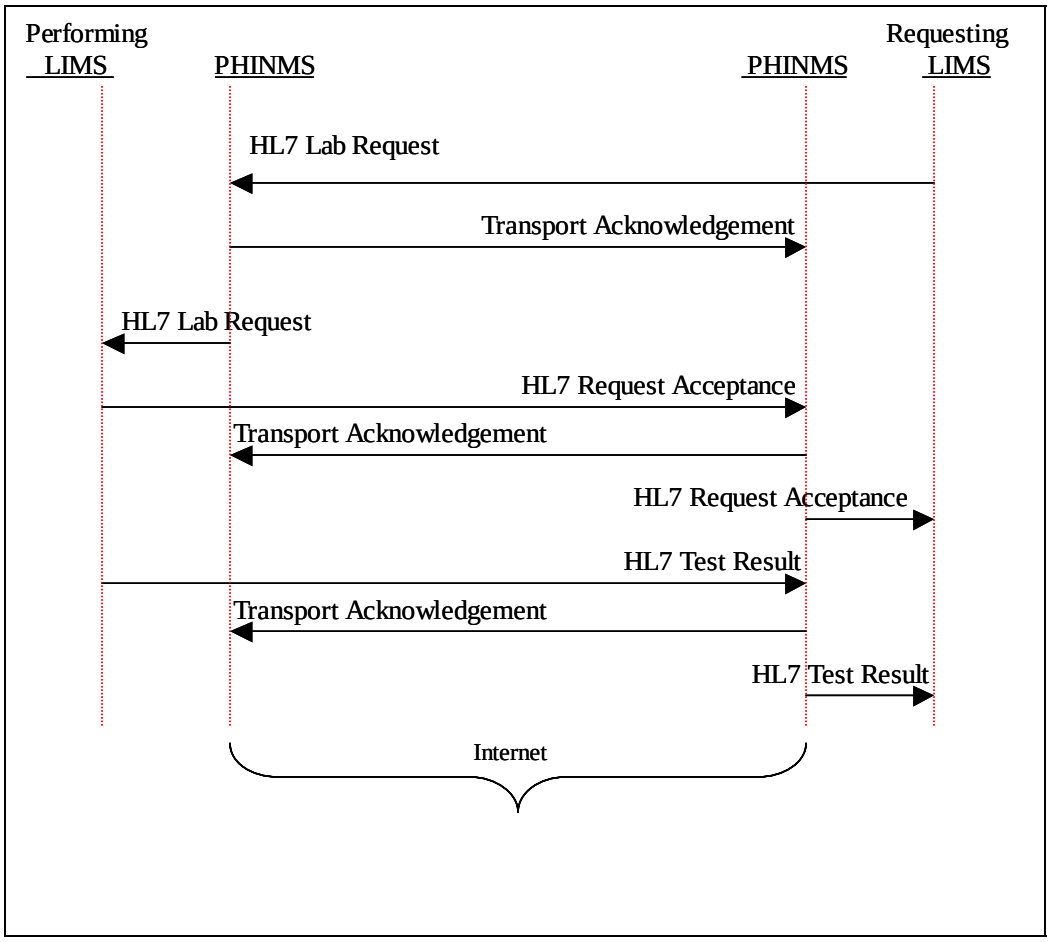

Figure 3- 2 Mutual Assistance- Electronic Laboratory Requests