Assure Health IT Standards for Public Health:

Review of PH Laboratory Domain Standards Use and Suggested Implementation Strategy for Clinical Integration

White Paper

2012

Baltimore, Maryland
The Public Health Data Standards Consortium (PHDSC, The Consortium) is a national non-profit membership-based organization of federal, state and local health agencies, professional associations, academia, public and private sector organizations, international members, and individuals.

The Consortium is committed to bringing a common voice from the public health community to the national efforts of standardization of health information technology and population health data in order to improve individual and community health.

To fulfill its mission the Consortium:

*Identifies priorities for new national standards* for population health data;

*Promotes integrating health-related information systems* to meet the needs of public and private organizations, agencies and individuals;

*Participates in national and international efforts* to standardize health-related information;

*Represents public health interests* in standards development organizations, data content committees and standards harmonization entities; and

*Educates* the public health community about health information technology standards and the health information technology community about public health.
The Association of Public Health Laboratories (APHL) is the national nonprofit representing governmental laboratories that protect the public’s health by detecting and monitoring health threats. Members include state, territorial and local public health labs; state environmental testing labs; state agricultural and food safety labs; and individual scientists, public health officials and academicians.

APHL’s mission is to promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs, and technologies which assure continuous improvement in the quality of laboratory practice and health outcomes.

To fulfill its mission, APHL’s focuses on the following areas:

**Workforce:** Advance the training, leadership development, recruitment & retention of a competent workforce to meet the needs of the public health laboratory system;

**Advocacy and Outreach:** Enhance the visibility, status & influence of the public health laboratory community through effective advocacy, strategic communications & public relations;

**Networking and Community Building:** Act as a focal point for the collection and dissemination of information throughout the public health community and to external partners;

**Informatics:** Improve the informatics capabilities of APHL & its members; and

**Laboratory Science, Standards and Practices:** Advance the development, use, and evaluation of technologies, quality systems and practices.
DISCLAIMER

This document was developed under the Cooperative Agreement with the Centers for Disease Control and Prevention (CDC), “Assuring HIT Standards for Public Health”, Grant No.: 3U38HM000455-03W1. The material in this document has not been subject to agency review and approval for publication as a Centers for Disease Control and Prevention (CDC) report. Mention of trade names, products, or services, does not convey, and should not be interpreted as conveying official CDC approval, endorsement, or recommendation.
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APHL Informatics Committee members and staff.
# Table of Contents

EXECUTIVE SUMMARY .................................................................................................................. 7

INTRODUCTION .............................................................................................................................. 8
  Rationale for the Project .................................................................................................................. 8
  Target Audience ........................................................................................................................... 11

BACKGROUND OF HIT STANDARDS AND THEIR IMPLEMENTATION EFFORTS IN PUBLIC HEALTH LABORATORIES AND NATIONAL ORGANIZATIONS .................................................................................................................... 12
  DATA STANDARDS ..................................................................................................................... 13
  INFORMATION CONTENT STANDARDS ..................................................................................... 15
  INFORMATION EXCHANGE STANDARDS ................................................................................... 15
  IDENTIFIER STANDARDS ........................................................................................................... 19
  PRIVACY AND SECURITY STANDARDS ................................................................................... 20
  FUNCTIONAL STANDARDS .......................................................................................................... 21
  OTHER STANDARDS: TRANSPORT MECHANISMS AS STANDARDS ........................................... 30

PUBLIC HEALTH LABORATORIES AND HEALTH IT ........................................................................ 34
  PUBLIC HEALTH LABORATORY COMMUNITY-BASED INITIATIVES .......................................... 34
  EXAMPLES OF NATIONAL PUBLIC HEALTH INITIATIVES ....................................................... 41

THE PHDSC HIT IMPLEMENTATION STRATEGY – OPERATIONALIZING HIT STANDARDS FOR PUBLIC HEALTH LABORATORIES .................................................................................................................... 46

ROADMAP FOR HIT STANDARDIZATION OF LABORATORY DATA EXCHANGES: PHDSC-APHL PARTNERSHIP ACTIVITIES ................................................................................................................................. 49
  WHAT – WHAT NEEDS TO BE ACCOMPLISHED? ...................................................................... 49
    Advocate for PHL in National Needs and Priorities for Standards ................................................ 52
    Participate in Standards Development .......................................................................................... 54
    Participate in Standards Harmonization ...................................................................................... 55
    Participate in Standards Testing .................................................................................................. 58
    Participate in Certification of Standards-based Products .............................................................. 59
    Deploy Certified HIT Solutions .................................................................................................. 60
  HOW – HOW TO ASSURE PUBLIC HEALTH PARTICIPATION IN THE HIT STANDARDIZATION AND DESIRED OUTCOMES ................................................................................................................................. 63

APPENDICES ................................................................................................................................... 65
  APPENDIX 1: TERMS AND DEFINITIONS .................................................................................... 65
  APPENDIX 2: PRIVACY AND SECURITY STANDARDS ................................................................. 66
Public Health Laboratories provide specialized testing for clinical care, surveillance and surge capacity during disasters. “Laboratories are key stakeholders in providing critical data to local, state, tribal and federal public health agencies to investigate individual cases of communicable and chronic diseases as well as to characterize and mitigate population-based public health threats.”

Health information technology (HIT) standards are the key to enabling electronic information exchanges (i.e., interoperability) between senders and receivers of laboratory information. A survey conducted by the Association of Public Health Laboratories (APHL) revealed tremendous variability, despite of the efforts for implementation of messaging standards at the partner labs, which rendered data sharing almost impossible, without additional effort to agree on a standard representation of the data across the laboratories. On the national level several efforts are under way to improve data exchange capabilities with a focus on the clinical domain, and integration of that domain with the work of public health laboratories needs to be improved upon.

Through partnerships, this White Paper comprehensively explores the state of HIT standards available for laboratory practices and in use in information exchanges. It also introduces an implementation strategy for HIT standardization of laboratory data exchanges to support public health laboratory business practices, their integration with their clinical partners and preparedness activities. The White Paper documents:

1 – Where Are we Now - Overview of HIT standards and their implementation efforts by public health laboratories and national organizations to date
2 – Where are we Going - Description of the HIT standards implementation strategy to improve laboratory information management systems (LIMS) interoperability with all its partners and suggestions for future projects

The White Paper describes project activities with various HIT standardization entities on multiple HIT standardization phases. It is focused on addressing incomplete and inconsistent adoption of the existing standards and absence of a sustainable approach for standardization of information systems in public health by operationalizing HIT standards that already exist for laboratory information exchanges. Lastly, it outlines the proposed Roadmap for HIT standardization for public health laboratory data exchanges.

The White Paper is targeted to the following three audiences: 1 – Leadership - public health leadership at the local, state and federal levels and national HIT leaders; and leadership of the State Health Information Exchanges (HIEs); 2 – Public health professionals involved in laboratory data exchanges – directors and staff of public health laboratories, public health preparedness programs and other programs; and 3 – IT professionals involved in HIT standardization – HIT vendors involved in HIT standardization activities (standards development, harmonization and testing; and standard-based products certification and deployment).

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Section 2

Introduction

Rationale for the Project

Public Health Laboratories provide specialized testing for clinical care, surveillance and surge capacity during disasters. Laboratory information management and business practices form the backbone of public health surveillance and healthcare delivery. As stated by Zarcone, et al: “Laboratories are key stakeholders in providing critical data to local, state, tribal and federal public health agencies to investigate individual cases of communicable and chronic diseases as well as to characterize and mitigate population-based public health threats.”

With hundreds of Public Health Laboratories (PHLs) operating on various state and local levels throughout the United States, approximately 100 of these laboratories provide comprehensive, high complexity services. This includes “centralized laboratories with multiple branch facilities (e.g., Texas, Florida); university-affiliated laboratories (e.g. Wisconsin, Nebraska); and consolidated laboratory services (e.g., Virginia). A PHL can have up to 10 different recipients of similar or identical information such as other public health laboratories; commercial laboratories; primary care providers; hospital infectious control practitioners; health program directors; state public health departments; the state chief medical/health officer; city or county chief medical/health officers; state epidemiologists; and federal agencies (e.g., Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA)).

According to a national survey, in 2007 almost 90% of PHLs had laboratory information management systems. However the capabilities of these LIMSs differ from the Electronic Health Records Systems (EHR-S), integrated laboratory Information systems (LISs) and among themselves. Just as varied as the services provided across the PHLs is the technical support for the LIMSs and thus their technical capabilities. A Lack of integration between PHL LIMSs and their recipients’ systems leads to duplication of efforts and increased costs of providing laboratory information. Various software products and varying data formats/standards used by individual systems make integration projects costly and often infeasible.

Health information technology standards are the key to enabling interoperability between senders and receivers of laboratory information. However, the survey conducted by the Association of Public Health Laboratories (APHL) revealed tremendous variability in the correct implementation of HIT standards, which rendered data sharing impossible without additional effort to map the data across the laboratories to a standard representation. This is a result from the fre-

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4 Same.
5 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011
6 PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011
10 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011
quent use of proprietary data, variability in the underlying data standards and set up within the LIMS as well as multiple choices of information exchange standards, security protocols, and network infrastructure in the U.S.\textsuperscript{11}

Today, neither public health laboratories, nor other laboratories, are fully interoperable in electronically reporting/exchanging data with their information exchange partners. Though due to its resource scarce nature the PHL community has always been collaboratively working on improving their workflows, service delivery and communications with their partners.

In 2006, members of the APHL Informatics Committee reviewed the need for and obstacles to building national interoperability.\textsuperscript{12} They identified the need to:

- harmonize the adoption of technical interoperability standards to support PHL electronic data exchange
- reduce the overhead or expense of transmitting laboratory test orders and results
- provide continuity of operations and surge capacity among PHLs
- share best practices in the adoption of LIMSs
- work more effectively with vendors of public health LIMS products and
- increase the effectiveness of identifying and propagating the adoption of new methodologies and technologies.

General barriers to effective electronic laboratory information exchange are (not in the order of priority):

Barrier I - The incomplete and inconsistent adoption of existing standards by the wide array of laboratories responsible for reporting laboratory results as well as by the EHR and the public health information systems they report to.

Barrier II - The lack of adoption of EHR-S\textsuperscript{13} in clinical settings (i.e., test order senders and result receivers) preventing electronic communication between providers and LIMS.

Barrier III - The use of proprietary, non-standardized information systems in public health preventing electronic communication between LIMS and public health programs (i.e., receivers of test results on public health threat conditions).

Barrier IV - The absence of a sustainable approach and funding to support the development of laboratory standards and their testing; and of certification and adoption of standards-based IT products in clinical, laboratory and public health settings.

Barrier V – The need for informatics-savvy personnel in PHLs to operate in a new HIT and information communication environment.

After review of existing standards, current initiatives showcasing successful implementations this paper’s focus is to address Barrier I (incomplete and inconsistent adoption of existing standards), Barrier III (use of proprietary, non-standardized information systems), and Barrier IV (absence of a sustainable approach for standardization) by operationalizing HIT standards that already exist for laboratory information exchanges. Our goal is to create an implementation strategy with a sustainable approach for public health laboratories to guide the development and


\textsuperscript{12} Same.

\textsuperscript{13} Office of National Coordinator for Health IT, DHHS, Health IT Adoption. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1152&parentname=CommunityPage&parentid=28&mode=2&in_hi_userid=11113&cached=true
consistent deployment of interoperable HIT standards in HIT products for the public health laboratory domain. By doing so, this will serve the business needs of public health laboratories and other public health programs involved in these initiatives.

The steps needed to operationalize HIT in the PH Laboratory domain are summarized in Table 1 and further described in Section 6:

<table>
<thead>
<tr>
<th>Standardization Phase</th>
<th>Definitions</th>
<th>Entity (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identify</strong> HIT Interoperability Needs and Priorities</td>
<td>After the review of business processes, use cases the functional requirements are described and compared to the existing standards. The subject matter expert need to be involved at this level to help identify any gaps in existing standards</td>
<td>HIT Policy Committee HIT Standards Committee ONC S&amp;I Framework CDC and APHL Laboratory Initiatives Laboratory Community of Practice CSTE PHDSC</td>
</tr>
<tr>
<td><strong>Develop and Maintain Standards</strong></td>
<td>Based on the functional requirements identified the standard development organizations (SDOs) create new or alter existing standards to meet the identified needs</td>
<td>International Health Terminology Standards Development Organization (IHTSDO, former SNOMED) Logical Observation Identifiers Names and Codes (LOINC) Health Level Seven (HL7) International Organization of Standardization (ISO)</td>
</tr>
<tr>
<td><strong>Select and Harmonize Standards</strong></td>
<td>Based on the functional requirements identified these groups gather stakeholders for the respective use cases and review and select the best suited existing standards and provide feedback to the SDOs, if needed</td>
<td>Integrating the Healthcare Enterprise (IHE) ONC Standards &amp; Interoperability (S&amp;I) Framework Public Health Reporting Initiative</td>
</tr>
<tr>
<td><strong>Test Standards</strong></td>
<td>The selected standards are being pilot tested to demonstrate usability and provide feedback to the SDOs and standards selection entities</td>
<td>IHE National Institute of Standardization (NIST)</td>
</tr>
<tr>
<td><strong>Certify Standards-based HIT Product</strong></td>
<td>Develop conformance criteria and enable HIT products to be tested and certified as being compliant with the selected standards to ensure a higher level of interoperability between partner systems</td>
<td>Authorized Testing and Certification Bodies (ONC-ATCB), e.g., Certification Commissions for Health IT (CCHIT)</td>
</tr>
<tr>
<td><strong>Deploy Standards-based HIT Product</strong></td>
<td>Encourage and provide support for the widespread implementation of the selected, tested and certified standards</td>
<td>IHE PHDSC APHL</td>
</tr>
<tr>
<td><strong>Outreach to Assure HIT Standardization for PHLs</strong></td>
<td>Ensure that the users of the standards provide feedback and have a voice at all levels of the HIT development – at the development level, the selection level (both technical and political) and the certification level.</td>
<td>PHDSC APHL</td>
</tr>
</tbody>
</table>

By doing so, this project will serve the business needs of public health laboratories, their clinical partners and other public health programs involved in these initiatives and leverage this key data source in a standardized way so that information can be quickly, reliably and economically shared, analyzed, and acted upon to improve clinical care, prevention, surveillance and management of communicable and chronic diseases.

**Target Audience**

The White Paper is targeted to the following three audiences:

1 – *Leadership* - public health leadership and decision-makers at the local, state and federal levels; national HIT leaders; and leadership of State Health Information Exchanges (HIEs) including State Chief Information Officers (CIOs). The goal is to communicate to them the challenges and possible solutions for enabling adoption of interoperable HIT solutions for public health laboratory data exchanges.

2 – *Health professionals involved in laboratory data exchanges* – directors and staff of public health laboratories, directors and staff at partner organizations of the public health laboratory such as providers, public health preparedness programs and other programs involved in laboratory data exchanges at the local, state and federal levels to engage them in HIT standardization activities (standards development, harmonization and testing; standard-based products certification; and selection of standard-based HIT products for their agencies/programs).

3 – *IT professionals involved in HIT standardization* – vendors of EHR-S, LIS and LIMS products involved in HIT standardization activities (standards development, harmonization and testing; and standard-based products certification and deployment) to address business needs of public health laboratories and programs in HIT standards to support laboratory health information exchanges.
Electronic communication across public health laboratory stakeholders is critical to assure that their data needs are addressed in real-time and in a high-quality manner. A PHL can have up to 10 different recipients of similar or identical information such as

1. Other public health laboratories
2. Commercial laboratories
3. Primary care providers
4. Hospital infectious control practitioners
5. Health program directors
6. State public health departments
7. State chief medical/health officer
8. City or county chief medical/health officers
9. State epidemiologists, and
10. Federal agencies.

To support these communications, PHL LIMSs have to exchange data with clinical EHR-S, other LIMSs, Public Health Information Systems (PH-IS) from various agencies and regional Health Information Exchanges (HIEs) using a variety of standards. In order to better understand how to reach the goal of interoperability with all partners in the PHL domain, a review of the different types of standards and their current use is provided here.

Standards are the key to information systems interoperability. Standardization, as defined by the International Organization for Standards (ISO), is the process of agreeing on standards, which represent the common language that allows the exchange of data between disparate data systems. The goals of standardization are to achieve comparability, compatibility, and interoperability between independent systems; to ensure compatibility of data for comparative statistical purposes; and to reduce duplication of effort and redundancies.

A Standard is a definition, set of rules or guidelines, format, or document that establishes uniform engineering or technical specifications, criteria, methods, processes, or practices that have been approved by a recognized standard development organization (SDO), or have been accepted by the industry as de facto standards, or de jure standards, i.e. formal legal requirements. De facto standards have become standards because a large number of companies have agreed to use them. They have not been formally approved as standards, but they are standards nonetheless.

In order to provide semantic interoperability several HIT Standards Categories need to be considered.

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In February 2006, the Health Information Technology Standards Panel (HITSP)\textsuperscript{18} identified the following health information technology standards categories\textsuperscript{19} with the respective examples:

<table>
<thead>
<tr>
<th>Standards Categories</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Standards</td>
<td>Vocabularies and terminologies</td>
</tr>
<tr>
<td>Information Content Standards</td>
<td>Reference information models (RIM)</td>
</tr>
<tr>
<td>Information Exchange Standards</td>
<td>Message-based and structured document-based</td>
</tr>
<tr>
<td>Identifier Standards</td>
<td>National Provider Identifier (NPI)\textsuperscript{20}</td>
</tr>
<tr>
<td>Privacy and Security Standards</td>
<td>Access control, audit, electronic consent</td>
</tr>
<tr>
<td>Functional Standards</td>
<td>Work processes, workflow and dataflow models</td>
</tr>
<tr>
<td>Other Standards</td>
<td>Internet standards, transport mechanisms</td>
</tr>
</tbody>
</table>

**Data Standards**\textsuperscript{21} are documented agreements on representations, formats, and definitions of common data. Data standards provide a method to codify in valid, meaningful, comprehensive, and actionable ways, information captured in the course of doing business. Data Standards are represented in vocabulary and terminology standards.

Vocabulary and terminology standards that are used in LIMS and LIS and should also be supported in EHR-systems:

- Logical Observation Identifiers Names and Codes (LOINC)\textsuperscript{22} for test orders and resulted tests
- INTSDO/Systematic Nomenclature for Medicine (SNOMED)\textsuperscript{23} should be used for lab tests results and specimen terms; it may also be used for procedures as well as diagnosis
- The Unified Code for Units of Measure (UCUM)\textsuperscript{24} for units of analysis
- Accredited Standards Committee X12 (HIPAA Transaction Format)\textsuperscript{25} for billing purposes
- International Classification of Diseases (ICD10/ICD)\textsuperscript{26,27} for diagnosis
- Health Level Seven (HL7) Version 2.x and Version 3\textsuperscript{28} for vocabulary
- Project-specific value sets, e.g., CDC Public Health Information Network -Vocabulary Access and Distribution System (PHIN VADS)\textsuperscript{29}

\textsuperscript{18} Health Information Technology Standards Panel (HITSP). URL: http://www.hitsp.org
\textsuperscript{20} Centers for Medicare and Medicaid Services, US Department of Health and Human Services; National Provider Identifier Standard. URL: http://www.cms.hhs.gov/NationalProviderIdentstand/
\textsuperscript{22} Logical Observation Identifiers Names and Codes (LOINC). URL: http://loinc.org/
\textsuperscript{23} Systematized Nomenclature of Medicine – Clinical Terminology. URL: http://www.ihtsdo.org/snomed-ct
\textsuperscript{24} The Unified Code for Units of Measure. URL: http://aurora.regenstrief.org/~ucum/ucum.html
\textsuperscript{25} Accredited Standards Committee X12. URL: http://www.x12.org
\textsuperscript{26} International Classification of Diseases, 10th Edition, Clinical Modification. URL: https://www.cdc.gov/ICD10/11b1_2011_ICD10CM_and_GEMs.asp
\textsuperscript{27} International Classification of Diseases, 9th Edition, Clinical Modification. URL: https://www.cdc.gov/icd9providerdiagnosticcodes/
\textsuperscript{28} Health Level Seven (HL7). URL: http://www.hl7.org
\textsuperscript{29} Centers for Disease Control and Prevention (CDC). Vocabulary Access and Distribution System (PHIN VADS). URL: http://phinvads.cdc.gov
Table 2 presents data from the 2010 survey of laboratory information systems (LIS) vendors on their capabilities to support the use of data standards if clients so wish, i.e., LIS vendors have capabilities to support these standards, but may not necessarily actually use them.

Table 2. Support for Data Standards by Laboratory Information Systems – 2010

<table>
<thead>
<tr>
<th>Data Standards</th>
<th>LIS Vendors = 35</th>
</tr>
</thead>
<tbody>
<tr>
<td>X12 (HIPAA Transaction Format)</td>
<td>33</td>
</tr>
<tr>
<td>LOINC</td>
<td>31</td>
</tr>
<tr>
<td>SNOMED</td>
<td>26</td>
</tr>
</tbody>
</table>

No data available about the use of data standards by PHLs.

Reportable Conditions Mapping Tables (RCMT) Project through a process engaging a wide range of stakeholders, including subject matter experts in laboratory medicine, epidemiology, infection prevention and informatics (especially vocabulary standards), as well as members of the EHR/LIS vendor community provided mapping of the laboratory tests and result codes related to Nationally Notifiable Conditions and Jurisdictional Reportable Conditions to standard vocabulary codes to achieve semantic interoperability. Specifically, it provides mappings between conditions and their associated codes in LOINC for laboratory tests and in SNOMED for test results. The RCMTs were previously known as the “Dwyer tables”, “Sable tables” or Notifiable Condition Mapping Tables (NCMTs). RCMT content for 109 reportable conditions has been published on June 30th, 2011, with on-going updates since laboratory tests and standard codes change over time via the CDC PHIN VADS.

The RCMT project was coordinated by the Standards Workgroup under the CDC and Council for State and Territorial Epidemiologists (CSTE) Joint Electronic Laboratory Reporting (ELR) Task Force, a collaborative effort between the CDC, APHL and CSTE to promote the implementation of ELR to public health.

The RCMTs can be used in EHR decision support systems to help identify patients who have reportable conditions, which would trigger public health case reporting and ELR.

Reportable Condition Ontology/Knowledgebase Project. Laboratory results are often a vital part in identifying communicable diseases that are of interest to public health. Automated laboratory data reporting will improve quality and timeliness of surveillance. The idea behind the Reportable Condition Ontology project is to provide a repository of all the laboratory tests and related results that should trigger a report to public health by jurisdiction based on the underlying CSTE position statements and the respective Technical Implementation Guides (TIGs). The vision is to have this repository be accessible in real time by any of the participating systems to review and identify the laboratory data that need to be reported to public health surveillance program in the affected jurisdiction. The RCMT are the underlying concept by which this Ontology would function – linking specific LOINC/SNOMED pairs to the reportable condition.

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31 Centers for Disease Control and Prevention (CDC). Reportable Conditions Mapping Tables Project. URL: http://www.cdc.gov/ehrmeaningfuluse/rcmt.html
### Information Content Standards

**Information Content Standards**[^32] define the content of information exchanges. First level information content standards define the structure and content organization of the electronic message/document information content. An example of a first level information content standard is the HL7 Reference Information Model (RIM)[^33] - a pictorial representation (an object model) of the clinical data (domains) which identifies the life cycle of events that a message or groups of related messages will carry. It is a shared model between all the domains and as such, is the model from which all domains create their messages. RIMs are information content standards, i.e., shared models of data organization between domains and, as such, are the models from which all domains create information exchange standards.

Second level information content standards define a ‘package’ of content standards (messages/documents). An example of a second level information content standard is HL7 – Continuity of Care Document (CCD)[^34].

### Information Exchange Standards

**Information Exchange Standards**[^35] define the structure and syntax of the electronic communication and are referred to as the standard ways of sending and receiving information. There are two information exchange standards: message-based, i.e., information is sent as a message; and document-based, i.e., information is sent as a structured document (form).

There are two types of information standards developed by HL7:

- message-based standard (messaging standard) - HL7 Version 2 and Version 3

These two standards are not interchangeable, but work is ongoing to make them more compatible.

**Message-based Information Exchange Standard (Messaging Standard).** HL7 Version 2 (V2) message-based standards are used in the United States. This standard enables point-to-point communication via direct interfaces between information senders and receivers, with each partner having a mean of 358 (24 -1000) point-to-point interfaces according to the 2010 CAP Survey.[^36]

There are multiple versions of the international HL7 V2 standard (also referred to as 2.x) in use, V2.8 being balloted in 2012. These versions are backwards compatible with each other, i.e., a system updated to a newer version is able to exchange data with any previous version. Each version also accommodates multiple message structures, based on the needs for each use case. These versions contain a high level of optionality to accommodate different needs in par-


[^33]: Health Level Seven (HL7). HL7 Reference Information Model. URL: [http://www.hl7.org/implement/standards/rim.cfm](http://www.hl7.org/implement/standards/rim.cfm)


[^36]: Same
In order to use these standards business partners (stakeholders) remove the optionality by creating an Implementation Guide (IG). However, due to the variance among these implementation guides, LIMS supporting one or another HL7 V2.x are not necessarily interoperable.

Data gathered from 56 state and local jurisdictions in 2010 by the National ELR Taskforce and APHL showed that there are multiple versions of HL7 messaging standards in use to send data from the laboratories to public health agencies (HL7 V2.3.x, V2.4 and V2.5.1). The most commonly used messaging standard in PHLs is V2.3.1 (Table 3).

<table>
<thead>
<tr>
<th>Information Exchange Standards</th>
<th>Number of Respondents (Total of 56 Jurisdictions)</th>
<th>ELR Survey</th>
<th>APHL Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Send</td>
<td>Receive</td>
<td></td>
</tr>
<tr>
<td>HL7 V2.2</td>
<td>1 (2%)</td>
<td>4 (8%)</td>
<td>NA</td>
</tr>
<tr>
<td>HL7 V2.3.x</td>
<td>4 (8%)</td>
<td>25 (44%)</td>
<td>6 (11%)</td>
</tr>
<tr>
<td>HL7 V2.3.1</td>
<td>25 (44%)</td>
<td>46 (82%)</td>
<td>47 (84%)</td>
</tr>
<tr>
<td>HL7 V2.4</td>
<td>2 (4%)</td>
<td>6 (10%)</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>HL7 V2.5</td>
<td>7 (12%)</td>
<td>7 (12%)</td>
<td>NA</td>
</tr>
<tr>
<td>HL7 V2.5.1</td>
<td>12 (22%)</td>
<td>9 (16%)</td>
<td>20 (36%)</td>
</tr>
</tbody>
</table>

Examples of nationally defined HL7 implementation guides for laboratory related data exchange are the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (ELR251PH-IG) and the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (LRI251-IG).

**HL7 Version 3 (V3)**, similar to HL7 V2.x, is an international standard for exchanging data between information systems. The HL7 Reference Information Model is the cornerstone of the HL7 Version 3 development process that was created as part of the Version 3 methodology to explicitly retain the context in which the information exchanged is used. The RIM is essential to increasing precision and reducing implementation costs thus V3 strives to improve the V2 process and its outcomes.

The development principles behind HL7 V3 lead to a more robust, fully specified standard. New capabilities offered in Version 3 include:

- Top-down message development emphasizing reuse across multiple contexts and semantic interoperability
- Representation of complex relationships
- Formalisms for vocabulary support
- Support for large scale integration
- Solving re-use and interoperability across multiple domain contexts

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37 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011
38 PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011
39 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011
40 PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011
41 https://www.hl7.org/store/index.cfm
42 http://www.hl7.org/ctl.cfm?action=ballots.home&ballot_cycle_id=524&ballot_voter_id=0

16
- A uniform set of models and
- Expanded scope to include community medicine, epidemiology, veterinary medicine, clinical genomics, security, etc.  

**Document-based Information Exchange Standard.** In September 2011 the Federal Advisory Committee Act (FACA) HIT Standards and Policy Committees approved the use one message-based standard - HL7 V2.5.1 - for laboratory, immunization and syndromic surveillance data exchanges for MU Stage 2 while also recommending the use of *HL7 Clinical Document Architecture (CDA)* standard as a future direction for HIT standards adoption in public health. The CDA standard was recommended in the proposed rules for MU Stage 2 for cancer reporting.

The HL7 CDA standard is part of the HL7 Version 3 standards family that is derived from the HL7 Reference Information Model to enable semantic consistency across platforms for the purpose of exchange and re-use of clinical data. CDA allows representation of clinical or public health information in a structured format (i.e., CDA templates) that is similar or identical to the paper forms formats. Thus CDA standard closely mirrors traditional paper-based reporting workflows as information is exchanged as documents not strings of words.

The HL7 CDA standard has persistence, stewardship, potential for authentication, wholeness, and is human readable while using RIM structured and controlled vocabulary to ensure semantic interoperability. It is implemented in Extensible Markup Language (XML). A CDA document has a header and a body. The header contains information about the patient, the encounter, and service providers. The body contains clinical content. HL7 is actively working on CDA Release 3.

CDA Release 2 (R2) has become widely used in implementation guides for document sharing such as the Continuity of Care Document, Medical Summary (MS), Emergency Department Referral Document (EDR), and Laboratory Reports. Additionally, CDA R2 document implementation guides have been created for public health use cases such as the Healthcare Associated Infection Report (HAI), Public Health Case Reports (PHCR), and the Immunization Document.

Outside the US a few countries have successfully implemented the HL7 CDA document information exchanges for *Salmonella* and *Shigella* notifiable conditions between sentinel clinical laboratories performing initial microbiology isolations, public health laboratories performing epidemiological typing, federal public health agency, regional epidemiologists analyzing the data and investigating outbreaks, and data managers/analysts dedicated to collaborative sharing of data and regional analysis.

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43 Health Level Seven (HL7). Frequently Asked Questions (FAQ). URL: [http://www.hl7.org/about/FAQs/index.cfm](http://www.hl7.org/about/FAQs/index.cfm)

44 Health IT Standards Federal Advisory Committee. Recommendations from the Public Health Surveillance Summer Camp. September 28, 2011. URL: [http://healthit.hhs.gov/portal/server.pt?open=512&objID=1817&parentName=CommunityPage&parentId=28&mode=2&in_hi_userid=11673&cached=true#092811](http://healthit.hhs.gov/portal/server.pt%3Fopen%3D512%26objID%3D1817%26parentName%3DCommunityPage%26parentId%3D28%26mode%3D2%26in_hi_userid%3D11673%26cached%3Dtrue%23092811)

45 Centers for Medicaid and Medicare Services. proposed rule for Stage 2 requirements for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. URL: [https://www.cms.gov/apps/media/press/factsheet.asp?Counter=4286&intNumPerPage=10&checkDate=&checkKey=&srchType=1&num-Days=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&yyear=&desc=&cboOrder=da te](https://www.cms.gov/apps/media/press/factsheet.asp%3FCounter%3D4286%26intNumPerPage%3D10%26checkDate%3D%26checkKey%3D%26srchType%3D1%26num-Days%3D3500%26srchOpt%3D0%26srchData%3D%26keywordType%3DAll%26chkNewsType%3D6%26intPage%3D%26showAll%3D%26pYear%3D%26yyear%3D%26desc%3D%26cboOrder%3Ddate)


47 Health Level Seven (HL7). Frequently Asked Questions. URL: [http://www.hl7.org/about/FAQs/index.cfm](http://www.hl7.org/about/FAQs/index.cfm)

The HL7 CDA Release 2 document-based information exchange standard provides benefits over HL7 electronic laboratory messaging. Today LIMSs have highly complex and expensive software for the determination of report copies, report routing, report preferences, report rendering, and report archiving. Once a laboratory has installed a LIMS, one is often confined to the abilities of that system or by the LIMS vendor fees for additional features, e.g., HL7 message interface. The generation of HL7 CDA R2 laboratory reports allows for more flexible management of these laboratory requirements. A report can be generated once, either within a LIMS or by a data import from a CDA generation system. Add-on technologies can then be responsible for the importing, transforming, routing, rendering and auditing functions.\textsuperscript{51}

An example of a CDA document (i.e., template, form) building tool is the Model Driven Health Tool (MDHT) Project.\textsuperscript{52} IBM Research has developed an open source Model-Driven Health Tool – MDHT - that allows the building of CDA templates for clinical documents. MDHT currently supports the Meaningful Use Standard, Healthcare Information Technology Standards Panel (HITSP) Patient Summary Document (C32)\textsuperscript{53} and the Consolidated CDA Project.\textsuperscript{54} MDHT was successfully used by the Veterans Health Administration (VHA). On November 23, 2011, ONC has announced that this tool will be used by the ONC S&I Framework Initiatives, e.g., the Transitions of Care and the Consolidated CDA initiatives.

No national survey data is available from PHLs on the ability of their LIMS to use CDA for laboratory result reporting today. For LIS the CAP Survey shows that about 30\% of LIS vendors can use CDA.\textsuperscript{55}

\textbf{When should one use messaging and when would the use of documents be more appropriate?}\textsuperscript{56} The development of HL7 V3 Messaging as well as CDA-document artifacts is based on the HL7 V3 HL7 Development Framework (HDF) and the Reference Information Model, RIM. HL7 itself hasn’t created any recommendation in this area. HIT vendors that have implemented both messages as well as documents mostly respond to the question by focusing on the nature of the use case and looking for a match with the characteristics of either messages or documents:

- Messages are generally used to support an ongoing process in a real-time fashion. They convey status information and updates related to one and the same dynamic business object. Messages are about “control” - they can represent requests that can be accepted or refused by the system and there are clear sets of expectations about what the receiver must do.

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\textsuperscript{51} Renly SR, Knoop SE, Kaufman JH, Ram R. Creating CDA R2 Laboratory Reports to Meet Public Health Surveillance Requirements: IBM Research Report

\textsuperscript{52} Open Health Tools. Model-Driven Health Tool (MDHT). Release 1.0. URL: https://mdht.projects.openhealthtools.org


\textsuperscript{54} Office of National Coordinator of Health IT (ONC. Standards and Interoperability (S&I) Framework. CDA Consolidation Project. URL: http://wiki.siframework.org/CDAConsolidation+WG


In such situations the latest version of the data is of importance to support an ongoing process, historic versions of one and the same object are generally not of importance apart from regulatory (e.g. auditing) purposes.

Messages by and large contain “current” data.

The more interactive and tightly coupled your communication process is, the more the use of messages is applicable.

- Documents are persistent in nature, have “static” content and tend to be used “post occurrence”, i.e. once the actual process is done. Documents are about persisting ”snapshots” as understood at a particular time.
- Documents contain data “as it was” when the document was originally created. For documents such as referrals and discharge summaries, it may be more appropriate to see the data as it was understood at the time the referral or summary was constructed rather than viewing the data as it exists now.
- Documents are “passive”. They capture information and allow that information to be shared. Documents can be superseded and corrected, but they are still “static documents” rather than dynamic objects.
- The more passive and loosely coupled your communication process is, the more the use of documents is applicable.

- Allow for both paradigms to coexist – use a use case driven approach to determine what paradigm forms the better solution for the use case.

### Identifier Standards

Identifier Standards provide a universal method to identify entities such as an individual (consumer), a healthcare provider, a healthcare organization, a payer, or others (clearinghouses, vendors, products, etc). Identifiers (IDs) are used extensively in virtually all information processing systems. Identifiers are the lexical tokens that name entities. The concept is analogous to that of a "name", which is essential for any kind of symbolic processing.

A number of national and international standard identifiers have been adopted in healthcare. In the United States, a National Standard Identifier for Individual and Organization Health Care Providers -- National Provider Identifier (NPI), a unique 10-digit identification number issued to healthcare providers in the United States by the Centers for Medicare and Medicaid Services (CMS) and a National Employer Identification Number (EIN) have been adopted for use in all electronic administrative and financial transactions, i.e., claims, claim payments, eligibility for providers engaged in transaction involving laboratories that perform diagnostic testing are required to be certified by Clinical Laboratory Improvement Amendments (CLIA) regulation. After successful inspection by CLIA, each laboratory under CLIA regulations is assigned an identifier (CLIA identifiers). These Identifiers apply to the entire laboratory organization.

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58 Center for Medicare and Medicaid Services (CMS) National Provider Identifier, NPI. URL: https://www.cms.gov/NationalProvIdentStand/01_Overview.asp#TopOfPage
60 Centers for Medicaid and Medicare Services (CMS). Clinical Laboratory Improvement Amendments (CLIA) regulation. URL: https://www.cms.gov/clia/
**Object Identifiers (OIDs)** can be used to identify facilities, for example within a laboratory organization. The CDC maintains a database that matches a CDC assigned OID to each CLIA number. The LIMS track providers by identifiers as well as the related organizations those providers work for.

The creation of a national patient identifier standard is still outstanding though many organizations have implemented internal **Master Patient Index (MPI)** applications, i.e., the systematic matching and merging of records in information systems to create an accurate, unique health record for each individual.\(^\text{61}\)

There are other identifiers for ingredients for drugs and biologics, identifiers for medical devices and durable medical equipment.

**Laboratory Identifiers (order, specimen, patient).** Within the laboratory every specimen is assigned a specimen ID or accession number. CLIA requires at least two IDs that allow for positive identification of the patient (name, date of birth, patient identifier). Other identifiers are used to track the test order both on the requestor side (placer order number) and on the laboratory side (filler number). The laboratory also tracks any identifier submitted to them by the test requestor (order placer), so that when the results are sent back they can be associated with the correct sample and patient. In order to maintain unique identifiers across all the organizations working with the laboratory, it is a best practice to keep track of who assigned the identifier in question (assigning authority), which in turn can also be done by identifier, like an OID, CLIA number or the NPI.

**Privacy and Security Standards**

**Privacy and Security Standards**\(^\text{62}\) are intended to ensure information security and confidentiality. **Information security** means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification or destruction. Security refers to physical, technological, or administrative safeguards or tools used to protect identifiable health information from unwarranted access or disclosure. Security is the set of actions an organization takes to protect that information. **Confidentiality** has been defined by the International Organization for Standardization (ISO) as "ensuring that information is accessible only to those authorized to have access" and is one of the cornerstones of information security. Confidentiality is one of the design goals for many cryptosystems, made possible in practice by the techniques of modern cryptography.

In 1996, the Department of Health and Human Services enacted the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Provisions\(^\text{63}\) to reduce the cost and administrative burdens of health care by allowing standardized, electronic transmission of administrative and financial transactions. HIPAA also introduced the first comprehensive federal privacy and security rules and guidelines to support and enable data and transaction standardization and exchange.

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\(^{61}\) Public Health Informatics Institute. The Unique Records Portfolio. URL: [http://phii.org/resources/UniqueRecordsPortfolio.asp](http://phii.org/resources/UniqueRecordsPortfolio.asp)


There are a number of security and privacy standards that can support public health laboratory data exchanges. These standards enable transport security, identification of persons and systems, privilege management and access controls, audit, policy agreements, and pseudonymization. These standards are generic and must be support by any systems participating in electronic health information exchanges, so they are viewed as the information technology infrastructure (ITI) standards.

**Integrating the Healthcare Enterprise (IHE)**\(^\text{64}\) is a multi-year initiative under the leadership of Health Information Management & Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE began in November 1998 as a collaborative effort to improve the way computer systems in healthcare share clinical information. IHE Technical Committees develop **Integration Profiles** and **Content Profiles** to assure that health information passes seamlessly from application to application, system to system, and setting to setting — across the entire healthcare enterprise.

**IHE Technical Frameworks**, the volumes in which IHE profiles are published, are annually expanded and continuously maintained by the IHE Technical Committees in 13 domains. Each domain is sponsored and overseen by organizations representing healthcare providers and HIT stakeholders in the domain. IHE domains include Anatomic Pathology; Cardiology; IT Infrastructure; Laboratory; Patient Care Coordination; Patient Care Device; Quality, Research and Public Health; Radiology; Eye Care; Radiation Oncology; and newly established Dental; Endoscopy; and Pharmacy domains.

IHE profiles provide precise implementation specifications (implementation guides) based on established standards to address specific HIT interoperability issues. They detail required actions for HIT systems to acquire, manage and communicate medical information effectively, while supporting efficient provider workflows and protecting private health information.

IHE profiles have provided the foundation for health information exchange networks in the US and worldwide. **IHE IT Infrastructure (ITI) Technical Framework**\(^\text{65}\) contains a number of IT infrastructure Integration Profiles that specify interoperability standards for information security infrastructure such as patient identity resolution, pseudonymization and others. **Appendix 2** provides detail description of these standards.

**Functional Standards**

**Functional Standards**\(^\text{66}\) describe, in an organized format, the participants (people and information systems), required functions & features and operational capabilities needed in a Software Application as defined by a qualified group of users (domain experts/stakeholders). **Functional requirements** are derived from the description of user’s business activities (business requirements). **Business requirements** are aimed to explain why a Software Application is needed. **Functional standard** describes what a Software Application must do, i.e. **functional requirements**, by translating **Business Requirements** into the following five functional categories:

1. **Collect/Input Data**, i.e. get data into the Software Application

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\(^{64}\) Integrating the Healthcare Enterprise (IHE). URL: [http://www.ihe.net](http://www.ihe.net)

\(^{65}\) Integrating the Healthcare Enterprise Information Technology Infrastructure Technical Framework. URL: [http://www.ihe.net/Technical_Framework/index.cfm#IT](http://www.ihe.net/Technical_Framework/index.cfm#IT)

2. **Manage Data**, i.e. receive data, verify data, store data, send data
3. **Analyze Data**, i.e. group data by similar attributes (location, condition, etc.)
4. **Integrate Data**, i.e. receive data from more that one data system/source
5. **Generate Output**, i.e. reports, summaries, alerts, notifications, etc.

For example, patient’s visit to a doctor (**business activity**) creates encounter data that the doctor will record/enter (**collect data**) in the Electronic Health Record System (EHR-S). This data entry has to be checked for quality assurance and added into the patient’s medical record in the EHR-S (**manage data**). This encounter data can be compared with the previous encounters’ data on this patient or with other patients’ data (**analyze data**). This encounter data may include medication prescription to be sent to a Pharmacy information system (**integrate data**). This encounter data may be given to a patient as a visit’s summary or has to be reported to a Public Health Agency (**generate output**).

**Functional requirements** are written by users (stakeholders) in a non-technical language in an organized format of the **Functional Requirements Analysis Document (FRAD)**. FRAD is used in software engineering to summarize the user’s functional requirements for a Software Application.

The Functional Requirements Analysis Document includes the following components:

1. **Problem-Solution** - description of the Problem; the business activity and health information exchange needs related to this activity, that the software application will help to address
2. **Goal** - goal of the software application
3. **Actors** - business actors (stakeholders) and technical actors (information systems, i.e. data sources) that will interact with the software application
4. **Functional Requirements** - actions that the software application will support
5. **Non-Functional Requirements** – descriptors of the software application operation, e.g., privacy and security requirements, periodicity of data exchanges and others
6. **Use Case Description** - a real clinical or public health scenario that describes the use of the software application in the context of business actors’ work processes
7. **Unified Modeling Language (UML)** **Diagrams** that depict actors and actions interactions in the context of the software application, i.e., Use Case Diagram and Workflow and Dataflow Diagram
8. **High-Level Architecture** of the software application
9. **Hardware and Software Requirements** of the software application
10. **Evaluation** of the software application development
11. **Timeline** for the software application development

A **Functional Standard** is a vehicle to assure that the work processes of users related to a particular business activity, i.e., patient care management, public health surveillance, etc., that involve electronic data exchanges are well understood and agreed upon first by users themselves and then communicated clearly to the developers as functional requirements for a Software Application. To ensure semantic interoperability those functional requirements need to be well de-
scribed and implemented in all systems participating in data exchange. Sections that follow provide examples of projects aimed to define functional standards for PHLs.

Public Health Collaborative Business Requirements Project\textsuperscript{69} was one of the first comprehensive assessments of the information needs of the PHL community. APHL and the Public Health Informatics Institute (PHII) worked with a number of PHLs to define core business processes relevant to the function and management of PHLs. Specifically, a detailed inventory of the 16 business processes of a typical PHL was developed such as:

1. Laboratory Test Processing (Clinical and Environmental), i.e. Receive/Process Test Orders
2. Test Scheduling
3. Proactive Specimen/Sample Collection (Pre-Scheduled Tests)
4. Specimen and Sample Tracking/Chain of Custody
5. Media, Reagent, Stains, Control, etc. Manufacturing
6. Inventory Control Including Kits & Forms Management
7. General Laboratory Reporting, \textit{i.e.}, Report Test Results
8. Statistical Analysis and Surveillance
9. Billing for Laboratory Services
10. Contract and Grant Management
11. Training, Education and Resources Management
12. Laboratory Certification/Licensing
13. Customer Concerns/Suggestions
14. Quality Control and Quality Assurance Management
15. Laboratory Safety and Accident Investigation
16. Laboratory Mutual Assistance/Disaster Recovery

This assessment documented laboratory workflow for each business process, information system involved, data requirements, and interdependencies across business processes. From the list above only Business Processes 1 and 7 (Orders/Results) require interoperability, therefore, the focus of this White Paper is on the following business processes:

- Business Process 1 (Tests Orders) requires interoperability between senders (e.g., EHR-S, HIE, and other LIMS) and receivers (e.g., PHL LIMS, PH-IS).
- Business Process 7 (Test Results) requires interoperability between senders, e.g., PHL LIMS and receivers (e.g., EHR-S, HIE, other LIMS).

HL7 Public Health Reporting Requirements Standard\textsuperscript{70} is a new standard to extend the HL7 Healthcare Quality Measure Framework (HQMF) standard, originally defined to support the specification of quality measures (eMeasures), to also support the expression of public health reporting requirements. As a structured document specification, this will allow for both a human readable expression as well as a machine-readable expression of the jurisdiction-specific reporting requirements. This standard will support the capability of a system to consume the requirements, and process those requirements against CDA-expressed content to determine


\textsuperscript{70} Public Health Data Standards Consortium (PHDSC). HL7 Public Health Reporting Requirements Standard. URL: https://wiki.phdsc.org/index.php/PH-Lab
whether a report should be made to public health, what to report, to whom to send the report, how to report, and when to report.

In order to facilitate better interoperability between EHR-S and PHL LIMS the HL7 Public Health Functional Profile (PHFP), a joint project of the PHDSC, CDC National Center for Health Statistics (NCHS) and the public health community at large is being updated requirements for data exchange with PHLs. The PHFP conforms to the HL7 Electronic Health Record System Functional Model (EHR-S FM) Release 1.1 and identifies functional requirements and conformance criteria for public health-clinical information collection, management and exchanges. The PHFP contains a core or common set of functional requirements identified across public health domains as well as specific functional requirements for these domains. The PHFP-Phase 1, successfully balloted in May 2011, is limited to specifying functional requirements in three public health domains:

- Early Hearing Detection and Intervention,
- Vital Records and
- Cancer.

In PHFP-Phase 2 will be balloted in spring 2012. It includes the following new public health domains:

- Public Health Laboratory,
- Birth Defects
- National Surveys
- Occupational Health and Safety
- Deep Venous Thrombosis and Pulmonary Embolism (DVT/PE)

The PHFP will be used as a reference for certification of EHR systems that include functionality to support public health domains (programs). Specifically, this profile will be used for developing certification criteria for EHR-S to support information exchanges for the EHDI and PH-Lab domains.

**The Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework (IHE Lab TF)** includes profiles addressing workflow and information sharing involving laboratories and their supporting systems (Table 4):

<table>
<thead>
<tr>
<th>#</th>
<th>Profile Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laboratory Testing Workflow (LTW)</td>
</tr>
<tr>
<td>2</td>
<td>Laboratory Device Automation (LDA)</td>
</tr>
<tr>
<td>3</td>
<td>Laboratory Point Of Care Testing (LPOCT)</td>
</tr>
<tr>
<td>4</td>
<td>Laboratory Code Set Distribution (LCSD)</td>
</tr>
<tr>
<td>5</td>
<td>Laboratory Specimen Barcode Labeling (LBL)</td>
</tr>
<tr>
<td>6</td>
<td>Sharing Laboratory Reports (XD-LAB)</td>
</tr>
</tbody>
</table>

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72 Integrating the Healthcare Enterprise Laboratory Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory
The laboratory workflow transactions related to the exchange and sharing of laboratory test orders and results support not only the clinical workflow, but can be leveraged to support public health laboratory information exchanges and reporting. The IHE-Lab Technical Framework introduces the following Actors (Figure 1):

- Order Placer (EHR-S)
- Order Filler (LIMS)
- Order Results Tracker (LIMS) and
- Automation Manager (LIMS).

A laboratory uses an Order Filler (OF) application to fulfill its orders. It handles its technical automation with the help of Automation Managers (AM), each of which may manage one or more Laboratory Devices (LD). The systems: Laboratory Information System (LIS), Laboratory Automation System (LAS), Devices (Dev) that support the IHE actors, may be interconnected in various ways. Please note that the CDC PHLISSA project described below uses the same terminology for PHL workflow actors.

**Figure 1. Laboratory Testing Workflow Actor Diagram**

**Updating Patient Information on the Test Order.** Patient information updates are introduced into the system at various stages of the analytical process using IHE Patient Demographic Query (PDQ) and Patient Administration Message (PAM) Profiles from the IHE IT Infrastructure Technical Framework. Order Placer, Order Filler and Order Results Tracker are grouped with appropriate actors of the PAM profile and/or the PDQ profile. This grouping ensures that these three actors are provided at any time with up-to-date patient demographic and encounter data.

The IHE-Lab actors are committed to updating their patient data automatically and without delay as soon as their paired PAM or PDQ actor is notified of this update. Thus the new patient data will be visible by the laboratory staff and by the ward staff as they are working on an order related to that patient or viewing the results of that order. Conversely, the Automation Manager actor receives patient demographic and encounter data only within the context of a Work Order.
Whenever some of the patient data changes (e.g. update patient name, change patient identifier, etc.) it is the responsibility of the Order Filler to forward this update to the Automation Manager for all Work Orders which are in process related to that patient, using transaction LAB-4. If there is no Work Order currently in process for that patient, the Automation Manager is not informed of the patient update. Thus the new patient data will be visible by the laboratory technical staff in Work Orders of the Automation Manager application.

**Figure 2** shows the process flow of an Order, with patient data update occurring during this process. “Patient data update” is to be understood in a broad meaning: It can be an update of the patient demographics, a change of patient identifier, a merger of two patient records, a link between two patient records, a change of patient class, a transfer or its cancellation, a change of patient account, or a few other trigger events.

![Laboratory Order Activity Diagram with Patient Data Update](image)

**Figure 2.** Laboratory Order Activity Diagram with Patient Data Update

**From Test Order to Test Result.** The patient specimen testing starts with a Work Order sent by the Order Filler to the Automation Manager (**Figures 1 and 2**). The Automation Manager splits this Work Order into a sequence of Work Order Steps (WOS), and schedules each step on a laboratory device (LD), e.g., aliquoter, robotic conveyer, analyzer, according to the organization of the laboratory automation (**Figure 3**).

Each WOS contains all information required by the target device to perform it: container identification, specimen information, target ID, operation to perform, and scheduled time. The Analytical Work Order Step (AWOS) also contains the list of clinical tests to perform, the patient identification, admission and clinical information, and the order information. The specimen information may include the ID, position, specimen type, volume, date and time of collection, ID of collector, and specimen pre-analytical status (e.g., “centrifuged”, “decapped”).

26
For some Analyzers that perform single tests (e.g., HbA1c), or a constant panel (Blood culture, Blood cell counts), the AWOS does not need to mention the tests to be performed.

By definition, a Work Order Step - WOS - is related to a single specimen. The specimen (primary or aliquot) is usually identified with a unique ID printed on a barcode label attached to the specimen container (see section above on Identifier Standards).

The laboratory technical staff supervises the various WOS using the Automation Manager and operating all necessary devices. The technical staff performs the technical validation of the results on the Automation Manager, which then sends these results back to the Order Filler. Should a specimen be damaged or lost, the Automation Manager will suspend or cancel its Work Order until the replacement specimen arrives.

The Automation Manager supports transactions for the normal process of specimen analysis as well as transactions for quality control (QC) testing. In addition, it supports automatic reruns triggered by out of range results, reruns requested during technical validation, and urgent tests.

**Reporting Laboratory Results.** Figure 4 presents the animated diagram of the public health laboratory results reporting workflow in the case of salmonella as it is presented in the IHE Sharing Laboratory Reports – Cross-Documents Sharing-Laboratory Reports (XD-Lab) – Content Profile. This Profile describes a laboratory report as a CDA electronic document to be available to the ordering provider’s EHR system, or patient’s Personal Health Record (PHR), or to be reported to a public health agency using one of the document sharing profiles, as defined in the IHE IT Infrastructure Technical Framework such as Cross Document Sharing (XDS) and Retrieve Form for Data Capture (RFD), i.e., pre-populating the public health report form (described below),
As a CDA document, this electronic document contains the set of results produced by a clinical laboratory or by a public health laboratory in fulfillment of one or more test orders for a patient. The report is shared in a human-readable and a machine-readable format; the latter is to facilitate the integration of these observations in the database of a consumer system.

The IHE XD-Lab Profile covers all laboratory specialties except anatomic pathology. The human rendering of the laboratory report defined in this Profile is compatible with laboratory regulations in various countries, including CLIA in the USA. The laboratory report described in this Profile, with its set of test results in a machine-readable format, may also be used to share historical results with appropriate content anonymization and patient identification pseudonimization to create shared distributed repositories of laboratory information.

There are two actors in this profile, the Content Creator and the Content Consumer (Figure 5) as follows:

- **Content Creator (Data Sender)** Actor (e.g., LIMS) is responsible for the creation of content (e.g., test results) and its transmission to a Content Consumer, e.g., HIE, EHR-S, PH-IS, Personal Health Record (PHR) and

- **Content Consumer (Data Receiver)** Actor (e.g., EHR-S and PH-IS) is responsible for viewing, importing, or other processing of content created by a Content Creator Actor.

Thus, Content (i.e., a laboratory report) is created by a Content Creator and is to be consumed by a Content Consumer.

![Figure 4. Specimen’s Work Order Steps (WOS) for Test Result Report](image)

![Figure 5. Exchanging the Laboratory Results: Actors in the XD-Lab Profile](image)
Figure 6 presents a generic laboratory workflow (processing laboratory test orders and laboratory test results reports) using IHE interoperability standards (Profiles).

Figure 6. Generic Laboratory Workflow and IHE Interoperability Standards
A work in progress, the **IHE Public Health Reporting Integration Profile**\(^{73}\) describes the use of IHE profiles to support patient- and population-level public health case reporting based on the HL7 Public Health Reporting Requirements Standard to automate the decision processing for triggering a report to public health. Laboratory reporting is one of multiple public health reporting use cases addressed by this profile. The profile uses examples of five notifiable conditions (Anthrax, Tularemia, Hepatitis B (hep-B), Tuberculosis (TB) and Influenza).

This profile also defines a high-level framework for harmonization of business areas, business processes and functional requirements for information systems across various public health domains/programs, e.g. communicable diseases, chronic diseases, maternal and child health, health statistics, environmental health and others.

**IHE Public Health Reporting Integration Profile**\(^{74}\) describes the use of IHE profiles to support individual- and population-level public health case reporting based on the HL7 Public Health Reporting Requirements Standard to automate the decision processing for triggering a report to public health. Laboratory reporting is one of multiple public health reporting use cases addressed by this profile. The profile uses examples of five notifiable conditions (Anthrax, Tularemia, Hepatitis B (hep-B), Tuberculosis (TB) and Influenza).

This profile also defines a high-level framework for harmonization of business areas, business processes and functional requirements for information systems across various public health domains/programs, e.g. communicable diseases, chronic diseases, maternal and child health, health statistics, environmental health and others.

**Other Standards: Transport Mechanisms as Standards**

**IHE IT Infrastructure (ITI) Technical Framework,**\(^75\) in addition to the privacy and security standards described above, also defines other IT infrastructure interoperability standards for health information exchanges including those for public health. For laboratory data exchanges, the IHE ITI Integration Profiles specify interoperability standards for (a) a document sharing infrastructure (cross-document sharing (XDS)), (b) form management (i.e., pre-populate electronic forms (retrieve form for data capture (RFD) for reporting); (c) a cross-enterprise document workflow (XDW) which defines the status of the workflow events (steps) by tracking the documents generated by those events; and others. **Table 5** lists examples of IHE IT Infrastructure profiles that support laboratory data exchanges.

**Table 5. Examples of IHE IT Infrastructure Profiles for Laboratory Data Exchanges**

<table>
<thead>
<tr>
<th>#</th>
<th>Profile Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Basic Patient Privacy Consents (BPPC)</td>
</tr>
<tr>
<td>2</td>
<td>Cross-Enterprise Document Sharing (XDS)</td>
</tr>
<tr>
<td>3</td>
<td>Cross-Enterprise Document Reliable Interchange (XDR)</td>
</tr>
<tr>
<td>4</td>
<td>Cross-Enterprise Document Media Interchange (XDM)</td>
</tr>
<tr>
<td>5</td>
<td>Cross-enterprise Sharing of Scanned Documents (XDS-SD)</td>
</tr>
</tbody>
</table>

\(^{73}\) Public Health Data Standards Consortium (PHDSC). IHE Public Health Reporting Integration Profile. URL: https://wiki.phdsc.org/index.php/PH-Lab

\(^{74}\) Public Health Data Standards Consortium (PHDSC). IHE Public Health Reporting Integration Profile. URL: https://wiki.phdsc.org/index.php/PH-Lab

\(^{75}\) Integrating the Healthcare Enterprise Information Technology Infrastructure Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#IT
Table 6 lists IHE profiles that define interoperability standards for test order/results workflow for the two public health conditions: Anthrax (public health preparedness) and Influenza (public health surveillance).

Table 6. Examples of the IHE Interoperability Standards for Patient-level Information Exchanges in PH-Lab Domains by Business Processes and Activities (Tasks)

<table>
<thead>
<tr>
<th>Business Processes / Activities (Tasks)</th>
<th>PH-Lab Domain</th>
<th></th>
<th>Examples of IHE Interoperability Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preparedness Reporting (Anthrax)</td>
<td>Public Health Surveillance (Influenza)</td>
<td></td>
</tr>
<tr>
<td>Order test</td>
<td>Input: Consent (or by statute)</td>
<td>Output: Test order</td>
<td>BPPC IHE-LAB TF</td>
</tr>
<tr>
<td>Conduct test</td>
<td>Input: Test order</td>
<td>Output: Test results</td>
<td>IHE-LAB TF (XD-Lab) IHE ITI TF (RFD/XDR/DSUB, NAV)</td>
</tr>
<tr>
<td>Interpret and report test results meeting reporting criteria</td>
<td>Input: Test results; Public Health Reporting Requirements</td>
<td>Output: Flags on abnormal results; Public Health Report</td>
<td>IHE ITI TF (RFD/RPE/ XDS/MPQ, DSUB, NAV) IHE-LAB TF IHE PH Reporting Profile &amp; HL7 Public Health Reporting Requirements</td>
</tr>
</tbody>
</table>

The CDC’s Public Health Information Network Messaging System (PHIN MS) is a software installed locally at each data exchange partner. The system securely sends and receives encrypted data over the Internet using Electronic Business Extensible Markup Language (ebXML) technology. PHIN MS enables the exchange of format agnostic data (text or binary file formats like .doc, .xls, .zip, .txt, .jpeg, .gif, etc as well as HL7 messages) a common approach to security and encryption, methods for dealing with a variety of firewalls, and Internet protection schemes. PHIN MS provides a standard way for addressing and routing content and exchanging transport level confirmations. PHIN MS supports the use of Route-not-Read (RnR) hubs.

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76 Integrating the Healthcare Enterprise (IHE). URL: [http://www.ihe.net](http://www.ihe.net)
The **Nationwide Health Information Network (NwHIN)**\(^{78}\) is the national initiative that defines standards, services and policies that enable secure health information exchange across diverse entities, within communities and across the country. A group of federal agencies, local, regional and state-level Health Information Exchange Organizations (HIEs) and integrated delivery networks, formerly known as the NHIN Cooperative, has been helping to develop the network services and policies for information sharing. The participating entities include:

- Centers for Disease Control and Prevention contracts to receive biosurveillance data
- Social Security Administration
- ONC - Beacon Communities and
- ONC - State HIE Cooperative Agreements.

The **Direct Project**,\(^{79}\) launched in March 2010, is defining standards and services required to enable secure, directed health information exchange among trusted providers via internet in support of Stage 1 Meaningful Use of Health IT incentive requirements (e.g., a primary care provider sending a referral or care summary to a local specialist electronically, or a physician requesting lab tests electronically).\(^{80}\)

The Direct Project has identified the use of Simple Mail Transfer Protocol (SMTP) as its primary mechanism for delivering healthcare content from a sender to a receiver.\(^{81}\) The SMTP is an internet standard for e-mail transmission across Internet Protocol (IP) networks. Participants in exchange are identified using standard e-mail addresses associated with X.509 certificates. The data is packaged using standard Multipurpose Internet Mail Extensions (MIME) content types. S/MIME (Secure/Multipurpose Internet Mail Extensions) is a standard for public key encryption and signing of MIME data. S/MIME functionality is built into the majority of modern email software and interoperates between them.

Authentication and privacy are obtained by using Cryptographic Message Syntax (S/MIME), and confirmation delivery is accomplished using encrypted and signed Message Disposition Notification. Optionally, certificate discovery of endpoints is accomplished through the use of the DNS (Domain Name System) -- a hierarchical distributed naming system for computers, services, or any resource connected to the Internet or a private network.

The Direct Project’ SMTP choice supports the environments which have minimal capabilities in terms of using Web Services and generating detailed metadata. In the healthcare ecosystem there are several existing environments which have adopted the use of Simple Object Access Protocol (SOAP)-based Web Services and detailed metadata. These environments have adopted a family of IHE profiles, each applied to a different type of use case, which have a common metadata model and make use of Web Services in a common way.

The most applicable IHE Information Technology Infrastructure Profiles to the Direct Project environment are:

---

- IHE Cross-Document Repository (XDR) Integration Profile which supports a direct push model from sender to receiver using Web Services transport
- IHE Cross-Enterprise Document Media Interchange (XDM) Integration Profile which supports a direct push model of a package of content where one of several optional transports is via SMTP.

On February 2, 2011 ONC announced that providers and public health agencies in Minnesota and Rhode Island began exchanging health information using specifications developed by the Direct Project. Other Direct Project pilot programs will be launched soon in New York, Connecticut, Tennessee, Texas, Oklahoma and California to demonstrate the effectiveness of the streamlined Direct Project approach, which supports information exchange for core elements of patient care and public health reporting.

CONNECT\(^2\) is a free, open source software solution that supports health information exchange – both locally and at the national level. CONNECT uses Nationwide Health Information Network standards, services, and policies to make sure that health information exchanges are compatible with other exchanges being set up throughout the country. CONNECT is the result of collaboration among federal agencies that is coordinated through the Federal Health Architecture program under ONC. This software solution, initially developed by federal agencies to support their health-related missions, is available for free to all organizations to help set up health information exchanges and share data using nationally recognized interoperability standards.

\(^2\) Office of National Coordinator for Health IT (ONC). CONNECT. URL: http://www.connectopensource.org/
Public Health Laboratory Community-Based Initiatives

To work towards establishing electronic communications between PHL partners and their information systems, the PHL community has been working on several electronic data exchange initiatives. We have divided these initiatives into two categories:

- Public Health Laboratory Community Initiatives and
- National Initiatives.

The following sections provide examples of these initiatives related to standardization of laboratory data exchanges in addition to those mentioned under the related standards categories above.

**Public Health Laboratories Interoperability Project (PHLIP).** In 2006, APHL and CDC collaborated on a PHLIP initiative to support automated electronic data exchange between PHLs, CDC, and regional partners. PHLIP technical work on standards is conducted by the PHLIP Vocabulary & Messaging Workgroup. The goals of PHLIP include, but are not limited to: improving the quality of interoperable data; piloting sustainable architecture for laboratory data exchange; sending test results from states to CDC programs using HL7 V2.3.1 message standards; increasing the use of Route-not-Read hubs for regional data exchange; and expanding these efforts beyond National Notifiable Diseases (NNDs). The initial prototype of the PHLIP electronic laboratory surveillance message (ELSM) for Influenza has been successfully implemented in over half of the World Health Organization (WHO) collaborating laboratories participating nationwide. What made the deployment of PHLIP so effective was the approach of using Technical Assistance Teams (TATs).

Another PHLIP initiative, the electronic order and test result (ETOR) message, is piloting HL7 V2.6 message with 3 PHLs sending harmonized Salmonella reference test orders to CDC and receiving related results back. Additionally, efforts have been made to prepare for Influenza surge capacity situations between several PHLs. Future directions include continued efforts by the TATs, capturing sentinel provider data, results of resistance testing and implementation of the HL7 V2.5.1 ELR constraining profile for ELSM. PHLIP is also a founding member of the Laboratory Messaging Community of Practice (LabMCoP). Table 7 summarizes PHLIP key products and services.

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84 http://www.phconnect.org/group/laboratorymessagingcommunityofpractice
Table 7. PHLIP: Key Products and Services

<table>
<thead>
<tr>
<th>#</th>
<th>Product/Service</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Management of an innovative community that leverages laboratorians, technical experts, informaticians, and public health experts</td>
<td>Advance standards-based electronic data sharing for public health</td>
</tr>
<tr>
<td>2</td>
<td>Support for a PHL’s selection, implementation, and management of an internal electronic data management capability (e.g., LIMS)</td>
<td>Advance standards-based electronic data sharing for public health</td>
</tr>
<tr>
<td>3</td>
<td>Development of use cases and workflows for each of the nationally notifiable diseases</td>
<td>Advance standards-based electronic data sharing for public health</td>
</tr>
<tr>
<td>4</td>
<td>Development of vocabulary coding schema and messaging</td>
<td>Support use cases and workflows (PHLIP creates mapping workbooks and encoding guidelines to document the data-exchange schema)</td>
</tr>
<tr>
<td>5</td>
<td>Provision of a forum and working groups</td>
<td>Support PHLs in their implementation of data exchange standards</td>
</tr>
<tr>
<td>6</td>
<td>Validation of data-exchange capabilities</td>
<td>Identify any issues with the data and initiate performance improvement activities, if necessary</td>
</tr>
<tr>
<td>7</td>
<td>Provision of a forum between states and CDC to determine opportunities and methodologies</td>
<td>Enable the emerging data-sharing network to improve the performance of public health programs and their outcomes (e.g., food safety, water safety, and influenza)</td>
</tr>
<tr>
<td>8</td>
<td>Leverage of an open-innovation network to accelerate progress in scientific discovery, technology adoption, and healthcare transformation</td>
<td>Advance standards-based electronic data sharing for public health</td>
</tr>
</tbody>
</table>

In terms of interoperability, PHLIP is focused on the lab data information exchanges as follows (Figure 7):

- **PHL LIMS (sender) communicates with other laboratories LIMSs (receiver) for surge capacity, continuity of operations and access to analytic capability lacking at one’s own laboratory**

- **Clinical EHR-S and HIEs (sender/receiver) communicate with PHL LIMS (receiver/sender) for test order and result communication and**

- **PHL LIMS (sender) with CDC PH-IS (receiver) for epidemiological services.**
The Public Health Laboratory Interoperability Solutions and Solution Architecture (PHLISSA) project is aimed at building PHL capacities for electronic exchange of laboratory orders and results—ETOR—with the similar stakeholders as in the PHLIP project (PHL—clinicians, PHL—PHL, and PHL—public health agencies) as mandated by American Recovery and Reinvestment Act (ARRA). PHLISSA is focused on architecture, interoperability hub, and Enterprise Service Bus (ESB).

For data content, PHLISSA is focused on Salmonella (limited to human isolates only) scenario. The information exchange involves state PHLs who participated in PHLIP and the National Salmonella Reference Laboratory at the CDC Office of Infectious Diseases (OID). PHLISSA Hub is envisioned to serve as an HIE information management system with the data routing services (PHIN-Messaging System (MS) Gateway and Nationwide Health Information Network (NwHIN) Connect Gateway); metadata repository and document repository services; and data analytics services.

Table 8 describes use cases included in PHLISSA. Please note that PHLISSA project uses the Test Order Placer/Order Filler terms to define senders and receivers of laboratory data. These terms were originally introduced in the IHE Laboratory Technical Framework documentation for interoperability standards.

Figure 7. Public Health Laboratories: Data Exchange Scenarios (Use Cases)

Table 8

| Use case                                                                 | Diagram | Business need                                                                 | Example                                                                    |
|-------------------------------------------------------------------------|---------|------------------------------------------------------------------------------|                                                                            |
| Unreported laboratory results from PHL to epidemiology services        | PHL1    | Laboratory-based surveillance (results only)                                 | Positive influenza test results to CDC, Influenza Division                 |
| PHL to PHL and PHL to CDC laboratory                                   | PHL1    | Service requests (test orders and results)                                   | Routine testing, such as measles immunoglobulin, Salmonella pulsed-field gel electrophoresis, and hantavirus polymerase chain reaction |
| PHL to PHL                                                             | PHL1    | Service requests (test orders and results)                                   | West Nile virus outbreak—state must divert sample surge to PHL2            |
| PHL to PHL, continuity of operations (test orders and results)         | PHL1    |                                                                              | State declares state of emergency (e.g., Louisiana post-Hurricane Katrina) |


36
<table>
<thead>
<tr>
<th>#</th>
<th>Use Case Name</th>
<th>Use Case Description</th>
</tr>
</thead>
</table>
| 1 | Electronic Test Order and Result (ETOR) | • PHL sends Laboratory Test Order to CDC Office of Infectious Diseases (OID) Laboratory  
• CDC sends Laboratory Order Responses (acknowledgement, reject, etc.)  
• CDC sends Laboratory Test Result to PHL |
| 2 | Report Notifiable Conditions | • Reportable laboratory findings (ELR) from  
  o Hospital EHR-S to a State/Local/Territorial Public Health Department (supports meaningful use). PHLISSA Hub will send a notification to sender (Clinical Care stakeholder or PHL)  
  o Clinical laboratory to a State/Local/Territorial Public Health Department  
  o PHL to a State/Local/Territorial Public Health Department  
• Public Health Case Report from Clinical Care Stakeholder to a State/Local/Territorial Public Health Agency. PHLISSA Hub will send a notification to sender (Clinical Care stakeholder) |
| 3 | Register Healthcare Document with the Hub Document Registry for future retrieval | • Laboratory Results  
• Public Health Case Report |
| 4 | Request and retrieve healthcare document from a Hub healthcare document registry | • Query the document registry for a list of available healthcare documents  
  o PHL to Hub registry  
  o CDC to Hub registry  
  o State Public Health Department to Hub registry  
  o Clinical Care stakeholder to Hub registry  
• Retrieve specific healthcare documents document repository and return to requestor  
  o PHL document repository  
  o State/Local/Territorial Public Health Agency document repository  
  o Clinical care stakeholder document repository |
| 5 | PHL to PHL Test Order and Result | • PHL Order Placer sends Laboratory Test Order to PHL Order Filler  
• PHL Order Filler sends order responses (acknowledgement, reject, etc.)  
• PHL Order Filler sends Test Result to PHL Order Placer |
| 6 | EHR/EMR to PHL Lab Test Order and Result | • Clinical stakeholder Order Placer (EHR-S) sends Laboratory Test Order to PHL Order Filler  
• PHL Order Filler sends order responses (acknowledgement, reject, etc.) to the Order Placer.  
• PHL Order Filler sends Test Result to Clinical stakeholder Order Placer (EHR-S) |
| 7 | Optional: Send unsolicited Lab Test Results | • PHL to a CDC OID laboratory  
• PHL to a Clinical stakeholder  
(Note: This is an optional Use Case) |

**Laboratory Technical Implementation Assistance for Public Health (LTIAPH).** In 2010, APHL received a Health Information Technology for Economic and Clinical Health (HITECH) grant to advance public health laboratory capacity to share laboratory orders and results electronically with clinical care and public health agencies in order to achieve Meaningful Use objectives. This project, The Laboratory Technical Implementation Assistance for Public Health (LTIAPH), provides guidance and technical assistance to state/territorial/large local public health laboratories and health departments to enhance critical IT infrastructure to support interoperabil-
ity of electronic laboratory data between clinical care (through EHRs) and public health agencies. LTIAPH works to identify data exchange strategies and feasible models of technical assistance that will build the framework for the interoperability of EHRs and public health to support meaningful use of lab data.

LTIAPH is working to define a common set of requirements for LIMS Minimum Data Elements, a Laboratory Reference Model and a Surveillance Data Reference Model, utilizing the HL7 Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health. LTIAPH also seeks to collect and harmonize terminology requirements across ELR, Lab-to-Lab and EHR data exchanges, in conjunction with all stakeholders (PHL, Public Health Agency and clinical care affiliates), and to document the minimum terminology requirements for a LIMS and/or broker infrastructure in a client PHL. LTIAPH is also collaborating with its sister grant the Laboratory Interoperability Cooperative (LIC), described below.

Guiding Principles:
- Prioritize data flows that are relevant to Meaningful Use: Reportable Laboratory Results objective.
- Assure that investments in one use case should carry over to many public health use cases.
- Pilot successful working models of a use case prior to recommending for broader adoption.
- Assure that implementation assistance is sensitive to current/existing systems.
- Evaluate and enhance existing capacity to enable scalable architecture that can adapt to future opportunities.
- Select technologies that leverage interoperability within public health organizations.
- Focus on high-impact and/or high volume transactions.

Approach:
- Offer menu-of-services that are grouped into general and targeted categories.
- Balance level-of-effort between providing and developing a common framework and re-useable components and one-on-one assistance.
- Promote adherence to interoperability standards in areas like laboratory processes, vocabulary and information technology.
- Engage with the Epidemiology & Laboratory Capacities for Infectious Diseases (ELC) grantees and develop scope-of-work based on their respective CDC approved Operational plans.
- Collaborate with other ELR efforts.
- Compile and share knowledge across grantees via different mechanisms.
- Leverage APHL’s efforts across the public health space to bring in expertise that can accelerate and enhance the solution, while contributing back from the project from a long-term interoperability strategy.
- Collaborate within a pre-defined operational framework with other companion ARRA-HITECH grants.
The **Laboratory Response Network (LRN)**\(^8^9\) is a coordinated network of public health and other laboratories for which CDC provides standard assays and protocols for testing biological and chemical terrorism agents. LRN Results Messenger (LRN RM) was created to provide LRN laboratories with the ability to manage and share standard laboratory results data securely with public health partners. LRN RM represents the first step in an incremental approach to providing full standards-based electronic data exchange for this vital laboratory network.

The **LIMS Integration (LIMSi)**\(^9^0\) project is a parallel effort to LRN RM. It represents the next generation of the incremental approach to data exchange for the LRN. Its purpose is to enable laboratories to fulfill data exchange needs for the LRN using their own systems. LIMSi is currently facilitating collaborative efforts between CDC and public health laboratory subject matter experts to refine system requirements needed to configure LIMS to manage LRN testing. The LIMSi project is also creating a constrained version of the PHIN Laboratory Generic message guide that specifically targets the messaging and data mapping needs for the LRN.

**LUNA and CDC STARLiMS**\(^9^1\) work together to improve communication between CDC and its Public Health Partners. Laboratory User Network Application (LUNA) is a free, secure, user-friendly, web-based interface that requires only an internet connection and an Secure Data Network (SDN) Digital Certificate to allow state and local agencies to communicate electronic test requests to the CDC. With the integration with CDC STARLiMS, these requests are automatically loaded into CDC STARLiMS and then released to the submitter, eliminating the need for mailing a paper version of the request and subsequently manually entering the data into CDC STARLiMS – a process more apt to produce errors and delays than this automated system. The electronic test requests then follow today’s standard testing and reporting procedures.

LUNA provides the means of uniquely identifying a specimen to make tracking the order and subsequent results an efficient process. At any time, the CDC and its partners can determine where the shipment is in transit, when it has been received, and once testing is complete, the results are immediately available to the partners as a Portable Document Format (PDF) file attached to the specimen record in LUNA. Having these electronic records has the additional benefit of providing the state laboratories and the CDC with an easily maintained and accessible record of each test.

LUNA, CDC STARLiMS, and Central Receiving (STAT) at the CDC Office of Infectious Diseases have been piloting the integration in the National Salmonella Reference Laboratory. The participating states sent requests for testing via LUNA. STAT will verify each test request, when the specimen is received. Upon verification, the request will go to the National Salmonella Reference Laboratory for testing.

To further enhance the efficiency of this process, LUNA provides a notification feature that sends email notifications and updates throughout the submission and testing process, ensuring that the organizations are informed of the status and progress of each specimen shipment. This

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\(^9^1\) LUNA and STARLiMS Integration. URL: [http://www.cdc.gov/phin/tools/luna/index.html](http://www.cdc.gov/phin/tools/luna/index.html)
feature is individually configurable, allowing each organization to choose the level of detail its personnel should receive during the course of the testing process.

The **CDC Electronic Laboratory Reporting (ELR) Task Force** is a collaborative effort between the CDC, APHL and CSTE to promote the implementation of ELR.

The ELR Vision is that all labs (public and private) conducting clinical testing identify laboratory results that indicate a potential reportable condition for one of the jurisdictions they serve, format the information in a standard manner, and transmit appropriate messages to the responsible jurisdiction; all jurisdictions can and do receive and utilize the data.

The Task Force was formed in the spring of 2010 and its steering committee identified five high-level priorities and created five working groups (Table 8):

- Develop a strategic plan for coordination between states, CDC and ONC
- Develop, evaluate and endorse standards to reduce variation in what is required for ELR across the nation
- Collaborate with APHL to compare and assure that PHLIP messages (formats, vocabulary, and transmission) and National Electronic Disease Surveillance System (NEDSS) messages are consistent and compatible to leverage the laboratory message infrastructure to communicate with clinicians, CDC, or state/local surveillance systems
- Document legal considerations for electronic laboratory reporting and make available for other states to consider and
- Articulate the resources needed to implement state/local ELR through a needs/capacity assessment.

**Table 8. CDC Electronic Laboratory Reporting (ELR) Task Force: Workgroups**

<table>
<thead>
<tr>
<th>#</th>
<th>Workgroup Name</th>
<th>Charge</th>
</tr>
</thead>
</table>
| 1  | Standards Workgroup                 | - Facilitate the reporting of laboratory data to public health agencies throughout the US by  
                                - Harmonizing existing ELR Messaging and Vocabulary Standards to reduce variations  
                                - Providing guidance with regards to the implementation of ELR Messaging and Vocabulary Standards |
| 2  | LIS Vendors & Large Lab Workgroup   | - Develop standards-compliant and efficient approach for vendors interfacing with public health  
                                - Build on work with large national labs to ensure full implementation of ELR  
                                - Get GIS software solutions to include appropriate ELR standards in their products prior certification |
| 3  | ELR Meaningful Use Workgroup        | - Develop a strategic plan for coordination and communication among states, CDC and ONC                                                                                                                                       |
| 4  | Legal Considerations Workgroup      | - Identifying key issues surrounding the implementation of ELR in the states  
                                - Research how selected states with illustrative or generalizable experience have coped with such legal issues  
                                - Based on information acquired, and if appropriate, consider                                                                                     |

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whether law-related products or tools useful to states regarding legal issues should be developed in the future

<p>| | |</p>
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<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Resources Needs &amp; Assessment Workgroup</td>
</tr>
</tbody>
</table>

## Examples of National Public Health Initiatives

The **CDC Public Health Information Network (PHIN)** is a national initiative to improve the capacity of public health to use and exchange information electronically by promoting the use of standards and defining functional and technical requirements⁹³. Through a set of standards-based services, applications and systems, PHIN has provided a framework to facilitate various types of information exchange. PHIN has the following goals and strategies⁹⁴:

1. Provide leadership in the selection and implementation of shared policies, standards, practices, and services for nationwide public health information exchange
   1.1. Develop a PHIN decision-making and policy framework that supports public health information exchange and information security
   1.2. Align PHIN standards and initiatives with national health IT initiatives
   1.3. Support a public health Standardization and Interoperability Framework leveraging models established by the Office of the National Coordinator for Health Information Technology (ONC)
   1.4. Promote and enable PHIN participation

2. Define, advocate for, and support public health needs and roles in national health information technology and exchange initiatives
   2.1. Facilitate public health participation in national health IT and exchange policy, standards, and implementation processes
   2.2. Develop and monitor metrics of participation in national public health information exchange

3. Perform key public health information exchange and standards management roles
   3.1. Operate and improve vocabulary, messaging, and brokering infrastructure
   3.2. Provision key public health data sets, including data sets of national importance
   3.3. Provide technology to support collaboration of public health information exchange

Table 9 presents PHIN products related to standardization of laboratory data exchanges.

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### Table 9. CDC PHIN Products and Services

<table>
<thead>
<tr>
<th>#</th>
<th>Product/Service Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PHIN Vocabulary Access and Distribution System (PHIN VADS)</td>
<td>PHIN VADS&lt;sup&gt;95&lt;/sup&gt; is a web-based enterprise vocabulary system for accessing, searching, and distributing vocabularies used within the PHIN. It promotes the use of standards-based vocabulary within PHIN systems to support the exchange of consistent information among Public Health Partners. Currently, there are 533 value sets and over 1,850,000 concepts in PHIN VADS based on the code system/domain recommendations from CHI (Consolidated Health Informatics) and value set recommendations from Health Information Technology Standards Panel (HITSP).&lt;sup&gt;96&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
| 2  | PHIN Implementation Guides | PHIN implementation guides<sup>97</sup> support and manage the message specification. They contain information about a specific message that a public health partner can use to support their implementation of PHIN requirements and/or recommendations for messaging and interoperability of information systems. PHIN MS Implementation Guides include:  
- PHIN Communication and Alerting (PCA) Guide v.1.3<sup>98</sup>  
- PHIN Exchange Developer Guide v1.0<sup>99</sup>  
- PHIN Directory Exchange Implementation Guide<sup>100</sup>  
- PHIN Secure Message Transport Guide<sup>101</sup>  
- PHIN Batch Specification<sup>102</sup> |
| 3  | HAN - Health Alert Network | CDC’s Health Alert Network (HAN)<sup>103</sup> provides information to state and local public health practitioners, clinicians, and public health laboratories, about urgent health events. HAN also provides opportunities for public health professionals to network and share promising practices and lessons learned related to partner communications and alerting. |
| 4  | PHIN Messaging System | The PHIN MS (Public Health Information Network Messaging System)<sup>104</sup> is a software system to securely send and receive encrypted data over the Internet in a standard way for addressing and routing content and to exchange transport transaction confirmations. |
| 5  | PHIN Message Quality Framework (MQF) | PHIN Message Quality Framework (MQF)<sup>105</sup> is an automated testing tool that provides senders the capability to test HL7 messages on their own prior to submitting them to other health partners or the CDC, therefore, decreases the cost and time to implement integrated systems. The MQF tool ensures messages adhere to standards defined in the messaging |

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<sup>96</sup>Health Information Technology Standards Panel (HITSP). URL: www.hitsp.org

<sup>97</sup>Centers for Disease Control and Prevention (CDC). PHIN Implementation Guides. URL: http://www.cdc.gov/phin/resources/PHINguides.html


guides by: validating the structure of the message, validating that messages are following the business rules defined for the message, and verifying that the vocabulary defined for the message is utilized. MQF Release 2.2 provides the capability for implementers, who have interface engines such as Rhapsody, Mirth, Cloverleaf/Quovadx, etc., to download conformance profiles that were developed based on the message specifications. The formats available for download are XML and Rhapsody S3D. The conformance profile is what the MQF application uses to perform the validation of the messages.

MQF introduced vocabulary validation through a real-time integration with PHIN VADS by accessing the Web services to validate that the vocabulary is valid for the specified message. The release supports vocabulary validation against the following published message standards:

- APHL PHLIP Messaging Guide for Influenza Test Result Reporting by Public Health Laboratories, ORU R01 HL7 v2.3.1, Document version 1.0.2, Sept. 15, 2009
- All Meaningful Use Specifications

| 6 | NEDSS (National Electronic Disease Surveillance System) | NEDSS\(^{106}\) is an Internet-based infrastructure for public health surveillance data exchange that uses specific PHIN (Public Health Information Network) and NEDSS Data Standards. NEDSS also relies heavily on industry standards (including: standard vocabulary code sets such as LOINC, SNOMED, and HL7), policy-level agreements on data access, and the protection of confidentiality. NEDSS represents an ongoing close collaboration between the CDC and its public health partners. NEDSS is not a single, monolithic application, but a system of interoperable subsystems, components and systems modules that include software applications developed and implemented by the CDC; those developed and implemented by State and Local health departments and those created by commercial services and vendors. |

**Meaningful Use (MU) of Health IT Stage 1.**\(^{107,108}\) Three public health domains (programs) have been adopted for MU Stage 1 of the HITECH-funded CMS Incentive Program:

1. Capability to submit electronic **syndromic surveillance** data to public health agencies and actual transmission according to applicable law and practice.

2. Capability to submit electronic data to **immunization** registries of Immunization Information Systems and actual submission in accordance with applicable law and practice.

3. Capability to submit **electronic data on reportable** (as required by state or local law) **lab results** to public health agencies and actual submission in accordance with applicable law and practice.

As more PHL partners adopt the new MU standards, the PHLs will also need to adopt those standards as well in order to remain relevant in today’s changing health care landscape.

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Public Health Laboratories and State Health Information Exchanges (HIEs). In July of 2010, the Office of National Coordinator for Health IT issued its “Requirements and Recommendations for the State Health Information Exchange Cooperative Agreement Program” to provide directions to state level information exchange efforts. The key HIE objective and deliverable in 2011 is the “receipt of structured laboratory results” with the state responsibility to “build capacity of public health systems to accept electronic reporting of immunizations, notifiable diseases and syndromic surveillance reporting from providers.” With funding from ONC, states are currently creating their HIE networks that will include electronic exchange of laboratory orders and results between EHR-systems and public health agencies.

The HIE architecture (Figure 8) is designed to enable collection and dissemination of data from disparate sources. HIE shared services may include but is not limited to:

- Electronic connectivity across stakeholders in the jurisdiction
- Electronic connectivity across jurisdictions
- IT infrastructure (e.g., servers, data and document storage, processing capability, bandwidth)
- Documents repositories and document location services
- Data repositories and data mapping/translational services
- Identify resolution services (e.g., master patient index (MPI)) and
- Decision support capability

![Figure 8. Example of State HIE Architecture](image)

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110 Johnson J. New Horizons with Health Information Exchange, Local Public Health Perspective. Presentation at the CCLHO Health Information & Data Committee on April 6, 2011
An HIE is viewed as a provider of IT infrastructure/data management services. In this role HIEs may compete with public health agencies that serve a similar role within a public health agency. The PHLISSA project described above clearly shows similarity of architecture and data management approaches/services between HIEs and public health.

Commonalities between HIE and public health approaches may serve as an enabler of interoperability for public health in general, and for laboratory data exchanges in particular. PHLs could utilize HIE infrastructure and services for communications with senders and receivers of laboratory data, including data mapping/translation services across proprietary LIMSs or data sharing across LIMSs with non-compatible information exchange standards.

**Laboratory Interoperability Cooperative (LIC)**\(^{111}\) is a 2-year CDC-funded project started in 2011 to enable hospitals to meet the MU requirements for electronic submission of laboratory results for reportable conditions to public health agencies. While technical standards exist to enable the secure, electronic exchange of laboratory results, the implementation and use of these standards for public health reporting by the commercial labs, hospitals and providers has been limited. The goal of the LIC is to provide an array of services to hospital laboratories to enable submission of reportable laboratory results to public health agencies as defined in the Meaningful Use final rules. The LIC project involves Surescripts, the College of American Pathologists (CAP), and the American Hospital Association. The project will provide capability for real-time reporting of laboratory tests to public health. Additionally, LIC will assist clinical laboratories with appropriate encoding of the reportable tests results at the point of origin.

\(^{111}\) Laboratory Interoperability Cooperative (LIC). Project. URL: www.LabInteroperabilityCoop.org
By **operationalizing** HIT standards for a particular public health domain (program) we mean:

1. **Use existing standards** to develop interoperability specifications (implementation guides, integration profiles, content profiles) or to enhance existing interoperability specifications at the national and international standards harmonization initiatives, e.g., IHE, ONC S&I Framework Initiatives
2. **Test** these specifications at the IHE Connectathon and demonstrate interoperability solutions at the national and international forums
3. **Develop certification criteria** for standards-based HIT solutions and enable certification of public health information systems
4. **Provide technical assistance** to support deployment of standards-based HIT solutions and
5. **Evaluate the effectiveness** of standards-based HIT solutions.

If the need for a new standard is identified, we will work with domain experts and the standards development organizations to develop this standard.

**Operationalizing** HIT standards for PHLs contributes to the overall PHDSC effort to build a *Coordinated Voice of Public Health on HIT Standards*.\(^{112}\) Building this Voice is the focus in the PHDSC methodology outlined in the *PHDSC Business Case: Role of Public Health in HIT Standardization*,\(^ {113}\) so that data collected at the point of care can be used and re-used across public health programs (domains) at all levels of government. Of importance in this work is the immediate engagement of all stakeholders in all HIT standardization phases (from the need analysis stage all the way through the deployment stage) via participation in the national standardization entities (Table 11).

Outreach through professional organizations of all stakeholders is critical as is the participation of the right subject matter experts for each standardization phase -- needs assessment, definition of the functional requirements and the information exchange content, development and testing standards and so on having access to the laboratory expertise is essential. It is just as important to have a good understanding of the technical expertise and abilities at each stakeholder for the implementation to be successful. Being able to provide standards knowledge as well as the tools that can help facilitate implementations as part of the technical assistance team is key to successful deployment beyond just the early adopters and IT savvy partners.

We implement our methodology by working with representatives from a particular domain (domain experts, public health professional association(s)) on various phases of HIT standardization by participating in various HIT standardization entities (Table 10).

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Table 10. HIT Standardization Phases and Entities

<table>
<thead>
<tr>
<th>HIT Standardization Phase (Products)</th>
<th>HIT Standardization Entity Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I - Identify HIT Interoperability Needs and Priorities (Business Cases, Use Cases)</td>
<td>HIT Policy Committee(^{114}) and HIT Standards Committee(^{115}) Formerly American Health Information Community (AHIC)(^{116})</td>
</tr>
<tr>
<td>II - Develop and Maintain Standards (Standard Specifications)</td>
<td>HL7, SNOMED, LOINC, ASC X12, ISO TC 215</td>
</tr>
<tr>
<td>III - Select and Harmonize Standards (Functional Requirements Assessment; Standards Gap Identification &amp; Harmonization; Dataset &amp; Value Set Development; Interoperability Specification Development)</td>
<td>Integrating the Healthcare Enterprise (IHE), ONC Standards and Interoperability Initiatives(^{117}) Formerly Health Information Technology Standards Panel (HITSP)</td>
</tr>
<tr>
<td>IV - Test Standards Interoperability (Software Instantiation, Conformance Testing)</td>
<td>IHE, National Institute of Standards (NIST), PHIN</td>
</tr>
<tr>
<td>V - Certify Standards-Based Products (Compliance Testing)</td>
<td>ONC Authorized Testing and Certifying Bodies (ATCB), PHIN</td>
</tr>
<tr>
<td>VI - Deploy Certified HIT Products (Deployment Reports)</td>
<td>Future IHE-PHDSC Deployment Workshops</td>
</tr>
</tbody>
</table>

The PHDSC has been using outreach activities for engaging stakeholders and achieving collaboration in HIT standardization since 2005 by working with several public health domains (programs) at standardization entities (HITSP, HL7, IHE) as follows:

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>• Biosurveillance</td>
<td>• Early Hearing Detection and Intervention (EHDI)</td>
</tr>
<tr>
<td>• Immunization</td>
<td>• Vital Records</td>
</tr>
<tr>
<td>• Electronic Laboratory Reporting</td>
<td>• Administrative Data Reporting</td>
</tr>
<tr>
<td>• Public Health Case Reporting</td>
<td></td>
</tr>
<tr>
<td>• Newborn Screening</td>
<td></td>
</tr>
<tr>
<td>• Child Health (Vital Records)</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 9** depicts PHDSC efforts in relation to the national HIT standardization Initiative including the Standards and Interoperability Framework (S&I Framework) developed by the Office of National Coordinator for HIT (ONC).

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\(^{114}\) Health Information Technology Policy Committee. URL: [http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=0&mode=2&in_hi_userid=10741&cached=true](http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=0&mode=2&in_hi_userid=10741&cached=true)


\(^{117}\) Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. URL: [http://healthit.hhs.gov/portal/server.pt?CommunityId=1206&spaceID=399&parentname=&control=SetCommunity&parentid=&PageID=0&space=CommunityPage&in_hi_totalgroup=1&in_hi_requeryd=1&in_hi_requdfolder=6652&in_ra_topoperator=or&in_hi_depth=1&in_hi_req_page=20&control=advancedstart&in_hi_req_obtype=18&in_hi_req_obtype=512&in_hi_req_obtype=514&in_hi_req_apps=1&in_hi_revealed=1&in_hi_userid=8969&in_hi_groupoperator=1=or&in_hi_model_mode=browse&cached=false&in_ra_groupoperator=1=or&in_tx_fulltext=5%2C261%2C5%2C261&Framework](http://healthit.hhs.gov/portal/server.pt?CommunityId=1206&spaceID=399&parentname=&control=SetCommunity&parentid=&PageID=0&space=CommunityPage&in_hi_totalgroup=1&in_hi_requeryd=1&in_hi_requdfolder=6652&in_ra_topoperator=or&in_hi_depth=1&in_hi_req_page=20&control=advancedstart&in_hi_req_obtype=18&in_hi_req_obtype=512&in_hi_req_obtype=514&in_hi_req_apps=1&in_hi_revealed=1&in_hi_userid=8969&in_hi_groupoperator=1=or&in_hi_model_mode=browse&cached=false&in_ra_groupoperator=1=or&in_tx_fulltext=5%2C261%2C5%2C261&Framework)

We will operationalize laboratory standards developed to date by the PHL community by enabling their validation through standards harmonization, testing and certification processes as it was done in the PHDSC projects for the other domains (e.g., EHDI, Vital Records and Administrative Data Reporting and other).
Our approach is to execute PHDSC methodology described in Section 4 by working with APHL and other PHL stakeholders in various HIT standardization phases and entities to develop, harmonize, test HIT interoperability standards; and certify and deploy standards-based HIT products.

This section describes:
- **What** needs to be accomplished to *operationalize* existing HIT standards for public health laboratory data exchanges, highlighting PHDSC partnerships with APHL, and
- **How** to assure public health participation in the HIT standardization and desired outcomes.

**WHAT – What needs to be accomplished?**

We will *operationalize* existing HIT standards for public health laboratory data exchanges by working with APHL in several national and international initiatives on various phases of HIT standardization as follows:

- Needs and Priorities
- Standards Development
- Standards Harmonization
- Standards Testing
- Certification of Standards-based HIT products
- Deployment of Certified HIT Products.

Through specific activities under this project *(Table 11)*, PHDSC will work with APHL and other PHL data exchange stakeholders to enable participation of representatives from PHLs in various HIT standardization entities such as HL7, IHE, ONC S&I Framework and others. PHDSC will also work with APHL to define strategies to increase PHL participation in HIT standardization to develop standards responsive to their needs as described in sections that follow.

Thus, Table 11 outlines the **Roadmap for Assuring HIT Standardization of Public Health Laboratory Data Exchanges** for the period of 2011-2013 with the list of project deliverables by HIT standardization phase and entity.
Table 11. PHDSC-APHL Project on HIT Standardization: Deliverables

<table>
<thead>
<tr>
<th>Standardization Phase</th>
<th>Entity</th>
<th>Products (Project Deliverables)</th>
</tr>
</thead>
</table>
2. User Story on Communicable Disease Reporting including Laboratory Orders/Result for the ONC S&I Framework Public Health Reporting Initiative |
| Develop and Maintain Standards | HL7 PHDSC                                   | 1. HL7 Public Health Reporting Requirements Standard  
2. Clinical Document Architecture (CDA) Templates for Laboratory Reports for selected conditions to be developed using Model Driven Health Tool (MDHT) |
| Select and Harmonize Standards | IHE ONC S&I Framework Public Health Reporting Initiative | IHE Public Health Reporting Integration Profile |
| Test Standards                | IHE HIMSS                                   | 1. Testing laboratory reports exchanges at IHE Connectathon  
2. Demonstration of laboratory reports exchanges the HIMSS Interoperability Showcase |
| Certify Standards-based HIT Product | CCHIT PHIN                                 | 1. HL7 Public Health Functional Profile – Public Health Laboratory Extension  
2. Certification Criteria for Laboratory HIT Products  
3. Established Certification Process for Public Health Laboratory HIT Products at CCHIT and PHIN |
| Deploy Standards-based HIT Product | IHE PHDSC APHL                             | 1. Methodology and instruments for conducting deployment workshops for public health laboratory stakeholders on technical assistance to deploy certified HIT products  
2. Participation in the design and development of the CDA for Public Health Pilot project in two states |
| Outreach to Assure HIT Standardization for PHLs | PHDSC APHL AHIMA                            | 1. Representation of PHL interests at HL7, IHE, ONC S&I Framework Initiatives and ONC-ATCB ONC-Authorized Testing and Certification Body (ATCB)  
2. Strategies to increase PHL participation in HIT standardization to develop standards that are responsive to their needs  
3. A metric for assuring that PHL participation in HIT standardization produces the desired outcomes from enabling electronic information exchanges across PHL partners  
4. Work with the survey teams from APHL and CAP (American College of Pathologists) to add additional questions to their survey to collect data on the PHL participation in |


120 Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Public Health Reporting Initiative. URL: http://wiki.siframework.org/Public+Health+Reporting+Initiative


122 Certification Commission for Health Information Technology (CCHIT). URL: http://www.cchit.org

HIT standardization and the impact of participation
Advocate for PHL in National Needs and Priorities for Standards

National health information exchange priorities are defined by the Federal Advisory Committees. These committees established under the Federal Advisory Committees Act (FACA), provide advice on health IT issues to the National Coordinator for Health Information Technology.

The Health Information Technology Policy Committee (HIT Policy Committee) was established by the Department of Health and Human Services (HHS) under the American Recovery and Reinvestment Act (ARRA) of 2009. The HIT Policy Committee makes recommendations to the HHS National Coordinator for Health Information Technology on a policy framework for the development and adoption of a nationwide health information infrastructure.

The Health Information Technology Standards Committee (HIT Standards Committee) also established by the HHS under ARRA of 2009 makes recommendations to the HHS National Coordinator for Health Information Technology on HIT standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. The HIT Policy and Standards Committees contributed to establishing the Meaningful Use of HIT regulation that specified objectives for EHR-S adoption in 2011-2016 (Figure 12).

Laboratory result submission to EHR-Ss and the “capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice” are included in the MU Stage 1 objectives (Figure 12).

During 2005-2009 the American Health Information Community (AHIC) - a federally-chartered advisory body - served in the capacity of the HIT Policy & Standards Committees to

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125 Federal Advisory Committees Act (FACA). Health Information Technology Policy Committee. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=0&mode=2&in_hi_userid=10741&cached=true
129 American Health Information Community (AHIC). URL: http://www.hhs.gov/healthit/community/background/
advance efforts on the development of a Nationwide Health Information Network. AHIC has defined priority areas (breakthroughs) and developed National Use Cases.\textsuperscript{130} (Figure 10).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{AHIC PRIORITIES AND USE CASE ROADMAP 2006-2009.png}
\caption{AHIC Priorities and Use Case Roadmap, 2006-2009}
\end{figure}

In the AHIC Use Cases laboratory orders submission from EHR-S to LIMS were addressed in Biosurveillance, 2006 and Newborn Screening, 2009; laboratory results reporting was addressed in the Laboratory Results Reporting to EHR, 2006 and Public Health Case Reporting, 2008.

\textbf{PHDSC-APHL Partnership Activities}

PHDSC will support APHL in its advocacy efforts to assure that PHLs needs for HIT standardization are included in the national HIT agenda.

The \textbf{Public Health Reporting Initiative}\textsuperscript{131} is under development to define the scope for a potential public health initiative at the ONC S&I Framework based on the needs of the public health community. This Initiative is aimed at developing a unified approach for integrating siloed public health information systems using harmonized HIT standards. The Initiative will entail harmonization of business processes, functional requirements for information systems, data needs and HIT standards across public health programs to inform the development of interoperable standards-based HIT solutions.

In 2011-2012, the Initiative will focus on the \textbf{Initial Public Health Report Use Case} with multiple User Stories under the following public health domains (programs):

- Child Health
- Communicable Diseases
- Chronic Diseases

\textsuperscript{130} American Health Information Community (AHIC). AHIC Use Cases and Extensions/Gaps. URL: \url{http://www.hhs.gov/healthit/usecases/}

Adverse Event Reporting and Other

The PHDSC-APHL team developed a User Story that describe laboratory orders/result data exchanges under these domains (programs) and will further work on developing the implementation guide to support this User Story (Table 11).

Participate in Standards Development

Standards development, according to the International Organization of Standardization (ISO), is conducted according to the following three principles:

- **Consensus** - the interests of all stakeholders are taken into account: manufacturers, users, vendors, consumer groups, testing laboratories, governments, engineering professions and research organizations
- **Industry wide** - standards solutions have to satisfy industries and customers worldwide
- **Voluntary** - international standardization is market driven and therefore based on voluntary involvement of all stakeholders in the market-place.

HIT standards are developed and maintained by Standards Development Organizations, Data Content Committees, Standards Setting Organizations, and Designated Standard Maintenance Organizations as follows:

- **Standards Development Organizations (SDOs)** are entities that develop, coordinate, promulgate, revise, amend, reissue, interpret, or otherwise maintain standards that address the interests of users outside the SDO. In the United States there are several hundred SDOs that are coordinated by the central National Standards Body (NSB) – the American National Standards Institute (ANSI). SDOs accredited by ANSI develop standards using open and transparent processes.

- **Data Content Committees (DCCs) and Standards Setting Organizations (SSOs)** are industry consortia or community-driven associations formed to expedite the standard development process or to develop standards for particular software solutions.

- **Designated Standard Maintenance Organizations (DSMOs)** are entities designated by the DHHS Secretary to maintain the national standards adopted by the Secretary under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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133 International Organization of Standardization (ISO). URL: http://www.iso.org/iso/standards_development.htm
135 Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. HIT Standards. DCC. URL: http://phdsc.org/standards/health-information/D_Standards.asp#List of Organizations
PHDSC-APHL Partnership Activities

If the need for a new standard is identified we will work with APHL subject matter experts and the standards development organizations to develop this standard.

In this project the PHDSC-APHL team will develop a new **HL7 Public Health Reporting Requirements Standard**. This standard will be based on the HL7 Healthcare Quality Measure Framework (HQMF) standard. Originally defined to support the specification of quality measures (eMeasures), the standards will also support the expression of public health reporting requirements. As a structured document specification, this will allow for both a human readable expression as well as a machine-readable expression of the jurisdiction-specific reporting requirements. This standard will support the capability of a system to consume the requirements, and process those requirements against CDA-expressed content. It will determine whether a report should be made to public health, what to report, to whom to send the report, how to report, and when to report. We anticipate balloting the new standard in August 2012 (**Table 11**).

Using the **Model Driven Health Tool (MDHT)** the PHDSC-APHL team will develop CDA R2 Templates for Laboratory Reports for selected conditions including Anthrax, Tularemia, Hepatitis-B, Tuberculosis and Influenza. We will use the input from the CDC RCMT project on LOINC/SNOMED data mapping for notifiable conditions and APHL PHLIP project data definitions for Influenza to define a CDA R2 Content for these conditions (**Table 11**).

**Participate in Standards Harmonization**

Standards harmonization\(^{137}\) is a process to ensure applicability of various standards for a Use Case that describes the use of a software application. Standards harmonization includes the following steps:

- Use Case development
- Use Case’s functional requirements analysis
- Identification of candidate standards
- Resolution of standards gaps, duplications and overlaps through the work with the standards development organizations
- Standards selection
- Construction of the Use Case’s Implementation Guide (Interoperability Specification)
- Implementation Guide’s inspection test
- Interoperability Specification release and dissemination.

In the United States, HIT standards harmonization activities have been carried out by several organizations described below.

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In 2005-2009, **Health Information Technology Standards Panel**\(^{138}\) was established as a co-operative partnership between the public and private sectors to achieve a broadly accepted set of standards to enable widespread interoperability among healthcare software applications, as they will interact in local and regional health information exchanges and in the Nationwide Health Information Network. The Panel’s purpose was to:

- Harmonize and integrate diverse standards that will meet clinical and business needs for sharing information among organizations and systems
- Establish HITSP interoperability specifications and promote their acceptance
- Support the implementation of HITSP interoperability specifications across the healthcare enterprise
- Facilitate the efforts of standards development organizations to maintain, revise, or develop new standards as required to support the HITSP Interoperability specifications

Supported by the contract from ONC to ANSI, HITSP develops interoperability specifications for the AHIC National Use Cases (**Figure 10**). Both HITSP methodology and interoperability specifications are widely used to enable standards-based information exchanges at the ONC S&I Framework initiatives and IHE.

In 2007 PHDSC has been invited by IHE to start a Public Health Domain at IHE that resulted in formation of the **IHE Quality Research and Public Health Committee**.\(^{139}\) PHDSC and IHE are collaborating to enable interoperability across clinical and public health enterprises. This includes the development of interoperability standards (Integration Profiles and Content Profiles) for information systems in several public health domains (programs) including *child health (newborn screening, immunization, vital records), chronic diseases (diabetes, cancer), and laboratory*; and work on information infrastructure issues such as *service-oriented architecture (SOA) for public health*. PHDSC member organizations, APHL, American Immunization Registry Association (AIRA), North-American Association of Central Cancer Registries (NAACCR), Software Partners, OZ Systems, Atlas Public Health, Scientific Technology Corporation and Greenway Medical Technology have been working on various public health projects at IHE.

**ONC Standards and Interoperability (S&I) Framework**\(^{140}\) was launched on January 7\(^{th}\), 2011 as a forum to collaborate on interoperability challenges critical to meeting Meaningful Use objectives for 2011. The ONC S&I Framework initiatives utilize the standard harmonization process established by HITSP. The 2011 S&I Framework Initiatives include *Certificate Interoperability (CI) Initiative; Data Segmentation Initiative; Lab Results Interface (LRI) Initiative; Provider Directories Initiative; Transitions of Care (ToC) Initiative; Query Health Initiative; esMD Initiative and others.*

The **ONC Standards & Interoperability Framework Lab Results Interface (LRI) Initiative** was created to support the Meaningful Use objective to send laboratory data to ordering provid-

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\(^{138}\) Health Information Technology Standards Panel. URL: [http://www.hitsp.org](http://www.hitsp.org)


\(^{141}\) Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Lab Results Interface (LRI) Initiative. URL: [http://wiki.siframework.org/Lab+Results+Interface+%28LRI%29+Initiative](http://wiki.siframework.org/Lab+Results+Interface+%28LRI%29+Initiative)
ers. The LRI Initiative is focused on harmonizing two standard specifications for ambulatory laboratory reporting, neither of which are adopted universally across the industry. The cost and time to initiate new electronic laboratory results interfaces hampers broad adoption of such interfaces. The field by field details of HL7 v2 implementation guides used by clinical laboratories and EHR-Ss vary, creating a need for mapping or configuration per interface. The prevalence of core subsets of LOINC codes for common tests and analytes also varies, causing downstream issues in decision support and quality reporting. The LRI Initiative developed the Laboratory Results Interface Initiative Implementation Guide based on the HL7 version 2.5.1 message-based standard that will be recommended as an information exchange standard for laboratory data under Meaningful Use.

The Public Health Laboratory Results Workgroup\(^{142}\) was created under the LRI Initiative to ensure that the LRI Implementation Guide does not contradict the current MU stage 1 standard for reporting lab results to Public Health Agencies. A strategy for harmonization in the long-term has been discussed in that group, but could not be included in the first release of the LRI guide.

The Public Health Reporting Initiative\(^{143}\) described above is the public health community-led activity at ONC that focuses on standards harmonization process for public health. In 2012 the Initiative’s participants will develop the Implementation Guide for the Initial Public Health Report Use Case that will specify HIT standards for laboratory test order/test result data exchanges between EHR-S, LIMSs and PH-ISs.

<table>
<thead>
<tr>
<th>PHDSC-APHL Partnership Activities</th>
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<tbody>
<tr>
<td>The PHDSC and APHL team will work on representing PHL interests in the national HIT standards harmonization activities as follows.</td>
</tr>
</tbody>
</table>

**Working with IHE**

The PHDSC-APHL team will harmonize the workflow and data requirements for data exchanges for the selected conditions (Anthrax, Tularemia, Hepatitis-B, Tuberculosis and Influenza) with the IHE Laboratory Technical Framework\(^{144}\) profiles including the Sharing Laboratory Reports (XD-Lab) Integration Profile.

Using the Laboratory domain as an example the PHDSC-APHL team will develop the IHE Public Health Reporting Integration Profile that will serve as an overarching HIT Standardization Framework for Public Health (Table 11).

**Working with ONC S&I Public Health Reporting Initiative**

The PHDSC-APHL team will participate in the development of the Implementation Guide for the Initial Public Health Report Use Case to specify HIT standards for laboratory test order/test result data exchanges between EHR-S, LIMSs and PH-ISs (Table 11).

\(^{142}\) Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Lab Results Interface (LRI) Initiative. Public Health Laboratory Results Workgroup. [URL](http://wiki.siframework.org/LRI+Public+Health+Lab+Results+WG)


\(^{144}\) Integrating the Healthcare Enterprise (IHE). Laboratory Committee. [URL](http://www.ihe.net/Technical_Framework/index.cfm#laboratory)
Participate in Standards Testing

Standards testing (reference implementation)\footnote{Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. Implementation of Standards-based Specifications. URL: http://www.phdsc.org/standards/health-information/ISB_Specifications.asp} is a process of demonstrating the use of standards in an information technology application.

IHE Connectathon\footnote{Integrating the Healthcare Enterprise (IHE). Connectathon. URL: http://www.ihe.net/News/connectathon_2012_na_registration.cfm} is the HIT industry’s largest interoperability testing event. The initial IHE Connectathon was held in 1999. The North American Connectathon has been held annually ever since and has grown steadily in the level and scope of participation. In 2012 more than 100 leading HIT companies and research organizations will participate to test more than 180 HIT systems for interoperability and compliance with IHE Profiles. This represents an increase of more than 20% over the 2011 event and indicates both the growing recognition in the HIT community of the need for standards-based interoperability and the growing embrace of IHE profiles as a practical means of attaining this goal.

The 2012 Connectathon will test HIT systems from across the spectrum of care. Profiles from eight of the 13 clinical and operational domains represented in IHE will be tested at the event including Anatomic Pathology, Cardiology, IT Infrastructure, Laboratory, Patient Care Coordination, Patient Care Device, Quality, Research and Public Health and Radiology. Separate annual Connectathon events are conducted in the Eye Care and Radiation Oncology domains. A parallel event in Europe was established in 2001 and has followed a similar trajectory. The next IHE Europe Connectathon will be held May 21-25, 2012 in Bern, Switzerland. Connectathons have also been held in Australia, China, Japan and Korea.

A technical project management team develops detailed test plans for each role (actor) being tested at the Connectathon and organizes the process to maximize interoperability testing between corresponding systems from different vendors. The team uses a suite of test tools for thousands of transactions among Connectathon participants, to monitor and record test results and simulate the functions of corresponding systems to enable rapid testing and debugging. Independent monitors observe and record test results, which are published in the Connectathon results database (http://connectathon-results.ihe.net/).

The HIMSS Interoperability Showcase\footnote{Health Information management and Systems Society (HIMSS) Interoperability Showcase. URL: http://www.himssconference.org/exhibition/interop.aspx} follows the IHE Connectathon to demonstrate to the healthcare community available HIT products that support systems interoperability. Organized in collaboration with IHE, the Interoperability Showcase exhibit provides a full landscape of health IT solutions, live demonstrations of interoperability, and educational opportunities that connect thousands of HIT end-users and buyers.

PHDSC-APHL Partnership Activities

The PHDSC and APHL team will work on testing HIT interoperability standards for laboratory data exchanges as follows.

Participate in the IHE Connectathon
In 2012 the PHDSC-APHL team will work with LIMS vendors to test CDA templates for laboratory reports developed for the selected conditions (Anthrax, Tularemia, Hepatitis-B, Tuberculosis and Influenza) in the Sharing Laboratory Reports (XD-Lab) Integration Profile of the IHE Laboratory Technical Framework. This testing may be held at the North American IHE Connectathon in January 2012 and/or European IHE Connectathon in May 2012 (Table 11).

Participate in the HIMSS Interoperability Showcase
The PHDSC-APHL team will work with HIT vendors to demonstrate interoperability solutions for exchanging CDA laboratory reports for the selected conditions at the HIMSS Interoperability Showcase in February 2012 (Table 11).

Participate in Certification of Standards-based Products

The Office of the National Coordinator has named the FACA HIT Policy and the HIT Standards Committees as the organizations that survey the landscape and offer recommendations for types of systems that ought to be certified. The ONC often accepts these recommendations and then instructs National Institute of Standards and Technology (NIST) to develop test scripts accordingly. NIST then develops and offers those scripts to the Authorized Testing and Certifying Bodies (ATCBs). The ONC-ATCBs are required to test and certify EHRs to the applicable certification criteria adopted by the Secretary under subpart C of Part 170 Part II and Part III as stipulated in the Standards and Certification Criteria Final Rule. This ensures that an EHR technology has the capabilities to meet the goals and objectives of Meaningful Use regulation.

The following organizations have been selected as ONC-ATCBs to perform Complete EHR and/or EHR Module testing and certification:

- ICSA Labs - Mechanicsburg, PA
- SLI Global Solutions - Denver, CO
- InfoGard Laboratories, Inc. – San Luis Obispo, CA
- Certification Commission for Health Information Technology (CCHIT) - Chicago, IL
- Drummond Group, Inc. (DGI) - Austin, TX and
- Surescripts LLC - Arlington, VA

**Scope of authorization:** EHR Modules: E-Prescribing, Privacy and Security.

Based on the NIST test scripts, the ATCBs developed testing and certification programs to certify EHR-S vendors capabilities in support of MU Stage 1.

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149 Integrating the Healthcare Enterprise (IHE). Laboratory Committee. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory
Some ATCBs offer “additional” testing and certification services (for testing and certifying systems beyond the MU list). These ATCBs are interested in receiving documentation by which they can develop certification scripts for systems that have not yet been identified by ONC as targets for certification.

The **HL7 Public Health Functional Profile (PHFP)** project of the PHDSC, CDC NCHS and the public health community at large\(^{153}\) (described above under the Functional Standards section) defines a set of functional requirements of the HL7 EHR-S Functional Model for information exchanges with public health programs’ information systems including Vital Records, Early Hearing Detection and Intervention (EHDI), Birth Defects, Cancer, NCHS National Surveys and Public Health Laboratories.

Based on the approach developed by the HL7 Child Health Workgroup using its Child Health Functional Profile for certifying EHR-S for pediatric care at the Certification Commission for HIT (CCHIT), the PHFP will be used for developing certification criteria for EHR-S to support information exchanges between clinical EHR-S and public health information systems.

<table>
<thead>
<tr>
<th>PHDSC-APHL Partnership Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Working with HL7</strong></td>
</tr>
<tr>
<td>Via participation in the development of the <strong>HL7 Public Health Functional Profile</strong>, PHDSC-APHL team have been working on reviewing the HL7 EHR Functional Model (direct care, supportive and infrastructure functions and conformance criteria) for bi-directional data exchanges between EHR-Ss and PHL LIMSs on laboratory test orders/results The Profile will be balloted in April 2012 (<strong>Table 11</strong>).</td>
</tr>
<tr>
<td><strong>Working with ONC ACTBs</strong></td>
</tr>
<tr>
<td>PHDSC-APHL team will further <strong>develop certification criteria</strong> for EHR-Ss and PHL LIMSs to support data exchanges and will work with the ONC-ACTBs to <strong>enable certification</strong> of EHR-Ss for sending laboratory test orders and receiving test results from LIMS. We will also work with the ONC-ACTBs and CDC PHIN to establish certification processes for PHL LIMSs for receiving laboratory test orders and sending test results to EHR-Ss (<strong>Table 11</strong>).</td>
</tr>
</tbody>
</table>

**Deploy Certified HIT Solutions**

Deployment of certified standards-based HIT solutions is the most critical component of enabling interoperability between clinical and public health information systems. All HIT standardization efforts are for naught unless legacy information systems are upgraded to utilize interoperability standards. Today, barriers for deploying interoperability standards in public health include:

- The lack of funding
- The lack of technical knowledge and

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\(^{153}\) Public Health Data Standards Consortium (PHDSC), Public Health Functional Profile Project. HL7 Public Health Functional Profile, Overview Chapter, 2011. URL: [https://wiki.phdsc.org/index.php/EHR-PH_APY3](https://wiki.phdsc.org/index.php/EHR-PH_APY3)
• The lack of coordinated/unified public health approach for adoption of interoperable HIT solutions across various public health programs at all levels of government.

Addressing the Lack of Funding. HITECH programs provide funding for EHR-S adoption in healthcare, i.e., supporting data sending systems. However, they provide very limited resources mostly via HIE programs for upgrading data receiving systems, e.g., laboratories, pharmacies, public health agencies. In public health, only immunization information systems received significant funding from CDC under HITECH.\textsuperscript{154}

There is a need to advocate for resources that will enable transition in Public Health from siloed, customized information systems to interoperable standards-based applications. The resources are needed for both developing the standards-based HIT solutions as well as for the deployment of certified applications. PHDSC estimated that the cost of participation of one subject matter expert in one standardization entity (e.g. IHE, HL7) is $39,500/year.\textsuperscript{155}

There is a need to estimate cost for deployment of certified HIT application in a public health program. The estimate should include costs associated with participation of a public health vendor and/or program staff in

(1) testing of standards-based solutions, e.g., at IHE Connectathon, to assure that interoperability standards serves program-specific needs
(2) certification of the standards-based public health application at ONC-ATCBs and
(3) deployment of the certified HIT application.

Addressing the Lack of Technical Knowledge. The APHL LTIAPH project - Laboratory Technical Implementation Assistance for Public Health, as described above, provides guidance and technical assistance to state/territorial public health laboratories and health departments to upgrade LIMSs to support interoperable data exchanges with clinical EHR-Ss and public health agencies’ PH-ISs.

The LTIAPH identifies data exchange strategies and feasible models of technical assistance that can help develop an approach for delivering technical assistance to upgrade legacy systems for PH,L as well as for other public health domains (programs).

IHE has been organizing the Deployment Workshops for users (program staff) to solicit their feedback on utilization of standards-based applications. PHDSC-APHL team is working to organize these workshops for PHL staff.

A new PHDSC-APHL-CSTE project on developing a Public Health Reporting Resource Repository of HIT standardization resources and tools is aimed to help public health professionals to participate in HIT standardization process. The Repository will be based on the PHDSC Web-based Resource Center\textsuperscript{156} that contains several Modules aimed to support the implementation...


\textsuperscript{155} Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. How much participation will cost and how it should be funded. URL: http://www.phdsc.org/standards/public-health-participation-hit-how-much.asp

\textsuperscript{156} Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. URL: http://phdsc.org/standards/resource-center.asp
of the PHDSC’s *Coordinated Public Health Action Plan on HIT Standards* developed as a part of the PHDSC Business Case: Role of Public Health in National HIT.157

The *HIT Standards Resources Module* is an informational resource that describes HIT standardization phases (Needs and Priorities for Standards, Standards Development, Standards Harmonization, Standards Testing, Standards-based HIT Product Certification, and Deployment); standardization entities and their products.

The *Public Health Participation in Health IT Standardization Module* is designed to address barriers for public health participation in the national HIT standardization efforts and help navigate through and participate in the standardization entities and their activities.

The *HIT Adoption Stories Module* is a searchable database on the varied uses of and activities related to health information technology in public health. The stories cover local, state, federal and international public health agencies, public health research, public health interoperability and standards development, and HIT resources, as well as broader HIT activities that affect public health.

**Addressing the Lack of Coordinated/Unified Public Health Approach for Adoption of Interoperable HIT Solutions across Various Public Health Programs at All Levels of Government.** There is an urgent need to assure coordination across programs and agencies with regard to the deployment of standard-based HIT solutions. Upgrades of public health information systems today should be conducted to assure interoperability of those systems with others within the agency to prevent additional re-development in the future. It is critical for public health programs to participate in the regional HIE initiatives. However, HIT upgrades related the MU Stage 1 public health objectives (laboratory reporting, immunization and syndromic surveillance) has to be conducted by taking into the account the needs for interoperability for other public health programs’ information systems in the agency.

PHDSC-APHL Team in partnership with the Council of State and Territorial Epidemiologists (CSTE) will be conducting a pilot project on deploying CDA-based HIT solutions for laboratory reports and case reports data exchanges in two states (*CDA for Public Health Pilot Project*). There is a need to engage the broader public health community in the design and development of this Pilot project, so the lessons learned and experience can be shared, thus enabling replication of these pilots in other states and/or programs. The APHL LTIAPH teams could contribute their expertise into working with the selected states for this Pilot project.

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The PHDSC and APHL team will work to address challenges related to deployment of certified HIT products as follows:

**Addressing the Lack of Funding**
We will develop estimates for the costs associated with participation of a public health vendor and/or program staff in (1) standards testing, (2) certification of the public health application at one of the ONC-ATCBs, and (3) deployment of the certified HIT application (Table 1).

**Addressing the Lack of Technical Knowledge**
PHDSC will work with APHL LTIAPH teams to learn from, document and expand on their experience in providing technical assistance to PHLs to support deployment of interoperable solutions (Table 1).

PHDSC will also work with APHL to develop IHE-PHDSC-APHL Deployment Workshops. These workshops will target users, (i.e. public health laboratory personnel and program staff) to get their feedback on the standards-based HIT products that were developed using IHE interoperability standards. This will help to understand what improvements, if any, are needed to support business processes of the laboratories and programs. This is the outreach component of the project (Table 11).

PHDSC will also work with APHL to develop a metric for **evaluating the effectiveness** of standard-based HIT solutions to support laboratory data exchanges (Table 11).

**Addressing the Lack of Coordination for Deployment**
PHDSC-APHL-CSTE team will work with APHL LTIAPH teams to learn from their experience to design and develop the CDA for Public Health Pilot Project (Table 11).

**HOW – How to assure public health participation in the HIT standardization and desired outcomes**

There is a need to develop metrics for assuring that PHL participation in HIT standardization produces the desired outcomes of enabling electronic information exchanges across PHL partners. To measure the HIT standardization impact, these metrics should include both quantitative measures (e.g., number of PHLs experts participating in HIT standardization entities; number and types of standards developed/used; number of orders/reports exchanged electronically; change in timeliness of reporting) and qualitative measures (e.g., change in completeness/correctness of orders/reports; change in duplicative testing; change in time for completing/sending the report).

Data on the use of HIT standards is presented in Section 3 derived from the APHL surveys of PHLs\(^\text{161,162}\) and the annual CAP Survey of LIS vendors.\(^\text{163}\) There is a need to better align these

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\(^{161}\) 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011

\(^{162}\) PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011

\(^{163}\)
surveys to generate a more comprehensive view on the level of HIT standards adoption and the impact of this adoption on PHLs.

<table>
<thead>
<tr>
<th>PHDSC-APHL Partnership Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHDSC will work with APHL to develop a metric for assuring that PHL participation in HIT standardization produces the desired outcomes of enabling electronic information exchanges across PHL partners.</td>
</tr>
<tr>
<td>The PHDSC-APHL team will use data on the use of various standards included in Section 5 of this document as indicators of the current use of HIT standards in PHL information systems to build before-after comparison.</td>
</tr>
<tr>
<td>The PHDSC-APHL team will work with the survey teams from APHL and CAP (American College of Pathologists) to add additional questions to their survey to collect data on the PHL participation in HIT standardization and the impact of this participation (Table 11).</td>
</tr>
</tbody>
</table>

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# Appendix 1: Terms and Definitions

The following terms are used in this White Paper (in alphabetical order):

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content Profile</strong></td>
<td>is a technical document that defines data content (data sets and value sets) standards for information exchanges within a context of user’s business activity. This term is used by the Integrating the healthcare Enterprise (IHE).</td>
</tr>
<tr>
<td><strong>Electronic Health Record (EHR)</strong></td>
<td>is information, assembled and maintained in an electronic format which pertains to the health status of an individual and the health services delivered to an individual.</td>
</tr>
<tr>
<td><strong>Health Information Exchange (HIE)</strong></td>
<td>is defined as the electronic movement of health-related information among organizations according to nationally recognized standards. To achieve its goals, the HIE itself must meet nationally recognized standards.</td>
</tr>
<tr>
<td><strong>Implementation Guide</strong></td>
<td>is a technical document that defines data content (data sets and value sets) and related standards for information exchanges within a context of user’s business activity. Implementation guides define constraints on a particular standard. This term is used by standard development organizations, e.g. HL7.</td>
</tr>
<tr>
<td><strong>Integration Profile</strong></td>
<td>is a technical document that defines standards for information exchanges within a context of user’s business activity. This term is used by the Integrating the Healthcare Enterprise (IHE) and is synonymous to the Interoperability Specification.</td>
</tr>
<tr>
<td><strong>Interoperability</strong></td>
<td>is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.</td>
</tr>
<tr>
<td><strong>Interoperability Specification</strong></td>
<td>is the term used by the Health Information Technology Standards Panel (HITSP) for the technical documents that defines interoperability standards for a selected use case.</td>
</tr>
<tr>
<td><strong>Standardization</strong></td>
<td>as defined by the International Organization for Standardization (ISO), is the process of agreeing on standards, which represent the common language that allows the exchange of data between disparate data systems. The goals of standardization are to achieve comparability, compatibility, and interoperability between independent systems, to ensure compatibility of data for comparative statistical purposes, and to reduce duplication of effort and redundancies.</td>
</tr>
<tr>
<td><strong>Technical Framework</strong></td>
<td>is a technical document that describes the relationship between Content Profiles (data sets and value sets) and Integration Profiles (information exchange standards) within a context of user’s business activity. This term is used by the Integrating the Healthcare Enterprise (IHE).</td>
</tr>
</tbody>
</table>

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164 Electronic Health Record. Definition is adapted from Institute of Medicine Report, 2002
165 The National Alliance for Health Information Technology. Report to the Office of the National Coordinator for Health Information Technology. Defining Key Health Information Technology Terms. 2008.
166 Interoperability. Definition is adapted from HL7 EHR Interoperability Working Group, 2007
## Appendix 2. Privacy and Security Standards

There are a number of security and privacy standards that can support public health laboratory data exchanges. These standards enable transport security, identification of persons and systems, privilege management and access controls, audit, policy agreements, and pseudonymization. These standards are generic and must be support by any systems participating in electronic health information exchanges. The table below provides description of these standards.

<table>
<thead>
<tr>
<th>Standards Organization</th>
<th>Standard</th>
<th>Standard Identifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>American National Standards Institute (ANSI) International Committee for Information Technology Standards</td>
<td>Information Technology - Role Based Access Control</td>
<td>#359-2004</td>
<td>This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. Visit <a href="http://www.ansi.org">www.ansi.org</a> for more information</td>
</tr>
<tr>
<td>American Society for Testing and Materials (ASTM) Standard</td>
<td>Specification for Audit and Disclosure Logs for Use in Health Information Systems</td>
<td># E2147-01</td>
<td>E2147-01 &quot;is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1).&quot; Visit <a href="http://www.astm.org">www.astm.org</a> for more information</td>
</tr>
<tr>
<td>Centers for Medicare and Medicaid Services (CMS)</td>
<td>National Provider Identifier (NPI)</td>
<td></td>
<td>NPI is a unique 10-digit identification number issued to healthcare providers in the United States by the Centers for Medicare and Medicaid Services (CMS). All individual HIPAA covered healthcare providers (physicians, nurses, dentists, chiropractors, physical therapists, etc.) or organizations (hospitals, home healthcare agencies, nursing homes, residential treatment centers, group practices, laboratories, pharmacies, medical equipment companies, etc.) must obtain an NPI for use in all HIPAA standard transactions, even if a billing agency prepares the transaction. Once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes. Visit <a href="http://www.cms.gov">www.cms.gov</a> for more information</td>
</tr>
<tr>
<td>Clinical Laboratory Improvement Amendments (CLIA) of 1988</td>
<td></td>
<td></td>
<td>Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. Visit <a href="http://www.fda.gov">www.fda.gov</a> and <a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a> for more information.</td>
</tr>
<tr>
<td>Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification</td>
<td>While not itself a standard, this federal regulation provides a listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial health care transactions, and protecting the security and privacy of health care information, as applied to the three types of defined covered entities: health plans, health care clearinghouses, and health care providers who conduct any of the specified health care transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Level Seven (HL7)</td>
<td>Role Based Access Control (RBAC) Healthcare Permissions Catalog Version 2.0, July 2005</td>
<td>Presents the healthcare permissions that may be assigned to licensed or certified healthcare providers. Visit <a href="http://www.hl7.org">www.hl7.org</a> for more information.</td>
<td></td>
</tr>
<tr>
<td>Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)</td>
<td>Audit Trail and Node Authentication (ATNA)</td>
<td>Provides a common standard audit trail for distributed applications.</td>
<td></td>
</tr>
<tr>
<td>Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)</td>
<td>Consistent Time (CT)</td>
<td>Coordinates time across networked systems to ensure time accuracy in patient records and to support security requirements.</td>
<td></td>
</tr>
<tr>
<td>Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)</td>
<td>Document Digital Signature (DSG)</td>
<td>Specifies the use of digital signatures for documents that are shared between organizations.</td>
<td></td>
</tr>
<tr>
<td>Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)</td>
<td>Supplement 2007 – 2008 Cross Enterprise User Assertion (XUA)</td>
<td>The Cross-Enterprise User Assertion Profile (XUA) provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. The latest version of the IHE framework is available at <a href="http://www.ihe.net">www.ihe.net</a>.</td>
<td></td>
</tr>
</tbody>
</table>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Supplement 2007 – 2008 Standard digital patient authorizations (Basic Patient Privacy Consent IHE-BPPC) | The XDS profile provides little guidance on supporting privacy policies within an affinity Domain. Documents can be marked with a confidentiality Code, but no information has been provided on how to use this information to support patient privacy concerns. This profile corrects that deficiency by describing a mechanism whereby an Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems).

There are three key parts of the profile:
1. The profile provides a content module for capturing a patient consent to a privacy policy or policies.
2. The profile describes how the confidentiality Code attribute of the XDSDocumentEntry metadata is used to support the consent policies.
3. Finally it describes the method by which XDS Consumer Actors can enforce the privacy policies determined by the document confidentiality Code and the patient privacy consents.

Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Healthcare Provider Directory | The Healthcare Provider Directory (HPD) profile supports queries against, and management of, healthcare provider information that may be publicly shared in a directory structure.

International Organization for Standardization (ISO) | Health informatics – Information technology – Open Systems Interconnection – Systems Management: Security alarm reporting function | Technical Specification #10164–Part 7: Security Alarm Reporting Function, 1992 | Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. Visit www.iso.org for more information.


International Organization for Standardization (ISO) | Health Informatics – Pseudonymization | Technical Specification # 25237 | This technical specification provides a conceptual model of the problem areas, requirements for trustworthy practices, and specifications to support the planning and implementation of pseudonymisation services.
<table>
<thead>
<tr>
<th>Organization / Standardization Body</th>
<th>Specification / Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internet Engineering Task Force (IETF)</td>
<td>Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS)RFC #2818, May 2000</td>
</tr>
<tr>
<td>Internet Engineering Task Force (IETF)</td>
<td>Simple Network Time Protocol (SNTP)RFC # 2030, October, 1996</td>
</tr>
<tr>
<td>Organization for the Advancement of Structured Information Standards (OASIS)</td>
<td>Web Services Security SOAP Message Security Version 1.0</td>
</tr>
<tr>
<td>Organization for the Advancement of Structured Information Standards (OASIS)</td>
<td>Security Assertion Markup Language (SAML) v2.0 OASIS StandardITU-T X.1141</td>
</tr>
<tr>
<td>International Standards Organization (ISO)</td>
<td>Healthcare Informatics – Functional and Structural RolesTS21298</td>
</tr>
<tr>
<td>International Standards Organization (ISO)</td>
<td>Health informatics — Classification of purposes for processing personal health informationTS14625</td>
</tr>
<tr>
<td>International Standards Organization (ISO)</td>
<td>Health informatics — Audit trails for electronic health records</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| International Standards Organization (ISO) | Health informatics — Electronic health record communication | TS 13606-4 (Sensitivity Class) | Part 4 of a multipart standard on Electronic Health Record Communication that describes requirements and a methodology for specifying the privileges necessary to access EHR data. Describes a set of 5 classes of sensitivity that may be used to classify health information to be shared.  
Within the ISO 13606-4 is a vocabulary for a 5-level sensitivity class to reflect typical functional health care information access sensitivities:  
- Personal care  
- Privileged care  
- Clinical care  
- Clinical management  
- Care management |
<p>| International Standards Organization (ISO) | Healthcare Informatics — Directory services for security, communications and identification of professionals and patients | ISO TS21091 | This technical specification reviews the health care specific requirements of the directory services, and defines associated standard specifications for inclusion of healthcare related information in the health care directory. This is currently on the standardization track as DIS 21091. |
| Organization for the Advancement of Structured Information Standards (OASIS) | Web Services Security SOAP Message Security Version 1.0 | | “Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e., support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message.” Visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> for more information |
| Organization for the Advancement of Structured Information Standards (OASIS) | ebMS OASIS/ebXML Messaging Services Specifications v2.1 | | Defines a Message Service protocol for reliable Business-to-Business data interchange. ebMS v2.1 adds quality of service features on top of transfer protocols such as HTTP and SMTP. Key qualities of service features include guaranteed delivery and nonrepudiation of receipt. ebMS v2.1 can reliably transfer any data type including XML, X12, EDIFACT, or binary data between two parties over the Internet. Visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> for more information |</p>
<table>
<thead>
<tr>
<th>Organization</th>
<th>Standard/Specification</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Organization for the Advance-</td>
<td>Security Assertion Markup Language (SAML) v2.0 OASIS Standard</td>
<td>SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. Visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> for more information.</td>
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<td>ment of Structured Information</td>
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<td>Standards (OASIS)</td>
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<td>ITU-T X.1141</td>
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<tr>
<td>International Standards Organization (ISO)</td>
<td>Privilege Management and Access Control</td>
<td>This 3-part technical specification defines an overview, model, and framework for managing privileges an access to sensitive, distributed health information. Privilege management and access control addresses security services required for communication and distributed use of health information.</td>
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<tr>
<td>TS26000/1/2/3</td>
<td></td>
<td>Part 1: Overview and policy management, describes the scenarios and the critical parameters in cross border information exchange. It also gives examples of necessary documentation methods as the basis for the Policy agreement.</td>
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<td>Part 2: Formal models, describes and explains, in a more detailed manner, the architectures and underlying models for the privileges and privilege management which are necessary for secure information sharing plus examples of Policy agreement templates.</td>
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<td>Part 3: Implementations, describes examples of implemental specifications of application security services and infrastructural services using different specification languages.</td>
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<td>ASTM</td>
<td>Standard Guide for Information Access Privileges to health information</td>
<td>This standards addresses access privilege and control requirements, healthcare professional roles within the US, and information/data requiring access control.</td>
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<td>E1986</td>
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<tr>
<td>International Standards Organization (ISO)</td>
<td>Healthcare Informatics PKI/1/2/3</td>
<td>This Standard describes the common technical, operational and policy requirements that need to be addressed to enable digital certificates to be used in protecting the exchange of healthcare information within a single domain, between domains and across jurisdictional boundaries.</td>
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<tr>
<td>IS17090</td>
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<tr>
<td>ASTM</td>
<td>Standard Guide for User Authentication and Authorization</td>
<td>This standard specifies requirements, methods, and mechanisms to authentication users for access and management of health information in centralized or distributed environments.</td>
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<td>E1985</td>
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<tr>
<td>FIPS</td>
<td>compliant tamper resistant media</td>
<td>Security requirements for cryptographic modules specifying tamper evident physical security or pick resistant locks. Level 2 provides for role-based authentication.</td>
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<td>FIPS 140-2</td>
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<tr>
<td>Federal Bridge</td>
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<td>The FBCA consists of a collection of PKI components (Certificate Authorities, Directories, Certificate Policies, and Certificate Practice Statements) that are used to provide peer-to-peer interoperability among Federal Agency.</td>
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<tr>
<td>Auditing Standards Board of the American Institute of Certified Public Accountants (AICPA)</td>
<td>Statement on Auditing Standards (SAS) No. 70</td>
<td>SAS-70 Level II</td>
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<td>Statement on Standards for Attestation Engagements (SSAE) No. 16</td>
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<td>Electronic Healthcare Network Accreditation Commission</td>
<td>Statement on Standards for Attestation Engagements (SSAE) No. 16</td>
<td>SSAE 16</td>
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<tr>
<td>International Standards Organization (ISO)</td>
<td>Health informatics: Security management in health using IS17799</td>
<td>IS27799</td>
</tr>
</tbody>
</table>
| International Standards Organization (ISO) | Security and privacy requirements for compliance testing of EHR systems | ISO DTS 14441 | This multi-part Technical Specification addresses security and privacy protection in electronic patient record systems at the point of care that are interoperable with EHR systems by providing:  
  • A set of core security and privacy requirements, along with the guidelines and best practices necessary for assessing and eventually ensuring compliance with those requirements;  
  • A profile of these requirements, including examples of proven testing procedures that have been developed to evaluate compliance with the necessary privacy and security requirements. |

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168 This guideline is consistent with the revised version of ISO/IEC 17799-1:2005.