HITSP Lab Report Document Component

HITSP/C37

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Population Health Technical Committee
Care Delivery Technical Committee

DOCUMENT CHANGE HISTORY

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1.3	Review Copy	Population Health Technical Committee Care Delivery Technical Committee	April 27, 2007
2.0	Released for Implementation	Population Health Technical Committee Care Delivery Technical Committee	May 11, 2007

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FIGURES AND TABLES

1.0 FOREWORD

This document is referred to as a Component and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.
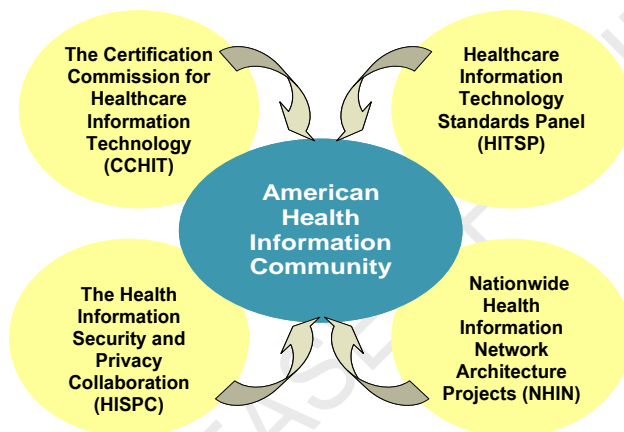
The American Health Information Community[1] (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the exchange of patient data (HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a Nationwide Health Information Network (NHIN). Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work in additional Use Case priority areas recommended by AHIC. This year,

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[1] http://www.hhs.gov/healthit/ahic.html

CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP[2] is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including Standards Development Organization (SDO) work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

The work of the HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

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[2] www.hitsp.org

This HITSP document pertains to the Interoperability Specification for the following:
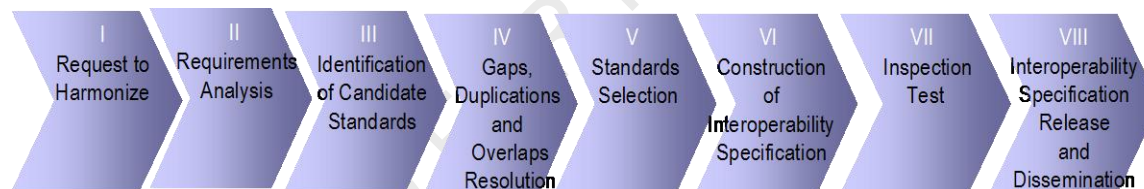
Use Case	Specific Scope of this Use Case
Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within this specific context of the Use Case. Please note that Patient Health Record (PHR) application considerations are out of scope, at this time.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three Use Cases (available at hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee (TC) followed an 8 step process, depicted below.

Figure 1.0-1 HITSP Harmonization Process Steps

I Request to Harmonize	II Requirements Analysis	III Identification of Candidate Standards	IV Gaps, Duplications and Overlaps Resolution	V Standards Selection	VI Construction of Interoperability Specification	VII Inspection Test	VIII Interoperability Specification Release and Dissemination

How to Read this Interoperability Specification

Each Interoperability Specification (IS) is actually a suite of documents that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements imposed by a given Use Case. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the Interoperability Specification provides recommendations and a roadmap for corrections to be made. This Interoperability Specification includes the Transaction Packages, Transactions, and Components.

2.0 INTRODUCTION

As an introduction to the Laboratory Report Document Component, this section provides a high level overview of an information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to the HITSP Acronyms List and an explanation of the conventions used to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to Section 3.0 Referenced Standards.

2.1 OVERVIEW

The purpose of this Component is to describe the specification for an electronic document as required by the HITSP interpretation of the ONC EHR and Biosurveillance Use Cases. This is based upon the standard Clinical Document Architecture Release 2 (CDA R2), as in the HL7 V3 2006 normative edition. The goals supported by this Component specification are stated in the EHR and Biosurveillance Use Cases:

- Transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician
- Transmission of complete, preliminary, final and updated (or notification) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)
- Transmit laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time

The Use Cases note that there are obstacles to achieving the stated goals. In particular, the following obstacle is delineated:

- Lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards

This Component is the result of a considered assessment of the current practices in electronic laboratory results reporting and the requirements of the Use Case. The Committees chose the IHE XD*-Lab Integration Profile because it generally meets the requirements of the Use Case and it represents the future direction for healthcare information sharing. The creation, use, and management of documents have a long tradition in healthcare and the electronic equivalent of a paper document is a useful and efficient paradigm to implement when sharing information.

The Health Level Seven (HL7) Clinical Document Architecture (CDA) is specified as Extensible Markup Language (XML) documents. The ease of rendering electronic information in human readable form can

be facilitated by XML. A 'document container' or document section/sub-section is similar to a named battery of laboratory tests, which collect the individual named laboratory tests. Finally, there are several other characteristics about an electronic document that make it well-suited for the HITSP Use Cases:

- Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements
- Stewardship – A clinical document is maintained by an organization entrusted with its care
- Potential for authentication - A clinical document is an assemblage of information that is intended to be legally authenticated
- Context - A clinical document establishes the default context for its contents
- Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document
- Readability – An XML clinical document can be rendered simultaneously in human readable and machine-interpretable forms[3]

This Laboratory Report Document Component is based on Volume 3 of the IHE Laboratory Technical Framework: IHE Content Integration Profile, Sharing Laboratory Reports (XD*-LAB). The IHE XD*-LAB Integration Profile was written and published in 2006 by the Integrating the Healthcare Enterprise (IHE) Initiative. The IHE XD*-LAB composite standard is reproduced in part in this specification with specific written permission from IHE. The IHE XD*-LAB profile provides a set of constraints on the HL7 V3.0 CDA standard to specialize that CDA to a Laboratory Report. The entire IHE XD*-LAB composite standard is in the public domain and available on the IHE Web Site.

Excerpts from that document are included here to highlight the HITSP approaches to implementation and to depict how the HITSP Laboratory Report Document Component should be populated. The descriptions for this Overview and parts of Section 4.2.3 Data Structure were taken in lengthy quotes from the publication and therefore, the same terms are used throughout this specification. These terms have the same meaning for purposes of this discussion.

IHE XD*-LAB describes the overview of this Integration Profile as follows:

> It describes a clinical laboratory report as an electronic document. Such an electronic document contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. The intention is to share this human readable laboratory report, in an Electronic Health Record (EHR) or in a Personal Health Record (PHR)[4], so that healthcare professionals taking care of the patient may access it and read it. In addition, this electronic laboratory report may contain test results in a machine readable format, to facilitate the integration of these observations in the database of a consumer system.

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[3] Adapted from HL7 CDA r2, §1.1 CDA Overview

[4] Although IHE discusses use in PHR applications, such use is outside the scope of the current AHIC Use Cases.

This content Integration Profile is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document. Although IHE states that it is not intended to address ordering and return of laboratory results to the ordering provider, HITSP does intend for it to be used for ordering and return of laboratory results to the ordering provider.

The scope covers the specialties already addressed by the IHE Laboratory Technical Framework: All laboratory specialties working on in-vitro specimens, including microbiology. The anatomic pathology specialty is not included in the scope of this Integration Profile. Blood Bank specialty is restricted to non-stock associated testing; results for Blood Banks (e.g. ABO blood group) are included.

The human rendering of the laboratory report defined in this Integration Profile is compatible with laboratory regulations in numerous 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.[5]

Table 2.1-1 Document Relationships

Related Documents	Document Description
HITSP/C36[6]	HITSP Lab Result Message Component
HITSP/C35	HITSP EHR Lab Terminology Component
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package
HITSP/T29	HITSP Notification of Document Availability Transaction

2.2   TECHNICAL ASSUMPTIONS AND SCOPE

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

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[5] IHE XD*-LAB §1.1 Scope

[6] The HITSP/C36 Lab Message component is included in this release as a **Review Copy** which outlines the use case and the direction for development of a profile of the HL7 2.5.1 Message specification. The Technical Committees are currently completing the detailed guidance information with an expected **Released for Implementation** in the third quarter of 2007. The HITSP encourages interested parties to become involved and participate in this activity. For information on becoming a member of the HITSP, please contact Jessica Kant for further information at jkant@himss.org.

2.2.1   INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standardized manner. Interoperability Specifications define the necessary business and technical actors, the transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

2.2.2   ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.2.3   THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure non-repudiation. Persistence as defined by Health Level Seven (HL7) means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Non-repudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

2.2.4   IMPLEMENTATION TESTING

The 2006 set of Interoperability Specifications were evaluated by inspection testers (desktop review) and reviewed by HITSP members prior to HITSP approval. Although the Interoperability Specifications are based on approved standards, when published, they represent combinations and constraints that have not been tested in actual implementations. HITSP enlisted partners to develop test plans, data and suites to test the implementation and then to support a program for progressive testing, feedback and

deployment of implementations. Feedback from test implementers has been used in the revisions in Version 2.0.

2.2.5   SECURITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) and its Administrative Simplification sections establish the minimum federal requirements for security and privacy of individually identifiable health information (IIHI). HIPAA requires that "covered entities" establish and maintain secure systems that protect IIHI from unauthorized disclosures while ensuring its availability for authorized uses. Most providers, health plans and intermediaries, and by contract their business associates, are covered by HIPAA regulation. However, HIPAA does not cover personal health records unless they are held by a covered entity, nor an individual's use of their own health information.

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP, based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes. Exceptions to the deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.

There is a special case for the Consumer Empowerment (CE) Use Case. In the first year of HITSP's work, the Consumer Empowerment TC is to provide an Interoperability Specification for sharing of demographic data, medication lists, and allergies *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case. However, HITSP requires further guidance on patient consent, particularly since patient consent is not addressed by HIPAA in the case of a personal health record (PHR) nor is it established within widely accepted PHR standards. Therefore HITSP identifies patient consent as a necessary pre-condition for successful implementation of a PHR that contains personal demographic data and medication histories. Patient consent will be documented as a pre-condition in the CE Interoperability Specification. Work on patient consent has been deferred until the second year of HITSP work.

2.3   AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

2.4   COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

2.5   ACRONYMS

The acronyms used in this document are contained in the HITSP Acronyms List.

2.6   CONVENTIONS

Conventions are used to convey the full descriptions and usage of standards in the Interoperability Specification and are contained in the HITSP Conventions List.

3.0 REFERENCED STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- Provisional - standards that are not yet but are expected to be approved by the Standards Organization by the time the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
  - o It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
  - o It is substantially the same as it was when it was provisionally used and
  - o It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are roadmapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as "Intended for Use" because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use "Provisional" or "Interim" standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard "Intended for Use" is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of "Interim" and "Intended for Use" standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

3.1 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The following standards are used to implement this Interoperability Specification:

Table 3.1-1 List of Standards

Standard	Description
Clinical Laboratory Improvement Amendments (CLIA) of 1988	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 www.fda.gov and www.cms.hhs.gov for more information.
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (XD*-LAB) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider. Visit www.ihe.net for more information.

NOTE:

A gap exists for a mapping from the HL7 V2.5[7] Laboratory Result message to a CDA-Lab document.

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[7] HITSP references HL7 2.5.1 messaging for lab results reporting and HL7 2.5 for other messages. Future maintenance work will move toward referencing a single HL7 version across HITSP documents.

4.0 COMPONENTS

4.1 CONTEXT OVERVIEW

The context for this component specification is to have laboratory results and interpretations structured as an XML document for interchange to meet requirements for human and machine readability. The context also introduces other properties of documents such as persistence, non-repudiation, and unique identification of documents.

This component specification is intended to be reusable by HITSP transactions and transaction packages. It describes an electronic version of a laboratory report structured as an electronic document following the IHE XD*-LAB and HL7 CDA R2 standards. As stated in the IHE Integration Profile, this specification operates within a larger framework. Please refer to IHE XD*-LAB and IHE IT Infrastructure Technical Framework, vol. 1 and 2 for details.

4.1.1 CONTEXTUAL CONSTRAINTS

Some of the constraints applied to the IHE XD*-LAB profile by this component are:

- Contrary to the IHE XD*-LAB profile, machine-processable entries are required in this HITSP Component
- Laboratory Results and Interpretations are intended to be constrained for clinical care and authorized public health uses; other secondary uses are not explicitly addressed
- Terminologies will be constrained to specified subsets as identified in the companion HITSP Laboratory Terminology Component
- CLIA requires that certain data elements be present in all laboratory results reports, such as laboratory name, the laboratory address, and the Medical Director's name. The IS requires these elements in the HL7 v.2.5.1 message and, by extension through the IS, in the CDA document. Although these are not required in the IHE Integration Profile, its document contains all necessary mark-up to convey the information. HITSP will request IHE to create a U.S. National Extension to make these explicit

HITSP has identified several gaps that should be investigated and resolved:

- Managing the use of OIDs across institutions is thought to be a gap in common, shared business rules
- There is a need to identify implementation specifications for management of replacement documents. This is thought to be a gap in common, shared business rules

4.1.2 TECHNICAL ACTORS

The Laboratory Report Document itself does not have actors. It is the "payload" for the Manage Shared Documents Transaction Package as described above. As such, various actors are engaged in interactions that transmit the payload document as described in Section 4.1.

4.2 INFORMATION INTERCHANGE COMPONENTS: RULES FOR IMPLEMENTING

The processes that are supported by this component specification are described in the Manage Sharing of Documents Transaction Package HITSP Interoperability Specification, HITSP/ISTP-13.

4.2.1 PROCESS PRE-CONDITIONS

Pre-conditions to this process are:

- The electronic laboratory result has been deemed releasable
- The laboratory result conversion into CDA format has been accomplished
- The repository must be capable of preserving data required by CLIA that is subsequently sent in the CDA

4.2.1.1 PROCESS TRIGGERS

Triggers for this process depend on the scenario that is using this component.

4.2.2 PROCESS POST-CONDITIONS

A post-condition for the process supported by this component is the storage of data for retrieval as a structured document.

4.2.2.1 PROCESS OUTPUTS

The output is the document itself in both human and machine readable forms[8].

4.2.3 DATA STRUCTURE

A CDA document comprises a header and a body. IHE defines the header as:

> The header identifies the patient, the clinical laboratory that produced the report, the physician that ordered the tests performed, the encounter in which this act was performed, and other participants to this document (author, custodian, legal authenticator…) This information SHALL be rendered to the human reader of the electronic document, together with the content of the body. Seeing the body of the document without the header makes no sense.[9]

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[8] The term "human readable" is somewhat ambiguous but is intended to speak to information that can easily be rendered for display and access by a human.

[9] IHE XD*-LAB §6.1 Header Rendering

The body comprises two levels. IHE defines the Level 2 body as:

> A clinical laboratory report SHALL have a structured Body. This body is organized as a tree of up to two levels of sections, delivering the human-readable content of the report: Top level sections represent laboratory specialties. A top level section may contain either one text block carrying all the results produced for this specialty or a set of leaf sections. In the first case the specialty section happens to be also a leaf section. In the latter case, each (second level) leaf section contained in the (top level) specialty section represents a reported item: i.e. a battery, a specimen study (especially in microbiology), or an individual test.

> In addition, any leaf section MAY contain a level 3 entry that contains the observations of that section in a machine-readable format.[10]

The Level 3 entry may be a multimedia entry or a machine processable entry. IHE defines them as follows:

> Level 3 entries dedicated to multimedia rendering. A leaf section of the Laboratory Report MAY have optional entries to carry the multimedia objects mentioned in level 2 narrative block, and provide their rendering. Multimedia rendering is based on the observation Media element in an entry dedicated to that purpose.[11]

And

> Each leaf section of the Structured Body of a Laboratory Report MAY contain one entry containing the machine-readable result data rendered in the section…

> The level 3 entries must be compatible with the results contained in message type POLB_MT004000 carried by the trigger event Result Complete (POLB_TE004200) or Result Corrected (POLB_TE004201), both derived from Result Event RMIM of HL7 V3 Laboratory Domain. Thus, a LIS able to produce HL7 V3 results messages will easily produce laboratory reports from the same data.[12]

NOTE:

In contrast to the above quotation regarding Level 3 entries, machine-readable observation entries are REQUIRED for all ONC harmonized Use Cases.

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[10] IHE XD*-LAB §7 Level 2: human-readable body of the report

[11] IHE XD*-LAB §8 Level 3 entries dedicated to multimedia rendering

[12] IHE XD*-LAB §9.1 Global model and general rules

For a data model of the machine-processable entry, please refer to Figure 9.1, 9.2, and 9.3: Representation of Machine-Processable Entry, in IHE section 9.1 Global Model and General Rules, following line 940.

4.2.3.1 DATA MAPPING

See the IHE Integration Profile and the HL7 CDA R2 Standard for a description of the data elements.

NOTE: HITSP has submitted comments to IHE to extend the XD*-LAB Integration Profile to include:
- The CLIA requirement for Reference Laboratory Name and Address and Name of Medical Director
- The Intended Recipients of the document

4.2.3.2 MINIMUM DATA-SET

See the IHE Integration Profile and the HL7 Version 3.0 CDA R2 Standard for a specification of the relevant value sets for this component.

4.2.4 ADDITIONAL SPECIFICATIONS

Not Applicable

5.0 CONSTRAINTS FOR REUSE

Not Applicable

6.0 CHANGE HISTORY

6.1   MAY 11, 2007

This document is now Released for Implementation.