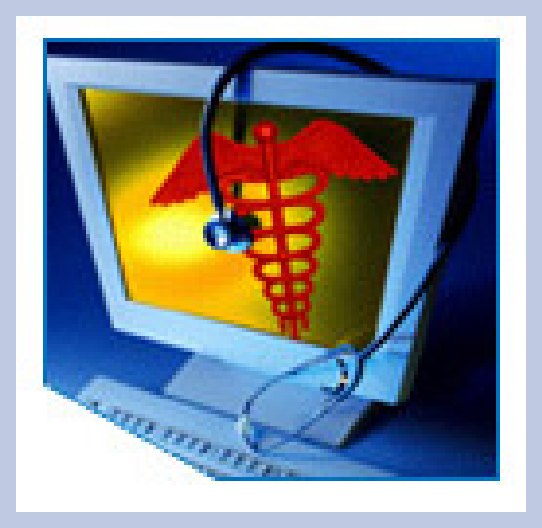
August 27, 2008
Version 2.2

HITSP Lab Report Document Component

HITSP/C37



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Management and Health Records Domain Technical Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Biosurveillance Technical Committee Electronic Health Record Technical Committee	August 18, 2006
1.1	Ready for Public Comment	Biosurveillance Technical Committee Electronic Health Record Technical Committee	September 12, 2006
1.2	Ready for Implementation Testing	Biosurveillance Technical Committee Electronic Health Record Technical Committee	October 20, 2006
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
2.0.1	Review Copy	Population Health Technical Committee Care Delivery Technical Committee	March 19, 2008
2.1	Released for Implementation	Population Health Technical Committee Care Delivery Technical Committee	March 27, 2008
2.1.1	Review Copy	Care Management and Health Records Domain Technical Committee	August 20, 2008
2.2	Released for Implementation	Care Management and Health Records Domain Technical Committee	August 27, 2008

TABLE OF CONTENTS

FIGURES AND TABLES

1.0 INTRODUCTION

As an introduction to the HITSP Lab Report Document Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Component Definition.

1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Component and background information about the underlying standards that the Component is based on. The purpose of this Component is to describe the specification for an electronic document as required by the AHIC EHR and Biosurveillance Use Cases. This is based upon the standard Health Level Seven (HL7) 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) laboratory results 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 Case notes 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 Lab Report Document 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 HITSP Technical Committees chose the Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 specification 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 HL7 CDA standard 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 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[1]

This Lab Report Document Component is based on the content specifications as defined in the IHE Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, published August 16, 2007. This document was written and published in 2006 and subsequently revised and republished by the IHE Initiative. The IHE LAB TF-3 profile is reproduced in part in this specification with specific written permission from IHE. The IHE LAB TF-3 profile provides a set of constraints on the HL7 V3.0 CDA standard to specialize CDA to support a Laboratory Report. The entire IHE LAB TF-3 profile 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 Lab 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 LAB TF-3 describes the scope as follows (quoted text begins here):

> 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)2, so that healthcare professionals taking care of the patient may access it and read it. In addition, this electronic

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

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

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.

This content Integration Profile is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document. Note: 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 Integration 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.[3]

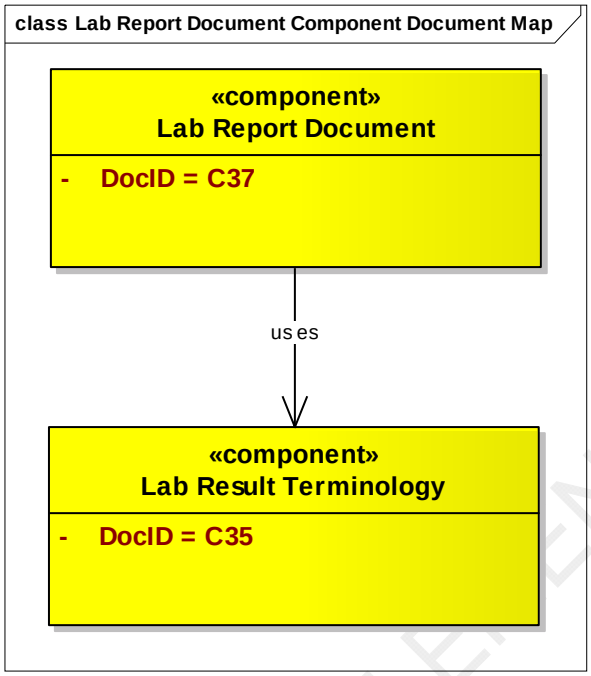
The quoted text for the IHE LAB TF-3 ends here.

1.2 COMPONENT DOCUMENT MAP

Each HITSP specification describes a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The current Lab Report Document specification is used with other constructs to meet the requirements of one or more ISs. Review Section 1.2 Interoperability Specification Document Map from the relevant IS to better understand the context, dependencies, and relationships between the constructs used to meet the IS requirements. The Document Map in Figure 1.2-1 depicts how this construct integrates and constrains HITSP constructs to support the information exchange, within the defined context of this document. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.

[3] IHE LAB TF-3 §1.1 Scope

Figure 1.2-1 Component Document Map



1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE) International. Copies of this standard may be retrieved from the IHE Web Site at www.ihe.net.

Certain materials contained in this Interoperability Specification are reproduced from Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2) with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.

1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from the www.hitsp.org Web Site.

Table 1.4-1 Reference Documents

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built
TN900 - Security and Privacy Technical Note	Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following: • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A glossary of terms used in all the Security and Privacy construct documents • A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.

2.0 COMPONENT DEFINITION

A Component defines atomic constructs used to support an information exchange or to meet an infrastructure requirement. This is accomplished by:

(a) Referencing one or more underlying standards
(b) Specifying constraints and other rules for using the standards

2.1 CONTEXT OVERVIEW

This section provides a general description of the Component. It includes a detailed definition of the Component and the reason for its use. It also provides all the necessary background information that further describes the context in which the Component is needed, and the base or composite standard that the Component is based on.

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, nonrepudiation 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 LAB TF-3 and HL7 CDA R2 standards specifications. As stated in the IHE Technical Framework, this specification operates within a larger framework. Please refer to IHE Laboratory Technical Framework Volume 3 (LAB TF-3) and IHE IT Infrastructure Technical Framework, vol. 1 and 2 for additional information.

Lab documents for exchange are described in this document; however the processes for the exchange of lab documents are described in HITSP/TP13 Manage Sharing of Documents.

Pre-conditions to the process of exchanging a Lab Document are:

- The order and specimen must have been received by the laboratory, and the ordered test performed
- The electronic laboratory result has been deemed releasable by the sender
- 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

A post-condition for the process supported by this component is the storage of the output data for retrieval as a structured document, in both human and machine readable forms.

2.1.1 COMPONENT CONSTRAINTS

This section describes the constraints that limit the context in which the Component may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

Table 2.1.1-1 Component Constraints

Constraint	Constraint Section
Laboratory Results and Interpretations are intended to be constrained for clinical care and authorized public health uses; other secondary uses are not explicitly addressed	N/A
Terminologies will be constrained to specified subsets as identified in the companion HITSP Lab Result Terminology Component	HITSP/C35 - Lab Result Terminology
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 elements explicit in the IHE Laboratory Framework TF-3	N/A

2.1.2 COMPONENT DEPENDENCIES

This section describes any specific mapping criteria for the standards underlying the Component. It elaborates on the relationships between different standards used by this Component, and how they map to each other. Additional required mapping criteria not currently enforced by the underlying standards, and any specific elements that are required for this mapping to succeed, are also provided.

Table 2.1.2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/C37 - Lab Report Document	Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, August 16, 2007	General	Base Standard
HITSP/C37 - Lab Report Document	HITSP/C35 - Lab Result Terminology	General	Supplies required vocabulary guidance information to be applied within the exchange document

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basic elements and secondary standards that are supported by this Component and the constraints that are being placed on those standards. Specifically, it describes the subset or constraints that are required for this Component,

and the minimum attributes of the Component as it relates to the base or composite standards on which it is based.

2.2.1 DATA MAPPING

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard, only the fields that HITSP is constraining differently from the standard will be described here.

Table 2.2.1-1 Data Mapping

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions	Additional Specification for Component
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 LAB TF-3 Integration Profile to include:

- The CLIA requirement for Reference Laboratory Name and Address and Name of Medical Director
- The Intended Recipients of the document

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.[4]

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 SHALL contain a level 3 entry that contains the observations of that section in a machine-readable format.[5]

[4] IHE LAB TF-3 §4.1.1 Header Rendering

[5] IHE LAB TF-3 §4.2 Level 2: human-readable body of the report

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.[6]

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 Laboratory Information System (LIS) able to produce HL7 V3 results messages will easily produce laboratory reports from the same data.[7]

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

For a data model of the machine-processable entry, please refer to Figure 4.4.1, 4.4.2, and 4.4.3: Representation of Machine-Processable Entry, in LAB TF-3 Section 4.4.1 Global Model and General Rules.

2.3 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 standards used by this Component specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 2.3.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 2.3.2)

[6] IHE LAB TF-3 §4.4 Level 3 entries dedicated to multimedia rendering

[7] IHE LAB TF-3 §4.4.1 Global model and general rules

- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Component specification (see Section 2.3.3)

2.3.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Component specification.

Table 2.3.1-1 Regulatory Guidance

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. For more information visit http://www.fda.gov and http://www.cms.hhs.gov

2.3.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Component specification, and a detailed description of each standard.

Table 2.3.2-1 Selected Standards

Standard	Description
Health Level Seven (HL7) Clinical Document Architecture Release 2 (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. For more information visit www.hl7.org
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, August 16, 2007	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (LAB TF-3) 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. For more information visit www.ihe.net

NOTE: A gap exists for a mapping from the HL7 V2.5.1[8] Laboratory Result message to a CDA-Lab document.

2.3.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Component specification.

Table 2.3.3-1 Informative Reference Standards

Standard Name	Description/Reason for Use
No applicable informative reference standards	

[8] 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.

3.0 TECHNICAL IMPLEMENTATION

3.1 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in Table 2.1.1-1, and implement all of the required actors, where defined, within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification with which this construct is associated.

3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for actor scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.

4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.

5.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

5.1 MAY 11, 2007

This document is now Released for Implementation.

5.2 MARCH 19, 2008

This document has been updated to include the HITSP Security and Privacy constructs and has been updated to reflect the new template.

The following changes have been made to the construct:

- Maintenance update to align this Component with the advancement of the IHE Laboratory Technical Framework Volume 3 (LAB TF-3) Specification; additional edits include typographical corrections and reformatting of text and tables to improve readability; significant changes are noted below.
- Sections 2.1.1 Component Constraints. The requirement for inclusion of machine processable entries (Level 3 entries) imposed by previous versions of this Component has been removed from Section 2.2.1 of this version as it is now imposed by the referenced specification
- Section 2.2.4 Data Structure, Paragraph 5. The updated IHE specification has now adopted requirements previously imposed by HITSP in Section 2.2.1, most notably the requirement for inclusion of machine processable entries (Level 3 entries). The change of MAY to SHALL in paragraph 5 reflects that change
- Section 2.3 List of Standards
  - Updated the IHE Lab Technical Framework standard to reflect the inclusion of the previous supplement into the IHE Laboratory Technical Framework document
  - Removed HIPAA and CLIA from Table 2.3-1 as these are guiding regulations, not standards
  - Removed Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2) as it is indirectly referenced by the IHE Laboratory Technical Framework standard.

5.3 MARCH 27, 2008

Upon approval by the HITSP Panel on March 27, 2008, this document is now Released for Implementation.

5.4 AUGUST 20, 2008

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References.

- The following standard has been added to the standards listing

- Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)

The title of the document was updated by removing the reference to IHE XD* Lab. Please see previous Change History items for more information on the standard list update that drove this change.

5.5 AUGUST 27, 2008

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.