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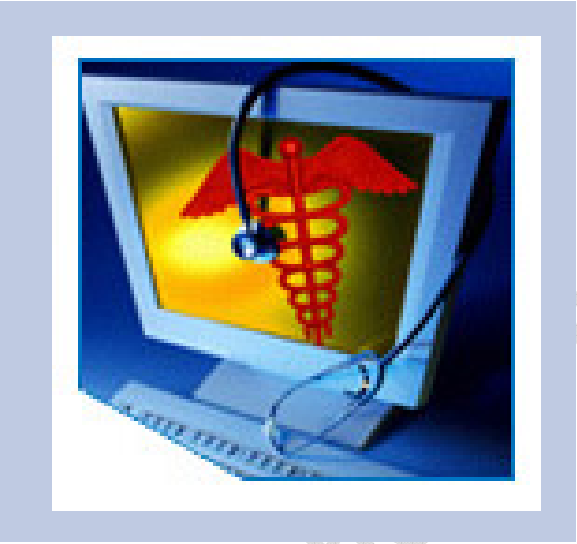
HITSP Interoperability Specification: Lab Report Document Component

HITSP/ISC-37



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Electronic Health Records Technical Committee
Biosurveillance Techncial Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Electronic Health Records –Technical Committee Biosurveillance Technical Committee	18 August 2006

1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) 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. 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 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 informatics to ensure that the resulting standards are globally relevant.
- Be use-case driven, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use case "breakthroughs areas" in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
2.	Consumer Empowerment	Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.
3.	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.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides, integration profiles to actions and actors that satisfy the requirements

imposed by the relevant use cases. 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.

2.0 INTRODUCTION

The purpose of this Component is to describe the specification for an electronic document as required by the vetted 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 lab 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 lab result data from electronically enabled health care 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 committee chose this 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 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 lab tests, which collect the individual named lab 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.

2.1 OVERVIEW

This Laboratory Report Document Component is based on Volume 3 of the IHE Laboratory Technical Framework: IHE Content Integration Profile, Sharing Laboratory Reports (XDS-LAB). That IHE document describes the overview of this 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), 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.
>
> This Content Integration Profile is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document. 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 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.

The IHE profile expressly excludes interim results and results returned to the ordering clinician. These two characteristics are part of the ONC harmonized EHR and Biosurveillance use cases. After some discussion, it seems likely that IHE will lift these restrictions. There is nothing in the profile itself that prohibits its use by ordering clinicians or to report interim results; they are there to define a separate space.

Related Documents	Document Description	Document Name and Location
HITSP/ISC-36	Component Specification for the HL7 V2.5 message to report lab results	ISC_HITSP_36_v1.0_2006

Related Documents	Document Description	Document Name and Location
HITSP/ISTP-13	HITSP Interoperability Specification for Manage Sharing of Docs Transaction Package	ISTP_HITSP_13_v1.0_2006
HITSP/IST-29	HITSP Interoperability Specification for Notification of document availability Transaction	ISTP_HITSP_29_v1.0_2006

Table 2.1-1 Document Relationships

2.2 AUDIENCE

The interoperability specification is designed to be used by analysts who need to understand the interoperability requirements for the described use cases, and by implementers working to develop interoperable applications. Understanding and using the relevant interoperability set of specifications is a key requirement for establishing interoperability compliance. In particular, some knowledge of HL7 Version 3, the HL7 Clinical Document Architecture, Release 2 (CDA R2), and the IHE XDS Laboratory Technical Framework is desirable.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to appendix for glossary.

2.4 CONVENTIONS

The graphics used in this specification are those provided in the IHE source document and are self explanatory. Tables are used to indicate standards categorizations, as well as dependencies and constraints between constructs.

2.5 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

HL7 materials used in this document have been extracted from relevant copyrighted materials with permission of Health Level Seven (HL7). Copies of this standard may be purchased from the Health Level 7 website at www.hl7.org.

NOTES:

- This document is intended to be reviewed and used in conjunction with the IHE Sharing Laboratory Reports (XDS Lab) Draft for Public Comment, Comments Due August 15 2006.

3.0 STANDARDS REFERENCES

The EHR Selected standards June v1.4 deliverable contains a list of all the considered standards and a designation as to which ones were selected and which ones were provisional. This selection was arrived at by a consensus of the members of the HITSP EHR and Biosurveillance Technical Committees. The criteria that were used for selection included the requirements of the use case, compatibility with other HITSP standards, and acceptance by the user community.

3.1 LIST OF BASE STANDARDS

Information Interchange Standards	
Standard	Description/Reason for selection/Reference
HL7 CDA Release 2	Standard architecture for representing electronic documents that meets the needs described in the use cases for machine readability and human readability for lab results and interpretations. Visit www.hl7.org for more information.
Terminology Standards	
see HITSP Interoperability Specification: Lab Terminology Component (HITSP/ISC-35)	Description/Reason for selection/Reference terminology standards incorporated by reference
Legislative Standards	
Standard	Description/Reason for selection/Reference
Clinical Laboratory Improvement Amendments (CLIA)	The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). Visit www.cms.hhs.gov/clia for more information.
Health Insurance Portability and Accountability Act (HIPAA)	National standards for the protection of health information, as applied to the three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct certain health care transactions electronically. Visit www.hhs.gov/ocr/hipaa for more information.

Table 3.1-1 List of Base Standards

NOTES:

1. Legislative Standards include regulatory requirements.
2. The inclusion of HIPAA above is intended to refer solely to the HIPAA Transactions, Codesets, and Identifiers rules.

3.2 LIST OF COMPOSITE STANDARDS

Composite Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement 2006-2007	Integration Profile for implementing a Lab Report as an electronic document.

Table 3.2-1 List of Composite Standards

4.0 COMPONENT

4.1 CONTEXT OVERVIEW

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

As stated in the IHE profile, this specification operates within a larger framework. Please refer to the IHE profile for details.

4.1.1 CONTEXTUAL CONSTRAINTS

Some of the constraints applied to the IHE profile by this component are:

- Contrary to the IHE profile quotation above, machine-processable entries are required in this HITSP Component.
- Lab Results and Interpretations are intended to be constrained for clinical care and authorized public health uses; other secondary uses are disallowed.
- Terminologies will be constrained to specified subsets as identified in the companion HITSP Laboratory Terminology Component.

There are some issues with the draft IHE profile that have been identified and are being addressed through comments to IHE:

- This profile is not intended to address ordering and return of laboratory results to the ordering provider.
- 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.
- CLIA requires that the outside lab director's name and address are included in the lab result report in these cases; this must be addressed in the IHE profile for machine-readable results.

A final version of this IHE profile (trial implementation version) is expected to be published in September, 2006.

4.1.2 TECHNICAL ACTORS

The Lab 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 Docs Transaction Package HITSP Interoperability Specification, HITSP/ISTP-13.

4.2.1 PROCESS PRE-CONDITIONS

A pre-condition to this process is the existence of an electronic lab result that has been deemed releasable, and its conversion into CDA format has been accomplished.

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.

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.

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

> 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.

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 observationMedia element in an entry dedicated to that purpose.

And

> Each leaf section of the structuredBody 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 lab reports from the same data.

The machine-processable entry follows the Clinical Statement pattern. This pattern is represented by the data model shown below in two parts:

NOTE:

1. In contrast to the above quotation, machine-readable observation entries are REQUIRED for all ONC harmonized use cases.
2. References to HL7 standards that are not yet normative must change to conform to normative HL7 standards if and as necessary.

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.

For a detailed explanation of the referenced data model, please see the IHE profile.

4.2.3.1 DATA MAPPING

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

4.2.3.2 MINIMUM DATA-SET

See the IHE 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 APPENDIX

6.1 GLOSSARY

Included is the common interoperability glossary that is used for all the Use Cases. This is the HITSP glossary that spans all the interoperability specifications, which can be found in the following folder on the HITSP site:
http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel