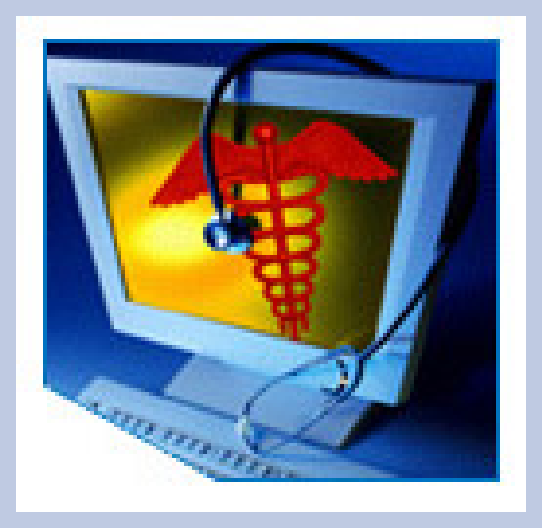
December 13, 2007
Version 2.1

HITSP Electronic Health Records Laboratory Results Reporting Interoperability Specification

HITSP/IS01



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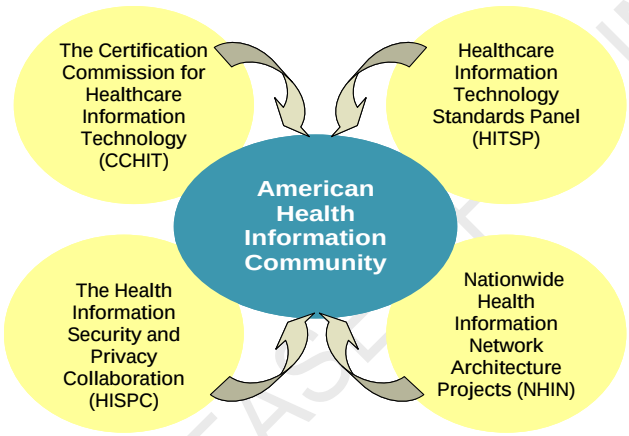
1.0 FOREWORD

This document is referred to as an Interoperability Specification 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, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In

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

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 (IS) 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 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.

This HITSP document pertains to the Interoperability Specification for the following:

[2] www.hitsp.org

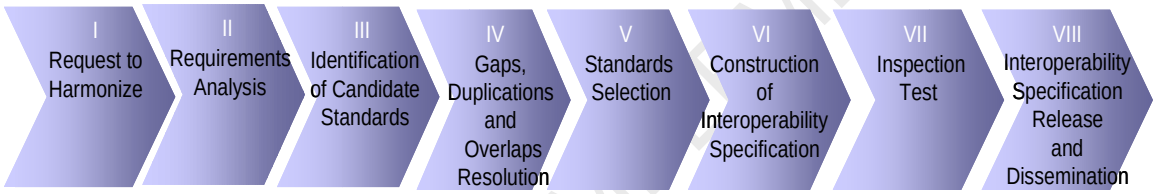
Use Case	Specific Scope of this Use Case
Electronic Health Records	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

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.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community (AHIC), as the representative of public and private health sector stakeholders, identified the three Use Cases (available at www.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 followed an 8 step process, depicted in Figure 1.0-1.

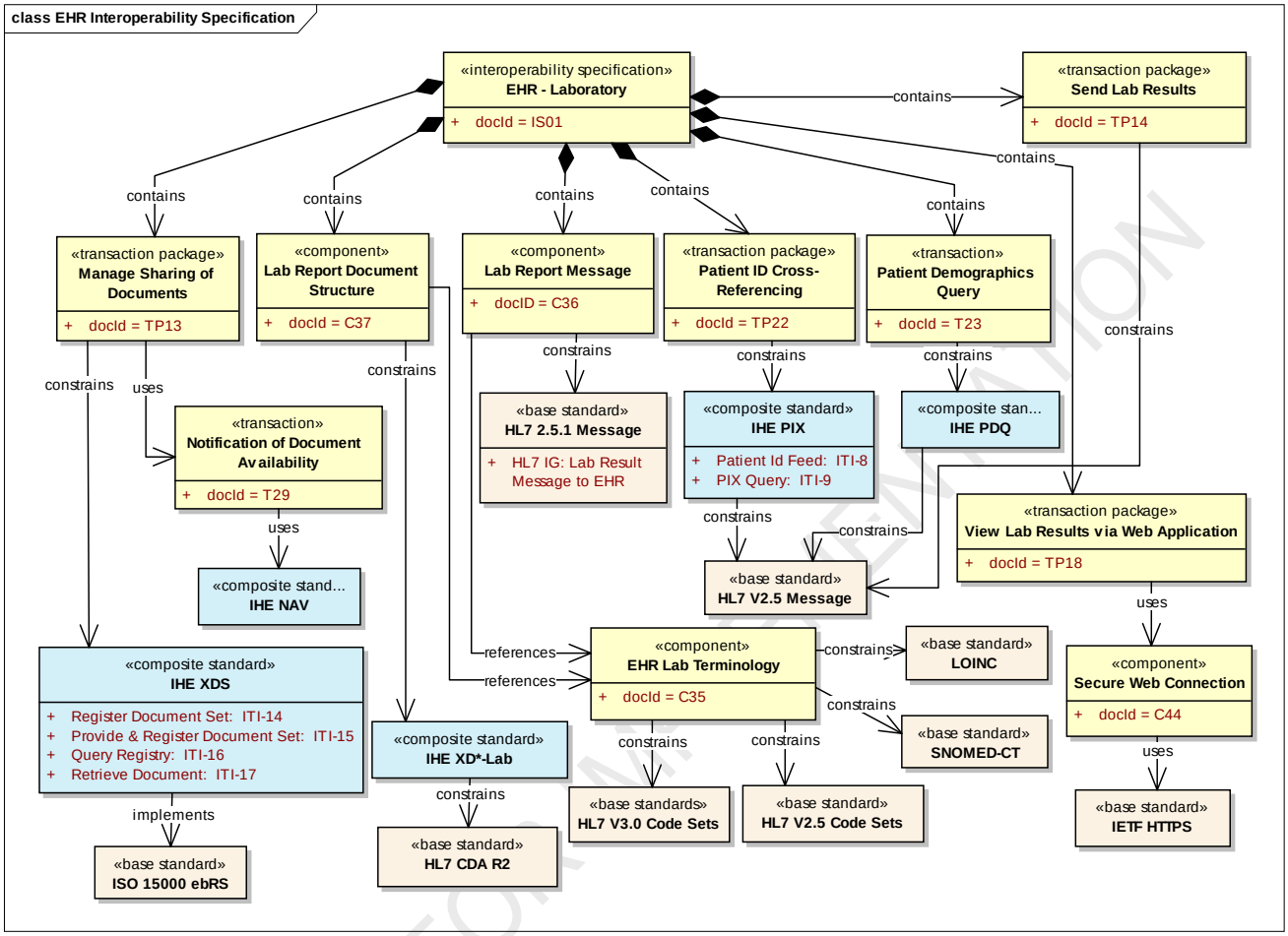
Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications to satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T), and Components (C). The roadmap depicted in Figure 1.0-2 identifies the HITSP constructs used to meet the IS requirements. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.

Figure 1.0-2 EHR Interoperability Specification



Note: For readability, not all composite standards (e.g. Unified Code for Units of Measure (UCUM)) or other regulatory mandates, such as HIPAA and CLIA, are included in Figure 1.0-2.

2.0 INTRODUCTION

As an introduction to the HITSP Electronic Health Records (EHR) Laboratory Results Reporting Interoperability Specification, 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.

2.1 INTEROPERABILITY SPECIFICATION OVERVIEW

The purpose of this Interoperability Specification is to describe the top-level specification for the HITSP EHR Use Case. This Use Case comprises two scenarios that describe the entities and interactions that would be needed to implement an electronic EHR or other clinical data system with a laboratory interface. The goals supported by this Interoperability Specification are stated in the EHR Use Case:

- 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 laboratory result (or notification of laboratory result) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)

This Interoperability Specification is designed to meet the specific requirements of the Harmonized Use Case for Electronic Health Records (Laboratory Results Reporting), March 19, 2006. These requirements involve sending laboratory results to clinicians for patient care. As such they are not one of the identified transactions under the Health Insurance Portability & Accountability Act of 1996 (HIPAA) Administration Simplification, which deal with standard transactions for Electronic Data Interchange (EDI) for the transmission of healthcare data such as claims and encounter information, payment and remittance advice, and claims status. However, it may be in the interest of covered entities to leverage their HITSP Interoperability Specification implementation in HIPAA transactions. Such use is beyond the scope of the assigned Use Case and requires extension of the Use Case by the AHIC and ONC. At its meeting on September 20, 2006, HITSP voted to recommend to AHIC that it expand the EHR Use Case “to include exchange of laboratory info with HIPAA covered entities.” The HIPAA standard transactions, code sets and claims attachments do not apply to this Interoperability Specification and its constructs. (See Security and Privacy below for application of the HIPAA security rules.)

Obstacles

The EHR 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 specification is the result of an assessment of the current practices in electronic laboratory results reporting and the requirements of the EHR Use Case. The Care Delivery Technical Committee (CD TC) chose this combination of standards because they meet the requirements of the Use Case and reflect both current practice and future directions for healthcare information sharing.

Top-Level EHR Constructs

This specification combines all of the Transaction Packages, stand-alone Transactions, and Components that comprise the solution set for the EHR Use Case. The core Transaction Packages are:

- The Send Laboratory Result Message Transaction Package includes all the data definitions and interactions for the Health Level Seven (HL7) V2.5.1 Laboratory Result Message. It relies on two Components:
  - The Laboratory Result Message Component (HITSP/C36) specifies constraints on the HL7 V2.5.1 message and
  - The EHR Laboratory Result Terminology Component (HITSP/C35) describes the vocabulary constraints
- The Manage Sharing of Documents Transaction Package is a generic document-sharing paradigm that can be used for any electronic document. For this specification, the document of interest is the HL7 Clinical Document Architecture (CDA) specification based on the Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework XD*-LAB.
  - The HITSP/C37 Laboratory Report Document Using IHE XD* Lab Component describes the Laboratory CDA document and
  - The HITSP/C35 EHR Laboratory Result Terminology Component describes the vocabulary constraints

Ancillary Transaction and Transaction Packages address Web Services, Notification of Document Availability, Patient Demographics Query (PDQ) and Patent ID Cross-Referencing (PIX).

The HITSP/IS01 Electronic Health Records Laboratory Results Reporting Interoperability Specification includes the following documents which are all necessary for implementation testing of the Interoperability Specifications.

Table 2.1-1 Related Documents

Related Documents	Document Description
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package
HITSP/TP14	HITSP Send Lab Result Message to Ordering Clinician and Providers of Care Transaction Package
HITSP/T18	HITSP View Lab Result from a Web Application Transaction
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package
HITSP/T23	HITSP Patient Demographics Query Transaction
HITSP/T29	HITSP Notification of Document Availability Transaction
HITSP/C35	HITSP EHR Laboratory Result Terminology Component
HITSP/C36	HITSP Laboratory Result Message Component
HITSP/C37	HITSP Lab Report Document Using IHE XD* Lab Component
HITSP/C44	HITSP Secure Web Connection Component

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.

2.2.1 REGULATORY COMPATIBILITY AND COMPLIANCE

A comparative analysis of the Laboratory CDA specification in this IS with the proposed HIPAA Claims Attachment for Lab found no conflicts.

Both the message and document structures referenced by this IS support the information for lab results in the scope of this Use Case as specified by CLIA. HITSP has made every effort to ensure that conformance to this specification enables reporting labs achieve CLIA compliance for this Use Case.

2.2.2 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.

2.2.3 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.

2.2.4 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.

2.2.5 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.

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. A standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes.

Specifications relating to security and privacy for this Interoperability Specification have been deferred to a future release, with the sole exception being the support of viewing a result document via secure web browser. At that time, security and privacy in the context of laboratory results transmission will be stated in each of the HITSP constructs as appropriate, e.g., secure communications is a security requirement on the transaction for the transmission of a message or document.

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

2.5 ACRONYMS

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

2.6 CONVENTIONS

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

2.7 REFERENCE DOCUMENTS

This section contains links to key reference documents and background material.

The HITSP Glossary provides definitions for relevant terms used by HITSP documents.

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:
  - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
  - It is substantially the same as it was when it was provisionally used and
  - 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

The following table lists the standards selected to implement the entire ONC harmonized Use Case for EHR LAB. 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 lower-level

constructs for EHR Laboratory specify where and how each standard is utilized within the Use Case. The CD TC was also informed by the HL7 U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) document.

Note: Industry use of HL7 v3.x and HL7 v2.x standards is evolving, and the expectation is that these standards will become more broadly used. The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. The CDA Release 2.0 distribution includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. The HL7 CDA Release 2.0 is a limited subset of HL7 V3. It builds upon other HL7 standards, including the HL7 Reference Information Model (RIM), Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and V3 Structures. This Implementation Specification does not imply a full adoption of HL7 v3 messaging, but just refers to HL7 CDA R2 and the limited subset of HL7v3 artifacts used by HL7 CDA R2.

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[3]	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 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org for more information.

[3] Please refer to section 2.1 Overview for discussion of Standard Transactions and Codesets and to section 2.2.5 for information relating to HIPAA Security and Privacy.

Standard	Description
Health Level Seven (HL7) Version 2.5/2.5.1[4]	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org 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.
Hypertext Transfer Protocol Secure (HTTPS) 443/tcp	http protocol over TLS/SSL
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. This supplement is available at www.ihe.net.

[4] HITSP references both HL7 2.5.1 messaging for lab results reporting and HL7 2.5 for other messages across the HITSP library of specifications.

Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	Supplement (ITI TF-Supplement) ITI-25 Notification of Document Availability (NAV), IHE TF Jun 28, 2005
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.
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. Visit www.snomed.org for more information.
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004	Describes eXtensible Markup Language (XML) and its usage characteristics. Consists of 4 parts: ebCPP, ebMS, ebRIM, and ebRS. Part 4 ebRS defines the interface between the registry and the registry clients, as well as the interaction protocols, message definitions and XML schema. Visit www.iso.org for more information.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. Visit aurora.regenstrief.org for more information.

3.2 STANDARDS GAPS AND OVERLAPS

Gaps

The CD TC has identified gaps in terminology standards for reporting laboratory results. These gaps are minimized by the selection of standards that give the widest coverage, but vocabulary domains with

clinical content are very large and encompass many specialties. The innovation in healthcare informatics is fast-paced, resulting in gaps as the standards attempt to catch up. In particular, the following gaps have been identified:

Table 3.2-1 Use Case Events and Associated Gaps

Event Code	Event Description	Identified Gaps	Recommended Resolution
3.3.1.1	Create test results	SNOMED CT covers many precise areas of laboratory, but some specialty areas may not be fully covered in sufficient depth.	This is a difficult gap to close. Use of local observation identifiers is unavoidable in some cases when there are no appropriate LOINC identifiers to use.
3.3.1.1	Create test results	LOINC coverage for Observation Identifier (OBX-3) and CDA Observation.code is not fully complete	LOINC and SNOMED share a common issue relating to incomplete coverage.
3.3.1.1	Create test results	Universal Service Identifier (OBR-4) and CDA ServiceEvent.Code do not have a standard vocabulary. While this code is not needed to convey a laboratory result, it is needed to understand what test was ordered.	There are a number of efforts underway to develop a terminology within some organizations, but these are often regional and vary by entity. There are also international efforts (Canada, Australia, and the UK, etc.) where this terminology is being developed nationally. HITSP could leverage some of these efforts after further analysis on current status.
3.2.3.0	Query for laboratory (historical) test results	Sharing of documents across XDS affinity domains (as defined by IHE XDS) not fully supported.	Undertake joint work with IHE to identify and develop specifications to meet HITSP requirements.

Standards Overlaps

In addition to gaps, there is a significant overlap. This overlap is well understood and monitored by the sponsoring SDO. A mapping from the HL7 Version 2.5.1 ORU^R01 message to the XD*-LAB constrained CDA document is a necessary accessory to this specification. This mapping will be the basis for interoperability between messages and documents.

Table 3.2-2 Overlaps

Event Description	Standard Duplication/ Overlap	Recommended Resolution
Multiple, including 3.2.1.0 and 3.4.1.1.	Results are reported through either the HL7 2.5.1 message or through the CDA document	It is recommended we leave this overlap in place because each solves different problems addressed by the Use Case, e.g., documents may be preferable for persistent storage.

Resolution Plan

The CD TC makes the following recommendation to resolve the identified gaps in terminologies:

Table 3.2-3 Resolution Plan

Date Identified	Task to be Accomplished/Who is involved
2006	Consider leveraging HITSP influence to coordinate and drive activities to develop a universal service identifier. Submitted request for action to HITSP Foundations Committee in 2007

Date Identified	Task to be Accomplished/Who is involved
2006	HITSP should ensure transparency in terminology development and other efforts in order to promote universal adoption of the selected terminologies for laboratory results reporting.
2007	HITSP to participate in IHE activities to develop specifications for the sharing of documents across XDS affinity domains.

4.0 INTEROPERABILITY REQUIREMENTS

4.1 USE CASE OVERVIEW

The EHR Use Case is relevant to clinical care providers who wish to have laboratory test results and laboratory interpretations electronically available for patients for whom they are providing care. Laboratory test results and interpretations are available for integration into an electronic health record (EHR), local or remote, or another clinical system. The Use Case includes two scenarios that cover typical interfaces involving an EHR system (or equivalent) and laboratory results.

The HITSP EHR specifications describe both a laboratory message transaction and a document sharing paradigm. Ordering providers of care always receive results as a laboratory message, non-ordering providers of care access historical laboratory results as documents, and "copy-to" providers of care may receive either messages or document availability notifications. The dual path of message and document is shown as alternatives to Scenario #1. Scenario #1a, is the messaging alternative and Scenario #2 is the document alternative.

Migration Path

There is a progression in the scenarios and scenario alternatives that provides a migration path for both consumers and suppliers of services to reach a fully-interoperable laboratory results environment.

- Scenario #1a, as a first step, provides an HL7v2.5.1 interface between the provider of care and the laboratory. This is similar to what is in practice today, but the constraints are tighter and there is a requirement for a tighter discipline with identifiers and vocabulary. This is the baseline scenario
- Scenario #1b expands the scenario to include HL7 CDA R2 laboratory report documents. It introduces the concept of a separate repository and a notification of document availability message
- Scenario #2 is the last step in the migration path. It introduces the Locator Service and the query for historical results

Web services are offered as an alternative at any point in the migration path, but they should be in place for Scenario #2. PIX and PDQ Transactions and the infrastructure to support them are best installed as soon as possible.

Note: Repository and locator service are functions that can be implemented in various architectures.

4.1.1 SCENARIO #1 OVERVIEW

In the first scenario, laboratory test results are transmitted as a result of the order. The specifics of the ordering process are outside the scope of this Use Case. The test results are sent directly to the clinician's EHR system (local or remote) and/or another clinical data system to provide laboratory results to ordering and non-ordering authorized recipients.

This scenario is shown with two alternatives. In the first alternative, HL7 V2.5.1 messages are used and in the second alternative, HL7 CDA R2 documents are used.

4.1.1.1 SCENARIO CONSTRAINTS

The constraints or modifications placed on this scenario are:

- Added interaction from laboratory to Provider of Care based on widespread usage of that interface today, and to meet needs implied in event code 3.4.1.1 and elsewhere. This has been shown in the Figure 4.1.1.8-1 for the Messaging Alternative
- The notification of laboratory report availability is sent by the laboratory instead of the Locator Service in Scenario #1b. This change was made because the XDS Document Sharing paradigm does not support a “push” distribution model and because it simplifies Scenario #2. After receiving Laboratory Report NAV, the actions to obtain the laboratory report document are described in Scenario 2

4.1.1.2 SCENARIO PRE-CONDITIONS

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of all personally identifiable health information as prescribed by the HIPAA, all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

Specific pre-conditions for this scenario include:

- Assume that all pre-conditions from the lower level constructs (Transaction Packages, etc.) are incorporated
- An order for a laboratory test has been created and accepted by the performing laboratory
- Relationships between organizations utilizing the HITSP IS are well defined and understood
- When needed, the patient is uniquely registered with the Patient ID Cross Referencing service
- The order contains an electronic address of all authorized electronic recipients
- Appropriate HITSP constructs for authorization, authentication and consent procedures are adopted by the actors in the exchange
- Secure electronic transport between sender(s) and receiver(s) is assumed to follow the appropriate HITSP security constructs

4.1.1.3 SCENARIO TRIGGERS

Triggers are conditions or real-world events that are necessary to start off any processing. The underlying processes need to recognize the following types of trigger events to initiate the Transactions in this specification:

- Assume that all scenario triggers from the lower level constructs (Transaction Packages, etc.) are incorporated
- The trigger for being able to transmit a result is that it is deemed as releasable

4.1.1.4 SCENARIO POST-CONDITIONS

Assume that all scenario post-conditions from the lower level constructs (Transaction Packages, etc.) are incorporated.

4.1.1.5 SCENARIO OUTPUTS

The output from these two scenarios is that the result is received and is viewable or can be processed.

4.1.1.6 SCENARIO BUSINESS ACTORS

Table 4.1.1.6-1 Scenario Business Actors

Actor	Description
Patient ID Cross-Referencing Service	An application that references a patient data base for the purpose of identifying a particular patient based on one of many IDs or by matching patient demographics.
Provider of Care	May be an individual, an organization or "system." When appropriate the Provider of Care perspective is further specified as an 'ordering Provider of Care' (responsible for ordering the laboratory test) or a 'provider of care' (providing care to the patient, but not the ordering Provider of Care).
Patient	Receiver of care from a healthcare professional.
Laboratory	Produces the laboratory results. Organizations operating as the Provider of Care perspective may also operate under the laboratory perspective if laboratory testing services are performed by the organization.
Repository	The system that provides the laboratory test results.

4.1.1.7 SCENARIO TECHNICAL ACTORS

A technical actor is a role assumed by an application for the purposes of performing some function. In this case, the function is to send or receive a transmission. The technical actors used by this specification are:

Table 4.1.1.7-1 Scenario Technical Actors

Actor	Description
Document Consumer	The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.
Document Registry	The Document Registry Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.

Actor	Description
Document Repository	The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a Uniform Resource Identifier (URI) to documents for subsequent retrieval by a Document Consumer.
Document Source	The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.
Laboratory Result Receiver	This actor is the recipient of laboratory result messages (i.e., the ordering clinician or other authorized provider of care).
Laboratory Result Sender	This actor sends laboratory results as messages or as documents to the ordering clinician or other authorized providers of care.
Notification Receiver	This actor receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them.
Notification Sender	This actor sends notifications of availability for documents in an XDS registry, and receives acknowledgements of these notifications.
Patient Identifier Cross Reference Consumer	Queries a Patient Identifier Cross Reference Manager for a set of identifiers for a patient.
Patient Identifier Cross Reference Manager	Responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains.
Patient Identity Source	Provider of unique identifiers for each patient.
Patient Demographics Supplier	Receives patient registration and update messages from other systems in the enterprise (*e.g.*, ADT Patient Registration systems), which may or may not represent different Patient ID Domains. It responds to queries for information.
Patient Demographics Consumer	Queries the Patient Demographics Supplier to obtain patient demographic data. It may receive matches for one or more patients that enable the selection of the desired patient.

4.1.1.8 SCENARIO ACTOR INTERACTIONS

This section describes the interactions between actors that comprise the two scenarios. The Transactions shown in the Unified Modeling Language (UML) diagrams are the Transactions specified in the various sub-components of this Interoperability Specification. The event codes from the ONC harmonized Use Case are annotated on the diagrams to show how the Transactions are implementing the Use Case.

Two alternatives were selected to implement this scenario. Figure 4.1.1.8-1 shows the interactions for the messaging alternative and Figure 4.1.1.8-2 for the document alternative.

In Scenario #1a, an HL7 V2.5.1 ORU^R01 message is sent form the laboratory to both the ordering provider and to non-ordering providers. These Transactions are described in the HITSP/TP14 Send Laboratory Result Message to Ordering Clinician and Providers of Care Transaction Package.

In Scenario #1b, the laboratory registers a laboratory report document in the repository and sends a notification of availability to the providers of care. The providers of care can then retrieve the document from the repository. These Transactions are described in the HITSP/T13 Manage Sharing of Documents

Transaction Package and the notification is described in the HITSP/T29 Notification of Document Availability Transaction.

Figure 4.1.1.8-1 Transactions for Messaging Alternative for Scenario #1

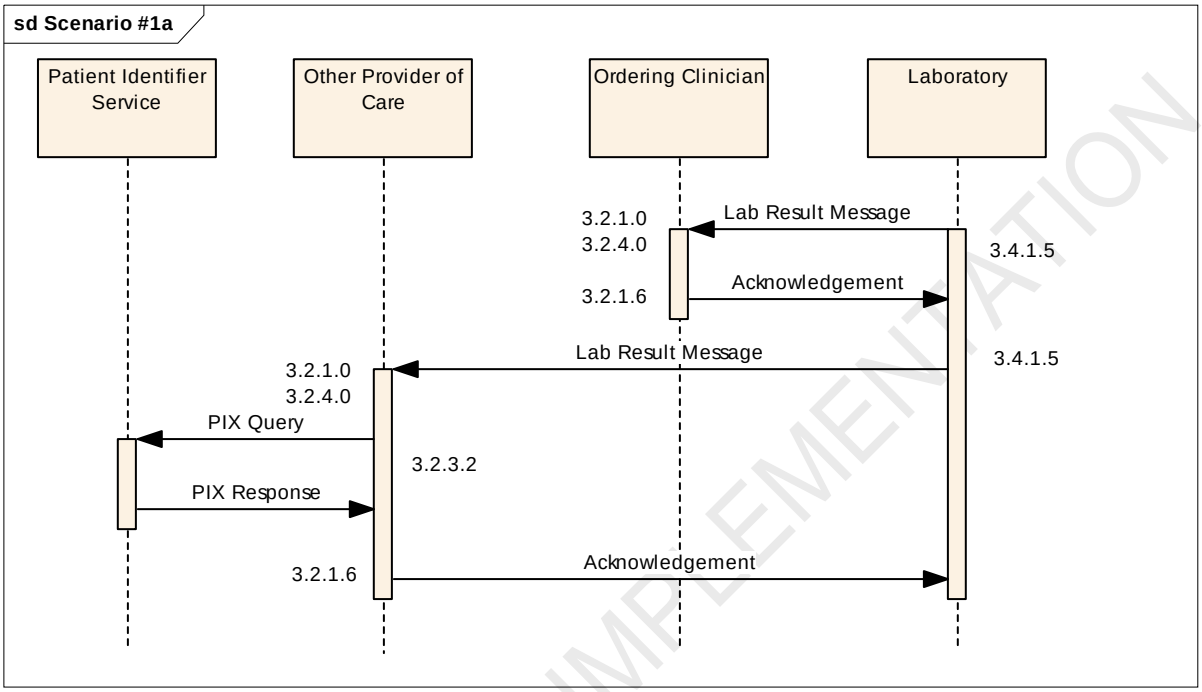
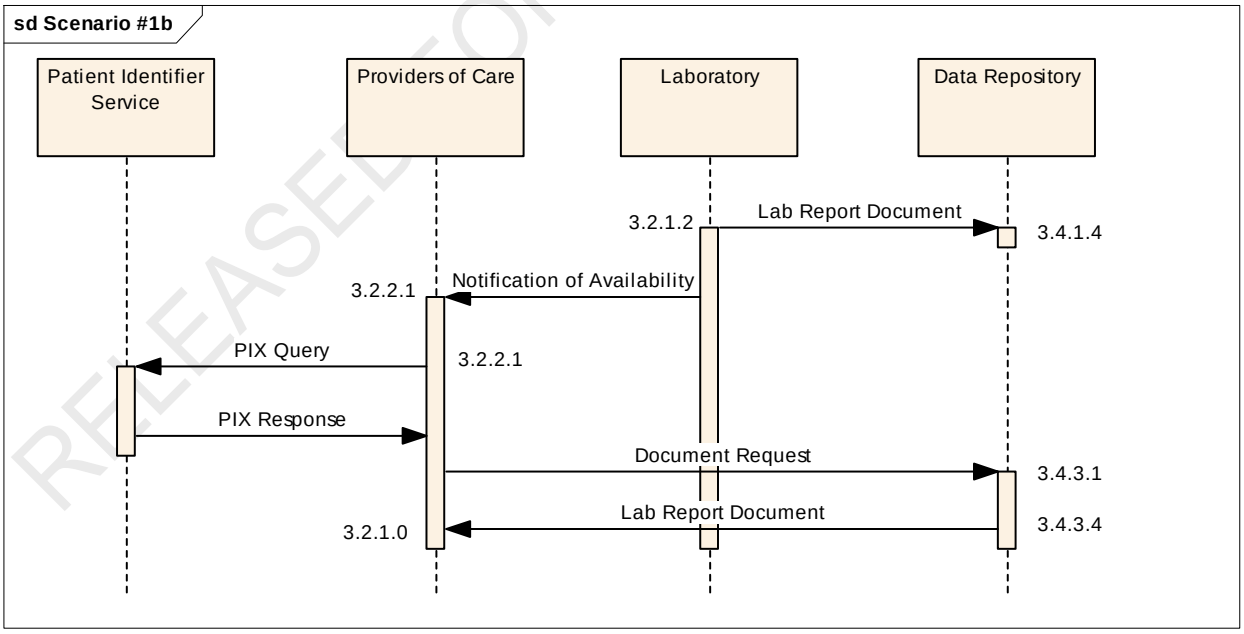


Figure 4.1.1.8-2 Transactions for the Document Alternative for Scenario #1



Note: For readability, acknowledgements have not been included in the diagrams in every instance. The table shown in section 6.1 of this document is an extract from the ONC harmonized Use Case and shows

acknowledgements and event codes where appropriate. Acknowledgements are a core component of the basic HL7 messaging specification.

The following tables show the mappings between the business actors in the EHR Use Case and the technical actors described for the Transactions. It is important to note that a business actor can assume the role of more than one technical actor depending on how many Transactions are involved.

Table 4.1.1.8-1 Mapping for Patient ID Cross-Referencing Transaction Package

Business Actor	Technical Actor
Patient Identifier Service	Patient Identifier Cross-Reference Manager
Provider of Care	Patient Identifier Cross-Reference Consumer

Table 4.1.1.8-2 Mapping for Patient Demographics Query Transaction

Business Actor	Technical Actor
Patient Identifier Service	Patient Demographics Supplier
Provider of Care	Patient Demographics Consumer

Table 4.1.1.8-3 Mapping for Manage Sharing of Documents Transaction Package

Business Actor	Technical Actor
Patient	Not Applicable (Patient Identifier Service is a stand-in for Patient)
Laboratory	Document Source
Provider of Care	Document Consumer
Repository	Document Repository
Locator Service	Document Registry

Table 4.1.1.8-4 Mapping for Send Laboratory Result Message to Ordering Clinician and Providers of Care Transaction Package

Business Actor	Technical Actor
Patient	Not Applicable (Patient Identifier Service is a stand-in for Patient)
Laboratory	Laboratory Result Sender
Clinician	Laboratory Result Receiver

Table 4.1.1.8-5 Mapping for Notification of Document Availability Transaction

Business Actor	Technical Actor
Laboratory	Notification Sender
Provider of Care	Notification Receiver

4.1.2 SCENARIO #2 OVERVIEW

A provider of care accesses historical test results related to a specific patient by first querying for the laboratory report document and then retrieving or receiving the data. Data may be sent automatically to the provider's EHR or other clinical system (local or remote) upon selection, or the provider may separately request the test results, possibly from a separate data repository.

This scenario extends the capabilities of Scenarios #1a and #1b by providing HL7 CDA laboratory reports to an authorized provider of care upon request. The provider queries a locator service for the location of a document and receives a pointer that is then used to retrieve the document. This allows for laboratory results to be stored in multiple repositories, but still requested from a single locator service.

4.1.2.1 SCENARIO CONSTRAINTS

The constraints or modifications placed on this scenario are:

- The laboratory results are only available as a CDA document
- The providers, laboratory, repository, and locator service must be part of an XDS affinity domain where all share a defined segment of the patient population

4.1.2.2 SCENARIO PRE-CONDITIONS

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of all personally identifiable health information as prescribed by the HIPAA, all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

Specific pre-conditions for this scenario include:

- All pre-conditions and activities defined in Scenario #1 have been fulfilled
- All pre-conditions from the lower level constructs (Transaction Packages etc) are incorporated
- The laboratory has registered the laboratory result document in the repository and the repository has notified the locator service of the document location
- Secure electronic transport and consent as defined by the HITSP security and privacy constructs is assumed between sender(s) and receiver(s)

4.1.2.3 SCENARIO TRIGGERS

Triggers are conditions or real-world events that are necessary to start off any processing. The underlying processes need to recognize the following types of trigger events to initiate the Transactions in this specification:

- Assume that all scenario triggers from the lower level constructs (Transaction Packages, etc) are incorporated
- There is a clinical need, or other authorized use, for the patient laboratory result(s)

4.1.2.4 SCENARIO POST-CONDITIONS

Assume that all scenario post-conditions from the lower level constructs (Transaction Packages, etc) are incorporated.

4.1.2.5 SCENARIO OUTPUTS

The output from this scenario is that the result is received and is viewable or can be processed.

4.1.2.6 SCENARIO BUSINESS ACTORS

Table 4.1.2.6-1 Scenario Business Actors

Actor	Description
Patient Identifier Service	An application that references a patient database for the purpose of identifying a particular patient based on one of many IDs or by matching patient demographics.
Provider of Care	May be an individual, an organization or "system." When appropriate the clinician perspective is further specified as an 'ordering clinician' (responsible for ordering the laboratory test) or a 'provider of care' (providing care to the patient, but not the ordering clinician).
Patient	Receiver of care from a healthcare professional.
Laboratory	Produces the laboratory results. Organizations operating as the provider of care perspective may also operate under the laboratory perspective if laboratory testing services are performed by the organization.
Repository	The system that provides the laboratory test results
Locator Service	Responds to queries for the test results by providing the list of available test results and their locations within data repositories.

4.1.2.7 SCENARIO TECHNICAL ACTORS

A technical actor is a role assumed by an application for the purposes of performing some function. In this case, the function is to send or receive a transmission. The technical actors used by this specification are:

Table 4.1.2.7-1 Scenario Technical Actors

Actor	Description
Document Consumer	The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.
Document Registry	The Document Registry Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.
Document Repository	The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer.

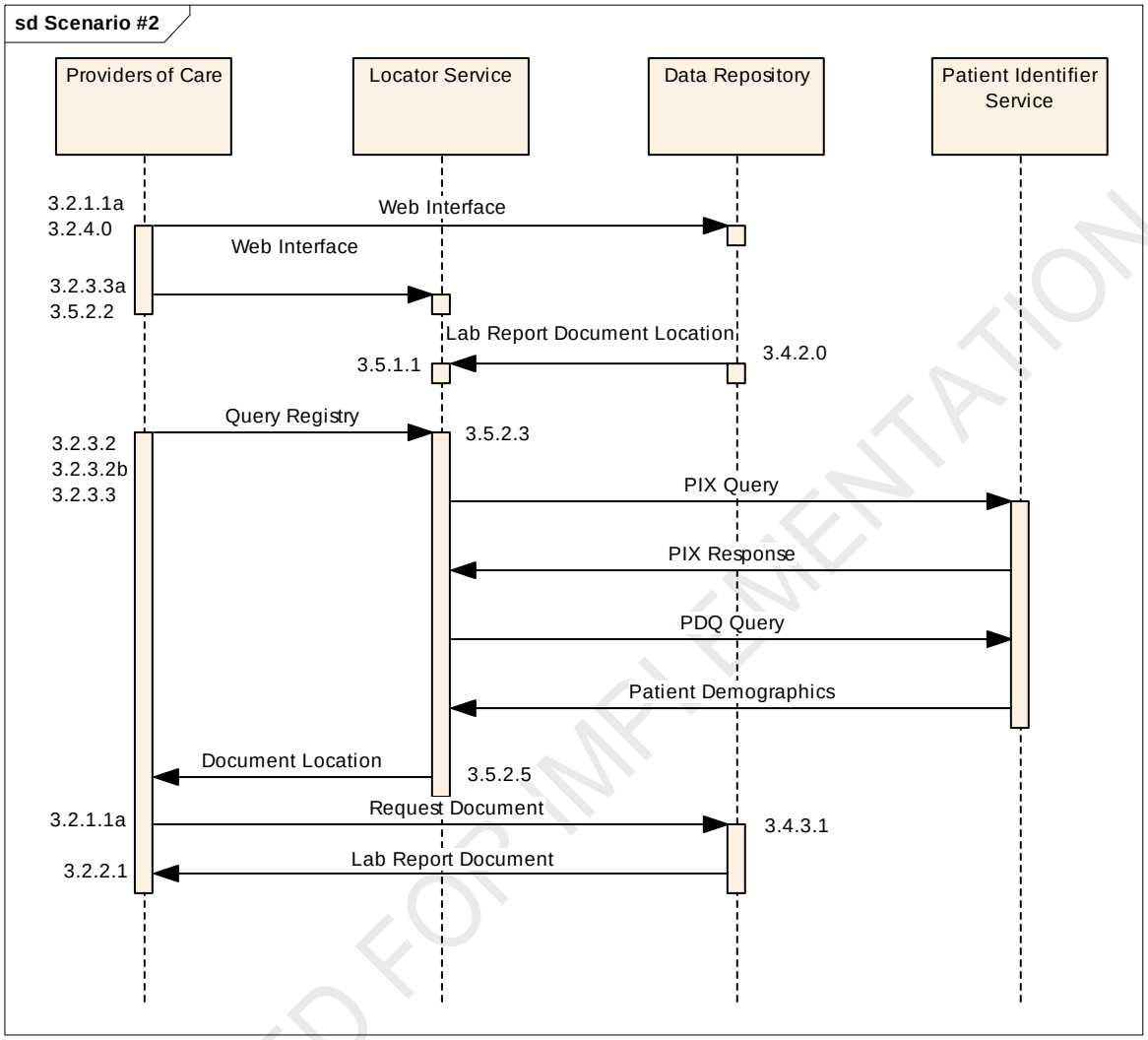
Actor	Description
Document Source	The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.
Notification Receiver	This actor receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them.
Notification Sender	This actor sends notifications of availability for documents in an XDS registry, and receives acknowledgements of these notifications.
Patient Identifier Cross Reference Consumer	Queries a Patient Identifier Cross Reference Manager for a set of identifiers for a patient.
Patient Identifier Cross Reference Manager	Responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains.
Patient Identity Source	Provider of unique identifiers for each patient.

4.1.2.8 SCENARIO ACTOR INTERACTIONS

This section describes the interactions between actors that comprise the scenario. The Transactions shown in the UML diagrams are the Transactions specified in the various sub-components of this Interoperability Specification. The event codes from the ONC harmonized Use Case are annotated on the diagrams to show how the Transactions are implementing the Use Case.

This scenario is dependent on Scenario #1b in that the laboratory must have registered the laboratory report document with the Data Repository. In Scenario #2, the Data Repository registers the document location with the Locator Service where it can be queried by Providers of Care. Providers of Care receive a link to the location of the document in response to their queries. This link allows them to retrieve the document from the repository. These Transactions are described in the HITSP/TP13 Manage Sharing of Documents Transaction Package and the notification is described in the HITSP/T29 Notification of Document Availability Transaction.

Figure 4.1.2.8-1 Transactions for Scenario #2



Note: For readability, acknowledgements have not been included in the diagrams in every instance. The table shown in section 6.1 of this document is an extract from the ONC harmonized Use Case and shows acknowledgements and event codes where appropriate. Acknowledgements are a core component of the basic HL7 messaging specification.

The following tables show the mappings between the business actors in the EHR Use Case and the technical actors described for the Transactions. It is important to note that a business actor can assume the role of more than one technical actor depending on how many Transactions are involved.

Table 4.1.2.8-1 Mapping for Consumer/Patient ID Cross-Referencing Transaction Package

Business Actor	Technical Actor
Patient ID Cross-Referencing Service	Patient Identifier Cross-Reference Manager
Provider of Care	Patient Identifier Cross-Reference Consumer

Table 4.1.2.8-2 Mapping for Manage Sharing of Documents Transaction Package

Business Actor	Technical Actor
Patient	Not Applicable (Patient Identifier Service is a stand-in for Patient)
Laboratory	Document Source
Provider of Care	Document Consumer
Repository	Document Repository
Locator Service	Document Registry
Locator Service	Patient Identity Source

Table 4.1.2.8-3 Mapping for Notification of Laboratory Report Availability Transaction

Business Actor	Technical Actor
Locator Service	Notice of Availability Sender
Provider of Care	Notice of Availability Receiver

4.2 LIST OF TRANSACTION PACKAGES AND INDEPENDENT TRANSACTIONS

The following list of Transaction Packages, Transactions, Components and their definitions used by the Interoperability Specification.

Table 4.2-1 Transactions Packages, Transactions and Components in this IS

Transaction Package/ Independent Transaction	Description	Document References
Send Laboratory Result Message to Ordering Clinician and Providers of Care	Specification for sending a laboratory result as a message or as a document	HITSP/TP14
Manage Sharing of Documents	Specification for a data locator and repository for shared storage of documents	HITSP/TP13
Patient ID Cross-Referencing	Uniquely identify a patient through query and/or matching of key elements	HITSP/TP22
Patient Demographics Query	Query and retrieve any patient demographic	HITSP/T23
Notification of Document Availability	Defines a mechanism for point-to-point notifications between systems or users within an XDS Affinity Domain. These notifications can be used to trigger various activities within applications that implement both XDS and NAV	HITSP/T29
View Laboratory Results from a Web Application	Allows a user to view a laboratory report through a secure browser	HITSP/T18

4.2.1 DEPENDENCIES

The following table shows a list of Transaction Packages with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific Transaction Package or independent Transaction specification. To support a dependent Transaction or Transaction Package, a technical actor must implement all the required constructs in the prerequisite Transaction Package, or be grouped together with another Transaction Package as specified in the table below:

Table 4.2.1-1 Dependencies

Transaction Package/ Independent Transaction	Depends On (Name of Transaction or Transaction Package that it depends on)	Dependency Type (Pre-requisite, grouping)	Purpose (Reason for this dependency)
Send Laboratory Result Message to Ordering Clinician and Providers of Care	Patient ID Cross-Referencing	Pre-requisite	Send Laboratory Result Message Transaction Package contains Patient ID Cross-Referencing
Patient ID Cross-Referencing	None	N/A	N/A
Manage Sharing of Documents	Structured Laboratory Document Component	Pre- requisite	Payload
Manage Sharing of Documents	Laboratory Result Terminologies Component	Pre- requisite	Vocabulary
View Laboratory Results from a Web Application	Secure Web Connection	Pre- requisite	Connection
Secure Web Connection	None		

4.2.2 CONSTRAINTS

Table 4.2.2-1 Constraints

Transaction Package/ Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Noted above in Sections: 4.1.1.1 4.1.2.1			

5.0 TECHNICAL IMPLEMENTATION

5.1 CONFORMANCE

A system conforming to this specification must implement this complete specification, subject to the optionality defined within this document. Conformance also includes supporting the pre and post conditions and implementing the constraints to the standards specified in the Component, Transaction and Transaction Package specifications associated with this Interoperability Specification as well as those in the Interoperability Specification.

5.2 SUPPORTING DOCUMENTS

The following documents were used to support the creation of this Interoperability Specification.

Table 5.2-1 Supporting Documents

Document Title	Relationship
Harmonized Use Case for Electronic Health Records (Laboratory Results Reporting), March 19, 2006	ONC harmonized Use Case that describes the requirements for the HITSP specifications

6.0 APPENDIX

6.1 USE CASE ACTIONS AND EVENTS

The following table is an extract from the Harmonized Use Case for Electronic Health Records (Laboratory Results Reporting), March 19, 2006. It describes the requirements for the HITSP specifications. (Source document is referenced in Table 5.2-1, Supporting Documents)

Table 6.1-1 Use Case Event/Action Codes and Descriptions

Event/Action Code	Description
3.1.1.0 Event: Provide patient identity information, update as needed	
3.1.1.1	Action: Provide identification data
3.1.2.0 Event: Identify providers of care, update as needed	
3.1.2.1	Action: Provide list of providers of care
3.1.2.1a	Alternate Action: Indicate that test results should not be made available to other providers of care
3.2.1.0 Event: Integrate results and view in EHR	
3.2.1.1a	Alternate Action: Send request for historical laboratory test result content to data repository(ies)
3.2.1.6	Action: Acknowledge receipt of laboratory results
3.2.2.0 Event: Receive notification of laboratory test results	
3.2.2.1	Action: Receive notification that test results are available
3.2.3.0 Event: Query for laboratory (historical) test results	
3.2.3.2	Action: Clinician and locator system agree on patient identity through patient trait matching
3.2.3.2b	Alternate Action: Clinician and locator system agree on patient identity based on patient identifier matching
3.2.3.3	Action: Transmit request for specific laboratory test results based on order number or other unique test result identification
3.2.3.3a	Alternate Action: Browse, select and confirm the relevant test results for the correct patient and transmit request
3.2.3.4	Action: Receive the data repository location where the test results are stored
3.2.4.0 Event: View results using another clinical data system (non–EHR system)	
3.2.4.1	Action: Send request for laboratory test result content to data repository(ies)
3.2.4.3	Action: Receive and view laboratory test results
3.2.4.5	Action: Acknowledge receipt of laboratory results
3.3.1.0 Event: Process laboratory Order	
3.3.1.1	Action: Create test results
3.3.1.2	Action: Send results to data repository
3.4.1.0 Event: Store laboratory results	
3.4.1.3	Action: Acknowledge receipt of test laboratory results
3.4.1.4	Action: Store test laboratory results
3.4.1.5	Action: Transmit laboratory test results to ordering clinician and other providers of care if appropriate

Event/Action Code	Description
3.4.2.0 Event: Notify locator service of laboratory results	
3.4.2.2	Action: Send result location and related information to locator service
3.4.3.0 Event: Process Request for Laboratory Test Results	
3.4.3.1	Action: Receive and validate the query request
3.4.3.4	Action: Transmit laboratory results of an identified patient to an ordering clinician or provider of care
3.5.1.0 Event: Publish availability of laboratory test results	
3.5.1.1	Action: Receive test result (file) location information and related information
3.5.2.0 Event: Process query to provide laboratory test result location(s)	
3.5.2.2	Action: Clinician and locator system agree on patient identity
3.5.2.3	Action: Receive request for laboratory test results based on laboratory order number or other unique laboratory test identifier
3.5.2.3a	Alternate Action: Provide laboratory result availability information based on clinician query/browse
3.5.2.5	Action: Send laboratory result location (links) pointers to authorized clinician.
3.5.3.0 Event: Notify provider(s) of care of new laboratory test results	
3.5.3.1	Action: Send notification to provider(s) of care

7.0 CHANGE HISTORY

The following sections provide the history of all changes made to this document since the last publication.

7.1 MAY 11, 2007

This document is now Released for Implementation.

7.2 DECEMBER 5, 2007

- Removed footnote regarding informative nature of C36 as that construct is now complete
- Removed references to HITSP/C45 - Acknowledgements, this construct is no longer required; the topic is covered in the referenced HL7 Implementation Guide that is used in HITSP/C36 - Lab Result Message Component

7.3 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.