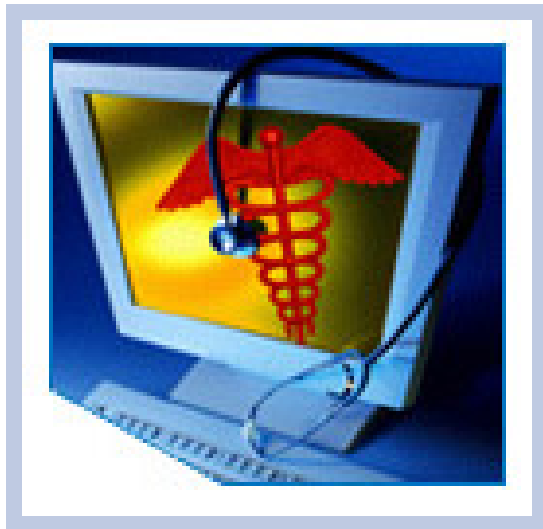


HITSP View Laboratory Results from a Web Application Transaction

HITSP/T18



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TABLE OF CONTENTS

1.0	FOREWORD	6
2.0	INTRODUCTION	9
2.1	Overview	9
2.2	Technical Assumptions and Scope	9
2.2.1	Interoperability Specifications Not Functional Specifications	9
2.2.2	Architectural Neutrality	9
2.2.3	The Use of Messages and Documents as Appropriate.....	10
2.2.4	Implementation Testing	10
2.2.5	Security and Privacy	10
2.3	Audience	11
2.4	Copyright Permissions.....	11
2.5	Acronyms.....	12
2.6	Conventions.....	12
3.0	REFERENCED STANDARDS.....	13
3.1	List of Standards.....	13
3.2	List of Components.....	14
3.2.1	Dependencies.....	14
3.2.2	Constraints	14
4.0	TRANSACTIONS.....	15
4.1	Context Overview	15
4.1.1	Contextual Constraints	15
4.1.2	Technical Actors	15
4.1.3	Actor Interactions.....	15
4.2	Process Flows	15
4.2.1	Process Pre-Conditions.....	15
4.2.2	Process Post-Conditions	15
4.3	Data Flows.....	16
5.0	CONSTRAINTS FOR REUSE	17
6.0	APPENDIX	18
6.1	Gaps	18
6.1.1	Terminology	18
6.1.2	Cross-Affinity Domain Document Sharing.....	18



7.0	CHANGE HISTORY	21
7.1	May 11, 2007	21

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FIGURES AND TABLES

Figure 1.0-1 HITSP Harmonization Process Steps	8
Figure 6.1.2-1 Affinity Domain.....	19
Table 2.1-1 Related Documents	9
Table 3.2-1 List of Components	14
Table 4.1.2-1 Technical Actors	15



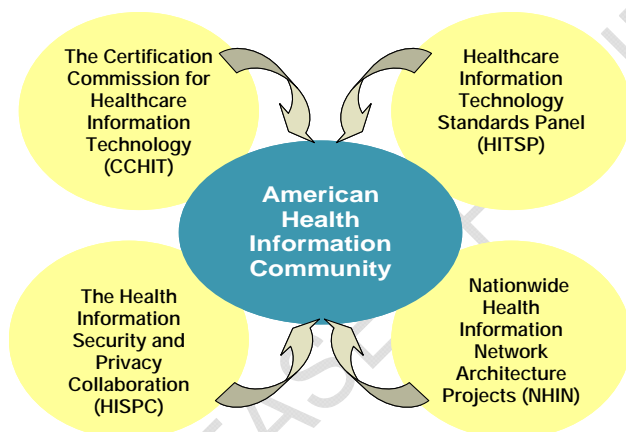
1.0 FOREWORD

This document is referred to as a Transaction 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. health care 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 Community¹ (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 HITSP² 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 the HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

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

² www.hitsp.org



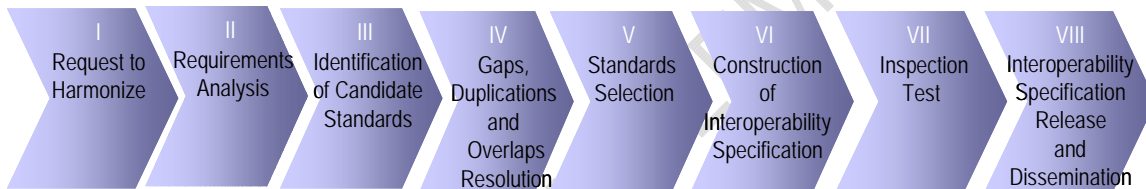
Use Case	Specific Scope of this Use Case
Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within this specific context of the Use Case.

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 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 below.

Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

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



2.0 INTRODUCTION

As an introduction to the View Laboratory Results from a Web Application Transaction, 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 Standards References.

2.1 OVERVIEW

This Transaction allows a user to view a laboratory report through a secure browser. This Transaction uses the HITSP/ISC-44 Secure Web Connection component. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements.

Table 2.1-1 Related Documents

Related Documents	Document Description
HITSP/C-44	HITSP Secure Web Connection

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 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

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

2.2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange



must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

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

2.2.4 IMPLEMENTATION TESTING

The 2006 set of Interoperability Specifications were evaluated by inspection testers (desktop review) and reviewed by HITSP members prior to HITSP approval. Although the Interoperability Specifications are based on approved standards, when published, they represent combinations and constraints that have not been tested in actual implementations. HITSP enlisted partners to develop test plans, data and suites to test the implementation and then to support a program for progressive testing, feedback and deployment of implementations. Feedback from test implementers has been used in the revisions in Version 2.0.

2.2.5 SECURITY AND PRIVACY

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



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

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

2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Cases 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

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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.

2.5 ACRONYMS

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

2.6 CONVENTIONS

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

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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

Network browser related standards are approved by the Internet Engineering Task Force (IETF) as a standard. IETF is the main standards organization for the Internet. The IETF is a large open international community of network designers, operators, vendors, and researchers concerned with the evolution of the



Internet architecture and the smooth operation of the Internet. It is open to any interested individual. 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.

3.2 LIST OF COMPONENTS

The following list of components and their definitions are used by the transaction specification.

Table 3.2-1 List of Components

Component Name	Description
HITSP/C-44	HITSP Secure Web Connection

3.2.1 DEPENDENCIES

None

3.2.2 CONSTRAINTS

None



4.0 TRANSACTIONS

Transactions are a logical grouping of actions, including necessary content and context that must all succeed or fail as a group.

4.1 CONTEXT OVERVIEW

Healthcare provider wishes to view laboratory results in a document repository.

4.1.1 CONTEXTUAL CONSTRAINTS

None

4.1.2 TECHNICAL ACTORS

Table 4.1.2-1 Technical Actors

Actor	Description
User	Healthcare professional who wishes to view a laboratory report on the web
Document Repository	Server where the document (e.g., laboratory report) resides

4.1.3 ACTOR INTERACTIONS

A. Technical actors

User

Document Repository

B. Transactions in which the technical actor is involved

View laboratory report

C. Components with which the technical actor is involved

Secure web connection

4.2 PROCESS FLOWS

4.2.1 PROCESS PRE-CONDITIONS

Laboratory report is resident in document repository

4.2.1.1 PROCESS TRIGGERS

User request

4.2.2 PROCESS POST-CONDITIONS

Document display



4.2.2.1 PROCESS OUTPUTS

Formatted web page, using standard web tool

4.3 DATA FLOWS

N/A

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5.0 CONSTRAINTS FOR REUSE

None

RELEASED FOR IMPLEMENTATION



6.0 APPENDIX

6.1 GAPS

6.1.1 TERMINOLOGY

“Document Registration Terminology” is a gap. This Component will include the set of vocabularies used in the XDS Document Registry to populate the meta-data associated with each document. There is no “ready terminology” to reference, but we will leverage subsets of existing terminology structures such as those used by LOINC Document dimensions.

6.1.2 CROSS-AFFINITY DOMAIN DOCUMENT SHARING

The HITSP Manage Sharing of Documents Transaction Package is based on the IHE-XDS Integration Profile referenced by HITSP from the IHE IT Infrastructure Technical Framework. This section discusses the precondition associated with document sharing environments across multiple independent (e.g., non affinity) domains.

The Integrating the Healthcare Enterprise (IHE) has defined an Integration Profile called Cross-enterprise Document Sharing (XDS), which defines document sharing among a number of entities or organizations forming an Affinity Domain using the IHE-XDS terminology.

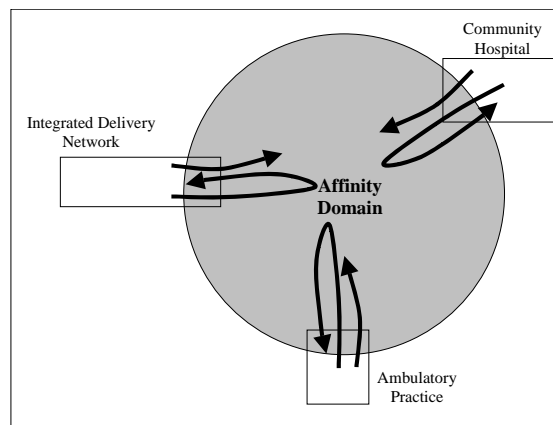
An Affinity Domain is a group of independent healthcare enterprises (organizations) that have agreed to exchange information using a common set of policies in order to share documents using the interoperability defined by the IHE-XDS Integration Profile. Implementations of affinity domains include:

- Sub-networks of the NHIN supported by a Regional Health Information Organization (RHIO)
- An Integrated Delivery Network (IDN)
- Specialized or Disease-oriented Care Communities
- Insurance Provider Supported Communities

The Affinity Domain is like membership to a “club”, it engages its “members” only in term of activities within the activities of the club. Each organization that has elected to join in a document sharing Affinity Domain has most likely different policies, IT infrastructure, information standards, etc.



Figure 6.1.2-1 Affinity Domain



Within an Affinity Domain, for the purpose of information exchange among the member organizations, certain common policies and business rules must be defined. Neither HITSP, nor IHE define these policies or what is the appropriate implementation of Affinity Domains for the NHIN, RHIOs, Sub-network Organizations or large enterprises such as Federal Agencies. HITSP does not rule on the number of organizations that partake. These choices are considered to be implementation, configuration or architecture decisions, not within the purview of HITSP.

Analysis

When multiple Affinity Domains are established, such as when multiple RHIOs or large enterprises need to be interconnected, the transactions specified by the Document Sharing Transaction Package are not sufficient for such larger scale implementations where multiple independent Affinity Domains are likely to be established.

Communication between different entities (Federal or non-Federal), even of large sizes are supported as long as they establish an Affinity Domain. However to support communication between different sets of entities that have already formed independent Affinity Domains, or large entities that wish to be their own Affinity Domain using IHE-XDS internally, extensions to the proposed specification are needed.

The IHE ITI Technical Committee published a white paper in Aug 2006 titled "Cross Community Information Exchange including Federation of XDS Affinity Domains" [http://www.ihe.net/Technical_Framework/index.cfm#IT]. In it they address some approaches to future IHE ITI Integration Profiles in support of hierarchical and lateral cross community communication. It is apparent that the majority of large single organization and federal agency communications will be of the lateral Cross Community communication type. It is expected that evaluation and prototyping efforts by the NHIN contracts and on-going standards development would inform future cross domain HITSP Interoperability Specifications.



Conclusion

The HITSP Manage Sharing of Documents Transaction Package addresses a number of environments while others are beyond its current scope:

1. *Single Organization – Stand-alone Affinity Domain*: An organization/enterprise implements IHE-XDS internally and chooses to be a single XDS Affinity Domain, where its internal systems are Document Sources and Document Consumers. There is a document registry and one or more document repositories in the Affinity Domain
2. *Multi-Organization – Stand-alone Affinity Domain*: A number of independent organizations choose to share documents by joining in an Affinity Domain. Each organization chooses to be a Document Source and /or Document Consumer. Each organization may also choose to be its own Document Repository or to use a shared Document Repository. There is a Document Registry in the Affinity Domain (possibly hosted by one of the member Organizations)
3. *Multi-Affinity Domains – Hierarchical Federation*: A number of Affinity Domains, each independently managed, choose to establish a federation. With a federation level PIX Manager and query to relevant XDS registries, cross-affinity domain access is possible (See IHE ITI Cross Community Information Exchange including Federation of XDS Affinity Domains)
4. *Multi-Affinity Domains – Lateral Cross-Community*: A number of Affinity Domains, each independently managed, wish to establish peer-to-peer communication without establishing a federation. (See white paper: IHE ITI Cross Community Information Exchange including Federation of XDS Affinity Domains)

Approaches 1, 2 and 3 are explicitly supported by the HITSP Manage Sharing of Documents Transaction Package with appropriate implementation/architecture decisions (e.g. multiple Federal Agencies choose to act as a Document Source/Document Consumer/Document Repository for selected types of documents and agree to establish an Affinity Domain by setting-up an XDS Registry with which they register the documents that they agree to share, under jointly agreed security and access control policies).

Approach 4 requires that HITSP address federation of affinity domains to support lateral cross-community communications.

HITSP Recommendation:

A next step for HITSP is to accelerate identification of standards for the "federation of affinity domains". HITSP should leverage lessons learned by the NHIN contractors, Connecting for Health, Federal Agencies, IHE and other implementation experiences.



7.0 CHANGE HISTORY

7.1 MAY 11, 2007

This document is now Released for Implementation.

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