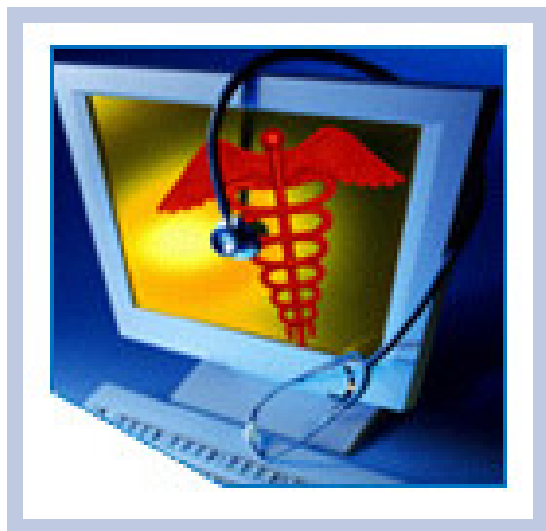


# HITSP Transfer of Documents on Media Transaction

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HITSP/T33



*Submitted to:*

**Healthcare Information Technology Standards Panel**

*Submitted by:*

**Security, Privacy and Infrastructure Domain Technical Committee**



## DOCUMENT CHANGE HISTORY

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## 1.0 INTRODUCTION

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

### 1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Transaction and background information about the underlying Components that the Transaction is based on.

A healthcare consumer may wish to move the contents of a Personal Health Record (PHR) using physical media to transport the information from a source to a destination. An example might be to transport data from one healthcare provider to another healthcare provider. The Transfer of Documents on Media Transaction describes both the type of media that may be used to write the contents of the PHR and provides a directory structure that must be followed in order for the contents to be successfully accessed and processed by subsequent healthcare providers.

This Transaction uses the IHE *Cross-Enterprise Document Media Interchange* Integration Profile developed by Integrating the Healthcare Enterprise (IHE), a companion to the IHE *Cross-Enterprise Document Sharing (XDS)* Integration Profile. This Integration Profile has been used by HITSP in a variety of Use Cases and harmonized under HITSP/TP13 Manage Sharing of Documents Transaction Package. HITSP/TP13 Manage Sharing of Documents facilitates the registration, distribution and on-line access of patient electronic healthcare records across health enterprises. *Cross-Enterprise Document Media Interchange (XDM)* uses the XDS- defined metadata formats in a simpler environment where media is interchanged rather than via on-line network interchanges.

This specification includes by reference the Transactions and Components that comprise the Transfer of Documents on Media Transaction. It describes the processes supported by these structures and the work that is accomplished by implementing this Transaction. Source material is from the IHE IT Infrastructure (ITI) Technical Framework (TF) Supplement 2006-2007 Cross-Enterprise Document Media Interchange (XDM) Integration Profile.

### 1.2 TRANSACTION DOCUMENT MAP

Each HITSP specification describes how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The



current Transfer of Documents on Media Transaction specification does not depend on any other HITSP constructs, however, it is used with other constructs to meet the requirements of one or more ISs. Review Section 1.2 Interoperability Specification Document Map from the relevant IS to better understand the context, dependencies, and relationships between the constructs used to meet the IS requirements.

### 1.3 COPYRIGHT PERMISSIONS

#### COPYRIGHT NOTICE

© 2008 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

DICOM materials used in this document have been extracted from relevant copyrighted materials with permission of the Digital Imaging and Communication Standards Committee. Copies of this standard may be retrieved from DICOM at <http://medical.nema.org>.

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

OASIS materials used in this document have been extracted from relevant copyrighted materials with permission of the Organization for the Advancement of Structured Information Standards (OASIS). Copies of this standard are available from OASIS at [www.oasis-open.org](http://www.oasis-open.org).

### 1.4 REFERENCE DOCUMENTS

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

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from the [www.hitsp.org](http://www.hitsp.org) Web Site.

**Table 1.4-1 Reference Documents**

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents



Reference Document	Document Description
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built
TN900 - Security and Privacy Technical Note	<p>Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:</p> <ul style="list-style-type: none"> <li>• The scope, reference policy background, and Security and Privacy principles used in the development of the constructs</li> <li>• A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs</li> <li>• A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases</li> <li>• A list of identified gaps and the recommended approaches to resolving those gaps</li> <li>• A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications</li> <li>• A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management</li> <li>• A glossary of terms used in all the Security and Privacy construct documents</li> <li>• A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment</li> </ul> <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>



## 2.0 TRANSACTION DEFINITION

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

### 2.1 CONTEXT OVERVIEW

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

This Transaction describes how information shall be structured on physical media in order to enable a consumer to transport information. It constrains the types of physical media that may be used to transfer the information and sets no limit on the number of individuals whose information may be contained on the media.

This HITSP Transaction builds upon existing standards by choosing the IHE *Cross-Enterprise Document Media Interchange (XDM)* Integration Profile published by Integrating the Healthcare Enterprise (IHE). Source material is from the XDM Supplement to the IHE IT Infrastructure (ITI) Technical Framework (TF), Volume 1 and Volume 2 (ITI TF-1 and ITI TF-2).

The IHE XDM Integration Profile, which is reproduced in part in this specification with written permission from IHE, explains how technical actors should comply with the proposed standards for interoperability. Key concepts from the IHE XDM Integration Profile are introduced in this document to help the reader understand the context of the Profile. The entire IHE XDM Integration Profile is also available at [www.ihe.net/Technical\\_Framework](http://www.ihe.net/Technical_Framework).

#### **Overview of XDM**

This section provides an overview of the IHE XDM Integration Profile. Its intent is to provide the reader with an introductory context for the XDM Profile. XDM defines the interchange of IHE *Cross-Enterprise Document Sharing (XDS)* Integration Profile document submission sets on media. It specifies the requirements for a directory structure and the physical media where the information will be stored. For more detailed explanations, examples and the complete specification, see the IHE XDM Integration Profile.

The text for the IHE XDM Integration Profile begins here:

The ***Cross-Enterprise Document Media Interchange*** IHE Integration Profile describes the exchange of a set of patient's documents between health IT systems, such as personal health



records systems, and EHR systems from physicians, hospitals, special care networks, or other healthcare professionals.

XDM should be used in a situation where the information receiver is an individual who will manually interpret or examine the data and associated documents as though they were using physical media.

The XDM Integration Profile is intended only for exchange of personal medical documents and not intended to address all cross-enterprise Electronic Health Record (EHR) communication needs. Some Use Cases may make use of other IHE Integration Profiles such as Cross-Enterprise Document (XDS), Document Digital Signature (DSG), Patient Identifier Cross-Referencing (PIX), Audit Trail and Node Authentication (ATNA).

This Profile is only defining the digital transport mechanism used for such Use Cases. Content transported will be detailed by Content Profiles such as that defined by the IHE PCC (Patient Care Coordination) domain.

The text for the IHE XDM Integration Profile ends here.

#### 2.1.1 TRANSACTION CONSTRAINTS

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

The XDM Integration Profile specifies that documents may be transferred on either CD-R, USB, or through email using ZIP. HITSP considers the transportation of a PHR through email as part of a broader network transfer of documents and is therefore constraining this Transaction to physical media to include only CD-R or USB when transporting a consumer's PHR. The Security and Privacy constraints related to the proper handling of this media and its content are beyond the scope of the current construct and are addressed by the referencing interface specification.

**Table 2.1.1-1 Transaction Constraints**

Constraint
Restrict physical media to either CD-R or USB

#### 2.1.2 TECHNICAL ACTORS

This section describes the technical actors that must be integrated in order to meet the interoperability requirements for this Transaction. A technical actor represents an entity internal to a software application,



which is engaged in one or more specific Transactions to support an aspect of a real world information interchange (e.g., set of message exchanges). The table below lists the technical actors involved in the Transaction, a definition of their roles, an indication of their optionality, the specific Transactions and content with which they are involved, and the optionality of the associated Transactions and/or content.

There are two technical actors involved in this Transaction. The Portable Media Creator distributes the document set on media to the consumer following the XDM directory structure to ensure the contents may be read by other Portable Media Importers. Once the consumer delivers the physical media, the Portable Media Importer processes the structured document set. The Portable Media Importer is required to process the structured document although it may also be able to process less structured content contained in a miscellaneous directory on the physical media as specified by XDM.

**Table 2.1.2-1 Technical Actors**

Technical Actor	Description	Used in Component/ Standard	Transaction / Content	T/C Optionality
Portable Media Creator	The Portable Media Creator writes the selected information from a consumer's PHR to media following the directory structure outlined by XDM	IHE XDM Integration Profile Section 16.1	Distribute Document Set on Media	R
Portable Media Importer	The Portable Media Importer processes all the contents written by a Portable Media Creator on the physical media. The Portable Media Importer must successfully process all documents	IHE XDM Integration Profile Section 16.1	Distribute Document Set on Media	R

**NOTE:** Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. Conditional footnotes are further described below.

### 2.1.3 ACTOR INTERACTIONS

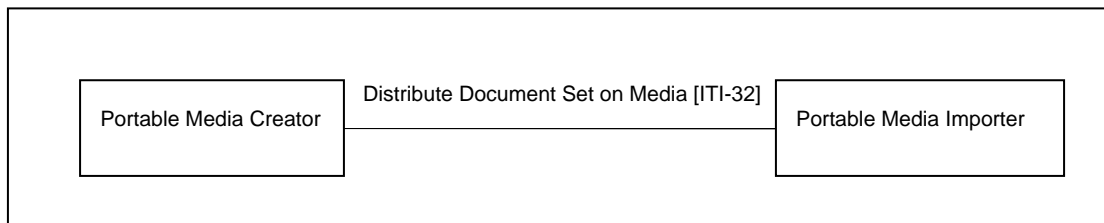
The following sections document the content of the Transaction and the basic process flows that are supported by the Transaction. It describes the underlying events that fulfill the Transaction, the sequence and timing of the events, and the specific actors involved. Process flow diagrams are provided to illustrate the process relationships.

The Portable Media Creator and Portable Media Importer have no direct interaction, but instead interact through media by either writing a document set to the media or by reading the document set on the media. The Portable Media Creator actor writes a document set to the media. The media is physically moved from the Portable Media Creator to the Portable Media Importer by the consumer. The Portable Media Importer processes the document set contained on the media.

The Transaction is described by IHE XDM Integration Profile as Distribute Document Set on Media Transaction (ITI-32).



**Figure 2.1.3-1 Actor Relationship**



#### 2.1.4 PRE-CONDITIONS

This section describes the necessary pre-conditions that must be in place prior to the start of the workings of the Transaction. The pre-conditions are used to convey any conditions that must be true at the outset of a Transaction. They describe the context that must be established before the Transaction is executed. They are not however the triggers that initiate the Transaction. Where one or more pre-conditions are not met, the behavior of the Transaction should be considered uncertain.

The only necessary pre-condition is that information must exist so that there is content for the Portable Media Creator actor to write to media.

**Table 2.1.4-1 Pre-conditions**

Pre-condition
It is expected that the security framework under which this Transaction operates is in accordance with the Interoperability Specification that references this construct. Therefore all applicable HITSP Security and Privacy constructs are implemented as required

##### 2.1.4.1 Process Triggers

This section describes the process triggers, including actors and/or processes, which are necessary to start the Transaction. They can invoke an automatic or manual process or result that in turn starts off the Transaction. A process trigger is not the same as a pre-condition that describes a context that needs to be in place at the start of the event.

**Table 2.1.4.1-1 Process Triggers**

Process Trigger
No applicable process triggers

#### 2.1.5 POST-CONDITIONS

This section provides an overview of the post-conditions or results that must occur at the end of the Transaction in order for the Transaction to be deemed successfully completed. This includes any required outputs from the Transaction, or specific actor states.



**Table 2.1.5-1 Post-conditions**

Post-condition
No applicable post-conditions

### 2.1.5.1 Required Outputs

This section identifies the required outputs that must be produced at the end of the Transaction in order for the Transaction to be deemed successfully completed. This includes the format and usage of the required output.

**Table 2.1.5.1-1 Required Output**

Required Output	Format/Usage
No applicable outputs	

### 2.1.6 DATA FLOWS

This section describes the basic data flows that are supported by this Transaction. It also describes the format of the data, the data sources, and the relevant actors involved in the successful flow of data for the Transaction. Any prevailing pre and post-conditions are identified, as well as the purpose of each data post-condition associated with each Transaction. Any data that need to be made available to particular actors are highlighted, as well as the conditions and processes that will use the data to achieve the stated post-conditions.

XDM specifies a directory structure that the Portable Media Creator must follow when writing data to media. The following citation is from the XDM Supplement describing how the contents must be structured. HITSP is also adhering to the XDM specification on file name and file directory restrictions.

The text from the IHE XDM Supplement begins here:

The requirements for media content are intended to promote the simple transfer of medical documents, including patient summaries, lab results, discharge letters and reports, and to allow for the viewing of such documents on general purpose computers by care providers or patients. Created media are required to contain documents and the relevant associated metadata. The media contain one or more Submission Sets including the documents and the associated metadata, organized in a well defined directory structure starting at the root level. The media content can be made web viewable by a web browser by providing optional files containing HTML content. This content must be based on the original documents in order to ensure consistency. Any ordinary web browser can be used to read these files. The Portable Media Importer ignores these files. They are just intended for the human recipient. Additional content may be present (files, directories), but can be ignored by the Portable Media Importer.

To summarize, the Portable Media Importer has two complementary ways to access the media and its content through a basic web browser:

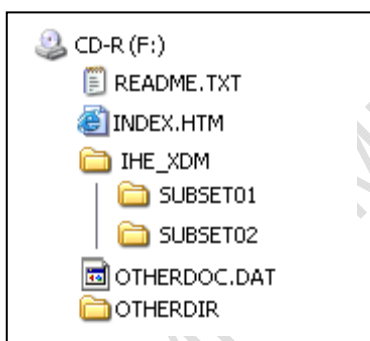


- By inspecting in the directory dedicated to XDM all the subdirectories that contain a specifically named metadata file compatible with XDM
- By presenting to the user the HTML index file that lists the submission sets and documents contained in the media

#### 2.1.6.1 Directory Structure on Media

The Portable Media Creator shall be able to include one or multiple submission set(s), including document(s) and associated metadata. Additionally it shall include a **README.TXT** file and **INDEX.HTM** and associated files for use to display the media content using a simple browser. It may include other files and directories that the Portable Media Importer will ignore.

**Figure 2.1.6.1-1 General Structure of the Media**



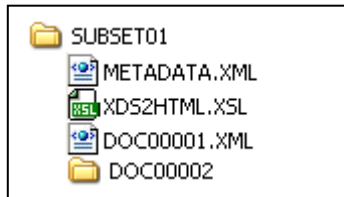
The media shall contain at the “root” directory level, as shown in the figure 2.1.6.1-1 above:

- An IHE XDM directory
- Two files for helping to access the content of the media: *README.TXT* and *INDEX.HTM*
- An Autorun file or equivalent shall not be present in the root directory. Executable files may be present, but shall not be configured to start automatically

As shown in the figure above, the *IHE\_XDM* directory shall contain one sub-directory per submission set included on the media.



**Figure 2.1.6.1-2 Structure of a Submission Set Directory on the Media**



As shown on the Figure 2.1.6.1-2 above, each submission set directory shall contain:

- A *METADATA.XML* file containing the XDS Registry metadata, as described in the section 3.14.4.1.2.7 Document Definition Metadata of the ITI TF-2 document
- One file for each “simple part” document referenced in the metadata as an XSDocumentEntry
- One sub-directory for each “multipart” document referenced in the metadata as an XSDocumentEntry (attribute mimeType set to “multipart/related”)
- Potentially other files and directories that are ignored by the Portable Media Importer

The text from the IHE XDM Supplement ends here.

Additional technical specifications for the document set stored on media may be found in the XDM Supplement.

## 2.2 LIST OF HITSP CONSTRUCTS

The following list of constructs and their definitions are used by the Transaction specification.

**Table 2.2-1 List of Constructs**

Construct Name	Technical Actors	Description	Event/Action Code	Content
No applicable HITSP constructs				

### 2.2.1 DEPENDENCIES

The following table shows a list of Components with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific construct:

**Table 2.2.1-1 Construct Dependencies**

Construct	Depends On (Name of Component that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
No applicable dependencies			



## 2.2.2 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

This section describes the constraints that further limit the constructs that are used by this Transaction.

**Table 2.2.2-1 Additional Constraints on Required Constructs**

Data Element	Construct	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
No applicable constraints				

## 2.3 **STANDARDS**

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The standards used by this Transaction specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declarations that HITSP must abide by (see Section 2.3.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 2.3.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Transaction specification (see Section 2.3.3)

### 2.3.1 REGULATORY GUIDANCE

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

**Table 2.3.1-1 Regulatory Guidance**

Standard	Description
No applicable regulatory guidance	

### 2.3.2 SELECTED STANDARDS

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



**Table 2.3.2-1 Selected Standards**

Standard	Description
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	This DICOM Standard describes the services and the data necessary for the interchange of information between digital imaging computer systems found in health care settings. PS 3.12 of the DICOM Standard articulates the structure between the Media Storage Model and specific media. Media physical characteristics are also covered. For more information visit <a href="http://medical.nema.org">http://medical.nema.org</a>
International Organization for Standardization (ISO) Health informatics - 9660 Level 1	Defines a common logical format for files and directories so discs written to ISO 9660 specifications can be read by a wide array of computer operating systems. For more information visit <a href="http://www.iso.org">www.iso.org</a>
USB Removable Device Type 2.0 (USB Implementers Forum)	The USB-IF was formed to provide a support organization and forum for the advancement and adoption of Universal Serial Bus technology. The Forum facilitates the development of high-quality compatible USB peripherals (devices), and promotes the benefits of USB and the quality of products that have passed compliance testing. For more information visit <a href="http://www.usb.org">www.usb.org</a>
XDM Supplement to the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)	This Supplement to the IHE IT Infrastructure Technical Framework defines the means to store and interchange personal medical documents on portable media. The current version of the XDM is specified in the XDM Trial Implementation Supplement to the ITI-TF, rev. 2.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. Visit <a href="http://www.ihe.net/technical_framework">http://www.ihe.net/technical_framework</a> for more information

### 2.3.3 INFORMATIVE REFERENCE STANDARDS

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

**Table 2.3.3-1 Informative Reference Standards**

Standard Name	Description/Reason for Use
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 <a href="http://www.ihe.net">www.ihe.net</a>
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>



Standard Name	Description/Reason for Use
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>

RELEASED FOR IMPLEMENTATION



## 3.0 TECHNICAL IMPLEMENTATION

### 3.1 CONFORMANCE

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

#### 3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards.

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

#### 3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

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



## 4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.

RELEASED FOR IMPLEMENTATION



## 5.0 CHANGE HISTORY

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

### 5.1 DECEMBER 5, 2007

No changes at this time.

### 5.2 DECEMBER 13, 2007

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

### 5.3 AUGUST 20, 2008

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

The following standards have been designated as informative reference:

- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0
- Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)
- Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)

### 5.4 AUGUST 27, 2008

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

