

HITSP Transfer of Documents on Media Transaction

HITSP/T33



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TABLE OF CONTENTS

1.0	INTRODUCTION.....	5
1.1	Overview.....	5
1.2	Copyright Permissions.....	5
1.3	Reference Documents.....	5
1.4	Conformance	6
1.4.1	Conformance Criteria	6
1.4.2	Conformance Scoping, Subsetting and Options	6
2.0	TRANSACTION DEFINITION.....	7
2.1	Context Overview	7
2.1.1	Transaction Constraints.....	8
2.1.2	Interfaces.....	8
2.1.3	Interface Interactions.....	8
2.1.4	Pre-conditions.....	9
2.1.4.1	Process Triggers	9
2.1.5	Post-conditions.....	9
2.1.5.1	Required Outputs	9
2.1.6	Data Flows.....	10
2.2	List of HITSP Constructs	10
2.2.1	Dependencies.....	10
2.2.2	Additional Constraints on Required Constructs.....	11
2.3	Standards	11
2.3.1	Regulatory Guidance.....	11
2.3.2	Selected Standards	11
2.3.3	Informative Reference Standards.....	12
3.0	APPENDIX.....	13
4.0	DOCUMENT UPDATES	14
4.1	December 5, 2007	14
4.2	December 13, 2007	14
4.3	August 20, 2008	14
4.4	August 27, 2008	14
4.5	December 10, 2008	14
4.6	December 18, 2008	14
4.7	June 30, 2009.....	14
4.8	July 8, 2009	14



FIGURES AND TABLES

Figure 2-1 Interface Relationship	9
Table 1-1 Reference Documents	6
Table 2-1 Transaction Constraints	8
Table 2-2 Interfaces	8
Table 2-3 Pre-conditions	9
Table 2-4 Process Triggers.....	9
Table 2-5 Post-conditions	9
Table 2-6 Required Output.....	9
Table 2-7 List of Constructs	10
Table 2-8 Construct Dependencies	10
Table 2-9 Additional Constraints on Required Constructs	11
Table 2-10 Regulatory Guidance	11
Table 2-11 Selected Standards	11
Table 2-12 Informative Reference Standards	12



1.0 INTRODUCTION

1.1 OVERVIEW

The HITSP Transfer of Documents on Media Transaction describes both the type of media (CD-ROM, USB Memory, and e-Mail) that may be used to write the documents and provides a directory structure that must be followed in order for the contents to be successfully accessed and processed by systems. An example might be to transport data from one healthcare provider to another healthcare provider, or a healthcare consumer may wish to move the contents of a Personal Health Record (PHR) using physical media or e-Mail.

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) - Cross-Enterprise Document Media Interchange (XDM) Integration Profile.

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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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.

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.

1.3 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material.

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



Table 1-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN900 - Security and Privacy Technical Note	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs

1.4 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.

1.4.1 CONFORMANCE CRITERIA

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

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

1.4.2 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 interface 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.



2.0 TRANSACTION DEFINITION

2.1 CONTEXT OVERVIEW

This Transaction describes how information shall be structured on media (CD-ROM, USB Memory, and e-Mail) in order to enable information transport. It constrains the types of 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. It includes an option for delivery of the content via e-Mail rather than on a physical 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 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 interfaces 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.

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 document submission sets on media (see IHE Cross-Enterprise Document Sharing-XDS for a definition of submission set). 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:

Cross-Enterprise Document Media Interchange (XDM) provides document interchange using a common file and directory structure over several standard media types. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM supports the transfer of data about multiple patients within one data exchange.

Physician to patient to physician - Bob has an MRI and cancer is diagnosed. He is given a CD-R with his MRI results and referral information on it to give to the specialist of his choice.

Patient visiting ED - In addition, Bob, the informed patient, maintains a copy of his EHR record at home and can bring the CD-R with him when he visits the ED for an unrelated emergency.

Physician to physician - Dr. Primary refers his aging patient Mr. Robinson to his first appointment with a gastroenterology specialist. He transfers relevant documents in a zip file attached to an email to the specialist.

The common thread of these Use Cases is that they are person-to-person communications. The XDM solution is intended to be easy to implement with pre-existing email clients, CD burners and USB ports. XDM does not include any additional reliability enhancements. XDM requires that the recipient be able to support human intervention in order to manually control the importing of the data (patient ID reconciliation, selection of patient of interest from possibly multiple patients' documents on the media).



XDM is document format agnostic, supporting the same document content as XDS and XDR. Document content is described in XDS Document Content Profiles. Examples are XDS-MS, XPHR, XDS-SD, and XD*-LAB.

XDM defines no new metadata. It leverages XDS metadata with emphasis on patient identification, document identification, description, and relationships.

A directory and file structure is documented for populating the media. This structure maintains separate areas for each patient listed and is supported on all referenced media types. Media and the structure were selected based on experience with media interoperability in Radiology, i.e. PDI profile. The media selected are the widespread CD-R, USB removable media, and email with ZIP attachment.

The text for the IHE XDM Integration Profile ends here.

2.1.1 TRANSACTION CONSTRAINTS

The IHE XDM Integration Profile specifies that documents may be transferred on either CD-R, USB, or through email using ZIP. 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 Transaction Constraints

Constraint
No applicable constraints

2.1.2 INTERFACES

There are two interfaces involved in this Transaction. The Portable Media Creator distributes the document sets on media following the XDM directory structure to ensure the contents may be read by other Portable Media Importers. Once media are delivered (e.g., consumer hand carrying), the Portable Media Importer processes the structured document set(s). 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 IHE XDM Integration Profile.

Table 2-2 Interfaces

Interface	Description	Used in Component/ Standard	Transaction/Content	T/C Optionality ¹
Portable Media Creator	The Portable Media Creator writes the selected information to media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	IHE XDM Integration Profile Section 16.1	Distribute Document Set on Media	R
Portable Media Importer	Media Importer reads the selected information from media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	IHE XDM Integration Profile Section 16.1	Distribute Document Set on Media	R

2.1.3 INTERFACE INTERACTIONS

The Portable Media Creator and Portable Media Importer have no direct interaction, but instead interact through media by either writing one or more document sets to the media or by reading the document set(s) on the media. Where the media is either USB, CD-R, or ZIP over e-Mail. The Portable Media Creator interface writes a document set to the media. The media is physically/e-Mail moved from the

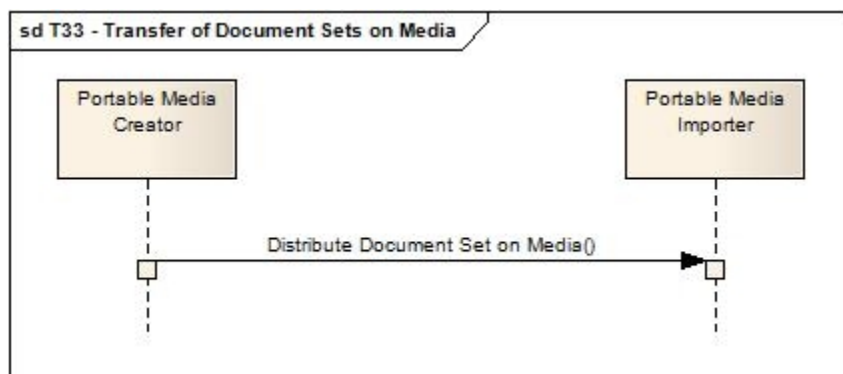
¹ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional



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 Interface Relationship



2.1.4 PRE-CONDITIONS

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

Table 2-3 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
The source of the information has data and documents stored in electronic format

2.1.4.1 PROCESS TRIGGERS

Table 2-4 Process Triggers

Process Trigger
No applicable process triggers

2.1.5 POST-CONDITIONS

Table 2-5 Post-conditions

Post-condition
The chosen document(s) are received by the Portable Media Importer interface

2.1.5.1 REQUIRED OUTPUTS

Table 2-6 Required Output

Required Output	Format/Usage
No applicable outputs	



2.1.6 DATA FLOWS

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, Section 16.4.3 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 contains 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.

Access to the content of an individual document is outside the scope of this Integration Profile and shall be addressed in specific IHE document content Integration Profiles.

The text for the IHE XDM, Section 16.4.3 ends here.

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

2.2 LIST OF HITSP CONSTRUCTS

Table 2-7 List of Constructs

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

2.2.1 DEPENDENCIES

Table 2-8 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

Table 2-9 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**

2.3.1 REGULATORY GUIDANCE

Table 2-10 Regulatory Guidance

Standard	Description
No applicable regulatory guidance	

2.3.2 SELECTED STANDARDS

Table 2-11 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 medical.nema.org
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	Provides document interchange using a common file and directory structure over several standard media types. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM supports the transfer of data about multiple patients within one data exchange. Visit www.ihe.net for more information
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 www.iso.org
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 www.usb.org



2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-12 Informative Reference Standards

Standard	Description
Internet Engineering Task Force (IETF), MIME Multipurpose Internet Message Extensions (RFC 2045 to RFC 2049)	The first and second documents in this set define MIME header fields and the initial set of MIME media types. The third document describes extensions to RFC 822 formats to allow for character sets other than US-ASCII. The fourth document describes what portions of MIME must be supported by a conformant MIME implementation. It also describes various pitfalls of contemporary messaging systems as well as the canonical encoding model MIME is based on. For more information visit www.ietf.org
Internet Engineering Task Force (IETF), SMTP Simple Mail Transfer Protocol (RFC 2821)	The objective of the Simple Mail Transfer Protocol (SMTP) is to transfer mail reliably and efficiently. SMTP is independent of the particular transmission subsystem and requires only a reliable ordered data stream channel. While this document specifically discusses transport over TCP, other transports are possible. For more information visit www.ietf.org
Internet Engineering Task Force (IETF), The MIME Multipart/Related Content-type (RFC 2387)	The Multipart/Related content-type provides a common mechanism for representing objects that are aggregates of related MIME body parts. This document defines the Multipart/Related content-type and provides examples of its use. For more information visit www.ietf.org
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 www.oasis-open.org
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 www.oasis-open.org



3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.



4.0 DOCUMENT UPDATES

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

4.1 DECEMBER 5, 2007

No changes at this time.

4.2 DECEMBER 13, 2007

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

4.3 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)

4.4 AUGUST 27, 2008

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

4.5 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

5064

The full text of the comments along with the Technical Committee's disposition can be reviewed on the [HITSP Public Web Site](#).

Minor editorial changes were made to this construct.

4.6 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

4.7 JUNE 30, 2009

Minor editorial changes were made to this document. Removed boilerplate text for simplification. The term "actor" was replaced with "interface".

4.8 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.

