Integrating the Healthcare Enterprise

IHE IT Infrastructure

Technical Framework Supplement

Support for Metadata-Limited Document Sources

Trial Implementation

Date: August 19, 2011

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework 8.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Trial Implementation as of August 19, 2011 and will be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the IT Infrastructure Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/iti/iticomments.cfm or by email to iti@ihe.net.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

General information about IHE can be found at: www.ihe.net

Information about IHE IT Infrastructure can be found at: http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm

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Introduction

This supplement adjusts the requirements of metadata attributes when used in an XDR or XDM context. Metadata is valuable to receivers of healthcare content to enable routing and pre-processing without the need to open the documents or understand the format of the documents. The XDS Profile has designed the use of metadata around the desire to enable document discovery, routing and pre-processing. When the level of metadata required by XDS is available, the XDR and XDM profiles should continue to make use of the XDS approach to metadata, including the rich level of metadata that receivers in an XDS environment are used to getting. This supplement focuses on situations where XDR or XDM are used in a more loose environment, where senders know less about what receivers understand - especially in coded values - or senders simply don't have the same level of depth of understanding of the content they are sending. This environment allows for less thoroughness in requirements for metadata. If a document originates in XDR or XDM with lowered level of metadata attributes requirements, it is likely that additional metadata will need to be generated in order to integrate that document into an XDS environment, therefore we encourage as much metadata be carried as is known by the sender.

Specifically this supplement adjusts the XDR and XDM environments as follows:

For XDR a new actor, Metadata-Limited Document Source, supplies documents and metadata to the Document Recipient but is not required to supply as many metadata attributes as the existing XDR Document Source actor is required to support. In particular the following attributes are required to be specified by an XDR Document Source but an XDR Metadata-Limited Document Source is only required to specify if the value is available: authorPerson, classCode, confidentialityCode, creationTime, formatCode, healthcareFacilityTypeCode, languageCode, patientId, practiceSettingCode, sourcePatientId, typeCode, contentTypeCode, codeList. Because patientId and sourcePatientId are not always available the new actor is required to specify sourcePatientInfo if content is available.

For XDM the requirements for the existing actors have been relaxed in the same way that is applied to the Metadata-Limited Document Source.

This supplement does not change the requirements on the content of any metadata attribute which, when supplied, must still be in accordance with the existing requirements.

Use Cases

The following use cases are added to the XDR and XDM profiles through editor boxes found later in the profile. They are included here as introductory material to provide the environment supported by the supplement.

Primary care provider refers patient to specialist

Dr. Primary is referring a patient to Dr. Specialist. Dr. Primary works in a single physician practice which has limited technology which is not yet well integrated. Dr. Specialist works in a fully integrated environment, with an EMR that can automatically process incoming data and present it in the most effective way. Dr. Specialist's EMR accepts XDR transactions but is not enabled to accept and process e-mail. Because Dr. Primary, and single physical practices like his, are a source of a significant number of referrals for Dr. Specialist, the ability to translate from e-mail to XDR is valuable to Dr. Specialist. In this case, this capability is provided by a state level organization, which accepts e-mail messages on behalf of its participants and converts them to XDR transactions for delivery to EMR's in the state.

To send a referral, Dr. Primary's referral coordinator uses an e-mail application to write a textual summary of the referral and attaches a set of PDF formatted scanned documents. The textual summary and PDF documents are encrypted and signed by the application and mailed to Dr. Specialist's e-mailed address. Dr. Specialist's e-mail address was provided by the state organization and the e-mail is received by the state's e-mail server. This state e-mail server application converts the e-mail into an XDR message, where the text of the e-mail is one of the documents being sent. The conversion service provided by the state e-mail server has access to only the content of the email and must be able to convert e-mail messages from many different types of senders, thus cannot be statically configured with information specific to any one sending party. The XDR transaction is sent to Dr. Specialist's EMR which accepts the content for processing. The state e-mail server application will be able to decrypt the content but will not be able to automatically generate the metadata required for XDR.

Current situation

Typically one of the following two approaches is used:

- For all required metadata which cannot be generated, a default value is defined by the state organization infrastructure and, possibly, communicated to Dr. Specialist. Dr. Specialist' EMR must understand this defaulted data and ensure that no misrepresentation of content results. For example, there is probably no patient identifier available. Since XDR specifies that the patient identifier should be known by the receiving system when an identifier arrives that is not known an appropriate workflow to handle this "default" value is needed. A similar set of special processing is needed for every case of a default being presented, which results in a non-interoperable system and a lot of custom coding for specific choices of defaults.
- The community defines its own set of required metadata, different than that specified by IHE. Dr. Specialist's EMR must be adjusted for this level of requirement and make appropriate choices for processing input that is not conformant with the XDR standard.

Improved situation

IHE defines a level of metadata conformance that is clearly articulated for uses such as this. The community adopts this level of metadata conformance for use in this use case and Dr. Specialist

ensures that his system supports this IHE specified level. When Dr. Specialist receives the content it is processed consistent with the use case, generally requiring human intervention to support routing and integration. If Dr. Specialist or the state organization did not want to support the requirement for human intervention the message could be rejected and that rejection communicated to the submitter.

This use case demonstrates a situation where the sender, Dr. Primary, has limited technical capabilities and as a result the receiver, in this case Dr. Specialist, has a greater responsibility in compensating for missing capability of the sender. Dr. Specialist has chosen to accept content that will likely require manual intervention to properly integrate it into his EMR. In addition, Dr. Specialist will have chosen an EMR which supports this manual intervention.

Specialist refers patient to hospital

After review of the patient referral, Dr. Specialist decides that this patient needs immediate hospitalization and refers the patient to Mercy Hospital which specializes in the patient's condition. Since the patient has never been to Mercy Hospital there is no patient record or patient identifier known to Mercy Hospital. Dr. Specialist's system includes the patient demographics in the XDR message sent to Mercy Hospital but cannot include a patient identifier that is useful at the destination. Mercy Hospital uses the patient demographics included in the XDR message to create the patient record and store the incoming data in that patient record. When the patient arrives at Mercy the information is available to begin immediate treatment.

Primary care provider refers patient to unknown specialist

Dr. Primary recommends the patient see a specialist, but allows the patient to choose her own specialist. Dr. Primary provides the patient with her records in XDM format on a CD. Since Dr. Primary cannot know what specialist will receive the records, much of the metadata required by XDM cannot be specified. In particular, patient identifiers will likely not be useful but patient demographics will be especially important.

Open Issues and Questions

- (9) The usefulness of this supplement content has been debated throughout its development and continues through Public Comment when few comments were received. It is postulated that deployments of XDR and XDM sometimes ignore the requirements on metadata as they develop their use of metadata. This supplement attempts to make those deployments conformant to the IHE XDR/XDM specifications by specifying minimal requirements on metadata supplied. Prior to movement to Final Text it is important that this intent be verified by actual deployments and products.

Closed Issues

- (1) Is an indicator needed to communicate to receiver that minimal metadata has been specified? If yes, what how should the indicator be specified? Suggestions for reflecting the different levels of metadata include a) use of objectType on document entry (note that affects submission set as well) b) use of SOAP header level element to warn receiver prior to processing the message contents. **Resolution (and discussion):** a flag is needed to enable the XDR Document Recipient to properly process the metadata. The flag should not be at the SOAP level because the SOAP content is often not available to the component that is processing metadata. Discussion of using objectType: there was concern that this is a complicated solution and a low level of implementation for a simple problem. Suggested that this solution should mean we are using a new transaction. Will make documentation complicated and make for confusion on the part of a non-upgraded receiver. Considered using a slot to carry the flag. Suggestion that using a Classification is more consistent with the concept. Agreed to use a Classification which identified that the object, either Document Entry or Submission Set, has been created under the lowered requirement level.
- (2) Is minimal metadata an option in XDR and XDM? Also considered just downgrading the XDR/XDM actor handling of metadata. **Resolution:** Support for lowered level of metadata requirements will be declared as an option in the XDR Document Recipient and a new actor will be created which will be the sender of XDR P&R with minimal metadata. This resolution requires a flag in the transaction to reflect that the minimal requirements apply – see issue (1). For discussion of XDM see issue (8).
- (3) Should a new method of documenting metadata be addressed as part of this work effort? **Resolution:** Re-documentation of metadata found to not be critical to completion of this work. This work item is deferred to be part of the general XD* redocumentation effort planned for future work cycles.
- (4) Does sourcePatientID allow more than one element? **Resolution:** CP 577 opened to resolve this question.
- (5) Should we adopt the Direct Project enhancements to submission set metadata for author and intendedRecipient to add an XTN value holding sender and recipient email addresses? CP 524 submitted on this issue. **Resolution**: Those extensions will be processed through the CP process but this text assumes the CP is approved.
- (6) Should we consider Folder metadata and applying minimal requirements for Folder metadata? **Resolution:** considered and updated to allow R2 for a couple items
- (7) Once the XDS Document Recipient has decided to implement the option to accept minimal metadata, what is the additional value of requiring the recipient to validate full metadata when the flag is not found? **Resolution:** Improves trouble shooting in connectathons and testing.
- (8) Need to review XDM and if the same approach from (2) will fit the XDM profile. **Resolution:** Agreed to downgrade the requirements of XDM to be the same as the

requirements for XDR limited metadata. The value of using new actors and an option on receiver was felt to be of little use in an XDM environment. Since XDM already works as a best fit transaction we decided to document it as such.

Volume 1 – Profiles

15.1 Actors/ Transactions

ITI Volume 1: Replace the current Figure 15.1-1 in section 15.1 with the following figure which adds the new actor to the Figure.

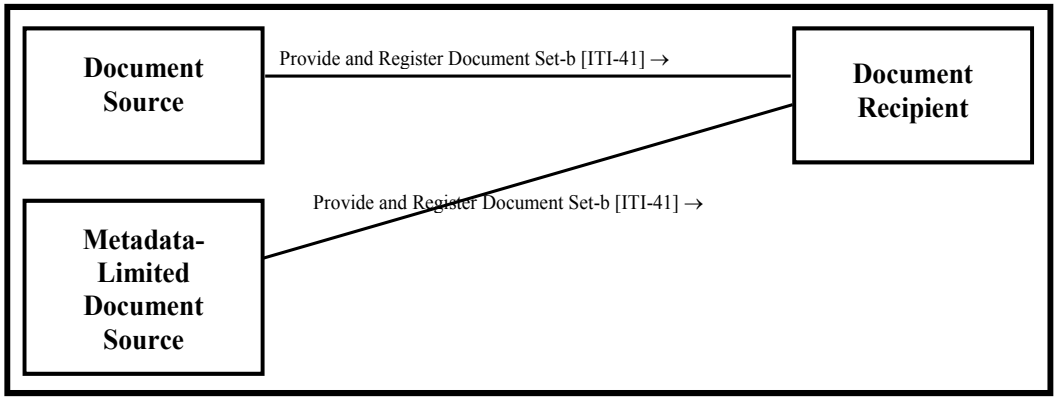

Figure 15.1-1 XDR Actor Diagram

ITI Volume 1: Update the XDR profile section 15.1 to add the new actor to Table 15.1-1:

Table 15.1-1 XDR Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Document Source	Provide and Register Document Set-b [ITI-41]	R	ITI TF-2:3.41
Metadata-Limited Document Source	**Provide and Register Document Set-b [ITI-41]**	**R**	**ITI TF-2:3.41**
Document Recipient	Provide and Register Document Set –b [ITI-41]	R	ITI TF-2:3.41

ITI Volume 1: Update the XDR profile section 15.2 as shown:

15.2 XDR Integration Profile Options

Options that may be selected for this Integration Profile are listed in Table 15.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 15.2-1 XDR - Actors and Options

Actor	Options	Vol & Section
Document Source	*Basic Patient Privacy Enforcement*	ITI-TF-2b: 3.41.4.1.3.1
Metadata-Limited Document Source	***Basic Patient Privacy Enforcement***	**ITI TF-2b: 3.41.4.1.3.1**
Document Recipient	*Basic Patient Privacy Enforcement*	ITI-TF-2b: 3.41.4.1.3.1
	Accepts Limited Metadata	**ITI TF-1:15.2.3**

15.2.1 Intentionally Left Blank

15.2.2 Basic Patient Privacy Enforcement Option

For this option, see ITI-TF-2b: 3.41.4.1.3.1

15.2.3 Accepts Limited Metadata

When the Document Recipient declares this option it will accept metadata entries from a Metadata-Limited Document Source which use the less rigorous metadata attribute requirements as shown in ITI TF-2b:3.41.4.1.2 Table 3.41.4.1.2-2.

ITI Volume 1: Section 15.3: Add to the list of Use Cases in Section 15.3 the first and second use cases from the Introduction, specifically "Primary care provider refers patient to specialist" and "Specialist refers patient to hospital"

ITI Volume 1: Update the XDR profile section 15.3 figure 15.3-1 to add Metadata-Limited Document Source to the process flow diagram as show below:

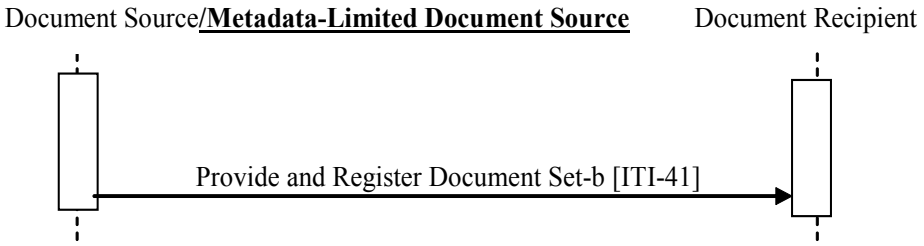

Figure 15.3-1 Process Flow in XDR Profile

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ITI Volume 1: Section 16.3: Add to the list of Use Cases in Section 16.3 the third use case from the Introduction, specifically "Primary care provider refers patient to unknown specialist"

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Appendix A Actor Summary Definitions

Add the following description of the new actor to Appendix A.

Metadata-Limited Document Source – The Metadata-Limited Document Source sends documents and metadata similar to a Document Source but is limited in the quantity of metadata it is able to provide.

Volume 2b – Transactions

ITI Volume 2b: Update the Distribute Document Set on Media transaction Section 3.32.4.1.2:

Note to Reviewers: *A lot of text is copied from the transaction without change. This supplement will not be modifying this copied text unless it pertains specifically to the changes in the supplement. The copied text is retained in this supplement only for the purposes of giving context to the changes.*

3.32 Distribute Document Set on Media

3.32.4.1.2 Message Semantics

The message semantics of this transaction are described in terms of content specifications for the 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 an ***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.

3.32.4.1.2.1 Media File system and File Naming Restrictions

The following restrictions are needed to ensure broad interoperability:

- Strict ISO 9660 Level 1 compliance for filenames and directories, even on non-CDR media.
- Strict ISO 9660 Level 1 compliance for recording methods on CDR media. This means no packet writing.
- Filenames should not be in lower case, nor have lower case equivalent file names encoded as Joliet or Rock Ridge extensions to the ISO 9660 file system.
- Only file and folder names referenced by the DICOMDIR file are restricted to 8 characters with no extension. Specifically, it is not permitted to name DICOM files based on their SOP Instance UID, since that would exceed the 8 character limit and use the illegal period character, and it is not permitted to add a ".dcm" extension or similar.

Note: Refer to RAD TF-3: Appendix E of the IHE Radiology Technical Framework for a reference to common implementation misinterpretations and/or errors that are detrimental to interoperability.

3.32.4.1.2.2 Content Organization Overview

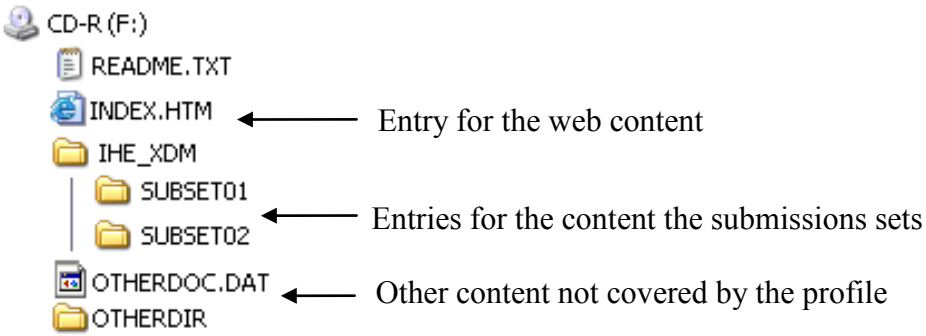


Figure 3.32.4.1-1 General structure of the media

The media shall contain at the "root" directory level, as shown in the figure 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.

There may be other files present on the media for other purposes, (e.g., use in compliance with the IHE Radiology PDI profile). The presence or absence of these files shall not affect performance of this transaction.

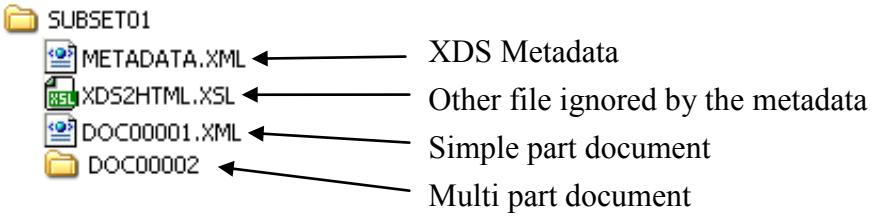


Figure 3.32.4.1-2 Structure of a submission set directory on the media

As shown on the figure above, each submission set directory shall contain:

- A *METADATA.XML* file containing the XDS Registry metadata, as described in ITI TF-3: 4.1.3.1 XDS Registry Submission Request~~7 Document Definition Metadata~~. This shall include the metadata as specified in Table 3.32.4.1-2 ~~This shall include all of the metadata that is specified for a Register Document Set-b [ITI-42].~~ This may include XDSFolder objects, associations, and other metadata contents. There is no relationship between an XDSFolder and a media directory, although some people do call media directories "folders". The metadata for the submission set shall include unique and different submissionTime.

- One file for each "simple part" document referenced in the metadata as an XDSDocumentEntry
- One sub-directory for each "multipart" document referenced in the metadata as an XDSDocumentEntry (see table 4.1-5, attribute mimeType set to "multipart/related")
- Potentially other files and directories that are ignored by the Portable Media Importer

Insert NEW Tables 3.32.4.1-1 and 3.32.4.1-2 into Section 3.32.4.1.2.2 at this point

Note to Reviewers*: the following new table changes the requirements of use of the following metadata attributes within XDM from R (as defined in ITI TF-V3 tables 4.1-5, 4.1-6 and 4.1-7) to R2.*

authorPerson, classCode, confidentialityCode, creationTime, formatCode, healthcareFacilityTypeCode, languageCode, patientId, practiceSettingCode, sourcePatientId, typeCode, contentTypeCode, codeList.

Because patientId and sourcePatientId are not always available, sourcePatientInfo is required if data is available.

Note that the Submission Set authorTelecommunication attribute is added via CP 524 which is not yet final.

Table 3.32.4.1-1 Codes for Portable Media Creator Column

Code	Meaning of code in Portable Media Creator Column
R	Required
R2	Required if Known
O	Optional
N/A	Not supported in this transaction

Table 3.32.4.1-2 ITI-32 Metadata Requirements

Metadata Element	Metadata Attribute	Portable Media Creator
DocumentEntry	author: authorPerson	R2
DocumentEntry	author: authorInstitution	O
DocumentEntry	author: authorRole	O
DocumentEntry	author: authorSpecialty	O
DocumentEntry	availabilityStatus	N/A

Metadata Element	Metadata Attribute	Portable Media Creator
DocumentEntry	classCode	R2
DocumentEntry	comments	O
DocumentEntry	confidentialityCode	R2
DocumentEntry	creationTime	R2
DocumentEntry	entryUUID	R
DocumentEntry	eventCodeList	O
DocumentEntry	formatCode	R2
DocumentEntry	hash	R
DocumentEntry	healthcareFacility TypeCode	R2
DocumentEntry	homeCommunityId	N/A
DocumentEntry	languageCode	R2
DocumentEntry	legalAuthenticator	O
DocumentEntry	mimeType	R
DocumentEntry	patientId	R2
DocumentEntry	practiceSettingCode	R2
DocumentEntry	limitedMetadata	N/A
DocumentEntry	repositoryUniqueId	N/A
DocumentEntry	serviceStartTime	R2
DocumentEntry	serviceStopTime	R2
DocumentEntry	size	R
DocumentEntry	sourcePatientId	R2
DocumentEntry	sourcePatientInfo	R2
DocumentEntry	title	O
DocumentEntry	typeCode	R2
DocumentEntry	uniqueId	R
DocumentEntry	URI	R
SubmissionSet	author: authorPerson	R2
SubmissionSet	author: authorInstitution	O
SubmissionSet	author: authorRole	O
SubmissionSet	author: authorSpecialty	O
SubmissionSet	author: authorTelecommunication	R2
SubmissionSet	availabilityStatus	N/A
SubmissionSet	comments	O
SubmissionSet	contentTypeCode	R2
SubmissionSet	entryUUID	R

Metadata Element	Metadata Attribute	Portable Media Creator
SubmissionSet	homeCommunityId	N/A
SubmissionSet	intendedRecipient	R2
SubmissionSet	patientId	R2
SubmissionSet	limitedMetadata	N/A
SubmissionSet	sourceId	R
SubmissionSet	submissionTime	R
SubmissionSet	title	O
SubmissionSet	uniqueId	R
Folder	availabilityStatus	N/A
Folder	codeList	R2
Folder	comments	O
Folder	entryUUID	R
Folder	homeCommunityId	N/A
Folder	lastUpdateTime	N/A
Folder	patientId	R2
Folder	limitedMetadata	N/A
Folder	title	O
Folder	uniqueId	R

The "multipart" document shall be structured as one sub-directory containing all the parts as file, including the "start" part corresponding to the main file to be open by the "multipart" document viewer. An example of "multipart" document is shown in Figure 3.32.4.1-3.

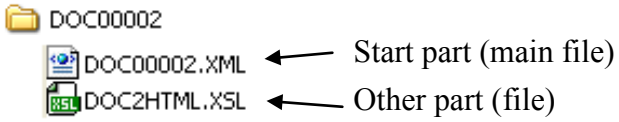


Figure 3.32.4.1-3 Structure on the media of a directory which is functionally equivalent to a "XDS multipart document"

ITI Volume 2b: Update the Provide and Register Document Set-b transaction Section 3.41:

Note to Reviewers: *A lot of text is copied from the transaction without change. This supplement will not be modifying this copied text unless it pertains specifically to the changes in the supplement. The copied text is retained in this supplement only for the purposes of giving context to the changes.*

3.41 Provide and Register Document Set-b

This section corresponds to Transaction [ITI-41] of the IHE Technical Framework. Provide and Register Document Set-b is used by the Document Source to provide a set of documents to the Document Repository, and to request that the Document Repository store these documents and then register them with the Document Registry. The Document Source **or Metadata-Limited Document Source** may also provide a set of documents to a Document Recipient.

Integration Profiles using this Transaction
Cross-Enterprise Document Sharing-b (XDS.b)
Cross-Enterprise Document Reliable Interchange (XDR)

The Provide and Register Document Set-b transaction describes the interaction between the Document Source**/Metadata-Limited Document Source** and the Document Recipient actors, and the Document Source and Document Repository actors. The interaction between the Document Repository and the XDS Document Registry is described separately in the Register Document Set-b Transaction [ITI-42].

This transaction aligns with the Registry Services standard (ebRS) for the format of the document metadata as defined in ITI TF-3: 4.1. The ebRS standard covers the interaction with a service that includes a registry with integrated repository. From the point of view of the Document Source, the separate nature of the XDS Document Registry and Document Repository actors is not relevant.

By specifying separate Document Registry and Document Repository actors, XDS offers additional flexibility of having a single Document Registry index content for multiple Document Repositories. The ebRIM portion of the registry standard supports this possibility though the ExternalLink object type.

In XDS, the documents and metadata go to the Document Repository actor and then the metadata is forwarded on to the Document Registry actor. They move in this direction for several reasons:

- Allows best reuse of ebXML Registry specified metadata and web services protocols
- Document Source only needs to know the identity of the Document Repository. Document Repository knows the identity of the Document Registry. If Provide and Register Document Set-b transaction were sent to the Document Registry then routing decisions for documents would be more complex.
- Resulting protocols are simpler
- Simplifies the common case where the Document Source and the Document Repository are grouped.

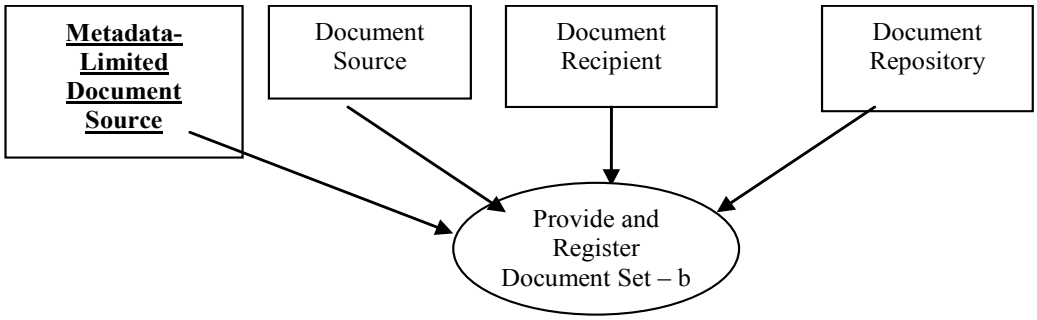
3.41.1 Scope

The Provide and Register Document Set-b transaction passes a Repository Submission Request (see ITI TF-3: 4.1.3.1) from a Document Source to a Document Repository/Document Recipient **or a Metadata-Limited Document Source to a Document Recipient**.

A Provide and Register Document Set-b transaction shall carry:

- Metadata describing zero or more documents
- Within metadata, one XDSDocumentEntry object per document
- XDS Submission Set definition along with the linkage to new documents and references to existing documents
- Zero or more XDS Folder definitions along with linkage to new or existing documents
- Zero or more documents

3.41.2 Use Case Roles



Actor: Document Source

Role: A system that submits documents and associated metadata to a Document Repository. Detailed requirements for this actor are discussed in ITI TF-2b: 3.41.6.1.

Actor: Metadata-Limited Document Source

Role: A system that submits documents and a limited set of associated metadata to a Document Recipient. Detailed requirements for this actor are discussed in ITI TF-2b: 3.41.6.1.

Actor: Document Recipient

Role: A system that receives a set of documents. Typically this document set will be made available to the intended recipient who will chose to either view it or integrate it into the Electronic Healthcare Record (EHR).

Detailed requirements for this actor are discussed in ITI TF-2b: 3.41.6.2.

Actor: Document Repository

Role: A document storage system that receives documents and associated metadata and:

- Stores the documents
- Enhances submitted metadata with repository information to enable later retrieval of documents
- Forwards the enhanced metadata to the Document Registry

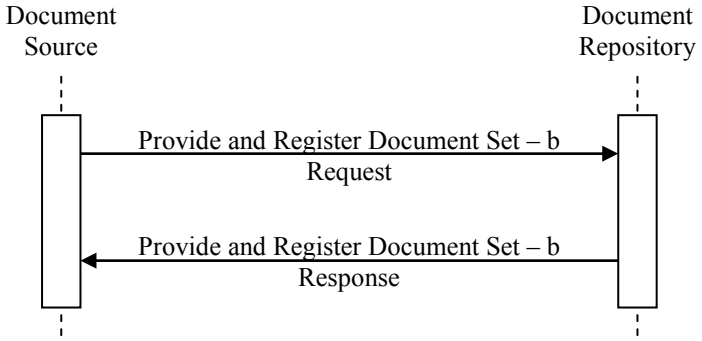
Detailed requirements for this actor are discussed in ITI TF-2b: 3.41.6.2.

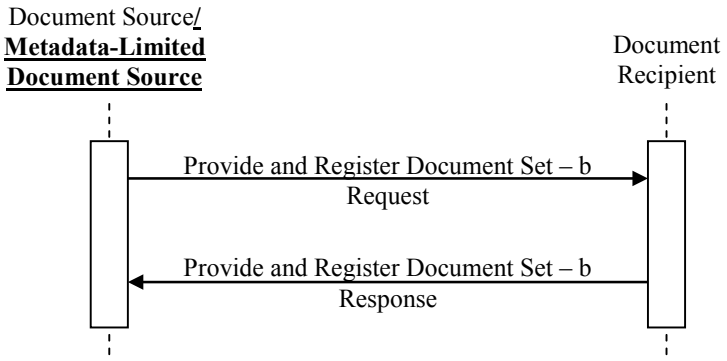
3.41.3 Referenced Standards

Implementors of this transaction shall comply with all requirements described in: ITI TF-2x: Appendix V: Web Services for IHE Transactions.

ebRIM	OASIS/ebXML Registry Information Model v3.0
ebRS	OASIS/ebXML Registry Services Specifications v3.0
Appendix V	ITI TF-2x:Appendix V Web Services for IHE Transactions Contains references to all Web Services standards and requirements of use
MTOM	SOAP Message Transmission Optimization Mechanism http://www.w3.org/TR/soap12-mtom/
XOP	XML-binary Optimized Packaging http://www.w3.org/TR/2005/REC-xop10-20050125/

3.41.4 Interaction Diagrams





3.41.4.1 Provide and Register Document Set-b Request

A Document Source **or Metadata-Limited Document Source** sends documents and associated metadata to a Document Recipient, or a Document Repository that has an associated Document Registry.

The Document Repository shall, upon receipt of a Provide and Register Document Set-b [ITI-41] transaction send a corresponding Register Document Set-b [ITI-42] transaction to the Document Registry actor.

- The Document Repository actor shall create and insert the XDSDocumentEntry.repositoryUniqueId, XDSDocumentEntry.size, and XDSDocumentEntry.hash attributes for each document received from the Provide and Register Document Set-b [ITI-41] transaction into the resulting Register Document Set-b [ITI-42] transaction metadata. The combination of XDSDocumentEntry.uniqueId and XDSDocumentEntry.repositoryUniqueId attributes value shall later be accepted in a Retrieve Document Set transaction [ITI-43] for that document and the document shall be returned.

3.41.4.1.1 Trigger Events

The Document Source **or Metadata-Limited Document Source**, based on a human decision or the application of a certain rule of automatic operation, wants to submit

- A set of zero or more documents to the Document Repository and the associated metadata to the Document Registry.

or

- A set of one or more documents to a Document Recipient.

3.41.4.1.2 Message Semantics

The sections in ITI TF-3: 4.1 specify the mapping of XDS concepts to ebRS and ebRIM semantics and document metadata. A full example of document metadata submission can be found in ITI TF-2x: Appendix W.

The Provide and Register Document Set-b message shall include the metadata attributes as defined in ITI TF-3: 4.1.3 XDS Submission Request Specification and table 3.41.4.1.2-2.

Insert NEW Tables 3.41.4.1.2-1 and 3.41.4.1.2-2 into Section 3.41.4.1.2 at this point

Notes to Reviewers*: the XDS Document Source and XDR Document Source columns are included for the purposes of context and are consistent with the requirements specified in ITI TF-3: 4.1.7 Document Definition Metadata.*

The table changes the requirements of use of the following metadata attributes by XDR Metadata-Limited Document Source from R (as defined in ITI TF-V3 tables 4.1-5, 4.1-6 and 4.1-7) to R2.

authorPerson, classCode, confidentialityCode, creationTime, formatCode, healthcareFacilityTypeCode, languageCode, patientId, practiceSettingCode, sourcePatientId, typeCode, contentTypeCode, codeList.

Because patientId and sourcePatientId are not always available, the new actor is required to specify sourcePatientInfo if data is available.

Note that the Submission Set authorTelecommunication attribute is added via CP 524 which is not yet final.

Table 3.41.4.1.2-1 Codes for Table 3.41.4.1.2-2 Columns

Code	Meaning
R	Required
R2	Required if Known
O	Optional
N/A	Not supported in this transaction

Table 3.41.4.1.2-2 ITI-41 Metadata Requirements

Metadata Element	Metadata Attribute	XDS Document Source	XDR Document Source	XDR Metadata-Limited Document Source
DocumentEntry	author: authorPerson	R	R	R2
DocumentEntry	author: authorInstitution	O	O	O
DocumentEntry	author: authorRole	O	O	O
DocumentEntry	author: authorSpecialty	O	O	O
DocumentEntry	availabilityStatus	N/A	N/A	N/A
DocumentEntry	classCode	R	R	R2
DocumentEntry	comments	O	O	O
DocumentEntry	confidentialityCode	R	R	R2
DocumentEntry	creationTime	R	R	R2
DocumentEntry	entryUUID	R	R	R
DocumentEntry	eventCodeList	O	O	O
DocumentEntry	formatCode	R	R	R2
DocumentEntry	hash	O	O	O
DocumentEntry	healthcareFacility TypeCode	R	R	R2
DocumentEntry	homeCommunityId	N/A	N/A	N/A
DocumentEntry	languageCode	R	R	R2
DocumentEntry	legalAuthenticator	O	O	O
DocumentEntry	mimeType	R	R	R
DocumentEntry	patientId	R	R	R2
DocumentEntry	practiceSettingCode	R	R	R2
DocumentEntry	limitedMetadata	N/A	N/A	R
DocumentEntry	repositoryUniqueId	N/A	N/A	N/A
DocumentEntry	serviceStartTime	R2	R2	R2
DocumentEntry	serviceStopTime	R2	R2	R2
DocumentEntry	size	O	O	O
DocumentEntry	sourcePatientId	R	R	R2
DocumentEntry	sourcePatientInfo	O	O	R2
DocumentEntry	title	O	O	O
DocumentEntry	typeCode	R	R	R2
DocumentEntry	uniqueId	R	R	R
DocumentEntry	URI	O	O	O
SubmissionSet	author: authorPerson	R	R	R2

Metadata Element	Metadata Attribute	XDS Document Source	XDR Document Source	XDR Metadata-Limited Document Source
SubmissionSet	author: authorInstitution	O	O	O
SubmissionSet	author: authorRole	O	O	O
SubmissionSet	author: authorSpecialty	O	O	O
SubmissionSet	author: authorTelecommunication	O	O	R2
SubmissionSet	availabilityStatus	N/A	N/A	N/A
SubmissionSet	comments	O	O	O
SubmissionSet	contentTypeCode	R	R	R2
SubmissionSet	entryUUID	R	R	R
SubmissionSet	homeCommunityId	N/A	N/A	N/A
SubmissionSet	intendedRecipient	O	R2	R2
SubmissionSet	patientId	R	R	R2
SubmissionSet	limitedMetadata	N/A	N/A	R
SubmissionSet	sourceId	R	R	R
SubmissionSet	submissionTime	R	R	R
SubmissionSet	title	O	O	O
SubmissionSet	uniqueId	R	R	R
Folder	availabilityStatus	N/A	N/A	N/A
Folder	codeList	R	R	R2
Folder	comments	O	O	O
Folder	entryUUID	R	R	R
Folder	homeCommunityId	N/A	N/A	N/A
Folder	lastUpdateTime	N/A	N/A	N/A
Folder	patientId	R	R	R2
Folder	Title	O	O	O
Folder	uniqueId	R	R	R

3.41.4.1.3 Expected Actions

~~**The Provide and Register Document Set-b message shall include the metadata attributes (as defined in ITI TF-3: 4.1.7 Document Definition Metadata)**~~

A Document Recipient receives the metadata and the associated document(s). It shall be able to interpret the submission without any context (e.g., a prior submission). **The Document Recipient may validate the metadata as described in Table 3.41.4.1.2-2.**

If the Document Recipient declares the Accepts Limited Metadata Option it shall not reflect an error because the limitedMetadata attribute is present. Furthermore, if the Document Recipient chooses to validate the metadata and the limitedMetadata attribute is present, it shall validate in accord with the requirements in Table 3.41.4.1.2-2 column labeled "XDR Metadata-Limited Document Source".

The Document Source may include Folders in metadata. If the Document Recipient is not able to process the Folder specific content it shall return a PartialFolderContentNotProcessed warning which includes a textual description identifying that Folder Content was not processed. In this case the Document Recipient is expected to have processed the rest of the submission successfully.

In the case where the Document Source submits a replacement of documents, if the Document Recipient is not able to process the replacement semantics in the submission it shall return a PartialReplaceContentNotProcessed warning which includes a textual description identifying that the replacement semantics were not processed. In this case the Document Recipient is expected to have processed the rest of the submission successfully.

A Document Repository shall forward the metadata to the Document Registry using the Register Document Set-b transaction [ITI-42].

The Document Repository receives this message. Each document within the message shall be stored into the Document Repository as an octet stream with an associated MIME type.

~~**The Document Source shall supply all necessary document metadata attributes with the exception of the ones below.**~~ The Document Repository shall modify the received document metadata before initiating the Register Document Set-b transaction to the Document Registry by adding/replacing:

- The repositoryUniqueId for this Document Repository to allow for the Document Consumer to correctly identify the proper Document Repository for each document (XDSDocumentEntry.repositoryUniqueId).
- A hash value (XDSDocumentEntry.hash).
- A size (XDSDocumentEntry.size).

A Register Document Set-b transaction with this modified metadata shall be issued to the Document Registry.

The Document Repository shall ensure that when any Retrieve Document Set transaction is received requesting a specific document(s), it shall be provided to the Document Consumer unchanged from the octet stream that was submitted (full fidelity repository) and shall match the size and hash attributes of the XDSDocumentEntry object.

If the Document Repository or Document Recipient detects a failure it shall return an error message to the Document Source **or Metadata-Limited Document Source** thus terminating this

transaction. The conditions of failure and possible error messages are given in the ebRS standard and detailed in ITI TF-3: 4.1.13 Error Reporting.

3.41.4.1.3.1 Basic Patient Privacy Enforcement Option

If the Basic Patient Privacy Enforcement Option is implemented:

1. The Document Source actor shall populate the confidentialityCode in the document metadata with the list of values that identify the sensitivity classifications that apply to the associated document. The confidentiality codes for different documents in the same submission may be different.
2. The Document Source actor shall be able to be configured with the Patient Privacy Policies, Patient Privacy Policy Identifiers (OIDs) and associated information necessary to understand and enforce the XDS Affinity Domain Policy. The details of this are product specific and not specified by IHE.
3. The Document Source actor may have user interface or business rule capabilities to determine the appropriate confidentiality codes for each document. The details of this are product specific and not specified by IHE. However, the information about how confidentiality codes are assigned must be part of the published policy for the XDS Affinity Domain. Note: For example, when publishing a document, the Document Source, might show a list of checkboxes where a user can select which of the available consents a document is to be published.
4. The Document Recipient actor shall be able to be configured with the Patient Privacy Policies, Patient Privacy Policy Identifiers (OIDs) and associated information necessary to understand and enforce the policies. The meanings of the codes on the media must be provided out of band, e.g., by telephone, fax, or email. The detail of how this is done is product specific and not specified by IHE. If the documents are transferred internally within the organization or to other members of the recipient's affinity domain, appropriate internal confidentiality codes shall be applied.
5. The Document Recipient actor shall have the ability to coerce the confidentiality code in the metadata associated with the document from the codes used by the Document Source to the codes used by the Document Recipient.
6. The Document Recipient actor shall abide by the XDS Affinity Domain Policies represented by the confidentialityCode in the metadata associated with the document. The Document Recipient actor likely will have user access controls or business rule capabilities to determine the details of how confidentiality codes apply to query results. The details of this are product specific and not specified by IHE. These rules shall reduce the query results to only those that are appropriate to the current situation for that actor and user.

3.41.6 Actor Requirements

This section summarizes the responsibilities of the actors relevant to this transaction.

3.41.6.1 Document Source or Metadata-Limited Document Source

An implementation of the Document Source **or Metadata-Limited Document Source** actor shall be capable of the following operations:

- Submit one or more documents. Whether a submission contains a single or multiple documents depends on workflows, policies, and other external factors which are outside of the scope of this transaction.

An implementation of the XDS Document Source actor may support one or more of the following XDS.b options:

- **Document Replace Option:** In this option the Document Source offers the ability to submit a document as a replacement for another document already in the registry/repository.
- **Document Addendum Option** In this option the Document Source shall offer the ability to submit a document as an addendum to another document already in the registry/repository.
- **Document Transformation Option** In this option the Document Source shall offer the ability to submit a document as a transformation of another document already in the registry/repository.

Note: In order to support document replacement/addendum/transformation grouping with the Document Consumer may be necessary in order to Query the registry (e.g., for UUIDs of existing document entries)

- **Folder Management Option.** In this option the Document Source offers the ability to perform the following operation:
  - Create a folder
  - Add one or more documents to a folder

Note: In order to support document addition to an existing folder, grouping with the Document Consumer may be necessary in order to Query the registry (e.g., for UUIDs of existing folder).

These operations are discussed in ITI TF-3: 4.1.3.4 Other Properties of Submission Requests.

3.41.6.2 Document Repository or Document Recipient

A Document Repository or Document Recipient shall be capable of accepting submissions containing multiple documents.

Note: The Document Source may submit single documents or multiple documents depending on its needs.

A Document Repository shall validate the following metadata element received as part of a Provide and Register transaction:

- **XDSDocumentEntry.uniqueId** – a submission shall be rejected if not unique within the repository and the hashes of the two documents do not match. If the hashes of the documents match, the Document Repository shall accept the duplicate document.

A Document Repository or Document Recipient shall validate the following metadata element received as part of a Provide and Register transaction:

- **XDSSubmissionSet.sourceId** – a Document Repository or Document Recipient may choose to accept submissions only from certain sources and use this field to perform the filtering.
- **XDSDocumentEntry.hash** – a submission shall be rejected if the hash is included in the submission and its value does not match the hash for the received document (ignoring case), as calculated by the Document Repository or Document Recipient; an XDSRepositoryMetadataError shall be returned on mismatch.
- **XDSDocumentEntry.size** – a submission shall be rejected if the size is included in the submission and its value does not match the size of the received document, as computed by the Document Repository or Document Recipient; an XDSRepositoryMetadataError shall be returned on mismatch.

Volume 3 – Cross-Transaction Specifications and Content Specifications

ITI Volume 3: Update Section 4.1.7 to indicate that the requirements for Provide and Register can be found in the transaction:

The source/query column indicates which attributes are required during submission, and whether the registry must support the ability to execute queries against them. **Requirements for use of metadata in the Provide and Register Transaction are specified in ITI TF-2b: 3.41.4.1.2 and those for Distribute Document Set on Media are specified in ITI TF-2b: 3.32.4.1.2.2.**

Table 4.1-4 Codes for Source/Query Column

Code	Meaning
R	Required
R2	Required if Known
O	Optional
P	Registry is not required to support query of this attribute.
Cp	Computed/Assigned by Repository, required in register transaction.
Cg	Computed/Assigned by Registry
Cx	Optionally Computed/Assigned by a Document Registry
Rc	**Required for Metadata-Limited Document Source.**

ITI Volume 3: Update Section 4.1.7 Table 4.1-5 to add the new metadata element and footnote the Source column

Table 4.1-5 Document Metadata Attribute Definition

XDSDocumentEntry Attribute	Definition	Source[1]	Constraints
limitedMetadata	Indicates whether the Document Entry was created using the less rigorous requirements of metadata as defined for the Metadata-Limited Document Source. The Document Entry is flagged using an ebRIM Classification with a classificationScheme of `urn:uuid:ab9b591b-83ab-4d03-8f5d-f93b1fb92e85`. The following example marks the "DocEntry" Document Entry as created via the less rigorous metadata requirements. <ExtrinsicObject id="DocEntry"> (…) <Classification classifiedObject="DocEntry" classificationNode="`urn:uuid:ab9b591b-83ab-4d03-8f5d-f93b1fb92e85`"/> (…) </ExtrinsicObject>	Rc	ebRIM

ITI Volume 3: Update Section 4.1.8 Table 4.1-6 to add the new metadata element and footnote the Source column

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Table 4.1-6 Submission Set Metadata Attribute Definitions

XDSSubmissionSet Attribute	Definition	Source[2]	Constraints
limitedMetadata	A flag that the associated SubmissionSet was created using the less rigorous metadata requirements as defined for the Metadata-limited Document Source. Coding:	Rc	ebRIM

[1] Requirements for use of metadata in the Provide and Register Transaction are also specified in ITI TF-2b: 3.41.4.1.2. Requirements for use of metadata in the Distribute Document Set on Media transaction are specified in ITI TF-2b: 3.32.4.1.2.2 and not in this table.

[2] Requirements for use of metadata in the Provide and Register Transaction are also specified in ITI TF-2b: 3.41.4.1.2. Requirements for use of metadata in the Distribute Document Set on Media transaction are specified in ITI TF-2b: 3.32.4.1.2.2 and not in this table.

XDSSubmission Set Attribute	Definition	Source [2]	Const raints
	The SubmissionSet is flagged using an ebRIM Classification with a classificationScheme of `urn:uuid:5003a9db-8d8d-49e6-bf0c-990e34ac7707`. **The following example marks the "SubmissionSet" SubmissionSet as created via the less rigorous metadata requirements.** **<RegistryPackage id="SubmissionSet">** **(…)** **<Classification classifiedObject="SubmissionSet" classificationNode="urn:uuid:a54d6aa5-d40d-43f9-88c5-b4633d873bdd"/>** **<Classification classifiedObject="SubmissionSet" classificationNode="`urn:uuid:5003a9db-8d8d-49e6-bf0c-990e34ac7707`"/>** **(…)** **</RegistryPackage>**		

650 *ITI Volume 3: Update Section 4.1.9 Table 4.1-7 to add the new metadata element and footnote the Source column*

Table 4.1-7 Folder Metadata Attribute Definitions

XDSFolder Attribute	Definition	Source [3]	Const raints
limitedMetadata	**A flag that the associated Folder was created using the less rigorous metadata requirements as defined for the Metadata-Limited Document Source.** **Coding:** **The Folder is flagged using an ebRIM Classification with a classificationScheme of `urn:uuid:2c144a76-29a9-4b7c-af54-b25409fe7d03`.** **The following example marks the "Folder" Folder as created via the less rigorous metadata requirements.** **<RegistryPackage id="Folder">** **(…)**	Rc	ebRIM

[3] **Requirements for use of metadata in the Provide and Register Transaction are also specified in ITI TF-2b: 3.41.4.1.2. Requirements for use of metadata in the Distribute Document Set on Media transaction are specified in ITI TF-2b: 3.32.4.1.2.2 and not in this table.**

XDSFolder Attribute	Definition	Source [3]	Constraints
	<Classification classifiedObject=”Folder” classificationNode=”urn:uuid:d9d542f3-6cc4-48b6-8870-ea235fbc94c2” id=”ID_061" objectType="urn:oasis:names:tc:ebxml-regrep:ObjectType:RegistryObject:Classification"/> **<Classification classifiedObject="Folder" classificationNode="urn:uuid:2c144a76-29a9-4b7c-af54-b25409fe7d03"/>** **(…)** **</RegistryPackage>**		

