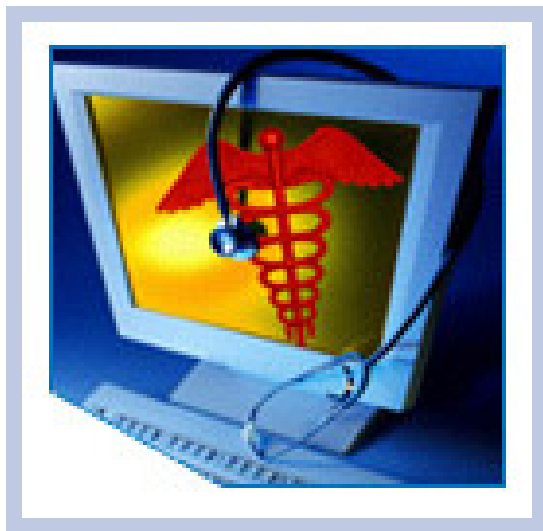


HITSP Sharing Radiology Results Transaction Package

HITSP/TP49



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RELEASED FOR IMPLEMENTATION



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1.0 INTRODUCTION

As an introduction to the HITSP Sharing Radiology Results Transaction Package, 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 the HITSP 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 Package Definition.

1.1 OVERVIEW

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

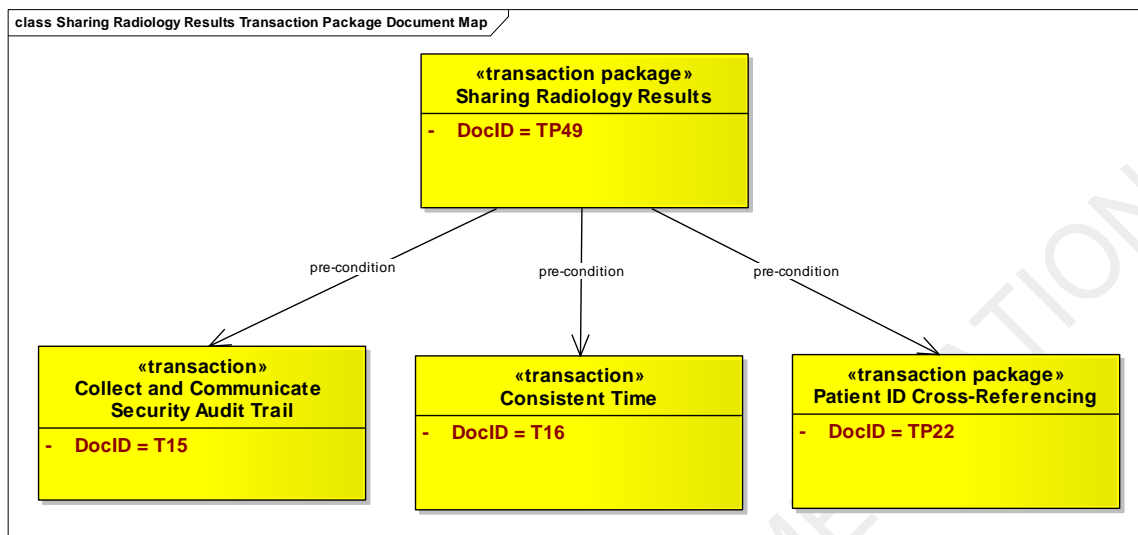
This Transaction Package supports the process of sharing radiology result data. Radiology result data are captured as part of the normal process of care performed by healthcare providers. This data can be made available through document sharing for both clinical care and public health purposes.

1.2 TRANSACTION PACKAGE DOCUMENT MAP

Each HITSP specification describes a suite of constructs that, taken as a whole, define 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 Sharing Radiology Results Transaction Package specification 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. The Document Map in Figure 1.2-1 depicts how this construct integrates and constrains HITSP constructs to support the information exchange, within the defined context of this document. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.



Figure 1.2-1 Transaction Package Document Map



1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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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 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.



Reference Document	Document Description
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
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"> • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A glossary of terms used in all the Security and Privacy construct documents • 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 <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>



2.0 TRANSACTION PACKAGE DEFINITION

Transaction Packages define how two or more Transactions are used to support a stand-alone information exchange within a defined context between two or more systems.

2.1 CONTEXT OVERVIEW

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

Per IHE-Rad-XDS-I

IHE IT Infrastructure has released the Cross-Enterprise Document Sharing (XDS) Integration Profile. It provides an integration solution to the problem of general-purpose document sharing in a broad healthcare environment.

This profile [XDS-I] specifies sharing of imaging “documents” such as radiology images and reports; it presents a solution for sharing imaging documents based on XDS. XDS-I extends XDS by sharing, locating and accessing DICOM instances from its original local sources, e.g., for radiologists or oncologists.

2.1.1 TRANSACTION PACKAGE CONSTRAINTS

This section describes the constraints that limit the context in which the Transaction Package 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.

Table 2.1.1-1 Transaction Package Constraints

Constraint
No applicable constraints

2.1.2 TECHNICAL ACTORS

This section describes the technical actors that need to be integrated in order to meet the interoperability requirements for this Transaction Package. A technical actor represents an entity internal to a software application, which is engaged in one or more specific Transactions to support a specific aspect of a real world information interchange (e.g., set of message exchanges). The table below lists the technical actors involved in the Transaction Package, 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.

All technical actors for this Transaction Package are described in Section 2.2 of IHE-Rad-XDS-I and as follows.

Table 2.1.2-1 Technical Actors

Actor	Description	Used in Component/ Standard	Transaction/Content	Optionality*
Imaging Document Source	The Imaging Document Source actor is the producer and publisher of imaging documents. It is responsible for providing imaging documents and metadata to the Document Repository actor, which subsequently registers the imaging documents with the Document Registry actor. It also supports the retrieval services for DICOM SOP Instances referenced in a published imaging manifest document.	HITSP/TP49	Provide and Register Imaging Document Set [RAD-54]	C[201]
			Retrieve Images [RAD-16]	R
			Retrieve Presentation States [RAD-17]	R
			Retrieve Reports [RAD-27]	R
			Retrieve Key Image Note [RAD-31], R	R
			Retrieve Evidence Documents [RAD-45]	R
			WADO Retrieve [RAD-55]	R
Document Source		HITSP/TP49	Provide & Register Document Set-b	C[202]
			Provide & Register Document Set	C[202]
Document Consumer	The Document Consumer actor queries a Document Registry actor for documents meeting certain criteria and retrieves selected documents from one or more Document Repository actors.	HITSP/TP49	Registry Stored Query	C[203]
			Retrieve Document Set	C[203]
			Stored Query	C[203]
Imaging Document Consumer	The Imaging Document Consumer actor parses an imaging manifest document that is retrieved by the Document Consumer actor from the Document Repository actor and retrieves DICOM SOP Instances referenced within that manifest from the Imaging Document Source actor.	HITSP/TP49	Retrieve Images [RAD-16]	C[206]
			Retrieve Presentation States [RAD-17]	O
			Retrieve Reports [RAD-27]	C[206]
			Retrieve Key Image Note [RAD-31]	O
			Retrieve Evidence Documents [RAD-45]	C[206]
			WADO Retrieve [RAD-55]	C[206]
Document Registry	The Document Registry actor maintains metadata about each registered document in a document entry. This includes a link to the Document Repository where the actual document is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of	HITSP/TP49	Patient Identity Feed	R
			Registry Stored Query	C[205]
			Provide & Register Document Set-b	C[205]
			Stored Query	C[205]



Actor	Description	Used in Component/ Standard	Transaction/Content	Optionality*
	document registration.		Provide & Register Document Set	C[205]
			Provide & Register Document Set (offline mode)	C[202]
Document Repository	The Document Repository actor persistently stores documents. It assigns and maintains a unique identifier for each document, to allow Document Consumers to retrieve them.	HITSP/TP49	Provide and Register Document Set-b	C[204]
			Register Document Set-b	C[204]
			Retrieve Document Set	C[204]
			Register Document Set	C[204]
			Provide & Register Document Set	C[204]
			Retrieve Document	C[204]
Patient Identity Source	The Patient Identity Source actor assigns a unique identifier to each instance of a patient as well as maintains a collection of identity traits.	HITSP/TP49	PIX Identity Feed	R

***NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.

Transaction/Content (T/C) Optionality Conditions

C[201] - At least one of the optional retrieve transactions is required to be supported. Refer to section 18.4 of IHE Radiology Technical Framework part 1 for additional requirements on the Imaging Document Consumer

C[202] - The Actor shall support at least one of these transactions

C[203] - The Document Consumer shall support either XDS.a transactions, XDS.b transactions or both. Where Identity Assertion is required, the Document Consumer shall support XDS.b (Registry Stored Query, Retrieve Document Set)

C[204] - The Document Repository shall support either XDS.a transactions, XDS.b transactions or both. Where Identity Assertion is required, the Document Repository shall support XDS.b (Provide & Register Document Set-b, Register Document Set-b, Retrieve Document Set)

C[205] - The Document Registry shall support either XDS.a transactions, XDS.b transactions or both. Where Identity Assertion is required, the Document Repository shall support XDS.b to query the registry (Registry Stored Query)

C[206] - Support of at least one of the three document types described by the options in section 18.2 of IHE Radiology Technical Framework part 1 is required

2.1.3 ACTOR INTERACTIONS

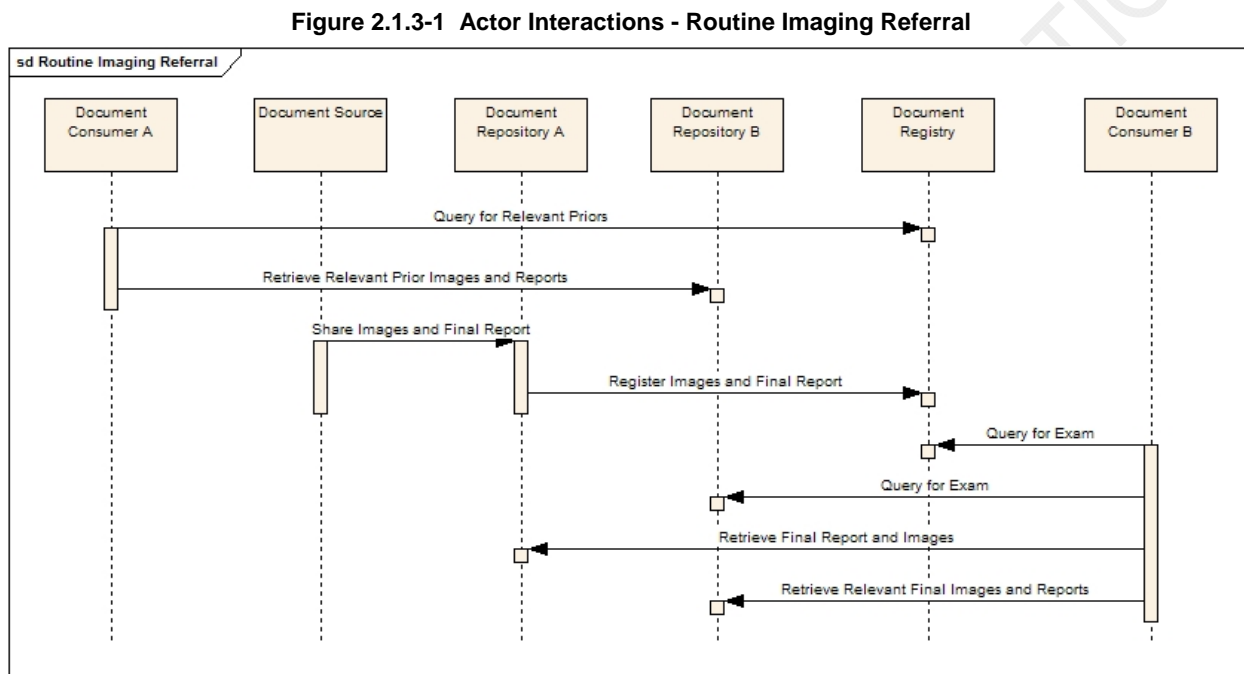
This section uses a Unified Modeling Language (UML) workflow diagram to depict the business and technical actors, the relevant events or actions in which they are involved and a mapping to the Transactions and Components that encapsulate the defined events/actions. It describes the underlying



events that fulfill the Transaction Package, the sequence and timing of the events and the specific actors involved. Process flow diagrams are also provided to illustrate the process relationships. A description of the UML diagram is also provided below the diagram.

All interactions associated with this Transaction Package can be found in Section 18 of IHE-Rad-XDS-I and are reproduced below.

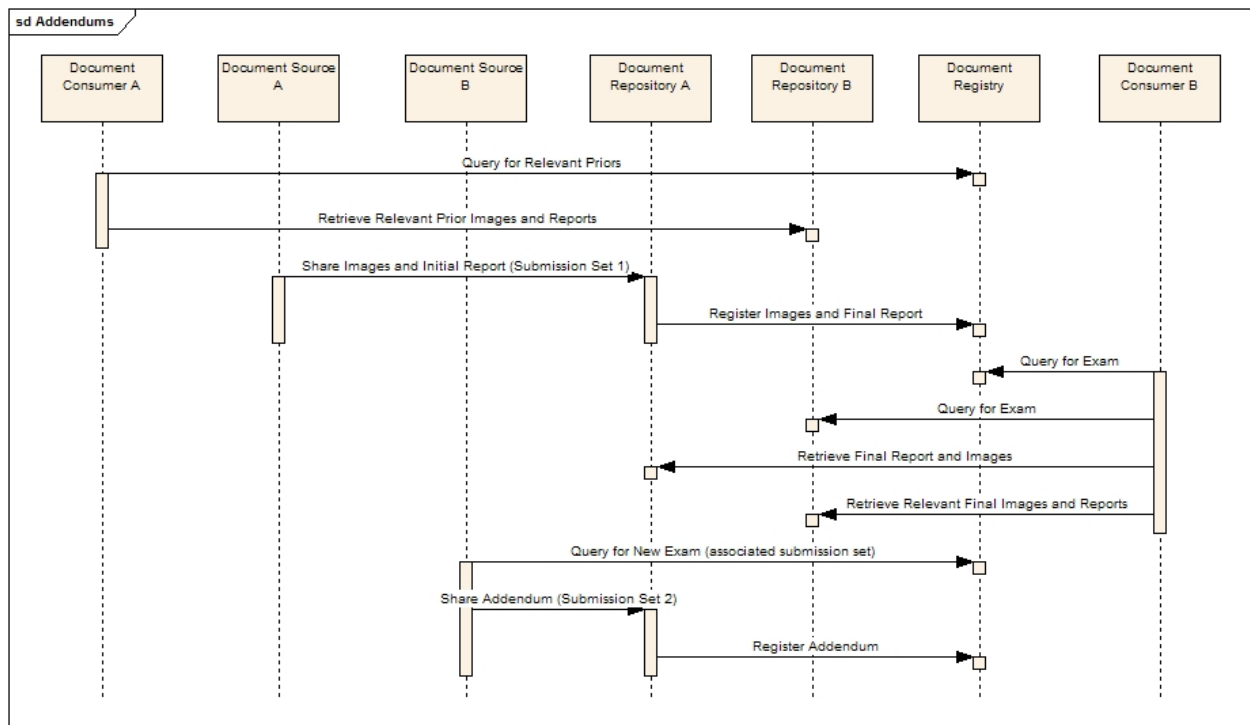
The following diagram shows the interactions involved in a routine imaging referral.



The following diagram shows the interactions involved in the case where an addendum is provided during the course of treatment.

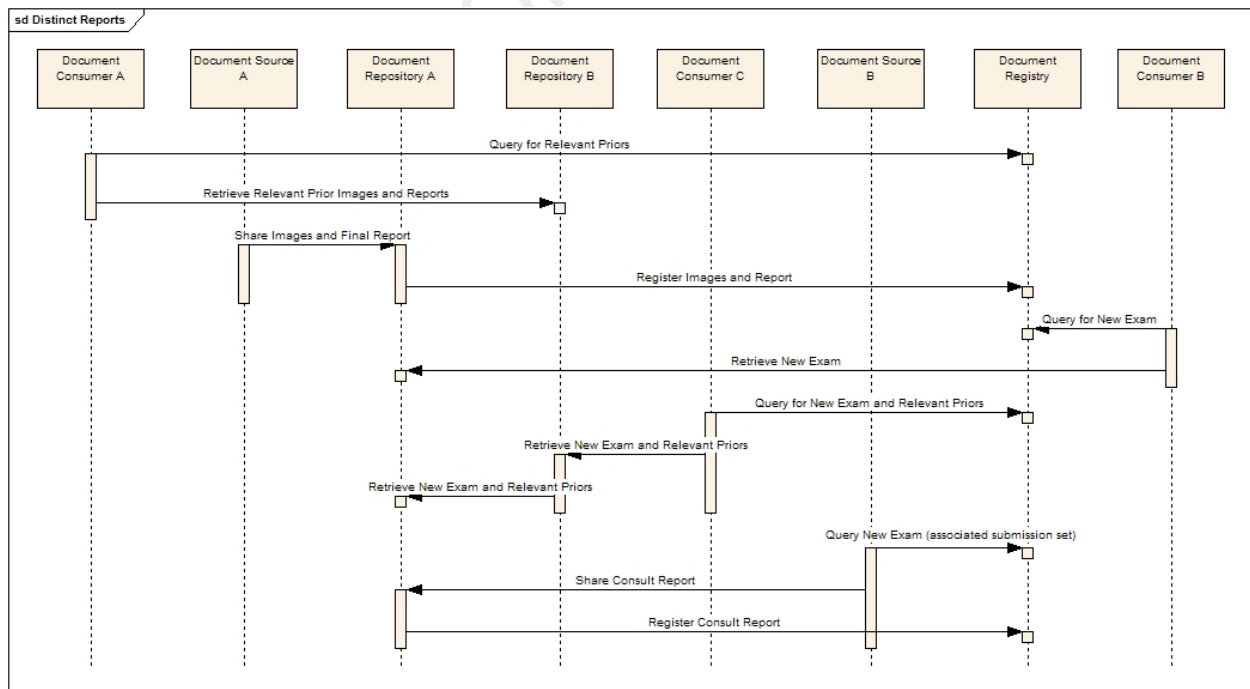


Figure 2.1.3-2 Actor Interactions - Addendums



The following diagram shows the interactions involved when separate and distinct reports are provided for the same imaging exam.

Figure 2.1.3-3 Actor Interactions - Distinct Reports



2.1.4 PRE-CONDITIONS

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

Table 2.1.4-1 Pre-conditions

Pre-condition
It is expected that the security framework under which this Transaction Package operates is in accordance with the Interoperability Specification that references this construct. Therefore all applicable HITSP Security and Privacy constructs are implemented as required
IHE Consistent Time Integration Profile is assumed as a Pre-condition to this Transaction Package (See HITSP/T16 - Consistent Time)
IHE ATNA Integration Profile is assumed as a Pre-condition to this Transaction Package (See HITSP/T15 - Collect and Communicate Security Audit Trail)
IHE Patient Identifier Cross-Referencing Integration Profile is assumed as a Pre-condition to this Transaction Package (see HITSP/TP22 - Patient ID Cross-Referencing)

2.1.4.1 Process Triggers

This section describes the triggers, including actors and/or processes, which are necessary to start the Transaction Package. They can invoke an automatic or manual process or result that in turn starts off the Transaction Package. A 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
Radiology images are ready for sharing

2.1.5 POST-CONDITIONS

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

Table 2.1.5-1 Post-conditions

Post-condition
Submitted imaging documents are successfully filed in the repository and their metadata are retrievable from the registry



2.1.5.1 Required Outputs

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

Table 2.1.5.1-1 Required Outputs

Required Output	Format/Usage
No applicable required outputs	

2.1.6 DATA FLOWS

This section describes the basic data flows that are supported by this Transaction Package. 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 Package. Any prevailing pre- and post-conditions are identified, as well as the purpose of each data post-condition associated with each Transaction Package. 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.

All process and data flows associated with this Transaction Package can be found in Section 18 of the IHE-Rad-XDS-I Integration Profile.

2.2 LIST OF CONSTRUCTS

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

Table 2.2-1 List of Constructs

Construct Name	Description	Content
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package	Manage Sharing of Documents is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package	The Patient ID Cross-Referencing (PIX) Transaction Package is a portion of the Interoperability Specifications that deals with identifying and cross-referencing different patient attributes for the same patient

2.2.1 CONSTRUCT DEPENDENCIES

The following table shows a list of constructs with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific Transaction Package specification.



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
Provide and Register Imaging Document Set	Patient Identity Feed	Pre-condition	Permit association of image documents with appropriate real or pseudo patient identifiers
WADO Retrieve Query Registry Retrieve Document Retrieve Images Retrieve Presentation States Retrieve Reports Retrieve Key Image Notes Retrieve Evidence Documents	Provide and Register Imaging Document Set <i>or</i> Register Document Set	Pre-condition	Define and populate domains containing imaging documents that may be queried and from which documents may be retrieved

2.2.2 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

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

All Constraints associated with this Transaction Package are specified in the IHE-Rad-XDS-I Integration Profile.

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 Package specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (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 Package 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 Package 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 Package specification, and a detailed description of each standard.

Table 2.3.2-1 Selected Standards

Standard	Description
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 8.0	The IHE Radiology Technical Framework specifies the Cross-Enterprise Document Sharing for Imaging (XDS-I) Integration Profile which enables sharing of imaging documents such as radiology images and reports across healthcare enterprises. XDS-I extends XDS by sharing, locating and accessing DICOM instances from its original local sources, e.g. for radiologists or oncologists. For more information visit www.ihe.net

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 Package specification.

Table 2.3.3-1 Informative Reference Standards

Standard Name	Description/Reason for Use
No applicable informative references	



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. A conformant system must also be constrained as specified in Table 2.1.1-1, and implement all of the required actors from Table 2.1.2-1, 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 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, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting 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.



5.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

5.1 MAY 11, 2007

This document is now Released for Implementation.

5.2 MARCH 19, 2008

This document has been updated to include the HITSP Security and Privacy constructs and has been updated to reflect the new template.

5.3 MARCH 27, 2008

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

5.4 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.

5.5 AUGUST 27, 2008

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

