

HITSP Sharing Radiology Results Transaction Package

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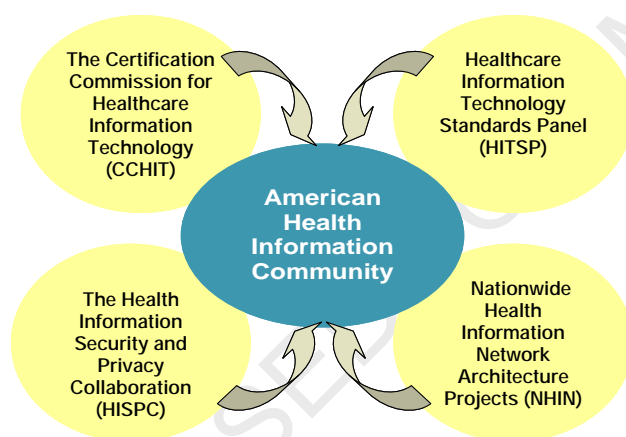
1.0 FOREWORD

This document is referred to as a Transaction Package and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.



The American Health Information Community¹ (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the

exchange of patient data (HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a nationwide health information network (NHIN). Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work in additional Use Case priority areas recommended by AHIC. This year, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record

¹ <http://www.hhs.gov/healthit/ahic.html>



products. In January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP² is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term “standard” refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including SDO work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

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

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

² www.hitsp.org



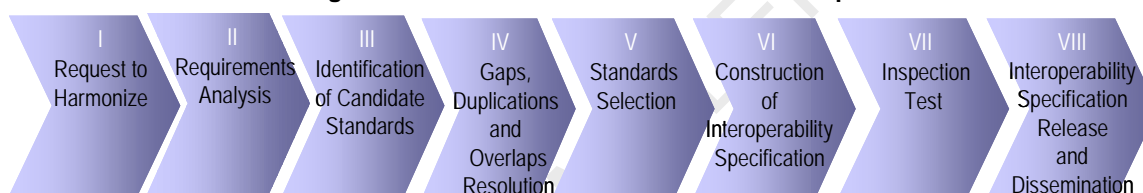
Use Case	Specific Scope of this Use Case
Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.

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

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three Use Cases (available at www.hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee followed an 8 step process, depicted below.

Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

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



2.0 INTRODUCTION

As an introduction to the HITSP Interoperability Specification: Sharing Radiology Results Transaction Package this section provides a high level overview of an information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to the HITSP Acronyms List and an explanation of the conventions used to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to Section 3.0.

2.1 OVERVIEW

This Transaction Package supports the sharing of radiology result data in a document sharing functional flow scenario. Radiology result data are captured as part of the normal process of care performed by healthcare providers.

2.2 TECHNICAL ASSUMPTIONS AND SCOPE

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

2.2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

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

2.2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document.



These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

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

2.2.4 IMPLEMENTATION TESTING

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

2.2.5 SECURITY AND PRIVACY

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

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the



need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP, based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes. Exceptions to the deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.

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

2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

2.4 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

© 2007 ANSI -This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE). Copies of this standard may be retrieved from the IHE at www.ihe.net.

2.5 ACRONYMS

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



2.6 CONVENTIONS

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



3.0 REFERENCED STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- Provisional - standards that are not yet but are expected to be approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
 - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
 - It is substantially the same as it was when it was provisionally used and
 - It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are roadmapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as "Intended for Use" because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use "Provisional" or "Interim" standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard "Intended for Use" is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of "Interim" and "Intended for Use" standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

The Population Health Technical Committee has focused its work around an analysis of the Biosurveillance Use Case provided by the American Health Information Community (AHIC). This work has also been informed by the proceedings of the AHIC Biosurveillance Data Steering Group (BDSG).



The Population Health TC has selected standards first in accordance with HITSP Tier 1 and Tier 2 criteria. The TC worked with USHIK to evaluate the metadata and repository for use in standards selection using demographic and encounter data as a test case. Note that the United States Health Information Knowledgebase (USHIK) provides and maintains a metadata registry of health information data element definitions, values and information models (www.ushik.org). The results and the resource will be used to extend this Interoperability Specification to additional domains and clinical data information exchange standards.

This TC has selected standards with more options than might otherwise be defined between communication partners. As Biosurveillance is based upon secondary use of clinical data, the processes and data capture options are somewhat opportunistic, and associated data mining processes have more latitude in translation and data preparation processes. Since it is important to maximize the data sources to contribute data to the biosurveillance information system, information exchange selections include options for data capture from both legacy environments and emerging environments. Vocabulary, message, and content standards have been selected in consideration of providing the most comprehensive, machine processable fulfillment of the data requirements provided by the AHIC BDSG.

3.1 LIST OF 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.

Table 3.1-1 List of Standards

Standard	Description
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 7.0	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. Visit www.ihe.net for more information.

3.2 LIST OF TRANSACTIONS

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

Table 3.2-1 List of Transactions

Transaction Name	Description	Document Name	Date Added
Provide and Register Imaging Document Set	Furnishes one or more image documents to a Document Repository and metadata to a Document Repository and Document Registry	IHE-Rad-54	9-2006
WADO Retrieve	Allows retrieval of image documents in DICOM format using HTTP/HTTPS protocols	IHE-Rad-55	9-2006
Register Document Set	Repository furnishes metadata to a Document Registry	IHE-ITI-14	9-2006
Query Registry	Searches for documents meeting a set of provider-supplied criteria, returns a list of corresponding document entries	IHE-ITI-16	9-2006



Transaction Name	Description	Document Name	Date Added
Retrieve Document	Returns documents, including multipart content, requested by a user	IHE-ITI-17	9-2006
Patient Identity Feed	Populates registry with patient identifiers (real and/or pseudo) that have been registered in an affinity domain	HITSP/ISTP-22	9-2006
Retrieve Images	Returns documents from an Imaging Document Source	IHE-Rad-16	9-2006
Retrieve Presentation States	Returns Grayscale Softcopy Presentation State (GSPS) information for an image or image set from an Imaging Document Source	IHE-Rad-17	9-2006
Retrieve Reports	Returns a diagnostic report from an Imaging Document Source	IHE-Rad-27	9-2006
Retrieve Key Image Note	Returns a Key Image Note from an Imaging Document Source	IHE-Rad-31	9-2006
Retrieve Evidence Documents	Returns an Evidence Document from an Imaging Document Source	IHE-Rad-45	9-2006

3.2.1 DEPENDENCIES

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

Table 3.2.1-1 List of Dependencies

Transaction Name	Depends On (Name of transaction that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
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

3.2.2 CONSTRAINTS

All Constraints associated with this transaction package are specified in IHE-Rad-XDS-I. No additional constraints are added by this HITSP Transaction Package.



4.0 TRANSACTION PACKAGES

4.1 CONTEXT OVERVIEW

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.

4.1.1 CONTEXTUAL CONSTRAINTS

No additional constraints are defined by this HITSP Transaction Package.

4.1.2 BUSINESS ACTORS

A Business Actor is a representation of a person, IT system, organization or any combination that is engaged, and benefits from the real world information interchange defined by a business Use Case.

The following Business Actors may interact with technical actors within this Transaction Package:

Table 4.1.2-1 List of Business Actors

Actor	Description
Clinician	In ambulatory and emergency department settings, the healthcare providers within Healthcare Delivery Organizations with direct patient interface in the delivery of care, including physicians, nurses, clinical supervisors. These business actors are involved in providing image data to the registry and repository, but are not specifically depicted within the transactions defined in this Transaction Package.

4.1.3 TECHNICAL ACTORS

All Technical Actors for this transaction package are described in Section 2.2 of IHE-Rad-XDS-I, as follows.

Table 4.1.3-1 List of Technical Actors

Actor	Description
Imaging Document Source	The Imaging Document Source actor is the producer and publisher of imaging documents. It is responsible for providing imaging documents and meta-data 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.
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.



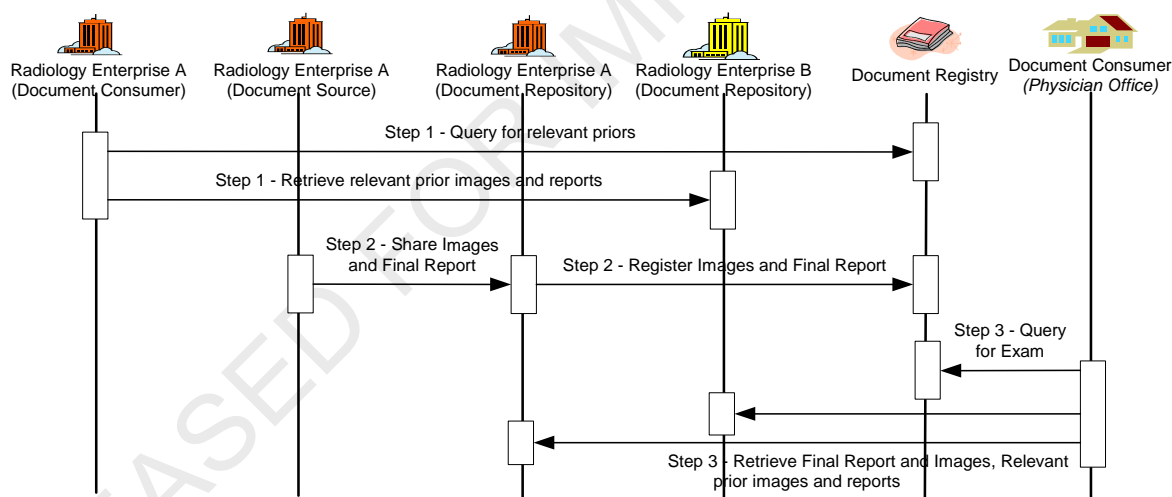
Actor	Description
Imaging Document Consumer	The Imaging Document Consumer actor parses an imaging manifest document that is retrieved by the Document Consumer actor from the Document Repository actor, and retrieves DICOM SOP Instances referenced within that manifest from the Imaging Document Source actor.
Document Registry	The Document Registry actor maintains meta-data 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 document registration.
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.
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.

4.1.4 ACTOR INTERACTIONS

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.

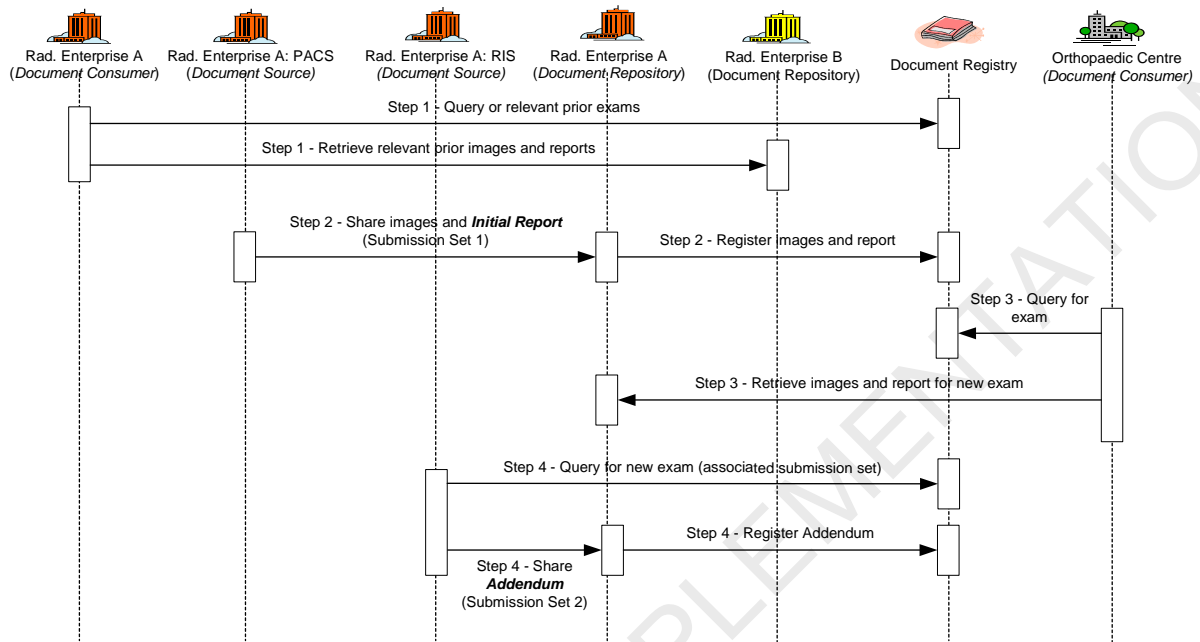
Figure 4.1.4-1 Actor Interactions - Routine Imaging Referral



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

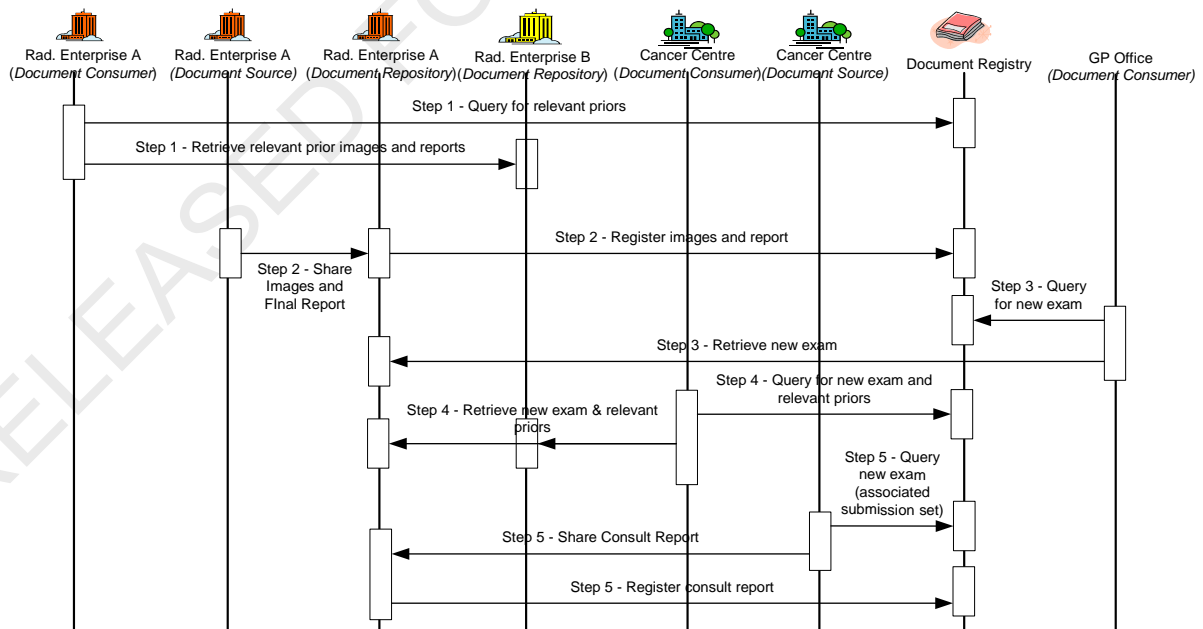


Figure 4.1.4-2 Actor Interactions - Addendums



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

Figure 4.1.4-3 Actor Interactions - Distinct Reports



4.2 PROCESS FLOWS

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

4.2.1 PROCESS PRE-CONDITIONS

IHE Consistent Time Integration Profile is assumed as a precondition to this transaction package.

IHE ATNA Integration Profile is assumed as a precondition to this transaction package.

IHE Patient Identifier Cross-Referencing Integration Profile is assumed as a precondition to this transaction package.

4.2.2 PROCESS POST-CONDITIONS

Submitted imaging documents are successfully filed in the repository and their metadata are retrievable from the registry.

4.3 DATA FLOWS

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



5.0 CHANGE HISTORY

5.1 MAY 11, 2007

This document is now Released for Implementation.

