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Ministry of Health



National eHealth Strategy and Change Management Office
(SCMO)

Enabling Standards-Based eHealth Interoperability

IS0005
Saudi eHealth Core Interoperability Specification for
Sharing Images and Imaging Reports

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Reports

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TABLE OF CONTENTS

1. INTRODUCTION	3
1.1 DOCUMENT PURPOSE.....	3
1.2 DESCRIPTION	3
1.3 SCOPE	3
1.4 METHODOLOGY	4
1.5 HOW TO READ THIS DOCUMENT	4
1.5.1 Where to Find Information	4
1.5.2 Related Documents	5
1.5.3 Document Conventions.....	6
2. USE CASE.....	8
2.1 USE CASE ACTORS AND SERVICES.....	8
2.2 DESIGN CONSTRAINTS AND ASSUMPTIONS	9
2.3 USE CASE FLOW OF EVENTS	10
2.3.1 Specific Workflow Scenarios.....	10
3. INTEROPERABILITY SPECIFICATION REQUIREMENTS	14
3.1 ACTOR MAPPING TO SAUDI EHEALTH IS SPECIFICATIONS.....	14
3.2 INTEROPERABILITY SEQUENCE DIAGRAMS	21
3.2.1 Main Flow Sequence Diagram.....	21
3.2.2 Amended Report (with optional Notification) sequence Diagram	27
4. CONFORMANCE TO THE SHARING IMAGES AND IMAGING REPORTS SPECIFICATION	31
4.1.1 Imaging Information Source Conformance	31
4.1.2 Imaging Information Consumer Conformance	32
4.1.3 Imaging Report Consumer Conformance	34
4.1.4 Imaging Repository Conformance	35
5. SAUDI EHEALTH CONSTRAINTS ON THE IHE CROSS-ENTERPRISE SHARING OF IMAGING INFORMATION (XDS-I) PROFILE AND DICOM STORAGE	38
5.1 REQUIREMENTS FOR IMAGING INFORMATION SOURCE USE CASE ACTOR	38
5.2 REQUIREMENTS FOR IMAGING INFORMATION CONSUMER USE CASE ACTOR	45
5.3 REQUIREMENTS FOR IMAGING REPORT CONSUMER USE CASE ACTOR	49
5.4 REQUIREMENTS FOR IMAGING REPOSITORY USE CASE ACTOR	50
6. REFERENCED DOCUMENTS AND STANDARDS.....	52
7. APPENDIX A – IMAGING MANIFEST DATA ATTRIBUTES	54
8. APPENDIX B – EXAMPLE MESSAGES	55

LIST OF TABLES

TABLE 2.1-1 USE CASE ACTORS	8
TABLE 2.1-2 USE CASE SERVICES	8
TABLE 3.1-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING INFORMATION SOURCE	15
TABLE 3.1-2 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING INFORMATION CONSUMER	16
TABLE 3.1-3 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING REPORT CONSUMER.....	18
TABLE 3.1-4 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING REPOSITORY	19
TABLE 5.1-1 ATNA DATA REQUIREMENTS FOR BEGINNING THE TRANSMISSION OF DICOM SOP INSTANCES	39
TABLE 5.1-2 ATNA DATA REQUIREMENTS FOR SUCCESSFUL TRANSMISSION OF DICOM SOP INSTANCES	40
TABLE 5.2-1 ATNA DATA REQUIREMENTS FOR SUCCESSFUL TRANSMISSION OF DICOM SOP INSTANCES	47
TABLE 6-1 INTERNAL REFERENCES	52
TABLE 6-2 EXTERNAL REFERENCES	53
TABLE 7-1 KEY LOGICAL DATA ATTRIBUTES FOR IMAGING MANIFEST	54

LIST OF FIGURES

FIGURE 1.5.2-1 SHARING IMAGES AND IMAGING REPORTS DOCUMENT ORGANIZATION	6
FIGURE 3.2.1-1 SHARING IMAGES AND IMAGING REPORTS SEQUENCE DIAGRAM (1).....	24
FIGURE 3.2.1-2 SHARING IMAGES AND IMAGING REPORTS SEQUENCE DIAGRAM (2).....	27
FIGURE 3.2.2-1 AMENDED REPORT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (1)	29
FIGURE 3.2.2-2 AMENDED REPORT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (2)	30

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1. INTRODUCTION

1.1 DOCUMENT PURPOSE

The purpose of this document is to address the Saudi eHealth Core Interoperability Specification for the Sharing Images and Imaging Reports. It forms a set of requirements that complements the set of IHE Profiles and DICOM Standards required by this specification with Saudi eHealth specific constraints. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Core Interoperability Specification is applicable to existing and new information systems to be connected to the national Saudi eHealth Exchange (SeHE) platform.

1.2 DESCRIPTION

This Core Interoperability Specification describes the technical requirements for the interface to share imaging reports and images via the Saudi eHealth Exchange (SeHE). This includes reports and images acquired on a broad range of imaging modalities. Two common examples are to store images and reports about a patient's current imaging procedure and the ability to access images/reports from imaging studies previously performed for that patient.

The data content shared are:

1. DICOM SOP Instances – various DICOM objects such as images, key image notes, presentations states, evidence documents, etc.
2. Imaging Manifest - a DICOM SOP Instance (i.e. Key Object Selection) that describes and collects references to the images and associated DICOM objects generated for a patient's imaging study.
3. Imaging Report – the physician's diagnostic report associated with the imaging study identified in its Imaging Manifest.

1.3 SCOPE

In Scope:

The scope of this document is the specification of how various Health IT systems are able to share images and imaging reports within the KSA. This specification supports the Saudi eHealth Sharing of Images and Imaging Reports Use Case.

The following topics are in scope for this Interoperability Specification:

- Use of IHE Cross-Enterprise Document Sharing (XDS.b) and IHE Cross-Enterprise Document Sharing for Imaging (XDS.b-I) Integration Profiles to store and consume images, imaging reports and imaging manifests
- Sharing the images, imaging reports and imaging manifests via an Imaging Repository on the SeHE Platform.

Out of Scope:

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

- Local hospital imaging workflow (i.e., imaging orders, imaging acquisition, etc.) is outside the scope of this Interoperability Specification.
- How local Health IT systems reconcile their local patient IDs and local imaging coded data elements (such as radiology imaging procedure codes, accession numbers, etc.) with the KSA-Wide codes and identifiers are outside the scope of this Interoperability Specification.
- Exchange of images on CD/DVDs is outside the scope of this Interoperability Specification.

1.4 METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated use case. These high-level requirements are not restated in this specification and readers may consider reviewing the related Use Case document.

1.5 HOW TO READ THIS DOCUMENT

1.5.1 Where to Find Information

This document contains four normative sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Contains an introduction to the Interoperability Specification (IS). This section contains a summary of the IS purpose and scope, as well as other content to help orient the first time reader to the topic of the IS and how it relates to other specifications in the SeHE architecture.

Section 2: Describes the use case, including design constraints and assumptions and the flows of information that will be specified in this IS. Section 2 also introduces scenarios that describe how the specified flows may be used in the Saudi eHealth context.

Section 3: Establishes the Core Interoperability Requirements for the Interoperability Specification

Section 4: Establishes the Conformance Requirements for the Interoperability Specification.

Section 5: Establishes the Saudi eHealth Constraints on the IHE Cross-Enterprise Sharing of Imaging Information (XDS-I) Profile and DICOM Storage.

Section 6: Lists the Saudi eHealth reference documents, as well as the international standards which underpin the Interoperability Specification.

Appendix A: Provides key imaging manifest data attributes

Appendix B: Provides IHE XDS-I sample messages

1.5.2 Related Documents

The Saudi eHealth Core Interoperability Specification (IS) is the sole entry point for the technology developers, the compliance assessment testing and certification, and the purchaser of IT systems in term of technical requirements.

It references a number of supporting Interoperability Specifications:

- *IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*
- *IS0101 Saudi eHealth Security and Privacy Interoperability Specification*
- *IS0102 Saudi eHealth Document Sharing Interoperability Specification*
- *IS0200 Saudi eHealth Terminology Repository*
- *IS0103 Saudi eHealth Radiology Report Content Interoperability Specification*
-

The above Saudi eHealth Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Saudi specific constraints. They also may be reused by other Core Interoperability Specifications.

This document fits into an overall specification framework described in Figure 1.5-1 Sharing Images and Imaging Reports Document Organization. Further descriptions and references for the documents identified below are provided in Section 6.

Implementations are required to conform to the requirements within this Core Interoperability Specification; all Saudi eHealth referenced Interoperability Specifications and the standards and profiles they specify.

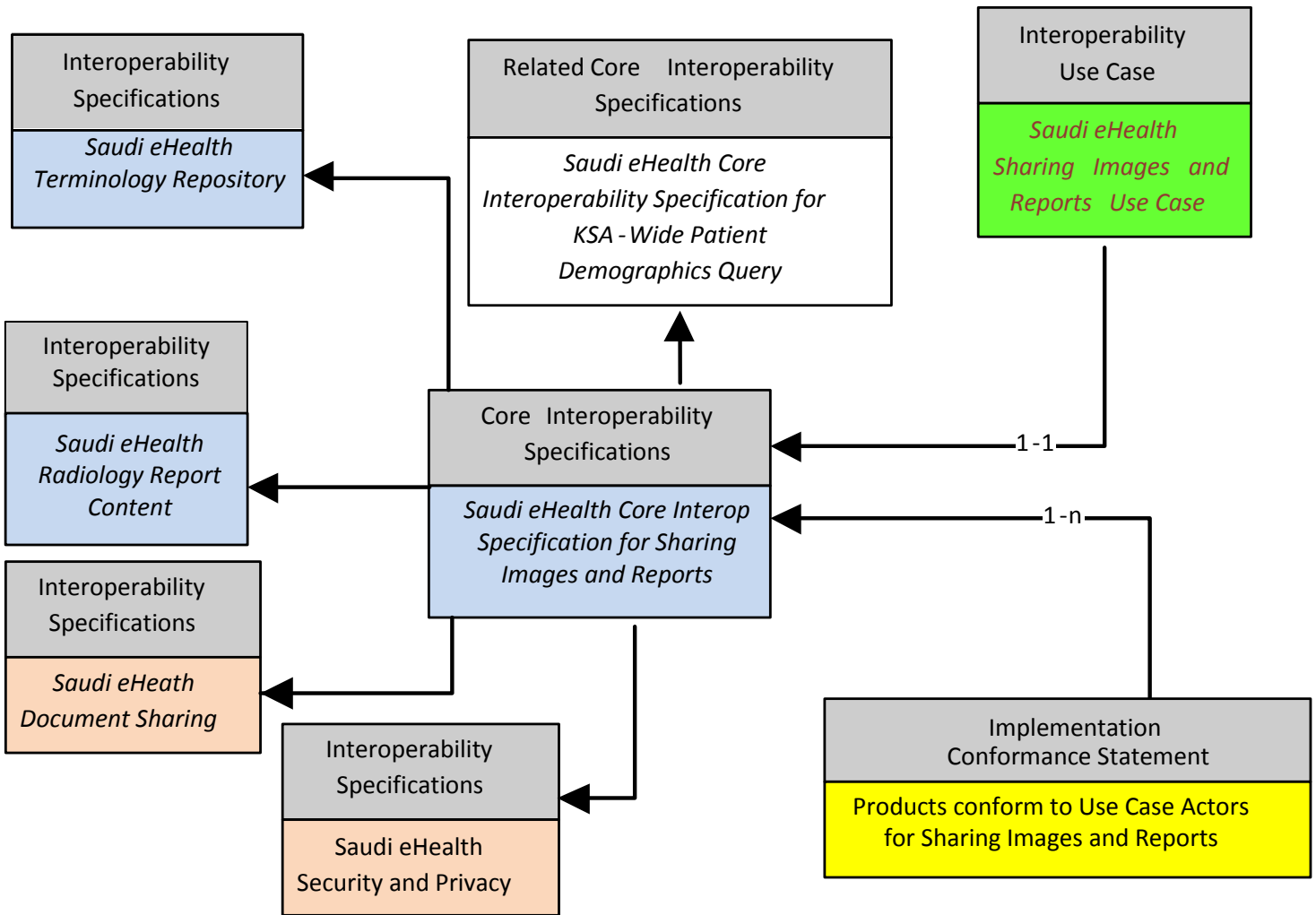


FIGURE 1.5-1 SHARING IMAGES AND IMAGING REPORTS DOCUMENT ORGANIZATION

1.5.3 Document Conventions

1.5.3.1 REQUIREMENTS NUMBERING CONVENTIONS:

All Saudi eHealth Interoperability Specifications contain numbered requirements that follow this format:

- [ABCD-###], where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and ### is the unique number for that requirement within the Interoperability Specification.
- Where a specific value set or code is required to be used, it can be found in the “IS0200 Saudi eHealth Terminology Repository”. The location and process to access the terminology repository will be specified in mechanisms external to this document.

Saudi eHealth numbered requirements are the elements of the Interoperability Specification that the system can claim conformance to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.

Please note that all Saudi eHealth numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

1.5.3.2 REQUIREMENTS LANGUAGE

Throughout this document the following conventions¹ are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification. (Note: “SHALL IF KNOWN” means that the tag must be sent. However, if there were no information, then this tag should be sent with a <nullflavor>).

SHALL NOT: the definition is an absolute prohibition of the specification.

SHOULD: there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

SHOULD NOT: there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

MAY or OPTIONAL: means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

¹ Definitions based upon RFC 2119

2. USE CASE

2.1 USE CASE ACTORS AND SERVICES

The Use Case Actors and the Services that are used by this Core Interoperability Specification are described at a functional level in the Saudi eHealth Interoperability Use Case document. Readers that wish to understand the mapping of Use Case Actors to real world products are recommended to read this Saudi eHealth Interoperability Use Case document. A brief description is provided in the following tables.

TABLE 2.1-1 USE CASE ACTORS

USE CASE ACTOR NAME	DESCRIPTION
Imaging Information Source	This Actor is a publisher of imaging documents. This includes a manifest document (i.e. identifies the series of images within an imaging study), images and imaging reports.
Imaging Information Consumer	The Actor queries and retrieves imaging manifest documents and retrieves the images referenced within that manifest from the Imaging Repository Actor.
Imaging Report Consumer	This Actor is responsible for querying and retrieving imaging diagnostic reports from the Imaging Repository.
Imaging Repository	This Repository provides long term storage of the images, imaging reports and imaging manifests. It also maintains metadata about each registered document. Responds to other Actors that query and retrieve imaging manifests, images and report documents.

How actual implementations support Use Case Actors may vary. Some of the Use Case Actors may be implemented through a single system or integrated set of systems provisioned by a single vendor. Others may be implemented by multiple systems or integrated sets of systems provisioned by multiple vendors. As described in Section 3, a single Use Case Actor is a logical grouping of multiple IHE Technical Framework actors, referred to as Technical Actors in the tables and figures in Section 3. Technical Actors may be fulfilled by multiple systems or integrated sets of systems provisioned by one or multiple vendors.

In specific implementation situations the vendor boundary does not align with the Use Case Actor. For example, a point of service system is from one vendor, while a gateway system which converts the point of service system to the Use Case Actor is from a different vendor. The interface between the two systems is not specified by this Core Interoperability Specification and is the responsibility of the implementation project.

TABLE 2.1-2 USE CASE SERVICES

USE CASE SERVICE NAME	DESCRIPTION
Publish Document(s)	Publish Document(s) is used by the Imaging Information Source to provide a set of documents (Imaging Manifests, reports) to the Imaging Repository and to request that it stores these documents and register their metadata.

Send Images	This service is used by the Imaging Information Source to transmit sets of images to the Imaging Repository.
Query/Retrieve Document(s)	This Service is used by the Imaging Information Consumer to query the Imaging Repository for information about documents stored and indexed by metadata and retrieve one or more relevant documents. This includes imaging reports and Imaging Manifests.
Notification of Document Availability	This service is issued by the Imaging Repository to notify an Imaging Information Consumer Actor of an imaging report and/or imaging manifest of interest that is available to be retrieved.
Retrieve Images	This service is used by the Imaging Information Consumer to retrieve sets of images from Imaging Repository Actor(s).

2.2 DESIGN CONSTRAINTS AND ASSUMPTIONS

The following design principles underlie this Interoperability Specification:

- It is expected that all services initiated or provided by these Actors operate in accordance to the Saudi Health Information Exchange Policies.
- The Use Case Flow of Events and the additional scenarios provided in Section 2.3 provide workflow assumptions.
- As a result of an imaging order within an authorized provider, an imaging study has been performed on a patient. This results in images, an imaging manifest and diagnostic report.
- The Imaging Repository will accept any DICOM image object with a SOP Class standardized by DICOM. (Note: SeHE may further restrict this list as a configuration choice). This includes diagnostics imaging modality generated images (e.g. CT, MR, Angiography X-Ray) as well as some multi-media consumer format encapsulated in DICOM SOP Classes to ensure an appropriate patient/acquisition header data (JPEG, MPEG, etc.). Note that images can also be embedded within some report formats (e.g. PDF).
- The complete set of images for a patient's study must be successfully sent to the Imaging Repository before the Imaging Manifest can be published (i.e. do not publish a manifest that references the patient's images until all the images are available in the Imaging Repository).
- Along with the Imaging Report and the Imaging Manifest, a set of required metadata has to be created by the Imaging Information Source and recorded in the Imaging Repository in order to allow Imaging Report Consumer and Imaging Information Consumer Actors to select relevant imaging reports and studies.
- It is the responsibility of the receiving Use Case Actors (Imaging Information Consumer and Imaging Report Consumer) to reconcile their local patient IDs and imaging coded data elements with the KSA-Wide Health ID and nationally specified Radiology Imaging Procedures codes and other coded information in the images, Imaging Manifest and report.

- It is expected that images retrieved from the Imaging Repository are able to be displayed, such as:
 - In the case of relevant priors, “side by side” display with images from the new imaging study (i.e. comparison of the old and new images) is expected.
 - For other scenarios, such as on-demand review of images (e.g. triggered by a remote consultation request).
- Document metadata subscription to receive notifications is expected to happen at the install/configuration time. This simplifies implementation until specific need for dynamic subscription has been identified.

2.3 USE CASE FLOW OF EVENTS

The Saudi eHealth Interoperability Use Case document describes the key workflows that are supported by this Core Interoperability Specification. A brief summary of the Use Case flows are provided below. For an in-depth understanding of the Use Case flows, it is recommended to read the Use Case document.

Main Flow: Imaging Information Source Use Case Actors publish images and imaging reports to the Imaging Repository. The Imaging Repository resides in the SeHE platform. Imaging Information Consumers/Imaging Report Consumers Use Case Actors that retrieve images and/or imaging reports from the Imaging Repository.

- **Alternative Flow 1:** Imaging Information Source Use Case Actors may be notified when the imaging documents are accessible within the Imaging Repository. For instance, this notification alerts the ordering physician that images and the imaging report are available for review.
- **Alternative Flow 2:** The radiologist that created the original report determines that important information was left out of the report. The radiologist creates an amended report to add the missing information. The Imaging Information Source actor publishes the amended report to the Imaging Repository. This new report references the original report and informs the Imaging Repository that it is an amendment to the original.

2.3.1 Specific Workflow Scenarios

The following sections provide various scenarios that complement the use case flow of events by using the defined transactions in a specific way. Some of these scenarios highlight variants to the use case flow of events while others describe local workflow situations that are beyond the scope of the use case but consistent with it. These workflow scenarios are not intended to be an exhaustive list.

2.3.1.1 SCENARIO 1: BASIC –PRE-FETCHING FOR A NEW RADIOLOGY ORDER

A patient is scheduled for a radiology imaging study at Healthcare Organization A. A search is performed to determine if related image sets and/or reports for the patient are available in the

Imaging Repository. After a successful match, the images/reports are automatically transmitted to the local Healthcare Provider and/or Organization for review

This scenario is a sub-set of the use case main flow of events.

2.3.1.2 SCENARIO 2: AD HOC OR ON-DEMAND IMAGE FETCH FROM IMAGING REPOSITORY

Ad hoc or “select from a list” queries require a user interface. The user interface is populated via a patient-based query made from the Healthcare Provider and/or Organization to the Imaging Repository (i.e., get a list of all imaging information that may be relevant to this patient). This user interface integration is outside the scope of this specification although the tag morphing discussion will apply to import the images and reports. For example, the local Patient ID may be different in separate Healthcare Organizations than the national Health ID.

This scenario is a sub-set of the use case main flow of events.

Note: It may be preferable to retrieve information prior to the patient’s visit (for performance reasons) rather than waiting to select from a list manually.

2.3.1.3 SCENARIO 3: PRE-FETCH OF RELEVANT PRIORS FROM IMAGING REPOSITORY INTO LOCAL HOSPITAL INITIATED BY PATIENT VISIT (NON-RADIOLOGY WORKFLOW)

There are other clinical areas such as oncology or neurology which need to view imaging studies and reports from multiple sites. For example, a follow-up, second opinion, consult, or treatment, visit may benefit from automatic pre-fetching based on scheduling or arriving message from a non-radiology scheduling system. Therefore a search is performed based upon the patient and the information in the scheduling and/or arrival message. After a successful match, the images/reports are automatically transmitted to the search location.

Furthermore, the pre-fetch criteria based on the originating system may be used differently. For example, a neurologist may not care what the modality type is (modality = “all”), but “Coarse Body Part” may only be neurology related (e.g. head or spine). An oncologist may want to see all available information. In this scenario the clinician (e.g., neurologist or oncologist) is able to review the images on the local Hospital system.

This scenario is a sub-set of the use case main flow of events.

2.3.1.4 SCENARIO 4: REPORT-ONLY PRIOR RETRIEVAL

There may be cases where physicians (e.g. referring physicians) only want to see prior reports and not sift through thousands of images.

From a system architecture perspective, it is preferable to have a viewer to view the report(s), which can typically be retrieved in a very short amount of time (as opposed to very large image sets). An ad hoc (on demand) query based on the patient’s Health ID would be sufficient to deliver the list of available reports. When the retrieve is performed, the application only requests the reports for the specific patient to be transferred.

This scenario is a sub-set of the use case main flow of events.

2.3.1.5 SCENARIO 5: REPORT IS AMENDED AFTER PRE-FETCH HAS OCCURRED TO LOCAL SYSTEM

An Imaging Report Consumer Use Case Actor queries and retrieves a patient's report from the Imaging Repository. There exists a condition where a report could be amended after it has been pre-fetched and stored locally to a different institution. It is advisable at the time of access by the local clinician to have the Use Case Actor that has pre-fetched this report to re-query the Imaging Repository to verify that it has not been deprecated and replaced by an amended report. If the pre-fetched report has been deprecated, then the Imaging Report Consumer retrieves the amended report.

This scenario is a sub-set of the use case Alternative Flow 2 events.

2.3.1.6 SCENARIO 6: IMAGES ARE ADDED/CHANGED AFTER PRE-FETCH HAS OCCURRED TO LOCAL SYSTEM

An Imaging Information Consumer Use Case Actor queries and retrieves a patient's images from the Imaging Repository. There exists a condition where additional images could be created or annotated after the study has been pre-fetched to a different institution. It is advisable at the time of access by the local clinician to have the Use Case Actor that has pre-fetched this imaging manifest to re-query the Imaging Repository to verify that an amended imaging manifest has not been deprecated and replaced by an amended manifest pointing at additional images. If the pre-fetched report has been deprecated, then the Imaging Information Consumer retrieves the additional images, and/or associated documents.

This scenario is a sub-set of the use case Alternative Flow 2 events.

2.3.1.7 SCENARIO 7: EMERGENCY PATIENT COMES IN AND IS IMAGED AT LOCAL SITE

If an emergency patient is unknown (i.e. cannot obtain/query its national Health ID), images that have been acquired (and possibly reported) are to remain local. Upon identifying the patient, the Use Case Actor queries the SeHE System to obtain the Health ID for the patient. The Health ID is used for the patient's records and the images/reports will be shared in the Imaging Repository. *This scenario defines local workflow that is outside the scope of the use case.*

Once the national Health ID is identified this scenario follows the use case main flow of event.

2.3.1.8 SCENARIO 8: AN IDENTIFIED EMERGENCY PATIENT COMES IN AND IS IMAGED BUT NOT YET REPORTED, WHEN THE PATIENT NEEDS TO BE TRANSFERRED TO ANOTHER SITE

If the patient is identified and their national Health ID matched, these images may be shared using its Health ID before the report is completed. This will allow the other site to use the images from the original site and not repeat the image acquisition. This is accomplished by having an Imaging Information Source Use Case Actor publish the images on the Imaging Repository. When the patient arrives at the second site, an Imaging Information Consumer Use Case Actor uses the patient's Health ID to query and retrieve the images from the Imaging Repository.

This is an exception to the use case main flow of events.

2.3.1.9 SCENARIO 9: AN UNIDENTIFIED EMERGENCY PATIENT COMES IN AND IS IMAGED BUT NOT YET REPORTED, WHEN THE PATIENT NEEDS TO BE TRANSFERRED TO ANOTHER SITE

If the patient is unidentified, and an imaging study is performed, these images may be shared into a HIE platform if the patient receives temporary Health ID. Otherwise, the imaging study will remain local, as only identified with a local patient ID.

Once a temporary or permanent Health ID is identified this scenario follows the use case main flow of event.

2.3.1.10 SCENARIO 10: SPLIT IMAGING PROCEDURES

For various imaging procedures it is useful for local PACS systems to “split” the imaging procedure. For example, a patient is having a CT “chest, abdomen, and pelvis” imaging study. Quite often this study is acquired with one DICOM imaging study. However, some PACS systems do not wish to keep this type of procedure as one imaging study and will “split” the study, for example, create one study for each body part (i.e. three studies). If this occurs, there are two typical workflows:

1. The “split” occurs before the information is shared with the Imaging Repository; therefore the workflow is very similar to the main workflow, except the PACS would share “three” studies, one for each “split” study with the relevant subset of information (i.e., images, imaging manifest and report). These three imaging manifests, sets of images and reports would all be linked to the same global accession number in the XDS metadata. This scenario is a sub-set of the use case main flow of events.
2. The “split” occurs after the single imaging study information is shared with the Imaging Repository; therefore the workflow is similar as an amendment to the images and/or report. The original imaging manifest would be replaced by the first (out of three) “split study” manifests with the relevant subset of the images being referenced. Two new imaging manifests would be created, referencing the relevant updated images being resent with “new study” unique identifiers. If each one of the split study is reported independently, distinct imaging reports would be shared. These three imaging manifests and reports would all be linked to the same global accession number in the XDS metadata. This scenario is a sub-set of use case Alternative Flow 2 events.

3. INTEROPERABILITY SPECIFICATION REQUIREMENTS

3.1 ACTOR MAPPING TO SAUDI EHEALTH IS SPECIFICATIONS

A system conforming to this Core Interoperability Specification shall claim conformance at the level of a Use Case Actor. A system may claim conformance to one or more Use Case Actors. Multiple systems may fulfill a Use Case Actor.

The Use Case Actors and the Services they support are described at a functional level in the Saudi eHealth Interoperability Use Case document. Services may be required, conditional or optional. The Use Case Actors, Service(s) and Optionality are conveyed in the first three columns of Interoperability Conformance Requirement tables shown below.

The second part of the table (columns 4-7) provides the mapping for the Use Case Actor to the detailed specifications (such as IHE Profiles, Technical Actors, Optionality) that systems shall implement to exchange healthcare information in the context of this Use Case.

For a selected Use Case Actor (a single row in the table), all the requirements listed in the second part of the table (columns 4-7) shall be implemented. This includes the referenced profiles and the standards specified (terminology or other). For each Technical Actor (whether required or optional), the last column references the detailed specification that constrain and extend of the implementation of this profile for KSA specific requirements. These specifications may be found in Sections in this core specification or in other referenced Saudi eHealth Interoperability Specifications (e.g. Saudi eHealth Security and Privacy Interoperability Specification, etc.).

Readers that wish to understand the mapping of Use Case Actors to real world products are recommended to read the Saudi eHealth Interoperability Use Case document.

TABLE 3.1-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING INFORMATION SOURCE

SHARING IMAGES AND IMAGING REPORTS			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Imaging Information Source	Publish Document(s)	R	Imaging Document Source	R	IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b)	IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports– Section 5.1. IS0200 Saudi eHealth Terminology Repository.
			Content Creator	R	IHE – Cross-Enterprise Scanned Document (XDS-SD)and HL7 Clinical Document Architecture (CDA) Release 2	IS0103 Saudi eHealth Radiology Report Content Interoperability Specification- Sections 3.1 and 4.1 IS0200 Saudi eHealth Terminology Repository.
			Document Source (grouped with a Document Administrator Actor)	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification - Section 3.2 IS0200 Saudi eHealth Terminology Repository.
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Send Images	R	Service Class User	R	DICOM – Storage Service Classes	IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports - Section 5.1

			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 3.1-2 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING INFORMATION CONSUMER

SHARING IMAGES AND IMAGING REPORTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Imaging Information Consumer	Query/Retrieve Documents(s)	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification - Section 3.3 IS0200 Saudi eHealth Terminology Repository.
			Imaging Document Consumer	R	IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b)	IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports - Section 5.2 IS0200 Saudi eHealth Terminology Repository.
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2

			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
Retrieve Images	R		Imaging Document Consumer	R	IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b)	IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports- Section 5.2
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
Notification of Document Availability	O		Document Metadata Notification Recipient	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability - Section 5.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 3.1-3 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING REPORT CONSUMER

SHARING IMAGES AND IMAGING REPORTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Imaging Report Consumer	Query/Retrieve Documents(s)	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification - Section 4.3 and IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports - Section 5.3 IS0200 Saudi eHealth Terminology Repository.
			Content Consumer	R	IHE – Cross-Enterprise Scanned Document (XDS-SD) and HL7 – Clinical Document Architecture (CDA) Release 2	IS0103 Saudi eHealth Radiology Report Content Interoperability Specification- Sections 3.2 and 4.2 IS0200 Saudi eHealth Terminology Repository.
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Notification of Document Availability	O	Document Metadata Notification Recipient	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability Specification - Section 5.2

			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 3.1-4 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMAGING REPOSITORY

SHARING IMAGES AND IMAGING REPORTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Imaging Repository	Publish Document(s)	R	Document Repository	R	IHE – Cross-Enterprise Document Sharing for Imaging (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification- Section 4.4 IS0200 Saudi eHealth Terminology Repository. IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports - Section 5.4
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Send Images	R	Service Class Provider	R	DICOM – Storage Service Classes	IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports - Section 5.4

			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
Query/Retrieve Document(s)	R		Document Registry and Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification- Section 4.4
			X-Service Provider	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
Retrieve Images	R		Imaging Document Source	R	IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b)	IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports - Section 5.4
			X-Service Provider	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

	Notification of Document Availability	R	Document Metadata Notification Broker	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability Specification Section 5.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

3.2 INTEROPERABILITY SEQUENCE DIAGRAMS

The following Sequence diagrams provide an overview of the combined flow of transactions resulting from the above selected profiles and standards. The Main Flow Sequence Diagram illustrates a very common (i.e., typical) workflow and other sequence diagrams are shown to provide an alternative to the main flow. Other sequence diagrams are possible but they cover the same key transactions with only slight variants of information exchange between the Use Case Actors, therefore, may be omitted. Reference the appropriate sections of Section 2.3 for more information of possible workflow scenarios. Examples are provided below.

The Sharing Images and Imaging Report sequence diagrams provide a high level sequence of events for the exchange of information for sharing a patient's images and imaging reports. It also illustrates typical security exchanges for authorized network communications and audit trail of patient information access.

3.2.1 Main Flow Sequence Diagram

The main flow sequence diagram is a scenario between a Healthcare Organization (where an imaging procedure has been performed on a patient) and a Healthcare Provider retrieving the images and imaging report for that patient. The sequence diagram depicts Use Case Actors and a number of transactions between IHE Profile Actors specified in the tables in Section 3.

Note: The Use Case Services are implemented using the underlying transaction(s) defined by the Profiles or Standards selected. Therefore, the Use Case Services are not depicted directly in the sequence diagrams.

Steps 1 – 12 are shown in Figure 3.2-1 Sharing Images and Imaging Reports Sequence Diagram (1).

1. Time synchronization occurs independently. These transactions may take place at any time and are shown at the beginning of the sequence diagram [IHE CT Profile: Maintain Time ITI-1].

2. The patient visits a hospital for an imaging procedure. In order to exchange the images, imaging manifest(s) and diagnostic report(s), the information is exchanged among the actors as described below. Before the information exchanges can take place, an authentication process takes place between the DICOM Service Class User (SCU)/Secure Node Actor and the DICOM Service Class Provider (SCP)/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

Note: The requirements on how to obtain a patient's KSA-Wide Health ID and key patient demographics are defined in IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query. The Health ID and key patient demographics attributes are used to identify the patient for which the Imaging Manifests and reports are shared. This ensures KSA-Wide identification of the patient in health records. This is not shown in the diagram and details to accomplish this are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

3. Following node authentication, the DICOM Service Class User transmits the images to DICOM Service Class Provider. [DICOM Storage SOP Classes: DICOM Storage]. The Imaging Repository Use Case Actor stores the images.
4. The DICOM Service Class User/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and Section 5.1]. The DICOM Service Class Provider/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

Note: There are actually two local audit record events, one audit record for the beginning of the image transmission and a second audit record for when all the images have been successfully sent. Only one local audit record is shown in the sequence diagram.

5. Upon the successful transmission of the images, the Imaging Information Source publishes the imaging manifest. Before the information exchange can take place, an authentication process between the Imaging Document Source/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].
6. Following node authentication, the Imaging Manifest is published [IHE XDS.I-b Profile: Provide and Register Imaging Document Set – MTOM/XOP RAD-68]. The Document Repository stores the Imaging Manifest.
7. The Document Repository registers the Imaging Manifest with the Document Registry [IHE XDS.b: Register Document Set – b ITI-42]. The Imaging Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
8. The Imaging Document Source/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b].
9. The Imaging Information Source publishes the imaging report. Before the information exchange can take place, an authentication process between the Imaging Document

Source/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

10. Following node authentication, the imaging report is published [IHE XDS.I-b Profile: Provide and Register Imaging Document Set – MTOM/XOP RAD-68]. The Document Repository stores the report.
11. The Document Repository registers the imaging report with the Document Registry [IHE XDS.b: Register Document Set – b ITI-42]. The Imaging Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

Note: The IHE XDS.b: [Register Document Set – b ITI-42] transaction is shown without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the Document Repository and Registry are implemented within the same systems. If these Actors are implemented in separate systems the authentication transaction would be required.

12. The Imaging Document Source/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b].

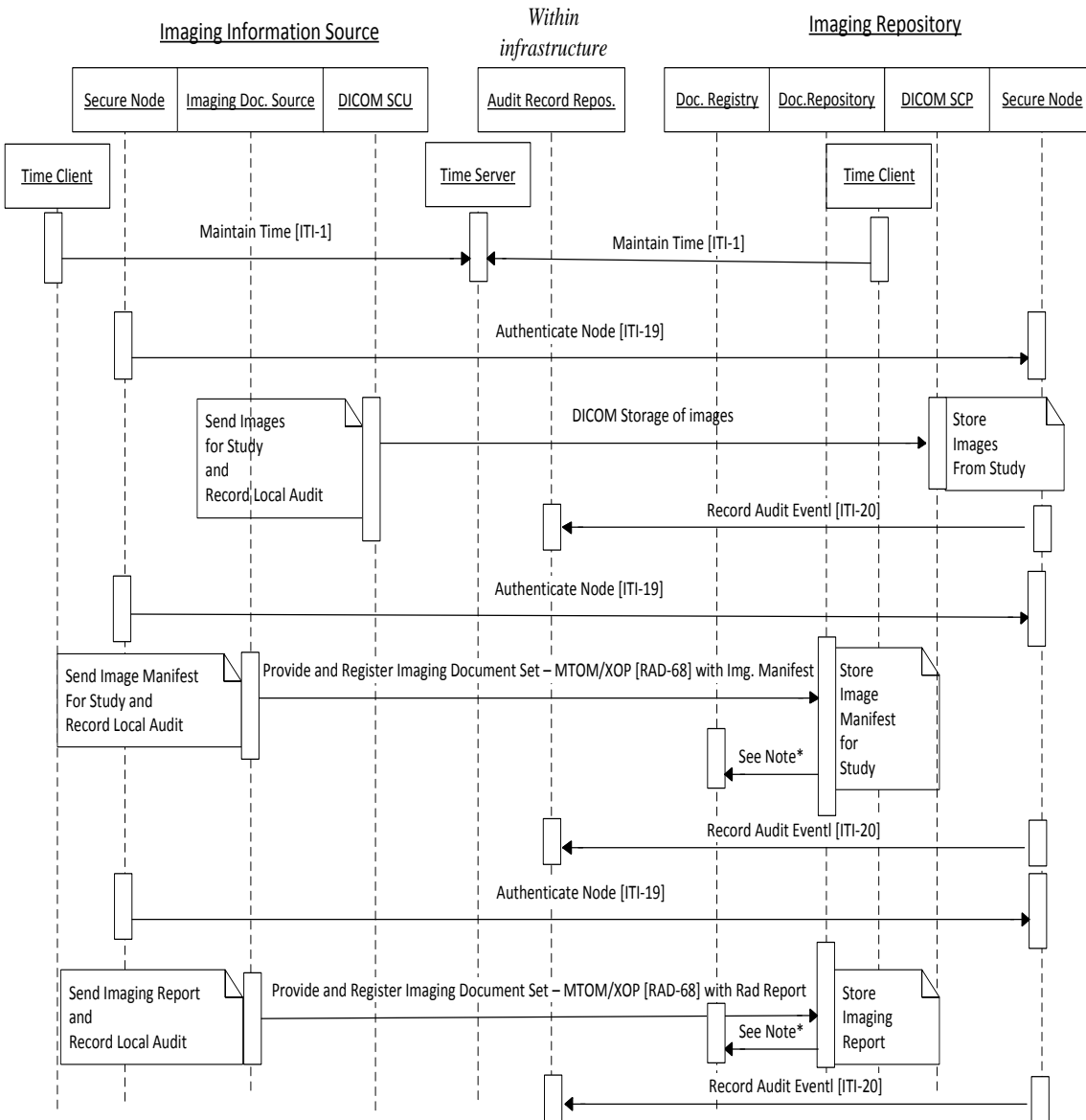


FIGURE 3.2-1 SHARING IMAGES AND IMAGING REPORTS SEQUENCE DIAGRAM (1)

Note: The IHE XDS.b: [Register Document Set – b ITI-42] transaction is shown without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the Document Repository and Registry are implemented within the same system. If these Actors are implemented in separate systems the authentication transaction would be required.

Steps 13 – 24 related to access to shared images, Imaging Manifests and reports are shown in Figure 3.2-2 Sharing Images and Imaging Reports Sequence Diagram (2).

Please note that Time Client and Time Server Actors have been omitted due to limited space on the diagram. The systems need to perform on-going time synchronization [IHE CT Profile: Maintain Time ITI-1] as shown in Step 1.

13. In order to locate and retrieve images and reports, the information is exchanged among the actors as described below. Before the information exchange can take place, an authentication process between the Document Consumer/Secure Node Actor and the Document Registry/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].
14. The Document Consumer/X-Service User queries the Document Registry/X-Service Provider to determine if the patient's report is available. As part of the query request, a user assertion is conveyed to verify that the physician is an authorized user to obtain patient information is performed [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40].
15. The Document Consumer/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b].
16. The Document Registry processes the query and responds with the information needed to retrieve both imaging reports and Imaging Manifests [IHE XDS-b: Registry Stored Query ITI-18].
17. The Document Registry/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
18. The Imaging Information Consumer and Report Consumer Use Case Actors retrieve the imaging report and manifest. Before the information exchange can take place, an authentication process between the Document Consumer/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].
19. The Document Consumer/X-Service User retrieves the image report and manifest. As part of the retrieve, a user assertion is conveyed to verify that the physician is an authorized user to obtain patient information is performed [IHE XDS.b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
20. The Document Consumer/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b]. The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
21. Once the images of interest are identified for retrieval, information is exchanged among the actors as described below. Before the information exchange can take place, an authentication process between the Imaging Document Consumer/Secure Node Actor and the Imaging Document Source/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

22. The Imaging Document Consumer/X-Service Users retrieves the images (DICOM SOP instances) from the Imaging Repository. As part of the retrieve, the verification of the user assertion is the basis to ensure that the physician is an authorized user to obtain patient information is performed [IHE XDS-I.b: Retrieve Imaging Document Set RAD-69] and [IHE XUA: Provide X-User Assertion ITI-40].

Note the transaction [IHE XDS-I.b: WADO Retrieve RAD-55] is an additional option to retrieve the images.

23. The Document Consumer/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b]. The Imaging Document Source/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
24. The images and reports are available for the Healthcare Provider for review.

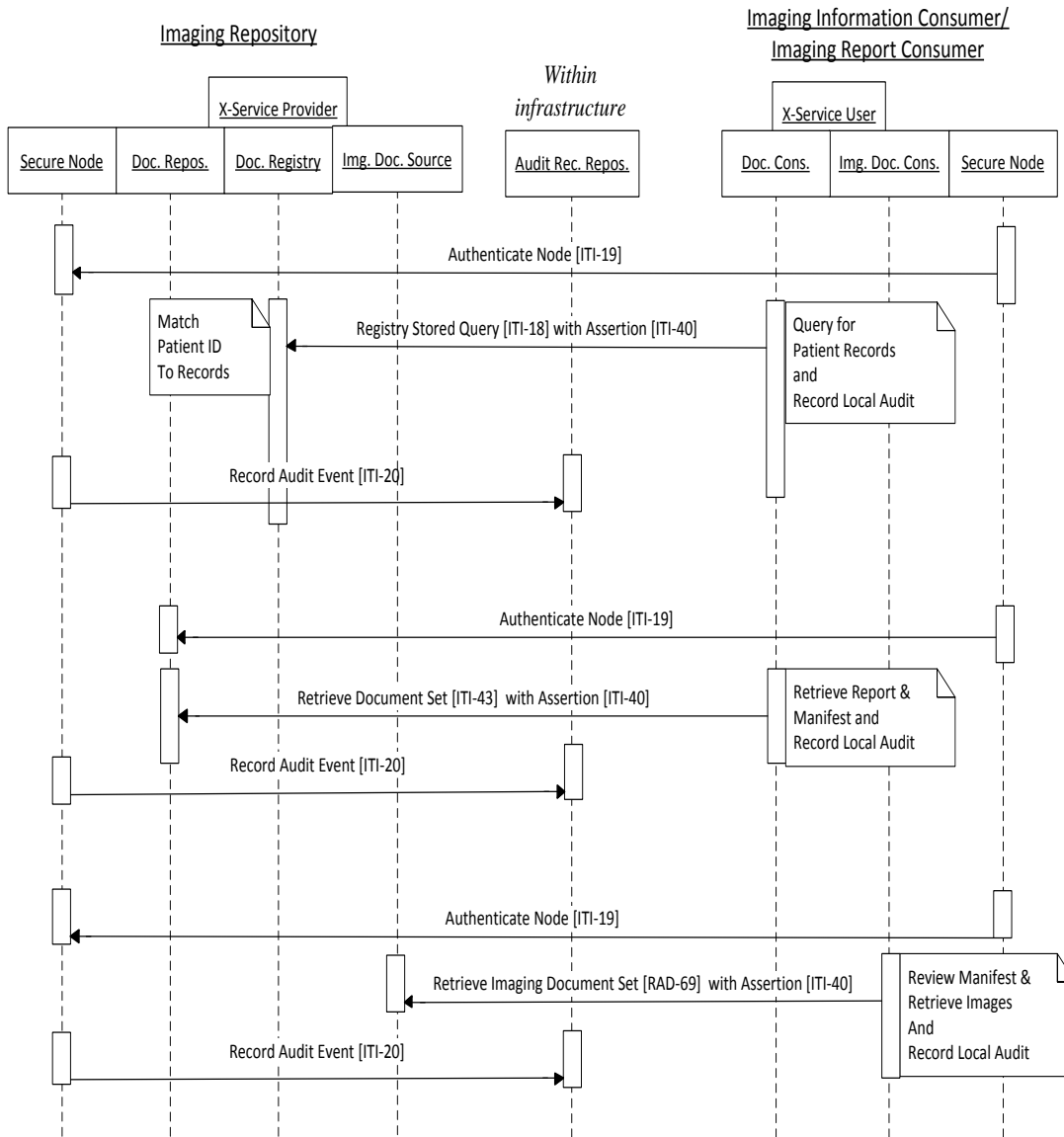


FIGURE 3.2-2 SHARING IMAGES AND IMAGING REPORTS SEQUENCE DIAGRAM (2)

Note: The IHE XDS.b: [Register Document Set – b ITI-42] transaction is shown without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the Document Repository and Registry are implemented within the same systems. If these Actors are implemented in separate systems the authentication transaction would be required.

3.2.2 Amended Report (with optional Notification) sequence Diagram

The amended report sequence diagram is for the scenario when an imaging report has been updated via an amendment. It also includes the optional interaction to provide an automatic

notification when the amended report is available for sharing. The main flow sequence diagram is a pre-condition to creating an amended report and is not repeated in this diagram. The sequence diagram depicts linkage of the Use Case Actors to the Profile Actors and a number of transactions between IHE Profile Actors specified in the tables in Section 3.

Note: The Use Case Services are implemented using the underlying transaction(s) defined by the Profiles or Standards selected. Therefore, the Use Case Services are not depicted directly in the sequence diagrams.

Steps 1 – 4 are shown in Figure 3.2-3 Amended Report with Optional Notification Sequence Diagram (1)

1. Time synchronization is not shown but occurs as shown in other diagrams [IHE CT Profile: Maintain Time ITI-1].
2. The radiologist that created the original report determines that important information was left out of the report. The radiologist creates an amended report to add the missing information. In order to exchange the diagnostic report it is accomplished among the actors as described below. Before this can take place, an authentication process between the Imaging Document Source/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

Note: When the amended report is published, the Imaging Information Source Use Case Actor informs the Image Repository Use Case Actor that it is a replacement to the original, a previously shared document. This information is used by the Image Repository to manage the two versions (i.e. deprecate the original image report and provide a link with the amended report).

3. Following node authentication, the amended imaging report is transmitted [IHE XDS.I-b Profile: Provide and Register Imaging Document Set – MTOM/XOP RAD-68]. The Imaging Repository Use Case Actor stores the report and deprecates the old version.
4. The Imaging Document Source/Secure Node Actor generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b] and the Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

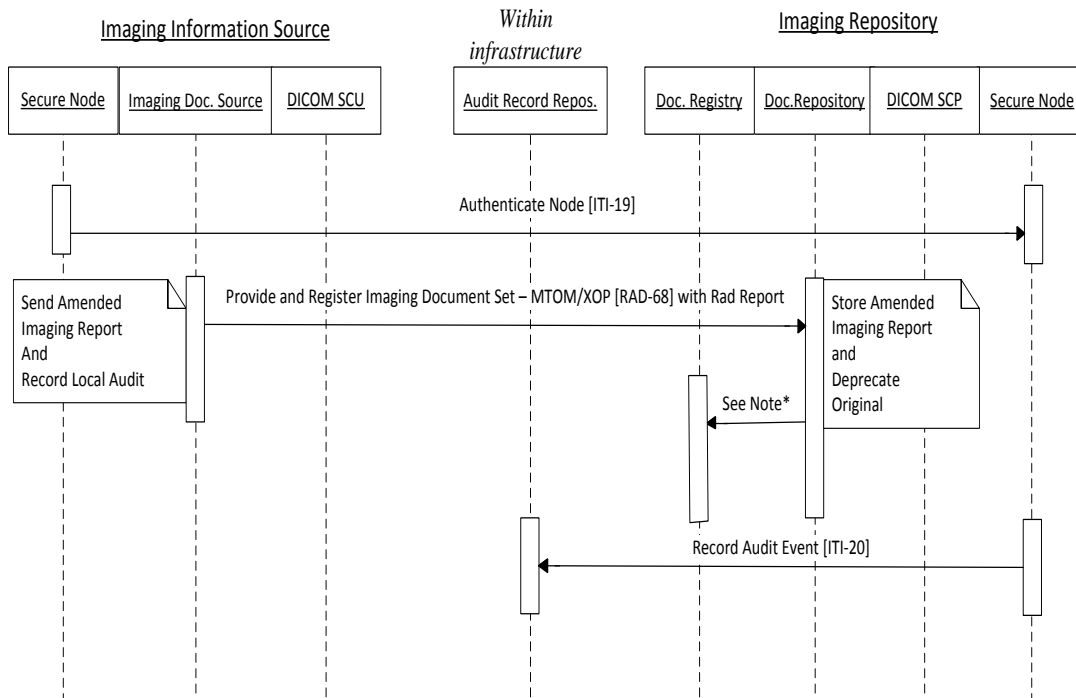


FIGURE 3.2-3 AMENDED REPORT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (1)

Note: The IHE XDS.b: [Register Document Set – b ITI-42] transaction is shown without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the Document Repository and Registry are implemented within the same systems. If these Actors are implemented in separate systems the authentication transaction would be required.

Steps 5 – 11 are shown in Figure 3.2-4 Amended Report with Optional Notification Sequence Diagram (2).

5. The Imaging Repository Use Case Actor notifies the Imaging Information Consumer/Imaging Report Consumer that an amended report was created. Before the information exchange can take place, an authentication process between the Document Repository/Document Metadata Notification Broker/Secure Node Actor and the Document Consumer/Document Metadata Notification Recipient/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].
6. Following node authentication, the notification of document availability is transmitted [IHE DSUB Profile: Document Metadata Notify ITI-53]. The Imaging Report Consumer Use Case Actor has been notified that the amended report is available.
7. The Document Consumer/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and

- IHE XDS.b). The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
8. Upon the successful transmission of the notification, the Imaging Information Consumer/Imaging Report Consumer uses the Document Consumer Technical Actor to retrieve the amended image report. Before the information exchange can take place, an authentication process between the Document Consumer/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].
9. The Document Consumer/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and IHE XDS.b). The Document Consumer/X-Service User retrieves the amended imaging report. As part of the retrieve, an assertion process to verify that the physician is an authorized user to obtain patient information is performed [IHE XDS.b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
10. The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
11. The physician reviews the amended report and provides follow up healthcare.

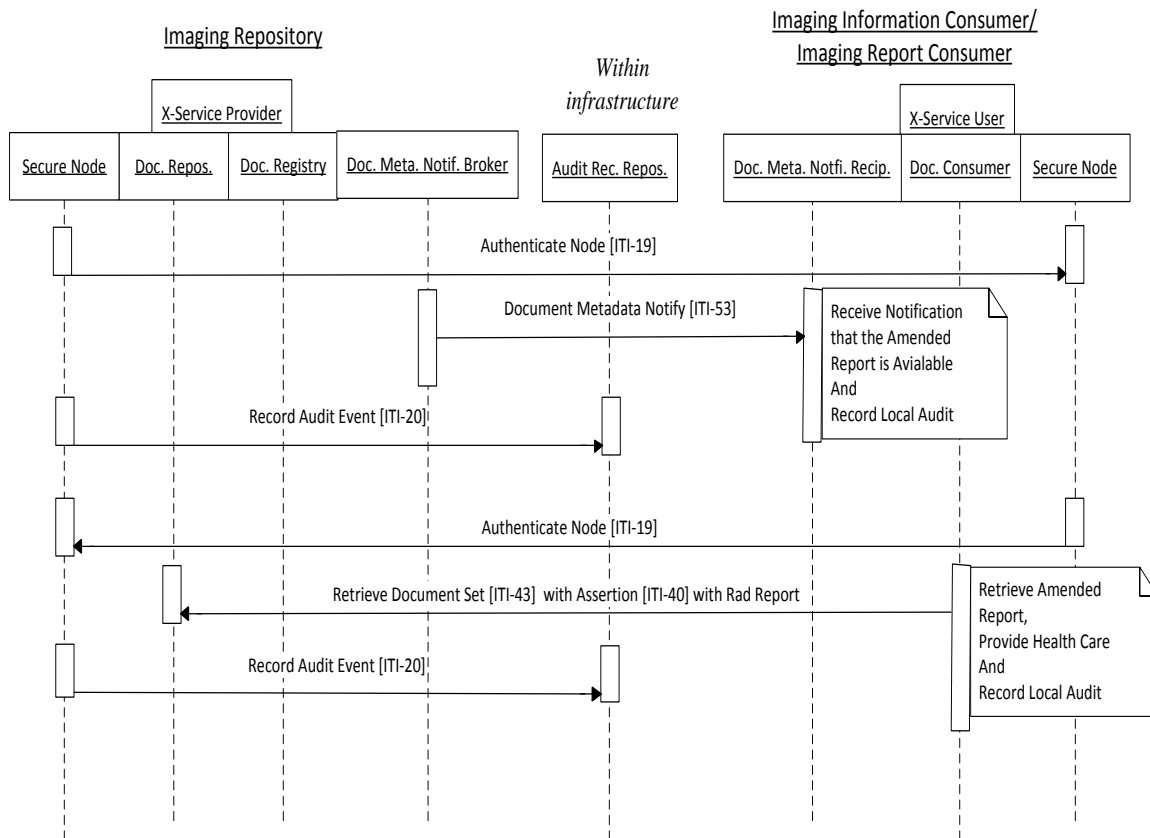


FIGURE 3.2-4 AMENDED REPORT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (2)

4. CONFORMANCE TO THE SHARING IMAGES AND IMAGING REPORTS SPECIFICATION

4.1.1 Imaging Information Source Conformance

Systems may claim conformance to the Sharing Images and Imaging Reports Interoperability Specification as an Imaging Information Source as follows:

“Sharing Images and Imaging Reports as an Imaging Information Source Use Case Actor”

This requires:

- to support the Publish Document(s) Service by conforming to:
 - [SIR-001]-IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile as an Imaging Document Source Actor with the additional constraints specified in:
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports*-- Section 5.1
 - IS0200 Saudi eHealth Terminology Repository.
 - [SIR-002] - IHE – Cross-Enterprise Scanned Document (XDS-SD) and HL7 Clinical Document Architecture (CDA) Release 2 Content Profiles as a Content Creator Actor with the additional constraints specified in:
 - IS0103 *Saudi eHealth Radiology Report Content Interoperability Specification* - Sections 3.1 and 4.1
 - IS0200 Saudi eHealth Terminology Repository.
 - [SIR-003] - IHE – Cross-Enterprise Document Sharing for Imaging (XDS.b) Integration Profile as a Document Source Actor (grouped with a Document Administrator Actor) with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 3.2
 - IS0200 Saudi eHealth Terminology Repository.
 - [SIR-004] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
 - [SIR-005] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- to support the Send Images Service by conforming to:

- [SIR-006] – DICOM Storage Service Classes as a Service Class User with the additional constraints specified in:
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.1
- [SIR-007] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
- [SIR-008] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

4.1.2 Imaging Information Consumer Conformance

Systems may claim conformance to the Sharing Images and Imaging Reports Interoperability Specification as an Imaging Information Consumer as follows:

“Sharing Images and Imaging Reports as an Imaging Information Consumer Use Case Actor”

This requires:

- To support the Query/Retrieve Document(s) Service by conforming to:
 - [SIR-010]- IHE – Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Consumer Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 3.3
 - IS0200 *Saudi eHealth Terminology Repository*.
 - [SIR-021] - IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) as an Imaging Document Consumer with the additional constraints specified in:
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.2
 - IS0200 *Saudi eHealth Terminology Repository*.
 - [SIR-011] - IHE – Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service User Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1
 - [SIR-012] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

- [SIR-013] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To support the Retrieve Images Service implementation by conforming to:
 - [SIR-014] – IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile as an Imaging Document Consumer Actor with the additional constraints specified in:
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.2
 - [SIR-015] - IHE – Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service User Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1
 - [SIR-016] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
 - [SIR-017] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To optionally support the Notification of Document Availability Service by conforming to:
 - [SIR-018] – IHE - Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Recipient Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 5.2
 - [SIR-019] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
 - [SIR-020] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

4.1.3 Imaging Report Consumer Conformance

Systems may claim conformance to the Sharing Images and Imaging Reports Interoperability Specification as an Imaging Report Consumer as follows:

“Sharing Images and Imaging Reports as an Imaging Report Consumer Use Case Actor”

This requires:

- To support the Query/Retrieve Document(s) Service by conforming to:
 - [SIR-022]- IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile as a Document Consumer Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.3
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.3
 - IS0200 Saudi eHealth Terminology Repository.
 - [SIR-023] - IHE – Cross-Enterprise Scanned Document (XDS-SD) and HL7 Clinical Document Architecture (CDA) Release 2 Content Profiles as a Content Consumer Actor with the additional constraints specified in:
 - IS0103 *Saudi eHealth Radiology Report Content Interoperability Specification*- Sections 3.2 and 4.2
 - IS0200 Saudi eHealth Terminology Repository.
 - [SIR-024] - IHE – Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service User Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1
 - [SIR-025] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
 - [SIR-026] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To optionally support the Notification of Document Availability Service by conforming to:
 - [SIR-027] – IHE - Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Recipient Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* -- Section 5.2
- [SIR-028] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
- [SIR-029] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

4.1.4 Imaging Repository Conformance

Systems may claim conformance to the Sharing Images and Imaging Reports Interoperability Specification as an Imaging Repository as follows:

“Sharing Images and Imaging Reports as an Imaging Repository Use Case Actor”

This requires:

- To support the Publish Document(s) Service by conforming to::
 - [SIR-031]- IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile as an Document Repository Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.4
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.4
 - IS0200 Saudi eHealth Terminology Repository.
 -
 - [SIR-032] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
 - [SIR-033] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To support the Send Images Service implementations by conforming to::
 - [SIR-034] – DICOM Storage Service Classes as a Service Class Provider with the additional constraints specified in:

- IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.4
- [SIR-035] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
- [SIR-036] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To support the Query/Retrieve Document(s) Service by conforming to:
 - [SIR-037]- IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile as a Document Registry and Document Repository Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.4
 - IS0200 Saudi eHealth Terminology Repository.
 - [SIR-038] - IHE – Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service Provider Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.2
 - [SIR-039] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
 - [SIR-040] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To support the Retrieve Images Service by conforming to:
 - [SIR-041] – IHE – Cross-Enterprise Document Sharing for Imaging (XDS-I.b) Integration Profile as an Imaging Document Source Actor with the additional constraints specified in:
 - IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* - Section 5.4

- [SIR-042] - IHE – Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service Provider Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.2
- [SIR-043] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
- [SIR-044] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To support the Notification of Document Availability Service by conforming to::
 - [SIR-045] – IHE - Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Broker Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 5.1
 - [SIR-046] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
 - [SIR-047] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

5. SAUDI EHEALTH CONSTRAINTS ON THE IHE CROSS-ENTERPRISE SHARING OF IMAGING INFORMATION (XDS-I) PROFILE AND DICOM STORAGE

This section defines required behavior rules for Use Case Actors defined in this Core Interoperability Specification.

This section specifies Saudi eHealth extensions and constraints to the IHE Cross-enterprise Document Sharing Profile and the DICOM Storage. All details of the IHE XDS-I integration profile and transactions are specified in IHE RAD TF-1: 18 (see Section 6). All details of the DICOM Storage Service Classes are specified in DICOM PS3.3 and PS3.4.

5.1 REQUIREMENTS FOR IMAGING INFORMATION SOURCE USE CASE ACTOR

The following rules shall be supported for the conformance to the Imaging Information Source Actor:

- [SIR-060] – The complete set of images for a patient’s imaging study referenced in an Imaging Manifest **SHALL** be successfully sent (using the Send Images Service) by the DICOM Storage Class User to the Imaging Repository acting as a DICOM Storage Service Class Provider *before* the Document Source performs the Provide and Register Document Set Transaction (IHE-RAD-68) to transmit the Imaging Manifest associated to a Study.

Note: This ensures that Imaging Document Consumer Actors do not attempt to retrieve images for which a Manifest has been published, but references images that are not in the Imaging Repository (XDS-I Imaging Document Source Technical Actors).

- [SIR-061] – Any failed transmission of DICOM SOP Instances (i.e. images via the Send Image Service) **SHALL** be automatically retried a configurable number of times (5 – 10 times), distributed over a configurable period of 1 to 12 hours. If after such retries, the transmission of one or more of the SOP Instances still fails, the transmission failures **SHALL** be locally reported and logged. No Imaging Manifest **SHALL** be published.

Note: It is common for sending systems to resend “all the images” of the study when failures occurred. If some of the images first sent were successful, they are already on the Imaging Repository. When they are sent during the “retry” transmissions, the Imaging Repository **SHOULD** respond to these “duplicate” images with a success status and throw them away. This is the most common architecture chosen by local PACS systems.

- [SIR-110]- Upon beginning the transmission of a study of DICOM images using the Send Image Service, an audit trail **SHALL** be generated. The content of the data is based upon the Audit trail events as specified in the IHE ATNA Integration Profile and Table 5.1-1. See IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.3.2 for more details.

TABLE 5.1-1 ATNA DATA REQUIREMENTS FOR BEGINNING THE TRANSMISSION OF DICOM SOP INSTANCES

	Field Name	Opt	Value Constraints
Event Audit Message/ EventIdentification	EventId	M	EV (110102, DCM, "Begin Transferring DICOM Instances")
	EventActionCode	M	"E" (Execute)
	EventDateTime	M	Shall be the time when the transfers started
	EventOutcomeIndicator	M	not specialized
	EventTypeCode	U	not specialized
Active Participant(Process that sent the data) (1)			
Active Participant (Other participants that are knows, especially third parties that are the requestor)(0..n)			
Active Participant (Process that received the data) (1)			
Participating Object (Studies being transferred) (1-n)			
Participating Object (Patient) (1)			

Where:

Process that sent the data (1) Audit Message/ ActiveParticipant	UserID	M	The identity of the process sending the data
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	M	EV(110153, DCM, "Source Role ID")
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized
Other participants that are knows, especially third parties that are the requestor (if known) (0..n) Audit Message/ ActiveParticipant	UserID	M	The identity of any other participants that might be involved and known, especially third parties that are the requestor
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	U	not specialized
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized

Process that received the data (1) Audit Message/ ActiveParticipant	UserID	M	The identity of the process receiving the data.
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	M	EV(110152, DCM, "Destination Role ID")
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized

Studies being transferred (1..n) Audit Message/ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	"2" (System)
	ParticipantObjectTypeCodeRole	M	"3" (report)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	EV (110180, DCM, "Study Instance UID")

	ParticipantObjectSensitivity	U	not specialized
	ParticipantObjectID	M	The Study Instance UID
	ParticipantObjectName	U	not specialized
	ParticipantObjectQuery	U	not specialized
	ParticipantObjectDetail	U	Not specialized
	ParticipantObjectDescription	U	not specialized
	SOPClass	MC	Element "ContainsSOPClass" with one or more SOP Class UID values
	Accession	U	not specialized
	NumberOfInstances	U	not specialized
	Instances	U	not specialized
	Encrypted	U	not specialized
	Anonymized	U	not specialized

Patient (1) (Audit Message/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	"1" (Person)
	ParticipantObjectTypeCodeRole	M	"1" (Patient)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	"2" = patient ID
	ParticipantObjectSensitivity	U	not specialized
	ParticipantObjectID	M	The Health ID of the patient
	ParticipantObjectName	U	The patient name
	ParticipantObjectQuery	U	not specialized
	ParticipantObjectDetail	U	not specialized
	ParticipantObjectDescription	U	not specialized

- [SIR-111]- Upon successfully transmitting a study of DICOM images using the Send Image Service, an audit trail **SHALL** be generated. The content of the data is based upon the Audit trail events as specified in the IHE ATNA Integration Profile and Table 5.1-2. See IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.3.2 for more details.

TABLE 5.1-2 ATNA DATA REQUIREMENTS FOR SUCCESSFUL TRANSMISSION OF DICOM SOP INSTANCES

	Field Name	Opt	Value Constraints
Event Audit Message/ EventIdentification	EventID	M	EV (110104, DCM, "DICOM Instances Transferred")
	EventActionCode	M	"R" (Read)
	EventDateTime	M	Shall be the time when the transfer has completed
	EventOutcomeIndicator	M	not specialized
	EventTypeCode	U	not specialized
Active Participant(Process that sent the data) (1)			
Active Participant (Other participants that are knows, especially third parties that are the requestor)(0..n)			
Active Participant (Process that received the data) (1)			

Participating Object (Studies being transferred) (1-n)
Participating Object (Patient) (1)

Where:

Process that sent the data (1) Audit Message/ ActiveParticipant	UserID	M	not specialized
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	M	EV(110153, DCM, "Source Role ID")
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized
Other participants that are known, especially third parties that are the requestor (if known) (0..n) Audit Message/ ActiveParticipant	UserID	M	not specialized
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	U	not specialized
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized

Process that received the data (1) Audit Message/ ActiveParticipant	UserID	M	not specialized
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	M	EV(110152, DCM, "Destination Role ID")
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized

Studies being transferred (1..n) Audit Message/ ParticipantObjectIdentification	ParticipantObjectTypeCode	M	"2" (System)
	ParticipantObjectTypeCodeRole	M	"3" (report)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	EV (110180, DCM, "Study Instance UID")
	ParticipantObjectSensitivity	U	not specialized
	ParticipantObjectID	M	The Study Instance UID
	ParticipantObjectName	U	not specialized
	ParticipantObjectQuery	U	not specialized
	ParticipantObjectDetail	U	not specialized
	ParticipantObjectDescription	U	not specialized
	SOPClass	MC	Element "ContainsSOPClass" with one or more SOP Class UID values
	Accession	U	not specialized
	NumberOfInstances	U	not specialized
	Instances	U	not specialized
	Encrypted	U	not specialized
Anonymized	U	not specialized	

Patient (1)	ParticipantObjectTypeCode	M	"1" (Person)
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ParticipantObjectTypeCodeRole	M	"1" (Patient)
ParticipantObjectDataLifeCycle	U	not specialized
ParticipantObjectIDTypeCode	M	"2" = patient ID
ParticipantObjectSensitivity	U	not specialized
ParticipantObjectID	M	The Health ID of the patient
ParticipantObjectName	U	The patient name
ParticipantObjectQuery	U	not specialized
ParticipantObjectDetail	U	not specialized
ParticipantObjectDescription	U	not specialized

- [SIR-062]- The Imaging Information Source Actor sends DICOM SOP Instances to an assigned Imaging Repository as defined by the SeHE deployment configuration. Next the Imaging Information Source Actor **SHALL** generate an Imaging Manifest referencing the DICOM SOP Instances successfully sent (i.e. it defines the content of the study to be shared). However the attributes Retrieve Location UID (0040,E011) and Retrieve AE Title (0008,054) **MAY** be set to any value.

Note: The Imaging Repository is responsible to modify the attribute Retrieve Location UID (0040,E011) in the Imaging Manifest to the repository where the DICOM SOP Instances have been stored (i.e. <repositoryUniqueId> UID).

- [SIR-117] – The ability to view images the same as viewed by other PACS systems is required. Therefore, the Imaging Information Source Actor **SHALL** be able to capture image display information and produce DICOM Greyscale Presentation State SOP Instances and to send them in the imaging study. This **SHALL** be accomplished according the functional requirements of the IHE Radiology Consistent Presentation of Images (CPI) Integration Profile.
- [SIR-118] – Users have the ability to flag one or more significant images in a study and include notes for those images. Therefore, the Imaging Information Source Actor **SHALL** be able to selects key images and notes using the information defined in the DICOM Key Object Selection SOP Instances and send them in the imaging study. This **SHALL** be accomplished according the functional requirements of the IHE Radiology Key Image Note (KIN) Integration Profile.
- [SIR-065] –The XDS Metadata associated with Imaging Manifests is defined in two parts. The non-imaging specific metadata are specified in the document – IS0101 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.2.1. The imaging specific extensions **SHALL** meet the following additional constraints:
 - [SIR-096] The classCode attribute **SHALL** contain one coded value which **SHALL** be "IMAGES".
 - [SIR-097] The practiceSetting attribute **SHALL** contain one coded value from the "KSA Organization Specialty" .

- [SIR-066] The typeCode Attribute **SHALL** be set to one coded value describing the Imaging Procedure performed on the patient for which the images were acquired. The coded value **SHALL** be defined by the "KSA Procedure Name" value set.
- [SIR-067] The eventCodeList **SHALL** contain one or more coded values describing the Imaging Modalities that have been used to perform the image acquisition of the patient for the diagnostics procedure. Each coded value **SHALL** be defined by the "Modalities"
- [SIR-068] The eventCodeList **SHALL** contain one coded values describing of the patient's Body Part that has been the subject of image acquisition for the diagnostics procedure. The coded value **SHALL** be defined by the "KSA Body Regions" value set
- [SIR-101] The mimeType attribute **SHALL** contain one coded value which **SHALL** be "application/dicom" for the imaging study manifest as described in the "MIME Type"
- [SIR-102] The formatCode attribute **SHALL** contain one coded value which **SHALL** be "1.2.840.10008.5.1.4.1.1.88.59" for the Imaging Manifest as described in the "KSA Format Code" value set.

- [SIR-070] –The XDS Metadata associated with Image Reports is defined in two parts. The non-imaging specific metadata are specified in the document - Saudi eHealth Document Sharing Interoperability Specification - Section 4.2.1. The imaging specific extensions **SHALL** meet the following additional constraints:
 - [SIR-098] The classCode attribute **SHALL** contain one coded value which **SHALL** be "REPORTS" for both the basic structure radiology report and for the display radiology report.
 - [SIR-071] The typeCode Attribute **SHALL** contain one coded value describing the Imaging Procedure performed on the patient for which the diagnosis is documented in the report. The coded values are defined by the "KSA Procedure Name" value set
 - [SIR-072] The eventCodeList **SHALL** contain one or more coded values describing the Imaging Modalities that have been used to perform the image acquisition on the patient for the diagnostics procedure which resulted in the report. Each coded value **SHALL** be defined by the "Modalities" value set
 - [SIR-073] The eventCodeList **SHALL** contain one coded value describing the patient's Body Part that has been the subject of image acquisition for the reported diagnostics procedure. The coded value **SHALL** be defined by the "KSA Body Regions" value set
 - [SIR-105] The mimeType attribute **SHALL** contain one coded value which **SHALL** be "text/xml" for both the basic structure radiology report and for the display radiology report as described in the "MIME Type" value set

- [SIR-106] The formatCode attribute **SHALL** contain one coded value which **SHALL** be “urn:ksa-ehealth:rad:basic-structured:2013” for the basic structured radiology report as described in the "KSA Format Code" value set.
- [SIR-107] The formatCode attribute **SHALL** contain one coded value which **SHALL** be “urn:ihe:iti:xds-sd:pdf:2008” for the for display radiology report as described in the "KSA Format Code" value set.
- [SIR-074] –If an Imaging Manifest has been published and assigned to an incorrect patient, the Imaging Document Source (Document Source of the IHE-XDS Profile grouped with a Document Administrator Actor-See KXDS-072 in IS0102) **SHALL** correct the error by using the [IHE XDS.b Supplement: Metadata Update: Delete Document Set Request ITI-62] to deprecate the original Imaging Manifest. A new Imaging Manifest **SHALL** be published and assigned to the correct patient with the references to the corrected DICOM images (i.e. corrected the patient information in the DICOM image header).
- [SIR-075] –If an Imaging Report has been published and assigned to an incorrect patient, the Imaging Document Source (Document Source of the IHE-XDS Profile grouped with a Document Administrator Actor-See KXDS-072 in IS0102) **SHALL** correct the error by using the [IHE XDS.b Supplement: Metadata Update: Delete Document Set Request ITI-62] to deprecate the original Imaging Report. A new Imaging Report **SHALL** be published and assigned to the correct patient.
- [SIR-076] –An Imaging Information Source **SHALL** publish radiology report(s) with content as specified in Saudi eHealth Radiology Report Content Interoperability Specification.
- [SIR-077] –An Imaging Information Source **SHALL** publish each radiology report in two different formats: a display report format and a basic structure report format. The display document **SHALL** be an XFRM (XDS transform relationship) of the parent document, the basic structure report.

5.2 REQUIREMENTS FOR IMAGING INFORMATION CONSUMER USE CASE ACTOR

The following rules shall be supported by the Imaging Information Consumer Use Case for its conformance to the Imaging Information Consumer Actor:

- [SIR-080] –An Imaging Information Consumer **SHALL** support image retrieve from an Imaging Information Source with either one or both of these transactions:
 - IHE XDS-I.b: Retrieve Imaging Document Set RAD-69 transaction
 - IHE XDS-I.b: WADO Retrieve RAD-55 transaction
- [SIR-081]- The attribute Retrieve Location UID (0040, E011) is used to identify the Imaging Repository where DICOM SOP Instances referenced within an Imaging Manifest have been stored. Therefore, it is used by the Imaging Information Consumer to determine the specific Imaging Repository from which to retrieve the DICOM SOP

Instances. The Imaging Information Consumer **SHALL** use the Imaging Manifest attribute Retrieve Location UID (0040, E011) value in the attribute <repositoryUniqueId> when performing the [IHE XDS-I.b: Retrieve Imaging Document Set RAD-69] or [IHE XDS-I.b: WADO Retrieve RAD-55] transactions.

Note: The <repositoryUniqueId> attribute is a UID assigned to each SeHE Imaging Repository. This UID allows Imaging Information Consumer Actors to know which Imaging Repository has stored the DICOM objects referenced by the Imaging Manifest.

- [SIR-082] – When retrieving a patient’s DICOM SOP Instances (e.g. images, presentations states, key image notes) that are referenced within an Imaging Manifest, it is the responsibility of the Imaging Information Consumer to rely on the Metadata associated with the Imaging Manifest to reconcile the KSA-Wide information with its local information and conventions. At a minimum, it **SHALL** reconcile:
 - The KSA-Wide Health ID with the local Patient ID
 - The Saudi eHealth Procedure Name Codes with the corresponding local Imaging Procedure Codes
 - The KSA-Wide Accession Number with a corresponding local Accession Number

- [SIR-089]- Upon successfully receiving a study of DICOM images using the Retrieve Images Service, an audit trail **SHALL** be generated. The content of the data is based upon the Audit trail events as specified in the IHE ATNA Integration Profile and Table 5.2-1.

TABLE 5.2-1 ATNA DATA REQUIREMENTS FOR SUCCESSFUL TRANSMISSION OF DICOM SOP INSTANCES

	Field Name	Opt	Value Constraints
Event Audit Message/ EventIdentification	EventID	M	EV (110104, DCM, "DICOM Instances Transferred")
	EventActionCode	M	C = (create) if the receiver did not hold copies of the instances transferred R = (read) if the receiver already holds copies of the SOP Instances transferred, and has determined that no changes are needed to the copies held. U = (update) if the receiver is altering its held copies to reconcile differences between the held copies and the received copies. If the Audit Source is either not the receiver, or otherwise does not know whether or not the instances previously were held by the receiving node, then use "R" = (Read).
	EventDateTime	M	Shall be the time when the transfer has completed
	EventOutcomeIndicator	M	not specialized
	EventTypeCode	U	not specialized
Active Participant (Process that sent the data) (1)			
Active Participant (Other participants that are knows, especially third parties that are the requestor) (0..n)			
Active Participant (Process that received the data) (1)			
Participating Object (Studies being transferred) (1-n)			
Participating Object (Patient) (1)			
Where:			
Process that sent the data (1) Audit Message/ ActiveParticipant	UserID	M	not specialized
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	M	EV(110153, DCM, "Source Role ID")
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized
Other participants that are knows, especially third parties that are the requestor (if known) (0..n) Audit Message/ ActiveParticipant	UserID	M	not specialized
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	U	not specialized
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized
Process that	UserID	M	not specialized

	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	M	not specialized
	RoleIDCode	M	EV(110152, DCM, "Destination Role ID")
	NetworkAccessPointTypeCode	U	not specialized
	NetworkAccessPointID	U	not specialized

Studies being transferred (1..n) Audit Message/ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	"2" (System)
	ParticipantObjectTypeCodeRole	M	"3" (report)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	EV (110180, DCM, "Study Instance UID")
	ParticipantObjectSensitivity	U	not specialized
	ParticipantObjectID	M	The Study Instance UID
	ParticipantObjectName	U	not specialized
	ParticipantObjectQuery	U	not specialized
	ParticipantObjectDetail	U	not specialized
	ParticipantObjectDescription	U	not specialized
	SOPClass	MC	Element "ContainsSOPClass" with one or more SOP Class UID values
	Accession	U	not specialized
	NumberOfInstances	U	not specialized
	Instances	U	not specialized
	Encrypted	U	not specialized
Anonymized	U	not specialized	

Patient (1) (Audit Message/ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	"1" (Person)
	ParticipantObjectTypeCodeRole	M	"1" (Patient)
	ParticipantObjectDataLifeCycle	U	not specialized
	ParticipantObjectIDTypeCode	M	"2" = patient ID
	ParticipantObjectSensitivity	U	not specialized
	ParticipantObjectID	M	The Health ID of the patient
	ParticipantObjectName	U	The patient name
	ParticipantObjectQuery	U	not specialized
	ParticipantObjectDetail	U	not specialized
	ParticipantObjectDescription	U	not specialized

- [SIR-083] – DICOM SOP Instances (e.g. images, presentation states, key image notes) retrieved on-demand from the Imaging Repository **SHALL** be received in such a way that the user on the receiving system is able to display them.
- [SIR-084] – DICOM SOP Instances (e.g. images, presentation states, key image notes) retrieved from the Imaging Repository as relevant priors associated to an imaging study being read, these images **SHALL** be received in such a way that the user on the receiving

system **SHALL** be able to display them “side by side” (i.e. comparison of the prior and new images).

- [SIR-085] – The ability to view images the same as viewed by other PACS systems is required. Therefore, the Information Consumer Actor **SHALL** be able to display images using the information defined in DICOM Greyscale Presentation State SOP Instances present in the imaging study. This **SHALL** be accomplished according the functional requirements of the IHE Radiology Consistent Presentation of Images (CPI) Integration Profile.

Note: The Information Consumer Actor need not support the transactions specified by IHE CPI, as these DICOM objects are exchanged in this Interoperability Specification using the Retrieve Images Service (IHE XDS-I.b), see Section 4.1.2.

- [SIR-086] – Users have the ability to flag one or more significant images in a study and include notes for those images. Therefore, the Information Consumer Actor **SHALL** be able to display key images and notes using the information defined in the DICOM Key Object Selection SOP Instances present in the imaging study. This **SHALL** be accomplished according the functional requirements of the IHE Radiology Key Image Note (KIN) Integration Profile.

Note: The Information Consumer Actor need not support the transaction specified by IHE KIN, as these DICOM objects are exchanged in this Interoperability Specification using the Retrieve Images Service (IHE XDS-I.b), see Section 4.1.2.

- [SIR-087] – When querying a Document Registry, an Imaging Information Consumer **SHALL** be able to support the return of several Imaging Reports and Imaging Manifests. An Imaging Manifest may be associated with different Imaging Reports (Same KSA-Wide Accession Number using Reference ID (See ITI TF-1: 10.2.6)).

5.3 REQUIREMENTS FOR IMAGING REPORT CONSUMER USE CASE ACTOR

The following rules **SHALL** be supported by the Imaging Report Consumer Use Case Actor for its conformance to the Imaging Report Consumer Actor:

- [SIR-088] – When retrieving a patient’s imaging report, it is the responsibility of the Imaging Report Consumer to rely on the Metadata associated with the Imaging Report to reconcile the KSA-Wide information with its local information and conventions. At a minimum, it **SHALL** reconcile:
 - The KSA-Wide Health ID with the local Patient ID
 - The Saudi eHealth Imaging Procedure Codes with the corresponding local Imaging Procedure Codes
 - The KSA-Wide Accession Number with a corresponding local Accession Number

- [SIR-113] – When retrieving a patient’s imaging reports, the Imaging Report Consumer **SHALL** receive them in such a way that the user on the receiving system is able to display them.
- [SIR-114] – When querying a Document Registry, an Imaging Report Consumer **SHALL** be able to support the return of several Imaging Reports and Imaging Manifests. An Imaging Report may be associated with different Imaging Manifests (Same KSA-Wide Accession Number using Reference ID (See ITI TF-1: 10.2.6)).
- [SIR-115] –An Imaging Information Consumer **SHALL** be able to process and display the radiology report(s) as specified in IS0103 *Saudi eHealth Radiology Report Content Interoperability Specification*.

Note: An Imaging Information Consumer **MAY** chose to leverage the transform relationships between imaging reports in different format in a variety of ways. It **MAY** display to the user a single report entry and select the most appropriate format(s) based on the intended processing function of the report content.

5.4 REQUIREMENTS FOR IMAGING REPOSITORY USE CASE ACTOR

- [SIR-090] – When responding to a query, the Document Registry Actor supported by an Imaging Repository Use Case Actor **SHALL** be able to support the return of several Imaging Reports and Imaging Manifests for the same patient. Imaging Reports are associated with Imaging Manifests using a KSA-Wide Accession Number stored in the metadata attribute referenceIdList (See IHE ITI TF-3: Section 4.2.3.2.28).
- [SIR-091] – The following stored queries **SHALL** be supported by the XDS Document Registry:
 - FindDocuments
 - FindSubmissionSets
 - GetAll
 - GetDocuments
 - GetAssociations
 - GetDocumentsAndAssociations
 - GetSubmissionSets
 - GetSubmissionSetAndContents
 - GetRelatedDocuments
 Folder related transaction may be optionally supported:
 - FindFolders
 - GetFolders
 - GetFolderAndContents
 - GetFoldersForDocument
- [SIR-092] –Verification **SHALL** be performed at appropriate times that the SOP Instance UIDs listed in the Imaging Manifest are present in the Imaging Repository. If it is not the case, the source of theses Imaging Manifest **SHALL** be identified as misbehaving and an error **SHALL** be locally logged.

Note: The Imaging Repository may contain images that are no longer referenced by an active Imaging Manifest. However, those images remained referenced in a deprecated Imaging Manifest.

- [SIR-095]- The Imaging Information Source Actor sends DICOM SOP Instances to an assigned Imaging Repository as defined by the SeHE deployment configuration. In order to distinguish the different SeHE Imaging Repositories, each is assigned a UID called <repositoryUniqueId>. As a result the Imaging Repository Actor **SHALL** modify the Imaging Manifest created by the Imaging Information Source Actor with the attribute Retrieve Location UID (0040,E011) set to the <repositoryUniqueId> UID value for the Imaging Repository where the DICOM SOP Instances referenced by the Imaging Manifest have been stored.

Note: The DICOM attribute Retrieve Location UID (0040,E011) is used to identify the location of the DICOM SOP Instances referenced within an Imaging Manifest. This UID allows Imaging Information Consumer Actors to know which Imaging Repository has stored the DICOM objects referenced by the Imaging Manifest. Therefore, enabling the ability to retrieve the DICOM objects using the [IHE XDS-I.b: Retrieve Imaging Document Set RAD-69] or [IHE XDS-I.b: WADO Retrieve RAD-55] transactions.

- [SIR-093] –An Imaging Information Source **SHALL** support image retrieve transactions initiated by Imaging Document Consumers using both the:
 - IHE XDS-I.b: Retrieve Imaging Document Set RAD-69 transaction
 - IHE XDS-I.b: WADO Retrieve RAD-55 transaction

6. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this interoperability specification.

TABLE 6-1 INTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide Health ID is used to register Imaging Manifests and reports for the correct patient.
IS0101 Saudi eHealth Security and Privacy Interoperability Specification	Specifies the interoperability standards and profiles along with the Saudi specific constraints that are required to provide the technical security measures, data protection, and privacy management that will facilitate the implementation of the Saudi eHealth Policies for Health Information Exchange in the Kingdom of Saudi Arabia among communicating IT systems.
IS0102 Saudi eHealth Document Sharing Interoperability Specification	Forms a “container” for set of requirements that complements the IHE Cross-enterprise Document Sharing (XDS) Profile and the IHE Document Metadata Subscription (DSUB) integration profile with Saudi eHealth specific constraints when it is called upon by any of the Core Interoperability Specifications.
IS0103 Saudi eHealth Radiology Report Content Interoperability Specification	Specifies the clinical content for the sharing of radiology reports based upon the IHE Scanned Document (SD) Content Profile. This interoperability specification focuses on the Saudi eHealth specific constraints. This document is applicable to existing and new information systems. These systems will be connected to the national Saudi eHealth Exchange (SeHE) platform.
IS0200 Saudi eHealth Terminology Repository	Specifies the terminology concepts and associated coded value sets for data elements used throughout the Saudi eHealth Interoperability Specifications.
UC0005 Saudi eHealth Imaging Interoperability Use Case	Specifies the Saudi eHealth Interoperability Use Case applicable to existing and new information systems to be connected to the national Saudi Health Information Exchange (HIE) Platform. The Imaging Use Case describes the capability to share imaging reports and images and also supports the submission of a tele-radiology order to a remote tele-radiology service via the national Saudi Health Information Exchange (HIE) platform.
Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the Saudi Health Information Exchange. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the Saudi Health Information Exchange managed health records, including those connected to the Saudi Health Information Exchange, their Business Associates, as well as any subcontractors of Business

	Associates. These policies apply to all information provided to or retrieved from the Saudi Health Information Exchange.
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TABLE 6-2 EXTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles Cross-Enterprise Document Sharing (XDS.b) – Section 10	Facilitates the registration, distribution and access across health enterprises of patient electronic health records. This profile is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti .
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integration Profiles, Supplement -- XDS Metadata Update	Updates the XDS and XDR profiles to add support for the updating and deleting of metadata. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 3 (ITI TF-3) Integrations Profiles, Section 4 Metadata used in Document Sharing profiles	Describes the metadata that is used in IHE profiles designed for sharing documents (Document Sharing profiles). The Document Sharing profiles are implementing the Document Sharing concept outlined in the ITI whitepaper entitled Health Information Exchange: Enabling Document Sharing Using IHE Profiles May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE Radiology (Rad) Technical Framework – Volume 1 (IHE Rad TF-1) Integrations Profiles– Cross-Enterprise Document Sharing for Imaging (XDS-I.b) – Section 18	Extends and specializes the mechanisms defined by XDS.b to support imaging “documents”, specifically including the following: <ul style="list-style-type: none"> • Imaging studies that include images acquired on a broad range of different modalities •Diagnostic reports resulting from the interpretation of one or more related imaging studies provided in a ready-for-display form •A selection of diagnostically significant images associated with the report content. May be obtained at http://www.ihe.net/Technical_Frameworks/#radiology .
IHE Radiology (Rad) Technical Framework – Volume 1 (IHE Rad TF-1) Integration Profiles– Consistent Presentation of Images (CPI) – Section 5	Specifies a number of transactions that maintain the consistency of presentation for grayscale images. The presentation of images depends upon the contrast/brightness and the spatial and graphical operations applied, such as user annotations, shutters, flip/rotate, display area selection, and zoom. May be obtained at http://www.ihe.net/Technical_Frameworks/#radiology
IHE Radiology (Rad) Technical Framework – Volume 1 (IHE Rad TF-1) Integrations Profiles– Key Image Note (KIN) – Section 8	Specifies transactions that allow a user to mark one or more images in a study as significant by attaching to them a note managed together with the study. This note includes a title stating the purpose of marking the images and, optionally, a user comment field. May be obtained at http://www.ihe.net/Technical_Frameworks/#radiology .

7. APPENDIX A – IMAGING MANIFEST DATA ATTRIBUTES

This Appendix provides the set of logical data attributes which are used for the Imaging Manifest. These attributes are shown in Table 5.4-1 Key Logical Data Attributes for Imaging Manifest.

Note: The imaging report data attributes are shown in the referenced document “Saudi eHealth Radiology Report Content Interoperability Specification”.

Note: The DICOM object data attributes (i.e. images, presentation states, etc.) are shown in the DICOM V3.0 Standard.

TABLE 5.4-1 KEY LOGICAL DATA ATTRIBUTES FOR IMAGING MANIFEST

ATTRIBUTE LOGICAL NAME	DICOM V3.0 ATTRIBUTE NAME	LOGICAL DEFINITION	TEXT/ CODED
Health ID or Local Patient ID	Patient ID (0010,0020)	An ID that identifies the patient for which this imaging manifest references.	ID Format
Patient's Name	Patient's Name (0010,0010)	The individual to whom the health record refers.	Name Formatted
Gender	Patient's Sex (0010,0040)	The administrative sex of the patient.	Coded
Birth Date	Patient's Birth Date (0010,0030)	The date of the birth of the patient.	Date Formatted
Study Date	Study Date (0008,0020)	Date the study started.	Date Formatted
Study Time	Study Time (0008,0030)	Time the study started.	Time Formatted
Accession Number	Accession Number (0008,0060)	The RIS generated order number for the imaging procedure(s) in the manifest.	ID/OID Formatted
Retrieve Location UID	Retrieve Location UID (0040,E011)	Unique identifier of the system where the DICOM Object(s) may be retrieved on the network.	UID Formatted
Study Instance UID	Study Instance UID (0020,000D)	Unique identifier for the study.	UID Formatted
Referenced Series Sequence	Referenced Series Sequence (0008,1115)	References one or more series within the imaging study, using the attribute Series Instance UID for each series referenced.	Sequence and UID Formatted
Referenced Image Sequence	Referenced SOP Sequence (0008,1199)	References one or more DICOM images or other DICOM objects within a series, using the attributes Referenced SOP Class UID and Referenced SOP Instance UID.	Sequence and UID Formatted

8. APPENDIX B – EXAMPLE MESSAGES

EXAMPLES WILL BE PROVIDED AS PART OF THE IS SPECIFICATION VALIDATION PROCESS. UNTIL THEN THIS SECTION WILL REMAIN BLANK.