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Enabling Standards-Based eHealth Interoperability

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Saudi eHealth Radiology Reports Content Interoperability Specification

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TABLE OF CONTENTS

1. INTRODUCTION	5
1.1 DOCUMENT PURPOSE.....	5
1.2 DESCRIPTION	5
1.3 SCOPE	5
1.4 RELATIONSHIP BETWEEN RADIOLOGY STRUCTURED REPORTS AND DISPLAYABLE REPORTS	6
1.5 METHODOLOGY	6
1.6 HOW TO READ THIS DOCUMENT	7
1.6.1 Where to Find Information	7
1.6.2 Related Documents	7
1.6.3 Document Conventions	8
1.6.4 Requirements Numbering Conventions:	8
2. COMMON HL7 CDA HEADER ATTRIBUTE CONSTRAINTS FOR RADIOLOGY REPORTS	10
2.1 RADIOLOGY REPORT SAUDI EHEALTH CONSTRAINTS	10
2.1.1 Common HL7 CDA Header Constraints	10
2.1.2 HL7 CDA Header Attributes Being Constrained for Radiology Reports	10
2.1.3 Specific HL7 CDA Header Constrained for Radiology Reports	11
2.1.4 InFullfillmentOf Constraints	12
2.1.5 DocumentationOf Constraints.....	12
3. SAUDI EHEALTH CONSTRAINTS USING IHE SCANNED DOCUMENT (XDS-SD) PROFILE	13
3.1 DISPLAYABLE RADIOLOGY REPORT CONTENT CREATOR	13
3.2 DISPLAYABLE RADIOLOGY REPORT CONTENT CONSUMER	13
4. SAUDI EHEALTH CONSTRAINTS USING THE HL7 CDA RELEASE 2 STANDARD	14
4.1 BASIC STRUCTURED RADIOLOGY REPORT CONTENT CREATOR.....	14
4.2 BASIC STRUCTURED RADIOLOGY REPORT CONTENT CONSUMER.....	14
5. REFERENCED DOCUMENTS AND STANDARDS.....	15
6. APPENDIX A – SAMPLE DISPLAYABLE RADIOLOGY REPORT DOCUMENT.....	17
7. APPENDIX B – SAMPLE BASIC STRUCTURED RADIOLOGY REPORT DOCUMENT.....	18

LIST OF TABLES

TABLE 2.1-1 CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR RADIOLOGY REPORTS	10
TABLE 5-1 INTERNAL REFERENCES	15
TABLE 5-2 EXTERNAL REFERENCES.....	15

LIST OF FIGURES

FIGURE 1.6.2-1 RADIOLOGY REPORT CONTENT DOCUMENT ORGANIZATION	8
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1.0	April 21, 2016	First Release	Saudi Health Council

1. INTRODUCTION

1.1 DOCUMENT PURPOSE

The purpose of this document is to support IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports* and its associated Use Cases. This specific document is centered on defining the content and format of radiology interpretation reports to be shared within the KSA. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Supporting Interoperability Specification is applicable to existing and new information systems. The systems will be connected to the national Saudi eHealth Exchange (SeHE) System.

1.2 DESCRIPTION

This Supporting Interoperability Specification describes the content and format of Radiology Reports. It is motivated by the need to have easy access for reviewing Radiology Reports within the KSA. These reports can be shared by Health IT systems via SeHE based upon the requirements defined in the Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports. This Supporting Interoperability specification defines two types of Radiology Reports, they are:

- A “Displayable Radiology Report” that includes structured header data and ready to display content for the purpose of viewing a Radiology Report in the same format as created by the source
- A “Basic Structured Radiology Report”, that includes structured header data and coded sections heading titles (such as History, Impressions, Findings, Conclusions, etc.)

1.3 SCOPE

In Scope:

The scope of this document is the specification of content and format of a Radiology Report to be exchanged within SeHE. It supports UC0005 Saudi eHealth Sharing Images and Imaging Reports Use Case.

This Interoperability Specification specifies two formats for a Radiology Report:

- For the Displayable Radiology Report, use of the IHE Scanned Document (XDS-SD) content profile to define a “displayable” Radiology Report based upon the Health Level Seven (HL7) Clinical Document Architecture (CDA) standard. The report content is divided into two major sections, the HL7 CDA header followed by the document body. The document body which consists of the radiology diagnostic report is encoded using the standard PDF format.
- For the Basic Structured Radiology Report, use of the HL7 CDA Rel 2 content and format to generate a Radiology Report with a structured document header and coded radiology section header titles. The interpretation content is unstructured text as it is the predominant mechanism to convey diagnostic Radiology Report information.

Out of Scope:

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

- The mechanisms for which Health IT systems share these images reports within SeHE and throughout the KSA
- Structured and coded section content to define computer processable content of the diagnostic interpretation of the report.
 Note: The use of the HL7 CDA Release 2 standard is expected to support future extensions of this Interoperability Specification with more structured report formats than the two specified in this version.
- The workflow to order, perform and generate Radiology Reports
- How Health IT systems display the Radiology Reports it creates and/or consumes

1.4 RELATIONSHIP BETWEEN RADIOLOGY STRUCTURED REPORTS AND DISPLAYABLE REPORTS

The Displayable Radiology Report is based on the IHE XDS-SD profile which uses the HL7 CDA Release 2 standard and provides additional constraints to the HL7 CDA header data and the PDF/A format of the document body. IHE defines two Actors relevant to this Interoperability Specification, they are:

- Content Creator – the creator of the document content
- Content Consumer – the consumer of the document content

The Basic Structured Radiology Report also uses the HL7 CDA Release 2 standard and uses the same set of additional constraints to the HL7 CDA header data as the Displayable Radiology Report; however the format of the document body is different and relies on the HL7 CDA Release 2 document body specification. The same two Actors are used:

- Content Creator – the creator of the document content
- Content Consumer – the consumer of the document content

See Section [55](#) for a brief description and information for how to obtain the documents.

1.5 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 Supporting 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 (See Section 5 for reference).

1.6 HOW TO READ THIS DOCUMENT

1.6.1 Where to Find Information

This document contains four normative sections, as well as informative appendices for the reader's 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: Specifies the common Saudi eHealth CDA Header attribute constraints for all HL7 CDA based Radiology Reports

Section 3: Specifies the common Saudi eHealth constraints for implementing Radiology Reports using IHE Scanned Document (XDS-SD) content profile for displayable reports

Section 4: Specifies the common Saudi eHealth constraints for implementing Radiology Reports using HL7 CDA Release 2 for structured titles for the CDA body section headings

Section 5: Lists the Saudi eHealth reference documents, as well as the international standards which underpin this Interoperability Specification.

Appendix A: Provides sample Radiology Report document based upon IHE XDS-SD

Appendix B: Provides sample Radiology Report document based upon HL7 CDA Release 2

1.6.2 Related Documents

The reader of the Supporting Interoperability Specification is assumed to be familiar with the HL7 CDA Release 2 Standard and the IHE Scanned Documents (XDS-SD) Content Profile. HL7 CDA Release 2 is the base standard used by this Supporting Interoperability Specification to define the format and structure of the Radiology Reports.

A Supporting Saudi eHealth Interoperability Specification (IS) may be referenced by one or more Core Saudi eHealth Interoperability Specifications. They may also reference other supporting Interoperability Specifications. A supporting Interoperability Specification is targeted to be a testable unit.

This supporting Interoperability Specification references the following Interoperability Specifications:

- IS0005 *Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports*
- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*
- IS0200 *Saudi Health Information Exchange Data Dictionary*

The above Saudi eHealth Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Saudi specific constraints.

This document fits into an overall specification framework shown in [Figure 1.6.2-1 Radiology Report Content Document Organization](#)

Organization. Further descriptions and references for the documents identified below are provided in Section 55.

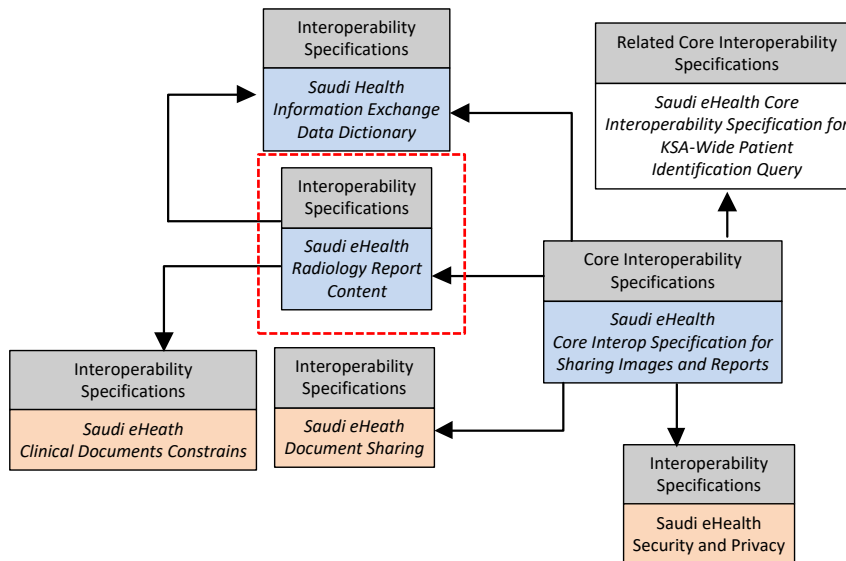


FIGURE 1.6.2-1 RADIOLOGY REPORT CONTENT DOCUMENT ORGANIZATION

1.6.3 Document Conventions

1.6.4 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 Health Information Exchange Data Dictionary”. The location and process to access the Health Information Exchange Data Dictionary 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.

1.6.4.1 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. COMMON HL7 CDA HEADER ATTRIBUTE CONSTRAINTS FOR RADIOLOGY REPORTS

HL7 CDA based documents are divided into two major sections, the HL7 CDA header followed by the document body. This Section provides Saudi eHealth constraints to the HL7 CDA header required to be implemented for both the Displayable Radiology Report and the Basic Structured Radiology Report defined in this supporting Interoperability Specification.

2.1 RADIOLOGY REPORT SAUDI EHEALTH CONSTRAINTS

2.1.1 Common HL7 CDA Header Constraints

[RADR-001] A Content Creator Actors creating the HL7 CDA Release 2 document header for the Displayable or Basic Structured Radiology Report **SHALL** support the Saudi eHealth Attribute and Data Type constraints (i.e., name format, date format, etc.) defined in the IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*.

[RADR-002] A Content Creator Actor creating the HL7 CDA Release 2 document header for the Displayable or Basic Structured Radiology Report **SHALL** support the additional Saudi eHealth Data Type constraints specific to radiology reports defined in Section 2.1.2 and 2.1.3.

2.1.2 HL7 CDA Header Attributes Being Constrained for Radiology Reports

TABLE 2.1-1 Constrained HL7 CDA Header Attributes For Radiology Reports provides a list of the HL7 CDA header attributes for which Saudi eHealth constraints specific to the header of Radiology Reports exist. The actual Saudi eHealth constraints are specified in Tables shown in Section **2.1.32-1.3**.

Note: a number of attributes in the header of radiology reports are not listed in Table 2.1.2-1. These attributes are not radiology specific constraints (e.g. patient names, identification, etc.) and are specified in IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*.

TABLE 2.1-1 CONSTRAINED HL7 CDA HEADER ATTRIBUTES FOR RADIOLOGY REPORTS

CDA HEADER ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION
Clinical Document		ClinicalDocument/

Code	The code specifying the particular kind of document.	./Code
Data Enterer		/ClinicalDocument/dataEnterer/assignedEntity/
Id	Represents the person's Id that transferred the information from other sources into the clinical document where the other sources wrote the content of the document. Such as the transcriptionist for dictated text.	./id
Name	Represents the name of the person that transferred the information from other sources into the clinical document where the other sources wrote the content of the document.	./assignedPerson/name
Organization id	Represents the organization Id the person belongs to.	./representedOrganization/id
Organization name	Represents the organization name the person belongs to	./representedOrganization/name
Participant Referring Physician		/ClinicalDocument/participant[@typeCode=REF]/associatedEntity
id	Represents the physician's ID that referred this patient for the imaging procedure.	./id
Name	Represents the physician's name that referred this patient for the imaging procedure.	./associatedPerson/name
Organization ID	Represents the organization's identifier that the referring physician belongs to.	./scopingOrganization/id
Organization Name	Represents the organization's name that the referring physician belongs to.	./scopingOrganization/name
InFulfillmentOf		/ClinicalDocument/inFulfillmentOf/order/
Order ID	Represents one or more accession numbers for the imaging procedure(s) this report documents.	./id
DocumentationOf		/ClinicalDocument/documentationOf/serviceEvent/
Imaging Procedure Code	Imaging procedure code used to perform the image acquisition.	./code
Imaging Procedure Description	Imaging procedure display name used to perform the image acquisition.	./code/@DisplayName
Study Instance UID	Unique identifier of the study(ies).	./id

2.1.3 Specific HL7 CDA Header Constrained for Radiology Reports

A Content Creator Actor creating a Radiology Report based upon the HL7 CDA Release 2 Standard **SHALL** support the Saudi eHealth constraints to the CDA Header as defined in the following Sections.

2.1.3.1 CLINICAL DOCUMENT CONSTRAINTS

[RADR-005] The **Code** value **SHALL** be selected from the “Radiology Reports Title” Value Set
[RADR-007] The **Clinical Document** **SHALL** contain exactly one [1..1] **Data Enterer** IF KNOWN

- [RADR-015] The **Clinical Document** SHALL contain exactly one [1..1] **Participants Referring Physician** IF KNOWN.
- [RADR-023] The **Clinical Document** SHALL contain exactly one [1..1] **InFullfillmentOf** IF KNOWN
- [RADR-027] The **Clinical Document** SHALL contain exactly one [1..1] **DocumentationOf** and SHALL NOT be null

2.1.3.2 DATA ENTERER CONSTRAINTS

- [RADR-008] The **Data Enterer** SHALL contain exactly one [1..1] **id** IF KNOWN.
- [RADR-009] The **Data Enterer** SHALL contain exactly one [1..1] **Name** and SHALL NOT be null
- [RADR-011] The **Data Enterer** SHALL contain exactly one [1..1] **Organization id** IF KNOWN.
- [RADR-012] The **Data Enterer** SHALL contain exactly one [1..1] **Organization Name** that SHALL NOT be null

2.1.3.3 PARTICIPANT REFERRING PHYSICIAN CONSTRAINTS

- [RADR-016] The **Participant Referring Physician** SHALL contain exactly one [1..1] **id** IF KNOWN.
- [RADR-017] The **Participant Referring Physician** SHALL contain exactly one [1..1] **Name** that SHALL NOT be null
- [RADR-019] The **Participant Referring Physician** SHALL contain exactly one [1..1] **Organization id** IF KNOWN.
- [RADR-020] The **Participant Referring Physician** SHALL contain exactly one [1..1] **Organization Name** IF KNOWN.

2.1.4 InFullfillmentOf Constraints

- [RADR-024] The **InFullfillmentOf** SHALL contain one or more [1..*] **Order id** value SHALL be set to the KSA-Wide Accession Number with its associated OID

2.1.5 DocumentationOf Constraints

- [RADR-028] The **DocumentationOf** SHALL contain one or more [1..*] **Imaging Procedure Code** that shall be selected from the “Imaging Procedure” value set
- [RADR-029] The **DocumentationOf** SHALL contain one or more [1..*] **Imaging Procedure Description**. SHALL be selected from the “Imaging Procedure” value set
- [RADR-030] The **DocumentationOf** SHALL contain one or more [1..*] **Study Instance UID** IF KNOWN.

3. SAUDI EHEALTH CONSTRAINTS USING IHE SCANNED DOCUMENT (XDS-SD) PROFILE

3.1 DISPLAYABLE RADIOLOGY REPORT CONTENT CREATOR

[RADR-035] A Content Creator Actor creating a Displayable Radiology Report **SHALL** support the Saudi eHealth HL7 CDA header constraints as defined in Section [2.12.1](#). No additional HL7 CDA header constraints are defined beyond those specified in IHE IHE Scanned Document (XDS-SD) Profile.

[RADR-040] A Content Creator Actor creating the document body of a Displayable Radiology Report **SHALL** support the IHE Scanned Document Content Profile XDS-SD using the PDF Option.

Note: IHE XDS-SD defines multiple options for the content of the document body. The intent of this Saudi eHealth program in using XDS-SD is to provide a “displayable report” to be shared as created/viewed by the Content Creator with the support of the PDF Option.

3.2 DISPLAYABLE RADIOLOGY REPORT CONTENT CONSUMER

[RADR-041] A Content Consumer Actor **SHALL** process a Displayable Radiology Report supporting the IHE Scanned Document Content Profile XDS-SD using the PDF Option, including processing the CDA header with constraints as defined in Section 2.1.

4. SAUDI EHEALTH CONSTRAINTS USING THE HL7 CDA RELEASE 2 STANDARD

4.1 BASIC STRUCTURED RADIOLOGY REPORT CONTENT CREATOR

[RADR-045] A Content Creator Actor creating a Basic Structured Radiology Report based upon the HL7 CDA Release 2 Standard **SHALL** support the Saudi eHealth HL7 CDA header constraints as defined in Section 2.12.1. No additional HL7 CDA header constraints are defined.

[RADR-046] A Content Creator Actor creating a Basic Structured Radiology Report based upon the HL7 CDA Release 2 Standard **SHALL** generate one or more document section, with coded Section Headings based upon the “Radiology CDA Section Heading” Value Set.

Note: HL7 CDA Release 2 is a robust standard which is able to support both displayable and structure data when creating a document. The intent of this Basic Structured Radiology Report in using HL7 CDA Release 2 is to generate a Radiology Report with a structured document header and coded radiology section titles. The interpretation content is unstructured text (within the section body) as it is the predominant mechanism to convey diagnostic Radiology Report information.

4.2 BASIC STRUCTURED RADIOLOGY REPORT CONTENT CONSUMER

[RADR-050] A Content Consumer Actor processing a Basic Structured Radiology Report **SHALL** support the Saudi eHealth HL7 CDA header with constraints as defined in Section 2.12.1.

[RADR-051] A Content Creator Actor processing a Basic Structured Radiology Report **SHALL** process the document sections with their coded section header based upon the “KSA Report Sections” Value Set.

[RADR-052] Implementations **MAY** ignore any coded entries within the sections of the document body.

Note: HL7 CDA Release 2 is a robust standard which is able to support various levels of structured data when creating a document. The intent of this Basic Structured Radiology Report in using HL7 CDA Release 2 is to allow Basic Structured Radiology Report Consumers to receive Radiology Reports with a structured document header and coded radiology section header titles (CDA Level 2), but also to process and ignore any structured interpretation content within the sections as code entries that may be specified in future further structured Radiology Reports (CDA Level 3).

5. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this Interoperability Specification.

TABLE 5-1 INTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
IS0005 Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports,	This Saudi eHealth Core Interoperability Specification for Sharing Images and Imaging Reports describes the technical requirements for the interface to share imaging reports and images via the Saudi eHealth Exchange (SeHE). This includes reports, images and image manifests acquired for a broad range of imaging modalities.
IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications	Specifies common constraints for clinical documents such as data elements of document headers that are common across the Saudi eHealth Project.
IS0200 Saudi Health Information Exchange Data Dictionary	Specifies the terminology concepts and associated coded value sets for specific data elements used for the laboratory domain.
UC0005 Saudi eHealth Imaging Interoperability Use Case	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.

TABLE 5-2 EXTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	An XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 further builds upon the Version 3.0 Reference Information Model (RIM) Standard. For more information See http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
IHE IT Infrastructure Technical Framework Volume 1 (ITI TF-1) Integration Profiles,– Final Text – Cross-Enterprise Sharing of Scanned Documents (Section 20 XDS-SD)	A variety of non-formatted healthcare reports, legacy paper, film, electronic and scanner outputted formats are used to store and exchange clinical documents. These formats do not have a uniform mechanism to store healthcare metadata associated with the documents, including patient identifiers, demographics, encounter, order, or service information. The association of structured, healthcare metadata with this kind of document is important to maintain the integrity of the patient health record as managed by the source system. It is necessary to provide a mechanism that allows such source metadata to be stored with the document. This profile defines how such information captured can be represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information. Furthermore, this

DOCUMENT STANDARD	OR	DESCRIPTION
		profile defines elements of the CDA R2 header necessary to minimally annotate these documents. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti

6. APPENDIX A – SAMPLE DISPLAYABLE RADIOLOGY REPORT DOCUMENT

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

7. APPENDIX B – SAMPLE BASIC STRUCTURED RADIOLOGY REPORT DOCUMENT

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