Digital Imaging and Communications in Medicine (DICOM)

Supplement 101: HL7 Structured Document Object References

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Foreword

There is a need for DICOM-based Application Entities to reference and/or access persistent data objects available outside the DICOM environment that are encoded using the HL7 Structured Documents (HL7-SD) format, in particular Clinical Document Architecture (CDA) documents. Similarly, there is a need for HL7 messages to reference DICOM Instances.

One use case is to provide a DICOM-based application with access to relevant CDA documents, such as pre-imaging-procedure lab test results, patient advance medical directives, or an outpatient history and physical report. There are defined network services that can retrieve the CDA documents (e.g., HTTP, as specified in the IHE Retrieve Information for Display Profile). However, there is still a need to encode the CDA document Instance Identifier (II) in DICOM instances, e.g., to provide a unified referencing of relevant prior objects in General Purpose Worklist Management Services, or to reference such CDA documents in a DICOM SR report, or in a DICOMDIR file for CDA documents included on DICOM exchange media.

A second use case is to provide a link between an SR document and its equivalent CDA document. CDA is now a formally adopted standard method in the USA for encoding claims attachments, including radiology and other imaging clinical reports, attached to HIPAA EDI transactions. Moreover, CDA is also emerging as a key element for a persistent-object-based Electronic Healthcare Record (EHR) integrating the entire healthcare enterprise. This drives the need for standard methods of encoding imaging procedure final clinical reports as CDA documents. However, the internal needs of the imaging department may dictate that those reports be created and be available as DICOM SR SOP Instances, managed in the DICOM infrastructure, to support future procedures with the same patient. Therefore, there is a need to have the same clinical report encoded in either or both SR and CDA formats with a minimum of transcoding issues.

Scope

This Supplement includes new attributes in various objects and services as required to support HL7-SD documents in DICOM-based workflows.

HL7 STRUCTURED DOCUMENT REFERENCES

This Supplement proposes a common method of referencing HL7-SD documents in DICOM instances, using the DICOM standard SOP Class / Instance paradigm and attributes. This allows references to HL7-SD documents to be carried in current data structures, such as COMPOSITE Content Items in SR documents, without requiring the definition of new IODs.

The first part of the DICOM document reference is the SOP Class UID. However, this requires a definition of SOP Class that can be applied in these non-DICOM object references. Within DICOM, the SOP Class specifies the Abstract Syntax. In HL7, the Abstract Syntax is specified using a Hierarchical Message Definition (HMD). Thus, this Supplement proposes using the Object Identifier (OID) of the Hierarchical Message Definition of the HL7 document class as the SOP Class UID for DICOM reference purposes. Note that the HL7 HMD does not imply a Network Service, as does the SOP Class, but this is considered no more significant than the use of network storage service SOP Class UIDs to identify the IOD of an object stored on DICOM interchange media using the media storage service. The important aspect is that the UID/OID identifies the Abstract Syntax.

The second part of the document reference is the SOP Instance UID. HL7-SD instances are natively identified by an attribute using the HL7 Instance Identifier (II) Data Type. A UID as defined by the DICOM UI Value

Representation is a valid identifier under the II Data Type; however, an II attribute is not always encodable as a UID. Therefore a UID is assigned for use within the DICOM Data Set that is mapped to the HL7-SD native Instance Identifier. This UID is required to be newly constructed if the native document identifier uses an OID longer than 64 characters, or if it is a "compound" Instance Identifier of a root OID and an Extension. If the instance identifier used natively within the referenced document is encodable using the UI VR, it may be used as the SOP Instance UID. The mapping from the UID to the II is always conveyed in each DICOM object that references an HL7-SD, even if the II is a simple UID and is used as the SOP Instance UID.

This Supplement proposes extensions of the SR, Modality Worklist, and General-Purpose Worklist SOP Classes to accommodate references to HL7-SD documents. It also proposes the ability to include HL7-SD documents on DICOM interchange media, and to reference them from the DICOMDIR.

Also note that an HL7-SD could be referenced in any place where a DICOM Instance can be referenced by a SOP Class/Instance UID pair (e.g., in the Referenced Instance Sequence (0008,114A) in composite IODs).

SR AND CDA REPORTING

In support of clinical reports encoded in both SR and CDA formats, this Supplement proposes extending the SR Information Object Definition with a reference to an instance's equivalent CDA document.

Additionally, this Supplement proposes a new Template that will facilitate the same clinical report being encoded in either or both SR and CDA formats with a minimum of transcoding issues for the content tree. This Template is a restricted subset of the existing TID 2000, and supports the plain dictated text imaging report which is easily transcoded to the attested narrative content block of a CDA document. It also supports a relatively small, but extremely powerful, increment of functionality over a plain dictated text report – the addition of image references with annotations.

An informative annex describes a use case dataflow for how a classical dictation/transcription reporting process can be augmented to include image references. This use case is based on the use of a Key Object Selection (KO) object to convey the selection of images from the softcopy review station to the report management system. The use case describes how transcription and KO objects can be combined into either or both an SR and a CDA formatted report.

One aspect of CDA reports is the presence of image references in the CDA document. This Supplement recommends an encoding of DICOM object references in CDA documents (and other HL7 v3 messages).

Note that the report encoding in SR and CDA is not required to be a reversible transcoding, and in fact defining a reversible transcoding applicable to a broad variety of environments has proven to be impracticable. Rather, the requirement is for *clinical equivalence* between the instances in the two formats, and the specific transcoding between SR and CDA formats is implementation-dependent. However, SR and CDA representations of a diagnostic report shall contain equivalent clinical content.

Structure of the Supplement

This Supplement modifies the following Parts of the DICOM Standard:

PS 3.3: Information Object Definitions

- Addition of Clinical Documents, as defined by HL7, to the Real World Models for Modality and General Purpose Worklists

- Inclusion of references to pertinent Documents in the Patient Medical Module, allowing such references in Modality and General Purpose Worklists
- Addition of a mapping mechanism to the SOP Common Module to support references to HL7 Structured Documents
- Addition of attributes to the SR Document General Module to harmonize with CDA header, and to support access to HL7 Structured Documents. The additional attributes support identification of participants in the production of SR Instances
- Inclusion of HL7 Structured Documents as a type of referenced Composite object in the SR Content tree
- Inclusion of references to HL7 Structured Documents in the DICOMDIR Directory structure, allowing the placement of HL7 Structured Documents on DICOM Interchange Media

PS 3.4: Service Class Specifications

- Addition of attributes for references to HL7 Structured Documents in the Modality and General Purpose Worklists using the Patient Medical Module

PS 3.6: Data Dictionary

- Addition of new attributes to Data Dictionary
- Addition of new UIDs

PS 3.10: Media Storage and File Format for Data Interchange

- Definition of encoding format for HL7 Structured Documents placed on DICOM Interchange Media

PS 3.16: Content Mapping Resource

- Clarification of the default Observer Context in TID 1001
- Definition of a template for a Transcribed Diagnostic Imaging Report, including referenced significant images

PS 3.17: Explanatory Information

- Description of a use case and data flow for Transcribed Diagnostic Imaging Report production with image references, including encoding of the report as an SR and/or a CDA document, and recommended mappings of image references to HL7 data structures.

Part 3 Addendum

Add the following to Part 3 Section 2:

2 Normative references

HL7 v3 DT R1	Health Level Seven Version 3 Standard: Data Types – Abstract Specification, Release 1
ANSI/HL7 CDA R1.0-2000	Health Level Seven Version 3 Standard: Clinical Document Architecture Framework, Release 1.0
HL7 v3 CDA R2-2005	Health Level Seven Version 3 Standard: Clinical Document Architecture Framework, Release 2
ANSI/HL7 SPL R1.0-2004	HL7 Structured Product Labeling Standard, Release 1.0
HL7 SCTP R1.0	HL7 Structured Clinical Trial Protocol Standard, Release 1.0
RFC 2396	Uniform Resource Identifiers (URI): Generic Syntax

Add the following to Part 3 Section 4:

4 Symbols and abbreviations

The following symbols and abbreviations are used in this Part of the Standard.

CDA	Clinical Document Architecture (HL7)
HMD	Hierarchical Message Description (HL7)
IHE	Integrating the Healthcare Enterprise
II	Instance Identifier (HL7)
OID	Object Identifier (ISO 8824)
SCTP	Structured Clinical Trial Protocol (HL7)
SD	Structured Documents (HL7)
SPL	Structured Product Labeling (HL7)
SR	Structured Reporting
UUID	Universal Unique Identifier (ISO/IEC 11578)
XDS	Cross-Enterprise Document Sharing Profile (IHE)
XML	Extensible Markup Language

Modify Part 3 Figure 7-3:

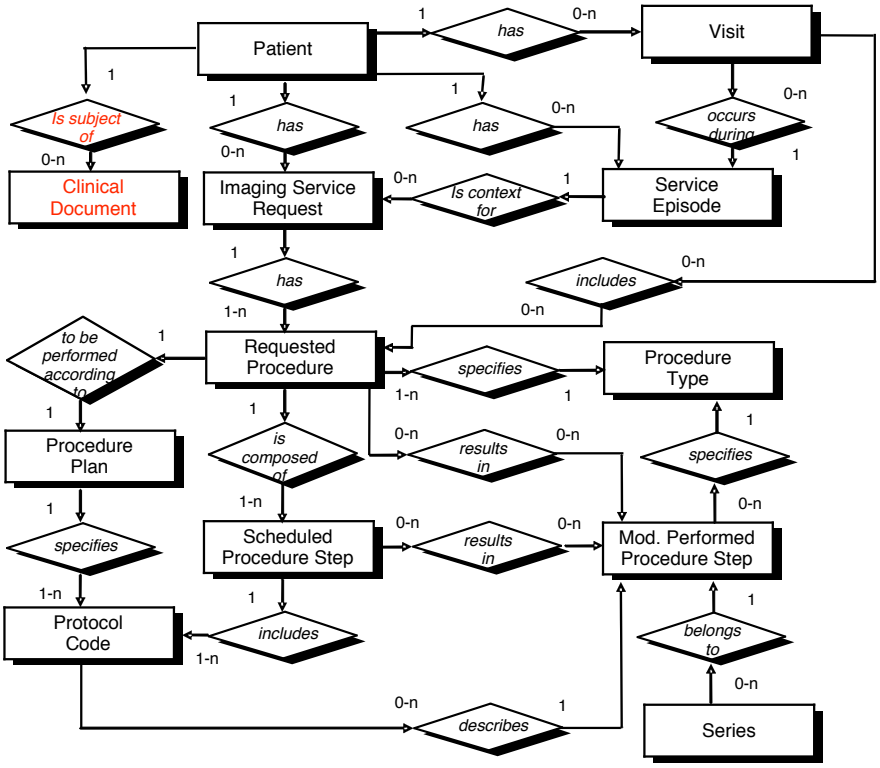

Figure 7-3.
MODEL OF THE REAL WORLD FOR THE PURPOSE OF MODALITY-IS INTERFACE

Add the following new section to Part 3 Section 7:

7.3.1.13 Clinical Document

A Clinical Document is a part of the medical record of a patient. A Clinical Document is a documentation of clinical observations and services and has the following characteristics:

- Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements.
- Stewardship – A clinical document is maintained by an organization entrusted with its care.
- Potential for authentication - A clinical document is an assemblage of information that is intended to be legally authenticated.
- Context - A clinical document establishes the default context for its contents.
- Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability – A clinical document is human readable.

Note: This definition is from ANSI/HL7 CDA R1.0-2000, and HL7 v3 CDA R2-2005.

Clinical Documents may provide significant context for the performance of imaging and related procedures, e.g., patient clinical history, pre-imaging-procedure lab test results, or patient advance medical directives.

Clinical Documents may be associated with Service Episodes, Service Requests, Requested Procedures, or other entities subsidiary to the Patient in the Real-World Model. Such associations are not explicitly modeled for the purposes of the Modality-IS or General Purpose Worklist contexts.

Clinical Documents are one sub-class of the class of healthcare Structured Documents; Structured Documents, in general, are not necessarily related to a patient. Structured Documents may be used for imaging procedure operational instructions, e.g., in product labeling, Procedure Plans, or patient care plans.

Notes: 1. The format and semantics of Structured Documents, including Clinical Documents, are defined outside the scope of the DICOM Standard (e.g., by HL7). DICOM provides the means to reference Structured Documents within the Modality-IS and General Purpose Worklist contexts.

2. The general class of Structured Documents is not modeled in the Real-World Model; only specific sub-classes, e.g., Clinical Documents, are modeled.

Modify Part 3 Figure 7-4.a:

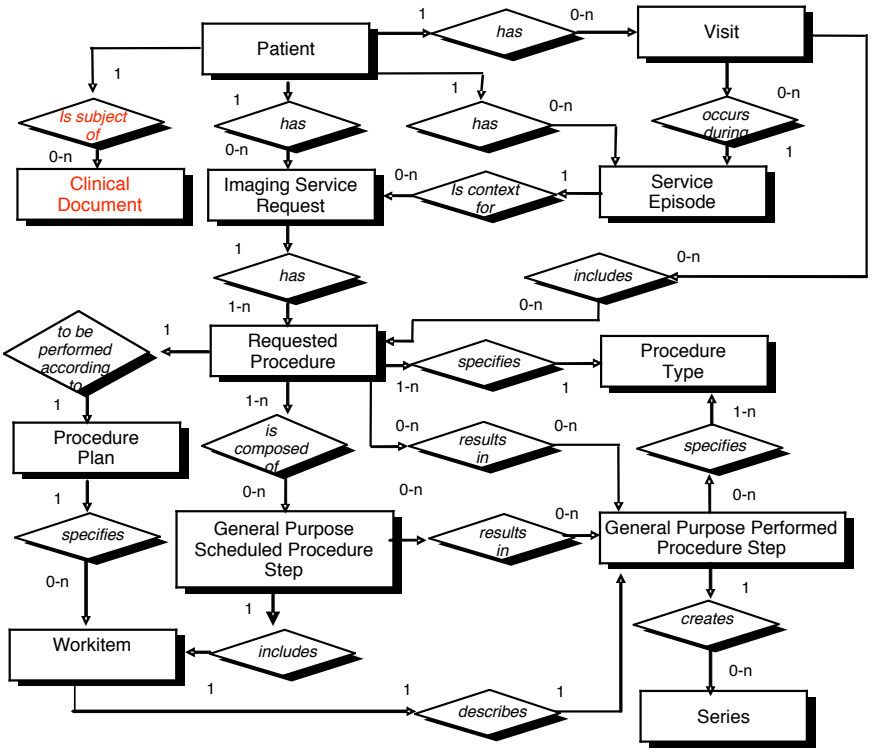

Figure 7.4.a
Model of the real world for the purpose of General Purpose Worklist interface

Modify Part 3 Table C.2-4 to include HL7-SD reference in Patient Medical Module (used in Modality and General Purpose Worklists):

C.2.4 Patient Medical Module

Table C.2-4 defines the Attributes relevant to a patient's medical state or history.

Table C.2-4
PATIENT MEDICAL MODULE ATTRIBUTES

Attribute Name	Tag	Attribute Description
…		
Patient State	(0038,0500)	Description of patient state (comatose, disoriented, vision impaired, etc.)
Pertinent Documents Sequence	**(0038,0100)**	**List of Documents (e.g., SR, or CDA) that contain information considered pertinent for the patient medical condition.** **Zero or more Items may be included in this sequence.**
>Referenced SOP Class UID	**(0008,1150)**	**SOP Class UID of the Referenced Document**
>Referenced SOP Instance UID	**(0008,1155)**	**SOP Instance UID of the Referenced Document**
>Purpose of Reference Code Sequence	**(0040,A170)**	**Describes the purpose for which the document reference is made. Zero or more Items may be present.**
>>Include 'Code Sequence Macro' Table 8.8-1		***No Baseline Context Group ID defined***
>Document Title	**(0042,0010)**	**Title of the referenced document.**

Modify Part 3 Table C.12-1 to include HL7-SD mapping in SOP Common Module:

C.12.1 SOP Common Module

Table C.12-1 defines the Attributes which are required for proper functioning and identification of the associated SOP Instances. They do not specify any semantics about the Real-World Object represented by the IOD.

Table C.12-1
SOP COMMON MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
…			
HL7 Structured Document Reference Sequence	**(0040,A390)**	**1C**	**Sequence of items defining mapping and/or access mechanism for HL7 Structured Documents referenced from the current SOP Instance. One or more Items may be included in this sequence.** **Required if HL7 Structured Documents are referenced within the Instance.**

>Referenced SOP Class UID	**(0008,1150)**	**1**	**Unique identifier for the class of HL7 Structured Document.**
>Referenced SOP Instance UID	**(0008,1155)**	**1**	**Unique identifier for the HL7 Structured Document as used in DICOM instance references.**
>HL7 Instance Identifier	**(0040,E001)**	**1**	**Instance Identifier of the referenced HL7 Structured Document, encoded as a UID (OID or UUID), concatenated with a caret ("^") and Extension value (if Extension is present in Instance Identifier).**
>Retrieve URI	**(0040,E010)**	**3**	**Retrieval access path to HL7 Structured Document. Includes fully specified scheme, authority, path, and query in accordance with RFC 2396**

Add new Part 3 sub-section C.12.1.1.6 for HL7 Structured Document Reference:

C.12.1.1.6 HL7 Structured Document Reference Sequence

The HL7 Structured Document Reference Sequence (0040,A390) identifies instances of Structured Documents defined under an HL7 standard. The HL7 standards that define such documents include the Clinical Document Architecture (CDA) and Structured Product Labeling (SPL) standards.

References to HL7 Structured Documents from within DICOM SOP Instances shall be encoded with a SOP Class UID and SOP Instance UID pair. The Abstract Syntax of an HL7 Structured Document is defined by its Hierarchical Message Description; the Object Identifier of the Hierarchical Message Description shall be used as the SOP Class UID for the Structured Document reference.

Notes: 1. The Hierarchical Message Description Object Identifiers are specified in the HL7 OID Registry (http://hl7.org/oid). The HL7 OIDs for these types of documents are:

CDA Release 1	2.16.840.1.113883.1.7.1
CDA Release 2	2.16.840.1.113883.1.7.2
SPL Release 1	2.16.840.1.113883.1.7.3

2. The Hierarchical Message Description Object Identifiers do not imply a network or media storage service, as do SOP Class UIDs. However, they do identify the Abstract Syntax, similar to SOP Class UIDs.

The HL7 Structured Document instances are natively identified by an attribute using the Instance Identifier (II) Data Type, as defined in HL7 v3 Data Types - Abstract Specification. A UID as defined by the DICOM UI Value Representation is a valid identifier under the II Data Type; however, an II attribute is not always encodable as a UID. Therefore a UID shall be constructed for use within the DICOM Data Set that can be mapped to the native instance identifier encoded as an HL7 II Data Type. This mapping is performed through the combination of the local Referenced SOP Instance UID (0008,1155) and the HL7 Instance Identifier (0040,E001) attributes in the HL7 Structured Document Reference Sequence (0040,A390).

Notes: 1. An HL7 II is not encodable as a UID if it exceeds 64 characters, or if it includes an extension. See HL7 v3 DT R1.

2. Even though an II may contain just a UID, applications should take care to use the II specified in HL7 Instance Identifier (0040,E001) to access the Structured Document. If the instance identifier used natively within the referenced document is encodable using the UI VR, i.e., it is an ISO 8824 OID up to 64 characters without an extension, it is recommended to be used as the Referenced SOP Instance UID within the current Instance.

3. The Referenced SOP Instance UID used to reference a particular HL7 Structured Document is not necessarily the same in all DICOM Instances. For example, two SR Documents may *internally* use different SOP Instance UIDs to reference the same HL7 Structured Document, but they will each contain a mapping to the same HL7 Instance Identifier as the *external* identifier.

4. The HL7 Instance Identifier is encoded in attribute (0040,E001) as a serialization of the UID and Extension (if any) separated by a caret character. This is the same format adopted in the IHE Cross-Enterprise Document Sharing (XDS) profile (see http://www.ihe.net).

5. See Figure C.12-x.

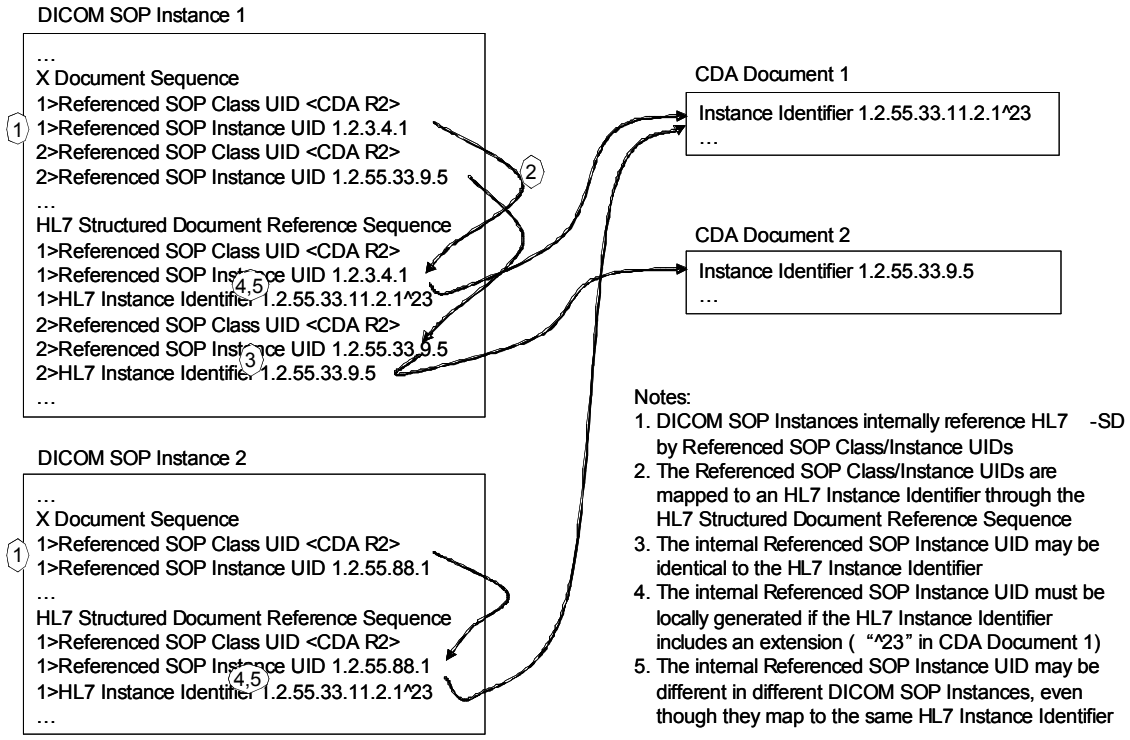

Figure C.12-x HL7 Structured Document References

Modify Part 3 Table C.17-2 to add participations and equivalent CDA document identifier to the SR header:

C.17.2 SR Document General Module

Table C.17-2 defines the general Attributes of an SR Document Instance. These Attributes identify the SR Document and provide context for the entire document.

295 **Table C.17-2**
SR DOCUMENT GENERAL MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
…			
Verifying Observer Sequence	(0040,A073)	1C	The person or persons authorized to verify documents of this type and accept responsibility for the content of this document. One or more Items may be included in this sequence. Required if Verification Flag (0040,A493) is VERIFIED. **Note: In HL7 Structured Documents, the comparable attribute is the "legalAuthenticator".**
>Verifying Observer Name	(0040,A075)	1	The person authorized by the Verifying Organization (0040,A027) to verify documents of this type and who accepts responsibility for the content of this document
>Verifying Observer Identification Code Sequence	(0040,A088)	2	Coded identifier of Verifying Observer. Zero or one Items shall be permitted in this sequence.
>>Include 'Code Sequence Macro' Table 8.8-1			***No Baseline Context ID defined***
>Verifying Organization	(0040,A027)	1	Organization to which the Verifying Observer Name (0040,A075) is accountable ~~**for this document**~~ in the current interpretation procedure.
>Verification Datetime	(0040,A030)	1	Date and Time of verification by the Verifying Observer Name (0040,A075).
Author Observer Sequence	**(0040,A078)**	**3**	**The person or device that created the clinical content of this document. This attribute sets the default Observer Context for the root of the content tree.** **Zero or one Items may be included in this sequence.**
>Include 'Identified Person or Device Macro' Table C.17-y			
Participant Sequence	**(0040,A07A)**	**3**	**Persons or devices related to the clinical content of this document.** **Zero or more Items may be included in this sequence.**

>Participation Type	**(0040,A080)**	**1**	**Participant's role with respect to the clinical content of this document. See C.17.2.5.** **Defined Terms:** **SOURCE – Equipment that contributed to the content** **ENT – Data enterer (e.g., transcriptionist)** **ATTEST – Attestor** **Note: In HL7 Structured Documents, the participation comparable to Attestor is the "Authenticator".**
>Participation Datetime	**(0040,A082)**	**2**	**Datetime of participation with respect to the clinical content of this document.**
>Include 'Identified Person or Device Macro' Table C.17-y			
Custodial Organization Sequence	**(0040,A07C)**	**3**	**Custodial organization for this SR Document instance. Represents the organization from which the document originates and that is in charge of maintaining the document, i.e., the steward of the original source document.** **Note: This may or may not be identical to the Institution identified in the Equipment Module.** **Zero or one Items may be included in this sequence.**
>Institution Name	**(0008,0080)**	**2**	**Name of Custodial Institution or Organization.**
>Institution Code Sequence	**(0008,0082)**	**2**	**Coded identifier of Custodial Institution or Organization.** **Zero or one Items may be included in this sequence.**
>>Include 'Code Sequence Macro' Table 8.8-1			***No Baseline Context ID defined***
…			
Pertinent Other Evidence Sequence	(0040,A385)	1C	…
>Include 'SOP Instance Reference Macro' Table C.17-3			
Equivalent CDA Document Sequence	**(0040,A090)**	**1C**	**Sequence specifying the CDA Document equivalent to the current SOP Instance. Only a single Item shall be permitted in this sequence. See C.17.2.6.** **Required if the identity of a CDA Document equivalent to the current SOP Instance is known at the time of creation of this SOP Instance.**
>Referenced SOP Class UID	**(0008,1150)**	**1**	**Unique identifier for the class of CDA Document.**

>Referenced SOP Instance UID	**(0008,1155)**	**1**	**Unique identifier for the CDA Document.**

Add new Part 3 sub-sections to C.17.2 for Participations and Equivalent CDA Document Sequence:

300 **C.17.2.4 Identified Person or Device Macro**

Table C.17-y defines the Attributes that identify a person or a device participating as an observer for the context of an SR Instance. This macro contains content equivalent to TID 1002 (see PS3.16).

Table C.17-y
Identified Person or Device Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Observer Type	(0040,A084)	1	Enumerated Values: PSN – Person DEV – Device
Person Name	(0040,A123)	1C	Name of the person observer for this document Instance. Required if Observer Type value is PSN.
Person Identification Code Sequence	(0040,1101)	2C	Coded identifier of person observer. Zero or one Items shall be permitted in this sequence. Required if Observer Type value is PSN.
>Include 'Code Sequence Macro' Table 8.8-1			*No Baseline Context ID defined*
Station Name	(0008,1010)	2C	Name of the device observer for this document instance. Required if Observer Type value is DEV.
Device UID	(0018,1002)	1C	Unique identifier of device observer. Required if Observer Type value is DEV.
Manufacturer	(0008,0070)	1C	Manufacturer of the device observer. Required if Observer Type value is DEV.
Manufacturer's Model Name	(0008,1090)	1C	Model Name of the device observer. Required if Observer Type value is DEV.
Institution Name	(0008,0080)	2	Institution or organization to which the identified person is responsible or accountable, or which manages the identified device.
Institution Code Sequence	(0008,0082)	2	Institution or organization to which the identified person is responsible or accountable, or which manages the identified device. Zero or one Items shall be permitted in this Sequence.

>Include 'Code Sequence Macro' Table 8.8-1	*No Baseline Context ID defined*

C.17.2.5 Verifying Observer, Author Observer, and Participant Sequences

The Verifying Observer Sequence (0040,A073), Author Observer Sequence (0040,A078), and Participant Sequence (0040,A07A) identify significant contributors to the SR document. The Author creates the clinical content of the document. The Verifying Observer verifies and accepts legal responsibility for the content. Other participants may include an Attestor, a person identified as a Participant who "signs" an SR document, but who does not have legal authority to verify the clinical content. E.g., an SR document may be authored and attested by a resident, and then verified by a staff physician; or a document may be authored by a CAD device and attested by a technologist, and then verified by a physician; or a technologist working with a measurement software package may be the author, the package is a Source participant, and the final content is verified by a physician.

An individual shall not be identified in both the Verifying Observer Sequence (as the legal authenticator) and in the Participant Sequence as an Attestor. An individual may be identified in both the Author Observer Sequence and either the Verifying Observer Sequence or the Participant Sequence.

The participation datetime for the Verifying Observer is conveyed in Verification Datetime (0040,A030) within the Verifying Observer Sequence, for the Author Observer in the Observation Datetime (0040,A032) in the main Data Set (see C.17.3), and for other participants in Participation Datetime (0040,A082) within the Participant Sequence.

C.17.2.6 Equivalent CDA Document Sequence

The Equivalent CDA Document Sequence (0040,A090) identifies an HL7 Clinical Document Architecture (CDA) Document that contains clinical content equivalent to this SR Document SOP Instance. This referenced CDA Document may be a source document that was transformed to create this SR Document, or it may be a transcoding of the content created simultaneously for both the SR Document and the CDA Document.

Notes: 1. Reference to a CDA Document created as a transcoding of the SR Document subsequent to the creation of the SR SOP Instance would not be encodable in that SOP Instance.

2. There is no requirement that the transform or transcoding between DICOM SR and HL7 CDA be reversible. In particular, some attributes of the DICOM Patient, Study, and Series IEs have no corresponding standard encoding in the HL7 CDA Header, and vice versa. Such data elements, if transcoded, may need to be encoded in implementation-dependent "local markup" (in HL7 CDA) or private data elements (in DICOM SR) in an implementation-dependent manner; some such data elements may not be transcoded at all. It is a responsibility of the transforming application to ensure clinical equivalence.

3. Due to the inherent differences between DICOM SR and HL7 CDA, a transcoded document should have a different UID than the source document.

The Referenced SOP Instance UID (0008,1155) in Items of this Sequence is mapped to the native HL7 Instance Identifier through the HL7 Structured Document Reference Sequence (0040,A390) of the SOP Common Module (see Section C.12.1).

Modify Part 3 Section C.18.3 to include HL7-SD references as a type of Composite Object references:

C.18.3 Composite Object Reference Macro

Table C.18.3-1 specifies the Attributes that convey a reference to a DICOM Composite Object that is not a DICOM Image or Waveform (such as an SR Document), **or to an HL7 Structured Document**.

Notes: 1. If a Softcopy Presentation State is to be applied to an Image, it should be referenced by an Image Reference Macro.

2. Other SR Documents may be referenced by this macro, but there is no facility to reference individual Content Items within those reports.

3. HL7 Structured Documents include, in particular, those conforming to the Clinical Document Architecture (CDA). See Section C.12.1.1.6 for further details about this type of referenced object.

Modify Part 3 Table F.3-3 to include references to HL7-SD objects within DICOMDIR:

F.3.2.2 Directory Information Module

…

Table F.3-3
DIRECTORY INFORMATION MODULE

Attribute Name	Tag	Type	Attribute Description
…			
Directory Record Sequence	(0004,1220)	2	...
…			
>Directory Record Type	(0004,1430)	1C	Defines a specialized type of Directory Record by reference to its position in the Media Storage Directory Information Model (see Section F.4). Required if the Directory Record Sequence (0004,1220) is not zero length. Enumerated Values (see Section F.5): PATIENT STUDY SERIES IMAGE OVERLAY MODALITY LUT VOI LUT CURVE TOPIC VISIT RESULTS INTERPRETATION STUDY COMPONENT STORED PRINT RT DOSE RT STRUCTURE SET RT PLAN RT TREAT RECORD PRESENTATION WAVEFORM SR DOCUMENT KEY OBJECT DOC SPECTROSCOPY RAW DATA REGISTRATION FIDUCIAL ENCAP DOC **HL7 STRUC DOC** …
…			

Modify Part 3 Table F.4-1 and Figure F.4-1 to specify HL7-SD object locations in the DICOMDIR tree:

F.4 BASIC DIRECTORY IOD INFORMATION MODEL

…

Table F.4-1
RELATIONSHIP BETWEEN DIRECTORY RECORDS

Directory Record Type	Section	Directory Record Types which may be included in the next lower-level directory Entity
(Root Directory Entity)	—	PATIENT, TOPIC, PRIVATE
PATIENT	F.5.1	STUDY, **HL7 STRUC DOC,** PRIVATE
…		
TOPIC	F.5.9	STUDY, SERIES, IMAGE, OVERLAY, MODALITY LUT, VOI LUT, CURVE, STORED PRINT, RT DOSE, RT STRUCTURE SET, RT PLAN, RT TREAT RECORD, PRESENTATION, WAVEFORM, SR DOCUMENT, KEY OBJECT DOC, SPECTROSCOPY, RAW DATA, REGISTRATION, FIDUCIAL, **HL7 STRUC DOC,** PRIVATE
…		
HL7 STRUC DOC	**F.5.x**	**PRIVATE**
PRIVATE	F.6.1	PRIVATE, (any of the above as privately defined)
MRDR	F.6.2	(Not applicable)

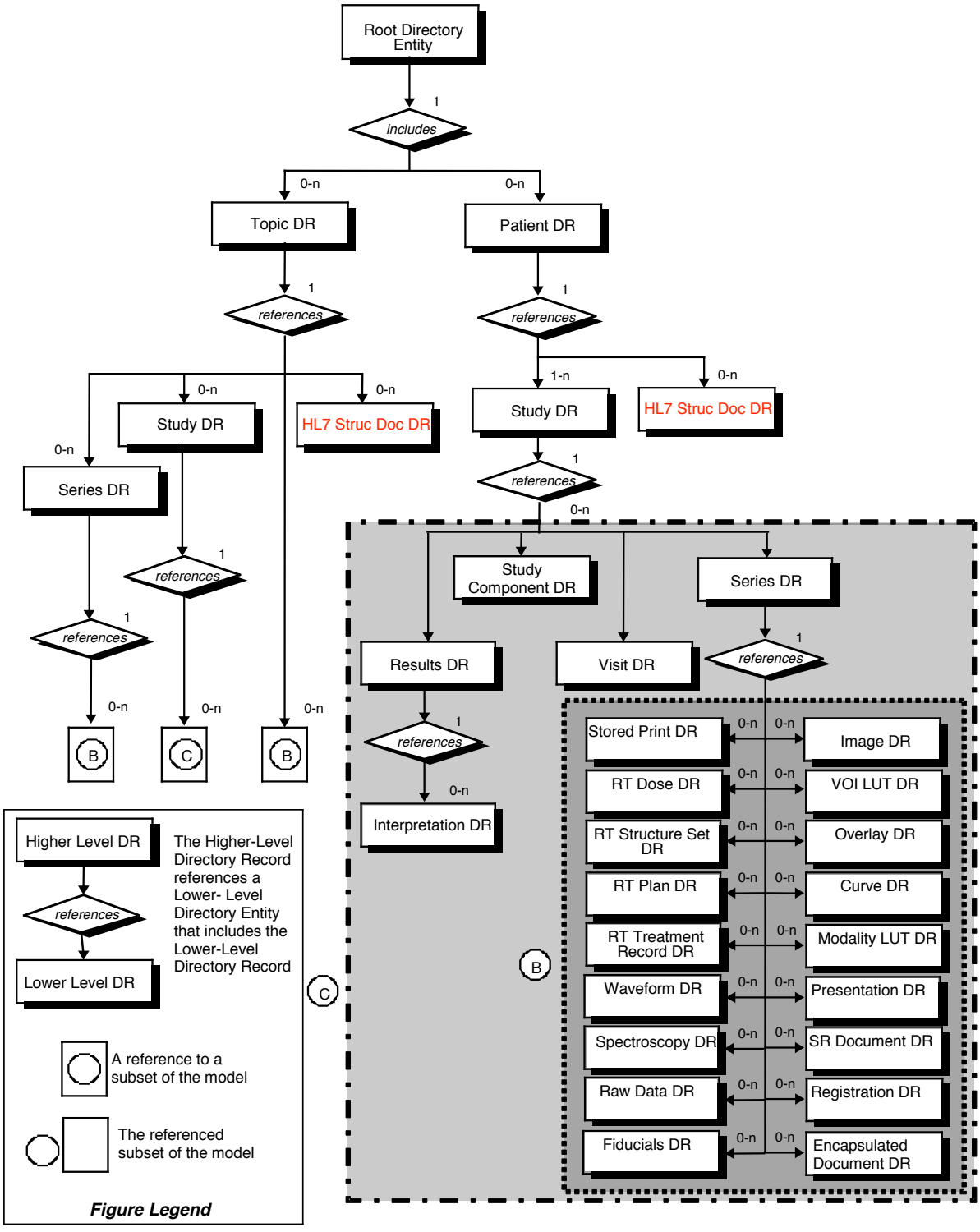

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Figure F.4-1
BASIC DIRECTORY IOD INFORMATION MODEL

Add Part 3 section F.5.x to specify HL7-SD record in the DICOMDIR:

F.5.x HL7 Structured Document Directory Record Definition

The Directory Record is based on the specification of Section F.3. It is identified by a Directory Record Type of Value "HL7 STRUC DOC".

Table F.5-x lists the set of keys with their associated Types for such a Directory Record Type. This Directory Record shall be used to reference an HL7 Structured Document and any of its referenced content encapsulated in a multi-part MIME wrapper (see PS3.10). This type of Directory Record shall not reference any Lower-Level Directory Entity.

Table F.5-x
HL7 Structured Document Keys

Key	Tag	Type	Attribute Description
Specific Character Set	(0008,0005)	1C	Required if an extended or replacement character set is used in one of the keys.
HL7 Instance Identifier	(0040,E001)	1	Instance Identifier from the referenced HL7 Structured Document, encoded as a UID (OID or UUID), concatenated with a caret (“^”) and Extension value (if Extension is present in Instance Identifier).
HL7 Document Effective Time	(0040,E004)	1	Effective Time from the referenced HL7 Structured Document
HL7 Document Type Code Sequence	(0040,E006)	1C	Document Type Code from the referenced HL7 Structured Document. Required if the HL7 Structured Document contains a Document Type Code.
>Include ‘Code Sequence Macro’ Table 8.8-1			*No BCID defined*
Document Title	(0042,0010)	1C	Document Title from the referenced HL7 Structured Document. Required if the HL7 Structured Document contains a Document Title.

Note: This directory record points to a CDA document that is stored on this media. The HL7 Document Effective Time and other information can be obtained from the CDA document.

Part 4 Addendum

Modify Part 4 Section K.4.1.1.3 to include HL7-SD mapping in Worklist Query response.

K.4.1.1.3 Identifier

Both the C-FIND request and response contain an Identifier encoded as a Data Set (see PS 3.5).

K.4.1.1.3.1 Request Identifier Structure

An Identifier in a C-FIND request shall contain

- Key Attributes values to be matched against the values of Attributes specified in that SOP Class.
- **Conditionally, the Attribute Specific Character Set (0008,0005). This Attribute shall be included if expanded or replacement character sets may be used in any of the Attributes in the Request Identifier. It shall not be included otherwise.**

The Key Attributes and values allowable for the query shall be defined in the SOP Class definition for the corresponding Worklist Information Model.

K.4.1.1.3.2 Response Identifier Structure

The C-FIND response shall not contain Attributes that were not in the request or specified in this section.

An Identifier in a C-FIND response shall contain:

- Key Attributes with values corresponding to Key Attributes contained in the Identifier of the request (Key Attributes as defined in K.2.2.1.)
- **Conditionally, the Attribute Specific Character Set (0008,0005). This Attribute shall be included if expanded or replacement character sets may be used in any of the Attributes in the Response Identifier. It shall not be included otherwise. The C-FIND SCP is not required to return responses in the Specific Character Set requested by the SCU if that character set is not supported by the SCP. The SCP may return responses with a different Specific Character Set.**
- **Conditionally, the Attribute HL7 Structured Document Reference Sequence (0040,A390) and its subsidiary Sequence Items. This Attribute shall be included if HL7 Structured Documents are referenced within the Identifier, e.g., in the Pertinent Documents Sequence (0038,0100).**

Modify Part 4 Section K.6.2.2.2 to include HL7-SD references in MWL Query with appropriate Return Key Type.

K.6.1.2.2 Modality Worklist Attributes

Table K.6-1 defines the Attributes of the Modality Worklist Information Model:

Table K.6-1 Attributes for the Modality Worklist Information Model

Description / Module	Tag	Matching Key Type	Return Key Type	Remark / Matching Type
…				
Patient Medical				
…				

Special Needs	(0038,0050)	O	2	
Pertinent Documents Sequence	**(0038,0100)**	**O**	**3**	**Pertinent Documents Sequence shall be retrieved with Universal Matching only**
>Referenced SOP Class UID	**(0008,1150)**	**-**	**1**	
>Referenced SOP Instance UID	**(0008,1155)**	**-**	**1**	
>Purpose of Reference Code Sequence	**(0040,A170)**	**-**	**2**	
>>Code Value	**(0008,0100)**	**-**	**1**	
>>Coding Scheme Designator	**(0008,0102)**	**-**	**1**	
>>Code Meaning	**(0008,0104)**	**-**	**1**	
>Document Title	**(0042,0010)**	**-**	**2**	
All Other Attributes from the Patient Medical Module		O	3	

Notes: 1. ...

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The attributes in Table K.6-1a are not part of the Worklist Information Model; their inclusion in the C-FIND request and response identifier are governed by rules in sections K.4.1.1.3.1 and K.4.1.1.3.2, respectively.

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Table K.6-1a
ATTRIBUTES FOR THE MODALITY WORKLIST C-FIND IDENTIFIER

Description	Tag	Request Identifier	Response Identifier	Remark Type
Specific Character Set	**(0008,0005)**	**1C**	**1C**	**This attribute is required if expanded or replacement character sets are used. See C.2.2.2 and K.4.1.1.3**
HL7 Structured Document Reference Sequence	**(0040,A390)**	**-**	**1C**	**One or more Items may be included in this sequence.** **Required if HL7 Structured Documents are referenced within the Identifier. See K.4.1.1.3**

>Referenced SOP Class UID	**(0008,1150)**	**-**	**1**	
>Referenced SOP Instance UID	**(0008,1155)**	**-**	**1**	
>HL7 Instance Identifier	**(0040,E001)**	**-**	**1**	
>Retrieve URI	**(0040,E010)**	**-**	**3**	

Modify Part 4 Section K.6.2.2.2 to include HL7-SD references in GP-WL Query with appropriate Return Key Type.

K.6.2.2.2 General Purpose Worklist Attributes

Table K.6-2 defines the Attributes of the General Purpose Worklist Information Model:

Table K.6-2 Attributes for the General Purpose Worklist Information Model

Description / Module	Tag	Match-ing Key Type	Return Key Type	Remark / Matching Type
…				
Patient Medical				
Pertinent Documents Sequence	**(0038,0100)**	**O**	**3**	**Pertinent Documents Sequence shall be retrieved with Universal Matching only**
>Referenced SOP Class UID	**(0008,1150)**	**-**	**1**	
>Referenced SOP Instance UID	**(0008,1155)**	**-**	**1**	
>Purpose of Reference Code Sequence	**(0040,A170)**	**-**	**2**	
>>Code Value	**(0008,0100)**	**-**	**1**	
>>Coding Scheme Designator	**(0008,0102)**	**-**	**1**	
>>Code Meaning	**(0008,0104)**	**-**	**1**	
>Document Title	**(0042,0010)**	**-**	**2**	
All **Other** Attributes from the Patient Medical Module		O	3	

Note: ...

The attributes in Table K.6-2a are not part of the Worklist Information Model; their inclusion in the C-FIND request and response identifier are governed by rules in sections K.4.1.1.3.1 and K.4.1.1.3.2, respectively.

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Table K.6-2a
ATTRIBUTES FOR THE GENERAL PURPOSE WORKLIST C-FIND IDENTIFIER

Description	Tag	Request Identifier	Response Identifier	Remark Type
Specific Character Set	(0008,0005)	1C	1C	This attribute is required if expanded or replacement character sets are used. See C.2.2.2 and K.4.1.1.3
HL7 Structured Document Reference Sequence	(0040,A390)	-	1C	One or more Items may be included in this sequence. Required if HL7 Structured Documents are referenced within the Identifier. See K.4.1.1.3
>Referenced SOP Class UID	(0008,1150)	-	1	
>Referenced SOP Instance UID	(0008,1155)	-	1	
>HL7 Instance Identifier	(0040,E001)	-	1	
>Retrieve URI	(0040,E010)	-	3	

Part 6 Addendum

445 ***Add the following to Part 6 Section 6 Registry of DICOM Data Elements:***

(0018,1002)	Device UID	UI	1
(0038,0100)	Pertinent Documents Sequence	SQ	1
(0040,A078)	Author Observer Sequence	SQ	1
(0040,A07A)	Participant Sequence	SQ	1
(0040,A07C)	Custodial Organization Sequence	SQ	1
(0040,A080)	Participation Type	CS	1
(0040,A082)	Participation Datetime	DT	1
(0040,A084)	Observer Type	CS	1
(0040,A090)	Equivalent CDA Document Sequence	SQ	1
(0040,A390)	HL7 Structured Document Reference Sequence	SQ	1
(0040,E001)	HL7 Instance Identifier	ST	1
(0040,E004)	HL7 Document Effective Time	DT	1
(0040,E006)	HL7 Document Type Code Sequence	SQ	1
(0040,E010)	Retrieve URI	ST	1

Add the following to Part 6 Annex A Registry of DICOM UIDs:

1.2.840.10008.1.2.6.1	RFC 2557 MIME encapsulation	Transfer Syntax	PS 3.10
1.2.840.10008.2.6.1	DICOM UID Registry	DICOM UIDs as a Coding Scheme	PS 3.6

Part 10 Addendum

Add the following to Part 10 Section 2:

2 Normative references

RFC 2557 MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)

Add the following to Part 10 Section 4:

4 Symbols and abbreviations

The following symbols and abbreviations are used in this Part of the Standard.

HTML	Hypertext Transfer Markup Language
MIME	Multipurpose Internet Mail Extensions
XML	Extensible Markup Language

Add the following Annex to Part 10:

Annex B HL7 Structured Document Files

Structured Documents as defined by an HL7 standard may be stored on DICOM Interchange Media, and may be referenced from within DICOM SOP Instances (including the DICOMDIR Media Storage Directory). Such references shall use a SOP Class UID, identifying the document class, and a SOP Instance UID. The SOP Instance UID is arbitrary, and the effective document instance identifier is encoded in the HL7 Instance Identifier (0040,E001) attribute (see PS3.3, “HL7 Structured Document Reference Sequence” for further information).

Notes: 1. The HL7 standards that define such documents include the Clinical Document Architecture (CDA), Structured Product Labeling (SPL), and Structured Clinical Trial Protocol (SCTP) standards.

2. The SOP Instance UID used to reference a particular HL7 Structured Document is not necessarily the same in all DICOM Instances. E.g., an SR Document and a DICOMDIR, both stored on the same media, may *internally* use different SOP Instance UIDs to reference the same HL7 Structured Document, but they will each provide a mapping to the same HL7 Instance Identifier as the *external* identifier.

An HL7 Structured Document is an aggregate multimedia object, consisting of a base XML-encoded document, plus zero or more referenced external multimedia components (e.g., graphics) that are considered an integral part of the object.

Such a document stored on DICOM Interchange Media shall be encoded as a Multipart MIME package, as described in RFC 2557 "MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)" (http://www.ietf.org/rfc/rfc2557.txt). A single package shall be stored in a single file, and shall encapsulate a single HL7 Structured Document and its referenced multimedia. The file shall be stored on the media with a File ID as defined for DICOM files. There shall be no preamble or header in the file prior to the MIME headers. For the purpose of identifying the Transfer Syntax of such a stored file from the DICOMDIR, the Transfer Syntax UID “1.2.840.10008.1.2.6.1” is specified for RFC 2557 MIME Encapsulation.

Notes: 1. A multipart MIME package is necessary for Structured Documents with referenced multimedia. Even though a simple Structured Document may consist of a single XML document, it is still encapsulated into a MIME package in accordance with the RFC 2557 MIME encapsulation Transfer Syntax.

2. The File ID, consistent with DICOM file naming rules, is limited to eight characters with no extension, in a directory structure where each directory is limited to an eight character name.

Any multimedia component that is included by reference in multiple HL7 Structured Documents stored on the same media shall be replicated into each referencing document MIME package.

Part 16 Addendum

Add DCMUID to coding schemes

Table 8-1 Coding Schemes

Coding Scheme Designator	Coding Scheme UID	Description
…		
DCMUID	1.2.840.10008.2.6.1	DICOM UID Registry

Change Part 16 Annex A: TID 1001 to indicate default Observer Context.

TID 1001
OBSERVATION CONTEXT
Type: Non-Extensible

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1		HAS OBS CONTEXT	INCLUDE	DTID (1002) “Observer Context”	1-n	MC	Required if all aspects of observer context are not inherited.	**Defaults to the attributes of the Author Observer Sequence (0040,A078), or the Verifying Observer Sequence (0040,A073) if the Author Observer Sequence is not present**
2		HAS OBS CONTEXT	INCLUDE	DTID (1005) “Procedure Context”	1	MC	Required if all aspects of procedure context are not inherited.	
3		HAS OBS CONTEXT	INCLUDE	DTID (1006) “Subject Context”	1	MC	Required if all aspects of observation subject context are not inherited.	

Add the following Template to Part 16 Annex A:

TID 2005 Transcribed Diagnostic Imaging Report

Basic report template for general diagnostic imaging interpretation reports produced in a dictation/transcription workflow. SR documents encoded using this template are intended to be transformable to HL7 Clinical Document Architecture format (see PS3.17).

This template can be instantiated only at the root node, and cannot be included in other templates.

Observation Context shall be inherited from outside the SR Content tree, and shall not be changed within the Content tree. To satisfy the requirement that Observer Context is inherited, either or both the Author Observer

Sequence (0040,A078) or the Verifying Observer Sequence (0040,A073) from the SR Document Module must be present in the SOP Instance.

Note: See Section on Observation Context Encoding in PS3.3

TID 2005
TRANSCRIBED DIAGNOSTIC IMAGING REPORT
Type: Non-Extensible

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	BCID (7000) Diagnostic Imaging Report Document Titles	1	M		
2	>	HAS CONCEPT MOD	CODE	EV (121049, DCM, ”Language of Content Item and Descendants”)	1	M		DCID (5000) Language
3	>	CONTAINS	CONTAINER	BCID (7001) Diagnostic Imaging Report Headings	1-n	M		
4	>>	CONTAINS	TEXT	BCID (7002) Diagnostic Imaging Report Elements	1	U		
5	>	CONTAINS	CONTAINER	EV (121180, DCM, “Key Images”)	1-n	U		
6	>>	CONTAINS	TEXT	EV (113012, DCM, ”Key Object Description”)	1	U		
7	>>	CONTAINS	IMAGE	Purpose of Reference is not used	1-n	M		

Content Item Descriptions

Row 3 CONTAINER Concept Name may be absent.

Row 7 IMAGE Concept Name shall be absent.

Add the following Term to Part 16 Annex B CID 7001:

CID 7001 Diagnostic Imaging Report Headings

Context ID 7001
Diagnostic Imaging Report Headings
Type: Extensible Version: ~~20030327~~2005mmdd

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
…		
DCM	**121180**	**Key Images**

Add the following Terms to Part 16 Annex D:

DICOM Code Definitions (Coding Scheme Designator "DCM" Coding Scheme Version "01")

Code Value	Code Meaning	Definition
.....		
121180	**Key Images**	**List of references to images considered significant**
121181	**DICOM Object Catalog**	**List of references to DICOM SOP Instances**

Part 17 Addendum

Add the following Annex to Part 17:

Annex X – Dictation-Based Reporting with Image References

This Annex describes a use of Key Object Selection (KO) and Grayscale Softcopy Presentation State (GSPS) SOP Instances, in conjunction with a typical dictation/transcription process for creating an imaging clinical report. The result is a clinical report as a Basic Text Structured Report (SR) SOP Instance that includes annotated image references (see section X.2). This report may also (or alternatively) be encoded as an HL7 Clinical Document Architecture (CDA) document (see section X.3).

Similar but more complex processes that include, for instance, numeric measurements and Enhanced or Comprehensive SR, are not addressed by this Annex. This Annex also does not specifically address the special issues associated with reporting across multiple studies (e.g., the "grouped procedures" case).

X.1 BASIC DATA FLOWS

X.1.1 Dictation/Transcription Reporting

During the softcopy reading of an imaging study, the physician dictates the report, which is sent to a transcription service or is processed by a voice recognition system. The transcribed dictation arrives at the report management system (typically a RIS) by some mechanism not specified here. The report management system enables the reporting physician to correct, verify, and "sign" the transcribed report. See Figure X.1-1. This data flow applies to reports stored in a proprietary format, reports stored as DICOM Basic Text SR SOP Instances, or reports stored as HL7 CDA instances.

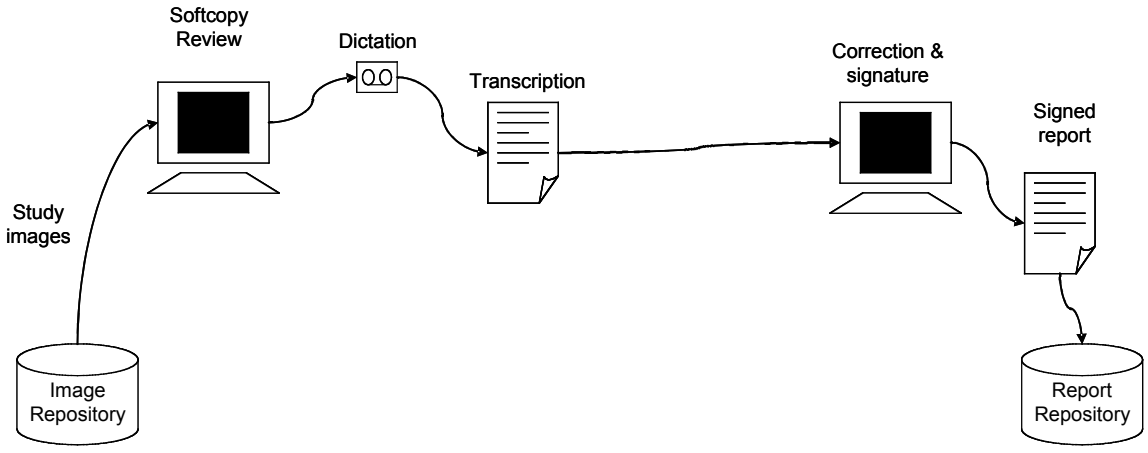

Figure X.1-1 Dictation/Transcription Reporting Data Flow

The report management system has flexibility in encoding the report title. For example, it could be any of the following:

- the generic title “Diagnostic Imaging Report”,
- a report title associated with the department (e.g., “Radiology Report”),
- a report title associated with the imaging modality or procedure (e.g., “Ultrasound Report”), or
- a report title pre-coordinated with the modality and body part (e.g., “CT Chest Report”).

There are LOINC codes associated with each of these types of titles, if a coded title is used on the report (see PS3.16 CID 7000).

The transcribed dictation may be either a single text stream, or a series of text sections each with a title. Division of reports into a limited number of canonically named sections may be done by the transcriptionist, or automated division of typical free text reports may be possible with voice recognition or a natural language processing algorithm.

For an electronically stored report, the signing function may or may not involve a cryptographic digital signature; any such cryptographic signature is beyond the scope of this description.

X.1.2 Reporting with Image References

To augment the basic dictation/transcription reporting use case, it is desired to select significant images to be attached (by reference) to the report. During the softcopy reading, the physician may select images from those displayed on his workstation (e.g., by a point-and-click function through the user interface). The selection of images is conveyed to the image repository (PACS) through a DICOM Key Object Selection (KO) document. When the report management system receives the transcribed dictation, it queries the image repository for any KO documents, and appends the image references from the KO to the transcription. In this process step, the report management system does not need to access the referenced images; it only needs to copy the references into the draft report. The correction and signature function potentially allows the physician to retrieve and view the referenced images, correct and change text, and to delete individual image references. See Figure X.1-2.

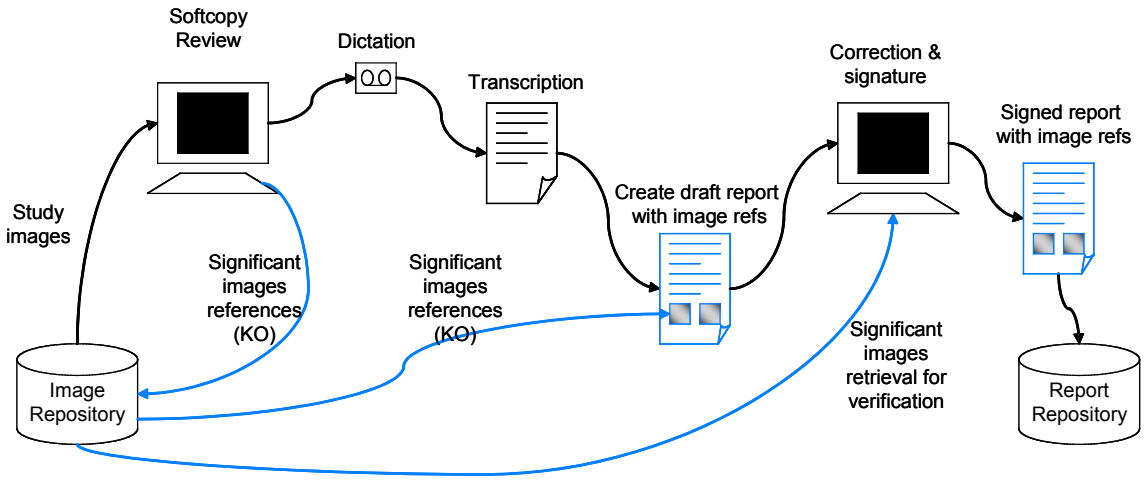

Figure X.1-2 Reporting Data Flow with Image References

The transcribed dictation must have associated with it sufficient key attributes for the report management system to query for the appropriate KO documents in the image repository (e.g., Study ID, or Accession Number).

Each KO document in this process includes a specific title “For Report Attachment”, a single optional descriptive text field, plus a list of image references using the SR Image Content Item format. The report management system may need to retrieve all KO documents of the study to find those with this title, since the image repository might not support the object title as a query return key.

Multiple KO instances may be created for a study report, e.g., to facilitate associating different descriptive text (included in the KO document) with different images or image sets. All KOs with the title “For Report Attachment” in the study are to be attached to the dictated report by copying their content into the draft report (see sections X.2 and X.3). (There may also be KOs with other titles, such as “For Teaching”, that are not to be attached to the report.)

The nature of the image reference links will differ depending on the format of the report. A DICOM SR format report will use DICOM native references, and other formats may use a hyperlink to the referenced images using the Web Access to DICOM Persistent Objects (WADO) service (see PS3.18).

X.1.3 Reporting with Annotated Images

The KO also allows the referencing of a Grayscale Softcopy Presentation State (GSPS) instance for each selected image. A GSPS instance can be created by the workstation for annotation (“electronic grease pencil”) of the selected image, as well as to set the window width/window level, rotation/flip, and/or display area selection of the image attached to the report. The created GSPS instances are transferred to the image repository (PACS) and are referenced in the KO document.

As with image references, the report management system may include the GSPS instance references in the report. When the report is subsequently displayed, the reader may retrieve the referenced images together with the referenced GSPS, so that the image is displayed with the annotations and other GSPS display controls. See Figure X.1-3.

Note that the GSPS display controls can also be included in WADO hyperlinks and invoked from non-DICOM display stations.

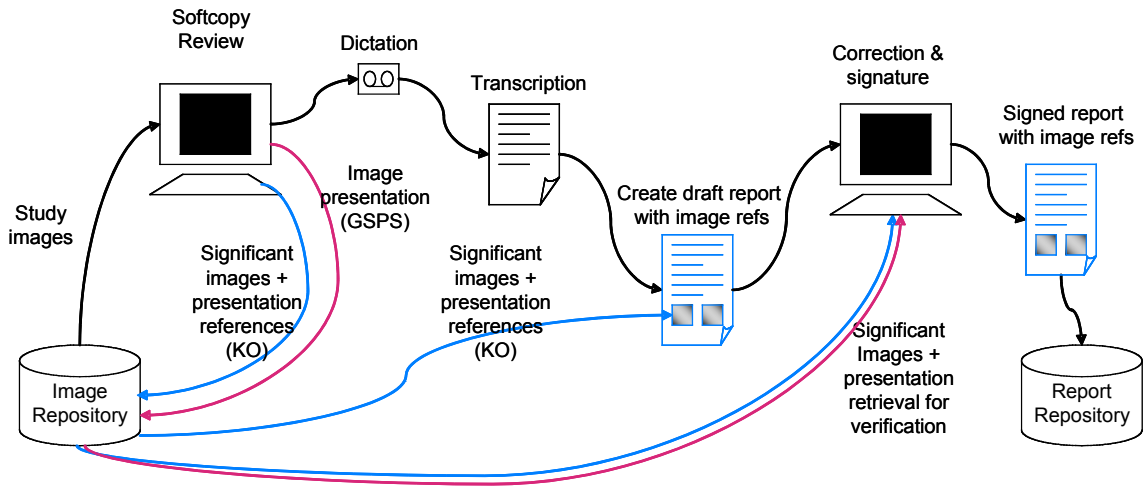

Figure X.1-3 Reporting Data Flow with Image and Presentation/Annotation References

X.2 TRANSCRIBED DIAGNOSTIC IMAGING SR INSTANCE CONTENT

This section describes the use of transcribed dictation and Key Object Selection (KO) instances to produce a DICOM Basic Text SR instance. A specific SR Template, TID 2005 (see PS3.16), is defined to support transcribed diagnostic imaging reports created using this data flow.

X.2.1 SR Header Content

The attributes of the Patient and Study Modules will be identical to those of the Study being reported. The following information is encoded in the SR Document General Module:

- Identity of the dictating physician (observer context) in the Author Sequence
- Identity of the transcriptionist or transcribing device (voice recognition) in the Participant Sequence
- Identity of the report signing physician in the Verifying Observer Sequence
- Identity of the institution owning the report in the Custodial Organization Sequence
- Linkages to the order and requested procedures in the Referenced Request Sequence
- A list of all images in the study in the Current Requested Procedure Evidence Sequence (from MPPS SOP Instances of the Study, or from query of the image repository)
- A list of all images not in the study, but also attached to the report as referenced significant images, in the Pertinent Other Evidence Sequence

X.2.2 Transcribed Text Data Format

The transcribed dictation is used to populate one or more section containers in the content tree of the SR Instance. If the transcription consists of a single undifferentiated text stream, it will typically be encoded using a single CONTAINER content item with Concept Name “Findings”, and the text encoded as the value in a subsidiary TEXT content item with Concept Name “Finding”. When the transcription is differentiated into multiple sections with captions, e.g., using the concepts in CID 7001 (see PS3.16), each section may be encoded in a separate CONTAINER, with the concept from CID 7001 as the container Concept Name, and the corresponding term from CID 7002 as the Concept Name for a subsidiary TEXT content item. See Figure X.2-1.

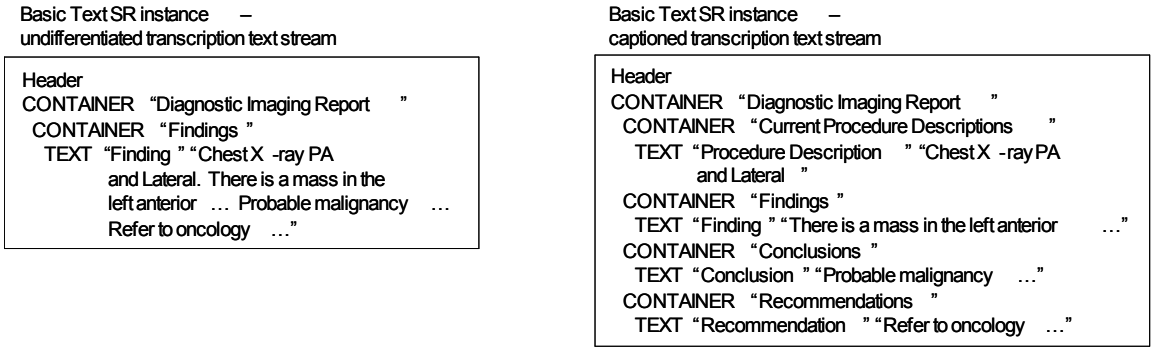

Figure X.2-1 Transcribed Text Content Tree

X.2.3 Image Reference Format

The content items from each associated KO object will be included in the SR in a separate CONTAINER with Concept Name (121180, DCM, "Key Images"). The text item "Key Object Description" and all image reference items shall be copied from the KO content tree to the corresponding SR container. See Figure X.2-2.

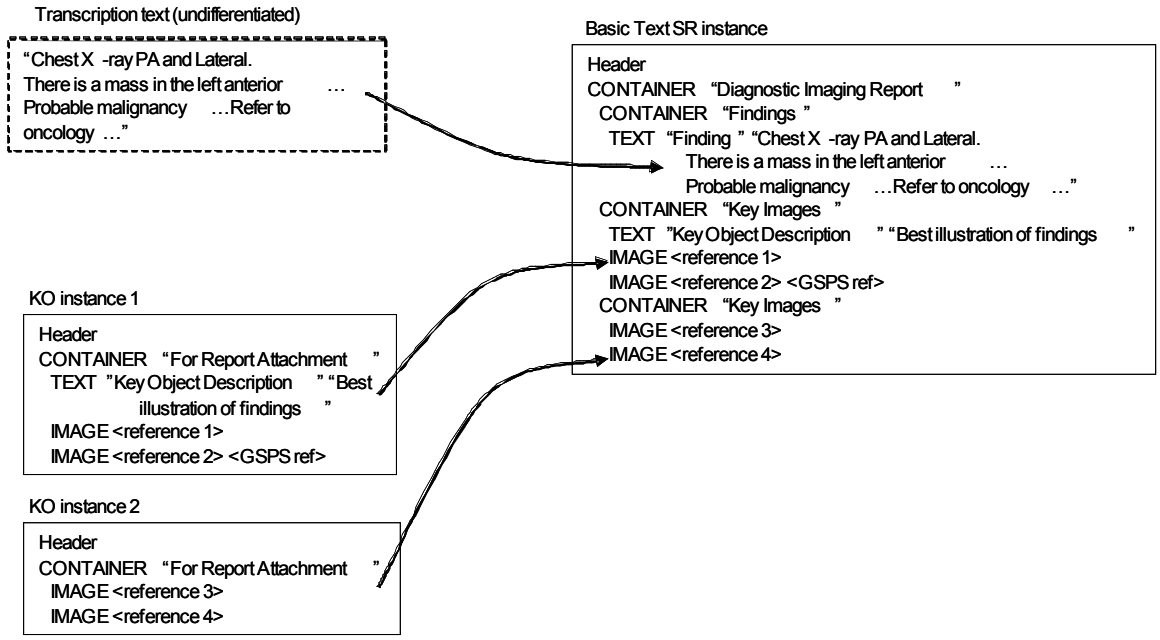

Figure X.2-2 Inputs to SR Basic Text Object Content Tree

The KO and SR IMAGE content item format allows the encoding of an icon (image thumbnail) with the image reference, as well as a reference to a GSPS instance controlling image presentation. Whether or not to include icons or GSPS references is an implementation decision of the softcopy review station that creates the KO; the IMAGE content item as a whole may be simply copied by the report management system from the KO to the Basic Text SR instance.

The intended process is that all KOs "For Report Attachment" are to be automatically included in the draft report. Therefore, the correction and signature function of the report management system should allow the physician to delete image references that were included, perhaps unintentionally, by the automatic process.

X.3 TRANSCRIBED DIAGNOSTIC IMAGING CDA INSTANCE CONTENT

This section describes the use of transcribed dictation and Key Object Selection (KO) documents to produce an HL7 Clinical Document Architecture (CDA) Release 2 document.

Note: While this section describes encoding as CDA Release 2, notes are provided about encoding issues for CDA Release 1.

X.3.1 CDA Header Content

The header of the CDA instance includes:

- Identity of the patient ("recordTarget" participation)
- Identity of the requested procedure ("documentationOf" act relationship)

- Identity of the dictating physician (“author” participation)
- Identity of the transcriptionist (“dataEnterer” participation)
- Identity of the report signing physician (“legalAuthenticator” participation)
- Identity of the institution owning the report (“custodian” participation)
- Identity of the request/order (“inFulfillmentOf” act relationship)

Note: The markup components in CDA Release 1 use different names.

X.3.2 Transcribed Text Content

Each transcription section can be encoded in a Section in the CDA document. The Section.Code and/or Section.Title can be derived from the corresponding transcription section title, if any. Although the transcription text can be encoded in the Section.Text without further markup, it is recommended that it be enclosed in <paragraph> tags.

X.3.3 Image References

Images are referenced using hypertext links in the narrative text. These links in CDA are not considered part of the attested content.

Notes: 1. The primary use case for this Annex is the dictation/transcription reporting model. In the historical context of that model, the images (film sheets) are usually not considered part of the attested content of the report, although they are part of the complete exam record. I.e., the report is clinically complete without the images, and the referenced images are not formally part of the report. Therefore, this Annex discusses only the use of image references, not images embedded in the report.

2. Being part of the attested content would require the images to be displayed every time the report is displayed – i.e., they are integral to understanding the report. If the images are attested, they must also be encapsulated with the CDA package. I.e., the CDA document itself is only one part of the interchanged package; the referenced images must also always be sent with the CDA document. If the images are for reference only and not attested, the Image Content Item may be transformed to a simple hypertext link; it is then the responsibility of CDA document receiver to follow or not follow the hyperlink. Moreover, as the industry moves toward ubiquitous network access to a distributed electronic healthcare record, there will be less need to prepackage the referenced images with the report.

In the current use case, there will be one or more KO instances with image references. Each KO instance can be transformed to a Section in the CDA document with a Section.Title “Key Images”, and a Section.Code of 121180 from the DICOM Controlled Terminology (see PS3.16). If the KO includes a TEXT content item, it can be transformed to <paragraph> data in that Section.Text of the CDA document. Each IMAGE content item can be transformed to a link item using the <linkHtml> markup.

Within the <linkHtml> markup, the value of the href attribute is the DICOM object reference as a Web Access to Persistent DICOM Objects (WADO) specified URI (see Table X.3-1).

Notes: 1. When a DICOM object reference is included in an HL7 CDA document, it is presumed the recipient would not be a DICOM application; it would have access only to general Internet network protocols (and not the DICOM upper layer protocol), and would not be configured with the means to display a native DICOM image. Therefore, the recommended encoding of a DICOM Object Reference in the CDA narrative block <linkHtml> uses WADO for access by the HTTP/HTTPS network protocol (see PS3.18), using one of the formats broadly supported in Web browsers (image/jpeg or video/mpeg) as the requested content type.

2. In CDA Release 1, the markup tag for hyperlinks is <link_html> within the scope of a <link> tag.

Table X.3-1 WADO Reference in an HL7 CDA <linkHtml>

WADO Component	Source
<scheme>://*<authority>*/*<path>*	Configuration setting, used by the conversion process, identifying the WADO server
?requestType=WADO	Fixed
&studyUID=*<uid>*	Study Instance UID for referenced image obtained from the Current Requested Procedure Evidence Sequence or the Pertinent Other Evidence Sequence in the KO Instance
&seriesUID=*<uid>*	Series Instance UID for referenced image obtained from the Current Requested Procedure Evidence Sequence or the Pertinent Other Evidence Sequence in the KO Instance
&objectUID=*<uid>*	Referenced SOP Instance UID from IMAGE content item
&frameNumber=*<list>*	Referenced Frame Number from IMAGE content item (if present)
&presentationUID=*<uid>*	Referenced SOP Instance UID from Referenced SOP Sequence within IMAGE content item
&presentationSeriesUID=*<uid>*	Series Instance UID for referenced presentation state obtained from the Current Requested Procedure Evidence Sequence or the Pertinent Other Evidence Sequence in the KO Instance
&contentType=video/mpeg	Present if Referenced SOP Class UID from IMAGE content item is for a multi-frame image IOD

Notes: 1. Literal strings are in normal typeface, while *<italic typeface within angle brackets>* indicates values to be copied from the identified source.

2. The default contentType for single frame images is image/jpeg, which does not need to be specified as a WADO component. However, the default contentType for multiple frame images is application/dicom, which needs to be overridden with the specific request for video/mpeg.

3. There is not yet a standard mechanism for minimizing the potential for staleness of the *<scheme>*://*<authority>*/*<path>* component.

X.3.4 Icons

If the IMAGE content item includes an Icon Image Sequence, the report creation process may embed the icon in the Section.Text narrative. The Icon Image Sequence Pixel Data is converted into an image file, e.g., in JPEG or GIF format, and base64 encoded. The file is encoded in an ObservationMedia entry in the CDA instance, and a <renderMultimedia> tag reference to the entry is encoded in the Section.Text adjacent to the <linkHtml> of the image reference.

X.3.5 Structured Entries

The Current Requested Procedure Evidence Sequence (0040,A375) of the KO instance lists all the SOP Instances referenced in the IMAGE content items in their hierarchical Study/Series/Instance context. It is recommended that this list be transcoded to CDA Entries in a Section with Section.Title “DICOM Object Catalog” and a Section.Code of 121181 from the DICOM Controlled Terminology (see PS3.16).

Notes: 1. Structured Entries are not defined in CDA Release 1.

2. Since the image hypertext links in the Section narrative may refer to both an image and a softcopy presentation state, as well as possibly being constrained to specific frame numbers, in general there is not a simple mapping from the <linkHtml> to an entry. Therefore it is not expected that there would be ID reference links between the <linkHtml> and related entries.

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The purpose of the Structured Entries is to allow DICOM-aware applications to access the referenced images in their hierarchical context.

The encoding of the DICOM Object References in CDA Entries is shown in Figure X.3-1 and Tables X.3-2 through X.3-6. All of the mandatory data elements for the Entries are available in the Current Requested
740 Procedure Evidence Sequence; optional elements (e.g., instance datetimes) may also be included if known by the encoding application.

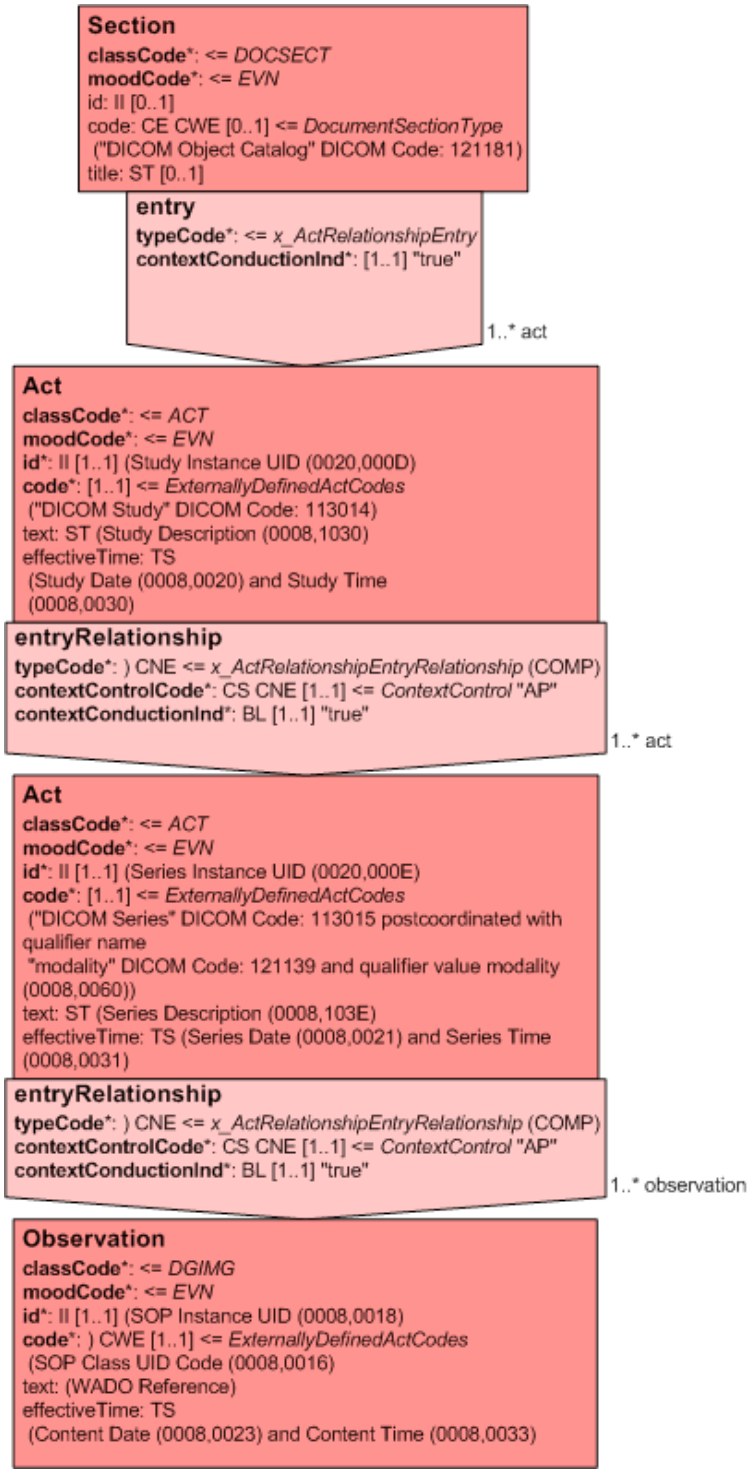

Figure X.3-1 CDA Section with DICOM Object References

745 Note: The format of Figure X.3-1 follows the conventions of HL7 v3 Reference Information Model diagrams.

Table X.3-2 DICOM Study Reference in an HL7 v3 Act (CDA Act Entry)

Attribute	Data Type	Multiplicity	Value
classCode	CS	1..1	ACT
moodCode	CS	1..1	EVN
id	II	1..1	*<Study Instance UID (0020,000D)* as root property with no extension property>
code	CD	1..1	<113014 as code property, 1.2.840.10008.2.16.4 as codeSystem property, DCM as codeSystemName property, "DICOM Study" as displayName property>
text	ST	0..1	*<Study Description (0008,1030)>*
effectiveTime	TS	0..1	*<Study Date (0008,0020)* and *Study Time (0008,0030)>*

Table X.3-3 DICOM Series Reference in an HL7 v3 Act (CDA Act Entry)

Attribute	Data Type	Multiplicity	Value
classCode	CS	1..1	ACT
moodCode	CS	1..1	EVN
id	II	1..1	*<Series Instance UID (0020,000E)* as root property with no extension property>
code	CD	0..1	<113015 as code property, 1.2.840.10008.2.16.4 as codeSystem property, DCM as codeSystemName property, "DICOM Series" as displayName property, *Modality* as qualifier property (see text and Table X.3-4)>
text	ST	0..1	*<Series Description (0008,103E)>*
effectiveTime	TS	0..1	*<Series Date (0008,0021)* and *Series Time (0008,0031)>*

The code for the Act representing a Series uses a qualifier property to indicate the modality. The qualifier property is a list of coded name/value pairs. For this use, only a single list entry is used, as described in Table X.3-4.

Table X.3-4 Modality Qualifier for the Series Act.Code

Property	Data Type	Value
name	CV	<121139 as code property, 1.2.840.10008.2.16.4 as codeSystem property, DCM as codeSystemName property, "Modality" as displayName property>
value	CD	*<Modality (0008,0060)* as code property, 1.2.840.10008.2.16.4 as codeSystem property, DCM as codeSystemName property, *Modality code meaning (from PS3.16)* as displayName property>

Table X.3-5 DICOM Composite Object Reference in an HL7 v3 Act (CDA Observation Entry)

Attribute	Data Type	Multiplicity	Value
classCode	CS	1..1	DGIMG
moodCode	CS	1..1	EVN
id	II	1..1	<*SOP Instance UID (0008,0018)* as root property with no extension property>
code	CD	1..1	<*SOP Class UID (0008,0016)* as code property, 1.2.840.10008.2.6.1 as codeSystem property, DCMUID as codeSystemName property, *SOP Class UID Name (from PS3.6)* as displayName property>
text	ED	0..1	<application/DICOM as mediaType property, *WADO reference* (see Table X.3-6) as reference property>
effectiveTime	TS	0..1	<*Content Date (0008,0023)* and *Content Time (0008,0033)*>

Notes: 1. The DGIMG class is used to reference all DICOM Composite Instances, not just diagnostic images.

2. The Observation.Text reference property may alternatively use a DICOM protocol based URI, rather than WADO, should such a URI be defined.

Table X.3-6 WADO Reference in an HL7 DGIMG Observation.Text

WADO Component	Source
<scheme>://*<authority>*/*<path>*	Configuration setting, used by the conversion process, identifying the WADO server
?requestType=WADO	Fixed
&studyUID=*<uid>*	Study Instance UID for referenced instance
&seriesUID=*<uid>*	Series Instance UID for referenced instance
&objectUID=*<uid>*	SOP Instance UID for referenced instance
&contentType=application/DICOM	Fixed

X.4.3 Using the WADO Reference for DICOM Network Protocol Retrievals

An application that receives a CDA with image references, and is capable of using the full services of DICOM upper layer protocol directly, can use the WADO parameters in either the linkHtml or in the DGIMG Observation.Text to retrieve the object using the DICOM network services. Such an application would need to be pre-configured with the hostname/IP address, TCP port, and AE Title of the DICOM object server (C-MOVE or C-GET SCP); this network address is not part of the WADO string. (Note that pre-configuration of this network address is typical for DICOM applications, and is facilitated by the LDAP-based DICOM Application Configuration Management Profile; see PS3.15.)

The application would open a Query/Retrieve Service Association with the configured server, and send a C-MOVE or C-GET command using the study, series, and object instance UIDs identified in the WADO query parameters. Such an application might also reasonably query the server for related objects, such as Grayscale Softcopy Presentation State.

Note: When using the C-GET service, the retrieving application needs to specify and negotiate the SOP Class of the retrieved objects when it opens the Association. This information is not available in the linkHtml WADO

reference; however, it is available in the DGIMG Observation.Code. It may also be obtained from the configured server using a C-FIND query on a prior Association.

X.4 SIMULTANEOUS SR AND CDA INSTANCE CREATION

The report may be created as both an SR instance and a CDA instance. In this case, the two instances are equivalent, and can cross-reference each other.

X.4.1 Equivalence

The CDA Document shall contain clinical content equivalent to the SR Document.

Note: The HL7 CDA standard specifically addresses transformation of documents from a non-CDA format. The requirement in the CDA specification is: "A proper transformation must ensure that the human readable clinical content of the report is not impacted."

There is no requirement that the transform or transcoding between DICOM SR and HL7 CDA be reversible. In particular, some attributes of the DICOM Patient, Study, and Series IEs have no corresponding standard encoding in the HL7 CDA Header, and vice versa. Such data elements, if transcoded, may need to be encoded in "local markup" (in HL7 CDA) or private data elements (in DICOM SR) in an implementation-dependent manner; and some such data elements may not be transcoded at all. It is a responsibility of the transforming application to ensure clinical equivalence.

Many attributes of the SR Document General Module can be transcoded to CDA Header participations or related acts.

X.4.2 Document Cross-Reference

Due to the inherent differences between DICOM SR and HL7 CDA, a transcoded document will have a different UID than the source document. However, the SR Document may reference the CDA Document as equivalent using the Equivalent CDA Document Sequence (0040,A090) attribute, and the CDA Document may reference the SR Document with a relatedDocument act relationship.

Since the ParentDocument target of the relatedDocument relationship is constrained to be a simple DOCCLIN act, it is recommended that the reference to the DICOM SR be encoded per Table X.3-4, without explicit identification of the Study and Series Instance UIDs, and with classCode DOCCLIN (rather than DGIMG).

Notes: 1. The Study and Series Instance UIDs would be encoded in the WADO reference in the Act.Text ED data type.

2. CDA Release 1 does not provide a standard for the relatedDocument relationship to another document.