

Digital Imaging and Communications in Medicine (DICOM)

Supplement 101: HL7 Structured Document Object References

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Foreword

60 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.

65 One use case is to provide a DICOM-based application with access to relevant CDA documents, such as pre-imaging-procedure lab test results, or patient advance medical directives, or an outpatient history and physical report. There is a defined network service 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.

70 A second use case is to provide a link between an SR document and its equivalent CDA document. CDA is now a formally adopted method in the US for encoding claims attachments, including radiology and other imaging clinical reports, 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 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. 75 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

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

HL7 STRUCTURED DOCUMENTS REFERENCES

85 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.

90 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 is equivalent to the Abstract Syntax. In HL7, the Abstract Syntax is specified as a Hierarchical Message Definition, or more simply as a Hierarchical Definition (for non-message data structures). 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 service SOP Class UIDs to identify the IOD of an object stored on DICOM interchange media. The important aspect is that the UID/OID identifies the Abstract Syntax.

95 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. If the instance identifier used natively within the referenced document is encodable using the UI VR, it

100 may be used as the SOP Instance UID. If it is not so encodable, a UID is constructed for use within the DICOM Data Set that can be mapped to the native Instance Identifier. This newly constructed UID is required 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. 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.

105 This Supplement proposes extensions of the SR, Modality and General-Purpose Worklist, and Relevant Patient Information Query 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-CDA TRANSCODING

110 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 its equivalent CDA document.

115 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 transcodable 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.

120 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 also includes the process of SR-CDA transcoding.

One aspect of SR-CDA transcoding 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).

125 Note that the transformation between SR and CDA is not a reversible transcoding; rather, it provides clinical equivalence between the instances in the two formats. Moreover, the specific transcoding between SR and CDA formats is implementation-dependent. There is no requirement that two applications be able to identically transcode an SR object to exactly the same CDA content and structure. However, all transcodings to CDA shall contain clinical content equivalent to the SR Document.

130 **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
- 135 – Inclusion of references to HL7 Structured Documents in the Patient Medical Module, allowing such references in Modality and General Purpose Worklists

- Addition of attributes to the SR Document General Module to harmonize with CDA header, and to support access to HL7 Structured Documents
- 140 – Inclusion of HL7 Structured Documents as a type of referenced Composite object in the SR Content tree
- Definition of Macros to support references to HL7 Structured Documents and identification of participants in the production of SR Instances
- Inclusion of references to HL7 Structured Documents in the DICOMDIR Directory structure, allowing the placement of HL7 Structured Documents on DICOM Interchange Media
- 145 PS 3.4: Service Class Specifications
 - Addition of attributes for references to HL7 Structured Documents in the Modality and General Purpose Worklists from the Patient Medical Module
 - Addition of attributes to the Relevant Patient Information Query response to support references to HL7 Structured Documents
- 150 PS 3.6: Data Dictionary
 - Addition of new attributes to Data Dictionary
- 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
- 155 – 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
- 160 – Description of a use case and data flow for Transcribed Diagnostic Imaging Report production, including transcoding of the report into a CDA document, and recommended mappings of image references to HL7 data structures.

Open Issues

165	1. Is use of SOP Class / Instance paradigm appropriate for referencing HL7 Structured Documents? Is it necessary in all cases of reference to HL7 Structured Documents, or only in SR Content Tree references (e.g., can it be removed from the Patient Medical Module)?
	2. Is the use of the HL7 Hierarchical Message Description (HMD) OID as the SOP Class for a Structured Document appropriate?
	3. The native Instance Identifier (II), if it is encodable as a UID, might be used as the SOP Instance UID. Should this be required, allowed, or disallowed? (This draft <i>allows</i> the use.)
170	4. Should the II reference be encoded as proposed using the UID^Extension format, or should its subcomponents be broken out into separate DICOM attributes, or should we use an XML structure? If encoded in XML, is there an issue with requiring UTF-8 encoding?
175	5. Is there a general problem of character sets and UTF-8 encoding for Instance Identifier extensions, Document Titles, and Retrieve URI strings? The issue arises when encoding a reference within a DICOM Instance that uses an ISO 2022 type character set extension.
	6. Are there a set of codes for the Purpose of Reference Code Sequence that would be appropriate for references to HL7 Structured Documents?
180	7. Is the placement of HL7 Structured Documents in the DICOMDIR tree appropriately limited to only have parent Topic or Patient? Should non-CDA Structured Documents be allowed at the first level, as proposed for Hanging Protocol objects on media (Supplement 60)?
	8. Should other attributes should be brought from the Structured Documents into the DICOMDIR record?
	9. Is the specification of a Transfer Syntax for Structured Documents on DICOM Interchange Media appropriate? (An alternate approach would be to add a condition to the DICOMDIR Referenced Transfer Syntax UID in File (0004,1512) to not apply to HL7 Structured Documents.)
185	10. Is it appropriate to require encapsulation of Structured Documents in a MIME package on media? The alternative is to allow simple Structured Documents to be bare XML documents with a different Transfer Syntax, but would have the disadvantage of having two means of encoding simple Structured Documents.
190	11. Where in the SR Document should we identify the dataEnterer (transcriptionist or machine identifier)? In the Content tree, or in new attributes in the SR Document General module (as proposed)? Should it be a generalized structure to handle any of the CDA header roles (or ASTM roles)?
195	12. How should we deal with HTML links to DICOM objects (in CDA) or to HL7 documents (in DICOM) becoming stale? Are there expectations that medical record URIs (as opposed to general WWW links) will less likely become stale over the useful life of the document reference? What are the expectations of different types of receiver of such links (e.g., referring physicians, in-house radiologists, patients, etc.) for their freshness over x amount of time (e.g., "buy before 6/14/2009"), and how does this vary across different types of referenced documents (images, clinical reports, etc.)
	13. How should the "Current Requested Procedure Evidence" be referenced in the CDA version of an SR document? The current proposal allows transcoding the Current Requested Procedure Evidence

200	Sequence into <link_html> references. Would referencing at the Series level be more appropriate? How would such Series level references be encoded?
205	14. Should DICOM object references in HL7 be limited to just the SOP Instance UID in a simple Act class clone, and presume there is a service to locate that Instance UID in the appropriate Study and Series context when necessary? Or should we use a structure of Act clones identifying the Study and Series? Or should we pursue adding the Study and Series UIDs to the DiagnosticImage subclass in the HL7 RIM?
	15. What should be the content of an SR to CDA mapping table?
210	16. For the CDA Structured Entry references to DICOM Instances, should a DICOM protocol URI be defined, e.g., "dicom://<authority>:<port>/<aetitle>?<studyuid><seriesUID><InstanceUID> ? What sort of service would this imply, C-MOVE, or C-GET, or whichever is negotiated in association establishment? Where in the DICOM standard should such a URI be documented?

Part 3 Addendum

Add the following to Part 3 Section 2:

2 Normative references

215	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
	ANSI/HL7 SPL R1.0-2004	HL7 Structured Product Labeling Standard, Release 1.0
220	HL7 SCTP R1.0	HL7 Structured Clinical Trial Protocol Standard, Release 1.0
	RFC 2396	Uniform Resource Identifiers (URI): Generic Syntax

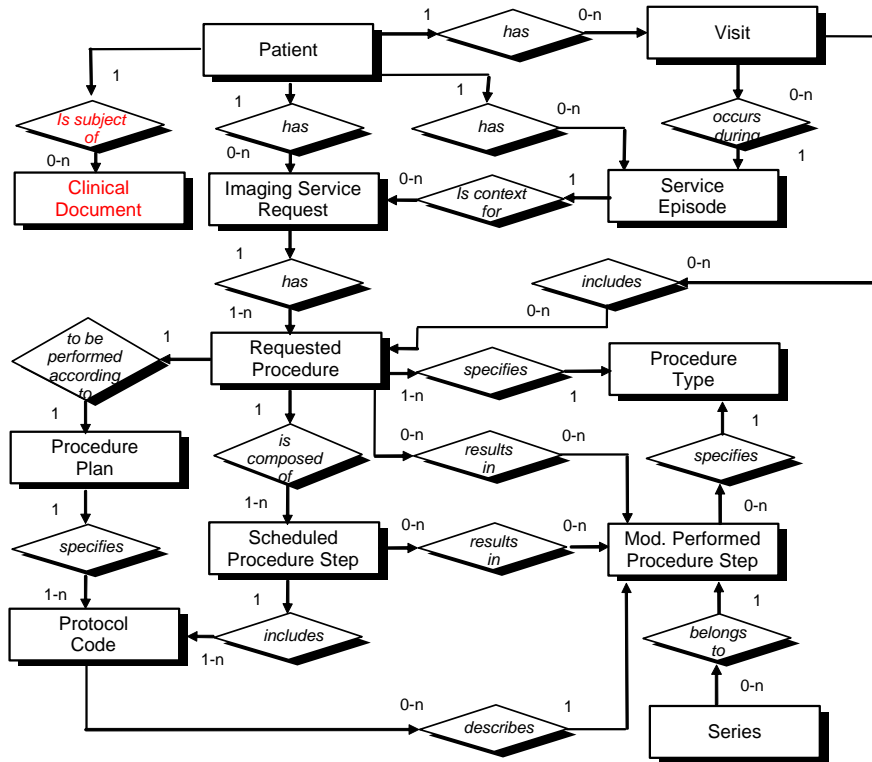
Add the following to Part 3 Section 4:

4 Symbols and abbreviations

225 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)
230	OID	Object Identifier (ISO 8824)
	SCTP	Structured Clinical Trial Protocol (HL7)
	SD	Structured Documents (HL7)
	SPL	Structured Product Labeling (HL7)
	SR	Structured Reporting
235	UUID	Universal Unique Identifier (ISO/IEC 11578)
	XDS	Cross-Enterprise Document Sharing Profile (IHE)
	XML	Extensible Markup Language

Modify Part 3 Figure 7-3:



240

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

245

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.

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Note: This definition is from ANSI/HL7 CDA R1.0-2000.

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.

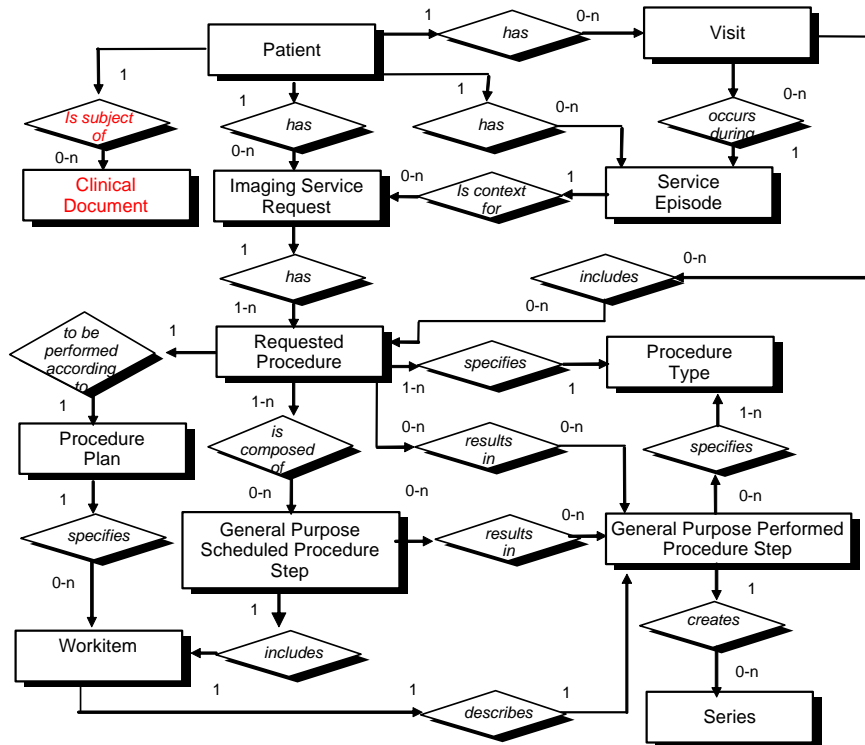
260 Clinical Documents may be associated with Service Episodes, Service Requests, Requested Procedures, or other entities subsidiary to the Patient in the Real-World Model. Such associations are not explicitly modeled for the purposes of the Modality-IS or General Purpose Worklist contexts.

265 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.

270 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:



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

Add the following new sections to Part 3 Section 10:

10.X HL7 STRUCTURED DOCUMENT REFERENCE MACRO

280 Table 10-x defines the Attributes that identify instances of Structured Documents defined under an HL7 standard. The HL7 standards that define such documents include the Clinical Document Architecture (CDA), Structured Product Labeling (SPL), and Structured Clinical Trial Protocol (SCTP) standards.

285 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:

- 290 CDA Release 1 2.16.840.1.113883.x.1.1
- CDA Release 2 2.16.840.1.113883.x.1.2
- SPL Release 1 2.16.840.1.113883.x.2.1
- SCTP Release 1 2.16.840.1.113883.x.3.1

2. The Hierarchical Message Description Object Identifiers do not imply a network service, as do SOP Class UIDs. However, SOP Class UIDs are also used to identify the Abstract Syntax in non-network situations (e.g., on DICOM Interchange Media), and a similar approach is taken with HL7 Structured Document definitions.

295 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,xxx1) attributes in this Macro.

305 Notes: 1. Even though an II may contain just a UID, applications should take care to use the II specified in (0040,xxx1) 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.

310 2. 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.

3. The HL7 Instance Identifier is encoded 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.himss.org/ihe>).

**Table 10-x
HL7 Structured Document Reference Macro Attributes**

Attribute Name	Tag	Type	Attribute Description
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.

315

HL7 Instance Identifier	(0040,xxx1)	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,xx10)	3	Retrieval access path to HL7 Structured Document. Includes fully specified scheme, authority, path, and query in accordance with RFC 2396

10.Y IDENTIFIED PERSON OR DEVICE MACRO

320 Table 10-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 10-y
Identified Person or Device Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Observer Type	(0040,A08z)	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.
<i>>Include 'Code Sequence Macro' Table 8.8-1</i>			
Station Name	(0008,1010)	2C	Name of the device observer for this document instance. Required if Observer Type value is DEV.
Device UID	(0008,xxxx)	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			

325

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.

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**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.)
<u>Pertinent Structured Document Reference Sequence</u>	<u>(0038,05xx)</u>	<u>List of HL7 Structured Documents that contain information that is considered pertinent for the patient medical condition.</u> <u>Zero or more Items may be included in this sequence.</u>
<u>>Purpose of Reference Code Sequence</u>	<u>(0040,A170)</u>	<u>Describes the purpose for which the document reference is made; this may be the coded document title. Zero or more Items may be present.</u>
<u>>>Include 'Code Sequence Macro' Table 8.8-1</u>		<u>No BCID defined</u>
<u>>Document Title</u>	<u>(0040,xxx4)</u>	<u>Title of the referenced document.</u>
<u>>Include 'HL7 Structured Document Reference Macro' Table 10-x</u>		

Modify Part 3 Table C.17-2 to include HL7-SD reference in SR documents, and to add participations to the SR header:

335 **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.

**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.
<i>>>Include 'Code Sequence Macro' Table 8.8-1</i>			
>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).
<u>Author Observer Sequence</u>	<u>(0040,A07x)</u>	<u>3</u>	<u>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 more Items may be included in this sequence.</u>
<i>>Include 'Identified Person or Device Macro' Table 10-y</i>			
<u>Participant Sequence</u>	<u>(0040,A07y)</u>	<u>3</u>	<u>Persons or devices related to the clinical content of this document. Zero or more Items may be included in this sequence.</u>

<u>>Participation Type</u>	<u>(0040,A08x)</u>	<u>1</u>	<u>Participant's role with respect to the clinical content of this document. See C.17.2.4.</u> <u>Defined Terms:</u> <u>AUTHEN – Authenticator</u> <u>ENT – Data enterer (transcriptionist)</u>
<u>>Participation Datetime</u>	<u>(0040,A08y)</u>	<u>2</u>	<u>Datetime of participation with respect to the clinical content of this document.</u>
<u>>Include 'Identified Person or Device Macro' Table 10-y</u>			
<u>Custodial Organization Sequence</u>	<u>(0040,A07z)</u>	<u>3</u>	<u>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.</u> <u>Note: This may or may not be identical to the Institution identified in the Equipment Module.</u> <u>Zero or one Items may be included in this sequence.</u>
<u>>Institution Name</u>	<u>(0008,0080)</u>	<u>2</u>	<u>Name of Custodial Institution or Organization.</u>
<u>>Institution Code Sequence</u>	<u>(0008,0082)</u>	<u>1</u>	<u>Coded identifier of Custodial Institution or Organization.</u> <u>Zero or one Items may be included in this sequence.</u>
<u>>>Include 'Code Sequence Macro' Table 8.8-1</u>			
...			
Pertinent Other Evidence Sequence	(0040,A385)	1C	...
<u>>Include 'SOP Instance Reference Macro' Table C.17-3</u>			
<u>HL7 Structured Document Reference Sequence</u>	<u>(0040,A39x)</u>	<u>1C</u>	<u>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 Content Sequence (0040,A730).</u>
<u>>Include 'HL7 Structured Document Reference Macro' Table 10-x</u>			

<u>Equivalent HL7 CDA Document Sequence</u>	<u>(0040,A09x)</u>	<u>1C</u>	<u>Sequence specifying HL7 CDA Document equivalent to the current SOP Instance. Only one Item may be included in this sequence. See C.17.2.5.</u> <u>Required if the identity of an HL7 CDA Document equivalent to the current SOP Instance is known at the time of creation of this SOP Instance.</u>
<u>>Include 'HL7 Structured Document Reference Macro' Table 10-x</u>			

340

Add new Part 3 sub-sections to C.17.2 for Participations and Equivalent HL7 CDA Document Sequence:

C.17.2.4 Participant Sequence

345 The Participant Sequence (0040,A07y) allows the optional identification of significant contributors to the SR document, other than the Author Observer (0040,A07x) and Verifying Observer (0040,A073). An Authenticator is a person 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 authenticated by a resident, and then verified by a staff physician; or a document may be authored by a CAD device and authenticated by a technologist, and then verified by a physician.

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

C.17.2.5 Equivalent HL7 CDA Document Sequence

355 The Equivalent HL7 CDA Document Sequence (0040,A09x) 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.

360 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.
 365 3. Due to the inherent differences between DICOM SR and HL7 CDA, a transcoded document should have a different UID than the source document.

370

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.

- 375 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.

380 **3. HL7 Structured Documents include, in particular, those conforming to the Clinical Document Architecture (CDA). See Section 10.x for further details to this type of reference.**

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

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

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)

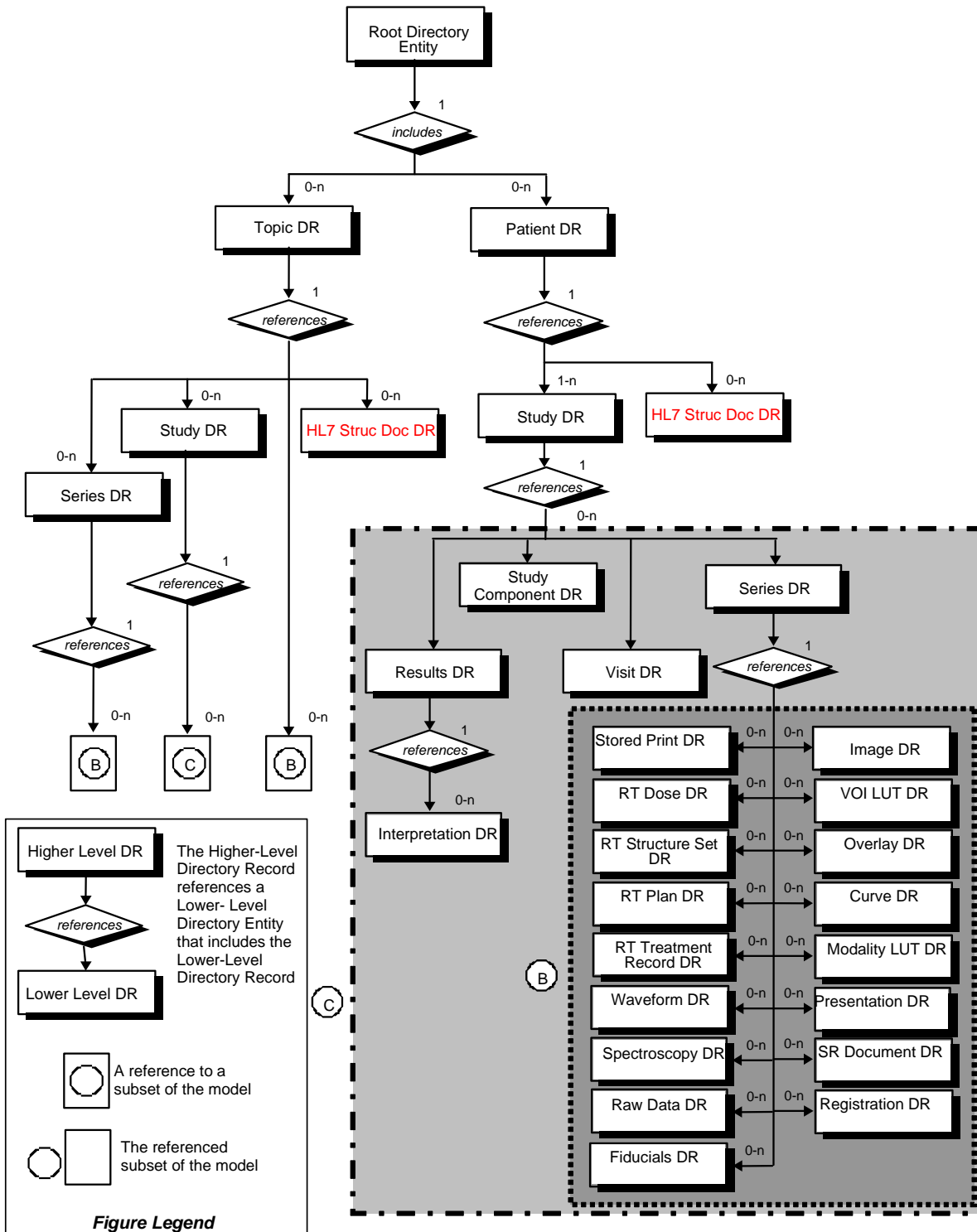


Figure F.4-1
BASIC DIRECTORY IOD INFORMATION MODEL

400 **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".

405 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 may 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,xxx1)	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).
Document Effective Time	(0040,xxx2)	1	Effective Time of the referenced HL7 Structured Document
Document Type Code Sequence	(0040,xxx3)	1C	Document Type Code of 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	(0040,xxx4)	1C	Document Title of the referenced HL7 Structured Document. Required if the HL7 Structured Document contains a Document Title.

410

Part 4 Addendum

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

415 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	Match- ing Key Type	Return Key Type	Remark / Matching Type
...				
Patient Medical				
...				
Special Needs	(0038,0050)	O	2	
<u>Pertinent Structured Document Reference Sequence</u>	<u>(0038,05xx)</u>	<u>O</u>	<u>3</u>	<u>Pertinent Structured Document Reference Sequence shall be retrieved with Universal Matching only</u>
<u>>Purpose of Reference Code Sequence</u>	<u>(0040,A170)</u>	:	<u>2</u>	
<u>>>Code Value</u>	<u>(0008,0100)</u>	:	<u>1</u>	
<u>>>Coding Scheme Designator</u>	<u>(0008,0102)</u>	:	<u>1</u>	
<u>>>Code Meaning</u>	<u>(0008,0104)</u>	:	<u>1</u>	
<u>>Document Title</u>	<u>(0040,xxx4)</u>	:	<u>2</u>	
<u>>Referenced SOP Class UID</u>	<u>(0008,1150)</u>	:	<u>1</u>	
<u>>Referenced SOP Instance UID</u>	<u>(0008,1155)</u>	:	<u>1</u>	
<u>>HL7 Instance Identifier</u>	<u>(0040,xxx1)</u>	:	<u>1</u>	
<u>>Retrieve URI</u>	<u>(0040,xx10)</u>	:	<u>3</u>	
All Other Attributes from the Patient Medical Module		O	3	

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

420

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				
<u>Pertinent Structured Document Reference Sequence</u>	(0038,05xx)	<u>O</u>	<u>3</u>	<u>Pertinent Structured Document Reference Sequence shall be retrieved with Universal Matching only</u>
<u>>Purpose of Reference Code Sequence</u>	(0040,A170)	:	<u>2</u>	
<u>>>Code Value</u>	(0008,0100)	:	<u>1</u>	
<u>>>Coding Scheme Designator</u>	(0008,0102)	:	<u>1</u>	
<u>>>Code Meaning</u>	(0008,0104)	:	<u>1</u>	
<u>>Document Title</u>	(0040,xxx4)	:	<u>2</u>	
<u>>Referenced SOP Class UID</u>	(0008,1150)	:	<u>1</u>	
<u>>Referenced SOP Instance UID</u>	(0008,1155)	:	<u>1</u>	
<u>>HL7 Instance Identifier</u>	(0040,xxx1)	:	<u>1</u>	
<u>>Retrieve URI</u>	(0040,xx10)	:	<u>3</u>	
All <u>Other</u> Attributes from the Patient Medical Module		O	3	

425

Modify Part 4 Section Q.2.1.1.3.2 (see CP475) to include HL7-SD references in Relevant Patient Information Query responses

Q.2.1.1.3.2 Response Identifier Structure

...

430

If the Content Sequence (0040,A730) includes references to Composite Objects that are HL7 Structured Documents, the Identifier in a C-FIND response shall contain the HL7 Structured Document Reference Sequence (0040,A39x), in accordance with Table Q.2-2. This Sequence provides attributes necessary to access the referenced Documents. The C-FIND Response shall have one HL7 Structured Document Reference Sequence item for each HL7 Structured Document Composite Object referenced in the Content Sequence. The HL7 Structured Document Reference Sequence attribute shall not be sent in the Request Identifier.

435

Note: See PS3.3, "HL7 Structured Document Reference Macro" for further information.

Table Q.2-2 Additional C-FIND Response Identifier Attributes

Description / Module	Tag	Return Key Type	Remark / Matching Type
...			
<u>HL7 Structured Document Reference Sequence</u>	<u>(0040,A39x)</u>	<u>1C</u>	<u>Sequence of items defining mapping and/or access mechanism for all HL7 Structured Documents referenced in the Content Tree. One or more Items may be included in this sequence.</u> <u>Required if Content Sequence (0040,A390) includes Content Items that reference Composite Objects that are HL7 Structured Documents.</u>
<u>>Referenced SOP Class UID</u>	<u>(0008,1150)</u>	<u>1</u>	<u>Unique identifier for the class of HL7 Structured Document.</u>
<u>>Referenced SOP Instance UID</u>	<u>(0008,1155)</u>	<u>1</u>	<u>Unique identifier for the HL7 Structured Document as used in DICOM instance references.</u>
<u>>HL7 Instance Identifier</u>	<u>(0040,xxx1)</u>	<u>1</u>	<u>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).</u>
<u>>Retrieve URI</u>	<u>(0040,xx10)</u>	<u>3</u>	<u>Retrieval access path to HL7 Structured Document. Includes fully specified scheme, authority, path, and query in accordance with RFC 2396</u>

Part 6 Addendum

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

(0008,xxxx)	Device UID	UI	1
(0038,05xx)	Pertinent Structured Document Reference Sequence	SQ	1
(0040,A07x)	Author Observer Sequence	SQ	1
(0040,A07y)	Participant Sequence	SQ	1
(0040,A07z)	Custodial Organization Sequence	SQ	1
(0040,A08x)	Participation Type	CS	1
(0040,A08y)	Participation Datetime	DT	1
(0040,A08z)	Observer Type	CS	1
(0040,A09x)	Equivalent HL7 CDA Document Sequence	SQ	1
(0040,A39x)	HL7 Structured Document Reference Sequence	SQ	1
(0040,xxx1)	HL7 Instance Identifier	ST	1
(0040,xxx2)	Document Effective Time	DT	1
(0040,xxx3)	Document Type Code Sequence	SQ	1
(0040,xxx4)	Document Title	ST	1
(0040,xx10)	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 (non-DICOM)	PS 3.10
-----------------------	-----------------------------	-----------------------------	---------

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)

450

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.

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

Add the following Annex to Part 10:

460

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,xxx1) attribute (see PS3.3, "HL7 Structured Document Reference Macro" 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.

475

480 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.

485 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.

490 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

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

**TID 1001
OBSERVATION CONTEXT
Type: Non-Extensible**

495

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.	<u>Defaults to the attributes of the Author Observer Sequence (0040,A07y), or the Verifying Observer Sequence (0040,A073) if the Author Observer Sequence is not present</u>
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 x2005 Transcribed Diagnostic Imaging Report

500

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.

505

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,A07y) 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

510

**TID x2005
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 (1211xx, 99sup101, "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

515 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

520

Context ID 7001

Diagnostic Imaging Report Headings

Type: Extensible

Version: 200303272005mmdd

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
...		
<u>99sup101</u>	<u>1211xx</u>	<u>Key Images</u>

Part 17 Addendum

525 **Add the following Annex to Part 17:**

Annex X – Dictation-Based Reporting with Image References

530 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. This report may further be transcoded to a HL7 Clinical Document Architecture (CDA) document.

X.1 BASIC DATA FLOWS

X.1.1 Dictation/Transcription Reporting

535 During the softcopy reading of an imaging study, the physician dictates his 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 an implementation-specific mechanism. The report management system enables the reporting physician to correct, verify, and “sign” the transcribed report. See Figure X.1-1. 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. This data flow
540 applies to both reports stored in a proprietary format, and reports stored using DICOM Basic Text SR SOP Instances.

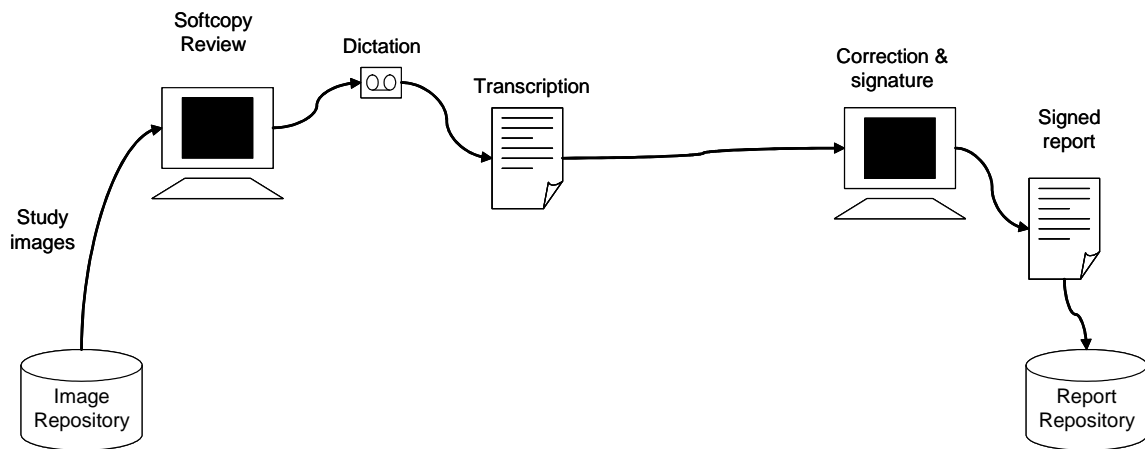


Figure X.1-1 Dictation/Transcription Reporting Data Flow

X.1.2 Reporting with Image References

545 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.
550 When the report management system receives the transcribed dictation, it queries the image repository for the

KO objects, and appends the image references 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.

555

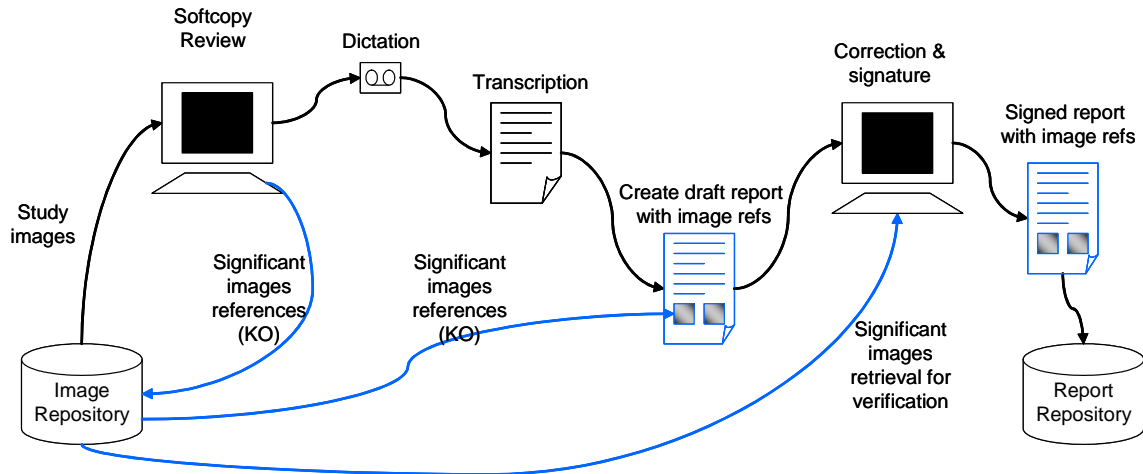


Figure X.1-2 Reporting Data Flow with Image References

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

560 The KO instances include a specific title “For Report Attachment”. The report management system may need to retrieve all KO instances of the study to find those with this title, since the image repository may not support the object title as a query return key.

Note that after the completion of report, there is no need to maintain the KO instances, since all of their information has been included into the report.

565 **X.1.3 Reporting with Annotated Images**

570 The format of the Image Content Item (used in 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 instance. 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-3.

575 Note that the GSPS image presentation controls can also be invoked from non-DICOM display stations through the facilities of the Web Access to DICOM Persistent Objects (WADO) service. See PS3.18.

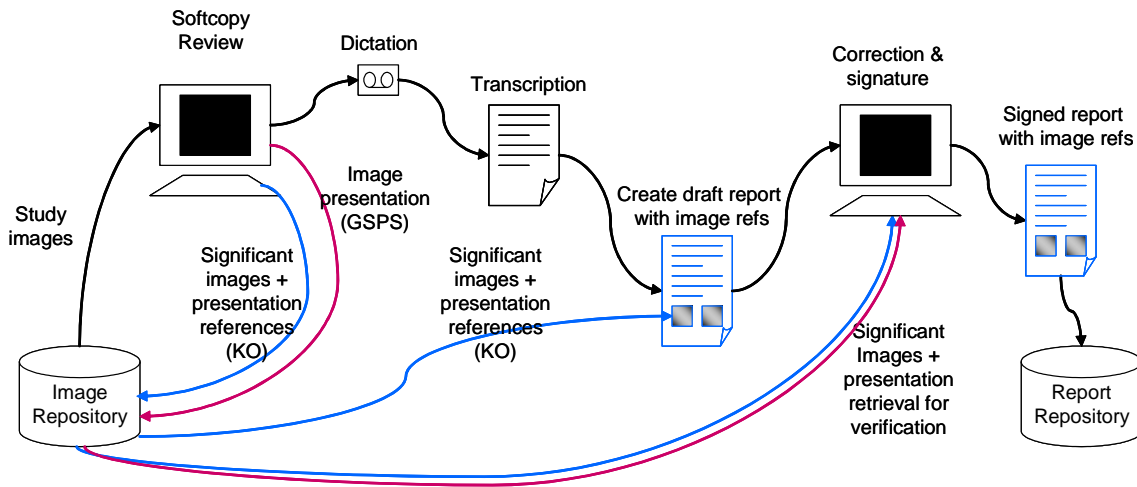


Figure X.1-3 Reporting Data Flow with Image and Presentation/Annotation References

X.2 TRANSCRIBED DIAGNOSTIC IMAGING SR INSTANCE CONTENT

580 A specific SR Template, TID x2005 (see PS3.16), is defined to support transcribed diagnostic imaging reports created in this data flow and stored as DICOM Basic Text SR objects.

X.2.1 SR Header Format

585 The header of the SR report instance must include the patient identity (subject context) in the Patient Module, the study identity (procedure context) in the Study Module, and the following information 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
- Linkage attributes to study workflow management in the Referenced Request Sequence
- 590 – 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

595 The report management system has flexibility in encoding the Document Title (see CID 7000). 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”).

600 **X.2.2 Text Data Format**

The transcribed dictation is 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.

605 The transcribed dictation is used to populate one or more section containers in the SR Instance. If a single text stream is provided, it will typically be encoded in a container with Concept Name "Findings", and the text in a subsidiary content item with Concept Name "Finding". With multiple transcription sections titled using the concepts in CID 7000 (see PS3.16), each section may be encoded in a separate container, with the concept from CID 7000 as the container Concept Name, and the corresponding term from CID 7001 as the Concept Name for a subsidiary text content item.

610 **X.2.3 Image Reference Format**

Each KO instance includes a single optional descriptive text field, plus a list of image references using the SR Image Content Item format.

615 Multiple KO instances may be created for a study report, either intentionally or not. An intentional use would be to facilitate associating different descriptive text with different images or image sets. All KOs with the title "For Report Attachment" in the study are associated with the report. (There may also be KOs with other titles, such as "For Teaching", that are not associated with the report.)

620 The content items from each associated KO object will be included in the SR in a separate container with Concept Name "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.2-1.

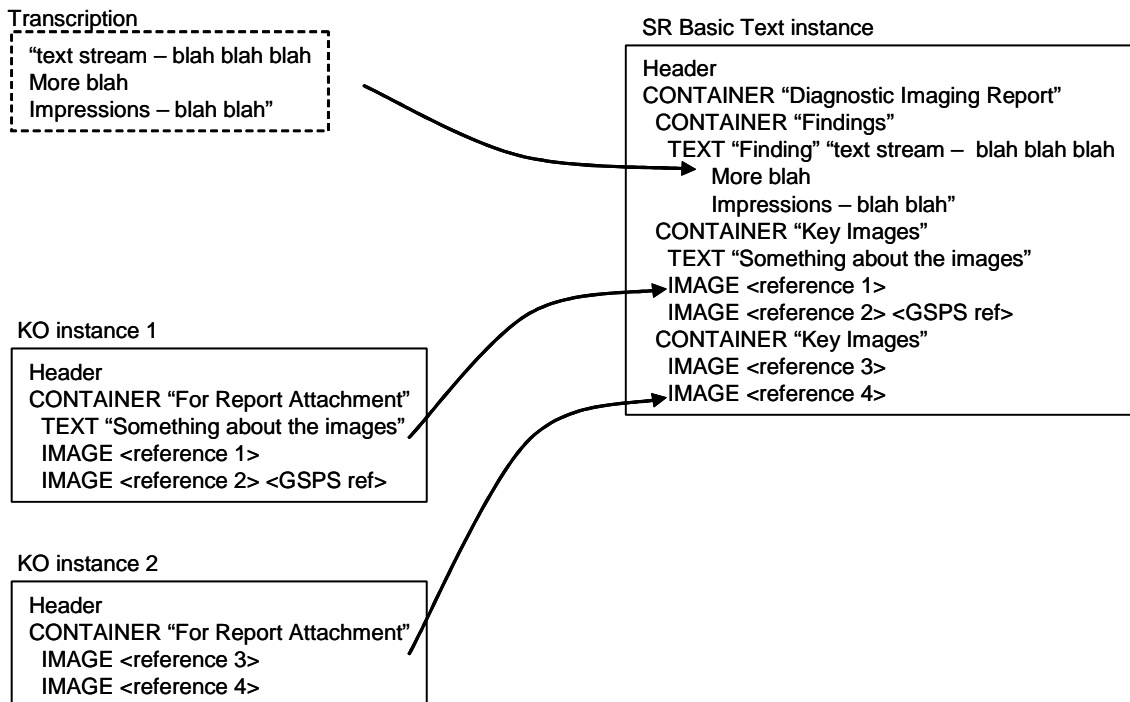


Figure X.2-1 Inputs to SR Basic Text Object Content Tree

The SR Image Content Item format allows the encoding of an icon with the image reference, as well as a reference to a GSPS instance controlling image presentation. Whether or not to include icons or GSPS

625 references is an implementation decision of the softcopy review station that creates the KO; the Image Content Item may be simply copied from the KO to the Basic Text SR instance.

The correction and signature function of the report management system should allow the physician to delete image references that were included, perhaps unintentionally, from multiple KO instances.

X.3 TRANSCODING SR TO CDA

630 The SR instance may be transformed or transcoded to a HL7 Clinical Document Architecture (CDA) document for dissemination outside the department (see Figure X-5). This may use the format of CDA Release 1 or CDA Release 2.

Note: The imaging report may be created as a CDA document directly, without an intermediate SR report. Such use is outside the scope of this Annex.

635

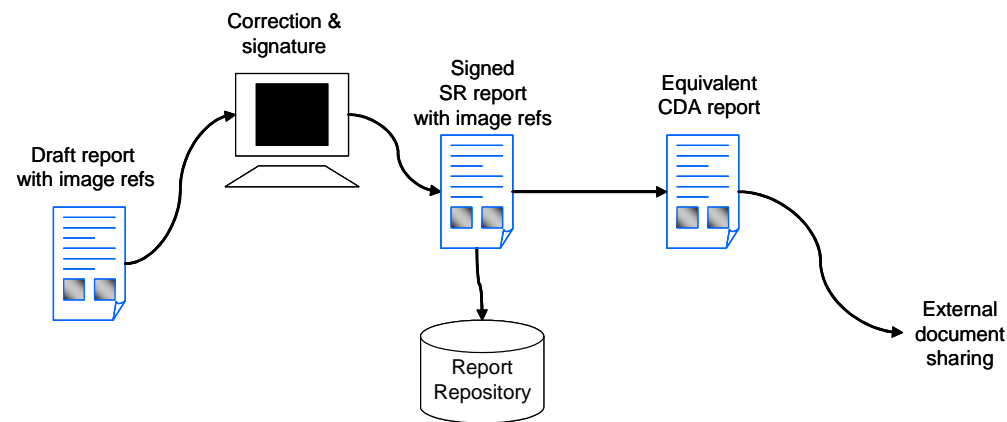


Figure X.3-1 SR Reporting Data Flow with CDA Transcoding

X.3.1 Equivalence

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

640 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."

645 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.

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

Note to Public Comment Reviewers: It would be useful to have a table describing an informative mapping of SR to CDA. Suggestions for the content of such a table are welcomed.

X.3.2 Transform Relationship

655 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 HL7 CDA Document Sequence (0040,A09x) attribute, and the CDA Document may reference the SR Document with a Transform relationship.

For CDA Release 2, the transform (parent document) relationship has a target Act of DOCCLIN.

To be resolved: Can a reference to an SR Instance be encoded in a DOCCLIN Act?

660 CDA Release 1 does not provide a standard for the Transform relationship to another document.

To be resolved: Do we need to specify a canonical Local markup for the SR parent document of a CDA Release 1?

X.3.3 Current Requested Procedure Evidence

665 One of the Type 1C attributes required in a complete SR document is the Current Requested Procedure Evidence Sequence (0040,A375), listing all the SOP Instances created for the current Requested Procedure. It is recommended that this list be transcoded to multiple link items using the <paragraph> <content> <link> <link_html> markup in a CDA Narrative Section with the caption “Current Requested Procedure Evidence”. (See Section X.4.1 on encoding of SOP Instance references with the <link_html> markup.)

Note: In CDA Release 2, the Section caption is encoded in the Section.Title attribute.

670

X.3.4 Text Content

675 Each Container in the Basic Text SR content tree can be transformed to a Section in the CDA document, and each subsidiary Text Content Item can be transformed to <paragraph> <content> data in that Section of the CDA document. The Section and Paragraph captions can be derived from the corresponding Container and Text Concept Names in the SR items, as created in the dictation/transcription process in the current use case (see section X.2.1).

Notes: 1. Even though the Container and Text Concept Names in the SR Instance are coded terms, they do not fall within the coded vocabulary constraint (LOINC Section Titles) for the CDA Release 1 caption_cd or CDA Release 2 Section.code. Since the caption codes are optional in CDA, only the title derived from the SR Concept Name Code Meaning attribute needs to be transcoded.

680

2. In CDA Release 2, the Section caption is encoded in the Section.Title attribute. The Paragraph construct is defined by the special markup for the narrative block in the Section.text attribute.

X.3.5 Image References

685 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.

690

Note: 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 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.

695

700 In the current use case, there will be one or more SR Containers, each titled “Key Images”, with image references. As described above (section X.3.3), the Container can be transformed to a Section in the CDA document with a section caption “Key Images”. The Key Images Container may contain a subsidiary Text

705 Content Item, copied from the KO "Key Object Description" Text Content Item. If there is such a Text Content Item, it can be transformed to <paragraph> <content> data in that Section of the CDA document. Each Image Content Item can be transformed to a link item using the <paragraph> <content> <link> <link_html> markup (see section X.4.1).

Note: While the Image Content Items could be transformed to multiple <content> items in a single <paragraph>, or even multiple <link> items in a single <content> item, the general approach of transcoding a DICOM SR Content Item to a CDA Paragraph is used, so that any coded Concept Name in the SR Content Item can be transcoded to the paragraph caption.

710

X.3.6 CDA Release 2 Structured Entries

In CDA Release 1, external non-attested content is referenced using the <link> markup within a narrative block. In CDA Release 2, both the <link> markup and non-attested structured Entries may be used. This Annex recommends encoding image references using both methods for CDA Release 2.

715 For CDA Release 2, each image reference will also be encoded as an Entry using an instance of the HL7 v3 Act class as the root, and subsidiary Acts for encoding additional identifiers such as a referenced GSPS (see section X.4.2). The root Act will include a reference to the narrative block <content> markup that encodes the same external image reference.

```

720 <section>
    <title>Key Images</title>
    <text>
      <paragraph>
        <content ID="image1">
          <link>
725             <link_html title="CT Image"
                href="https://pacs.poupon.edu/wado.jsp?...">
          </link>
        </content>
      </paragraph>
    </text>
    <entry>
      ...
      <act>
735         <classCode code="DGIMG">
         <moodCode code="EVN">
         <code code="CT"
             codeSystem="1.2.840.10008.2.16.4"
             codeSystemName="DCM"
             displayName="CT"/>
740         <originalText>
             <reference value="#image1"/>
         </originalText>
         <text reference="https://pacs.poupon.edu/wado.jsp?... " >
745             ...
         </act>
      ...
    </entry>
  </section>

```

Figure X-6 CDA Rel.2 Image Reference in both <link_html> and Entry, with linking

750 **X.3.7 Image Reference Retrieval Format**

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.

755 Therefore, the recommended encoding of a DICOM Object Reference in the CDA narrative block <link_html> uses the Web Access to Persistent DICOM Objects (WADO) specified URI 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.

760 However, the structured Entries of the CDA Release 2 format are intended for automated processing, and any automated processing of images would be expected to handle DICOM formats. Therefore, the external media reference for the CDA Release 2 structured Entries is recommended to use the WADO URI for access by the HTTP/HTTPS network protocol, but using “application/DICOM” as the requested content type.

X.4 ENCODINGS

765 Note to Public Comment reviewers: There is a significant issue with the recommended content of the URI resource identifier – what should be used for the access scheme (e.g., HTTP) and what should be used for the identification of the target authority (i.e., the system to which the query is directed), since typical URLs may become “stale”. See the “dicom” listserv discussion on this topic at <http://hl7.org/Special/committees/lists.cfm> (this site requires a free registration). The final selection of an approach will depend heavily on recommendations developed during Public Comment.

X.4.1 DICOM Object Reference in <link_html>

770 The encoding of a DICOM Object Reference in an HL7 CDA <link_html> markup in the narrative block uses the WADO-specified URI as shown in Table X.4-1.

Table X.4-1 DICOM Object Reference in an HL7 CDA <link_html>

Attribute	Value
href	<WADO reference, contentType=image/jpeg or video/mpeg as appropriate>
title	for SR objects: <Code Meaning for Concept Name of Root, optionally with Code Meaning for Concept Code of “Procedure Reported” or “Document Title Modifier” Concept Modifier Items> for other objects: <derived from name corresponding to SOP Class UID, leaving off “Storage Service”>

All other <link_html> attributes are not used.

775 The href attribute includes the complete WADO query URI, including the URI scheme and authority, and contentType and charset parameters (see PS3.18). As noted in Section X.3.7, it is recommended that image references in <link_html> specify a non-DICOM image format, e.g., with contentType=image/jpeg.

Note that the title attribute may need to be converted to the UTF-8 character set from the character set used for encoding the DICOM object.

780 **X.4.2 DICOM Object Reference in an HL7 v3 Act**

Note to Public Comment reviewers: The content of this section is still under development, and will depend heavily on recommendations developed during Public Comment and in consultation with HL7. There are three proposals for possible encodings of DICOM Object References in HL7 v3 Acts:

785

1. The DICOM object reference is limited to just the SOP Instance UID in a simple Act class clone. There is presumed to be a service to locate that Instance UID in the appropriate Study and Series context when necessary for retrieval.

790

2. The DICOM object reference is the SOP Instance UID in an Act class clone, which has "component" ActRelationships from other Act clones identifying the Study and Series. This structure, however, makes it difficult to have a "has presentation" ActRelationship to another Act representing a Presentation State instance, since that instance would need to sit in another such hierarchical structure (and such relationship would need to be across tree branches).

795

3. The DICOM object reference is encoded in a DGIMG (Diagnostic Image) class clone (a subclass of Act), and the Study and Series Instance UIDs are added to the Diagnostic Image class in the HL7 RIM.

Note that the current use case does not require references to Series or Study level objects, and the means of encoding such references in HL7 is out of scope for this Supplement.

Also out of scope of this Supplement, but which should be considered in consideration of the resolution of this issue, is how to handle references to non-image DICOM objects (e.g., RT Plan, Presentation State, Key Object Selection) E.g., should the DGIMG class definition be extended to include all DICOM Composite objects (not just images?)

800

The encoding of a DICOM Object Reference in an HL7 v3 Act is shown in Table X.4-2. This would be used in CDA Release 2 for referencing a parent SR Document that was transformed to the CDA Document, or in a structured Entry.

Table X.4-2 DICOM Object Reference in an HL7 v3 Act

Attribute	Data Type	Value
classCode	CS	for parent SR object: DOCCLIN for other SR objects: DOC for image objects: DGIMG for other objects: OBS
moodCode	CS	EVN
id	II	1..1 <SOP Instance UID as root property with no extension property>
code	CD	for SR objects: <Concept Name of Root - no post-coordination with Concept Modifier codes> for other objects: <modality>
title	ST	for SR objects: <Code Meaning for Concept Name of Root, optionally with Code Meaning for Concept Code of "Procedure Reported" or "Document Title Modifier" Concept Modifier Items> for other objects: <derived from name corresponding to SOP Class UID, leaving off "Storage Service">
text	ED	<WADO reference, contentType=application/DICOM>

805

The WADO reference is encoded in an ED abstract data type. The encoding of the WADO URI is as follows:

- The WADO contentType parameter is encoded in the ED mediaType property.
- The WADO charset parameter is encoded in the ED charset property.

- The entire WADO query, including the `contentType` and `charset` parameters, plus the URI scheme and authority, is encoded in the ED reference property.

810

Note to Public Comment reviewers: the following tables are one possible way to encode a Series or Study as a Cluster (a subclass of Act).

Table X.4-3 DICOM Series Reference in an HL7 v3 Act

Attribute	Data Type	Value
classCode	CS	CLUSTER
moodCode	CS	EVN
id	II	1..1 <Series Instance UID as root property with no extension property>
code	CD	<modality>? (113015, DCM, "Series")?
text	ST	<Series Description>

815

Table X.4-4 DICOM Study Reference in an HL7 v3 Act

Attribute	Data Type	Value
classCode	CS	CLUSTER
moodCode	CS	EVN
id	II	1..1 <Study Instance UID as root property with no extension property>
code	CD	<procedure code>? (113014, DCM, "Study")?
text	ST	<Study Description>

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

820 An application that is capable of using the full services of DICOM upper layer protocol directly can use the WADO parameters to identify the object within 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 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.)

825 The application would open a Query/Retrieve service association with the configured server, and send a C-MOVE 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.

830