Digital Imaging and Communications in Medicine (DICOM)

Supplement 114: DICOM Encapsulation of CDA Documents

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VERSION: Final Text January 22, 2007

Developed pursuant to DICOM Work Item 2003-12-C

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Scope and Field of Application

This supplement proposes additions to the DICOM Standard to provide for the encapsulation of documents that have been encoded using the HL7 Clinical Data Architecture (CDA) format, so that these documents may be exchanged between various types of equipment using DICOM messages.

HL7 has developed the Clinical Data Architecture (CDA) as a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. Clinical evidence, measurements and reports may be generated in a CDA format. The normative encoding of CDA documents uses markup based on the HL7 v3 XML Implementation Technology Specification. However, the CDA standard does not specify the messaging or storage mechanisms for the management of such documents.

In order to exchange and/or handle these documents in an efficient manner in an imaging environment, especially as input to an imaging procedure or for imaging reports, it is useful to be able to “wrap” these types of documents in a DICOM container. They can thus be exchanged as DICOM objects using the DICOM Storage Service, and accordingly archived and retrieved.

Therefore, this supplement defines a SOP Class for CDA documents encapsulated into Composite DICOM SOP Instances, so that they can be exchanged using the appropriate Service Classes.

The CDA format specification is available from HL7. See: http://www.hl7.org.

This Supplement proposes changes to the following Parts of the DICOM Standard:

- PS 3.2 - Conformance
- PS 3.3 - Information Object Definitions
- PS 3.4 - Service Class Specifications
- PS 3.6 - Data Dictionary
- PS 3.10 - Media Storage and File Format for Media Interchange
- PS 3.15 - Security and System Management Profiles

Changes to NEMA Standards Publication PS 3.2-2006

Digital Imaging and Communications in Medicine

Part 2: Conformance

Item: Add to table A.1-2 categorizing SOP Classes:

The SOP Classes are categorized as follows:

Table A.1-2
UID VALUES

UID Value	UID NAME	Category
…	…	…
1.2.840.10008.5.1.4.1.1.104.2	**Encapsulated CDA Storage SOP Class**	**Transfer**
…	…	…

Changes to NEMA Standards Publication PS 3.3-2006

Digital Imaging and Communications in Medicine (DICOM)

Part 3: Information Object Definitions

Modify Section A.1.4 Overview of the Composite IOD Module Content – Insert Encapsulated CDA

Table A.1-2
COMPOSITE INFORMATION OBJECT MODULES OVERVIEW - NON-IMAGES

IODs Modules	…	Encapsulated CDA	…
Patient		**M**	
Patient Summary			
Specimen Identification			
Clinical Trial Subject		**U**	
General Study		**M**	
Patient Study		**U**	
Clinical Trial Study		**U**	
Study Content			
Encapsulated Document Series		**M**	
Clinical Trial Series		**U**	
…			
General Equipment		**M**	
SC Equipment		**M**	
…			
Encapsulated Document		**M**	
…			
SOP Common		**M**	

Modify Annex A – Insert new section for Encapsulated CDA IOD

A.45.2 Encapsulated CDA Information Object Definition

A.45.2.1 Encapsulated CDA IOD Description

The Encapsulated CDA Information Object Definition (IOD) describes an HL7 Clinical Document Architecture (CDA) document that has been encapsulated within a DICOM information object.

A.45.2.2 Encapsulated CDA Entity-Relationship Model

The E-R Model in Section A.1.2 of this Part applies to the Encapsulated CDA IOD.

A.45.2.3 Encapsulated CDA IOD Module Table

Table A.45.2-1 specifies the Encapsulated CDA IOD Modules.

Table A.45.2-1
Encapsulated CDA IOD MODULES

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	Encapsulated Document Series	C.24.1	M
	Clinical Trial Series	C.7.3.2	U
Equipment	General Equipment	C.7.5.1	M
	SC Equipment	C.8.6.1	M
Encapsulated Document	Encapsulated Document	C.24.2	M
	SOP Common	C.12.1	M

A.45.2.4 Encapsulated CDA IOD Content Constraints

The Encapsulated Document (0042,0011) attribute shall contain an HL7 CDA document of Release 2 or later. Any non-XML multimedia content shall be encoded in-line. The MIME Type of Encapsulated Document (0042,0012) value shall be ‘text/XML’.

Modify Annex C.24 –Clarifications for Encapsulated Documents

C.24.1 Encapsulated Document Series Module

Table C.24-1 defines the Encapsulated Document Series Attributes.

Table C.24-1
Encapsulated Document Series Module Attributes

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	The modality appropriate for the encapsulated document. This Type definition shall override the definition in the SC Equipment Module. See section C.7.3.1.1.1 for Defined Terms. **Note: SR may be an appropriate value for an Encapsulated CDA document with a structured XML Body.**
…			

C.24.2 Encapsulated Document Module

Table C.24-2 defines the Encapsulated Document Attributes.

Table C.24-2
Encapsulated Document Module Attributes

Attribute Name	Tag	Type	Attribute Description
Instance Number	(0020,0013)	1	A number that identifies this SOP Instance. The value shall be unique within a series.
Content Date	(0008,0023)	2	The date the document content creation was started.
Content Time	(0008,0033)	2	The time the document content creation was started.
Acquisition Datetime	(0008,002A)	2	The date and time that the original generation of the data in the document started.
Burned In Annotation	(0028,0301)	1	Indicates whether or not the encapsulated document contains sufficient burned in annotation to identify the patient and date the data was acquired. Enumerated Values: YES NO **Identification of patient and date as text in an encapsulated document (e.g., in an XML attribute or element) is equivalent to "burned in annotation". A de-identified document may use the value NO.**
Source Instance Sequence	(0042,0013)	1C	A sequence that identifies the set of Instances that were used to derive the encapsulated document. One or more Items may be included in this Sequence. Required if derived from one or more DICOM Instances. May be present otherwise.
>Referenced SOP Class UID	(0008,1150)	1	Uniquely identifies the referenced SOP Class.

>Referenced SOP Instance UID	(0008,1155)	1	Uniquely identifies the referenced SOP Instance.
Document Title	(0042,0010)	2	The title of the document. Note: In the case of a PDF encapsulated document, this may be the value of the "Title" entry in the "Document Information Directory" as encoded in the PDF data.
Concept Name Code Sequence	(0040,A043)	2	A coded representation of the document title. Zero or one item may be present.
>Include 'Code Sequence Macro' Table 8.8-1			*Baseline Context Group 7020*
Verification Flag	(0040,A493)	3	Indicates whether the Encapsulated Document is Verified. Enumerated Values: UNVERIFIED = Not attested by a legally accountable person. VERIFIED = Attested to (signed) by a Verifying Observer or Legal Authenticator named in the document, who is accountable for its content.
HL7 Instance Identifier	**(0040,E001)**	**1C**	**Instance Identifier of the encapsulated HL7 Structured Document, encoded as a UID (OID or UUID), concatenated with a caret ("^") and Extension value (if Extension is present in Instance Identifier).** **Required if encapsulated document is a CDA document.**
MIME Type of Encapsulated Document	(0042,0012)	1	The type of the encapsulated document stream described using the MIME Media Type (see RFC 2046).
List of MIME Types	**(0042,0014)**	**1C**	**MIME Types of subcomponents of the encapsulated document.** **Required if the encapsulated document incorporates subcomponents with MIME types different than the primary MIME Type of the encapsulated document.** **Note: An Encapsulated CDA that includes an embedded JPEG image and an embedded PDF would list "image/jpeg\application/pdf".**
Encapsulated Document	(0042,0011)	1	Encapsulated Document stream, containing a document encoded according to the MIME Type.

Note**s**: **1.** One could distinguish four stages in the creation of the Encapsulated Document Object, identified by the following Attributes…:

105 **2. DICOM does not specify requirements for consistency between DICOM attribute values and data in the encapsulated document. It is expected that applications will ensure consistency in a manner appropriate to the application. For example, the Patient ID in an encapsulated CDA document may be that of a different institution, which originated the document, and it may be appropriate for the DICOM attribute value to be different.**

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C.24.1.1 Attribute Requirements for Encapsulated CDA Document

For an Encapsulated CDA Document, Document Title (0042,0010) shall have the value of the CDA Document Title, if one is present in the encapsulated document. Concept Name Code Sequence (0040,A043) shall have the value of the CDA Document Type Code, with transcoding as necessary for converting the HL7 CE Data Type to the DICOM Code Sequence item. The MIME Type of Encapsulated Document (0042,0012) value shall be 'text/XML'.

Modify Annex F.5 –Clarifications for Encapsulated Documents

F.5.32 Encapsulated 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 "ENCAP DOC." Table F.5-32 lists the set of keys with their associated Types for such a Directory Record Type. The description of these keys may be found in the Modules related to the Encapsulated Document IE of ~~**the**~~ Encapsulated ~~**PDF**~~ **Document** IOD**s**. This Directory Record shall be used to reference an Encapsulated ~~**PDF**~~ **Document** SOP Instance. This type of Directory Record may reference a Lower-Level Directory Entity that includes one or more Directory Records as defined in Table F.4-~~**2**~~**21**.

Note: Other Encapsulated Document SOP Classes may be added to the standard in the future and these will likely be referenced by this directory record. Therefore, the MIME Type should be checked rather than assuming that the referenced file contains PDF.

Table F.5-32
Encapsulated 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.**
Content Date	(0008,0023)	2	The date the content creation started.
Content Time	(0008,0033)	2	The time the content creation started.
Instance Number	(0020,0013)	1	A number that identifies this instance
Document Title	(0042,0010)	2	The title of the document.
HL7 Instance Identifier	**(0040,E001)**	**1C**	**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).** **Required if encapsulated document is an HL7 Structured Document.**
Concept Name Code Sequence	(0040,A043)	2	A coded representation of the document title. Zero or one item may be present.
>Include 'Code Sequence Macro' Table 8.8-1		1	*Baseline Context Group 7020*
MIME Type of Encapsulated Document	(0042,0012)	1	The type of the encapsulated document stream described using the MIME Media Type (see RFC 2046).

Any other Attribute of the Encapsulated Document Module except Encapsulated Document (0042,0011)		3	

F.5.33 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.5-33 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 **stored on the interchange media but not** encapsulated in a **DICOM SOP Instance. The document may be encoded as an XML document with in-line multimedia content, or may be encoded in a** multi-part MIME wrapper (see PS3.10). This type of Directory Record ~~**shall not reference any Lower-Level Directory Entity**~~ **may reference a Lower-Level Directory Entity that includes one or more Directory Records as defined in Table F.4-1**.

Table F.5-33
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. **Only a single Item shall be permitted in this Sequence.**
>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.

Changes to NEMA Standards Publication PS 3.4-2006

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Part 4: Service Class Specifications

Modify Annex B.5 Standard SOP Classes – add new item.

B.5 STANDARD SOP CLASSES

Table B.5-1
STANDARD SOP CLASSES

SOP Class Name	SOP Class UID	IOD (See PS 3.3)
…		
Encapsulated CDA Storage	**1.2.840.10008.5.1.4.1.1.104.2**	**Encapsulated CDA IOD**
…		

Modify Annex I.4 Media Storage Standard SOP Classes – add new item.

I.4 MEDIA STANDARD STORAGE SOP CLASSES

Table I.4-1
Media Storage Standard SOP Classes

SOP Class Name	SOP Class UID	IOD Specification
…		
Encapsulated CDA Storage	**1.2.840.10008.5.1.4.1.1.104.2**	**Encapsulated CDA IOD**
…		

Changes to NEMA Standards Publication PS 3.6-2006

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Part 6: Data Dictionary

Modify PS3.6 Section 6 – add new attribute

6 Registry of DICOM data elements

Tag	Name	VR	VM
...			
(0042,0014)	**List of MIME Types**	**LO**	**1-n**

Modify PS3.6 Annex A Registry of DICOM unique identifiers (UID) – add new items.

Annex A Registry of DICOM unique identifiers (UID) (Normative)

Table A-1 lists the UID values that are registered and used throughout the Parts of the DICOM Standard. This central registry ensures that when additional UIDs are assigned, non-duplicate values are assigned.

Table A-1
UID VALUES

UID Value	UID NAME	UID TYPE	Part
…			
1.2.840.10008.1.2.6.2	**XML Encoding**	**Transfer Syntax**	**PS 3.10**
…			
1.2.840.10008.5.1.4.1.1.104.2	**Encapsulated CDA Storage**	**SOP Class**	**PS 3.4**

…			

Changes to NEMA Standards Publication PS 3.10-2006

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Part 10: Media Storage and File Format for Media Interchange

Modify PS3.10 Annex B – clarify use of encapsulated and unencapsulated HL7 documents on media.

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). **There are two alternatives for storage of such documents – they may be encapsulated in DICOM SOP Instances, or they may be stored as native HL7 objects (unencapsulated).**

An Encapsulated CDA is referenced from the Media Storage Directory like any other DICOM SOP Instance.

~~**Such r**~~**R**eferences **to a native (unencapsulated) Structured Document** ~~**shall**~~ use a SOP Class UID, identifying the document class, and a SOP Instance UID. The SOP Instance UID is arbitrary, and the ~~**effective**~~ **native** document instance identifier is encoded in the HL7 Instance Identifier (0040,E001) attribute (see PS3.3, **"HL7 Structured Document Directory Record Definition" and** "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.

3. It is recommended that an HL7 Structured Document that can be associated with a patient and study be encapsulated in a DICOM SOP Instance, and that the SOP Instance UID of that encapsulation be used consistently for all references.

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. **The multimedia components may be encoded in-line in the XML document, or they may be referenced external objects.**

Such a document stored on DICOM Interchange Media shall be encoded as **either:**

- **an XML document with any multimedia components encoded in-line, and stored in a single file. 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 XML content. For the purpose of identifying the Transfer Syntax of such a stored file from the DICOMDIR, the Transfer Syntax UID "1.2.840.10008.1.2.6.2" is specified for an XML encoded document.**
- 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 **XML file or** MIME package **file**.

Changes to NEMA Standards Publication PS 3.15-2006

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Part 15: Security and System Management Profiles

Modify PS3.15 Annex C – add encapsulated documents to electronic signature profiles

C.2 CREATOR RSA DIGITAL SIGNATURE PROFILE

…

As a minimum, an implementation shall include the following attributes in generating the Creator RSA Digital Signature:

a. the SOP Class and Instance UIDs
b. the SOP Creation Date and Time, if present
c. the Study and Series Instance UIDs
d. any attributes of the General Equipment module that are present
e. any attributes of the Overlay Plane, Curve or Graphic Annotation modules that are present
f. any attributes of the General Image and Image Pixel modules that are present
g. any attributes of the SR Document General and SR Document Content modules that are present
h. any attributes of the Waveform and Waveform Annotation modules that are present
i. any attributes of the Multi-frame Functional Groups module that are present
j. any attributes of the Enhanced MR Image module that are present
k. any attributes of the MR Spectroscopy modules that are present
l. any attributes of the Raw Data module that are present
m. any attributes of the Enhanced CT Image module that are present
n. any attributes of the Enhanced XA/XRF Image module that are present
o. <u>any attributes of the Encapsulated Document module that are present</u>

...

C.3 AUTHORIZATION RSA DIGITAL SIGNATURE PROFILE

....

As a minimum, an implementation shall include the following attributes in generating the Authorization RSA Digital Signature:

a. the SOP Class and Instance UIDs
b. the Study and Series Instance UIDs
c. any attributes whose Values are verifiable by the technician or physician (e.g., their Values are displayed to the technician or physician)
d. any attributes of the Overlay Plane, Curve or Graphic Annotation modules that are present
e. any attributes of the General Image and Image Pixel modules that are present
f. any attributes of the SR Document General and SR Document Content modules that are present
g. any attributes of the Waveform and Waveform Annotation modules that are present
h. any attributes of the Multi-frame Functional Groups module that are present
i. any attributes of the Enhanced MR Image module that are present
j. any attributes of the MR Spectroscopy modules that are present
k. any attributes of the Raw Data module that are present
l. any attributes of the Enhanced CT Image module that are present
m. any attributes of the Enhanced XA/XRF Image module that are present
n. <u>any attributes of the Encapsulated Document module that are present</u>