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Correction Number CP-1765
Log Summary: Retire DICOMDIR reference to unencapsulated CDA on media
Name of Standard PS3.3, PS3.6, PS3.10 2018b
Rationale for Correction: Sup 101 HL7 Structured Document Object References (FT 2005/06/15) added a mechanism to reference non-DICOM files, specifically HL7 CDA files and/or MIME multipart-related files containing HL7 CDA and their accompanying supporting files. Sup 114 DICOM Encapsulation of CDA Documents (FT 2007/01/22) provided an alternative mechanism with the ability to encapsulated CDA in DICOM, and extended rather than retiring the previously defined mechanism. It is proposed to retire the unencapsulated approach, since there is no evidence that indexing unencapsulated CDA files from the DICOMDIR has ever been used, encapsulation is the preferred approach (consistent with the approach for PDF and 3D manufacturing formats), and IHE specifies alternative mechanisms for indexing metadata for non-DICOM files (XDM profile). This change does not preclude inclusion of unencapsulated CDA (or any other) format documents that are not referenced by the DICOMDIR, e.g., in the manner defined in the IHE XDM profile in which such non-DICOM files are described in the METADATA.XML file. The corresponding Transfer Syntaxes are also retired, since they are not used for any other purpose in DICOM.
Correction Wording:

*Amend DICOM PS3.10 as follows (changes to existing text are bold and **underlined** for additions and **~~struckthrough~~** for removals):*

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.

~~References to a native (unencapsulated) Structured Document use a SOP Class UID, identifying the document class, and a SOP Instance UID. The SOP Instance UID is arbitrary, and the native document instance identifier is encoded in the HL7 Instance Identifier (0040,E001) attribute (see ????, "HL7 Structured Document Directory Record Definition" and "HL7 Structured Document Reference Sequence" for further information).~~

Note

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 multimedia components (e.g., graphics) that are considered an integral part of the object. The multimedia components **~~may~~shall** be encoded in-line in the **encapsulated** XML document**~~, or they may be referenced external objects~~unless they are references to other DICOM SOP Instances contained on the media**.

~~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 RFC2557 "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 RFC2557 MIME Encapsulation.~~**

Note

~~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. There may also be alternate file identifiers (e.g., links) to those files that use less restricted file names (see ???).~~

~~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.~~

*Amend DICOM PS3.3 as follows (changes to existing text are bold and **underlined** for additions and **~~struckthrough~~** for removals):*

F.3.2.2 Directory Information Module

...

Table F.3-3. Directory Information Module Attributes

Attribute Name	Tag	Type	Attribute Description
>Directory Record Type	(0004,1430)	1	Defines a specialized type of Directory Record by reference to its position in the Media Storage Directory Information Model (see Section F.4). **Enumerated Values:** **PATIENT** **...** **ENCAP DOC** **~~HL7 STRUC DOC~~** **VALUE MAP** **...** **PRIVATE** Privately defined record hierarchy position. Type shall be defined by Private Record UID (0004,1432). **Note** 1. Enumerated Values PRINT QUEUE, FILM SESSION, FILM BOX, and IMAGE BOX were previously defined **~~in DICOM for this Attribute~~**. They are now retired. See PS3.3-1998. 2. Enumerated Values OVERLAY, MODALITY LUT, VOI LUT, CURVE, TOPIC, VISIT, RESULTS, INTERPRETATION, STUDY COMPONENT and STORED PRINT were previously defined **~~in DICOM for this Attribute~~**. They are now retired. See PS3.3-2004. 3. Enumerated Value MRDR was previously defined **~~in DICOM for this Attribute~~**, to allow indirect reference to a File by multiple Directory Records. It is now retired. FSUs and FSRs are unlikely to be capable of supporting this mechanism. See PS3.3-2004. 4. **Enumerated Value HL7 STRUC DOC was previously defined. It is now retired. See PS3.3-2018b.**

F.4 Basic Directory IOD Information Model

Table F.4-1. Relationship Between Directory Records

Directory Record Type	Section	Directory Record Types that may be included in the next lower-level directory Entity
(Root Directory Entity)		PATIENT, HANGING PROTOCOL, PALETTE, IMPLANT, IMPLANT ASSY, IMPLANT GROUP, PRIVATE
PATIENT	???	STUDY, **~~HL7 STRUC DOC,~~** PRIVATE
STUDY	???	SERIES, PRIVATE
SERIES	???	IMAGE, RT DOSE, RT STRUCTURE SET, RT PLAN, RT TREAT RECORD, PRESENTATION, WAVEFORM, SR DOCUMENT, KEY OBJECT DOC, SPECTROSCOPY, RAW DATA, REGISTRATION, FIDUCIAL, ENCAP DOC, VALUE MAP, STEREOMETRIC, PLAN, MEASUREMENT, SURFACE, TRACT, ASSESSMENT, PRIVATE
IMAGE	???	PRIVATE

Directory Record Type	Section	Directory Record Types that may be included in the next lower-level directory Entity
...	...	...
ENCAP DOC	???	PRIVATE
~~**HL7 STRUC DOC**~~	~~**F.5.33**~~	~~**PRIVATE**~~
...	...	...

Note

1. Directory Record Types PRINT QUEUE, FILM SESSION, FILM BOX, and IMAGE BOX were previously defined ~~**in DICOM**~~. They have been retired. See PS3.3-1998.

2. Directory Record Types OVERLAY, MODALITY LUT, VOI LUT, CURVE, TOPIC, VISIT, RESULTS, INTERPRETATION, STUDY COMPONENT, STORED PRINT and MRDR were previously defined ~~**in DICOM**~~. They have been retired. See PS3.3-2004.

3. **Directory Record Type HL7 STRUC DOC was previously defined. It has been retired. See PS3.3 2018b.**

F.5 Definition of Specific Directory Records

Replace old Figure F.4-1:

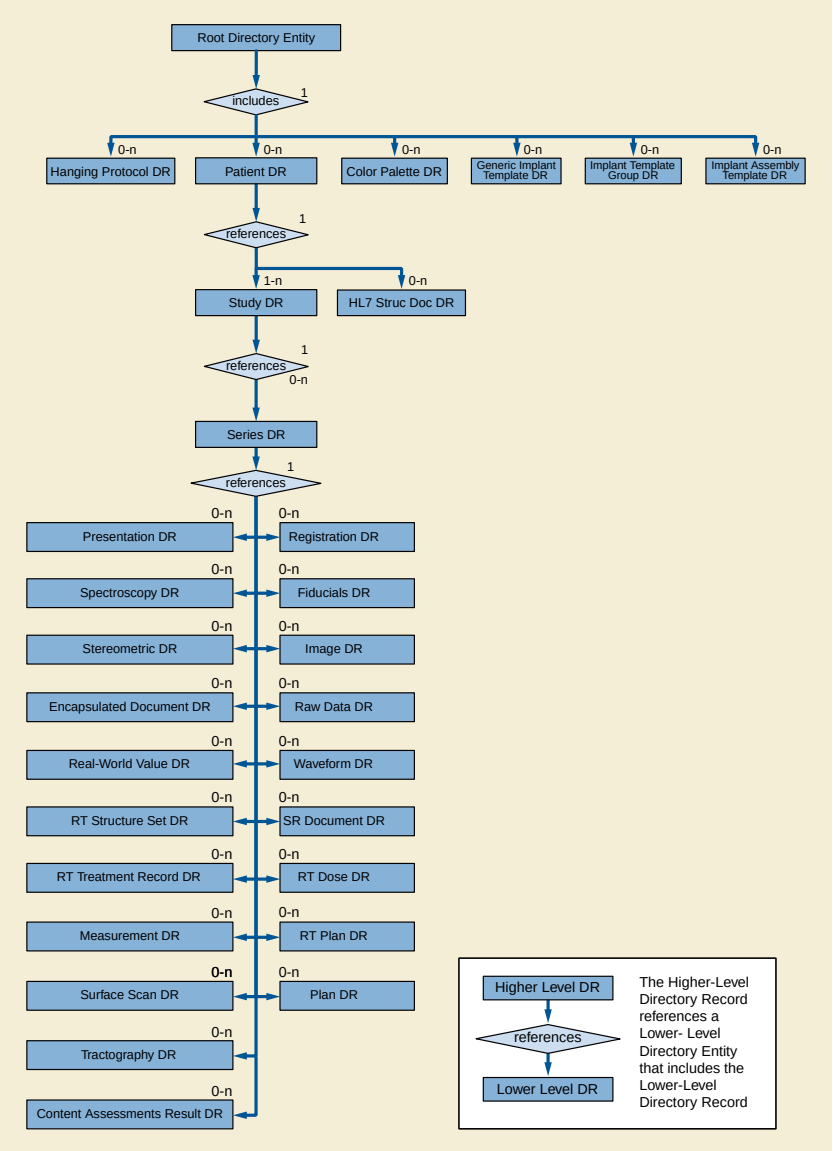

Figure F.4-1. Basic Directory IOD Information Model

with new Figure F.4-1 that does not contain HL7 STRUC DOC:

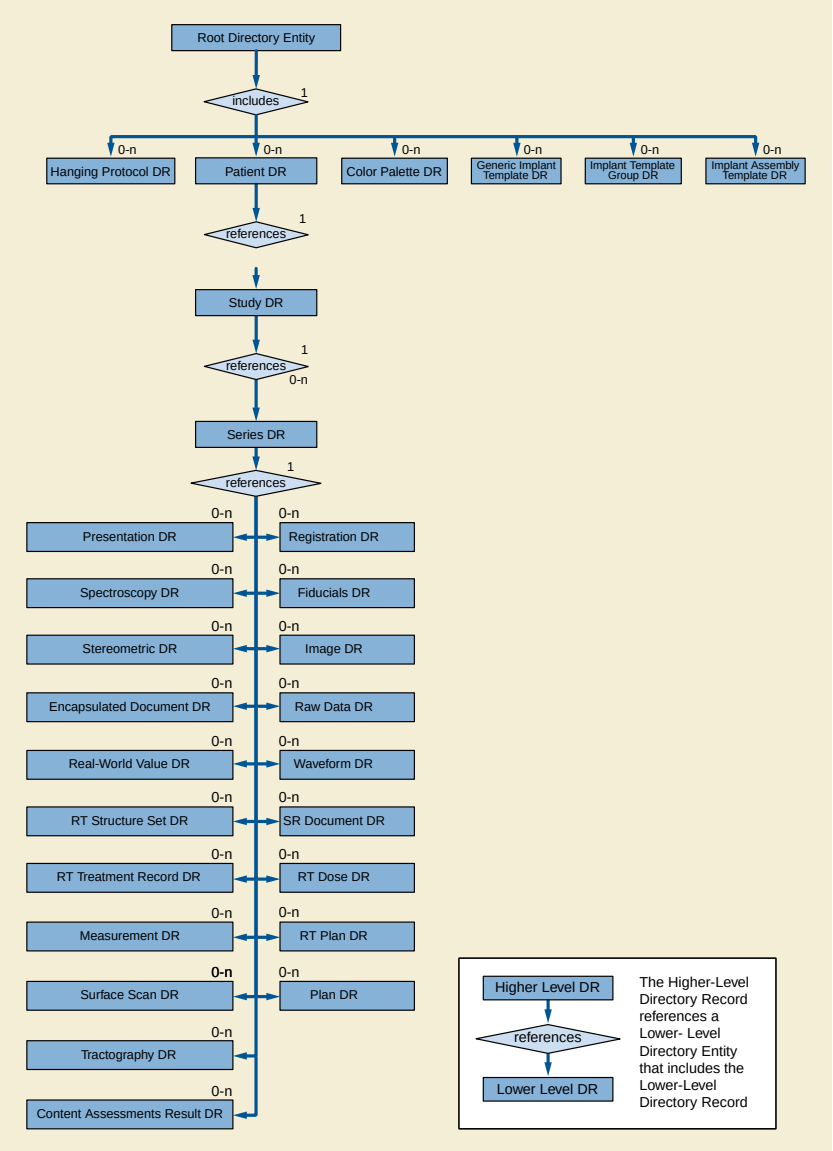

Figure F.4-1. Basic Directory IOD Information Model

Note

Normalized Print media storage was previously defined in DICOM. It is now retired. See PS3.3-1998.

...

F.5.33 HL7 Structured Document Directory Record Definition

Retired. See PS3.3 20xxy. ~~The Directory Record is based on the specification of ???. 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 ????). This type of Directory Record may reference a Lower-Level Directory Entity that includes one or more Directory Records as defined in Table F.4-1.~~

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.~~ ~~Only a single Item shall be included in this Sequence.~~ ~~Required if the HL7 Structured Document contains a Document Type Code.~~
~~>*Include ???*~~			~~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.~~

*Amend DICOM PS3.6 as follows (changes to existing text are bold and **underlined** for additions and ~~struckthrough~~ for removals):*

A Registry of DICOM Unique Identifiers (UIDs) (Normative)

Table A-1. UID Values

UID Value	UID Name	UID Type	Part
1.2.840.10008.1.2.6.1	*RFC 2557 MIME encapsulation* ***(Retired)***	*Transfer Syntax*	*????*
1.2.840.10008.1.2.6.2	*XML Encoding* ***(Retired)***	*Transfer Syntax*	*????*