

HITSP Unstructured Document Component

HITSP/C62



Healthcare Information Technology Standards Panel

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(Formerly Security and Privacy Technical Committee)**



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1.0 INTRODUCTION

1.1 OVERVIEW

The HITSP Unstructured Document Component is provided for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF. It is based on the Cross-Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF).

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.3 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from www.hitsp.org.

Table 1-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN901 - Clinical Documents	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs

1.4 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

1.4.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also implement all of the required interfaces within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification or Capability with which this construct is associated.

1.4.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for interface scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This



construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.



2.0 COMPONENT DEFINITION

2.1 CONTEXT OVERVIEW

This Component describes a document that contains “information blocks” which are not limited by format, with the exception that it must be possible to generate an image (renderable). Sufficient metadata must be present to describe that information. This document body could include an unstructured (e.g UTF8 Text) presentation preserved format, such as PDF which is readily usable by end users such as consumers and providers. The PDF document format is further specified in the International Organization for Standardization (ISO) PDF/A ISO#19005-1b, Document management - Electronic document file format for long-term preservation standard. Any constraints surrounding use of presentation preserving formats are specified in the appropriate IS.

This construct relates to patient identifiable documents which are not natively structured. The means to transport such a document is not specified by this construct. Other HITSP constructs may be used (e.g., HITSP/TP13 Manage Sharing of Documents, HITSP/T31 Document Reliable Interchange or HITSP/T33 Transfer of Documents on Media).

This Component produces output as a CDA document using the nonXMLbody element that contains a reference to the filename where the information block is encapsulated with the attributes of a document, such as persistence, authenticity, wholeness, etc. Examples of documents that would be embedded in the CDA document include plain text notes to the patient, notes from the patient, or a presentation preserved document such as a PDF of a scanned image of a legacy immunization card¹.

The metadata requirements represented in this construct include the following:

- document title
- description
- date
- patient identifiers
- demographics encounter order service data

Further details on the requirements of the construct are provided in IHE Cross-Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile from IHE ITI-TF Rev 5, Volume 1, Section 18, and Volume 2, Section 5.2. Additional constraints on CDA content defined within the IHE Integration Profiles are specified in HITSP/C83 CDA Content Modules.

2.1.1 COMPONENT CONSTRAINTS

Table 2-1 Component Constraints

Constraint	Constraint Section
This construct should not be used when the data are structured	N/A
Each document pertains to one and only one patient	N/A

¹ This construct is not a replacement for DICOM managed images



2.1.2 COMPONENT DEPENDENCIES

Table 2-2 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/C62 Unstructured Document	HITSP/C83 CDA Content Modules	General	HITSP/C83 defines basic constraints on content modules contained in the header and nonXMLbody
HITSP/C83 CDA Content Modules	HITSP/C80 Clinical Document and Message Terminology	General	Vocabulary constraints on content modules defined in HITSP/C83

2.2 RULES FOR IMPLEMENTING

The rules for implementing this construct are contained in the IHE Cross-Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile from IHE ITI-TF Rev 5, Volume 1, Section 18, and in Volume 2, Section 5.2. Additional constraints on CDA content defined within the IHE Integration Profiles are specified in HITSP/C83 CDA Content Modules.

2.2.1 DATA MAPPING

All data elements are defined in Volume 2, Section 5.2 of IHE Cross-Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile from IHE ITI-TF. Additional constraints on CDA content defined within the IHE Integration Profiles are specified in HITSP/C83 CDA Content Modules.

Table 2-3 Data Mapping

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements / Pre-conditions	Additional Specification for Component
Described in IHE XDS-SD, see also HITSP/C83 CDA Content Modules						

2.3 STANDARDS

2.3.1 REGULATORY GUIDANCE

Table 2-4 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	

2.3.2 SELECTED STANDARDS

Table 2-5 Selected Standards

Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile	This Integration Profile defines how to store healthcare metadata in clinical documents, including patient identifiers, demographics, encounter, order or service information, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information within a nonXMLBody. For more information visit www.ihe.net to retrieve Volume 1, and Volume 2 of the Framework



Standard	Description
International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)	Specifies how to use the Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents. It is applicable to documents containing combinations of character, raster and vector data. For more information visit www.iso.org

2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-6 Informative Reference Standards

Standard	Description
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2.0 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org
Internet Engineering Task Force (IETF) The application/pdf Media Type (RFC 3778)	PDF, the 'Portable Document Format', is a general document representation language that has been in use for document exchange on the Internet since 1993. This document provides an overview of the PDF format, explains the mechanisms for digital signatures and encryption within PDF files, and updates the media type registration of 'application/pdf'. For more information visit www.ietf.org
Internet Engineering Task Force (IETF) Tags for the Identification of Languages, "Request for Comment" (RFC) #3066, January, 2001	Describes a language tag for use in cases where it is desired to indicate the language used in an information object, how to register values for use in this language tag, and a construct for matching such language tags. For more information visit www.ietf.org



3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.

RELEASED FOR IMPLEMENTATION



4.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

4.1 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

5616, 5668

Minor editorial changes were made to this construct.

4.2 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

4.3 JUNE 30, 2009

Minor editorial changes were made to this document. Removed boilerplate text for simplification. The term “actor” was replaced with the term “interface”.

4.4 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.

