

HITSP/C32 Test Package

HITSP Summary Documents Using HL7 CCD

Version 2.1
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Package Contents

- A folder (HITSP_C32_templates) containing Schematron entity files for testing HITSP/C32 documents against the v2.1 Profile.
- A copy of the HITSP/C32 profile (2007-12-13 v2.1) downloaded from the HITSP repository at ANSI.
- A folder (HITSP_C32_examples) containing sample XML files that are valid CCD documents and an XML transform (HumanViewCCD.xsl) for transforming the XML files into human readable output files.
- A folder (cdar2c32) containing the original HL7 CDA/R2 schema along with NIST produced schema extensions as permitted by CCD and as indicated by the HITSP/C32 profile of CCD.
- A Schematron file (HITSP_C32.sch) that references and implements the Entity files in HITSP_C32_templates.
- A NIST Disclaimer file (please read).
- This file (in word and pdf formats) describing the contents of the package.

Schematron Entity Files

The HITSP/C32 specification v2.1 defines 17 templateIds. NIST has defined one schematron entity file for each of these templateIds. If a CCD instance document claims conformance to HITSP/C32 then the existence of one templateId (2.16.840.1.113883.3.88.11.32.1) is required in the root ClinicalDocument element. The other templateIds are optional.

The HITSP/C32 profile is not yet clear on whether or not C32 data element rules should be enforced in the absence of explicit C32 templateIds for elements other than the root ClinicalDocument and Optional (O) modules. Since all HITSP/C32 data elements are identifiable whether or not a C32 templateId is present, the constraint rules for each C32 data element are always executed. The NIST C32 validator will return a validation “Error” only when a C32 constraint is violated and an appropriate C32 templateId is present in the module being tested; it will return a “Constraint Violation” warning message when a C32 constraint is violated but an appropriate C32 templateId is NOT present in the module being tested. It will return a “Warning” warning message in two situations: 1) when an optional C32 templateId is not

present, and 2) when a Required-if-Known (R2) data item is missing. The validator also returns a number of “Note” messages to explain some of the options in the HITSP/C32 rules and to identify Optional (O) data elements that are defined in the C32 profile. The web site will soon offer options to the user to return just Errors, just Errors and Warnings, or all responses, including Notes.

CDA R2 and CCD Validation

All of the sample documents (except those containing specific C32 “sdtc” extensions) are valid CDA/R2 documents that validate to the XML schema provided with the CDA/R2 specification from HL7. In addition, most of the sample documents validate as both CDA/R2 and ASTM/HL7 CCD documents according to the CDA/R2 and CCD validators available at the NIST and Alschuler Associates web sites:

NIST <http://xreg2.nist.gov:8080/hitspValidation/validation.jsp>
Alschuler Associates <http://www.alschulerassociates.com/validator/> .

HITSP/C32 Validation at NIST web site

NIST has a new experimental web site to check validation of various CDA profiles and guidelines, especially those produced by IHE and HITSP Patient Care and Laboratory. The URL is:

<http://xreg2.nist.gov/cda-validation>

This site explains the CDA Guideline Validation project at NIST and includes pointers to the NIST validation page referenced above. The Schematron entity files included with this package are implemented at this site.

Sample HITSP/C32 Documents

CD_Minimal_No_C32_templateIds.xml

This document was produced with minimal content as allowed by the CDA/R2 schema and the CCD validation rules. It does not contain any HITSP/C32 templateIds. When checked for HITSP/C32 validation at the NIST web site it raises an Error indicating that the root HITSP/C32 templateId (2.16.840.1.113883.3.88.11.32.1) must be present on the ClinicalDocument element before a document can claim C32 conformance. It also raises multiple other Errors and Warnings associated with that templateId.

CCD_Minimal_ALL_C32_templateIdsAtRoot.xml

This document was produced with minimal content as allowed by the CDA/R2 schema and the CCD validation rules. It has CDA and CCD template ids in its root ClinicalDocument element. It also carries all 17 HITSP/C32 template ids on the same root element, only one of which is in the correct location. This document produces a large number of HITSP/C32 errors, mostly from HITSP/C32 templateIds placed in incorrect locations and missing content required by a given templateId. It also produces multiple Warnings and guidance Notes.

CCD_HITSP_C32_Minimal_NoSections_Valid.xml

This document was produced with minimal content as allowed by the CDA/R2 schema and the CCD validation rules. It has CDA and CCD template ids in its root ClinicalDocument element as well as a single HITSP/C32 templateId (2.16.840.1.113883.3.88.11.32.1) to indicate conformance to the HITSP/C32 profile. Since all CCD sections defined in C32 are optional, this example only has CDA Header content (e.g. Patient, Providers, Participants, etc.) with no CDA Section content.

CCD_HITSP_C32_Minimal_WithSections_Valid.xml

This document was produced from the above Minimal_NoSections document by adding all of the CCD Sections identified in the C32 profile. The document was then modified to remove all Errors and Constraint Violations. Using the NIST site for validation will still return a large number of other Warnings and Notes.

CCD_HITSP_C32_Minimal_WithEntries_Valid.xml

This document was produced from the above Minimal_WithSections document by adding a single CCD Entry for each CCD Section. The document was then modified to remove all Errors and Constraint Violations. Using the NIST site for validation will still return a large number of Warnings and Notes.

CCD_HITSP_C32_HistoryAndMedications_WithAllR2Elements.xml

This document was produced from the above by focusing on the C32 modules that were Required (R) in previous versions of HITSP/C32, previously named Registration and Medications. Those sections are no longer required in the C32 profile and the profile name is now HITSP Summary documents Using HL7 CCD. The document was then modified to remove all of the Warning messages that indicate a Required-if-Known (R2) data element is missing.

CCD_HITSP_C32_Valid_WithViolations.xml

This document is a modification of the CCD example document that came with the CCD download from the HL7 web site. The document has a CCD Section for nearly all of the CCD Section templateIds and contains legitimate medical information for most of the sections. We've added nearly all of the HITSP/C32 templateIds (correctly positioned) so validation at the NIST site thus applies all of the rules contained in the 17 entity files included in this package. The document was then modified to remove all Errors and most Constraint Violations; some were left just for demonstration purposes. Using the NIST site for validation will still return a large number of Warnings and Notes.

CCD_HITSP_C32_v2.1_Examples.xml

This document is a modification of the above that attempts to add all of the Examples presented in the HITSP/C32 profile. Each example is identified with a Figure ID (e.g. Figure 2.2.1.5-1 Healthcare Provider Example) taken from C32 v2.1. This exercise produced a number of small errors from the examples that were then corrected so that the result would validate to C32.

CCD_HITSP_C32_MedicationsTemplate_Small.xml

This document was prepared to concentrate only on the Medications section of the HITSP/C32 specification. The purpose was to provide a conforming HITSP/C32 document that contains a Medications section with all important CCD Medications required-if-Known (R2) elements present in the document and some relevant Optional (O) elements. It validates cleanly to all

HITSP/C32 validation rules. It produces multiple Warnings and lots of Notes, including optional additional items that could have been included in the Medications data elements. It is NIST intent to use this document as a template for producing randomized samples that will validate to CCD and/or HITSP/C32 Medication sections.

CCD_HITSP_C32_MedicationsTemplate_Robust.xml

This document is a modification of the Medications_Small document above to add all Optional (O) data elements identified in the Medications section of the HITSP/C32 profile. It makes liberal use of the nullFlavor attribute on many elements to indicate that a lot of information is not known.

JohnHalamkaCCDDocument_CCDOnly.xml

This document was downloaded from the HITSP home page at ANSI. It is an example of a conformant CCD document with medical data for the chairman of the standards panel. It is posted there with his permission. It validates as a CCD document at the NIST CDA validation web site. When validated against C32 it raises a number of minor, easily correctable, errors.

JohnHalamkaCCDDocument_C32.xml

This document is a modification of the above JohnHalamkaCCD document to add a single HITSP/C32 templateId (2.16.840.1.113883.3.88.11.32.1) on the root element. The document was then further edited (without changing any meaning!) to remove all HITSP/C32 generated Errors and Constraint Violations. The modified document validates cleanly at the NIST site. The validation report presents a large number of Warnings and Notes, mainly for other information that could have been included.