

# Clinical Package Validator v2.3

## Release Note

17 July 2015

Approved for external information

### EP-2134:2015 Clinical Package Validator v2.3

## 1 Overview

The Clinical Package Validator (Validator) is a tool to help vendors test whether a healthcare software system is producing clinical documents and clinical packages that conform to some NEHTA eHealth specifications.

The Validator does not test conformance against all specifications. This *Release Note* defines a set of tests that are supported, tests partially supported, and a general description of the types of tests not supported (as detailed in Section 0 on page 3).

Results from the Validator must not be relied upon to determine software conformance when declaring conformance to the PCEHR System Operator. A vendor will need to supplement results from the Validator with their own testing before declaring conformance.

*Note that the Validator was previously published as part of the Clinical Documents Integration Toolkit under the name CDA Validator. It is now published as a separate end product.*

## 2 Release rationale

Version 2.3 of the Clinical Package Validator has been released to:

- Support the validation of eHealth Diagnostic Imaging Reports that reference clinical information outside the clinical package (e.g. a diagnostic image on a website), through the automation of version 1.5 of the *Conformance Test Specification for CDA<sup>®</sup> Packaging*.<sup>1</sup>
- Provide a platform that enables the automation of conformance test cases and test scenarios, through the application of Schematron<sup>2</sup> rules that are in addition to those in a PCEHR template package.

See Section 5 for further details of improvements.

## 3 Summary of functionality

The Validator is developed by NEHTA and is a Microsoft Windows based tool that performs a number of operations. It requires .NET 4 framework and SQL CE 3.5 to be installed on the machine, which are included as part of the installation (see *Clinical Package Validator 2.3*

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<sup>1</sup> Available from <https://www.nehta.gov.au/implementation-resources/clinical-documents/common-clinical-document>

<sup>2</sup> Schematron is a rule-based validation language that is capable of expressing constraints on XML data elements that cannot be expressed in a schema.

*Installation and Configuration Guide*<sup>3</sup>). The user is responsible for ensuring relevant licences are in place.

CDA<sup>®</sup> documents are built to a certain level of conformance from a basic CDA<sup>®</sup> header accompanied by an attachment, through to a fully populated CDA<sup>®</sup> body with SNOMED CT-AU, Australian Medicines Terminology (AMT) or PBS coding.<sup>4</sup>

The Validator tests a CDA<sup>®</sup> document for:

- schema validation (tests its structure)
- Schematron validation (set of rules that partially meet the CDA<sup>®</sup> implementation guide, structured content specification and PCEHR conformance profile) to a conformance level chosen by the user. The Validator does not test all requirements in these specifications; its use is strictly limited, as described in Section 0.
- use of SNOMED CT-AU, AMT or PBS codes as specified in the CDA<sup>®</sup> implementation guide (partial testing only – see Table 3 on page 8)
- use of other terminologies (partial testing only – see Table 3 on page 8).

If provided with a clinical package or a clinical package within an HL7<sup>®</sup> MDM wrapper, the Validator applies the test cases in version 1.5 of the *Conformance Test Specification for CDA<sup>®</sup> Packaging* for the PCEHR and provider-to-provider (P2P) contexts (see Section 4.1).

For HL7<sup>®</sup> MDM messages (which contain the clinical package in Base64 format), there are currently no specific tests, except that the CDA<sup>®</sup> package can be extracted from a specific element.

Once the Validator tests have been performed, an onscreen report is generated and displayed along with a rendering of the CDA<sup>®</sup> document, the XML document, an optional clinical packaging report, optional signature report, terminology report, a log and an optional test summary report, which can be saved as a record of some of the testing performed by a vendor in its overall work to determine software conformance.

As per the Non-Production Disclaimer applicable to the Validator, the Validator should not be relied on to determine software conformance. The Validator tests need to be accompanied by other test artefacts to demonstrate how a vendor satisfied themselves that the software was conformant before declaring conformance to the PCEHR System Operator.

### 3.1 Product components

Table 1: Clinical Package Validator product components

Identifier	Component	Comment
NEHTA-2129:2015	Release Note	This document
NEHTA-2112:2015	Software Package v2.3	Contains: <ul style="list-style-type: none"><li>• Clinical Package Validator Install (an .exe file containing the Clinical Package Validator 2.3 software)</li><li>• ISSetupPrerequisites (a folder of installation scripts for prerequisite software)</li><li>• Non-production disclaimer</li></ul>

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<sup>3</sup> Available for download from <https://www.nehta.gov.au/implementation-resources/ehealth-reference-platform/clinical-package-validator>

<sup>4</sup> IHTSDO<sup>®</sup>, SNOMED<sup>®</sup> and SNOMED CT<sup>®</sup> are registered trademarks of the IHTSDO. HL7 and CDA are registered trademarks of Health Level Seven International.

Identifier	Component	Comment
NEHTA-2093:2015	Installation and Configuration Guide	A PDF file containing instructions on how to successfully install and configure the Clinical Package Validator 2.3.
NEHTA-2092:2015	User Guide	A PDF file containing instructions on how to use the Clinical Package Validator 2.3 to assist testing clinical documents and clinical packages

## 4 Scope of tests

### 4.1 Scope of tests for clinical package validation

Clinical package test cases are documented in the *Conformance Test Specification for CDA<sup>®</sup> Packaging v1.5*. The Validator's in scope tests include many of these test cases.

The following table lists the clinical package test cases in the *Conformance Test Specification for CDA<sup>®</sup> Packaging v1.5*, and information about their support by the Validator. The tests performed depend on whether the PCEHR or P2P context is selected (the contexts are explained in section 2.1.1 of the *Clinical Package Validator 2.3 User Guide*).

All test cases in the *Conformance Test Specification for CDA<sup>®</sup> Packaging v1.5* are listed in Table 2. If a new version of the *Conformance Test Specification for CDA<sup>®</sup> Packaging* is created containing a clinical package test case not listed in the table below, then it is not tested by the Validator and is not an in scope test. The vendor will need to run their own tests to determine conformance with the requirement related to that test.

*The following notations are used in Table 2: A (automated), M (Manual), N/A (not applicable), NR (not reported). See the table notes on page 7 for further details of these notations.*

Table 2: Scope of tests for clinical package validation

Test Case	PCEHR	P2P	Description
<i>Test set: Context PCEHR</i>			
DEXS-L_154	A	N/A	Verify the package contains only CDA_ROOT.XML, CDA_SIGN.XML and packaged attachments.
DEXS-L_155	A	N/A	Verify the package does not contain INDEX.HTM, README.TXT or repository metadata.
DEXS-L_156	A	N/A	Verify that any attachments are not CDA <sup>®</sup> packages or CDA <sup>®</sup> documents.
DEXS-T_121	A	N/A	Verify that the CDA <sup>®</sup> package contains one, and only one, signature file.
DEXS-T_125	A	N/A	Verify that the packaged attachment files are located in the same folder as the CDA_ROOT.XML document.
CPCD_023741	A	N/A	Verify the CDA <sup>®</sup> package only references attachments that are of the supported MIME type.
CPCD_024629	A <sub>3</sub>	N/A	Verify the CDA <sup>®</sup> package only references packaged attachments where the filename extensions are those listed for the supported MIME types.

Test Case	PCEHR	P2P	Description
CPCD_024630	A <sub>3</sub>	N/A	Verify all packaged attachments have filename extensions which matches their MIME type.
CPCD_023743	A	N/A	Verify the CDA <sup>®</sup> package is not larger than 10MB.
CPCD_023744	A <sub>1</sub>	N/A	Verify the eSignature for the CDA <sup>®</sup> package has been signed with a NASH PKI certificate for a healthcare provider organisation, or a supporting organisation (a CSP or GSO).
<i>Test set: Context P2P</i>			
P2P_T13	N/A	A	Verify that the CDA <sup>®</sup> package zip does not contain repository metadata.
CPCD_023748	N/A	A <sub>1</sub>	Verify that the eSignature for the signed CDA <sup>®</sup> package has been signed with a NASH PKI certificate for a healthcare provider organisation.
<i>Test set: Base CDA Package</i>			
PKG_CDA_002	A	A	Verify the base CDA <sup>®</sup> package contains one and only one root entry.
PKG_CDA_004	A	A <sub>4</sub>	Verify that, for every reference to a packaged attachment, there is a corresponding document in the CDA <sup>®</sup> package.
PKG_CDA_005	N/A	A	Verify that, for every reference to a CDA <sup>®</sup> package packaged attachment, there is a corresponding item in the CDA <sup>®</sup> package.
PKG_CDA_006	NR	M <sub>1</sub>	Verify the list of eSignatures in a CDA <sup>®</sup> package.
PKG_CDA_007	A	A <sub>5</sub>	Verify all eSignatures are valid eSignatures.
<i>Test set: Signed CDA Package</i>			
PKG_CDA_013	A	A	Verify the CDA <sup>®</sup> package contains one or more eSignatures.
<i>Test set: XDM-ZIP Representation</i>			
XDM_ZIP_105	N/A	N/A	Verify the zip file is a valid XDM-Zip CDA <sup>®</sup> package.
XDM_ZIP_106	A	A	Verify there is one submission set.
XDM_ZIP_108	A	A	Verify the CDA <sup>®</sup> document has the filename CDA_ROOT.XML.
XDM_ZIP_109	A	A	Verify that an eSignature has the filename CDA_SIGN.XML.
<i>Test set: eSignature</i>			
PKG_CDA_024	A	A	Verify eSignature XML document conforms to a Signed Container defined by ATS 5821-2010 <sup>5</sup> and the root element is a signedPayload element
PKG_CDA_025	A	A	Verify the Signed Payload contains only one ds:Signature element.
XSP_SCP_000	A	A	Verify that the eSignature Signed Payload is valid against the Signed Payload and Signed Payload Data XML schemas.

<sup>5</sup> ATS 5821-2010 E-health XML secured payload profiles, Standards Australia, available from: <http://infostore.saiglobal.com/store/details.aspx?ProductID=1391034>

Test Case	PCEHR	P2P	Description
XSP_SCP_001	A	A	Verify the id attribute is unique within the signed XML document.
XSP_SCP_002	A	A	Verify the sp:signedPayloadData element is the only element signed by all the signatures.
XSP_SDP_000	A	A	Verify that the Signature element of the signedPayload is valid against the XML Signature Schema.
XSP_SDP_001	A	A	Verify that a detached signature is used by ensuring the signature element references an XML document or element in the same document.
XSP_SDP_002	A	A	Verify that Exclusive XML Canonicalisation was used on the signed contents in the ds:SignedInfo element.
XSP_SDP_003	A	A	Verify the Algorithm attribute = 'http://www.w3.org/2001/10/xml-exc-c14n#' for the ds:CanonicalisationMethod element.
XSP_SDP_004	A	A	Verify the Algorithm attribute = 'http://www.w3.org/2000/09/xmldsig#rsa-sha1' for the ds:SignatureMethod element.
XSP_SDP_004_1	A	A	Verify the ds:SignatureMethod algorithm was used to calculate the signature value.
XSP_SDP_005	A	A	Verify there are one or more ds:Reference elements in the ds:SignedInfo element.
XSP_SDP_006	A	A	Verify that each ds:Reference element in ds:SignedInfo contains a URI attribute.
XSP_SDP_007	A	A	Verify the URI attribute of ds:Reference has a '#' character followed by a fragment identifier.
XSP_SDP_008	A	A	Verify the fragment identifier after the '#' character matches the id attribute in sp:signedPayloadData.
XSP_SDP_009	A	A	Verify a ds:Transforms element is present in ds:Reference element.
XSP_SDP_010	A	A	Verify there is only one ds:Transform element in the ds:Transforms element.
XSP_SDP_011	A	A	Verify the Exclusive XML Canonicalisation algorithm was used on the content being signed.
XSP_SDP_012	A	A	Verify the Algorithm attribute = 'http://www.w3.org/2001/10/xml-exc-c14n#' for the ds:Transform element.
XSP_SDP_013	A	A	Verify the value of ds:DigestValue element matches value calculated using SHA-1 algorithm on Exclusive XML Canonicalisation of signed payload.
XSP_SDP_014	A	A	Verify the Algorithm attribute = 'http://www.w3.org/2000/09/xmldsig#sha1' for the ds:DigestMethod element.
XSP_SDP_015	A	A	Verify the ds:KeyInfo element is present in ds:Signature.

Test Case	PCEHR	P2P	Description
XSP_SDP_016	A	A	Verify the ds:X509Data element is present in ds:KeyInfo element.
XSP_SDP_017	A	A	Verify the ds:X509Certificate element is present in ds:X509Data element.
XSP_SDP_018	A	A	Verify X509Certificate element contains the encoded value of the signing certificate.
XSP_SDP_019	A	A	Verify that ds:Signature element does not contain a ds:Object element.
PKG_CDA_026	A	A	Verify the sp:signedPayloadData element contains only one s:eSignature element.
PKG_CDA_027	A	A	Verify there is one ds:Reference element in the Manifest, and that it is set to the SHA-1 digest of the root XML document.
PKG_CDA_029	A <sub>2</sub>	A <sub>2</sub>	Verify that the person that approved the eSignature can be identified from the value contained in the s:approver element of the signature.
PKG_CDA_030	A	A	Verify the s:signingTime element contains a valid time.
PKG_CDA_031	A	A	Verify the s:signingTime element includes an explicit timezone.
<i>Test set: CDA XML Document</i>			
PKG_CDA_014	A	A	Verify the CDA <sup>®</sup> document is valid for its document type.
PKG_CDA_015	A	A	Verify any packaged attachments are represented using an ED-type element.
PKG_CDA_016	A	A	Verify the ED-type element integrityCheckAlgorithm = 'SHA-1'.
PKG_CDA_017	A	A	Verify the ED-type element contains a single cda:reference element.
PKG_CDA_018	A	A	Verify reference element has a 'value' attribute containing a valid URI.
PKG_CDA_019	A	A	Verify that any ED-element using SHA-1, containing a single reference and the reference value is a URI identical to the name of a document in the CDA package, refers to a packaged attachment.
PKG_CDA_020	A	A	Verify the integrityCheck attribute of any ED-element matches the SHA-1 digest of the referenced atomic packaged attachment.
PKG_CDA_021	A <sub>3</sub>	A <sub>3</sub>	Verify the mediaType attribute of any ED-type elements is of an agreed Internet type.
PKG_CDA_022	N/A	A	Verify the integrityCheck attribute of any ED-type elements matches the SHA-1 digest of any one eSignature inside the CDA <sup>®</sup> package packaged attachment.
PKG_CDA_023	N/A	A	Verify the mediaType attribute of any ED-type elements is 'application/x.electronichealth.cda.package' for a CDA <sup>®</sup> package packaged attachment.

Test Case	PCEHR	P2P	Description
CDAR_AS_050	A	A	Verify that, for each linkHtml element in the CDA <sup>®</sup> document, if the linkHtml element contains a relative reference, then verify the document being referenced exists in the CDA <sup>®</sup> package.
CDAR_AS_053-06	A	A	Verify that no attachments contain executable code (e.g. JavaScript code in HTML documents).
CDAR_AS_053-07	A	A	Verify that no referenced attachments require resources to be downloaded from external network locations, unless the document is of the type that allows references to objects outside of the CDA <sup>®</sup> package.
CDAR_AS_053-10	A	A <sub>4</sub>	Verify that all referenced attachments are located within the CDA <sup>®</sup> package and are in accordance with the CDA <sup>®</sup> Packaging Specification, unless the document is of the type that allows references to objects outside of the CDA <sup>®</sup> package.
PKG_024732	A	A	Verify that, where the document is of the type that allows references to objects outside of the CDA <sup>®</sup> package and the reference is to an external location or website, the reference is a non zero-length string containing a Uniform Resource Identifier (URI).
PKG_024988	A	A	Verify that, where the document is of the type that allows references to an object outside the CDA <sup>®</sup> package and the reference is to an external atomic attachment or website, the reference is represented by an ED-element.
PKG_025077	A	A	Verify that, where the document is of the type that allows references to objects outside of the CDA <sup>®</sup> package and the reference is to an atomic attachment, it has an approved media type and filename extension.
PKG_024990	M <sub>2</sub>	M <sub>2</sub>	Verify that, where the document is of the type that allows references to attachments outside the CDA <sup>®</sup> package and the reference is to an external atomic attachment and an integrityCheck is included, the integrityCheck attribute has a value that is the SHA-1 digest of the byte stream and the value of the integrityCheckAlgorithm attribute (if included) is SHA-1.
<i>Test set: Clinical Package</i>			
PKG_PKG_009	NR	M <sub>1</sub>	Verify that each identifier associated with a member of the CDA <sup>®</sup> package is not an empty value and conforms to the URI specification.
PKG_PKG_010	NR	M <sub>1</sub>	Verify that each identifier associated with a member of the CDA <sup>®</sup> package is unique.

### Table notes

- A The test case is automated without exceptions.
- A<sub>1</sub> The test case is automated with the exception of the test step requiring the validation of the NASH certificate by accessing the NASH service to determine if the certificate is on the revocation list.
- A<sub>2</sub> The test case is automated with the exception of the test step requiring the validation of the healthcare identifier by accessing the Healthcare Identifiers Service.

- A<sub>3</sub> The test case is automated; however the Validator does not report the correct result if the clinical document attachment is compressed (requirements for compressed attachments are listed in the HL7<sup>®</sup> Version 3 Standard: Data Types - Abstract Specification, Release 1).
- A<sub>4</sub> The test case is automated; however the Validator does not report the correct result if a clinical document attachment is in a different folder to the clinical document (this is allowed in the P2P context and disallowed in the PCEHR context).
- A<sub>5</sub> The test case is automated with the exception that the only eSignature that is verified is the one with filename CDA\_SIGN.XML (multiple eSignatures are allowed in the P2P context and disallowed in the PCEHR context).
- M<sub>1</sub> The Validator does not report any outcome for the test case. The test result is determined only after a manual inspection of the package index if one is present in the clinical package (a package index is allowed in the P2P context and disallowed in the PCEHR context).
- M<sub>2</sub> The Validator does not report any outcome for the test case. The test case may be performed using the guidance provided in version 1.5 of the *Conformance Test Specification for CDA<sup>®</sup> Packaging*.<sup>6</sup>
- NR The test result is not reported by the Validator as it cannot fail in the selected context.
- N/A The test result is not reported by the Validator as the test case is not applicable for the selected context.

## 4.2 Scope of tests for clinical terminology validation

With some exceptions, the values of codes for code systems are *not tested* by the Validator. The exceptions are the validation of codes from the code systems listed below.

Table 3: Scope of tests for clinical terminology validation

Code system	Version	Date of publication	Source
Australian Medicines Terminology (AMT)	V2.54	28 Mar 2014	<a href="https://www.nehta.gov.au/implementation-resources/ehealth-foundations/australian-medicines-terminology">https://www.nehta.gov.au/implementation-resources/ehealth-foundations/australian-medicines-terminology</a>
	V2.55	28 Apr 2014	
	V2.56	30 May 2014	
	V3 20141231	31 Dec 2014	
	V3 20150228	28 Feb 2015	
	V3 20150331	31 Mar 2015	
	V3 20150430	30 Apr 2015	
	V3 20150531	31 May 2015	
V3 20150630	30 Jun 2015		
Australian and New Zealand Standard Industrial Classification (ANZSIC)	2006	2006	<a href="http://www.abs.gov.au/ausstats/abs@.nsf/mf/1292.0">http://www.abs.gov.au/ausstats/abs@.nsf/mf/1292.0</a>

<sup>6</sup> Available from <https://www.nehta.gov.au/implementation-resources/clinical-documents/common-clinical-document>



Code system	Version	Date of publication	Source
Australian and New Zealand Standard Classification of Occupations (ANZSCO)	First edition, revision 1	25 June 2009	<a href="http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/1220.0Main+Features1First%20Edition,%20Revision%201">http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/1220.0Main+Features1First%20Edition,%20Revision%201</a>
Australian Vaccines codes	-	-	<a href="http://www.humanservices.gov.au/health-professionals/services/australian-childhood-immunisation-register/acir-vaccine-code-formats">http://www.humanservices.gov.au/health-professionals/services/australian-childhood-immunisation-register/acir-vaccine-code-formats</a>
Clinical specialty codes	-	21 Nov 2013	<a href="http://meteor.aihw.gov.au/content/index.phtml/itemId/329673">http://meteor.aihw.gov.au/content/index.phtml/itemId/329673</a>
HL7 identifier types	V2.6	2007	<a href="https://www.hl7.org/special/committees/vocab/V2_6_Appendix_A.pdf">https://www.hl7.org/special/committees/vocab/V2_6_Appendix_A.pdf</a>
HL7 service delivery role types	V3	7 Aug 2008	<a href="http://hl7.org/implement/standards/fhir/v3/vs/ServiceDeliveryLocationRoleType/index.html">http://hl7.org/implement/standards/fhir/v3/vs/ServiceDeliveryLocationRoleType/index.html</a>
PBS codes (Item codes and Manufacturer codes)	Jun 2015	1 Jun 2015	<a href="http://www.pbs.gov.au/browse/downloads">http://www.pbs.gov.au/browse/downloads</a>
SNOMED CT-AU reference set	20150531	31 May 2015	<a href="http://www.nehta.gov.au/implementation-resources/ehealth-foundations/snomed-ct-au">http://www.nehta.gov.au/implementation-resources/ehealth-foundations/snomed-ct-au</a>

## 4.3 Scope of template package validation

### 4.3.1 Clinical documents in scope

The Validator performs test for the following types of clinical documents:

- Advance Care Directive Custodian Record
- Australian Childhood Immunisation Register
- Australian Organ Donor Register
- Birth Details
- Child Parent Questionnaire
- Consumer Entered Achievements
- Consumer Entered Measurements
- Discharge Summary
- eHealth Diagnostic Imaging Report
- eHealth Dispense Record (previously known as PCEHR Dispense Record)
- eHealth Pathology Report
- eHealth Prescription and Dispense View
- eHealth Prescription Record (previously known as PCEHR Prescription Record)
- eReferral
- Event Summary
- Health Check Assessment

- Health Check Schedule View
- Medicare DVA Benefits Report
- Medicare Overview
- Observation View
- Personal Health Note (previously known as Consumer Entered Notes)
- Personal Health Summary (previously known as Consumer Entered Health Summary)
- Pharmaceutical Benefits Report
- Shared Health Summary
- Specialist Letter

The template packages can be imported from the personally controlled electronic health record (PCEHR) software vendor test environment (SVT) or downloaded from the relevant clinical document end product (available from <http://www.nehta.gov.au/implementation-resources/clinical-documents>).

The following sections give general descriptions of the types of tests that are either fully or partially *excluded* from the Validator. A vendor must conduct their own testing to supplement the Validator's automated tests (described in Section 0).

#### 4.3.2 Tests that must be done manually

These tests are not (and cannot be) automated in the Validator due to the nature of the tests:

- Tests for the equivalence between clinical information in a clinical document in atomic format versus the clinical information in the narrative blocks in a clinical document.
- Tests for consistency between the definition of a component of a clinical document (i.e. a section, data group or data element) and the information in that component.
- Clinical document tests that can only be performed by looking up an external software system (e.g. the healthcare identifiers service, the HL7<sup>®</sup> OID registry).
- Validation of the values of codes for most code systems (e.g. SNOMED CT-AU, AMT, PBS, clinical specialty codes, Australian vaccine codes). The exception is the validation of codes where the set of values is listed in the CDA<sup>®</sup> implementation guides. The Validator has a separate code validation facility to assist with the validation of codes.

#### 4.3.3 Tests not included in this release

The following tests are not included in the Validator, but may be included in a future release:

- PCEHR usability recommendations related to the content of a clinical document.
- Requirements for terminology codes (e.g. a code must be a specific length for it to be an AMT code).
- Requirements for clinical document narrative blocks, stated in the *CDA Rendering Specification*<sup>7</sup> and the HL7<sup>®</sup> CDA<sup>®</sup> R2 specification<sup>8</sup> (e.g. the requirement for the allowed set of markup content; the requirements for the inclusion of style codes).
- Data elements in a clinical document that are individually conformant but, when combined, do not make sense and are likely to result from an error in the clinical information system (e.g. having a fully structured address without the state; having a healthcare provider's contact details listed as their home details).

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<sup>7</sup> Available from <https://www.nehta.gov.au/implementation-resources/clinical-documents/common-clinical-document>

<sup>8</sup> Available from Available from <http://www.hl7.org/implement/standards/cda.cfm>

#### 4.3.4 Tests partially supported in this release

The following tests are only partially supported by the Validator in this release:

- Requirements in specifications not published by NEHTA but which must be implemented in order to conform to the CDA<sup>®</sup> implementation guides. For example, *Health Care Client Identification* (SA 5017); HL7<sup>®</sup> data types v1 specification, HL7<sup>®</sup> CDA<sup>®</sup> R2 specification.
- Requirements for identifiers in a clinical document (e.g. the same identifier should be used for every occurrence of an object in a clinical document, and different objects must not have the same identifier).
- Requirements for entity identifiers and entitlements (e.g. a Medicare card number cannot be used for an entity identifier for a person; a local entity identifier must contain the 'extension' attribute).
- Requirements for data types used in NEHTA's structured content specifications (e.g. the requirements for CodeableText, CodedText, Duration, Quantity).
- Requirements in the conformance profile for a specific type of document. The coverage depends on the type of clinical document. For example, the PCEHR template packages do not enforce any clinical documents requirements in the conformance profile for eHealth Prescription Record.

Given these functions are only partially tested, a vendor cannot rely on the Validator to test these functions.

## 5 Improvements in this release

- Automation of version 1.5 of the *Conformance Test Specification for CDA<sup>®</sup> Packaging*.
- Ability to import template packages from the PCEHR software vendor test environment or in ZIP format downloaded from the NEHTA website (<http://www.nehta.gov.au/>).
- User-friendly presentation of information in an eSignature including information within the NASH certificate.
- Support for case significance when validating terminology code display names.
- Improved validation of codes from the following code systems, by validating codes that may be included anywhere in a clinical document: Australian Medicines Terminology (AMT), Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU), PBS Item codes. Validation is only performed where the reference set is defined in a CDA<sup>®</sup> implementation guide.
- Validation of codes from the following code systems: Australian and New Zealand Standard Industrial Classification (ANZSIC), Australian and New Zealand Standard Classification of Occupations (ANZSCO), Australian Vaccines codes, Clinical specialty codes, HL7<sup>®</sup> identifier types, HL7<sup>®</sup> service delivery role types, PBS Manufacturer codes.
- Production of the test report in Adobe PDF format.
- Permits the inclusion of user defined Schematron rules.
- Miscellaneous performance and usability improvements.

## 6 Support

For further support or to provide feedback, please email the NEHTA Help Centre at [help@nehta.gov.au](mailto:help@nehta.gov.au) or phone 1300 901 001. Your views on the scope and usability of the Validator will inform future releases.

## 7 Future releases

The Validator will be released on an ad-hoc basis, based on providing new functionality or other changes as required.

## Release history

Version	Date	Comment
1.12.2	20 Aug 2012	Validation rules aligned with PCEHR R1c (patch for v1.12)
1.12.5a	15 May 2013	Revised validation rules (patch for v1.12, to replace v1.12.5)
1.12.5	20 March 2013	Revised validation rules (patch for v1.12)
1.12.7	8 Jan 2014	Schematron libraries installed in PCEHR release 4, supporting HPI-I relaxation (patch for v1.12, to replace v1.12.5a)
1.12.8	8 Jan 2014	Schematron libraries installed in PCEHR release 4, mandating HPI-I inclusion (patch for v1.12, to replace v1.12.5a)
1.12	15 July 2012	Functionality, validation rules and terminology aligned with PCEHR R1b
2.0	22 August 2014	New package validation function built; Schematron libraries removed; added ability to load template packages for the validation of clinical documents and CDA <sup>®</sup> packages
2.1	20 January 2015	New and more consistent user interface with summary screen, drag and drop functionality, better handling of files, user management of terminology database, inclusion of version 1.2.9 of the generic style sheet.
2.2	–	Not released
2.3	17 July 2015	Name change to Clinical Package Validator. Supports the validation of eHealth Diagnostic Imaging Reports that reference clinical information outside the clinical package (e.g. a diagnostic image on a website). Provides a platform that enables the automation of conformance test cases and test scenarios, though the application of Schematron rules that are in addition to those in a PCEHR template package.

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**Contact for enquiries**

Telephone: 1300 901 001 or email: [help@nehta.gov.au](mailto:help@nehta.gov.au)

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