



Clinical Package Validator User Guide

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The Clinical Package Validator does not test software against all conformance requirements.

Results from the Clinical Package Validator must not be relied upon to determine software conformity. Vendors must run additional tests on software before declaring software conformance to the My Health Record System Operator.

Refer to the Clinical Package Validator Product Data Sheet *for information about the scope of this tool, and the* Source Code Licence and Production Disclaimer *contained in the software package for appropriate use of the tool.*

For further guidance, contact the Agency Help Centre on 1300 901 001 or <u>help@digitalhealth.gov.au</u>.

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Document information

Key information

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1 Introduction

1.1 Purpose

This document is a guide for developers and testers who use ("users") version 2.5 of the Clinical Package Validator ("the Validator") to test whether their healthcare software system is producing clinical packages and documents that conform to the relevant specifications for the document type.

To the extent users wish to use the Validator to test conformance, users should not rely on the Validator alone to determine conformance, and independent testing will be required. The Validator is a tool to assist users only. The Validator does not test all conformance specifications and users should carefully read the *Clinical Package Validator Product Data Sheet*. For further guidance, contact the Agency Help Centre on 1300 901 001 or help@digitalhealth.gov.au.

1.2 Intended audience

This document is intended for:

- testers who use the Validator to assess whether their healthcare software system produces clinical documents and clinical packages that conform to the relevant specifications; and
- developers who use the Validator to provide quick feedback for software development.

1.3 Scope

This document describes the use of the Validator to test:

- whether the syntax and structure of a clinical document are conformant with specifications, and
- whether codes within a clinical document can be found in code systems supported by the Validator.

It also describes how the Validator can be used to validate certain clinical packages and an HL7 Medical Document Management (MDM) wrapped clinical package.

1.4 Overview

The Validator is a tool for testing whether a healthcare software system is producing certain (but not all) clinical documents that conform to the relevant document CDA implementation guide, structured content specification, and the My Health Record conformance profile specification.

In addition, the Validator tests certain (but not all) codes in clinical documents, and tests clinical packages to determine whether they conform to the packaging specifications.

The Validator does not test all conformance specifications and users should carefully read the *Clinical Package Validator Product Data Sheet* to determine what the Validator cannot be used for, and for further guidance contact the Agency on 1300 901 001 or <u>help@digitalhealth.gov.au</u>.

2 Tests performed by the Validator

The Validator performs the following tests:

- package validation;
- template validation; and
- code validation.

It can be used to assist a vendor testing the following types of files:

- a clinical document;
- a clinical package containing a clinical document, eSignatures, and other documents (e.g. attachments); and
- an HL7 MDM wrapped clinical package containing a clinical document.

Please refer to the *Clinical Package Validator Product Data Sheet* for further details of tests in scope.

2.1 Package validation

2.1.1 Package requirements

The clinical package requirements describe how to construct a conformant ZIP file containing a clinical document, create and include eSignatures, and properly reference attachments from that clinical document.

The requirements for a clinical package are described in the *CDA Package* specification [NEHTA2011a] and the *Clinical Documents - Common Conformance Profile* [NEHTA2015c]. Requirements for referencing attachments are listed in the *CDA Package* specification [NEHTA2011a], *CDA Rendering Specification* [NEHTA2012a], and the *Clinical Documents - Common Conformance Profile* [NEHTA2015c].

Additional requirements for clinical packages apply, depending on whether the My Health Record (MHR) or provider to provider (P2P) context is selected by the user. The *PCEHR Document Exchange Service Logical Service Specification* [NEHTA2014b] and the *PCEHR Document Exchange Service Technical Service Specification* [NEHTA2014c] list requirements that apply to clinical packages sent to the My Health Record system (referred to as the My Health Record context). Requirements for clinical packages sent from one healthcare provider to another healthcare provider (referred to as the P2P context) are listed in the *P2P Document Delivery Technical Service Specification* [NEHTA2012b].

The P2P context imposes fewer constraints on a clinical package than the My Health Record context. For example, a general practitioner may attach a report from a pathology laboratory to an eReferral that is to be sent to a specialist. If, however, the eReferral is to be sent to the My Health Record system, the general practitioner cannot attach the pathology report to the eReferral, because only the author of a document can upload that document to the My Health Record system.

2.1.2 Assessing a clinical package using the Validator

To determine whether a clinical package conforms to some packaging requirements, the Validator applies a non-exhaustive set of tests. The tests that are applied will depend on whether the user has selected the My Health Record or P2P context (Section 3.2.4) and on whether the Validator is able to perform the tests. You should refer to the *Clinical Package Validator Product Data Sheet* or contact the Agency Help Centre on 1300 901 001 or <u>help@digitalhealth.gov.au</u> to confirm that the Validator may be used to carry out the required tests. If the user selects the My Health Record context, only the set of tests for the My Health Record context is applied. Similarly, if the P2P context is selected, only the set of tests for the P2P context is applied.

Some of the clinical package test cases applied by the Validator for both the My Health Record and P2P contexts are described in the *Conformance Test Specification for CDA Packaging* [NEHTA2015b].

2.1.3 Limitations of package validation

The package validation function of the Validator has the following limitations:

- 1 In both the My Health Record and P2P contexts:
 - a The tests that are applied to an attachment to a clinical document do not work if the attachment is compressed.
 - b The Validator checks the dates and times within a Public Key Infrastructure (PKI) certificate to make sure that the certificate was valid when it was used to sign a clinical document. It does not, however, check whether the certificate was on the revocation list when the clinical document was signed.
 - c The Validator does not check whether national healthcare identifiers in the eSignature are registered in the national healthcare identifier service. Nor does it determine whether there is any relationship between the identifier for the approver, the identifier in the certificate, and the identifiers in the clinical document.
 - d Some types of clinical documents may contain a reference to a file (e.g. an image) on a network location such as a website. The Validator does not verify the value of the integrityCheck attribute that may be associated with such a reference.¹
- 2 In the P2P context:
 - a Package validation tests are not applied to an attachment to a clinical document if that attachment is a clinical package. In this case, the tester must extract the attachment from the clinical package and manually apply the Validator to it.
 - b The tests that are applied to an attachment to a clinical document do not work if the attachment and clinical document are in different folders.
 - c A clinical package may contain multiple eSignature files; typically, one for each person who approved the clinical document and the clinical information within it. The primary eSignature file has the filename

¹ To perform this verification, a tester may access tools or websites that apply the SHA-1 calculation to the referenced file. It is important to note that the Agency's specifications require the inclusion of the integrity check value in a base64 format rather than in a hexadecimal format.

CDA_SIGN.XML and this is the only eSignature validated by the Validator. The Validator will report if it finds other eSignatures, but it will not validate them.

d A clinical package may contain a package index, but the Validator does not examine the package index when validating a clinical package.

2.2 Template validation

The Validator can apply two templates to a clinical document:

- 1 a My Health Record template which is applied by the My Health Record system to a clinical document uploaded to it; and
- 2 an additional template containing additional validation rules.

A My Health Record template exists for each type of clinical document at each level of conformance. When a clinical document is being validated, the Validator will apply the template that the user has decided is relevant to that document including user-generated templates.

An additional template containing additional validation rules may also be applied if:

- a template in the My Health Record system does not yet have a complete set of rules for all mandatory requirements; or
- a template is needed to apply quality criteria other than conformance tests

My Health Record templates may be obtained from a number of sources:

- template package libraries published on the Agency website², which contain a set of clinical document template packages; and
- template packages included in the My Health Record software vendor test environment.

Additional template packages are being developed by the Agency.

A template consists of the Australian CDA schema and Schematron rules. The Australian CDA schema constrains the set of data elements that may be used in a clinical document. The Australian CDA schema also contains rules that define the data types that are allowed for a data element, their attributes, and the allowed parent/child relationships. Schema rules are not specific to a type of clinical document or a conformance level, but are derived from the *HL7 Clinical Document Architecture, Release 2.0* specification [HL72004] and the *Australian CDA Schema Extension* [NEHTA2014a].

Schematron is a rule-based validation language that is capable of expressing constraints that cannot be expressed in a CDA schema. My Health Record templates contain Schematron rules developed for each type of clinical document at each level of conformance. These rules describe the required cardinality of data elements in a clinical document and the relationships between these data elements. They also check whether a data element value is an allowed value.

Schematron rules are derived from the My Health Record conformance profile for each type of clinical document, the relevant structured content specification, the relevant CDA implementation guide, and specifications referred to by these documents.

² These can be derived from the relevant clinical document end product at <u>http://www.digitalhealth.gov.au/implementation-resources/clinical-documents</u>.

The Validator applies template validation to the following:

- Clinical documents created by clinical information systems and contracted service provider systems, such as:
 - birth details, child parent questionnaires, consumer entered achievements, consumer entered measurements, discharge summaries, eHealth diagnostic imaging reports, eHealth dispense records, eHealth pathology reports, eHealth prescription records, eReferrals, event summaries, health check assessments, shared health summaries, and specialist letters.
- Clinical documents created by consumer portals, such as:
 - advance care directive custodian documents, personal health notes, and personal health summaries.
- Clinical documents created by Medicare repositories, such as:
 - Australian immunisation register reports, Australian organ donor register reports, Medicare Department of Veterans' Affairs (DVA) benefits reports, and pharmaceutical benefits reports.
- Clinical documents created by the My Health Record system, such as:
 - eHealth prescription and dispense views, health check schedule views, Medicare overviews, and observation views.

2.2.1 Limitations of validation by My Health Record templates

The My Health Record template validation function of the Validator has a number of limitations. These are listed in detail in the *Clinical Package Validator Product Data Sheet*.

Broadly speaking, the following high level limitations apply:

- 1 My Health Record templates published by the Agency have been developed for My Health Record requirements rather than P2P requirements. If the P2P context is selected and the Validator reports that the clinical document references attachments of a disallowed type, the template error message may be ignored because the error message only applies to the My Health Record context.
- 2 My Health Record template validation only checks whether the minimum requirements for a conformance level have been met. No checks are applied to those data elements in a clinical document that are not required for that conformance level. For example, because the body of a conformance level 2 document need not contain structured data, the template for a level 2 document does not contain any checks for structured data. The Validator will ignore any structured data that may be present in a document that is being assessed for level 2 conformance. To assess this structured data, a template for level 3A conformance may be applied by the Validator, even though the document is only being assessed for level 2 conformance.
- 3 Extensions to a clinical document are only subjected to Australian CDA schema checks. The My Health Record templates contain no Schematron rules for these extensions. Extensions may be additional sections or data elements that have not been defined in the relevant CDA implementation guide. A clinical

document may also be extended by incorporating information from any detailed clinical model published by the Agency.

4 My Health Record templates do not include rules for every conformance requirement listed in the specifications. They are only an aid for assessing the conformance of clinical documents. Validation using My Health Record templates must be accompanied by manual inspection of clinical documents and the application of the relevant conformance test specification for the selected type of clinical document.

An additional template with additional rules developed by the user may be applied to assist a user in overcoming these limitations.

2.3 Code validation

Terminology codes from code systems that are static and small in size (e.g. types of telecommunication address) are validated during template validation; whereas codes from code systems that are regularly updated or are large in size may be validated during code validation.

The Validator checks each code system identifier in a clinical document to determine whether it is one of the code system identifiers listed in Table 1. It then determines whether the associated code and display name are present in the relevant code system, and if the code system name has the expected value.

| Code system name | Code system identifier |
|---|--------------------------------|
| Australian Medicines Terminology (AMT) version 3 | 2.16.840.1.113883.6.96 |
| Australian Medicines Terminology (AMT) version 2 | 1.2.36.1.2001.1004.100 |
| Australian and New Zealand Standard Industrial Classification (ANZSIC) | 1.2.36.1.2001.1005.47 |
| Australian and New Zealand Standard Classification of Occupations (ANZSCO) | 2.16.840.1.113883.13.62 |
| Australian Vaccines codes | 1.2.36.1.2001.1005.17 |
| Clinical specialty codes | 2.16.840.1.113883.3.879.329673 |
| HL7 identifier types | 2.16.840.1.113883.12.203 |
| HL7 service delivery role types | 2.16.840.1.113883.1.11.17660 |
| PBS Item codes | 1.2.36.1.2001.1005.22 |
| PBS Manufacturer codes | 1.2.36.1.2001.1005.23 |
| Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU) | 2.16.840.1.113883.6.96 |

The Validator validates primary codes and translated codes for all conformance levels³, thereby looking up and validating every code in a clinical document that belongs to the code systems listed in Table 1.

2.3.1 Reference set validation

CDA implementation guides for clinical document types specify reference sets for some of the coded fields. Reference sets are subsets of codes applicable to particular usage contexts.

In addition to the generic validation of codes against code sets (see section 2.3), the Validator performs additional validation against reference sets where these are specified in the CDA implementation guide of the particular document type.

Table 2 lists the code systems for which reference sets are currently available.

| 2.16.840.1.113883.6.96 |
|------------------------|
| 2.16.840.1.113883.6.96 |
| 1.2.36.1.2001.1004.100 |
| |

Table 2 - Code systems with additional validation against reference sets

Reference sets are specified in the 'Vocab' column of CDA implementation guides. Figure 1 shows the 'Vocab' column of the *eReferral CDA Implementation Guide*.

| NEHTA SCS Data Compon- ent | Data Component Definition | Card | CDA Schema Data Element | Vocab | Comments |
|---|---|------|--|--|---|
| CDA Body Level 3 Data Elements | | | Context: ClinicalDocument/component/structuredBody/component[med_hist]/section | | |
| Problem/Diagnosis | The problems and/or diagnoses that form part of the | 0* | entry[prob] | | |
| | past and current medical history of the subject of care. | | entry[prob]/observation | | |
| | | | entry[prob]/observation/@classCode="OBS" | | |
| | | | entry[prob]/observation/@moodCode="EVN" | | |
| | | | enty[prob]/observation/id | UUID This is a technical identifier that is used for system purposes such as matching. If a suitable internal key is not available, a UUID may be used. | See <id> for avail- able attributes.</id> |
| | | | entry[prob]/observation/code | | |
| | | | entry[prob]/observation/@code="282291009" | | |
| | | | entry[prob]/observation/@codeSystem="2.16.840.1.113883.6.96" | | |
| | | | entry(prob)/observation/@codeSystemName="SNOMED CT-AU" | | |
| | | | entry[prob]/observation/@displayName="Diagnosis interpretation" | | |
| Problem/Diagnosis > Problem/Diagnos- is Identification | Identification of the problem or diagnosis. | 11 | entry[prob]/observation/value:CD | SNOMED CT-AU Problem/Diagnosis Reference Set | See <code> for available attributes.</code> |
| Problem/Diagnosis > Date of Onset | Estimated or actual date the Problem/Diagnosis began, in the opinion of the clinician. | 01 | entry[prob]/observation/effectiveTime | | See <time> for available attributes.</time> |

Figure 1: Vocab column of eReferral CDA implementation guide

The Validator examines a pre-configured set of locations in clinical documents from a set of clinical document types to make sure that the codes in those locations are from the specified reference sets.

These locations have been configured for the following types of clinical documents:

• Discharge Summary;

³ The code system used by a health software system is considered the *primary code system*. If the primary code system is mapped to another code system, a code from the second code system is called a *translation* and may be included in a clinical document.

- eHealth Diagnostic Imaging Report;
- eHealth Dispense Record;
- eHealth Prescription Record;
- eReferral;
- Event Summary;
- Shared Health Summary;
- Specialist Letter.

In the example in Figure 1, the Validator determines whether codes used for the Problem/Diagnosis data element within an eReferral clinical document are contained within the Problem/Diagnosis reference set of the SNOMED CT-AU code system.

If the Validator finds a code from a code system that is not listed in Table 1, it will report a warning to indicate it cannot validate the code.

2.3.2 Case significance

If a code in a clinical document is from a code system derived from SNOMED CT, including SNOMED CT-AU and AMT version 3, the Validator will use case significance to determine whether the value of the display name of that code is the preferred term. Display names of codes from other code systems supported by the Validator are not considered to be case sensitive.

The *SNOMED CT Technical Implementation Guide* [IHTSDO2014] describes how case significance can be used to determine whether a clinical document display name matches the preferred term from the relevant specification.

If the preferred term is entirely case sensitive, the case and text used in the clinical document display name must exactly match that of the preferred term. If only the initial character of the preferred term is case insensitive, the initial character of the display name may be either lower or upper case (i.e. the initial character of other words in the term are case sensitive). If the entire preferred term is case sensitive, the text in the display name may be either lower or upper case.

2.3.3 Limitations of code validation

The code validation function of the Validator has many limitations, including the following:

- 5 Validation of ANZSCO codes uses the Australian and New Zealand Standard Classification of Occupations, First Edition Revision 1, issued 25 June 2009. Previous and later versions of ANZSCO are not supported by the Validator.
- 6 Code validation is not yet available for all types of clinical documents supported by version 2.5 of the Validator.
- 7 The Validator searches a clinical document for occurrences of the code system identifiers listed in Table 1 and overlooks occurrences of other code system identifiers. The user must manually inspect a clinical document for occurrences of other code system identifiers to verify the associated code system name, code and display name.

2.4 Other limitations of the Validator

In addition to the limitations of package validation (Section 2.1.3), template validation (Section 2.2.1) and code validation (Section 2.3.3), the following limitations also apply to version 2.5 of the Validator:

- 8 Where the Validator can be used to test a clinical document (please refer to the *Clinical Package Validator Product Data Sheet*), the Validator renders that clinical document into a human-readable form. Its rendering conforms to most, but not all, of the generic requirements for the rendering of clinical documents stated in the *CDA Rendering Specification, Clinical Documentation* [NEHTA2012a].
- 9 The generic requirements for rendering clinical documents do not apply to eHealth prescription and dispense views, even though these views are clinical documents. The Validator does not implement the specific requirements for rendering eHealth prescription and dispense views, but instead applies the generic CDA rendering requirements.
- 10 The Validator does not test for conformance to the requirements for authoring a clinical document, listed in the *CDA Rendering Specification, Clinical Documentation* [NEHTA2012a].
- 11 Some types of conformance tests are inherently manual and cannot be automated in the Validator. For example, the Validator cannot test whether clinical information in the structured data of a clinical document is equivalent to clinical information in the narrative of that document.

As a result of these and other limitations, the validation of a clinical document cannot be solely performed by the Validator. It must be accompanied by manual inspection of the clinical document's XML file.

3 Using the Validator

This section describes the menus, parameters, commands and other features of the Validator. It also describes the results and reports generated by the Validator.

3.1 Validator menus

This section describes the purpose of each Validator menu option.

Note: Gaps in the file paths within the following screenshots should feature your username or equivalent when following the documented procedures.

3.1.1 File menu

| File Confi | guration Help | |
|-------------|--|---|
| Exit | | |
| Hie : | Select an input file to validate | |
| | | |
| Template: | × | |
| | | ~ |
| Addn Rules: | Select additional rules template folder for validation | |

Figure 2: File menu option

• File \rightarrow Exit

The Validator will close if this menu option is selected.

3.1.2 Configuration menu

| File | Con | figuration Help | | |
|--|-------|--|--|------|
| | | Manage Templates | | |
| | | Manage Terminology | | 2070 |
| | | Manage Temporary File Location | | |
| Temp | late: | | The second secon | |
| Addn Rules: Select additional rules template folder fo | | Select additional rules template folder fo | or validation | |

Figure 3: Configuration menu options

• Configuration → Manage Templates

Template Management: This menu option allows the user to import and manage My Health Record templates for validating clinical documents (Figure 4). Template management is described in the *Clinical Package Validator Installation and Configuration Guide*.

| _ | Template Manager | | × |
|-----------------------|--|-----|----|
| | plates | | |
| NASH Test Certificate | CN=English Harriette, DC=8003618233358307, DC=id, DC=electronichealth, DC=net, DC=au | | ~ |
| Templates Packages | Local Template Packages | | |
| | Import selected > Import all >> | | |
| Refresh from SVT | Add From Zip File Delete | | |
| | | Clo | se |

Figure 4: Template management menu

• Configuration \rightarrow Manage Terminology

Terminology Management: This menu option allows the user to see which terminology datasets are installed, load new terminology datasets, and remove terminology datasets (Figure 5). Terminology management is described in the *Clinical Package Validator Installation and Configuration Guide*.

| t . | Terminology | × |
|---|---|---|
| Configuration and Runcime Terminology DB File: Terminology/DB.sdf 355MB Terminology Loaded: Australian Medicines Terminology (AMT), 255 Australian Medicines Terminology (AMT), 125 Australian PBS Code, 20170101 SNOMED CT-AU, http://snomed.info/sct/32506021000036107/version/20161231 | NB: Select the root folder after unzipping the terminology package. The subfolder should be called RF2Reases for SNOMED/AMT. From Dec 2015 SNOMED Ard AMT come in one file. The Load SNOMED/AMT v3 now only supported the format. ANHT v3 is no longer supported. Load SNOMED/AMT V3: Folder Zp Load AMT V3: Folder Zp Load PBS: Folder Zp For SNOMED/AMT data visit this website https://www.healthterminologies.cov.ay For SNOMED/AMT data visit this website, and select http://www.abs.gov.au/browsel/downloads | |
| Remove old dataset | Compress DB | |
| | Close |] |

Figure 5: Terminology management menu

• Configuration → Manage Temporary File Location

Default Temp Directory Path: This menu option allows the user to change the location used for storing temporary files (Figure 6). More information is described in the *Clinical Package Validator Installation and Configuration Guide*. Please note the text in RED. This highlights that the Validator will delete every file and subfolder in this temporary folder, every time it runs. So do not set it to any folder that contains files you need to keep.

| | Configuration | × | | | |
|----------|---|----|--|--|--|
| De | fault Temp Directory Path : | | | | |
| C:\ | DigitalHealth\CPV25\Temp | | | | |
| AN EV | Use this path to point to where you store your temporary data. PLEASE NOTE, ANYTHING IN THIS DIRECTORY (including sub-directories) WILL BE DELETED EVERY TIME THE VALIDATOR RUNS, so don't set it to a directory where you have data you wish to keep. | | | | |
| | Save Cance | el | | | |

Figure 6: Default temp directory path menu

3.1.3 Help menu

• Help \rightarrow About

This menu option displays the version number, copyright, and acknowledgements for the Validator.

3.2 Validator parameters

Before the Validator can validate a clinical document or clinical package, some parameters must first be set.

If the Validator has been installed and configured according to the *Clinical Package Validator Installation and Configuration Guide*, the only parameter that may need to be set is the clinical document or package to be validated. The full set of parameters that may be set are listed in Table 3.

Please refer to the *Clinical Package Validator Product Data Sheet* for more details on the scope of template package validation.

| Parameter | When to set |
|--|--|
| Clinical document or package to be validated | Always. |
| Template to be applied | If there is more than one template to select from. |
| Additional template to be applied | If an additional template package is to be applied. |
| Context | If the context is not the default value of 'My Health Record'. |

| Table 3 – N | /alidator | parameters |
|-------------|-----------|------------|
|-------------|-----------|------------|

3.2.1 File parameter

The **File** parameter displays the location of the document that is to be validated (Figure 7).

| Fie : | Select an input file to validate | | MHR | Run Conformance |
|------------|--|---------|-----|-----------------|
| | | - | P2P | Show Report |
| emplate: | | * | | |
| ddn Rules: | Select additional rules template folder for validation | | | |

Figure 7: File parameter

The Validator uses the filename extension to determine the type of the file to be validated:

- a file with the `.xml' or `.XML' filename extension is assumed to be a clinical document;
- a file with the `.zip' filename extension is assumed to be a clinical package; and
- a file with the `.hl7' filename extension is assumed to be an HL7 MDM wrapped clinical package.

Two options are provided for selecting the file that is to be validated. The first option is to select the file by browsing:

1 Click the **XML** button (Figure 8).

| File Confi | guration Help | | | |
|-------------|--|---|-----|-----------------|
| File : | Select an input file to validate | | MHR | Run Conformance |
| | | - | P2P | Show Report |
| Template: | | | | |
| Addn Rules: | Select additional rules template folder for validation | | | |
| Information | | | | |

Figure 8: Selecting the XML button

2 Navigate to the location of the clinical document, clinical package or HL7 MDM wrapped clinical package, select the file and click **Open** (Figure 9).

| 📋 Open | | | | | × |
|--|--|--------------------|-----------|---|---|
| Solve ↓ test ↓ | | | | ✓ Search test | ٩ |
| Organize 🔻 New folder | | | | !≡ ▼ 🗖 | 0 |
| 🔆 Favorites | Name | Date modified | Туре | | |
| 🐌 Downloads | 🚮 1.3.16.1.38818.2305739 - MBS | 22/05/2013 5:42 PM | Compresse | | |
| 🧮 Desktop | 👍 CDA_in_CDA | 9/05/2014 4:42 PM | Compresse | | |
| 🕮 Recent Places | CDA_IN_CDA_2 | 9/05/2014 4:42 PM | Compresse | | |
| 🧮 Desktop (2) | CDA_SIGN | 30/04/2014 12:50 | XML File | | |
| | 🌗 Discharge_Summary_Invalid_codeSystem | 4/06/2014 11:38 AM | Compresse | | |
| 🥽 Libraries | event summary | 16/04/2014 3:16 PM | XML File | | |
| Documents | SharedHealthSummary - Christine Dunca | 1/05/2014 4:26 PM | XML File | | |
| 🎝 Music | TestData_7.hl7 | 11/04/2014 1:58 PM | HL7 File | | |
| Pictures | 🜗 TestData_7 | 11/04/2014 1:58 PM | Compresse | | |
| Subversion | | 13/05/2014 10:05 | XML File | | |
| 📑 Videos | 🚮 TestData_9 | 30/04/2014 12:50 | Compresse | | |
| r Computer ẫ SYSTEM (C:) Metwork | < III. | | | Select a file to preview. | |
| File name: | | | | CDA Validator Files Open Cancel | • |

Figure 9: Selecting the file to be validated

The second option for selecting the file to be validated is to drag the file and drop it into either the **File** field or the **Information** tab (Figure 10).

| File Configuration Help | | | |
|--|---------|-----|-----------------|
| File : Select an input file to validate | | MHR | Run Conformance |
| | | P2P | Show Report |
| Template: | | | |
| Addn Rules: Select additional rules template folder for validation | | | |
| Information | | | |
| Configuration and Runtime Information | | | |

Figure 10: Selecting the file to be validated by dragging and dropping

The Validator automatically examines the content of the file to determine the type of the clinical document being validated. The types of clinical documents that are known to the Validator are listed in section 2.2. The clinical document type is displayed in the Document Type field in the Information tab (Figure 11).

| File : | C: \temp\eReferral.zp | | MHR | Run Conformance |
|------------|---|---|-------|-----------------|
| | | | O P2P | Show Report |
| emplate: | e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ver 32624) | - | | |
| Idn Rules: | Select additional rules template folder for validation | 0 | | |
| mation | peect autional rues tempate rouer for valuation | | | |

Figure 11: Document Type field displaying the type of the clinical document being validated

If the Validator cannot determine the type of the clinical document being validated, an error message is displayed (Figure 12).

| File Error | X |
|--|---------------------|
| Error: Could not determine message type from Xml. Pr | ocessing terminated |
| | ОК |

Figure 12: Error message when the type of a clinical document is unknown

The Validator may display other error messages if a severe error prevents it from continuing (Figure 13 and Figure 14).

| Error |
|-------------------------|
| CDA_ROOT.XML not found. |
| ОК |

Figure 13: Error message when opening a ZIP file that is not a clinical package

| File error | 23 |
|---|----|
| An error occured trying to parse the input file, or the XML is not well formed enough to process. No futher processing can commence. | |
| Error: '''' is an unexpected token. The expected token is '='. Line 7, position 19. | |
| ОК | |

Figure 14: Error message when opening an XML file that does not conform to the HL7 CDA R2 specification

The Validator will display an error message if it does not have a template to validate the type of clinical document that has been imported (Figure 15).

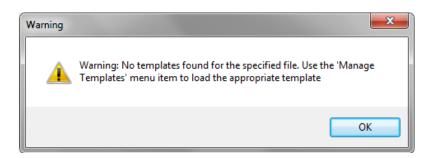


Figure 15: Error message when there is no template for the type of clinical document

3.2.2 Template parameter

The **Template** parameter displays the My Health Record template to be used for validating the selected clinical document (Figure 16).

| File Configuration Help | | | |
|--|---|-----|-----------------|
| File : Select an input file to validate | - | MHR | Run Conformance |
| Template: | | P2P | Show Report |
| Addn Rules: Select additional rules template folder for validation | | | |
| Information | _ | | |

Figure 16: The My Health Record template to be used for validation

The **Template** field has no information before a clinical document is selected. Once a document is selected, the Validator will determine the type of the selected document.

The Validator needs a My Health Record template for each type of clinical document at each level of conformance. As templates are revised, more than one template may exist for a specific clinical document type and conformance level. Testers should use the most recent version of a template unless there is a reason for choosing an earlier version. A template package directory is published on the Agency website.⁴

If the Validator has more than one template for the type of document to be validated, the **Template** field will contain a drop-down list of all templates that may be applied so that the user can select a template (Figure 17).

⁴ <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-2321-2016</u>

| rie : | C:/temp/CDA_DS1.zp | - | MHR | Run Conformance |
|-------------|--|---|-----|-----------------|
| | | | P2P | Show Report. |
| Template: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | - | | |
| Addn Rules: | e Decharge Summay 1A (12.36.1.2001.1006.1.20000.18.wr 32620) e Decharge Summay 1A (12.36.1.2001.1006.1.20000.23.wr 32620) e Decharge Summay 1B (12.36.1.2001.1006.1.20000.19.wr 32620) | • | | |
| Information | e-Discharge Summary 1B (1.2.36.1.2001.1006.1.20000.24 ver.32620) | | | |
| Templ | – Oscharge Summary 18 (1.2.36:1.2001.1006.1.2000.0.5 ver 147) – Discharge Summary 2 (1.2.36:1.2001.1006.1.20000.10 ver 148) – Oscharge Summary 2 (1.2.36:1.2001.1006.1.20000.20 ver 32620) – e-Discharge Summary 3 (1.2.36:1.2001.1006.1.20000.25 ver 32620) – Oscharge Summary 3 (1.2.36:1.2001.1006.1.20000.25 ver 32620) – Oscharge Summary 3 (1.2.36:1.2001.1006.1.20000.25 ver 32620) – e-Discharge Summary 3 (1.2.36:1.2001.1006.1.20000.25 ver 32620) – e-Discharge Summary 3 (1.2.36:1.2001.1006.1.20000.25 ver 32620) – e-Discharge Summary 3 (1.2.36:1.2001.1006.1.20000.22 ver 32620) – e-Discharge Summary 38 (1.2.36:1.2001.1006.1.20000.22 ver 32620) e-Discharge Summary 38 (1.2.36:1.2001.1006.1.20000.2000.18 | | | |
| (| Ionformance Level: 1A | | | |
| Temp | late Effective Date: Monday, 1 April 2013 Template Version: 32620 | | | |

Figure 17: Selecting a template

The **Template** field displays the document type, conformance level and template identifier for each template. Detailed information about the selected template will be displayed in the **Information** tab (Section 3.4).

A warning message is displayed if a template for the type of clinical document being validated is not available (Figure 18).

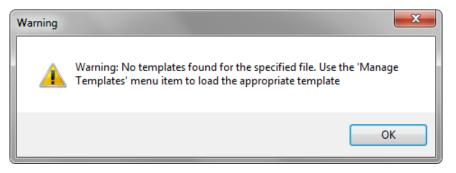


Figure 18: Warning message if a template is not available

3.2.3 Addn Rules parameter

The **Addn Rules** parameter displays the additional template to be used for validating a clinical document (Figure 19). Information about the role of an additional template is provided in section 2.2.

| File : | C:\temp\CDA_DS1.zp | | MHR | Run Conformance |
|----------------------|--|---|-----|-----------------|
| | | | P2P | Show Report |
| Template: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | • | | |
| Addn Rules: | Select additional rules template folder for validation | 6 | | |
| Information | | | | |
| Configu | ration and Runtime Information | | | |
| participation of the | Document Type: Discharge Summary | | | |

Figure 19: The additional validation template

Two options are provided for selecting the location of an additional template. The first option is to select the additional template by browsing:

1 Click the folder button (Figure 20).

| File : | C:\temp\CDA_DS1.zp | | MHR | Run Conformance |
|------------|--|---|-----|-----------------|
| | | | P2P | Show Report |
| Template: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | • | | |
| ddn Rules: | Select additional rules template folder for validation | 6 | | |
| formation | | | | |
| Configu | ration and Runtime Information | | | |

Figure 20: Selecting the folder button

2 Navigate to the directory in which the additional template is stored (Figure 21).

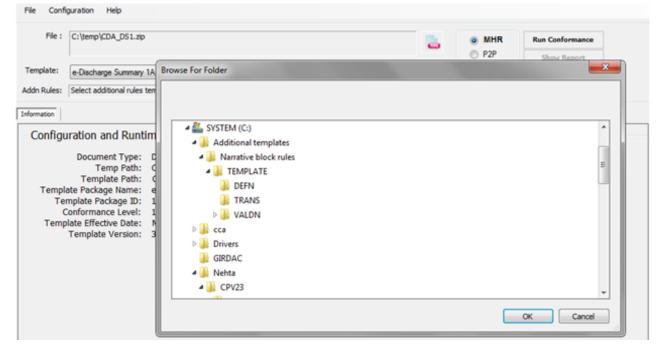


Figure 21: Navigating to the directory containing the additional template

3 Select the additional template (Figure 22).

| Browse For Folder | × |
|---|-----------|
| | |
| | |
| 🔺 💒 SYSTEM (C:) | • |
| Additional templates | |
| A District And A District A Distribution A DistributionA Distribution A Distribution A DistributionA Distr | _ |
| A 📙 TEMPLATE | E |
| 🐌 DEFN | |
| 🐌 TRANS | |
| D 🎉 VALDN | |
| D 🍌 cca | |
| 🛛 🖉 Drivers | |
| J GIRDAC | |
| 4 📙 Nehta | |
| 4 🎍 CPV23 | - |
| | |
| | OK Cancel |

Figure 22: Locating and selecting the additional template

In Figure 22, 'C:\Additional templates\Narrative block rules' is the subdirectory in which the additional template was stored.

It is important to select the 'Additional templates\Narrative block rules' subdirectory rather than the 'Additional templates\Narrative block rules\TEMPLATE' subdirectory. The 'Additional templates\Narrative block rules' subdirectory is referred to as a *template package*. It contains the additional template, an index and a README file (Figure 23).

| Name | Date modified | Туре | Size | |
|------------|------------------|------------------|------|------|
| 🐌 TEMPLATE | 29/06/2015 12:34 | File folder | | |
| 🥫 index | 23/04/2015 12:24 | Firefox HTML Doc | | 1 KB |
| README | 23/04/2015 12:24 | Text Document | | 1 KB |

Figure 23: Contents of a template package

An error message is displayed if the combined length of the template location and folder name is more than 80 characters (Figure 24).

| File Error | × |
|------------------|-------------|
| Template Locatio | n too long. |
| | ОК |

Figure 24: Error message when the combined length of the template location and folder name is too long

The second option for selecting the location of an additional template is to drag the template folder and drop it into the **Addn Rules** field (Figure 25).

| File : | C:\temp\CDA_D51.zp | | MHR | Run Conformance |
|------------|--|---|-----|-----------------|
| | 1 | | P2P | Show Report |
| Template: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | - | | |
| ddn Rules: | Select additional rules template folder for validation | 0 | | |
| nformation | | | | |
| Config | uration and Runtime Information | | | |

Figure 25: Dragging and dropping an additional template folder into the Addn Rules field

3.2.4 Context parameter

The Validator requires a user to select the context for validating a clinical package. The selection of context determines which tests will be applied when a clinical package is validated (Section 2.1).

The Validator supports the My Health Record and P2P contexts:

- The My Health Record context is the set of tests that apply to a clinical package sent to the My Health Record system.
- The P2P context is the set of tests that apply to a clinical package sent from one healthcare provider to another.

The default context for the Validator is My Health Record.

If a file with the '.hl7' filename extension is imported into the Validator, it is assumed to be an HL7 MDM wrapped clinical package and the Validator changes to the P2P context, as the My Health Record system does not support HL7 MDM. For all other types of files the P2P context must be explicitly selected (Figure 26).

| File Config | guration Help | | | |
|-------------|--|---|----------------|-----------------|
| File : | C:\temp\CDA_DS1.zip | 5 | © MHR @ P2P | Run Conformance |
| Template: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | | | |
| Addn Rules: | Select additional rules template folder for validation | | | |
| Information | | | | |

Figure 26: Selecting the P2P context

3.3 Conformance levels

The conformance level against which a clinical document is to be validated is not explicitly selected. Instead, the user selects the My Health Record template package that applies to the type of clinical document and conformance level against which the clinical document is being assessed (Section 3.2.2).

Detailed descriptions of each conformance level can be found in *Clinical Documents* - *Common Conformance Profile* [NEHTA2015c]. In general, the conformance levels

are 1A, 1B, 2, 3A, and 3B. The conformance levels that actually apply depend on the type of the clinical document. The allowed conformance levels for each type of clinical document are listed in the relevant conformance profile in the end product published on the Agency website⁵ (e.g. the event summary conformance profile is part of the Event Summary end product).

3.3.1 Conformance level 1A

A conformance level 1A clinical document has an XML header, and an XML body containing only a caption and a reference to an attached file. The administrative details form part of the header. In this example, the referral is an Adobe PDF file and the link to the referral is all that is contained in the XML body.

In a conformance level 1A clinical document, the data that would normally appear in the body of the document is instead included in an attached file. The Validator can only validate data that appears in the header of the document.

The rendered view of a conformance level 1A eReferral is shown in Figure 27. If the referral is an image (e.g. a JPEG file), the image may be displayed in the body of the rendered document, depending on the type of image.

| File : C:\temp\@Referral_ | 1A.2p | - | MHR Run Conformance P2P Show Report | |
|---|---|---|---|--|
| mplate: e-Referral 1A (1.2. | 36.1.2001.1006.1.21000.13 ver 32624) | - | | |
| n Rules: Select additional rul | es template folder for validation | 6 | | |
| mation Rendered Document | Sign File Sign File Information Template Validation Report Packa | ge Report Reference Sets Othe | er Terminology Aspects | |
| ick Forward | | | | |
| arry JAMES DoB | 6 Au | ferral 9 2012 3 6067 9001 0791 | | |
| | START OF | DOCUMENT | | |
| thor Doctor one 03457 | Henry Button (General Medical Practitioner) 54566 | | | |
| thor Doctor one 03457 | r Henry Button (General Medical Practitioner) 54566 File | TIVE DETAILS | | |
| | r Henry Button (General Medical Practitioner) 54566 File | TIVE DETAILS | | |
| thor Doctor one 03457 tructured Body tuctured Body File Patient Name | Henry Button (General Medical Practitioner) 54566 File ADMINISTRA Barry JAMES | | Doctor Henry Button (General Medical | |
| thor Doctor one 03457 tructured Body nutured Body File Patient Name Sex | Henry Button (General Medical Practitioner) 54566 File ADMINISTRA Barry JAMES Male | Author Name | Practitioner) | |
| thor Doctor one 03457 tructured Body utured Body File Patient Name Sex Indigenous Status | Henry Button (General Medical Practitioner) 54566 File ADMINISTRA Barry JAMES Male Aboriginal but not Torres Strait Islander origin | Author | | |
| thor Doctor one 03457 tructured Body Furtured Body File Patient Name Sex Indigenous Status Date of Birth | Henry Button (General Medical Practitioner) 54566 File Barry JAMES Male Aboriginal but not Torres Strait Islander origin 4 Apr 1991 (21y) * Age is calculated from date of birth | Author Name Organisation | Practitioner) Good Hospital Surgical Ward 255 Azanian St, Upper Mount Gravatt, QLD, | |
| thor Doctor one 03457 tructured Body File Patient Name Sex Indigenous Status | Henry Button (General Medical Practitioner) 54566 File ADMINISTRA Barry JAMES Male Aboriginal but not Torres Strait Islander origin 4 Apr 1991 (21y) | Author Name Organisation Department | Practitioner) Good Hospital Surgical Ward | |
| thor Doctor one 03457 tructured Body File Patient Name Sex Indigenous Status Date of Birth IHI Temporary Address | Henry Button (General Medical Practitioner) 54566 File Barry JAMES Male Aboriginal but not Torres Strait Islander origin 4 Apr 1991 (21y) * Age is calculated from date of birth 8003 6067 9001 0791 1 Gold Coast Hwy, Biggera Waters, QLD, 4216, Australia | Author Name Organisation Department Home Address Phone | Practitioner) Good Hospital Surgical Ward 255 Azanian St, Upper Mount Gravatt, QLD, 4122, Australia 0345754566 (Workplace) | |
| thor Doctor one 03457 tructured Body wetweed Body File Patient Name Sex Indigenous Status Date of Birth IHI | Henry Button (General Medical Practitioner) 54566 File Barry JAMES Male Aboriginal but not Torres Strait Islander origin 4 Apr 1991 (21y) * Age is calculated from date of birth 8003 6067 9001 0791 1 Gold Coast Hwy, Biggera Waters, QLD, 4216, | Author Name Organisation Department Home Address | Practitioner) Good Hospital Surgical Ward 255 Azanian St, Upper Mount Gravatt, QLD, 4122, Australia 0345754566 (Workplace) | |

Figure 27: Rendered view of a level 1A eReferral

⁵ http://www.digitalhealth.gov.au/implementation-resources/clinical-documents

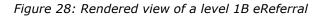
3.3.2 Conformance level 1B

A conformance level 1B clinical document has an XML header, and an XML body that includes at least one section that contains a label and a narrative block with clinical information. The data for the body is included in the narrative block(s) and may also appear as structured data.

As structured data is not required in the body of a level 1B clinical document, any structured data in the body will not be validated by the Validator using a conformance level 1B template. Any terminology codes from supported code systems will however be validated.

The rendered view of a conformance level 1B eReferral is shown in Figure 28. There is only one section in the body of this rendered eReferral, although level 1B clinical documents may have more than one section. The label of the section is **Content** and the text below the label is the rendered text from the narrative block.

| File Configuration Help | | | | | |
|---|---|---------------|--------------------------------------|------------------------------------|---|
| File : C:\temp\EReferral_18.zip | | - | MHR P2P | Run Conformance | |
| Template: e-Referral 1B (1.2.36.1.2001.1006.1.21000.19 ver 32 | 624) | • | | | |
| Addn Rules: Select additional rules template folder for validation | | 6 | | | |
| Information Rendered Document Sign File Sign File Information | Template Validation Report Package Report R | eference Sets | Other Terminology As | pects | |
| Back Forward | | | | | |
| Barry JAMES DoB 4 Apr 1991 (21y*) | e-Referral 6 Aug 2012 SEX Male IHI 8003 6067 90 | 01 0791 | | | |
| | START OF DOCUMEN | т | | | Ľ |
| Good Hospital Author Doctor Henry Button (General Me 0345754566 Content Referral Detail Date and Duration | dical Practitioner) | | | | - |
| Date | Duration | | | | |
| 12 Dec 2011 16:10+1000 | 6 month | | | | |
| Reason for Referral | | | | | |
| Thank you for seeing Mr James for assessment and pain, worse after food and possibly worse after eatir frequency and intensity but he remains afebrile and Full blood count is normal. | g fatty food. Please would you consid | er him for | cholecystectomy | as his RUQ pain is increasing both | |
| Medications | | | | | |
| Medications | | | | | |
| Medication | Direction | | | | |
| Tritace 10 mg capsule: hard, 30 capsules | 1 tablet o | nce daily | orai | | |
| Medical History Medical History - Procedures | | | | | |
| Date Time | Procedure | | Comment | s | |
| 25 Apr 1998 16:33+1000 | Primary uncemented total knee repl | acement | Cementles | SS | |
| | | | | | |



3.3.3 Conformance level 2

A conformance level 2 clinical document has an XML header and an XML body that contains all the mandatory sections specified in the relevant CDA implementation guide. Each mandatory section has a label and a narrative block with clinical information. The data for the body is included in the narrative blocks and may also appear as structured data.

As structured data is not required in the body of a level 2 clinical document, any structured data in the body will not be validated by the Validator using a conformance level 2 template. Any terminology codes from supported code systems will however be validated.

The rendered view of a conformance level 2 eReferral is shown in Figure 29. Each section has a label and a narrative block.

| File Configuration Help | | | | | |
|---|--|--|-------------------------------------|---|---------------|
| File : C:\temp\EReferral_2.zip | | - | MHR P2P | Run Conformance | |
| Template: e-Referal 2 (1 2 36 1 2001 1006 1 21000 20 v | er 32624) | • | | | |
| Addn Rules: Select additional rules template folder for valid | iðon | 0 | | | |
| Information Rendered Document Sign File Sign File Inform | ation Template Validation Report Package Report | Reference Sets | Other Terminology / | Aspects | |
| Back Forward | | | | | |
| Barry JAMES DoB 4 Apr 1991 (21y*) | e-Referral 6 Aug 2012 SEX Male IHI 8003 6067 9 | 001 0791 | | | |
| | START OF DOCUME | NT | | | |
| Author Doctor Henry Button (Gener | al Medical Practitioner) | | | | |
| Author Doctor Henry Button (Gener Phone 0345754566 Referral Detail | al Medical Practitioner) | | | | |
| Author Doctor Henry Button (Gener Phone 0345754566 Referral Detail | al Medical Practitioner) Duratio | n | | | |
| Author Doctor Henry Button (Gener Phone 0345754566 Referral Detail Date and Duration | | | | | |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 | Duratio | | | | |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons | gentleman, der him for d | cholecystectomy | as his RUQ pain is in | creasing both |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons | gentleman, der him for d | cholecystectomy | as his RUQ pain is in | creasing both |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. Medications | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons | gentleman, der him for d | cholecystectomy | as his RUQ pain is in | creasing both |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. Medications | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons | n gentleman, der him for o ows 3/4 full r | cholecystectomy | as his RUQ pain is in | creasing both |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. Medications Medications | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons and is not jaundiced. Abdo US report sh Directio | n gentleman, der him for o ows 3/4 full r | cholecystectomy moderate sized r | as his RUQ pain is in | creasing both |
| Author Doctor Henry Button (Gener 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. Medications Medications Medication Tritace 10 mg capsule: hard, 30 capsules | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons and is not jaundiced. Abdo US report sh Directio | gentleman, , der him for o ows 3/4 full r | cholecystectomy moderate sized r | as his RUQ pain is in | creasing both |
| Author Phone Doctor Henry Button (Gener 0345754566 Referral Detail Date Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. Medications Medication Trace 10 mg capsule: hard, 30 capsules Medical History | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons and is not jaundiced. Abdo US report sh Directio | gentleman, , der him for o ows 3/4 full r | cholecystectomy moderate sized r | as his RUQ pain is in | creasing both |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing Mr James for assessment pain, worse after food and possibly worse after frequency and intensity but he remains afebrile Full blood count is normal. Medications Medications | Duratio 6 mont and management. Barry is a 21 year old eating fatty food. Please would you cons and is not jaundiced. Abdo US report sh Directio | gentleman, , der him for o ows 3/4 full r | cholecystectomy moderate sized r | r as his RUQ pain is in mobile gall stones. LF | creasing both |

Figure 29: Rendered view of a level 2 eReferral

3.3.4 Conformance level 3A

A conformance level 3A clinical document has an XML header, and an XML body that contains all the mandatory sections specified in the relevant CDA implementation guide. Each mandatory section has a label and a narrative block with clinical information. In addition, each section has structured clinical information for mandatory data elements.

Any terminology codes from supported code systems will be validated by the Validator (Section 2.3).

A rendered conformance level 3A clinical document is identical to a rendered conformance level 2 clinical document. Similarly, the XML files are identical except the XML file of the level 3A document contains additional structured data.

3.3.5 Conformance level 3B

A conformance level 3B clinical document has an XML header, and an XML body that contains all mandatory sections specified in the relevant CDA implementation guide. Each mandatory section has a label and a narrative block with clinical information. In addition, each section has structured clinical information for mandatory data elements.

A conformance level 3B clinical document must contain codes from specified code systems, which is optional for lower levels of conformance. Terminology codes such as AMT, SNOMED CT-AU, or PBS must be present wherever they are allowed in the level 3B clinical document. The Validator will check whether the codes used in the clinical document can be found in the specified code systems (Section 2.3).

Any terminology codes from supported code systems will be validated by the Validator (Section 2.3).

A rendered conformance level 3B clinical document is identical to a rendered conformance level 2 and 3A clinical document. The XML file of a level 3B clinical document is identical to the XML file of a level 3A clinical document, except the XML file of the level 3B document must also contain codes from the specified code systems.

3.4 Configuration and runtime information

The **Information** tab displays information about the type of the clinical document being validated and information about the template (Figure 30).

| net | C:\temp\CDA_DS1.zip | | MHR | Run Conformance |
|----------|--|---|-----|-----------------|
| | | | P2P | Show Report |
| mplate: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | • | | |
| n Rules; | Select additional rules template folder for validation | 6 | | |
| mation | | | | |
| | ration and Runtime Information | | | |

Figure 30: Configuration and runtime information

The information displayed is described in Table 4.

Table 4 – Configuration and runtime information displayed in the Information tab

| Label | Description |
|-------------------------|--|
| Document Type | The type of the clinical document to be validated. |
| Template Package Name | The name of the template package as recorded in the template package metadata. |
| Template Package ID | The identifier of the template package as recorded in the template package metadata. |
| Conformance Level | The conformance level as recorded in the template package metadata. |
| Template Effective Date | The date the template package was approved as recorded in the template package metadata. |

| Label | Description |
|------------------|--|
| Template Version | The version number of the template package as recorded in the template package metadata. |
| Template Path | The location of the template package. |
| Temp Work Path | The location used by the Validator to store temporary files. |
| Zip file size | The size of the zip file (if the file is a zip file). |

If both the Document Type and the Template Package Name fields display names of differing types of documents, an incorrect template package has been selected.

Note: Some document names have changed over time, so it is possible that the Document Type and Template Package Name fields may display different names for the same type of document. This is not a problem, and validation can proceed normally.

If an additional template is selected, the Information tab displays information about the additional template (Figure 31).

| File Configuration Help | | |
|---|--|--|
| File : C:\DigitalHealth\DS-Ma | ax-Dodgy.zip | MHR Run Conformance P2P Show Report |
| Template: e-Discharge Summary | 1A (1.2.36.1.2001.1006.1.20000.23 ver 32620) | |
| Addn Rules: C:\DigitalHealth\IQRv1 | 1.3 | |
| Information | | |
| Configuration and Runt | ime Information | |
| | te Package | Files found in zip file: |
| Conformance Level: Template Effective Date: Template Version: Template Path: | e-Discharge Summary 1.2.36.1.2001.1006.1.20000.23 1A Monday, 1 April 2013 32620 C:\DigitalHealth\CPV25\Templates\1.2.36.1.2001.1006.1.20000.23.32620 C:\DigitalHealth\CPV25\Temp | IHE_XDM/SUBSET01/CDA_ROOT.XML IHE_XDM/SUBSET01/CDA_SIGN.XML IHE_XDM/SUBSET01/path1234.pdf IHE_XDM/SUBSET01/x-ray.jpg IHE_XDM/SUBSET01/logo.png |
| Addition | nal Rules | |
| Template Package Name: Template Package ID: Conformance Level: Template Effective Date: Template Version: Template Path: | Generic Wednesday, 30 November 2016 | |

Figure 31: Information about an additional template

The information displayed about the additional template is described in Table 5.

| Label | Description |
|-------------------------|---|
| Template Package Name | The name of the additional template package as recorded in the template package metadata. |
| Template Package ID | The identifier of the additional template package as recorded in the template package metadata. |
| Conformance Level | The conformance level as recorded in the additional template package metadata. |
| Template Effective Date | The date the additional template package was approved as recorded in the template package metadata. |
| Template Version | The version number of the additional template package as recorded in the template package metadata. |
| Template Path | The location of the additional template package. |

Table 5 –Information about the additional template

3.5 Run Conformance command

The **Run Conformance** command allows a user to request the Validator to test whether a clinical document or clinical package (for which the Validator may be used) conforms to the relevant specifications (Figure 32), subject to the limitations set out in the *Clinical Package Validator Product Data Sheet*.

| File Config | puration Help | | | | |
|-------------|--|---|----------------|-----------------|--|
| File : | C:(temp)(CDA_D51.zp | 3 | ● MHR ○ P2P | Run Conformance | |
| Template: | e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) | | | | |
| Addn Rules: | C:\Additional templates\Viarrative block rules | | | | |
| Information | | | | | |
| Configu | ration and Runtime Information | | | | |

Figure 32: Requesting the Validator to test the conformance of a clinical document or clinical package

The tests that are performed vary with the type of object being validated:

- 1 If the object is a clinical package (i.e. a .zip file), the package will be validated as well as the clinical document within the clinical package.
- 2 If the object is an HL7 MDM wrapped clinical package (i.e. an .hl7 file), the clinical package is extracted and both the clinical package and the clinical document within it are validated.
- 3 If the object is a clinical document (i.e. an .xml or .XML file), the clinical document is validated but package validation is not performed.

Template validation is applied to every type of supported clinical document. Validation results are displayed on the graphical user interface (Section 3.6).

3.6 Validation results

The following tabs are used to display the results of a clinical document or clinical package validation (for which the Validator may be used).

Ele Configuration Main

3.6.1 Information tab

In addition to displaying the information listed in section 3.4, the **Information** tab also contains a summary of the validation results.

| Label | Description |
|--------------------------------|---|
| Template Validation Results | The total number of errors reported by template validation. |
| Package Results | The total number of errors reported by package validation. This information is only included if a clinical package was validated. |
| Reference Set Results | The total number of errors and warnings reported by validation of codes against reference sets, where specified in CDA implementation guide. |
| Other Terminology Results | The total number of errors and warnings reported by validation of codes against supported code systems. |
| Additional Rules | The total number of errors reported by validation using the additional template. This information is only included if additional rules have been applied. |

3.6.2 Rendered Document tab

The **Rendered Document** tab displays the rendered clinical document (for which the Validator may be used) that is being validated (Figure 33).

| 116 0010 | garaget rep | | | |
|-------------|---|-----------|-----------------|-----------------|
| Fie : | C:\bemp\DS 3A.zip | | MHR | Run Conformance |
| | | | P2P | Show Report |
| Template: | e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | | | |
| Addn Rules: | Select additional rules template folder for validation | | | |
| Information | Rendered Document Sign File Sign File Information Template Validation Report Package Report | Reference | Sets Other Term | inology Aspects |

Figure 33: Rendered Document tab

Figure 34 is an example of a rendered clinical document displayed on the **Rendered Document** tab. The **Back** and **Forward** buttons allow the user to go back to the rendered view of the clinical document, or forward from the rendered view of the clinical document.

| | P | | | MHR Ru | n Conformance |
|--|--|--|---|---------------------------------|------------------------------|
| | | | | © P2P | Show Report |
| Normal Street Street Street Street | mary 3A (1.2.36.1.2001.1006.1.2 | 20000.26 ver 32620) | - | | |
| in Rules: Select addition S | ign File Information Template V | /alidation Report Package Report | Reference Sets Other Termi | nology Aspects | |
| mation Rendered Document | Sign File Sign File Informati | on Template Validation Report | Package Report Terminology Rep | port Other Terminology R | roqu |
| ck Forward | | | | | |
| | | | ge Summary | | |
| r Ludwig HOBBS | DoB 26 Apr 1995 (16 | | Aug 2013 HI 8003 6083 3334 56 | 84 MRN 1234 | 56 |
| County HOBBS | 000 20 Mpi 1995 (10 | oyy Sex Male 11 | 10003 0003 3334 30 | MIG4 1234 | <i></i> |
| | | | | | |
| | | START C | F DOCUMENT | | |
| GOOD Hospi | tal | | | | |
| thor Naith | an Sttas (Medical Practiti | | | | |
| | ian Sttas (Medical Practic) | oners nec) | | | |
| ione (02) | 9881 8000 | New York Concerns and the | | | |
| scharge To Othe | 9881 8000 r (includes discharge to u | sual residence, own accom | | | |
| scharge To Othe | 9881 8000 r (includes discharge to u | New York Concerns and the | | | |
| scharge To (02) scharge To Othe instit welfa | 9881 8000 r (includes discharge to u ution (includes prisons, h | sual residence, own accom | | | |
| one (02) scharge To Othe instit welfa | 9881 8000 r (includes discharge to u ution (includes prisons, h ire services)) | sual residence, own accom ostels and group homes pro | oviding primarily | | |
| one (02) scharge To Othe instit welfa | 9881 8000 r (includes discharge to u ution (includes prisons, h ire services)) | sual residence, own accom | oviding primarily | | |
| one (02) scharge To Othe instit weifz vent s Discharge Summary | 9881 8000 r (includes discharge to u ubon (includes prisons, h re services)) updates a previous Disch | sual residence, own accom ostels and group homes pro | oviding primanily | | |
| one (02) scharge To Othe institu- weifz vent s Discharge Summary Problems/Dia | 9881 8000 r (includes discharge to u ubon (includes prisons, h re services)) updates a previous Disch | sual residence, own accom ostels and group homes pro | oviding primanily | | |
| one (02) scharge To Othe institu- weitz vent s Discharge Summary Problems/Dia | 9881 8000 r (includes discharge to u ution (includes prisons, h ire services)) updates a previous Disch gnoses This Visi | sual residence, own accom ostels and group homes pro | oviding primanily | us | Onset Date |
| one (02) scharge To Othe institution weifa vent is Discharge Summary Problems/Dia Diagnoses for Curre | 9881 8000 r (includes discharge to u uton (includes prisons, h re services)) updates a previous Disch gnoses This Visi ent Visit and Previous. | sual residence, own accom ostels and group homes pro harge Summary Document I t (Event > Problems/Diagnoses | oviding primanily ld: 1282824903 This Visit) | 70.0 | Onset Date 14-Aug-2013 |
| one (02) scharge To Othe institution weifa vent s Discharge Summary Problems/Dia Diagnoses for Curre Diagnosis Elevation of SaO2 | 9881 8000 r (includes discharge to u ution (includes prisons, h ire services)) updates a previous Disch gnoses This Visi ent Visit and Previous. Type | sual residence, own accom ostels and group homes pro harge Summary Document I t (Event > Problems/Diagnoses Ranking | oviding primanily Id: 1282824903 This Visit) Stat | 70.0 | |
| one (02) scharge To Othe institution weifa vent s Discharge Summary Problems/Dia Diagnoses for Curre Diagnosis Elevation of SaO2 | 9881 8000 r (includes discharge to u uubon (includes prisons, h re services)) updates a previous Disch gnoses This Visi ent Visit and Previous. Type Discharge | sual residence, own accom ostels and group homes pro harge Summary Document I t (Event > Problems/Diagnoses Ranking | oviding primanily Id: 1282824903 This Visit) Stat | 70.0 | |
| one (02) scharge To Othe institu- weifa vent s Discharge Summary Problems / Dia Diagnoses for Currer Diagnosis Elevation of SaO2 Problems for Currer | 9881 8000 r (includes discharge to u upon (includes prisons, h re services)) updates a previous Disch gnoses This Visi ent Visit and Previous. Type Discharge nt Visit and Previous. | sual residence, own accom ostels and group homes pro arge Summary Document 1 t (Event > Problems/Diagnoses Ranking Primary | oviding primanily (d: 1282824903 This Yist) Stat Activ | de Classification | 14-Aug-2013 |
| one (02) icharge To Othe institu- weifan rent s Discharge Summary Problems/Dia Diagnoses for Currer Diagnosis Elevation of SaO2 Problems for Currer Problem Asthma | 9881 8000 r (includes discharge to u uubon (includes prisons, h re services)) updates a previous Disch gnoses This Visi ent Visit and Previous. Type Discharge nt Visit and Previous. Status | sual residence, own accom ostels and group homes pro harge Summary Document I t (Event > Problems/Diagnoses Ranking Primary Ranking Primary | oviding primanily Id: 1282824903 This Visit) Stat Activ Onset Date | de Classification | 14-Aug-2013 Date Reported |
| In the second se | 9881 8000 r (includes discharge to u uubon (includes prisons, h re services)) updates a previous Disch gnoses This Visi ent Visit and Previous. Type Discharge nt Visit and Previous. Status Active | sual residence, own accom ostels and group homes pro harge Summary Document I t (Event > Problems/Diagnoses Ranking Primary Ranking Primary | oviding primanily Id: 1282824903 This Visit) Stat Activ Onset Date | re Classification Medical | 14-Aug-2013 Date Reported |

Figure 34: Rendered clinical document displayed on the Rendered Document tab

3.6.3 Sign File tab

The **Sign File** tab displays the contents of the CDA_SIGN.XML file in a clinical package (Figure 35). The **Sign File** tab is only displayed when the file being validated is either a clinical package or an HL7 Medical Document Management (MDM) wrapped clinical package.

| File : C:\temp\DS 3A.zp | | @ MHR | Run Conformance |
|--|-------------|-------------------|-----------------|
| | _ | P2P | Show Report |
| Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | | | |
| Addn Rules: Select additional rules template folder for validation | 6 | | |
| nformation Rendered Document Sign File Sign File Information Template Validation Report Package Report | Reference S | ets Other Termino | logy Aspects |

Figure 35: Sign File tab

Figure 36 is an example of a CDA_SIGN.XML file that is displayed on the **Sign File** tab.

| File : | C:/bemp/05 3A.zp | | | | | 100 | - | Run Conformance | |
|------------|--|---------------|-------------------------------|--|----------------|----------------|---------------|----------------------|------------------|
| | | | | | | - | MHR 0 P2P | | |
| | | | | | | - | 0.00 | Show Report | |
| remplate: | e-Discharge Summ | ny 3A (1.2.3 | 36 1 2001 1006 1 2000 | 00.26 ver 32620) | | | | | |
| dán Rules: | Select additional rul | es template f | folder for validation | | | 0 | | | |
| lomation | Rendered Document | Sign File | Sign File Information | Template Validation Report | Package Report | Reference Sets | Other Termino | ology Aspects | |
| csione | Payload voins | http:// | as electronich | ealth.net.au/xsp/x | esd/SinnedPa | wload/201 | 0*> | | |
| | natures> | | | | | .,, | | | |
| | | "http://v | www.w3.org/2 | 2000/09/xmldsig#* | > | | | | |
| - | <signedinfo></signedinfo> | | | | | | | | |
| | | | | ttp://www.w3.org/ | | | | | |
| | | | | www.w3.org/2000/ 26-b56b-3109a9af | | rsa-sha1" | /> | | |
| | Contenence UP Transforms | | 0100-0100-40 | X0-D20D-31039391 | 4/21 > | | | | |
| | | | "http://www | w.w3.org/2001/10 | /vml-evc-ct | 40.8" 15 | | | |
| | <td></td> <td></td> <td></td> <td>/ Anni GAC CI</td> <td></td> <td></td> <td></td> <td></td> | | | | / Anni GAC CI | | | | |
| | | | thm="http://w | ww.w3.org/2000/0 | 9/xmldsig#s | ha1" /> | | | |
| | | | | em2Msa3Cw= <td></td> <td></td> <td></td> <td></td> <td></td> | | | | | |
| | | | 50 | | | | | | |
| 3 | | | | | | | | | |
| | | ue>nbSK | hwni0AUL3E2F | Bj10573ianQ5WA3D | LxZ+SqJgpJz | Z3nGwJmU | j8hxnYfMC | WdH7YF6eD6Z6n | IrTe4kBW/dYhiJSs |
| | <keyinfo></keyinfo> | | | | | | | | |
| | - <x509data></x509data> | | | | | | | | |
| | | ificate>M | AIIFhDCCBGyg | AwIBAgIDBe5AMA0 | GCSqGSIb3D | QEBBQUAM | H8xCzAJB | GNVBAYTAkFVMQ | wwCgYDVQQKEwN |
| | | | | | | | | | |
| | | | | | | | | | |
| | Signature> | | | | | | | | |
| | gnatures> | | able stab de | 26-b56b-3109a9af4 | 7365 | | | | |
| | | | | tronichealth.net.au | | IvedleSin | nature/201 | 2*> | |
| | | | | 2000/09/xmldsig# | | / xsu/ esig | interest you | | |
| | - Reference UR | | | room, ast minuside | | | | | |
| - | | | | ww.w3.org/2000/0 | 9/xmidsia#s | ha1* /> | | | |
| - | <digestmeth< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></digestmeth<> | | | | | | | | |
| - | | | | | | | | | |
| - | | | | SPTU9QZPOD7w=< | | | | | |
| | DigestValue | | | | | | | | |
| | <digestvalue <q1:signingtime< td=""><td>>H3mBa</td><td>ahDjzm8Q4wN</td><td></td><td>/DigestValue></td><td></td><td></td><td></td><td></td></q1:signingtime<></digestvalue | >H3mBa | ahDjzm8Q4wN | | /DigestValue> | | | | |
| | <pre>dbigestValue <q1:signingtime <q1:approver=""> </q1:signingtime></pre> | >H3mBa | ahDjzm8Q4wN 94-11T13:58:54 | SPTU9QZPOD7w=< | DigestValue> | | | | |

Figure 36: Display of a CDA_SIGN.XML file

3.6.4 Sign File Information tab

The **Sign File Information** tab displays selected information from the CDA_SIGN.XML file in a clinical package (Figure 37). This complements information in the **Sign File** tab as this information is more readable. Information from the Public Key Infrastructure (PKI) certificate is also displayed.

The **Sign File Information** tab is only displayed when the file being validated is either a clinical package or an HL7 Medical Document Management (MDM) wrapped clinical package.

| File Configuration Help | | | |
|---|---------------|------------------|-----------------|
| File : C:\temp\DS 3A.zip | | MHR | Run Conformance |
| | | P2P | Show Report |
| Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | | | |
| Addn Rules: Select additional rules template folder for validation | | | |
| Information Rendered Document Sign File Sign File Information Template Validation Report Package Report R | eference Sets | Other Terminolog | gy Aspects |

Figure 37: Sign File Information tab

Figure 38 is an example of the information displayed on the **Sign File Information** tab.

| File : | C: (temp)/DS 3A.zip | | | | | 1 | MHR | Run Conformance | |
|-------------|---|---|---|--|------------------|----------------|-------------------|---------------------------|----------------------|
| | 1 | | | | | | © P2P | Show Report | |
| Template: | e-Discharge Summary | 3A (1.2.) | 6.1.2001.1006.1.2000 | 00.26 ver 32620) | | 11. C | | | |
| Addn Rules: | Select additional rules t | template | folder for validation | | | - | | | |
| Information | Randered Document S | gn File | Sign File Information | Template Validation Report | Package Report | Reference Sets | Other Terminology | Aspects | |
| CDA S | ign File Informati | on | | | | | | | |
| 00110 | girtine timertinge | | | | | | | | |
| | | | | | | | | | |
| | Signing Tir | ne: 2 | 014-04-11713:58: | 54.538054+10:00 | | | | | |
| | Signing Tir Approver Person | | 014-04-11T13:58: ttp://ns.electronicf | 54.538054+10:00 health.net.au/id/hi/hpii/ | /1.0/800361916 | 6674595 | | | |
| 8 | | Id : h | | | /1.0/800361916 | 6674595 | | | |
| | Approver Person | Id: h ne: N | ttp://ns.electronich | health.net.au/id/hi/hpii | /1.0/800361916 | 6674595 | | | |
| | Approver Person Approver Person Nar | īd:h ne:N ateт | ttp://ns.electronich laithan Sttas his is a NASH Certifi | health.net.au/id/hi/hpiij Icate | | | FORGS8120, DC- | -8003629900019338, DC=1d, | DC=electronichealth |
| | Approver Person Approver Person Nar ganisation Certific Subje Valid Pro | Id: h ne: N ate T ect: C im: 4 | ttp://ns.electronic laithan Sttas his is a NASH Certifi N=general.800362 /04/2013 9:50:13 | health.net.au/id/hi/hpii kate 29900019338.id.electro PM | | | FORGS8120, DC- | =8003629900019338, DC=id, | DC=electronichealth, |
| | Approver Person Approver Person Nar ganisation Certific Subjo Valid Fre Valid Ter Valid | Id: h ne: N ate T ect: C im: 4 To: 4 | ttp://ns.electronic laithan Sttas his is a NASH Certifi N=general.800362 /04/2013 9:50:13 /04/2015 9:50:12 | health.net.au/id/hi/hpii/ Icate 29900019338.id.electro PM FM | nichealth.net.au | , O=MEDTEST | FORGS8120, DC- | =8003629900019338, DC=id, | DC=electronichealth |
| | Approver Person Approver Person Nar ganisation Certific Subje Valid Pro | Id: h ne: N ate T ect: C im: 4 To: 4 | ttp://ns.electronic laithan Sttas his is a NASH Certifi N=general.800362 /04/2013 9:50:13 /04/2015 9:50:12 | health.net.au/id/hi/hpii kate 29900019338.id.electro PM | nichealth.net.au | , O=MEDTEST | FORGS8120, DC= | =8003629900019338, DC≃id, | DC=electronichealth, |

Figure 38: Display of eSignature file information

The information displayed is listed in Table 7.

| Label | Description |
|--------------------------|--|
| Signing Time | The date and time that the clinical document was signed using the PKI certificate. |
| Approver Person Id | The identifier of the approver, in the form of a Uniform Resource Identifier (URI). The approver is the person that reviewed and approved the content of the clinical document [NEHTA2015c]. |
| | Possible values are: |
| | • 'http://ns.electronichealth.net.au/id/null/person/1.0' if there was no approver. |
| | 'http://ns.electronichealth.net.au/id/hi/hpii/1.0/' followed by the approver's HPI-I. |
| | 'http://ns.electronichealth.net.au/id/hi/ihi/1.0/' followed by the approver's IHI. |
| | The domain namespace of an organisation followed by a local identifier. In this case the organisation is the one that allocated the identifier to the approver. |
| Approver Person Name | The title and name of the person that reviewed and approved the content of the clinical document. If the name is 'NA', there was no approver. |
| Organisation Certificate | States whether the certificate is a National Authentication Service for Health (NASH) Public Key Infrastructure (PKI) certificate. |

| Table 7 – Summary | of information | displayed in | the Sian | File Infor | mation tab |
|-------------------|-----------------|---------------|-----------------|------------|-------------------|
| Table / Summary | 01 111011110101 | uispiayea iii | une Sign | | nation tab |

| Label | Description |
|-----------------------------------|---|
| Subject | A set of domain components ('DC'), an organisation name ('O') and a common name ('CN'). |
| | The attributes most relevant to conformance testing are the organisation name, and the national healthcare identifier which is one of the domain components and is also found within the common name. The organisation name and identifier are the name of the healthcare provider organisation or supporting organisation that the certificate was assigned to, and the identifier of that organisation. |
| Valid From | The start of the validity period for the PKI certificate. The date is displayed in green if the current date (not the signing date) is at or after the start of the validity period, otherwise it is red. |
| Valid To | The end of the validity period for the PKI certificate. The date is displayed in green if the current date (not the signing date) is at or before the end of the validity period, otherwise it is red. |
| Certificate Policies | States whether the certificate is for a healthcare provider individual, a healthcare provider organisation or a supporting organisation. |
| Other eSignature files in package | The name(s) of any other eSignature files found within the clinical package. These names are found by opening the clinical package whereas all of the information above this row in this table is obtained from the CDA_SIGN.XML eSignature file. |

Figure 39 is another example of the information displayed on the **Sign File Information** tab when a certificate is not a NASH certificate, the certificate policy is unrecognised and a second eSignature file was found in the clinical package.

| File : | C:\temp\clinical docume | ent.zp | | | - | MHR . | Run Conformance |
|------------|--|--|---|----------------|----------------|-------------------|----------------------------|
| | 1 | | | | - | P2P | Show Report |
| Template: | Shared Health Summar | y 3A (1.2.36.1.2001.1006.1.16 | i565.8 ver 36326) | | ÷ | | |
| ddn Rules: | Select additional rules t | template folder for validation | | | | | |
| formation | Rendered Document Si | ign File Sign File Information | Template Validation Report | Package Report | Reference Sets | Other Terminology | Aspects |
| CDA S | ign File Informati | on | | | | | |
| | Signing Tin Anorover Person | | | /1.0/800361156 | 6666875 | | |
| | Signing Tin Approver Person Approver Person Nan ganisation Certific | Id : http://ns.electronict ne : Or Kimberlee Skaar | health.net.au/id/hi/hpii/ e | /1.0/800361156 | 6666875 | | |
| | Approver Person Approver Person Nan | Id : http://ns.electronich ne : Dr Kimberlee Skaar afte This is not a NASH C ect : CN=general.800362 m : 5/03/2012 9:42:49 To : 5/03/2013 8:00:00 | health.net.au/id/hi/hpii/ e Jertificate 10833337558.id.electro PM | | | 305, DC=ELECTI | RONICHEALTH, DC=NET, DC=AU |

Figure 39: An unrecognised type of certificate and a second eSignature

3.6.5 Template Validation Report tab

The **Template Validation Report** tab displays the results of the My Health Record template validation (for which the Validator may be used) and the clinical document XML file (Figure 40).

| File : | CritempiDS 3A.ap | 12 | MHR | Run Conformance |
|------------|--|----|-------|-----------------|
| | 1 | | © P2P | Show Report |
| femplate: | e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | 3 | | |
| dan Rules; | Select additional rules template folder for validation | 0 | | |

Figure 40: Template Validation Report tab

Any template validation issue is displayed in this report along with information about the issue, and the context of the issue. A template validation report is generated each time the Validator is run.

Schema issues are displayed before Schematron issues, followed by a display of the clinical document XML file. Figure 41 shows a report with a schema issue highlighted.

| | | 2 | * MHN 0 P2P | Run Conformance Show Report | |
|--|--|-----------------------------|----------------------------------|--------------------------------------|--|
| rolate: e Dacharge Summary 34 | (1.2.36.1.2001.1006.1.20000.26 ver 32620) | • | | | |
| Rules: Select additional rules ter | nglate folder for validation | 0 | | | |
| ution Randend Document Sign | File Spr File Information Template Yoldeton Report | Package Report Reference Se | ts Other Terminolog | IV Aspects | |
| | | Temp | late Valida | ition Report | |
| LIDATION STATUS | Complete | | | | |
| IRVICE NAME | Discharge Summary - 3A | | | | |
| RVICE PROVIDER | NEHTA | | | | |
| ANDARD TYPE | CDA R2 | | | | |
| ANDARD VERSION | N/A | | | | |
| TE OF TEST | 20150702 | | | | |
| 4E OF TEST | 073748.5530519 +1000 | | | | |
| ORT POSITIVE INDICATO | OR True | | | | |
| SULT OF TEST | False | | | | |
| ROR COUNT | 2 | | | | |
| | | | | | |
| ARNING COUNT | | | | | |
| | See Package Report Tab | | | | |
| GNATURE VALIDATION Message (Une:233 Pos:10) The namespace 'umchi7-org | element 'effectiveTime' in namespace | 'um:hl7-org:v3' has inv | Error | | rrg:v3'. List of possible elements expected: 'width, high' |
| IARNING COUNT SONATURE VALIDATION (Message (une:233 Pos:10) The namespace 'um:hi7-org | element 'effectiveTime' in namespace | 'um:h7-org:v3' has inv | Error | | vrg:v3'. List of possible elements expected: 'width, high' |
| IGNATURE VALIDATION Message (Une:233 Pos:10) The pamespace 'unrith' or Message Error: e-Discharge Si Global Cincal Docum Time" tag - The 'low Appear only once. Ch Tume/low' rags to fin tags. Refer to sector | element 'effectiveTime' in namespace grV3'. ummary - ent check for t ag shal eck al t he duplicate | "um:hl7-org:v3" has inv | Error Context /ClinicalDoc | ument[1]/componentOf assingEncounter | |

Figure 41: Template Validation Report tab with schema issue highlighted

Figure 42 shows the report with Schematron issues highlighted.

| | | - | P2P Run Conformance P2P Show Report | | |
|--|--|-------------------------------|---|--|-------|
| e Dacharge Summary 3/ | A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | • | | | |
| Rules: Select additional rules te | nglate folder for validation | 6 | | | |
| ution Rendered Document Sig | File Sign File Information Template Validation Report | Package Report Reference Sets | Other Terminology Aspects | | |
| | | Templa | ate Validation Report | | |
| LIDATION STATUS | Complete | | | | |
| RVICE NAME | Discharge Summary - 3A | | | | |
| RVICE PROVIDER | NEHTA | | | | |
| TANDARD TYPE | CDA R2 | | | | |
| ANDARD VERSION | N/A | | | | |
| TE OF TEST | 20150702 | | | | |
| ME OF TEST | 073748.5530519 +1000 | | | | |
| | | | | | |
| | OR True | | | | |
| | OR True False | | | | |
| SULT OF TEST | | | | | |
| SULT OF TEST ROR COUNT | False | | | | |
| ESULT OF TEST ROR COUNT ARNING COUNT | False | | | | |
| ISULT OF TEST IROR COUNT WANNING COUNT ISNATURE VALIDATION Message | False 2 See Package Report Tab element 'effectiveTime' in namespace 'u | rn:hl7-org:v3' has inval | id child element 'low' in namespace 'urnchi7-or Errors | g:v3'. List of possible elements expected: 'width, hig | h' in |
| ESULT OF TEST RROR COUNT SCHATURE VALIDATION Message (Line:233 Pos:10) The namespace 'um:h2-on | False 2 See Package Report Tab element 'effectiveTime' in namespace 'u | rm:N7-org:v3" has inval | | g:v3'. List of possible elements expected: 'width, hig | h' in |
| hamespace 'um:hl7-on Message Error: e-Discharge S Global Clinical Docum 'time' tag - The 'low appear only once. Cl time/low' tags to fin tags, Refer to secto | False 2 See Package Report Tab element, 'effectiveTime' in namespace 'u grv3'. ummary - sent check for ' tag shal heck al d the dupkore | rn:h7-org:v3' has inval | Errors | | h' in |

Figure 42: Template Validation Report tab with Schematron errors highlighted

Figure 43 shows a report where no schema or Schematron issues were found during template validation.

| File Configuration Help | | |
|---|---|--|
| Pie : C/bero/D5 3A.zo | 20 Bur Conference 0 F2 ¹⁰ Show Report | |
| Template: e-Dacharge Summar | many 3A, (1.2.36.1.2001.1006.1.20000.26 ver 12620) - | |
| Addn Rules: Select additional rules | rules tenglate föder for valdation | |
| femation Rendered Document | t Bign File Bign File Information Templana Validation Report Package Report Reference Sets Other Templana Validation Appents | |
| | Template Validation Report | |
| VALIDATION STATUS | Complete | |
| SERVICE NAME | Discharge Summary - 3A | |
| SERVICE PROVIDER | NEHTA | |
| STANDARD TYPE | CDA R2 | |
| STANDARD VERSION | N/A | |
| DATE OF TEST | 20150702 | |
| TIME OF TEST | 074036.4803435 +1000 | |
| REPORT POSITIVE INDIC | DICATOR True | |
| RESULT OF TEST | True | |
| ERROR COUNT | 0 | |
| WARNING COUNT | | |
| SIGNATURE VALIDATION | ION See Package Report Tab | |
| | | |
| <pre>trainCode code="Ad" typeId code="Ad" typeId code="Ad" thepIateId root="A tid root="2.35.11140 code odd="18744-5" coffectiveId="Ad" confidentialtyCode confidentialtyCode charguageCode code=" castId root="1.2.34. typeId="Code" castId root="L.3.45. typeId="Code" castId root="L.3.45. typeId="Code" castId root="L.3.45."</pre> | 6.460.1.113653.1.0* extension="POCD_NEDCOD40//> *1.2.30.1.2001.100.1.001.101.00.149* extension="1.0"/> 14042202132021320213202129211954641007456597*/> >* codeSystem="2.16.460.1.113683.6.1* codeSystemSame="LOENC" displaySame="Discharge Summarization Note"/> lue="20100141334-1000"/> dot multiParce="ML"/> #**en_A277/> St.1.2003.1005.16.50.2.1005520.774005.1.1242424903*/> | |
| <pre>cpatientBole> cid root="423bEd91-b caddr use="H"> country>Australiac/</pre> | 1-8207-4764-8908-0x4264592349*/> #C/downtaty> == | |

Figure 43: Template Validation Report tab reporting no errors

The upper portion of the report includes a summary of the schema and Schematron errors, and contains the following information.

| Label | Description | | | | | |
|---------------------------|--|--|--|--|--|--|
| Validation status | Complete indicates the Validator has completed the validation process. If the Validator does not complete the validation process, the text An Error occurred while trying to run the Validator. No Output was produced. will be displayed. | | | | | |
| Service name | The type of the clinical document and the target conformance level. | | | | | |
| Service provider | Australian Digital Health Agency | | | | | |
| Standard type | HL7 CDA R2 indicates the clinical document specifications are based on release 2 of the HL7 Clinical Document Architecture [HL72004]. | | | | | |
| Standard version | This field is not used. | | | | | |
| Date of test | The date in the yyyymmdd format. | | | | | |
| Time of test | The time when the test was run. | | | | | |
| Report positive indicator | The Report positive indicator is currently always set to True . | | | | | |
| Result of test | The overall result of the validation. The result is True if template validation found no issues, and False if issues were found during template validation. | | | | | |
| Issue count | The total number of schema and Schematron issues. | | | | | |
| Warning count | The total number of warnings. | | | | | |
| Signature validation | Indicates whether any errors were found in the eSignature. N/A is displayed if there was no eSignature. See Package Report Tab is displayed if there was an eSignature to validate. | | | | | |

Table 8 - Report labels

If schema issues are found, the middle portion of the report contains the XML line number where the issue is located, the position of the issue within the line, and a description of the issue (Figure 41).

If Schematron issues are found (Figure 42), the middle portion of the report contains the information in Table 9.

| Label | Description |
|---------|--|
| # | The issue number. |
| Message | The issue message. |
| Context | The location in the XML where the issue was found (XPath). |
| Test | The Go To Issue link at the end of the test information can be used to go to the location of the issue in the clinical document XML file. |

Table 9 - Schematron issue information

Figure 44 is an example of information that is displayed in the **Template Validation Report** tab when a **Go To Issue** link is selected. The issue message highlighted in red indicates the XML element that was in issue.

| File Configuration Help | | |
|---|---|-----|
| File : Critemp105 3A.ap | UHR BACConference | |
| Template: e-Decharge Summary 3 | A. (1.2.36.1.2001.1006.1.20000.25 ver.33620) | |
| Addh Rules: Select additional rules to | englate folder for validation | |
| | | |
| Information Rendered Document Sig | pr Mie I Sign Mie Siehemanien Tempiere Valideere Report Reference Setz Other Terminology Aspects | |
| | Template Validation Report | |
| VALIDATION STATUS | Complete | 11 |
| SERVICE NAME | Discharge Summary - 3A | 11 |
| SERVICE PROVIDER | Australian Digital Health Agency | 1.7 |
| STANDARD TYPE | CDA R2 | 11 |
| STANDARD VERSION | N/A | 1.1 |
| DATE OF TEST | 20150702 | 1.1 |
| TIME OF TEST | 074204.5490982 +1000 | 1.7 |
| REPORT POSITIVE INDICAT | IOR True | 1.7 |
| RESULT OF TEST | False | 11 |
| ERROR COUNT | 2 | 1.7 |
| WARNING COUNT | | 11 |
| SIGNATURE VALIDATION | See Package Report Tab | 11 |
| Error #1 - count(cda:low) > | | |
| 100 | | |
| <pre>deffectiveTime></pre> | 1011101433+1000* /> | |
| | | |
| | | |
| | reports an error for the following. Check the IG> | |
| | itionCode code="3" codeSystem="2.16.840.1.113883.13.45" codeSystemName="AINW Mode of Separation" displayName="Discharge/transfer to (an)other psychiatric | a |
| | ipant typeCode="DIS"> | |
| <time> <low value="*/</td"><td>4444444 JL</td><td></td></low></time> | 4444444 JL | |
| | | 00 |
| | EVENUE (P | |
| cassignedEntity | P | |
| | fe131-b223-4e90-901f-9d47ac4b8a0a* /> | |
| | 253111" code5ystem="2.16.040.1.113003.13.62" code5ystemName="1220.0 = ANISCO = Australian and New Zealand Standard Classification of Occupations, First N | £ |
| | | |

Figure 44: Template Validation Report tab when a **Go to Issue** link is selected

Figure 45 shows the display of a clinical document XML file. The clinical document XML file is presented immediately after the display of any Schematron issues.

| File Configuration Help | |
|---|--|
| Ple I Criterep DS 34.4p | P2 Res Conformance Description |
| Template: a-Decharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 3 | N) • |
| Addn Rules: Select additional rules template folder for validation | 0 |
| Information Rendered Document Sign File Sign File Information Templete | Package Report Reference Sets Other Terminology Aspects |
| | Template Validation Report |
| VALIDATION STATUS Complete DERVICE ANAME Discharge Summary - 3A. SERVICE PROVIDER Turolinge Summary - 3A. STANDARD TYPE CDA. R2 STANDARD VERSION N/A DATE OF TEST 20150782 TIME OF TEST 074401.7540349 +1000 REPORT POSITIVE INDOCATOR True RESULT OF TEST VARDING COUNT 0 VARDING COUNT See Package Report Tab | citi f Aueric . |
| crealsCode code="42"/> crypelS noce"2.16.10.11385.1.1" extension complainedS motor"1.2.361.2001.1001.101.100.1 complainedS motor"1.2.361.2001.1001.101.100.104" cod motor"2.38.131662230233023329311954645 code code="1842_3" codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.1.31 offcol:weilSetWide: codeSyntem="2.16.460.2.100552 oversionShabet: value="2"/> | 12.4° matemation="1.4"> tentalion="1.0"> "HE4937%> HE4937%> H33.6.1° codeSystemShame="LOINC" displayShame="Discharge Summarization Bote"/> "T4005.1.1282824900*/> " codeSystem="1.2.36.1.2001.1001.101.104.20104" codeSystemShame="NCTIS Document Status Values"/> |

Figure 45: Template Validation Report tab displaying a clinical document XML file

3.6.6 Additional Rules Report tab

The **Additional Rules Report** tab displays the outcome of applying additional rules to the clinical document (Figure 46). This tab is only displayed if an additional template package was imported into the Validator (Section 3.2.3).

| File: | C: (temp/DS 3A. ap | | | | | | MHR | Run Conformance |
|------------|---------------------|----------------|-----------------------|----------------------------|-------------------------|---------|-------------------|----------------------------|
| | | | | | | 0.000 | P2P | Show Report |
| Template: | e-Discharge Summ | any 3A (1.2 | 36 1 2001 1006 1 2000 | 0.26 ver 32620) | • | | | |
| ddn Rules: | C: \Additional temp | kates/\$karrat | ive block rules | | | 0 | | |
| formation | Rendered Document | Sign File | Sign File Information | Template Validation Report | Additional Rules Report | Package | e Report Referenc | e Sets Other Terminology A |

Figure 46: Additional Rules Report tab

Information is displayed in the **Additional Rules Report** tab in the same way as information is displayed in the **Template Validation Report** tab (Section 3.6.5).

3.6.7 Package Report tab

The **Package Report** tab displays the results of package validation (for which the Validator may be used) (Figure 47). This tab is only displayed after a clinical package or an HL7 MDM wrapped clinical package has been validated (Section 3.2.1).

| Pie Configuration Help | | | | |
|---|---------------|------------------|-----------------|--|
| Pile : C:(temp/DS 3A.ap | | * MHR | Run Conformance | |
| | | P2P | Show Report | |
| Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | 9 | | | |
| Addn Rules: Select additional rules template folder for validation | 0 | | | |
| Information Rendered Document Sign File Sign File Information Template Validation Report Package Report | eference Sets | Other Terminolog | y Aspects | |

Figure 47: Package Report tab

The **Package Report** tab displays the validation result for each test case that was applied for the selected context, and a symbol that summarises each validation result (Figure 48). Section 2.1 provides information about these test cases.

| | C:\temp\D5 3A.zp | | MHR | Run Conformance | | |
|--------------------|--|----------------|------------------|-----------------|--------|-------------|
| | | | P2P | Show Report | | |
| slate: | | • | | | | |
| Rules: | Select additional rules template folder for validation | | | | | |
| tion | Rendered Document Sign File Sign File Information Template Validation Report Package Report | Reference Sets | Other Terminolog | y Aspects | | |
| | | | | | Ov | erride Resu |
| | | | | | | |
| Pa | ckaging Validation | | | | | |
| Da | te: 2/07/2015, 7:47:11 AM | | | | | |
| | | | | | | |
| | E Deserved | | | | | |
| N XN | | | | | | |
| | _014 - Verify the CDA Document is valid for its document type | | | | | |
| | | | | | ^ | |
| | | | | | | ~ |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| CD4 | A RES - Verify any nachaned attackments are represented usion as ED-type element | | | | | |
| | _015 - Verify any packaged attachments are represented using an ED-type element | | | | 4 | |
| | _013 - Verify any packaged attachments are represented using an ED-type element | | | | * | _ |
| | 1_013 - Vevify any packaged attachments are represented using an ED-type element | | | | * | _ |
| | 1_013 - Verify any packaged attachments are represented using an ED-type element | | | | A U | _ |
| Run | | | | | A W | _ |
| Run G_CDA | _015 - Verify any packaged attachments are represented using an ED-type element _016 - Verify the ED-type element integrityCheckAlgortihm = 'SHA-1' | | | | v | _ |
| Run | | | | | * | _ |
| Run | | | | | v | _ |
| Run G_CDA | | | | | v | - |
| Run | | | | | v | - |
| Run CDV Run | | | | | v | - |
| Run _CDA Run | _016 - Verify the ED-type element integrityCheckAlgortihm = 'SHA-1' | | | | v | - |
| CDA | _016 - Verify the ED-type element integrityCheckAlgortihm = 'SHA-1' | | | | 4 4 | - |
| CDA | _016 - Verify the ED-type element integrityCheckAlgortihm = 'SHA-1' | | | | 4 4 | - |

Figure 48: Package Report tab showing results of clinical package validation

Package validation symbols and their meanings are listed in Table 10.

| Table 10 - Package | validation | symbols |
|--------------------|------------|---------|
|--------------------|------------|---------|

| Symbol | Explanation | Usage |
|----------|-------------|---|
| V | Pass | The Validator determined a definite 'Pass' for the test case. |
| × | Fail | The Validator determined a definite 'Fail' for the test case. |
| P | Warning | The outcome of the test case can only be determined through manual inspection and then a decision of 'Pass' or 'Fail'. |
| - | Not Run | The test case is conditional (e.g. upon an attachment being present) and the validation was not run as the condition was not met. |

3.6.8 Reference Sets tab

The **Reference Sets** tab (Figure 49) displays the results of validations of codes against reference sets where these are specified in the CDA implementation guide for the particular document type (see section 2.3.1 for details).

| Pile Config | uration Nep | | | | |
|-------------|--|---------|----------------|---------------------------|---------|
| File : | C: (temp/(D5 3A.ap | | MHR | Run Conformance | |
| | | _ | O P2P | Show Report | |
| Template: | e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.25 ver 32620) | • | | | |
| Addn Rules: | Select additional rules template folder for validation | - | | | |
| Information | Rendered Document Sign File Sign File Information Template Validation Report | Package | Report Referen | ce Sets Other Terminology | Aspects |

Figure 49: Reference Sets tab

Reference set validation results are displayed for every data element for which the CDA implementation guide specifies a reference set in its 'Vocab' column. They include information that describes the validation result and a symbol representing this result (Figure 50).

| | C/temp/DS 3A.zp | | * MHR | Run Conforman | | | |
|--|---|---|---|---|--|--------------------------------------|------------------|
| | | - | 0 P2P | Show Report | | | |
| empiates | e Decharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) - | 1 | | | | | |
| dn Rules: | Select additional rules template folder for validation | 6 | | | | | |
| ormation | Rendered Document Sign File Sign File Information Template Validation Report Package Report | Reference Set | 5 Other Terminol | ogy Aspects | | | |
| | | | | | | | Override Results |
| | | | | | | | Override Result |
| erminolo | ocy Validation | | | | | | |
| | SARCENTER STREET, | | | | | | |
| roblem | /Diagnosis > Problem/Diagnosis Description | | | | | | |
| | and the second and the second second | | | | | | |
| o metching | p code found for '301483011' in code system '2.16.840.1.113883.6.96' for the reference = 301483011 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Asthma Calculated | set 'Probler | n Diagnosia (PD | | and all the day of the | a m. a februar | |
| | <pre>ton[1]/ida.component[1]/ida.setion[1]/ida.entry[1]/ida.observation[1]/ida.value[1]</pre> | Name (Co | (CANER-DOC)/10 | ind shoes compo | vend strogerenvi | convectional r h constrainte | ~ |
| roblem | /Diagnosis > Problem/Diagnosis Description | | | | | | |
| | | | | | | | |
| | | | | | | | |
| ode Value | g code found for '413014010' in code system '3.16.840.1.113883.6.96' for the reference = 413014010 Codedystem = 2.16.840.1.113883.6.96 Ouplay Name= Elevation of Sa02 sporent[2]/distanction[1]/distancesconer[1]/distancescine]1/distancescine]/2[/distancescine] | Calculated | Name / oda / Clini | y calDocument[1]/c | daxcomponent[1 |)/cda.structured8ody | × |
| ode Value 1]/cda:com | + 413014010 Codedystem + 2.16.840.1.113883.6.96 Display Name+ Elevation of SaO2 | Calculated n[1]/cdarw | Name/oda/Cirv Hus[1] | calDocument[1]/c | da.component[1 |) ^r oda i structured Body | × |
| i)/dation | 413214010 Codedpatem = 2:16.840.1.113883.6.96 Daplay Name Elevation of 3e02 paperent(2)/cds.usetion(1)/cds.component(1)/cds.usetion(1)/cds.usety(2)/cds.usetsyn(2)/cds.usets | Calculated n[1]/cdarw | Name/oda/Cirv Hus[1] | calDocument[1]/c | da :component[1 |)'da studuredilody | × |
| ode Value 1)/cda.com Jinical I o matching ames/cda | + 413014010 Codedystem = 2.16.840.1.113883.6.96 Display Name= Elevation of SaO2 sponent[2]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[2]/cda:bbaevatio | Calculated n[1]/cdario cal Inter | Name/(darCin /los[1] vention Des | celDocument(1)/c | |)/ofa-structuredNody | * |
| ode Value 1)/cdancon Sinical I o matching ames/cda cdancode/(| 413214010 Codedpatem = 2:16.840.1113883.649 Daplay Name Elevation of 3a02 posent(2)/cds.usetion(1)/cds.component(1)/cds.usetion(1)/cds.usety(2) | Calculated n[1]/cdarw cal Inter de/@code+ | Name/IdarCin Hos[1] Vention Des | celDocument(1)/c | | Yoda istractured lively | * |
| ode Value)/darcon linical I o matching ameu/oda darcoda/(est Spe | * 413614010 Codedpatem = 2:16.840.1.113883.496 Daplay Name Elevation of 3e02 spenent(2)/cds.usetion(1)/cds.component(1)/cds.usetion(1)/cds.usety(2) | Calculated n[1]/cdarw cal Inter de/@code+ | Name/IdarCin Hos[1] Vention Des | celDocument(1)/c | |)/cde.istructuredBody | × |
| ode Value)/oda.com linical I o matching amer/oda de.code/(est Spe o matching amer/oda de.code/(ot.20117 | 413614010 Codedpatem = 2:16.840.1113883.636 Daplay Name Elevation of 3e02 papenet(2)/delaustical/11/delausticad/11/delaustical/11/delausticad/11/delaus | Calculated n(1)/cdarw Cal Inter de/@code= Location | Name_/odarCin ilus[1] vention Des '101.16006']/ed I Name = '103.16006']/ | calDocumant(1)/c cription a.component/cda | section | sde/goode = | × - |
| ofe Value Volaccon Einical I ormatchin imet/dat decode/(est Spe imatchin imet/dat 01.2017 02.16136 | 413214010 Codedpatem = 2:16.840.1113883.490 Daplay Name Elevation of 3e02 posent(2)/cds.usetion(1)/cds.usetion(1)/cds.usetive(2)/cds | Calculated n(1)/cdarw Cal Inter de/@code= Location | Name_/odarCin ilus[1] vention Des '101.16006']/ed I Name = '103.16006']/ | calDocumant(1)/c cription a.component/cda | section | sde/goode = | × |
| ode value)/claiton linical I o matching imme:/claid deitcode/(est Spe o matching imme:/claid 01.20117 02.16136 est Spe o matching o mat | 413014010 Codedpatem = 2:16.840.1113883.640 Daplay Name Elevation of 3e02 papenet(2)/deliaisetion(1)/ | Calculated n(1)/cdarw cal Inter de/@code+ Location ode/@code (@classCod | Neme(rodarChrw Hor(2) Tot.16006')/ed Name = '103.16006')/e = '086')/obre | calbocument(1)/cfa | section le section (cdarco darobservation (c | sda/ĝecda = darceda/ĝecda = | × - - |

Figure 50: Reference Sets tab showing results of reference set validation

Validation result symbols and their meanings are listed in Table 11.

| Symbol | Explanation | Usage |
|----------|-------------|---|
| V | Pass | All attributes of the data element have the expected value. |
| × | Fail | A code of the required type was found but did not have the expected value, or the display name was not correct. |

Table 11 – Reference set validation symbols

| Symbol | Explanation | Usage |
|--------|-------------|---|
| - | Warning | An attribute of the data element does not have the expected value and the test result can only be determined through manual inspection and then a decision of 'Pass' or 'Fail'. |
| | Not Run | The data element is either not present or does not contain terminology codes. |

If the conformance level is 3B, the Validator reports a Fail (\thickapprox) if a clinical document does not use the code set specified in the 'Vocab' column of the relevant CDA implementation guide.

For all conformance levels, the Validator reports a Fail (i) if:

- the value of a code does not exist in the terminology reference set specified in the relevant CDA implementation guide; or
- the display name of a code in a clinical document does not match that code's display name in the terminology reference set.

For all conformance levels, the Validator reports a Warning (Improved the provided the provided

- the code system name in a clinical document is not the name specified for that code system; or
- the clinical document contains a code from a code system that is not supported by the Validator.

3.6.9 Other Terminology Aspects tab

The **Other Terminology Aspects** tab (Figure 51) displays the results of validating any codes within the clinical document (for which the Validator may be used) that are members of the code systems listed in Table 1.

| File : | C:'pemp\DS_3A.sp | 2 | * MHR | Run Conformance |
|-------------|---|-----------|-----------------|-----------------|
| | | | P2P | Show Report |
| Template: | e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | | | |
| Addn Rules: | Select additional rules template folder for validation | | | |
| Information | Rendered Document Sign File Sign File Information Template Validation Report Package Report | Reference | Sets Other Term | inology Aspects |

Figure 51: Other Terminology Aspects tab

Information is displayed in the **Other Terminology Aspects** tab in the same way as information is displayed in the **Reference Sets** tab (Section 3.6.8).

3.7 Override Results command

After the validation has been performed (for a purpose for which the Validator may be used), the **Override Results** command is displayed in the Terminology Report tab (Figure 52).

| File : | C: (temp/DS 3A.ap | 2 | MHR | Run Conformance | |
|------------|---|---|-----|-----------------|--|
| | | | P2P | Show Report | |
| emplate: | e-Discharge Summary 3A. (1.2.36.1.2001.1006.1.20000.26 ver 32620) | | | | |
| ddn Rules: | Select additional rules template folder for validation | 0 | | | |

Figure 52: Override results command displayed in Other Terminology Aspects tab

The Validator allows the user to override package and code validation results. This is useful for tests that may result in a 'Warning' rather than a 'Pass' or a 'Fail'. A 'Warning' is displayed when the outcome of a test can only be determined by manual inspection.

The Validator allows a user to manually change a test result when a 'Warning' message is displayed. Although the purpose of this command is to allow a user to override a 'Warning' test result, the command also allows the user to override a 'Pass' or 'Fail' result. Overriding a 'Fail' result may result in an overall 'Pass' being reported in the test report although the My Health Record system may reject the clinical document when it is uploaded.

By selecting **Override Results,** a new window that allows the user to select the code validation result to be overridden is displayed (Figure 53).

| Passed Warning | | |
|--|--------------|--|
| XPath AssessmentComments | ActualResult | Override Result |
| Code Value = 430698003 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Replacement of total knee joint Calculated Name/cda Clinica | | |
| Code Value = 399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Name= chest x-ray Calculated Name:/cda.ClinicalDocument[1]/oda.c | Warning | |
| Code Value = 426496006 CodeSystem = 2.16.840.1.113883.6.96 Display Name = Hydrogen cyanide gas Calculated Name //oda:ClinicalDocum | Warning | - |
| Code Value = 80313002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Palpitations Calculated Name-/cda:ClinicalDocument[1]/cda:c | Warning | - |
| | | XPath AssessmentComments ActualResult Code Value = 430598003 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Replacement of total knee joint Calculated Name/cda ClinicalDocument[1]/cda.c Warning Code Value = 4399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Name= chest x-ray Calculated Name/cda ClinicalDocument[1]/cda.c Warning Code Value = 426496006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Hydrogen cyanide gas Calculated Name/cda ClinicalDocum Warning |

Figure 53: Overriding a code validation result

The XPath column contains the value of the code, the code system object identifier, the value of the display name, and the location of the data element that contains the code.

The user can manually record a new result and the reason for the change (Figure 54).

Note: To avoid processing errors, double quotation marks ("") should be used rather than single quotes (') to record the reason for the change. For example, "SNOMED CT-AU" should be used rather than 'SNOMED CT-AU'.

| Failed | Passed Warning | | | | |
|--------|--|---|--------------|----------------|---|
| | XPath | AssessmentComments | ActualResult | OverrideResult | |
| 1 | Code Value = 430698003 Code System = 2.16.840.1.113883.6.96 Display Na | The actual name of SNOMED is close enough to the expected value of SNOMED CT-AU | Warning | Warning | • |
| | Code Value = 399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Na | | Warning | | • |
| | Code Value = 426496006 CodeSystem = 2.16.840.1.113883.6.96 Display N | | Warning | | - |
| | Code Value = 80313002 CodeSystem = 2.16.840.1.113883.6.96 Display Na | | Warning | | - |

Figure 54: Recording a new code validation result and the reason for the change

The override changes the overall test result displayed on the Validator's Information tab (Section 3.6.1).

3.8 Show Report command

The **Show Report** command (Figure 55) allows a user to request the Validator to create a test report (for which the Validator may be used). It also creates an HTML file that is a rendered view of the clinical document that has been validated.

| Field | Critempip5 3A.ap | 3 | * MHR | Run Conformance | |
|------------|--|---|-------|-----------------|--|
| | | | © P2P | Show Report | |
| Template: | e-Decharge Summay 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620) | | | | |
| ádn Rules: | Select additional rules template folder for validation | 0 | | | |

Figure 55: Requesting the Validator to create a test report

The Validator also provides the user with the option of entering information about the tests performed including the name of the author and tester; the names of the software development and tester organisations; and information about the software being tested and the test environment (Figure 56). This information is remembered and does not need to be re-entered every time the Validator is used.

| Conformance Report Information | — X | |
|---------------------------------------|-----------------|---|
| Report Details | | |
| Author Name: | | |
| Software Development Organisation: | | |
| Report Identifier: | | |
| Developer Name: | | |
| Name of implementation under test: | | |
| Version of implementation under test: | | |
| Test environment: | | |
| Location of assessment (address): | | |
| Tester name: | | |
| Tester organisation: | | |
| Other information: | | |
| | | |
| | Continue Cancel |] |

Figure 56: Recording information about the tests performed

The test report is in Adobe PDF format and contains:

- assessment details, such as the conformance level, context and template ID;
- a list of terminology codes used;
- a summary of the validation test results;
- a detailed error report for each type of validation;
- a reference to the HTML file containing the rendered view of the clinical document that has been validated; and

The PDF file is saved and is located in the same directory as where the target file has been selected from.

The summary of the validation test results shows the overall result and the total number of issues and warnings reported by the Validator (Figure 57).

Note: If there are warnings but no issues, the overall test result recorded is a 'Pass', as shown in the 'Overall result' for the 'Other Terminology Validation' in Figure 57.

| | Overall result | Error count | Warning count | Comments |
|------------------------------|-------------------|----------------|------------------|----------|
| Template Validation | × | 2 | 0 | |
| Package Validation | × | 12 | 0 | |
| Terminology Validation | × | 1 | 10 | |
| Other Terminology Validation | ~ | 0 | 4 | |
| Additional Rules Validation | - | 0 | 0 | |

Figure 57: Test report showing a summary of the validation results

If a validation result is overridden before the test report is generated, the report records the original result, the new result, and the reason why the original result was overridden (Figure 58). The Validator uses the new result when it produces the summary of validation results in the test report.

| # | CodeSet/Code/Name | Comment | Resul t | Overr ide |
|---|--|---|-------------|--------------|
| 1 | Code Value = 73817000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Enteritis due to radiation | The actuial codeSystemName value "SNOMED" is close enough to the expected value "SNOMED CT-AU" | Warni ng | Pass |
| | Calculated XPath:/cda:ClinicalDocument[1]/cda:component[1]/cda:struct uredBody[1]/cda:component[1]/cda:section[1]/cda:component [1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:value[1] | | | |



3.9 Cumulative report of test results

The Validator creates a cumulative report of test results in the file report.csv which is located in the same directory as where the target file has been selected from. A new row is added to this file each time a clinical document or clinical package (for which the Validator may be used) is validated. The information recorded in this file is listed in Table 12.

| Label | Description |
|------------------|---|
| Input File Name | The filename of the clinical document or clinical package that was validated. |
| Test Date | The date and time the file was assessed by the Validator. |
| Template Name | The name of the My Health Record template package as recorded in the template package metadata. |
| Template ID | The identifier of the My Health Record template package as recorded in the template package metadata. |
| Template Version | The version number of the My Health Record template package as recorded in the template package metadata. |

| Table 12 - | Information | in the | report.csv file |
|------------|-------------|--------|-----------------|
| Table 12 - | Innormation | in the | report.csv me |

| Label | Description |
|----------------------------|---|
| Template Effective Date | The date the My Health Record template package was approved as recorded in the template package metadata. |
| Conformance Level | The conformance level as recorded in the template package metadata. |
| Test Context | The value is either 'MHR' or 'P2P'. |
| Package Errors | The number of clinical package errors. |
| Package Warnings | The number of clinical package warnings. |
| Template Errors | The number of errors reported by applying the My Health Record template package. |
| Template Warnings | The number of warnings reported by applying the My Health Record template package. |
| | Note: template packages in the My Health Record system do not report warnings. |
| Additional Rules Issues | The number of issues reported by applying the additional template package. |
| Additional Rules Warnings | The number of warnings reported by applying the additional template package. |
| Reference Set Errors | The number of errors reported by applying reference set validation (Section 2.3.1). |
| Reference Set Warnings | The number of warnings reported by applying reference set validation (Section 2.3.1). |
| Other Terminology Errors | The number of errors reported when validating codes from supported code systems. |
| Other Terminology Warnings | The number of warnings reported when validating codes from supported code systems. |
| Summary | An overall Pass or Fail. |

4 Examples of validation

This section provides examples to demonstrate how the Validator can be used to validate clinical documents and clinical packages (for which the Validator may be used). The Validator is a tool to assist users only and while it assists in testing conformance, it does not, and should not be relied upon to test all conformance specifications. Please refer further to the *Clinical Package Validator Product Data Sheet* and confirm your intended use with the Agency Help Desk on 1300 901 001.

4.1 Validate a 3A eReferral clinical package, My Health Record context

The following example shows how the Validator may be used to assess an eReferral clinical document within a clinical package for level 3A conformance in the My Health Record context.

1 If the Validator has been installed and configured but is not already launched, launch the Validator as follows.

If using Windows 7, navigate to **Start** > **All Programs** > **Agency** > **Clinical Package Validator**.

If using Windows 8 or above, click the Windows icon to open the Metro view and either search for "Clinical Package Validator" or visually locate the application menu.

| <u>i</u> | Clinical Package Validator v2.5 | | - 🗆 × | |
|--|--|---------|-----------------|--|
| File Configuration Help | | | | |
| File : Select an input file to | validate | MHR P2P | Run Conformance | |
| Template: | ✓ | | | |
| Addn Rules: Select additional rules | template folder for validation | | | |
| Information | | | | |
| Document Type: Template Package Name: Template Package ID: Conformance Level: Template Effective Date: | te Package Document Type Template Package Name Template Package ID Conformance Level | | | |

The default screen will appear (Figure 59).

Figure 59: Default Validator screen

- 2 Click the XML button () next to the **File** parameter and locate the clinical package to be validated, or drag the clinical package onto the **Information** tab or the **File** location field (Section 3.2.1).
- 3 If more than one eReferral template is imported in the Validator, select the relevant template for a level 3A eReferral (Figure 60).

The default context for validating a clinical package is My Health Record (Section 3.2.4).

| File Confi | puration Help | | |
|-------------|---|-----|-----------------|
| File : | C:\temp\eReferral.zp | MHR | Run Conformance |
| | | P2P | Show Report |
| Template: | e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624) | | |
| Addn Rules: | Select additional rules template folder for validation | | |
| Information | | | |

Figure 60: Template selection

Figure 61 shows the Validator **Information** tab, after the parameters for testing an eReferral for level 3A conformance in the My Health Record context have been selected.

| File Confi | guration Help | | | |
|-------------|---|----------|-----|-----------------|
| File : | C:\temp\eReferral.zip | | MHR | Run Conformance |
| | | | P2P | Show Report |
| Template: | e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624) | • | | |
| Addn Rules: | Select additional rules template folder for validation | Contract | | |
| Information | | | | |
| Configu | ration and Runtime Information | | | |

Figure 61: Information tab showing information about the clinical document and template package

4 Click the **Run Conformance** button to perform the validation (Figure 62).

| File Confi | guration Help | | | |
|-------------|---|-----------|--------------------------------------|-----------------|
| File : | C:\temp\eReferral.zip | 5 | MHR P2P | Run Conformance |
| Template: | e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624) | | | |
| Addn Rules: | Select additional rules template folder for validation | \square | | |
| Information | | | | |
| Configu | ration and Runtime Information | | | |

Figure 62: Selecting the **Run Conformance** button

The **Information** tab shows a summary of the validation results (Figure 63). In this example there are 32 template errors, 6 CDA Package errors, 5 reference set errors and 0 warnings for other terminology aspects.

| | | | | dator development\CDA Vali refer to WEB-CDAR_AS_05 | | | - | MHR | Run Conformance |
|---|---|---------------------------------|---|---|----------------|------|-------------|-----------------|-----------------|
| remplate: e-Referral 38 (1.2.36.1.2001.1006.1.21000.17 ver 32624) | | | | | | | | | Show Report |
| ddn Rules: | Select additional re | ules template | e folder for validation | | | | 0 | | |
| formation | Rendered Document | Sign File | Sign File Information | Template Validation Report | Package Report | Refe | erence Sets | Other Terminolo | gy Aspects |
| Ťe | late Package Nan emplate Package Conformance Lev plate Effective Da Template Versio | ID: 1.2.3 el: 38 te: Mono | 6.1.2001.1006.1.21 day, 1 April 2013 | 000.17 | Vali | dati | on Sum | mary | |

Figure 63: Information tab showing a summary of the validation results

The **Rendered Document** tab displays a rendered view of the eReferral that was validated (Figure 64).

| File : C:templefteferral.zp | | Sand Sand | • MHR • P2P | Run Conformance Show Report |
|--|--|--|----------------------------|--|
| Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 3 | 824) - |] | | |
| ddn Rules: Select additional rules template folder for validation | | 0 | | |
| information Rendered Document Sign File Sign File Informatio | on Template Validation Report Package Report | Reference Sets | Other Termi | nology Aspects |
| Back Forward | | | | |
| Beau O'KEEFE DoB 6 Jun 2005 (7y) | e-Referral 6 Aug 2012 SEX Male IHI 8003 6067 9000 | 0495 | | |
| | START OF DOCUMENT | | | |
| Phone 0345754566 | | | | |
| Phone 0345754566 Referral Detail Date and Duration Date | Duration | | | |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 | | | | |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral | Duration 6 month | | | |
| Phone 0345754566 Referral Detail Date Date 0 12 Dec 2011 16:10+1000 0 | Duration 6 month e handler with pain in his Left knee. He i | | ee whilst di | sembarking from an aircraft at work. |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas baggag WorkCover have requested that he seek an conion | Duration 6 month e handler with pain in his Left knee. He i | | ee whilst di | sembarking from an aircraft at work. |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas baggag WorkCover have requested that he seek an opinion Medications | Duration 6 month e handler with pain in his Left knee. He i | | ee whilst di | sembarking from an aircraft at work. |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas baggag WorkCover have requested that he seek an opinion Medications | Duration 6 month e handler with pain in his Left knee. He i | | ee whilst di | sembarking from an aircraft at work. |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas baggag WorkCover have requested that he seek an coinion Medications Medications | Duration 6 month e handler with pain in his Left knee. He from a specialist to ascertain the extent Directions 6 to 8 hour | of his injury. | Do not exce | sembarking from an aircraft at work, ed 4 within 24 hours. Do not crush, che rric-coated tablet. Swallow the pill whol |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas baggag WorkCover have requested that he seek an opinion Medications Medications Medications Medications | Duration 6 month e handler with pain in his Left knee. He from a specialist to ascertain the extent Directions 6 to 8 hour or break an | of his injury. s as needed. t extended-rel | Do not exce ease or ent | ed 4 within 24 hours. Do not crush, che |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas begoag WorkCover have requested that he seek an opinion Medications Medications Medication naproxen 250 mg tablet, 50 | Duration 6 month e handler with pain in his Left knee. He from a specialist to ascertain the extent Directions 6 to 8 hour or break an | of his injury. s as needed. t extended-rel | Do not exce ease or ent | ed 4 within 24 hours. Do not crush, che rric-coated tablet. Swallow the pill whol |
| Phone 0345754566 Referral Detail Date and Duration Date 12 Dec 2011 16:10+1000 Reason for Referral Thank you for seeing this 7 year old Qantas baggag WorkCover have requested that he seek an opinion Medications Medications Medication naproxen 250 mg tablet, 50 tramadol hydrochloride 50 mg capsule, 20 | Duration 6 month e handler with pain in his Left knee. He from a specialist to ascertain the extent Directions 6 to 8 hour or break an | of his injury. s as needed. t extended-rel | Do not exce ease or ent | ed 4 within 24 hours. Do not crush, che rric-coated tablet. Swallow the pill whol |

Figure 64: Rendered Document tab showing a rendered view of the validated clinical document

4.1.1 View information about the eSignature file

The **Sign File Information** tab displays information about the primary eSignature file of the clinical package (Figure 65).

| | C: Venp'elleferal.ap | | | | | 1 | * MHR | Ban Conformance | | |
|---------------------------------------|---|--------------------|---|----------------------------|-----------------|-------------|-------------------|-----------------|--|--|
| | | | | | | | © P2P | Show Report | | |
| Template: e-Refemal 3A (1.2.36.1.2001 | | | 96.1.21000.21 ver 3263 | e. | | | | | | |
| ddn Rules: | E Select additional rules template folder for validation | | | | | 0 | | | | |
| nformation | Rendered Document | Sign File | Sign File Information | Template Validation Report | Package Report | Reference S | Sets Other Termin | ology Aspects | | |
| CDA SI | on File Informati | ion | | | | | | | | |
| | | M: N | | elth.net.au/id/hi/hpii/1/ | 0/8003615833334 | 118 | | | | |
| | Approver Person Approver Person Nar panisation Certific | ad : he me : Do | tp://ns.electroniche xtor Henry Button | alth.net.au/id/hi/hpii/1/ | 0/8003615833334 | 118 | | | | |

Figure 65: Sign File Information tab showing a summary of information about the primary eSignature file

This includes information about an approver's name and HPI-I, whether the PKI certificate had expired at the time of running the validation, and whether the PKI certificate is a NASH certificate.

The approver's name and HPI-I reported by the Validator in this tab can be used to check whether the healthcare software system is recording the same person as the approver of the clinical document.

In the above example, the Validator reported that the PKI certificate had expired when the validation was performed. This is not a problem if the certificate had not expired when the clinical document was signed.

In the above example, the Validator reported that the organisation certificate was not a NASH certificate. It is a requirement that all certificates used for signing clinical packages be NASH PKI certificates for healthcare provider organisations or NASH PKI certificates for supporting organisations. This error is also reported against the relevant test case in the **Package Report** tab.

The information displayed in the **Sign File Information** tab is usually the only information about the eSignature that is needed for validating a clinical document.

Additional information about the eSignature may be obtained by examining the CDA_SIGN.XML file displayed in the **Sign File** tab. In the following example, the PKI certificate is displayed to the right of the <X509Certificate> XML tag (Figure 66).

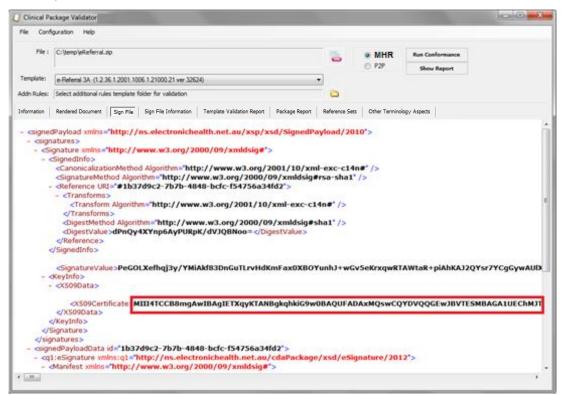


Figure 66: Sign File tab displaying the PKI certificate in the CDA_SIGN.XML file

To examine the PKI certificate, use a text editor to copy and save it to a document with the `.cer' filename extension. Double-click to open the saved document and view the certificate (Figure 67 and Figure 68).

| Certificate |
|--|
| General Details Certification Path |
| Certificate Information |
| Windows does not have enough information to verify this certificate. |
| |
| |
| Issued to: bay-hill-hospital.nehta.net.au |
| Issued by: SubCA |
| Valid from 13/ 07/ 2012 to 7/ 07/ 2013 |
| Install Certificate Issuer Statement |
| ОК |

Figure 67: A view of the PKI certificate

| Certificate | × |
|---|--|
| General Details Certification Path | |
| Show: <a>All> | - |
| Field | Value 🔺 |
| Valid from EValid to Subject | Friday, 13 July 2012 11:08:13 Sunday, 7 July 2013 12:00:00 bay-hill-hospital.nehta.net.au, ≡ |
| Public key Authority Information Access Enhanced Key Usage | RSA (2048 Bits) [1]Authority Info Access: Acc Server Authentication (1.3.6 |
| Certificate Policies | [1]Certificate Policy:Policy Ide |
| Subject Alternative Name | DNS Name=hav-hill-hospital n |
| [1]Certificate Policy: Policy Identifier = 1.2.36, 1.2001. [1,1]Policy Qualifier Info: Policy Qualifier Id=CPS Qualifier: | .1002.1.3.1.4.3 |
| http://policy.testsubmod1.pki.elect licy/NASH_HPIO_CP.pdf [1,2]Policy Qualifier Info: | ronichealth.net.au/testsubmod1/po |
| Ed Learn more about <u>certificate details</u> | lit Properties Copy to File |
| | ОК |

Figure 68: PKI certificate details

4.1.2 Display template validation results

To view the detailed template validation results, click the **Template Validation Report** tab (Figure 69). In this example, the error count was zero as no errors were found during template validation. The clinical document still needs to be manually inspected for conformance to requirements because not all conformance tests can be specified in a template (Section 2.2.1).

| File : C:\pemp\eReferral.zip | | | MHR | Run Conformance | |
|--|---|--------------------|---------------|-----------------|--|
| | | - | P2P | Show Report | |
| emplate: e-Referral 3A (1.2.36.1.2 | 001.1006.1.21000.21 ver 32624) | • | | | |
| Idn Rules: Select additional rules ter | plate folder for validation | | | | |
| formation Rendered Document Sig | n File Sign File Information Template Validation Report Package Rep | ort Reference Sets | Other Termino | ology Aspects | |
| | | Templa | te Valid | ation Report | |
| ALIDATION STATUS | Complete | | | | |
| SERVICE NAME | e-Referral - 3A | | | | |
| SERVICE PROVIDER | NEHTA | | | | |
| STANDARD TYPE | CDA R2 | | | | |
| STANDARD VERSION | N/A | | | | |
| DATE OF TEST | 20150702 | | | | |
| TIME OF TEST | 075747.1382712 +1000 | | | | |
| REPORT POSITIVE INDICATO | OR True | | | | |
| RESULT OF TEST | True | | | | |
| ERROR COUNT | 0 | | | | |
| WARNING COUNT | | | | | |
| SIGNATURE VALIDATION | See Package Report Tab | | | | |
| e (| | | | | |
| <pre><typeid 1.2.3<br="" root="2.16.840. <templateId root="><templateid 76af7a71-f400<br="" root="1.2.3 <id root="><code code="57133-1" oc<br=""><title>e-Referral</titl <effectiveTime value="1"</pre></td><td></td><td>2"/></td><td></td><td></td><td>rg/2001</td></tr></tbody></table></title></code></templateid></typeid></pre> | | | | | |

Figure 69: Template Validation Report tab showing template validation results

4.1.3 Display package validation results

To view the detailed package validation results, click the **Package Report** tab (Figure 70). The Validator reports some errors with the clinical package in this example, including the absence of a valid NASH certificate.

| File : | C: (temp/yelkeferral.ap | | • M IR • P2P | | onformance ov Report | | | |
|-------------------------------|---|--------------------|-----------------|------------|-------------------------|-------------------|--------------------------------|-----------------|
| emplater | e Referal 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624) | • | | | | | | |
| dn Rules: | Select additional rules template folder for validation | • | | | | | | |
| rmation | Rendered Document Sign File Sign File Information Template Validation Report Package Report | Reference Sets | Other Terminol | ogy Aspect | s | | | Duervide Result |
| NCD_P_0 | CP442_4 - Verify all packaged attachments have filename extensions which matches t | heir HIHE type | | | | | | |
| | | | | | | | | |
| | | | | | | | - | ~ |
| | 3743 - Verify that CDA package is not larger than 10HB | | | | | | | * |
| | 3743 - Verify that CDA package is not larger than 10HB | | | | | | | * * |
| PCD_022 | 3743 - Verify that CDA package is not larger than 10HB 2744 - Verify that a signed CDA package sent to the PCEHR system SHALL either costa a Signature with a valid RASH PKI certificate for supporting organisations | in an eSignature w | ith a valid N | ASH PRI | certificate fo | r healthcare prov | e ider organisations, o | * |
| PCD_023 | 3744 - Verify that a signed CDA package sent to the PCEHR system SHALL either costa | - | | | | | v der organisations, o v | * |
| CD_023 etain an ili COA | 3744 - Verify that a signed CDA package sent to the PCEHR system SHALL either conta a sSignature with a valid RASH PKI certificate for supporting organisations | nisation, or a sup | porting orga | nisation | (a CSP or GSC | | v der organisations, o v | * * |

Figure 70: Package Report tab showing package validation results

4.1.4 Display code validation results

To view the detailed code validation results, click the **Reference Sets** tab (Figure 71) and the click the **Other Terminology Aspects** tab (Figure 72). If any warning is reported, the clinical document must be manually inspected to determine whether a 'Pass' or 'Fail' should be recorded for the relevant code. The override facility may be used to record the outcome of this inspection (Section 3.7).

| Fig. : | | | | | | | | | | | |
|--|--|--------------|--|--|---|------------------------------------|---|--|---|--------------------------|-----------------|
| Pille 2 | C/genp/elleferal. | no | | | | - | . NHK | Run Conform | | | |
| ndate | - Defend the relation | a sola sol | 6.1.21000.21 ver 3262 | | | | © P2P | Show Repo | n | | |
| | Select additional rule | | | 7 | | - | | | | | |
| In Rules: | Select additional rul | | | | | | 1 | | | | |
| mation | Rendered Document | Sign File | Sign File Information | Template Validation Report | Package Report | Reference | Sets Other Term | inology Aspects | | | |
| | | | | | | | | | | | Override Result |
| _ | | | | | | | | | | | |
| | ogy validation | | | | | | | | | | |
| | | | | | | | | | | | |
| verse | Reaction > 9 | Substanc | e/Agent | | | | | | | | |
| | | | | | | | | | | | |
| | og elements found | | | | | | | | | | _ |
| | | | | Body/eduloamposent/st | | | | | | | |
| | Loope (besticide w) | ide particip | antRole/cds playing | eboor abo/vritivility | a ration (can the | e/Drode - | - 101 30113 he | danentry/clarac | Cost of the Posts | | _ |
| | | | | | | e/Doode - | - 101-20113 14 | darentry/coarac | Construction Broom | | |
| | | | Event > Manif | | | e/Brode - | - 101-20113 h | da antry tida at | | | |
| Nerse matche | Reaction > I | Reaction | Event > Manif | estation | | | | | | | |
| matcher matcher matcher | e Reaction > I | Reaction | Event > Manif | estation | a section(cda.cod | e/őcode - | - 101.20113'34 | darantiy/cdarad | tfoda model Brode | | _ |
| matchic matchic wei/colu 2.1551 | e Reaction > I ng elements hund inClinicalDocument 7 Victor entryRelati | Reaction | Event > Manif | estation Body/ode:component/od Ie/Brode = '102.16474' | a section(cda.cod | e/őcode - | - 101.20113'34 | darantiy/cdarad | tfoda model Brode | | _ |
| dverse matcho matcho 02.1551 | e Reaction > I ng elements hund inClinicalDocument 7 Victor entryRelati | Reaction | Event > Manif | estation Body/ode:component/od Ie/Brode = '102.16474' | a section(cda.cod | e/őcode - | - 101.20113'34 | darantiy/cdarad | tfoda model Brode | | - |
| dverse matche 12.1551 roblen | Reaction > I g elements found (ChriselDocument 7)/clasentryRelation A/Diagnosis > | Reaction | Event > Manif mentiodenatured observation[nda.co n/Diagnosis Ic | estation Body/rods:component/rd ls/Brode = '102.16474' Sentification | arsection[cds.cod /cds.antryRelatio | e/@code - nship[rda | - '101.20113')4 observe?ton/@r | da ientry/cda iac laxeCode = 'OB | t[cd=:cod=/@cod= []/od=:obervatio | n/idanioda | - |
| dverse matche 02.1551 roblen | Reaction > 1 | Reaction | Event > Manif met/objatistics objective/objective n/Diagnosis 14 2.16.040.1.113003 | estation Body/ods:component/td fer@code = '102.16474' dentification 4.95 Display Namen Est | la raection[oda rood]rodarantryRelatio antical hypertensio | e/@code - nship[rda | - '101.20113')4 observe?ton/@r | da ientry/cda iac laxeCode = 'OB | t[cd=:cod=/@cod= []/od=:obervatio | n/idanioda | - |
| dverse matcho mac/cdu co.1551 roblen de valu //da-co | e Reaction > 1 ing elements found informationument informationu | Reaction | Event > Manif met/ofentructured observation(ofence n/Diagnosis 1c 2.16.040.1.113003 is entry(13)/ofences | estation Body/cds:component/ud fer@code = '102.14474' fentification 4.96 Display Name= fis evation(1)/cds:relog(1) | la raection[oda rood]rodarantryRelatio antical hypertensio | e/@code - nship[rda | - '101.20113')4 observe?ton/@r | da ientry/cda iac laxeCode = 'OB | t[cd=:cod=/@cod= []/od=:obervatio | n/idanioda | - |
| dverse matcho matcho co. 1951 roblen sta sta yota valu j/ota-co | e Reaction > 1 ing elements found informationument informationu | Reaction | Event > Manif met/objatistics objective/objective n/Diagnosis 14 2.16.040.1.113003 | estation Body/cds:component/ud fer@code = '102.14474' fentification 4.96 Display Name= fis evation(1)/cds:relog(1) | la raection[oda rood]rodarantryRelatio antical hypertensio | e/@code - nship[rda | - '101.20113')4 observe?ton/@r | da ientry/cda iac laxeCode = 'OB | t[cd=code/@code 1]/ode-observatio | n/idanioda | - |
| dverse matcho mac/cdi col.1353 roblen de Valu J'oda-co roblen ode foun | Reaction > I reserves hours Constant Document Constant Document Constant Document Constant Document Polagnosis > A/Diagnosis > document | Reaction | Event > Manif observation[cda.com n/Diagnosis Te 2.16.646.1.113883 in entry[1]/cda.com n/Diagnosis Te t match. Expected. | estation Body/cda:component/id bd/gcode = '103.16474' dentification 4.96 Display Names fas evation[1]/cda:value[1] dentification Myocardial infarction | le section (offerced) rode centry it electro entitel hypertensio | e/@code nship[rde n Celoulet | - 101.20113')/ observation/go ted Name./ola.d | daramby/tidarad lassCode = 1080 DinicalDocuman | f(cda rocda/ĝosda 12]/da observatio 4(1)/da osmpona | n/cda.soda n/cda.soda | - |
| dverse s matcho imes/cds 02.1351 roblen ide value (roblen ide foun ide foun | c Reaction > 1 or alternetis found (ClinearDocument T)/rds.entryRelation a/Diagnosis > e = 39421000 Cos mponent(3)/rds.e a/Diagnosis > d but the display = = 22298006 Cos | Reaction | Event > Manif nert/ofautructured observation(ofaucos n/Diagnosis Ic 2:16.040.3:113003 intertry[1]/ofaucos n/Diagnosis Ic 4:math, topetheli | estation Body/ods.component/ud lef@code = '102.164'd' Jentification 4.96 Display.Name= Ess erration[1]/ods.reske[1] Jentification Myscandal infarction" (-3.96 Display Name= Hys | a section(ofa-cod) ofa-antip(felatio antial hypertensio ocardial Infarction | e/@code nship[rde n Celoulet | - 101.20113')/ observation/go ted Name./ola.d | daramby/tidarad lassCode = 1080 DinicalDocuman | f(cda rocda/ĝosda 12]/da observatio 4(1)/da osmpona | n/cda.soda n/cda.soda | - |
| matcho mec/cda 0.1551 oblen de Value /oda.co oblen de foun de Value /oda.co | c Reaction > 1 or alternetis found (ClinearDocument T)/rds.entryRelation a/Diagnosis > e = 39421000 Cos mponent(3)/rds.e a/Diagnosis > d but the display = = 22298006 Cos | Reaction | Event > Manif mart/ola attructured observation/ola new n/Diagnosis I (2.16.040.1.113883 intertry[1]/ola obse n/Diagnosis I (4.math, Streether 4.math, Streether 3.16.040.1.113883 intertry[2]/ola obse | estation Body/cda:component/id bd/gcode = '103.16474' dentification 4.96 Display Names fas evation[1]/cda:value[1] dentification Myocardial infarction | a section(ofa-cod) ofa-antip(felatio antial hypertensio ocardial Infarction | e/@code nship[rde n Celoulet | - 101.20113')/ observation/go ted Name./ola.d | daramby/tidarad lassCode = 1080 DinicalDocuman | f(cda rocda/ĝosda 12]/da observatio 4(1)/da osmpona | n/cda.soda n/cda.soda | - |

Figure 71: Reference Sets tab showing reference set validation results

| File Conf | guration Help | | | | | | | | | | | |
|-------------------------------|--|-------------------------|--|---|-------------------------------------|---------------------------------|-------------------------------------|---|---------------------------------|---|-----------------|--|
| File : | C/pempleReferra | .ap | | | | - | MHR | Run Conformance Show Report | | | | |
| Template: | e-Referal 3A (1.2 | 36,1.2001.1 | 006.1.21000.21 ver 32 | 124 | - | | | Second and a | | | | |
| dán Rules: | Select additional n | Aes template | fulder for validation | | | 0 | | | | | | |
| formation | Rendered Document | Sign File | Sign File Information | Template Validation Report | Package Report | Reference Sets | Other Terminology | y Aspects | | | | |
| | | | | | | | | | | | Overvide Result | |
| | | | | | | | | | | | | |
| | | | | 083.6.96 Display Name- Idamaction[1]/datentr | | | | | | | - | |
| SNOME | р ст | | | | | | | | | | | |
| ass Iode Valu 1)/cda.co | e = 88101002 Ce mponent[5]/cda | deSystem section[1]/ | + 2.16.840.1.1138 cds:component[1]/ | 13.6.95 Display Name+ Iodapaction[1]/odapactor | Pathology diagn ([1]/cda.observa | nsix Calculate dion[1]/ofane | f Name / IdarClo rbyRelationahip | nicalDocument[1]/r (5]/cda:observation | daicomponen n[1]/odaicoda | (1)/olantraturedlody [1] | ~ | |
| NOME | р ст | | | | | | | | | | | |
| lode Valu | a = 386344002 C | odeSystem | = 2.16.840.1.113 | di 'Laboratory data inter 583.6.96 Diaplay Namen (1)/eda.componant(1)/r | Laboratory find | ings data inte acentry[1]/cd | pretation Calcul aubservation[1] | sted Name //odarCl //odarentryRelation | inicalDocymen ship[6]/ola-si | t[1]/cda.component iservation[1]/cda.code[1] | 1 | |
| SNOME | р ст | | | | | | | | | | | |
| lio matchi liama://e | ng elements foun d:"[@codeByster | d 1472.16.84 | 0.1.113883.6.96] | | | | | | | | - | |
| Australi | an Medicines | Termin | ology (AMT) | | | | | | | | | |
| Code Valu | = 27555011000 ructuredBody[1]/e | 0361 Code | System = 1.2.36.1 | ystem (1.3.36.1.2001.1 .2001.1004.100 Display [1]/ode.evity[1]/ode.au | Name# Asprince | | | | | | - | |
| | | | | | | | | | | | | |

Figure 72: Other Terminology Aspects tab showing code validation results

4.1.5 Generate a test report

To generate a test report in Adobe PDF format, click the **Show Report** button (Figure 73). Enter details of information to be included in the report and then click the **Continue** button (Figure 74).

| se Cont | guration rep | | | | | | | | |
|-----------------------------|---|---------------------|---------------------------------------|-----------------|---------------------------------|------------------------------|-------------------------|-----------------------------------|------------------|
| Pie : | Critempi platernis.pp | 2 | * MHR | - | Run Conform Show Repo | - | | | |
| enplate: | e Referal 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624) | | | L | | | | | |
| dn Rulesi | Select additional rules template folder for validation | 0 | | | | | | | |
| formation | Rendered Document Sign File Sign File Information Template Validation Report Package | Report | Reference Sets | s [| Other Terminok | ogy Aspects | | | |
| | | | | | | | | | Overvide Results |
| | | | | | | | | | |
| eas ode Valu]/ode:co | e = 30(552006 CodeSystem = 2.16.640.1.113883.6.96 Display Name= report status Calcula mponent(5)/cds-section(1)/cds-component(1)/cds-section(1)/cds-setty(1)/cds-observation(| ited ha | me l/odar Clinica JentryRelational | iDeo Np(4 | want[1]/cda //cda.obsava | icomponent) Hon(1)/cdat | (1)/otheraty code(1) | ucturedBody | ~ |
| NOME | D CT | | | | | | | | |
| asis ode Valu | a = 88101002 CodeSystem = 2.16.843.1.113883.6.96 Display fiame= Pathology diagnosis mpower(1)/vda sactor(1)/vda compower(1)/vda antioc(1)/vda antio(1)/vda antioc | Calculat (13/ofe | ed Names/cdar sentryRelational | Clinic No(3 | alCocument() //ode:observo | 1)/oda.comp etion(1)/oda | onent[1]/c code[1] | de structuredilo | a 🖌 |
| NOME | р ст | | | | | | | | |
| odė Valu | d but the display, name did not match. Expected: "Laboratory data interpretation" = 386344002 CodeBystem = 2.36.540.1.13883.6.49 Org/ay Name* Laboratory findings wherealbudy/jude incompared/21/dis used/scillar.compared/11/display. | data int | terpretation Cal da observation | culati (1)/4 | ed Name Joda (a lentry talat | -ClinicalDoo tenship[6]/b | ament[1]/i decobuero | oda.component etion[1]/eda.com | (4) P |
| NOME | рст | | | | | | | | |
| | ng elements found n *[@coded;ystem=1:16.840.1.113883.4.96] | | | | | | | | - |
| ustrali | an Medicines Terminology (AMT) | | | | | | | | |
| ode Valu | ng code Round Rav 379550118000361' in rode evetem '1.3.36.1.2001.1004.100' = 227550118000361 CodeBydem = 1.3.36.1.3001.1004.100 Coupley Remain Represent 23 untureRody[1]/da.component[2]/ode.sentron[1]/da.antry[1]/da.subtranceAdministration 4(1] | | | | | | | | - P |
| ustrali | an Medicines Terminology (AMT) | | | | | | | | |
| | | | | | | | | | |

Figure 73: Generating a test report

| () Conformance Report Information | × |
|---------------------------------------|--|
| Report Details | |
| Author Name: | John Goodson |
| Software Development Organisation: | Good software coporation |
| Report Identifier: | 2015-06-15-01 |
| Developer Name: | |
| Name of implementation under test: | Good clinical information system |
| Version of implementation under test: | 4.0 |
| Test environment: | Windows 7 |
| Location of assessment (address): | 400 George Street, Brisbane, QLD, 4000 |
| Tester name: | John Goodson |
| Tester organisation: | Good software coporation |
| Other information: | |
| | |
| | Continue Cancel |

Figure 74: Adding test report information

The test report is now complete (Figure 75).

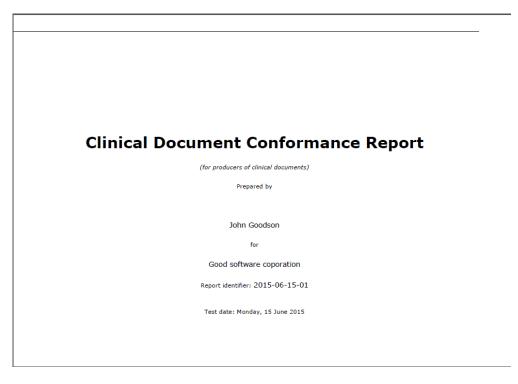


Figure 75: Completed test report

4.2 Examples of code validation

The Validator examines codes and their associated display names in some clinical documents and compares these against codes and display names in supported code systems. It then reports whether a code in a clinical document and its associated display name are valid i.e. the Validator will report a 'Pass', 'Fail' or 'Warning' for that code and display name.

A 'Warning' is reported if the Validator is unable to find a matching code and display name in a supported code system. As a warning may be reported due to an underlying error in the clinical document, warnings are investigated to determine why a code or display name in the clinical document could not be found in the supported code system. This helps the tester to determine whether to override the 'Warning' and record a 'Pass' or 'Fail' for that code and display name.

This section contains examples of code validation performed on some clinical documents created by actual health software systems, including examples where the result of code validation was overridden.

Please refer to the *Clinical Package Validator Product Data Sheet* for further details on the scope of tests for clinical terminology validation.

4.2.1 Australian Vaccine code error

Figure 76 shows a 'Warning' reported in the **Other Terminology Aspects** tab because the value of the displayName attribute for an Australian Vaccine code in a clinical document was not the expected name.

An examination of the list of Australian Vaccine codes (in the Australian Vaccine codes <u>website⁶</u>) showed that the expected displayName for the vaccine code 'ADT' is 'ADT' (the vaccine brand name). The override facility was used to report a 'Fail' because the displayName in the clinical document was 'BOOSTRIX'.

The display name is the name associated with a code, and both the code and display name should be imported into a clinical document from a code system. The originalText element is used to record text that is typed in or selected by a healthcare provider. In this example, the originalText element was not present in the clinical document. Instead of storing this text in the originalText element, the healthcare software system may have mistakenly recorded the text in the displayName attribute instead.

Australian Vaccine Code

Code found but the display name did not match. Expected: 'ADT' Code Value = ADT CodeSystem = 1.2.36.1.2001.1005.17 Display Name= BOOSTRIX Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody [1]/cda:component[5]/cda:section[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]

Figure 76: Other Terminology Aspects tab showing a warning for an Australian Vaccine code

4.2.2 ANZSCO code error

Figure 77 shows a 'Warning' reported in the **Other Terminology Aspects** tab because an Australian and New Zealand Standard Classification of Occupations (ANZSCO) code in the clinical document was not a valid code.

An examination of the set of ANZSCO codes showed that '2515' was not a valid code as it did not have the required six characters. '2515' indicates a group of classifications so trailing zeroes should have been added to this code i.e. '251500'. The letters 'nfd' (not further defined) should also have been added to the display name of the code i.e. 'Pharmacists nfd' [ABS1220.0]. The override facility was used to report a 'Fail'.

⁶ <u>http://www.humanservices.gov.au/health-professionals/services/australian-childhood-immunisation-register/acir-vaccine-code-formats</u>

ANZSCO Type Code

No matching code found for '2515' in code system '2.16.840.1.113883.13.62' Code Value = 2515 CodeSystem = 2.16.840.1.113883.13.62 Display Name= Pharmacists Calculated Name:/cda:ClinicalDocument[1]/cda:author[1]/cda:assignedAuthor [1]/cda:code[1]

Figure 77: Other Terminology Aspects tab showing a warning for an ANZSCO code

4.2.3 Australian PBS item code error

Figure 78 shows a 'Warning' reported in the **Other Terminology Aspects** tab because a PBS item code was not valid.

When a PBS item code is used to identify a therapeutic good in an eHealth prescription record or eHealth dispense record, the code must be at least six characters in length [NEHTA2015d]. The override facility was used to report a 'Fail' because the PBS item code only had five characters i.e. '1081X'. If the PBS item code had been prepended with one or more zeroes (e.g. '01081X'), the Validator would not have a reported a 'Warning'.

Australian PBS Code

```
No matching code found for '1081X' in code system '1.2.36.1.2001.1005.22'
Code Value = 1081X CodeSystem = 1.2.36.1.2001.1005.22 Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[1]/cda:section
[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:compable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]
```

Figure 78: Other Terminology Aspects tab showing a warning for an Australian PBS item code

4.2.4 Health Care Facility Type code error

Figure 79 shows a 'Warning' reported in the Other Terminology Report tab because the ANZSCO code that was used to describe the role of the document author i.e. '253111' did not have the matching ANZSCO code system identifier. Instead, the Validator found the ANZSIC code system identifier i.e. '1.2.36.1.2001.1005.47 and ANZSIC is used to describe the role of an organisation or facility, not the role or occupation of a person. The override facility was used to change the 'Warning' into a 'Fail' because the ANZSCO code system identifier should have been used.

Health Care Facility Type Code

No matching code found for '253111' in code system '1.2.36.1.2001.1005.47' Code Value = 253111 CodeSystem = 1.2.36.1.2001.1005.47 Display Name= General Medical Practitioner Calculated Name:/cda:ClinicalDocument[1]/cda:author [1]/cda:assignedAuthor[1]/cda:code[1]

Figure 79: Other Terminology Aspects tab showing a warning for a healthcare facility type code

4.2.5 Valid Australian Vaccine code

Figure 80 shows a 'Warning' and Figure 81 shows a 'Pass' for an Australian Vaccine code in an event summary. The 'Warning' was displayed in the **Reference Sets** tab and the 'Pass' was displayed in the **Other Terminology Aspects** tab.

The Validator examines the locations in a clinical document where an AMT, SNOMED CT-AU or PBS item code is expected, and reports a 'Warning' in the **Reference Sets** tab if one of the locations contains a code from an unexpected code system. In this example, the Validator expected a code from the AMT code system but instead found a code from the 'Australian vaccines codes' code system.

In the **Other Terminology Aspects** tab, however, the Validator reported a 'Pass' because the Validator found a code and display name from a code system supported by the Validator i.e. the 'Australian vaccines codes' code system.

The override facility was used to change the 'Warning' in the **Reference sets** tab into a 'Pass' because the Validator found a valid code from a supported code system and an AMT code is not mandatory when a clinical document is being tested for level 3A conformance.

Immunisation > Therapeutic Good Identification

No matching code system found; Found: Australian Vaccine Code[1.2.36.1.2001.1005.17] Expected: 1.2.36.1.2001.1004.100 or 2.16.840.1.113883.6.96 Code Value = PRPT CodeSystem = 1.2.36.1.2001.1005.17 Display Name= ACTHIB Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody [1]/cda:component[5]/cda:section[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]

Figure 80: Reference Sets tab showing a warning for an Australian Vaccine code

Australian Vaccine Code

Pass Code Value = PRPT CodeSystem = 1.2.36.1.2001.1005.17 Display Name= ACTHIB Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody [1]/cda:component[5]/cda:section[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]

Figure 81: Other Terminology Aspects tab showing a pass for an Australian Vaccine code

4.2.6 SNOMED CT-AU display name error

Figure 82 shows a 'Fail' reported in the **Reference Sets** tab for the display name of a SNOMED CT-AU code. The Validator reported that the display name 'Myocardial infarction' was expected but 'Myocardial Infarction' was found.

An examination of the SNOMED CT-AU database shows that the value of the case significance indicator for SNOMED CT-AU code '22298006' is '90000000000000020002', meaning that only the first character of the first word is case insensitive and all other characters are case sensitive i.e. the allowed spellings are either 'myocardial infarction' or 'Myocardial infarction'. The Validator correctly reported a 'Fail' for the display name in the clinical document.

```
Problem/Diagnosis > Problem/Diagnosis Identification
```

Code found but the display name did not match. Expected: 'Myocardial infarction' Code Value = 22298006 CodeSystem = 2.16.840.1.13883.6.96 Display Name= Myocardial Infarction Calculated Name:/cda:ClinicalDocument[1]/cda:component [1]/cda:structuredBody[1]/cda:component[3]/cda:estrion[1]/cda:component[1]/cda:component[1]/cda:component[3]/cda:component

Figure 82: Reference Sets tab showing a SNOMED CT-AU display name error

4.2.7 Valid omission of a code

Adverse Reaction > Substance/Agent

No matching code system found; Found: none Code Value = CodeSystem = Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:act [1]/cda:satticipant[1]/cda:participantRole[1]/cda:playingEntity[1]/cda:code[1]

> Figure 83 shows a 'Warning' reported by the Validator in the **Reference Sets** tab. No code was found in any of the locations where the Validator searches for codes. In this example, the clinical document was an event summary, which was being tested for level 3A conformance so inclusion of the code was optional. The 'Warning' was overridden with a 'Pass'.

Adverse Reaction > Substance/Agent

No matching code system found; Found: none Code Value = CodeSystem = Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:act [1]/cda:participant[1]/cda:participantRole[1]/cda:playingEntity[1]/cda:code[1]



4.2.8 SNOMED CT-AU code error

Figure 84 shows a warning reported by the Validator in the **Other Terminology Aspects** tab for the code '152305019'. An examination of the SNOMED CT-AU code set showed that '152305019' is a description identifier, rather than a concept identifier. The 'Warning' was overridden with a 'Fail' because a concept identifier should have been used.

SNOMED CT

No matching code found for '152305019' in code system '2.16.840.1.113883.6.96' Code Value = 152305019 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Allergy to nuts Calculated Name:/cda:ClinicalDocument[1]/cda:component [1]/cda:truturedBody[1]/cda:component[1]/cda:section[1]/cda:section[1]/cda:section[1]/cda:section[1]/cda:participant[1]/cda:participantRole [1]/cda:playingEntity[1]/cda:code[1]

Figure 84: Other Terminology Aspects tab showing a warning for a SNOMED CT-AU code

5 Batch validation

As an alternative to using the graphical user interface of Validator 2.5, the command line interface can be used to perform template, package, and code validation (for which the Validator may be used), and to produce test reports in XML format. The command line interface is used to validate batches of clinical documents and clinical packages. To confirm when the Validator can be used please refer to the *Clinical Package Validator Product Data Sheet* and confirm the intended use with the Agency Help Desk on 1300 901 001.

The Validator's command line interface is intended for use by software developers and testers using scripts or a batch file. For example, a software developer can create a script to command the Validator to validate a file, or to analyse test reports to determine whether any errors were found or if an expected error was reported. The script is invoked through the Validator command line interface.

5.1 Using the command line interface

To validate a file using the Validator command line interface:

 Open the Windows Command Prompt (Figure 85) by selecting Start -> All programs -> Accessories, and then clicking Command Prompt.

Note: The username that is displayed will vary from user to user.



Figure 85: Command prompt

2 Navigate to the root directory by typing the command cd and then press Enter (Figure 86).

| C3. | Command Prompt | - | × |
|--|--|---|---|
| Microsoft Windows [Ve (c) 2013 Microsoft Co | rsion 6.3.9600] rporation. All rights reserved. | | ^ |
| C:\Users\User Name>cd | N | | |
| C: \> | | | |
| | | | |

Figure 86: Root directory

3 Navigate to the Validator directory (i.e. 'CPV25') by typing the command cd "DigitalHealth\CPV25" and then press Enter (Figure 87).



Figure 87: Navigating to the Validator directory

4 Launch the Validator through the command line interface by typing the command

CPvalidator.exe "FileDirectory" "FileName/Pattern" "TemplateDirectory" "Target" "IncludePDFReport" "AdditionalRulesTemplateFolder"

where:

- a FileDirectory is the absolute path to the directory that contains file to be validated;
- **b** FileToValidate is the file/pattern of files to be validated;
- c TemplateDirectory is the OID of the template package which must have been downloaded already through the GUI;
- d Target is the context for package validation, i.e. My Health Record or P2P;
- e IncludePDFReport is either True or False depending on if you require the PDF summary report (which is saved and located in the same directory as where the target file has been selected from);; and
- f AdditionalRulesTemplateFolder is the absolute path to the root directory that contains the template package with additional validation rules.

Then press Enter.

If no additional rules are to be applied during package validation, the "AdditionalRulesTemplatePath" can be excluded from the above command (Figure 88).

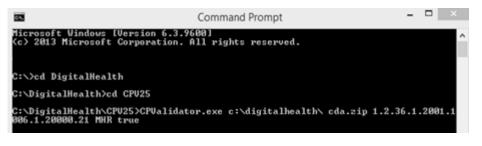


Figure 88: Launching the Validator through the command line interface

5 If, however, additional rules are also to be applied during package validation, the "AdditionalRulesTemplatePath" should be included in the above command (Figure 89).

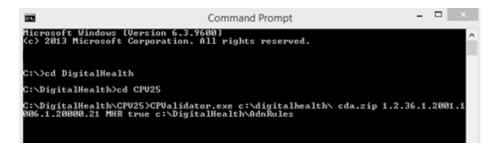


Figure 89: Launching the Validator through the command line interface

- 6 To use the command line interface, there are a number useful tips.
 - a Make sure you execute the command from the C:\DigitalHealth\CPV25 directory as the executable needs a number of files in order to run.
 - b Put quotation marks around each parameter, as for example some directory names have spaces in their names.
 - c For directory paths, use a double backslash as the application interprets single backslashes as escape characters
 - d For processing multiple files at the same time, you can only process files of the same document type, given that you have to specify the template type.

Below are some examples of how to use the command line interface.

Drop into a command prompt and type:

CD C:\DigitalHealth\CPV25

Example 1: single file with no PDF report

cpvalidator "c:\\temp\\" "cda.xml" "1.2.36.1.2001.1006.1.170.5" "MHR" "false"

Example 2: multiple files with a PDF report

cpvalidator "c:\\temp\\" "pres*.xml" "1.2.36.1.2001.1006.1.170.5" "MHR" "true"

Example 3: single file using an additional rules template

cpvalidator "c:\\temp\\" "cda.xml" "1.2.36.1.2001.1006.1.170.5" "MHR" "false" "c:\\temp\\AdnRulesTemplate"

Example 4: single zip file testing for Point to Point (P2P) rules and a report

cpvalidator "c:\\temp\\" "cda.zip" "1.2.36.1.2001.1006.1.170.5" "P2P" "true"

5.2 Analysing validation results

Validation results are stored in XML files in the "C:\DigitalHealth\CPV25\Temp" directory (Figure 90). If a script is written to validate a batch of clinical packages or clinical documents, it could contain instructions to copy these files to another directory after each validation because these files will be removed when another validation is performed. This is not mandatory as if you request the report PDF, it should contain all the details you need about each file, in addition to the report.csv file.

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|---------------|----------------------|---|--------------------|----------------|
| File Home S | are View | | | ~ |
| 🖻 🏵 🝷 🕇 🜗 | This PC → Windows (C | C:) → Nehta → CPV24 → Temp | ✓ C Search Ten | np 🔎 |
| ☆ Favorites | ^ Name | * | | Date modified |
| Desktop | EventSummary | /TestSet01_1A.zip.xml_Error_output | 15/04/2016 9:55 AM | XML_ERROR_OUT |
| Downloads | EventSummary | /TestSet01_1A.zip_Additional_output | 15/04/2016 9:55 AM | ZIP_ADDITIONAL |
| Recent places | EventSummary | /TestSet01_1A.zip_Error_output_Term | 15/04/2016 9:55 AM | ZIP_ERROR_OUTP |
| | EventSummary | /TestSet01_1A.zip_Other_Terminology_Valid | 15/04/2016 9:55 AM | ZIP_OTHER_TERM |
| 🝓 Homegroup | EventSummary | /TestSet01_1A.zip_PkgValResult | 15/04/2016 9:55 AM | ZIP_PKGVALRESU |
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| 8 items | | | | 855 |

Figure 90: Storage of validation results including additional template validation results

The XML files created by the Validator to store validation results are listed in Table 13, where <FileName> is the name of the file (i.e. clinical package or clinical document) that was validated.

| File name | Description |
|---|---|
| <filename>.xml_Error_output.xml</filename> | An XML report of template validation errors. |
| <filename>.xml_PkgValResult.xml</filename> | An XML report of package validation errors. This report is only produced if the file that was validated was either a clinical package or an HL7 MDM wrapped clinical package. |
| <filename>_Error_output_Term.xml</filename> | An XML report of reference set validation errors. |
| <filename>_Other_Terminology_Validations.xml</filename> | An XML report of other terminology aspects validation errors. |
| <filename>_Additional_output.xml</filename> | An XML report of additional template validation errors. |
| | Note: This xml file only appears if the AdditionalRulesTemplatePath is used. |

Table 13 - Files created by the Validator to store validation results

The file "report.csv" (Section 3.9) contains a cumulative summary of test results and the XML files listed in Table 13 contain detailed test results. The cumulative summary of test results may be used to complement analysis of the detailed test results.

A user of the Validator may write a script to interrogate the test report XML files. Unlike the graphical user interface where an image is displayed for a test result (Figure 91), the test results in the XML files are stored as references to an image (Figure 92) i.e. the graphical user interface reports a 'Fail' as the test result XML files report a 'Fail' as .

```
CPCD_023744 - Verify that a signed CDA package sent to the PCEHR system SHALL either contain an eSignature with a valid NASH PKI certificate for healthcare provider organisations, or contain an eSignature with a valid NASH PKI certificate for supporting organisations
Fail: CDA Package has NOT been signed with a NASH PKI certificate for a healthcare provider organisation, or a supporting organisation (a CSP or GSO).
```

Figure 91: Graphical user interface with image reporting a 'Fail' for clinical packaging test case CPCD_023744

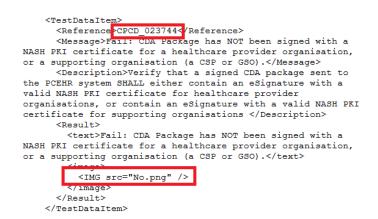


Figure 92: XML file with image reference reporting a 'Fail' for clinical packaging test case CPCD_023744

Scripts that interrogate the test result XML files should search for XML tags with references to an image. They should not search the error message for 'Pass', 'Fail' or 'Warning' text (Figure 92).

Table 14 describes the image reference associated with each test result.

| Test result | Image reference |
|-------------|--------------------------|
| Pass | |
| Fail | |
| Warning | |
| Not Run | |

| Table 14 - | Test results | and image | references |
|------------|--------------|-----------|------------|
|------------|--------------|-----------|------------|

Acronyms

| Acronym | Description |
|--------------|--|
| AMT | Australian Medicines Terminology |
| CDA | Clinical Document Architecture |
| DVA | Department of Veterans' Affairs |
| HL7 | Health Level Seven |
| HTML | HyperText Markup Language |
| JPEG | Joint Photographic Experts Group (image format) |
| MDM | Medical Document Management |
| NASH | National Authentication Service for Health |
| P2P | provider to provider |
| PBS | Pharmaceutical Benefits Scheme |
| РКІ | Public Key Infrastructure |
| SNOMED CT-AU | Systematized Nomenclature of Medicine Clinical Terms - Australia |
| URI | Uniform Resource Identifier |
| XML | Extensible Markup Language |
| ZIP | archive file format |

Glossary

| Term | Meaning |
|-----------------|--|
| body | The body of a clinical document contains the clinical information. |
| header | The header of a clinical document contains information about the patient, healthcare provider and administrative details. |
| narrative block | A narrative block is an XML fragment enclosed within <text> elements. A narrative block contains unstructured narrative text that is to be rendered into human-readable form. The narrative block may contain XML tags that rendering systems use to format the narrative.</text> |
| SNOMED CT | Systematized Nomenclature of Medicine - Clinical Terms is the internationally pre-eminent clinical terminology that has been identified as the preferred national terminology for Australia and has been endorsed by all Australian governments. |
| SNOMED CT-AU | SNOMED CT Australian Release (SNOMED CT-AU) is the Australian extension to SNOMED CT, providing local variations and customisations of terms relevant to the Australian healthcare community. It includes the international resources along with all Australian developed terminology. |
| structured data | Structured data is an XML fragment intended for computer processing. Structured data is not rendered for human readers. Some structured data is referred to as `coded data' as it is associated with a code system. |

References

| Reference | Description |
|--------------|---|
| [HL72004] | HL7 Clinical Document Architecture, Release 2.0; Health Level Seven International, 2004; <u>http://www.hl7.org/</u> |
| [IHTSDO2014] | SNOMED CT Technical Implementation Guide; International Health Terminology Standards Development Organization, 2014; http://www.snomed.org/ |
| [NEHTA2011a] | CDA Package, version 1.0; NEHTA, 2011; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-</u> <u>documents/EP-2320-2016/NEHTA-1229-2011</u> |
| [NEHTA2012a] | CDA Rendering Specification, version 1.0; NEHTA, 2012; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-</u> <u>documents/EP-2320-2016/NEHTA-1199-2012</u> |
| [NEHTA2012b] | P2P Document Delivery Technical Service Specification, version 1.1; NEHTA, 2012; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-1254-2012/NEHTA-1227-2012</u> |
| [NEHTA2014a] | Australian CDA Schema Extension, version 3.0; NEHTA, 2014; <u>https://www.digitalhealth.gov.au/implementation-resources/ehealth-reference-platform/EP-2344-2016/NEHTA-2150-2014</u> |
| [NEHTA2014b] | PCEHR Document Exchange Service Logical Service Specification, version 1.3.1; NEHTA, 2014; <u>https://www.digitalhealth.gov.au/implementation-resources/national-</u> <u>infrastructure/EP-2109-2015/NEHTA-1970-2014</u> |
| [NEHTA2014c] | PCEHR Document Exchange Service Technical Service Specification, version 1.5.1; NEHTA, 2014; <u>https://www.digitalhealth.gov.au/implementation-resources/national-</u> infrastructure/EP-2109-2015/NEHTA-1971-2014 |
| [NEHTA2015b] | Conformance Test Specification for CDA Packaging, version 1.5; NEHTA, 2015; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-</u> <u>documents/EP-2320-2016/NEHTA-2065-2015</u> |
| [NEHTA2015c] | Clinical Documents - Common Conformance Profile, version 1.6; NEHTA, 2015; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-</u> <u>documents/EP-2320-2016/NEHTA-1850-2015</u> |
| [NEHTA2015d] | eHealth Prescription Record - PCEHR Conformance Profile, version 1.3; NEHTA, 2015; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-</u> <u>documents/EP-1919-2015/NEHTA-1912-2015</u> |