Australian Government
Australian Digital Health Agency

Clinical Package Validator
User Guide

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V2.5
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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 help@digitalhealth.gov.au.

Australian Digital Health Agency
Level 25, 56 Pitt Street
Sydney, NSW 2000
Australia
www.digitalhealth.gov.au

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Document information

Key information

Owner	EGM Innovation & Development
Contact for enquiries	Australian Digital Health Agency Help Centre Phone 1300 901 001 Email help@digitalhealth.gov.au

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2.1	20 January 205	Feature and usability enhancements.
2.2	--	Not published.
2.3	17 July 2015	Software enhancements (see release note for details).
2.4	20 May 2016	Software enhancements (see release note for details).
2.5	29 May 2017	Software enhancements (see release note for details).

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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 help@digitalhealth.gov.au.

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 help@digitalhealth.gov.au 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 website[2], 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 http://www.digitalhealth.gov.au/implementation-resources/clinical-documents.

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.

Table 1 - Code systems supported by the Validator

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 levels[3], 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.

Table 2 - Code systems with additional validation against reference sets

Code system name	Code system identifier
Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU)	2.16.840.1.113883.6.96
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

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 Component	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 past and current medical history of the subject of care.	0..*	**entry[prob]**		
			entry[prob]/**observation**		
			entry[prob]/observation/**@classCode="OBS"**		
			entry[prob]/observation/**@moodCode="EVN"**		
			entry[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 available attributes.
			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/Diagnosis Identification**	Identification of the problem or diagnosis.	1..1	entry[prob]/observation/**value:CD**	SNOMED CT-AU Problem/Diagnosis Reference Set	See <code> for available attributes.
Problem/Diagnosis > **Date of Onset**	Estimated or actual date the Problem/Diagnosis began, in the opinion of the clinician.	0..1	entry[prob]/observation/**effectiveTime**		See <time> for available attributes.

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

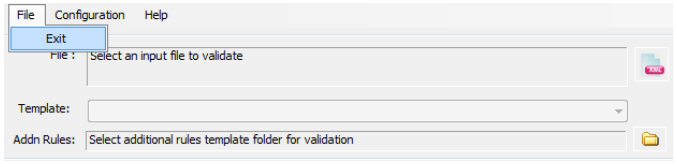

Figure 2: File menu option

- File → Exit

The Validator will close if this menu option is selected.

3.1.2 Configuration menu

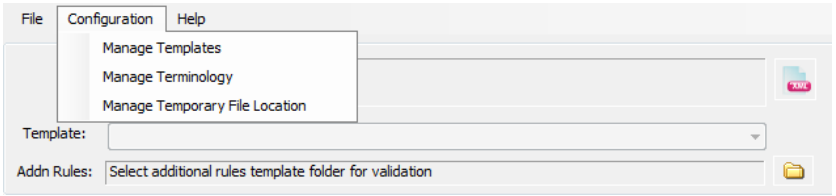

Figure 3: Configuration menu options

- 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*.

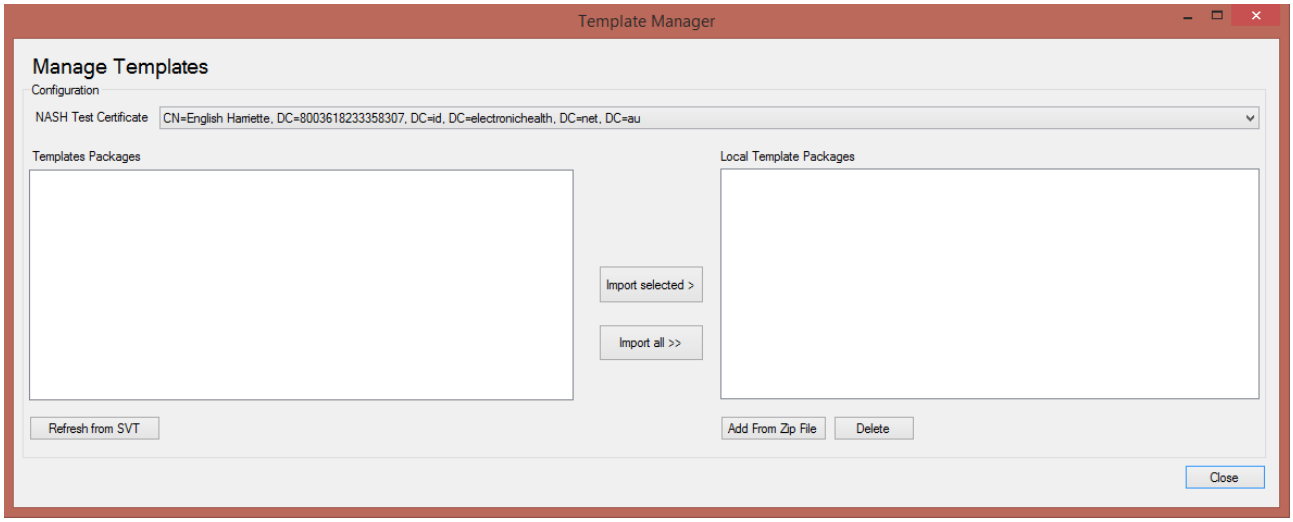

Figure 4: Template management menu

- Configuration → 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*.

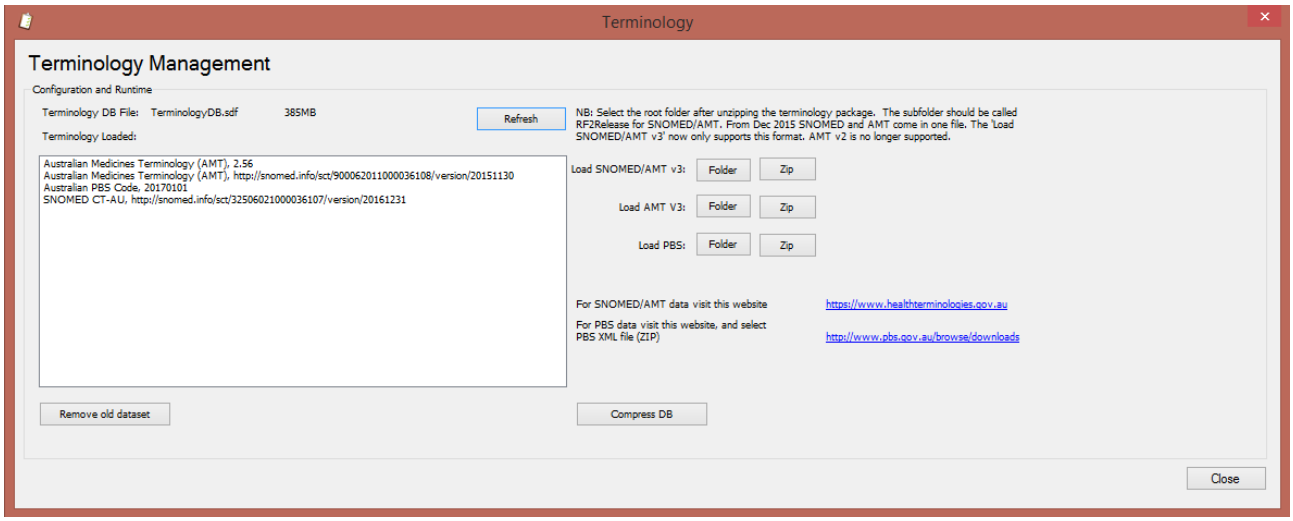

Figure 5: Terminology management menu

- 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.

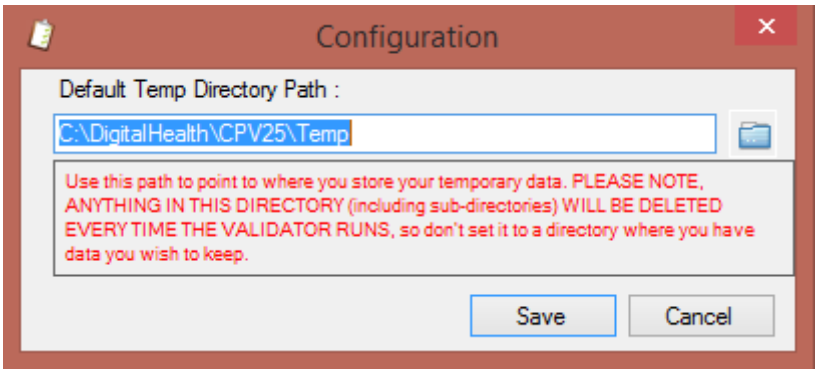

Figure 6: Default temp directory path menu

3.1.3 Help menu

- Help → 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.

Table 3 – Validator parameters

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'.

3.2.1 File parameter

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

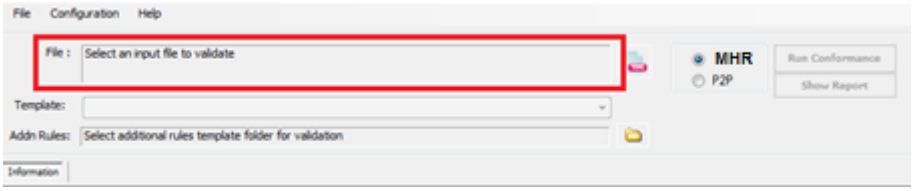

Figure 7: File parameter

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).

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).

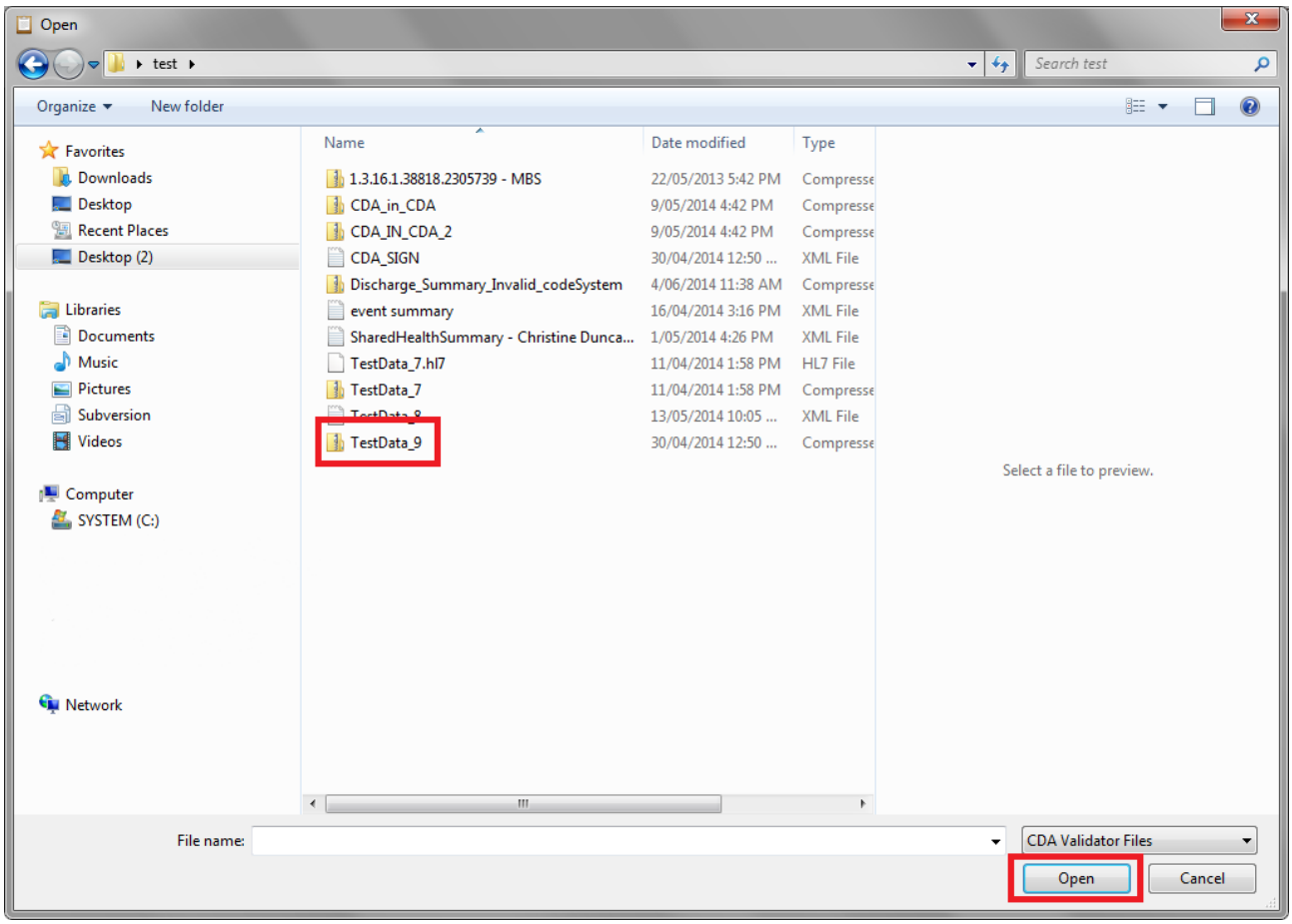

Figure 9: Selecting the file to be validated

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).

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**).**

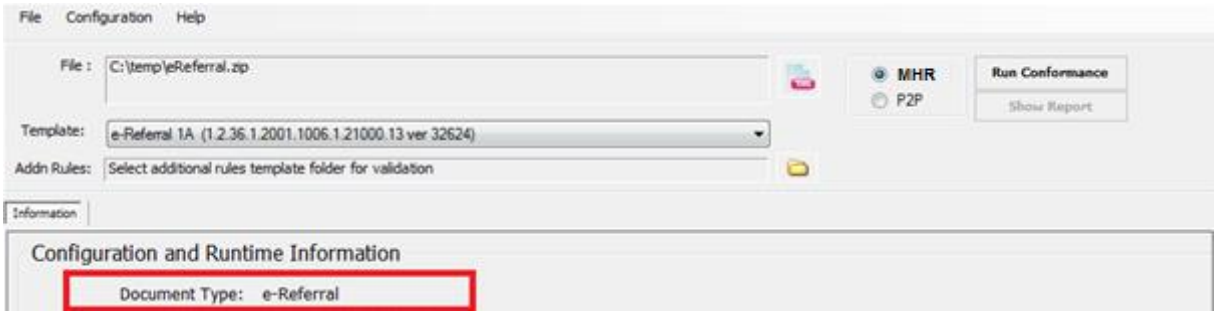

Figure 11: Document Type field displaying the type of the clinical document being validated

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

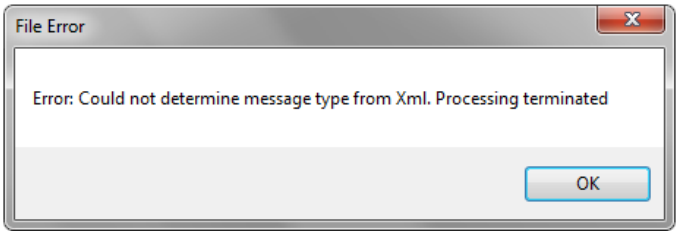

Figure 12: Error message when the type of a clinical document is unknown

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

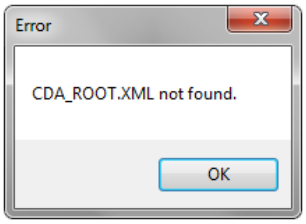

Figure 13: Error message when opening a ZIP file that is not a clinical package

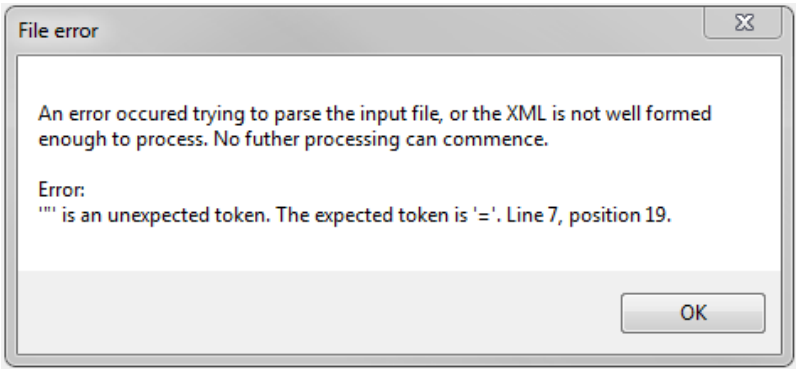

Figure 14: Error message when opening an XML file that does not conform to the HL7 CDA R2 specification

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**).**

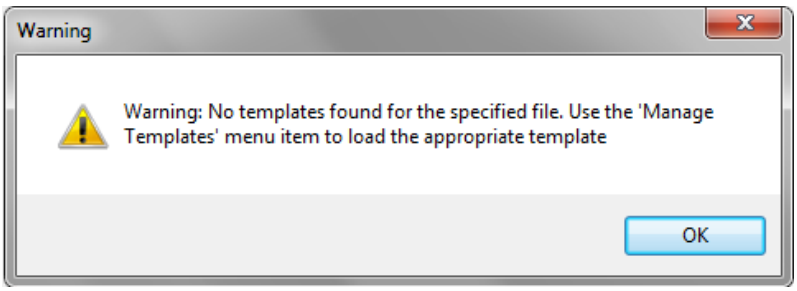

Figure 15: Error message when there is no template for the type of clinical document

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).

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] https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-2321-2016

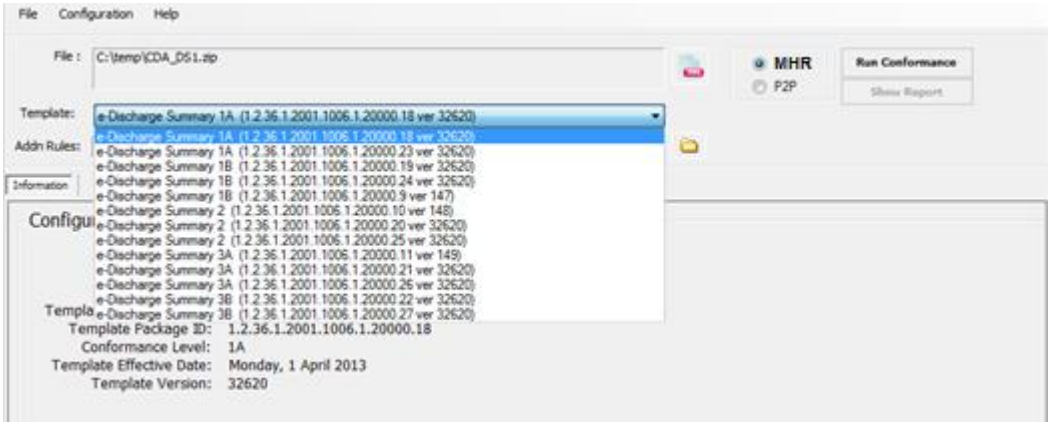

Figure 17: Selecting a template

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).

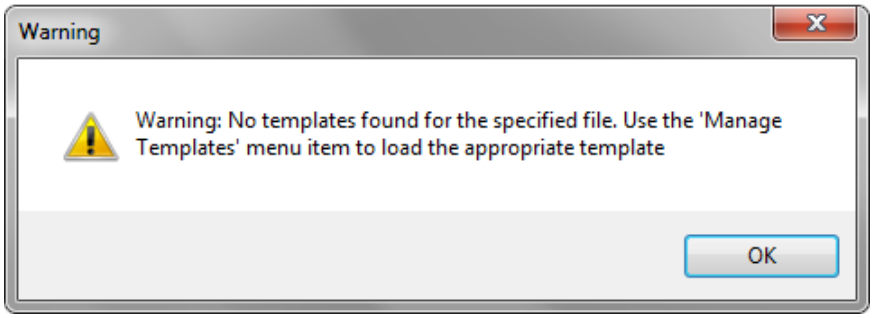

Figure 18: Warning message if a template is not available

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.

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).

Figure 20: Selecting the folder button

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

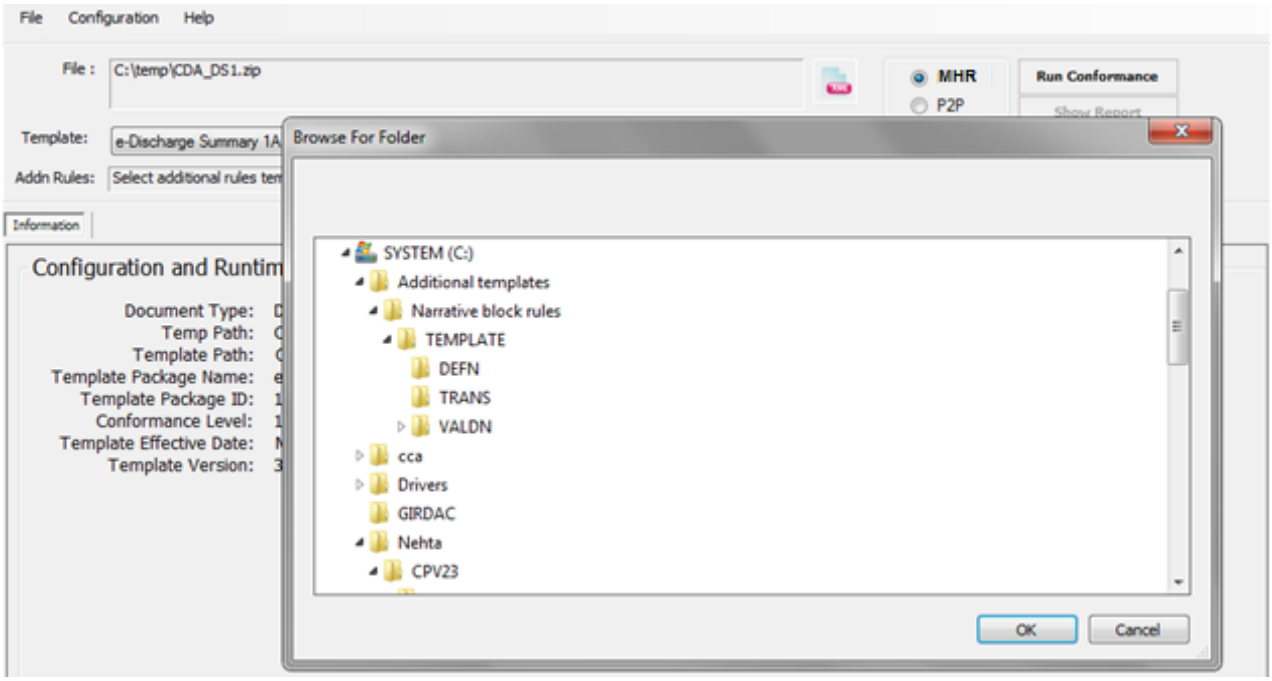

Figure 21: Navigating to the directory containing the additional template

3 Select the additional template (Figure 22).

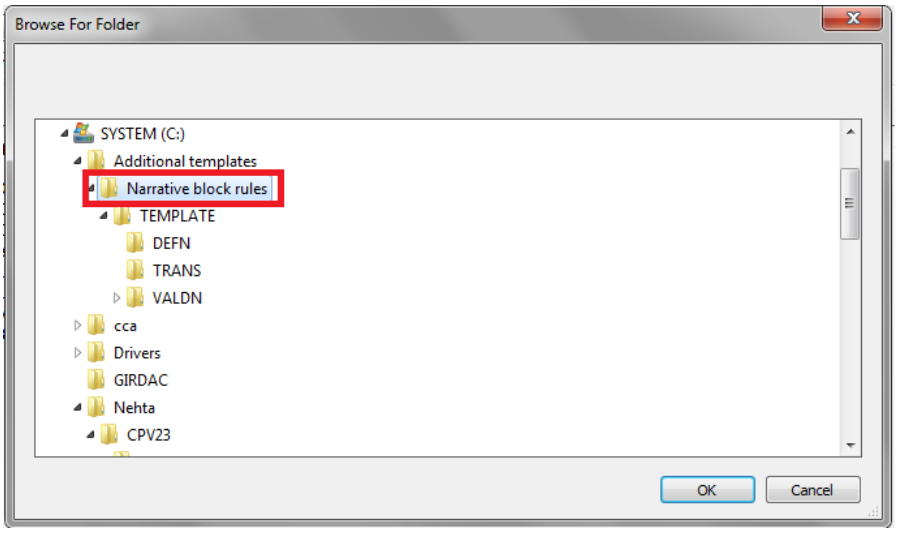

Figure 22: Locating and selecting the additional template

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).

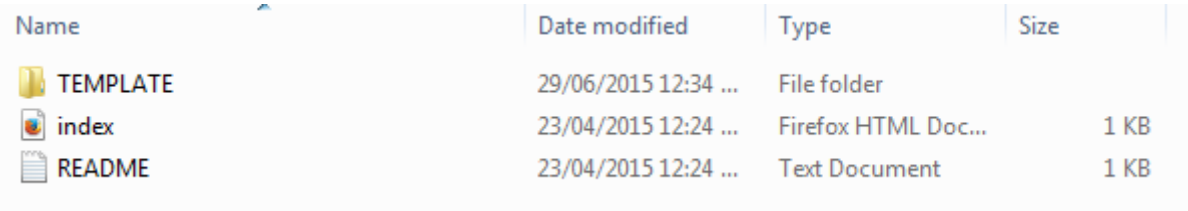

Figure 23: Contents of a template package

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

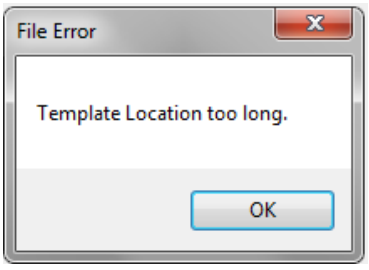

Figure 24: Error message when the combined length of the template location and folder name is too long

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).

*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).

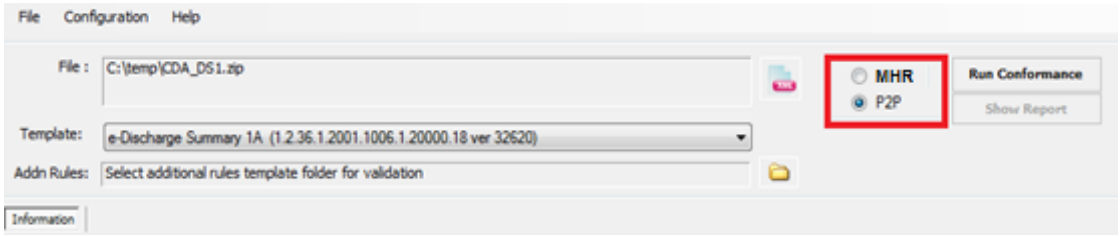

Figure 26: Selecting the P2P context

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 website[5] (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.

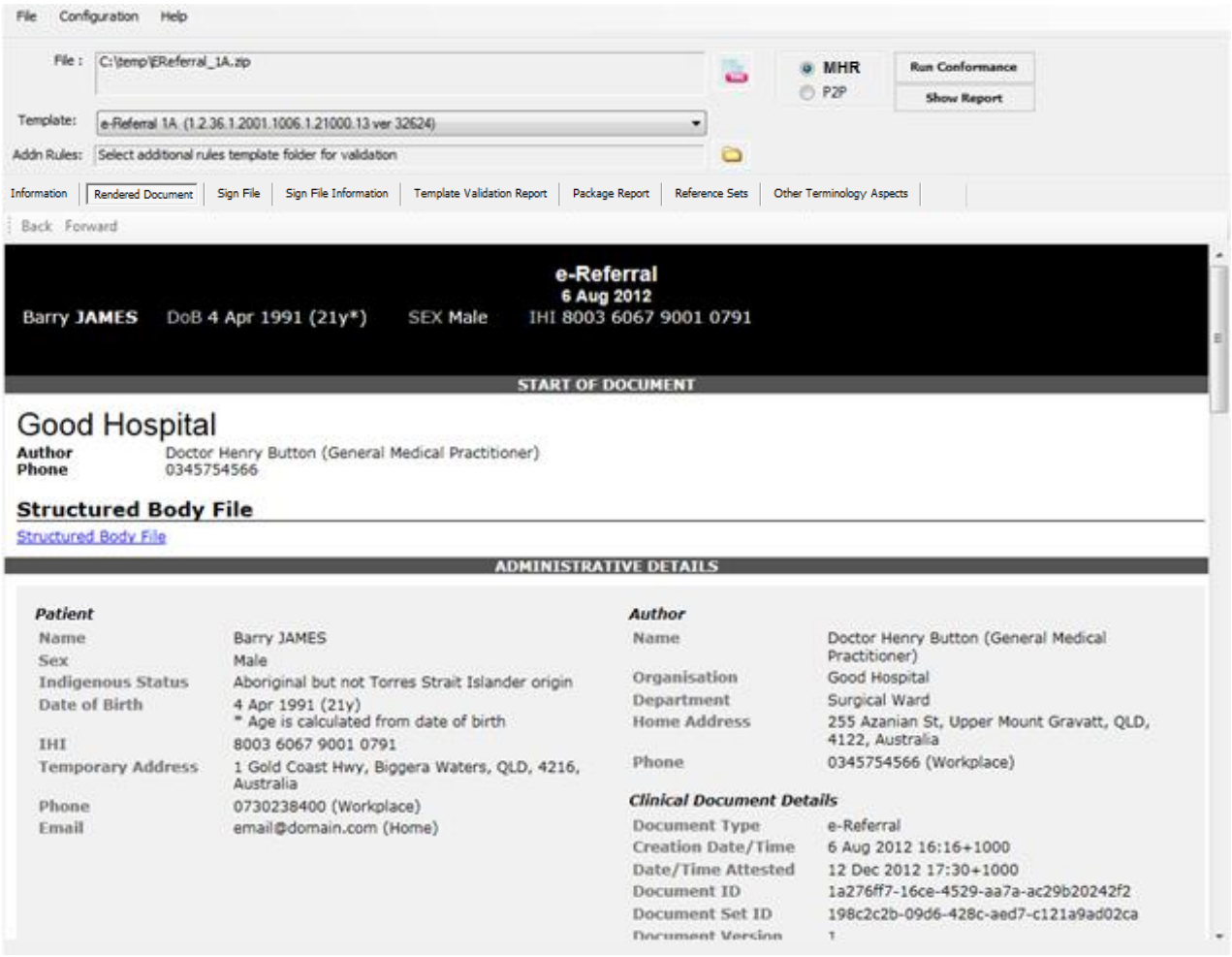

Figure 27: Rendered view of a level 1A eReferral

[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.

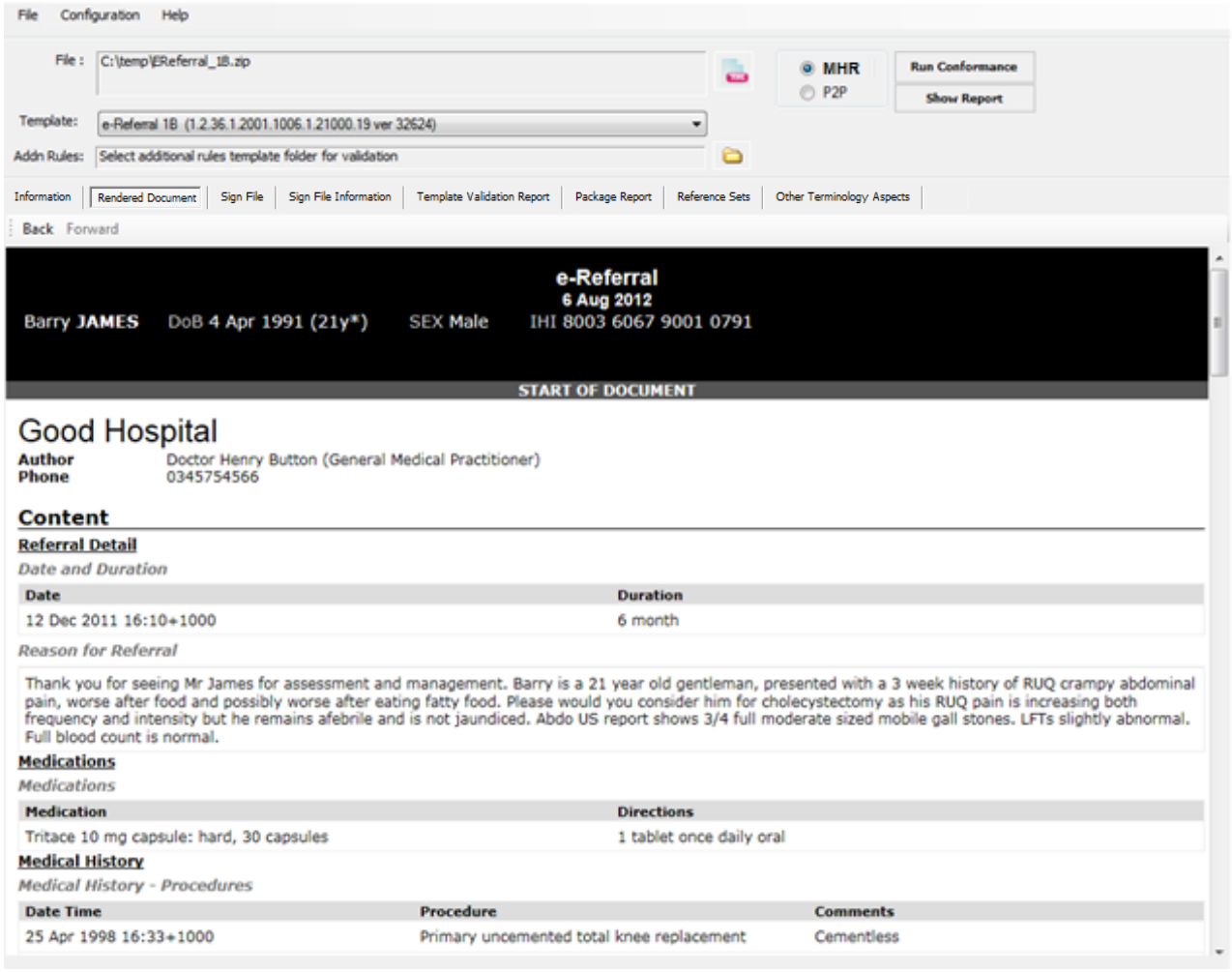

Figure 28: Rendered view of a level 1B eReferral

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.

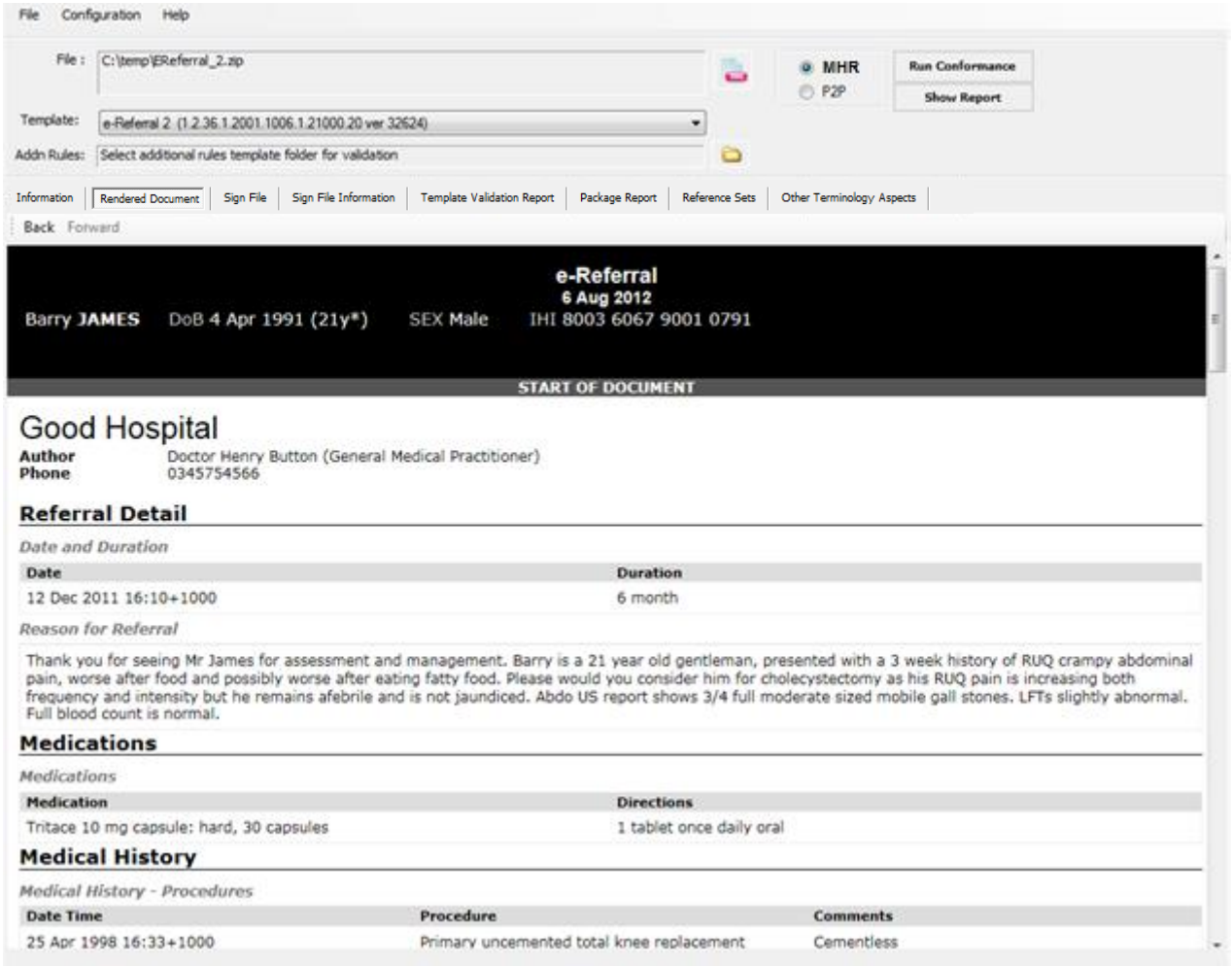

Figure 29: Rendered view of a level 2 eReferral

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).

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).

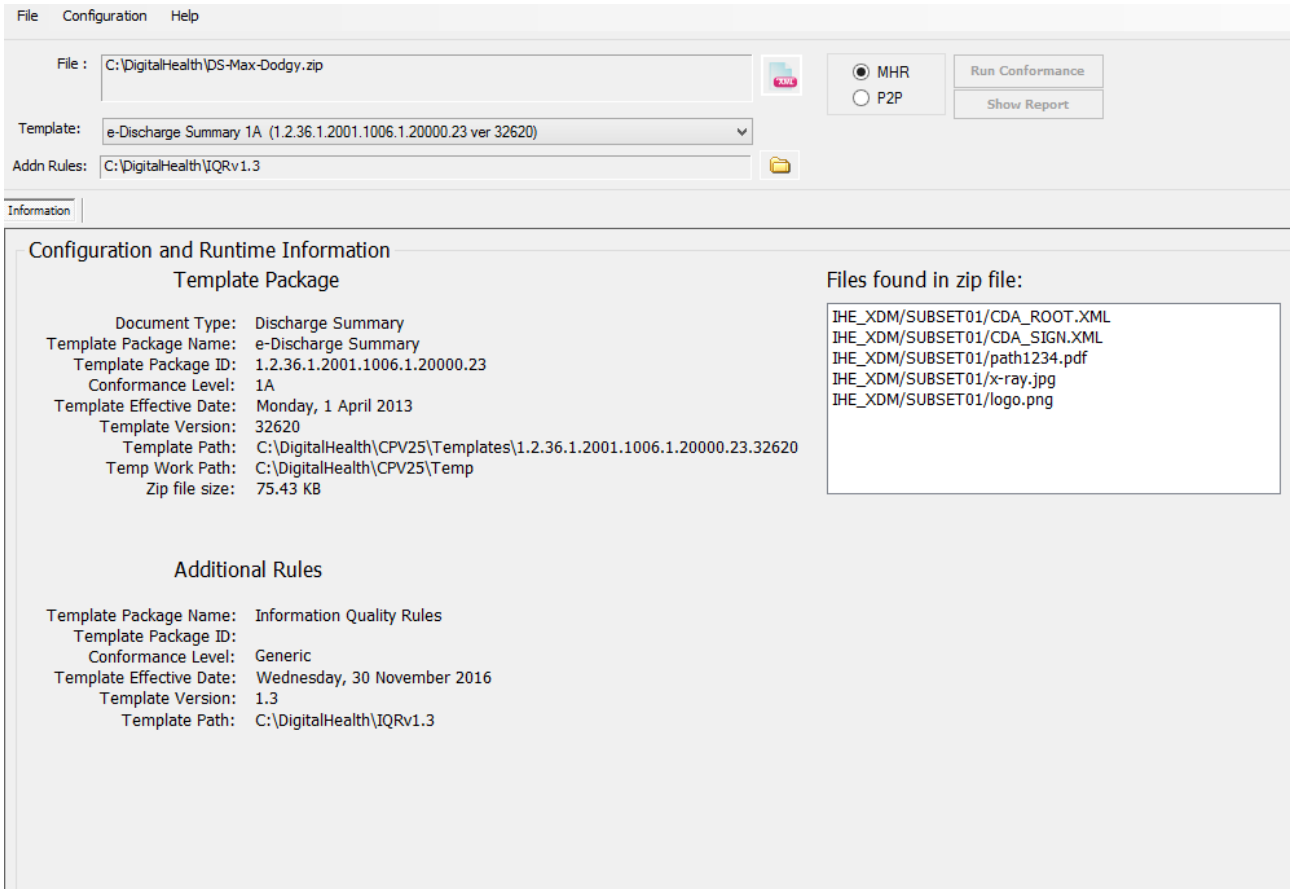

Figure 31: Information about an additional template

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

Table 5 –Information about the additional template

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.

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*.

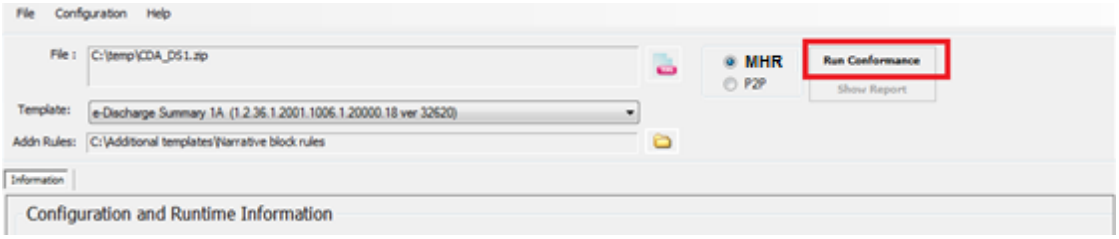

Figure 32: Requesting the Validator to test the conformance of a clinical document or clinical package

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).

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.

*Table 6 – Summary of validation results displayed in the **Information** tab*

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).

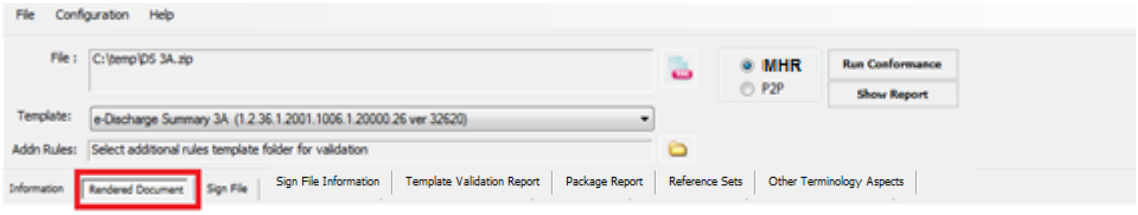

Figure 33: Rendered Document tab

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 to the attachment.

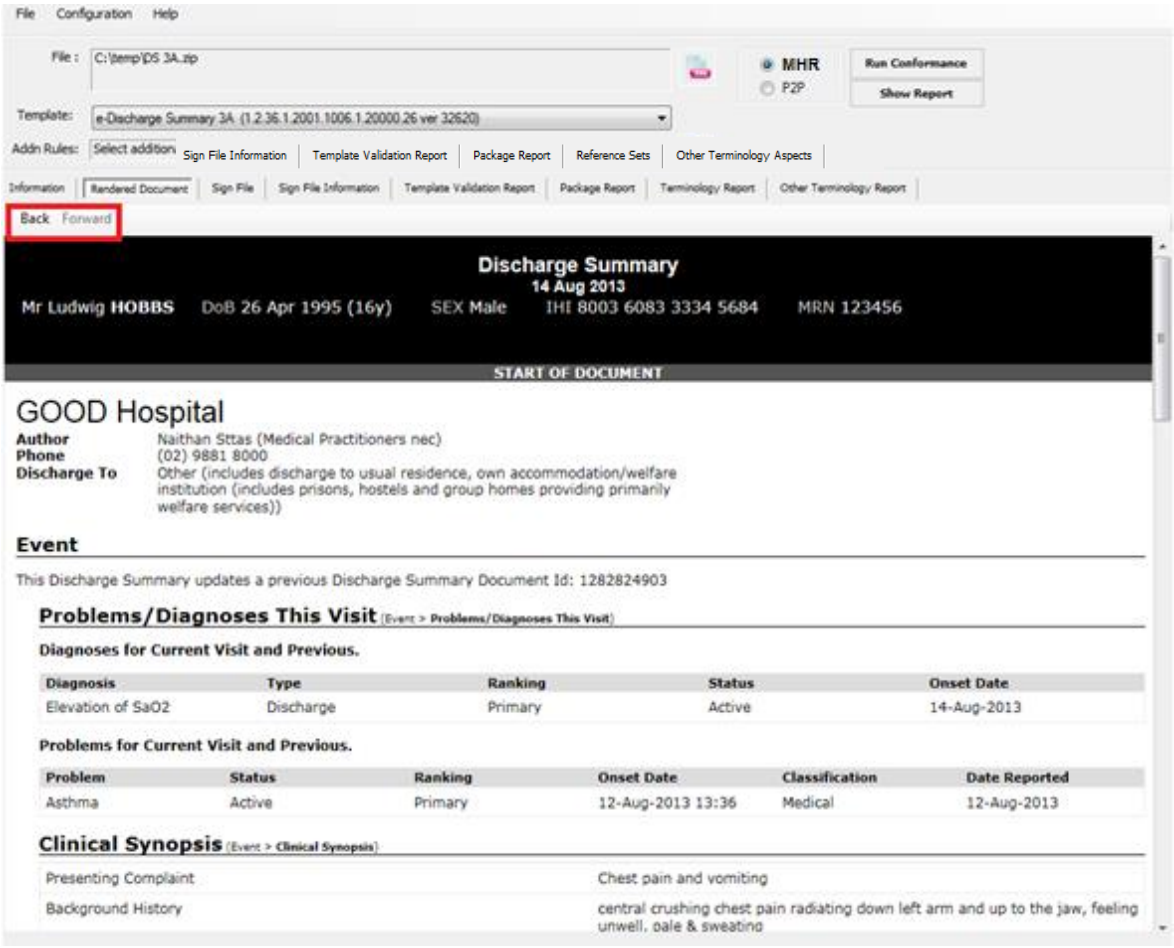

Figure 34: Rendered clinical document displayed on the Rendered Document tab

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.

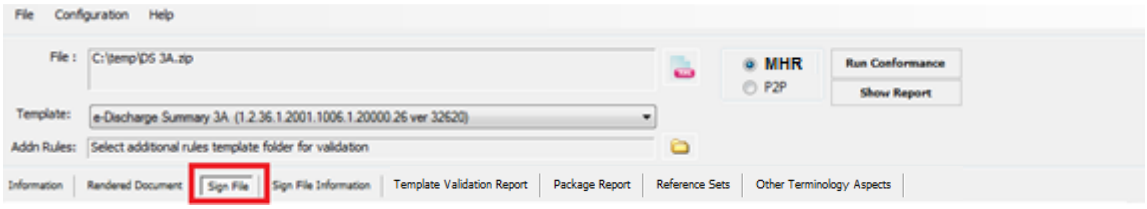

Figure 35: Sign File tab

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

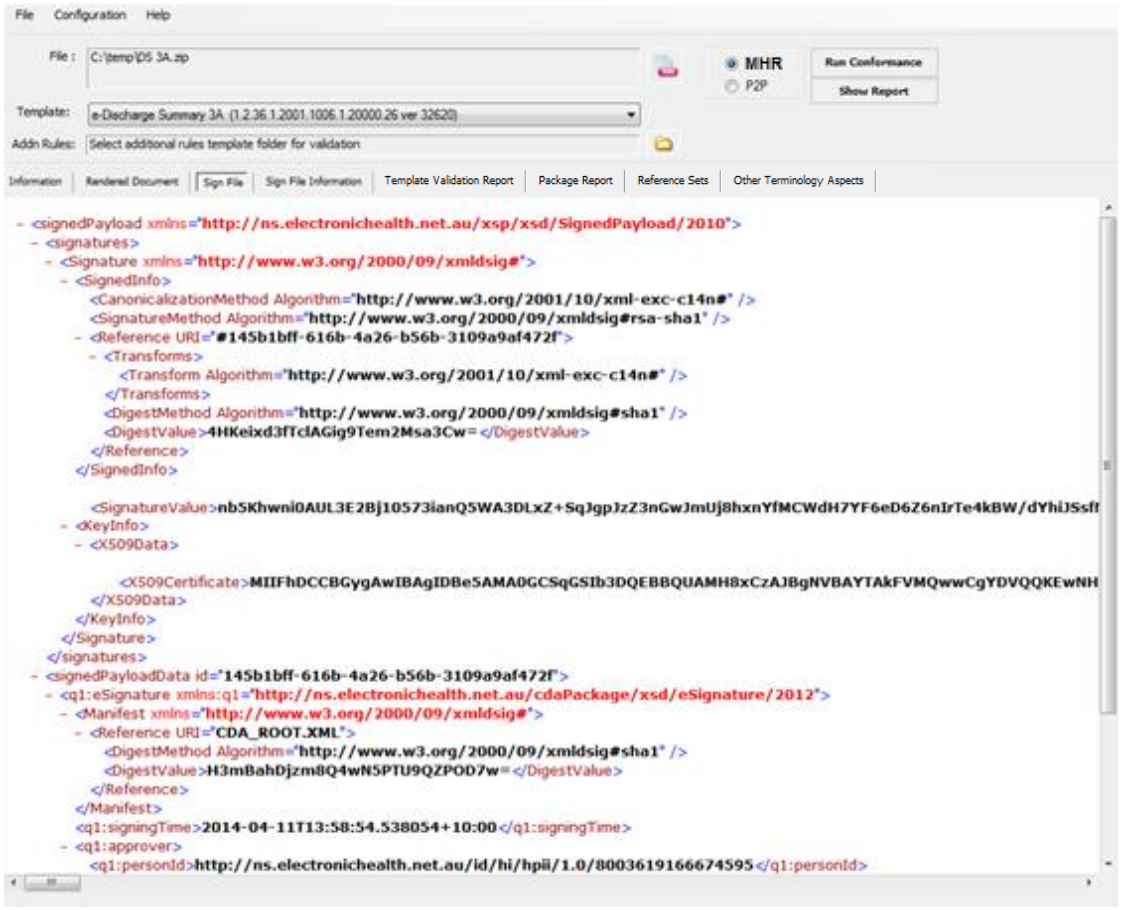

Figure 36: Display of a CDA_SIGN.XML file

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.

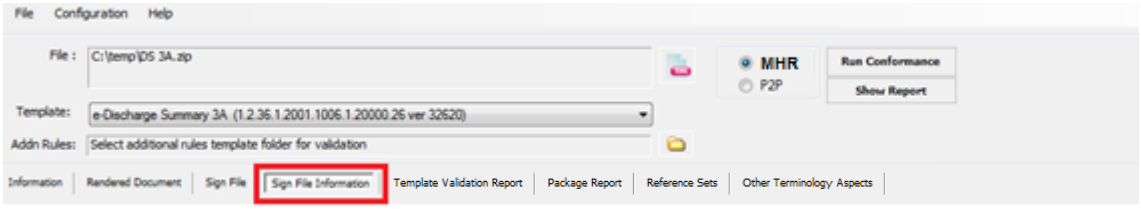

Figure 37: Sign File Information tab

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

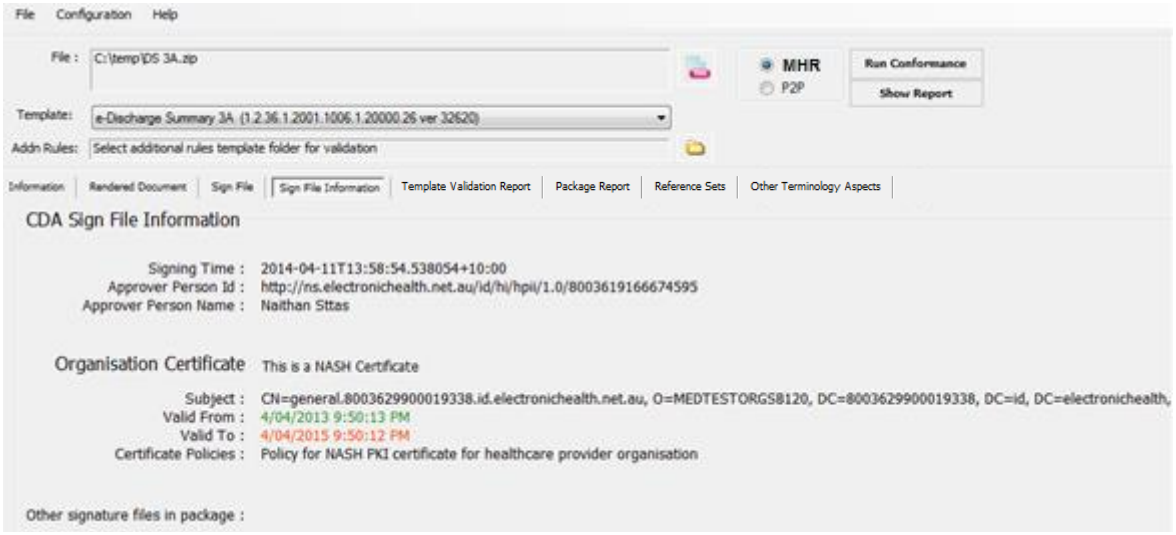

Figure 38: Display of eSignature file information

The information displayed is listed in Table 7.

*Table 7 – Summary of information displayed in the **Sign File Information** tab*

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.

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.

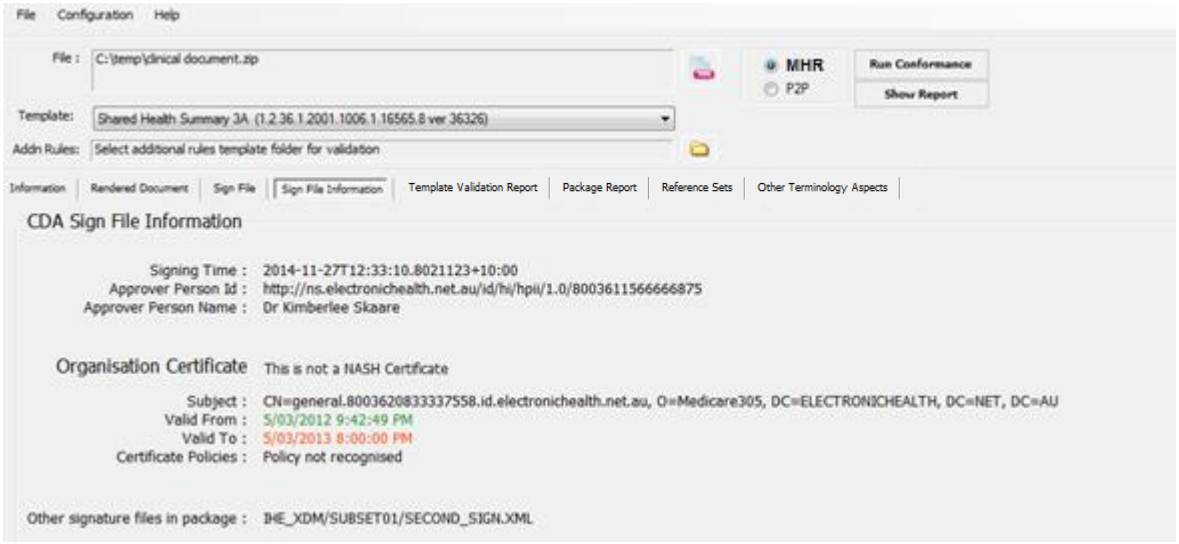

Figure 39: An unrecognised type of certificate and a second eSignature

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).

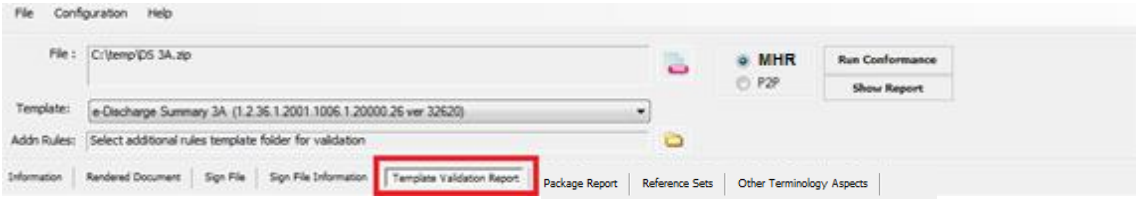

Figure 40: Template Validation Report tab

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.

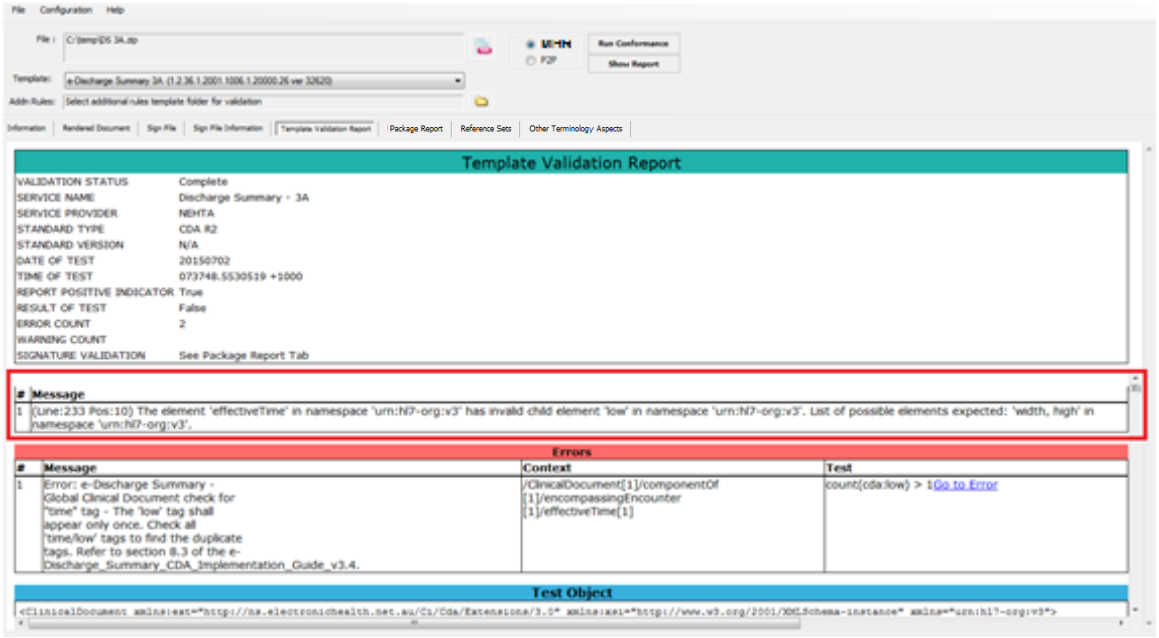

Figure 41: Template Validation Report tab with schema issue highlighted

Figure 42 shows the report with Schematron issues highlighted.

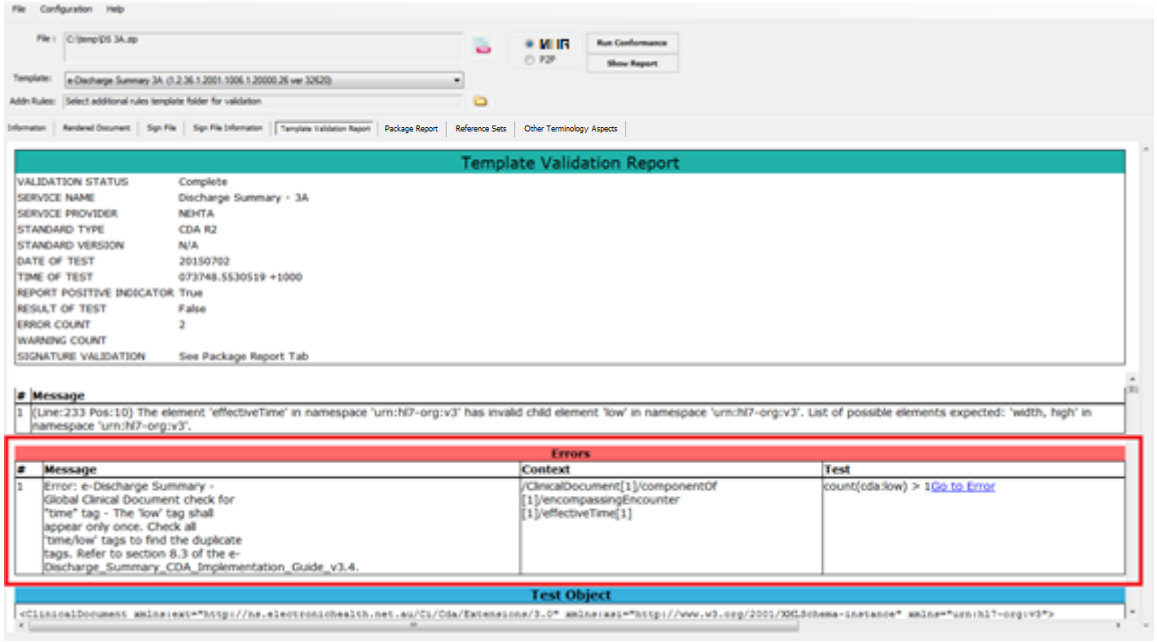

Figure 42: Template Validation Report tab with Schematron errors highlighted

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

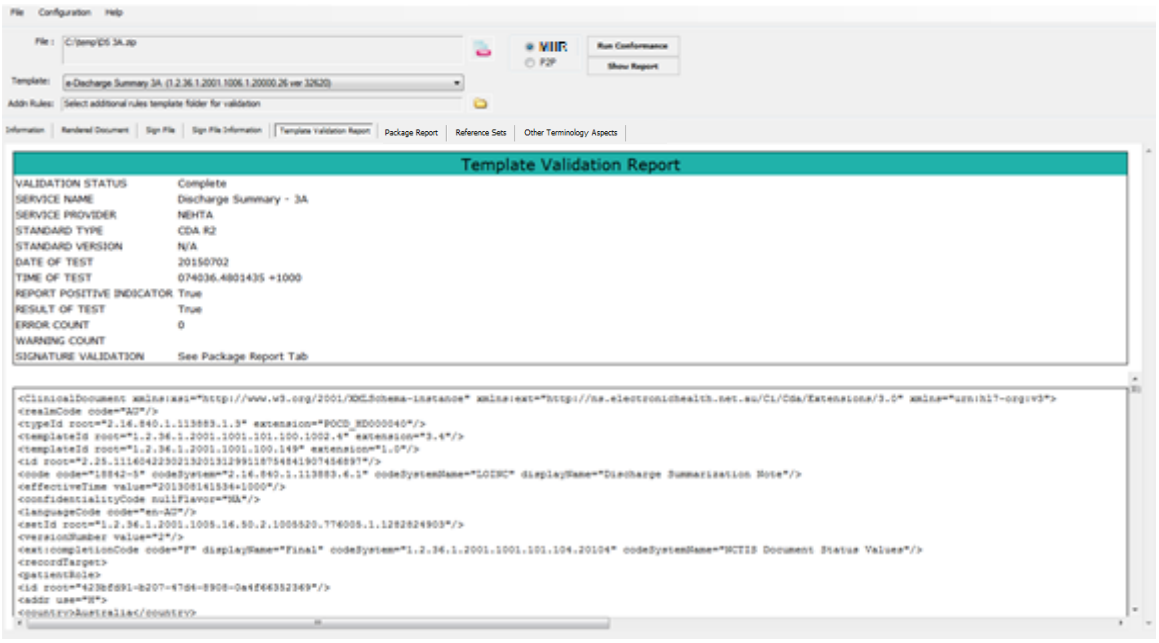

Figure 43: Template Validation Report tab reporting no errors

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

Table 8 - Report labels

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.

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.

Table 9 - Schematron issue information

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.

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.

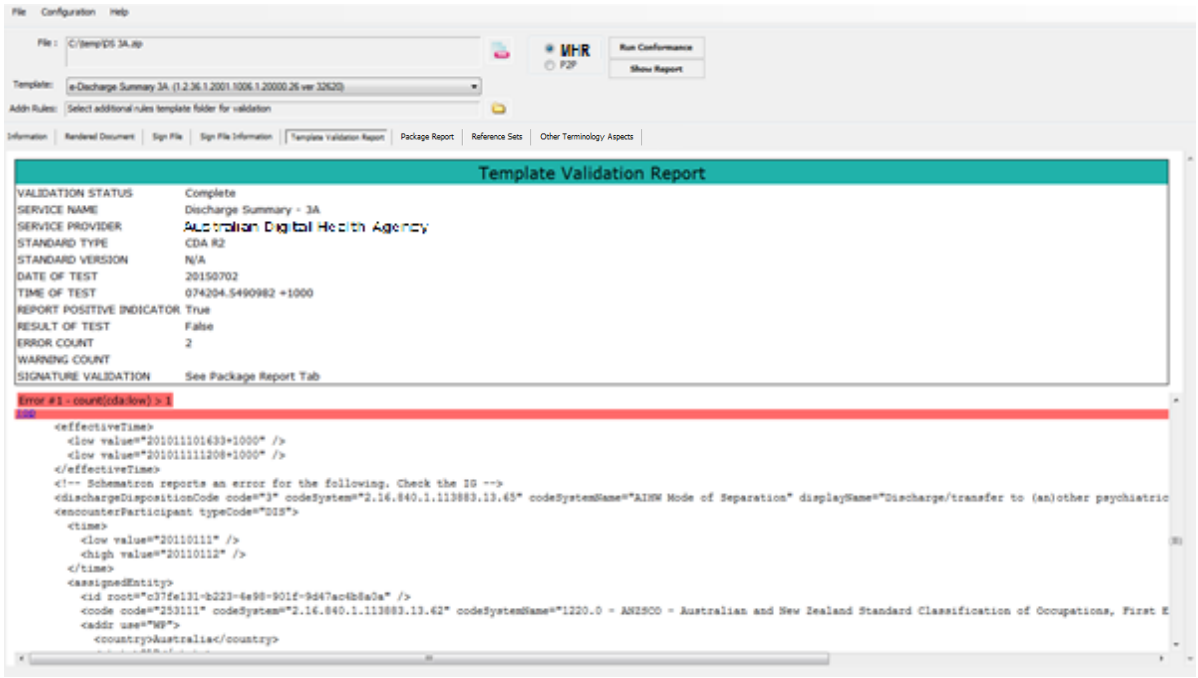

*Figure 44: Template Validation Report tab when a **Go to Issue** link is selected*

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.

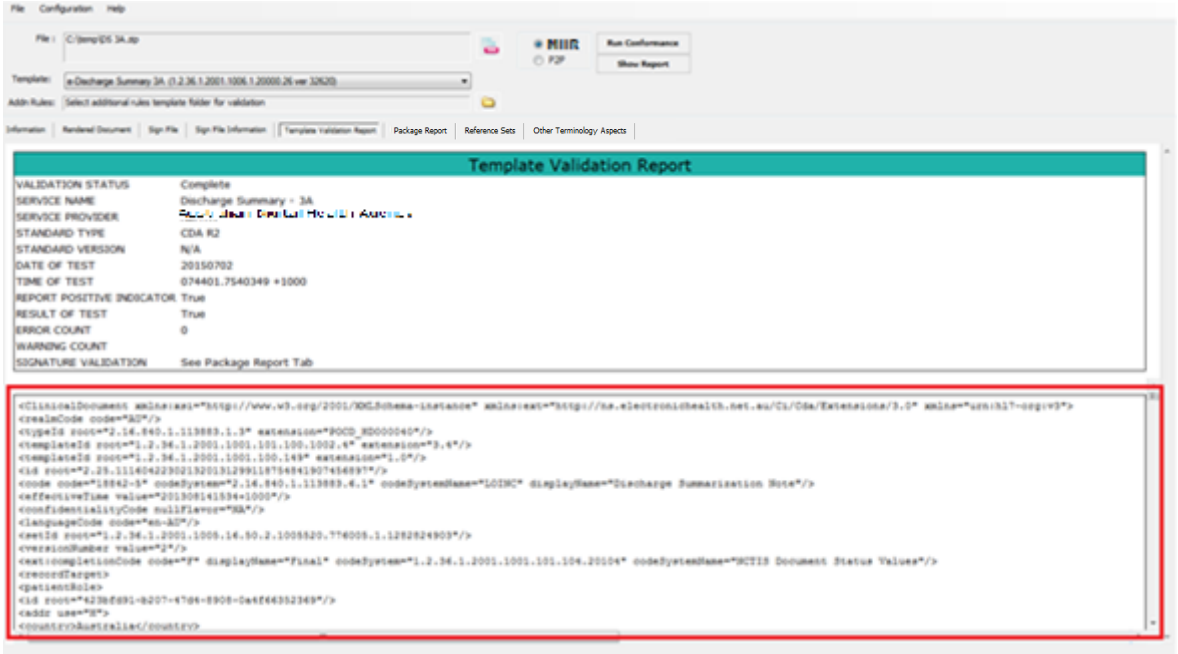

Figure 45: Template Validation Report tab displaying a clinical document XML file

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).

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).

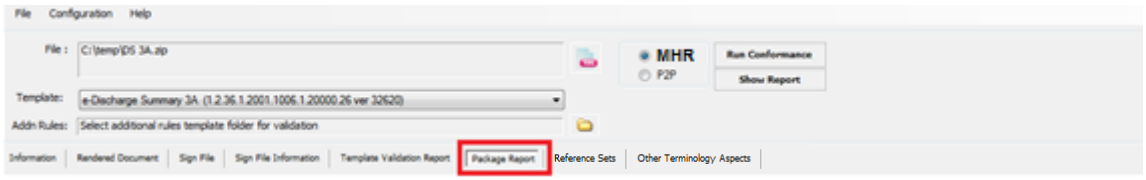

Figure 47: Package Report tab

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.

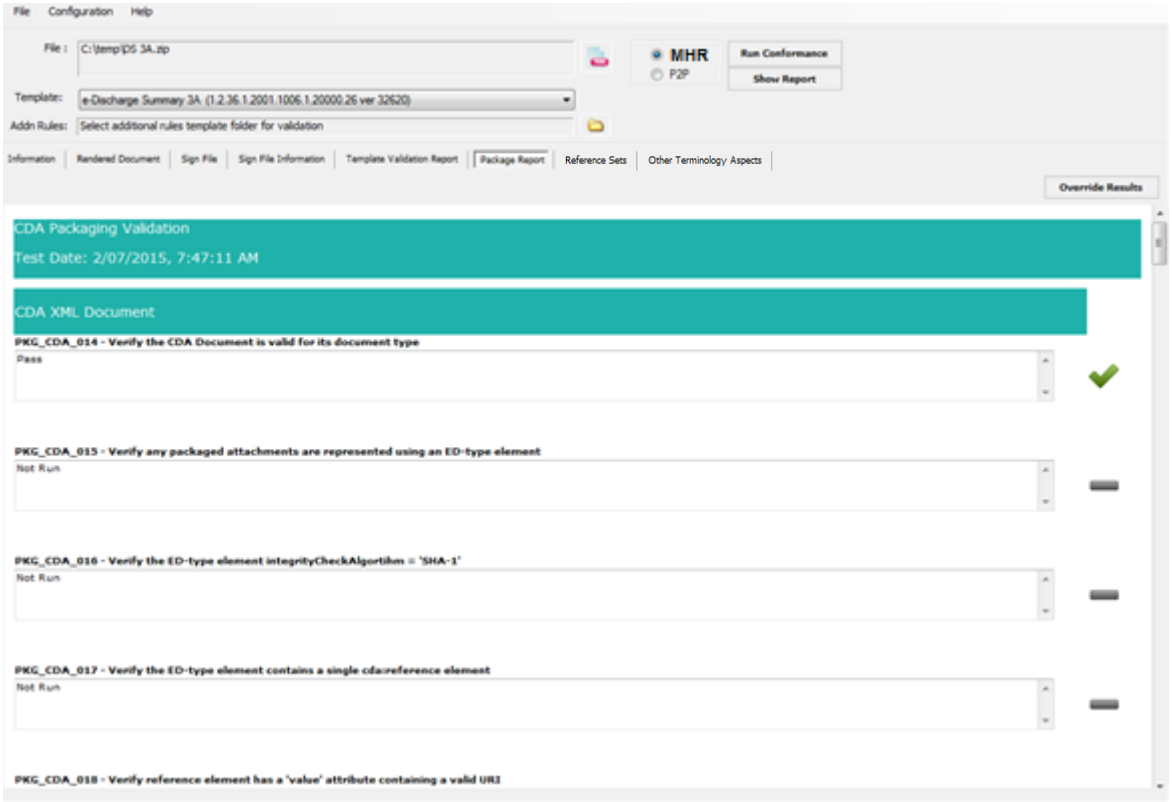

*Figure 48**: **Package Report** tab showing results of clinical package validation*

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

Table 10 - Package validation symbols

Symbol	Explanation	Usage
	Pass	The Validator determined a definite 'Pass' for the test case.
	Fail	The Validator determined a definite 'Fail' for the test case.
	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).

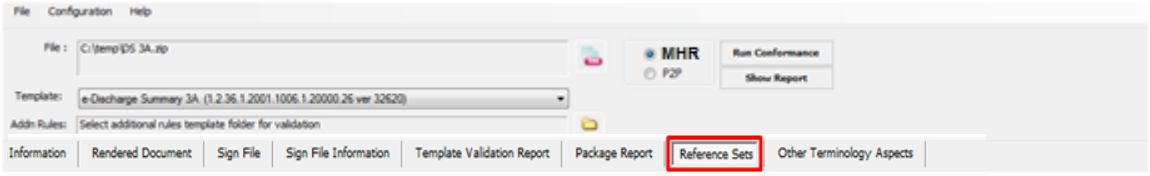

Figure 49: Reference Sets tab

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).

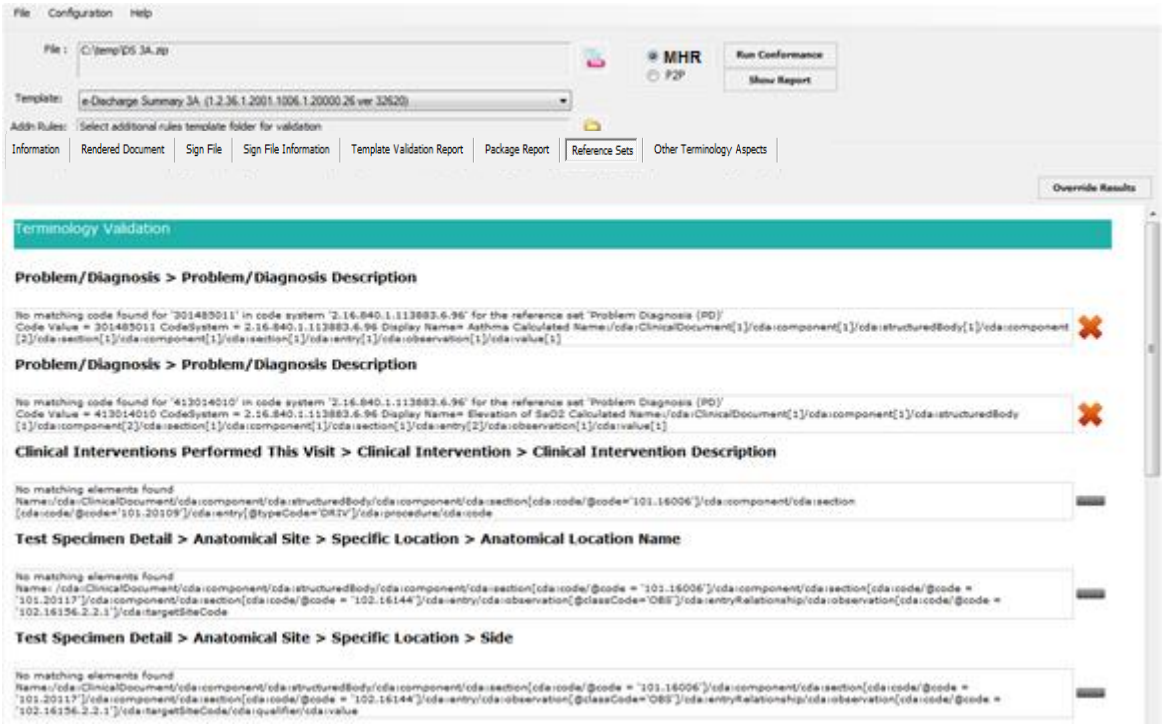

Figure 50: Reference Sets tab showing results of reference set validation

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

Table 11 – Reference set validation symbols

Symbol	Explanation	Usage
✔	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.

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 ( ) 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 ( ) 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 ( ) if:

- 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.

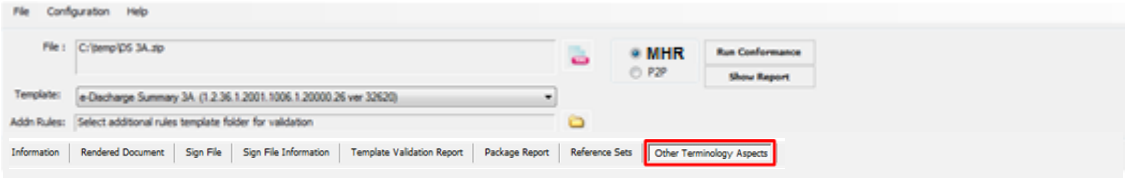

Figure 51: Other Terminology Aspects tab

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).

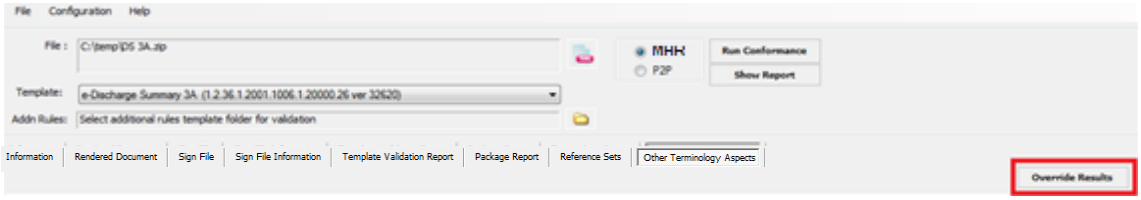

Figure 52: Override results command displayed in Other Terminology Aspects tab

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).

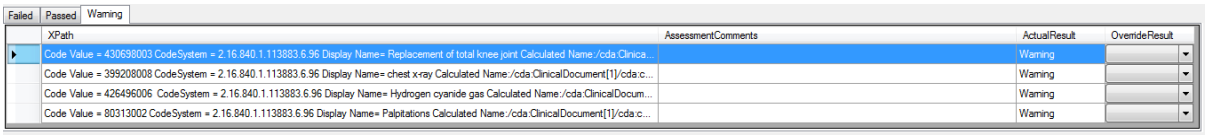

Figure 53: Overriding a code validation result

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'.

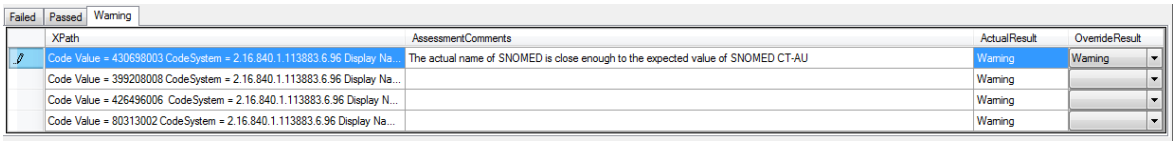

Figure 54: Recording a new code validation result and the reason for the change

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.

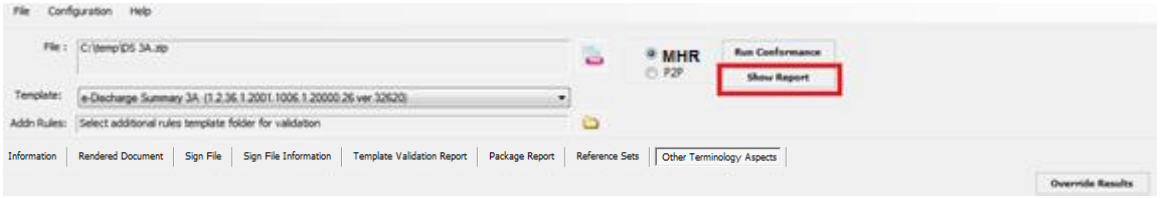

Figure 55: Requesting the Validator to create a test report

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.

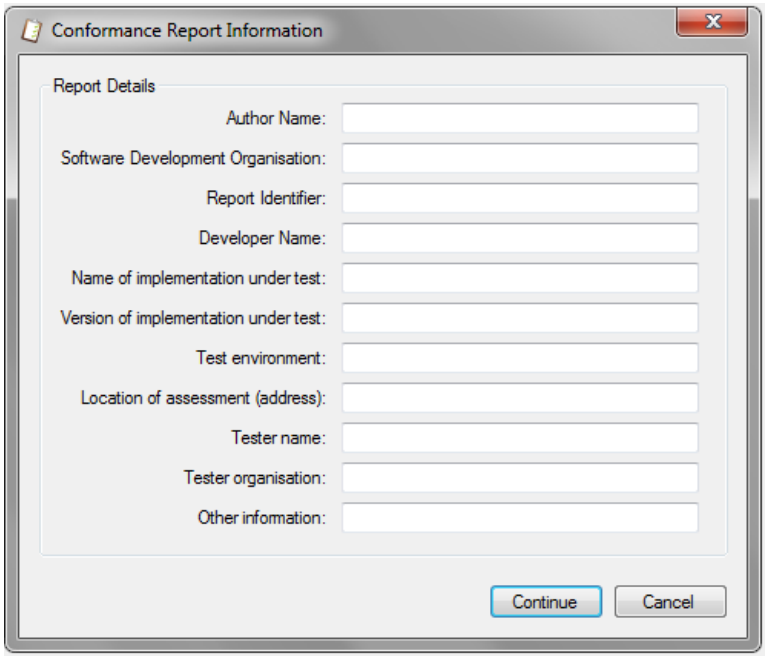

Figure 56: Recording information about the tests performed

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	Result	Override
1	Code Value = 73817000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Enteritis due to radiation Calculated XPath:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[1]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:value[1]	The actuial codeSystemName value "SNOMED" is close enough to the expected value "SNOMED CT-AU"	Warning	Pass

Figure 58: Record of an overridden test result in a test report

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.

Table 12 – Information in the report.csv file

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.

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.

The default screen will appear (Figure 59).

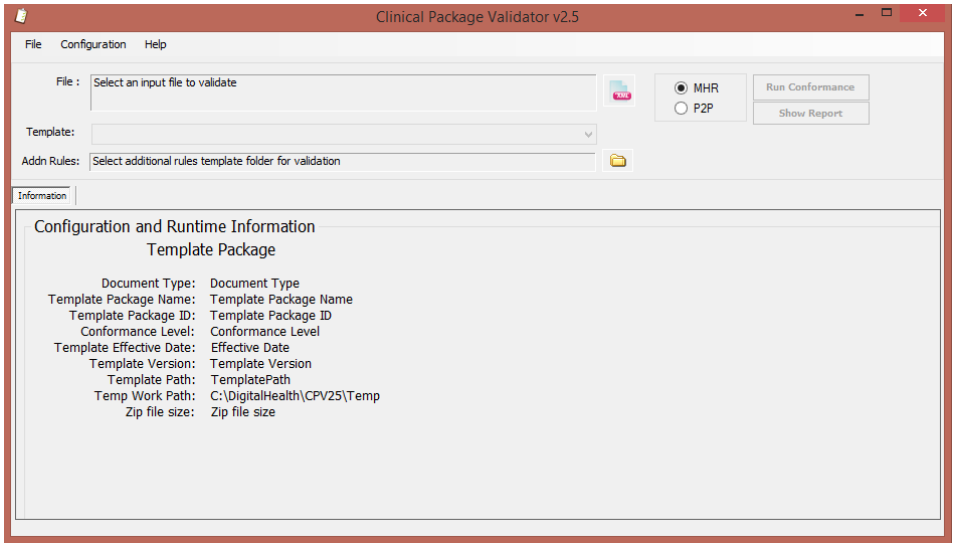

Figure 59: Default Validator screen

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).

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.

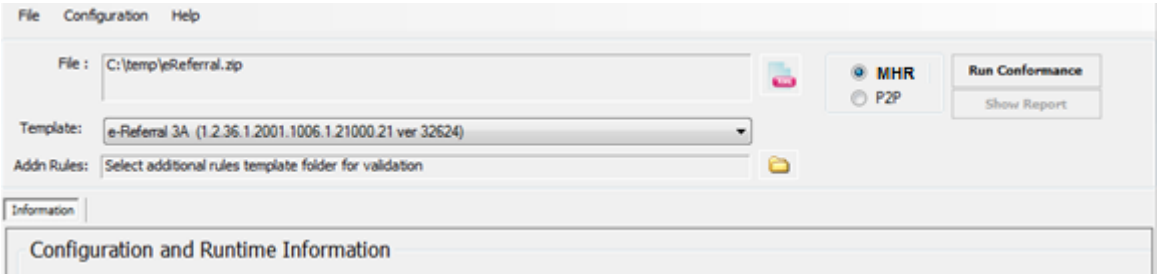

Figure 61: Information tab showing information about the clinical document and template package

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

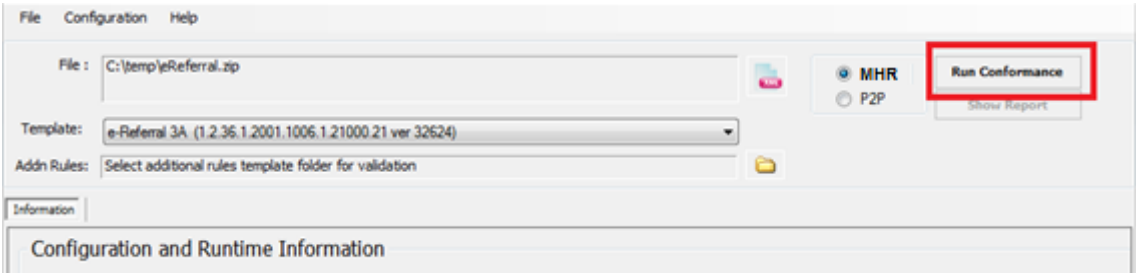

*Figure 62: Selecting the **Run Conformance** button*

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.

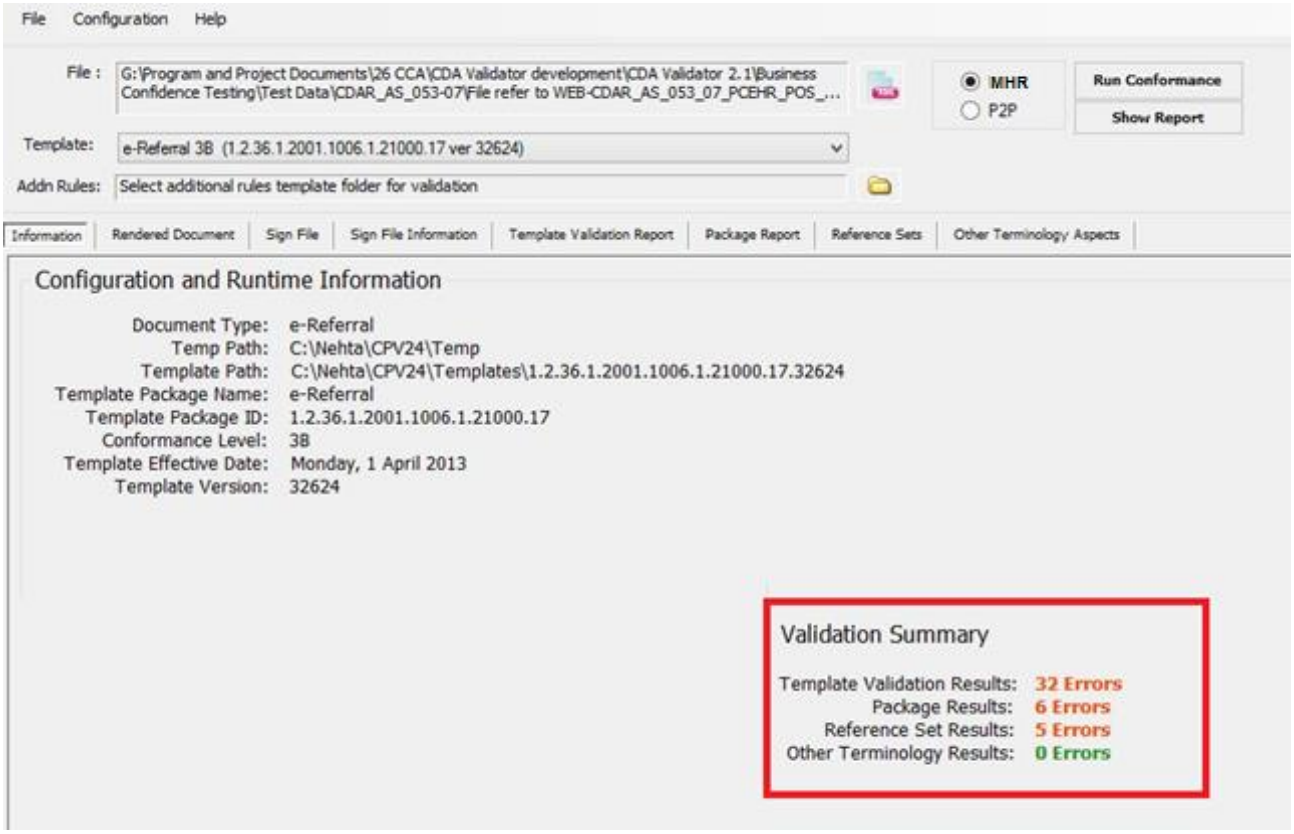

Figure 63: Information tab showing a summary of the validation results

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

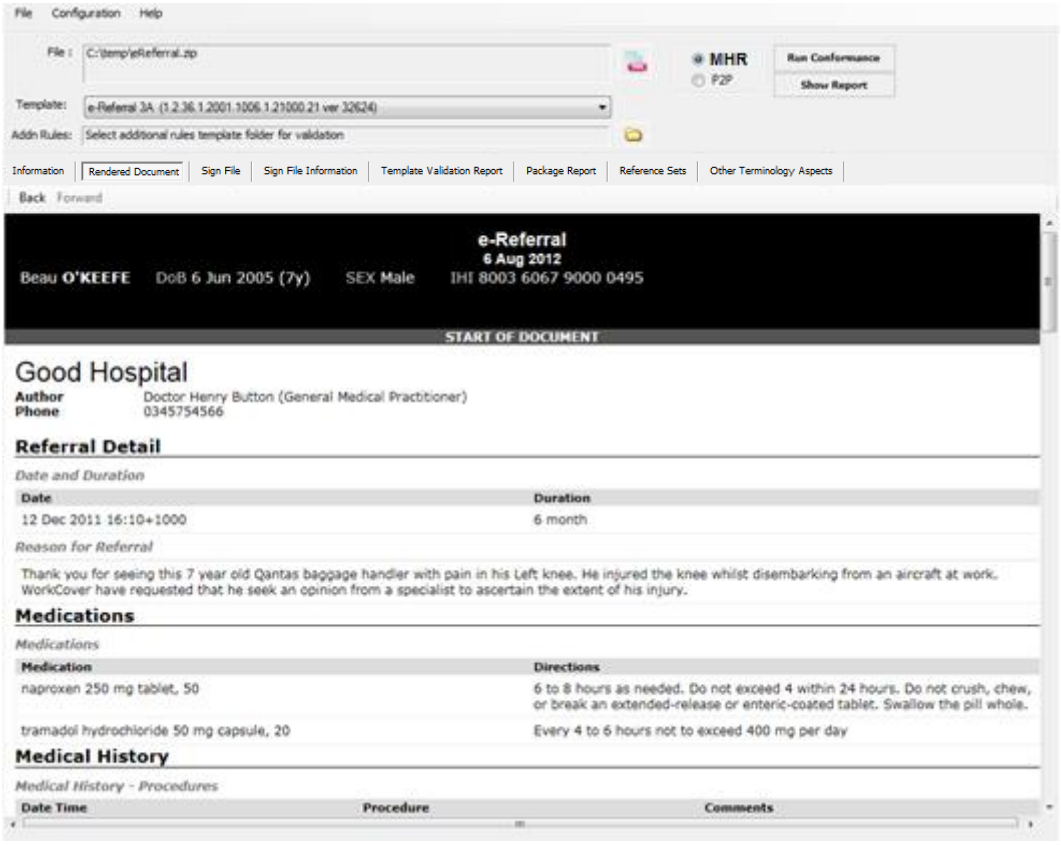

Figure 64: Rendered Document tab showing a rendered view of the validated clinical document

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).

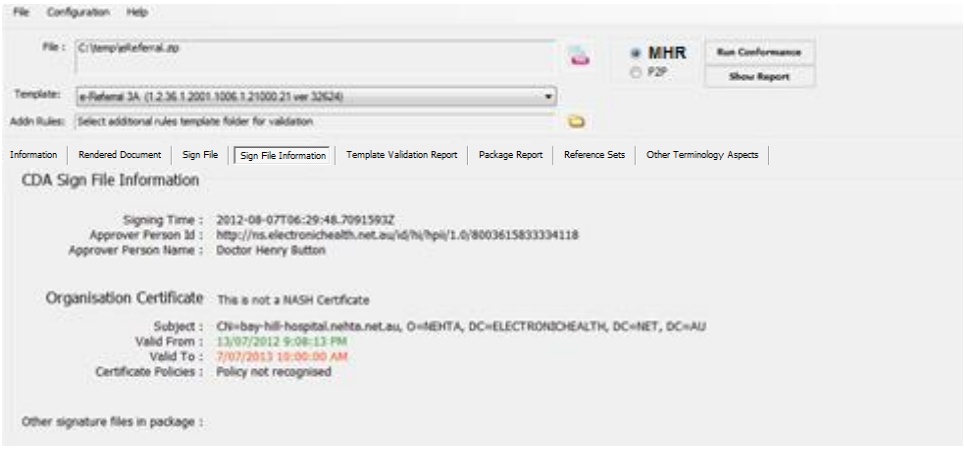

Figure 65: Sign File Information tab showing a summary of information about the primary eSignature file

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).

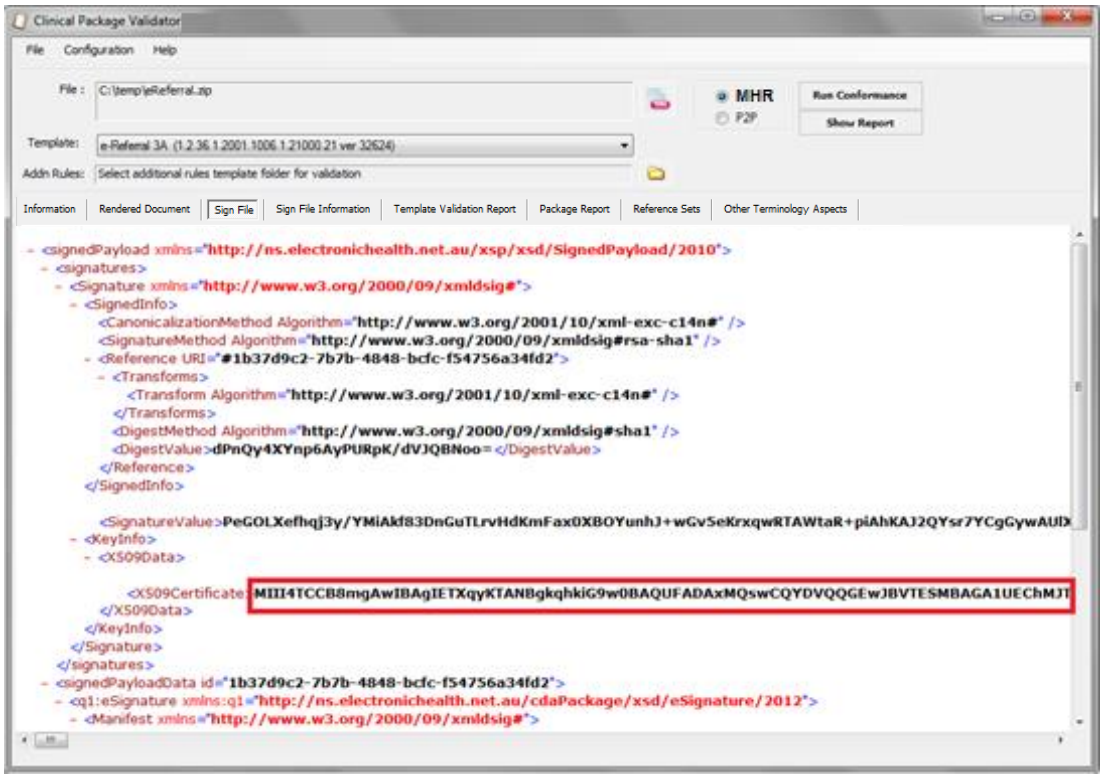

Figure 66: Sign File tab displaying the PKI certificate in the CDA_SIGN.XML file

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).

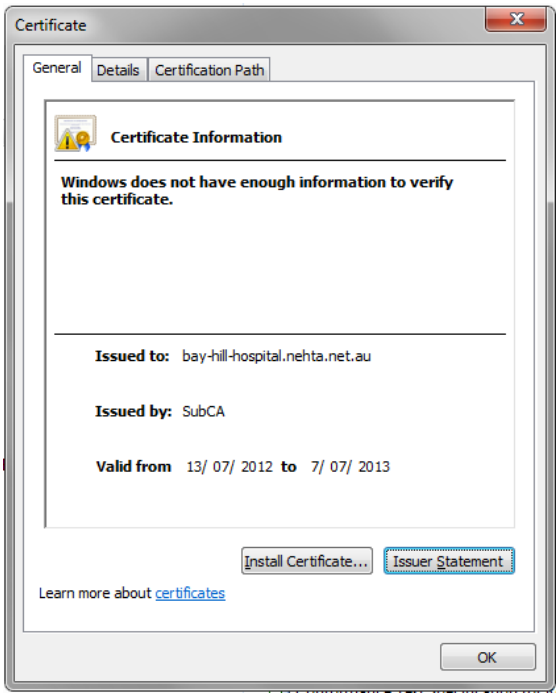

Figure 67: A view of the PKI certificate

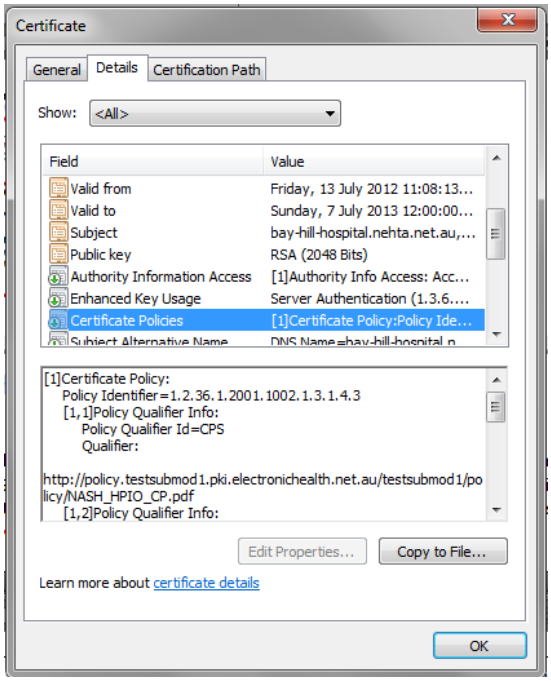

Figure 68: PKI certificate details

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).

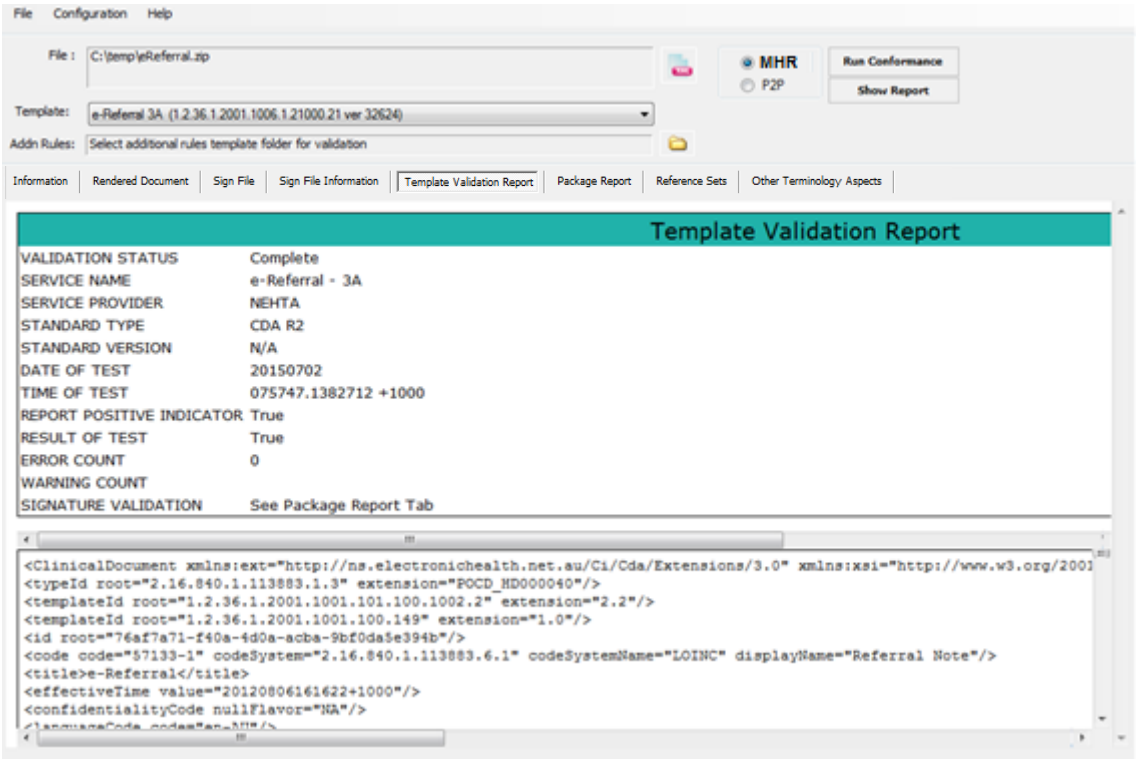

Figure 69: Template Validation Report tab showing template validation results

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.

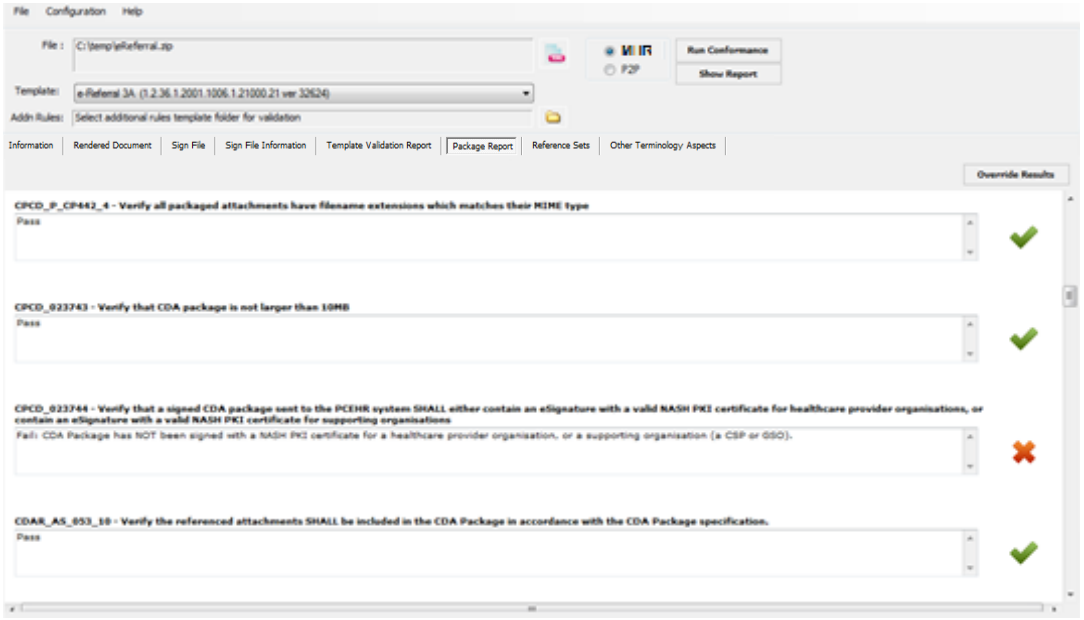

Figure 70: Package Report tab showing package validation results

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).

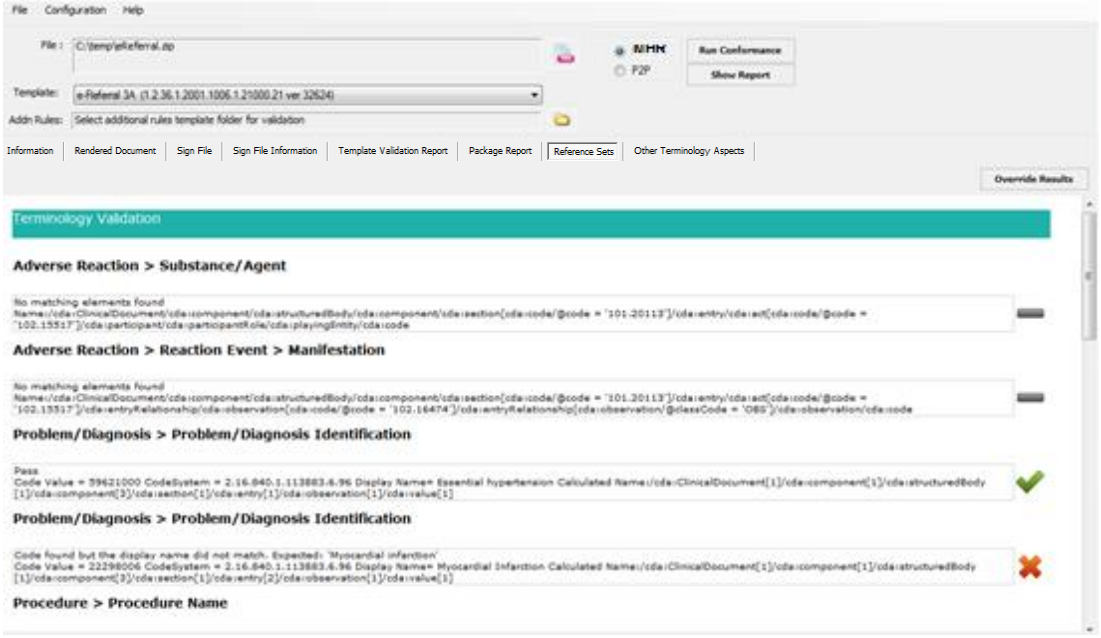

Figure 71: Reference Sets tab showing reference set validation results

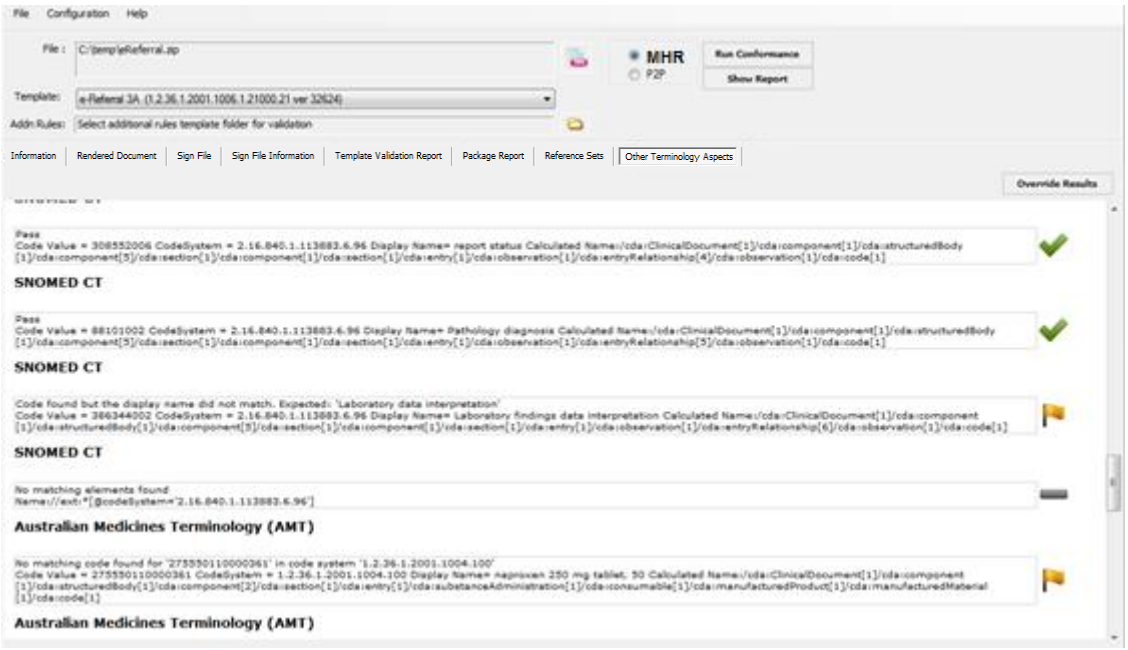

Figure 72: Other Terminology Aspects tab showing code validation results

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).

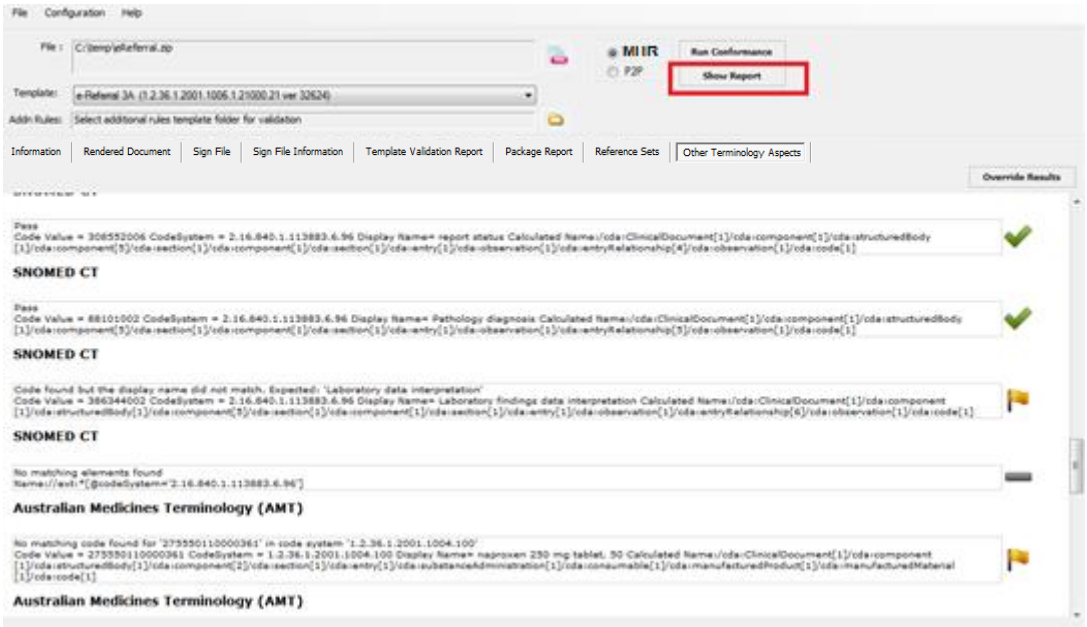

Figure 73: Generating a test report

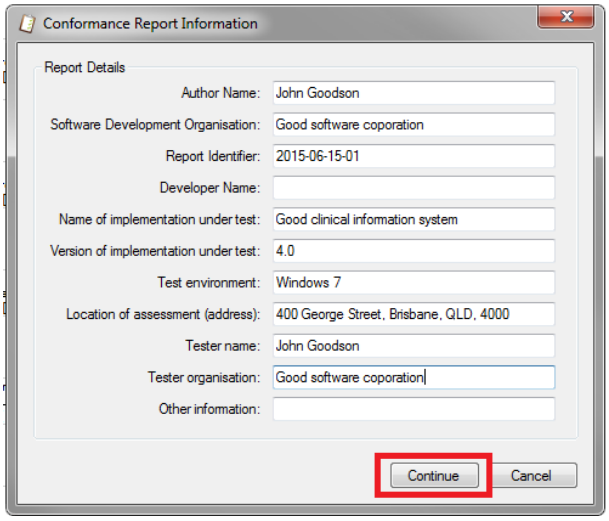

Figure 74: Adding test report information

The test report is now complete (Figure 75).

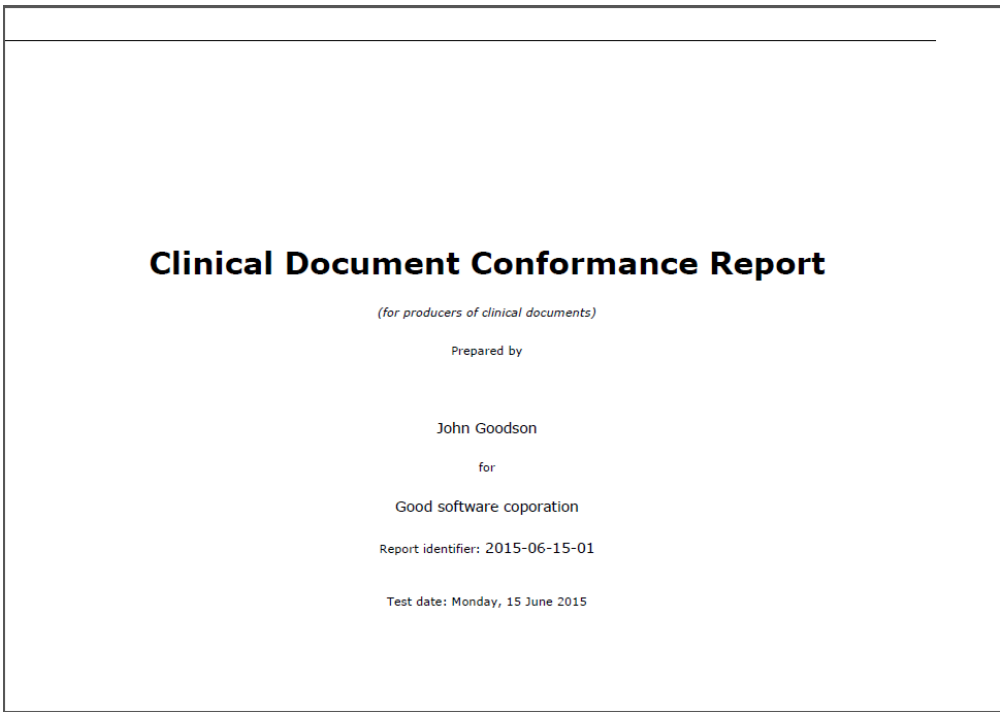

Figure 75: Completed test report

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 website[6]) 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.

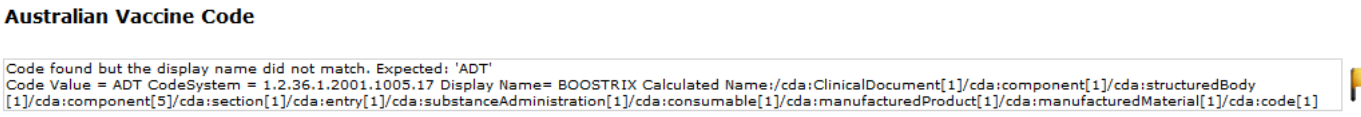

Figure 76: Other Terminology Aspects tab showing a warning for an Australian Vaccine code

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

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:consumable[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.

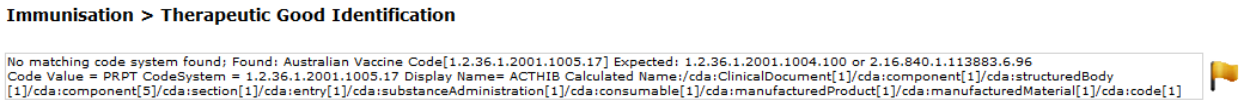

Figure 80: Reference Sets tab showing a warning for an Australian Vaccine code

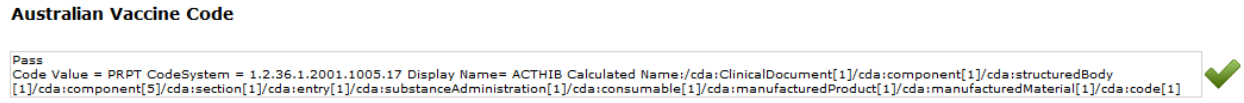

Figure 81: Other Terminology Aspects tab showing a pass for an Australian Vaccine code

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 '900000000000020002', 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.

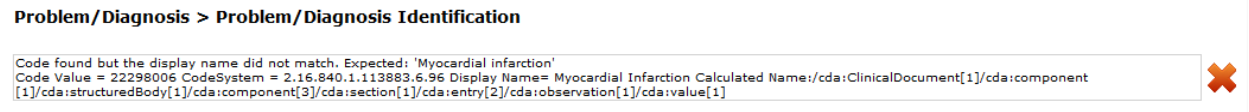

Figure 82: Reference Sets tab showing a SNOMED CT-AU display name error

4.2.7 Valid omission of a code

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'.

Figure 83: Reference Sets tab showing a warning for an omitted code

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.

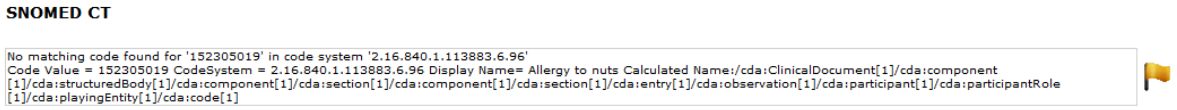

Figure 84: Other Terminology Aspects tab showing a warning for a SNOMED CT-AU code

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:

1 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.

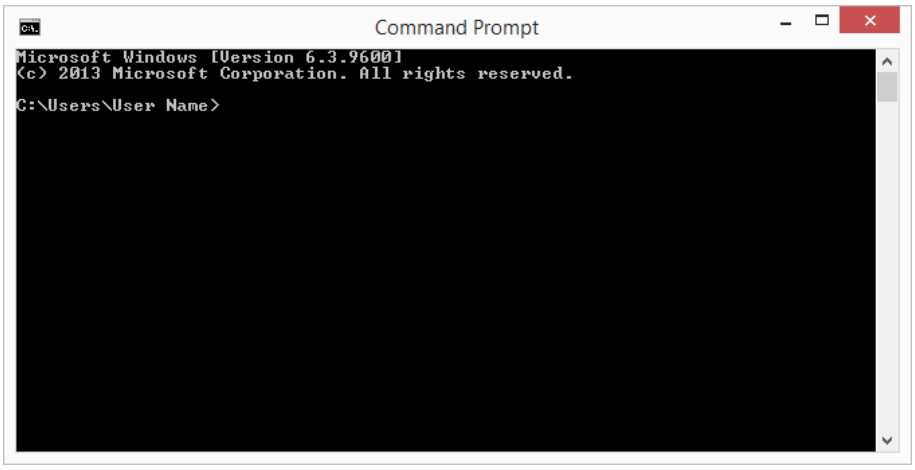

Figure 85: Command prompt

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

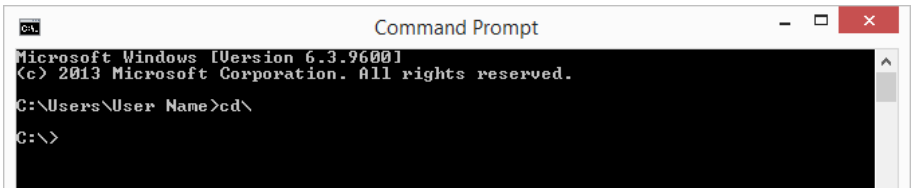

Figure 86: Root directory

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).

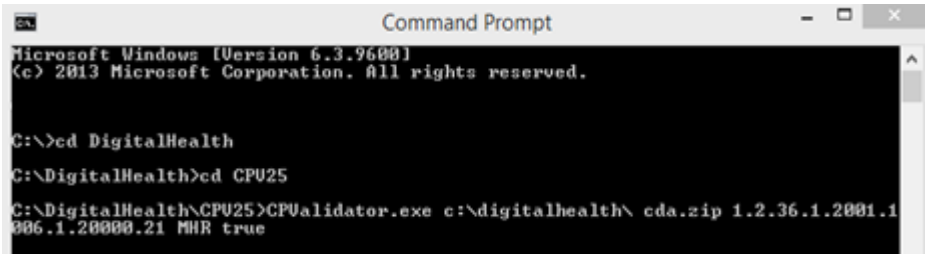

Figure 88: Launching the Validator through the command line interface

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

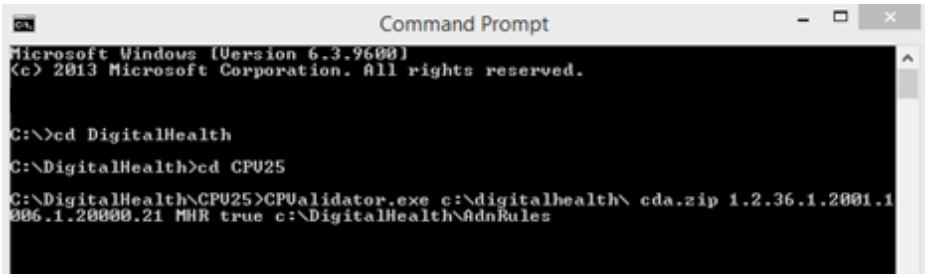

Figure 89: Launching the Validator through the command line interface

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.

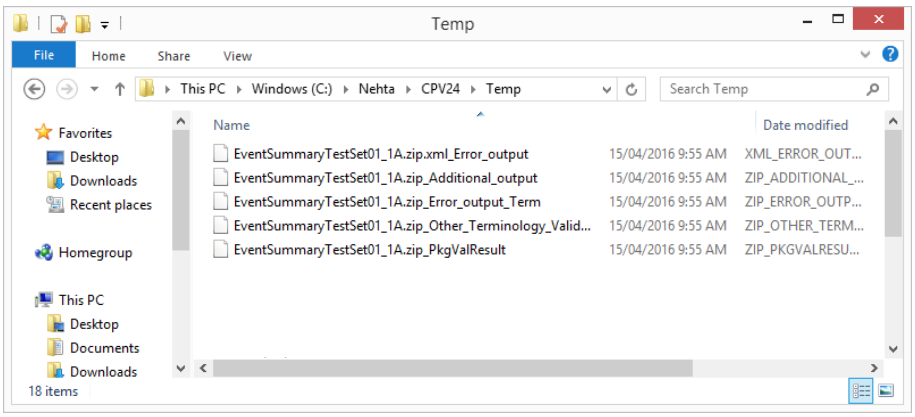

Figure 90: Storage of validation results including additional template validation results

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.

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

File name	Description
<FileName>.xml_Error_output.xml	An XML report of template validation errors.
<FileName>.xml_PkgValResult.xml	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	An XML report of reference set validation errors.
<FileName>_Other_Terminology_Validations.xml	An XML report of other terminology aspects validation errors.
<FileName>_Additional_output.xml	An XML report of additional template validation errors. ***Note:*** *This xml file only appears if the AdditionalRulesTemplatePath is used.*

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 ✖ whereas the test result XML files report a 'Fail' as <IMG src="No.png" />.

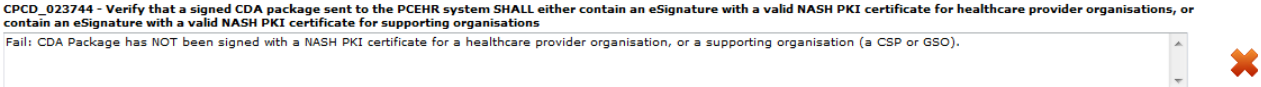

Figure 91: Graphical user interface with image reporting a 'Fail' for clinical packaging test case CPCD_023744

```
    <TestDataItem>
      <Reference>CPCD_023744</Reference>
      <Message>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).</Message>
      <Description>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 </Description>
      <Result>
        <text>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).</text>
        <image>
          <IMG src="No.png" />
        </image>
      </Result>
    </TestDataItem>
```

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.

Table 14 – Test results and image references

Test result	**Image reference**
Pass	<IMG src="Accept.png" />
Fail	<IMG src="No.png" />
Warning	<IMG src="Warning.png" />
Not Run	<IMG src="NA.png" />

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
PKI	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.
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; http://www.hl7.org/
[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; https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-1229-2011
[NEHTA2012a]	CDA Rendering Specification, version 1.0; NEHTA, 2012; https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-1199-2012
[NEHTA2012b]	P2P Document Delivery Technical Service Specification, version 1.1; NEHTA, 2012; https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-1254-2012/NEHTA-1227-2012
[NEHTA2014a]	Australian CDA Schema Extension, version 3.0; NEHTA, 2014; https://www.digitalhealth.gov.au/implementation-resources/ehealth-reference-platform/EP-2344-2016/NEHTA-2150-2014
[NEHTA2014b]	PCEHR Document Exchange Service Logical Service Specification, version 1.3.1; NEHTA, 2014; https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/EP-2109-2015/NEHTA-1970-2014
[NEHTA2014c]	PCEHR Document Exchange Service Technical Service Specification, version 1.5.1; NEHTA, 2014; https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/EP-2109-2015/NEHTA-1971-2014
[NEHTA2015b]	Conformance Test Specification for CDA Packaging, version 1.5; NEHTA, 2015; https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-2065-2015
[NEHTA2015c]	Clinical Documents - Common Conformance Profile, version 1.6; NEHTA, 2015; https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-1850-2015
[NEHTA2015d]	eHealth Prescription Record - PCEHR Conformance Profile, version 1.3; NEHTA, 2015; https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-1919-2015/NEHTA-1912-2015