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Clinical Package Validator 2.3
Installation and Configuration Guide

17 July 2015

Approved for external use

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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 PCEHR System Operator.

Refer to the Clinical Package Validator Release Note *for information about the scope of this tool, and the NEHTA Non-Production Disclaimer for appropriate use of the tool.*

For further guidance, contact the NEHTA Help Centre on 1300 901 001 or help@nehta.gov.au.

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Council of Australian Governments

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Document information

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Product version history

Product version	Date	Release comments
2.0	22 August 2014	Major release.
2.1	20 January 2015	Feature and usability enhancements.
2.2	–	Not published.
2.3	17 July 2015	Software enhancements (see release note for details).

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1 Introduction

1.1 Purpose

This document describes how to install and configure version 2.3 of the Clinical Package Validator ("the Validator"). The Validator has been created to help software developers determine whether their healthcare software system produces certain clinical documents that conform to clinical document specifications, and clinical packages that conform to clinical package specifications.

The Validator does not test all conformance specifications and you must read the Release Note for the Validator carefully which indicates what is out of scope, and therefore what additional tests you will need to run to determine if a clinical document conforms to clinical document specifications.

1.2 Intended audience

This document is intended for:

- testers who use the Validator to assist them in assessing whether their healthcare software system produces clinical documents that conform to some clinical document specifications, and clinical packages that conform to some clinical package specifications;
- developers who use the Validator to provide quick feedback during software development; and
- administrators who need to install the Validator for other users.

The Validator does not test all conformance specifications and you must carefully read the Release Note for the Validator which indicates what is out of scope.

1.3 Scope

This document describes the system requirements, administrator rights, and supporting software needed for installing the Validator. It also describes how to install and configure the Validator.

1.4 Overview

The Validator is a tool that can assist testing of whether a healthcare software system is producing clinical documents that conform to the relevant Clinical Document Architecture (CDA®) implementation guide, structured content specification, and PCEHR conformance profile specification. It is not comprehensive. In addition, the Validator tests some terminology codes in clinical documents, and runs some clinical package tests to determine whether they conform to some packaging specifications.

The Validator applies limited template validation to:

- the following clinical documents created by clinical information systems and contracted service provider systems:
  - 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.

- the following clinical documents created by consumer portals:
  - advance care directive custodian documents, personal health notes, and personal health summaries.
- the following clinical documents created by Medicare repositories:
  - Australian childhood immunisation register reports, Australian organ donor register reports, Medicare Department of Veterans' Affairs (DVA) benefits reports, and pharmaceutical benefits reports.
- the following clinical documents created by the PCEHR system:
  - eHealth prescription and dispense views, health check schedule views, Medicare overviews, and observation views.

2 Before you begin

2.1 Prerequisites

Before installing and configuring the Validator, you must have:

- administrator rights to your PC;
- Windows XP, Windows Vista, Windows 7 or Windows 8;
- 2GB minimum memory;
- 4GB recommended memory; and
- 1GB minimum disk space free.

If the following software is not already installed on your computer and your computer does not use Windows 8, it will be automatically installed during the installation of the Validator (Section 3):

- .NET Framework 4.0 or a later version; and
- Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop.

If your computer uses Windows 8, Microsoft SQL Server will need to be installed manually (Section 3.2).

Version 2.3 of the Validator allows more than one version of the software to operate on the same computer (Section 2.2). It is now no longer necessary for a user to uninstall previous versions of the Validator.

A NASH test certificate must be installed before a user can access template packages in the PCEHR software vendor test (SVT) environment (Section 2.3).

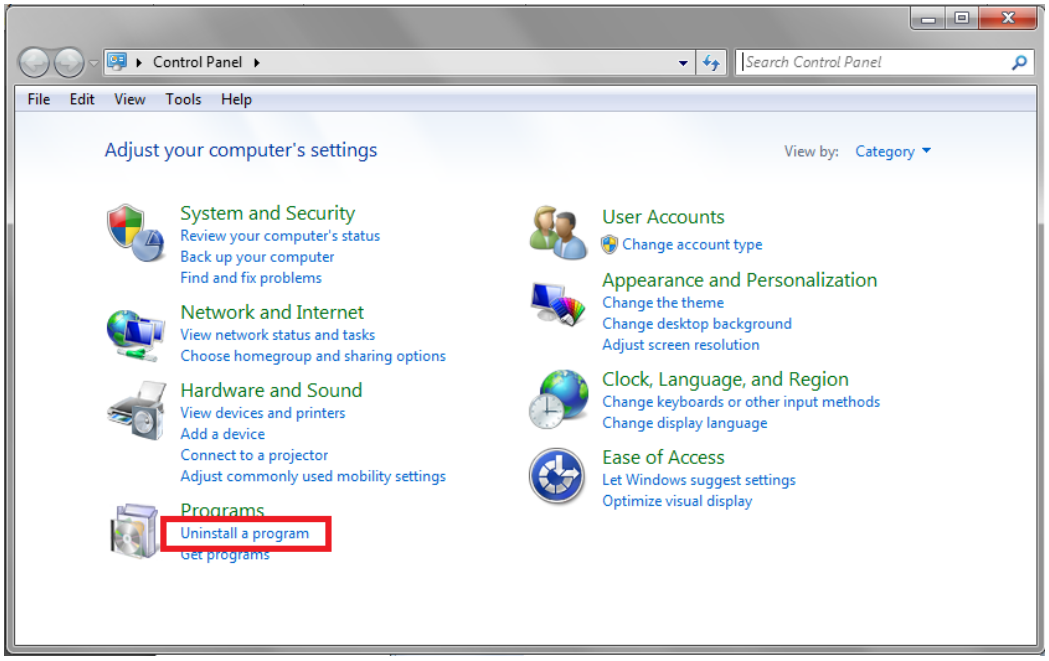
You must also be aware that the Validator runs only a subset of the complete set of tests you must run to validate whether a document is conformant with the clinical document specifications.

2.2 Uninstall an earlier version of the Validator

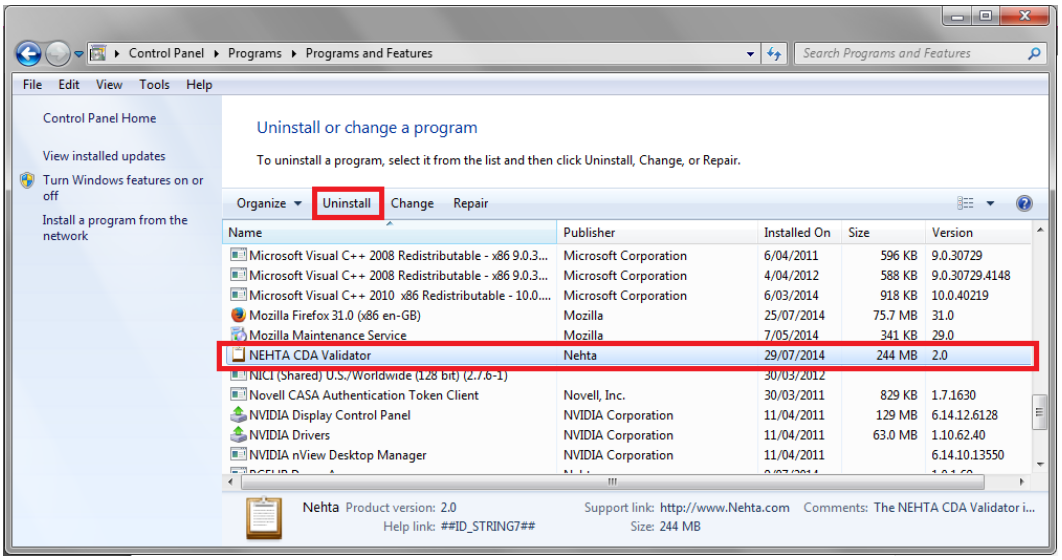
Version 2.3 of the Validator allows more than one version of the software to operate on the same computer, so there is now no longer a need to uninstall earlier versions of the Validator.

Follow the steps below if an earlier version of the Validator is already installed and you want to remove it, otherwise go to Section 2.3.

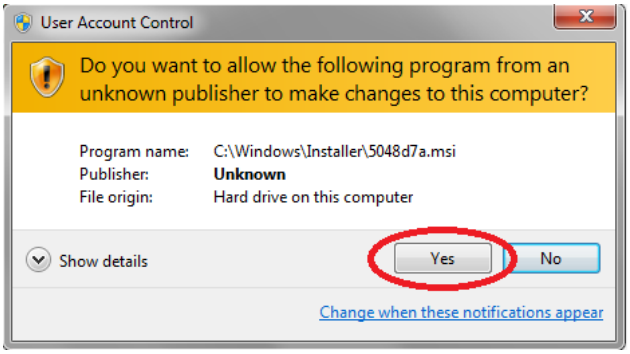
1 If an earlier version of the Validator is already installed, select **Uninstall a program** from the Windows Control Panel.



2 Select the version of the Validator to be uninstalled and then select **Uninstall**.



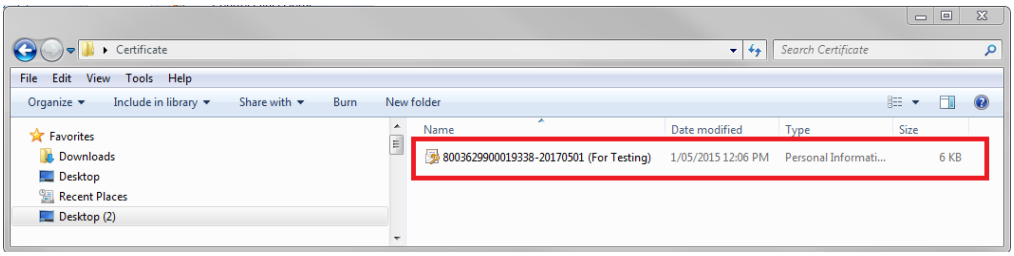
Note: The **Uninstall** option may be selected from the menu, or found by clicking the right mouse button.

3	If the following security screen appears, select **Yes** to allow the Uninstall process to proceed. 
4	The uninstall process will continue to completion.
End	

2.3 Install a NASH test certificate

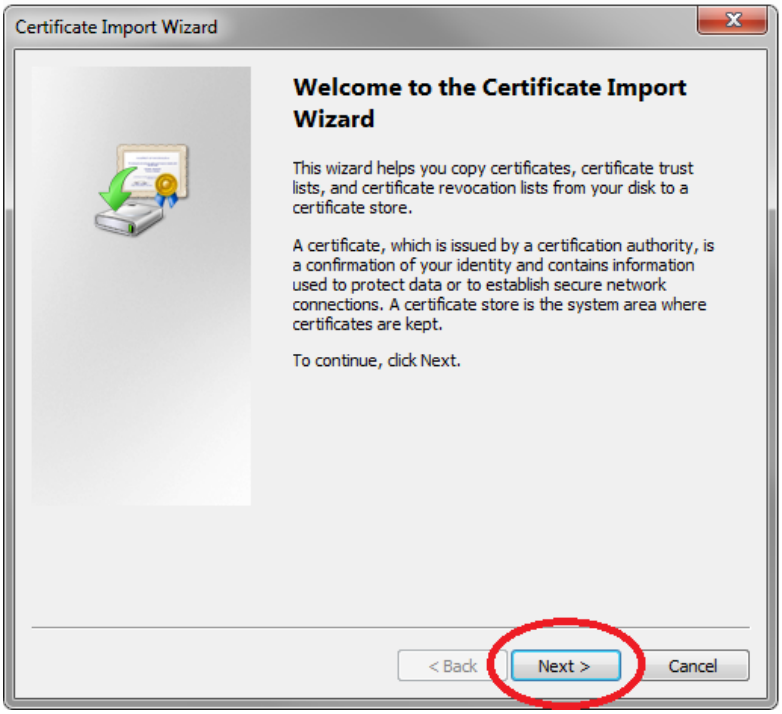
As an alternative to importing template packages from the NEHTA website, the Validator allows a user to import some template packages from the PCEHR software vendor test environment, provided a valid NASH test certificate has already been installed.[1]

Follow the steps below to install a NASH test certificate, otherwise go to Section 3.

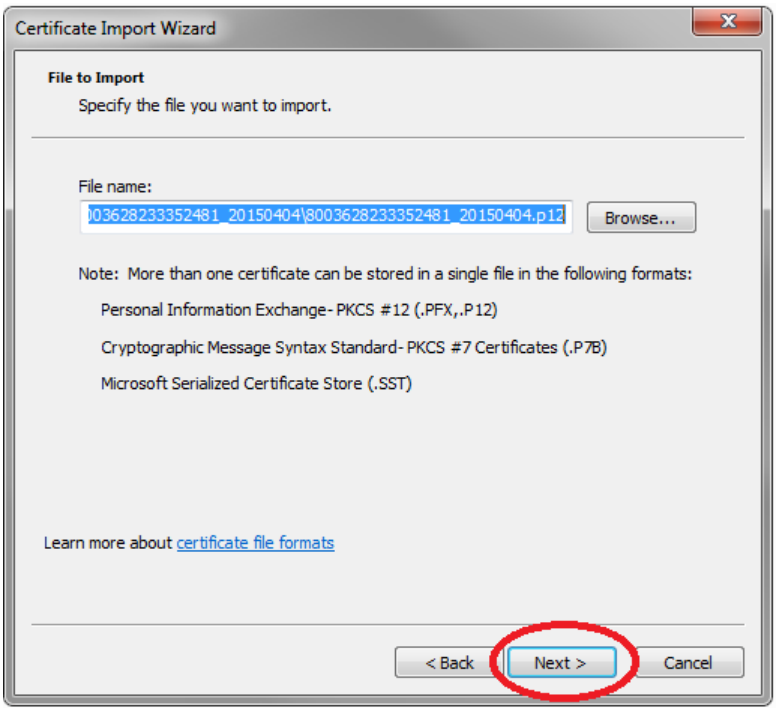
1	Navigate to the folder that contains your NASH test certificates.  **Note.** If you do not have any NASH test certificates, contact the Department of Human Services Online Technical Support helpdesk: otsliaison@humanservices.gov.au.

[1] The Validator can apply any template package. A template package is something that meets the requirements in the *PCEHR Template Service - Template Package Technical Specification v1.0*, available from: https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1514-2012/NEHTA-1042-2012

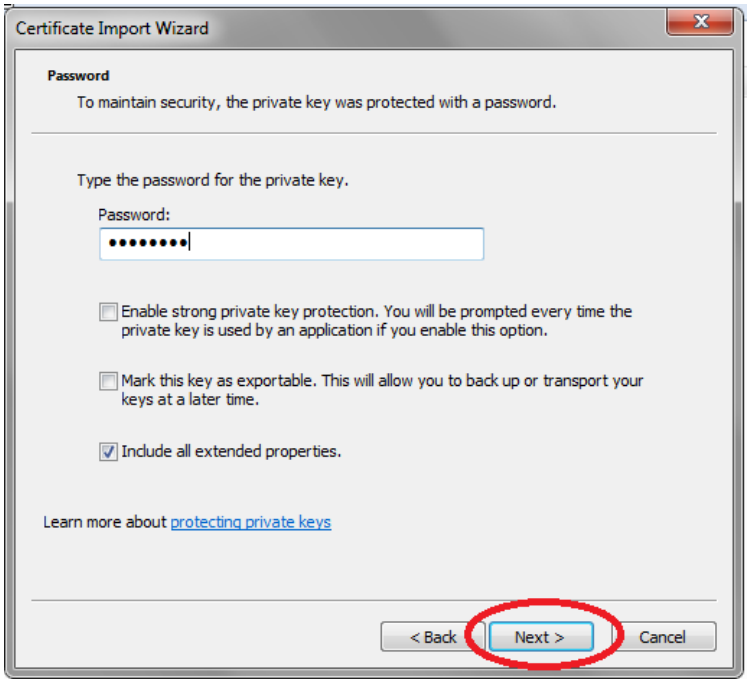
2 Double-click the relevant certificate to launch the Certificate Import Wizard and select **Next**.



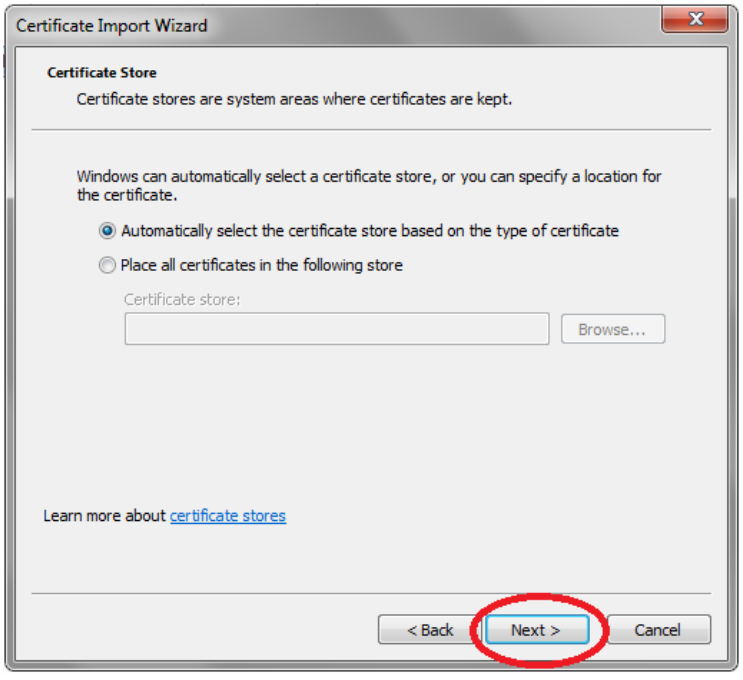
3 Select **Next**.



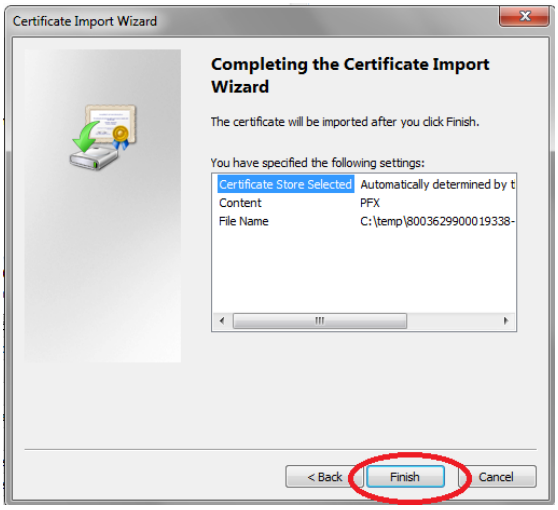
4 Enter the password and select **Next**.



5 Select **Next**.



6 Select **Finish**.



Note: You may need to restart your computer so that the Validator can detect the newly installed NASH test certificate.

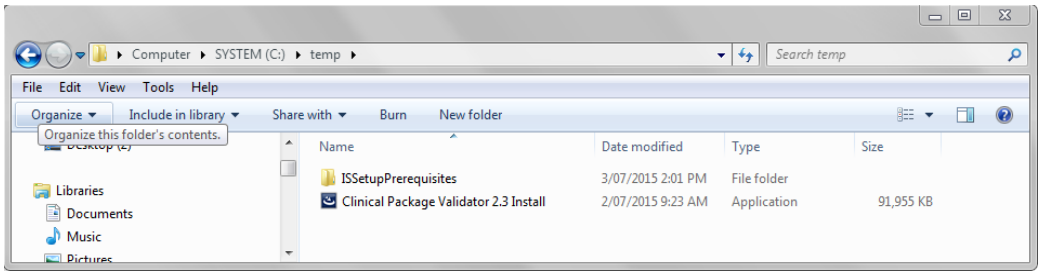
End

3 Install the Validator and prerequisite software

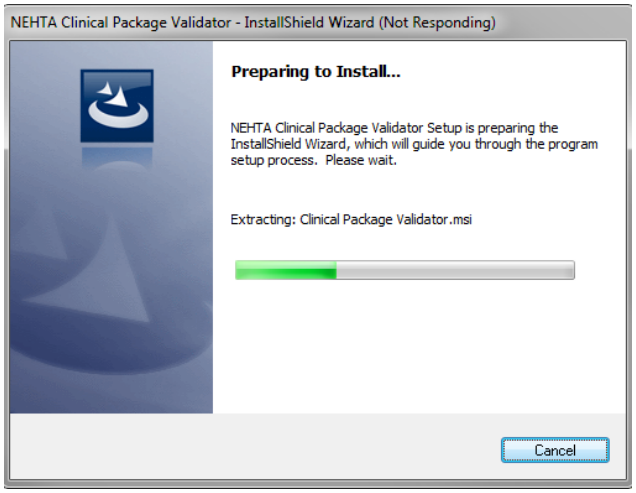
3.1 Install version 2.3 of the Validator

This procedure requires that .NET Framework 4.0 (or a later version) and Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop are installed. If this software is not already installed on your computer and your computer does not use Windows 8, it will be automatically installed during the installation of the Validator. If your computer uses Windows 8, Microsoft SQL Server will need to be installed manually (Section 3.2).

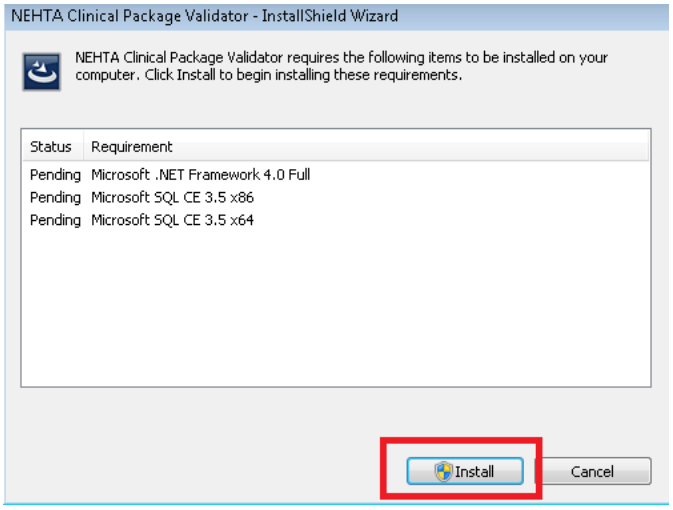
To install the Validator, follow the steps below.

1	Locate the **Clinical Package Validator 2.3 Install.exe** file and the **ISSetupPrerequisites** folder within the expanded .ZIP file that contained this guide. Save the **Clinical Package Validator 2.3 Install.exe** file and the **ISSetupPrerequisites** folder to a preferred location on a local drive (e.g. C:\temp). **Note:** The Validator installation may not work from a network drive. **Note:** The **Clinical Package Validator 2.3 Install.exe** file and the **ISSetupPrerequisites** folder must be co-located. **Note:** The **ISSetupPrerequisites** folder contains prerequisite software that will be installed along with the Validator if the prerequisite software is not already installed on your computer.
2	Open Windows Explorer and navigate to the **Clinical Package Validator 2.3 Install.exe** file. Double-click the file to install the software. 
3	**Note:** Windows may mark files downloaded from the Internet as 'Blocked'. This prevents the Validator from running. To unblock a file, right click on it and select **Properties**, then select **Unblock** in the 'General tab' followed by **OK**.
4	Once the file is unblocked, continue installing the Validator by once again double clicking the **Clinical Package Validator 2.3 Install.exe** file.

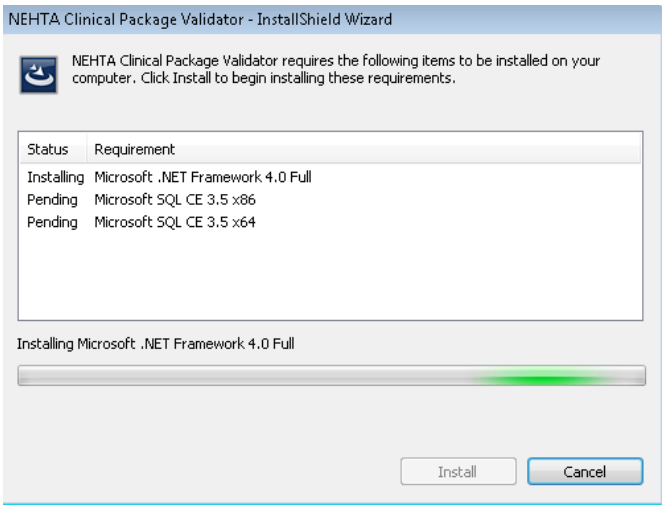
5 The InstallShield Wizard will open.



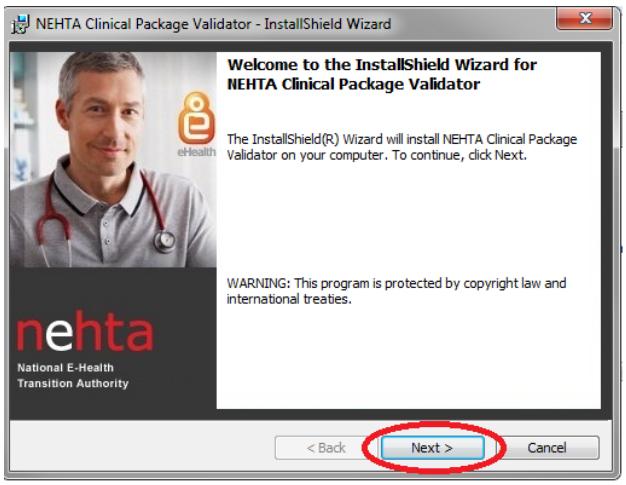
6 The Validator installation script will check for the presence of the prerequisite software. A message is displayed if any prerequisite software needs to be installed. To continue select **Install**.



7 The prerequisite software will be installed.

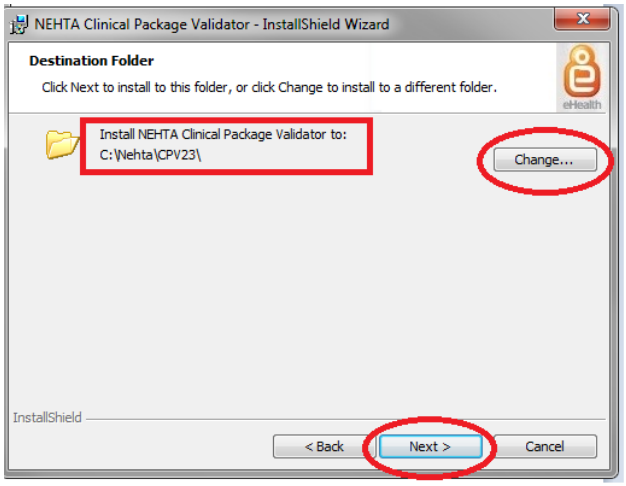


8 When the InstallShield Wizard has completed opening, select **Next**.

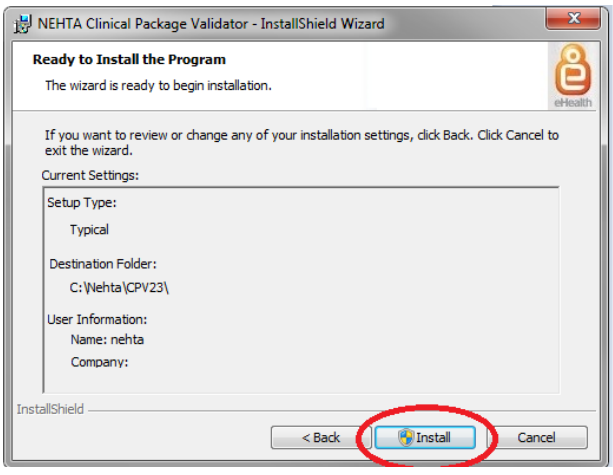


9 The default install location is C:\Nehta\CPV23\. To change the install location, select the **Change** button and choose another location on the C: drive, if preferred.

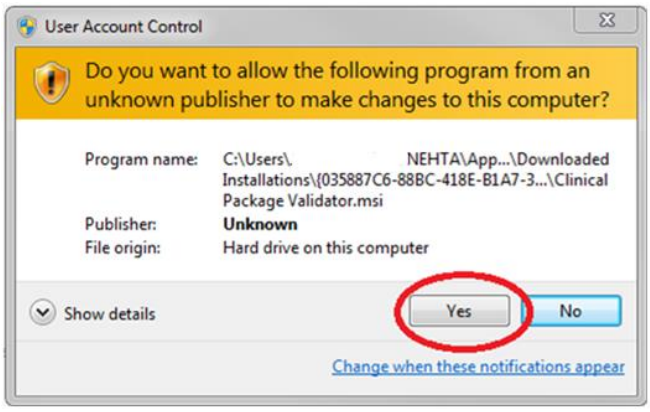
Once the preferred install location is chosen, select **Next**.



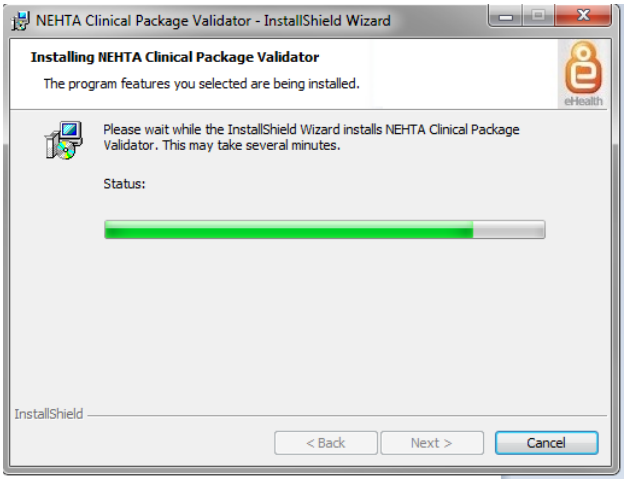
10 Select **Install**.



11 If the following security screen appears, select **Yes** to allow the installation to proceed.



12 The Validator will start installing.



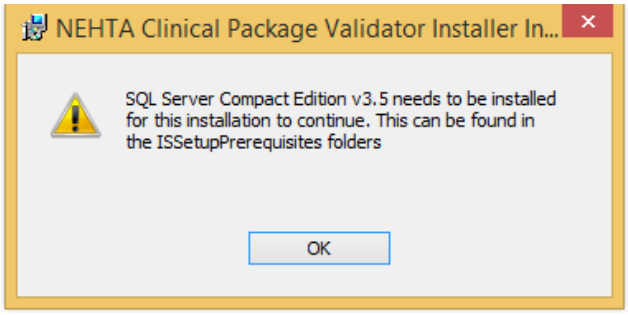
13 Once the Validator installation is complete, select **Finish**.

The Validator is now installed.

End

Note: During the installation process the Clinical Package Validator 2.3 installation script will determine whether the prerequisite software is already installed on the computer. If the software is not already installed, the Clinical Package Validator 2.3 installation script will run the additional installation scripts in the **ISSetupPrerequisites** folder to install the prerequisite software.

However, if the operating system is Windows 8, the Clinical Package Validator 2.3 installation script will be unable to detect if Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop is already installed, and the following message is displayed.



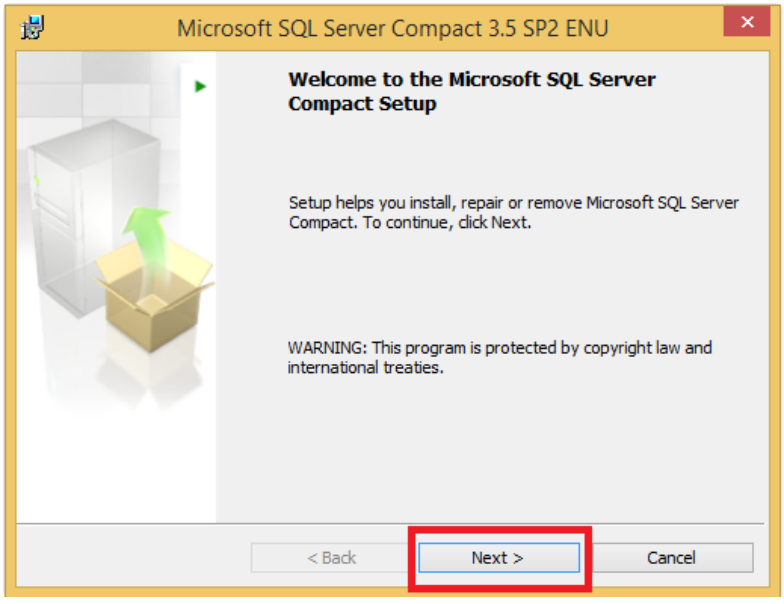
If the above message is displayed, go to Section 3.2. If the above message is not displayed, go to Section 4.

3.2 Manually install Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop

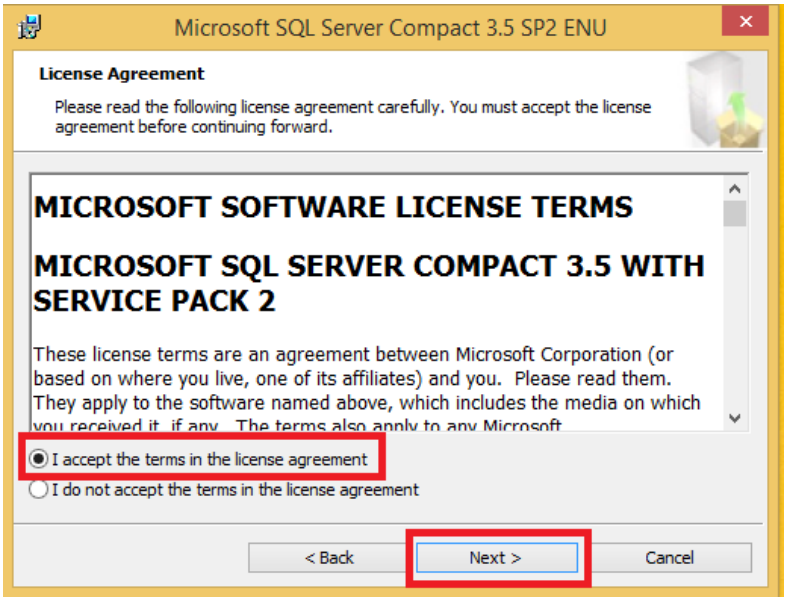
The Microsoft SQL Server Compact 3.5 Service Pack 2 for Windows Desktop is the software used by the Validator to store terminology datasets. If it is not already present on the computer, it is automatically installed by the Validator, unless the operating system is Windows 8 in which case it must be installed manually.

To manually install Microsoft SQL Server, follow the steps below.

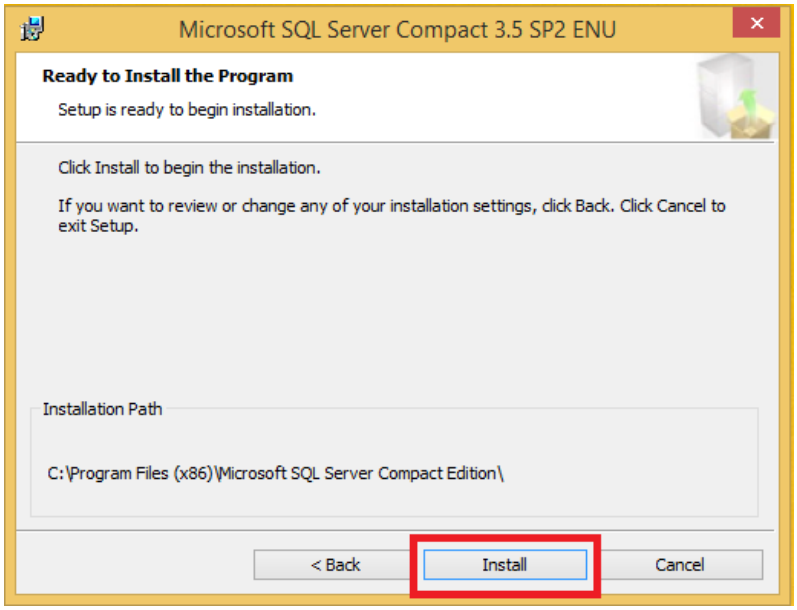
1	Select the **SSCERuntime_x86-ENU.msi** installation script in the ISSetupPrerequisites\{B1165B38-CA52-11E0-A63D-7C004824019B} folder.
2	When the following screen appears, select **Next**.



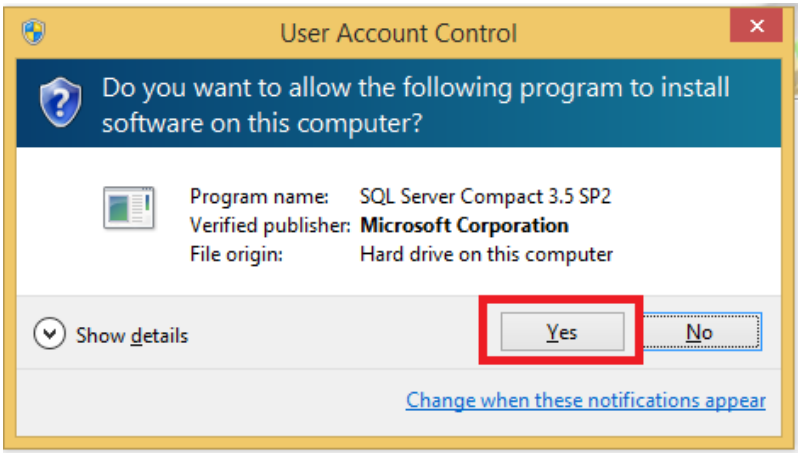
3 If you accept the license agreement terms, select **I accept the terms in the license agreement** and then select **Next**.



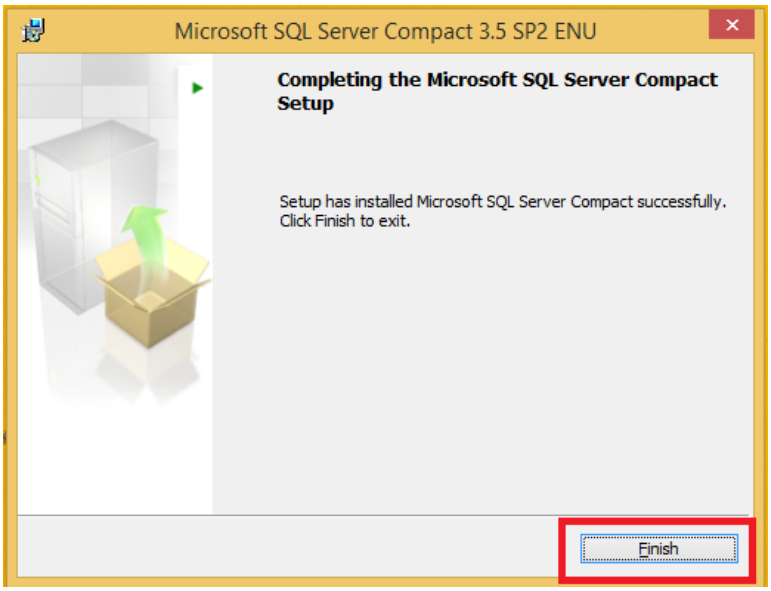
4 To install the software select **Install**.



5 If the following message is displayed select **Yes**.



6 To end the installation process select **Finish**.



7 If the computer uses a 64-bit operating system, an additional installation script needs to be applied.

Select the **SSCERuntime_x64-ENU.msi** installation script in the ISSetupPrerequisites\{B9E5C848-CA52-11E0-9D02-80004824019B} folder and follow the steps to complete the installation process.

End

4 Configure the Validator

4.1 Select template packages

The Validator uses template packages to assess whether some clinical documents conform to published specifications. Template packages include schema and Schematron rules.

The Validator needs a template for each type of clinical document that is in scope for the Validator to test and for 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 (e.g. if healthcare software with access to the PCEHR system is revised, then it may be less risk to continue using the template rather than a new version).

The Validator does not test all conformance specifications. Please refer to the Validator Release Note for further information about exclusions and the Non-Production Disclaimer.

Template packages may be obtained by:

1 downloading the template packages from the NEHTA website and importing them into the Validator; or

2 importing the template packages from the PCEHR software vendor test environment into the Validator.

For either option, the clinical documents template package directory on the NEHTA website should be viewed to determine which version of the template packages should be used.

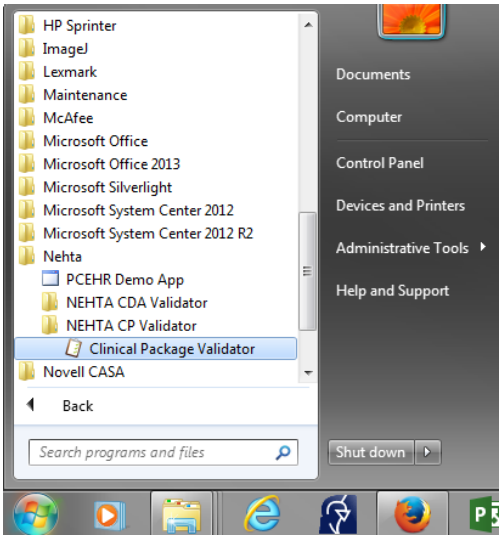
To view the clinical documents template package directory, follow the steps below.

1	Download the clinical documents template package directory from the NEHTA website[2] and save a copy. **Note:** If the webpage for the template package directory states that a newer version is available, download the newest version.
2	Read the 'usage instructions' worksheet in the template package directory spreadsheet and determine from the 'directory' worksheet the template package identifier and version number to use. **Note:** An 'HPIIRelaxed' template package may only be used to upload documents to the PCEHR system with the permission of the PCEHR system operator.
End	

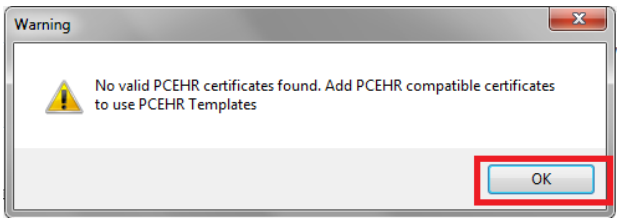
[2] https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1818-2015/NEHTA-2002-2015

4.2 Launch the Validator

1 Launch the Validator by selecting Start > All Programs > Nehta > NEHTA CP Validator > Clinical Package Validator

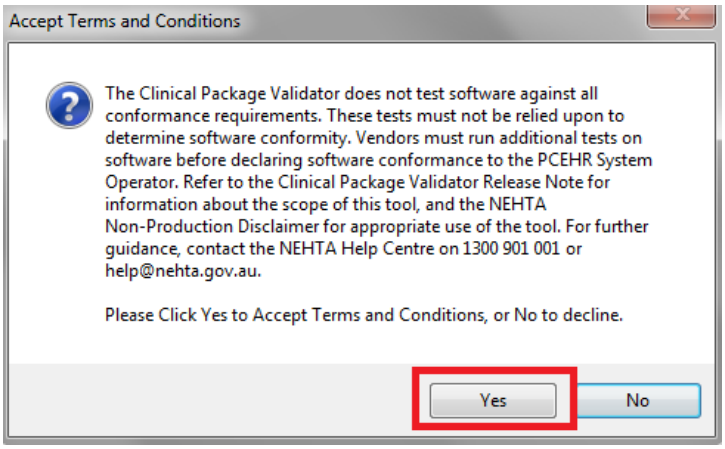


2 A warning message is displayed if the Validator detects that a NASH test certificate has not been installed. To continue select **OK**.

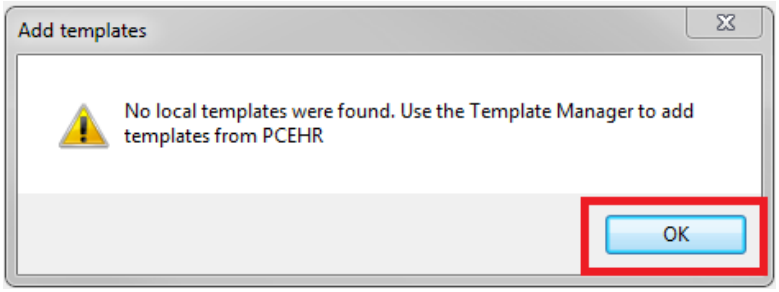


Note: The Validator may be used without a NASH test certificate if template packages are downloaded from the NEHTA website and imported into the Validator. The recommended approach, however, is to import template packages from the PCEHR software vendor test environment. To install a NASH test certificate, exit the Validator and follow the steps in Section 2.3.

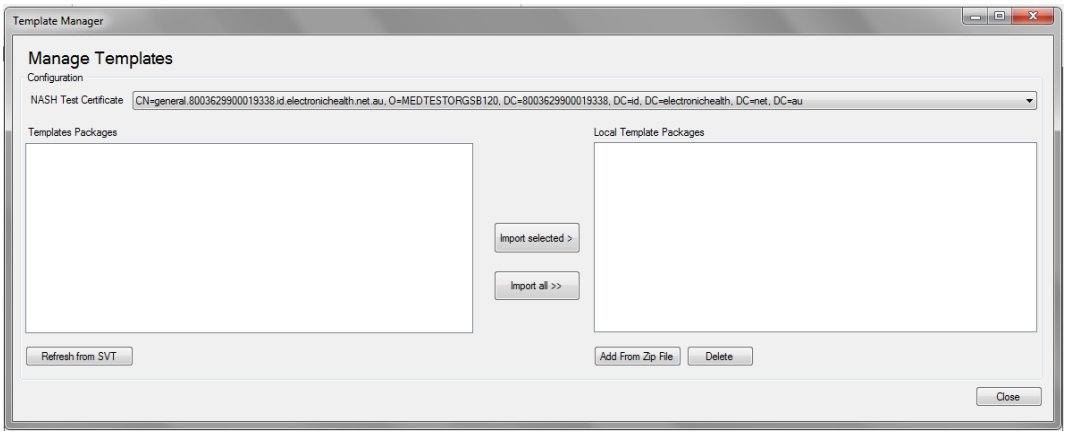
3 There may be a delay of several minutes before the terms and conditions message below is displayed. If you accept these terms and conditions, select **Yes** to continue. If you select **No**, the Validator will close.



4 If the following message is displayed, select **OK**.



5 The template manager will now be displayed.



To proceed, either import template packages from the PCEHR software vendor test environment (SVT) (Section 4.3) or import template packages downloaded from the NEHTA website (Section 4.4).

End

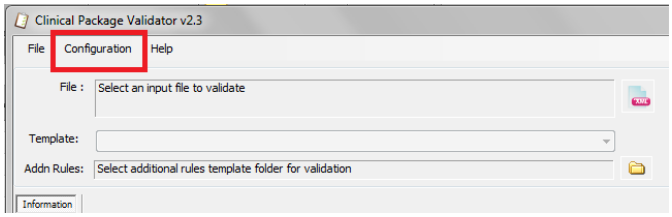
4.3 Import template packages from the PCEHR SVT

Template packages may be imported from the PCEHR software vendor test (SVT) environment as an alternative to importing them from the NEHTA website (Section 4.4).

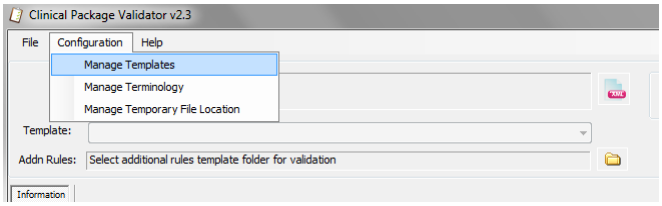
Note: A NASH test certificate must first be installed before template packages can be imported from the SVT environment (Section 2.3).

To import template packages from the PCEHR SVT environment, follow the steps below.

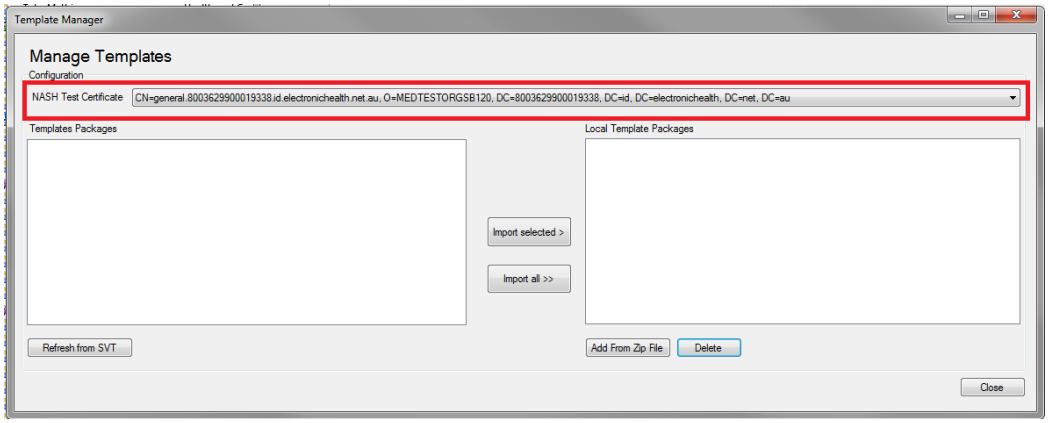
1 Select the **Configuration** menu.



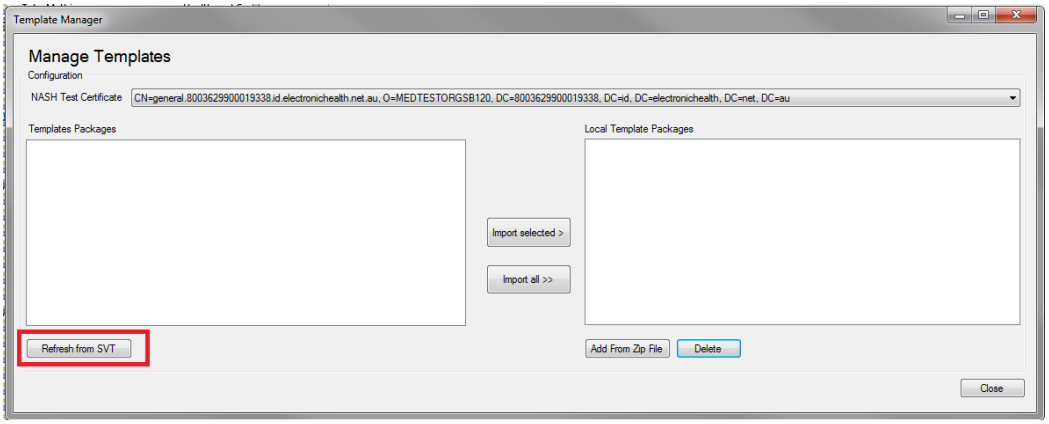
2 Select **Manage Templates**.



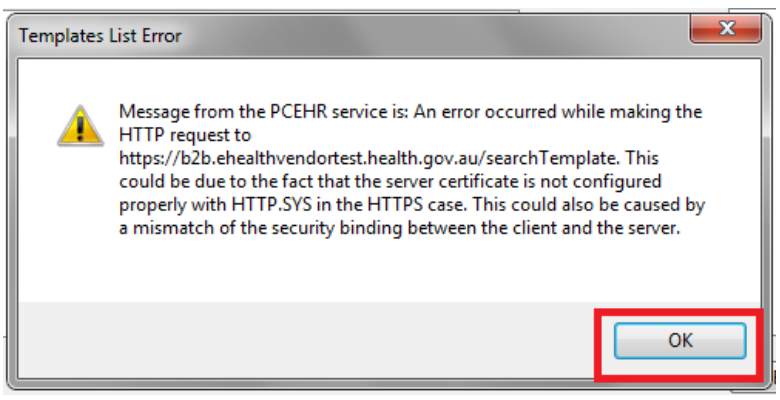
3 If one or more NASH test certificates have been installed, the available certificates will be displayed in a pull down list. Select the certificate to be used.



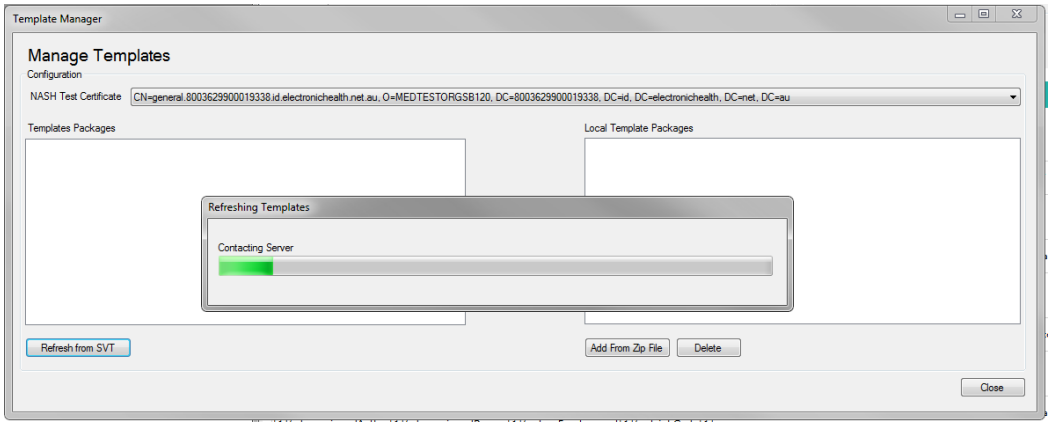
4 To obtain the list of template packages that may be imported from the PCEHR SVT environment, select **Refresh from SVT**.



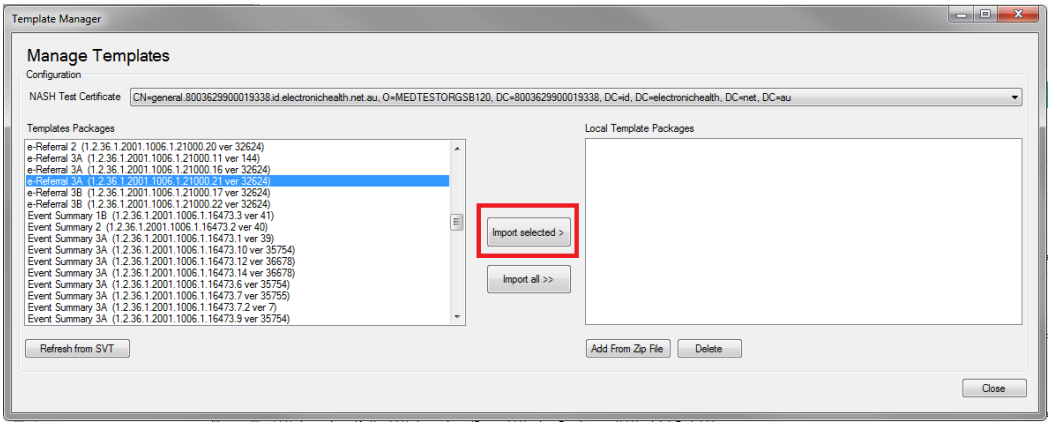
5 An error message is displayed if the PCEHR software vendor test environment cannot be contacted. To continue, select **OK** and determine if there is a working connection to the Internet.



6 The list of template packages will be obtained from the PCEHR SVT.

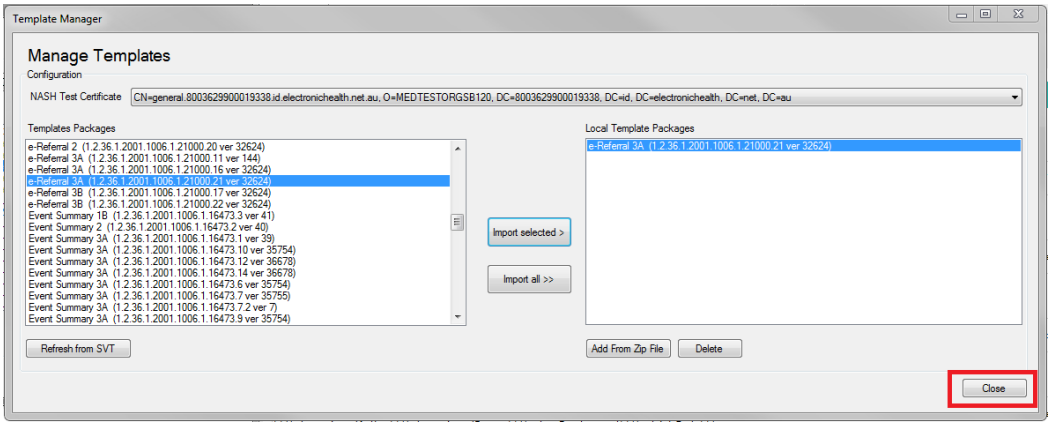


7 Choose the required template package and select **Import selected.**



Note: An **Import all** option is also provided.

8 Verify that the template package has been imported into the Validator and select **Close**.



End

4.4 Import template packages downloaded from the NEHTA website

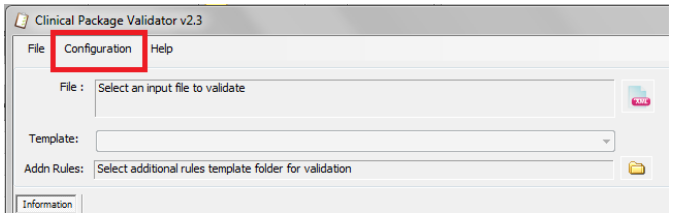
Template packages may be downloaded from the NEHTA website and imported into the Validator as an alternative to importing them from the PCEHR software vendor test environment (Section 4.3). To download a template package from the NEHTA website, follow the steps below.

1 Download the template package library from the selected clinical document type end product, available from https://www.nehta.gov.au/implementation-resources/clinical-documents.

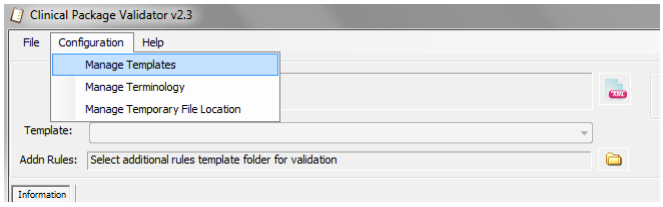
2 Unzip the template package library ZIP file and save the selected template packages to a preferred location.

Note: A template package is in the form of a ZIP file within the template package library. Earlier versions of the Validator needed the template package ZIP file to be unzipped, whereas version 2.3 of the Validator imports the template package ZIP file.

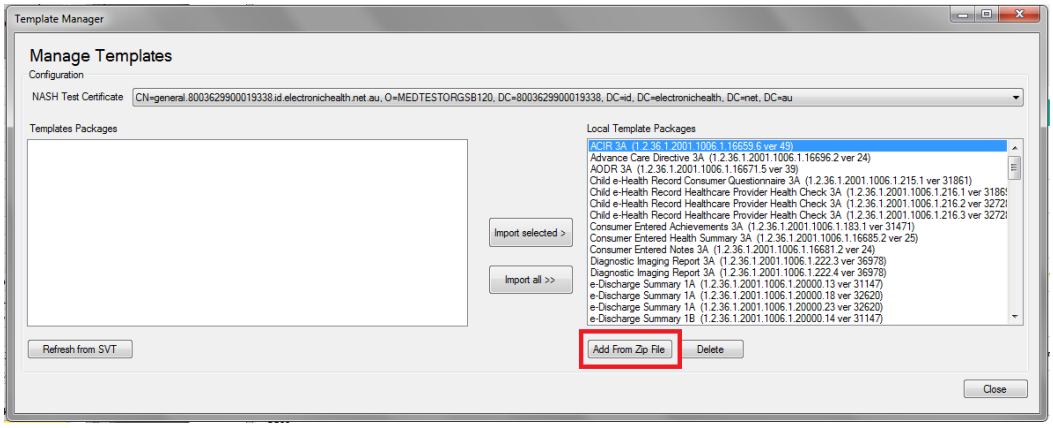
3 To import the downloaded template package, select the **Configuration** menu.



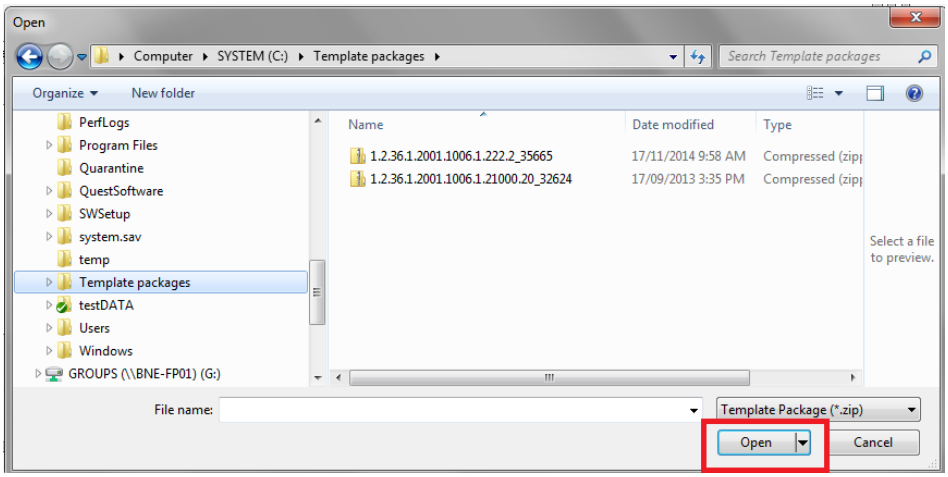
4 Select **Manage Templates**.



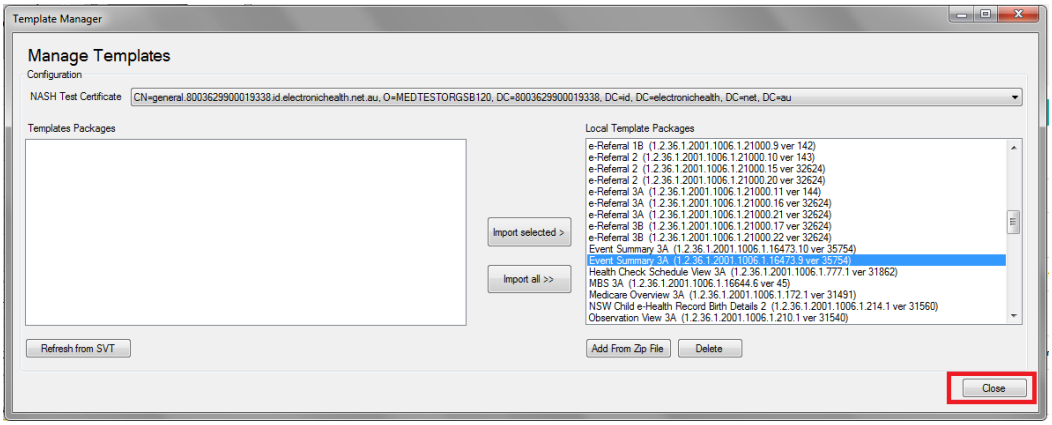
5 Select **Add From ZIP File**.



6 Navigate to the directory in which the downloaded template package has been stored, locate the required template package ZIP file and select **Open**.



7 Verify that the template package has been imported into the Validator and select **Close**.

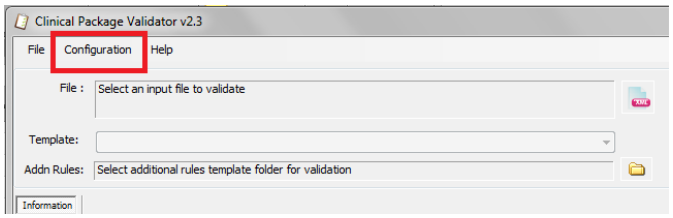


End

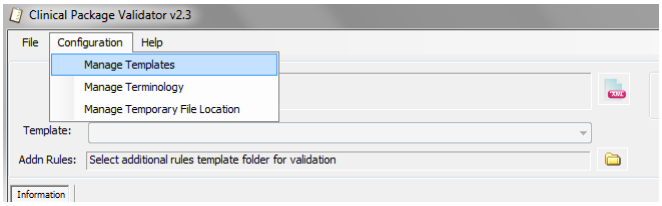
4.5 Delete template packages

Template packages imported into the Validator should be deleted if they are no longer needed.

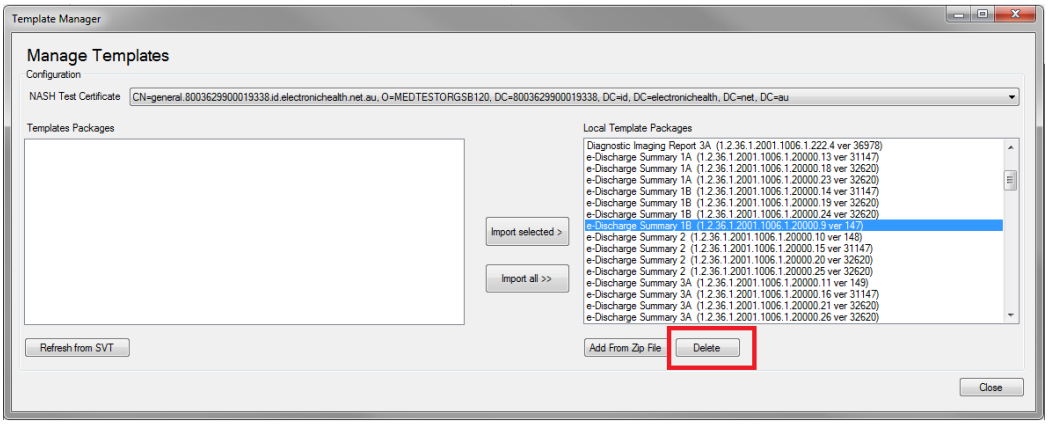
1 To delete a template package from the Validator, select the **Configuration** menu.



2 Select **Manage Templates**.



3 Choose the template package to be deleted and select **Delete**.



End

4.6 Configure clinical terminology datasets

The Validator provides limited testing of terminology. Refer to the Product Release Note for what is out of scope.

The Validator is preloaded with clinical terminology datasets. As clinical terminology is frequently revised, resulting in new versions of clinical terminology datasets being regularly published, the Validator allows an administrator or user to upload new versions of the terminology datasets listed in Table 1.

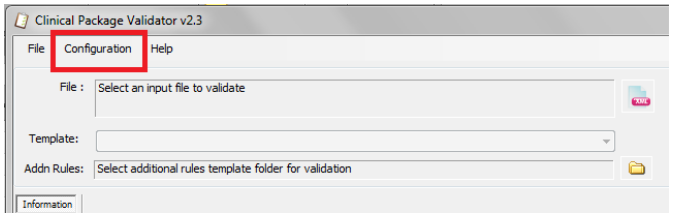
Unlike previous versions, version 2.3 of the Validator allows a user to import AMT, SNOMED CT-AU, and PBS clinical terminology datasets in ZIP format.

Table 1 - Code systems the user can import into the Validator

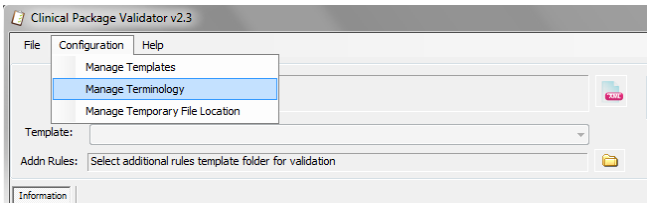
Code system name	Code system identifier
Australian Medicines Terminology (AMT) version 3	2.16.840.1.113883.6.96
Australian Medicines Terminology (AMT) version 2	1.2.36.1.2001.1004.100
PBS Item codes	1.2.36.1.2001.1005.22
PBS Manufacturer codes	1.2.36.1.2001.1005.23
Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU)	2.16.840.1.113883.6.96

4.6.1 Determine which terminology datasets are loaded

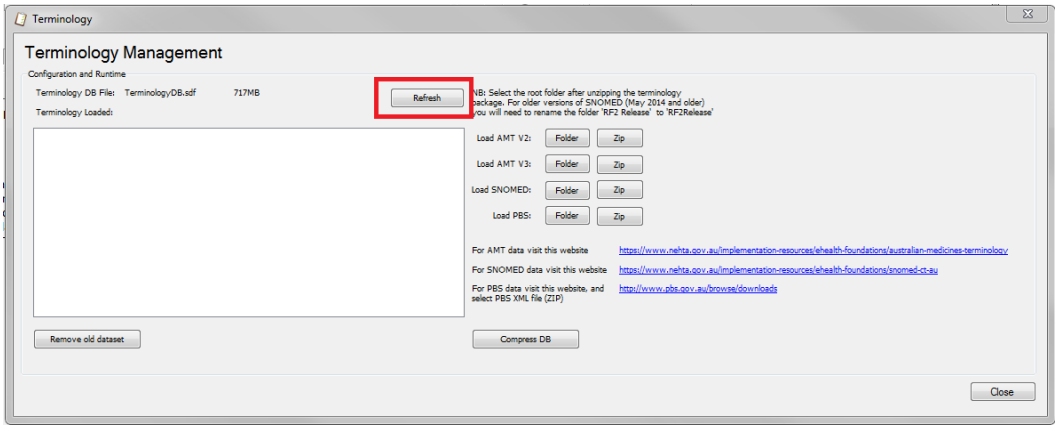
1 To determine which versions of terminology datasets are already present in the Validator database, select the **Configuration** menu.



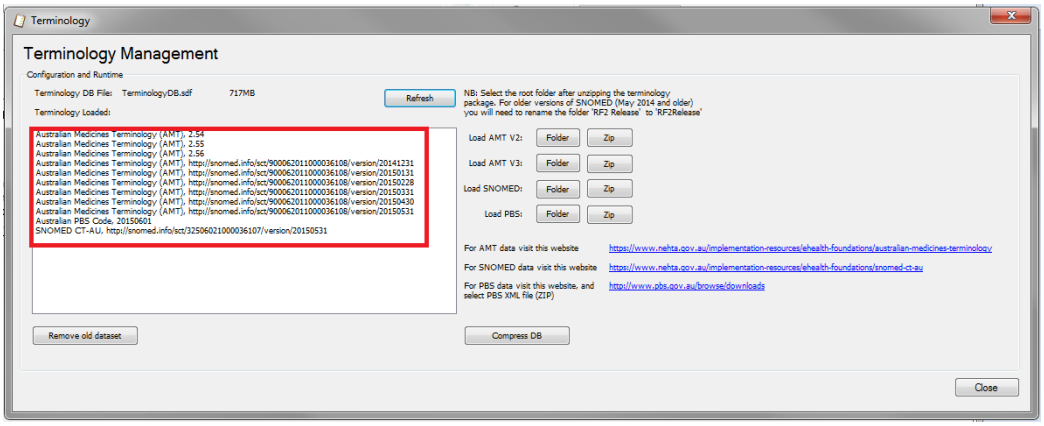
2 Select **Manage Terminology**.



3 Select **Refresh**.



4 A list of terminology datasets and their versions will be displayed.

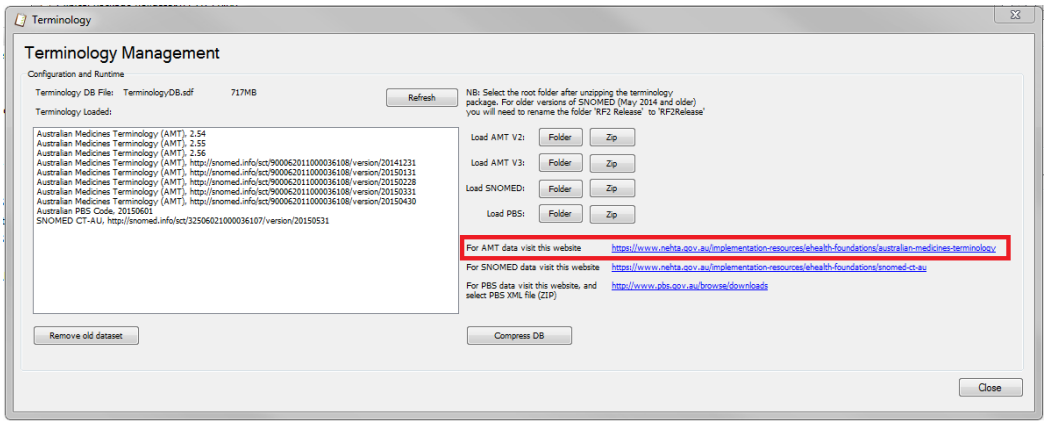


- AMT version 2 uses the version number format '2.nn' (e.g. '2.56').
- AMT version 3 uses the version number format 'http://snomed.info/sct/900062011000036108 /version/YYYYMMDD' where 'YYYYMMDD' is the date of release of a specific AMT version 3 dataset (e.g. 'http://snomed.info/sct/900062011000036108/version/20140630').
- PBS uses the version number format 'YYYYMMDD' where 'YYYYMMDD' is the date of release of a specific PBS dataset (e.g. '20141130').
- SNOMED CT-AU uses the version number format 'http://snomed.info/sct/32506021000036107/version/YYYYMMDD' where 'YYYYMMDD' is the date of release of a specific SNOMED CT-AU dataset (e.g. 'http://snomed.info/sct/32506021000036107/version/20141130').

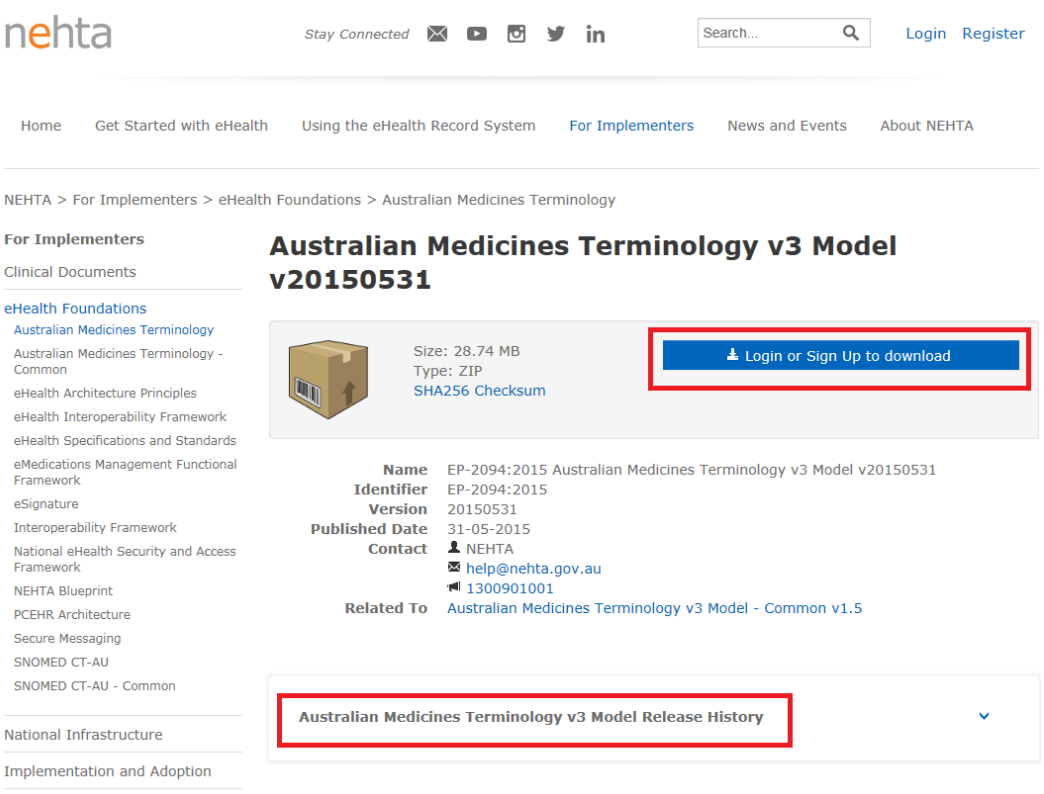
Note: PBS Item codes and PBS Manufacturer codes are both included in the PBS dataset.

4.6.2 Find and load another version of the AMT dataset

1 To find and load another version of the AMT dataset, select the link to the AMT website in the **Terminology Management** facility. You would do this if your clinical document uses a terminology release that is not one of the versions included in the Validator.

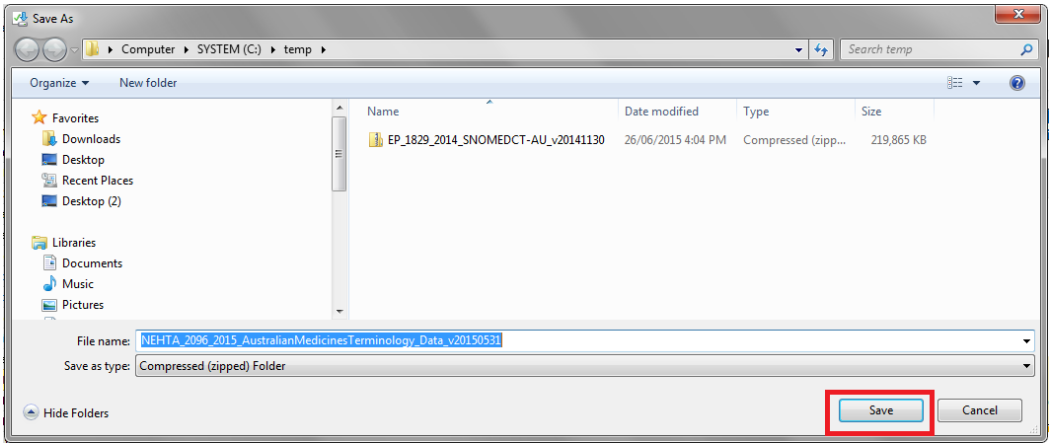


2 Either select **Login or Sign Up to download** to download the latest version of AMT v3, which is presented by default, or select **Australian Medicines Terminology v3 Model Release History** to select and download earlier versions of AMT (i.e. either v3 or v2).

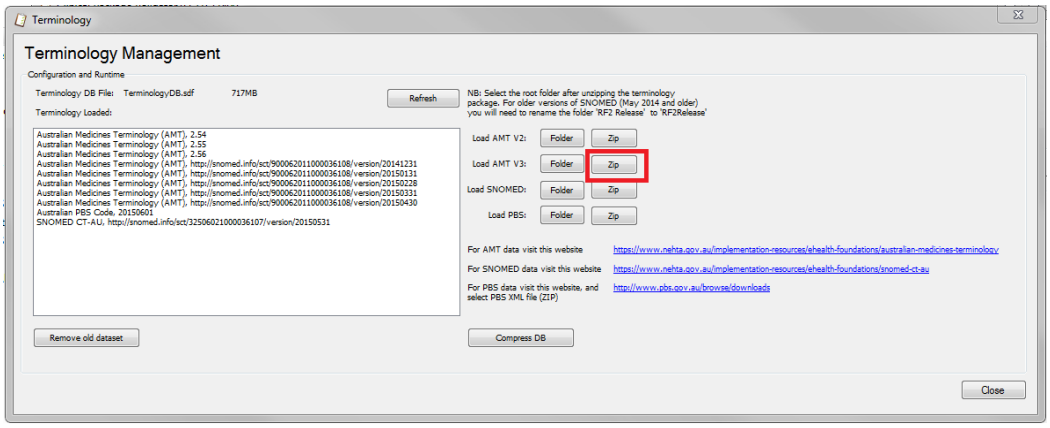


Note: If you have already logged in to the NEHTA website, a **Download** button will be presented rather than **Login or Sign Up to download**.

3 Save a copy of the selected AMT XML file in the C:\temp directory or some other local directory.

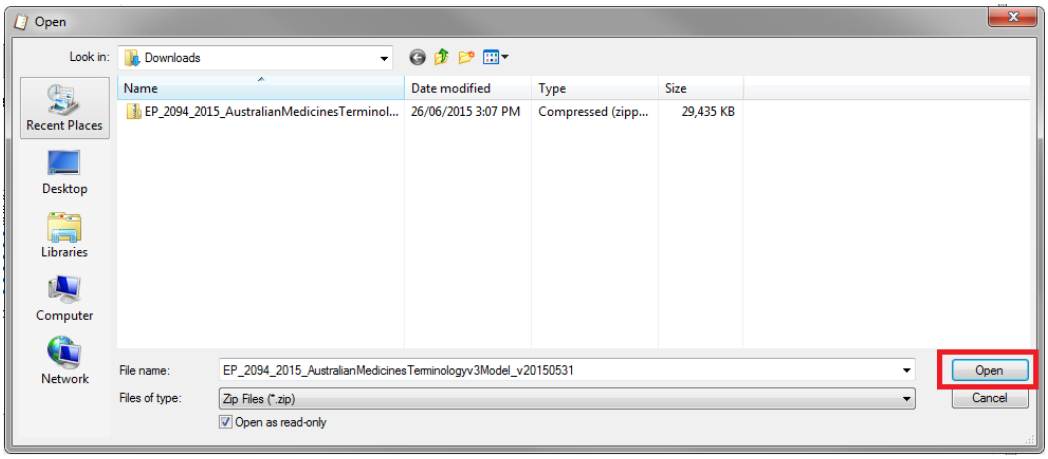


4 Import the downloaded AMT package ZIP file by selecting **Zip** for either 'Load AMT V2' or 'Load AMT V3' (depending on the version that was downloaded from the NEHTA website).

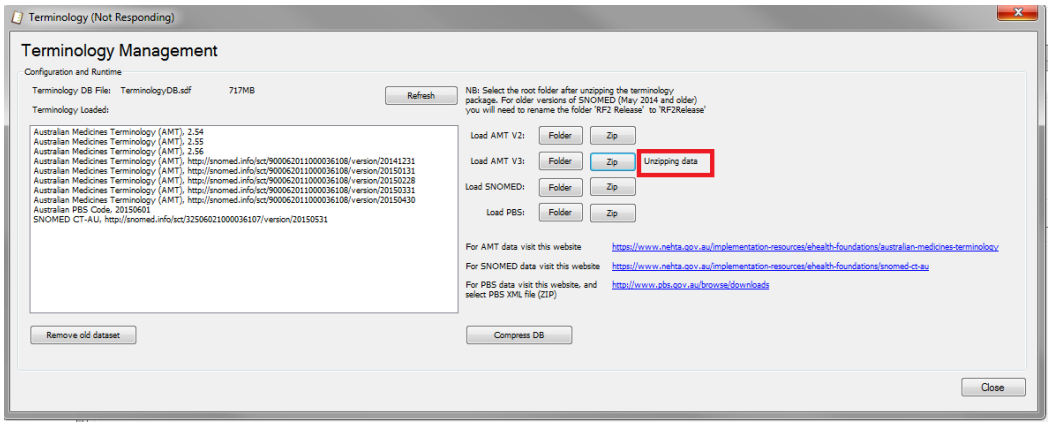


Note: If the AMT package ZIP file was already downloaded and unzipped into a folder, the contents of the folder may be imported by selecting **Folder**.

5 Select the AMT package ZIP file and select **Open**.

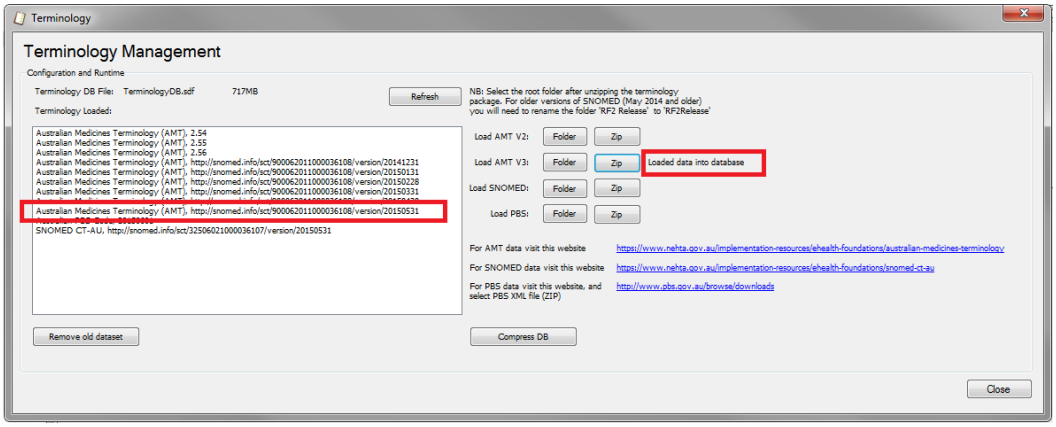


6 The message 'Unzipping data' is displayed while the AMT dataset is being imported.



Note: The loading process may take many minutes to complete.

7 Confirm that the AMT dataset has been successfully loaded into the Validator database. The message 'Loaded data into database' should appear next to the button that was selected to load the dataset, and the terminology dataset should appear in the 'Terminology Loaded' list.

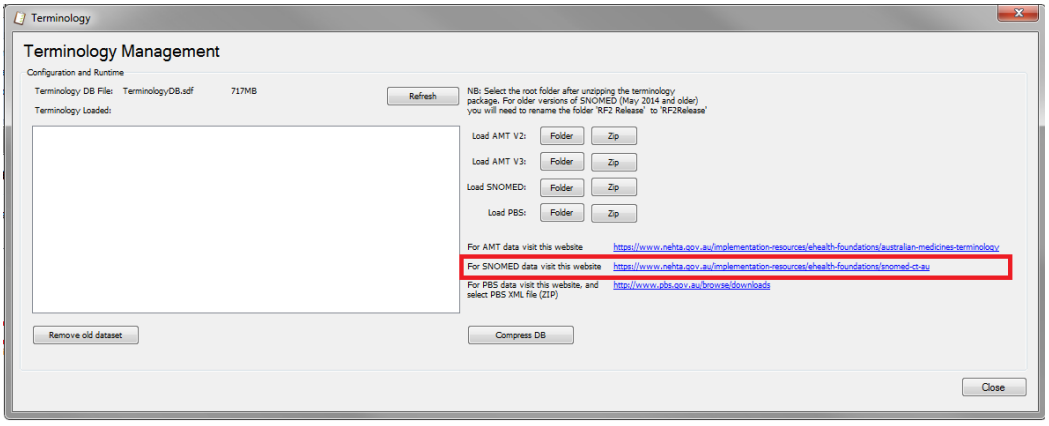


Note: The **Refresh** button may need to be selected to see the list of loaded terminology datasets.

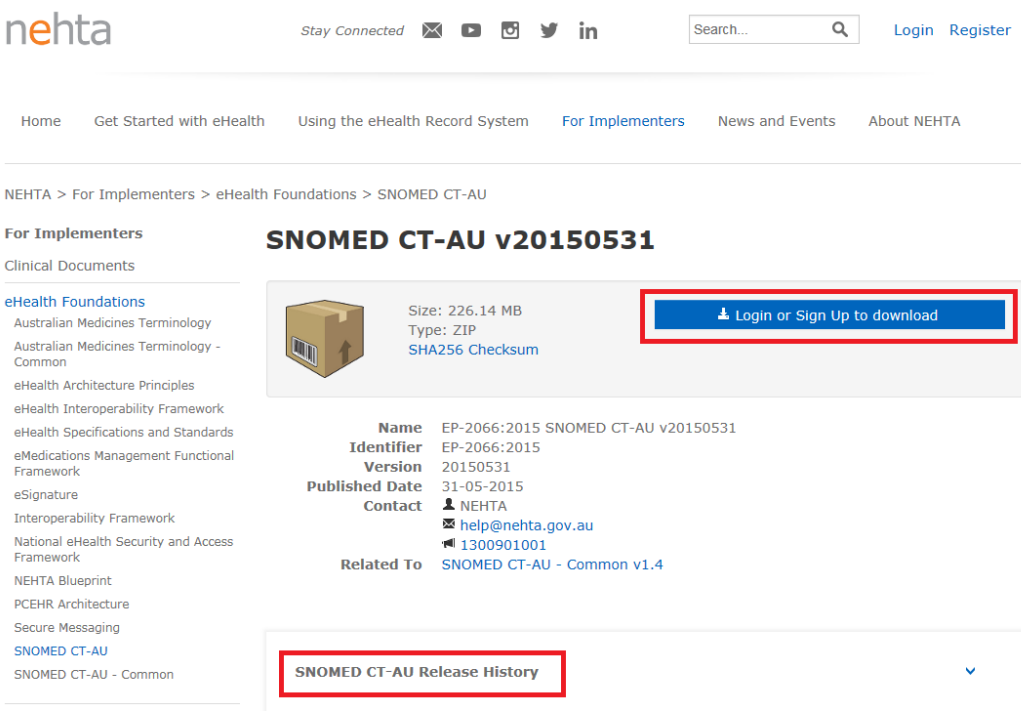
End

4.6.3 Find and load another version of the SNOMED CT-AU dataset

1 To obtain and load another version of the SNOMED CT-AU dataset, select the link to the SNOMED CT-AU website. You would do this if your clinical document uses a terminology release that is not one of the versions included in the Validator.

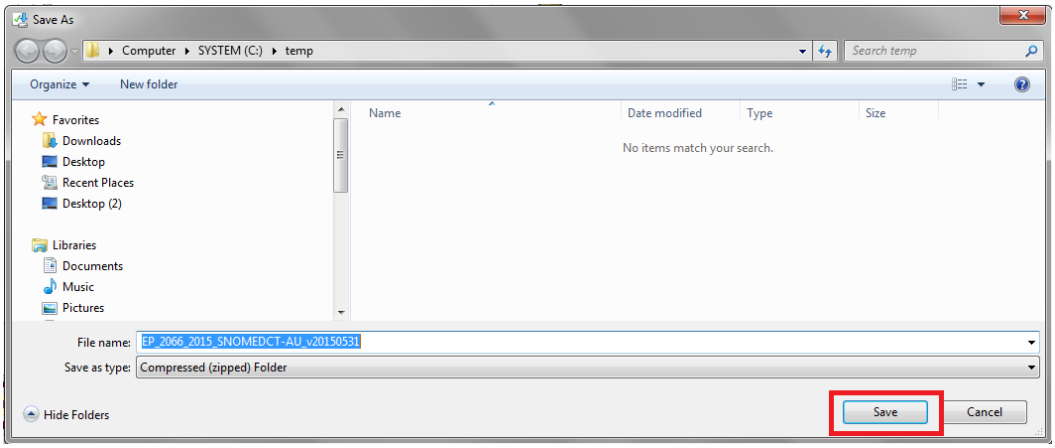


2 Either select **Login or Sign Up to download** to download the latest version of SNOMED CT-AU, which is presented by default, or select **SNOMED CT-AU Release History** to select and download an earlier version.

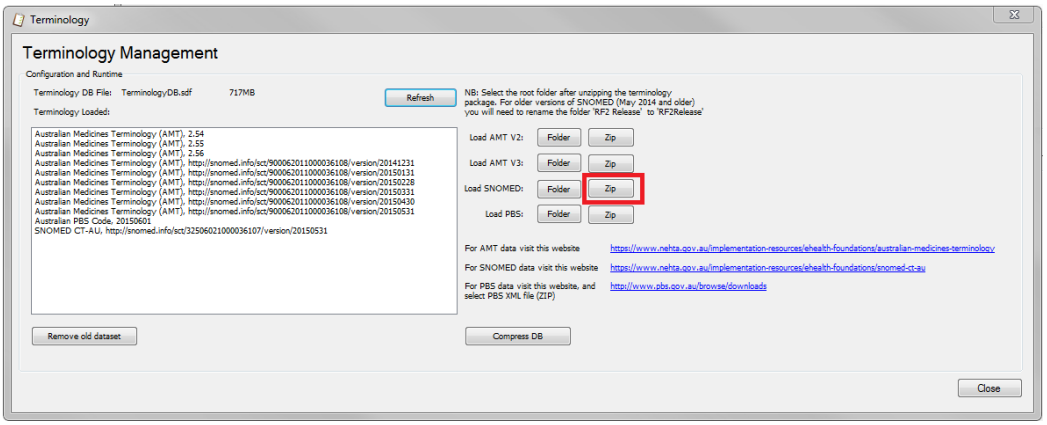


Note: If you have already logged in to the NEHTA website, a **Download** button will be presented rather than **Login or Sign Up to download**.

3 Save a copy of the selected SNOMED CT-AU XML file in the C:\temp directory or another local directory.

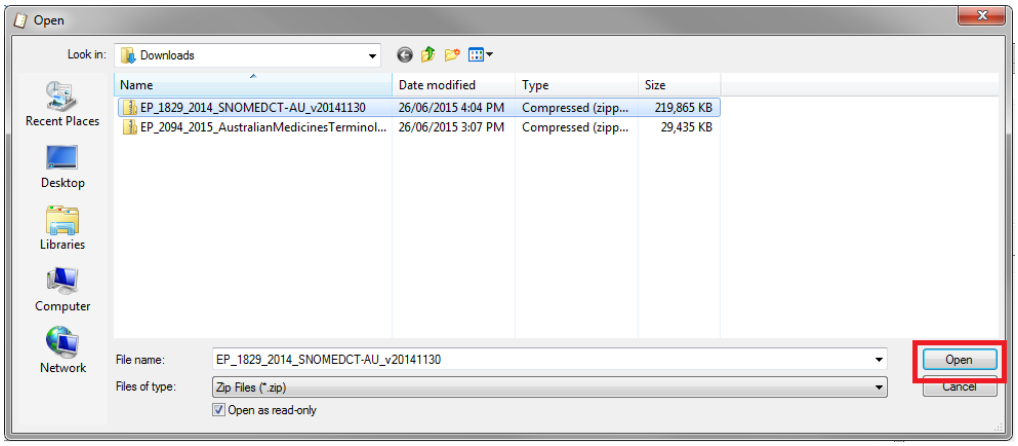


4 Import the downloaded SNOMED CT-AU package ZIP file by selecting **Zip** for 'Load SNOMED'.

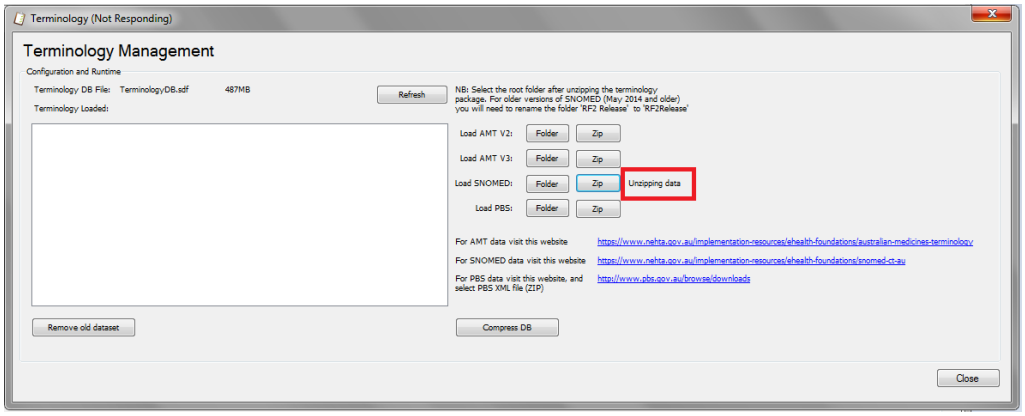


Note: If the SNOMED CT-AU package ZIP file was already downloaded and unzipped into a folder, the contents of the folder may be imported by selecting **Folder**.

5 Select the SNOMED CT-AU package ZIP file and select **Open**.

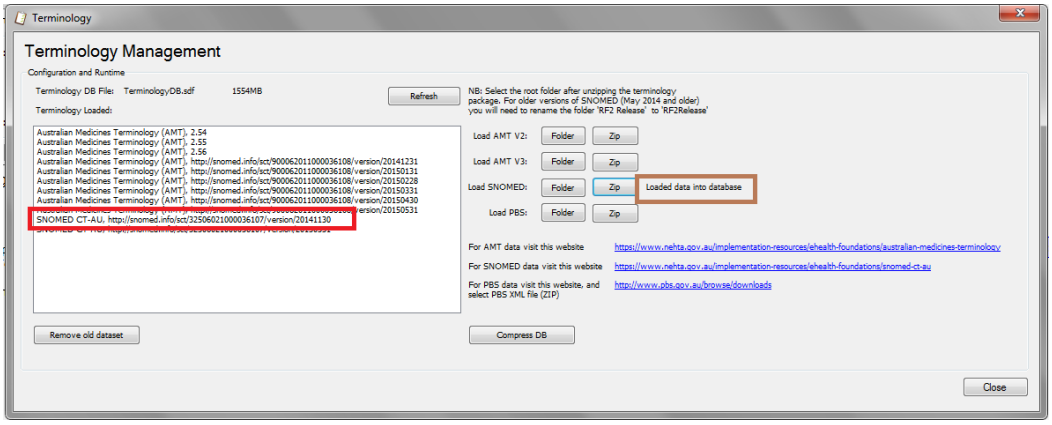


6 The message 'Unzipping data' is displayed while the SNOMED CT-AU data is being imported.



Note: The loading process may take many minutes to complete.

7 Confirm that the SNOMED CT-AU dataset has been successfully loaded into the Validator database. The message 'Loaded data into database' should appear next to the button that was selected to load the dataset and the terminology dataset should appear in the 'Terminology Loaded' list.

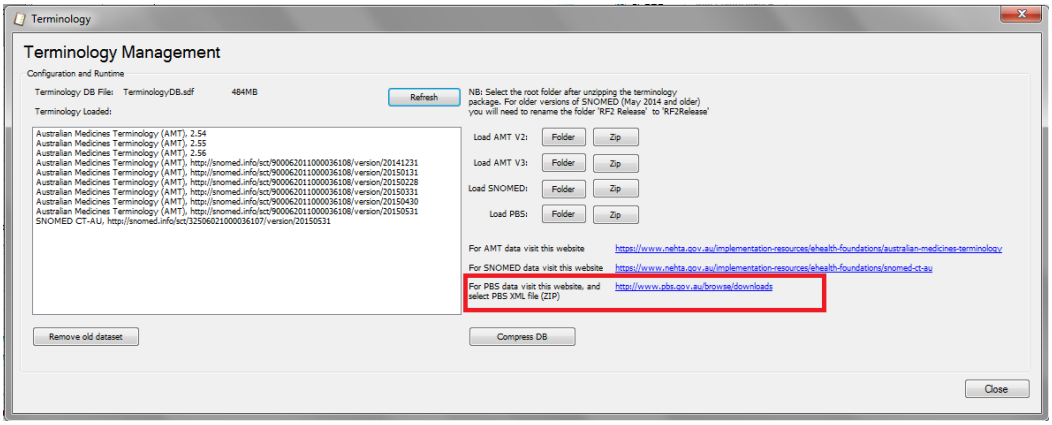


Note: The **Refresh** button may need to be selected to see the list of loaded terminology data.

End

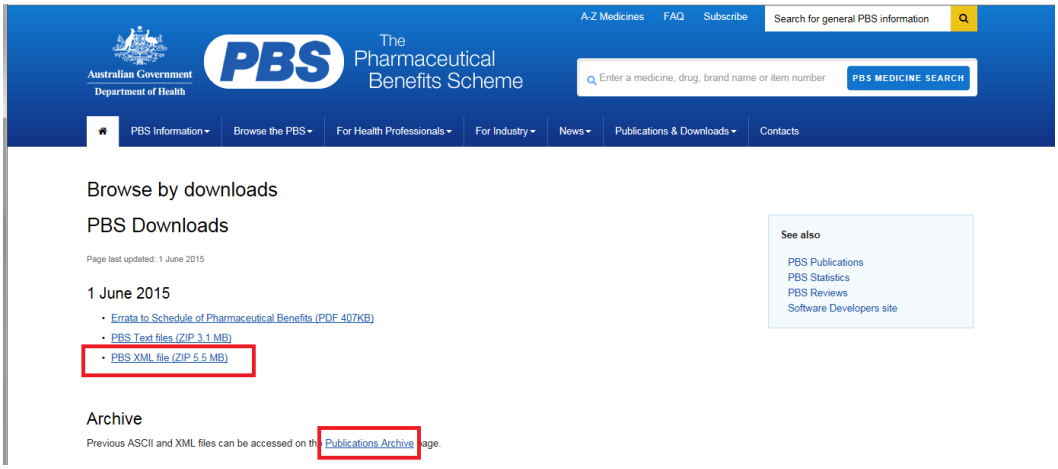
4.6.4 Find and load another version of the PBS dataset

1 To obtain and load another version of the PBS dataset, select the link to the PBS website.

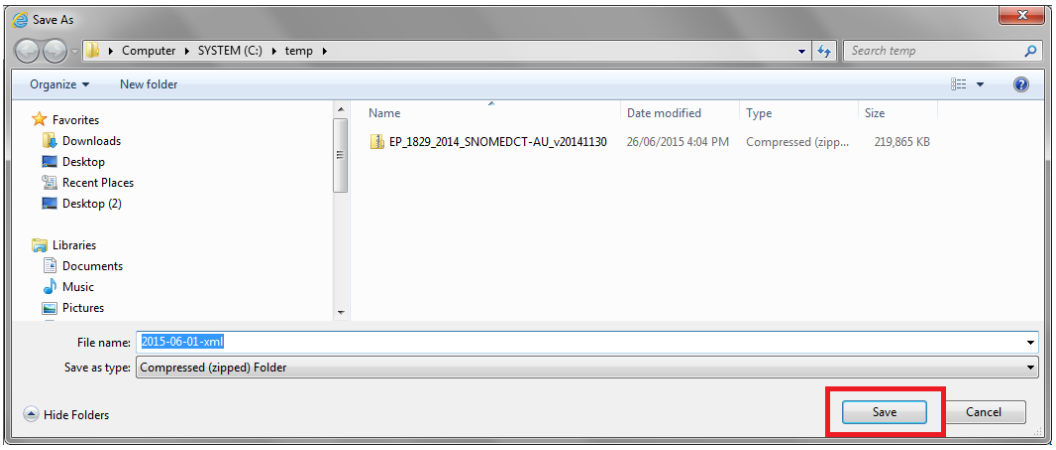


Note: PBS Item codes and PBS Manufacturer codes are both included in the PBS dataset.

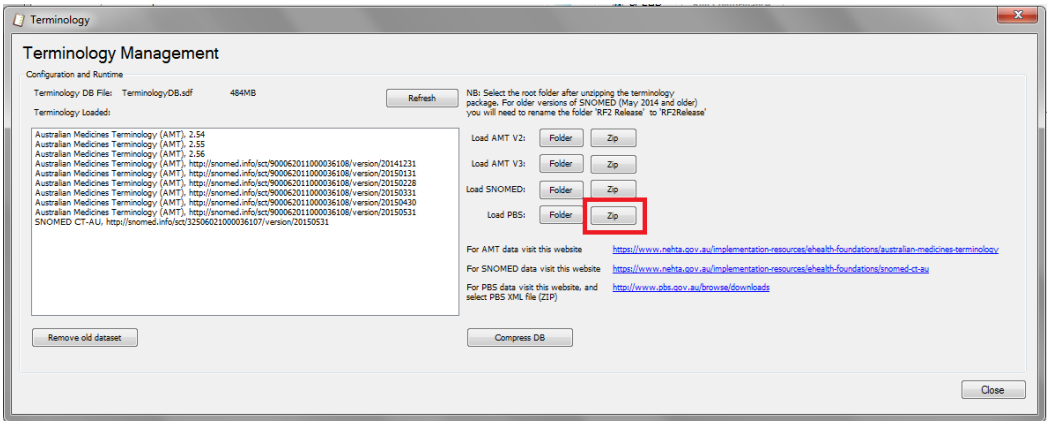
2 Either download the latest version of the PBS dataset by selecting the **PBS XML file** link, or select **Publications Archive** to choose an earlier version of the PBS dataset.



3 Save a copy of the selected PBS XML file in the C:\temp directory or another local directory.

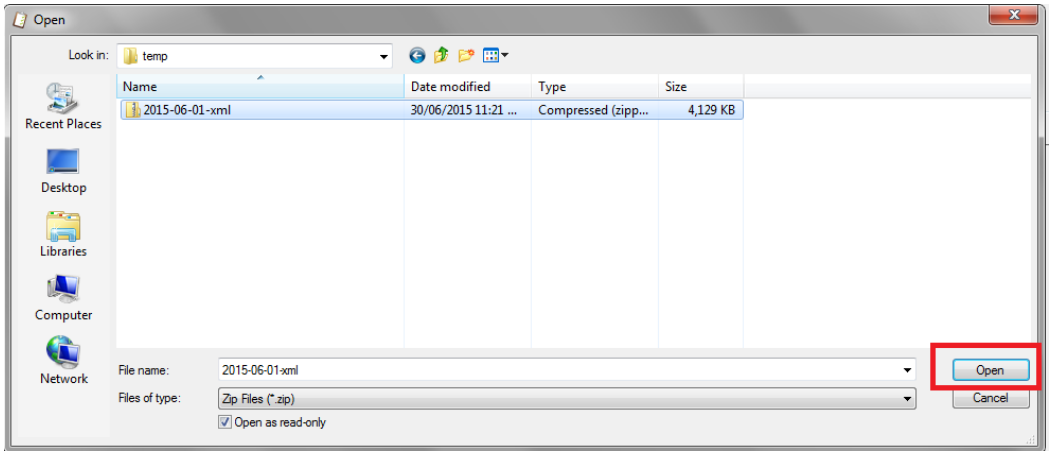


4 Import the downloaded PBS package ZIP file by selecting **Zip** for 'Load PBS'.

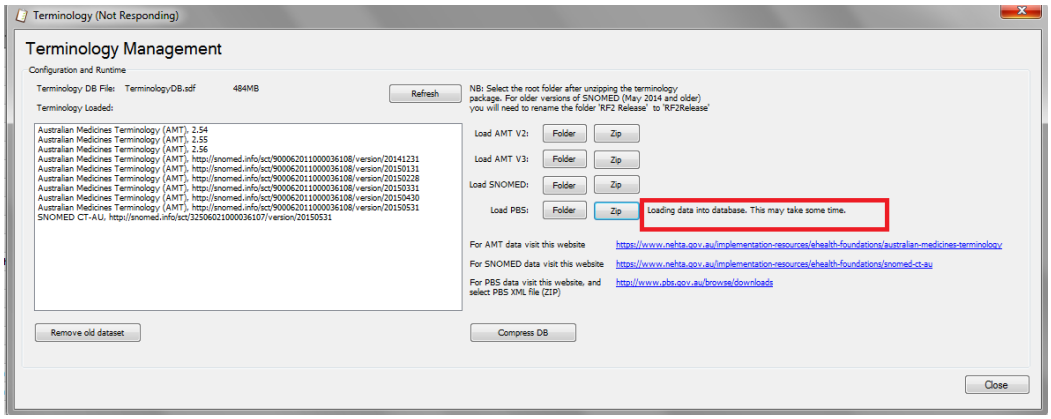


Note: If the PBS package ZIP file was already downloaded and unzipped into a folder, the contents of the folder may be imported by selecting **Folder**.

5 Select the PBS package ZIP file and select **Open**.

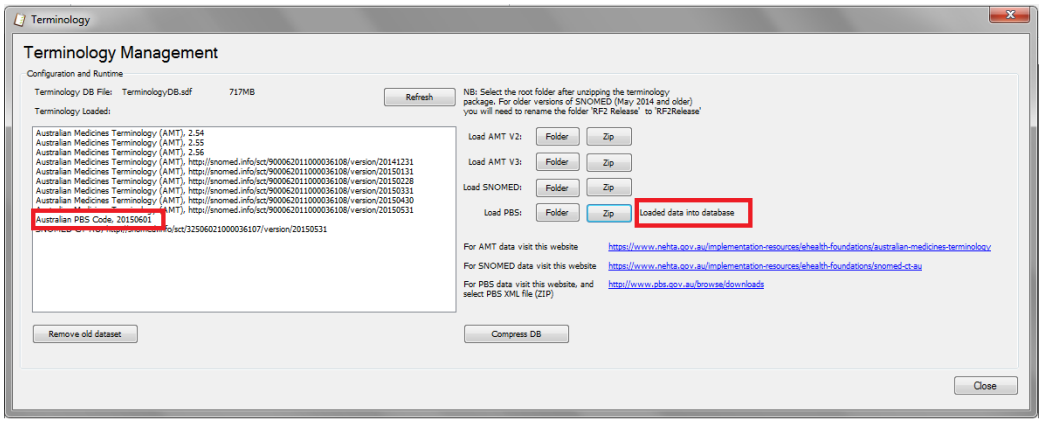


6 Two messages (i.e. 'Unzipping data' then 'Loading data into database. This may take some time.') are displayed while the PBS data is being imported.



Note: The loading process may take many minutes to complete.

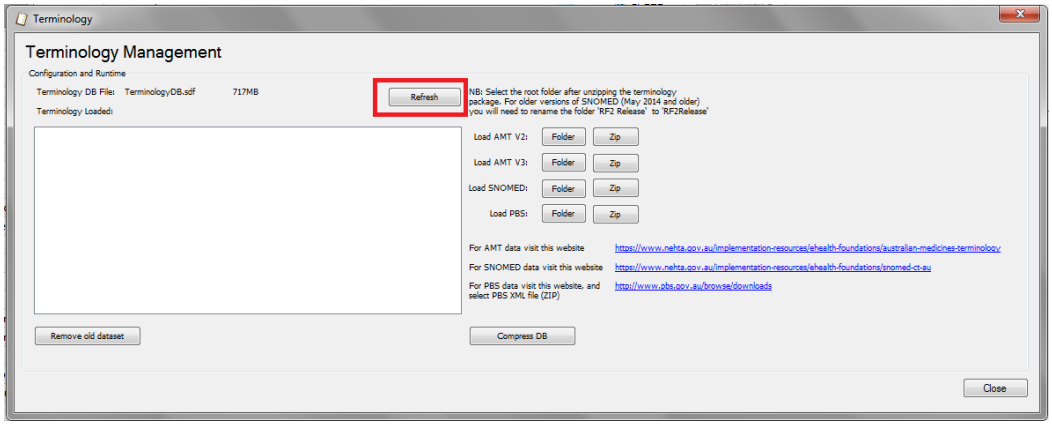
7 Confirm that the PBS dataset has been successfully loaded into the Validator database. The message 'Loaded data into database' should appear next to the button that was selected to load the dataset.



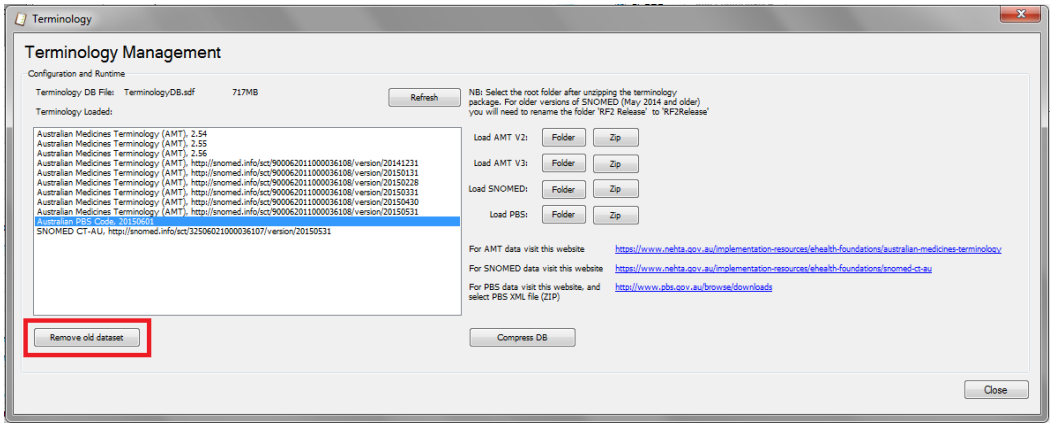
End

4.6.5 Remove a terminology dataset

1 If the list of terminology datasets currently loaded into the Validator is not displaying, select **Refresh**.

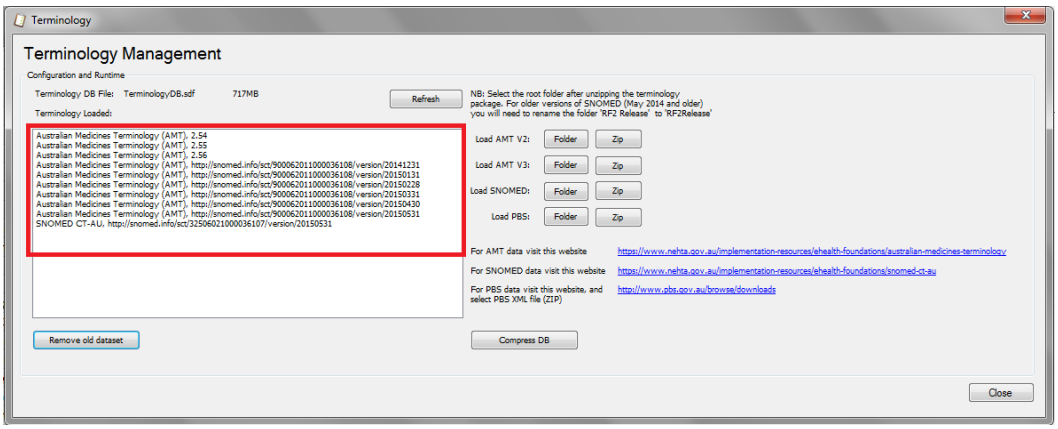


2 Choose the dataset to be removed and select **Remove old dataset**.



Note: The removal process may take many minutes to complete.

3 Confirm the dataset is no longer present in the list of loaded datasets.

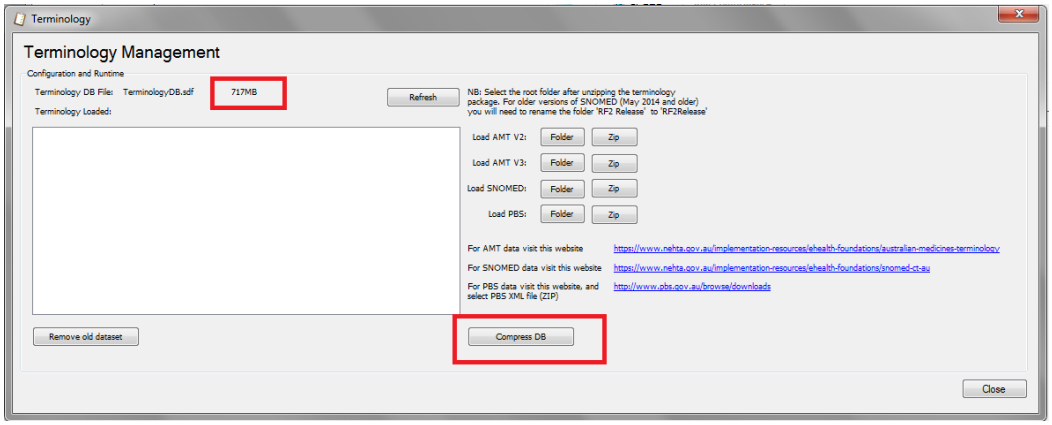


End

4.6.6 Compress the database

The Validator's terminology database may be compressed to reduce its size. Compression removes unused space and reduces the footprint of the database on the disk. Compression should be done after loading and/or removing datasets. Compressing the database does not affect the performance of the Validator.

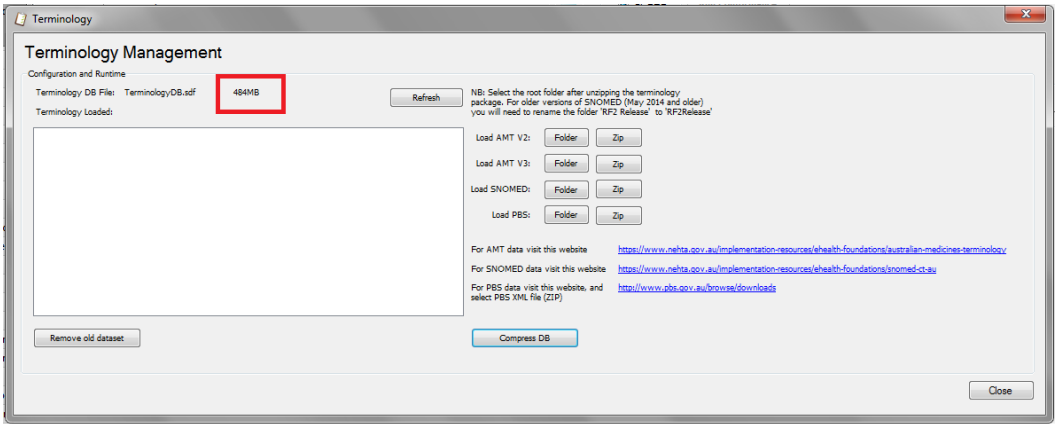
1 View the size of the database and select **Compress DB** to reduce its size.



In this example, the size of the database before compression is 717 Mb.

Note: The compression process may take many minutes to complete.

2 View the size of the database again to confirm that the compression has been successful.



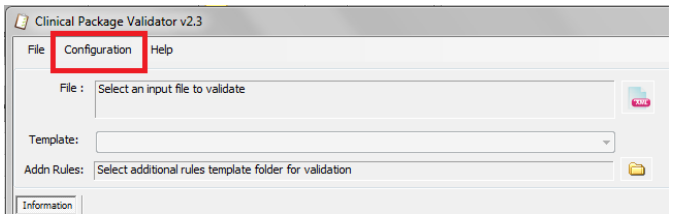
In this example, the size of the database after compression is 484 Mb.

End

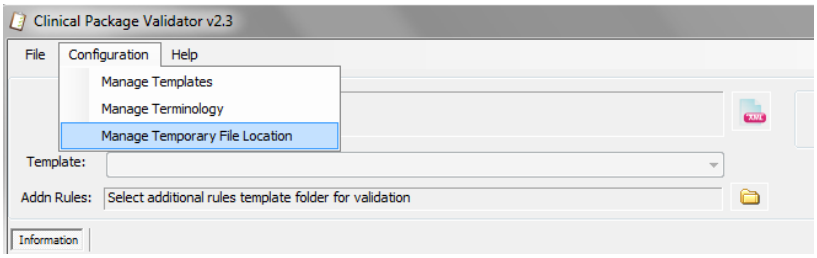
4.7 Configure the temporary file location

The Validator stores a set of files for a temporary period. By default these are stored in C:\Nehta\CPV23\Temp although a different location can be selected if required.

1 To change the location used by the Validator to store temporary files, select the **Configuration** menu.

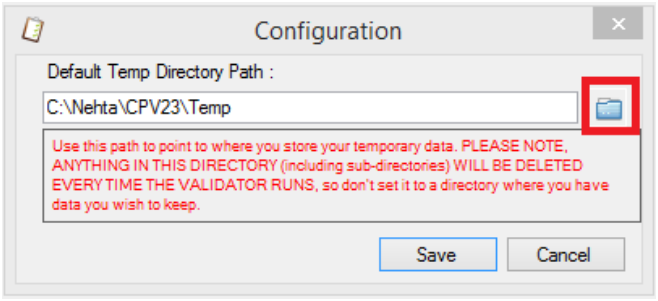


2 Select **Manage Temporary File Location**.

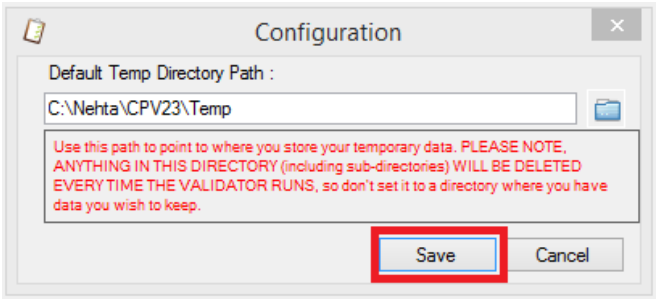


3 Either type the path of the new temporary file location, or use the folder icon to browse for the folder.

Please note the text in RED. The Validator will delete every file and subfolder in this temporary folder, every time it runs. Do not set it to any folder that contains files you need to keep.



4 To save the new temporary file location, select **Save**.



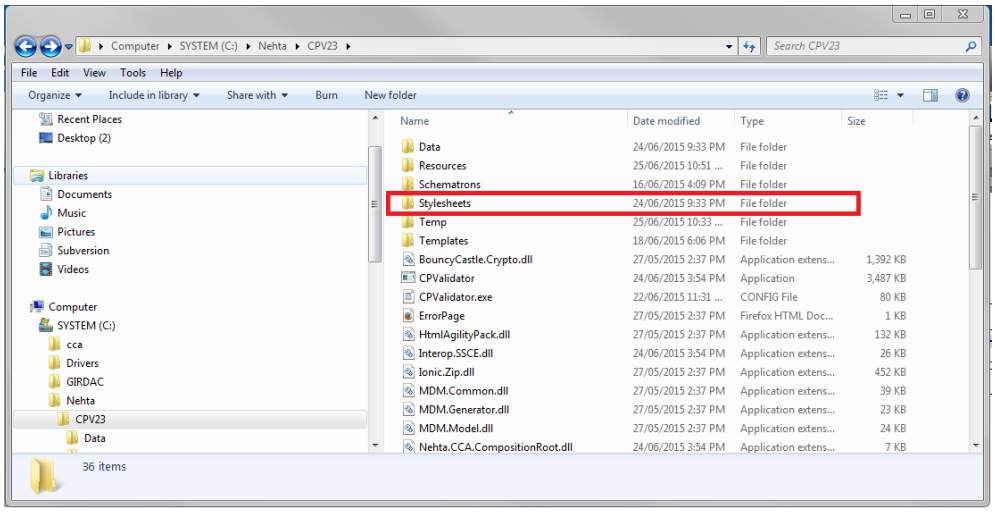
End

4.8 Install a new version of the NEHTA generic style sheet

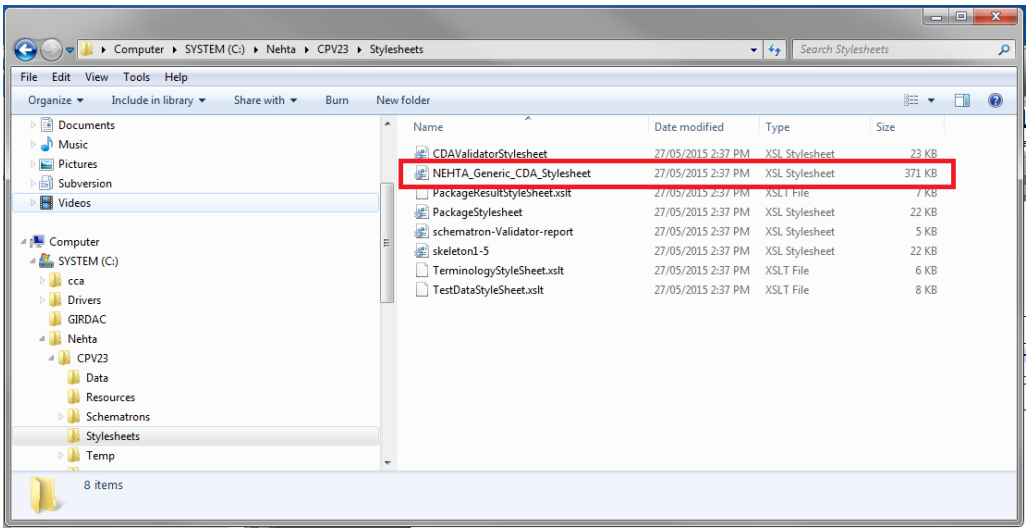
1 The Validator is provided with version 1.2.9 of the NEHTA generic style sheet (Generic CDA® Style Sheet – stylesheet no CSS v1.2.9) to display clinical documents. This style sheet is available from the NEHTA website[3] (document identifier NEHTA-1924:2014).

To install a different version of the NEHTA generic style sheet, stop the Validator if it is already running.

2 Navigate to the folder where the Validator is installed (usually **C:\Nehta\CPV23**) and select the **Stylesheets** subfolder.



3 Locate and delete the **NEHTA_Generic_CDA_Stylesheet** file from this folder and replace it with the new style sheet, using the same name.



4 Start the Validator.

The Validator will now use the new version of the style sheet.

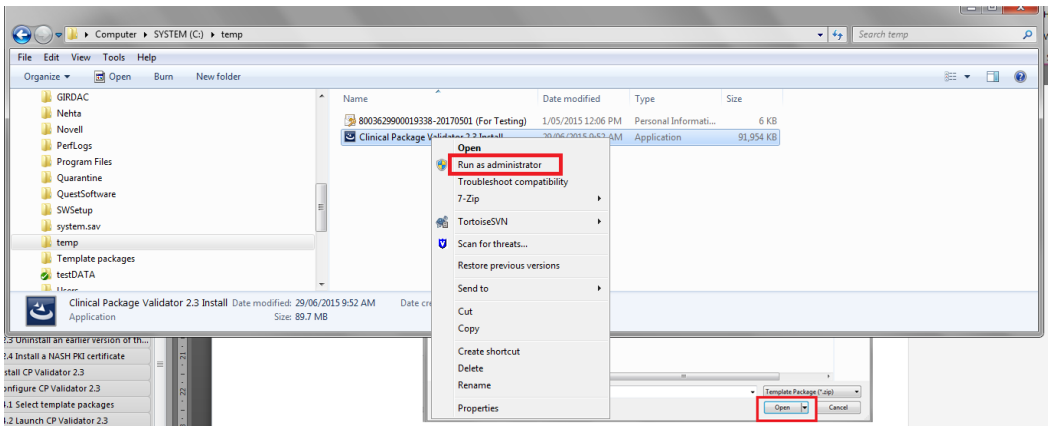
End

[3] https://www.nehta.gov.au/implementation-resources/ehealth-reference-platform/EP-2041-2015/NEHTA-1924-2014

5 Troubleshooting

5.1 Unexpected behaviour

The Validator may display unexpected behaviour if its installation was unsuccessful. If this happens, follow the steps below.

1	Uninstall any previous versions of the Validator (Section 2.2).
2	Delete the C:\Nehta directory and the temporary file location (Section 4.7).
3	Ensure the **Clinical Package Validator 2.3 Install.exe** file is on the desktop or a local drive (e.g. C:\).
4	Right click the **Clinical Package Validator 2.3 Install.exe** file and select **Run as administrator**. 
5	Enter the admin password if requested.
6	Complete the installation of the Validator (Section 3).
End	

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA®	Clinical Document Architecture. CDA is a registered trademark of HL7 International.
CSS	Cascading Style Sheets
DVA	Department of Veterans' Affairs
NASH	National Authentication Service for Health
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally controlled electronic health record
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SNOMED CT-AU	Systematized Nomenclature of Medicine Clinical Terms – Australia
SVT	Software Vendor Test environment
XML	Extensible Markup Language