Australian Government
Australian Digital Health Agency

Information Quality Rules
User Guide

7 August 2019 Version 1.6

Approved for external use

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The Australian Digital Health Agency's Information Quality Rules are a set of instructions which operate with the Agency's Clinical Package Validator and My Health Record template packages to test conformance to some, but not all requirements for clinical documents. The Information Quality Rules are provided to assist testing purposes only and are not intended for and must not be used in a production or clinical environment.

The combination of the Information Quality Rules, the Clinical Package Validator and My Health Record template packages does not test against all conformance requirements.

Test results from the use of the Information Quality Rules tool must not be relied upon to declare software conformity to the My Health System Operator requirements or otherwise. Vendors must run their own independent additional tests on software before declaring software conformance to the My Health Record System Operator.

The Information Quality Rules tool is licensed in accordance with the licence terms distributed with the IQ Rules.

For further information, contact the Australian Digital Health Agency Help Centre on 1300 901 001 or help@digitalhealth.gov.au.

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Document version	Date	Release comments
1.5	18 Oct 2017	The first version to be provided to software developers. Versions prior to this were used within the Australian Digital Health Agency.
1.5.1	22 Nov 2017	Updated user guide for the IQ Rules v1.5.1 maintenance release.
1.6	7 August 2019	Updated user guide for IQ Rules v1.6.

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1 Introduction

1.1 Purpose

This document is a guide for developers, testers and analysts who use version 1.6 of the Information Quality Rules ('the IQ Rules').

The IQ Rules are a set of machine readable instructions and not software. The IQ Rules are intended to be used in a testing, non-clinical environment only. The IQ Rules are licensed for use by the Agency in accordance with the licence terms distributed with the IQ Rules.

The IQ Rules must be used in conjunction with the Agency's Clinical Package Validator v2.8 (the **Validator**). The Validator is also used in conjunction with the Agency's My Health Record template packages which are different sets of instructions that apply some of the tests for conformance to My Health Record system conformance requirements. Both the IQ Rules and the My Health Record template packages instruct the Validator assist with the assessment of some, but not an exhaustive set of, conformance requirements and quality of information in a clinical document and in a collection of clinical documents. To the extent users wish to use these test tools to test conformance to the My Health Record system requirements, users should not rely on the test tools alone to determine conformance and additional testing is required. Further testing to My Health Record system conformance requirements can be carried out through manual application of the Conformance Test Specification for Authoring Systems published by the Australian Digital Health Agency.

In this document, a term used that is defined in the *My Health Records Act 2012* (Cth) has the same meaning given to that term in that Act.

For further information, contact the Agency Help Centre on 1300 901 001 or help@digitalhealth.gov.au.

1.2 Intended audience

This document is intended for use in a testing, non-clinical environment by:

- developers who want quick feedback for software development;
- testers who assess whether their healthcare software system produces clinical documents that conform to the relevant specifications; and
- analysts who assess the quality of information in collections of clinical documents and in digital health records.

1.3 Scope

This document describes the application of version 1.6 of the IQ Rules. The IQ Rules provide instructions for tests of the types of documents listed in Appendix A.2 of this document only.

The IQ Rules may be used to:

- assist in assessing conformance of individual clinical documents to some mandatory and recommended My Health Record system conformance requirements e.g. usability requirements; and

- report the outcome of analysing collections of clinical documents, e.g. report the frequency of occurrence of selected data elements.

The IQ Rules supplement the assessments of clinical documents performed by the My Health Record template packages and the Validator. The use of the IQ Rules should not be relied on to test conformance to all requirements, even if the use of the IQ Rules do not report any errors. Use of the IQ Rules does not guarantee conformance to the My Health Record system conformance requirements as some conformance requirements cannot be tested through use of the IQ Rules. Further testing to My Health Record system conformance requirements can be carried out through manual application of the Agency's Conformance Test Specification for Authoring Systems version 1.1 published on the Agency website at this location.

The scope of the tests that the IQ Rules support are set out in Appendix A of this document.

The IQ Rules contain:

- rules that report a definite pass or fail to meet some My Health Record system conformance requirements;
- rules that report suspected issues that need to be further assessed by developers, testers or analysts; and
- rules that report statistical information.

This document introduces the scope of version 1.6 of the IQ Rules. Users of the IQ Rules also need to understand how to use Validator version 2.8 and the My Health Record template packages. That information is provided by the Clinical Package Validator Installation and Configuration Guide and the Clinical Package Validator User Guide published on the Agency website at this location.

Additional information may be obtained by contacting the Agency on 1300 901 001 or help@digitalhealth.gov.au.

1.4 Overview

The Agency develops and maintains the following tools for assessing the conformance of clinical documents:

- My Health Record template packages;
- the Validator; and
- The IQ Rules.

A My Health Record template package contains a set of rules to instruct the Validator and partially assesses a clinical document's conformance to the Agency's clinical document specifications. The rules are applied by the Validator and also by the My Health Record system. The My Health Record system applies a template package to every document uploaded to it by healthcare software systems, and a document is only accepted if no errors are found by the My Health Record template package.

The Validator is a software tool for applying the My Health Record template packages in a test environment only. It also applies additional conformance tests to assess the conformance of:

- clinical terminology in a clinical document; and
- a clinical package, which is a ZIP file that contains a clinical document, any attachments and a digital signature.

The Agency licenses the Validator and publishes release notes here. Note that version 1.6 of the IQ Rules needs version 2.8 of the Validator.

The Conformance Test Specification for Authoring Systems published here was developed by the Agency to provide a comprehensive set of tests that apply to any type of clinical document. It contains hundreds of test cases that take a considerable amount of time to apply. The IQ Rules automate most of the test cases in the Conformance Test Specification for Authoring Systems so that a comprehensive set of conformance tests can be applied more efficiently.

1.4.1 Assessing conformance to mandatory requirements

The combination of the My Health Record template packages, the Validator and the IQ Rules tests whether clinical documents (referred to in Appendix A.2 of this document) conform to some of the mandatory conformance requirements for uploading clinical documents to the My Health Record system. These tools do not provide instructions for applying a comprehensive set of tests and developers/users must apply their own additional tests before declaring conformance to the My Health Record system requirements. Accordingly, users of these tools should carefully read the Validator Product Data Sheet and the IQ Rules Scope Statement in Appendix A of this document to determine what each of these tools do. For further guidance contact the Agency on 1300 901 001 or help@digitalhealth.gov.au.

1.4.2 Assessing conformance to recommended requirements

It is not mandatory that recommended requirements in the Agency's clinical document specifications need to be supported by healthcare software, although the quality and usability of clinical information maybe improved if they are implemented. The recommended requirements include:

- the use of text formatting, tables and lists so that healthcare providers may readily understand information when viewing a clinical document; and
- the use of clinical terminology to describe concepts such as medications, adverse reactions, and medical history.

The IQ Rules may be applied to clinical documents to determine the level of support for recommended requirements.

1.4.3 Assessing the quality of information in collections of documents

The IQ Rules may be used to examine information in collections of clinical documents referred to in Appendix A.2 of this document, such as a set of documents created by a clinical information system or a set of documents in a My Health Record.

Version 1.6 of the IQ Rules:

- Applies the National Guidelines for On-Screen Display of Clinical Medicines Information published by the Australian Commission on Safety and Quality in Health Care which discourages the use of Latin and abbreviations in the directions for taking medicines;
- Applies some recommendations in the National Guidelines for On-Screen Presentation of Discharge Summaries published by the Australian Commission on Safety and Quality in Health Care; and
- Counts the occurrence of specific clinical information, including information that is optional but which improves the usefulness of clinical information, such as the reason for prescribing a medication.

2 Before you begin

Version 2.8 of the Validator is required to operate IQ Rules version 1.6 as the IQ Rules uses ISO Schematron, XPath 3.1, XPath and XQuery Functions and Operators 3.1, XSLT 2.0 and external functions that are supported by Validator 2.8, but are not supported by previous versions of the Validator.

Before the IQ Rules is installed, the Validator 2.8 software and documentation must be downloaded and installed according to the instructions in the Clinical Package Validator Installation and Configuration Guide.

> ***Note: Versions of the Validator are published on the digital health website here but Validator 2.8 is not yet published on the digital health website. Until it is, Validator 2.8 may be obtained by contacting the Agency on 1300 901 001 or help@digitalhealth.gov.au.***

If the clinical documents to be assessed include AMT, SNOMED CT-AU or PBS clinical terminology, Validator 2.8 should be configured to contain the versions of these code systems that have been used in the clinical document. Terminology configuration instructions are provided in the Clinical Package Validator Installation and Configuration Guide. Refer to section 5.5 of this document for information about how the IQ Rules selects a version of clinical terminology.

3 Install the IQ Rules

The IQ Rules contains the components listed in Table 1.

Table 1: Components of the IQ Rules

Component	Filename	Format
Information Quality Rules Test Licence	IQRules_Test_Licence.pdf	Adobe Acrobat Document
Information Quality Rules configuration file v1.6	IQConfig.xml	XML document
Information Quality Rules v1.6	IQRules_v1.6.zip	Compressed (zipped) folder
Information Quality Rules Release Note v1.6	IQRules_Release_Notes_v1.6.pdf	Adobe Acrobat Document
Information Quality Rules User Guide v1.6	IQRules_UserGuide_v1.6.pdf	Adobe Acrobat Document

The IQ Rules uses the following folders:

- C:\DigitalHealth\ClinicalDocuments
- C:\DigitalHealth\ClinicalDocuments\Collection
- C:\DigitalHealth\ClinicalDocuments\Superseded
- C:\DigitalHealth\ClinicalDocuments\Temp

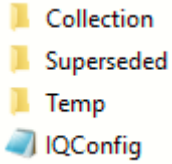
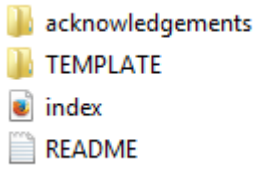
The IQ Rules will look for the 'IQConfig.xml' configuration file in the C:\DigitalHealth\ClinicalDocuments folder.

These folders must be created before the IQ Rules is used, and the configuration file for the IQ Rules should be copied to the C:\DigitalHealth\ClinicalDocuments folder.

The C:\DigitalHealth folder is also used by the Clinical Package Validator. Validator v2.8 uses the folder C:\DigitalHealth\CPV28.

To install the IQ Rules, follow the steps below:

1	Open Windows Explorer and navigate to the DigitalHealth folder on the C: drive. This folder will already be present if the Validator was installed.
2	Create a new subfolder with the name 'ClinicalDocuments'.
3	Navigate to C:\DigitalHealth\ClinicalDocuments and create a new subfolder with the name 'Collection', a new folder with the name 'Superseded' and another new folder with the name 'Temp'.

4	Copy or move the IQ Rules configuration file 'IQConfig.xml' to the C:\DigitalHealth\ClinicalDocuments folder.
5	Verify that the C:\DigitalHealth\ClinicalDocuments folder contains the following items: 
6	Navigate to the folder where the IQ Rules will be installed, such as the Desktop or a subfolder of C:\DigitalHealth.
7	Copy or move the IQ Rules file 'IQRules_v1.6.zip' to this folder.
8	Unzip the IQ Rules file.
9	Verify that the IQRules_v1.6 folder has been created and contains the following items: 

4 Configure the IQ Rules

The IQ Rules configuration file 'IQConfig.xml' is used to modify the operation of the IQ Rules.

4.1 Configuration flags

Configuration flags are used to turn specific rules in the IQ Rules on or off. Within 'IQConfig.xml' is a series of configuration flags that are set to either 'true' or 'false' and these are described in Table 2.

Table 2: IQ Rules configuration flags

Configuration flag	Explanation	Default value
`about-IQ-Rules`	Information about the IQ Rules and their configuration is reported if this flag is set to "true".	true
`test-data`	Setting this to "true" indicates the clinical document contains test data. In that case test and example object identifiers are allowed.	false
`allow-debug`	Information used for debugging purposes is reported if this flag is set to "true".	false
`allow-hints`	Hints to suggest the manual application of tests are reported if this flag is set to "true".	true
`allow-ratings`	Allows the priority ratings to be reported if this flag is set to "true". If test-data is "true" then allow-ratings is set to "false" regardless of the value in the configuration file.	false
`assess-values`	This is set to "true" to request the IQ Rules to determine that the value of a CodeableText data element is consistent with the definition of the data element[1], and to verify the consistency of the originalText element, primary and translation codes. If test-data is "true" then assess-values is set to "false" regardless of the value in the configuration file.	true
`assess-class`	This is reserved for future use.	
`coding`	This is set to "true" to request the IQ Rules to code a collection of concepts. This is reserved for future use.	false
`collection-same-record`	This is set to "true" if all documents in the collection were from the same My Health Record.	false
`collection-same-system`	This is set to "true" if all documents in the collection were created by the same software system.	true
`narrative-auto-generated`	This flag is set to "true" if all narratives have been automatically generated by the healthcare software system.	false

[1] The value of an originalText element is assessed and any code that is a member of a national code system is assessed to determine if it is a member of the specified value domain. Regardless of the `assess-values` flag a code is assessed to determine if it is a member of the national code system.

narrative-derived	This flag is set to “true” if all narratives have been derived from information in the entry elements, regardless of the value of the entry element typeCode attribute.	false
report-data	The values of data elements in the Agency's information models are reported if this flag is set to “true”.	false
report-data-quality	The IQ Rules reports the following if this is set to “true”: • Use of deprecated data elements and attributes; • Recommendations for Entity Identifiers and Entitlements; • Adherence to some requirements in the National Guidelines for On-Screen Display of Clinical Medicines Information and the National Guidelines for On-Screen Presentation of Discharge Summaries published by the Australian Commission for Safety and Quality in Health Care; • Recommendations for eHealth Prescription Records and eHealth Dispense Records; • Adherence to recommendations for improving the appearance of a rendered clinical document; • Adherence to the Guidance for Use of Medical Nomenclatures in Information Exchange v1.2; and • Conformance to the Agency’s My Health Record Usability Recommendations v1.4.	
report-statistics	Statistics gathered from a set of documents is reported if this flag is set to “true”.	false
report-terminology-concepts	When this flag is set to “true” text-based descriptions of medical concepts are reported as well as any codes that match the concepts.	false
conformance-level	This is set to the conformance level claimed for the clinical document(s) being analysed and if included must either be “1A”, “1B”, “2”, “3A” or “3B”. Use of the flag is meaningful for the types of clinical documents which are permitted to have any level of conformance (e.g. Discharge Summary, Special Letter and eReferral).	
conformance-profile-version	This flag is applicable for those types of clinical documents when more than one conformance profile version uses the same version of the CDA Implementation Guide. If the flag is not included then the tests applied by the IQ Rules are for the latest version of the conformance profile corresponding to a CDA Implementation Guide. This flag currently applies to Prescription Record and Dispense Record and the flag may have the value “1.3” or “1.4”, where “1.4” is the default value.	

The default configuration for the IQ Rules is intended to meet the needs of a developer of a healthcare software system that creates clinical documents. The IQ Rules may be used to test conformance to some, but not all mandatory My Health Record system conformance

requirements. The details of the scope of what test cases the IQ Rules may be used to assist are set out in Appendix A of this document.

The configuration file needs to be changed if the scope of testing differs from what is described above.

To configure the IQ Rules, follow the steps below.

1	Navigate to C:\DigitalHealth\ClinicalDocuments.
2	Select **IQConfig.xml** with the right mouse button and then select either 'Edit' or 'Open with' followed by Notepad or WordPad or a similar editor.
3	Change the value of the configuration flags to either 'true' or 'false' or another value as needed for the assessment that is to be performed using the IQ Rules.
4	Close the configuration file.

4.2 Narrative fixed text

The term 'fixed text' refers to text in clinical document (of a type referred to in Appendix A.2 of this document) narratives that has a fixed value regardless of which healthcare consumer the clinical document applies to. For example, the narrative of a Medication section of a clinical document may contain a table heading or label with the name 'Medication'.

The IQ Rules compares information in the narratives with information in the structured data within the body of a document[2] for the following reasons:

1 The Agency's clinical document specifications require all clinical information in the structured data to also be present in the corresponding narrative. When comparing text in the structured data with text in the narrative, the IQ Rules first removes fixed text from the narrative.

2 If the narrative is derived from information in the structured data, the IQ Rules determines if the narrative contains any text that is not in the structured data.

If the information in a narrative does not match information in the structured data, the IQ Rules will warn of a potential mismatch so that an analyst can manually compare the information. If the mismatch is due to the presence of narrative fixed text, the analyst may inform the IQ Rules of the fixed text by recording the fixed text in the IQ Rules configuration file, thereby reducing the number of unnecessary warnings.

The IQ Rules ignores the following items when comparing information in the narratives with information in the structured data within the body of a document:

3 Text within the following narrative elements:

- `<th>` (a table heading cell)
- `<caption>` (a caption)

4 Special characters in the narrative such as punctuation and brackets;

5 Fixed text found in documents uploaded to the My Health Record system[3]; and

6 Fixed text recorded in the IQ Rules configuration file.

[2] Information in <entry> elements.

[3] This is recorded in the IQ Rules' internal knowledgebase.

Follow the steps below to inform the IQ Rules of fixed text that is not catered for by items 1 to 3 above.

1	Navigate to C:\DigitalHealth\ClinicalDocuments.
2	Select **IQConfig.xml** with the right mouse button and select either 'Edit' or 'Open with' followed by Notepad or WordPad or a similar editor.
3	Move to the `<narrative-fixed-text>` element of the configuration file.

4	For each item of fixed text, create a `<fixed-text>` element with a 'value' attribute whose value is the fixed text. The following example shows that "Primary Procedure" and "Secondary Procedure(s)" are fixed text.
	
	`<narrative-fixed-text>`
	`  <fixed-text value="Primary Procedure" />`
	`  <fixed-text value="Secondary Procedure(s)" />`
	`</narrative-fixed-text>`

4.3 Narrative foreground and background colours

By default the narrative foreground text is black on a white background and this may be varied with use of the xFgColour and xBgColour style codes for foreground and background colour. One of the conformance test cases in the Conformance Test Specification for Authoring Systems assesses if clinical information in narrative text is visible and readable when the colour of either the foreground or background differs from the default colour, therefore the IQ Rules reports a hint to the tester to determine if the text is visible and readable. When a colour combination has been determined to be suitable then it may be added to the IQ Rules configuration file so that the IQ Rules accepts that colour combination.

Follow the steps below to inform the IQ Rules of a readable colour combination.

1	Navigate to C:\DigitalHealth\ClinicalDocuments.
2	Select 'IQConfig.xml' with the right mouse button and select either 'Edit' or 'Open with' followed by Notepad or WordPad or a similar editor.
3	Move to the `<narrative-colours>` element of the configuration file.

4	For each colour combination, create a `<colours>` element with an 'fg' attribute whose value is the six character hexadecimal colour code for the foreground and a 'bg' attribute whose value is the six character hexadecimal colour code for the background. The fg attribute need not be recorded if it has the default value 000000 (black) and the bg attribute need not be recorded if it has the default value ffffff (white).
	The following example includes a foreground 0000f5 colour code (i.e. blue) on the default background and a foreground ffffff (white) colour code with a background 727272 (dark grey) colour code.
	
	`<narrative-colours>`
	`  <colours fg="0000f5" />`
	`  <colours bg="727272" fg="ffffff" />`
	`</narrative-colours>`

4.4 Custom sections

The CDA Implementation Guide for a specific type of clinical document lists sections that may be included in the clinical document and a clinical document may also include other sections if their presence is not prohibited by conformance requirements. One of the conformance test cases in the Conformance Test Specification for Authoring Systems assesses if the presence of a section not included in the CDA Implementation Guide is acceptable. The IQ Rules reports a hint to the tester if a clinical document contains an unknown custom section, which is either a section defined in the CDA Implementation Guide for another type of clinical document or a section defined by the developer of a health software system. Information about a custom section may be recorded in the IQ Rules configuration file after it has been assessed by the tester.

Follow the steps below to inform the IQ Rules of a custom section that either passes or fails the conformance tests.

1	Navigate to C:\DigitalHealth\ClinicalDocuments.
2	Select 'IQConfig.xml' with the right mouse button and select either 'Edit' or 'Open with' followed by Notepad or WordPad or a similar editor.
3	Move to the `<custom-sections>` element of the configuration file.

4 For each custom section, create a `<section>` element with the following attributes:

a) The section's identification information which may be either or both the following:

i. A 'title' attribute if the section has a title.

ii. A 'code' and a 'codeSystem' attribute if the section has these attributes.

b) The identifier of the type of clinical document that may contain the custom section. The identifier consists of a 'doc-code' and a 'doc-codeSystem' attribute.

c) The location of the custom section in the clinical document using one of the following options:

i. If the custom section is a component of the document body and not a child of another section then include a 'parent' attribute with the value 'body'.

ii. If the custom section is a child of another section then include 'parent-code' and 'parent-codeSystem' attributes whose values are the code and codeSystem of the parent section.

d) If the section is not an acceptable extension (i.e. fails the conformance tests) then include a 'disallowed' attribute with the value 'yes' and a 'reason' attribute whose value is text describing the reason why the extension is not acceptable. If the section is an acceptable extension then the 'disallowed' attribute may be omitted or be present with the value 'no'.

The following example records that the Medical History section defined by the Agency Digital Health Agency is acceptable for inclusion in the body of a Discharge Summary.

```
<custom-sections>

    <section code="101.16117" codeSystem="1.2.36.1.2001.1001.101"
          title="Medical History" doc-code="18842-5"
          doc-codeSystem="2.16.840.1.113883.6.1" parent="body" />

</custom-sections >
```

5 Tests performed by the IQ Rules

5.1 Comparison with the My Health Record template packages

The My Health Record system applies a My Health Record template package (published by the Agency) when a clinical document is uploaded to it and rejects a document if the template package reports an error in that document. Any error found by a My Health Record template package will result in a clinical document being rejected by the My Health Record system so My Health Record template packages are only used to report definite conformance errors.

The My Health Record template packages test for conformance to a subset of the My Health Record system conformance requirements only, for example:

- Narrative conformance errors are not reported;
- Conformance to many HL7 data type requirements is not assessed;
- There is limited support for assessing clinical terminology;
- Data components that are extensions to the CDA implementation guide are not assessed; and
- Structured data in the body of a level 1B or level 2 clinical document is not assessed.

In addition, the scope of the My Health Record template packages is restricted to only assessing conformance, so assessment to other types of quality criteria is out of scope.

For these reasons, the IQ Rules have been created to complement the assessments performed by the My Health Record template packages but, individually or together, they do not provide instructions for performance of a comprehensive set of test cases and developers and users must perform their own additional tests. Table 3 compares the types of assessments performed by My Health Record template packages with those performed by the IQ Rules.

Table 3: Comparison of assessments performed by Template packages and IQ Rules

Type of assessment	Template Packages	IQ Rules
Incorrect cardinality	In scope	Out of scope
Structured data - narrative consistency	Out of scope	In scope
Narrative formatting	Out of scope	In scope
Coded data	Mostly out of scope (only small static code systems are assessed)	Over 40 code systems are assessed (see appendix A.5) including AMT, PBS, LOINC and SNOMED CT-AU. Exceptions include MBS (see appendix A.6).

Type of assessment	Template Packages	IQ Rules
Assessment of clinical document extensions	Out of scope	In scope for Prescription record and Dispense record.
Assessment of structured data in level 1B and level 2 documents	Out of scope	In scope
Assessment of conformance to data type requirements	Limited support	In scope
Comparison of superseded and replacement documents	Out of scope	In scope
Comparison of information in document collections	Out of scope	In scope for comparing Exclusion statements, Adverse Reaction Type and Vaccine Sequence Number.
Gathering of statistical information from document collections	Out of scope	In scope for collections of Prescription records and Dispense records.

5.2 Comparison with Validator version 2.8

As well as providing a platform for applying the IQ Rules and My Health Record template packages, Validator version 2.8 tests for code validation and package validation. There is some duplication of code and package validation by the Validator and the IQ Rules, as described below.

5.2.1 Code validation

The IQ Rules provide machine readable instructions to the Validator to assess coded information e.g. codes used for clinical terminology and codes used for administrative information. The code systems supported by the IQ Rules are listed in Appendix A.5 of this document. The code systems assessed by the Validator and reported in the **Reference Sets** and **Other Terminology Aspects** tabs are also assessed by the IQ Rules and reported in the **Additional Rules Report** tab although, unlike the Validator, the assessment performed by the IQ Rules is based on some conformance test cases in the Agency's in the Conformance Test Specification for Authoring Systems version 1.1.

As the IQ Rules performs all code validation that is performed by the Validator, there is no need to examine the information in the **Reference Sets** and **Other Terminology Aspects** tabs.

5.2.2 Clinical Package validation

Clinical package validation includes an assessment of the way in which a clinical document references attachments. The relevant My Health Record system mandatory conformance requirements are listed in Agency specifications such as the CDA Package specification and the Common Conformance Profile for Clinical Documents published here.

If the Validator is applied to a clinical package (i.e. a file that has the appearance of a ZIP archive), the Validator performs clinical package validation and reports the results in the **Package Report** tab. Clinical package validation is not performed by either the Validator or the My Health Record template packages if the Validator is applied to a clinical document XML file. As some clinical packaging requirements for attachments apply to the clinical document XML file, the IQ Rules test

for conformance to these requirements regardless of whether the Validator is applied to a clinical document XML file or a ZIP archive.

5.3 Conformance Test Specification for Authoring Systems

The primary objective of the IQ Rules is provide instructions to automate some, but not all of, the test cases in the Conformance Test Specification for Authoring Systems version 1.1 published here.

Although the Conformance Test Specification for Authoring Systems applies to any type of document, the IQ Rules cannot apply the test cases without a list of data elements and their Agency-defined data types[4]. The IQ Rules therefore contains a list of data elements and their data types for the types of documents listed in Appendix A.2.

5.4 Additional conformance tests

The IQ Rules applies tests based on the following specifications published by the Agency:

1. My Health Record Usability Recommendations v1.4;
2. Supplementary Notes for Implementers Relating to Clinical Document Presentation v1.0; and
3. Guidance for Use of Medical Nomenclatures in Information Exchange v1.2.

The IQ Rules also applies some tests based on the National Guidelines for On-Screen Display of Clinical Medicines Information published here by the Australian Commission on Safety and Quality in Health Care, and the National Guidelines for On-Screen Presentation of Discharge Summaries published here.

5.5 Selection of clinical terminology

The IQ Rules uses three sources of information about clinical terminology:

1. Its own data file that stores terminology from code systems that rarely change, i.e. new versions of these code systems are rarely issued[5] by the owners of these code systems.
2. AMT, SNOMED CT-AU[6] and PBS[7] terminology in the Validator's database.
3. Codes such as Australian Vaccine codes, LOINC and SNOMED CT-AU[8] in a Terminology Server implementation of the CSIRO Ontoserver (see here for information about the Ontoserver). For example, the National Clinical Terminology Service operates an Ontoserver containing SNOMED CT-AU and Australian Vaccine codes, and the CSIRO operate an Ontoserver containing SNOMED CT-AU and LOINC codes.

New versions of some clinical terminology code systems are published frequently, for example a new version of SNOMED CT-AU and PBS is published every month. The National Clinical Terminology Service Terminology Server has copies of new monthly versions of SNOMED CT-AU whereas the Validator's database only contains the versions that have been manually imported into it.

[4] Agency-defined data types include CodedText, CodeableText, TimeInterval, DateTime, and others.
[5] For example, if a new version of a code system is issued once every three years then it is regarded as a rarely changing code system.
[6] In 2015 AMT was incorporated into SNOMED CT-AU.
[7] This includes PBS Item codes and PBS Manufacturer codes.
[8] AMT version 3 has been included in SNOMED CT-AU since November 2015.

The Terminology Server may be the National Terminology Server operated by the Agency, the CSIRO Terminology Server or some other terminology server. The selection is made using the Validator's configuration file.

A two-stage process is used to determine which version of a code system to use when assessing a clinical document:

1 The ideal version to use is first determined. The ideal version is the version recorded in the data element with clinical terminology[9]; otherwise, the ideal version is the last version of the code system that was published before the clinical document was created.

2 The IQ Rules chooses a source of terminology information in the following order:

   a If the ideal version identified in the previous step is present, then that is used;

   b If a version published prior to the ideal version is present, then that is used[10];

   c If a version published after the ideal version is present, then that is used.

Information about a clinical term may change over time. For example, when the formula of a medicine is changed, the status of its terminology code may be changed to 'inactive' and a new terminology code issued.

The preferred and synonymous terms associated with a terminology code may also be changed at any time, regardless of whether the status of that code has been changed to 'inactive' or has remained unchanged.

Given that information about a clinical term may change over time, and that preferred and synonymous terms associated with a terminology code may also change at any time, the most accurate assessment of a clinical document is made when the Validator uses the versions of the code systems that were used to create the clinical document.

[9] The version is stated in the codeSystemVersion attribute.

[10] If there is more than one version available that was published prior to the ideal version then the one with a publication date closest to the publication date of the ideal version is used.

6 Using the IQ Rules

6.1 Operation with Validator 2.8

The IQ Rules are imported into the Validator using the **Addn Rules** input field (Figure 1). The location of the IQ Rules is stated in step 9 of section 3.

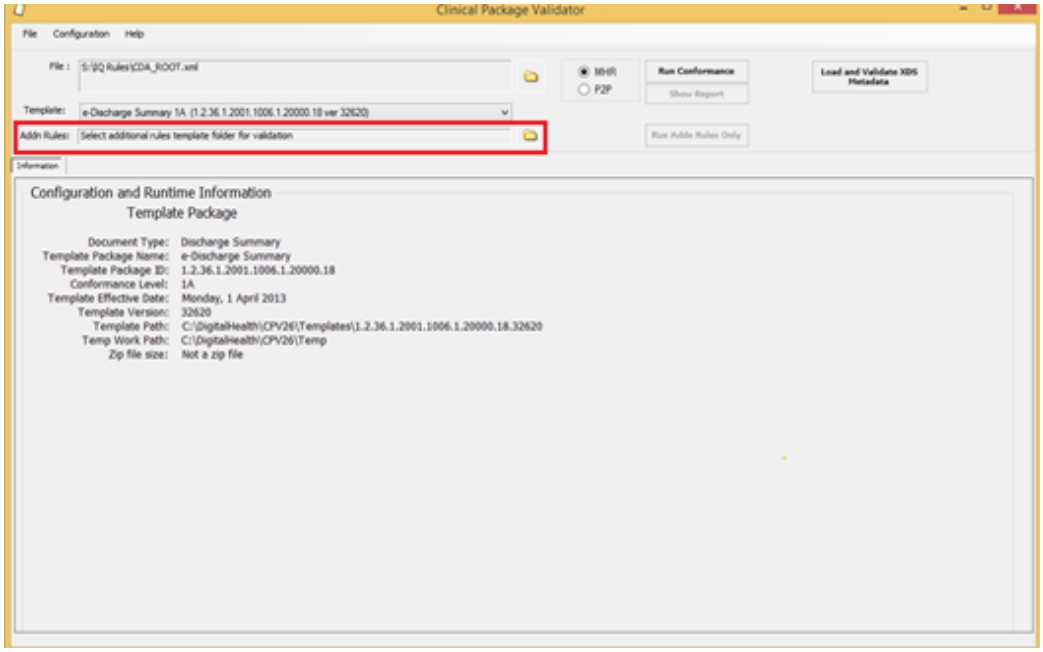


*Figure 1: The **Addn Rules** field used for importing the IQ Rules*

Information about the IQ Rules is then displayed on the **Information** tab of the Validator (Figure 2).

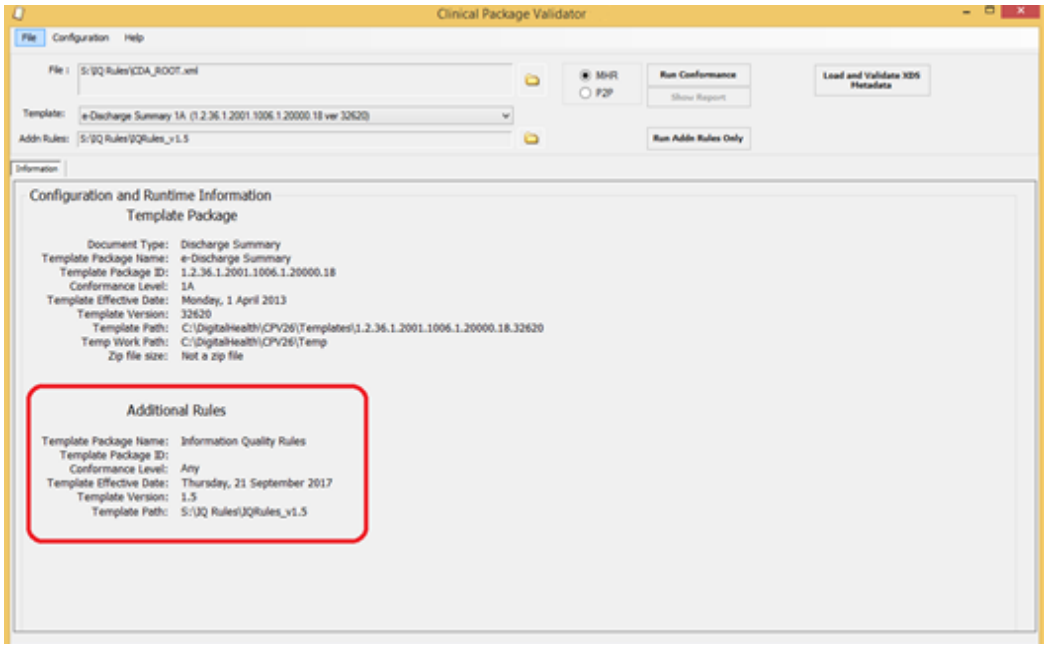


*Figure 2: **Information** tab showing information about the IQ Rules*

When the **Run Conformance** command is selected, the Validator applies the relevant My Health Record template package and the IQ Rules, and the number of issues reported by the IQ Rules is listed next to the **Additional Rules** label in the **Validation Summary** section of the **Information** tab (Figure 3). The detailed report created by applying the IQ Rules may be displayed by selecting the **Additional Rules Report** tab in Figure 3.

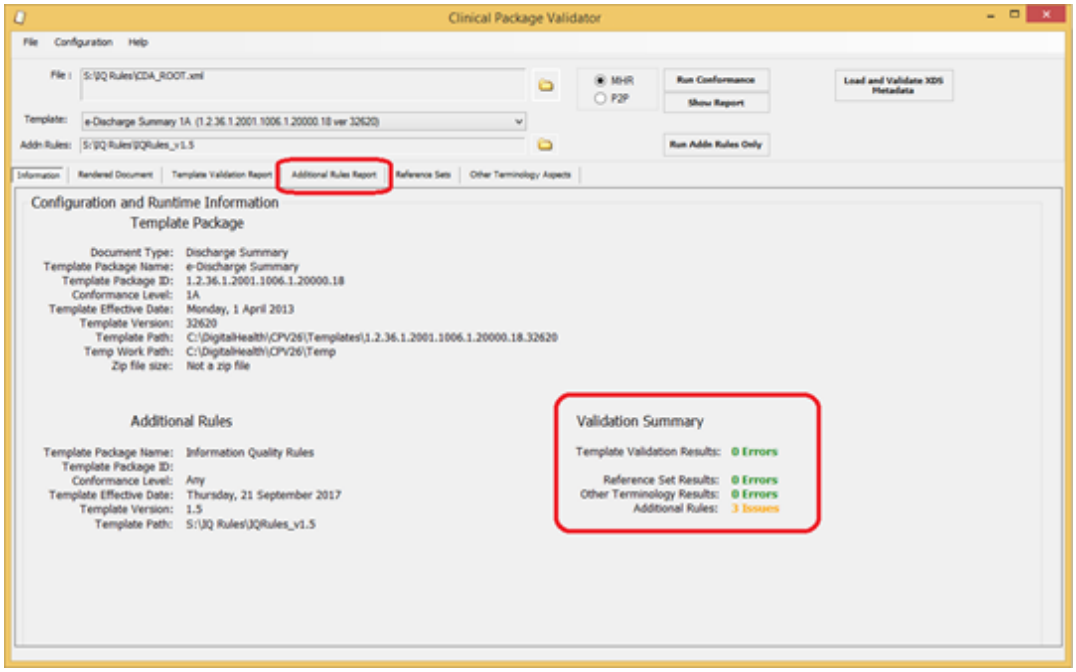


Figure 3: The number of issues reported by the IQ Rules

After the **Additional Rules Report** tab is selected, the messages reported by the IQ Rules are displayed on the left of the screen, and the right of the screen contains a link to the data element to which the message applies (Figure 4).

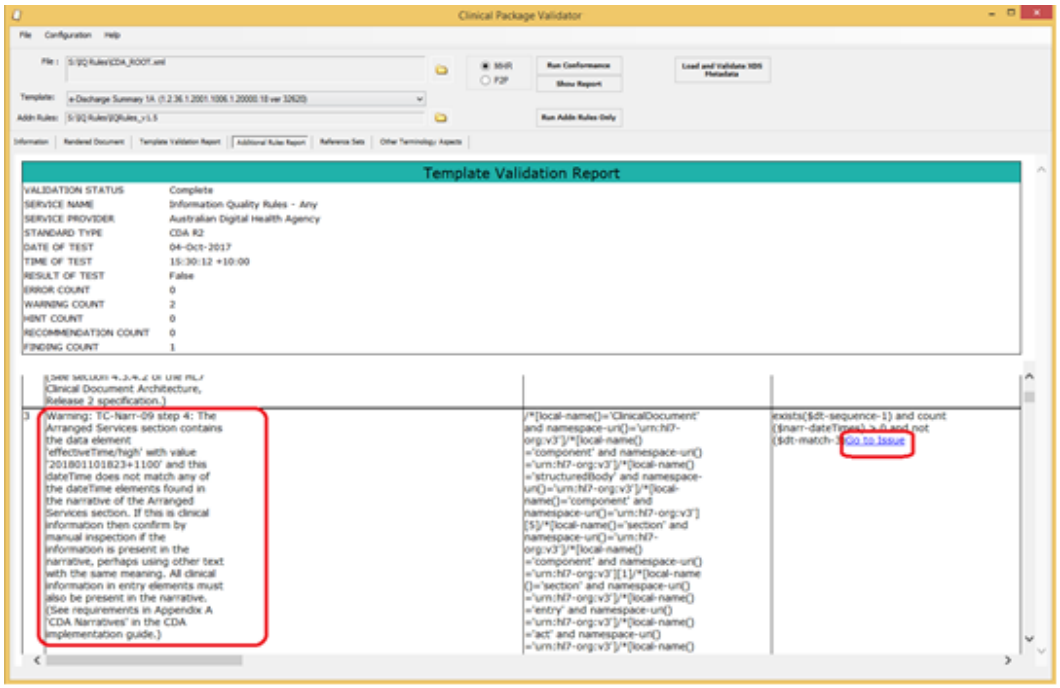


Figure 4: Viewing messages reported by the IQ Rules

6.2 Assessing automatically generated narratives

The tests applied by the IQ Rules to automatically generated narratives vary depending on the values of the `narrative-auto-generated` and `narrative-derived` configuration flags, and the value of the `typeCode` attribute in `<entry>` elements of the clinical document being assessed. Table 4 lists the tests that are applied.

Table 4: Tests applied to automatically generated narratives

	A section with at least one <entry> element with `typeCode="DRIV"`	**`narrative-derived = "true"`**	**`narrative-auto-generated = "true"`**
Tests for automatically generated narratives	Applied to the section	Applied to all sections with an `<entry>` element	Applied to all sections
Test for information that is in the narrative but not in `<entry>` elements	Applied to the section	Applied to all sections with an `<entry>` element	Not applied

The following information describes the process used by the IQ Rules to determine which tests to apply:

1. If a section has a narrative and at least one `<entry>` element with `typeCode="DRIV"` then the tests listed in Table 4 are applied to that section regardless of the value of the `narrative-derived` and `narrative-auto-generated` flags.
2. If a section has a narrative and at least one `<entry>` element and the flag `narrative-derived = "true"` then the tests listed in Table 4 are applied to that section regardless of the value of the `narrative-auto-generated` flag.

3 If a section has a narrative and the flag `narrative-auto-generated = "true"` then the tests listed in Table 4 are applied to that section.

6.3 Assessing replacement and superseded documents

When a new version of a clinical document is created, the previous version is referred to as the superseded document and the new version is referred to as the replacement document. Specific conformance requirements apply to the content of the replacement document.

The IQ Rules assesses the replacement document for conformance to these specific requirements when the superseded document is put into the C:\DigitalHealth\ClinicalDocuments\Superseded folder. The IQ Rules look for any XML file with the filename extension '.xml' or '.XML' and will only apply the tests for a replacement document if there is only one XML file in the Superseded folder. The document comparison is not performed if there are none or more than one XML file in the Superseded folder, and documents in that folder of any other type are ignored. The replacement document may be in any location other than the Superseded folder i.e. the replacement document must not be in the Superseded folder.

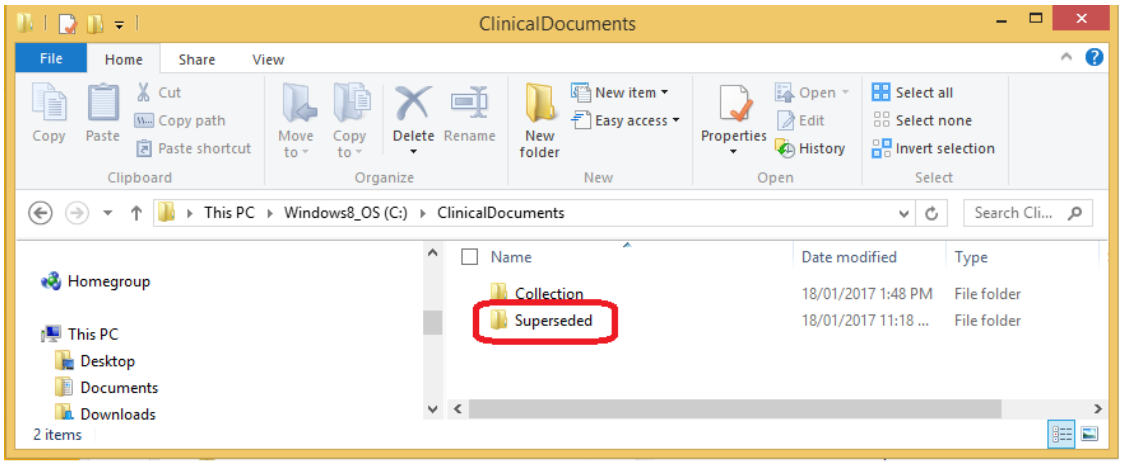


Figure 5: The Superseded folder

Note: The superseded document XML file must be copied to the Superseded folder, not the clinical package ZIP file. Any subfolders are ignored.

If the IQ Rules finds a clinical document in the Superseded folder, the document imported into the Validator is automatically assessed for conformance to the requirements that apply to a replacement document.

Note: Remember to remove the superseded document from the Superseded folder when the assessment has been completed.

6.4 Assessing information in a collection of documents

The IQ Rules is able to compare information in the sorts of clinical documents listed in Appendix A.2. This is performed when the IQ Rules finds clinical documents in the C:\DigitalHealth\ClinicalDocuments\Collection folder and the flag `collection-same-record` or `collection-same-system` is set to `"true"`.

The IQ Rules looks for XML files with the filename extension '.xml' or '.XML' and will only perform the comparison if there is more than one XML file in the Collection folder. Documents of any other type in the folder are ignored.

The IQ Rules assumes the clinical document imported into the Validator is one of the documents in the Collection folder.

Note: When a collection of clinical documents of the sort listed in Appendix A.2 is to be analysed, put all the documents into the Collection folder, including the document(s) that will be imported into the Validator.

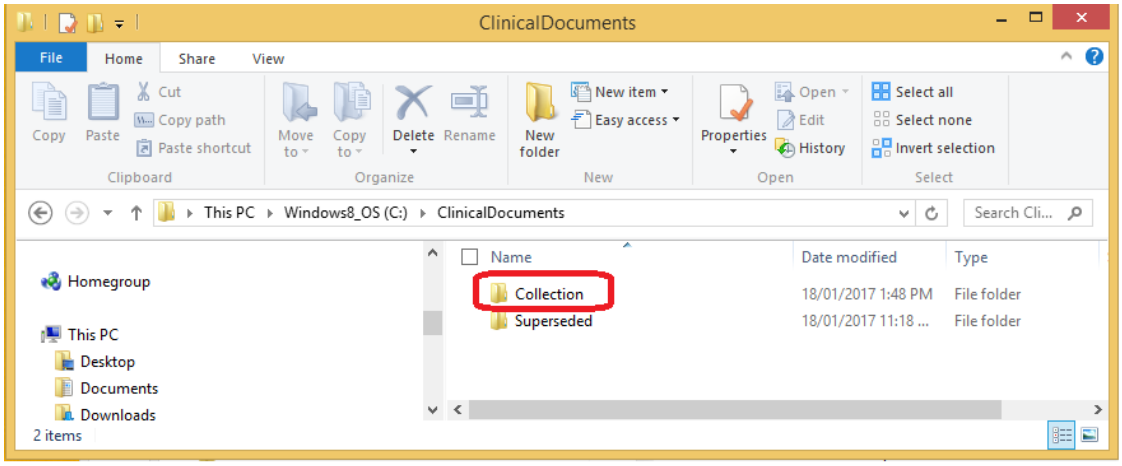


Figure 6: The Collection folder

Note: The clinical document XML files must be copied into the Collection folder, not the clinical package ZIP files. Any subfolders are ignored.

If the IQ Rules finds any clinical documents in the Collection folder, the document imported into the Validator is automatically compared to the clinical documents in the Collection folder.

Note: Remember to remove the documents from the Collection folder when the assessment has been completed.

6.5 Messages reported by the IQ Rules

6.5.1 Message types

Although the Validator uses the term 'issue' to describe anything reported by the IQ Rules, not everything reported by the rules is an issue. The types of messages reported by the IQ Rules are listed in Table 5.

Table 5: Types of messages reported by the IQ Rules

Message type	Explanation
Error	A failure to meet a mandatory conformance requirement.

Message type	Explanation
Warning	A possible failure to meet a mandatory conformance requirement, to be confirmed by manual inspection.
Recommendation	Advice on how to improve the quality of the clinical document, including conformance to recommended requirements.
Hint	A suggestion to examine something further.
Finding	A report of information found in one or more clinical documents, such as statistical information gathered by examining a collection of documents. Debugging information is also reported as a finding.

6.5.2 Message format

Messages contain the fields listed in Table 6.

Table 6: Format of messages reported by the IQ Rules

Message field	Explanation
Message type	The message types listed in Table 5.
Test case identifier (optional)	A message generated by applying a test case includes the test case identifier.
Message text	The text of the message. Message text is intended to be sufficiently understandable so that the message can be copied into a report to a software developer.
Reference to requirements (optional)	A reference to software requirements is included in messages that report issues with conformance to these requirements.
Additional information (optional)	Some messages contain additional information to help understand the issue reported in the message text.
Source of additional information (optional)	If additional information is included, the source of the additional information is stated.

Figure 7 to Figure 12 highlight each field of an example message reported by the IQ Rules:

Warning: TC-Doc-01: All 3 documents in the collection have the Immunisations Exclusion Statement with the code='03' (None supplied). Exclusion statement information is time-specific so its validity may not extend beyond the point in time when the information is recorded and the information is valid only for a specific point in time for each healthcare consumer. Therefore when each document in a collection has the same value for the exclusion statement there is a need to determine if the clinical document authoring system is automatically recording the exclusion statement instead of allowing healthcare providers to record information, which is an error if it is occurring. Confirm if automatic recording of the exclusion statement is occurring. (See section 4.2 of the Medication Instruction and Action Detailed Clinical Model Specification v2.4) The 'none supplied' exclusion statement may be used when there are no items to list and a healthcare provider has not chosen the 'none known' or 'not asked' exclusion statements. 'None supplied' does not imply anything about whether there are items, or whether they are known, or why no items are supplied. (See section 2.1 of the My Health Record Usability Recommendations v1.3)

Figure 7: Message type

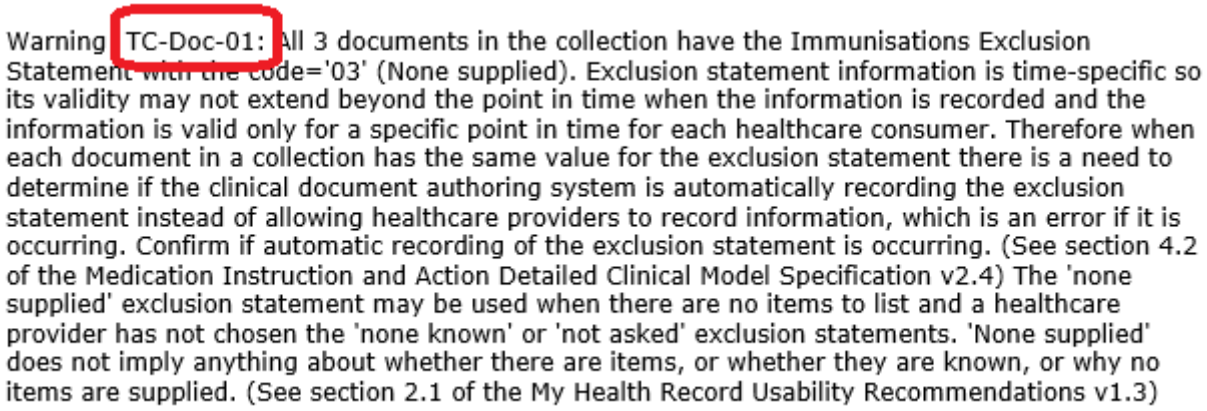


Figure 8: Test case identifier

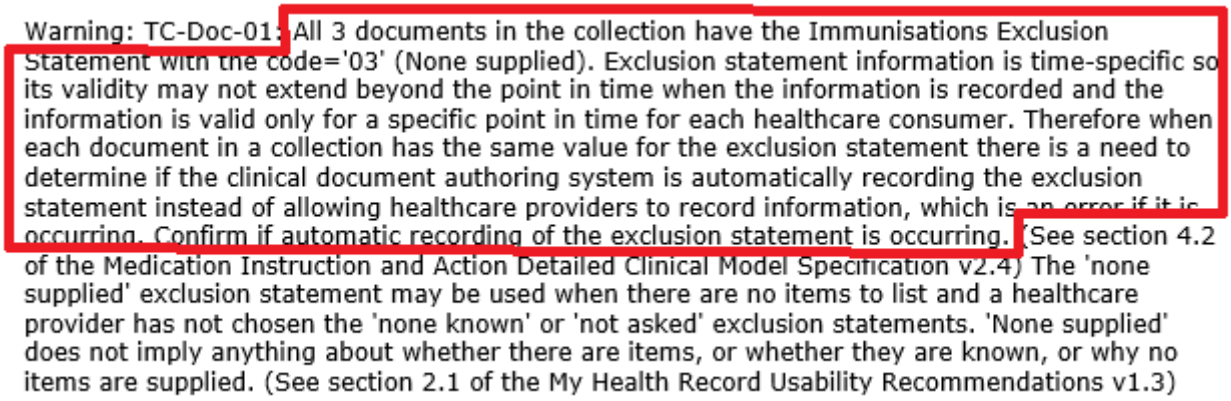


Figure 9: Message text

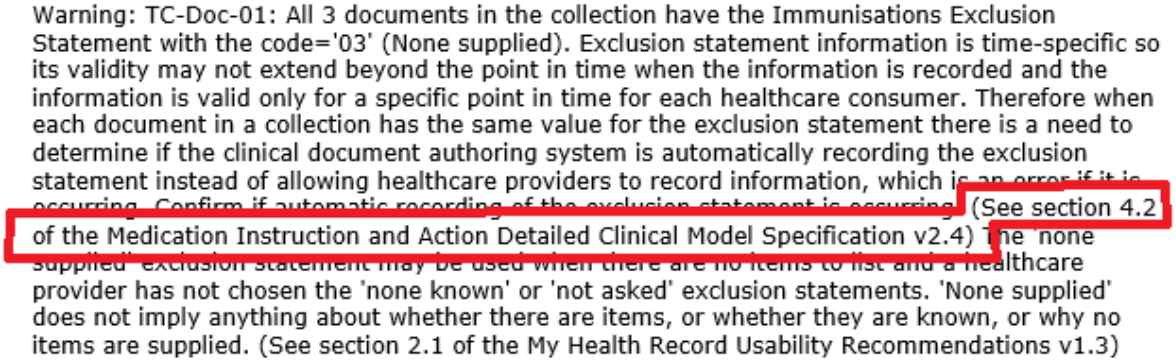


Figure 10: Reference to requirements

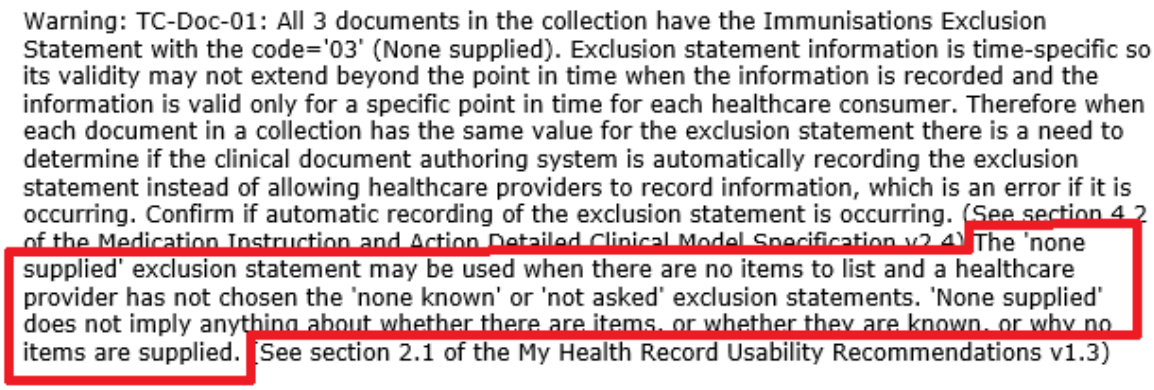


Figure 11: Additional information

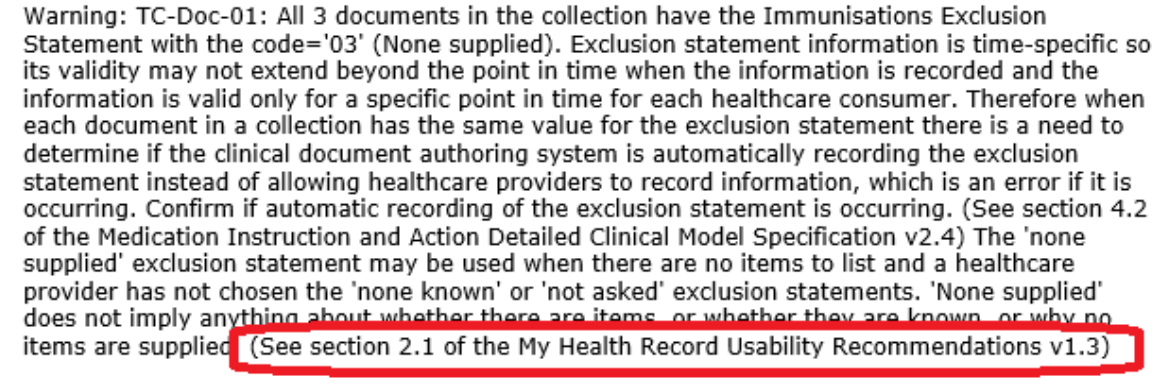


Figure 12: Source of additional information

6.5.3 Redaction

Text in a clinical document may be included in a report created by the IQ Rules if the inclusion of the text helps to explain the issue being reported. Therefore the IQ Rules applies a redaction algorithm to hide personal information in the text.

The IQ Rules applies the following process when creating a report.

1. A list of names is compiled by finding ‘name/family’ and ‘name/given’ elements in the clinical document. This applies to healthcare consumers and healthcare providers.
2. A message created by the IQ Rules to include in a report is scanned to find any family and given names found in the previous step. The family and given names are replaced with redacted versions. For example, “John SMITH” is replaced with “Jxxx SXXXX”.

If a clinical document narrative contains a name that is not in ‘name/family’ and ‘name/given’ elements then it is possible that the name may be included in the report. For example a narrative may include the name of a healthcare provider that is not mentioned elsewhere in the clinical document. Therefore, even though the above process is automatically applied by the IQ Rules any personal information that remains in a report must be manually redacted.

6.6 Conformance testing

A primary purpose of the IQ Rules is to provide instructions to automate some tests for the conformance of healthcare software systems (also known as Authoring Systems) that produce

clinical documents of the sorts listed in Appendix A.2. The clinical document specifications provided by the Australian Digital Health Agency are a subset of the specifications to which a healthcare provider software system must conform, so software developers may not be aware of the full set of clinical document conformance requirements. An advantage of using the IQ Rules and the Conformance Test Specification for Authoring Systems is that many, but not all, test cases are recorded in one place, reducing the need for software developers to find and read all the applicable specifications. Developers should however also be aware of all relevant clinical document specifications and their relationships to each other.

To be permitted to upload clinical documents (of the type referred to in Appendix A.2 of this document) to the My Health Record system, a healthcare software system developer must declare conformance to a version of the My Health Record conformance profiles for the types of documents produced by their healthcare software system.

For each type of clinical document of the type referred to in Appendix A.2 of this document, the source of the requirements is the conformance profile for that type of document, as well as the requirements in the technical specifications referenced by that conformance profile.

Clinical document specifications exist in a hierarchy, and specifications at one level of the hierarchy may override specifications at a lower level of the hierarchy when there is a need to constrain a more general requirement. The following diagram shows a hierarchy of specifications, with blue shading used for specifications published by the Australian Digital Health Agency and yellow shading used for specifications published by other organisations. Green shading indicates a specification or registry for a namespace used in clinical documents. Note that the diagram is provided for illustrative purposes only, and does not show a complete list of specifications and registries.

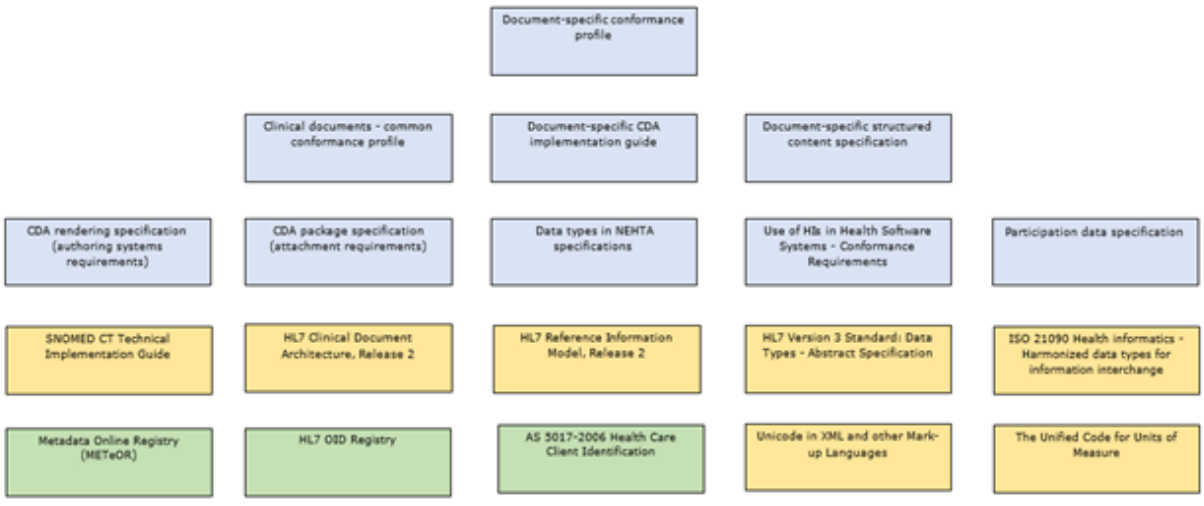


Figure 13: Example hierarchy of technical specifications for clinical document conformance

When declaring conformance to the My Health Record system requirements, a developer need only declare conformance to the conformance profile for a specific type of document. There is no need to declare conformance to any other technical specification as the conformance profile for a specific type of document references the other technical specifications for that type of document.

6.7 Using batch validation to test for conformance

To assess the conformance of a collection of clinical documents, the IQ Rules are used to apply the Validator to each clinical document in a collection of clinical documents to be assessed. The clinical documents must be the sort listed in Appendix A.2. Rather than repeatedly applying the Validator using its graphical user interface, batch validation is done more efficiently by using the Validator's command line interface described in section 5 of the Clinical Package Validator v2.8 User Guide.

For example, a batch file[11] may be created as follows:

```
CD C:\DigitalHealth\CPV28\

CPValidator.exe "C:\\ClinicalDocuments\\Collection" "*.xml"
"1.2.36.1.2001.1006.1.170.4" "MHR" "false"
"C:\\Users\\username\\Desktop\\work\\IQRules_v1.6" "true"

pause
```

In the above example:

- The `Collection` folder only contains clinical document XML files[12];
- The My Health Record template ID `"1.2.36.1.2001.1006.1.170.4"` applies to all documents in the collection;
- The parameter `"MHR"` requests the Validator to assess the clinical documents for conformance to the requirements for the My Health Record system;
- The parameter `"false"` requests the Validator to not create the test report PDF file or the rendered view of the clinical document;
- The second last parameter is the location of the IQ Rules;
- The last parameter `"true"` requests the Validator to examines XML files in all subfolders of the current folder; and
- The `pause` command is not needed but its inclusion keeps the command line window open after all documents in the collection have been assessed, so that any errors from the batch validation may be viewed.

The second example below is a batch file to validate clinical packages without specifying the My Health Record template identifier. In this case the Validator will apply the IQ Rules and its own tests for clinical packages and will not apply a My Health Record template package.

```
CD C:\DigitalHealth\CPV26\

CPValidator.exe "C:\\ClinicalDocuments\\Collection" "*.zip" "" "MHR" "false"
"C:\\Users\\username\\Desktop\\work\\IQRules_v1.6" "true"

pause
```

[11] A file with the '.bat' filename extension.
[12] The parameter `"*.zip"` is needed if the folder contains clinical packages.

The output of batch validation may be assessed by examining individual test report PDF files, as well as the analysis.csv and report.csv files that contain the overall validation test results.

The following batch file unzips all zip files in a folder and subfolders, which is useful when the IQ Rules is to be used to compare all documents in a collection (see the configuration flags in section 4.1).

```
REM C:\Program Files\7-Zip\
@ECHO OFF
REM Zip files in current folder

   for %%f in (*.zip) do (
      REM echo %%f
      "C:\Program Files\7-Zip\7z.exe" x -r -o"%%~nf" "%%~nf.zip"
    )

REM Zip files in sub folders
   for /D %%d in (*.) do (
      rem echo %%d
        for %%g in ("%%d\*.zip") do (
             rem echo %%g
             rem echo %%~ng
             "C:\Program Files\7-Zip\7z.exe" x -r -o"%%~ng" "%%g"
        )
    )
```

6.8 Assessing data quality

There are several dimensions to clinical data quality; and although conformance to the My Health Record system requirements is often the sole focus of an analysis, it is only one of the dimensions of data quality. The IQ Rules tool can report on other dimensions of data quality and can apply a wide variety of quality criteria to:

- An individual clinical document of one of the sorts listed in Appendix A.2;
- A collection of clinical documents in a My Health Record;
- A collection of clinical documents of one of the sorts listed in Appendix A.2 from the same source (e.g. from the same healthcare software system); or
- A large collection of clinical documents spanning many digital health records and sources of information.

The process used to apply the IQ Rules for testing conformance to the My Health Record system requirements is also the process used to assess other dimensions of data quality. The only difference is the scope of the assessment which is selected by setting the relevant flags in the IQ Rules configuration file, described in section 4.1.

6.9 Statistics reporting

The IQ Rules tool analyses information in collections of documents described in section 6.8 so it is able to report statistical information about them. To gather statistics, the `report- statistics` flag must be set to “true” and the Validator must be applied to one of the documents in the

collection. The IQ Rules will assess this document for conformance[13] and will report statistical information about all documents in the collection. The range of statistical information that may be reported by version 1.6 of the IQ Rules will be further developed in the future.

[13] Assessing one of the documents for conformance is a side-effect of using version 2.8 of the Validator. In the future it may be possible to gather statistical information without needing to assess a document for conformance.

7 Software developer guide to conformance testing

Although the Validator, My Health Record template packages and the IQ Rules assist with conformance testing, they should not, individually or used together, be relied upon to test for conformance to all requirements i.e. even if these test tools do not report any errors, conformance is not guaranteed as conformance to some requirements cannot be assessed by them and manual application of some test cases is required. Please also refer to the Clinical Package Validator Product Data Sheet and the IQ Rules scope statement in Appendix A.

7.1 Setup

Follow the steps below to setup the test tools for conformance testing:

1	Download Validator 2.8 software and documentation and install the software according to the instructions in the Clinical Package Validator Installation and Configuration Guide. See the note in section 2 about obtaining Validator 2.8.
2	Ensure the Validator contains the versions of SNOMED CT-AU or PBS clinical terminology that have been used in the clinical document. Install these versions, if needed, by following the instructions in the Clinical Package Validator Installation and Configuration Guide. See section 5.5 for information about how the IQ Rules selects a version of clinical terminology.
3	The Validator can apply the IQ Rules without applying a My Health Record template package, but if a template package is to be used then download the Template Package Directory from here[14] and identify the ID of the template package that corresponds to the claimed conformance level and version of the My Health Record conformance profile that the healthcare software system was developed to conform to. There are two template package variants that correspond to most conformance profiles: the default variant and the HPI-I relaxed variant. The default variant must be used unless permission has been obtained from the Australian Digital Health Agency to use the HPI-I relaxed variant. For example, if the software system was developed to conform to Event Summary My Health Record Conformance Profile version 1.4 and the claimed conformance level is 3A then the default template ID to use is '1.2.36.1.2001.1006.1.16473.14'. If permission has been granted by the Australian Digital Health Agency to use the HPI-I relaxation then template ID '1.2.36.1.2001.1006.1.16473.15' should be used.
4	Install and configure the IQ Rules using the instructions in section 3 and section 4 of the IQ Rules user guide, and knowledge of the scope of the healthcare software system. For example: • If the software was developed to conform to requirements in the Guidance for Use of Medical Nomenclatures in Information Exchange v1.2 then set `report-data-quality` to `"true";`

[14] At the time the IQ Rules User Guide was written, this link referenced the current version of the user guide. If the webpage states that a new version is available then use the latest version.

7.2 Assess clinical packages

This process uses Validator 2.8 with the My Health Record template package selected during setup, and may optionally use the IQ Rules. Use of the IQ Rules is optional for assessing clinical packages as the IQ Rules may be used to assess clinical documents (as described in section 7.3.).

If the healthcare software system produces clinical documents and not clinical packages then proceed to section 7.3.

Follow the steps below to assess a set of clinical packages for conformance:

1	Obtain and store in any folder a collection of clinical packages created by the healthcare software system. The clinical packages should contain a variety of information and attachments such as a logo, images or Adobe PDF files (if supported by the software). Note: A clinical package has the appearance of a ZIP archive.
2	Apply the Validator with the template package selected during setup to each of the clinical packages. Note: This step may be performed by either using a bat file to apply the Validator in batch mode; or by applying the Validator to each clinical package using the Validator's graphical user interface.
3	Review error messages reported by the Validator and work out how to correct the errors. Note: An "Error" message is a report of a failure to conform to a mandatory requirement and must be corrected.
4	Review any warnings reported by the Validator, manually apply the test case listed in each warning message, determine whether or not there is an error and work out how to correct the errors. Note: A "Warning" message indicates a possible failure to conform to a mandatory requirement. Manual inspection of the clinical package and knowledge of the digital health specifications and test cases is needed to determine whether there is an actual error. If manual inspection of the clinical package results in the 'warning' being determined to be an error then the error must be corrected.

7.3 Assess clinical documents

This process uses the IQ Rules with Validator 2.8 and the My Health Record template package selected during setup.

Follow the steps below to assess a set of clinical documents for conformance:

1	Obtain and store in the C:\DigitalHealth\ClinicalDocuments\Collection folder, of a subfolder, a collection of clinical documents created by the healthcare software system. The clinical documents should contain a variety of information and references to attachments such as a logo, images or Adobe PDF files (if supported by the software). Note: This collection of clinical document XML files may be obtained from clinical packages that were assessed for conformance by using a bat file to unzip the clinical packages (see sections 6.7 and 7.2). Storing the collection of clinical documents in the C:\DigitalHealth\ClinicalDocuments\Collection folder is essential as some conformance errors are only detected when then IQ Rules compares information in the document collection. The IQ Rules requires the clinical documents, i.e. the XML files, to be stored in the C:\DigitalHealth\ClinicalDocuments\Collection folder or a subfolder in order to compare the documents in the collection. If the collection of clinical documents includes superseded and replacement documents, then the superseded document(s) should not be included in the C:\DigitalHealth\ClinicalDocuments\Collection folder.
2	Apply the Validator with the IQ Rules and the template package selected during setup to each of the clinical documents. Note: This step may be performed by either using a bat file to apply the Validator in batch mode; or by applying the Validator to each clinical package individually using the Validator's graphical user interface.
3	Review error messages reported by the Validator and work out how to correct the errors. Note: An "Error" message is a report of a failure to conform to a mandatory requirement and must be corrected.
4	Review any warnings and hints reported by the Validator, manually apply the test case listed in each warning and hint message, determine whether or not there is an error and work out how to correct the errors. Note: A "Warning" message' indicates a possible failure to conform to a mandatory requirement. Manual inspection of the clinical document XML file and knowledge of the clinical document specifications and test cases is needed to determine whether there is an actual error. If manual inspection of the clinical document XML file results in the 'warning' being determined to be an error then the error must be corrected. A "Hint" message provides guidance on further actions to take to assess conformance. The actions should be taken and any errors found as a result of taking these actions should be corrected.

5	Review any recommendations reported by the Validator. If a recommendation is related to an in-scope requirement then treat the recommendation as an error and work out how to correct the error. For example, conformance to the Guidance for Use of Medical Nomenclatures in Information Exchange v1.2 is not mandatory for obtaining access to the My Health Record system so a failure to implement any of the guidance will be reported by the IQ Rules using a "Recommendation" message. However, when developing a healthcare software system, conformance to the Guidance for Use of Medical Nomenclatures in Information Exchange v1.2 may be in scope, e.g. there may be a contract that mandates the implementation of the guidance. If this is the case, a "Recommendation" message should be managed as if it is an "Error" message.

7.4 Assess superseded and replacement clinical documents

This process uses the IQ Rules with Validator 2.8 and the My Health Record template package selected during setup.

The process described in this section compares a superseded clinical document with the replacement clinical document. For most types of documents, the healthcare software system is required to have the ability to supersede a clinical document and upload the replacement document to the My Health Record system. An exception is healthcare software systems that only produce Shared Health Summaries. If the healthcare software system only produces a type of clinical document that has no requirement to be superseded, then the following steps may be omitted.

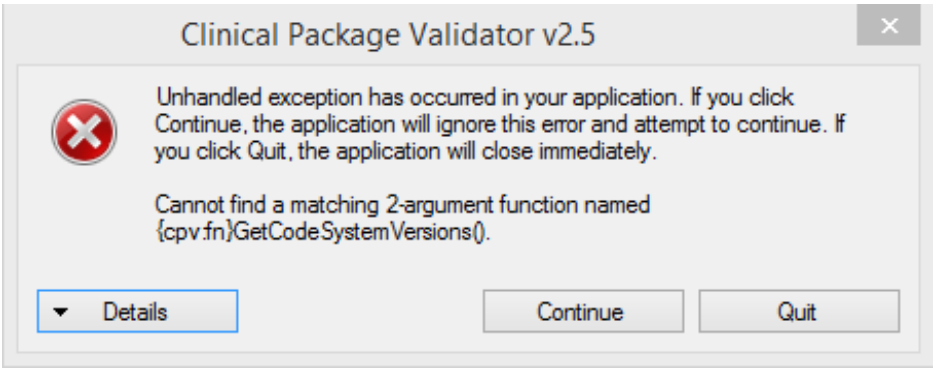
Follow the steps below to compare a clinical document with the document that it superseded:

1	Store the superseded document in the C:\DigitalHealth\ClinicalDocuments\Superseded folder or a subfolder and store the replacement document in the C:\DigitalHealth\ClinicalDocuments\Collection folder or a subfolder. Note: The IQ Rules will only compare the superseded and replacement documents if there is one document in the C:\DigitalHealth\ClinicalDocuments\Superseded folder and subfolders. Other documents may be present in the C:\DigitalHealth\ClinicalDocuments\Collection folder although it is recommended that that folder only contain the replacement document. The superseded and replacement clinical document XML files must be stored in these folders, rather than the clinical packages.
2	Apply the Validator with the IQ Rules and the template package selected during setup to the replacement document. Note: There is no need to apply the Validator to the superseded document as the IQ Rules will read that document and compare it to the replacement document.
3	Review errors, warnings, hints and recommendations reported by the Validator, assess them as described in steps 3, 4 and 5 of section 7.3, and correct any errors.

8 Troubleshooting

8.1 Unhandled exception error: missing 2-argument function

If the Validator applies the IQ Rules to a clinical document and the following error is displayed then the wrong version of the Validator was used.



Follow the steps below to resolve this.

1	Select 'Quit' on the error message.
2	Follow the steps in section 7.1 of this user guide to install and configure Validator 2.8.
3	Use Validator 2.8 to apply the IQ Rules to the clinical document.
End	

8.2 Unexpected messages about clinical terminology

The IQ Rules accesses clinical terminology in its own data file, the Validator's database and a Terminology Server when assessing clinical terminology in a document (see section 5.5 for more information). The Terminology Server is another software system accessed over the network and the IQ Rules may report unexpected messages if the Terminology Server cannot be accessed.

8.2.1 Temporarily unavailable

The IQ Rules may access the Terminology Server a number of times when assessing a clinical document and a message such as the following one may be reported if the query of the Terminology Server timed out (i.e. if the Terminology Server was temporarily unavailable):

> Finding: (p-TS-CD-TGI-Defn): An error was reported when accessing the terminology server when assessing the Therapeutic Good Identification data element containing the term: 'OxyContin tablet (modified release tablet) 20 mg'. The analysis should be retried as the terminology server may have been temporarily unavailable. If the problem persists then report the issue to the Australian Digital Health Agency for investigation.

In this situation the IQ Rules should be reapplied to the clinical document.

8.2.2 Permanently unavailable

In other situations the inability to access the Terminology Server may be permanent, as illustrated by the following example.

A clinical term may have synonymous terms, e.g. “Appendicectomy” is synonymous with “Excision of appendix”; or terms that are not synonymous but are related, e.g. “Allergic Reaction” is related to “Allergy”.

The IQ Rules uses knowledge of synonymous and related terms when assessing clinical documents, including the synonymous terms recorded in the Terminology Server, and unexpected warnings may be reported if the IQ Rules does not have access to the Terminology Server. For example, in the SNOMED CT-AU code system, “Appendicectomy” is synonymous with “Excision of appendix”, but if the IQ Rules is not able to access this information then the following warning may be reported when a document containing these terms is being assessed:

> Warning: TC-Types 66 step 1: The data element 'procedure/code' in the Clinical Interventions Performed This Visit section has originalText "Excision of appendix", code "80146002" and displayName "Appendicectomy" from codeSystem "2.16.840.1.113883.6.96" (SNOMED CT-AU). The concept described by the primary code may be inconsistent with the concept described by the originalText element. Confirm that the originalText describes the same concept as the primary code. (See sections 8.1 and 7.5.2.4.8 of ISO 21090 'Health informatics - Harmonized data types for information interchange'.) The value of the displayName attribute was used to match the originalText as synonyms of the primary code "80146002" were not available. The originalText element is required to be the text seen or selected by the person that entered the information. (See section 7.5.2.4.8 of ISO 21090 ''Health informatics - Harmonized data types for information interchange'.)

Follow the steps below to resolve this:

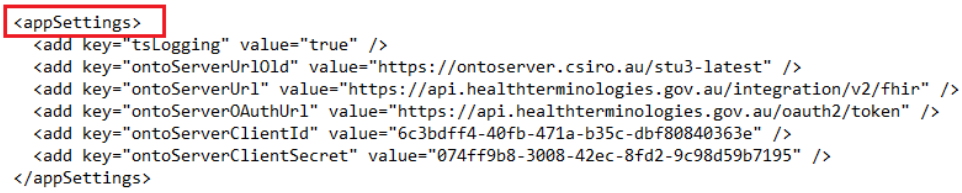
1	Find information about the configuration of the IQ Rules in the Validator’s **Additional Rules Report** tab or the Validator’s test report PDF file. By default, the first message is information about the configuration of the IQ Rules, and information about access to a Terminology Server is displayed at the end of the first message. If the first message does not provide information about the IQ Rules configuration then follow the procedure in section 4 to set the `about-IQ-Rules` flag to report configuration information.
2	Check the last part of the configuration message to see if the IQ Rules had access to a Terminology Server. This report was generated by IQ Rules version 1.4.10 issued by the Australian Digital Health Agency 19 Sep 2017 with the following configuration: about-IQ-Rules = 'true' allow-debug = 'false' allow-hints = 'true' allow-ratings = 'true' collection-same-record = 'false' collection-same-system = 'true' narrative-auto-generated = 'false' narrative-derived = 'false' report-data = 'false' report-deprecated-recommendations = 'false' report-identifier-recommendations = 'false' report-medicines-recommendations = 'false' report-pres-disp-recommendations = 'false' report-rendering-recommendations = 'false' report-statistics = 'false' report-terminology-recommendations = 'false' report-usability-recommendations = 'false'. The Clinical Package Validator's database contains the following code systems and versions: AMT v2 (2.56); AMT v3 (http://snomed.info/sct/900062011000036108/version/20151130); PBS (20170701); PBS Manufacturer (20170701); SNOMED CT-AU (http://snomed.info/sct/32506021000036107/version/20170731) The IQ Rules did not have access to a Terminology Server.
3	If the IQ Rules did not have access to a Terminology Server then determine if there is an Internet connection.
4	If there was no Internet connection then establish one and reapply the Validator to the clinical document; otherwise contact the Agency on 1300 901 001 or help@digitalhealth.gov.au for assistance with accessing a Terminology Server.

5	If the configuration message reported that the IQ Rules had access to a Terminology Server then follow the instructions in the Clinical Package Validator Installation and Configuration Guide to determine if the Validator's database contains the versions of the clinical terminology code systems that were used to create the clinical document; or install those versions, if needed, and reapply the Validator to the clinical document.
6	If the problems persists after trying the steps above then contact the Agency on 1300 901 001 or help@digitalhealth.gov.au about including the synonymous terms in the data files used by the IQ Rules.
7	If the issue cannot be resolved in a suitable timeframe then ignore the warning about the synonymous or related terms if you are confident that the terms are synonymous or related.
End	

8.3 Long run times

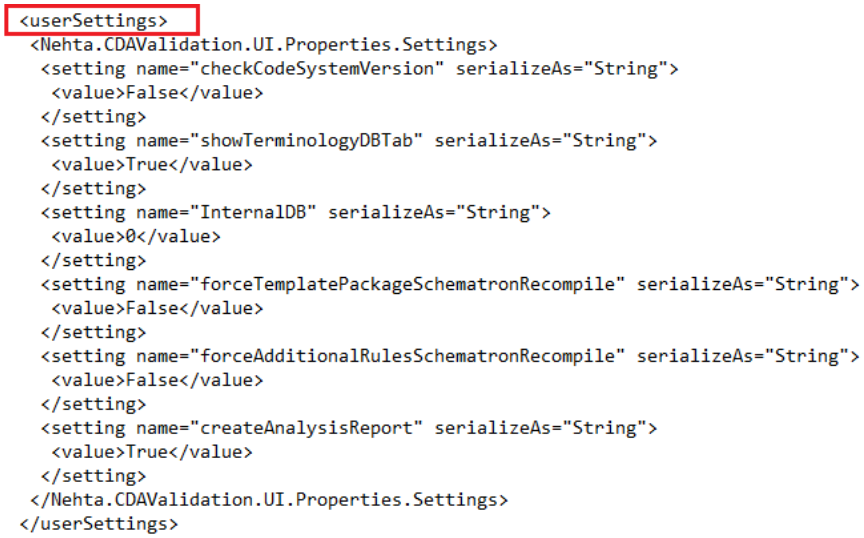
The amount of time taken by the IQ Rules to analyse a document varies with the size of the document and the number of errors. For many documents, however, such as a Shared Health Summary, the run time is generally a few minutes.

The following steps may be taken to reduce the time taken by the IQ Rules to analyse clinical documents.

1	Operate the Validator in batch mode with the command line setting to request the Validator to not create the test report PDF file or the rendered view of the clinical document. The test report PDF files are time consuming to create and need not be created as test results are also recorded in the analysis.csv file created by the Validator.
2	a. Go to the folder where the Validator is installed, which is C:\DigitalHealth\CPV28 by default unless another folder was selected during its installation. b. Open the configuration file **CPValidator.exe.config** with a text editor such as Notepad. c. Find the 'appSettings' in the configuration file.  d. Change the 'tsLogging' value to 'false'. e. Close the configuration file and restart the Validator. This instructs the Validator to not log its access to the Terminology Server.

3	a. Navigate to C:\DigitalHealth\ClinicalDocuments. b. Select **IQConfig.xml** with the right mouse button and then select either 'Edit' or 'Open with' followed by Notepad or WordPad or a similar editor. c. If the value of the `'report-terminology-concepts'` flag is `'true'` and there is no need to report terminology concepts then change it to `'false'`. d. If the value of the `'report-data-quality'` flag is `'true'` and there is no need to report data quality other than conformance then change it to `'false'`. e. If the value of the `'report-data'` flag is `'true'` and there is no need to report the data elements then change it to `'false'`. f. If the value of the `'assess-values'` flag is `'true'` and there is no need to assess the value of CodeablText data elements then change it to `'false'`. g. If the value of the `'allow-debug'` flag is `'true'` and there is no need to debug the operation of the IQ Rules change it to `'false'`. h. Close the configuration file. Setting the `'report-terminology-concepts'` flag to `'false'` may reduce the number of times the Terminology Server is accessed, thereby reducing the time for the IQ Rules to analyse a clinical document.
End	

The IQ Rules will take considerably longer to run if the Validator is not properly configured. If the run time is of the order of 30 minutes or more, follow the steps below.

1	Shut down the Validator.
2	Go to the folder where the Validator is installed, which is C:\DigitalHealth\CPV28 by default unless another folder was selected during its installation.
3	Open the configuration file **CPValidator.exe.config** with a text editor such as Notepad.
4	Find the 'userSettings' near the end of the configuration file. 

```
<userSettings>
 <Nehta.CDAValidation.UI.Properties.Settings>
  <setting name="checkCodeSystemVersion" serializeAs="String">
   <value>False</value>
  </setting>
  <setting name="showTerminologyDBTab" serializeAs="String">
   <value>True</value>
  </setting>
  <setting name="InternalDB" serializeAs="String">
   <value>0</value>
  </setting>
  <setting name="forceTemplatePackageSchematronRecompile" serializeAs="String">
   <value>False</value>
  </setting>
  <setting name="forceAdditionalRulesSchematronRecompile" serializeAs="String">
   <value>False</value>
  </setting>
  <setting name="createAnalysisReport" serializeAs="String">
   <value>True</value>
  </setting>
 </Nehta.CDAValidation.UI.Properties.Settings>
</userSettings>
```

5	Check the value of the 'forceTemplatePackageSchematronRecompile' and the 'forceAdditionalRulesSchematronRecompile' settings. If the value of 'forceAdditionalRulesSchematronRecompile' is 'True', the Validator is forced to regenerate the IQ Rules style sheet every time a clinical document is assessed and that process can take 12 to 15 minutes. Similarly, if the value of 'forceTemplatePackageSchematronRecompile' is 'True', the Validator is forced to regenerate the style sheet in the My Health Record template package every time that template package is used. The default values for both settings is 'False' and they should only be set to 'True' when the Validator is used to develop new My Health Record template packages or additional rules.

```
<userSettings>
 <Nehta.CDAValidation.UI.Properties.Settings>
  <setting name="checkCodeSystemVersion" serializeAs="String">
   <value>False</value>
  </setting>
  <setting name="showTerminologyDBTab" serializeAs="String">
   <value>True</value>
  </setting>
  <setting name="InternalDB" serializeAs="String">
   <value>0</value>
  </setting>
  <setting name="forceTemplatePackageSchematronRecompile" serializeAs="String">
   <value>False</value>
  </setting>
  <setting name="forceAdditionalRulesSchematronRecompile" serializeAs="String">
   <value>False</value>
  </setting>
  <setting name="createAnalysisReport" serializeAs="String">
   <value>True</value>
  </setting>
 </Nehta.CDAValidation.UI.Properties.Settings>
</userSettings>
```

6	If either of the 'forceTemplatePackageSchematronRecompile' or 'forceAdditionalRulesSchematronRecompile' settings is 'True' then change the settings to 'False'.
7	Close the configuration file and restart the Validator.
End	

8.4 Further assistance

The Agency Help Centre may be contacted on 1300 901 001 or help@digitalhealth.gov.au for the following types of requests:

- Assistance on how to assess data quality using the IQ Rules and Validator;
- Help to understand the report created by the Validator when applying the IQ Rules;
- Suggestions for further enhancements of the tools.

Appendix A Scope Statement

A.1 Conformance Test Specification for Authoring Systems

One of the main reasons for using the IQ Rules is to assess the conformance of healthcare software that authors clinical documents. This is achieved by automating, where possible, test cases in the Conformance Test Specification for Authoring Systems version 1.1.

This appendix is organised in the same way as the Conformance Test Specification for Authoring Systems which is comprised of four feature sets; each feature set contains a number of test sets, each test set contains a number of test cases and some test cases have multiple steps.

This appendix provides information about the coverage and automation of each of the above test cases by the IQ Rules.

> ***Note:*** *An objective in developing the IQ Rules was to only report the root cause of an error i.e. only one message should be reported for any error. By contrast, manually applying test cases from the* Conformance Test Specification for Authoring Systems *may result in more than one test case reporting a fail for an error.*
>
> *For example, the UniqueIdentifier data type is a specialisation of the HL7 II (Instance Identifier) data type, and the test case for the UniqueIdentifier data type, TC-Types-11, states that a fail is to be reported for TC-Types-11 if a fail is reported for any test case in the TS-II test set. The IQ Rules, however, do not necessarily report a fail for TC-Types-11 if there is a fail reported for one of the test cases in the TS-II test set. This is intended so that the root cause of an error is more easily identified and is not obscured by a multitude of error messages.*

> ***Note:*** *The data hierarchy table in every CDA Implementation Guide lists some data elements using a grey icon with a note that these are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use and they usually have no clinical significance. The IQ Rules does not assess these data elements.*

The following sections describe the extent to which test sets in the Conformance Test Specification for Authoring Systems version 1.1 are covered and automated by the IQ Rules. There is one section for every feature set[15], and a table for each test set[16] comprising that feature set. The test sets are listed in alphabetical order; and every test set has a table that lists the test cases[17] for that test set.

Table 7 provides information about the symbols that describe the coverage and automation of each test case.

[15] Feature set identifiers commence with 'FS'.
[16] Test set identifiers commence with 'TS'.
[17] Test case identifiers commence with 'TC'.

Table 7: Explanation of symbols that describe the coverage and automation of test cases

Symbol	Coverage	Automation
F	The scope of the test case is fully covered by the IQ Rules (see the note above).	The IQ Rules fully automates the part of the test case that is covered. Full automation means that a message reported by applying a test case is either an error or a recommendation[18]. If the test case priority is mandatory or conditional and the clinical document being assessed fails the test case then the IQ Rules reports an error. If the test case priority is optional and the clinical document being assessed fails the test case then the IQ Rules reports a recommendation.
P	The scope of the test case is partially covered by the IQ Rules.	The IQ Rules partially automates the part of the test case that is covered. Partial automation means that a message reported by applying a test case is either an error, a recommendation, a warning or a hint. When a warning or a hint is reported, the tester must manually apply the test case.
R	The entire scope of the test case is the application of one or more referenced test cases[19].	The scope of automation is defined by the scope of automation of the referenced test case(s).
N	There is no coverage of the test case.	There is no automation of the test case.
-	There is no test step in the conformance test specification that corresponds to the test case identifier so no coverage is needed.	There is no test step in the conformance test specification that corresponds to the test case identifier so no automation is needed.

Commonly used coverage and automation indicators include:

- F (coverage) & F (automation) meaning the test case is fully covered and fully automated;
- F (coverage) & P (automation) meaning the test case is fully covered and partially automated;
- P (coverage) & F (automation) meaning the test case is partially covered and the part that is covered is fully automated;
- P (coverage) & P (automation) meaning the test case is partially covered and the part that is covered is partially automated;
- N (coverage) & N (automation) meaning there is neither coverage nor automation of the test case;
- R (coverage) & R (automation) meaning the coverage and scope of automation is that of the referenced test cases. Any message reported by the IQ Rules uses the identifier of the referenced test cases;

[18] No message is reported if a test case is passed.

[19] For example TC-Types-32 is passed if TS-UID is passed.

- - (coverage) & - (automation) meaning there is no test step to apply.

A.1.1 FS-Doc (Clinical documents)

This section contains a table for each test set in the FS-Doc feature set within the Conformance Test Specification for Authoring Systems v1.1. The FS-Doc feature set contains tests for the header and body of a clinical document.

Table 8: TS-AdminObs (Administrative Observations) test set

Test case	Coverage	Automation	Explanation
TC-Doc-40	F	F	

Table 9: TS-Body (CDA body) test set

Test case	Coverage	Automation	Explanation
TC-Doc-23	N	N	
TC-Doc-24	F	F	
TC-Doc-25	F	F	A recommendation is reported if a document fails the test case.
TC-Doc-41	F	F	

Table 10: TS-Dext (Document extensions) test set

Test case	Coverage	Automation	Explanation
TC-Doc-28 Step 1	P	P	If extensions are permitted then an error is reported if the data component is one that is known to conflict with other data components in the information model[20]; otherwise a hint is reported.
TC-Doc-28 Step 2	R	R	See the coverage tables for TS-GCD, TS-Body, and TS-Dext and for FS-Types in appendix A.1.3 and FS-Narr in appendix A.1.2.
TC-Doc-28 Step 3	P	P	If a section of a clinical document has the codeSystem "1.2.36.1.2001.1001.101" and that section is not one of those specified by the CDA implementation guide for that document type, and if extensions are permitted then a warning is reported if the section is not one of the Agency-defined sections, and a hint is reported if it is an Agency-defined section but assessment of the section is not in scope for the current version of the IQ Rules. The sections in scope are listed in appendix A.3. If the section is listed in appendix A.3 then the IQ Rules assesses

[20] In the current version of the IQ Rules, this is the ext:policyOrAccount data component.

			the conformance of the section's data elements using the FS-Types test cases. The IQ Rules would ideally also check conformance to the cardinality requirements but that is not in scope for the current version of the IQ Rules.
TC-Doc-28 Step 4	P	F	An error is reported for extensions when the document is of one of the types which are not allowed to include extensions. If extensions are disallowed, this is stated in the conformance profile for the specific type of document. The following types of extensions are assessed in the TC-Doc-28 test steps: 1 Document sections that contain a narrative, <entry> or <component> elements and which are not one of the Agency-defined sections listed in appendix A.3. 2 An Agency-defined section that is one of the sections listed in appendix A.3 but which is not included in the information model for the specific type of document. 3 Sections identified by the NCTIS Data Components code system '1.2.36.1.2001.1001.101' which have a code that is not listed in appendix A.3. 4 Agency-defined sections that contain <entry> elements but the information model for the section does not specify <entry> elements. 5 Data components not listed in the CDA implementation guide for the type of document being assessed that have a code that is a member of the NCTIS Data Components code system '1.2.36.1.2001.1001.101'. 6 Attributes and elements that are extensions to the Agency-defined data types listed in appendix A.4. 7 Data components in <entry> elements of an eHealth Prescription Record or eHealth Dispense Record that are not listed in the information model. Items (1) and (2) are only applied to the types of documents that are listed in appendix A.2 whereas items (3), (4) and (6) are applied to any type of document. Item (5) is currently only used in step 4.
TC-Doc-29	-	-	There is no test case.
TS-Doc-36	N	N	

Table 11: TS-DocIdent (Document identification, revisions & addenda) test set

Test case	**Coverage**	**Automation**	**Explanation**
12TC-Doc-32 Step 1	F	F	An error is reported if two or more documents in a collection have the same setId. It is assumed that the collection does not contain a document that is a replacement or addendum to another document in that collection.
TC-Doc-32 Step 2	F	F	An error is reported if the versionNumber element has a value attribute and if the value is not greater than or equal to 1.
TC-Doc-33	F	P	In general an error is reported if any step in the test case fails. The exception is that a warning is reported if either the replacement document creation time or the superseded document creation time has a time zone and the other document does not.
TC-Doc-34	N	N	
TC-Doc-35	N	N	
TC-Doc-38	F	F	An error is reported if there is no root attribute, if there is a nullFlavor for the document identifier, or if more than one document in the collection has the same document identifier.

Table 12: TS-GCD (General clinical document) test set

Test case	Coverage	Automation	Explanation
TC-Doc-01	P	P	An error is reported for the following scenarios: 1 The value of the <high> and <low> elements of the substance administration <repeatNumber> data element are not greater than zero. 2 The value of the <sequenceNumber> data element is not greater than zero. 3 The <telecom> element has a telephone number 'tel:0' or a fax number 'fax:0'. 4 An Entitlement Validity Duration has a <low> element or a value attribute when the entitlement is a Medicare number of a DVA file number. 5 The prescription expiry date does not occur after the date when the prescription was written in a Prescription Record. 6 There is no principal medical problem or diagnosis in the Problem/Diagnosis of the Problem/Diagnoses This Visit section in a Discharge Summary. 7 A data element contains a year that is not greater than 1899 and less than 2300. 8 The value of an <addr> element (such as <streetAddressLine>) has the format of an email address. 9 An Agency-defined section that is not the Adverse Reactions section contains an Adverse Reactions Exclusion Statement. 10 An Agency-defined section that is not the Ceased Medications section contains a Ceased Medications Exclusion Statement. 11 An Agency-defined section that is not the Current Medications on Discharge section contains a Current Medications on Discharge Exclusion Statement. 12 An Agency-defined section that is not the Immunisations section contains an Immunisations Exclusion Statement. 13 An Agency-defined section that is not the Medications section contains a Medications Exclusion Statement. 14 An Agency-defined section that is not the Problems/Diagnoses This Visit section contains a Problems and Diagnoses Exclusion Statement. 15 An Agency-defined section that is not the Medical History section contains a Problems and Diagnoses Exclusion Statement or a Procedures Exclusion Statement. 16 The status code in a Dispense Record is 'active' even though there are no more dispenses available. 17 The status code in a Dispense Record is 'completed' even though more repeats are available. 18 The Medication Entries with Summary section has information about more than one prescription item. 19 The Medication Entries with Summary section has a Total Number of Known Supplies data element with a value that is less than zero or greater than the Maximum Number of Permitted Supplies. 20 The Medication Entries with Summary section has a Maximum Number of Permitted Supplies data element with a value that is less than one and is not the value of the Maximum Number of Repeats plus one. 21 The Number of this Dispense data element has a value that is less than one or is greater than the value of <repeatNumber>/<high>, in a Dispense Record. 22 A Therapeutic Good Identification data element has an AMT v3 or AMT v3 code and the displayName is not the preferred term.

			23 A Medication section[21] has two Medication Instructions for the same medication, each with different values for the Medication Instruction Instance Identifier, and either: a All other content is identical; or b All other content is identical except for a 'translation' element of the Therapeutic Good Identifier; or c The medications are the same but there are different values for Change Type. 24 The value of the Document Creation Time is inconsistent with the value of the following data elements: Authored date/time, Attested date/time, Reporting Pathologist Participation Period, Reporting Radiologist Participation Period, Reporting Pathologist Participation Period, Reporting Radiologist Participation Period, Problem/Diagnosis Date of Onset, Problem/Diagnosis Date of Resolution/Remission, Procedure DateTime Started, Medical History Item TimeInterval and Procedure DateTime. A warning is reported in the following scenarios: 1 An <addr>/<additionalLocator> element seems to have an invalid value, i.e. one that may not be an Address Site Name, Floor Level Type, Floor Level Number, Lot Number, or Delivery Point Identifier. 2 A <name> <given> or <family> element contains numbers. 3 A name prefix seems to be included in the <name>/<family> element. 4 A name suffix seems to be included in the <name>/<given> element. 5 A <name>/<given> element contains spaces. 6 A custom-defined section contains an Adverse Reactions Exclusion Statement, a Ceased Medications Exclusion Statement, a Current Medications on Discharge Exclusion Statement, an Immunisations Exclusion Statement, a Medications Exclusion Statement, a Problems and Diagnoses Exclusion Statement or a Procedures Exclusion Statement. 7 The flag `collection-same-system="true"` and all documents in a collection with an Immunisations, Adverse Reactions, Medications, Problems and Diagnoses, Procedures, Current Medications on Discharge or Ceased Medications Exclusion Statement has the code "01" (none known) or "02" (not asked) or the same nullFlavor. 8 The flag `collection-same-system="true"` and all Shared Health Summaries in a collection with an Immunisations, Adverse Reactions, Medications, Problems and Diagnoses or Procedures Exclusion Statement has the code "03" (none supplied). 9 The flag `collection-same-system="true"` and every Exclusion Statement in a collection of documents has the code "01" (none known) or "02" (not asked). 10 The flag `collection-same-system="true"` and every Exclusion Statement in a collection of Shared Health Summaries has the code "03" (none supplied). 11 The flag `collection-same-system="true"` and every Vaccine Sequence Number in a collection of documents has the same value. 12 A Medication section[22] has two Medication Instructions for the same medication and the instructions differ and do not meet any of the criteria listed in item 23 above for reporting an error. 13 The value of the Authored date/time data element is inconsistent with the value of the Attested date/time data element.

[21] The section with the code "101.16146".

[22] The section with the code "101.16146".

			A recommendation is reported for the following scenarios: 1 The flag `collection-same-system="true"`, the flag `report-data-quality ="true"` and every Exclusion Statement in a collection of Shared Health Summaries has the Exclusion Statement code for None Supplied. 2 The flag `collection-same-system="true"`, the flag `report-data-quality="true"` and every Adverse Reaction Type in a collection of documents have the same code. A hint is reported for the following scenarios: 1 A healthcare provider organisation or individual has no fixed address. 2 A date's time zone is not the time zone of an Australian state or territory.
TC-Doc-02	F	F	The IQ Rules incorporates the Australian CDA schema extension.
TC-Doc-03	-	-	There is no test case.
TC-Doc-04	-	-	There is no test case.
TC-Doc-05 Step 1	P	F	An error is reported for the following scenarios: 1 The <name> element of a healthcare participant that is a person does not include the <family> element or the <name> contains information that is not contained entirely within the elements of <name>. 2 The <addr> contains information that is not contained entirely within the elements of <addr>. 3 The Employment Detail is present without the Employer Organisation. 4 The Therapeutic Good Identification in a Prescription Record or Dispense Record is present without an originalText or it is present with a nullFlavor. 5 The <setId> or document <id> in a Prescription Record or Dispense Record does not contain a root attribute, or the value of the root attribute is not an UUID, 6 The <setId> is not present in a Prescription Record or Dispense Record. 7 The clinical document <versionNumber> in a Prescription Record or Dispense Record is omitted or does not have a value. 8 The <relatedDocument>/<parentDocument> header element in a Prescription Record or Dispense Record that superseded a previous version of that document is not present or does not have a typeCode attribute with the value 'RPLC'. 9 The Quantity Description in a Prescription Record is is present with a nullFlavor. 10 The DateTime of Dispense Event in a Dispense Record is not present with a value; or the DateTime of Dispense Event has a nullFlavor. 11 The Dispense Item Identifier in a Dispense Record is not present with a value; or the Dispense Item Identifier has a nullFlavor. 12 An Adverse Reactions section has an exclusion statement and also has Agent Descriptions with a proper value. 13 The Problems/Diagnoses This Visit section has an exclusion statement and also has Problem/Diagnosis Descriptions with a proper value. 14 The Immunisation section has an exclusion statement and also has a vaccine (Therapeutic Good Identification) data element with a proper value. 15 The Medications section has an exclusion statement and also has a medicine (Therapeutic Good Identification) data element with a proper value. 16 The Current Medications section has an exclusion statement and also has a medicine (Therapeutic Good Identification) data element with a proper value. 17 The Ceased Medications section has an exclusion statement and also has a medicine (Therapeutic Good Identification) data element with a proper value. 18 The Recommendations section has an exclusion statement and also has a Recommendation Narrative with a proper value.

			19 The Medical History section has an exclusion statement for problems and diagnoses; or an exclusion statement for procedures; and also has an Uncategorised Medical History Item (also known as an Other Medical History Item). 20 The Medical History section has an exclusion statement for problems and diagnoses, and also has a Problem/Diagnosis Identification with a proper value. 21 The Medical History section has an exclusion statement for procedures, and also has a Procedure Name with a proper value. 22 The Imaging Examination Result section of a Diagnostic Imaging Report has a title and no narrative. 23 The Pathology Test Result section of a Pathology Report has a title and no narrative.
TC-Doc-05 Step 2	P	P	An error is reported for the following scenarios: 1 The Adverse Reaction Manifestation, Adverse Reaction Substance/Agent or Medicine data element in a Personal Health Summary contains a code. 2 If DateTime Authored and DateTime Attested do not have the same value in an Advance Care Directive Custodian Record, Discharge Summary, eReferral, Event Summary, Shared Health Summary or Specialist Letter. 3 The DateTime Attested data element in an Event Summary developed to version 1.3 of the CDA implementation guide only has a date, or a Shared Health Summary developed to version 1.4 of the CDA implementation guide only has a date. 4 There is no <relatedDocument> data element with typeCode 'XFRM', in a Prescription Record or Dispense Record. 5 There is more than one <relatedDocument> data element with typeCode 'XFRM' or 'RPLC', in a Prescription Record or Dispense Record. 6 There is a <relatedDocument>data element with typeCode that is neither 'XFRM' nor 'RPLC', in a Prescription Record or Dispense Record. 7 The <relatedDocument>/<parentDocument>/<code> data element does not have the same value as the <ClinicalDocument>/<code> element, in a Prescription Record or Dispense Record. 8 When the <relatedDocument> element has typeCode 'RPLC', in a Prescription Record or Dispense Record: a The <parentDocument>/<id> data element is either omitted or does not meet the requirement to have a root attribute that is a UUID and no extension attribute. b The <parentDocument>/<setId> data element is either omitted or does not have a value that equals the <ClinicalDocument>/<setId>. c The <parentDocument>/<versionNumber> data element is either omitted, does not have a value or the value is not less than the value of <ClinicalDocument>/< versionNumber>. 9 A Therapeutic Good Identification data element has an AMT code and a PBS Manufacturer Code is also present, in a Prescription Record or Dispense Record. 10 The document author's entitlement technical identifier has a different value from the <author>/<assignedAuthor>/id>, in a Prescription Record. 11 The dispensing organisation's entitlement technical identifier has a different value from the <healthCareFacility>/<id>, in a Dispense Record. 12 The <relatedDocument> element with typeCode 'XFRM' does not contain an <id> element, in a Dispense Record. 13 The Prescription Item Identifier does not contain a root attribute whose value is an OID or the extension attribute is omitted or has no value, in a Prescription Record or Dispense Record. 14 The <statusCode>/<code> element in a Dispense Item section has a value that is neither 'active' nor 'completed'.

			15 The <legalAuthenticator>/<assignedEntity>/<id> does not have the same value as the <author>/<assignedAuthor>/<id> data element when the dispensing pharmacist is the legal authenticator, in a Prescription Record or Dispense Record. 16 The <representedCustodianOrganization>/<id> does not have the same value as the <healthCareFacility>/<id> when the custodian organisation is the healthcare facility, in a Prescription Record or Dispense Record. 17 The Dispense Record Link Target data element does not meet the requirement that the reference value must begin with a '#' and point to a <linkHtml> element in the corresponding narrative, in a Prescription and Dispense View. 18 The Prescription Record Link Target data element does not meet the requirement that the reference value must begin with a '#' and point to a <linkHtml> element in the corresponding narrative, in a Prescription and Dispense View. 19 The Observation DateTime and Image DateTime in an Imaging Examination Result section do not have the same value, in a Diagnostic Imaging Report. 20 The Problem/Diagnosis Date of Onset data element or the Problem/Diagnosis Date of Resolution/Remission data element in a Medical History section contains a time. 21 The Observation DateTime and Image DateTime in a Pathology Test Result section do not have the same value. 22 The Related Document Report DateTime <low> element in a Pathology section contains a date but no time. 23 The Subject of Care technical identifier has a different value from the Subject of Care Entitlement technical identifier. A warning is reported in the following scenarios: 1 The<relatedDocument>element with typeCode 'XFRM' has an <id> and the value of the root attribute is a UUID OID, in a Dispense Record. A hint is reported in the following scenarios: 1 A <parentDocument>/<id> has a root attribute with the value '1.2.36.1.2001.1005.35' or '1.2.36.1.2001.1005.36'[23], in a Dispense Record. 2 The Prescription Item Identifier data element root attribute is a UUID OID, in a Prescription Record or Dispense Record.
TC-Doc-06	N	N	
TC-Doc-07	-	-	There is no test case.
TC-Doc-08	F	F	
TC-Doc-09	F	F	

[23] These identifiers are used by one pf the software developers as they were included in the digital health specifications other developer's often mistakenly use them.

TC-Doc-37	P	F	The following assessments are performed: 1 If a document section has <entry> elements then the IQ Rules reports an error if the following sections do not have a proper value or an exclusion statement stating why a proper value is not provided: ○ Adverse Reactions; ○ Problems/Diagnoses This Visit; ○ Immunisation; ○ Medications; ○ Current Medications; ○ Ceased Medications; ○ Recommendations; 2 If a Medical History section has <entry> elements then the IQ Rules reports an error if there is not: ○ At least one problem or diagnosis with a proper value or an exclusion statement for problems and diagnoses; ○ At least one procedure with a proper value or an exclusion statement for procedures; 3 If the Event Details section has <entry> elements then the IQ Rules reports an error if the Clinical Synopsis Description does not have a proper value. For CodeableText data elements a proper value has a code or a non-null originalText that appears to provide information rather than a statement that there is no information. For Text data elements a proper value has text that appears to provide information rather than a statement that there is no information.

Table 13: TS-Head (CDA header) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Doc-10	-	-	There is no test case.
TC-Doc-11	P	F	The test is in scope for the My Health Record template packages but an error is reported by the IQ Rules if the following mandatory document header data elements are omitted as the My Health Record template packages do not report their omission. These data elements are mandatory only when stated in the applicable Structured Content Specification or CDA Implementation Guide[24]. 1 DateTime Prescription Written; 2 DateTime Authored; 3 DateTime Attested; and 4 Encounter Period end date.
TC-Doc-12	-	-	There is no test case.
TC-Doc-13	-	-	There is no test case.
TC-Doc-14	N	N	
TC-Doc-15	N	N	
TC-Doc-22	N	N	

[24] For some types of clinical documents the CDA implementation guide mapping table states that the 'value' attribute is mandatory whereas for other types the value attribute is not mandated.

TC-Doc-39	P	F	A recommendation is reported when a clinical document does not have a title.

Table 14: TS-Level (Conformance level) test set

Test case	Coverage	Automation	Explanation
TC-Doc-16	N	N	
TC-Doc-17	N	N	
TC-Doc-18	N	N	
TC-Doc-19	P	P	A warning is reported if a document contains only one section other than the Administrative Observations section where that section is defined in the digital health specifications but does not have <entry> elements in the section or any of its subsections but the document has other sections defined in the digital health specifications containing <entry> elements. Reporting the omission of data elements that are mandatory for level 3A is in scope for the My Health Record template packages but an error is reported by the IQ Rules if the following data elements are omitted as the My Health Record template packages do not report their omission. 1 Reporting Pathologist in the Pathology section of a Pathology Report; and 2 Reporting Radiologist in the Diagnostic Imaging section of a Diagnostic Imaging Report.
TC-Doc-20	N	N	
TC-Doc-21	N	N	

Table 15: TS-Logo (Logos) test set

Test case	Coverage	Automation	Explanation
TC-Doc-26 Step 1	F	F	
TC-Doc-26 Step 2	P	F	An error is reported if the observationMedia element does not reference an attachment.
TC-Doc-27	N	N	

Table 16: TS-Vers (Rendering version management) test set

Test case	Coverage	Automation	Explanation
TC-Doc-30	N	N	

TC-Doc-31	N	N	

A.1.2 FS-Narr (Narratives)

This section contains a table for each test set in the FS-Narr feature set within the Conformance Test Specification for Authoring Systems v1.1. The FS-Narr feature set contains tests for the narratives of a clinical document.

In general, the FS-Narr tests are applied to any section of any type of clinical document. A small number of test cases, however, need knowledge of data elements in a section of a document before they can be applied.

Table 17: TS-Auto (Auto generated) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Narr-11	P	F	An error is reported if a healthcare identifier is present in an automatically derived narrative but does not have the required format.
TC-Narr-12	N	N	
TC-Narr-13	N	N	
TC-Narr-14	N	N	
TC-Narr-15	P	P	A warning is reported if a date[25] is present in an automatically derived narrative but does not have the required format. The IQ Rules applies the test case to narrative elements of the following formats: • dd/mm/yyyy (e.g. 5/12/2012) • dd-Mmm-yyyy (e.g. 5-Dec-2012) • dd Mmm yyyy (e.g. 5 Dec 2012) • yyyymmdd (e.g. 20121205) All examples may include times and time zones. The IQ Rules recognises that a narrative element may consist of dates separated by ` -> ` or ` – ` and the element is assessed as a possible time interval.
TC-Narr-16	F	F	An error is reported if a three-letter month is a valid month and does not have the format 'Mmm'.
TC-Narr-17	N	N	
TC-Narr-18	F	F	An error is reported if a date has mixed separators.
TC-Narr-19	N	N	
TC-Narr-20	-	-	There is no test case.
TC-Narr-21	N	N	
TC-Narr-22	N	N	
TC-Narr-23	N	N	
TC-Narr-24	N	N	
TC-Narr-25	N	N	

[25] The test is only applied to valid dates, e.g. 02/13/2012 has an invalid month.

TC-Narr-26	P	F	A recommendation is reported if the document contains a date with a time zone that is not one of the Australian time zones.
TC-Narr-27	P	F	The test case is applied if dates are present in a section's structured data and an error is reported if the section's structured data has mixed time zones or if the time zones differ from the document creation time zone, and if a narrative date time element does not have a time zone. See the coverage information for TC-Narr-15 for information about how the IQ Rules recognises a text element as a date.
TC-Narr-93	F	P	If the flag narrative-derived="true" or if typeCode="DRIV" is present to indicate that the narrative contains the same information as the structured data then: 1 If the narrative element is a <linkHtml> element that references a file (i.e. if the URI uses the file scheme) then an error is reported if the structured data does not contain an <externalAct>, <externalDocument>, <externalObservation> or <externalProcedure> that references the same file. 2 Otherwise a warning is reported if information in the narrative could not be found in the structured data. Note that the rules do not allow for the possibility that an entry element may reference a narrative element. The IQ Rules first assesses if a narrative element may be a date or a time interval and it looks for the information in the structured data (see the coverage information for TC-Narr-15 for information about how the IQ Rules recognises a text element as a date). If the narrative element has the format 'nnn xxx' where nnn is a number and xxx is a unit from The Unified Code for Units of Measure[26] then the narrative element is assumed to be a physical quantity and the IQ Rules looks for the physical quantity in the structured data. If the narrative element has the appearance of a healthcare identifier then the IQ Rules looks for the healthcare identifier in an Entity Identifier within the structured data. If the narrative element appears to be text then the following approach is applied: 1 Text elements in the structured data are examined to see if there is matching text. 2 If (1) fails then the following attributes of elements in the structured data are examined for matching text: displayName, extension, value and code. 3 If (2) fails then the IQ Rules finds the structured data elements that have a nullFlavor attribute or a code and codeSystem attribute. a The preferred terms for the set of nullFlavor and code attributes are compared to the narrative element[27]. b If (3a) fails then the synonyms for the set of nullFlavor and code attributes are compared to the narrative element.

Table 18: TS-Ext (Extensions) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Narr-88	N	N	

[26] See http://unitsofmeasure.org/trac.

[27] The preferred term for a nullFlavor is the name listed in section 7.1.4 of ISO 21090 'Health informatics - Harmonized data types for information interchange'. For SNOMED CT codes the preferred term is the preferred synonym and for other code systems the preferred term is the name associated with the code.

Table 19: TS-Info (Information content) test set

Test case	Coverage	Automation	Explanation
TC-Narr-08	F	P	An error is reported if an Agency-defined section has been found that has no descendent sections and there is no ancestor section containing a narrative with information and where the corresponding narrative contains no information except for fixed text and information in <th> and <caption> elements. The test is not applied to narrative blocks containing a <renderMultiMedia> element.
TC-Narr-09			*General comment about the TC-NArr-09 test steps:* In an Agency-defined section of a clinical document only the data elements specified by the Agency are examined in the application of the TC-Narr-09 test steps, whereas if the section is not Agency-defined then all data elements are examined.
TC-Narr-09 Step 1	F	P	A warning is reported if values of data elements with the Agency-defined Boolean or UniqueIdentifier data types are not found in the narrative. A warning is also reported if the medication repeat number is not found in the narrative.
TC-Narr-09 Step 2	P	P	A hint is reported if the originalText or displayName of any of the following elements is found in the narrative of another section: Adverse Reaction, Agent Description, Adverse Reaction Substance/Agent, Immunisations Therapeutic Good Identification, Medical History Procedure Name, Medications Therapeutic Good Identification The search is restricted to the narratives of the following sections: Clinical Interventions Performed This Visit, Clinical Synopsis, Clinical Synopsis Description, Event, Problems/Diagnoses This Visit, Response Details, Recommendations, Referral Detail, Requested Service.
TC-Narr-09 Step 3	F	P	If a narrative includes revision information an error is reported if the revision is a deletion and a warning is reported if the revision is an insertion.
TC-Narr-09 Step 4	F	P	If date/time data elements can be extracted from the narrative then an error is reported if the value of a data element of the HL7 TS or IVL<TS> data type is not one of the date/times extracted from the narrative. If date/time data elements cannot be extracted from the narrative then a warning is reported if the narrative does not seem to contain the data element of the HL7 TS or IVL<TS>data type.
TC-Narr-09 Step 5	F	P	A warning is reported if a narrative element has white text on a white background or black text on a black background. A hint is reported if a narrative element has coloured text or text on a coloured background.
TC-Narr-09 Step 6	F	P	A warning is reported if the value and unit of a data element of the HL7 PQ data type is not found in the narrative. If a value is a boundary of a quantity range then a hint is reported if the 'inclusive' attribute does not have the default value.
TC-Narr-09 Step 7	F	P	A warning is reported if the value or synonym of text in an <entry> element is not found in the narrative. The following approach is applied: 1 A section's <entry> elements are examined to find any elements containing text. For example, elements of the HL7 ST and ED data types may contain text. The test is not applied to text in a translation element as that is not expected to be in the narrative. 2 The corresponding narrative is examined to find matching text. 3 If the text is an <originalText> element then the IQ Rules finds synonymous terms for the text and looks for the synonyms in the narrative: a If the data element containing the <originalText> has a codeSystem and code that is known to the IQ Rules then the IQ Rules obtains the synonymous terms (including the preferred term) for the code and searches for them in the narrative.

			b If the data element containing the <originalText> has a codeSystem and code that is not known to the IQ Rules then the IQ Rules uses the displayName (if present) in the clinical document as the synonymous term for the code and searches for it in the narrative. Translation elements are not used in the search for synonymous terms. Any punctuation and other special characters are ignored and case differences are not considered, that is a case insensitive match is performed.
TC-Narr-09 Step 8	F	P	A warning is reported if the value of a data element of the HL7 INT or REAL data type is not found in a narrative that contains a table.
TC-Narr-09 Step 9	F	P	A warning is reported if the name of a nullFlavor, or a synonym of the name, is not found in the narrative.
TC-Narr-09 Step 10	P	P	A warning is reported if a CodeableText or CodedText displayName's value or synonym is not found in the narrative. The test is applied only to data elements where the Structured Content Specification states the type is CodedText or the type is CodeableText and the code system is one of those listed in appendix A.5. If the data element contains an originalText then step 7 is applied rather than step 10.
TC-Narr-09 Step 11	P	P	If the IQ Rules is able to obtain the code's preferred term or synonymous terms from its data sources including the terminology server then a warning is reported if one of the term is not found in the narrative.
TC-Narr-09 Step 12	F	P	If the value or meaning of an exclusion statement is not found in the narrative then an error is reported if the value of another type of exclusion statement is in the narrative otherwise a warning is reported.
TC-Narr-09 Step 13	F	F	An error is reported if information referenced from any <externalAct>, <externalDocument>, <externalObservation> or <externalProcedure> in the <entry> elements is not referenced by <linkHtml> in the corresponding narrative.
TC-Narr-09 Step 14	F	F	When a section contains an <observationMedia>, <observation> or an <act> element that references multimedia that may contain clinical information, an error is reported if the corresponding narrative does not contain a corresponding <renderMultiMedia> element.
TC-Narr-10	N	N	

Table 20: TS-Mark (Markup content) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Narr-28	P	F	An error is reported if RTF or HL7 v2 markup is found.
TC-Narr-29	F	F	An error is reported if any text in the narrative is not contained within narrative block elements.
TC-Narr-30	N	N	
TC-Narr-31	F	F	A recommendation is reported if free text is found that is not in a paragraph.
TC-Narr-32	-	-	There is no test case.
TC-Narr-33 Step 1	F	F	An error is reported if a <linkHtml> element has no href attribute.
TC-Narr-33 Step 2	F	F	An error is reported if the <linkHtml> href attribute with a same-document reference does not reference an ID attribute in another element in the same or a different narrative block, a <section>, <observationMedia> or <renderMultiMedia> element within the clinical document.

TC-Narr-33 Step 3	P	F	When the <linkHtml> href attribute is an absolute URI an error is reported if it does not have the general URI syntax or if the URI scheme is neither "pcehr" nor one of the registered schemes. An error is also reported if the URI has the "mailto" or "pcehr" schemes and does not have the syntax required by those schemes.
TC-Narr-34	-	-	There is no test case.
TC-Narr-35	-	-	There is no test case.
TC-Narr-36	-	-	There is no test case.
TC-Narr-37	-	-	There is no test case.
TC-Narr-38	F	F	An error is reported if <footenoteRef> element has a reference that does not reference a <footnote> in any narrative block.
TC-Narr-39	F	F	An error is reported if a <paragraph> has a <caption> but the <caption> is not the first information in the <paragraph>.
TC-Narr-40	-	-	There is no test case.
TC-Narr-41	F	F	An error is reported if an <item> has a <caption> but the <caption> is not the first information in the <item>.
TC-Narr-42	-	-	There is no test case.
TC-Narr-43	-	-	There is no test case.
TC-Narr-44	-	-	There is no test case.
TC-Narr-45	-	-	There is no test case.
TC-Narr-46	-	-	There is no test case.
TC-Narr-47	-	-	There is no test case.

Table 21: TS-Narr (General narrative) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Narr-01	-	-	There is no test case.
TC-Narr-02	N	N	
TC-Narr-03	-	-	There is no test case.
TC-Narr-04	-	-	There is no test case.
TC-Narr-05	-	-	There is no test case.
TC-Narr-06	N	N	
TC-Narr-07	N	N	

Table 22: TS-Ref (References) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Narr-89	F	F	An error is reported if a <renderMultiMedia> element has an invalid reference.

TC-Narr-90	-	-	There is no test case.
TC-Narr-91	F	F	An error is reported if a <renderMultiMedia> element is present without a caption but refers to an HTML, PDF, RTF or Plain Text attachment.
TC-Narr-92 Step 1	F	F	An error is reported if an attachment referenced from a <linkHtml> element is also referenced from an <observationMedia> element.
TC-Narr-92 Step 2	F	F	An error is reported if an attachment referenced from a <renderMultiMedia> element is also referenced from an <externalAct>, <externalDocument>, <externalObservation> or <externalProcedure> element.

Table 23: TS-Style (Style codes) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Narr-63 Step 1	F	F	An error is reported if a styleCode attribute is used in a narrative element that is not a <content>, <list>, <paragraph>, <item>, <th> or <td> element.
TC-Narr-63 Step 2	F	F	An error is reported if a <content>, <item> or <paragraph> element has an invalid styleCode attribute.
TC-Narr-63 Step 3	F	F	An error is reported if a <th> or <td> element has an invalid styleCode attribute.
TC-Narr-63 Step 4	F	F	An error is reported if a <list> element has an invalid styleCode attribute.
TC-Narr-63 Step 5	F	F	An error is reported if a <table> element has a styleCode attribute however this is reported as a failure to pass step 1 as step 5 is covered by step 1.
TC-Narr-64	F	F	An error is reported if the value of a styleCode attribute has multiple style codes but they are separated by two or more spaces.
TC-Narr-65	-	-	There is no test case.
TC-Narr-71	N	N	
TC-Narr-72	F	F	An error is reported if an xFgColour styleCode does not have a valid value.
TC-Narr-73	F	F	An error is reported if an xFontSizeEm styleCode does not have a valid value.
TC-Narr-74	F	F	An error is reported if an xFontSizePx styleCode does not have a valid value.
TC-Narr-75	F	F	An error is reported if an xColWidthPx styleCode does not have a valid value.
TC-Narr-76 Step 1	F	F	An error is reported if a styleCode attribute is used in a narrative element that is not a <content>, <list>, <paragraph>, <item>, <th> or <td> element.
TC-Narr-76 Step 2	F	F	An error is reported if a <content>, <item> or <paragraph> element has an invalid styleCode attribute.
TC-Narr-76 Step 3	F	F	An error is reported if a <th> or <td> element has an invalid styleCode attribute.
TC-Narr-76 Step 4	F	F	An error is reported if a <list> element has an invalid styleCode attribute.
TC-Narr-76 Step 5	F	F	An error is reported if a <table> element has a styleCode attribute however this is reported as a failure to pass step 1 as step 5 is covered by step 1.

Table 24: TS-Tab (Tables & Lists) test set

Test case	Coverage	Automation	Explanation
TC-Narr-48	-	-	There is no test case.
TC-Narr-49	F	F	A recommendation is reported if a table does not contain a header or if there is a header but not a single heading row.
TC-Narr-50 Step 1	F	F	An error is reported if a table heading row (i.e. a row consisting only of <th> elements) is not in a <thead> element.
TC-Narr-50 Step 2	F	F	
TC-Narr-51	F	F	An error is reported if a row consisting only of <td> elements is not in a <tbody> element.
TC-Narr-52	-	-	There is no test case.
TC-Narr-53	F	F	A hint is reported if a table cell has both rowspan and colspan greater than "1" or if a cell has rowspan or colspan equal to "0", otherwise an error reported if a table does not have the same number of columns in every row. If the flag `report-rendering-recommendations` is set to `"true"` then a recommendation is reported if a cell has rowspan or colspan equal to "0" as not all browsers support that value.
TC-Narr-54	-	-	There is no test case.
TC-Narr-55	-	-	There is no test case.
TC-Narr-56	-	-	There is no test case.
TC-Narr-57	F	F	A recommendation is reported if a <table> does not have a <caption>.
TC-Narr-58	-	-	There is no test case.
TC-Narr-59	N	N	
TC-Narr-60	F	F	An error is reported if a <list> <item> contains a <table> or <paragraph>.
TC-Narr-61	-	-	There is no test case.
TC-Narr-62	F	F	An error is reported if a <list> has more than three levels of nesting.

A.1.3 FS-Types (Data types and data groups)

This section contains a table for each test set in the FS-Types feature set within the Conformance Test Specification for Authoring Systems v1.1. The FS-Types feature set contains test cases for

Agency-defined data types, Agency-defined data groups and HL7 data types used in a clinical document.

A.1.3.1 FS-types test sets for Agency-defined data types

The test cases listed here apply to data elements that have been assigned an abstract data type that has been defined by the Australian Digital Health Agency.

Structured Content Specifications list the data elements in a document header, and the data elements in Agency-defined sections (see appendix A.3) of clinical documents, and each data element's abstract data type.

The types of clinical documents assessed by the IQ Rules are listed in appendix A.2, and the document sections assessed by the IQ Rules are listed in appendix A.3.

Table 25: TS-BTB (Basic, text and binary data types) test set

Test case	Coverage	Automation	Explanation
TC-Types-01	F	F	Note that when the IQ Rules applies test cases from other test sets any error is reported using the other test case identifier, rather than using the TS-BTB test case identifier.
TC-Types-02	F	F	As above.
TC-Types-03	P	F	As above. The Text data elements that are not assessed are Australian Address Site Name, Australian Level Number, Australian Lot Number, Australian Postal Delivery Number, Electronic Communication Address, International State/Province, International Postcode.

Table 26: TS-Coded (Coded data types) test set

Test case	Coverage	Automation	Explanation
TC-Types-04 Step 1	F	F	Note that when the IQ Rules applies test cases from other test sets any error is reported using the other test case identifier, rather than using the TS-Coded test case identifier.
TC-Types-04 Step 2	F	F	
TC-Types-05	N	N	
TC-Types-06 Step 1	R	R	
TC-Types-06 Step 2	F	F	
TC-Types-07 Step 1	F	F	Note that when the IQ Rules applies test cases from other test sets any error is reported using the other test case identifier, rather than using the TS-Coded test case identifier.

TC-Types-07 Step 2	P	F	In general, the IQ Rules applies this test to CodedText data elements in the header of documents of the types listed in appendix A.6 and the CodedText data elements in the document sections listed in appendix A.7, with the following exceptions: 1 Australian Level Type; 2 Australian Street Type; 3 Australian Street Suffix; and 4 Australian Postal Delivery Type.
TC-Types-08	P	F	TC-Types-08 is applied for CodedText only. There is no need to apply TC-Types-08 to CodeableText as TC-Types-04 step 2 achieves the same outcome.
TC-Types-09	-	-	There is no test case.

Table 27: TS-Cont (Continuous set data types) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-21	F	F	Note that when the IQ Rules applies test cases from other test sets any error is reported using the other test case identifier, rather than using the TS-Cont test case identifier.
TC-Types-22	F	F	As above.

Table 28: TS-IL (Identifier and location data types) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-10	F	F	Note that when the IQ Rules applies test cases from other test sets any error is reported using the other test case identifier, rather than using the TS-IL test case identifier.
TC-Types-11	F	F	As above.
TC-Types-12	-	-	There is no test case.

Table 29: TS-Quant (Quantity data types) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-13	F	F	Note that when the IQ Rules applies test cases from other test sets any error is reported using the other test case identifier, rather than using the TS-Quant test case identifier.
TC-Types-14	F	F	As above.

TC-Types-15	F	F	As above.
TC-Types-16	F	F	As above.
TC-Types-17	F	F	As above.
TC-Types-18	F	F	As above.
TC-Types-19	-	-	There is no test case.
TC-Types-20	-	-	There is no test case.

A.1.3.2 FS-Types test sets for Agency-defined data groups

The test cases listed here apply to data groups defined by the Australian Digital Health Agency that are used in clinical documents regardless of the type of document.

Table 30: TS-AddrDG (Address data group) test set

Test case	Coverage	Automation	Explanation
TC-Types-40	P	F	The IQ Rules reports an error if there are more than two addresses associated with a healthcare participant in a single data component. The IQ Rules does not count the number of addresses in the entire document that are for the healthcare participant.
TC-Types-41	F	F	
TC-Types-42	F	F	
TC-Types-43	F	F	
TC-Types-44	N	N	
TC-Types-45	N	N	
TC-Types-46	N	N	
TC-Types-47	N	N	

Table 31: TS-EntId (Entity identifier) test set

Test case	Coverage	Automation	Explanation
TC-Types-23 Step 1	R	R	See the coverage table for TS-IL, TS-CD and TS-ST.
TC-Types-23 Step 2	P	P	An error is reported in the following scenarios: 1 The value of the root attribute identifies a namespace that is known to not apply to healthcare participants. 2 An entity identifier in the <patient> data element: a Contains a root attribute whose value commences with '1.2.36.1.2001.1003' but does not contain a national healthcare identifier for a healthcare consumer; or

			b The root attribute identifies a namespace that is known to not apply to a healthcare consumer; or c The code element is present and has a value that is not applicable for a healthcare consumer. 3 An entity identifier in a data element used for a healthcare provider organisation: a Contains a root attribute whose value commences with '1.2.36.1.2001.1003' but does not contain a national healthcare identifier for a healthcare provider organisation; or b The root attribute identifies a namespace that is known to not apply to a healthcare organisation; or c The code element is present and has a value that is not applicable for a healthcare provider organisation. 4 An entity identifier in a data element used for a healthcare participant that may be a consumer or a healthcare provider individual and it: a Contains a root attribute whose value commences with '1.2.36.1.2001.1003' but does not contain a national healthcare identifier for a person; or b The root attribute identifies a namespace that is known to not apply to a person; or c The code element is present and has a value that is not applicable for a person. 5 An entity identifier in the <assignedAuthoringDevice> data element and the root attribute identifies a namespace that is known to not apply for a device. 6 An Entity Identifier contains a Medicare card number or contains a root attribute whose value is the identifier for a Medicare card number. A warning is reported in the following scenarios: 1 The root attribute commences with '1.2.36.1.2001.1005.41' (the identifier of the namespace for healthcare providers and legal authenticators) and the <code> element is present with codeSystem '2.16.840.1.113883.12.203' but the value of the code attribute does not have the value 'EI'. 2 The root attribute commences with '1.2.36.1.2001.1005.29' (the identifier of the namespace for healthcare consumers) and the <code> element is present with codeSystem '2.16.840.1.113883.12.203' but the value of the code attribute is not one of those known to be applicable for healthcare consumers. 3 The value of the root attribute identifies a namespace known to the IQ Rules and the <code> element is present with codeSystem '2.16.840.1.113883.12.203' (HL7 Identifier Types) and a code that is a member of that code system but the code is not one of those known to be applicable for the namespace. 4 An entity identifier is in the <patient> data element and: a The value of the root attribute is not one of those that is known to apply to healthcare consumers; or b The code is present and is not one of those known to be applicable for a healthcare consumer. 5 A data element that is not <patient> but is used to identify a healthcare participant that is a person contains an entity identifier with a value of the root attribute that identifies a namespace that is not known to be one of those that may be used for a person. 6 An entity identifier is in the <assignedAuthoringDevice> data element and: a The value of the root is not one of those that is known to apply to devices; or b The value of the root attribute commences with '1.2.36.1.2001.1003' but does not contain a national healthcare identifier for a device[28].

[28] A PCEHR Assigned Identifier – Device (PAI-D) is the national healthcare identifier for a device.

			7 A data element used to identify a healthcare organisation contains an entity identifier with a value of the root attribute that identifies a namespace that is not known to be one of those that may be used for an organisation. a The value of the root is not one of those that is known to apply an organisation; or b The code is present and is not one of those known to be applicable for a healthcare organisation. A hint is reported in the following scenarios: 1 An entity identifier contains a code element with a code and the codeSystem attribute is not only of those known to be valid or invalid to use in an entity identifier.
TC-Types-24	F	F	An error is reported if the value of the root attribute identifies a namespace that is known to not apply to healthcare participants. A warning is reported if the value of the root attribute commences with '1.2.36.1.2001.1005.41' (the identifier of the namespace for healthcare providers and legal authenticators) and the <code> element is present with codeSystem '2.16.840.1.113883.12.203' but the value of the code attribute does not have the value 'EI'.
TC-Types-25	F	P	An error is reported if the value of the root attribute identifies a code system or has a value that identifies a namespace that is known to be invalid for use in the entity identifier. A warning is reported if the value of the root attribute is not known to be invalid and does not identify one of the namespaces known to be used for entity identifiers.
TC-Types-26	-	-	
TC-Types-27	-	-	
TC-Types-28	P	F	An error is reported if the assigningGeographicArea/name attribute is present and: 1 Has a value that is not one of the values listed in AS 5017-2006: Healthcare Client Identifier Geographic Area; or 2 The entity identifier contains a national healthcare identifier but the value of the assigningGeographicArea/name is not "National Identifier".
TC-Types-29	F	P	An error is reported in the following scenarios: 1 The value of the root attribute commences with "1.2.36.1.2001.1005.29" and the codeSystem attribute is either not present or does not have the value "2.16.840.1.113883.12.203". 2 The <code> element is present with codeSystem "2.16.840.1.113883.12.203" (HL7 Identifier Types) and the code is one of the codes for a healthcare consumer and either: a The codeSystemName attribute is not present or does not have the value 'Identifier Type (HL7)'; or b The extension attribute is not present or does not have a non-null value; or c The assigningAuthorityName attribute is not present or does not have a non-null value. Other errors are reported by rules that apply test cases in the TS-II test set. A hint is reported if the entity identifier is a local identifier for a healthcare consumer, that is, the <code> element is present with codeSystem "2.16.840.1.113883.12.203" (HL7 Identifier Types) and a code that is used for local medical records; and the value of the root attribute identifies a name space known to the IQ Rules but it is not known if the namespace applies to healthcare consumers.

TC-Types-30	F	P	An error is reported in the following scenarios: 1 The value of the root attribute commences with "1.2.36.1.2001.1005.41" and the codeSystem attribute is either not present or does not have the value "2.16.840.1.113883.12.203". 2 The <code> element is present with codeSystem "2.16.840.1.113883.12.203" (HL7 Identifier Types) and the code is "EI" and either: a The codeSystemName attribute is not present or does not have the value 'Identifier Type (HL7)'; or b The extension attribute is not present or does not have a non-null value; or c The assigningAuthorityName attribute is not present or does not have a non-null value. Other errors are reported by rules that apply test cases in the TS-II test set. A hint is reported if the entity identifier is a local identifier for a healthcare provider individual, that is, the <code> element is present with codeSystem "2.16.840.1.113883.12.203" (HL7 Identifier Types) and a code that is used for local medical records; and the value of the root attribute identifies a name space known to the IQ Rules but it is not known if the namespace applies to healthcare consumers.

Table 32: TS-Entit (Entitlement) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-31 Step 1	N	N	
TC-Types-31 Step 2	R	R	See the coverage tables for TS-IL, TS-Coded and TS-Cont.
TC-Types-32	R	R	See the coverage table for TS-UID.
TC-Types-33	F	F	
TC-Types-34	F	F	The TS-II test cases also check the value of the extension attribute so any extension attribute errors are reported by the IQ Rules using the TS-II test case identifier.
TC-Types-35	F	F	
TC-Types-36	F	F	
TC-Types-37	F	F	The TS-UID test cases check the validity of the root attribute so any root attribute errors are reported by the IQ Rules using the TS-UID test case identifier.
TC-Types-38	F	F	
TC-Types-39	F	F	

A.1.3.3 FS-Types test sets for HL7 data types

The test cases listed here apply to data elements that have one of the HL7 data types. Two scenarios apply:

1 A data element and its type may be stated in the HL7 Reference Information Model and the CDA schema; or

2 A data element may contain a type declaration.

For example:

- According to the HL7 Reference Information Model, an `<act>/<negationInd>` data element has the HL7 BL data type, so no type declaration is needed.
- Alternatively the BL type may be assigned to a data element using the XML type declaration attribute `xsi:type="BL"`.

Table 33: TS-BL (Boolean) test set

Test case	Coverage	Automation	Explanation
TC-Types-50	F	F	

Table 34: TS-CD (Concept descriptor) test set

Test case	Coverage	Automation	Explanation
TC-Types-57	P	P	An error is reported in the following scenarios: 1 An <externalAct>, <externalDocument>, <externalObservation> or <externalProcedure> contains a <code> element and the name of the attachment indicates that the value of the code is not the correct one for the type of attachment. 2 An Entity Identifier contains a code used to classify an entitlement. 3 An ANZSCO code is used to classify the role of a healthcare facility (i.e. the <healthCareFacility> element). 4 Two or more translation elements contain the same AMT v2, SNOMED CT-AU, PBS or PBS Manufacturer code. A warning is reported in the following scenarios: 1 An ANZSCO code has been used classify the role of a healthcare participant that appears to be an organisation. 2 An AZNSCO code has been used to describe a healthcare provider individual's role, occupation or position in the organisation and the ANZSCO code is not one of the codes that are expected for a healthcare provider individual.

			3 A data element contains an ANZSCO code and the data element is not one of those used to classify a person's role, occupation or position in the organisation. 4 A data element of the HL7 CD data type contains an originalText and no code and the value of the originalText matches multiple adjacent elements in the narrative.
TC-Types-58	F	F	

TC-Types-59	F	P	An error is reported under the following scenarios: 1 The codeSystem is '1.2.36.1.2001.1001.101' (NCTIS Data Components) and the code is not a character string consisting of two numeric strings separated by a period (.). 2 The codeSystem is '1.2.36.1.2001.1004.100' (AMT v2) and a the code is a numeric string and either commences with '0' or the length of the numeric string is not greater than five and less than nineteen digits; or b the code is not a member of the AMT v2 code system. 3 The codeSystem is '1.2.36.1.2001.1005.47' (ANZSIC) and the code is not a four digit numeric string. 4 The codeSystem is '2.16.840.1.113883.13.62' (ANZSCO) and the code is not a six digit numeric string. 5 The codeSystem is '2.16.840.1.113883.6.1' (LOINC) and the code is not a numeric string of between 1 and 8 digits followed by '-' following by a check digit. 6 The codeSystem is '1.2.36.1.2001.1005.11.1' (MIMS) and the code is not a numeric string consisting of a minimum of five digits. 7 The codeSystem is '1.2.36.1.2001.1005.22' (Australian Pharmaceutical Benefit Schedule) and a the code does not consist of five numbers followed by an uppercase letter; or b the code is not a member of the PBS code system. 8 The codeSystem is '1.2.36.1.2001.1005.23' (Australian Pharmaceutical Benefit Schedule Manufacturer) and a the code does not consist of two letters; or b the code is not a member of the PBS Manufacturer code system. 9 The codeSystem is '2.16.840.1.113883.6.96' (SNOMED CT, SNOMED CT-AU and AMT v3) and a the code is a numeric string and either commences with '0' or the length of the numeric string is not greater than five and less than nineteen digits; or b the code is not a member of the code system or is present with an 'inactive' status; or c the code is a SNOMED CT description ID or relationship ID rather than a concept ID. 10 The codeSystem is not one of those listed above but is one of those listed in appendix A.5 and the value of the code attribute is not one of the codes for the code system. A warning is reported under the following scenario: 1 The codeSystem is '1.2.36.1.2001.1001.101' (NCTIS Data Components) and the value of the code attribute is not one of the codes for the code system, as the IQ Rules does not contain all the codes in this code system. A hint is reported if the codeSystem is '2.16.840.1.113883.6.96' (SNOMED CT) and the code is not a numeric string, so the tester may determine if the code is a SNOMED CT expression. If the codeSystem has a valid value but is not one of those listed in appendix A.5 or appendix A.6 the hint reported for TC-Types-62 includes a statement to verify the code. No message about the code is reported if the code system is one of those listed in appendix A.6.
TC-Types-60	F	P	An error is reported under the following scenarios: 1 A CodeableText data element has the primary or translation codeSystem "2.16.840.1.113883.6.96", a code is present, there is no nullFlavor "OTH", the code is an active code in the SNOMED CT-AU code system and the code is not a member of the specified value domain (i.e. reference sets).

			2 A CodeableText data element has the primary or translation codeSystem "2.16.840.1.113883.6.96", a code is present with nullFlavor "OTH", the code is an active code in the SNOMED CT-AU code system and the code is a member of the specified value domain (i.e. reference sets). A warning is reported under the following scenarios: 1 A CodeableText data element has the primary or translation codeSystem "2.16.840.1.113883.6.96", a code is present, there is no nullFlavor "OTH", the code is an inactive code in the SNOMED CT-AU code system.
TC-Types-61	F	F	
TC-Types-62	F	P	An error is reported under the following scenarios: 1 The value of the codeSystem attribute does not have the format of an OID or UUID. 2 The value of the codeSystem attribute is an OID and the OID has an invalid value (it is an invalid namespace or it has been used as the root attribute in an Entity Identifier of Entitlement). A hint is reported if the value of the codeSystem attribute has a valid value but is not one of the known ISO, HL7 or local coding systems listed in appendix A.5 and appendix A.6.
TC-Types-63	F	P	An error is reported under the listed in appendix A.5 or appendix A.6 the hint reported for TC-Types-62 includes a statement to verify the codeSystemVersion.
TC-Types-64	N	N	
TC-Types-65	F	P	With the exception of code system '2.16.840.1.113883.6.96' (SNOMED CT, including SNOMED CT-AU and AMT v3) if the code system is one of those listed in appendix A.5 a hint is reported if displayName is present and is value is not the value stated in the code system documentation, or a synonymous value. If the code system is '2.16.840.1.113883.6.96' and the reference set is one of those listed in appendix A.5 an error is reported if the value of the displayName is neither the preferred term nor a synonym listed in the code system. If the code system is '2.16.840.1.113883.13.65' (AIHW Mode of Separation) and the value of the displayName is one of the meanings listed on the AIHW website then a recommendation is reported to use the values listed in section 3.3.4 of version 1.5 of the Discharge Summary Conformance Profile. The following matching rules are applied: 1 If the code system is '2.16.840.1.113883.6.96' then the match is perform according to the value of the caseSignificanceId for the preferred term and synonyms. 2 For other code systems punctuation characters are removed and case differences are ignored. If the codeSystem has a valid value but is not one of those listed in appendix A.5 or appendix A.6 the hint reported for TC-Types-62 includes a statement to verify the value of the displayName. No message about the displayName is reported if the code system is one of those listed in appendix A.6.
TC-Types-66 Step 1	P	P	An error is reported if a data element is a therapeutic good identifier, a code is a medicinal product and the text is a trade produce, or vice versa. An error is reported if the value of the originalText indicates there is no known value for the concept and either: 1 A primary code is present and the primary code system does not contain any code with a value that indicates there is no known value for the concept; or 2 A translation code is present and the translation code system does not contain any code with a value that indicates there is no known value for the concept. Otherwise a warning is reported if the concept described by the primary code or translation code seems to be inconsistent with the concept described by the

			originalText (if present). The following describes how the concept described by a code is compared to the originalText: 1 If the IQ Rules has access to a code's synonyms, including the preferred synonym, then the synonyms will be compared to the originalText, otherwise the value of the displayName attribute is treated as a synonym and will be compared to the originalText. 2 Prior to the comparison special characters are removed and letters are converted to lower case. Numbers are separated from letters (e.g. 30mg becomes 30 mg). 3 The number of distinct words in each synonym is counted and the number of distinct words in the originalText is counted. 4 When comparing the originalText to a synonym: a The number of distinct words common to the originalText and the synonym are counted. b The number from step (a) is divided by the number of distinct words in the originalText. c The number from step (a) is divided by the number of distinct words in the synonym. d The average of the numbers from steps (b) and (c) is determined and if the number if greater than or equal to a minimum threshold then the originalText and synonym are regarded as describing the same concept. 5 Step (4) is repeated for each synonym and if the originalText matches no synonyms then a warning is reported.
TC-Types-66 Step 2	F	F	
TC-Types-67 Step 1	F	F	
TC-Types-67 Step 2	P	P	An error is reported if a data element is a therapeutic good identifier, a code is a medicinal product and the text is a trade produce, or vice versa. A warning is reported if the concept described by the primary code seems to be inconsistent with the concept described by the translation code (if present). The following describes how the concepts are compared: 1 If the IQ Rules has access to a code's synonyms, including the preferred synonym, then the synonyms of the primary code will be compared to the synonyms of the translation code. If the IQ Rules does not have access to a code's synonyms then the displayName in the clinical document is used instead and is treated as a synonym. 2 Prior to the comparison special characters are removed and letters are converted to lower case. Numbers are separated from letters (e.g. 30mg becomes 30 mg). 3 The number of distinct words in each synonym is counted. 4 When comparing a synonym of the primary code with a synonym of the translation code: a The number of distinct words common to each pair of synonyms is counted. b The number from step (a) is divided by the number of distinct words in the primary code's synonym. c The number from step (a) is divided by the number of distinct words in the translation code's synonym. d The average of the numbers from steps (b) and (c) is determined and if the number if greater than or equal to a minimum threshold then the synonym of the primary code and the synonym of the translation code are regarded as describing the same concept. 5 Step (4) is repeated for each synonym for the primary code and for the translation code and if no synonym of the primary matches a synonym of the translation code then a warning is reported.

TC-Types-68 Step 1	P	P	The test step is automated if the code system is '2.16.840.1.113883.6.96' (SNOMED CT, including SNOMED CT-AU and AMT v3). If the codeSystem has a valid value but is not one of those listed in appendix A.5 or appendix A.6 a hint is reported to verify the value of the qualifier.
TC-Types-68 Step 2	N	N	
TC-Types-68 Step 3	P	P	The test step is automated if the code system is '2.16.840.1.113883.6.96' (SNOMED CT, including SNOMED CT-AU and AMT v3). If the codeSystem has a valid value but is not one of those listed in appendix A.5 or appendix A.6 a hint is reported to verify the value of the qualifier.

Table 35: TS-Class (Reference information model classes) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-110	P	F	When the clinical document specifications state that a choice of data types apply to a data element depending on the type of observation, an error is reported if the data element has one of the types that is not allowed by the clinical document specifications. The data elements that this applies to are Individual Pathology Test Result Value in a Pathology Test Result section, and Imaging Examination Result Value in an Imaging Examination Result section. An error is reported if the observation value uses a character string to record a quantity or quantity interval.

Table 36: TS-CS (Coded Simple) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-115	F	F	
TC-Types-116	F	F	

Table 37: TS-ED (Encapsulated data) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-51	P	F	An error is reported if a data element of the ED data type contains zero bytes of data but has no nullFlavor and no <reference>. No check is applied to the item referenced by an ED element and thumbnails and compression properties are not assessed. The IQ Rules do not allow for the possibility that an entry element may reference a narrative element.

TC-Types-52	F	F	An error is reported if a data element of the ED data type contains inline data and is either within an <observationMedia> with a logo or the <observationMedia> is referenced by a <renderMultiMedia> element.
TC-Types-53	F	F	
TC-Types-54	P	P	The test case TC-Types-54 is the application of the Conformance Test Specification for CDA Packaging. Some of tests in this conformance test specification are applied by the IQ Rules. An error is reported if: 1 a data element that does not have the ED data type references an attachment; 2 a data element references an attachment but does not have exactly one <reference> element; 3 a data element of the ED data type references an attachment references an attachment but the integrityCheckAlgorithm attribute has been set to a value other than "SHA-1"; 4 a data element of the ED data type references a packaged attachment but does not have the integrityCheck attribute; 5 a data element of the ED data type references a gif, jpeg, pdf, png, tiff, text, html or rtf attachment but does not have the appropriate mediaType. A warning is reported if a data element of the ED data type references an attachment and: 1 the mediaType is not one of the types that are permitted by the My Health Record system; or 2 the filename extension is not one of those permitted by the My Health Record system; or 3 the filename extension and mediaType have values permitted by the My Health Record system but the mediaType did not correspond to the filename extension A hint is reported if a data element of the ED data type has a mediaType that is not for a gif, jpeg, pdf, png, tiff, text, html or rtf attachment.
TC-Types-114	P	P	An error is reported if a data element of the ED data type contains text with known mark-up characters used in clinical document narratives and a warning is reported if the text appears to contain mark-up characters that may be derived from narrative mark-up. Other types of mark-up are not currently detected.

Table 38: TS-II (Instance identifier) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-70	F	F	
TC-Types-71	F	F	
TC-Types-72	F	F	
TC-Types-73	F	P	If an extension attribute is present then: 1 an error is reported if the root attribute has been determined to be invalid; and 2 a hint is reported if the root attribute is an OID and has not been determined to be either valid or invalid.
TC-Types-74	F	P	If there is no extension or nullFlavor attributes then:

			1 an error is reported if the value of the root attribute is an identifier for a namespace; and 2 a hint is reported if the value of the root attribute is an OID and has not been determined to be either valid or invalid.
TC-Types-75 Step 1	P	P	Clinical document identifiers are examined with the exception of those within Entity Identifiers and Entitlements and technical identifiers in the legalAuthenticator, representedCustodianOrganization, patientRole, assignedAuthor, associatedEntity and assignedEntity data elements. An error is reported for the following scenarios: 1. an identifier is used for both the clinical document id and setId, 2. a Dpsense Record or a Prescription Record contains a 'relatedDocument/parentDocument/id' element where the 'relatedDocument' has typeCode='XFRM' and the instance identifier has the same value as a 'relatedDocument/parentDocument/id' element where the 'relatedDocument' has typeCode='RPLC'. 3. two or more sections of a document have a different type (as indicated by the code element) and the same identifier. Otherwise a warning is reported if an identifier seems to have been used for more than one item.
TC-Types-75 Step 2	P	F	An error is reported in the following scenarios: 1. an extension attribute has the format of an HPI-I or HPI-O and the value of the root attribute is one of the HPI-O based identifiers. 2. an Entity Identifier contains an extension attribute that has the format of an HPI-I or HPI-O. 3. the value of the root attribute identifies a known and support code system (i.e. those listed in appendix A.5 but not appendix A.6) and the value of the extension attribute is not a member of the code system. 4. an instance identifier contains a PBS Manufacturer code in the extension attribute but the code is not a member of the PBS Manufacturer code system.
TC-Types-76	P	P	If the value of the root attribute contains an IHI an error is reported if the assigningAuthorityName attribute does not have the value "IHI". If the value of the root attribute is an OID then a hint is reported so the tester may verify the value of the assigningAuthorityName attribute.
TC-Types-77	F	F	
TC-Types-78	F	F	
TC-Types-79	F	F	
TC-Types-80	F	F	
TC-Types-81	F	F	
TC-Types-82 Step 1	F	F	
TC-Types-82 Step 2	F	F	
TC-Types-83 Step 1	F	F	
TC-Types-83 Step 2	F	F	
TC-Types-83 Step 3	F	F	
TC-Types-83 Step 4	F	F	

TC-Types-83 Step 5	F	F	
TC-Types-84	F	F	
TC-Types-85	F	F	
TC-Types-86 Step 1	F	F	
TC-Types-86 Step 2	F	F	
TC-Types-87 Step 1	F	F	
TC-Types-87 Step 2	F	F	
TC-Types-88	F	F	
TC-Types-89	F	F	
TC-Types-90	F	F	
TC-Types-91	F	F	
TC-Types-92	F	F	
TC-Types-111	F	F	

Table 39: TS-INT (Integer) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-95	F	F	

Table 40: TS-IVL (Interval) test set

Test case	**Coverage**	**Automation**	**Explanation**
TC-Types-102	F	F	
TC-Types-103	F	F	
TC-Types-104	F	F	

Table 41: TS-NF (NullFlavor) test set

Test case	Coverage	Automation	Explanation
TC-Types-48	P	P	An error is reported in the following scenarios: 1 A data element of the HL7 'BL', 'INT', 'PIVL', 'PQ', 'REAL', 'TEL' or 'TS' data types contains a nullFlavor attribute as well as a value. 2 A data element of the HL7 'CS' data type contains nullFlavor OTH. 3 A data element of the Agency-defined 'CodedText' data type contains nullFlavor with a value that does not indicate no value is provided for the data element, i.e. if the nullFlavor is not NI, UNK, ASKU, NAV, NASK, MSK or NA. 4 A data element contains a value of nullFlavor that is disallowed by a mandatory requirement in a CDA Implementation Guide mapping table. 5 A data element of the HL7 'CD', 'CS', 'ED', 'II', 'IVL' data types contains a value and also contains nullFlavor attribute with one of the values that indicate there is no value for the data element (i.e. 'UNK', 'ASKU', 'NAV', 'NASK' and 'MSK'). A hint is reported in the following scenarios: 1 A data element of the HL7 'TS' data type contains nullFlavor PINF or NINF; or if a data element of the HL7 'IVL' data type contains nullFlavor PINF for the high element or NINF for the low element, so the tester may determine if the correct nullFlavor has been selected; 2 A data element contains the nullFlavor DER, so the tester may determine if the use of that nullFlavor is valid. 3 A data element of the HL7 ''ST', 'RTO' data types contains a value and also contains nullFlavor attribute with one of the values that indicate there is no value for the data element (i.e. 'UNK', 'ASKU', 'NAV', 'NASK' and 'MSK'). 4 A data element of the HL7 'ED' data type contains a text value and not a reference and also contains nullFlavor attribute with one of the values that indicate there is no value for the data element (i.e. 'UNK', 'ASKU', 'NAV', 'NASK' and 'MSK').
TC-Types-49 Step 1	F	F	
TC-Types-49 Step 2	F	F	
TC-Types-49 Step 3	F	F	

Table 42: TS-PIVL (Periodic Interval) test set

Test case	Coverage	Automation	Explanation
TC-Types-117	F	P	An error is reported if neither nullFlavor, period nor frequency are present, or if both period and frequency are present. If a periodic interval has a period and a phase then an error is reported if the phase width is unbounded and a hint is reported if the phase width is bounded so that the tester may determine if the phase width is within the period.

Table 43: TS-PQ (Physical quantity) test set

Test case	Coverage	Automation	Explanation
TC-Types-93	F	F	
TC-Types-94	F	F	

Table 44: TS-PQ.TIME (Period of Time) test set

Test case	Coverage	Automation	Explanation
TC-Types-98	F	F	

Table 45: TS-REAL (Real) test set

Test case	Coverage	Automation	Explanation
TC-Types-96	F	F	

Table 46: TS-RTO (Ratio) test set

Test case	Coverage	Automation	Explanation
TC-Types-97	F	F	

Table 47: TS-ST (Character string) test set

Test case	Coverage	Automation	Explanation
TC-Types-55	F	F	
TC-Types-56	P	P	An error is reported if a data element contains text with known mark-up characters used in clinical document narratives and a warning is reported if the text appears to contain mark-up characters that may be derived from narrative mark-up. Other types of mark-up are not currently detected.

Table 48: TS-TEL (Telecommunications address) test set

Test case	Coverage	Automation	Explanation
TC-Types-69	F	F	
TC-Types-118	P	P	An error is reported under the following conditions: 1 The data element contains a same-document reference and there is no corresponding data element in the document; 2 The data element contains an absolute URL and the URI contains characters disallowed by the URI specification (RFC 3896); 3 The data element contains an absolute URI that does not have the general URI syntax or if the URI scheme is neither "pcehr" nor one of the registered schemes; and 4 The data element contains an absolute URI of the "mailto" or "pcehr" schemes and does not have the syntax required by those schemes.

Table 49: TS-TS (Time stamp) test set

Test case	Coverage	Automation	Explanation
TC-Types-99	F	F	

TC-Types-100	F	F	
TC-Types-101	F	F	

Table 50: TS-UID (Unique identifier) test set

Test case	Coverage	Automation	Explanation
TC-Types-105	F	F	
TC-Types-106	F	F	
TC-Types-107	F	P	An error is reported if: 1 An OID arc is either disallowed or its value is not one of the allowed values according to the information about the namespace listed in either the HL7 OID Registry or the OID Repository; 2 The OID commences with '1.2.36.' but does not have the syntax of an ACN or ABN OID; 3 The OID commences with '2.25.' but does not have the syntax of a UUID OID; or 4 The OID is registered as an OID to be used solely for development and testing purposes. A hint is reported if an OID is not one of the OIDs known to be valid, does not commence with '1.2.36.' or '2.25.' and if it is not one of the OIDs known to be invalid.
TC-Types-108	F	F	
TC-Types-109	F	P	A hint is reported if the length of an OID arc indicates the arc may be derived from an Australian Business Number or Australian Company Number, so the tester may verify the OID.

A.1.4 FS-Auth (Authoring systems)

This section contains a table for each test set in the FS-Auth feature set within the Conformance Test Specification for Authoring Systems. The FS-Auth feature set contains test cases that assess how information entered into a document authoring system is reproduced in a clinical document.

Table 51: TS-Addr (Address) test set

Test case	Coverage	Automation	Explanation
TC-Auth-52	N	N	
TC-Auth-53	P	P	A warning is reported if a home address has been included for the legal authenticator, a healthcare provider individual or a healthcare provider organisation.
TC-Auth-54	N	N	

Table 52: TS-Behav (Behaviour) test set

Test case	Coverage	Automation	Explanation
TC-Auth-01	N	N	
TC-Auth-02.1	N	N	
TC-Auth-02.2	N	N	
TC-Auth-02.3	N	N	
TC-Auth-03	N	N	
TC-Auth-04	N	N	
TC-Auth-05	N	N	

Table 53: TS-Content (Clinical document content) test set

Test case	Coverage	Automation	Explanation
TC-Auth-07	F	P	A hint is reported if a data element has a time of midnight. In addition, if a collection of documents is available from the same health software system and the flag `collection-same-system` has the value `"true"` then DateTime and TimeInterval data elements are assessed and a warning is reported if all occurrences of the elements have a time of midnight.
TC-Auth-08	N	N	
TC-Auth-09	P	F	An error is reported if a clinical document narrative renderMultiMedia or linkHtml element contains a URL commencing with 'ftp:', 'http:', 'https:' or 'file:', with the exception of Diagnostic Imaging Reports as they are permitted to include a reference to a document on an external location.
TC-Auth-12	N	N	
TC-Auth-13	P	P	The IQ Rules looks for narrative text that may have originally been tabular information, where the table rows are separated by 'br', 'paragraph', 'content' or 'items' elements and the separators between table cells in each row were not included in a manner that retains the distinction between columns. The test examines separators consisting of multiple spaces or tabs.
TC-Auth-15	N	N	
TC-Auth-17	-	-	There is no test case.
TC-Auth-18	N	N	
TC-Auth-19	-	-	There is no test case.
TC-Auth-20	N	N	
TC-Auth-21	N	N	
TC-Auth-22	N	N	
TC-Auth-23	-	-	There is no test case.
TC-Auth-24	N	N	

TC-Auth-55	P	P	A warning is reported if a clinical document created on or after 2016 contains a data element with the AMT version2 code system identifier '1.2.36.1.2001.1004.100'.

Table 54: TS-eComm (Electronic communication detail) test set

Test case	Coverage	Automation	Explanation
TC-Auth-49	N	N	
TC-Auth-50	F	P	A warning is reported if a home, primary home or vacation home telecommunications details has been included for the legal authenticator, a healthcare provider individual or a healthcare provider organisation.
TC-Auth-51	N	N	

Table 55: TS-Ident (Identification, revisions & addenda) test set

Test case	Coverage	Automation	Explanation
TC-Auth-26	N	N	
TC-Auth-27	N	N	

Table 56: TS-Pers (Person) test set

Test case	Coverage	Automation	Explanation
TC-Auth-28	-	-	There is no test case.
TC-Auth-29	N	N	
TC-Auth-30	N	N	
TC-Auth-31	N	N	
TC-Auth-32	N	N	
TC-Auth-33	N	N	
TC-Auth-34	N	N	
TC-Auth-35	N	N	
TC-Auth-36	-	-	There is no test case.
TC-Auth-37	N	N	
TC-Auth-38	N	N	

TC-Auth-39	P	F	Steps 2, 3 and 4 of the test case have been partially implemented by using information in a clinical document.
TC-Auth-40	-	-	There is no test case.
TC-Auth-41	N	N	
TC-Auth-42	P	F	Steps 2, 3 and 4 of the test case have been partially implemented by using information in a clinical document.
TC-Auth-43	N	N	
TC-Auth-44	N	N	
TC-Auth-45	N	N	
TC-Auth-46	F	P	A hint is reported if an ANZSCO code ending in '99' has been used for any healthcare participant's role. A warning is also reported if a Shared Health Summary author's role has an ANZSCO code that is not one of the codes for one of the permitted occupations[29].
TC-Auth-47	F	P	A hint is reported if an ANZSCO code ending in '99' has been used for any healthcare participant's occupation. A warning is also reported if a Shared Health Summary author's occupation has an ANZSCO code that is not one of the codes for one of the permitted occupations.
TC-Auth-48	F	P	A hint is reported if an ANZSCO code ending in '99' has been used for any healthcare participant's position in organisation. A warning is also reported if a Shared Health Summary author's position in organisation has an ANZSCO code that is not one of the codes for one of the permitted occupations.

A.2 Types of clinical documents assessed by the IQ Rules

The IQ Rules includes tests for the types of documents listed in Table 57. This table also includes the My Health Record template ID and the version(s) of the CDA Implementation Guide supported by the IQ Rules.

Table 57: Types of clinical documents assessed by the IQ Rules

Type of clinical document	**My Health Record Template ID**	**CDA Implementation Guide Version(s)**
Advance Care Directive Custodian Record	1.2.36.1.2001.1001.101.100.1002.156	1.0
Australian Childhood Immunisation Register document	1.2.36.1.2001.1001.101.100.1002.144	1.1
Australian Organ Donor Register	1.2.36.1.2001.1001.101.100.1002.147	1.1
Diagnostic Imaging Report	1.2.36.1.2001.1001.100.1002.222	1.0
Discharge Summary	1.2.36.1.2001.1001.101.100.1002.4	3.4
eHealth Dispense Record	1.2.36.1.2001.1001.100.1002.171	1.0
eHealth Prescription Record	1.2.36.1.2001.1001.100.1002.170	1.0
eReferral	1.2.36.1.2001.1001.101.100.1002.2	2.2
Event Summary	1.2.36.1.2001.1001.101.100.1002.136	1.2, 1.3
Medicare/DVA Benefits Report	1.2.36.1.2001.1001.101.100.1002.140	1.1
Pathology Report	1.2.36.1.2001.1001.100.1002.220	1.0
Personal Health Summary	1.2.36.1.2001.1001.101.100.16685	1.0
Pharmaceutical Benefits Report	1.2.36.1.2001.1001.101.100.1002.142	1.1

[29] A Medical Practitioner, a Registered Nurse or an Aboriginal or Torres Strait Islander healthcare worker.

Type of clinical document	My Health Record Template ID	CDA Implementation Guide Version(s)
Prescription and Dispense View	1.2.36.1.2001.1001.100.1002.179	1.0
Shared Health Summary	1.2.36.1.2001.1001.101.100.1002.120	1.3, 1.4
Specialist Letter	1.2.36.1.2001.1001.101.100.1002.132	1.3

A.3 Agency-defined sections assessed by the IQ Rules

The IQ Rules assesses Agency-defined sections of clinical documents. The rules for these sections are based on the specifications for the types of documents listed in Table 57.

Table 58 lists Agency-defined sections of clinical documents that are assessed by the IQ Rules, and their section code. Each section code is from the NCTIS Data Components code system whose identifier is "1.2.36.1.2001.1001.101".

The specifications for sections that are used in more than one type of document may vary slightly depending on the type of document.

Table 58: Agency-defined sections assessed by the IQ Rules

Section Title	Section Code
Administrative Observations	102.16080
Advance Care Information	101.16973
Adverse Reactions	101.20113
Alerts	101.20021
Arranged Services	101.16021
Australian Childhood Immunisation Register Entries	101.16658
Ceased Medications	101.16146.4.1.2
Clinical Interventions Performed This Visit	101.20109
Clinical Synopsis	102.15513.4.1.1
Current Medications on Discharge	101.16146.4.1.1
Diagnostic Imaging	101.16945
Diagnostic Investigation	101.16146
Diagnostic Investigations	101.20117
Dispense Item	102.16210
Event	101.16006
Event Details	101.16672
Exclusion Statement	102.16134.179.1.1
Health Profile	101.16011
Imaging Examination Result	102.16145
Immunisations	101.16638
Medical History	101.16117
Medicare/DVA Funded Services	101.16643
Medication Entries with Summary	101.16795

Section Title	Section Code
Medications	101.16146
Medications[30]	101.16022
Pathology	101.20018
Pathology Test Result	102.16144
Pharmaceutical Benefit Items	101.16649
Plan	101.16020
Prescribing and Dispensing Reports	101.16794
Prescription Item	102.16211
Problems/Diagnoses This Visit	101.16142
Recommendations	101.16606
Record Of Recommendations And Information Provided	101.20016
Referral Detail	102.16347
Requested Service	102.20158
Response Details	101.16611

A.4 Agency-defined data types assessed by the IQ Rules

Requirements for the following abstract data types are assessed by the IQ Rules. They are defined by the Agency[31] and are specialisations of HL7 data types. They are used in the Participation Data Specification and Structured Content Specifications.

- Boolean
- CodeableText
- CodedText
- DateTime
- Duration
- EncapsulatedData
- Integer
- Link
- Quantity
- QuantityRange
- QuantityRatio
- Real
- Text
- TimeInterval
- UniqueIdentifier

[30] This is the Discharge Summary Medications section.

[31] See "Data Types in NEHTA Specifications: A Profile of the ISO 21090 Specification" Version 1.0.

A.5 Code systems supported by the IQ Rules

Table 59 lists code systems used by the IQ Rules to assess a clinical document.

Table 59: Code systems supported by the IQ Rules

Code system name	Code system identifier
AS 5017-2006 Health care Client Identifier Geographic Area	2.16.840.1.113883.13.63
AS 5017-2006 Health Care Client Sex	2.16.840.1.113883.13.68
AS 5017-2006 Health Care Client Source of Death Notification	2.16.840.1.113883.13.64
Australian Medicines Terminology (AMT) v2	1.2.36.1.2001.1004.100
Australian and New Zealand Standard Classification of Occupations (ANZSCO) First Edition, Revision 1 and version 1.2	2.16.840.1.113883.13.62
Australian and New Zealand Standard Industrial Classification (ANZSIC) 2006	1.2.36.1.2001.1005.47
Australian PBS Code	1.2.36.1.2001.1005.22
Australian PBS Manufacturer Code	1.2.36.1.2001.1005.23
Australian Vaccine Code	1.2.36.1.2001.1005.17
DICOM Controlled Terminology	1.2.840.10008.2.16.4
Episode of admitted patient care's separation mode	2.16.840.1.113883.13.65
HL7 Act Code	2.16.840.1.113883.5.4
HL7 Diagnostic service section ID	2.16.840.1.113883.12.74
HL7 Employee Job Class	2.16.840.1.113883.5.1059
HL7 Identifier Type	2.16.840.1.113883.12.203
HL7 Modality	2.16.840.1.113883.12.259
HL7 Observation Interpretation	2.16.840.1.113883.5.83
HL7 Observation Interpretation Normality	2.16.840.1.113883.1.11.10206
HL7 Participation Function	2.16.840.1.113883.5.88
HL7 Provider Role	2.16.840.1.113883.12.286
HL7 Provider Role	2.16.840.1.113883.12.443
HL7 Result Status	2.16.840.1.113883.12.123
HL7 Role Class	2.16.840.1.113883.5.110
HL7 Role Code	2.16.840.1.113883.5.111
HL7 Route of Administration	2.16.840.1.113883.12.162

Code system name	Code system identifier
HL7 Service Delivery Location Role Type	2.16.840.1.113883.1.11.17660
HL7 Specimen Type	2.16.840.1.113883.5.129
HL7 Substance Admin Substitution	2.16.840.1.113883.5.1070
METeOR 329673 Clinical Specialties	2.16.840.1.113883.3.879.329673
METeOR 532097 Clinical Specialties	2.16.840.1.113883.3.879.532097
METeOR 314867 Employment Type	2.16.840.1.113883.3.879.314867
METeOR 291036 Indigenous Status	2.16.840.1.113883.3.879.291036
NCTIS Anatomical Region Values	1.2.36.1.2001.1001.101.104.17008
NCTIS Change Type Values	1.2.36.1.2001.1001.101.104.16592
NCTIS Concurrent Supply Grounds Values	1.2.36.1.2001.1001.101.104.16085
NCTIS Data Components	1.2.36.1.2001.1001.101
NCTIS Document Status Values	1.2.36.1.2001.1001.101.104.20104
NCTIS Entitlement Type Values	1.2.36.1.2001.1001.101.104.16047
NCTIS Global Statement Values	1.2.36.1.2001.1001.101.104.16299
NCTIS Medical Benefit Category Type Values	1.2.36.1.2001.1001.101.104.16095
NCTIS Recommendation or Change Values	1.2.36.1.2001.1001.101.104.16594
NCTIS Request Urgency Values	1.2.36.1.2001.1001.101.104.16127
NCTIS Result Status Values	1.2.36.1.2001.1001.101.104.16501
NCTIS Vaccine Cancellation Reason Type Values	1.2.36.1.2001.1001.101.104.16755
SNOMED CT-AU	2.16.840.1.113883.6.96

A.6 Code systems that are known to, but not used by, the IQ Rules

Some code systems are known to the IQ Rules but the IQ Rules is not capable of verifying the value of a code or displayName from these code systems.

If a clinical document contains coded data from one of these code systems then the IQ Rules verifies the value of the codeSystem attribute. The IQ Rules does not, however, verify the value of the displayName attribute. The value of the code attribute may be checked by the IQ Rules to ensure it has the correct format but no other checks of the code attribute are applied.

Known but unsupported code systems include national code systems, as well as code systems used by developers of software that accesses the My Health Record system. Table 60 lists national[32] code systems that are known to the IQ Rules although the IQ Rules does not have access to the set of codes in these code systems.

[32] These are the code systems published by the Australian Government or referenced in the digital health specifications published by the Australian Digital Health Agency.

Table 60: Known but unsupported national code systems

Code system name	Code system identifier
Australian MBS Code	1.2.36.1.2001.1005.21
Australian Streamlined Authority Approval Number	1.2.36.1.2001.1005.24

Table 61 lists national code systems where the IQ Rules has access to a subset of the codes in the code system.

Table 61: National code systems with limited support

Code system name	Code system identifier
Logical Observation Identifier Names and Codes (LOINC)	2.16.840.1.113883.6.1

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA®	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
HL7	Health Level Seven
LOINC	Logical Observation Identifier Names and Codes
MBS	Medicare Benefits Schedule
NCTIS	National Clinical Terminology Information Service
PBS	Pharmaceutical Benefits Scheme
SNOMED CT-AU	Systematized Nomenclature of Medicine – Clinical Terminology - Australia

Glossary

Term	Meaning
IQ Rules	Information Quality Rules