Clinical Information Systems Connecting to the PCEHR System

Conformance Assessment Scheme

Version 1.1 — 23 July 2012

Approved for Release

(Review scheduled for December 2012)

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Document version control

Revision history

Version	Date	Comments
0.1	29 February 2012	First draft.
0.2	2 March 2012	First draft for consultation.
0.3	26 March 2012	Incorporated relevant feedbacks from NEHTA personnel and released as a draft for consultation.
0.4	18 April 2012	Incorporated relevant feedbacks received in writing, and updated to reflect the industry consultation on 10 and 11 April 2012 attended by DOHA, MSIA, AIIA, Vic Health and ACT Health.
0.5	7 June 2012	Draft with the observed self-assessment process proposed by the eHealth CCA Governance Group.
0.6	8 June 2012	Incorporated internal review comments.
0.7	13 June 2012	Incorporated feedback from review at CCA Governance Group
1.0	15 June 2012	Released – fit for early practical implementation. A review of this document is scheduled for December 2012.
1.1	23 July 2012	See appendix B for details.

1 Introduction

1.1 Purpose

This document describes the process for assessing a Clinical Information System (CIS) for conformance to the relevant specifications when connecting and interacting with the National Personally Controlled Electronic Health Records (PCEHR) System.

Conformance assessment provides assurance that a software implementation adheres to eHealth specifications. It gives users of conforming implementations confidence that an implementation will behave as expected, perform functions in a known manner, has interfaces or formats that adhere to the specifications and is likely to interoperate with the National PCEHR System.

A conformance assessment scheme describes how a software system will be assessed and tested for conformance to an eHealth specification. It also describes the artefacts, including software and documentation that support conformance assessment activities.

1.2 Scope

The scope of PCEHR CIS conformance assessment is for testing the conformance of the behaviour of a CIS that will access the PCEHR System through the PCEHR B2B Gateway Service.

Within the context of the PCEHR programme, a clinical information system (CIS) is defined as "*a system that may deal with the collection, storage, retrieval, communication, or use of health related data, information and knowledge pertaining to subjects of care. The system may comprise of one or more applications or components. It is anticipated that the CIS would connect to the HI Service or connect to another system that does connect to the HI Service*"

To meet the conformance requirements for CIS, the following needs to be also met:

> **Healthcare Identifiers (HI) Service** - A CIS needs to use the HI Service for identification of healthcare recipients. Therefore it must conform to applicable HI software conformance requirements [NEHTA2011c]. A CIS will be assessed for conformance to these requirements according to the process described in the HI conformance assessment scheme [NEHTA2011a].

Clinical documents - A CIS may produce and upload clinical documents to the PCEHR System. The CIS may also download or remove clinical documents from the PCEHR System. The CIS must therefore conform to:

- Requirements associated with uploading, downloading and removing clinical documents to and from the PCEHR System; and
- Requirements for the content of clinical documents.

These requirements and associated specifications are listed in the software conformance requirements for CIS connecting to the PCEHR System [NEHTA2012b] and the conformance profiles for clinical documents[1].

Developers of clinical information systems are also recommended to meet the following requirements:

Digital credentials - A CIS should support the use of national digital credentials (NASH or interim DHS credentials) for communicating with the PCEHR System. Therefore, it should meet the recommended conformance requirements for use of digital credentials [NEHTA2012c].

Conformance test specifications and test tools are applied to assess the CIS for conformance to these requirements.

In addition to exchanging clinical documents, the CIS also interacts with the PCEHR System for other purposes (for example to check if a PCEHR record exists and to gain access to a PCEHR). The CIS must conform to the conformance requirements associated with these interactions [NEHTA2012b]. Conformance test specifications are also applied to assess the CIS for conformance to these requirements.

The CIS would also need to meet a Notice of Connection (NOC) with the PCEHR system as well as meet the conformance requirements as defined in the CIS conformance requirements.

The scope does not include testing the conformance of software that does not access the PCEHR System via the PCEHR B2B Gateway Service. This may be included within the scope of the document in a future revision.

1.3 Intended audience

The intended audience includes:

- Vendors, developers and contracted service providers of clinical information systems;
- Health jurisdictions and healthcare providers that utilise clinical information systems; and
- Software test laboratories.

1.4 Contact details

Any comments or feedback should be sent to: nehtasupport@nehta.gov.au

[1] [NEHTA2012m, NEHTA2012d, NEHTA2012e, NEHTA2012f, NEHTA2012g, NEHTA2012h, NEHTA2012i, NEHTA2012j]

2 Abbreviations and terminology

AMT	Australian Medicines Terminology
CDA	HL7 Clinical Document Architecture; an XML-based standard that specifies the encoding, structure and semantics of clinical documents exchanged between health software systems described in a CDA Implementation Guide.
CIS	Within the context of the PCEHR programme, a clinical information system (CIS) is defined as a system that may deal with the collection, storage, retrieval, communication, or use of health related data, information and knowledge pertaining to subjects of care. The system may comprise one or more applications or components.
Conformance	Conformance is a measurement (by testing) of the adherence of an implementation to a specification or standard.
CSP	Contracted Service Provider of a healthcare provider organisation means an entity that provides: • Information technology services relating to the PCEHR system; or • Health information management services relating to the PCEHR system; to the healthcare provider organisation under a contract with the healthcare provider organisation.
Developer	An organisation that creates an implementation using the PCEHR specifications. A developer may be an organisation that develops a software product, or a provider of eHealth services. The conformance assessment process applies to all of these organisations.
HI	Healthcare Identifier: a national identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient as defined in the Healthcare Identifiers Act [HIACT2010].
Implementation	A software system created by a developer to conform to a specification or standard.
NOC	Notice of Connection
Object of assessment	An eHealth system or service, or a component of an eHealth system or service, which will be assessed for conformance.
PCEHR	Personally Controlled Electronic Health Record.
PCEHR System	The national system that contains Personally Controlled Electronic Health Records.
SNOMED CT-AU	Australian extension of SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms)
Test	The determination of one or more characteristics of an object of conformance assessment according to a documented procedure. Testing is a process applied to software in a test environment.
Test Summary Report	A Test Summary Report documents the results of the test performed by a test laboratory on behalf of a developer.

3 Requirements for CIS conformance assessment

3.1 The approach to conformance testing

Use cases [NEHTA2012a] and conformance requirements [NEHTA2012b] have been developed to help software developers create a Clinical Information System (CIS) that:

- Minimise risks to patient safety, privacy and information security; and
- Implement good practice in exchanging clinical documents with the National PCEHR System.

Conformance testing provides one mechanism through which these risks can be mitigated. Other mechanisms for risk mitigation may include, but not limited to, implementation guidelines, local policies or procedures, user education and training. Risk mitigations other than conformance testing are out of scope. Risks for deployment and implementation are not covered within this document.

3.2 Object of conformance assessment

The conformance assessment process described in this document applies to the assessment of the object described below.

Clinical Information System (CIS) - A Clinical Information System deals with the collection, storage, retrieval, communication and use of health related data, and information and knowledge pertaining to subjects of care [AS5021]. Clinical Information Systems may include, but are not limited to, General Practitioner systems, pharmacy systems, hospital systems, patient administration systems, aged care systems and specialist systems.

A CIS may consist of a number of separate but interacting systems. In this case, the object of assessment refers to these separate interacting systems as a whole which make up an overall CIS and these may be one or more CIS's.

A Contracted Service Provider (CSP) may provide a range of services but not limited to host a CIS on behalf of one or more healthcare provider organisations.

A CIS may be a Producer, which is a system that creates and uploads clinical documents to the PCEHR System.

A CIS may also be a Consumer, which is a system that downloads documents from the PCEHR System.

3.3 Relevant technical requirements

Conformance requirements and relevant specifications for a CIS connecting to the PCEHR System are listed in the following documents:

1. Use of Healthcare Identifiers in Health Software Systems: Software Conformance Requirements [NEHTA2011c & NEHTA2012q];
2. Conformance Profiles for Clinical Documents[2]; and

[2] [NEHTA2012m, NEHTA2012d, NEHTA2012e, NEHTA2012f, NEHTA2012g, NEHTA2012h, NEHTA2012i, NEHTA2012j]

3. Clinical Information Systems Connecting to the PCEHR System: Conformance Requirements [NEHTA2012b].

The following specification is available for developers wanting to meet the recommended requirements for use of digital credentials:

1. Use of Digital Credentials in Health Software Systems: Conformance Requirements [NEHTA2012c];

3.4 Conformance requirements for CIS

3.4.1 Healthcare Identifier (HI) Service

A CIS needs to use valid healthcare identifiers when interacting with the PCEHR System. Without a valid Individual Healthcare Identifier (IHI), a CIS may incorrectly associate information with the wrong healthcare recipient on the PCEHR System or locally. Also a valid Healthcare Provider Identifier Individual (HPI-I) is required to identify the author of a clinical document uploaded to the PCEHR System. Requirements 019100 and 019429 in the conformance requirements for a CIS connecting to the PCEHR System [NEHTA2012b] state the requirements for valid Healthcare Identifiers. Information in Table 1 and 2 below support those requirements.

A) IHI - A CIS connecting to the PCEHR System **SHALL** have passed HI Notice of Connection (NOC) and CCA test cases for **at least one** of the following HI Requirements.

Requirement	Use Case	Description
005872	UC.015 UC.035	IHI Validation - Revalidation of individual IHIs
005877	UC.025	IHI Validation - Batch refresh
005812	UC.010 UC.015	IHI Search - IHI Number search
005813	UC.010 UC.015	IHI Search - Medicare card search
005814	UC.010 UC.015	IHI Search - DVA File number search
005815	UC.010 UC.015	Detailed IHI search (uses addresses)

Table 1: HI requirements for validating or searching for an IHI

B) HPI-I - A CIS connecting to PCEHR **SHOULD** have passed NOC and CCA for **at least one** of the following HI Requirements

Requirement	Use Case	Description
010041	UC.130	Search for an individual healthcare provider directory entry
010040	UC.240	Validation of healthcare provider identifiers with the HI Service

Table 2: Object of conformance assessment

3.4.2 Digital credentials

A CIS connecting to the PCEHR System must use national digital credentials for communicating with the PCEHR System. The CIS is recommended to meet the following conformance requirements related to use of an organisational digital credential (containing a HPI-O identifier).

A) A CIS Producer (i.e. a CIS needing to upload documents to the PCEHR System) **SHOULD** conform to the following requirements:

1. **All** the following conformance requirements for use of a digital credential as a subscriber:
    i. None

B) A CIS Consumer (i.e. a CIS needing to download documents from the PCHER System) **SHOULD** conform to the following requirements:

1. **All** the following conformance requirements for use of a digital credential as a relying party:
    i. 017870
    ii. 017871
    iii. 017872
    iv. 017873
    v. 017874
    vi. 017954
    vii. 017951
    viii. 017953
    ix. 017875
    x. 019140

3.4.3 Clinical documents

The PCEHR System enables healthcare providers to share clinical information with other providers in the form of clinical documents. A CIS connecting to the PCEHR System allows its users to upload, download or remove clinical documents to and from the PCEHR System. Use cases related to clinical documents are listed below:

A) A CIS Producer (i.e. a CIS needing to upload documents to the PCEHR System) **SHALL** conform to the mandatory and relevant conditional requirements in the following:

1. **All** the following CIS use cases:
    i. UC.CIS.001
    ii. UC.CIS.201
    iii. UC.CIS.202 (not applicable for Shared Health Summary)
    iv. UC.CIS.203
2. The PCEHR conformance profiles for the types of clinical documents supported by the CIS.

B) A CIS Consumer (i.e. a CIS needing to download documents from the PCHER System) **SHALL** conform to the mandatory and relevant conditional requirements in the following:

1. **All** the following CIS use cases:
    i. UC.CIS.001
    ii. UC.CIS.002
    iii. UC.CIS.204
2. The PCEHR conformance profiles for the types of clinical documents supported by the CIS

4 Testing CIS conformance

This section describes the process of assessing an implementation for conformance to the requirements stated in section 3.4.

4.1 Conformance assessment process

The process of assessing the conformance of a CIS needing to connect to the PCEHR System is performed by Observed Self-Assessment. See the following documentation for a description of this process:

- Self-Assessment Process for CIS Connecting to PCEHR: Guide for Participants [NEHTA2012r].

4.2 Conformance test specifications

Conformance test specifications provide the details of tests performed during the conformance assessment.

Conformance test specifications include:

1. Test cases:
    a. A test case is a set of inputs, execution conditions and expected results; and
    b. Each test case translates a conformance requirement into a concise, insular test with a clear objective and criteria for passing.
2. Test data (if needed) - data used to apply the test cases.

Conformance test specifications for a CIS connecting to the PCEHR System are described in Table 3.

Conformance tests	Description
Conformance tests for Clinical Information Systems [NEHTA2012n].	Tests for conformance to the requirements for use cases for CIS Producers or CIS Consumers, listed in sections 3.4.3.
Conformance test specifications for digital [NEHTA2012o].	Tests for conformance to the requirements for use of digital credentials by CIS Producers or CIS Consumers listed in section 3.4.2.
Conformance test specification for use of healthcare identifiers [NEHTA2012p].	Tests for conformance to the software requirements related to the HI use cases identified in the PCEHR conformance profiles for clinical documents in section 3.4.3.
Conformance test specification for PCEHR conformance profiles for clinical documents [NEHTA2012s].	Tests for conformance to the specifications for clinical documents. This also references the test specification for conformance to the authoring and rendering requirements for clinical documents.

Table 3: Conformance test specifications

4.3 Testing clinical documents

The aspects to testing the conformance of a clinical document include:

1. Checking the clinical document package, to determine its conformance to the CDA packaging requirements [NEHTA2011d], to determine the attachments are of the allowed types, and to check the validity of the signature.
2. Checking the syntax of the clinical document for conformance to the requirements in the relevant Structured Content Specification, CDA Implementation Guide and conformance profile specifications. Syntax checking includes examining the structural information components and atomic data; data types, cardinality constraints and other syntax checks. Clinical documents to be sent to the PCEHR System must meet a minimum level of conformance as described in the relevant PCEHR conformance profile. The conformance assessment process for a particular document type consists of the generation of test clinical documents of that document type and checking if they meet the minimum level of conformance with the Structured Content Specification and CDA Implementation Guide. The input data used for the generation of the test clinical documents is specified in the Clinical Document Test Data. Syntax checking is a process automated through the use of the CDA Validator.
3. Checking the content of the data elements to determine that data in a clinical document issued by the CIS matches the data entered into the CIS (e.g. to check that a date of birth in the clinical document is the same date of birth entered into a CIS user interface). Checking the content of the data elements requires manual review but is supported through the use of the CDA Validator.
4. For vendors who are using clinical terminology. The following checks are applied when testing the use of Australian Medicines Terminology (AMT) and SNOMED CT-AU concepts in a clinical document:
    a. Each AMT or SNOMED CT-AU concept used in the clinical document must be encoded using the concept ID as code and the concepts Preferred Term as displayName.
    b. The concept in the clinical document must identify the terminology (AMT or SNOMED CT-AU) and the release it belongs to, through codeSystem and codeSystemVersion.
    c. The concept used in the clinical document must be relevant to the document element in which the concept is used. For example, only Problem/diagnosis concepts are to be used in a Problem/diagnosis element of the clinical document.
    d. The concept used in the clinical document must belong to the most recent terminology release or a release that is not older than 180 days.
    e. Clinical terminology checks are automated through the use of the CDA Validator.

4.4 HI conformance testing

Clinical information systems connecting to the PCEHR System must correctly identify healthcare recipients to ensure health information is associated with the right healthcare recipient. This requires the CIS to conform to the software conformance requirements associated with the healthcare identifier use cases identified in the Common Conformance Profile for Clinical Documents [NEHTA2012d] (section 3.4.3). Conformance of a CIS to HI

conformance software conformance requirements is assessed using the process described in the HI conformance assessment scheme [NEHTA2011a].

4.5 Conformance test tools

The efficient application of test cases listed in the conformance test specifications is supported by the use of conformance test tools.

The CDA validator test tool checks the level of conformance of a clinical document to the CDA implementation guide, structured content specification and some requirements within the conformance profile specifications. The tool includes validation of the Australian Medicines Terminology and SNOMED CT-AU concepts used in the clinical documents.

The CDA validator consists of CDA validation software, schematron libraries, CDA schemas and an installation guide.

4.6 Success criteria

Criteria for successfully claiming conformance to the PCEHR CIS conformance requirements are:

1. The implementation must support the mandatory and relevant conditional conformance requirements that correspond to the relevant use cases;
2. A 100% pass rate is required for the test cases corresponding to these conformance requirements; and
3. A 100% pass rate is required for all conformance tests for recommended conformance requirements for which a developer wants to claim conformance.

4.7 Conformance test reporting by software developers

A conformance test summary report must be produced by the person who performed the conformance tests. The information that must be included in the conformance test summary is as follows:

1. Name of the organisation: The organisation that performed the conformance tests;
2. Name of the Authorising Officer: The authorising person from the organisation;
3. Date: The date on which the tests were performed;
4. Full suite of information: the information required to identify the implementation tested for conformance;
5. Conformance test specifications and tools: Name and version used to perform the tests;
6. Test environment: Information about the computing environment used to perform the tests, such as the operating system name and version, types of web browsers and versions;
7. Version: Version of the implementation that was tested;
8. Test case results: the result from executing each test case for each conformance requirement that the developer claims to have implemented.

9. Conformance test summary – a statement indicating whether the implementation meets the minimum conformance requirements.

4.8 Declaring conformance

The prerequisite for declaring the conformance of an implementation is:

1. Conformance test success criteria must be met.

The developer then declares the conformance of their CIS (the implementation) by completing and submitting a Declaration of Conformity for CIS Connecting to the PCEHR System [NEHTA2012l], supporting Implementation Conformance Statement [NEHTA2012k] and test summary report to NEHTA as secretariat to CCA Governance Group. The declaration of conformity and implementation conformance statement together form a developer's claim of conformance of their implementation. The test summary report provides the evidence that the claim of conformance is valid.

Submission of a PCEHR declaration of conformity and supporting documentation to NEHTA is proof of completion of the conformance tests and is mandated to obtain access to the PCEHR services when the PCEHR B2B NOC is completed. This is submitted to the National Infrastructure Operator prior to being given access to the PCEHR B2B web services.

The developer may give permission for the publication of their self-declaration on the eHealth register on www.ehealthcca.com.au.

5 Ongoing validity of conformance

5.1 Conformance and implementation versioning

A developer may revise their implementation to create a new version, including:

1. A major version, which may contain significant new functionality compared to the preceding version;
2. A minor version, which may contain incremental additional functionality compared to the preceding version; and
3. A maintenance version, which may correct one or more defects in a previously issued version.

Regardless of whether a new version is major, minor or a maintenance version, the new version must be retested for conformance if:

- A conforming system is enhanced to support one or more use cases that were not supported by the preceding version of the system. The new version will require conformance testing against every applicable conformance requirement associated with that use case(s).
- A conforming system is enhanced to include sub-sections of use cases that were not tested in the conforming version of the system. The new version will require conformance testing against every applicable conformance requirement associated with the whole use case(s).
- A conforming system is modified so its existing support for software conformance requirements may be impacted. The new version will require conformance testing against every applicable conformance requirement associated with the whole use case(s).

5.2 Conformance and version of the technical specifications

If a version of the software conformance requirements is superseded by a new version, an implementation that has been declared conformant must conform to the new version twelve (12) months after the date of publication of the new version of the software conformance requirements. Note this does not replace the need to reassess conformance if an implementation is modified (section 5.1).

5.3 Validity period

A CIS's declaration of conformance to the software conformance requirements has no expiry date. The declaration only applies to the version of the implementation and the version of the PCEHR CIS software conformance requirements, identified in the declaration of conformance.

If the CIS needs to be resubmitted to the PCEHR NOC testing process the vendor should review whether the software should be retested and their declaration of conformity reissued.

Appendix A: References

Appendix A lists all the documents referred to by this document. At the time of publication, the document versions listed below were valid. However, readers are encouraged to refer to most recent version of these documents.

[AS5021] AS 5021:2005 - The language of health concept representation, Standards Australia, 2005

[HIACT2010] Healthcare Identifiers Act 2010

[NEHTA2011a] Healthcare Identifiers Software, Conformance Assessment Scheme V3.0, NEHTA, 3 May 2011

[NEHTA2011b] Use of Healthcare Identifiers in Health Software Systems, Business Use Cases V2.2, NEHTA, 15 December 2011

[NEHTA2011c] Use of Healthcare Identifiers in Health Software Systems: Software Conformance Requirements V1.4, NEHTA, 3 May 2011; plus published amendments

[NEHTA2011d] CDA Package, V1.0, NEHTA, 30 November 2011

[NEHTA2012a] Clinical Information Systems Connecting to the PCEHR System: Use Cases, V1.0, NEHTA, 8 May 2012

[NEHTA2012b] Clinical Information Systems Connecting to the PCEHR System: Conformance Requirements, V1.4, NEHTA, 15 June 2012

[NEHTA2012c] Use of Digital Credentials in Health Software Systems: Conformance Requirements, V1.2, NEHTA, 1 June 2012

[NEHTA2012d] Common Conformance Profile for Clinical Documents, V1.3, NEHTA, 17 May 2012

[NEHTA2012e] PCEHR Conformance Profile for Shared Health Summary Clinical Documents, V1.3, NEHTA, 17 May 2012

[NEHTA2012f] PCEHR Conformance Profile for Event Summary Clinical Documents, V1.1, NEHTA, 16 March 2012

[NEHTA2012g] PCEHR Conformance Profile for Discharge Summary Clinical Documents, V1.3, NEHTA, 17 May 2012

[NEHTA2012h] PCEHR Conformance Profile for Electronic Referral Clinical Documents, V1.3, NEHTA, 17 May 2012

[NEHTA2012i] PCEHR Conformance Profile for Specialist Letter Clinical Documents, V1.3, NEHTA, 17 May 2012

[NEHTA2012j] PCEHR Conformance Profile for Medicare Documents, V1.0, NEHTA, 9 March 2012

[NEHTA2012k] CIS Connecting to the PCEHR System - Implementation Conformance Statement Proforma, NEHTA, 2012

[NEHTA2012l] CIS Connecting to the PCEHR System - Declaration of Conformity, NEHTA, 2012

[NEHTA2012m] PCEHR Conformance Profile for Consumer Entered Information Clinical Documents V1.1, NEHTA, 17 May 2012

[NEHTA2012n] Conformance test specification: Clinical Information Systems Connecting to the PCEHR System, V1.1, NEHTA, 15 June 2012

[NEHTA2012o] Conformance test specification: Use of Digital Credentials in Health Software Systems, V0.3, NEHTA, 1 June 2012

[NEHTA2012p] Use of Healthcare Identifiers in Health Information Systems: Conformance Test Specification, V1.7.1, NEHTA, 24 May2012

[NEHTA2012q] Use of Healthcare Identifiers in Health Software Systems – Amendment 1: Additions and Extensions to Software Conformance Requirements V1.4 for the use of HPI-Is and HPI-Os by local systems, NEHTA, 24 May 2012

[NEHTA2012r] Self-Assessment Process for CIS Connecting to PCEHR: Guide for Participants, V0.2, NEHTA, 30 May 2012

[NEHTA2012s] Conformance Test Specification: Conformance Profiles for Clinical Documents, V0.1, NEHTA, 1 June 2012

Appendix B: Change Log

This appendix lists the major changes and fixes applied to this document.

ID	Section	Change Detail	Rationale
1	1.2, 3.3, 3.4.2	The requirements for use of digital credentials are now recommended rather than mandatory.	A decision by the eHealth CCA Governance Group.

Changes from Version 1.0 (15 Jun 2012) to Version 1.1 (23 Jul 2012)