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Healthcare Identifiers Software Conformance Assessment Scheme

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4.0	03 November 2020	Removed the references to NATA accredited software test laboratories

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Executive Summary

The Australian Digital Health Agency (the Agency) in consultation with the health sector including Services Australia, the Department of Health, the Medical Software Industry Association (MSIA), the Australian Information Industry Association (AIIA), the Aged Care IT Vendors Association (ACIVA), state and territory health departments, has developed conformance requirements and an assessment process to support the safe use of healthcare identifiers by health software systems.

The Healthcare Identifiers Service was developed to assign, issue and maintain national healthcare identifiers for consumers and providers. The healthcare identifiers enable health software systems to associate health information about a healthcare recipient accurately, securely and consistently within a healthcare context.

Software systems requiring direct access to the HI Service must complete both HI conformance testing (as documented in this HI Conformance Assessment Scheme) and Services Australia's Notice of Connection (NOC) testing process. The conformance testing described in this document are often referred to as the 'CCA' tests. The CCA tests performed to assure the safe use of healthcare identifiers by a health software system and the NOC tests are performed to determine that the software can connect to the HI Service.

This first phase of the healthcare identifiers conformance requirements applies to software systems that directly access the healthcare identifiers (HI) Service. For software systems that do not directly access the HI Service, but manage and use local copies of healthcare identifiers, it is strongly recommended that these systems still undergo HI conformance testing to support the correct handling of identifiers.

The HI Conformance Assessment Scheme and associated test specifications aim to define consistent testing of health software systems that provides a sufficient assurance of conformance to the software requirements for use of healthcare identifiers.

Correct handling and use of healthcare identifiers by software systems will improve efficiency and quality of healthcare and reduce errors in managing patient information. Conversely, clinical safety risks may arise from incorrect or inappropriate use of healthcare identifiers.

Due to the significance of these risks, health software systems are to be assessed for conformance to requirements for the use of healthcare identifiers. The health software sector and the Department of Health have agreed testing is to be mandated for new or significantly changed software systems to assure safe use of identifiers.

This testing will be conducted with the Agency using an observed self-assessment format. Trained Agency testers will participate in an observation session and observe the vendor self-testing their software by using the test cases published by the Agency.

The healthcare identifiers conformance test specifications contain a set of conformance test cases derived from conformance requirements for the use of healthcare identifiers. Test cases are grouped by business use case. Conformance test specifications have both positive and negative functional test cases, to detect incorrect behaviour and ensure wrong data is handled correctly.

1 Introduction

1.1 Document purpose

This document describes the scheme for assessing the conformance of health software systems to requirements for the use of healthcare identifiers (referred to here as the HI software conformance requirements).

1.2 Scope

The scope of HI conformance assessment is to test the conformance to the HI software conformance requirements of health software that will directly access the HI Service.

The scope does not include testing conformance to the HI software conformance requirements of health software that manages healthcare identifiers but does not directly access the HI Service. This may be included within the scope of the document in future.

It is strongly recommended that systems that do not directly access the HI Service still undergo conformance assessment to ensure their product uses and manages healthcare identifiers in a manner that supports clinical safety, security and privacy.

Correct handling of healthcare identifiers by health software systems will assist in the reduction of errors and increase efficiency in managing patient information, potentially leading to improvements in the quality of patient healthcare.

A second phase of development of the HI conformance assessment scheme will include the following items:

1. Conformance requirements and testing for health software that manages and uses healthcare identifiers but does not directly access the HI Service; and
2. Approach to retesting (when a new version of health software is issued by a developer; when the HI software conformance requirements are updated, when NOC tests are repeated and when the HI Service is updated).

1.3 Intended audience

The intended audience includes:

- Developers of health software that use healthcare identifiers;
- Operators and owners of digital health services that use healthcare identifiers;
- Health departments, healthcare providers and systems integrators that implement software systems that use healthcare identifiers; and

In this document, a 'developer' is any organisation that develops a health software system that manages and uses healthcare identifiers.

1.4 Acknowledgements

Contributions to this document is acknowledged by the Agency. Members of the healthcare identifiers working group include Services Australia, the Department of Health, the Medical Software Industry Association, the Australian Information Industry Association, Aged Care IT Vendors Association, the Tasmanian Department of Health and Human Services, the Victorian Department of Health, the ACT Department of Health and the NT Department of Health. Contributors during the public comment period include other health jurisdictions, vendors and government authorities.

2 Requirements for HI Conformance assessment

2.1 The approach to conformance testing

HI software conformance requirements [ADHA2011a] have been created to help software developers develop health software that:

- Minimises risks to clinical safety, privacy and information security;
- Implements good practice in the acquisition, use and disclosure of healthcare identifiers;
- Assists healthcare providers to comply with the *Healthcare Identifiers Act 2010* [HIACT2010] and the Healthcare Identifiers Regulations 2010 [HIREGS2010]; and
- Achieves the expected benefits of using healthcare identifiers.

Correct use of the HI Service's Individual Healthcare Identifiers (IHIs) will improve the efficiency and quality of health care. The adoption of IHIs by healthcare providers with the support of software systems will help to address the management of disparate patient information. Conversely, HI implementations that do not properly manage and use local copies of individual healthcare identifiers may pose a risk to clinical safety and fail to realise the full benefits of using the HI Service's IHIs.

When healthcare identifiers are incorrectly managed:

- A healthcare recipient may be misidentified (e.g. due to transcription errors in manually entered identifiers);
- More than one healthcare identifier may exist for the same healthcare recipient; and
- The same identifier may be associated with records of more than one healthcare recipient.

Associating the wrong health information to a healthcare recipient can jeopardise clinical safety, through the introduction of errors such as:

- Medication errors;
- Incorrect surgical interventions; and
- Diagnostic testing errors.

To mitigate these risks and achieve the benefits of using the HI Service's IHIs:

- Conformance tests are derived from HI conformance requirements;
- Conformance tests include both positive and negative functional test cases to ensure that wrong behaviour or wrong data is handled correctly; and
- Software conformance testing is to be performed by vendors during an observed self-assessment session with the Agency.

Health software vendor representatives, the Department of Health and Services Australia have agreed that testing must be performed by vendors during an observed self-assessment session with the Agency to ensure that identified risks for the clinically-safe use of identifiers are properly addressed.

2.2 Organisations that participate in HI conformance assessment

Organisations that participate in HI conformance assessment are listed in Table 3.1.

Organisation	Roles
Developer	An organisation that creates a HI implementation using HI conformance requirements.
The Agency	An assessor of conformance to HI conformance requirements.

Table 3.1: Roles and organisations in HI conformance assessment

2.3 Relevant technical requirements

Detailed conformance requirements are listed in the following requirements:

- Use of Healthcare Identifiers in Health Information Systems: Software Conformance Requirements [ADHA2011a].

2.4 Conformance requirements

Conformance requirements are defined for a set of business use cases that describe the usage of healthcare identifiers by health software [ADHA2011d]. To determine which conformance requirements apply to a health software implementation, a developer first identifies the business use cases that apply to their HI implementation. Once these are known, the conformance requirements corresponding to the relevant business use cases are identified [ADHA2011a]. Support for some of the conformance requirements is mandatory for the selected business use cases while others are recommended.

Business use cases are described in terms of business process models to illustrate the workflow, tasks and decisions for each business use case. They are intended to be generic and applicable to any healthcare setting. Aspects of a business use case that must be supported by HI implementations are explicitly stated as HI conformance requirements.

HI implementations must conform to the conformance requirements of business use cases they support and not implement any prohibited capabilities for these business use cases.

2.5 Services Australia’s testing requirements for the HI Service interface

A health software system may obtain access to the HI Service either:

- Directly, through web services that access the HI Service interface; or
- Indirectly, through third-party software that accesses the HI Service.

To implement web services for the HI Service, Services Australia’s Licensed Material should be used. The HI Service Licensed Material contains information for developers such as the HI Service System Interface Specifications [HISIS], HI Service Developers Guide, Web Services Description Language definitions and XML Schema definitions. The Licensed Material may be obtained when developers accept the terms and conditions of the Licence Agreement - Use of the Healthcare Identifiers Licensed Material for Notice of Connection.

Services Australia manages the Notice of Connection (NOC) testing process. The NOC tests that a software system can connect to the HI Service. Services Australia does not charge developers to test for a NOC.

NOC testing is performed independently to the HI conformance tests. The HI conformance tests are performed to assure the safe use of healthcare identifiers by a health software system and the NOC tests are performed to determine that software can connect to the HI Service.

NOC testing and HI conformance testing may be performed in any order although it is recommended that NOC testing is performed first.

Further information regarding the Licensed Material and NOC testing process may be obtained from the Services Australia website:

<https://www.servicesaustralia.gov.au/organisations/health-professionals/subjects/healthcare-identifiers-service-software-developers>

2.6 Services Australia's vendor environment

Services Australia's vendor environment allows developers to develop and test their HI implementations to ensure they will connect to the HI Service. Services Australia's NOC testing is also performed in the vendor environment.

Access to the vendor environment is given to developers once they have accepted the terms and conditions of the Licence Agreement - Use of the Healthcare Identifiers Licensed Material for Notice of Connection. Test data for the HI Service web services will be given to developers to assist with transmissions into the vendor environment.

The vendor environment is shared by other developers doing business for other Services Australia online programs. Services Australia does not charge developers for use of the vendor environment.

Further information can be obtained from the Services Australia website:

<https://www.servicesaustralia.gov.au/organisations/health-professionals/subjects/healthcare-identifiers-service-software-developers>

3 Conformance assessment process

This section describes the process for assessing the conformance of a HI implementation to the software requirements for the use of healthcare identifiers.

3.1 HI conformance assessment

HI conformance assessment tasks are illustrated in Figure 4.1.

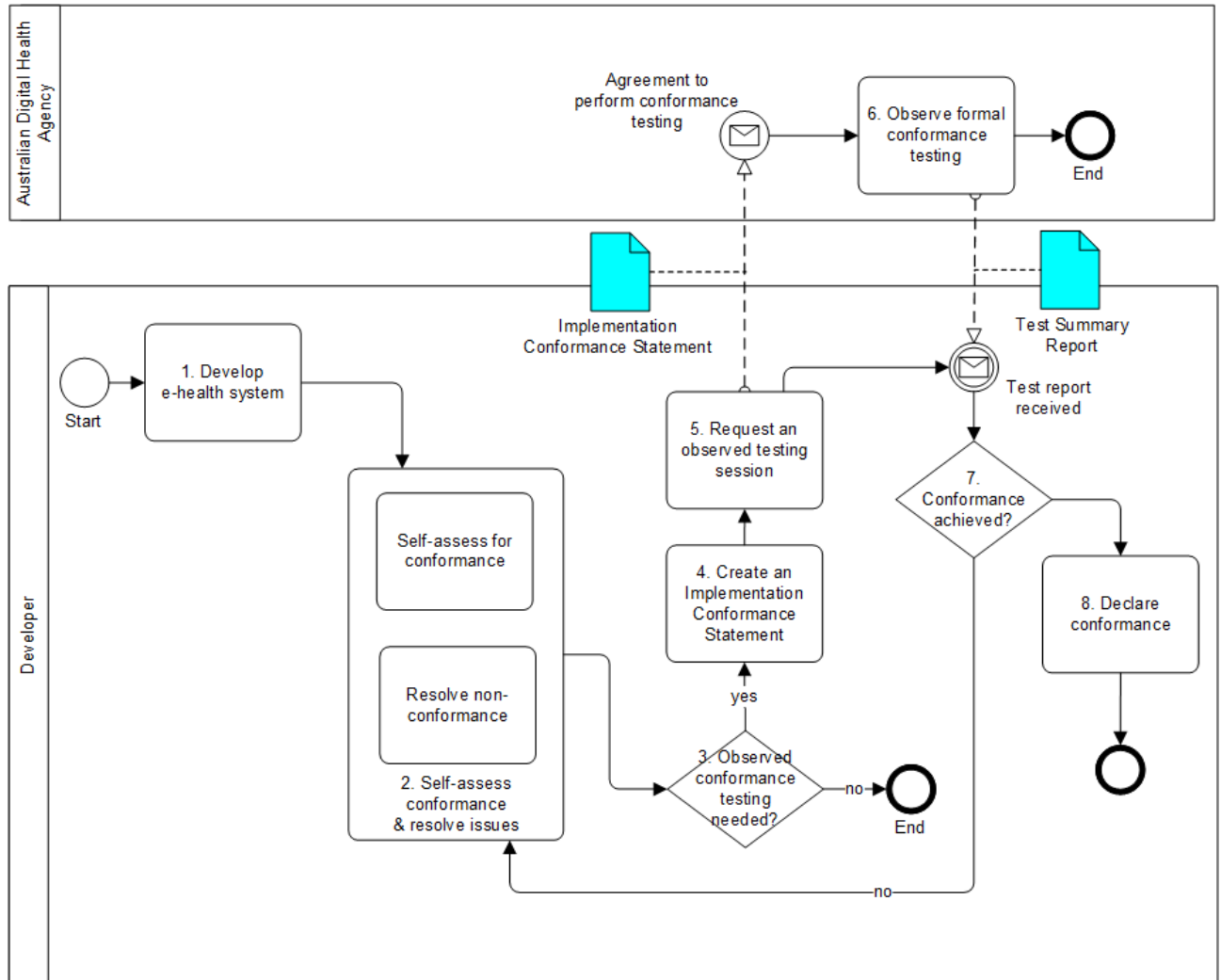


Figure 4.1: Conformance assessment process

HI conformance testing tasks are described in Table 4.1, including decisions on whether some of these tasks need to be performed.

	Process Item	Type	Description
1	Develop digital health system	Task	The developer creates, or modifies, a health system that uses healthcare identifiers.
2	Self-assess conformance & resolve issues	Task	Once a HI implementation has been created or modified to support the HI conformance requirements, the developer may perform their own assessment of the HI implementation's conformance to these requirements. Conformance test documentation describes the tests to be applied (see section 3.3).
3	Observed conformance testing needed?	Decision	<p>The HI implementation must be submitted to a observed self-assessment session for an assessment of conformance, if any of the following is true (see section 4.1):</p> <ul style="list-style-type: none"> • The HI implementation has not previously been declared conformant; • A new version of the HI implementation has been created that affects the implementation's conformance to the HI software requirements; • A previous version of the HI implementation has been declared conformant but the developer has subsequently enhanced the HI implementation to support additional business use cases or conformance requirements and wants to claim conformance for these; • A new version of the HI conformance requirements has been issued and the developer wants to claim conformance to this new version; or • A new version of the HI implementation has been created with changes to software components that access and/or manage healthcare identifiers.
4	Create an Implementation Conformance Statement	Task	The developer creates an Implementation Conformance Statement to indicate the conformance requirements supported by their HI implementation (see section 3.2).
5	Request an observed testing session	Task	The developer can organise an observed self-assessment session with the Agency. The completed ICS (step 4) will assist in understanding the developer's testing needs.
6	Observe formal conformance testing	Task	Formal conformance assessment is performed by the vendor while the Agency observes.
7	Conformance achieved?	Decision	The Agency will advise the developer whether their HI implementation conforms to HI conformance requirements and advice the developer on necessary software changes.
8	Declare conformance	Task	The developer declares the conformance of the HI implementation (see section 3.6).

Table 4.1: HI conformance assessment tasks and decisions

3.2 Implementation Conformance Statements

To test the conformance of a health software system under test (referred to here as the implementation), a statement of its capabilities and options implemented may be needed. This is called an Implementation Conformance Statement (ICS).

An ICS:

- Enables a developer to precisely state the conformance requirements that are supported by a HI implementation;
- Is used in communications with the Agency and may be used in communication with potential purchasers of a HI implementation; and
- May be used by an organisation wanting to procure a HI implementation, to specify the features they require.

An ICS proforma for healthcare identifiers is provided for developers [ADHA2011b]. The developer is responsible for describing their HI implementation in the ICS.

The ICS is used as follows:

1. The developer obtains an ICS proforma, along with instructions for completing the proforma;
2. The developer uses tables within the ICS to indicate which conformance requirements are supported by the HI implementation;
3. If formal conformance assessment is required, the developer sends the ICS to the Agency when they request formal software testing;
4. The Agency will only test those features that the developer includes in the ICS; and
5. The developer revises the ICS to only claim conformance to conformance requirements that the Agency has found to be supported by the HI implementation.

Email help@digitalhealth.gov.au for a copy of the ICS proforma for healthcare identifiers.

3.3 Conformance test specifications

The HI conformance test specifications [ADHA2011c] provide details of tests to be performed when assessing conformance. The HI conformance test specifications contain test cases that translate conformance requirements into concise, self-contained tests with a clear objective and criteria for passing. A test case is a set of inputs, execution conditions and expected results that has been developed to verify that a developer has correctly implemented the conformance requirements.

The HI conformance test specification identifies one or more test cases for each conformance requirement. Test cases reference items in the proforma Implementation Conformance Statement, so that applicable test cases can be applied.

Email help@digitalhealth.gov.au for a copy of the HI conformance test specifications and information about test data.

3.4 Success criteria

Criteria for successfully claiming conformance to the HI conformance requirements are:

1. The HI implementation must support the mandatory conformance requirements that correspond to the relevant business use cases (section 2.4);
2. A 100% pass rate is required for the test cases (section 3.3) 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.

3.5 Conformance test reporting

A conformance test summary report will be produced by the Agency. The conformance test summary report must include:

1. The name of the organisation and person that performed the conformance tests;
2. The date on which the tests were performed;
3. The full suite of information required to identify the HI implementation tested for conformance, including the name and version number;
4. The names and versions of the conformance test specifications and tools used to perform the tests;
5. The version of the HI software conformance requirements to which the HI implementation conforms;
6. Information about the computing environment used to perform the tests, such as the operating system name and version;
7. The result of executing each test case for each conformance requirement that the developer claims to have implemented; and
8. A statement indicating if the HI implementation meets the conformance requirements for each supported business use case (section 2.4).

The conformance test summary report is issued by the Agency to the developer and copied to Services Australia. The copy sent to Services Australia is needed for the task of declaring conformance.

3.6 Declaring conformance

Prerequisites for declaring the conformance of a HI implementation are:

1. Conformance test success criteria must be met (section 3.4); and
2. Conformance testing must be performed by the vendor whilst observed by the Agency.

The developer then declares the conformance of their health software system (the HI implementation) by submitting a HI declaration of conformity [ADHA2011e] and supporting implementation conformance statement to Services Australia (DevSupport@servicesaustralia.gov.au). The HI declaration of conformity and implementation conformance statement together form a developer's claim of conformance of their HI implementation.

Services Australia will receive the conformance test summary report from the Agency by the developer. Services Australia will examine the conformance test summary report to ensure it supports the developer's claim of conformance of their HI implementation.

Submission of a HI declaration of conformity and supporting documentation to Services Australia is proof of completion of the CCA tests and is mandated to obtain access to the HI Service. A health software system

that requires access to the HI Service will be granted access only after the successful completion of both the HI conformance tests and the NOC tests.

The developer may optionally request that the HI implementation be listed in the Australian Register of Conformity. Listing the HI implementation in this register is a public declaration of the conformance.

4 Ongoing validity of conformance

4.1 Conformance and versioning

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

- A major version, which may contain significant new functionality compared to the preceding version;
- A minor version, which may contain incremental additional functionality compared to the preceding version; and
- 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 submitted for formal conformance testing if:

- A conforming system is enhanced to support business use cases that were not supported by the preceding version of the system e.g. a system that was tested without merging capability has been expanded to now include merging capability.
- The new version will require conformance testing against every applicable conformance requirement associated with that business use case(s).
- A conforming system is enhanced to include sub-sections of business use cases that were not tested in the conforming version of the system e.g. a system that was tested without the capability to store unverified IHIs is expanded to include the capability to store unverified IHIs.
- The new version will require conformance testing against every applicable conformance requirement associated with the whole business use case(s).
- A conforming system is modified so its existing support for HI software conformance requirements may be impacted e.g. a system that was tested with the capability to merge patient demographic data has been modified to use a different merge technique.
- The new version will require conformance testing against every applicable conformance requirement associated with the whole business use case(s).
- A new version of the HI implementation has been created with changes to software components that access and manage healthcare identifiers.

The new version will need to be retested for conformance to the HI requirements for the supported business use case(s).

A developer may submit their HI implementation for formal conformance testing regardless of the scope of the revision.

4.2 Conformance and version of the HI software conformance requirements

If a version of the HI software conformance requirements is superseded by a new version, an HI 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 HI software conformance requirements. Note this does not replace the need to reassess conformance if an HI implementation is modified (section 4.1).

4.3 Validity period

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

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

Glossary

Term	Meaning
Conformance	A determination (by testing) of the adherence of an implementation to a specification or standard.
Conformance requirement	A technical requirement in a specification to be supported by a developer's implementation.
Developer	An organisation that develops a health software system using the HI software conformance requirements.
HI	Healthcare Identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient as defined in the Healthcare Identifiers Act [HIACT2010].
ICS	Implementation Conformance Statement.
HI implementation	A health software system that manages and uses local copies of healthcare identifiers.
NOC	Notice Of Connection. The term 'NOC' refers to Services Australia's testing process to determine health software can connect to the HI Service.
Object of assessment	A health software system or service, or a component of a health software system or service, which is assessed for conformance.
Test Summary Report	Documents the results of tests performed by the developer whilst observed by the Agency.

Appendix A References

This appendix lists documents that provide information for or about this document. At the time of publication, the document versions listed below were valid. However, as all documents are subject to revision, readers are encouraged to use the most recent versions of these documents.

- [HIACT2010] Healthcare Identifiers Act 2010.
- [HIREGS2010] Healthcare Identifiers Regulations 2010.
- [HISIS] Healthcare Identifiers Service System Interface Specifications, Services Australia.
- [ADHA2011a] Use of Healthcare Identifiers in Health Information Systems: Software Conformance Requirements, version 3.1, Australian Digital Health Agency, 2014.
- [ADHA2011b] HI Implementation Conformance Statement Proforma, version 3.2, Australian Digital Health Agency, 2014.
- [ADHA2011c] Use of Healthcare Identifiers in Health Information Systems: Conformance Test Specifications, version 3.1, Australian Digital Health Agency, 2014.
- [ADHA2011d] Healthcare Identifiers - Business Use Cases, Australian Digital Health Agency, 2011
- [ADHA2011e] Healthcare Identifiers – Declaration of Conformity, version 3.1, Australian Digital Health Agency, 2014