



**Australian Government**

**Australian Digital Health Agency**



## **Healthcare Identifiers Service Conformance Assessment Scheme**

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1.0	8 November 2020	Updated to refer to the conformance requirements for health software systems' use of healthcare identifiers. Changes made to the assessment process diagram. A reference to the E-Health Register was added.
2.0	31 March 2011	Final version, incorporating feedback from public comments.
3.0	3 May 2011	The process of declaring conformance was modified.
4.0	3 November 2020	Removed the references to NATA accredited software test laboratories
5.0	7 July 2025	Updated in line with Healthcare Identifiers Service - Conformance Profile v5.0.

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## Executive summary

The Healthcare Identifiers Service (HI Service) was developed to assign, issue and maintain unique national healthcare identifiers for healthcare recipients, providers, and organisations across the healthcare system. This enables 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 performed is 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 HI Service.

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

Due to the significant clinical safety risks that may arise from incorrect use of healthcare identifiers, 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 Healthcare Identifiers Service Conformance Profile [ADHA2025a]).

## 1.2 Scope

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

The scope does not include testing conformance to the conformance profile 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 uses 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.

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

## 2 Requirements for HI conformance assessment

### 2.1 Approach to conformance testing

The conformance requirements [ADHA2025a] 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* [HIACT2021] and the Healthcare Identifiers Regulations 2010 [HIREGS2020]
- 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.
- 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
- diagnostic testing errors.

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

- Conformance tests are derived from conformance profile requirements.
- Conformance tests include both positive and negative functional test cases to ensure that wrong behaviour or wrong data is handled correctly.
- Software conformance testing is to be performed by developers 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 developers 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

The organisations that participate in HI conformance assessment, and their role, are listed below.

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

## 2.3 Relevant technical requirements

Detailed conformance requirements are listed in the Healthcare Identifiers Service - Conformance Profile [ADHA2025a].

## 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 [ADHA2025a]. 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 in the conformance profile [ADHA2025a]. Support for some of the conformance requirements is mandatory for the selected business use cases, while others are recommended.

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. Business use cases 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 Profile requirements section 2.4.

## 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, 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 (NOC).

Services Australia manages the NOC testing process to test that a software system can connect to the HI Service. Services Australia does not charge developers for NOC testing.

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



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 (test) environment allows developers to develop and test their HI implementations to ensure they can 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:

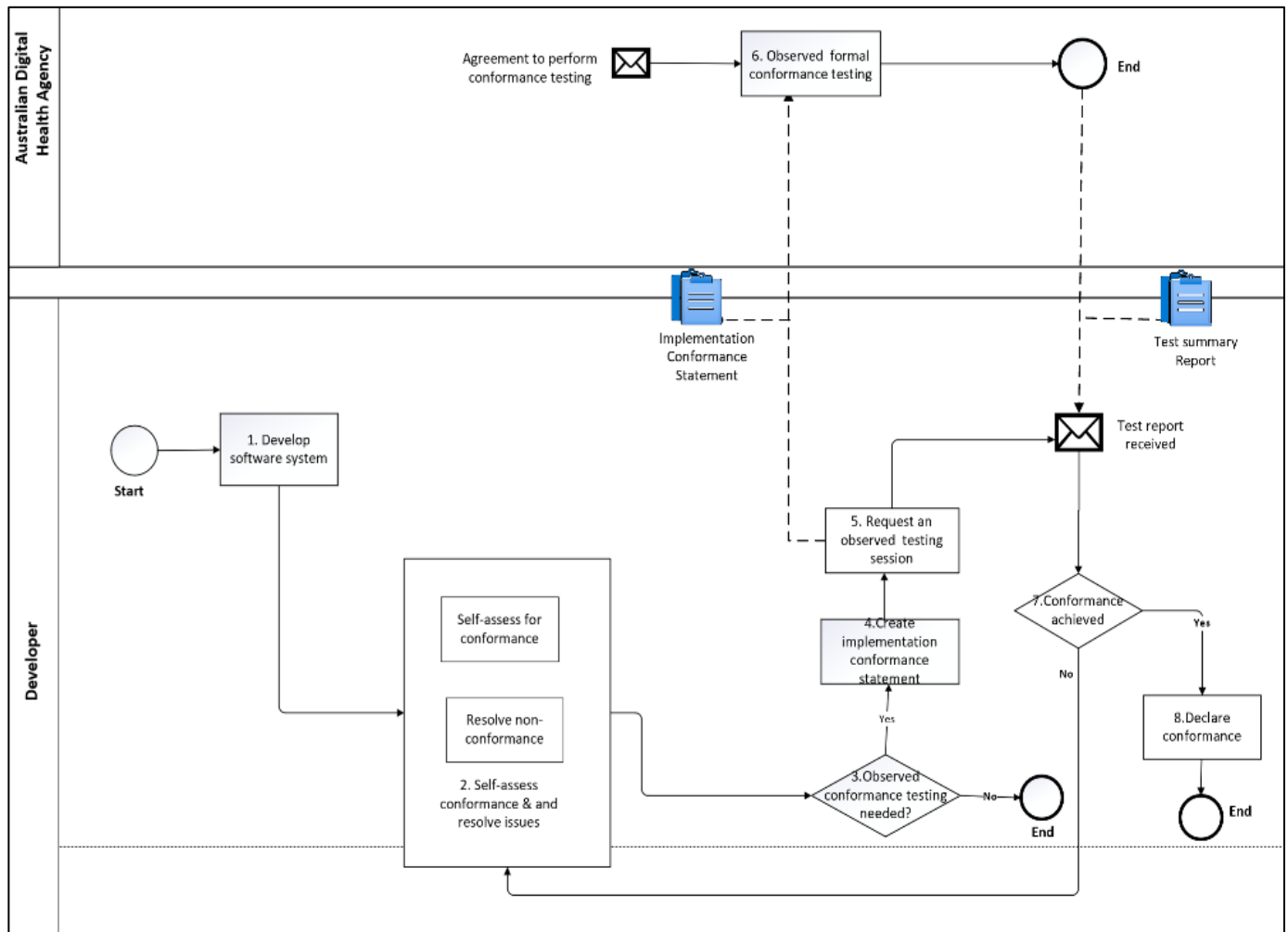
<https://www.servicesaustralia.gov.au/organisations/health-professionals/subjects/healthcare-identifiers-service-software-developers>

### 3 Conformance assessment process

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

#### 3.1 HI conformance assessment

HI conformance assessment tasks are illustrated below.



HI conformance testing tasks are described below, including decisions on which tasks need to be performed.

	Process Item	Type	Description
1	Develop software system	Task	The developer creates, or modifies, a health system that uses healthcare identifiers.
2	Self-assess conformance and resolve issues	Task	Once an HI implementation has been created or modified, 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 for an observed conformance testing, if any of the following is true (see section 4.1):</p> <ul style="list-style-type: none"> <li>• The HI implementation has not previously been declared conformant.</li> <li>• A new version of the HI implementation has been created that affects the implementation's conformance to the HI software requirements.</li> <li>• 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.</li> <li>• A new version of the conformance profile requirements has been issued and the developer wants to claim conformance to this new version.</li> <li>• A new version of the HI implementation has been created with changes to software components that access and/or manage healthcare identifiers.</li> </ul>
4	Complete an Implementation Conformance Statement (ICS)	Task	The developer completes 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 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 conformance profile 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).

## 3.2 Implementation Conformance Statement

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 or 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
- may be used by an organisation wanting to procure a HI implementation, to specify the features they require.

An ICS for healthcare identifiers is provided for developers [ADHA2025b]. The developer is responsible for describing their HI implementation in the ICS.

The ICS is used as follows:

1. The developer obtains an ICS, which has instructions for completion.
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.
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.

## 3.3 Conformance test specifications

The HI conformance test specifications [ADHA2025c] 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 ICS, so that applicable test cases can be applied.

## 3.4 Success criteria

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

- The HI implementation must support the mandatory and relevant conditional conformance requirements that correspond to the relevant business use cases [ADHA2025a].
- A 100% pass rate is required for the test cases (section 3.3) corresponding to these mandatory and relevant conditional conformance requirements.
- 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. This 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 conformance profile 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.
- 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 declaring conformance.

### 3.6 Declaring conformance

Prerequisites for declaring the conformance of an HI implementation are:

1. Conformance test success criteria must be met (section 3.4), and
2. Conformance testing must be performed by the vendor while 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 [ADHA2025e] and supporting implementation conformance statement to Services Australia ([DevSupport@servicesaustralia.gov.au](mailto: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. 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 conformance 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.

Listing the HI implementation in this register is the Agency's public declaration of the conformance.

## 4 Ongoing validity of conformance

### 4.1 Conformance and implementation 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
- 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 additional features (i.e conditional requirement 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.
- A conforming system is modified so its existing support for conformance profile 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.
- 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 Service Conformance Profile requirements

If a version of the conformance profile requirements is superseded by a new version, an HI implementation that has been declared conformant must conform to the new version 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

Software assessed as conformant against version 5.0 or later of the HI Service Conformance Profile has a conformance validity period of 3 years from the date of the latest production access letter issued by Services Australia. These conformance start and end dates will be recorded on the published HI Service Conformance Register.

The software declaration of conformance applies only to the version of the HI implementation, and the version of the conformance profile requirements, identified in the declaration of conformance.

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

The implementation will remain conformant when the following conditions apply:

- The software vendor has declared conformance to the current conformance profile or related technical documents including the conformance assessment scheme (this document) if the previously declared conformance profile is sunsetted.
- The software developer must always comply with the obligations specified in the HI Conformance Vendor Declaration Form.
- The software is re-tested in accordance with section 4.1 of this document.
- The software developer demonstrates an action plan for resolution of any investigation or incident.
- The software remains within the 3-year conformance validity period as recorded on the HI Service Conformance Register.

## 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.
healthcare identifier	An identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient as defined in the Healthcare Identifiers Act [HIACT2021].
HI implementation	A health software system that manages and uses local copies of healthcare identifiers.
Notice of Connection (NOC)	Services Australia's testing process to determine whether health software can connect to the HI Service.
test summary report	Documents the results of tests performed by the developer while being observed by the Agency.



## References

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