

Conformity Assessment Roadmap for Secure Message Delivery (SMD)

Current October 2010

CCA-26-02-013 V1.0

Introduction

The objective of this paper is to inform the medical software industry about the conformity assessment process supporting the national specifications for secure messaging in e-health. The method reflects NEHTA's general approach to software conformity assessment and is underpinned by a Consensus Statement endorsed by industry in 2009. The process is timed to support initial implementations of Secure Message Delivery (SMD), commencing in 2010, based on the SMD specifications contained in the Standards Australia Technical Specifications ATS5820-22.

Work to Date

The SMD secure messaging specifications have been developed by the Practice Incentive Program (PIP) Working Group, formed in March 2009 in response to DoHA's PIP 2009 scheme. These specifications have undergone further review and contribution by the IT14 community and have since been published as the Australian Technical Specifications ATS5820-22 through Standards Australia.

NEHTA has been working on the conformance assessment for SMD since September 2009 with the goal of providing an appropriate and consistent common base for conformance testing. In conjunction with the Conformance Subcommittee of the PIP Working Group, NEHTA has produced an SMD conformance assessment scheme and associated conformance test specifications.

Conformance test cases are constructed to address identified areas of risk for functional testing of both normal behaviour (positive testing) and exception behaviour (negative testing). The scope of testing is justified by, and traceable to, the risk assessment. Tests are structured to address specific messaging roles – eg sender, receiver – and the sets of test cases relevant to each role are listed in the test specifications.

The assessment scheme targets third-party testing as the desired means of testing, given the risks associated with many implementers needing to establish interoperability.

The proposed scope of testing is described in the conformance test specifications.

Developer Materials

SMD Conformance Assessment Scheme

This document describes the scheme for assessing the conformance of a health IT software system to the SMD specifications. It is the overarching document that describes the object of conformance assessment, how it is to be performed, who should undertake conformance assessment and the prerequisites for declaring conformance of an implementation.

SMD Implementation Conformance Statement

The SMD ICS proforma is a checklist that outlines the functional areas and optional conformance points of SMD. It

(ICS) Proforma	allows the user to indicate which of these functional areas and conformance points are supported by their implementation. The SMD ICS proforma supports the processes of testing and claiming conformance. It is used by developers to communicate to a test laboratory the options implemented and provides information to potential purchasers about the supported SMD features of an implementation.
SMD conformance test scenarios	The SMD test scenarios contain logical groupings of test cases that are applied when testing an implementation of SMD for conformance to the specification. The tests verify whether an implementation conforms to a group of requirements or conformance points. These test scenarios provide a high-level structure to support the definition of more detailed conformance test cases.
SMD, WSP and XSP conformance test cases	The conformance test cases translate each conformance point into a set of tests with a clear objective and criteria for passing.

The CCA test specifications are intended to provide a common baseline for use by test laboratories, software developers and systems integrators.

Standards Australia

NEHTA has included SMD conformance specifications in the IT-14 work program to become Standards Australia specifications, complementing the standards journey of the SMD messaging specifications ATS5820-22.

This will provide a broad industry consultation for the scope and methods for SMD conformance testing.

Consultation and Phase-in

The goal is to have SMD implementations available for third-party testing in early 2011. Until such a service is available, testing will rely on self-assessment.

Industry consultation on the SMD conformance test specifications is explicit in their submission to Standards Australia process and inclusion in the IT-14 conformity assessment task force.

Industry Testing and Tools

NEHTA is working with the National Association of Testing Authorities (NATA) to determine an accreditation scheme for independent test laboratories for SMD testing, making use of the SMD test specifications. The objective is to have an accreditation scheme available by the end of 2010 and accredited testing services available in early 2011.

NEHTA is producing test harness software for automated testing of SMD implementations which will be made available free to industry in support of developers for self-testing and test laboratories. The test harness software is not intended to have any mandatory use, however NEHTA recommends common-use tools as key to removing

cost barriers for the national take-up of SMD messaging and assisting a consistent approach to conformance testing.

The test harness software will be made available in phased releases from October 2010 and provided in complete form by March 2011. It will be made available to industry via the CCA Test Interest Group (TIG) web portal.

The cost of testing will be determined by services market forces, however NEHTA is keen to ensure the conformity assessment overheads are as low as possible by its investment in common-use test specifications and tools.

Summary

What do developers need to do? Developers can obtain SMD specifications ATS5820-22 from Standards Australia. These are available to download at no cost.

Developers can register with the NEHTA CCA Test Interest Group (TIG) to obtain SMD test specifications and software tools. To register, developers should send an email to cca@nehta.gov.au

There will be ample advance notice of any phasing-in and about the timing of any changes.

What will it cost? The cost of SMD third-party testing will be determined by the market and is yet to be defined.

What controls will there be over the amount of testing required? The software industry will be consulted about SMD assessment and testing requirements as part of the Standards Australia IT-14 program for conformity assessment.

For more information: contact the NEHTA CCA team at cca@nehta.gov.au.