



Specifications and Standards Plan

PCEHR System

Version 1.4 –9 November 2011

Final

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1 Introduction

1.1 Purpose of this Document

This document outlines the plan for the National E-Health Transition Authority (NEHTA) to:

- Develop, Deliver and Support NEHTA specifications based on available industry, Australian and International standards supporting the implementation of the Personally Controlled Electronic Healthcare Record (PCEHR) System by 1 July 2012.
- Contribute to the ongoing development of relevant Australian and International Standards associated with the PCEHR through Standards Australia's IT-014 work plan.
- This plan describes a strengthened end to end process for the development and documentation of eHealth requirements and confirms the ongoing intention and commitment to take the standards components of these through the formal Standards Australia processes.
- This document provides a schedule of deliverables associated with this plan.

This document is based on the September 2011 (final) release of the PCEHR System Concept of Operations (ConOps) [NEHT2011a], the PCEHR High Level System Architecture [NEHTA2011b], and will be updated to reflect:

- Later versions of the PCEHR Concept of Operations if required.
- Ongoing consultation regarding the PCEHR Concept of Operations.
- Learning from the lead eHealth Sites.
- Detailed design and planning with the National Infrastructure Partner (NIP), National Change and Adoption Partner (NCAP) and the Benefits Evaluation Partner (BEP).
- Feedback from software developers and implementers.

1.2 Objectives of this Plan

- To ensure that software developers and implementers will have an agreed set of logical and technical specifications to guide enhancement of their systems in order to participate in the PCEHR System.
- To provide specifications against which production-ready software can be tested for Conformance, Compliance and Accreditation, to be connected to the PCEHR System for 1 July 2012.
- To ensure that the specifications are built using available and applicable existing Standards¹, and where appropriate, that the specifications will be used to inform the ongoing development and implementation of relevant Australian Standards.
- To inform the scoping, resourcing and prioritisation of the Standards Australia IT-014 Health Informatics work program.
- Where relevant, to ensure that the development of specifications for the PCEHR aligns with and facilitates the Standards Australia development process, in such a way that NEHTA, Department of Health and Ageing, Standards Australia and the IT-014 Health Informatics community are clear on roles, responsibilities and deliverables.

¹ These may include existing NEHTA Managed Specifications, and national and international standards.

- To establish an approach to enable software developers and implementers:
 - To understand how they may participate in the development of the initial and ongoing versions of specifications (and related standards where relevant).
 - To know when and how versions of specifications will be published.
 - To be supported in their implementation of the specifications.

1.3 Scope of this Plan

The scope of this plan includes the full list of expected NEHTA Managed Specifications for the PCEHR System (artefacts) against which:

- Software developers and implementers can enhance their systems.
- Production ready software² can undertake Conformance, Compliance and Accreditation to connect to the PCEHR by 1 July 2012.

This plan includes the following information:

- The name and functional purpose of each artefact.
- Any existing specifications and/or standards on which each artefact will be based.
- For each artefact, whether it is to be proposed as a new or revised Australian Technical Specification (or other related Standards Publications as outlined in Appendix A), and if so, the proposed process³ and anticipated date when the new/revised Standards Publications may become available.
- The change management process which will govern the further development and release of versions of the artefact.
- An outline of the consultation process that NEHTA will undertake to develop each artefact, and harmonisation of NEHTA developed specifications with Australian Standards.

1.4 Intended Audience

This document is intended for:

- Prospective developers and implementers of PCEHR-related functionality, including jurisdictions, lead eHealth sites (Wave sites) and software vendors.
- The PCEHR National Infrastructure Partner (NIP), Change and Adoption Partner (CAP) and the Benefits Evaluation Partner (BEP).
- Standards Australia and the IT-014 Health Informatics community.
- Department of Health and Ageing eHealth Division, and state and territory health jurisdictions.

This document is based on, and assumes the audience has read, the September 2011 release of the PCEHR System Concept of Operations (ConOps) [NEHT2011a].

1.5 Related Documents

- PCEHR Concept of Operations v1.0 [NEHT2011a]
- PCEHR Standards Review [NEHT2011e]
- PCEHR Standards Analysis v3.8 [NEHT2011c]
- PCEHR Business Requirements v1.07 [NEHT2011f]

² Production software includes all software required to support components of the PCEHR System, including core PCEHR System components, conformant repositories, and clinical software systems.

³ The process will depend on whether a revision to an existing Australian Standard is proposed, or whether a new Australian Standard is proposed, and the type of Standard proposed (see Table 4 for types of Standards Publications).

- PCEHR High Level System Architecture v1.34 [NEHT2011b]

This document should be read in conjunction with the PCEHR Standards Review and Analysis documents, published at the same time as this document.

1.6 Questions and Feedback

Feedback from the review of this document should be provided by email to <pcehr@nehta.gov.au>.

2 Specifications Development

2.1 Specifications Developed for the National PCEHR System

The Australian Government will deliver a PCEHR System and associated services as part of a \$466.7 million investment announced in the 2010/11 federal budget. The PCEHR Programme will provide all Australians who wish to participate with the ability to register for their own personally controlled electronic health record from 1 July 2012.

The approach to building the national PCEHR System is based on a combination of 'top down' national initiatives and 'bottom up' lead implementation projects. This will allow the delivery of tangible eHealth project outcomes on the ground – critical for building clinical, consumer and political support for the national PCEHR agenda – while at the same time ensuring a focus on the national frameworks and actions required to deliver a national electronically interoperable health care system.

Lead Implementation Sites⁴ are made up of health sector organisations partnering to establish a community of interest focused on implementing PCEHR components. These components support sharing or aggregation of electronic health information at a geographic or sector functional level, such as health record repositories, discharge summary capabilities or medications management capabilities.

Successful implementation of the national PCEHR System (and other elements of the national eHealth programme) depends on having:

- Robust, stable and timely specifications available for use by participants in the National PCEHR System.
- A transparent process for consultative development and certainty of the management of necessary changes to specifications.
- Adoption of applicable existing national and international standards, and commitment to progress new specifications through the Standards Australia process.
- Responsible processes whereby candidate novel requirements for existing national and international standards are fed back through the standards development processes.

NEHTA is responsible for a range of activities required to deliver national eHealth capability, including the design and specification of the PCEHR System, the core components of which are to be developed and delivered by a National Infrastructure Partner, with oversight by NEHTA and the Department of Health and Ageing.

As a principle, NEHTA specifications will adopt existing specifications and standards, and may inform further development of these specifications and standards. It is noted that there has been extensive work in Australia on the development of health informatics standards by Standards Australia's IT-014 Health Informatics community. This range of existing Australian Standards includes a number of standards that support integration of eHealth systems, many of which are based on international standards. In addition, NEHTA is committed to progressing novel specifications, where a suitable existing Standard does not exist through the Standards Australia development and publication process.

The PCEHR and related foundational development is under a very strict timeframe to implement an operational PCEHR which meets the policy intent and useability requirements of health care professionals and Australians from 1 July 2012. The take-up and effectiveness of the PCEHR is based on voluntary support from healthcare professionals as well as the software industry that supports them and an opt-in for people who want to register for and use a PCEHR. Given the reliance on

⁴ <http://www.nehta.gov.au/ehealth-implementation/pcehr-lead-sites>

Third Party Software Developer support for this program, it is an imperative that the final documented specifications and associated standards are available as early as possible, and that they remain stable with consistent change control across all specifications and standards. It is also essential that all stakeholders, including Third Party Software Developers, can and do participate in the development of specifications and standards to maximise the potential of the PCEHR System and its adoption.

The PCEHR system (Figure 1 below) encompasses a series of specifications for the core PCEHR system interactions, integration with National eHealth Foundations infrastructure services and specifying the exchange of clinical documents.

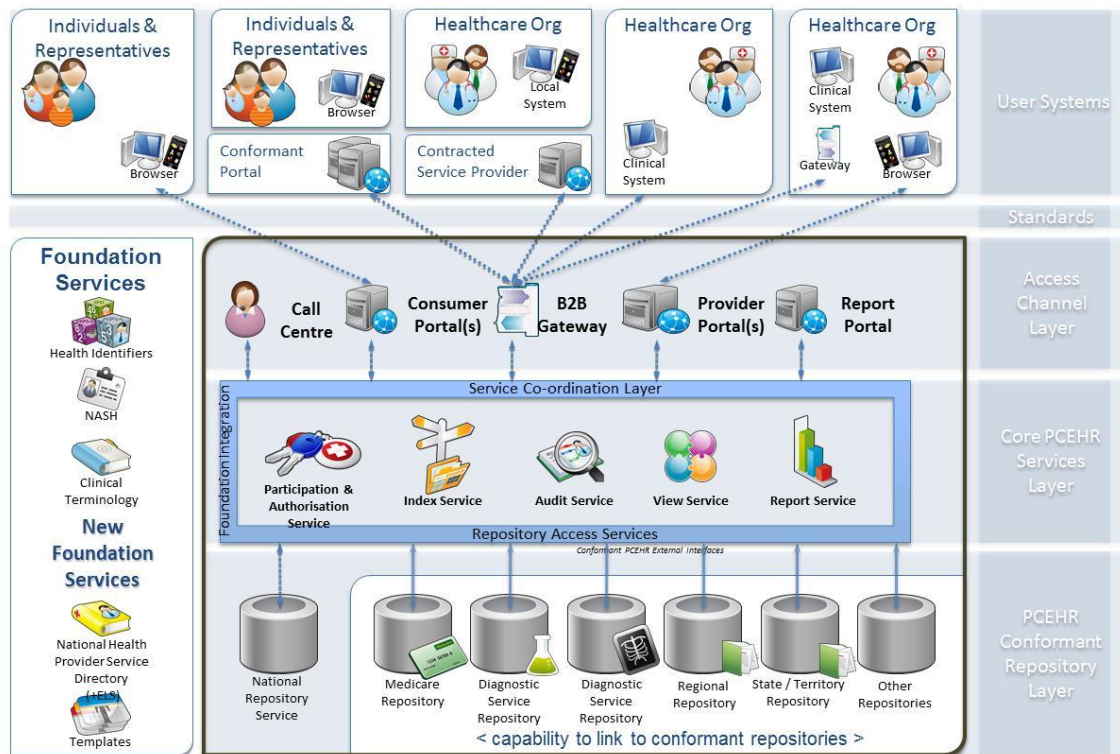


Figure 1: PCEHR conceptual system diagram⁵

The various specifications that are to be delivered for the PCEHR System and their logical groupings are outlined below:

Clinical Documents

- Advance Care Directive
- PCEHR Consolidated View
- PCEHR Consumer Entered Information
- Discharge Summary
- Electronic Medications Management
- eReferral
- PCEHR Event Summary
- PCEHR Shared Health Summary
- Specialist Letter

PCEHR Core System

- PCEHR B2B Gateway
- PCEHR Call Centre Service
- PCEHR Core Security - PCEHR Security Policy
- PCEHR Participation & Authorisation Service
- PCEHR Conformant Portal
- PCEHR Portlet Catalogue Service

⁵ The National Health Services Directory is a Government initiative under the leadership of the National Health Call Centre Network (NHCCN) of which NEHTA is actively engaged to ensure functional design integration and interoperability with the PCEHR.

- PCEHR Repository Services
- PCEHR Conformant Repository Services
- PCEHR Template Service

eHealth Foundations

- eHealth Architecture
- PCEHR Foundation Clinical Informatics
- National Authentication Service for Health (NASH)
- Secure Messaging Delivery
- Healthcare Identifiers Service (HI)

2.2 Specifications Change Control

Management of changes to specifications is vital to provide stakeholders and industry with confidence and assurance in both the processes undertaken and the specifications delivered. NEHTA specification development will provide the same stability and operate in a similar manner to the Standards change control processes.

It is NEHTA's intention to ensure that specifications are made available as soon as possible to support software vendors and implementers. NEHTA will also ensure that these final releases are developed collaboratively through focused workshops and workgroups.

Specification Publication

As outlined above, NEHTA specifications are published under strict release controls, ensuring that the specification meets determined requirements and has achieved the necessary and compulsory assurances steps for Interoperability, Clinical Assurance and Useability. In co-operation with the PCEHR National Change and Adoption Partner, a new collaborative portal / website the Learning Centre for Vendors has been launched in order to publish all Ready to Implement – National PCEHR specifications. This site will include capabilities to suitably register users who access the specifications, ensuring that important specification related notifications can be communicated.

The new service will ensure Vendors and Implementers are notified of any change proposal and the proposed timing before any change is approved. The specific details of this site will be provided when they become available through NEHTA's web site, and will accommodate access to completed specifications by implementers and software vendors in line with the delivery dates provided via the "Specification & Standards Roadmap" available on the website.

The NEHTA vendor integration web site is located at:

<http://www.nehta.gov.au/vendors>

In addition, the PCEHR Specifications Delivery Schedule is provided as Appendix B to this plan.

Specification Support

All specifications released for Lead Implementation Sites and the national PCEHR System will be supported for a minimum of two years from the release date, and will remain stable from their release date with changes strictly managed to meet specific criteria. NEHTA specifications are version controlled and required changes will be reflected as increments of the specification version number.

Change Control Principles

Change control processes and structured release management for specifications provides assurance for software vendors and implementers, ensuring that change to the specifications occurs for specific reasons, namely:

- Critical errors/issues identified that could impact patient safety.
- An issue exists within the specification that means it will cause problems in connecting to the national infrastructure.
- There is a legislative requirement.

NEHTA, in consultation with the Department of Health and Ageing, has developed a robust change control process to support specifications for the lead implementation sites and the National PCEHR System. This change control process ensures that requirements for change from the sector, that are based on the principles outlined above, can be collected, assessed, considered and approved for endorsement, and ultimately communicated to vendors and implementers via the publication process and a notification system. Vendors will be invited to participate in the change control process.

Requests for change of specifications or other enquiries in regard to the specifications should be directed to pcehr@nehta.gov.au email address, or by contacting the PCEHR Programme by telephoning NEHTA on (02) 8298 2600.

Notification of change

A notification process has been established so that software vendors and implementers are advised of critical changes to specifications in advance of the changes being implemented. This process will be outlined on the Learning Centre for Vendors, and incorporated into the new publication service.

New Specifications

New versions of specifications are projected for release at a future point (at a minimum post July 2012 and likely to tie into the release of the Standards Australia publications where this is applicable) and may be required to address additional lessons learnt through implementations, to provide new features or enhancements and consider advice from the vendor and standards community engagement.

2.3 The Role of NEHTA within Standards Development

The development of nationally consistent Standards publications for eHealth software and service delivery is a core principle underpinning NEHTA's work programme. It is a vital mechanism for ensuring the quality and consistency of domestic systems and effective alignment with international products and services.

Part of NEHTA's purpose, articulated in the NEHTA Strategic Plan Refresh 2011/2012 [NEHT2011c] is:

To enable the progression and accelerate the adoption of eHealth through infrastructure integration and standards for health information.

The Strategic Plan includes two guiding principles and several strategic priorities directly related to this Standards Plan.

Related Guiding Principles:

Guiding principle 6: Remain at the forefront of legislation, policy, and standards development related to eHealth.

Guiding principle 8: Work with industry to establish products that are standards based and support the delivery of an industry based conformance, compliance and accreditation function for health standards, in line with the CCA consensus statement.

Related Strategic Priorities:

Strategic priority 1.1 Define, inform and support the national eHealth architecture and standards

Action 6: Ensure that NEHTA-developed specifications are progressed through Standards Australia to become national standards where appropriate, with support provided for their adoption and utilisation in industry.

Strategic priority 3.2 Deliver the core components of the PCEHR by July 2012

Action 4: Facilitate the development of standards to support the core PCEHR capabilities.

Action 5: Facilitate the development of conformance tests to support the core PCEHR capabilities.

Strategic priority 4.3 Drive the successful delivery of eHealth implementations across the nation.

Action 7: Drive implementation capability uplift within NEHTA and eHealth sites, to ensure projects are set up for success and meet their goals. Provide vendors with a range of implementation support, such as Implementation Toolkits to assist vendors with product development.

These guiding principles and strategic priorities require NEHTA to work collaboratively with industry, to contribute to and observe lessons from the national and international eHealth community, and to drive the development of national and international standards across eHealth initiatives. This fundamental position drives the engagement rationale for specifications development by NEHTA.

2.4 Working with Standards Australia

NEHTA has committed to working together with Standards Australia to deliver specifications which are suited to form the basis for development within the Standards Australia's IT-014 Health Informatics community, and to subsequently enable conformance testing using the National Association of Testing Authorities' accredited testing facilities, as agreed in the CCA Consensus Statement.

A close working relationship between NEHTA and the Standards community is supported by Standards Australia and the Department of Health and Ageing, and it is expected that the community will play a key role in the successful deployment of eHealth systems in 2011/2012 and into the future.

Standards Australia will be working closely and consulting with the IT-014 community to agree on committee capacity to develop and deliver on this program of work. It is acknowledged that the target publication dates are subject to review and change after the First Committee Draft has been reviewed by the relevant IT-014 subcommittee or working group.

2.5 PCEHR Standards Review and Analysis

In January 2011, NEHTA engaged an independent Standards Consortium, made up of local and international experts from the Standards Community, to review the PCEHR Concept of Operations (April edition) and recommend the most appropriate Australian and International Standards to support specification, development and delivery of the PCEHR System for use in the Australian health sector.

Using the review and the PCEHR High-Level System Architecture (HLSA) [NEHT2011b], NEHTA produced a comprehensive analysis of these Standards (the PCEHR Standards Analysis [NEHT2011c]) to be applied to the design, profiled for use within specifications, or developed for the PCEHR. The analysis identified 145 functional areas where Standards are relevant within the context of delivering the PCEHR System.

Following analysis of these 145 functional areas, NEHTA identified 49 discrete work items to be delivered (based on PCEHR Release 1 priorities and other required NEHTA specifications) to realise the functionality needed by PCEHR and lead implementations sites for 1st July 2012.

Figure 2 is a graphical summary of these above inputs into development of this Specification and Standards Plan and the resulting work plan.

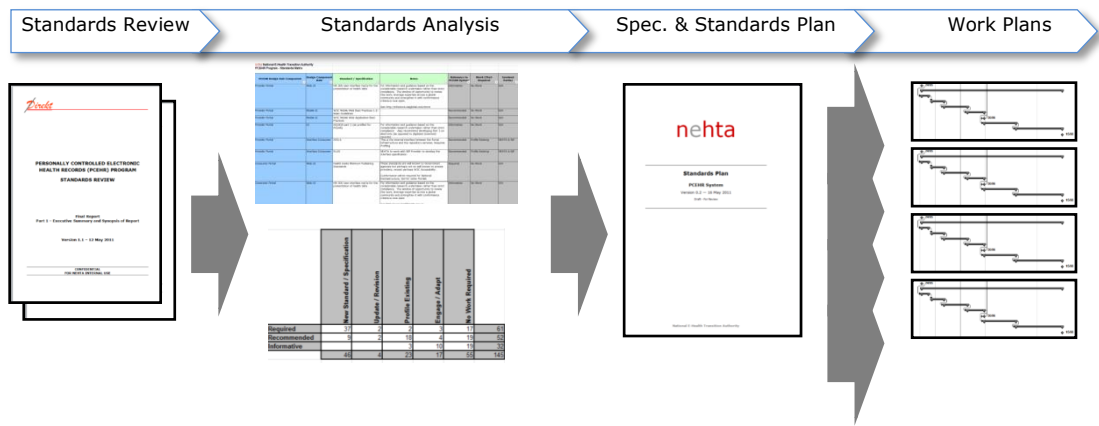


Figure 2: Development of NEHTA specifications and Standards Plan

The Proposed Programme of Work (detailed in section 4) and Delivery Schedule (detailed in Appendix B) provides the basis for managing and delivering work plans to ensure the necessary specifications and Standards publications are delivered as required.

2.6 Compliance, Conformance and Accreditation

Conformance and compliance regimes are required for software vendors implementing against NEHTA specifications, requirements and standards. NEHTA will adhere to the Compliance, Conformance and Accreditation (CCA) consensus statement.

The current approach to compliance, conformance and accreditation is via a staged implementation of the regime. Lead implementation sites will use test labs to test conformance to functionality when test lab accreditation has been established. This currently includes Secure Messaging and Healthcare Identifiers and this list is expected to grow over time. For other specifications where test lab accreditation is not complete, there will be self-assessment with declaration of conformance. The self-assessment will evolve into specifications that test labs will be accredited to test, following a risk assessment to determine if first or third party testing is appropriate.

The observed self-assessment approach is applied in this manner as it is the only approach that can be used before industry consultation on CCA is completed and test labs are accredited for all specifications. The conformance test cases and processes being used in Lead Implementation Sites provide an effective trial for the specifications, and will be enhanced based on lessons learnt in these sites.

It is expected that the experience gained in the Lead Implementation Sites programme will place NEHTA in a favourable position to begin broader industry consultation and prepare for further test lab accreditation.

Testing for conformance to specifications for the national PCEHR Systems will be performed by test labs accredited by the National Association of Testing Authorities (NATA) to perform PCEHR conformance testing.

3 Specifications and Standards Development Strategy

This section describes the NEHTA specifications development and publication process in greater detail, and its alignment to the Standards Australia development and publication process. In addition this section provides an overview of current processes and describes the rationale for change and the process that has emerged through joint development with the Department of Health and Ageing, Standards Australia and advice and guidance from industry experts.

The NEHTA specifications development and publication process is relevant to all NEHTA specifications articulated in this plan.

The NEHTA specification development process will be one of the following:

- Adopt and profile applicable existing Standards in line with the PCEHR Standards Analysis.
- Collaborate with Standards Australia on the development of new Standards Publications, as described below.
- Produce Specifications that do not need to be established as an Australian Standard.

NEHTA will continue to drive development of Specifications through its engagement mechanisms with stakeholders and industry and will also continue to focus and contribute its effort and leadership through the Standards Australia IT-014 Technical Committee and its sub groups.

The current and proposed processes are described below, as well as the rationale for change.

3.1 Current Development Strategy

The current process to develop Standards Australia publications is through two separate, related processes – the NEHTA specification Process and the Standards Australia Development Process. The connection is maintained through the NEHTA specification publication, which is used as an input to the Standards development process.

Figure 3 illustrates the two processes.

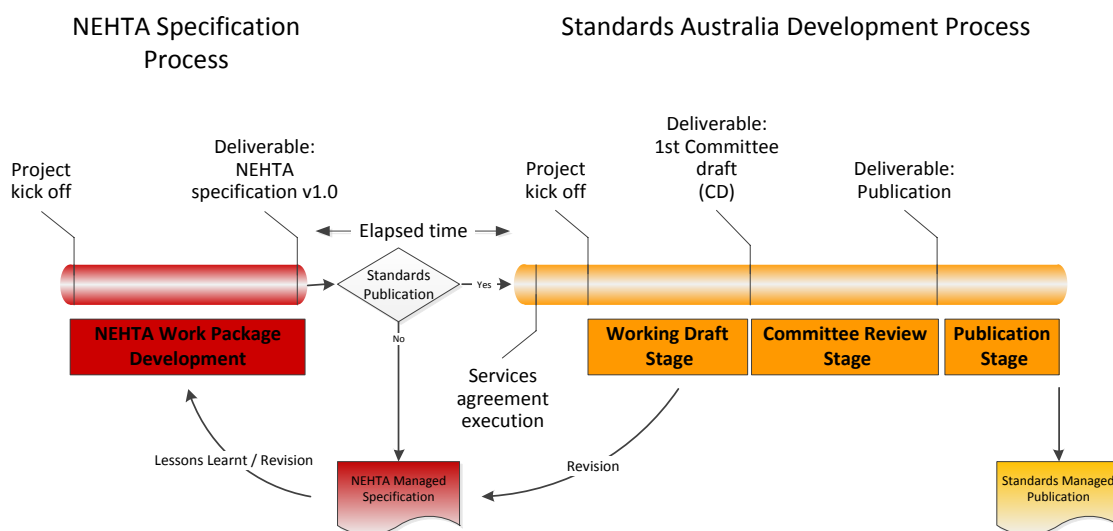


Figure 3: Current Process for Standards Development

The NEHTA Work Package Development Stage delivers a NEHTA Managed Specification and makes this available to vendors through publication to NEHTA's vendor integration web site. This is followed by an often considerable time delay while a proposed work item for Standards Australia is developed and submitted to the Department before the Working Draft Stage of the Standards Australia development process begins. This process lag allows for significant variance, miscommunication and uncertainty regarding the status of the various specifications.

Considerable re-work is often required during the Working Draft Stage, due to the length of elapsed time, as well as the lack of skills and knowledge continuity that often occurs between the two processes.

This document outlines a plan that seeks to address and mitigate these concerns.

Overview of NEHTA specification Process

NEHTA produces eHealth specifications for interoperability⁶ as the output of projects that are managed in accordance with the PRINCE2⁷ and MSP⁸ project and programme management methodologies.

NEHTA employs a Product Development and Delivery Policy describing our approach to specifying a top-level product delivery framework, product controls, accountabilities and responsibilities and end-to-end lifecycle management disciplines. NEHTA has adapted ITIL⁹ IT Service Management controls for its product control approach. ITIL IT Service Management controls are separated into four main control areas:

- Product Strategy Controls – concentrates on ensuring that a strategy is defined, maintained and implemented. It introduces concepts such as value creation, market definition and solution space. It focuses on enabling practical decision making and maximising the economic life of products.
- Product Design Controls – start by setting clear business, information and technology requirements, and leads into the development and delivery of solution design artefacts that meet those defined requirements and outcomes. Product Design ensures appropriate harnessing of availability, capacity, continuity and service level management concepts, and supplier management including warranty and utility.
- Product Transition Controls – bridge the gap between development projects, and implementation and operations delivery projects. It provides clear accountabilities and responsibilities for key processes like change, configuration and release management.
- Product Operation Controls – ensure that there are robust end-to-end practices which support responsive and stable delivery and continuous improvement.

Within the Architecture and Design discipline, NEHTA applies rigorous application of industry best practice architecture methodologies (for example TOGAF¹⁰ and ATAM¹¹) and requirements management and process modelling tools ensuring that specifications have traceability to requirements, are fit for purpose, are consistent, integrated and interoperable.

Key aspects of the process by which NEHTA develops work products include:

- Use of Reference Groups as endorsed by NEHTA's Stakeholder Reference Forum¹² and focussed workgroups and workshops comprising representatives of

⁶ NEHTA also produces frameworks, guides and designs, and manages operations of national eHealth infrastructure. This document is particularly interested in specifications for interoperability and their related journey to Standards Publications.

⁷ <http://www.prince-officialsite.com/>

⁸ <http://www.msp-officialsite.com/>

⁹ <http://www.itil-officialsite.com/>

¹⁰ <http://www.opengroup.org/togaf/>

¹¹ <http://www.sei.cmu.edu/architecture/tools/evaluate/atam.cfm>

¹² <http://www.nehta.gov.au/about-us/stakeholders>

all key stakeholder groups including vendors and industry representatives who provide input, guidance and endorsement of work products during their development.

- Involvement of NEHTA clinical leaders and clinical safety unit at all stages of development.
- Involvement of NEHTA eHealth Architecture and Analyst Capability Practice specialist resources.
- Involvement of NEHTA Privacy and Policy, Security and Standards and Interoperability units.
- Engagement of external consultants to contribute specialist knowledge.
- Application of NEHTA design, architecture/interoperability and clinical safety governance processes to ensure a quality outcome that is fit for purpose and fit for market.
- A managed programme of public consultations and communications before release and following publication. This includes mechanisms to manage and control the publication and engage with the public to collect feedback, as well as controlling necessary changes and notifications.
- Use of the NEHTA Reference Platform to build reference implementations and to support integration of vendor products and provide direct integration support to software vendors through NEHTA's Vendor Panel agreements.

A typical project delivers a number of work products, including:

- **Concept of Operations:** a user-oriented document that describes the characteristics for a proposed system from the viewpoint of the individuals and organisation who will use it.
- **Community Model:** an architectural model that formally defines the business context for a particular eHealth solution in terms of communities, roles and policies that constrain the community participants.
- **Clinical Scenarios:** a scenario uses a series of healthcare activities to describe the anticipated impact that the introduction of a new eHealth service will have.
- **Business Requirements and Detailed Information Requirements:** these specifications include testable statements of requirements aligning to both clinical and administrative use cases and scenarios to describe the solution.
- **Solution Design:** this describes the reference architecture. It includes platform-independent architectural models as well as principles, patterns and standards that apply to implementations. Design decisions embodied in the Solution Design are traceable back to the business requirements.
- **Logical Service Specification:** a logical specification for one or more eHealth services.
- **Structured Content Specification (SCS):** defines the logical information models for the clinical information payloads that will be transferred by an eHealth service. (previously named Structured Document Template)
- **Technical Service Specification:** an implementable specification that conforms to the Logical Service Specification.
- **CDA Implementation Guide:** specifies conformance requirements for the clinical information payloads that will be transferred as CDA documents and necessary guidance on the appropriate rendering of the document.
- **Conformance Test Plan:** specifies the relative conformance points, and compliance test plan for a specification. The plan should be relative to the maturity of both the specification, and the market implementation maturity.

Although not all the work product deliverables are directly relevant to the development of Standards Publications, they are all important in providing context and rationale to items such as Structured Content Specifications, and Logical or

Technical Service Specifications. These items are ultimately the input to a Standards development process and, importantly, used in the development of health software products.

Overview of Standards Australia Development Process

The current Standards Australia Development Process has six stages of activity:

Stage 0: Proposal Stage

The Proposal Stage is the first stage in development of a Standard. It involves the submission of a new work (project) proposal by an external proponent, followed by a formal evaluation and approval of the project by Standards Australia. At this stage, the Project Manager (PM) responsible for delivering the project is usually appointed.

Stage 1: Working Draft (WD) Stage

The Working Draft Stage covers the preparation of a Working Draft (WD). A WD should include a basic framework for the draft document and propose the best technical solution to the problem being addressed. The objective of the WD Stage is to provide the Committee with a First Committee Draft (CD) and hence a starting point and focus for discussion and comments. Ideally, the WD should be provided with the Project Proposal – in these cases, this stage maybe omitted.

Stage 2: Committee Review Stage

The Committee Review Stage is the principal stage during which comments from Committee Members are taken into consideration, with a view to reaching Committee agreement on the technical content of the draft to be released for Public Commenting. Successive Committee drafts may be considered until agreement is reached on the technical content. Once Committee agreement has been attained, the text is finalised for submission as the Public Comment Draft Standard (PCD).

Stage 3: Public Commenting Stage

The Public Commenting Stage is the stage during which the Public Comment Draft Standard (PCD) is formally made available to the public for comment and the comments received are reviewed by the Committee. Once agreement has been attained regarding the resolution of the public comments, the draft Standard is finalised for submission as the Committee Ballot Draft (CBD).

Stage 4: Balloting Stage

The Balloting Stage is the stage during which the Committee Ballot Draft (CBD) is circulated to all Committee Members for a formal vote to approve the draft Standard.

If the approval criteria are met (includes achievement of consensus), then the Standard is available for publication. If the approval criteria are not met, then the Standard is returned to the Committee for reconsideration.

Stage 5: Publication Stage

Once a final draft Standard has been approved, only minor editorial changes (i.e. typographical but no technical content changes), if and where necessary, are introduced into the final text. The final text is sent to SAI Global to publish the Standard.

Stage 6: Review Stage

All Standards are regularly reviewed to determine whether the Standard remains current, requires amendment, should be withdrawn or is now obsolete.

3.2 Rationale for Change

As described above, many of the NEHTA specifications will be progressed towards Australian Standards publications. The rationale for harmonising the processes described above is based on a number of factors and influences, including the following.

- The current NEHTA specification process is rigorous, with high levels of stakeholder consultation. However, the resulting specification deliverables, while comprehensive, will benefit from formal recognition of status from the Standards community.
- There is often a considerable amount of time between the completion of the NEHTA Work Package Specification Stage and the start of the Standards Australia Working Draft Stage.
- This time lapse in the development lifecycle results in loss of applied knowledge, history and learning, and often results in considerable re-work and re-education being performed during the Working Draft Stage. This would make it difficult to manage variance between final NEHTA specifications implemented into lead sites and further specification and standards development.
- From a resourcing and skills perspective, some of the subject matter experts are involved in both the NEHTA Work Package Specification Stage and the Standards Australia Working Draft Stage, which is a duplication of effort. This is unsustainable given the scarcity of subject matter expertise in this field and the reality of time pressures on the PCEHR Programme.
- The tight timeframes for the development and delivery of the PCEHR System, balanced against NEHTA's strategic priority to lead the development of eHealth Standards, mean that a new optimised and connected process is required.

3.3 Proposed Development Strategy

This section outlines the proposed new development strategy to develop NEHTA specifications that are required to move into the Australian Standards development processes. The proposed new development strategy has been developed in collaboration with Standards Australia, Chair of IT-014, Chair of HL7 Australia, Department of Health and Ageing and NEHTA. It takes into account the following key perspectives:

- Standards Australia Development Process
- NEHTA Product Development and Delivery Lifecycle
- eHealth Lead Implementation Site requirements
- PCEHR requirements and timeframes

The proposed development strategy uses Tiger Teams to jump start the development of specifications towards publication. This Tiger Team approach has been successfully used by NEHTA and its stakeholders in the past to tackle problems in a focussed and output-driven manner.

Definition: Tiger Team

A Tiger Team is a group of experts assigned to investigate and/or solve technical or systemic problems.

One of the earliest known references to a Tiger Team is believed to have been from Aerospace Design, in 1964 when it was said "In case the term 'tiger team' is unfamiliar to you, it has been described as a team of undomesticated and uninhibited technical specialists selected for their experience, energy, and imagination, and assigned to track down relentlessly every possible source of failure in a spacecraft subsystem"

Taken from Wikipedia

For NEHTA purposes Tiger Teams are groups of subject matter experts brought together to work on a particular problem or issue related to the eHealth Program. This would include aspects of clinical use, consumer advocacy, government policy advice and technical use and speciality.

NEHTA will leverage its existing approach and methodology to establish and manage the required Tiger Teams drawing significantly on our stakeholder community through the NEHTA Reference Groups. As a principle, NEHTA seeks to engage early and often, providing as much lead time as possible to Tiger Team members to ensure that critical information can be considered, including management of feedback to inform solution design.

NEHTA's PCEHR team, in consultation with NEHTA's Reference Group co-chairs, will:

- Propose the formation of the appropriate Tiger Teams, and their respective Reference Group reporting relationships.
- Support the formation of the Tiger Teams, including providing key resources and recommending membership nominations from the following areas, as appropriate:
 - subject matter experts, including clinical representation
 - vendor and industry
 - National Infrastructure Partner
 - Benefits Evaluation Partner
 - Change and Adoption Partner
 - Lead site implementation partners
 - membership from the IT-014 Health Informatics community
- Support the management and operations of the Tiger Team activities as required.

The Tiger Teams will contribute to the development of NEHTA Managed Specifications (NMS), which will be supported in the market and which are implementation ready. These specifications may then be submitted to the Standards Australia development process where they will progress through the IT-014 committee processes to publication. NEHTA's responsibility is to provide leadership and active support to see NEHTA Managed Specifications identified as Standards Australia candidates progressed through the Standards Australian publication and development process. This is shown in Figure 4.

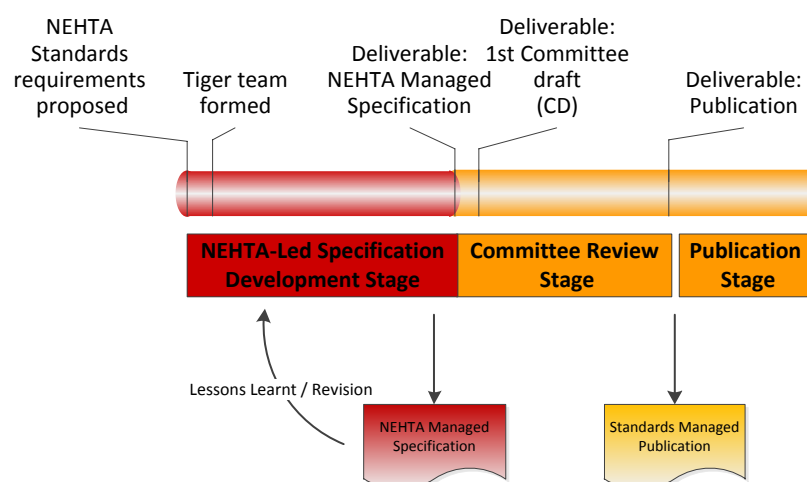


Figure 4: Proposed Process for Standards Development

It is critical that the Tiger Team process is open, inclusive and responsive to all issues raised and that the IT-014 community are tightly integrated into the development and communication process, actively soliciting, resolving and making available feedback, actions and contributions.

The new proposed development strategy using Tiger Teams includes a set of tasks mapped against the participants in those tasks, as shown in Table 1.

An important part of this aligned strategy is the effective management of variance of the NEHTA specification to the Standards Development process, whereby information from the Standards Development process can be drawn back to NEHTA for inclusion in future NEHTA specification releases within the designated Change Control Principles.

Table 1: Key tasks in proposed development strategy

	Task	All Specifications / Publications		Required for Standards Publication		
		NEHTA	NEHTA Led Tiger Team	DOHA	IT-014-XX	Standards Australia
NEHTA-Led, Specification Development Through Tiger Team Activities						
NEHTA-Led Specification Development Stage	PCEHR Standards Requirements Proposal		✓		Via Standards Australia	✓ Support
	Tiger Team Formation	✓				
	Subject Matter Expertise	✓	✓	✓ Participating members	✓ Participating members	
	Knowledge Transfer	✓			Acceptance	On hold pending Committee draft
	Project Management	✓				
	Specification Drafting Cycle - draft, peer review and resolution	✓	✓		✓ Participating members	
	Approval from NEHTA Design Authority	✓				
	Completion of NEHTA Managed Specification (NMS)	✓	✓		✓ Participating members	
NEHTA Managed Specifications not continuing to Standards Publication may complete here.						
	Tiger Team Acceptance and Submission of Draft to IT-014 -XX	Accept			Accept	Receipt
First Committee Draft (CD) Delivered / Transition to Standards Australia						
	Acceptance of IT-014 Work Plan and Execution of Contract (Acceptance as Committee Draft (CD))			✓	✓	✓
Committee Review Stage	Project Management					✓
	Committee Review Process	✓ Participating members			✓	✓ Resources Required
	Editorial Checking and Proofreading					✓
	Distribution for Peer Review					✓
	Receipt of Peer Review Comments					✓
	Resolution of Peer Review comments	✓ Participating members			✓	✓
	Conflict Resolution if Required	✓ Participating members			✓	✓
	Ongoing Management of Variations	✓				
	Editorial Checking and Proofreading					✓
Publication Stage	Committee Request Publication	✓ Participating members			✓	
	Notify IT-14 Parent Committee of Publication					✓
	Editorial Checking and Proofreading					✓
	Publication and Distribution					✓
	Review and Maintenance of Publication	✓ Participating members				✓

3.4 NEHTA-Led Specification Development Stage

This section gives a high level description of each of the activities in the NEHTA-Led Specification Development Stage outlined in Table 1 above.

PCEHR Standards Requirement Proposal

A work item proposal (scoping of work required) is submitted to IT-014-XX sub-committee and, once accepted, goes to the IT-014 Parent Committee for acceptance to then submit to the Department for formal acceptance and approval for the work programme.

Note: If the IT-014-XX committee is unable to participate, for whatever reason, the work item proposal will go directly to the IT-014 Parent Committee for consideration.

Tiger Team Formation

Tiger Teams have been identified based on the need to address a number of work bundles identified in the PCEHR Standards Requirements. Five Tiger Teams have been identified, with each team progressing one or more work bundles.

The teams and their proposed work bundles are as follows:

- Continuity of Care
 - Discharge Summary
 - eReferral
 - Event Summary
 - Shared Health Summary
 - Advance Care Directive
 - Consolidated View
 - Specialist Letter
 - Consumer Entered Information
- Medications Management
 - Electronic Transfer of Prescription
 - Electronic Medications Profile
- Technical and Identification
 - Identification
 - Architecture
 - Security
- Infrastructure Services
 - Secure Message Delivery and Business-to-Business Integration
 - Repositories
 - Portals and Portal Services
- Clinical Informatics
 - Foundation Clinical Informatics

It is proposed that Tiger Teams focussed on technical standards development are co-led by PCEHR participation and an IT-014-XX representative(s). If more than one of the IT-014-XX committees is involved, one would take the co-lead on behalf of the IT-014 community.

Tiger teams must also include suitable representation from the National Infrastructure Partner, Change and Adoption Partner, and the Benefits Evaluation

Partner, as well as contribution from the Lead Implementation Sites and Jurisdictions.

The terms of reference for Tiger Teams should reflect that the IT-014-XX nominees act on behalf of their committee and that they accept the two-way flow of information and documents – from the Tiger Team to IT-014-XX, and feedback from IT-014-XX back to the Tiger Team.

The precise approach to committee chairing will need to be ratified and driven by the time and content requirements of the PCEHR Programme.

Subject Matter Expertise

Tiger Teams focussed on technical standards development will call for subject matter expertise from IT-014-XX via Standards Australia. Tiger Teams will be assembled by PCEHR and the inclusion of funded IT IT-014-XX participants will be based on a nomination and selection process.

In addition, any self-funded IT-014-XX committee member can participate (consistent with IT-014-XX's usual participation practice). PCEHR (NEHTA) will facilitate the Tiger Team meetings, effectively providing the secretariat to the IT-014-XX committees on each topic.

Knowledge Transfer

Throughout the development process, NEHTA will ensure that all agendas, drafts and comment resolution documentation will be shared with IT-014-XX to ensure knowledge transfer.

Project Management

NEHTA will provide project management services throughout the NEHTA-Led Specification through coordination of Tiger Team activities.

Specification Drafting Cycle

The drafting cycle will follow the Standards Australia methodology for drafting, peer review and resolution of comments. This cycle may require additional Tiger Teams focussed to support this task.

Approval from NEHTA Design Authority

Once approval for a specification has been granted by the NEHTA Design Authority and/or a subordinate Programme Design Authority, a managed version of a specification can be released and published. The NEHTA Design Authority is responsible for ongoing change management of the NEHTA Managed Specification.

If a specification is destined to progress towards Standards Publications, the subsequent steps below will be followed.

Completion of NEHTA Managed Specification

Once all comments have been resolved and consensus reached, the Specification will be classified as a NEHTA Managed Specification (NMS). The NMS will be approved by the NEHTA Design Authority to signify that it is "implementation ready".

For specifications that are not destined to become Standards Publications, the development process will cease here, and the publication will come under NEHTA's standard version and change management control.

For specifications destined to progress towards Standards Publication, the subsequent steps below will proceed.

Tiger Team Acceptance and Submission of Draft to IT-014-XX

Completion of the NEHTA-Led Specification Development Stage will produce the following key outputs:

- NEHTA Managed Specification (NMS) that will be in an acceptable form for use within the industry. This specification will be supported as a controlled version by NEHTA;
- The NMS will be submitted to Standards Australia, along with key artefacts developed during this phase of the process including, but not limited to:
 - agendas of meetings or workshops
 - other relevant documentation, including drafts, comment resolution documentation and minutes if required

The provision of appropriate documentation gathered during the NEHTA-Led Specification Stage, along with continuity of membership through the inclusion of IT-014 members, should ensure an efficient transition to Standards Australia and into the Committee Review Stage – in terms of both time and continuity of knowledge management.

Tiger Teams support NEHTA to produce a NEHTA Managed Specification, and as outlined above developing a suitable information flow of relevant information and people into the Standards development process in necessary.

The Tiger Team process will need to support the consensus position for IT-014 Committee Drafts, of Standards Australia Publications, where appropriate.

One mechanism NEHTA may employ would be the establishment of specialist Tiger Teams that can support the transition of NEHTA Managed Specifications into artefacts suitable for review by Standards Australia, to achieve a consensus agreement with relevant IT-014 committees that the specification is fit to be published by Standards Australia as a Committee Draft. This is largely driven by the tight timeframes that the Program is operating too.

It is suggested that these specialist Tiger Teams would follow a specification development process based upon the IT-014 Standards Australia development processes where possible.

Committee Review Stage

Once the submission from the NEHTA-Led Specification Development Stage has been accepted by Standards Australia, the NEHTA Managed Specification becomes the Committee Draft for consideration by the relevant IT-014 sub-committee or working group.

At this point, the Standards Australia 'Committee Review Stage' continues in the same way it currently does.

NEHTA will play a key role through sub-committees by participating in the following:

- Committee review process.
- Resolution of peer review comments.
- Conflict resolution if required.

In addition, NEHTA will play an active role in the 'Ongoing Management of Variations' through continuously evaluating comments from the peer review process to determine their impact and influence upon NEHTA Managed Specifications.

Publication Stage

Once the Committee Review Stage has completed, the Standards Australia 'Publication Stage' continues in the same way it currently does.

NEHTA will play a key role through sub-committees by participating in the following:

- Committee request publication.
- Review and maintenance of publication.

The information presented in this section has outlined in detail the activities NEHTA will engage in when progressing specifications to Standards Australia publications. This process flow provides details on roles and responsibilities on NEHTA and the Standards Australia IT-014 community to work together.

Where a NEHTA specification has been published in advance of the Standards Australia process being finalised, there will be a reasonable period allowed from the time the final Standard is published for vendors to change their system to adopt the Standard and if necessary achieve CCA against the Standard. If a specification is to be replaced with a finalised standard, those vendors that have registered for the NEHTA specifications will be advised via email and consulted on appropriate timeframes for the implementation against the newly finalised Standard.

4 Specification Programme of Work

This section outlines NEHTA's specifications, the location to find out when they will be available for software vendors and implementers, and their relationship to existing standards and requirements for new standards development.

4.1 Explanation of Column Headings

Table 2: Explanation of column titles for proposed programme of work

Column Heading	Definition
Solution Bundle	Grouping of domain-specific artefacts that are allocated to the various Tiger Teams: EMM (Electronic Medications Management) etc.
Solution Description	This is a description of the Solution Bundle
Specification	The title of the specification, referring to the name of a NEHTA artefact. <i>Note: see section 4.2 for the naming convention.</i>
Existing Standards Publication	Any existing standards publications that are to be leveraged in the development of a specification.
New Standard Publication	The title / name of the candidate Standards publication to be delivered. In some cases this may not be known at the time of writing this document, but will be declared through NEHTA's eHealth Standards Catalogue in the near future.
Target Publication	The Work Programme date when Standards Australia anticipates to complete publication of the work item. This is subject to the number and complexity of comments received during peer review (for lower consensus documents where required) and public comment period (Australian Standards).
Publication Type	The expected publication type, for example ATS / ATR / AHB etc.

Note: Empty cells are greyed out where 'not applicable' to avoid confusion.

4.2 Specification Naming Convention

Each NEHTA specification contains a number of key component parts. Some of these parts are required in the development of the specification, and others are directly consumed by vendors supporting implementation and operation, or directing their software product's technological application of the specification.

The NEHTA specifications described in this plan relate directly to components that are used by software vendors and implementers. The complete set of all artefacts for NEHTA products are available on NEHTA's web site:

<http://www.nehta.gov.au>

Table 3 the Proposed programme of work for Specifications and Standards uses the following naming convention to describe the various specification deliverable items:

Solution Bundle – Bundle Composition

Where:

- **Solution Bundle** is the name of the solution bundle, for example 'eReferral'
- **Bundle Composition** is the name of the logical grouping of artefacts within the bundle. These generally fall into one of three categories:
 - *Logical Service and (Structured Content Specification or Structured Document Template)*: The "Solution" Logical Service is expressed as the Structured Content Specification or Structured Document Template. This is the information model that underpins the conceptual expression of the clinical payload that supports the specific clinical pathway. e.g. A Discharge Summary supporting Acute Care episode to General Practice. This logical model is abstracted away from the technology and implementation decisions that will be made during adoption. This is often referred to as "platform independent"
 - *Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)*: The "Solution" Technical Services include the components required to express the logical service through technology platform-dependent implementations. The Technical Services incorporates the chosen standardised methods to represent and transport the clinical content. For example, in the case of NEHTA a specification, the content is carried in an HL7 Clinical Document Architecture (CDA) XML package over Web Services, as described in the NEHTA Secure Messaging Delivery (SMD) stack.
 - *eHealth Conformance Profile*: The "Solution" Conformance Profile specifies the key points of conformity within the logical and technical services components. The Conformance Profile precisely describes how a vendor is expected to demonstrate compliance against the specification. For example, how the product "generates" the CDA Package, or "consumes" a CDA document sent from another organisation.

If an item does not fall into one of the above descriptions, it will be appropriately named.

4.3 Programme of Work for PCEHR Standards and Specifications

Table 3: Proposed programme of work for Specifications and Standards

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
Advance Care Directive	An Advance Care Directive, often referred to as a Living Will, is a written statement regarding someone's wishes for their future health care.	Advance care directive - Structured Content Specification and Logical Service		Advance care directive - Structured Content Specification and Logical Service	2013	ATS
Diagnostic Services	This community led ¹³ specification relates to Pathology and Medical Imaging (Diagnostics) Services.			Community Led: Diagnostic Services 4700.2	Jan-12	AS
Discharge Summary	e-Discharge Summaries will enable the electronic exchange of comprehensive and accurate patient reports between hospitals and primary healthcare sectors	Discharge summary - eHealth conformance profile		Discharge summary - eHealth conformance profile	Jun-12	ATS
				Community Led: Discharge Summary - Legacy Messaging Specification (HL7 v2)	Jun-12	ATS
		Discharge Summary - Structured Content Specification and Logical Service		Discharge Summary - Structured Content Specification and Logical Service	Jun-12	ATS
		Discharge Summary - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)		Discharge Summary - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)	Jun-12	ATS

¹³ Community Led work items that may have relevance to the PCEHR have been noted in this Table. The work is not led by NEHTA, and will not result in a NEHTA Managed Specification, but my inform NEHTA Specifications and the PCEHR Design.

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
eHealth Architecture	eHealth Interoperability provides the framework in which business, information, and technical specifications come together to define and deliver end-to-end solutions. This defines a set of foundational concepts and templates allowing independent analysis and development approaches to recognise layers of interoperability and define agreement points within requirements, analysis, and design.	eHealth Interoperability Architecture - standards framework - eHealth Service Specifications and Services Oriented Architecture (SOA)	National eHealth Framework (NeHF), NEHTA Interoperability Framework	eHealth Interoperability Architecture - standards framework - eHealth Service Specifications and Services Oriented Architecture (SOA)	Mar-12	AHB
Electronic Medications Management	Through e-Medication Management prescriptions may be securely transmitted direct from the GP's desktop to the dispensing pharmacy.	Electronic Transfer of Prescriptions - eHealth Conformance Profile		Electronic Transfer of Prescriptions - eHealth Conformance Profile	Jun-12	ATS
		Electronic Transfer of Prescriptions (ETP) - Structured Document Template and Logical Service		Electronic Transfer of Prescription - ATS4700.3.1 (Structured Document) Template and ATS 4700.3.2 (Logical Services Model)	Jun-12	ATS
		Electronic Transfer of Prescription (ETP) - Technical Services Specifications for Prescription, Dispense Record, Prescription Request (CDA Implementation Guide, CDA Rendering Guide & Web Services Platform Specification)		Electronic Transfer of Prescription - ATS4700.3.3 (ePrescription CDA), ATS4700.3.4 (Dispense Record CDA), ATS4700.3.5 (Prescription Request CDA), ATS4700.3.6 (Web Services Platform)	Jun-12	ATS

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
eReferral	e-Referrals facilitate the seamless exchange of significant patient information from one treating healthcare provider to another.	eReferral - eHealth conformance profile		eReferral - eHealth conformance profile	Jun-12	ATS
				Community Led: eReferral - Legacy Messaging Specification (HL7 v2)		ATS
		eReferral - Structured Content Specification and Logical Service		eReferral - Structured Content Specification and Logical Service	Jun-12	ATS
		eReferral - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)		eReferral - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)	Jun-12	ATS
Healthcare Identification	The HI Service helps to identify people and organisations involved in healthcare across Australia, using a unique 16 digit identification number.		A number of International and Local Standards were applied in the design and operation of the HI Service	Community Led: AS4700 series update to include identification and identifier requirements		ATS
National Authentication Service for Health	NASH delivers nationwide authentication for healthcare organisations and providers based on digital certificates, managed through Public Key Infrastructure and secured by smartcards. Certificate-based authentication will be available to any healthcare provider organisation registered with a HPI-O and individual providers with a HPI-I.	Credential Management Services Specifications Token Management Services Specification Card Specifications	PKCS MS CAPI OCSP Global Platform ISO 7816 ISO 14443 ISO 24727			

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
PCEHR Consolidated View	The consolidated view presents a snap shot of an individual's health status drawn from multiple sources and it automatically assembles an individual's allergies and adverse reaction, medications, medical history and immunisations from a range of clinical documents in a single view.	PCEHR consolidated view output - eHealth conformance profile		PCEHR consolidated view output - eHealth conformance profile	Jun-12	ATS
		PCEHR consolidated view output - Technical Services Specification (EndPoint Spec, Implementation Guide & Rendering)	Health Insite Minimum Publishing Standards see http://www.healthinsight.gov.au	PCEHR consolidated view output - Technical Services Specification (EndPoint Spec, Implementation Guide & Rendering)	Jun-12	ATS
		PCEHR consolidated view output -Structured Content Specification and Logical Service		PCEHR consolidated view output -Structured Content Specification and Logical Service	Jun-12	ATS
PCEHR Consumer Entered Information	Consumers are able to enter information into the PCEHR System through the Consumer Portal	Consumer Entered Information - eHealth conformance profile		Consumer Entered Information - eHealth conformance profile	Jun-12	ATS
		Consumer Entered Information - Structured Content Specification and Logical Service		Consumer Entered Information - Structured Content Specification and Logical Service	Jun-12	ATS
		Consumer Entered Information - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)		Consumer Entered Information - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)	Jun-12	ATS
PCEHR B2B Gateway	The Business-to-Business (B2B) Gateway allows a range of systems to access the PCEHR System, including: clinical systems, systems integrated via a gateway and contracted service providers acting on behalf of healthcare organisations.	PCEHR B2B Gateway Logical and Technical Service Specification	ATS 5820 eHealth Web Services Profile ATS 5821 eHealth XML Secured Payload Profile			

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
PCEHR Call Centre Service	The PCEHR System operator will provide a Call Centre Service to allow individuals to obtain general information about the PCEHR System, register/withdraw from the PCEHR System and manage their access controls.	Call Centre Service Interface Specification				
PCEHR Participation & Authorisation Service	The Participation and Authorisation Service stores individuals' participation preferences and manages access controls to an individual's PCEHR.	Participation & Authorisation Service Interface Specification	Secure Token Service: OASIS XACML 2.0, Security Assertion Markup Language (SAML) 2.0, ISO 17090-1:2008 Parts 1-3: Health Informatics - Public Key Infrastructure			
PCEHR Portlet Catalogue Service	The Portlet Catalogue Service provides for the integration of remote content and application logic into an end-user presentation by allowing eHealth application designers to discover and select a rich choice of compliant remote content from the PCEHR System.	Portlet Catalogue Service Interface Specification	OASIS Web Services for Remote Portlets v2.0, Portlet Specification JSR168 & JSR286			
PCEHR Template Service	The Template Service provides definitions about the types of healthcare information that can be shared via the PCEHR System (and other systems).	Template Service Interface Specification	ISO/IEC 11179-Series Information Technology Metadata Registries.			

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
PCEHR Core Security (PCEHR Security Policy)	The PCEHR System will protect the personal information it holds through strong authentication of individuals and users, provision of access controls, auditing, security testing and education and training of users.	The Core Security Services for the PCEHR Security & Access Architecture will be described through a set of Security Polices for the PCEHR.	National eHealth Security & Access Framework (HB174 to be updated) ISO 27000-series security management, ISO 27799:2008 Health Informatics Security in Health IETF / RFC 1305 Network Time Protocol ISO/DIS 27789 Audit Trails for electronic health records IHE Audit Trail and Node Authentication (ATNA) integration profile			
PCEHR Event Summary	An Event Summary is used to capture key health information about significant healthcare events that are relevant to the ongoing care of an individual.	Event Summary - eHealth conformance profile		Event Summary - eHealth conformance profile	Jun-12	ATS
		Event Summary - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)		Event Summary - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)	Jun-12	ATS
		Event Summary -Structured Content Specification and Logical Service		Event Summary -Structured Content Specification and Logical Service	Jun-12	ATS
PCEHR Foundation Clinical Informatics	Establishes the standardisation for the use of clinical document exchange stored within and exchanged through the PCEHR.	Profile of ISO/HL7 27932:2009 Clinical Document Architecture, [to include forms based communication]		Profile of ISO/HL7 27932:2009 Clinical Document Architecture, [to include forms based communication]	Jun-12	ATS

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
PCEHR Conformant Portal	The purpose of the conformant portal is to allow independently operated consumer-oriented portals to access the PCEHR System, thereby giving individuals a choice in how they access their PCEHR.	PCEHR Conformant Portal Specification	WebUI: HB 306 MobileUI: W3C Mobile Best Practice 1.0, W3C Mobile Web Application Infra: OASIS Web Services for Remote Portlets v2.0, Portlet Specification JSR168 & JSR286			
PCEHR Repository Services and PCEHR Conformant Repositories	In addition to the National Repositories Service, the PCEHR System will have the capability to connect to other conformant repositories operated by a conformant repository provider.	PCEHR Repository Services - Logical service specification				
		PCEHR Repository Services - Technical Specification	RLUS, ATNA and ATS 5820 eHealth Web Services Profile			
		PCEHR Conformant Repository Services - Logical Services		PCEHR Conformant Repository Services - Logical service specification	Jun-12	ATS
		PCEHR Conformant Repository Services - Technical Services	IHE XDS.b, RLUS, ATNA and ATS 5820 eHealth Web Services Profile	PCEHR Conformant Repository Services - Technical Services	Jun-12	ATS
PCEHR Shared Health Summary	The Shared Health Summary provides clinically moderated information about an individual's allergies/adverse reactions, medicines, medical history and immunisations.	Shared Health Summary - Structured Content Specification		Shared Health Summary - Structured Content Specification	Jun-12	ATS
		Shared Health Summary - eHealth conformance profile		Shared Health Summary - eHealth conformance profile	Jun-12	ATS

Solution Bundle	Description	Specification	Existing Standards Publication	New Standard Publication	Target Pub.	Pub. Type
		Shared Health Summary - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)		Shared Health Summary - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)	Jun-12	ATS
Secure Message Delivery	The documents which describe the Secure Messaging Delivery, Web Services Profile and the XML Secure Payload profile specifications are now Technical Specifications published by Standards Australia. The Endpoint Location Service specification is now a Technical Report also published by Standards Australia	Secure Message Delivery - Conformity Assessment Specification		Secure Message Delivery - Conformity Assessment Specification	Mar-12	ATS
		Upgrade ATS 5820 e-Health web services profile	ATS 5820 e-Health web services profile	AS 5820 e-Health web services profile	Mar-12	AS
		Upgrade ATS 5821 e-Health XML secured payload profiles	ATS 5821 e-Health XML secured payload profiles	AS 5821 e-Health XML secured payload profiles	Mar-12	AS
		Upgrade ATS 5822 e-Health Secure Message Delivery	ATS 5822 e-Health Secure Message Delivery	AS 5822 e-Health Secure Message Delivery	Mar-12	AS
Specialist Letter	The PCEHR System will support the collection of Specialist Letters.	Specialist Letter - eHealth conformance profile		Specialist Letter - eHealth conformance profile	Jun-12	ATS
		Specialist Letter - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)		Specialist Letter - Technical Services Specification (SMD, CDA Implementation Guide & CDA Rendering)	Jun-12	ATS
		Specialist Letter -Structured Content Specification and Logical Service		Specialist Letter -Structured Content Specification and Logical Service	Jun-12	ATS

Appendix A Standards Development Process and Terminology

In order to describe the pathways for Specifications and Standards within this document, readers need to be familiar with the Standards publication process and related terminology, summarised below.

Standards Publications

Standards publications are documents that set out specifications and procedures designed to ensure that products, services and systems are safe, reliable and consistently perform as intended. They establish a common language which defines quality and safety criteria.

Standards publications can be guidance documents including:

- Australian Standards®
- International Standards and Joint Standards
- Codes
- Specifications (such as Australian Technical Specifications)
- Handbooks
- Technical Reports
- Guidelines.

Within the context of this document, unless specifically stated otherwise, the term 'Standards publications' is used to mean any of these publication types.

Table 4 gives a brief description of the key Standards publications that NEHTA is involved in developing. These Standards publications form the basis of the work programme in section 4.

Table 4: Description of Standards publications

Standards publication	Abbrev.	Description (from Standards Australia website)
Australian Standard	AS	A high level, authoritative consensus document which sets out guidelines, specification and principles. Australian Standards must undergo a public comment period and achieve Committee consensus prior to publication.
Australian Technical Specification	ATS	A peer-reviewed normative document subject to a limited form of transparency, and not requiring the support of the full consensus process (as would be required for the development of an Australian Standard). A technical specification may be prepared in a field where the subject matter or related aspects is undergoing rapid change and where speed of delivery is of paramount importance. It would normally be expected that an Australian Standard would eventually be developed to supersede the Technical Specification. The development of such a subsequent Australian Standard would be strengthened by the information gained from use of the Technical Specification that preceded it.
Australian Handbook	AHB	An informative peer-reviewed document to support a Standard or series of Standards already in place, or where no Standard exists but content is considered in the public interest.

Standards publication	Abbrev.	Description (from Standards Australia website)
Australian Technical Report	ATR	An informative document containing information on the material to which it refers, giving guidance on its interpretation and application. Similar to a Technical Specification, a Technical Report is not subject to the full consensus process (as would be required for the development of an Australian Standard) but will undergo peer review.
ISO (International Standards Organization)	ISO/A	ISO (International Organization for Standardization) is the world's largest developer of standards. To ensure compliance with the International Code of Good Practice, ISO standards will be adopted or profiled where possible.

These Standards publications will go through different stages during their development, as described in the next section.

NEHTA Managed Specification (NMS)

A NEHTA Managed Specification (NMS) is a NEHTA specification that has been:

- Endorsed by the relevant Tiger Team¹⁴.
- Approved by the NEHTA Design Authority.
- Accepted by NEHTA for trial use in Australian eHealth implementation and regarded as “implementation ready”.

In addition, NEHTA specifications that will progress towards Standards Publications will be accepted by NEHTA for submission to Standards Australia for consideration as a Committee Draft.

All NEHTA Managed Specifications will be supported by NEHTA for at least 2 years.

Committee Draft (CD)

A Committee Draft is a specification accepted by the relevant Standards Australia IT-014-XX¹⁵ working group for submission to peer review as an Australian Technical Specification.

Deliverable Publication

A Deliverable Publication occurs in the final stage of the standardisation process, at which time an edited final document is provided to SAI Global¹⁶ by Standards Australia for publication.

Note: Some Standards publications, for example, Australian Standards, will be subject to further public balloting processes and therefore go through additional lifecycle statuses, such as Public Commenting Draft (PCD) or, in the case of ISO Standards, Final Draft International Standard (FDIS). These additional publications types are outside the scope of this document as we do not currently anticipate any NEHTA specifications progressing to this point.

¹⁴A Tiger Team is a group of experts assigned to investigate or resolve clinical use, policy, security or technical or systemic issues. This is explained further in section 3.3

¹⁵ XX represents the number assigned to the specific sub-committee.

¹⁶SAI Global provides aggregated access services to Australian Standards, Handbooks and Report publications.

Appendix B PCEHR Specifications Delivery Schedule

The Specifications and Standards Plan for PCEHR outlines a series of solution bundles. These solution bundles are categorised into three groups:

- Clinical Documents – these specifications describe the content and structure of the clinical information exchanged between healthcare providers to support a consumer’s eHealth journey.
- PCEHR System Services – these specifications describe the PCEHR Core Services that healthcare organisations and consumers will interact with.
- eHealth Foundations – these specifications and frameworks describe foundation for eHealth.

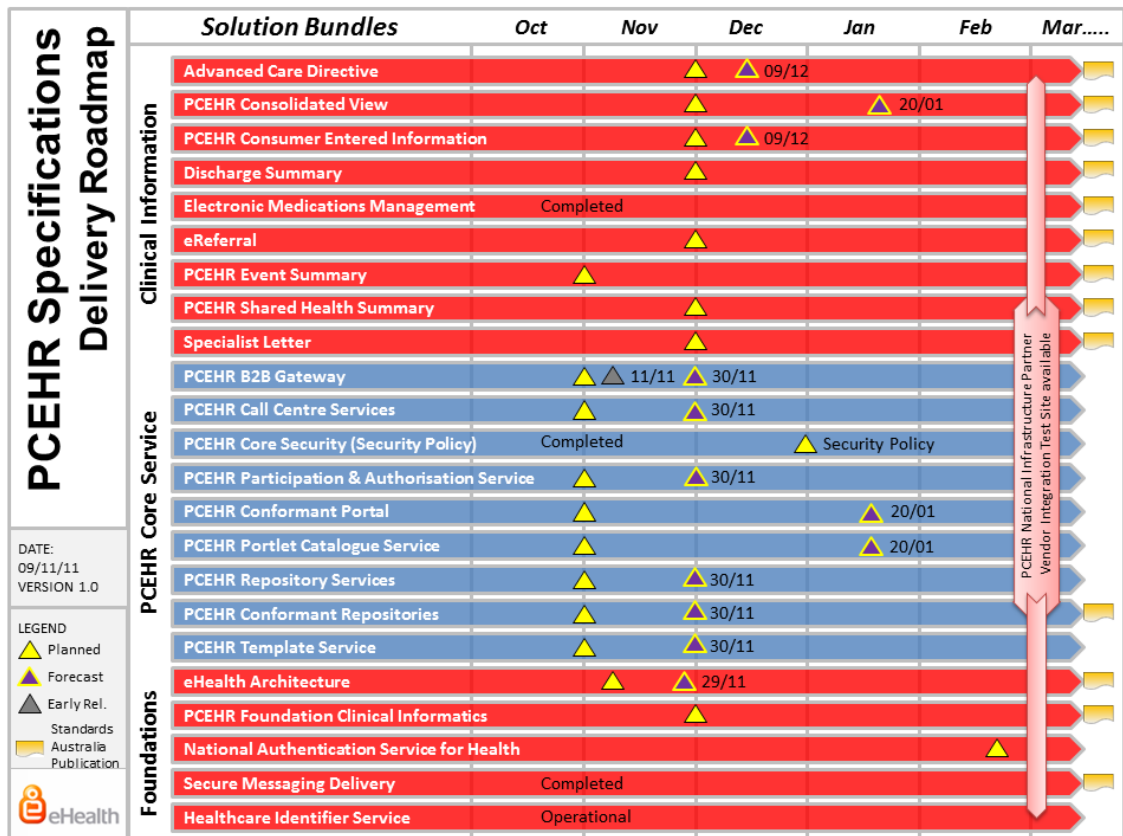


Figure 5: PCEHR Specifications Delivery Roadmap

The PCEHR Specifications Delivery Schedule is illustrated in Figure 5 as a Roadmap. In addition Table 5 provides a tabular form of the PCEHR Specifications Delivery Schedule.

Table 5: PCEHR Specifications Delivery Schedule

Solution Bundle	Description	Scheduled Delivery Date	Forecast Delivery Date	Notes.
Clinical Documents				
Advance Care Directive	Will provide notification for clinicians of the location and/or contact for an individual's Advanced Care Directive often referred to as a Living Will, which is a written statement regarding someone's wishes for their future health care.	30/11/2011	9/12/2011	-
Discharge Summary	e-Discharge Summaries will enable the electronic exchange of comprehensive and accurate patient reports	30/11/2011	-	On target
Electronic Medications Management	Through e-Medication Management prescriptions may be securely transmitted direct from the GP's desktop to the dispensing pharmacy.	Completed	-	-
eReferral	eReferrals facilitate the seamless exchange of significant patient information from one treating healthcare provider to another.	30/11/2011	-	On target
PCEHR Consolidated View	The consolidated view presents a snap shot of an individual's health status drawn from multiple sources and it automatically assembles an individual's allergies and adverse reaction, medications, medical history and immunisations from a range of clinical documents in a single view.	30/11/2011	20/1/2012	-
PCEHR Consumer Entered Information	Consumers are able to enter information into the PCEHR System through the Consumer Portal	30/11/2011	9/12/2011	-

Solution Bundle	Description	Scheduled Delivery Date	Forecast Delivery Date	Notes.
PCEHR Event Summary	An Event Summary is used to capture key health information about significant healthcare events that are relevant to the ongoing care of an individual.	31/10/2011	-	Extensions to the solution bundle are expected by 4/11/2011
PCEHR Shared Health Summary	The Shared Health Summary provides clinically moderated information about an individual's allergies/adverse reactions, medicines, medical history and immunisations.	30/11/2011	-	On target
Specialist Letter	An electronic Specialist Letter is the return communication from a specialist to a general practitioner following an eReferral.	30/11/2011	-	On target
PCEHR Core System				
PCEHR B2B Gateway ¹⁷	The Business-to-Business (B2B) Gateway allows a range of systems to access the PCEHR System, including: clinical systems, systems integrated via a gateway and contracted service providers acting on behalf of healthcare organisations.	31/10/2011	30/11/2011	Early release of Technical Specifications on 11/11/2011. These specifications will be extended to support additional requirements as other functional services are presented through the B2B Gateway. ¹⁸

¹⁷ PCEHR Specifications incorporate capabilities to support the Commonwealth's investment in the lead implementation eHealth sites. For example, the PCEHR B2B Gateway Technical Interface as designed and developed by the National Infrastructure Partner incorporates capabilities to support the use of IHE XDS.b based Repository Interfaces.

¹⁸ The PCEHR B2B Gateway Technical Interface incorporates capabilities to support the Lead Implementation Sites (specifically XDS.b based Repository Interfaces). These technical interfaces represent one of the components of the Logical Services Specification supporting a range of clinical information system interactions with the PCEHR.

Solution Bundle	Description	Scheduled Delivery Date	Forecast Delivery Date	Notes.
PCEHR Call Centre Service	The PCEHR System operator will provide a Call Centre Service to allow individuals to obtain general information about the PCEHR System, register/withdraw from the PCEHR System and manage their access controls.	31/10/2011	30/11/2011	-
PCEHR Participation & Authorisation Service	The Participation and Authorisation Service stores individuals' participation preferences and manages access controls to an individual's PCEHR.	31/10/2011	30/11/2011	-
PCEHR Portlet Catalogue Service	The Portlet Catalogue Service provides for the integration of remote content and application logic into an end-user presentation by allowing eHealth application designers to discover and select a rich choice of compliant remote content from the PCEHR System.	31/10/2011	20/1/2012	Portal Strategy to be developed for 30/11/2011 ¹⁹
PCEHR Core Security (PCEHR Security Policy)	The PCEHR System will protect the personal information it holds through strong authentication of individuals and users, provision of access controls, auditing, security testing and education and training of users. The development of the Security and Access Requirements and Architecture will inform the PCEHR Security Policy.	Completed and provided to the National IP to support Core Security Architecture	-	The follow on PCEHR Security Policy will be developed in December.

¹⁹ The PCEHR Portal Strategy will be made available prior to the final release of logical and technical interfaces to support transition planning and market readiness for Conformant Consumer Portals.

Solution Bundle	Description	Scheduled Delivery Date	Forecast Delivery Date	Notes.
PCEHR Conformant Portal	The purpose of the conformant portal is to allow independently operated consumer-oriented portals to access the PCEHR System, thereby giving individuals a choice in how they access their PCEHR.	31/10/2011	20/1/2012	Portal Strategy to be developed for 30/11/2011
PCEHR Repository Services	In addition to the National Repositories Service, the PCEHR System will have the capability to connect to other conformant repositories operated by a conformant repository provider.	31/10/2011	30/11/2011	Early release of the B2B Gateway technical specification will be made available to support transition planning 11/11/2011
PCEHR Conformant Repository	The Conformant Repository Specification provides the overview of a conformant repository operator and its interactions with GP Clinical Information Systems.	31/10/2011	30/11/2011	Early release of the B2B Gateway technical specification will be made available 11/11/2011.
PCEHR Template Service	The Template Service provides definitions about the types of healthcare information that can be shared via the PCEHR System (and other systems).	31/10/2011	30/11/2012	-

Solution Bundle	Description	Scheduled Delivery Date	Forecast Delivery Date	Notes.
eHealth Foundations				
eHealth Architecture	eHealth Interoperability provides the framework in which business, information, and technical specifications come together to define and deliver end-to-end solutions. This defines a set of foundational concepts and templates allowing independent analysis and development approaches to recognise layers of interoperability and define agreement points within requirements, analysis, and design.	4/11/2011	29/11/2011	Preparing document based on tiger team feedback for Standards Australia
PCEHR Foundation Clinical Informatics	Establishes the standardisation for the use of clinical document exchange stored within and exchanged through the PCEHR.	30/11/2011	-	On target
Secure Messaging Deliver	The documents which describe the Secure Messaging Delivery, Web Services Profile and the XML Secure Payload profile specifications are now Technical Specifications published by Standards Australia. The Endpoint Location Service specification is now a Technical Report also published by Standards Australia	Completed.	-	Standards Australia (ATS 5820, 5821, 5822)

Solution Bundle	Description	Scheduled Delivery Date	Forecast Delivery Date	Notes.
National Authentication Service for Health (NASH)	NASH delivers nationwide authentication for healthcare organisations and providers based on digital certificates, managed through Public Key Infrastructure and secured by smartcards. Certificate-based authentication will be available to any healthcare provider organisation registered with a HPI-O and individual providers with a HPI-I.	27/02/2012	-	On target
Healthcare Identifier Service	The HI Service helps to identify people and organisations involved in healthcare across Australia, using a unique 16 digit identification number.	Operational Service	-	-

Reference List

- [NEHT2011a] National E-Health Transition Authority 2011, Concept of operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system, 9 September 2011, NEHTA Version 1.0
- [NEHT2011b] National E-Health Transition Authority 2011, High Level System Architecture PCEHR System, version 1.34, 2 June 2011
- [NEHT2011c] National E-Health Transition Authority 2011, PCEHR Standards Analysis, version 3.8, 2 June 2011
- [NEHT2011d] NEHTA Strategic Plan Refresh 2011/2012
- [NEHT2011e] Direkt 2011, Personally Controlled Electronic Health Records (PCEHR) Program, Standards Review, version 1.0, May 2011
- [NEHT2011f] Business Requirements, PCEHR System, version 1.07, 7 June 2011