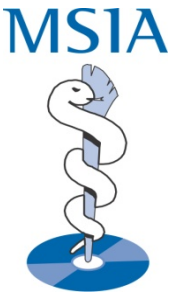


Dr Ian Holland

Committee Secretary
Senate Standing Committee on Community Affairs
PO BOX 6100
Parliament House
Canberra ACT 2600
By email
community.affairs.sen@aph.gov.au

Dear Dr Holland,

I am writing to provide additional information in response to questions asked of the MSIA on 6 February at the Committee Inquiry into the Personally Controlled Electronic Health Records Bill 2011.

…

Question 2-Senator McKenzie

> ***Senator McKENZIE:*** *The final paragraph of page 10 of your submission has an example of overstatement before substance or delivery. There are numerous other examples. I wonder if you could provide a few more on notice.*
> ***Dr McCauley****: Sorry—overstatement on delivery by NEHTA?*
> ***Senator McKENZIE****: Yes. There is a whole list: 'poor planning, failure to complete to deadlines and a range of other unacceptable behaviour that contravene normal Australian business practices.'*
> ***Dr McCauley:*** *We would be happy to do that.*

Final paragraph MSIA Submission on pg 10: On the subject of the "Final" specifications:-

The MSIA has chosen this one example of overstatement before substance or delivery – there are numerous other examples of poor planning, failure to complete to deadlines and a range of other unacceptable behaviour that contravene normal Australian business practices – these have led to a reluctance to commit to development work in such a changing and uncertain environment. The risks are great, and the potential for errors that cost lives is high – "first do no harm" is a good motto.

1. "*Overstatement before substance or delivery*" - Specifications

The example that MSIA chose to illustrate 'overstatement before substance or delivery' and summarised at Appendix 3 of the MSIA submission needs further clarification in light of the statements made by Peter Fleming when questioned at Senate Estimates on 15th of February.

The names "Vendor Portal" and "Software Developer Resource Centre" are used interchangeably by the committee and others. The site can be accessed at **vendors.nehta.gov.au/** and is co-branded with both the NEHTA and the DOHA logo.

> Senator BOYCE is referring to the documents on the vendor portal website and asks:
> **"Does this mean I can use that information today if I were a software developer?**
> **Mr Fleming "Absolutely"**
> **Senator BOYCE "Is it fit for practice?**
> **Mr Fleming "Absolutely"**
> **...**
> **Senator BOYCE "Are they complete?"**
> **Mr Fleming "Absolutely"**

The table at Appendix 1 shows the status of the 23 "bundles" from the point of view of the vendor developer community- the NEHTA's Dashboard overview of the status of these bundles is also included.

Only five, possibly seven of the 23 bundles can be regarded as "delivered", "complete" or "fit for practice".

Later in answer to a question from the CHAIR Peter Fleming indicated that ***"Yesterday was the first time I had heard that comment"*** in relation to concern relating to the status of the documents on the vendor portal.

Concerns with these documents were raised by the MSIA at the meetings of the eHealth ICT Implementation Group in October, November and December 2011 which Peter Fleming attended. Appendix 2 contains an extract from the minutes of the October meeting detailing concerns raised by industry. This continued to be discussed at the November and December meetings.

Some NeHTA staff were certainly aware that there were concerns about the status of the documents in the vendor portal. It was raised at a teleconference on December 21, 2011 attended by NEHTA, the National Change and Adoption Partner (NCAP), where both Mukesh Haikerwal and Andrew Howard from NEHTA were in attendance. Andrew Howard told the MSIA attendees (CEO and President) that all the documents on the portal were "fit for use"

This prompted a review by MSIA of the documents on the site following further comments from vendors to the MSIA. An email was sent to all the MSIA members on the 25th January, 2012 and had "**Caveat Emptor**- **Vendor Portal"** in the subject line and contained the following paragraphs.

> ***NB: Caveat emptor – The description by any NEHTA/DoHA person that the documents on the vendor website are "Final" because it says so on the front should be balanced with a careful look inside for any one of the following:***
> - ***missing documents in the set with no due date for release;***
> - ***reference to the general NEHTA site for related documents (with no link – and you will never find them!) ; -***
> - ***a list of unresolved "known issues" ;***
> - ***or a planned review in March 2012 or other date prior to 1 July 2012;***
> - ***parts of the document missing and awaiting Tiger Team review;***
> - ***any reference to a 1b release etcetera;***

Believe me I know – I have looked at all 105 up-loaded (as at Monday) and all 5,616 pages. I reckon that there are still about 6,000 pages to come!! About 15% of the documents are not in fact the latest published version and if you are a Wave vendor you need to check your Wave portal documents are the latest ones...I know for sure some are not! <u>You have been warned!"</u>

The email containing these comments was sent to the nominated staff at NEHTA, DOHA and Medicare (before 8am on the 25th January) who receive a copy of the MSIA Vendors Daily Update as a courtesy.

Further, it seems unlikely that Peter Fleming had not read the MSIA Submission to the Inquiry or if not, his staff had not read it and alerted him to the concerns expressed in our submission. It seems difficult to understand how he was unaware of the issues at the ICT meeting on the day before Senate Estimates.

2. *"Overstatement before substance or delivery" –The Building Blocks*

There are four key foundation blocks that industry were promised and considered necessary before the PCEHR could be built[1]

- Australian Medicines Terminology (AMT)
- Healthcare Identifiers
- NASH
- Secure messaging

This was reinforced by a series of media statements over a number of years – examples below.

"This is the year of delivery:NEHTA " Peter Fleming. January, 2009
http://m.zdnet.com.au/this-is-the-year-of-delivery-nehta-339294585.htm

Project Phases and dates as outlined in NEHTA Annual Report 2008-2009
http://content.yudu.com/Library/A1pq6g/Pulse+ITNovember2010/resources/30.htm

"**Nehta adds final touches to e-health**" interview with Peter Fleming July 2010
http://www.theaustralian.com.au/australian-it/nehta-puts-finishing-touches-to-health-identifier-plan/story-e6frgakx-1225890944023

"It's like putting a man on the moon" Peter Fleming August 2011
http://www.australianageingagenda.com.au/2011/08/23/article/Its-like-putting-a-man-on-the-moon/YFBNQDGARA.html

"E-Health will become a reality this year" Peter Fleming, February 2011
http://www.theaustralian.com.au/australian-it/e-health-will-become-a-reality-this-year/story-fn7uxvjw-1226005571991

a) Australian Medicines Terminology (AMT)

The AMT is a key part of the Clinical terminology Foundation and will be critical for establishing a current medication list from disparate systems for the PCEHR. Most of the proposed benefits claimed for the PCEHR come from the prevention of medication misadventures.2

[1] NEHTA Blue print v.1 10 August 2010, p21-22

Industry were told AMT went "live" in one hospital in Victoria in August 2010[3]
However Peter Fleming at the Senate Inquiry on the 5th of February 2012 some 18 months later, said

"Australian Medicines Terminology is starting to be used in Victorian Hospitals"

The MSIA believes it is only being used in one hospital – which is no different from any other single hospital based system. The AMT was also" paused" for a number of months in late 2011 - there were none of monthly updates that are essential for "live" use with patients. The AMT for some reason does not appear in the 23 bundles referred to previously.

Most healthcare software vendors will purchase AMT (mapped to Australian medications) from a third party (when it is available), some will manage their own version AMT. Medicinces information makes up a key part of the decision support processes for doctors within practice software - such as alerts for drug/drug, drug/pregnancy or drug/condition interactions. Clinicians have been waiting for this terminology to be available since NEHTA was created (it has been promised in various forums since late 2010).

b) Healthcare Identifiers Service (HI Service)
Peter Fleming announced, as one of NEHTA's achievements, at the National e Health Conference in November/December 2010[4] that the "*HI Service Goes live – 23 million individual health care Identifiers allocated".*

At the time Peter Fleming was speaking DOHA and Medicare had called a halt to any use of the Healthcare Identifier Service because of safety issues raised by the MSIA.

At a meeting on the 29th October 2010, the MSIA raised issues relating to the safe use of the Healthcare Identifier System, and followed up with a requested paper for the Department of Health and Ageing, called *"Summary of Risks –HI Service*" dated 8th November, 2010. This was sent on that date to senior staff at both DoHA and Medicare. A less technical version was sent to others.

Senators should be very careful to understand what witnesses mean when they say a system is "live". Senators may find it helpful to ask whether "live" means that a system is being used for the care of real patients, or is it just a milestone towards being used, or being tested, or just turned on (without any end user systems being connected to it).

Further Issues were raised at the 18 January **2011** meeting. It is disappointing that Medicare and DOHA staff attend these meetings and have either not understood the issues or not briefed the Medicare CEO or the DOHA Deputy Secretary as to the patient safety risks that were being reviewed.

---

[2] Pulse IT Magazine at http://content.yudu.com/Library/A1pq6g/Pulse+ITNovember2010/resources/30.htm
[3] NEHTA Media centre (10 August, 2010)
[4] "eHealth making it happen" Slide 8 downloadable from http://www.google.com.au/search?q=NEHTA+%22peter+Fleming%22+2010&ie=utf-8&oe=utf-8&aq=t&rls=org.mozilla:en-GB:official&client=firefox-a

Mr Fleming at the Senate Inquiry referred to the MSIA white paper raising these issues and claimed to have responded to it. MSIA has never received any written acknowledgement of the white paper from NEHTA.

We note that Mr Fleming told the Inquiry that NEHTA ***"have done detailed analysis of match rates and have published the implications of that"*** The MSIA is aware of Victorian results but not of any published NEHTA results.

Vendors are not yet clear what role the individual Healthcare Identifier numbers will play in the PCEHR. At a webinar recently (recording available on NEHTA's website at http://www.nehta.gov.au/ehealth-implementation/pcehr-standards) on the 22nd of February, 2012, it was clear that not only was the PCEHR registration process not locked down (neither policy nor technically) but the scenario considered most likely was the "known customer model" and there was no mention of use of an Healthcare Identifier number as part of that process.

c) National Authentication Service for Health (NASH)

NASH development tools have been promised to solution developers several times – there was a meeting of vendors and NASH staff on 24 May, 2011 and only two meetings since. NASH has now been abandoned for use in anything solutions that are due for delivery by July 1 2012.

d) Secure Messaging

Peter Fleming told the Inquiry that ***"The Northern Territory is using the secure messaging delivered through the Australia Standards and NEHTA is closely supporting these projects***

This is not possible as the only Australian standard – an Australian Technical Standard that was developed in 2009 in conjunction with some 20 vendors - was predicated on having a functioning Healthcare Identifier Service (all three numbers – individual, provider and organisational) and NASH, neither of which are available anywhere in Australia.

e) NEHTA Communication with Industry (and the Health Sector Generally)

NEHTA's communication with the software vendor community has tended to be through the media or via the website. Businesses intending to make development and investment decisions have found the moving targets very unsettling. Companies that ramped up to become early adopters found they had been let down by promises made about NEHTA deliverables.

3 *Unacceptable Business Practices*

NEHTA relies on a large number of vendor volunteers to attend meetings, review documents and assist where possible. Vendors attending on behalf of the MSIA as representatives have to abide by a code of practice that can be found on the MSIA website at www.msia.com.au It could be supposed that because NEHTA is using volunteers, that a higher level of communication, and consideration should be required
We note a couple of examples only.

b) During a Summit of all the Reference Groups in 2010 the MSIA President and MSIA CEO noticed on a slide prepared for the NEHTA Board, outlining all recent "engagement" processes, an all day meeting with vendors on the 21st January 2010. On inquiring why MSIA were not invited, we were told by Andrew Howard from NEHTA that there were no vendors invited on that day – the role of vendors during that day-long "engagement" with industry

were taken by NEHTA staff. Other summit attendees were concerned that they too had been role-played by NEHTA staff!

c) Preparation for meetings do not meet normal business expectations, although there has been some improvement from a very low base. Meetings are often scheduled with very little notice, and large documents are often sent for review less than 24 hours before a meeting. An example is the 6 documents sent on the afternoon of Thursday 16th of December, 2011 for feedback to be returned by noon the next day (over 140 technical pages). When detailed and technical feedback is provided it is often not incorporated or acknowledged. Issues are not well documented, minute taking is poor, and much time has been wasted going over the previous meetings' work.

d) On another occasion, with some eight NEHTA people in the room (and DOHA representatives), the vendor community wished to base the discussion on a current NEHTA document that was relevant to the subject of the meeting. The NEHTA staff denied it existed although it was circulated to the subsequent teleconference that afternoon, having been downloaded from the NEHTA website.
There has been a NEHTA culture of denial and secrecy across a great number of issues.

e) The MSIA attends a large number of meetings in government agencies, not for profits and associations. NEHTA stands out – it is without peer in its failure to follow basic business practice.

f) Proposals and letters to the CEO are neither acknowledged, nor responded to. The MSIA has had no written communication from the NEHTA CEO since early 2011.

g) The MSIA has met with the NEHTA CEO and Chairman of the NEHTA Board on more than one occasion to discuss its grave concerns relating to NEHTA's interference in the market place. NEHTA has selectively funded a small subset of primary care vendors to the detriment of the rest of the sector and has funded an untested, unproven vendor for the Wave 1 sites, without going through an open market selection process. Industry is also concerned by the $50 million spent on consultancies in 12 months without any tendering or expression of interest processes

4 A vendor's voice – from the Waves.

"In my opinion, the PCEHR story has deteriorated significantly even since the Senate hearings:

1. I believe NASH is now off the rails and has been dropped by the NIP for 1 July
2. All Lead site consented consumers must be re-consented (and possibly re-identified!) for PCEHR enrolment
3. All Lead site enrolled practices must be re-enrolled for the PCEHR
4. No clinical records that pre-date 1 July 2012 will be allowed into the PCEHR (including all of the clinical records amassed by the Lead Sites)
5. There will not be a release of Primary care system software that can connect to the PCEHR until at least July (and more likely September)
6. GP Vendors have not implemented the Basic Vendor Repository interface, despite it being specifically developed as a short to medium term solution for PCEHR system connectivity
7. There is now a strong DOHA push for the NIP repository to store everything,to the extent that practices are being actively discouraged from even thinking about subscribing to conformant repositories;

8. There is no sign (or even advice) from NEHTA about a national provider directory
9. There is no sign (or even advice) from NEHTA about a national ELS index
10. The HI Service still cannot do what it is supposed to do - after twenty months of "live" operation and $135m

I do not think it would have been possible to devise a worse strategy to implement a national PCEHR if one had set out to do so from the outset."

The MSIA has taken the view, informed by its members, that we, the software vendors, need NEHTA to be the best it can be. We hope that the Inquiry will be able to recommend the kind of change that will allow that to occur. This will require some cultural and leadership change and increased transparency, accountability and governance.

Kind regards

Bridget Kirkham

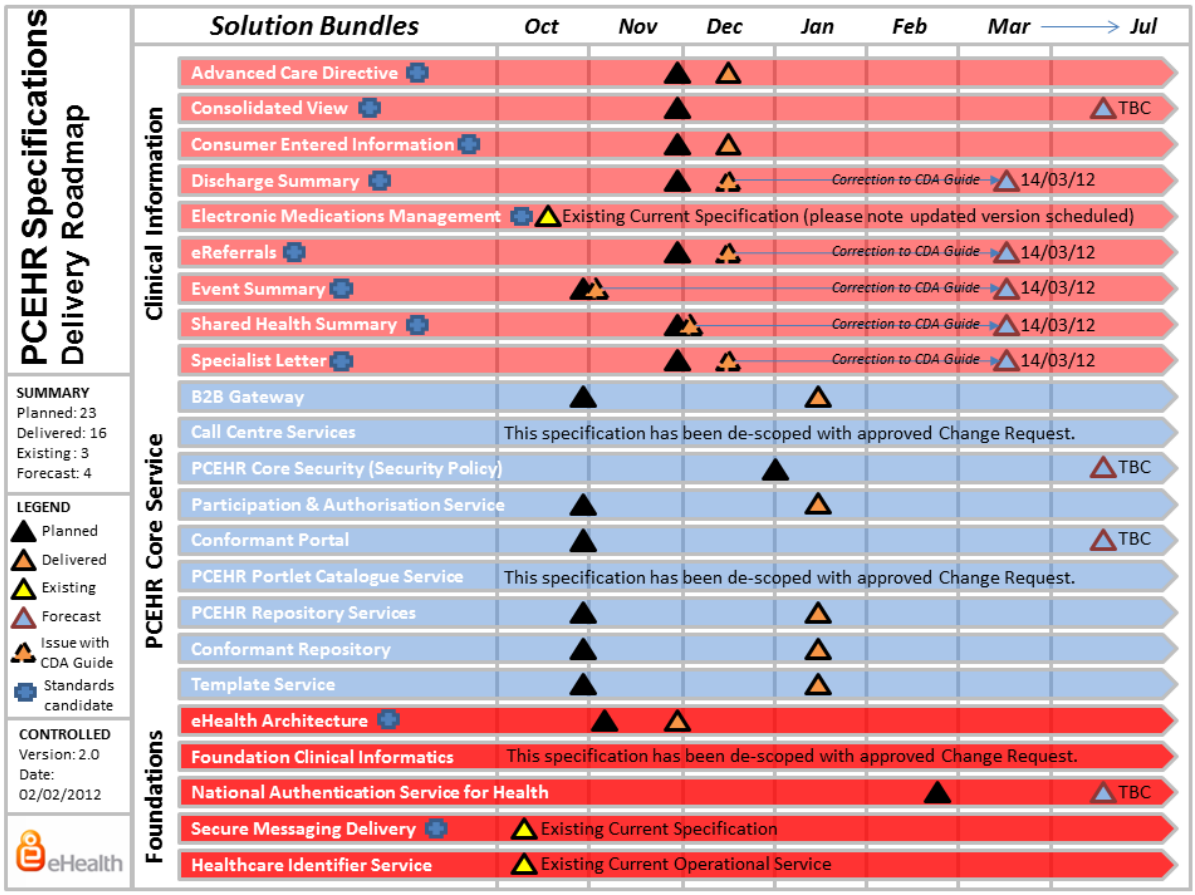
CEO MSIA
0427 844 645
www.msia.com.au

Appendix 1.

	Bundle	**Claimed Status**	**MSIA Comment**	**Actual Status**
1	Advanced Care Directive	Existing as of December 2011	No clinical content	Delivered
2	Consolidated View	July 2012 (seven months late)*****	Depends on terminology bound data in CDA documents –descoped until at least 2013	Not delivered
3	Consumer Entered Information	Existing as of December 2011	No useful clinical content – not accessible by clinicians	Delivered, no clinical utility
4	Discharge Summary	Existing as of December 2011	Withdrawn until "Late March"# to correct specification errors	Not delivered
5	Electronic Medication Management	Existing as of October 2011	ETP; legacy spec from 2010, for information only; not related to spec currently going through standards process; Delivered specification is not fit for use	Legacy specification delivered, not fit for use
6	eReferrals	Existing as of December 2011	Withdrawn until "Late March" to correct specification errors	Not delivered
7	Event Summary	Existing as of December 2011	Withdrawn until "late March" to correct specification errors	Not delivered
8	Shared Health Summary	Existing as of December 2011	Withdrawn until "Late March" to correct specification errors	Not delivered
9	Specialist Letter	Existing as of December 2011	Withdrawn until "Late March" to correct specification errors	Not delivered
10	B2B Gateway	Existing as of January 2012	Inadequately reviewed; likely to require modifications during implementation	Delivered, but not of standards quality
11	Call Centre Services	No status	De-scoped	Not delivered
12	PCEHR Core Security (Security Policy)	July 2012 (seven months late)		Not delivered
13	Participation and Authorisation Service	Existing as of January 2012	Tiger team review process is unclear; unlikely to have been adequately reviewed	Delivered? Fit for use?
14	Conformant Portal	July 2012 (seven months late)	One Tiger Team phone meeting to date; only	Not delivered

			reviewed by 2 or 3 people	
15	PCEHR Portlet Catalogue Service	Existing as of January 2012	De-scoped according to the NEHTA Vendor web site	Not delivered
16	PCEHR Repository Service	Existing as of January 2012	Covered by B2B and XDS? Probably not adequately reviewed.	Delivered? Fit for use?
17	Conformant Repository	Existing as of January 2012	No test framework available	Delivered but critical areas such as document deletion still not finalised.
18	Template Service	Existing as of January 2012	Minimal discussion at Tiger Team	Role and functionality in PCEHR remains unclear – not adequately reviewed.
19	eHealth Architecture	Existing as of November 2011	DOHA is attempting to force healthcare practices and vendors to not adhere to this architecture (attempts to exclude conformant repositories)	Delivered
20	Foundation Clinical Informatics	No status	De-scoped	Not delivered
21	National Authentication Service for Health	July 2012, five months late	Already looking like it will be later than July 2012	Not delivered
22	Secure Message Delivery	Existing as of October 2011	**Developed by joint MSIA /NEHTA working group in 2009 and a Standards Australia Technical Standard since 2010. Test process delivered by IHE in 2009. Multiple vendor implementations awaiting dependent and critical infrastructure – NASH and ELS (Endpoint locations service.**	Delivered but key infrastructure required from NEHTA before it can be used as designed.
23	Healthcare Identifier Service	Existing as of October 2011	One of three services available and that one is incomplete/not fully functional	Partially. Not suitable for use with the PCEHR.
Total			**5-7/23 Delivered or partially delivered as of 1/3/2012**	

*** Based on NEHTAs own document, which is reproduced below:**



 # Information from vendor website at vendors.nehta.gov.au/

NOTES: Many of the repository and interface specifications have not been adequately reviewed. It is not possible to assess whether specifications are "fit for use" because they have not been implemented or tested. They have deviated from existing standards in many places and cannot be assessed without actually implementing and testing

---

Appendix 2 – Extract from minutes of the eHealth ICT Implementation Group held 26.Oct.2011, This meeting was attended by the NeHTA CEO.

Update on NEHTA Specifications and Standards Development

Fionna Granger asked Paul Madden to lead the discussion on the Specifications and Standards Plan, and asked the industry association representatives to provide feedback from their consultation with their respective members.

Loretta Johnson provided feedback from the AIIA:

- Members raised a number of concerns with the process for development of, and consultation on, the specifications and standards
- concern with the apparent domestic nature of the process – need for assurance that the standards will leverage international standards
- seeking an assurance around the governance of change control to ensure certainty and stability of standards

The AIIA recognise the necessarily pragmatic approach given the time imperatives on the PCEHR program – and while the process is not perfect, they are prepared to work with DOHA and NEHTA to move the process forward.

Caroline Lee provided feedback from the ACIVA (noting that ACIVA would also provide written comments):

- there is confusion amongst members as to what will be expected under PCEHR – greater clarity would provide context and assist members in commenting on materials such as the standards plan
- questions around the NEHTA management of implementation of CCA and how this will support the commitment to 2 year specifications/standards
- will there be any support/funding for aged care vendors to develop conformant solutions?

The MSIA provided feedback supporting the views of the AIIA and ACIVA, especially the need take these through the Standards Australia process and leverage international standards, and further noting:

- the NEHTA plan, while seeking to mirror the Standards Australia process, does not have the same degree of transparency nor controls around due process – time frames and consultation processes etc
- the tiger teams are not providing sufficient access to industry to be involved in the consultation processes due to the unrealistic timeframes
- while the objective of certainty and stability is supported, this should not be at the cost of quality of the specifications and standards. There is a concern that the specifications will not be at a sufficient stage of development/maturity to be locked-in or to be advanced as standards and subject to CCA processes.
- it will be the vendor industry that will bear the costs and impacts of poor quality products and or processes.
- the MSIA CEO Forum called for a pause in the PCEHR program to address these concerns

Paul Madden responded to the industry feedback by summarising what he saw as the detail needed to inform further consideration of the process and timeframes for development of the specifications and standards.

- A progress report on the specifications to be developed, the scheduled date of release and a status report on the progress of development for each standard.
- An assessment from the tiger teams of the level of maturity and quality of each of the specifications scheduled for release at 31 Oct and 30 Nov.
- Documentation of the Change Control process and other assurances as to the certainty and stability of the specifications and standards, including the processes to address Clinical Safety Issues
- Documentation of the CCA process.

David Bunker and Andy Bond, NEHTA, addressed a number of the issues raised around the schedule of specifications, the processes of review to date and the use of tiger teams.

- There was an acknowledgement that the timeframes for the specification development process were very tight and a strong assurance of the desire to appropriately bring the vendor community into the consultation loop.
- NEHTA indicated that all specifications scheduled for 31 October release (as detailed in the Specifications and Standards Plan) were on track, with the only exception being the Consumer Portal Interface.
- NEHTA indicated that the specifications development process had involved extensive consultation and review, including through the NEHTA reference groups and other specialists. The specifications will be of the best quality possible given the timelines and dependencies.
- NEHTA also noted that the development process will be ongoing, after the release of the specifications, through the tiger teams and as part of the process of advancing towards standards, through IT014 and the Standards Australia process.
- However NEHTA acknowledged that broad public consultation on some specs was imminent.

In respect of the Change Control Process, Paul Madden sought views from industry on what mechanisms of assurance could be provided as to the certainty and stability of the specifications and standards.

The MSIA indicated that industry seek quality and stability of the specifications. There is a risk that stability may not be able to be secured, and to this extent, industry may ask that DOHA/NEHTA accept responsibility and provide an undertaking to support industry for any associated impacts. The suggested form of support could vary, depending on the nature of the change to a specification/standards and an analysis of its impact, but could include:

- Training support
- Supported CCA testing processes

- Financial support for re-development costs.

It was agreed that a document be developed, detailing the process for change control and the governance structures supporting the process which would be included in the terms, conditions and licensing agreements. The triggers for change will be clearly identified and defined (clinical risk, legislative change and system errors). The change process will include an impact analysis as a part of the due process.

In respect of the CCA Process, Paul Madden asked that MSIA elaborate on their expectations from the process, and the aspects in the current CCA system which are not meeting expectations.

MSIA indicated that they will be providing a full report to the CCA Governance Committee by 4 November for discussion at a special purpose meeting planned for 10 November. The concerns are not so much about quality as quantity – recent messages suggesting some 12 or more CCA processes, occurring on an annual basis, have raised significant concerns with industry.

It was agreed that if these issues are not resolved at the CCA Governance meeting, they should be escalated to the ICT IIG for further consideration at the 16 November meeting.

Action 2.1: ACIVA to provide written summary of comments from members on the NEHTA Specifications and Standards Plan.

Action 2.2: NEHTA to provide further information in respect of the due process for development of, and consultation on the specifications:

- detail of the stakeholders – organisations and/or specialisations – involved in the processes of development and review of the specifications to date.

- detailed schedule for the Tiger Team reviews of specifications and for the stages in the review process from now to the release date.

- assessment of the quality of the draft specifications from the first Tiger Team consultations, and estimate of the time needed to have until ready for release.

Action 2.3: DOHA to coordinate, in consultation with NEHTA and the industry bodies, detailed documentation of the process for change control, including an impact analysis.

Action 2.4: DOHA to organise for the NCAP to provide information on the assessment of the readiness of the States to take up PCEHR – expectations around their commitment and capability.

Action 2.5: Secretariat to organise for feedback from the CCA Governance Group meeting on 10 November, and to escalate the issue of CCA processes to the November ICT IIG meeting if not adequately resolved in that meeting.