IT-014 Health Informatics Committee

Executive Summary Report

ISO Meeting

23- 27 May 2011

Version: Release 1.0
Date Issued: 24 June 2011
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Collated by: Standards Australia

With input from Australian Delegation and other employer funded Australians at the meeting:

- *Richard Dixon Hughes (Head of Delegation)*
- *Heather Grain (Delegate)*
- *David Rowlands (Delegate)*
- *Patricia Williams (Delegate)*
- *Anthony Maeder (Delegate)*
- *Michael Steine (Delegate)*
- *Andrew Caswell (WG8 Secretariat)*
- *Naomi Ryan (WG8 Secretariat – not funded through DOHA)*
- *Vince McCauley (Reserve- attending but not funded through DOHA)*

INTRODUCTION

The International Organization for Standardization (ISO) is the world's largest developer of standards. Although ISO's principal activity is the development of technical standards, ISO standards also have important economic and social repercussions. ISO is a network of the national standards institutes of 162 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland.

ISO develops health informatics standards through technical committee ISO/TC 215 Health Informatics, which conducts its activities through the following working groups (WGs) and other organisational units:

- TC 215 Executive Council - responsible for executive leadership and strategy
- WG 1 Data Structure
- WG 2 Data Interchange
- WG 3 Semantic Content [Convenor: Heather Grain (Australia)]
- Traditional Medicine Task Force (reporting through WG 3)
- WG 4 Security, Safety and Privacy
- Patient Safety & Quality Task Force (reporting through WG 4)
- WG 6 Pharmacy and Medication Business
- WG 7 Devices
- WG 8 Business Requirements for EHRs [Secretariat: Australia]
- Operations and Harmonization Committee – coordinates working group activity, secretariat processes and TC 215 work program.

The first ISO/TC 215 meeting for 2011 was held from 23 to 27 May in Kuopio, Finland and was attended by 9 Australian delegates (7 funded by the Department of Health and Ageing).

ISO/TC 215's activities are mirrored in Australia by Standards Australia Technical Committee, IT-014 on Health Informatics.

The benefits that the Australian Healthcare Community derives from Australian representation at international meetings such as this one are significant and ongoing. It is recognised that it is vitally important to ensure that an Australian national position is represented at such meetings. The most effective way of achieving this is to ensure that a delegation is comprised of the appropriate mix of skills and expertise in order that priority areas are comprehensively addressed.

ISO health informatics standards have tended to focus on policy, governance and functional best practice applicable to the e-health agenda - as opposed to the technical perspective found in HL7 and the content perspective of International Health Terminology Standards Development Organisation (IHTSDO). However, the formal relationships between each of these organisations are being extended through regular meetings of their representatives through the Joint Initiative Council (JIC) resulting in increasing collaborative effort to harmonise standards development along a continuum that includes policy, governance, quality/safety and implementation pathways. As a result, ISO TC 215 has provided an international forum in which key technical standards such as HL7v2.5, HL7v3 RIM, coordinated data types, HL7v3 CDA R2 and the CDISC BRIDG model are being jointly developed for acceptance as full international standards.

OBJECTIVES OF THE MEETING

Australia participates in international standards development activities in accordance with its obligations under World Trade Organisation treaties. The overarching objectives are to benefit the Australian health system and wider community by:

- Improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice.
- Promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing local health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different standards across domestic and international markets.
- Improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems.

Specific objectives for Australian engagement in international standardization via ISO TC215 (Health Informatics) include:

- Monitoring and influencing ISO TC215's strategic positioning and business model, encouraging it in leading collaboration with other global Standards Development Organisations (SDOs), and assessing and influencing its outputs so as to maximise Australia's capacity to ensure that our health information interchange and related requirements are supported unambiguously by international standards. A more global approach to standards development was a specific request to ISO from a range of national eHealth programs, including Australia's.
- Negotiating specific objectives for EHR, Personal Health Record (PHR) and health ICT safety standards.
- Progressing EHR Communication, Data Harmonisation, Subject of Care Identification, Provider Identification, and EHR/PHR Systems requirements standards into and through balloting, and assessing and contributing to other standards required for implementation of EHR and personal health record (PHR) applications, including updates to TS 18308.
- Advocating for consistency between major SDOs currently developing approaches to EHR interoperability, including consistency regarding data types, object constraint models, health information service architectures, and clinical information models and their representation.
- Facilitating consistency and collaboration between global SDOs in development and adoption of health informatics standards – including encouragement of and participation in harmonisation activities through the Joint Initiative Council (JIC) of ISO, CEN, HL7, IHTSDO, CDISC and GS1 and the JIC Harmonisation stream at ISO/TC 215 meetings (ISO TC215 /WG9).
- Leading development of consistent terminology and an approved lexicon of terms and thesaurus for use across all ISO health informatics standards.
- Progressing information security standards, including (where appropriate) encouraging finalization of standards on: Secure archiving of electronic health records; Security management in health using ISO/IEC 27002; Privilege management and access control (PMAC); Audit trails for electronic health records; Functional and structural roles; Information security management for remote maintenance of medical devices (guideline); Dynamic VPN access to health networks, and EN13606 Part 4 within ISO.
- Supporting the proposed liaison between ISO TC215 and ISO/IEC Joint Technical Committee 1 (JTC 1) with a view to encouraging collaboration on IT standards affecting health care delivery and avoiding duplication of work.

Relevance to NEHTA programs - NEHTA has endorsed a range of Australian Standards derived from international standards work some of which were included in a National eHealth Standards Catalogue. A more recent review has identified many of potential relevance to development of the Personally Controlled Electronic Health Record (PCEHR). As the implementation of PCEHR and other eHealth initiatives is based on a growing body of these standards, it is important that Australia continues to be involved in the international forums that develop, manage and maintain these, and other potentially relevant, health informatics standards.

ISO TC 215 holds two full international meetings per year. The first (in May) is known as the "Plenary Meeting" because it includes plenary sessions in which formal resolutions are taken in addition to meetings of TC 215's eight domain-specific working groups.

The second meeting, (in September/October) is the "Joint Working Group Meeting" because it mainly comprises meetings of the working groups but, in recent years, has also included a smaller "mini-plenary" to progress urgent matters.

The Plenary Meeting for 2011 was hosted by the ISO national member body for Finland (SFS) and covered five days from 23 to 27 May in accordance with the agenda below.

The meeting was attended by some 200 delegates from 21 participating member countries and included representatives of liaison organisations including TC 249 (TCM), IHTSDO, GS1, WHO, ICH, JTC1, CDISC and IEEE.

Being held in Europe, most sessions were held jointly with the European CEN/TC 251 Health Informatics committee and its four working groups.

The event is a true working meeting, not a conference, with many individual groups meeting to develop, discuss and improve ISO standards, processes and implementation guides and to determine the most effective way to meet the needs of the stakeholders – both those present at the meeting and those in the wider community of interest.

The meeting was preceded by a one-day working session for the project team working on ISO Technical Report 14639 Capacity-based ehealth architecture roadmap. The Australian delegation also met on the Sunday before the official meeting commenced.

The number of concurrent sessions and the unavailability of experts in some of the TC 215 subject areas make it difficult for small delegations to effectively follow the issues and to influence change in all of the active areas.

This particular Australian delegation had a good mix of skills across the areas that we were able to cover and we had virtually no duplication. Nevertheless, residual gaps in funded attendance highlighted the fact that the delegation had fewer experts than really required to address all of Australia's interests appropriately. To provide the required coverage and mix of skills, we should have had approximately two extra funded delegates.

MEETING AGENDA AND LOGISTICS

The agenda for the five days of the main TC 215 meeting was as follows:

ISO/TC 215 and CEN TC 251 Health Informatics Plenary Meetings
Kuopio Finland 23-27 May 2011

Date	Time	Note: All Monday Meetings will be in Puijonsarvisali (Topelius-Snellman-Canth) Room						
Mon 23-May	1000-1100	**Operations and Harmonization meeting** — **Invite Only**						
	1130-1430	**Executive Council** (includes lunch) — **Invite Only**						
	1500-1600	**Discussion by ISO-CS on Changes to RA's and the process to update/ballot yearly** — **Everyone may attend**						
	1630-1830	**Open Forum: JIC report and 215 Re-organization Report and Discussion** — **Everyone may attend**						
	Room							
Working Group		215-WG 1 251-WG1	WG2	215-WG3 251-WG 2	215-WG4 251-WG3	WG6	215-WG7 251-WG 4	Task Forces
Room Assigned		Snellman	Ferdi	Canth	Luentosali	Samuel	Renkku	Topelius
24-May	0730 - 0900							
	0900- 1000	Opening Plenary -						
	1000-1030	Coffee Break						
	1030-1215	• Welcome, introductions & roll call • Agenda Review • Any Other Business? • Published Standards o ISO FDIS 18308 (WG8) o ISO IS 21667 (WG1) 13606-1 Review ISO TR 14292	Opening of the WG 2 Roll call and introductions Adoption of the agenda Approval of minutes Report of the WG 2 (acting) Secretariat Report of Work Program CDISC-BRIDG Model Status Clinical Trials Registration and Registry (CTR&R) NWIP review	Welcome, introductions & roll call • Agenda Review Review Minutes/Actions • Any Other Business? • o EN12264/17115 Vocab Term System o 13119 Metadata 13120 Syntax Classification of Systems in Healthcare TMTF meeting in Ferdi	Welcome and meeting schedule overview Work program update 17090 PKI revision	• Welcome & agenda review • Update on ISO/DTR 10895 Health informatics - Business Requirements for the Reporting of Pharmacist Services • Update on NWIP Health Informatics - Business requirements for a syntax to exchange structured dose information for medicinal products	• Welcome, introductions, review agenda • Review minutes/actions • Any Other Business? • Report of recent meetings (IEEE 11073 meeting, IEEE 11073 PHD meeting)	Traditional Medicine Task Force
	1215 - 1315	Lunch						
	1315 - 1500	• Framework for National Health Information Systems • ISO TR 14639 Business requirements for an e-health architecture for developing and emerging countries - Parts 1 – Status report ISO TR 14639 Part 2 – Status report	Genomics - Pedigree Topic ISO 13449 HL7 V3 Reference Information Model - Maintenance Release Process- Follow up to Rotterdam Resolution and coordination with similar maintenance release needs	1828 Categorical structure for terminologies of surgical procedures 18104 Categorical structures for representation of nursing diagnoses and nursing action in terminological systems	TF Health Cards	Ballot results NWIP ISO/DTS 16791 Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers	• Report of SAMD, EU Formal Objections (13485, 14971) • Network Risk Management ISO/IEC JWG7 80001-x update • Update on ISO/IEC JWG7 NWIP Healthcare Software Systems	JWG 9- Harmonization Session
	1500 - 1515	Coffee Break						
	1515 - 1700	• ISO TR 14639 Part 2 – Status report • Enterprise Architecture Technical Report (CEN)	Work Item Status IHE Use Cases Integ profiles Docu Reg TR 13128 Health Applications on Mobile/Smart Devices	16278 ID status of structures for representing HA with Term systems 12300 Update	14441 Security & privacy requirements of EHR-systems for use in conformity assessment	Update on prEN ISO 27953 parts 1 & 2 (ICSR)	• Review of the work plan (215/WG7 & 251/WGIV) • Review of ballots for review (215/WG7 & 251/WGIV)	
	1830-2000	Social event at Kuopio City Hall, host Markku Tervahauta, Director, Social and Health, City of Kuopio						

Date	Time	WG 1/8	WG2	WG3	WG4	WG6	WG7	Task Forces
Room Assigned		Snellman	Ferdi	Canth	Luentosali	Samuel	Renkku	Topelius
Wed	0730 - 0845							
	0845 - 0900							
25-May	0900-1030	Comb - WG1,WG3, WG8. Sessions EHR Preservation Wo Chang NIST (10 min) • ISO 13972 Quality requirements and methodology for detailed clinical models (1 & 2) Request to move to CD DTR 13054, Standards Knowledge Management	Quality Measures for Telehealth TS 13131 Coordination: ITU-T SG 17 *Request for comments on draft Recommendation Integrated framework for telebiometric data protection in e-Health and worldwide telemedicine	Report from TMTF 16843 Categorical structures for representation of acupuncture part 1& 2 and NWIPs from TC 249	WG4/WG7 Risk management, patient safety, health software and medical devices: General update and coordination *Request for comments on draft Recommendation Integrated framework for telebiometric data protection in e-Health and worldwide telemedicine	prEN ISO 11238: DIS ballot disposition of comments	WG4/WG7 Risk management, patient safety, health software and medical devices: General update and coordination	JIC Executive session
	1030-1045	Coffee Break						
	1045-1215	• Decision support and alerts	Terminology Binding Rules NWIP Presentation and Discussion	16277-1 structure of representation of clinical findings in TM update 12310-12975 NWIP for strufture and maintenance of HI glossary	WG4/WG7 Risk management, patient safety, health software and medical devices: NWIP Healthcare Software Systems	prEN ISO 11615 & 11616: DIS ballot disposition of comments	WG4/WG7 Risk management, patient safety, health software and medical devices: NWIP Healthcare Software Systems	JIC Executive session
	1215 - 1315	Lunch						
	1315 - 1500	WG1/WG4/WG7/WG8 NWIP Standards for safe health software TR	WADO-Web Services Web Access to DICOM persistent Objects by means of Web Services ISO 12974 Web Access Reference Manifest IS 10159	Revision on 17117 OID Discussion: 13581 & 13582	WG1/WG4/WG7/WG8 NWIP Standards for safe health software TR	ISO/TR 14872 "Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information	WG1/WG4/WG7/WG8 NWIP Standards for safe health software TR	
	1500 - 1515	Coffee Break						
	1515 - 1700	Chair: WG3, Heather Grain Session 1: ContSys Concept modelling – what is it and why does it matter	WG2 Closing Plenary and resolutions	Chair: WG3, Heather Grain Session 1: ContSys Concept modelling – what is it and why does it matter	16114 EHR migration 21091 Directory services	prEN ISO 11239 & 11240: DIS ballot disposition of comments	open for carry over discussions from this morning/afternoon	
	1730-1830							
	1830-2200	Health Innovation meeting hosted by Kuopio Innovation and Technopolis (max 100 participants, register at SFS desk in Puijonsarvi during meeting)						

Date	Time	WG 1	Room Open	WG3	WG4	WG6	WG7	Task Forces
Room Assigned		Snellman	Ferdi	Canth	Luentosali	Samuel	Renkku	Topelius
Thurs	0730 - 0845							
	0845 - 0900							
26-May	0900 - 1030	ContSys Shared session with WG1/3/8 Walkthrough of the key areas • Just a few examples of concepts	open	ContSys Shared session with WG1/3/8 Walkthrough of the key areas • Just a few examples of concepts	EN 13608 Security for healthcare communication EN 12251 Password identification 22600 Privilege management and access control	Formal WG 6 meeting	WG 7	JWG 9- Harmonization Session
	1030-1045	Coffee Break						
	1045 - 1215	• ISO NWIP PHR system functional model • 10781-r2 Public Health Standards - Business Requirementds & Evaluation	open	Formal Meeting Resolutions	27789 Audit trails 22857 and 16864 Data protection in trans-border flows	Formal WG 6 meeting	WG 7	
	1215 - 1315	LUNCH						
	1315 - 1500	WG 1 and formal resolutions	WG 8	Open	Joint formal meeting ISO/WG 4 and CEN/WG III	open	WG 7	
	1500 - 1515	Coffee Break						
	1515 - 1600	CEN WG 1 Resolutions	WG8 resolutions	Open	Resolutions	open	WG 7 Resolutions	CEN WG 1?
	1600-1700	Review of WG Resolutions with Audrey/Mike for correct ballot designation, for completeness and use of the resolution						
	Delegate Meetings 1700-1800	United Kingdom	United States	Australia	Japan	Netherlands	Canada	Mexico
Date	Time	WG1	WG2	WG3	WG4	WG6	WG7	Task Forces
Fri	0730 - 0845							
	0845 - 0900							
27-May	0900 - 1030	Plenary Day 0900-1700 Puijonsarvisali (Topelius-Snellman-Canth)						
	1030-1045	Coffee Break						
	1045 - 1215	Plenary Day 0900-1700 Puijonsarvisali (Topelius-Snellman-Canth)						
	1215 - 1315	Lunch						
	1315 - 1500	Plenary Day 0900-1700 Puijonsarvisali (Topelius-Snellman-Canth)						
	1500 - 1515	Coffee Break						
	1515 - 1700	Plenary Day 0900-1700 Puijonsarvisali (Topelius-Snellman-Canth)						

The meeting was preceded by a one-day meeting of the project team working on ISO Technical Report 14639 - Capacity-based eHealth architecture roadmap.

RECOMMENDATIONS ARISING FROM THE MEETING

The principal issues / actions and recommendations identified by the Australian delegation at the May 2011 ISO TC 215 meeting are summarised in this section. Alignment to the IT-014 Committee Structure is also listed.

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
Executive Council - upcoming TC 215 meetings	The TC 215 meeting schedule had become tenuous with Korea becoming unavailable for the next meeting in October 2011. In addition, no countries had committed to hosting TC 215 meetings in 2012. Having been the host in 2002 and again in 2007, it is again getting around to being Australia's turn but preliminary discussions indicated that the earliest that funding could be considered for Australia to host TC 215 would be in 2012/13 year. Following discussion at both JIC (to coordinate meeting schedules) and at Executive Council, the lack of hosts appears to have been largely resolved for 2011/12 and 2012/13, with the following now being planned: • October 2011: Chicago (subject to AHIMA securing the TC 215 secretariat) • May 2012: Vancouver (to abut the HL7 meeting at the same location) • October 2012: Austria (tentative) • May 2013: Japan (tentative) **Action: IT-014 and Standards Australia note that an urgent request to host TC 215 in Australia now appears unlikely but that IT-014 should pursue the feasibility of support to make a firm offer for 2013/14 or 2014/15.**	IT-014 and Standards Australia for discussion with DoHA
Organization & Business Plan Task Force (OBP TF)	The report of the OBP TF was considered. It proposed: some changes to TC 215 scope, a revised structure for work coordination; reducing the number of standing WGs and greater use of task forces to progress particular projects. The TF was continued with the task of developing an implementation plan. Richard Dixon Hughes and Heather Grain continue as TF members. Any change in TC 215 structure will have implications for IT-014, CEN and other countries' TC 215 mirror group structures; however, IT-014 is facing similar pressures and considering similar changes. **Action: IT-014 take into account potential changes in TC 215 organisation in determining any new IT-014 structure and the potential for change in mirror committee requirements.** **Action: IT-014 continue to support Australian participation in the TC 215 organisation and business plan task force by considering the reorganisation proposals and providing input into the implementation planning through Richard Dixon Hughes and Heather Grain.**	IT-014 Richard Dixon Hughes & Heather Grain (as TF members)

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
Registration Authorities (RA)/ Maintenance Authorities (MA)	Some TC 215 activities (e.g. Identification of Medicinal Products – IDMP) generate standards and related code sets that need frequent updating. ISO/IEC rules for RAs and MAs to address these needs were presented and suggestions made for use of an RA. While TC 215 (and Australian delegates) need to be aware of these approaches, TC 215 decided to complete relevant standards before contemplating use of an RA or MA structure. **Action: IT-014 and delegates to future TC 215 meetings note the potential to use RA and MA structures to manage standardized content that need frequent updating and keep abreast of changing rules and requirements in this area.**	IT-014 Delegates to future TC 215 meetings
Joint Initiative Council(JIC)	HIMSS is giving up the TC215 and JIC secretariats, the chair of the JIC has now progressed to SDOs that were not involved in its inception and a new Joint Initiative (JI) charter is being prepared. There is a growing risk that lessons learnt will be lost (particularly the need to negotiate joint balloting and comment reconciliation up front). Opportunities for input from national bodies and individual experts (through JWG) also appear likely to be reduced unless the continuing role of JWG is recognised. While these changes may suit the agendas of some of the participating SDOs, the risk is that the JIC becomes less influential and less effective in addressing stakeholder calls for a harmonisation of SDO work and output. **Action: Through influence at ISO TC 215, HL7 and CEN, IT-014 continue to promote the importance of JIC having appropriate processes to receive input from national bodies and individual experts, particularly in relation to progression.**	IT-014 and ISO TC 215 Delegation Members
Working Group 1 (Data Structures) Detailed Clinical Models (DCM)	ISO 13972 Quality requirements and methodology for detailed clinical models. This 2-part standard has attracted a lot of interest and debate in Australia. Notwithstanding Australia originally voting against the document (because its original focus was too narrow and excluded use of modelling paradigms other than UML), Australian experts are making a significant contribution to its development. • Part 1 is on "Quality processes regarding detailed clinical model development, governance, publishing and maintenance - proposed as a Committee Draft (CD) • Part 2 is on "Quality attributes of detailed clinical models" A draft of each part is being reviewed by the nominated experts and refined before being balloted more widely among TC 215 members. The principal IT-014 engagement with this work is through IT-014-09 with active input from NEHTA and Ocean Informatics **Action: Australian experts to review and provide feedback directly to ISO project lead, William Goossen (NL), on proposed CD for Part 1 and Part 2.** **Action: IT-014-09 to monitor progress, review and arrange input for proposed ballots of Part 1 and Part 2.**	IT-014-09 (leading) IT-014-06-06 NEHTA Nominated Australian experts: - Evelyn Hovenga - Heather Leslie - Stephen Chu - Richard Dixon Hughes Standards Australia as WG8 secretariat

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
Working Group 2 (Data Interchange) BRIDG model for biomedical research	ISO 14199 BRIDG Domain Analysis Model for protocol-driven biomedical Research is a JIC-endorsed project jointly sponsored by HL7, CDISC and ISO which is migrating the BRIDG model (originally developed and still maintained by CDISC) into a full international ISO standard. The aim is to provide a common framework for collection of clinical research data that streamlines collection and facilitates re-use. As the CDISC version of the standard is updated annually, arrangements for keeping versions in sync remain a challenge. **Action: IT-014 to seek NH&MRC input to validate the model from Australia's perspective.**	IT-014-06 (leading) IT-014-09 Potentially – NH&MRC
WG 2 Clinical trials registration & reporting (CTR&R)	The primary purpose of CTR&R standard is to provide seamless data exchange between global pharmaceutical sponsors and clinical trial registration authorities such as US (ClinicalTrials.gov), European Medicines Agency (EMA) (EudraCT) and WHO (Clinical Trial Registry). It is proposed as a 2-part standard intended to meet global requirements for clinical trials registration (Part 1) as well as reporting of trial status and summary results (Part 2). The current focus has been almost exclusively on Part 1 and is being led by CDISC and the Regulated Clinical Research Information Management (RCRIM) WG within HL7 International. (See: http://www.hl7.org/Special/committees/rcrim/index.cfm) A proposal to ballot a new work item proposal (NP) to develop an international standard was approved and Australian input should soon be required to respond to the ballot. Australian interests should consider whether to become involved in the Part 2 work and guideline collation activities, in particular to harmonize these with Australian national trends for eResearch e.g. ARCS (Association of Regulatory and Clinical Scientists) and ANDS (Australian National Data Service). **Action: On receipt of the ballot documentation, IT-014 to seek input from the local clinical trials community on Australian perspectives and potential participation in the work.**	IT-014
WG 2 IHE process and integration profiles	ISO technical report ISO/TR 28380 seeks to document IHE processes and key outcomes, providing IHE with a claim to some recognition and acceptance on the part of the international standards community. During the first phase of this project two parts of TR 28380 are being produced, dealing with: • The IHE global standards adoption process (Part 1); and • IHE Integration and Content Profiles (Part 2) Unfortunately, despite a positive vote in August 2007, the approved drafts have yet to be updated into final form and published. Processes for keeping Part 2 updated are also being contemplated. In the closing plenary, Australia expressed concern at the delay in concluding this work – pointing out that the work is often mis-quoted as being complete and that such a long delay in publication would lead to any type of standards project other than a technical report being cancelled. **Action: IT-014 to work with IHE Australia in monitoring progress of TR 28380 and encouraging its finalisation, publication and regular update.**	IT-014-06 IHE Australia HL7 Australia

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 2 Clinical Document Registry Federation	ISO TR 13128, originally proposed by Korea, defines an extension to the IHE Document Registry in order to allow a federated registry/access model. A draft of the proposed TR passed ballot in November 2010 with some significant issues being raised in comments. It is unclear whether IHE supports the proposed approach. The comments received during the ballot process are being incorporated into a revised draft of the Technical Report, which will then be submitted directly for publication. **Action: IT-014 note the pending publication of TR 13128 and obtain feedback from relevant interests on its potential relevance in the context of various PCEHR projects.**	IT-014 (IT-014-09 leading) IHE Australia
WG 2 Expressing terminology constraints on coded data elements	TC 215 agreed to hold an NP ballot seeking approval for work on a new ISO standard: "*Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange*". It will address how to define and express terminology constraints applicable to coded data elements used in standards and standardized eHealth information models. The approach is focussed on HL7 information models and is designed for use with the new ISO 21090 harmonised datatypes and CTS2. An earlier draft has already been balloted in HL7, and the ISO product will be a subset of the HL7 work and subject to joint copyright. This work Item is potentially relevant to the HL7 Messaging (IT-014-06), Terminology (IT-014-02) and datatypes within the EHR Interoperability (IT-014-09) domains – with the ballot currently planned to open in Jun/Jul 2011. Consideration needs to be given to whether such a standard should be closely tied to HL7v3 constructs or more generally applicable to any form of detailed clinical model. **Action: IT-014-02, IT-014-06 and IT-014-09 to track this work item and collaborate with NEHTA, HL7 Australia and other key stakeholders to inform Australia's position on the NP ballot.**	IT-014-09 (leading) IT-014-02 IT-014-06 Collaborating with: - NEHTA - HL7 Australia - IHE Australia
Working Group 3 (Semantic Content) Clinical Decision Support (CDS)	Rikard Lövstrüm & Heather Grain presented to a joint meeting of WG 1, WG 8 and WG 3 on the work to produce authoritative consolidated specifications in the area of Clinical Decision Support and Clinical Alerts. Existing work item based on adapting Australian handbook is being extended to target a 3-part international technical specification aimed at different audiences. • ISO TS 14668-1 … Clinical decision support – Part 1: System foundations; document being completed for balloted from mid-July 2011 • ISO TS 14668-2 … Clinical decision support – Part 2: Technical foundations; new work item ballot is imminent • ISO TS 14668-3 … Clinical decision support – Part 3: Alert system requirements; new work item ballot is imminent	IT-014 (via task-specific group) Collaborating with: - NEHTA, - HL7 Australia ACSQHC - DoHA - Jurisdictions - Clinical Professions

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	This work is of potential relevance to many Australian interests including PCEHR. Consideration needs to be given to how IT-014 would like to manage the 3 ballots for this work item and ensure harmonisation with HL7 activities in the technical area. It is suggested that a task specific group on this activity be created within IT-014. **Action: IT-014 to engage widely to formulate response to the upcoming CDS ballots** **Action: IT-014 to consider the need for a task-specific group to focus on clinical decision support and related aspects of patient safety.**	
WG 3 Mapping of terminologies	Work to produce ISO Technical Report 12300 (renamed: *"Principles of mapping terminological systems"*) is led by Australia and passed an initial ballot but with many comments. Given the level of comment and a proposed restructure to improve clarity, a revised version is being prepared for re-ballot. Australia is responsible for the re-draft. **Action: IT-014-02, as the Australian mirror group, to provide oversight and input needed to deliver text revision for re-ballot of ISO TR 12300.**	IT-014-02 Heather Grain
WG 3 Terms used in terminology practice	The following health informatics standards are due for review: • *EN 12264 Categorial structures of system concepts* • *ISO 17115 Vocabulary of terminological systems* It is proposed that the terminology proposed in these documents be harmonised and form part of the online health informatics glossary, rather than being the subject of separate publications. Input will be sought from IT-014-02 to assist in the harmonisation process and to advise on the related update of: *ISO 17117 Terminological Resources – Part 1 Characteristics*. **Action: IT-014-02 to review and provide input on proposals to harmonise terms from ISO 17115 and EN 12264.**	IT-014-02
WG 3 ContSys –System of concepts to support continuity of care	The proposed *ISO 13940 ContSys* standard (based on refinement of an established European standard) will provide a framework of common concepts for expressing clinical and workflow activities and requirements surrounding the delivery of healthcare. A committee draft (CD) is being prepared and requires detailed Australian input to ensure harmonisation with approaches and activities used in this country (and also HL7 and the SKMT glossary). The CD is planned to be out for a 3 month ballot from October. **Action: IT-014 to initiate establishment of a broadly-based taskforce to manage the review of ContSys requirements and to provide oversight and comments upon this work as it develops through CD, DIS and FDIS stages over the next few years.**	IT-014, NEHTA, Jurisdictions

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 3 Nursing diagnosis and nursing actions in terminological systems	The UK is leading work on *ISO 18104 Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems*, updating existing published work. The ballot to accept the committee draft (CD) for circulation as a draft international standard (DIS) closed the week before the TC 215 meeting. The ballot passed with comments giving significant support for the proposed updates and, particularly improvements in the representation of nursing actions. **Action: IT-014 to ensure engagement and input from appropriate nursing bodies in Australia in the review and progression of work on *ISO 18104*.**	IT-014, with IT-014-02 leading
WG 3 Measurement of conformance of terminological systems	A full working draft of the proposed technical report *ISO TR 12310 Principles and Guidelines for the measurement of conformance in the implementation of terminological systems* was received 2 weeks prior to the meeting. Upgrade from a Technical Report to a Technical Specification is being considered to enable it to specify conformance requirements, with comments now being sought (preferably by end-June 2011). This work is of direct relevance to the implementation of SNOMED-CT in Australia and needs active input from NEHTA and the Australian Clinical Terminology User Group (ACTUG). **Action: IT-014-02 to continue discussion, engaging with NEHTA and ACTUG, and manage submission of Australian comments to support upgrade of the document to support its use in conformance testing of terminology implementations.**	IT-014, with IT-014-02 leading Collaborations: - NEHTA - ACTUG
WG 3 OID registries	• *ISO/NP 13581 Guidance for maintenance of object identifiers* • *ISO/NP 13582 Communication model and XML interface specification for OID registries* Development of these standards is a joint activity of TC215, HL7 and other relevant ISO technical committees, which seeks to provide a consistent approach to management of object identifiers and their metadata across OID registries. The draft documents need to be circulated at committee level for wider input before release to DIS ballot. Australian review of the draft documents will be required. **Action: IT-014 to identify the relevant sub-group(s) for review, potentially IT-014-06 (leading), IT-014-02 with input from HL7 Australia and NEHTA.**	IT-014 potentially through: - IT-014-06 - IT-014-02 HL7 Australia NEHTA
Working Group 4 (Security, Privacy & Patient Safety) Transborder flows of personal health information	New work on a proposed international standard *ISO 16864 Health Informatics – Data protection in trans-border flows of personal health information* passed its NP ballot but did not attract the required commitment of 5 experts. The work aims to subsume and update the guidelines in *ISO 22857:2004* and two similar European standards – consolidating them into a single document. This work is of growing relevance as jurisdictions look to provide trans-border access to EHR information.	IT-014

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	Queensland Health provided comments but, as a supporter of the project, Australia should have nominated an expert to work on the project but did not do so. **Action: IT-014 to seek an Australian expert to nominate for work on development of ISO 16864 (by mid-July).** **Action: IT-014 secretariat to ensure relevant Australian experts are nominated in support of positive TC 215 votes.**	
WG 4 Security & privacy requirements for use in compliance testing of EHR systems	*ISO/DTS 14441 Health informatics – Security and privacy requirements for compliance testing of EHR systems* is a draft technical specification currently targeting two parts: • *Part 1: Foundation* • *Part 2: Protection profile for small scale patient health record systems* These technical specifications will provide a framework, guidance and specific requirements on security and privacy protection for use in conformance testing of EHR systems. Further parts are planned. Drafts of the technical specifications are being developed by a project team with Part 1 being fairly advanced and work planned through 2011/Q3-Q4 on Part 2. The work is potentially very relevant to Australia as we move toward CCA regimes to support PCEHR. Work on assimilation of over 100 comments from the initial NP ballot is being progressed by international teleconferences, which are open to any who can contribute their time and expertise. Australia did not originally provide comments. Trish Williams is prepared to participate in calls but broader Australian review and input is required as the basis for more informed input. **Action: IT-014-04 to manage broadly based review of ISO/DTS 14441 work items and Part 1 draft with a view to developing Australian requirements for input to the work and subsequent comment on the new 14441 documents as they are circulated for ballot.** **Action: Trish Williams to attend online meetings and liaise with IT-014-04 and potential Australian stakeholders.**	IT-014 with IT-014-04 leading Collaborations: - NEHTA/CCA - IT-012 (info sec) Trish Williams
WG 4 Privilege management & access control	Work is commencing on the systematic review of the 3-part ISO 22600 series of technical specifications on privilege management and access control (PMAC) with a view to their being updated and upgraded to full international standards. These documents have been the subject of thorough review and are increasingly relevant as Australia encourages the uptake and exchange of electronic health record information in a secure environment that protects the privacy of individual health information. **Action: IT-014, through IT-014-04 to engage with widely with potentially relevant interests in the systematic review and upgrade of the IS0 22600 series of PMAC documents.**	IT-014 with IT-014-04 leading

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 4 Security and privacy in personal health systems	TC 215/WG 4 had a presentation and discussion of security and privacy issues in Personal Health Systems (PHS), which include: pHealth, Ubiquitous health, CyberHealth, Internet based health and healthcare applications (e.g. HealthVault, Google Health, Health Facebook), iPAD and mobile-phone based apps for health services and sensor systems. The use of these tools and services introduces security and privacy threats which do not exist in today's dedicated healthcare ICT solutions. Many of the security and privacy threats are not just healthcare specific. A discussion paper is proposed to identify what standards exist to address these emerging threats, how they might be applied to address potential threats from use PHS and whether there are any gaps in standards work to protect against these threats. **Action: IT-014 to consider whether and how to contribute to a discussion paper on the potential impact and use of personal health systems with respect to security privacy concerns.**	IT-014 with IT-014-04 leading
WG 4 Gap analysis -	To assist forward planning, WG 4 is to conduct a gap analysis for standards across its domain of Health informatics Security, Privacy and Safety. This will be undertaken by a project team consisting of Bernd Blobel (DE), Lori Reed-Fourquet (US), Maria (NO) Alessandra Pastorino (IT), Pekka Ruotsalainen (FI) and Trish Williams of Australia. **Action: IT-014 note Australian participation by Trish Williams in the ISO/TC 215/WG 4 gap analysis for standards in Security, Privacy and Safety and request that she keep IT-014 and IT-014-04 informed of progress and opportunities for review and/or input.**	Trish Williams IT-014-04
Working Group 6 (Pharmacy and Medication) New project on electronic prescriptions	A proposal to ballot a new project (NP) on *"Requirements for electronic prescriptions"* was approved. This standard will specify general principles for electronic prescriptions and the content needed to facilitate the exchange and processing of an electronic prescription. The scope is limited to the content of the electronic prescription and does not include the means by which electronic prescriptions and dispensing notifications are exchanged or otherwise communicated. The Australian work on Electronic Transfer of Prescriptions (ETP) was presented to WG 6 and was influential in developing the proposal for the new work item. **Action: IT-14-06-04 to review the NP ballot proposal (expected mid-July or later) in collaboration with the NEHTA EMM team with a view to nominating an Australian expert to support the work.**	IT-014-06-04 (leading) Collaborations: - NEHTA - Potential Meds TF - DoHA/PSB

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 6 Individual Case Safety Report (ICSR)	The ISO 27953 ICSR standard has passed final FDIS ballot but publication has been delayed because of issues related to its being published as a joint ISO and HL7 document. These issues are expected to be resolved by July. **Note:** TGA are understood to be currently assessing adoption of a previous version which will make them out of step with other regulators such as the EMEA (European Medicines Agency) and FDA (Food and Drug Administration – US). **Action: IT-014 to contact TGA in regards to their plans for ICSR.** **Action: IT-014 to initiate proposed task-specific group on Medications and request it to consult and advise on potential Australian/NZ adoption of the ICSR standards.**	IT-014 Potential Meds TF (leading) Collaborations: - IT-014-06-04 - NEHTA - TGA - DoHA/PSB
WG6 Identification of medicinal products (IDMP)	The series of 5 standards for *Identification of Medicinal Products (IDMP)* define data elements and structures for the unique identification and exchange of regulated information on medicinal products. Over 1500 comments were received during the DIS ballots and these have now all been resolved, with the following being noted: • prEN ISO 11238 (substances). Most comments were editorial. Proposed changes to substance models were non-persuasive • prEN ISO 11239 (pharmaceutical dose forms, units of presentation, routes of administration and packaging). Most changes were to align with the other 4 standards. • prEN ISO 11240 (units of measurement) – clarifications on alignment with SI Units added. Both 2- or 3-letter country and language codes are now proposed as acceptable. • prEN ISO 11615 (regulated medicinal product information) Over 500 comments were received on this document – some related to compliance with new EU regulations. Some others addressed the conceptual model design. • prEN ISO 11616 (regulated pharmaceutical product information). References to dosage administered were removed and additions were made to cater for products combining medical devices and pharmaceutical products For all 5 standards the editors agreed to have the final revised documents incorporating the agreed changes ready for the TC 215 secretariat by 27 June 2011. A technical report (TR14872) on implementation of the IDMP standards (and managing the associated vocabularies) is also being prepared and has been approved to proceed directly to publication when ready (planned for March 2012). It will provide a process for the IDMP vocabularies to be maintained without use of an ISO "Registration Authority" until use of IDMP is established. **Action: IT-014 to refer review of FDIS ballot for the 5 IDMP standards to proposed task-specific medications group and also TR 14872. Alignment with other Australian initiatives such need to be assessed.**	Potential Meds TF (leading) IT-014-02

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 6 Machine-readable coding of medicinal products	The NP ballot to approve work on *ISO/DTS 16791 Business Requirements for an international machine-readable coding system for medicinal products* was passed. A draft technical specification is being prepared (under GS1 leadership) and is expected to be ready for DTS ballot by March 2012. The project lead is Gary Hartley (GS1 NZ). Pat Gallagher and Tania Snioch (GS1 Australia) are two of the seven nominated experts working on the project. **Action: IT-014 to (a) support the nominated experts; and (b) collaborate with GS1 Australia and GS1 NZ in reaching out to local interests to ensure that Australian/NZ needs are reflected in the initial draft and to build a community able to contribute to the DTS ballot.**	IT-014 Collaborations: - IT-014-06-04 - Potential Meds TF Nominated Australian experts: - Pat Gallagher - Tania Snioch
WG6 Model for dose syntax	The NP ballot to approve work on *ISO/DTS 17251 Business requirements for a syntax to exchange structured dose information for medicinal products* closed on 28 May 2011 (and was passed). A new project leader is being sought to lead preparation of the DTS document, with the aim of being ready for DTS ballot in March 2012. Austria was the only country to vote negatively – raising questions of compatibility with other work from HL7, IHE, CEN and ISO. These matters should be discussed by WG6 at the October meeting of TC 215 and Australia needs to be across the issues to ensure that both the work (and our DTS ballot) are based on a solid foundation. **Action: IT-14-06-04 to review the ballot draft and comments received to assess potential alignment to ETP dosage syntax and other local medications management initiatives with a view to monitoring and/or influencing the direction of work when discussed at the Oct 2011 TC215 meeting.**	IT-014-06-04 (leading) Australian delegates to TC 215 in Oct 2011 Collaborations: - Potential Meds TF - NEHTA/eMM
Working Group 7 (Devices)	This working group's focus was twofold: • Joint items with WG4 on medical device and health software safety (reported under WG 4 and/or as specific items later in this report) • Adoption of IEEE/HL7/IEC/IHE standards for devices work. This meeting was a joint committee of ISO TC215 and CEN TC251 (WG IV) device experts. WG7 has a long history of working closely with medical device standards being progressed by HL7, IEEE, IHE and IEC – with much of the joint development being done in these other groups and then adopted as international standards through TC 215. **Action: IT-014 to continue efforts to monitor and contribute to work on clinical device communication, interfaces and safety through IT-014 leadership and selective engagement with relevant stakeholder groups including MSIA, TGA and device manufacturers.**	IT-014 generally with input on specific issues via leadership of IT-014-06 IT-014-09 IT-014-12
WG 8 Published Standards	The following two standards have been passed and published: • ISO FDIS 18308 (WG8) • ISO IS 21667 (WG1) **Action: IT-014 through IT-014-09 to consider adoption of these Standards for Australia.**	IT-014 with IT-014-09 leading Standards Australia as WG8 secretariat

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 8 EHR Communication	13606-1 Part 1: Reference model A systematic review is due for some but not all 'parts' of this document. It was agreed that all 5 'parts' should be reviewed together as a bundle and a New Proposal (NP) submitted for systematic review at that time in May 2012. **Action: IT-014-09 to monitor and become involved in systematic review of all 5 documents in a year and consider adoption into Australia.**	IT-014 IT-014-09 Standards Australia as WG8 secretariat
WG 8 PHR	ISO TR 14292 Personal health records definition, scope and context There was much discussion regarding recent comments, particularly from Finland, relating to the EHR PHR "continuum" diagram in the document (originally proposed by Heather Leslie of Australia). The diagram was re-drafted to incorporate 3 sections depicting the transition from individually controlled health records (PHR) through information exchange and shared use to health care provider controlled health records (EHR). Other comments were also resolved including Australia's comments on alignment of definitions. The updated draft has been sent out for approval from all countries. **Action: IT-014-09 to monitor, review and respond to updated document by 30 June.**	IT-014-09 Standards Australia as WG8 secretariat Nominated Australian experts: - Heather Leslie - R. Dixon Hughes
WG 8 eHealth architecture roadmap – Part 1: national initiatives	ISO/TR 14639-1 … Capacity-based ehealth architecture roadmap Part 1: Overview of national ehealth initiatives Patrick Whitaker of WHO presented. It was noted that this technical report provides an introduction for low income countries to the ISO Standards world. This document is currently out to ballot until the end of July 2011. Australia is one of the cornerstone contributors and has already made comments – other countries were encouraged to do the same. **Action: IT-014-09 and nominated Australian experts to monitor developments and manage local review and ballot response.**	IT-014-09 Nominated Australian experts: - R. Dixon Hughes - Anthony Maeder - Ken Tallis (AIHW) Collaboration: - Andy Bond (NEHTA) Standards Australia as WG8 secretariat
WG 8 eHealth architecture roadmap – Part 2: architectural components & roadmap	ISO/TR 14639-2 HI – Capacity-based ehealth architecture roadmap – Part 2: Architectural components and maturity model The scope of this project has been substantially re-engineered. The eHealth Architecture Reference Model was presented. Many contributors/editors have been involved in this document. Organisational issues associated with maturity levels need resolution. This TR will complement and support the general requirements of the proposed ISO/TR 16555 Health Informatics - Framework for National Health Information Systems, which is based on systematised production of measures originally defined for the WHO Health Metrics Network. Completion of draft is expected by the end of the year (with Richard Dixon Hughes of Australia being one of the lead authors). **Action: IT-014-09 to monitor progress, review the document and consider contributing expert information to other sections of the draft document.**	IT-014-09 and Standards Australia as WG8 secretariat Nominated Australian experts: - R. Dixon Hughes (co-lead on Part 2) - Anthony Maeder Collaboration: - Andy Bond (NEHTA)

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
WG 8 EHR Preservation	Electronic Health Records Preservation Wo Chang, from National Institute of Standards and Technology (NIST) in the United States, presented on the long-term preservation and management of EHRs/PHRs. Preservation of EHR information to ensure its long-term storage and accessibility for health care and clinical research is problematic. Much of the data is stored in proprietary systems which are rapidly becoming obsolete and policies are needed to accommodate this reality. The single greatest obstacle to preservation, sharing and re-use of EHR data is a lack of Standards. Critical areas for standards include defining standard interoperable mechanisms for messaging, metadata, file format, packaging, and interfaces, etc. Dipak Kalra (UK) suggested that WG 3 might be a good base for such work within TC 215. Whilst WG 4 was the most appropriate place to address principles of consent and curation of metadata. This is potentially important to Australia as maintenance of electronic records becomes more relevant with the introduction of PCEHR and the more general move to electronic health records. **Action: IT-014-09 to monitor and become involved where possible as. IT-014-04, IT-014-02, IT-014-06-06 to all consider involvement.**	IT-014 with IT-014-09 leading Collaborators: - IT-014-02 - IT-014-04 - IT-014-06-06 Standards Australia as WG8 secretariat
WG 8 EHR System Functional Model	ISO NWIP 10781-revision 2 presented by Gary Dickinson/Don Mon Input has been captured from many sources (ISO, CEN, HL7, CCHIT, PHRS) over the months of review. Work in progress incorporates functions/criteria from Records Management/Evidentiary Support FP There has been significant work involving HL7 Security Co-Chairs to update and NIST (to incorporate US Meaningful Use Stage 1 & 2 Criteria) -Ballot Draft due to be ready in August -TC215 Ballot due to open in October **Action: IT-014-09 to monitor and assist moving document forward.**	IT-014-09 Standards Australia as WG8 secretariat
WG 8 SKMT	DTR 13054, Standards Knowledge Management Tool (SKMT) Andrew Grant presented this tool which covers both learning and decision making applications of the information being accumulated on health informatics standards in the SKMT database. It also incorporates Knowledge Management, Cognitive aspects and Knowledge structure- Ontologies in a spider approach to information with the ability to drill down along Conceptual, Logical or Physical dimensions. See http://www.hiwiki.org website for more information. The group were asked to consider a new work item TS on standards classification. However, it was agreed this is a tool or possibly a TR but not a TS. **Action: IT-014 to monitor development of SKMT and encourage use from all IT-014 sub-groups.**	IT-014 with IT-014-02 lead Standards Australia as WG8 secretariat

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
Traditional Medicine Task Force (TMTF)	The TMTF sought and was granted additional time on the TC 215 meeting schedule. Progress was achieved in the following areas: • Much clearer division of activity between ISO/TC 249 Traditional Chinese Medicine and ISO/TC 215's TMTF; • A proposal to form a Joint Working Group of TC249 and TC215 for traditional medicine is being prepared; • The TMTF has 3 active work items (below) and has identified a further 6 for development and consideration; and • Greater understanding by TM experts of existing health information modelling approaches – and the relationship to storage and use of information in eHealth application. The approved active work items are: • ISO/NP 16277-1 … Structure of representation of clinical findings in traditional medicine – Part 1: Traditional East Asian Medicine. Led by Korea, a draft document for committee discussion and ballot is expected later this year • ISO 16843 Health Informatics – Categorial structures for representation of acupuncture - Part 1 acupuncture points - Part 2 needling In relation to ISO 16843, additional experts are needed. Australia has a major industry in both traditional medicine and traditional medicine education and needs to build capacity to contribute to these work items as the current expertise within IT-014 does not actively cover this area. **Action: IT-014 to seek relevant Australian experts to contribute to standards work in the fields of health informatics associated with TM/TCM and consider forming a suitable forum in which this might occur.**	IT-014
Telehealth	ISO/TS 13131 Quality Criteria for Services and Systems in Telehealth This approved work item seeks to define criteria for a process or the whole of processes aiming at improving or enabling health and health care using information technology and telecommunications to reduce the effect of distance in space and/or time between the actors. A recommendation was made at the October 2010 meeting that the TS be sent for ballot; however, some further expert input was received which has been incorporated in the latest committee draft (version 4). The document is now in a well developed form with numerous original aspects now clarified, and there are no outstanding matters raised by any Australian experts during circulation in IT-14-12 and to other experts. Australian support during the ballot phase is therefore well justified and should therefore be expected from IT-14, notwithstanding any further inputs which occur when it is circulated more widely for comment.	IT-014-12 (leading)

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
	This item is potentially of high strategic importance to Australia, as it will define norms for operation of telehealth activities and may imply the scope for "acceptable" telehealth items within health agencies or for practitioners. Stronger engagement of Australia is desirable and should be discussed by IT-014. **Action: IT-014 to continue its support of this item during the ballot phase with specialist input from IT-014-12.**	
Safety of health Software Guideline report	There is an ever-expanding and confusing collection of standards that directly and indirectly deal with the potential impact of software applications on patient safety. There is also increasing regulatory activity, which stems from, but is not limited to, regulation of software as a medical device (SAMD). Some of the associated assurance regimes are potentially very expensive and several proposed standards in this area (based on the UK NHS software safety regime) were previously rejected because of industry concerns. There is a growing body of evidence that increasing use of ICT in healthcare can lead to hazards that threaten patient safety – as well as delivering many benefits. As software plays an increasing role in delivery of safe healthcare it is important that there be systems to identify, communicate and avoid concurrent hazards threatening patient safety A Canadian proposal for TC 215 to produce a technical report (TR) on "Guidance on Standards for Enabling Safety in Health Software" was discussed in joint session of affected working groups and strongly supported. This technical report will provide guidance on which standards are applicable to enabling safety in health software, classifying them using an approach based on risk management and quality management principles. It does not address regulatory issues. It will further identify standards to support risk management and identify applicability of those standards to the lifecycle of software. Following TC 215 endorsement, an NP ballot to approve commencing work is expected soon. It is imperative that Australia reviews the ballot materials and makes a contribution to ensure the Australian context is encapsulated within the TR. The TR may also shape and progress standards adoption within Australia in regard to patient safety perspectives. IT-014 is considering forming an appropriate PS&CDS group to progress consideration of patient safety and clinical decision support issues within its domain and this NP ballot provides a useful starting point for understanding software safety standards issues. **Action: IT-014 refer the NP ballot on Standards for Enabling Safety in Health Software to an appropriate group for review and comment and use it as an opportunity to engage more widely with those having potential interests in the field of health software safety such as ACSQHC.**	IT-014 with proposed PS&CDS leading Collaborations: - IT-014-01-Meds - ACSQHC - NEHTA - DoHA

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
Requirements for health software	There is renewed activity from the medical devices community (working through IEC/62A) to establish requirements for health software. Their current work focussed on Part 1 of *IEC 82304-1 Health software systems* (relating to "general requirements") concerns many in TC 215. The major issues are the potential imposition of device-specific inspection and approval processes more suited to embedded systems, excessive focus on the responsibilities of software suppliers and losing focus on the key role and responsibility of those who implement and use applications. Work in this area is managed through IEC/62A/JWG7, which is a joint working group of TC 215 and IEC/62A, and it meets around 5 to 6 times a year, which makes it difficult for TC 215 and IT-014 to track the work and represent wider health informatics viewpoints. The proposed standard regards healthcare software as software used to aid diagnosis, treatment or monitoring of a patient, compensation or alleviation of disease, injury or disability. There was general agreement that the scope is too broad and ill-defined and cannot be supported “as is”. The first requirement is to define precisely the concepts being referenced, remove “device” related language such as “manufacturer” and extend to end-to-end clinical software and the entire software life-cycle. While many in the IT-014 and wider Australian health software industry have interests and concerns at the impacts of work on requirements (and associated regulation) of health software, engagement is difficult and costly. To effectively influence outcomes, Australian representation at JWG7 would need to be considered. JWG7 meets in June in San Antonio and October in Brussels. **Action: IT-014 to continue monitoring developments in t standards for health software and seek to inform and engage with affected interests in Australia, particularly through MSIA.**	IT-014 with IT-014-12 leading
Proposal to require biometric identification in health care applications	Under liaison arrangements with TC 215 an ITU-T study group submitted the third draft of a proposed ITU standard ("draft recommendation") TD 1818 Telebiometric Data Protection in eHealth applications. This item was also discussed jointly with WG4 and WG7 and many concerns were raised. It was the view of many of those present that the work, as presently proposed, is totally inappropriate and makes wide-ranging assertions about identification risks with the apparent intent of imposing biometric identification on many health care processes. The approach seems to be based on technology push rather than detailed health needs, the drafting is poor, there is a lack of clinical process understanding, terminology or models and this omission is major and must be addressed if the item is to progress as joint work. The consensus is the item should be dropped, or at least substantially reworked with TC215 involvement. **Action: IT-014 as Australian mirror committee to TC 215 to support any action by TC 215 and its working groups to resolve the currently unsatisfactory proposal from ITU-T in relation to biometric identification.**	

Topic	Issue/Action and Recommendations for Australia	Suggested responsibility & alignment to IT-014
Organisation / Ops Harmonisation	Ballot processes have been failing due to the required experts from at least 5 different countries. It was noted by the TC 215 secretariat and approved by TC 215 plenary that additional experts can be nominated after close of a ballot. **Action: IT-014 to nominate Australian experts when submitting positive votes where possible and, where not possible at time of submission to commence search for relevant expert for nomination within 30 days.**	IT-014 Standards Australia as TC 215 NMB
Delegation logistics	It has been suggested that a more formal induction procedure and mentoring be provided for newer Australian delegates to ISO meetings. **Action: IT-014 leadership and recent new delegates to confer on developing induction materials, processes and mentoring that will facilitate new member participation without being too burdensome on either the delegation leaders/sponsors or new delegates.**	R. Dixon Hughes (leading) with - Heather Grain - Trish Williams - Michael Steine

FUNDING SOURCE SUMMARY AND ATTENDANCE

Nine Australians attended as representatives for the duration of this ISO TC 215 meeting. The funding source for these delegates is indicated in the table below.

Funding Source	Number	Change from Previous Meeting
Full funding by employer: Private	1	+1
Full funding by employer: States/Territories or National Initiatives (NEHTA)	0	0
Full funding by Standards Australia – WG secretariat (transitional)	1	+1
Funding Assistance – DOHA through Standards Australia contract	7	0
Total:	**9**	**+2**

The overall Australian delegation in Kuopio was smaller than for some previous meetings because there were no NEHTA representatives at the meeting.

AUSTRALIAN POSITIONS HELD BY DELEGATES

The DOHA funded delegates were selected through an independent panel process jointly with NEHTA, DOHA, HL7 Australia and Standards Australia. The positions of these delegates (including leadership positions) are listed below.

Attendee	Position (held at the meeting)	Funding Source	Working Group or Committee
Richard Dixon Hughes	Head of Delegation	Standards Australia via the DoHA Funding Agreement	Executive Council member JIC Harmonisation, JIC Executive (as HL7 alternate) WG8 and WG1, inc joint WG4. ISO/TR 14639 team meeting (Sun) Leader eHealth architecture component model work.
Heather Grain	Delegate	Standards Australia via the DoHA Funding Agreement	Executive Council member WG3 (as convener), WG9 (harmonisation) Traditional Medicine Task Force Leader of Clinical Decision Support and Mapping work items.
David Rowlands	Delegate	Standards Australia via the DoHA Funding Agreement	WG2 WG9 (harmonisation)
Patricia Williams	Delegate	Standards Australia via the DoHA Funding Agreement	WG4
Anthony Maeder	Delegate	Standards Australia via the DoHA Funding Agreement	WG2, WG8, Traditional Medicine Task Force WG9 (harmonisation)
Michael Steine	Delegate	Standards Australia via the DoHA Funding Agreement	WG6 WG9 (harmonisation)
Andrew Caswell	Secretariat	Standards Australia via the DoHA Funding Agreement	WG8
Naomi Ryan	Secretariat	Standards Australia Funding	WG8
Dr Vince McCauley	Delegate	Self Funded	WG7

ABBREVIATIONS

ACSQHC	Australian Commission on Safety and Quality in Health Care
ACTUG	Australian Clinical Terminology Users Group
ADL	Archetype Definition Language
AG	Advisory Group
AHIMA	American Health Information Management Association
AHML	Australian Healthcare Messaging Laboratory
ANSI	American National Standards Institute
CCHIT	(US) Certification Commission for Health Information Technology
CD	Committee Draft (third stage in developing an ISO or IEC standard)
CDA	Clinical Document Architecture
CDISC	Clinical Data Standards Interchange Consortium
CDS	Clinical Decision Support
CEN	European Committee for Standardization (Comité Européen de Normalisation)
DAM	Domain Analysis Model (comprehensive model of a domain)
DCM	Detailed Clinical Model
DICOM	Digital Imaging and Communications in Medicine
DIS	Draft International Standard (fourth stage in developing an ISO or IEC standard – the main opportunity for public input)
DoHA	(Australian Government) Department of Health and Ageing
DMP	Dossier Médical Partagé (Shared Medical Record) (France)
DSTU	Draft Standards for Trial Use (HL7 and ANSI)
EC	European Commission [the administrative arm of the EU]
EHR	Electronic Health Record
EHRS or EHR-S	Electronic Health Record System
EMEA	European Medicines Agency
EN	European Standard (Européen Norm)
EU	European Union
FDIS	[ISO] Final Draft International Standard (for vote to publish)
GS1	An international SDO – primarily in the supply-chain domain
HDF	HL7 Development Framework
HIE	Health Information Exchange
HIMSS	Healthcare Information and Management Systems Society
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven (International)
HSSP	Healthcare Services Specification Project [joint HL7/OMG]
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICSR	Individual Case Safety Report [related to Medicines/Devices]
IDMP	Identification of Medicinal Products
IEC	International Electrotechnical Commission (an international SDO)
IEEE	Institute of Electrical & Electronic Engineers (US) (also an SDO)
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IS	International Standard
ISO	International Organization for Standardization
ISO/CS	ISO Central Secretariat
IT-014	Standards Australia Committee IT-014 (Health Informatics)
ITU-T	International Telecommunications Union – Standards Division
JI	Joint Initiative [of ISO, CEN, HL7, CDISC, IHTSDO and GS1]
JIC	Joint Initiative Council (responsible for JI governance)
JTC 1	ISO/IEC Joint Technical Committee 1 Information Technology
JWG	Joint Working Group [under the JI, unless otherwise specified]
LOINC	Logical Observation Identifiers Names and Codes

List of Acronyms (continued)

NEHTA	(Australian) National E-Health Transition Authority
NH&MRC	National Health and Medical Research Council
NHIN	(US) National Health Information Network
NHS	(UK) National Health Service
NIH	(US) National Institutes of Health
NMB	National Member Body [of ISO or CEN]
NP	New Work Item Proposal (current ISO/IEC abbreviation)
NWIP	New Work Item Proposal (obsolete ISO/IEC abbreviation – see "NP")
OCL	Object Constraint Language
OID	Object Identifier
OMG	Object Management Group
ONC	Office of the National Coordinator for Health Information Technology (within US Department of Health nd Human Services)
OSI	Open Systems Interconnection
OWL	Web Ontology Language
PDF	Portable Document Format
PHR	Personal Health Record
PoC	Point-of-Care
RHIO	(US) Regional Health Information Organisation
RIM	Reference Information Model
RLUS	Resource Locate Update Service (HSSP)
RM-ODP	Reference Model of Open Distributed Processing
SDO	Standards Development Organisation
SIG	Special Interest Group
SKMT	Standards Knowledge Management Tool
SMTP	Simple Mail Transfer Protocol
SNOMED	Systematised Nomenclature of Medicine
SOA	Service Oriented Architecture
SOAP	Simple Object Access Protocol
TCM	Traditional Chinese Medicine
TCP/IP	Transmission Control Protocol/Internet Protocol
TF	Task Force
TM	Traditional Medicine
TR	Technical Report (an informative ISO or IEC standards publication)
TS	Technical Specification (a normative standards publication having a lower level of consensus than a full international standard)
UCUM	Unified Code for Units of Measure [Regenstrief Institute]
UML	Unified Modelling Language
W3C	World Wide Web Consortium
WD	Working Draft (second stage in developing an ISO or IEC standard)
WG	Working Group or Work Group (in HL7)
WGM	Working Group Meeting
WHO	World Health Organization
XDS	(IHE's) cross enterprise Data Sharing protocol
XML	eXtensible Markup Language