IT-014 Health Informatics Committee

Australian Delegation Report

ISO/TC 215 Health Informatics Plenary and Working Group Meeting

Rio de Janeiro, Brazil, May 2010

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

- *Richard Dixon Hughes (Delegate)*
- *Heather Grain (Delegate)*
- *Prof Evelyn Hovenga (Delegate)*
- *Dr Heather Leslie (Delegate)*
- *Prof Anthony Maeder (Delegate)*
- *Dr Andy Bond (NEHTA)*
- *Dr Stephen Chu (NEHTA)*
- *Tina Connell-Clark (NEHTA)*
- *Andrew Howard (NEHTA) (plenary only)*
- *Andrew Caswell (Standards Australia)*
- *Kylie Sugar (Standards Australia)*

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1 SUMMARY OF KEY OUTCOMES

This report covers the proceedings, issues and actions for consideration by Australia from the ISO/TC 215 Health Informatics Committee meeting, which took place between 9 and 13 May 2010 in Rio de Janeiro, Brazil. The event included the annual TC 215 plenary session as well as meetings of the TC 215 Executive Committee, various other leadership groups, working groups and task forces, specifically:

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

In addition, TC 215 hosted a face-to-face meeting of the Joint Initiative Council (JIC) and the JIC Harmonization Open Forum at which collaborative projects potentially involving several JIC members are discussed, approved and tracked. The current members of the JIC are: ISO/TC 215, CEN/TC 251, HL7 International, CDISC, IHTSDO and GS1.

Key points arising from the May 2010 meeting included the following:

1. **TC 215 Work program**. TC 215 is currently working on some 105 standards projects and continues to have a very active work program – both in its own right and, increasingly, as a focal point for joint projects with other SDOs through the JIC.
2. **Incoming Chair's challenge to TC 215**. Dr Chris Chute of the Mayo Clinic (USA), newly appointed as TC 215 chair from 1 January 2010, commented on the growing world-wide focus on health informatics. His view is that TC 215 needs to align better with its National Member Bodies (NMBs) and their national eHealth programs and work toward a set of products that form a more consistent and coherent part of overall eHealth environment.
3. **TC 215 Business Planning and Reorganization Task Force**. As part of addressing these challenges, the Executive Council established a Task Force (TF) to revisit two issues – the TC 215 business plan and options for reorganizing the work and structure of TC 215. Richard Dixon Hughes and Heather Grain are both members of the Task Force, which will meet by teleconference with a goal of having both a finalized business plan and recommendations on organization by next year. The TF is chaired by Jeremy Thorp (UK NHS) and will provide a progress report to the October 2010 meeting in Rotterdam.

It is also an ISO requirement that technical committee business plans be regularly reviewed and kept up to date. TC 215 has been somewhat slow in meeting its obligations in this area.

4. **Options for WG1 and WG8 activities and leadership**. Prior to this meeting, Canada had announced that it would relinquish the secretariat and convenorship of WG1. For some time now, WG1 (Data Structure) and WG8 (Business Requirements for EHRs) have mostly met together, having a large common membership and many joint projects. Standards Australia provides the secretariat for WG8, which also has a Canadian convenor and a Brazilian vice-convenor.

   Proposals to merge WG1 and WG8 have been under informal discussion for some time and the Australian delegation considered that the required election of a new convenor and vice-convenor for WG1 at this meeting and the need to find a new secretariat provided the ideal opportunity to merge the two WGs, if it were to occur.

   Accordingly, agreement was sought and obtained from Standards Australia and DoHA for the Australian delegation to actively support merging the activities or WG1 and WG8 and to offer Standards Australia as the secretariat of the combined group (as we would be relinquishing WG8). Australia argued for the merge at the Executive Council and offered to host the combined secretariat but the TC 215 chair preferred to await the findings of the business planning and reorganization task force before making any changes.

5. **Elections for WG1 leadership positions**. Professor Stephen Kay (UK) was elected as Convenor, and Dr Don Mon (AHIMA USA) being elected as Vice-Convener. Canada has been prevailed upon to continue providing the WG1 secretariat services for a few more months until a replacement can be found. Australia continues to service WG8 but was therefore unable to assist by taking over WG1 as both WG8 and WG1 were continuing as a separate entities.

6. **Balancing WG8 and WG1 work program**. If it is to exist independently, Australia indicated that WG8 should be more active and have clear responsibility for more of the TC 215 project workload, including some projects not transferred from WG1 when WG8 was formed.

   Prof. Kay, the incoming chair of WG1, is currently also chair of the European CEN/TC251/WG1 mirror committee and is keen for WG1 to operate more independently of WG8, although there is a large common membership that does not want too many scheduling conflicts at TC 215 meetings.

   At the 30-day post meeting teleconferences of the TC 215 Operations & Harmonization Committee (OHC), which determines the allocation of activities to TC 215 working groups, Kylie Sugar and Heather Grain supported more projects being assigned to WG8 (with some success).

7. **Change of TC 215 Secretariat**. The Health Information Management Systems Society (HIMSS) announced that it is withdrawing from being the TC 215 Secretariat on behalf of ANSI (the American National Standards Institute). In response to questions from Australia, it was confirmed that ANSI has sought expressions of interest from other US-based organisations and will be advised by the US TC 215 TAG in selecting an appropriate organisation with compatible objectives to support TC 215. A candidate likely to be acceptable to the broader TC 215 membership is interested in taking on the role, for which HIMSS has allowed a 12-month hand-over period. The Australian delegation will continue to monitor developments in this space.

8. **JIC/JWG engagement and harmonization processes**. Driven by the new JIC chair, Kees Molenaar from Europe, an increase in size from three to six participating SDOs, experiences over the first few years of its operation, and the need for greater formal communication at executive level to ensure that joint projects progress satisfactorily, the JIC is in the process of re-shaping how it operates. Part of this has affected the way in which information is shared and harmonisation

activities are reviewed and planned – activities which were being run through ISO/TC 215/WG9 (JWG) with three co-conveners and Standards Australia providing the secretariat.

Under the new regime, JIC has taken more direct control of harmonization activities – with less involvement of individuals from across the various SDOs in debate and decision-making. The new process operates at 3 levels – open forums for sharing information; "JIC harmonization track" sessions to align the interests of participating SDOs and potential joint projects, and formal JIC meetings at which the participating SDOs approve each joint project and the terms on which it is to be conducted and determine harmonization policies and processes.

The new format does bring greater focus to harmonization activities and is a considerable improvement. However, it has assed additional sessions for consideration of harmonization work in parallel with the core working group sessions – spreading delegation personnel even more thinly. Nevertheless, the Australian delegation managed to make significant contributions to detailed discussion of proposed joint work items.

It is understood that WG9 secretariat services are no longer required from Standards Australia under the new arrangements, but this should be confirmed.

10. **Detailed Clinical Models project (DCM)**. At the previous NWIP ballot, Australian stakeholders had expressed considerable concern about the direction being taken by the DCM project. Following a detailed discussion at this meeting, it was agreed that the project would initially focus on quality measures applicable at the various stages of the DCM lifecycle with and would not prescribe a single representational technology. New teams and leaders were agreed to work on the five parts of the document with Evelyn Hovenga and Richard Dixon Hughes to produce a preliminary draft of the introductory part and Heather Leslie and Stephen Chu contributing to other parts.

11. **Clinical Alerts, User Interfaces (UI) and Clinical Decision Support (CDS)**. Guidance documents have been proposed in these areas. In the case of UI and CDS, ISO/TC 215/WG 3 is looking toward producing international technical reports based on existing Australian documents compiled by IT-014-02. The proposed report on standards for clinical alerts is based on European work led by Sweden; however, there was considerable concern that the proposed work is too broad and insufficiently harmonised with the proposed UI and CDS work items and insufficiently informed from a patient safety and cultural perspective. At NP ballot as a new work item, the clinical alerts topic received sufficient member countries in favour to pass but failed on the grounds that five experts had not been nominated to work on it. The matter was put to the TC 215 plenary which rejected

    These topics are of considerable interest to Australia (as demonstrated by our having already commenced two key documents in this area). Through Heather Grain as convenor of TC 215/WG 3, Australia is also involved in negotiating the harmonisation of these items and their progression. It is important that Australia support the work on these items.

12. **TC 215 involvement in ISO/TMB Privacy Steering Committee (PSC)**. At the request of international privacy commissioners, a privacy steering committee has been set up by ISO/TMB to examine standards in privacy and has invited relevant interests to participate in a 2 day conference in October to examine how to progress. TC 215 will have 2 delegates endorsed by the JIC to represent the eHealth SDOs. It would appear that initiatives arising from the TMB/PSC are likely to change or limit the scope of the work of JTC1/SC27 that is widely followed in the eHealth area.

It is important that IT-014 monitors developments and ensures that the needs of the Australian eHealth sector and privacy legislation are taken into account as these events unfold and that any needs for health sector standards or codes are identified.

Information on the business transacted at the closing plenary session, including all formal resolutions, is provided in sections 21 and 22 of this report, with potential need for Australian input being noted, where relevant.

2 ISSUES AND RECOMMENDATIONS

The principal issues actions and recommendations identified by the Australian delegation at the May 2010 HL7 Working Group Meeting (WGM) in Rio de Janeiro are summarised in this section.

Topic	Issue/Action/Recommendations	Owners
Communication of TC 215 activity and engagement with strategic stakeholders	Need for greater awareness and effective and efficient communication of TC 215 activities and greater engagement with relevant stakeholders. **Action: IT-014, Standards Australia and NEHTA** **To consider further strategies to engage with and support communication with Australian healthcare decision makers and implementers of national e-health initiatives to improve e-health knowledge, skills and risk management in Australia and to better utilize the standards available as well as to provide a stronger view of the continuum of standards.**	IT-014 Standards Aust NEHTA
Australian input to TC 215 business plan and reorganization task force - 1	Executive Council established a task force to review the TC 215 business plan and options for reorganization. Richard Dixon Hughes and Heather Grain were accepted as members of the task force, chaired by Jeremy Thorp (UK) to make recommendations by early next year. **Action: Richard Dixon Hughes and Heather Grain** **To keep IT-014 informed of the activities of the TC 215 business planning and reorganization task force and the alternative structures for TC 215.**	R Dixon Hughes & Heather Grain IT-014
Australian secretariat support for WG8	Through its eHealth team, Standards Australia provides the secretariat for ISO/TC 215/WG 8. WG8 has a large overlap in membership with WG 1 and shares most of its sessions with WG 1. Joint activity has tended to be driven by WG1 with WG8 being less active. Given that there is work of interest to Australia needing to be progressed and that the TC 215 chair has decided not to consider merging WG 1 and WG 8 (at least for the next 12 months) it is important that the WG 8 agenda be meaningful to Australia and be managed proactively. **Action: Standards Australia (eHealth team) to proactively manage the WG8 secretariat with a view to ensuring that WG8 gains responsibility for and progresses relevant work items of interest to Australia.**	Standards Australia eHealth team (WG8 Secretariat) Assisted by IT-014-09

Topic	Issue/Action/Recommendations	Owners
Transition of TC 215 Secretariat services	HIMSS announced that it is withdrawing from providing TC 215 Secretariat services on behalf of ANSI. While the replacement is a matter for ANSI as the US national member body of ISO, the organisation selected and its approach will have a major influence on how TC 215 operates in the international arena. It is understood that a suitable replacement is interested in taking on the role; however, it is important that Australia continue to monitor developments in this space and, where possible, ensure that Australian interests are preserved through the transition period. **Action: Australian HoD (Richard Dixon Hughes):** **To monitor and keep IT-014 informed of developments in finding a replacement for HIMSS as the provider of TC 215 secretariat services, and use Australia's influence with a view to securing a smooth transition to the new provider and an improved level of service.**	Australian TC 215 HoD
Identification and nomination of Australian experts for TC 215 work items.	For potential new work items, there is a need to identify whether Australian expertise is required and, where relevant, the particular skills required and individuals who are qualified and willing to undertake the work. The requirements for Australian input need to be identified in meeting reports and through in the activities of IT-014 and its sub-groups. **Action: Australian reports on TC 215 meetings** **To identify upcoming work items so that IT-014 and its subcommittees can consider the need, types and required skills of Australian experts for submission with new work items.** **Action: IT-014 and/or the relevant mirror group(s) to consider needs and skills required for Australian experts for submission with each new work item ballot.**	Australian TC 215 delegations IT-014 & its sub-groups mirroring TC 215 WG activity.
On-going review and progression of TC 215 work.	Developing responses to upcoming ballots for both on-going and proposed new work items as noted in: • Report on WG 1 (Data Structure) in section 10 below • Report on WG 2 (Data Interchange) in section 10.4 below • Report on WG 3 (Semantic Content) in section 12 below • Report on WG 4 (Security, Safety and Privacy) in section 13 below • Report on WG 6 (Pharmacy and Medication Business) in section 14 below • Report on WG 7 (Devices) in section 15 below • Report on WG 8 (Business requirements for EHR) in section 16 below , • Report on resolutions at the closing plenary in section 16 below . **Action: IT-014 and subcommittees (as identified in respective reports)** **To review TC 215 activities, watch developments and engage with relevant Australian stakeholders to inform Australian responses to ballots and deliberations at TC 215 meetings.**	IT-014 and its subcommittees as noted in respective reports.

Topic	Issue/Action/Recommendations	Owners
Update IT-014 work plan with WG1 mirror projects	**Action: IT-014 (secretariat)** **To note following WG1 work items on project plan as mirror projects:** **(1) Identity Management Framework Task Group. Prelim work item (to IT-014-09).** **(2) ISO/TS 27527 - Provider identification. Revise/upgrade published work (to IT-014-02)** **(3) ISO/TS 22220 – Identification of subjects of care Revise/upgrade published work (to IT-014-02)** **(4) Health Summary Record/Core data sets. Prelim work item (to IT-014-09)** **(5) Health information systems requirements framework. Prelim work item (to IT-014-09).**	IT-014 and its subcommittees
Detailed Clinical Models – quality criteria	Australian concerns about the direction of this work appear to have been addressed. A revised approach and project team structure have been identified. **Action (1): Evelyn Hovenga and Richard Dixon Hughes to produce a preliminary draft of the introductory part in the series** **Action (2): Heather Leslie and Stephen Chu to contribute to other parts.**	IT-014-09 (lead) collaborating with IT-014, and IT-014-02 IT-014-06-06 NEHTA
Standards Convergence to Promote EHR Interoperability.	Australia was one of those that previously voted against this work item on the grounds that it was too wide-ranging and not suitable for a normative international technical specification but has agreed to support its progression as a technical report. As part of this compromise, it was agreed that Richard Dixon Hughes would assist with re-drafting a new work item proposal for the technical report. **Action: Richard Dixon Hughes (IT-014-09)** **To assist with re-drafting a new proposal and scope for a technical report addressing "Standards Convergence to Promote EHR Interoperability"**	IT-014-09
Update IT-014 work plan with WG2 mirror projects	**Action: IT-014 (secretariat):** **To note following WG2 work items on project plan as mirror projects:** **(1) Telehealth Systems - Teleradiology Interoperability. Prelim work item (to IT-014-12)** **(2) ISO/DTS 21089 Trusted end-to-end information flows. Prelim work item (to IT-014-09)**	IT-014 and its subcommittees

Topic	Issue/Action/Recommendations	Owners
Overcoming difficulties in harmonising joint work	Based on its experience, WG2 has found joint development and maintenance of standards in collaboration with HL7 and other SDOs time consuming and difficult to synchronise effectively (examples include data types, HL7v3, CDA, CDISC BRIDG). While stakeholders want a single internationally-endorsed standard, current processes for joint work risk delaying output by years or having the "definitive" ISO versions of key joint standards being out of step with work in the originating SDO, be it HL7, IHE or CDISC. The goal of efficiently producing joint standards deserves pursuit but further changes in are required to **Action: Australian TC 215 delegations and IT-014 to:** **(1) promote joint work on development and maintenance of health Informatics standards being carried out efficiently either through a single joint process or in the most appropriate forum, even if this means bypassing traditional structures, and** **(2) use TC 215 Business Planning and Reorganisation TF processes to encourage TC 215 to support joint work as a peak force for endorsement of e-health standards.**	IT-014 Australian TC 215 delegations
Update IT-014 work plan with WG3 mirror projects	**Action: IT-014 (secretariat):** **To note following WG3 work items on project plan as mirror projects:** **(1) ISO 18104 Integration of a reference term model for nursing. For systematic review (to IT-014-02)** **(2) Proposed technical report on User Interface Requirements (to be progressed by IT-014-02 based on an existing Australian work)**	IT-014 and its subcommittees
Clinical Alerts, User Interfaces (UI) and Clinical Decision Support (CDS)	Australia was the originator of the UI and CDS work now being progressed within ISO TC215. European work on standards for [clinical] alerts failed to attract sufficient experts at initial NP ballot but has raised the need for better coordination of these three work items, which will require significant Australian input; nevertheless, there is considerable interest in and need for an appropriate technical report on standards for alerts, allergies and adverse reactions. **Action: IT-014-02** **To lead a broadly based activity to review current work on clinical alerts (including allergies and adverse reactions) and TC 215 proposals for a technical report and develop recommendations to guide both local Australian work and the Australian position on international work in this area.**	IT-014-02 (lead) IT-014, and IT-014-06-04 IT-014-06-06 IT-014-09 NEHTA
Measuring conformance in implementation of terminological systems	*ISO/TR 12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems* – Australia to contribute to initial draft of this new technical report and its harmonisation with ISO/TS 17117. **Action: IT-014-02** **To lead substantial Australian input into preparation of the initial draft of ISO/DTR 12310, which is expected to be circulated for international comment prior to the next meeting in October.**	IT-014-02
Need to consider recent WG 4 publications for local adoption	**Action: IT-014-04:** **To review recent publications by TC 215/WG 4 (particularly PMAC series) and report to IT-014 on whether local adoption, adaptation or input to next systematic review warrants consideration.**	IT-014-04 reporting to IT 014

Topic	Issue/Action/Recommendations	Owners
Update IT-014 work plan with WG4 mirror projects	**Action: IT-014 (secretariat):** **To note following WG4 activities on project plan as a mirror projects:** **(1) TC 215 interaction with ISO/TMB Privacy Steering Committee (to IT-014 supported by IT-014-04)** **(2) Tracking implications of work by ISO/JTC1 SC27 WG5 (Identity management and privacy technologies) on health informatics standards (to IT-014, supported by IT-014-02, IT-014-04, IT-014-09 and IT-012)**	IT-014 and its subcommittees
Update IT-014 work plan with WG6 mirror projects	**Action: IT-014 (secretariat):** **To note following WG6 work items on project plan as mirror projects:** **(1) TR 25257 - Business Requirements for an international coding system for medicinal products. Review of report published last year (to IT-014 with input from IT-014-06-04, IT-014-02, IT-014-10, NEHTA)** **(2) Generic model for dose syntax. Prelim work item (to IT-014 with input from IT-014-06-04 and NEHTA)**	IT-014 and its subcommittees
Update IT-014 work plan with WG7 mirror projects	**Action: IT-014 (secretariat):** **To note following WG7 work items on project plan as mirror projects: ISO/IEEE 11073 – 10400, 20401, 30400, 30503, 00101, 10316, 10441 and 10442 as preliminary /preparatory work (to IT-014-12)**	IT-014 and its subcommittees
Risk management for IT-networks incorporating medical devices	Recent compromises with the ISO risk management community and potential for the IEC/ISO 80001-series to become part of international medical devices regulation and also potentially impose obligations on facilities that use devices (including software applications) were noted. Greater engagement by groups likely to be affected would be welcome. **Action: Australian TC 215 delegations, IT-014, and IT-014-04:** **To continue tracking progress of the IEC/ISO 80001 series and engage with interested parties in Australia, including OB/7 and MSIA.**	Australian TC 215 delegations; IT-014, and IT-014-04

3 INTRODUCTION

This report covers the proceedings, issues and actions for consideration by Australia from the ISO/TC 215 Health Informatics Committee meeting, which took place between 9 and 13 May 2010 in Rio de Janeiro, Brazil.

Standards are central to Australia's national e-health agenda, and awareness of the status of international standardisation is important to standards developers, to the health ICT industry and to the health sector generally in this country.

Australia is a strong supporter of World Trade Organization (WTO) best practice in standardization which emphasises adoption of "international standards" in preference to the development of local standards. Within this context, trade in health information systems, supporting infrastructure such as clinical terminology and conformance testing services, and even health service provision are increasingly becoming international in their scope - emphasising the need for appropriate international health informatics standards. It is vitally important to ensure that an Australian national position is represented the development of these standards. This is most effectively achieved by ensuring that Australian delegations with appropriate mixes of skills and expertise continue to participate in the relevant international standards meetings and that priority areas are adequately addressed.

The International Organization for Standardization (ISO) develops health informatics standards through technical committee ISO/TC 215 Health Informatics. 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 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.

This report identifies priority areas for strategic engagement from all relevant parties in Australia who have an interest in the national e-health agenda, health informatics, informational aspects of quality and safety and an update on areas identified in previous reports as requiring ongoing input.

This report is produced as a result of input from all members of the Australian delegation to the May 2010 TC 215 meeting, who were co-funded by the Australian Government, Department of Health and Ageing, without whose support Australia's contribution and ability to respond to the issues discussed here would be severely diminished.

The voluntary contribution of significant time and effort that the Australian delegates spent preparing for, attending, contributing to and reporting on this meeting were invaluable. Some volunteers are

totally unpaid for this work, while others receive support from generous employers through time release. We are grateful to those employers who support their staff in these activities, particularly the National e-Health Transition Authority (NEHTA), who funded four additional Australian delegates..

Information is presented by topic and areas of specific concern to Australian stakeholders are highlighted and appropriate action should be considered by those stakeholders. Information is provided for contact to Australian expertise in each area for those who would like further information or to participate. Many of the issues will be discussed in detail at upcoming IT-014 subcommittee and working group meetings which are open to all interested parties.

For details of IT-014 subcommittees and working groups contact Kylie Sugar at Standards Australia (kylie,sugar@standards.org.au).

4 MEETING OVERVIEW

ISO/TC 215 holds two full international meetings per year. The first (in April/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, known as the "Joint Working Group Meeting", usually comprises meetings of the working groups but, in recent years, has also included a smaller "mini-plenary" to progress urgent matters.

This, the Plenary Meeting for 2010, was hosted by ABNT (Assocão Brasiliera de Normas Tecnicas), the Brazilian ISO national member body, and was held in Barra de Tijuca, Rio de Janeiro from Sunday, 9 to Thursday, 13 May (inclusive).

The meeting was attended by around 150 delegates from 16 countries and included representatives of liaison organisations including CEN, HL7, IHTSDO, WHO, CDISC, GS1, IHE and IEEE.

As can be seen from the more detailed agenda set out on the next page, the meeting covered 4¾ days and took place in four main parts:

1. a full day of leadership meetings on the Sunday, prior to the official opening plenary on the Monday
2. three days of project work in parallel streams - with some sessions being held jointly, including most meetings of WG1 and WG8
3. the 2010 plenary, which was held on the Thursday - where resolutions were considered, discussed and votes taken to direct future action of the TC and its WGs, and
4. Additional activities and processes supporting harmonization of standards development across SDOs through processes established by the Joint Initiative Council (JIC – which has ISO/TC 215, CEN/TC 251, HL7 International, CDISC, IHTSDO and GS1 as its present members)

   In addition to there being a three-hour series of sessions on the Sunday to discuss harmonisation issues, the JIC itself met for ½ day on the Tuesday and there were another two ¼ day "JIC Harmonization Track" meetings in parallel with mainstream WG activities on the Tuesday and Wednesday afternoons.

Formal sessions commenced at 8 or 9 am and ran to 5pm with additional out of hours meetings being common. This was a true working meeting with each of the groups discussing the development and improvement of standards, processes and implementation practices with a view to determining the most effective way to meet the needs of stakeholders and the wider community.

Agenda

Date	Time										
Sun	0830-1030	Operations & Harmonization Meeting Alhambra 1									Secretary
9-May	1100-1400	Executive Council Alhambra 1									Room
	1430-1800	Information Session (1430-1530) JIC Harmonization Open Forum (1600-1700) Unconference (1700-1800) Alhambra 1 and 2									Open 9 May
Working Group		215-WG 1/8	WG2-a	WG2-b	215-WG3	215-WG4	WG6	215-WG7	WG 8	Task Forces	Secretary Room
Room Assigned		Alhambra 1	Alvorada 1	Alvorada 2	Windsor	Alhambra 2	Imperial	Bandeirantes	Itamaraty	Liberdade	Catete
	0730 - 0845										
Mon	0845 - 0900										
	0900- 1000	Opening Plenary - Alhambra 1 and 2									
10-May	1000-1030	Coffee Break									
	1030-1215	WG1/8 Welcome, Agenda, WG Elections and NWIPs Review	Welcome and Agenda Reports of the Working Groups Strategic Discussion (Full WG)	Welcome and Agenda Reports of the Working Groups Strategic Discussion (Full WG)	Welcome and Agenda 12300 Mapping of Term and Revision of TS 1171713581 and 82 OID documents/review prelim work items WG Election	Welcome and Agenda, Work Plan and NWIPs Proposals	Welcome Agenda review #10895 #11595 #27953-1	Welcome and Agenda Work program review	open	Open	OPEN 0830-1830
	1215 - 1315	DCM Project team meeting	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch		
	1315 - 1500	WGs 1/8 (WG1 Host) TS 22220 discussion DCM 13972	Welcome and Introductions Minutes of last meeting and matters arising 12974: WADO –WS Web access to DICOM persistent objects by means of web services	Welcome; Review agenda and work item status 28380: (TR) IHE Integration Profiles - Review reformat of Part 1 and Part 2 ballot results Action Plan for the NWIP for Phase II (Use Cases and Integration Profiles) and review of NWIP draft.	Revision of ISO 18104: 2003 – HI – Integration of a reference term model for nursing	Risk Management WG 4 AND 7 80001 TR development (WG7 Host)	#27953-1	Risk Management - report on JWG7 WG 4 AND 7 Join DCM discussion (WG1)	open	Patient Safety and Quality	OPEN 0830-1830
	1500 - 1515	Coffee Break									
	1515 - 1700	WG1/8 (WG1 Host) * Standards Convergence (WG TBD) * 21667 HICF	10159: Web Access Resource Manifest (WARM) Review of comments received from DIS ballot	13131: Quality Criteria for Services and Systems in Telehealth (13131) Review NWIP initial draft (TeleHealth)	ISO 12975 - guidelines for main of term systems, ISO 12310 - guidelines for measurement of conformance 28379 Common Glossary	HI: Security and privacy requirements for compliance testing of EHR systems -Part 1: Foundation	#27953-2	Join Telehealth discussion (WG2-b)	CDISC Meeting	Traditional Medicine Task Force	OPEN 0830-1830
Invitation Only Meetings	1730-1830	DCM Project Team meeting	Brazilian Government		Australian Delegation						OPEN 0830-1830
Date	Time	WG 1/8	WG2-a	WG2-b	WG3	WG4	WG6	WG7	WG 8	Task Forces	
Room Assigned		EL Pardo 1	Alvorada 1	Alvorada 2	Windsor	El Pardo 2	Imperial	Bandeirantes	Itamaraty	Liberdade	Catete
	0730 - 0845										
Tue	0845 - 0900										
11-May	0900-1030	WG1/8 (WG8 Host) 13054 Knowledge Management of HI Standards WG1/4/8 (WG1 Host) * Purposes for EHR Data	21090: Health Informatics – Harmonized data types Reconciliation of DIS ballot comments Release of FDIS – Progress toward publication (Graham Woody) Discussion of HL7 RIM Anual Update Process vis-à-vis the ISO Process (Woody Beeler)	13449: Clinical Genomics – Family History Disposition of Comments resulting from DIS ballot	NP - Structure for rep'n of clinical find in traditional medicine Part 1: Traditional East Asian medicine, ISO 13120 - syntax to represent content of med classification systems	WG 4 and Health Cards TF	#11238	Continue Work program review, MFER, IEEE PHD items	WG1/8 (WG8 Host) 13054 Knowledge Management of HI Standards WG1/4/8 (WG4 Host) * Purposes for EHR Data	JIC Executive session	OPEN 0830-1830
	1030-1045	Coffee Break									
	1045-1215	WGs 1/8 (WG8 Host) • 18308 Requirements for an EHR Reference Architecture • Personal Health Records - Definition, scope, context and global variations of use	13128: Health informatics – Clinical Document Registry Federation (TR) Review of revised draft of document	14199: CDISC BRIDG Model Review Public Comments from BRIDG ballot	prEN ISO 1828 - Cat struct for term systems of surg procedures, prEN ISO 13940-1 & 2 - Systems of concepts for continuity of care prEN ISO 13119 - Clinical knowledge resources - metadata,	WG 4 Health informatics -- Security aspects of EHR migration	#11615	Continue Work program review, MFER, IEEE PHD items	WGs 1/8 (WG8 Host) • 18308 Requirements for an EHR Reference Architecture Bellagio Declaration (WHO) - eHealth Enterprise Arch • Personal Health Records - Definition	JIC Executive session	OPEN 0830-1830
	1215 - 1315	Lunch	Lunch	Lunch	Lunch	PSQ	Lunch	Lunch	Lunch	Lunch	
	1315 - 1500	WG1/8 (WG8 host) • Business requirements for an eHealth architecture for dev.& emerging countries • 10781 EHR S FM	New Work Item Proposals (Woody Beeler) Discussion of SWG scope Any Other Business	14199: CDISC BRIDG Model Review Public Comments from BRIDG ballot (continued)	prEN ISO 15521 - Identification of status of structures for represent'n of human anatomy Review of preliminary work items	HI: Security and privacy requirements for compliance testing of EHR systems -Part 1: Foundation	First hour: #11240 Second hour: Joint with WG 3	Continue Work program review, MFER, IEEE PHD items	WG1/8 (WG8 host) • Business requirements for an eHealth architecture for dev.& emerging countries • 10781 EHR S FM	JIC Harmonization Track	OPEN 0830-1830
)	1500 - 1515	Coffee Break									
	1515 - 1700	WG1/2/8 WG1 Host * BRIDG ----- WG1/3/8 (WG1 Host) * CDSS * Alerts	BRIDG with 1/8 Joint Meeting and resolutions	Joint Meeting and resolutions	Clinical Decision supp systems/User Interface req/Alerts - Joint - WGs 1/3/8 (WG1 Host)	Classification of Data Purposes and Compliance Testing for EHR	#11616	Join Alerts discussion (WG1/8/3)	WG8	Meet to discuss TC 249 meeting	OPEN 0830-1830
Invitation Only Meetings	1730-1830		Brazilian Delegation		Australian Delegation		EU HOD Meeting				OPEN 0830-1830
	1830-2130	Reception in El Pardo									

Date	Time	WG 1	Room Closed	Room closed	WG3	WG4	WG6	WG7	WG8	Task Forces	
Room Assigned		EL Pardo 1	Alvorada 1	Alvorada 2	Windsor	El Pardo 2	Imperial	Bandeirantes	Itamaraty	Liberdade	Catete
Wed	0730 - 0845										
	0845 - 0900										
12-May	0900 - 1030	WG resolution development	open	open	WG resolution development	HI: Security and privacy requirements for compliance testing of EHR systems -Part 2: Protection profile for small-scale electronic patient record systems	#11239	WG resolution development	WG8 formal meeting	Open	OPEN 0830-1830
	1030-1045	Coffee Break									
	1045 - 1215	WG resolution development	open	open	Closing and WG resolution development	Discussion of scope and potential for a new standard covering other (Clinical) aspects of audit WG1/WG8 Invitation	Maintenance	Closing and WG resolution development	WG resolution development	Open	0830-1830 Resolutions
	1215 - 1315	Lunch									
	1315 - 1500	WG resolution development	open	open	Open	WG4 Formal Meeting WG Elections	WG 6 formal meeting	Open	WG resolution development	Open	0830-1830 Resolutions
	1500 - 1515	Coffee Break									
	1515 - 1600	Closing and WG resolution development Due at 1600	TC 215 Glossary Meeting	open	Open	Closing and WG resolution development Due at 1600	WG 6 formal meeting WG resolution development Due at 1600	Open	Closing and WG resolution development Due at 1600 (if not completed earlier)	JIC Harmonization Track	0830-1830 Resolutions
	1600-1700	Review of WG Resolutions with Audrey/Mike for correct ballot designation, for completeness and use of the resolution template with correct dates.									0830-1830 Resolutions
	Delegate Meetings 1700-1800	Canadian Delegation	Brazilian Delegation	Korea Delegation	Australian Delegation	US Delegation	Japan Delegation	UK Delegation	Netherlands	open	Closed

Date	Time	WG1	WG2	WG 2	WG3	WG4	WG6	WG7	WG8	Task Forces	Catete
Thu	0730 - 0845										
	0845 - 0900										
13-May	0900 - 1030	Plenary Day 0900-1700 EL Pardo 1 and 2									Secretary
	1030-1045	Coffee Break									
	1045 - 1215	Plenary Day 0900-1700 EL Pardo 1 and 2									Room
	1215 - 1315	Lunch									
	1315 - 1500	Plenary Day 0900-1700 EL Pardo 1 and 2									closed
	1500 - 1515	Coffee Break									
	1515 - 1700	Plenary Day 0900-1700 EL Pardo 1 and 2									

The number of concurrent sessions, and the wide variety of content requiring a variety of expertise makes it difficult to effectively follow all the issues and to influence change across the entire spectrum of TC 215 activity.

5 AUSTRALIAN PARTICIPATION

5.1 PARTICIPATION LOGISTICS

ISO/TC 215 generally has up to eight concurrent streams at its meetings and the actual agenda for each work group tends to vary from that published prior to the meeting, depending on the availability of key contributors, many of whom have commitments to multiple groups.

Given the limited size of the Australian delegation and the expertise and interests of the delegates, the delegation necessarily covers some areas in greater depth than others with the allocation of responsibilities taking into account and the priorities set out in IT-014's current objectives for Australian engagement in international standards development as discussed with DoHA.

On this occasion, it was unfortunate that Australia was unable to attract a delegate devoted to the activities of WG4 Security, Safety and Privacy as this WG is involved in a range of international standards work relevant to the use of e-Health systems across the Globe, including current activities in Australia. Although partly covered by generalists from the Australian delegation at this meeting, other areas in which greater specific expertise would be desirable are Pharmacy (WG 6), Data Interchange (WG 2, which has two sub-streams) and the emerging area of Patient Safety and Quality.

To monitor and plan its involvement, the Australian delegation met on a regular basis to identify emerging issues and the sessions which should be covered - particularly noting those that are relevant to the Standards Australia IT-014 and/or NEHTA work plans.

In all, the Australian Delegation comprised 11 persons, most of whom contributed to this report. The funding source for these delegates is indicated in Table 1 below.

Table 1 Delegation funding source

Funding Source	Number
Full funding by employer: Private	0
Full funding by employer: States/Territories or National Initiatives	4
Expenses fully met by DoHA through Standards Australia contract	5
Expenses partly met by DoHA through Standards Australia contract	0
Standards Australia staff supporting Australian secretariats expenses met by DoHA	1
Standards Australia staff supporting Australian secretariats expenses met by Standards Australia	1
Total:	**11**

The DoHA funded delegates were selected through an independent panel process run jointly by NEHTA, DoHA and Standards Australia.

One delegate originally selected was unable to attend which was unfortunate as the perspective of the delegation was not as broad as desired. The delegation's capacity to deliver the intended outcomes of participation, information distribution back in Australia and to influence developments to support Australian requirements is enhanced by a balanced delegation of experienced people along with "new blood" who can both challenge the processes and increase the pool of understanding of these complex issues in Australia. Attendance of NEHTA personnel as part of the Australian delegation helped to provide direct two-way communication between ISO/TC 215 activity and implementation of Australian national eHealth initiatives and was welcomed by the other members of the delegation.

Attendees from other countries are largely funded to attend by their employer or as consultants to national programs to influence ISO developments, and to return expertise to their own country. This support by Governments and employers does not negate the voluntary nature of much of the work which is done on weekends and evenings, out of work time, but does indicate the value attached to the activities by employers and national programs around the world.

Action resulting from previous reports

Following previous recommendations:

- Australian Government support for the Australian delegation has continued. IT-014, Standards Australian and the delegates continue to consider how communication of the knowledge gained can be effectively and efficiently communicated back into the Australian e-health community.
- Ongoing Government support of Australian delegations is appreciated and continues to be required to enable progress in this area.
- Improvements in the delegate selection process and transparency have occurred and will continue to be monitored for ongoing improvement.
- The need for a longer-term perspective (beyond 12 months) within the e-health standards program, and for flexibility to adapt to a changing international e-health standards landscape has been recognised in the recent discussion of the IT-014 work program for 2010/11, 2011/12 and subsequent years, and is being reflected in the associated funding agreements between Standards Australia and DoHA.

  Action: IT-014, Standards Australia and NEHTA to consider further strategies to engage with and support communication with Australian healthcare decision makers and implementers of national e-health initiatives to improve e-health knowledge, skills and risk

management in Australia and to better utilize the standards available as well as to provide a stronger view of the continuum of standards.

5.2 COVERAGE

Table 2 (below) summarises the various TC 215 groups which met during the May 2010 meeting and also serves to indicate the structure of TC 215 with its working groups, task forces and executive committees.

The number of concurrent sessions, and the wide variety of content requiring a variety of expertise makes it difficult to effectively follow all the issues and to influence change across the entire spectrum of TC 215 activity.

Table 2 Meeting Schedule highlighting areas of Australian interest

TC 215 Committee, Working Group or Task Force	Sun	Mon	Tue	Wed	Thu
Operations and Harmonization Meeting (Convenors, Vice-Convenors and Secretaries)	X				
Executive Council (Heads of Delegation, Convenors, Vice-Convenors and Secretaries)	X				
SDO Harmonization Meetings (inc WG 9) (open to all delegates) Now including WG 9 – Joint Working group for SDO Harmonization	X		X	X	
Plenary Opening (all)		X			
Patient Safety and Quality Task Force		X			
WG 1 – Data Structure (mainly joint with WG8)		X	X	X	
WG 2 – Data Interchange			X		
Subgroup 1 - Architecture		X	X		
Subgroup 2 - Methodology		X	X		
WG 3 – Semantic Content (Australian Convenor)		X	X	X	
Traditional Medicine TF (reports through WG3) & TC249 discussions		X		X	
WG 4 – Security		X	X	X	
Health Cards Task Force (reports to WG4, replacing WG5 since 2008)			X		
WG 6 – Pharmacy and Medication Business		X	X	X	
WG 7 – Devices		X	X	X	
WG 8 – Business Requirements for EHR (mainly joint with WG1; Australian Secretariat).		X	X	X	
Joint Initiative Council (Closed executive session)			X		
Australian Team Meetings	X	X	X	X	X
TC 215 Plenary (reports and resolutions)					X
Multidisciplinary Task Force	Formally discontinued at this meeting				
E-Business for Healthcare Transactions Task Force (originally aimed at liaison with UN-CEFACT and OASIS)	Formally discontinued at this meeting				
TC 215 Business Planning & Organisation Task Force	Established at this meeting – to work by teleconference & report to Exec Council				

5.3 AUSTRALIAN LEADERSHIP POSITIONS

Positions currently held by Australians within TC 215 are listed in Table 3 below. It should be noted that convenors, and heads of delegations are automatically members of the Executive Council, and that convenors, vice-convenors and secretaries are members of the Harmonisation and Operations Committee.

Table 3 Leadership positions

Working Group or Committee	Position	Status	Person
WG 3 – Semantic Content (Terminology)	Convenor	Elected (Re-elected this meeting)	
WG 8 - Business Requirements for EHR	Secretariat	Appointed	Standards Australia (Kylie Sugar)
WG 9 – Joint Working Group for SDO Harmonisation	Secretariat	Australian activity suspended as pending	Standards Australia
Australian Delegation	Head of Delegation	Appointed	Richard Dixon Hughes
TC 215 Business Planning and Reorganization Task Force	Members	Appointed	Richard Dixon Hughes Heather Grain
ISO/IEC JTC 1 Liaison to TC 215	Nominated JTC 1 Liaison Officer	Appointed by JTC 1	Richard Dixon Hughes

6 TC 215 MEMBERSHIP AND ORGANISATION

The current TC 215 "Participating" P-Members and "Observing" O-Members by continent are as follows:

Continent	P-Members	O-Members
Africa	Kenya	South Africa, Zimbabwe
North America	Canada, USA	
South America	Brazil	Argentina, Ecuador
Asia	China, Japan, Korea, Malaysia	Hong Kong, India, Iran, Mongolia, Singapore, Thailand
Europe :	Armenia, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Russian Federation, Serbia, Slovakia, Spain, Sweden, Turkey, United Kingdom	Bulgaria, Croatia, Cyprus, Hungary, Israel, Poland, Portugal, Romania, Ukraine, Switzerland
Oceania :	Australia, New Zealand	
	Total = 29 (15 present)	**Total = 20 (1 present)**

Participating member countries have voting rights and obligations to host meetings and provide secretarial support to the activities of the TC. The current Chair of ISO/TC 215 is Dr Christopher Chute, from the Mayo Clinic, USA, who took over on 1 January 2010.from Dr Yun Sik Kwak of Korea (who served in the role for the maximum period of 6 years)

The Secretariat also services the ***Joint Initiative on Health Informatics Standards Development Organisation Harmonisation*** (JI). This initiative is realised through an executive-level **Joint Initiative Council (JIC)** that has the objectives of reducing overlap and inconsistency and promoting economy of effort in the standards development activities of ISO/TC 215, CEN/TC 251, HL7 and other health informatics standards development organisations (SDOs).

The *Joint Working Group on Health Informatics SDO Harmonisation* (JWG) is formally constituted as ISO/TC 215 Working Group 9. It was established to review cross-SDO work programs and make recommendations for harmonisation to the JIC. It works with the JIC and traditionally had co-chairs drawn from HL7, ISO/TC 215 and CEN/TC251. With expansion of JIC from 3 to 6 members, the JIC and ISO/TC 215 leadership have been reviewing the way in which joint work is reviewed and managed and, as covered elsewhere in this report, have started making changes which significantly affect the operation, membership and functioning of the JWG.

Through WG 7, TC 215 also participates in a joint working group with IEC/SC62A and IEEE, constituted as IEC/62A/JWG7. This group is focused on controversial new technical standards on *"Application of risk management to information technology (IT) networks incorporating medical devices"*. More details are available at: http://www.iec.ch/dyn/www/f?p=102:14:0::::FSP_ORG_ID:2471.

7 TC 215 WORK PROGRAM

Up until May 2010, the ISO/TC 215 Health Informatics committee had published some 77 ISO deliverables (i.e. International Standards, Technical Specifications, Technical Reports etc). [1]

A further 12 deliverables have been sent to ISO Central Secretariat for final editing and publication.

TC 215 currently has some 105 ISO deliverables on its active work program, distributed among the Working Groups as follows:

WG 1	*Data Structure*	4 items
WG 2	*Data Interchange*	13 items
WG 3	*Semantic Content*	18 items
WG 4	*Security, Safety and Privacy*	10 items
WG 6	*Pharmacy and Medication Business*	12 items
WG 7	*Devices*	34 items
WG 8	*Business Requirements for EHRs*	5 items
Electronic Health Cards Task Force		9 items

These include 33 preliminary work items being drafted or under active consideration and 17 existing publications now scheduled for systematic review. The 33 preliminary work items include 19 device interface specifications that are being developed by IEEE but have been identified for fast-track adoption through TC 215/WG 7.

Joint work is often performed in conjunction with other groups having formal liaisons with TC 215 – CDISC, DICOM, GS1, ICN, IHTSDO, IMIA, UNECE, WHO, IHE, CEN, IEC. The relationship between ISO and CEN is long-standing and is formalized in the Vienna agreement. There is also a "pilot agreement" between ISO/TC 215 and HL7 that provides for normative HL7 standards to be brought into ISO for acceptance. Recent discussions at JIC and JWG information sessions have sought to clarify

[1] Source for all figures given in this section: TC 215 Work Plan spreadsheet (as updated to May 2010) and supplied by TC 215 secretariat shortly after the meeting.

how and when these arrangements might be used and when work should be conducted as joint projects approved through the Joint Initiative Council.

8 TC 215 EXECUTIVE COUNCIL

The TC 215 Executive Council comprises the TC 215 Chair, the Head of Delegation for each country, and the Convenor and Vice-Convenor of each TC 215 Working Group. Its role is to consider issues of governance and process relevant to the TC. Meetings of the Executive Council are chaired by the TC 215 Chair, and are not generally open to delegates, other than the council members.

Delegate Attendance	Richard Dixon Hughes (Australian HoD) Heather Grain (Convener WG3)

8.1 TC 215 CHAIR'S REPORT

In his report to the Executive Council, Dr Chute spoke briefly, emphasising that the world is focused on health informatics and thus TC 215 has an important to role to play and can significantly impact this area. However to make 215 successful:

- TC 215 must align what it does with the needs of the National Member Bodies (NMBs) and the national eHealth ;
- TC 215 products, and health IT deliverables in general, would be better received if, in aggregate, they were to form a consistent whole; and
- TC 215 has made excellent contributions thus far but must make further opportunities to increase cohesion and consistency of our products.

In discussion, it was agreed that, to do this, TC 215 must revisit two issues – the business plan, and TC structure and organization. The Executive Committee formed a task force to review these issues with the goal of having a finalized business plan and options for reorganization by next year (the task force and its activities are reported more fully in section 8.2 below).

Outcomes for Australia

There is a need to ensure that the activities of TC 215 (and the international and national standards that flow from its activities) continue to align with the needs of Australian stakeholders – which includes TC 215 working collaboratively in a peak role alongside HL7, IHTSDO, GS1 and national programs.

Richard Dixon Hughes and Heather Grain are both members of the TC 215 Business Planning and Reorganization Task Force being chaired by Jeremy Thorp (UK NHS). The activity is progressing by teleconference.

8.2 TC 215 BUSINESS PLANNING AND REORGANIZATION TASK FORCE

The ISO/TC 215 business plan was first produced in 2004 with an updated draft being completed in January 2009. This draft was reviewed by the Executive Council at the April/May 2009 meeting in Edinburgh.

After repackaging to include material accepted by the Executive Council in Edinburgh, a further draft of the business plan was to have been circulated to national member bodies for consideration and

discussion at the October 2009 meeting in Durham. This was not achieved but a markup of the most recent draft was tabled at the Durham meeting with acceptance being deferred pending review by the incoming chair. and discussion. Previous plans of accepting a revised version at the May 2010 meeting were unable to be progressed, given the incoming chair's views on the need for more fundamental review.

ISO requires all its TCs to keep their Business Plans publicly available and up to date (annual revisions are common). TC 215's is already some years out of date, so any further delay may become a compliance issue.

At the meeting of the ISO TC 215 Executive Council on Sunday 9 May 2010, it was agreed that a Task Force should be constituted to consider:

- the forward business plan for TC 215;
- options for reorganizing the work of TC 215 (including the designated Working Groups).

The draft TC 215 business plan produced in 2009 summarised the main objectives and priorities as being to:

- enhance the interoperability of clinical systems and patient data throughout the world;
- harmonize existing and emerging Health IT standards to establish a global framework for Health IT operations;
- develop standards/specifications for Health IT interoperability where gaps are identified.

During 2010, a number of convenor positions have come up for election, and this has prompted discussions amongst the Executive Council as to whether there could be better ways of organising the work of TC 215. Alongside this, there have been challenges as to the relevance and usefulness of TC 215 outputs for national member bodies and industry. The Task Force provides an opportunity to consider these issues and make recommendations as to the way forward.

Proposed Approach

The proposed approach is in three stages:

- to validate the objectives for the Committee as expressed in the previous business plan
- to identify a range of organisational options for delivering against these objectives and a set of criteria against which the options might be assessed, and
- to appraise the organisational options and make recommendations for the future operation of the Committee.

There is some concern that the current structure does not accurately reflect the work that the TC does and needs to do in the future. In particular, there are resource issues where some experts cannot attend all relevant discussions occurring in separate WGs. There is a need to become more efficient in use of resources, especially as the topics of the WGs become more intertwined. Also, there is a wish to include making standards participation available and affordable to emerging and developing countries.

Membership of the Task Force

Volunteers were sought for membership of the Task Force. The aim is for this exercise to be inclusive, however, so that all Committee members have the opportunity to comment and contribute. It is

expected that monthly teleconferences will be arranged, with a profile of topics for discussion. The current participant list is shown overleaf.

Timescales

The proposal is for a two-stage process, with interim deliverables planned for discussion in Rotterdam (October 2010) and a final deliverable for review and approval at the May 2011 meeting in Finland, as follows:

- Interim Deliverable (October 2010). This would aim to:
  - provide an agreed description of scope and objectives for the Committee
  - identify potential organisational models, and
  - propose a process for the appraisal of these models, including appropriate assessment criteria.
- Final Deliverable (May 2011). This would make formal recommendations for the organisational structure of TC 215 and its working groups.

Action: Richard Dixon Hughes and Heather Grain to keep IT-014 informed of the activities of the TC 215 business planning and reorganization task force and the alternative structures for TC 215.

8.3 OPTIONS FOR WG1 AND WG8 ACTIVITIES AND LEADERSHIP

Prior to the meeting, Canada had announced that it would relinquish the secretariat and convenorship of WG1. For some time now, WG1 (Data Structure) and WG8 (Business Requirements for EHRs) have mainly met together, having a large common membership and many joint projects. Standards Australia provides the secretariat for WG8, which has a Canadian convenor and a Brazilian vice-convenor.

Proposals to merge WG1 and WG8 have been under informal discussion for some time and the Australian delegation considered that the required election of a new convenor and vice-convenor for WG1 at this meeting and the need to find a new secretariat provided the ideal opportunity to merge the two WGs.

Following on from Dr Chute's introduction, Australia raised the question of overlap between the activities of WG1 and WG8. It was Australia's position that a combination of factors - Canada's relinquishment of both the secretariat and convenorship of WG1, the Vice-Convenorship having also become vacant, the overlap in WG1 and WG8 membership and the two WGs holding most meetings as joint meetings – provided the ideal opportunity to combine the two WGs (at least on a trial basis). Australia confirmed that, if this were done, Standards Australia would be prepared to continue to provide the secretariat of the combined new working group.

This was discussed briefly before Dr Chute indicated his preference to not make any changes until he had the report back from the Business Planning and Reorganization Task Force.

Outcomes for Australia

Prior to departure for Rio, agreement has been sought and obtained from Standards Australia and DoHA for the Australian delegation to actively support merging the activities or WG1 and WG8 and to offer Standards Australia as the secretariat of the combined group (as we would be relinquishing WG8).

Australia argued for the merge of WG1 and WG8 at the Executive Council and offered to host the combined secretariat but the TC 215 Chair preferred to await the findings of the business planning and reorganization task force before making any changes. As a result, WG1 held office-bearer elections (see notes on WG1 below)

WG8 and WG1 work program

If it is to exist independently, Australia considers WG8 should be more active and have clear responsibility for more of the TC 215 project workload, including some projects not transferred from WG1 when WG8 was formed. Prof. Kay, the incoming chair of WG1, is currently also chair of the European CEN/TC251/WG1 mirror committee and is keen for WG1 to operate more independently of WG8, although there remains a large common membership that does not want too many scheduling conflicts at TC 215 meetings.

Outcomes for Australia

As WG8 secretariat, Standards Australia is working actively with the WG8 convenor (Dr Marion Lyver, Canada), vice-convenor (Dr Beatriz Leao, Brazil) and also the WG1 leadership to ensure that WG8 gains responsibility for relevant work items of interest to Australia and organises the activities of WG8 to progress them effectively (in collaboration with WG1, where possible). A teleconference of the O&H committee held 30 days after the Rio meeting agreed to all but one of Australia's requests.

Action: Standards Australia (eHealth team) to proactively manage the WG8 secretariat with a view to ensuring that WG8 gains responsibility for and progresses relevant work items of interest to Australia.

8.4 CHANGE OF TC 215 SECRETARIAT

The Health Information Management Systems Society (HIMSS) announced that it is withdrawing from being the TC 215 Secretariat on behalf of ANSI (the American National Standards Institute). In response to questions from Australia, it was confirmed that ANSI has sought expressions of interest from other US-based organisations and will be advised by the US TC 215 TAG in selecting an appropriate organisation with compatible objectives to support TC 215.

Outcomes for Australia

From informal confidential discussions, the Australian delegation understands that ANSI has identified a candidate organisation which is likely to be acceptable to the broader TC 215 membership and is interested in taking on the role, for which HIMSS has allowed a 12-month hand-over period. The Australian delegation will continue to monitor developments in this space.

Action: Australian HoD (Richard Dixon Hughes) to monitor and keep IT-014 informed of developments in finding a replacement for HIMSS as the provider of TC 215 secretariat services, and use Australia's influence with a view to securing a smooth transition to the new provider and an improved level of service.

8.5 AVOIDING SCOPE OVERLAP WITH NEW ISO TC249 (TRADITIONAL CHINESE MEDICINE) COMMITTEE

There is considerable risk that the new ISO technical committee TC 249 (Traditional Chinese Medicine) will have a scope that allows overlap with TC 215 in the area of health informatics. One preliminary

meeting had already taken place where scopes were discussed and better defined. A follow-up meeting to ratify the outcome of these discussions was planned to take place at the first TC 249 plenary in Beijing in early June 2010. Executive Council discussed its representation as the TC 249 look to pass the agreement at their next Plenary.

8.6 REVIEW OF LIAISON ORGANISATIONS

Under ISO/IEC directives, organisations may be members of a TC with liaison status. Depending on the level and type of liaison, they may be informed of and contribute to TC and working group activities. but they are not voting members as are the participating national member bodies.

Current active internal ISO and IEC liaisons include:

- ISO/TC 37 - Terminology and other language and content resources
- ISO/IEC JTC1 – Information Technology (Richard Dixon Hughes - AU is the JTC1 liaison officer to TC 215)
- IEC/TC62 - Electrical equipment in medical practice
- IEC/SC62A - Common aspects of electrical equipment used in medical practice

A further 20 or so ISO and JTC 1 TCs and SCs are identified on the ISO website as internal liaisons but do not appear to be actively engaging with JTC 1.

Current TC 215 Category A liaisons were reported as including:

- CDISC – Clinical Data Interchange Standards Consortium
- COCIR – European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (based in Europe but operating more widely)
- DICOM – Digital Medical Imaging and Technology
- GS1, the principal international organisation for supply chain standards
- ICN - International Council for Nurses
- IMIA - International Medical Informatics Association (nobody has attended for at least 3 years as a formal representative)
- WHO - World Health Organization

Category A liaisons are organisations that make an effective contribution to the work of a technical committee. They are given access to all relevant documentation (at the committee level), are invited to meetings and have the right to nominate experts to participate in working groups and project teams. To be eligible as a Category A liaison, an organisation should be a fully international organisation (as opposed to a body that is limited to a national or supranational regional focus).

Two pending Category A liaisons were discussed at Executive Council:

- HON (Health On the Net). The application from this health content monitoring and certification organisation is being progressed.
- NORMAPME (European Office of Crafts, Trades and Small and Medium sized Enterprises for Standardisation). The application is currently deferred. Canada has voted against due to concerns that this group is not a standards organization, and has a regional focus is on protection of trade for Europe and do not have a clear collaborative interest.

Current Category D liaisons (which operate at the level of individual WGs) were reported as including:

- Continua Alliance (for Working Group 7)
- ICH – International Classification of Drugs for Harmonization (for Working Group 6)
- IHE – Integrating the Healthcare Enterprise (for Working Group 2)

8.7 UPCOMING TC 215 MEETINGS

In reviewing the location and timing of upcoming TC 215 meetings, it was noted that a clash had arisen between the ISO/TC 215 plenary meeting in Finland and the HL7 May 2011 Working Group Meeting in Orlando, Florida both of which were scheduled for the week of 15-19 May 2011. Apparently the clash arose when Finland moved the TC 215 meeting from June to May without confirming the final dates of the Orlando HL7 meeting (which had originally been proposed for Sydney). On discovering the clash, the TC 215 Chair and Secretary explored options with the Finnish delegation and discussed the matter further at the JIC.

A further special meeting of Executive Council and other relevant parties was convened to discuss how to manage the clash. After discussion at the JIC and noting that the financial penalties for moving the HL7 WGM were too great, the TC 215 leadership (supported by the CEN/TC 215 Chair) proposed that the meetings be allowed to occur concurrently but with TC 215/WG2 meeting in Orlando and, possibly, making greater use of video/electronic conferencing.

Outcomes for Australia

As a country with a relatively small health informatics community that is active in both HL7 and TC 215, Australia, along with Canada and Germany, led the argument against allowing this clash to continue, actively proposing a range of alternatives and noting the impossibility of using electronic conferencing to resolve the proposed conflict.

Other countries were similarly dismayed and the leadership of TC 215 agreed to reconsider their proposal.

While the Finnish delegation at the Rio meeting was adamant that nothing could be done to resolve the situation from their end, Standards Finland (Hillevi Vuori) was subsequently able to move the TC 215 meeting to 22-26 May 2011, the week after HL7. Australia has recorded its appreciation for their efforts in this regard.

As subsequently proposed by the TC 215 Secretariat, the upcoming meetings of the ISO TC/215 Health Informatics Committee are scheduled for:

10-13 Oct 2010	Rotterdam, The Netherlands	Working Group Meeting joint with CEN/TC251
23-27 May 2011	Kuopio, Finland	Plenary and WG Meetings
Oct 2011	Dates & location tbc (Beijing had been proposed but China was not present in Rio)	Joint Working Group Meeting

Some other meetings on in 2011 that have the potential to clash and/or compete with ISO/TC 215 include:

- AMIA: 25-27 May 2011 Orlando (limited conflict – different audience)
- HIMSS Asia –Pac: 20-23 September 2011 Melbourne

- HL7 May WGM: 16-20 May 2011 Orlando
- IHTSDO 11-15 April 2011 Denmark
- WoHIT 9-12 May 2011 Budapest

As some two-thirds of ISO/TC 215 P-members are from Europe, and there is a strong desire to harmonise with the activities of the European Health Informatics standards activities undertaken through CEN, the TC 215 Executive Council attempts to have at least one meeting a year in Europe - to be a joint with CEN/TC251.

9 OPERATIONS AND HARMONIZATION COMMITTEE

At each meeting of the TC there is a meeting of Convenors, Vice Convenors and Secretaries to coordinate activities of the meeting and the TC. The meeting is chaired by the TC 215 Secretary and is not open to other delegates.

Delegate Attendance	Heather Grain (WG3 Convenor) Andrew Caswell, Kylie Sugar (WG8 Secretariat)

Ensuring meeting overlap and travel time between JIC member meetings are reasonable, protect volunteer capacity and safe travel, it was requested that the JIC develop a shared meeting calendar with other members of the JIC to avoid overlap and ensure at least 2 days between meetings, and where significant travel is needed between meetings at least 3 days between meetings.

To assist in meeting operations (particularly when members are not able to be physically present) it was requested that TC 215 develop a set of standard requirements for working group meetings and plenary sessions including:

- Internet access sufficient to support every attendee in all rooms
- Teleconference / webinar facilities
- Disabled access (it should be possible to ensure disabled access to all meeting rooms)

Cost mitigation strategies also need to be considered to cope with major travel interruptions.

Outcomes for Australia

Where new work items are coming forward from working group, the report of the ISO meeting should identify requirements regarding the offering of Australian experts. The need to offer an expert should be considered by the relevant mirror working group within IT-014 and, where relevant, appro0priate experts should be identified and put forward to Standards Australia for inclusion in the ballot. This process ensures that Australian expertise is placed where required. Expertise skill requirements should be identified to ensure that appropriate experts are identified and this should be considered in delegation composition.

Action: Reports on TC 215 meetings to identify upcoming work items so that IT-014 and its subcommittees can consider the need, types and required skills of Australian experts for submission with new work items. [In this report, please refer to sections on individual WGs and on the final resolutions].

Action: IT-014 and/or the relevant mirror group(s) to consider needs and skills required for Australian experts for submission with each new work item ballot

10 WG 1 - DATA STRUCTURE

Delegate Attendance	Heather Leslie, Evelyn Hovenga Richard Dixon Hughes (WG8 joint topics) Andrew Caswell, Kylie Sugar (WG8 secretariat) Stephen Chu (NEHTA) Occasional attendees: - Heather Grain, - Anthony Maeder - Tina Connell-Clark (NEHTA) - Andy Bond (NEHTA)

Most of the WG1 program was held jointly with WG8 with the chair alternating between convenors, depending on the particular work item being discussed.

More than 60 Delegates attended, representing at least 12 countries and at least 3 liaisons (WHO & IHTSDO and ISO/TC 106)

Elections for WG1 leadership positions led to Professor Stephen Kay (UK) being elected as Convenor, and Dr Don Mon (AHIMA USA) being elected as Vice-Convener. Canada has been prevailed upon to continue providing the WG1 secretariat services for a few more months until a replacement can be found. Australia continues to service WG8 but was therefore unable to assist by taking over WG1 as it was continuing as a separate entity.

10.1 WORK ITEMS

Work item / notes	Australian responsibilities/comments
• Identity Management Framework Task Group Prelim work item. Lead: Bryan Manning – UK. No progress	IT-014-09 to watch/manage (leading) in consultation with IT-014-02 & IT-014-04
• Standards Convergence to Promote EHR Interoperability Failed NP ballot as ISO/TS. To be resubmitted as an ISO/TR. Lead: Gary Dickinson – US. Controversial.	IT-014-09 to watch/manage Dixon Hughes nominated to assist
• Quality requirements and methodology for detailed clinical models (DCM) (Lead: William Goossen – NL. Controversial. Australia previously voted 'no' – actively participating in driving more acceptable outcome) See section 0 below.	IT-014-09 leading active involvement. Nominated experts actively participating include Dixon Hughes, Hovenga, Heather Leslie and Stephen Chu (NEHTA). IT-014-06-06 and IT-014-02 also seeking engagement .
• Health Indicators Conceptual Framework Lead: Indra Pulcins – CA. Passed DIS ballot – now moving to FDIS	IT-014-09 leading active involvement. Also on work program for local adoption (100102)
• Provider Identification Lead: Neil Gardner – CA; Heather Grain - AU. Joint with WG 4 and WG 8. ISO/TS 27527 now at publication. Next step is review for incorporation of biometric measures and elevation to IS.	IT-014-02 (project 8101) to watch/manage (leading) in consultation with IT-014-04 and IT-014-09 Move from IT-014-09 to IT-014-02
• Identification of subjects of health care Lead: Heather Grain – AU. ISO/TS 22220 was published in 2009 but to be re-balloted to incorporate biometric measures	IT-014-02 (project 8101) leading active involvement in consultation with IT-014-04 and IT-014-09

• Deployment of a Clinical Data Warehouse Lead: Andrew Grant –CA. ISO/TS 29585 now at publication. Next step is review for elevation to IS.	IT-014-09 to watch/manage and consider for local adoption
• EHR Definition Scope and Content (ISO/TR 20514) Due for review 2011.	IT-014-09 to watch/manage (leading) in conjunction with IT-014-04and consider driving move from WG1 to WG8.
• EHR Communication Part 5 Interface Specification ISO 13606–5 published February 2010	Publication of this final piece of the 13606 series of EHR communication standards informs IT-014-09 project 5281.
• Health Summary Record/Core data sets Preliminary proposal –currently identifying a lead.	IT-014-09 to watch/manage
• Health information systems requirements framework Proposed by WHO from work on Health Metrics Network (HMN)	IT-014-09 to watch/manage

Action: IT-014 to note following WG1 work items on project plan as mirror projects:
(1) Identity Management Framework Task Group. Prelim work item (to IT-014-09).
(2) ISO/TS 27527 - Provider identification. Revise/upgrade published work (to IT-014-02)
(3) ISO/TS 22220 – Identification of subjects of care Revise/upgrade published work (to IT-014-02)
(4) Health Summary Record/Core data sets. Prelim work item (to IT-014-09)
(5) Health information systems requirements framework. Prelim work item (to IT-014-09).

10.2 DETAILED CLINICAL MODELS (DCM) PROJECT

In reporting to WG1, the project lead, Dr William Goossen noted that the work was progressing slowly. As a result of discussion, it was agreed that, in developing the first working draft, the specification should not attempt to define a reference information model and that use of UML would be part of the informative content (rather than being normative); modelling content would be generic.

At the previous NWIP ballot, Australian stakeholders had expressed considerable concern about the direction being taken by the DCM project. Following detailed discussion at this meeting, it was agreed that the project would initially focus on quality measures applicable at the various stages of the DCM lifecycle and would not prescribe a single representational technology. New teams and leaders were agreed for work on the five parts of the document.

Emphasis would be given to parts 1, 2, and 4, with part 3 to be more general than was provided in the earlier draft. There would also be a part zero to provide context (with Hovenga and Dixon Hughes nominated to provide initial draft). The next draft is due by the end of August for consideration at the Rotterdam meeting.

Action (1): Evelyn Hovenga and Richard Dixon Hughes to produce a preliminary draft of the introductory part in the series

Action (2): Heather Leslie and Stephen Chu to contribute to other parts.

10.3 STANDARDS CONVERGENCE TO PROMOTE EHR INTEROPERABILITY

Australia had voted against this overly wide-ranging work item being commenced as a normative international technical specification. This view was shared by many other countries and the work item, as originally proposed, was rejected.

It was agreed that Australia and others would not oppose this work proceeding in the form of a Technical Report identifying relevant standards work. As part of this compromise, Richard Dixon Hughes agreed to assist with re-drafting a new work item proposal for the technical report.

Action: Richard Dixon Hughes (IT-014-09) to assist with re-drafting a new proposal and scope for a technical report addressing "Standards Convergence to Promote EHR Interoperability"

10.4 CDS, USER INTERFACES AND ALERT INFORMATION

The following topics were addressed in a joint session of WG1 (hosting), WG3 and WG8 and have been reported under WG3 in section 12 below

- Principles and Desirable Features of Clinical Decision Support
- Guidance on requirements for user interface in healthcare delivery systems.
- Alert information in health records

11 WG 2 - DATA INTERCHANGE

Delegate Attendance	Anthony Maeder Andy Bond (NEHTA) Occasional Attendees - Richard Dixon Hughes, - Evelyn Hovenga - Tina Connell-Clark (NEHTA)

The WG 2 secretariat has been vacant since Adrian Stokes (UK) withdrew at the Durham meeting and this needs to be resolved. Klaus Veil (AU) had been invited to take on the role but IT-014 had not seen resourcing this role as a current priority for Australia.

WG 2 has traditionally conducted much of its business in two parallel streams – Architecture and Methodology. Australia raised the question as to whether all 3 days could be used instead of holding concentrated parallel sessions on first 2 days, which would allow smaller delegations to cover other WGs of interest and give more time to attend and cover all WG 2 items. Canada and USA agreed that a 3-day arrangement with more plenary sessions would be more productive and inclusive.

The future strategy and scope for WG2 needs greater clarity. In theory, WG2 focuses on messaging and communication of health information, rather than “information structure” (WG1) or "coding of content" (WG3 and IHTSDO/ SNOMED). In practice, WG2 is the committee most closely associated with HL7 and has progressed HL7v2.5, HL7v3 RIM, HL7v3 CDA, HL7 HDF to become international standards. Current WG2 work on genomics, data types and the BRIDG model also originated in and closely parallels work within HL7. On the methodology side, WG2 is the vehicle for recognition of IHE processes within the ISO community.

Conformance testing and compliance and quality are now seen as part of WG2 scope.

11.1 WORK ITEMS

ISO/DIS 10159 Web access resource manifest (WARM) passed ballot with no negative votes or significant change and so will automatically proceed directly to publication as an international standard.

Editorial issues holding up the FDIS ballot of the ISO 21090 Harmonized data types standard were reported to have been resolved, with the draft to be finalised for ballot shortly.

Work item / notes	Australian responsibilities/comments
• Telehealth Systems - Teleradiology Interoperability (Preliminary item – being negotiated with Brazil)	IT-014-12 to watch/manage with input from IT-014-06 Add to IT-014 work program as a mirror project.
• Trusted end-to-end information flows Lead: Gary Dickenson –US. DTS 21089 is a preliminary work item likely to be absorbed by work on "Standards convergence to support EHR interoperability"	IT-014-09 to watch/manage (as part of standards convergence work)
• The BRIDG domain analysis model for protocol-driven biomedical research. ISO 14199 is an active joint project with CDISC (Iberson-Hurst) lead – about to proceed to DIS ballot	IT-014-06 to watch/manage
• Messages and Communication - Web Access to DICOM persistent Objects by means of Web Services. ISO 10974 is at committee draft stage.	IT-014-06 to watch/manage
• Clinical Genomics Pedigree Topic. Lead: HL7 (Kaufman). ISO 13449 is at committee stage progressing toward DIS ballot.	IT-014-06 to watch/manage
• Quality Criteria for services and systems for telehealth Lead: Netherlands. ISO 13131 is an active project targeting a technical specification.	IT-014-12 to watch/manage See comments at section 11.2 below
• Clinical Document Registry Federation Lead: Byoung-Kee Yi – KR. TR 13128 in preparation	IT-014-06 to watch/manage
• Messages and Communication - Web Access Reference Manifest Lead: Nick Brown – UK. IS 10159 passed DIS ballot and is in process of being published.	IT-014-06 to watch/manage. Consider whether local adoption warranted
• Harmonized Data Types for Information Interchange Lead: HL7 (Grahame Grieve – AU). ISO 21090 is a foundation eHealth interoperability standard. The joint work is at FDIS stage (final normative in HL7). It has been unconscionably delayed by ISO editorial bureaucracy	IT-014-09 (lead) actively managing with a view to completion of FDIS ballot with input from IT-014-06
• IHE Global Standards Adoption Part 2 - Integration and Content Profiles	IT-014-06 to watch/manage
• IHE Global Standards Adoption Part 1 - Process	IT-014-06 to watch/manage

Action: IT-014 to note following WG2 work items on project plan as mirror projects:
(1) Telehealth Systems - Teleradiology Interoperability. Prelim work item (to IT-014-12)
(2) ISO/DTS 21089 Trusted end-to-end information flows. Prelim work item (to IT-014-09)

11.2 QUALITY CRITERIA FOR SERVICES AND SYSTEMS OF TELEHEALTH

The new work item proposal (NP ballot) for ISO/TS 13131 was approved a year ago based on previous Dutch work, which focussed on identifying acceptable telemedicine practices (partly for reimbursement purposes). A change in project leadership has caused delay.

A working document was distributed last month, modified from the original Dutch document but is still to localised to the Dutch in outlook and needs to address a wider scope to include; business processes, the role of EHR in telehealth environment; terminology in the domain; role and coverage of

other standards (e.g. 11073, 20601, ISO 9000); application in the contest of self-help groups. Issues for the working document: include scope, normative references, terms and definitions, quality aspects (and need to separately address institutional processes, care consumer related processes, telehealth technology production/delivery and service level processes).

Scope and the key concepts to be included in the definition of "telehealth" remains the biggest issues. The title has been changed to telehealth, with telemedicine being seen as a subset of telehealth; however, the text still focuses on telemedicine.

Brazil has examined definitions to provide input to scope discussions. Should the scope be defined by the objectives of which services to be covered? This could be too limiting, but the concept that it does apply to a service is useful. The SKMT definition (from Canada, 10 years ago) for Telehealth is: *"use of ICT to deliver health services and transmit health information over both short and long distances etc. encompassing treatment, preventative and curative aspects"*. In terms of domains, how far should the definitions and scope go in relation to encompassing: Allied health involvement? Telecare organisations? Remote patient monitoring? The definition of telehealth needs further work, but if the scope of the type of health processes to be addressed (e.g. by defining the actors: payers, providers, consumers), this project should be able to proceed with work on the quality model aspects.

Australia (Maeder) suggested change of title to “Tele-delivery of Clinical Service Delivery” but such a change was ruled outside of ISO process. Australia (Hovenga) suggested that refining the means and participants for transmission of data may be able to limit scope, but this was seen as not covering all aspects of the intention of coverage (e.g. monitoring for clinical purposes vs monitoring for prevention). Canada proposed that scope for the document be described and rather than defining telehealth due to different definitions in different countries. Brazil proposed that a simple definition of Telehealth be used: electronic delivery of information for health care and services at a distance. Scope of the quality aspects also needs to be refined: not about intrinsic quality aspects of software or hardware development. ISO Quality: characteristics required to meet stated or implied needs.

The progress the document it will be re-worded to refer to telehealth internally, and provide a non-exhaustive list of examples of where it might be used. Australia (Maeder) suggested list of examples should be illuminating, not definitive to encourage use of this document on a wider front. Australia (EH) asked if technical constraints/requirements (e.g. resolution of images, type of equipment) should be included in quality considerations, but this is seen as specification resulting from aspect of quality considered relative to risks identified. However some examples of what may be out of scope, including “clinical best practice”, and how they may be addressed, should be mentioned.

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, thereby discouraging adoption of telehealth for fear of not meeting “best-practice” standards. Stronger engagement of Australian input than IT-014-12 has so far been able to supply is desirable and should be discussed at IT-014 level.

11.3 CDISC BRIDG MODEL

The Committee Draft (CD) ballot was passed (46 votes) with 200 comments, despite out-of-date status: general problems of maintenance process (e.g. for RIM) and for boundary/context setting. Only some of the comments were addressed in the TC 215 meeting with a more substantial reconciliation session planned for the HL7 meeting at the same location the following week. The plan is to have a document ready for DIS ballot by the Oct 2010 ISO meeting.

Active participants in the BRIDG work are predominantly based in the US – notably CDISC, NCI, FDA and HL7.

BRIDG defines a shared view of dynamic and static semantics, for protocol-driven research and associated regulatory artefacts, fitting with business/requirements analysis of software development lifecycle and intersecting with the HL7 RIM via DAM (Domain Analysis Model): use cases, ultimately leading to XML messages. The model has three inter-related layers - a "non-technical" information model layer in UML using ISO & HL7 data types (EAXMI); "business models" DAM (OWL-DL) (e.g to capture adverse event rules - components: event, actions taken etc); and the RIM-based HL7v3 DMIM used to define the XML messages. Some of the issues arising in comments included:

- How will BRIDG deal with future assurance of access, distribution, maintenance and monitoring? BRIDG will produce updated versions but this raises questions about how the ISO version can be up to date without going back through the lengthy ISO ballot process?
- Does ISO have to maintain a full copy of the latest version of the document within the ISO system so that anyone can access it? The ISO DICOM standard points to the open source version on the DICOM website. Could CDISC be maintained this way? Also a unique version number for documents needs to be adopted by CDISC and used to refer to documents.
- If DAM is normative (was informative in original TS), what doe this mean in practice? is it necessary to use it i.e. must the researcher adhere to it? Must only researchers use it, or can users in other communities (e.g. pharmacy) use it? How do overlapping semantics impact the broader community?
- Is DAM and RIM content necessary to ensure "computable semantic interoperability"? (This was deemed out of scope.)
- Is there a "dynamic" aspect or is it only "static"? Although the potential to change or define additional variants exists, the examples given are all "static". Perhaps "dynamic" should be removed from title (but this leads to trouble with already approved title in CDISC).
- How definitive is BRIDG in allowing or expressing research protocols? BRIDG is not intended to prescribe research protocols but to allow them to be represented and mapped. There is a question of whether the RIM modelling needs to be included in the BRIDG definition, which will cause more maintenance issues.
- How will DAMs influence the development of standards? Rests on differences in philosophy for standards between the incremental and hierarchical approaches. Will/should the BRIDG DAM be the only vehicle for description in both technical and political domains for clinical research protocols? Is it adequate for this?
- Should not use same names in CMETS as in HL7, need to have unique identifier names (for all RIM based static models).
- Many types of data for results (eg lesion size, cell type) which are commonly used for cases considered; more could be submitted for future incorporation, or users can just construct their own by agglomerated "other" research data element type. Intention of BRIDG is to allow users to specify as they need, but also to share useful or common situations.

Outcome for Australia

Anthony Maeder noted that it is not clear that the BRIDG model has any strong strategic importance or local variant issues for Australia and perhaps should not be high on our priorities.

11.4 FUTURE OF JOINT WORK WITH HL7, CDISC AND OTHER SDOS

WG2 is finding joint development and maintenance of standards in collaboration with HL7 and other SDOs time consuming and difficult to synchronise effectively – with the risk that joint work is delayed by years or that the ISO versions of key joint standards are always out of step with work in the originating SDO, be it HL7, IHE or CDISC.

Action: Australian TC 215 delegations and IT-014 to:
(1) promote joint work on development and maintenance of health Informatics standards being carried out efficiently either through a single joint process or in the most appropriate forum, even if this means bypassing traditional structures, and
(2) use TC 215 Business Planning and Reorganisation TF processes to encourage TC 215 to support joint work as a peak force for endorsement of e-health standards.

12 WG 3 - SEMANTIC CONTENT

Delegate Attendance	Heather Grain (WG3 Convenor) Others attended joint sessions with WG1/8

Some 30 delegates attended WG 3, representing 11 countries and 1 liaison.

Heather Grain was approved as Convenor for an additional 3 year term.

12.1 WORK ITEMS

Work item / notes	Australian responsibilities/comments
• The categorization and nomenclature of medical devices - requirements and analysis. Lead: CEN (delayed)	IT-014-02 to watch/manage
• Criteria for the categorization and evaluation of terminological systems. Lead: Anne Casey – UK. Involves update of existing ISO/TS 17113 and its elevation to a full international standard. Closing plenary accepted WG 3 recommendation that this work remain at preliminary stage for the present (resolution 26)	IT-014-02 to watch/manage
• Proposed technical specification on user interface requirements– Preparation of preliminary drafts (to be based on existing Australian documentation and UK NHS research)	IT-014-02 to actively lead the project and produce initial draft
• Alert information in health records. Lead: Rikard Lövström – SE. NP ballot for ISO/TS 16279 failed for want of 5 experts. After plenary vote, scope to be revised and harmonised before resubmission for a second NP ballot. See comments at section 12.4 below	IT-014-02 to lead broadly based activity to secure Australian input and position on clinical alerts, allergies, adverse events. Need for compliance with ISO/TS 22789 may be worth considering.
• System of concepts to support continuity of care – Part 1: Basic Concepts. Lead: François Mennerat – FR. Elevation of existing European EN13940-1 to ISO standard. Committee draft approved – preparing for DIS ballot	IT-014-02 to watch/manage
• System of concepts to support the continuity of care - part 2: Core process and work flow in health care Lead: François Mennerat – FR. Elevation of existing European EN13940-2 to ISO standard. Work item approved and CD draft being prepared ballot.	IT-014-02 to watch/manage actively and prepare response to 2-month CD ballot

• Identification of the status of structures for representation of human anatomy within healthcare terminological systems Lead: Jean Marie Rodrigues – FR . TR 16278 recently passed NP ballot with draft now being prepared for DTR ballot	IT-014-02 to watch/manage
• Structure of representation of clinical findings in traditional medicine - Part 1: Traditional East Asian Medicine Lead: Kyungmo Park – KR. TS 16277-1 recently passed NP ballot. Draft now being prepared for DTS ballot	IT-014-02 to watch/manage
• Guidelines for the principles and desirable features of clinical decision support systems. Lead: Heather Grain – AU. Draft of TR 14668 now being prepared for DTR ballot. See comments at section 12.4 below re harmonisation with other work	IT-014-02 to actively assist (based on existing AU work). Heather Grain is project lead.
• Communication and Metadata Model and XML-interface specification for OID registries in healthcare Lead: HL7 (Kai Heitmann). Draft of TS 13582 now being prepared for DTS ballot	IT-014-02 to watch/manage (leading) with input from IT-014-06
• Guidance for maintenance of object identifiers (OIDs) Lead: Sylia Thun - DE. Draft of TR 13581 now being prepared for DTR ballot. Active work item with JTC 1 and HL7 liaison leading to productive work at a detailed level.	IT-014-02 to watch/manage with input from IT-014-06. Liaison with JTC1 and ITU-T coordinated thru Grain and Dixon Hughes
• Guidelines for the principles and desirable features of clinical decision support systems. Lead: Heather Grain – AU. Draft of TR 14668 being prepared for DTR ballot. Also see comments at section 12.4 below.	IT-014-02 to prepare initial draft based on existing AU work. Input to be sought from other IT-014 groups and wider eHealth community. Heather Grain is project lead.
• Clinical knowledge resources – Metadata. Lead: Gunnar Klein – SE. Draft of ISO 13119 (based on CEN/TS 15699) has passed CD ballot and is being prepared for joint DIS ballot under Vienna Agreement with CEN lead.	IT-014-02 to watch/manage Given CEN lead, need to ensure European work is appropriate
• A syntax to represent the content of clinical classification systems in health care. Lead: Ronald Cornet - NL. Draft of ISO 13120 (based on CEN/TS 14463) passed CD ballot in January 2010 and is being prepared for joint DIS ballot in under Vienna Agreement with CEN lead. Note – name changed from *"A syntax to represent the content of medical classification systems"* at this meeting – see section 12.6 below.	IT-014-02 to watch/manage Given CEN lead, need to ensure European work is appropriate IT-014 secretariat to note and apply change of name (and confirm TC 215 amends on its work program)
• Categorical structure for terminologies of surgical procedures. Lead: Jean Marie Rodrigues - FR. Draft of ISO/EN1828 (based on CEN draft) passed CD ballot and is being prepared for joint DIS ballot in under Vienna Agreement with CEN lead.	IT-014-02 to watch/manage Given CEN lead, need to ensure European work is appropriate
• Guidelines for the maintenance of terminological systems Lead: Beverly Knight – CA. Draft of TR 12975 being prepared for DTR ballot (since Nov 2008) This is an active work item currently being progressed.	IT-014-02 to watch/manage and provide input to this active work item
• Principles and guidelines for the measurement of conformance in the implementation of terminological systems Lead: Beverly Knight – CA. Draft of TR 12310 being prepared for DTR ballot (since May 2008) This is an active work item currently being progressed.	IT-014-02 to watch/manage and provide input to this active work item

• Mapping of terminologies to classifications. Lead: Heather Grain – AU. Draft of TR 12300 being prepared for DTR ballot (Since May 2008). Active work item with WHO and IHTSDO input.	IT-014-02 to watch/manage and provide input to this active work item and upcoming DTR ballot
• Common Glossary for ISO/TC 215. Lead: Heather Grain – AU. WG3 recommendation to discontinue work on the production of TS 28379 as a publishable document was approved by the closing plenary (resolution 25) – recognising that such a publication would not be effective under ISO rules and has been bypassed by the database of health informatics standards terms being maintained through SKMT.	IT-014-02 to engage actively in working with IT-014 and its other sub-groups on maintaining and using the heath informatics standards glossary within SKMT tool. Heather Grain is project lead for this on-going activity.
• Conceptual Framework for patient findings and problems in terminologies. ISO/TS 22789 has been sent to ISO/CS for publication. Progress in publication to be tracked.	IT-014-02 to watch/manage and give consideration to local adoption as an Australian technical report.
• Integration of a reference term model for nursing. Review/update of ISO 18104 first published as a cornerstone TC 215 standard in 2003 is a current active work item.	IT-014-02 to watch/manage

Glossary harmonisation and knowledge management of health informatics standards

The glossary harmonisation process, developed by Australia with support from IT-014-02 and SKMT tooling developed by Canada is being trialled throughout ISO TC 215 work groups, considered by HL7 and will be reviewed by the JIC member organisations.

Categorial structures for nursing activity (update of ISO 18104: 2003)

WG3 is reviewing potential errors and improvements while preparing a detailed update, after which a proposed new version will be circulated with proposals to resolve current issues. IT-014-02 will have input to this process.

Action: IT-014 to note following WG3 work items on project plan as mirror projects:
(1) ISO 18104 Integration of a reference term model for nursing. For systematic review (to IT-014-02)
(2) Proposed technical report on User Interface Requirements (to be progressed by IT-014-02 based on existing Australian work)

12.2 USER INTERFACE REQUIREMENTS

There was strong support for advancing this work item arising from the presentation made to a joint session of WGs 1, 8 and 3. The document will provide guidance for the design of effective user interfaces for health information systems based on the following principles:

(a) Fit with workflow

(b) Pattern recognition

(c) Information priority in design

(d) Suited to intermittent users

(e) Multiple users of single machines

(f) Error/warning message overload

(g) User acceptability

Successful system adoption and use is dependent upon user satisfaction with the system interface design; however, this work will stop short of the issues of usability testing processes of the traditional software engineering approach.

A group of 'workers' has been established to review the internationalised version of the document, which will be prepared by Australia in order to have a draft ready for discussion at the next meeting – in preparation for ballot. Additions arising from discussion at the joint session in Rio include:

- Risk management of user interface in a clinical care environment
- Section on testing processes and conformance

12.3 CLINICAL DECISION SUPPORT SYSTEMS REQUIREMENTS

There was strong support for advancing this work item arising from the presentation made to a joint session of WGs 1,8 and 3. The document will define the types of clinical decision support systems used in health care and provides guidance on the—

(a) functional features of clinical decision support systems required to support clinical decision making;

(b) key principles for presentation of knowledge in clinical decision support systems;

(c) principal content elements required for decision support system development; and

(d) principal governance processes required for the maintenance of clinical knowledge represented in clinical decision support systems.

Guidance on additional inclusions and content was requested by Australia in order to prepare the initial international draft. Requested additions included:

- Risk management approach to clinical decision support
- Section on testing processes and conformance
- Identification of relationship to Alert work item.

12.4 CDS, USER INTERFACES AND ALERT INFORMATION

The following three topics were discussed in joint session of WG1, WG3 and WG8:

- Principles and Desirable Features of Clinical Decision Support
- Guidance on requirements for user interface in healthcare delivery systems.
- Alert information in health records

The first two of these three topics are based on work done in Australia by IT-014-02 and are being progressed through WG3; however, in Rio, they were presented to a joint meeting of WG1, WG3 and WG8 hosted by WG1 with much of the debate coming from members of WG1/WG8

It is important that these items be harmonized and compatible with each other and with clinical care process projects (WG3) and standards for clinical devices (WG7). They are important for Australia in the short term as there is much software/systems development work currently underway in this area. If we can press for the harmonisation and scope resolution to be achieved early it will help achieve faster results.

At the plenary session, TC 215 declined to approve the alert information topic progressing being re-balloted as a new work item until a more acceptable draft is available that does not make presumptions about user interface requirements.

As the originator of the UI and CDS work there is also considerable interest in and need for an appropriately harmonised technical report on standards for alerts, allergies and adverse reactions. Development of an Australian position and recommendations on approach and content needs to be informed and will require significant input from a range of Australian interests, including IT-014 and several of its sub-groups as well as NEHTA and, potentially, others.

Action: IT-014-02 to lead a broadly based activity to review current work on clinical alerts (including allergies and adverse reactions) and TC 215 proposals for a technical report and develop recommendations to guide both local Australian work and the Australian position on international work in this area.

12.5 PRINCIPLES AND GUIDELINES FOR THE MEASUREMENT OF CONFORMANCE IN THE IMPLEMENTATION OF TERMINOLOGICAL SYSTEMS

The proposed work on ISO/TR 12310 identifies the attributes and associated benefits and risks of clinical terminology and the systems that support them, to assist in selection of terminologies/classifications. It also highlights difficulties associated with using partial solutions and will be harmonised with ISO/TS 17117: *Criteria for the categorisation and evaluation of terminological systems*.

Action: IT-014-02 to lead substantial Australian input into preparation of the initial draft of ISO/DTR 23210, which is expected to be circulated for international comment prior to the next meeting in October.

12.6 SYNTAX TO REPRESENT THE CONTENT OF CLASSIFICATION SYSTEMS IN HEALTH CARE (CLAML)

Australian comments were well received and TC 215 approval given to amend the title to refer to classification systems in "health care", rather than "medical classification systems". Both IHTSDO and WHO are engaged in and supportive of the work, which will be realised with continuous support from WHO-FIC collaborating centres. Although IHTSDO is supportive, SNOMED CT is out of scope for ClaML as it is a third generation terminological system.

The UK still have concerns and have sought 'proof of concept' testing on a wider range of in-scope terminologies – beyond OPS (German procedure classification), ICD and other European classifications that have already been tried.

13 WG 4 - SECURITY, SAFETY AND PRIVACY

Delegate Attendance	Limited coverage of key issues - Andy Bond (NEHTA) - Richard Dixon Hughes, Anthony Maeder, Heather Leslie

Some 33 delegates attended various WG 4 sessions representing 13 countries.

This meeting marked significant changes in WG 4 leadership after 6 years. The new office bearers are:

- Lori Reed-Fourquet, Convenor (US)
- Luuc Posthumus , Vice Convenor (NL)
- Elaine Sawatsky, Interim Secretary (for one year) (CA)

Ross Fraser (CA) was thanked for his work and leadership as convenor.

The new Vice-Convenor, Luuc Posthumus is currently also convenor of CEN/TC 251/WG iii, the CEN mirror committee to ISO/TC 215/WG4, which should aid collaboration and harmonisation between CEN/TC 251 and ISO/TC 215 in the area of health informatics security, privacy and patient safety standards.

WG 4 and the closing TC 215 plenary paid tribute to the late Colin Nolder (UK) who died on April 20, 2010. He was remembered as an energetic chair of the CEN/TC 251/WG iii mirror committee to TC 215/WG 4, an acknowledged expert with many decades of security experience, and a true English gentleman, who had always been a pleasure to work with.

It was noted that WG4 had published the following items since the previous meeting in October 2009:

- ISO TS 22600-3 Privilege management and access control – Part 3: Implementations (published November 2009)
- ISO TS 21547 Secure archiving of electronic health records – Principles and requirements (published February 2010)
- ISO TR 21548 Secure archiving of electronic health records – Guidelines (published January 2010)
- ISO TR 11633-1 Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and Risk assessment (published November 2009)
- ISO TR 11633-2 Information security management for remote maintenance of medical devices and medical information systems - Part 2: Implementation of ISMS (published November 2009)
- ISO TR 11636 Dynamic on-demand virtual private network for health information infrastructure (published November 2009)

Action: IT-014-04 to review recent publications by TC 215/WG 4 (particularly PMAC series) and report to IT-014 on whether local adoption, adaptation or input to next systematic review warrants consideration.

13.1 WORK ITEMS

Work item / notes	Australian responsibilities/comments
• Guidelines on data protection to facilitate trans-border flows of personal health information. Preliminary work approved 2008 but does not currently appear to be active.	IT-014-04 to watch/manage
• Guidance on the application of risk analysis and management across the health informatics domain Preliminary work approved 2008 but does not currently appear to be active.	IT-014-04 to watch/manage
• Security aspects of EHR record migration Lead: CEN (Pekka Ruotsalainen – FI). Work item to produce TR 16114 recently passed initial NP ballot with many comments from AU, CA, DE, JP, UK. Suggested changes to preliminary draft discussed with second draft to be prepared for discussion at next meeting prior to DTR ballot.	IT-014-04 to watch/manage and provide input to this active work item
• Security and privacy requirements of EHR systems for use in conformity assessment - Part 1: Foundations. Leads: Luis Kiatake - BR, Alessandra Pastorino – IT, Neil Gardner – CA. Preliminary draft of TS 14441-1 has been produced and was discussed by WG 4 over several sessions. Note: Main topic renamed from "Security and privacy requirements of EHR systems for use in conformity assessment" (see plenary resolution 30)	IT-014-04 to watch/manage and provide input to this active work item IT-014 secretariat to note and apply change of name (and confirm TC 215 amends on its work program)
• Security and privacy requirements of EHR systems for use in conformity assessment - Part 2: Protection profile for small-scale electronic patient record systems. Leads: Luis Kiatake - BR, Alessandra Pastorino – IT, Neil Gardner – CA. Material produced for ITS 14441-2 was discussed at some length by WG 4. Note: Main topic renamed from "Security and privacy requirements of EHR systems for use in conformity assessment" (see plenary resolution 31)	IT-014-04 to watch/manage and provide input to this active work item IT-014 secretariat to note and apply change of name (and confirm TC 215 amends on its work program)
• Classification of data purposes for processing of personal health information Leads: Dipak Kalra – UK , Elaine Sawatsky – CA. Following discussion and resolution of issues at the Rio meeting final draft of TS 14265 planned to proceed to imminent DTS ballot. Further comments are at section 13.2 below	IT-014-04 (lead) to watch/manage and provide input to this active work item (including DTS ballot) with support from IT-014-09 and IT-014-02
• Audit trails for Electronic Health records Lead: Luuc Posthumus (NL). Work on ISO 27789 has been underway for some years with CD ballot being passed in Oct 08. Drafting has been slow and a work plan is now in place to ensure the item is finished and goes to DIS ballot before 15 Sep, otherwise it will be in breach of the ISO progression rules. Aspects not related to security/privacy will not be covered and will be referred to the Patient Safety & Quality TF, WG 1 and WG 8.	IT-014-04 to watch/manage and provide input as appropriate with involvement of IT-014-09
• Directory Services for healthcare providers, subjects of care and other entities. Lead: Lori Fourquet – US. ISO/TS 21091 was published in 2005 and is being updated to a full international standard but does not appear to have progressed since passing DIS ballot in April 2009.	IT-014-04 to watch/manage and provide input as appropriate, with involvement of IT-014-06, IT-014-02 and IT-014-09

• Tracking implications of work by ISO/JTC1 SC27 WG5 (Identity management and privacy technologies) on health informatics standards Following a formal request to WG4 requesting liaison and participation in several projects, a number of WG4 members have agreed to comment on SC27 WG5 drafts.	IT-014 to watch/manage, supported by IT-014-04 (lead), IT-014-02, IT-014-09 and IT-012
• TC 215 interaction with ISO/TMB Privacy Steering Committee (PSC). Leads: Alessandra Pastorino – IT & Elaine Sawatsky – CA. This is a potentially important development in privacy standards that may impact See section 13.3 below.	IT-014 to watch/manage, supported by IT-014-04 (lead) and collaborating with Standards Australia (ISO Desk) and IT-012

Action: IT-014 to note following WG4 activities on project plan as a mirror projects:
(1) TC 215 interaction with ISO/TMB Privacy Steering Committee (to IT-014 supported by IT-014-04)
(2) Tracking implications of work by ISO/JTC1 SC27 WG5 (Identity management and privacy technologies) on health informatics standards (to IT-014, supported by IT-014-02, IT-014-04, IT-014-09 and IT-012)

Health cards

WG 4 oversees the Health Cards Task Force, which provides residual maintenance of the various health cards standards developed by the former WG 5. The meeting noted the following status of work on maintaining health card standards

Health card standard	Current status
IS 21549-1 Patient Health card data - Part 1: General structure	Passed first systematic review 2007 – confirmed with corrections.
IS 21549-2 Patient Health card data - Part 2: Common objects	Passed first systematic review 2007 – confirmed with corrections.
IS 21549-3 Patient Health card data - Part 3: Limited clinical data	Passed first systematic review 2007 – confirmed with corrections.
IS 21549-4 Patient Health card data - Part 4: Extended clinical data	Published 2006. Passed first systematic review Mar 2010 Being revised based on comments received.
IS 21549-5 Patient Health card data - Part 5 Identification data	Published 2008.
IS 21549-6 Patient Health card data - Part 6 Administrative data	Published 2008.
IS 21549-7 Patient Health card data - Part 7 E-Prescription/medication data	Published 2007.
IS 21549-8 Patient Health card data - Part 8: Links	Final FDIS ballot closed on 25 May 2010
ISO 20301 Health cards – General characteristics	Published 2006. Passed first systematic review Mar 2010. Task group has begun revising the standard in light of comments from Australia and Brazil
ISO 20302 Health cards - Numbering system and registration procedure for issuer identifiers	Published 2006. Passed first systematic review Mar 2010 Only a typo was found, and a minor ambiguity in the introduction – and revised version submitted to ISO/CS for publication.

While Australia currently has limited interest in the health card standards, we have participated at various times to assist in the development of appropriate standards.

Outcomes for Australia

Over time, Australia has contributed significantly to the work of WG4, providing the initial drafts of ISO 27799:2008 - Security management in health using ISO/IEC 27002, and contributing expert input and critical comment during development of:

- ISO/TS 22600 Privilege management and access control (PMAC)
- ISO/TS 21298 Functional & structural roles;
- ISO/TS 13606-4 EHR communication – Part 4: Security
- ISO/TS 23257 Pseudonymisation

Privacy and security are essential components of the Australian eHealth program but greater engagement of relevant experts and affected parties is required to progress the local work of IT-04-04, potential adoption of relevant TC 215/WG4 standards in Australia and feedback of local experience as WG4 reviews ISO technical specifications for upgrade to full international standards.

13.2 CLASSIFICATION OF DATA PURPOSES FOR PROCESSING OF PERSONAL HEALTH INFORMATION

This relatively simple standard aims to provide a uniform classification of proposed uses for personal health information to facilitate uniform automated interpretation of privacy/consent policies. Although simple, it is important that it is capable of being applied in conjunction with role identification and access control standards to fulfil proposed needs.

At this meeting, Australia successfully supported retaining a separate class covering uses of personal information in the provision of emergency care (some had argued that this was the same as any other form of care delivery only the role was different – but Australia felt that consumers would relate better to a separate class of use).

13.3 TC 215 INPUT TO CONSIDERATION OF ISO STANDARDS ON PRIVACY

At the request of international privacy commissioners, a privacy steering committee has been set up by ISO/TMB to examine standards in privacy. TC 215 is represented by WG4 members Alessandra Pastorino (Italy) and Elaine Sawatsky (Canada).

A 2 day conference will take place in Berlin immediately prior to the TC 215 meeting in Rotterdam. Relevant healthcare privacy standardization activities of JIC member organizations are being identified, with a view to TC 215 presenting an overview on behalf of all JIC members at this conference.

Given this ISO initiative and the support of the privacy commissioners, Australia cannot presume that proposed ISO/IEC JTC1/SC27 standards for privacy management frameworks and systems will necessarily prevail. It is important that IT-014 ensures that the needs of the Australian eHealth sector and privacy legislation are taken into account as these events unfold and that any needs for health sector standards or codes are identified.

13.4 SECURITY AND PRIVACY REQUIREMENTS OF EHR SYSTEMS FOR USE IN CONFORMITY ASSESSMENT

Australia facilitated discussion to assist WG4 come up with the new title for this series of products as the previous title "Security and privacy requirements for compliance testing of EHR systems" was found

to be ambiguous (it is not the testing that needs to be secure and private, it is the functioning of the EHR systems). WG4 expressed appreciation for this brief contribution.

14 WG 6 - PHARMACY AND MEDICATION BUSINESS

Delegate Attendance	Limited coverage of key issues - Evelyn Hovenga

For several years, WG6 activities have been dominated by two major pieces of joint ISO/CEN work – the Identification of Medicinal Products (IDMP) and the Individual Case Safety Report (ICSR) series of standards. The pharmaceutical industry, regulators and informaticians are all involved in the work, with much of the time at meetings being spent in detailed work on these documents; however, there is some occasional interest in other items.

Some 30 delegates attended various WG 6 sessions at this meeting - representing 11 countries and 3 liaisons.

The focus at this meeting was on progressing the two parts of the ICSR standard and the five IDMP standards, all of which are joint work items being coordinated through JIC, this involved:

- Completing the resolution of comments
- Improving the consistency and structure of the documents
- Planning the next steps / meeting schedule

14.1 WORK ITEMS

Work item / notes	Australian responsibilities/comments
• HL7 Structured Product Labelling standard. Lead was HL7 (Beeler/Hammond). Project 27952 failed NP ballot in 2006. It has not officially been withdrawn but is inactive.	IT-014-06-04 to monitor and advise of any action required
• HL7 Product Stability data standard. Lead was HL7 (Beeler/Hammond). Project 27954 failed NP ballot in 2006. It has not officially been withdrawn but is inactive.	IT-014-06-04 to monitor and advise of any action required
• Pharmacovigilance – Test names and units for reporting laboratory results. IS11595 passed NP ballot in 2008 but appears inactive. If it is to progress, harmonisation would be a key issue to resolve.	IT-014-06-04 to monitor and advise of any action required
• Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information. Lead: Tim Buxton – UK. Work on TR 14872 passed NP ballot in Dec 2009 with draft document being prepared for DTR ballot.	IT-014-06-04 to watch/manage and provide input to this work item as appropriate.
• Business Requirements for the Reporting of Pharmacist Services Lead: Nigel Cox – UK. Work on TR 10895 passed NP ballot in Aug 2007; however, before proceeding further in preparing a draft document for DTR ballot, WG6 has committed to a discussion with WG3 regarding possible synergy with similar work originating from nursing. nursing	IT-014-06-04 to monitor and advise of any action required

• Identification of medicinal products (IDMP) - Data elements and structures for the unique identification and exchange of regulated medicinal product information Updated draft of ISO 11615 to be submitted for DIS ballot July 2010. Note – change of project title (resolution 42).	IT-014-06-04 to watch/manage and provide input collaborating with IT-014, IT-014-02, NEHTA
• Identification of Medicinal Products (IDMP) – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information Updated draft of ISO 11616 to be submitted for DIS ballot July 2010. Note – change of project title (resolution 40).	IT-014-06-04 to watch/manage and provide input collaborating with IT-014, IT-014-02, NEHTA
• Identification of Medicinal Products (IDMP) – Data elements and structures for the unique identification and exchange of regulated information on substances. Updated draft of ISO 11238 to be submitted for DIS ballot July 2010. Note – change of project title (resolution 34).	IT-014-06-04 to watch/manage and provide input collaborating with IT-014, IT-014-02, NEHTA
• Identification of Medicinal Products (IDMP) – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging Updated draft of ISO 11239 to be submitted for DIS ballot July 2010. Note – change of project title (resolution 36).	IT-014-06-04 to watch/manage and provide input collaborating with IT-014, IT-014-02, NEHTA
• Identification of Medicinal Products (IDMP) –Data elements and structures for the unique identification and exchange of Units of Measurement Updated draft of ISO 11240 to be submitted for DIS ballot July 2010. Note – change of project title (resolution 38).	IT-014-06-04 to watch/manage and provide input collaborating with IT-014, IT-014-02, NEHTA
• Pharmacovigilance - Individual case safety report (ICSR)- Part 1: The framework for adverse event reporting	IT-014-06-04 to watch/manage and collaborate with IT-014, TGA
• Pharmacovigilance - Individual case safety report - Part 2: Human pharmaceutical reporting requirements for ICSR	IT-014-06-04 to watch/manage and collaborate with IT-014, TGA
• Business Requirements for an international coding system for medicinal products. Revision of TR 25257 published in 2009 now being considered as a potential new work item –see 14.2 below	IT-014 to watch/manage with input from IT-014-06-04, IT-014-02, IT-014-10, NEHTA
• Generic model for dose syntax Potential new work item –see 14.3 below	IT-014 to watch/manage with input from IT-014-06-04 and NEHTA

Action: IT-014 to note following WG6 work items on project plan as mirror projects:
(1) TR 25257 - Business Requirements for an international coding system for medicinal products. Review of report published last year (to IT-014 with input from IT-014-06-04, IT-014-02, IT-014-10, NEHTA)
(2) Generic model for dose syntax. Prelim work item (to IT-014 with input from IT-014-06-04 and NEHTA)

14.2 TR 25257 BUSINESS REQUIREMENTS FOR AN INTERNATIONAL CODING SYSTEM FOR MEDICINAL PRODUCTS

It is proposed that *TR 25257 - Business Requirements for an international coding system for medicinal products*, which was published in August 2009 (with lead: Ock-Hee Oh – KR) be reviewed and updated on the grounds .

- Parts are now superseded by recent legal changes in several jurisdictions
- Aspects need to be harmonised with emerging IDMP work, and

- Developing work within GS1 should be referenced

The revision is being promoted by GS1 as a potential new JIC work item. In discussion among the Australian delegation it was agreed that Australia should support this proposal being progressed. It will enable closer engagement with GS1 by NEHTA.

14.3 GENERIC MODEL FOR DOSE SYNTAX

This new work item put forward by the UK is aiming at being developed as joint work sponsored though the JIC. It does not seek to prescribe the terminology (which is handled by IDMP) but rather the syntax for expressing medication administration (route, site etc), medication (active ingredients etc), dose quantities (duration, rate, etc) and dosage calculation/conversion rules.

The NWIP documentation is expected in July/August. Australia should seek an expert as this impacts on NEHTA work and, also, international archetype development.

15 WG 7 – DEVICES

Delegate Attendance	Limited coverage of key issues: - Anthony Maeder - Richard Dixon Hughes

Principal Australian involvement with WG7 was in joint sessions with WG1 (re DCM), WG2 (re telehealth), WG1/3/8 (re CDSS and alerts).

WG7 has a long history of working closely with medical device standards being progressed by HL7, IEEE and IEC – with much of the joint development being done in these other SDOs and then adopted as international standards through TC 215.

A major focus is WG7 contributing experts to joint work on the IEC/ISO 80001 standards on "risk management for IT-networks incorporating medical devices" being produced by the IEC SC62A/JWG 7 group in active collaboration with TC 215/WG7 and IEEE. These standards are focussed on safety and have the potential to impact a wide range of equipment used in health care settings. They are being progressed through meetings held about 4 to 6 times per year in conjunction with meetings of the parent SDOs.

15.1 WORK ITEMS

Work item / notes	Australian responsibilities/comments
• Medical waveform format – Encoding rules, DICOM-ECG Japan lead. Preparatory stage – apparently inactive.	IT-014 to monitor – not currently allocated
• Personal health device communication - Technical report – Overview. IEEE lead. Preparatory stage – proposal awaited	IT-014-12 to watch/manage
• HL7 Annotated ECG Waveform Data Standards HL7 lead (Beeler/Hammond) – proposal withdrawn	No action required
• Personal health device communication – Device specialization – Common framework. 11073-10400 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Point-of-care medical device communication – Application profile – Common networking infrastructure. 11073-10401 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects

• Point-of-care medical device communication – Transport profile – Ethernet. 11073-30400 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Point-of-care medical device communication – Transport profile – RF wireless – Local area network (wLAN). 11073-30503 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Point-of-care medical device communication – Technical report – Guidelines for the use of RF wireless technology. 11073-10101 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Point-of-care medical device communication - Device specialization - Dialysis device. 11073-10316 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Personal health device communication - Device specialization – Cardiovascular fitness and activity monitor 11073-10441 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Personal health device communication - Device specialization – Strength fitness equipment. 11073-10442 at prelim stage	IT-014-12 to watch/manage Add to IT-014 mirror committee projects
• Application of risk management for IT-networks incorporating medical devices – Guidance for health delivery organizations	IT-014-12 to watch/manage
• Application of risk management for IT-networks incorporating medical devices – Guidance for wireless networks	IT-014-12 to watch/manage
• Application of risk management for IT-networks incorporating medical devices – Guidance for the communication of medical device security needs, risks and controls	IT-014-12 to actively watch/manage with input from IT-014 and IT-014-04
• Application of risk management for IT-networks incorporating medical devices – step by step risk management of medical IT networks - practical applications and examples	IT-014-12 to actively watch/manage with input from IT-014 and IT-014-04
• Personal health device communication - Device specialization – Medication Monitor	IT-014-12 to watch/manage
• Point-of-care medical device communication - Application profile - Optional package, Remote control	IT-014-12 to watch/manage
• Point-of-Care Medical Device Communication - Framework & overview	IT-014-12 to watch/manage
• Point-of-care Medical Device Communication - Application profiles MIB Elements	IT-014-12 to watch/manage
• Point-of-care medical device communication – Application profile, Association Control Function	IT-014-12 to watch/manage
• Point-of-Care Medical Device Communication - Application profile, Polling Mode	IT-014-12 to watch/manage
• Point-of-care medical device communication – Application profile, Asynchronous Mode	IT-014-12 to watch/manage
• Point-of-care Medical Device Communication - Application gateway, HL7 (v2) observation reporting interface	IT-014-12 to watch/manage
• Point-of-Care Medical Device Communication - Nomenclature Annotated ECG	IT-014-12 to watch/manage
• Point-of-care medical device communication - Nomenclature, Implantable Device, Cardiac	IT-014-12 to watch/manage
• ISO/IEC 80001 Part 1: Application of Risk Management for IT -- Networks incorporating medical devices	IT-014-12 to actively watch/manage with input from IT-014 and IT-014-04
• Personal health device communication – Device specialization – Pulse oximeter	IT-014-12 to watch/manage
• Personal health device communication – Device specialization – Blood pressure monitor	IT-014-12 to watch/manage

• Personal health device communication – Device specialization – Glucose meter	IT-014-12 to watch/manage
• Personal health device communication – Device specialization – Thermometer	IT-014-12 to watch/manage
• Personal health device communication – Device specialization – Weighing scale	IT-014-12 to watch/manage
• Personal health device communication – Device specialization – Independent living activity hub	IT-014-12 to watch/manage
• Personal health device communication – Application profile – Optimized exchange protocol	IT-014-12 to watch/manage

Action: IT-014 to note following WG7 work items on project plan as mirror projects: ISO/IEEE 11073 – 10400, 20401, 30400, 30503, 00101, 10316, 10441 and 10442 as preliminary /preparatory work (to IT-014-12)

15.2 IEC/ISO 80001 SERIES - RISK MANAGEMENT FOR IT-NETWORKS INCORPORATING MEDICAL DEVICES

At the request of the Standards Australia OB/7 committee (which is Australia's peak group focussed on business risk management standards – a concept largely developed in Australia) Australia voted against this work in the DIS/CDV ballot late last year. Through TC 215, this led to significant communication between the ISO risk management experts and the medical devices community and highlighted a need for some changes to avoid future miscommunication and progressive harmonisation of terminology.

It has been agreed that 80001 will stay compatible with terminology and approaches used in the 14971 (medical devices) regime with an explanation of its special focus and potential for later alignment with the ISO 31000-series of risk management standards.

The potential for the IEC/ISO 80001-series to become part of international medical devices regulation and also potentially impose obligations on facilities that use devices (including software applications) was noted. Greater engagement by groups likely to be affected would be welcome.

Action: Australian TC 215 delegations, IT-014, and IT-014-04 to continue tracking progress of the IEC/ISO 80001 series and engage with interested parties in Australia, including OB/7 and MSIA.

16 WG 8 - BUSINESS REQUIREMENTS FOR EHR

Delegate Attendance	Richard Dixon Hughes, Heather Leslie, Evelyn Hovenga Andrew Caswell, Kylie Sugar (WG8 Secretariat) Stephen Chu (NEHTA) Occasional attendees: - Tina Connell-Clark, Andy Bond (NEHTA) - Heather Grain, Anthony Maeder

Most of the WG8 program was held jointly with WG1 with the chair alternating between convenors, depending on the particular work item being discussed.

16.1 WORK ITEMS

Work item / notes	Australian responsibilities/comments
• TR 14639-1: eHealth enterprise architecture for emerging and developing countries - Part 1: Environmental Scan Leads: Beatriz Leao – BR, Patrick Whitaker – WHO See section 16.2 below	IT-014-09 to watch/manage and provide input Dixon Hughes, Maeder & Tallis (AIHW) contributing as experts
• TR 14639-2: eHealth enterprise architecture for emerging and developing countries - Part 2: Business Requirements Leads: Beatriz Leao – BR, Patrick Whitaker – WHO See section 16.2 below	IT-014-09 to watch/manage and provide input Dixon Hughes, Maeder & Tallis (AIHW) contributing as experts
• Personal Health Records: Definition, Scope and Context Leads: Dipak Kalra – UK, Gora Datta – US Second draft of TR 14292 nearing completion following and incorporation of feedback from NP ballot and discussion at this and previous meeting.	IT-014-09 to watch/manage and provide input collaborating with IT-014-06-06 Heather Leslie, Dixon Hughes, contributing as experts
• Knowledge Management of Health Information Standards Lead: Andrew Grant – CA Closely linked with Heather Grain's glossary work.	IT-014-09 to watch/manage (leading) and provide inputs in concert with IT-014-02
• ISO18308 Requirements for EHR reference architecture Lead: Dipak Kalra – UK Updated draft for FDIS ballot nearing completion following DIS re-ballot.	IT-014-09 to watch/manage and provide input collaborating with IT-014-06-06, NEHTA
• EHR Systems Functional Model (EHR-S FM) Release 2 HL7 lead. Update of ISO 10781 published in 2009 as joint project to reflect current work on production of EHR-S FM R2	IT-014-09 to watch/manage and provide input as appropriate.

16.2 EHEALTH ENTERPRISE ARCHITECTURE FOR EMERGING AND DEVELOPING COUNTRIES

WHO requested that TC 215 undertake the development of this technical report, which is being developed in two parts – an environmental scan and a set of business requirements for national/regional business e-health architecture.

To progress the work, WHO funded a team of relevant experts to attend an out-of-session workshop in Bellagio, Italy in March, which included Richard Dixon Hughes and Anthony Maeder from Australia. The Australian representatives had provided input to the environmental scan which included commentary from themselves, AIHW and NEHTA. Richard Dixon Hughes took on a leadership role in producing the first draft of the business requirements document based on discussions at the workshop. WG8 noted that much of the work is not particularly specific to emerging and developing countries – although some components of the architecture (particularly related to community care, population health and supply chain) are realised differently and others (related to more advanced capabilities) are less relevant in developing and emerging countries.

Outcomes for Australia

Although Australians have been assisting the progression of this work for the wider benefit of the international community, it is not presently an Australian priority, although the final documents should provide a framework applicable to particular Australian contexts.

16.3 PERSONAL HEALTH RECORDS: DEFINITION, SCOPE AND CONTEXT

This work being led by Dipak Kalra (UK) was presented on his behalf by Gora Datta (USA) and is aimed at a technical report that seeks to provide a researched definition and framework for work on the personal health record (PHR) – similar to earlier work (led by Australia) that led to ISO/TR 20514 on EHR definition, scope and context. The work aims to:

- provide a definition of the personal health record
- describe the classification of personal health records
- describe the ways in which the inclusion and engagement of individuals in managing their health and health care impacts on the roles of the personal health record, and
- illustrate this through case study examples.

Coming up with an acceptable, clear definition of a PHR is proving to be a problem (and is probably impossible) as the term has different characteristics in different contexts and most attempted definitions are actually descriptions of the differences in context, rather than definitions of the record.

There was discussion of the proposed "axes" or "dimensions" that can be used classify various different types of PHR functionality. Heather Leslie (Australia) gave a presentation highlighting that there is a continuum in the health record space that ranges from a person's own collection of health information through to a shared clinical EHR at the other end of the spectrum.

The current work program allows for input from experts and WG8 through to mid-August, leading to a final proposed draft being submitted for DTR ballot by mid-September, provided no significant changes are required.

Outcomes for Australia

Heather Leslie has agreed to assist Dipak Kalra (UK) in drafting definitions and incorporating her diagram of the PHR continuum into the body of the document.

This is an informational report. While it will not directly impact on any developments in Australia, it deserves careful review by IT-014 and its subcommittees to ensure but hopefully be a useful resource into the future.

16.4 REQUIREMENTS FOR EHR REFERENCE ARCHITECTURE (18308)

Australia played a key role in the original development of this technical specification, which is now being reviewed for elevation to a full international standard. Its main use is as a framework to assess the extent to which the information structures used within a system enable the effective representation and use of an individual's health record as part of clinical care. The main issues relate to the appropriate definition of an electronic health record to be used, ensuring that the standard sets out requirements for architectural components (as distinct from EHR systems and functions), its treatment of some privacy/consent terminology and harmonization with the HL7 EHR systems functional model (also an ISO standard).

Outcomes for Australia

Australian experts are providing input into the next step of producing the final draft for FDIS ballot (at which further change is not permitted – so changes need to be incorporated now).

16.5 HL7 EHR SYSTEMS FUNCTIONAL MODEL (EHR-S FM) – RELEASE 2

In November 2009 Release 1.1 of the HL7 EHR-S FM was published jointly by HL7 and as ISO 10781, a full international standard. The earlier release 1 of the HL7 EHR S FM specification was widely used in the US as the basis for CCHIT certification of EHR systems to establish provider eligibility for certain government subsidies and as a set of functional requirements for use in systems acquisition. Australia made significant contributions to development of the original R1 document; however, while international input is continually being sought and is gratefully received, most requests for change have come from its use in the US.

A new consolidated Release 2 is now under development as an HL7 project targeting eventual joint adoption as an HL7 normative specification and an update to ISO 10781. Production of R2 incorporates functional requirements added through experience in various contexts such as the ambulatory care functional profile, records management and evidentiary support functional profile and the incorporation of material from harmonisation with around 20 other sources including ISO 18308, the so-called HL7 EHR Interoperability Model, US-HITSP use cases and the Canadian EHR Blueprint 2015 project. The work is being progressed with personnel donated by AHIMA with weekly teleconferences and several out-of-cycle meetings planned in Chicago.

WG8 supported a resolution being put to the TC 215 plenary for the update of ISO 10781 to reflect EHR-S FM R2 to be accepted as a new TC 215 work item, which was passed. Acceptance as an ISO work item will help its endorsement as a joint JIC project.

Outcomes for Australia

This work is monitored on behalf of Australia through IT-014-09 with occasional participation in project calls. The EHR-S FM is potentially a valuable resource for those seeking to acquire, accredit or certify health information systems on the basis of functionality. While Australian viewpoints were built into the initial R1 product, there is a risk that, with heavy use in the US being the major driver for R2 and our inability to put significant resources into further development R2 product will be less suited to Australian needs. Nevertheless, Australia strongly supports the R2 work being an HL7/ISO joint project (with HL7 lead) and has successfully campaigned for TC 215's involvement in this project to be managed within WG8.

Although Australia has only been peripherally involved in drafting the revisions for R2, we should ensure that the product is reviewed thoroughly as it nears completion. IT-014 and HL7 Australia need to ensure that the existence and capability of the EHR-S FM are appreciated in Australia and, provided there is demand, facilitate production of Australian functional profiles for its local application.

16.6 PHR SYSTEMS FUNCTIONAL MODEL (PHR-S FM)

HL7 published the PHR-S FM was published as a "Draft Standard for trial use" (DSTU) last year. At this meeting, it was put forward as a potential new work item within ISO TC 215, with a view to publication of the normative edition in HL7, ISO (and potentially CEN) being accepted as joint work managed through the JIC. The resulting standard would be a companion to ISO 10781 EHRS FM.

WG8 supported a resolution being put to the TC 215 plenary for the PHR-S Functional model to be a new TC 215 work item, which was passed by the plenary.

Outcomes for Australia

Functional profiles based on the PHR-S FM are potentially applicable to the provision of iEHR capability in Australia.

Australia strongly supported the PHR-S work being progressed as an HL7/ISO joint project (with HL7 lead) and has successfully campaigned for TC 215's involvement in this project to be managed within WG8.

17 TRADITIONAL MEDICINE TASK FORCE (TM TF)

Delegate Attendance	Heather Grain Anthony Maeder

The area of traditional medicine has been highly controversial, particularly in relation to differences between China and other East-Asian powers over the name, scope and location of ultimate authority within the field.

ISO/TMB has now approved the request of the Standardization Administration Association of China (SAC) to form a new technical committee, TC 249, focussed on "Traditional Chinese Medicine (TCM)", with SAC as secretariat. A plenary was held in Beijing on the 7-9 June 2010. The TC 215 argument that traditional medicine should be supported by the same health informatics frameworks as other clinical disciplines through TC 215 was accepted by ISO against the wishes of SAC.

At the meeting of the TC 215 Executive Council, Dr Chute, Dr Kwak and Ken Toyoda agreed to attend the TC 249 plenary with the aim of promoting on-going communication between TC 249 and TC 215.

Given these events, the terms of reference for the TM TF were updated to highlight its role in reviewing proposed work on health informatics for traditional medicine and ensuring it is addressed by the most appropriate TC 215 WG(s). TC 215 has a broader scope than TC 249 in that TC 215 may address the needs of any form of TM within the meaning of the WHO definition of Traditional Medicine, which is broader than Chinese and/or East Asian traditional medicine.

Reporting through WG 3, the TM TF will assist TC 215 to ensure that its work on metadata, safety and quality related to patient information, terminologies, ontologies, classifications and information models considers the needs of TM communities; however, its scope does not include creation, endorsement, or maintenance of names and definitions of entities and relationships that make up subject matter of TM.

New work items in preliminary stage (to have drafts prepared for the next meeting) are:

- Categorial structure of manipulation of acupuncture in traditional East Asian Medicine, and
- Categorial structure of acupuncture point in traditional East Asian Medicine.

Outcomes for Australia

As a society which is increasingly supporting a mix of Western and complementary traditions to medical care, Australia facilitated much of the early work to bring complementary and traditional forms of medicine into TC 215 activities and is pleased that these efforts have matured to the point where TM TF activities will be driven by those active in the field. On-going geopolitical differences over the naming, scope and control of TCM/TEAM are disappointing but need not stand in the way of meaningful progress.

18 PATIENT SAFETY AND QUALITY TASK FORCE (PSQ-TF)

Delegate Attendance	Anthony Maeder Richard Dixon Hughes (briefly)

Noting growing world-wide emphasis on patient safety and quality of care (PSQC), this task force is planning to produce a technical report on how TC 215 can support PSQC through its standardization activities. In the first instance, the PSQ-TF will review current health informatics standards against a general process-control model of care delivery - considering the following aspects: workflow, metrics, control logic, and control actions - and identifying potential gaps. Preliminary work has found that many health informatics standards (from ISO, CEN, HL7, IHTSDO etc) already provide relevant support if applied at key points but their relationship to PSQC needs to be better understood - and their adoption encouraged.

Definitions of quality and patient safety were discussed, noting the differences between the ISO 9000 view of quality (adherence to process) and clinical perspectives on patient-centric care (best outcomes for each patient /cohort - and avoidance of harm). It was also noted that the report is not about the quality and safety of software used in healthcare, but how software applications and health informatics can be used in clinical processes to improve PSQC. An accelerated work program was proposed with fortnightly meetings through May/June to produce a draft report for distribution to TC 215 member bodies for review in July/August and report back to the October 2010 TC 215 meeting in Rotterdam. It is intended that the report will identify any required standards activities and inform the next stage of TC 215 business planning and reorganisation task force work.

Outcomes for Australia

The Australian delegation is concerned that the proposed approach may be overly dominated by the "process engineering" perspective and that the task force may be too inwardly focused, lacking significant new input from the clinical quality and safety community.

Circulation of the draft technical report is an opportunity for IT-014 to engage with the ACSQHC and other groups interested in PSQC.

Australia noted that there needs to be convergence and/or reconciliation of the definitions of quality used in various TC 215 work items (eg.13131 Quality Criteria for Telehealth).

19 JIC HARMONIZATION ACTIVITIES

Delegate Attendance	Joint Initiative Council (JIC) & Harmonization Task Force - Information session & open forum - Most delegates JIC Harmonization Track - partial attendance and input from: - Heather Leslie - Richard Dixon Hughes - Andy Bond (NEHTA)

Driven by new chair Kees Molenaar from Europe, an increase in size from three to six participating SDOs, experiences over the first few years of its operation and the need for greater formal communication at executive level to ensure that joint projects progress satisfactorily, the JIC is in the process of re-shaping how it operates.

Part of the required change has affected the ways in which information is shared and harmonisation activities are reviewed and planned. These supporting activities were being run through ISO/TC 215/WG9 (JWG), which had three co-conveners (one each from ISO/TC 215, CEN/TC251 and HL7) with Standards Australia providing the secretariat. JWG meetings were relatively open with direct input from a wide range of experts that happened to be present wherever it met. The meetings grew very large and suffered from a lack of continuity.

Under the new regime, JIC has taken more direct control of the activities of the JWG – with less involvement of individual experts from across the various SDOs in the decision-making processes within the JWG.

At the Rio meeting, the previous WG9 (JWG) activity was replaced by an information session and open forum at which progress with harmonisation projects and harmonisation topics were discussed (that part being similar to earlier WG9/JWG meetings).

More formal presentations by potential joint projects were then addressed in later "JIC harmonization track" sessions, which were scheduled in parallel with the main stream WG sessions. Each SDO on the JIC had a formal representative present in these sessions to interact with potential projects These sessions were minuted by the JIC secretariat (rather than by WG9).

Outcomes for Australia

Under the new arrangements, it is understood that WG9 secretariat services are no longer required from Standards Australia.

The new format with a "JIC harmonization track" does bring greater focus and formality to harmonization activities and is a considerable improvement but this has come at an additional cost in terms of the number of important issues that need to be addressed in parallel by the Australian delegation, which made significant contributions to detailed discussion on the scopes and activities of proposed new joint work items, which included:

- Clinical Information Models – noting work in HL7 (10 pilots), ISO Quality criteria for DCM and IMHC
- Generic medication syntax – following ISO NWIP and CD based on UK NHS approaches (see WG6)
- Proposed balloting of ISO/TS 10871 EHR System functional model R2 jointly in ISO and HL7 – effective coordination of balloting remains a challenge.
- Monitoring and possibly providing input/frameworks as jurisdictions move toward software products being licensed as medical devices.

  This is relevant to patient safety and needs to be supported by uniform, cost effective, internationally accepted conformance programs. The risk is regulatory diversity. From a standards perspective, IEC62 leas on this and Australia should support their work to avoid duplication.
- ISO/TMB proposals to develop international standards on privacy and need for TC 215 to represent the broader eHealth community at the October conference (see WG4).

20 TC 215 OPENING PLENARY

Delegate Attendance	Richard Dixon Hughes (Head of Delegation) Heather Grain (WG 3 convener) Andrew Caswell, Kylie Sugar (WG 8 secretariat) Anthony Maeder, Evelyn Hovenga, Heather Leslie Tina Connell Clark, Andy Bond (NEHTA)

The opening plenary is largely a formality at which the following business was transacted:

1. Opening of the meeting – Welcome by ISO/TC 215 Chair, Dr. Chris Chute
2. Welcoming Remarks – Official welcome to Rio de Janeiro, Brazil from
   a) Head of Delegation for Brazil and the ABNT representative: Ms. Marcia Elizabeth Marinho de Silva
   b) Brazilian Ministry of Health, José Carlos Souza Santos Jorge from the national DATASUS information technology program within the Ministry of Health
3. Roll call of ISO/TC 215 Participating Member Countries – noting that the following 15 “P” members were present - Australia, Finland, Germany, Italy, Japan, Korea, Malaysia, The Netherlands, Brazil, Canada, Russian Federation, Spain, Sweden, United Kingdom, and United States
4. Sponsor Remarks - Mr. Lincoln Moura
5. Organisational announcements

21 TC 215 CLOSING PLENARY

Delegate Attendance	Richard Dixon Hughes (Head of Delegation) Heather Grain (WG 3 convener) Andrew Caswell, Kylie Sugar (WG 8 secretariat) Evelyn Hovenga Heather Leslie Anthony Maeder Andy Bond, Tina Connell Clark, Stephen Chu(NEHTA) Andrew Howard (NEHTA)

The closing plenary addressed the following agenda, with all resolutions being separately recorded in section 22 below along with the Australian delegation's understanding of the likely actions to ensue.

1. Opening of meeting by Dr. Chute, Chair of ISO/TC 215
2. Recognition of Singapore as an Observing/Associate Member who participated in the meeting.
3. Recognition of liaisons who participated in the meeting: CDISC, GS1, IHTSDO, WHO, ICH, IHE, JTC1 and TC 210 [Richard Dixon Hughes –AU is ISO/IEC liaison officer to TC 215]
4. Roll Call of ISO/TC 215 Participating Member Delegates. The following 15 of the "P" members were present and participated in the final plenary: - Australia, Finland, Germany, Italy, Japan, Korea, Malaysia, The Netherlands, Brazil, Canada, Russian Federation, Spain, Sweden, United Kingdom, and United States

   In addition, regrets were noted from: Austria, Denmark, Ireland, Norway and Slovakia.

The following "P" members did not attend or communicate their regrets: - Armenia, Belgium, China, Czech Republic, Kenya, New Zealand, Serbia, and Turkey.

The Australian delegation particularly noted that Austria, China, France, Norway and Turkey had been unable to be present as these countries have had significant input in recent meetings. It was positive that Spain had been able to be present.

5. Adoption of agenda

6. ISO/TC 215 Chair and Executive Council report. Dr. Chute gave a verbal report covering:

   - His imperatives for ISO/TC 215 as originally discussed with the Executive Council and reported at section 8.1 above;
   - Key points from the Executive Council meeting, with particular emphasis on:
     (a) The proposed activities of the Business Planning and Reorganization Task Force
     (b) The need to manage potential overlaps with the new ISO/TC 249 (TCM) committee.
   - His personal thanks for everyone's hard work during the meeting.

   Resolutions arising from the Chair and Executive Council report are covered in section 22 below

7. TC 215 Secretary's report. Key points addressed included:

   - 41 ballots were held since the previous plenary producing 39 voting results
   - There are 120 ISO deliverables in various stages of progression
   - 2 face to face meetings were held in 2009:
   - The Edinburgh plenary in April attracted 230 delegates, and
   - The October working group meeting, mini-plenary and Global Summit in Durham, North Carolina attracted some 200 delegates
   - TC 215 currently has 29 "P" member bodies with the most recent additions being Armenia and Kenya, and 20 observing member bodies.
   - Next Meeting will be held in Rotterdam – Netherlands from 10 – 13 October 2010.
   - HIMSS will be discontinuing sponsorship of the US secretariat and will relinquish it sometime in the next year. There are strong potential expressions of interest from US organisations and there will be a 1 year transition process.
   - Harmonization. Cross SDO work is increasing through both bilateral agreements (CEN Vienna Agreement, HL7 Pilot Process and IEEE PSDO) and the JIC with a new model being introduced for harmonisation sessions, commencing at this meeting.
   - New "open and transparent" work process.
   - Upgrade of online support for committee work – notably the online glossary and the e-balloting portal.
   - Liaisons with other ISO and IEC committees and other SDOs.

8. Resolutions from the Working Groups. The convener of each working group then gave a brief PowerPoint presentation on their group's activity and led voting on the resolutions put forward by her/his working group. The more significant material covered in these presentations has been

covered in the working group reports above and the resolutions are reported in full in sections recorded in section 22 below.

9. Reports to the TC215 Plenary.

9(a) Patient Safety and Quality Task Force – by Lori Fourquet - copy of presentation available [Also see section 18 above]

Australian comments noted in the minutes included: the accelerating interest in the PSQ topic and AU support for the work of the TF. As a country AU encouraged TC215 as a whole to conduct an active outreach program to those who support the IT and quality community to contribute to the work and encourage broadened engagement within the topic and TF.

Lori Fourquet responded by noting – once the draft of the document is distributed, she encouraged NMBs to reach out to the relevant experts within the country to engage them in the activity. It was also noted that PSQ may be a topic under consideration during the restructuring activity.

9(b) JIC Report by JIC chair, Kees Molenaar of CEN/TC 51 (copy of presentation available) – also see section 19 above.

9(c) Report from JTC1 to TC 215 by Richard Dixon Hughes (JTC 1 liaison to TC 215) - copy of presentation available.

9(d) Presentation by Elaine Sawatsky and Alessandra Pastorino on the ISO/TMB Privacy Steering Committee (copy of presentation available) – also see section 13.3 above

10. Date/place of next ISO/TC 215 plenary: Kuopio, Finland 23-27 May 2011 [confirmed after the plenary – see section 8.7 above.

11. Report on location of next ISO/TC 215 Joint WGM (report available) 10-13 October 2010 in Rotterdam, The Netherlands by Dr. William Goossen (copy of presentation available).

12. 2011 JWG (Sep/Oct) date still open: Coordination of meetings to be placed on the JIC agenda as a standing item.

13. Adjournment/Closure of meeting.

Outcomes for Australia

Australia contributed significantly to discussion during the closing plenary and was generally satisfied with the outcomes.

As convenor of WG3, Heather Grain presented the report on WG3.

As ISO/IEC JTC1 liaison officer to TC 215, Richard Dixon Hughes presented the JTC1 liaison report.

WG7 (and others) had major discussions on software as medical device workshop on this planned for Oct 2010 meeting: this should be of interest to Australia.

WG4 is involved in organising a 2 day conference in Rotterdam in the 2 days before the Oct 2010 meeting on Security and Privacy: this should be of interest to Australia.

22 RESOLUTIONS FROM THE TC 215 CLOSING PLENARY

Resolutions for the final plenary are drafted by the working groups, task forces and other constituent bodies within TC 215 and must follow wording set out in common templates circulated by the TC 215 Secretariat. The resolutions are required to have been drafted by the afternoon before the final plenary so that they can be circulated to national delegations in time for review before the plenary (recognising that some countries also need to get advice and/or translate the material).

In this process, contentious issues tend to be raised and discussed during WG sessions or, at the latest, when the proposed resolutions are circulated to the national delegations with consensus on most matters being achieved by negotiation before they are presented to the plenary. Under this process, while some items are contested on the floor of the plenary, it is normal for the vast majority of resolutions to be passed.

22.1 RESOLUTIONS APPROVED

The following resolutions were approved at the closing plenary session - with specific Australian involvement being noted, where relevant.

Resolution	Further action	By
1. Resolved that ISO/TC 215 accepts the report and resolutions of the Executive Council.	Chair's verbal summary to be minuted BP&R TF to address in business plan	TC215 Secretariat BP&R TF
2. Resolved that ISO/TC 215 approves the Executive Council proposal to establish a new task force for organizational and strategic issues, further to discuss the organizational structure, business process and meeting structure and to re-write a new Business Plan. Interim deliverable in October 2010 in Rotterdam and final deliverable to be in Finland May 2011.	Convene monthly BP&R TF teleconferences Develop plan & interim findings (by Oct 2010)	Jeremy Thorp (TF Chair) BP&R TF AU: Dixon Hughes & Grain on the TF
3. Resolved that ISO/TC 215 approves the Executive Council proposal that new work on Patient Safety and Quality plus Emerging and Developing Countries remain in current status while the new re-alignment and strategic task force considers their placement in the TC 215 organizational structure.	PSQ TF to continue with current PSQ proposals WG 1, 8 & Exec Council to continue E&D work PSQ & ED to be addressed in TC215 business plan	PSQ TF WG1, WG8 & Exec Council BP&R TF
4. Resolved that the ISO/TC 215 approves the Executive Council re-affirmation of the WG8 and WG1 recommendation to urge the members of the Joint Initiative Council (JIC) to address their respective SDOs to ask for full collaboration to make the products of their SDOs available for developing and emerging countries in way that makes widespread dissemination in these countries feasible while developing new markets for SDO products.	ISO, CEN, HL7, CDISC, IHTSDO & GS1 to be approached via JIC to make eHealth standards more readily available & affordable	TC215 Secretariat (to put on JIC agenda)

Resolution	Further action	By
5. Resolved that ISO/TC 215 approves the Executive Council proposal for the participation of Dr. Chute, Dr. Kwak and Mr.Toyoda to represent ISO/TC 215 at the upcoming meeting of ISO/TC 249 [Traditional Chinese Medicine]	TC 215 representatives to attend TC 249 plenary in Beijing & negotiate separation of scope	Dr. Chute, Dr. Kwak and Mr Toyoda
6. Resolved that ISO/TC 215 approves the Executive Council proposal to disband the 2 inactive task forces, e-Business for Healthcare Transactions, Multi-disciplinary Task Force.	Disband inactive task forces	TC 215 Secretariat BP&R TF
7. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 1.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat
8. Resolved that ISO/TC 215 approves the WG1 recommendation to approve the WG1 officers as follows: - Stephen Kay, Convenor - Don Mon, Vice Convenor	Update TC215 info to reflect appointments Resource attendance of officers	TC 215 & WG Secretariats Appointed officers &/or their NMBs
9. Resolved that ISO/TC 215 approves the WG1 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of "Health informatics Framework for National Health Information Systems" for approval as a new work item targeting a Technical Specification and that the Form 4 and a document arrives at the TC Secretariat no later than June 10, 2010 to be placed on the ISO/TC 215 balloting portal no later than June 24, 2010.	*Health informatics framework for national health information systems* - provide documents for NP ballot by 10 Jun 2010.	WG1 project lead and experts WG1 Secretariat AU: IT-014 for ballot response
10. Resolved that ISO/TC 215 approves the WG1 recommendation that the ISO/TC 215 Secretariat circulates the DTS ballot of "ISO 22220 Identification of subjects of health care" for approval as a Technical Specification and that the document arrives at the TC Secretariat no later than May 31, 2010 to be placed on the ISO/TC web site no later than June 14, 2010.	*ISO 22220 Identification of subjects of health care* - provide documents for DTS ballot by 31 May 2010.	WG1 project lead and experts WG1 Secretariat AU: IT-014 for ballot response
11. Resolved that ISO/TC 215 approves the WG1 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of "Standards Convergence to promote electronic health record interoperability" for approval as a new work item targeting a Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than June 10, 2010 to be placed on the ISO/TC 215 balloting portal no later than June 24, 2010.	*Health informatics framework for national health information systems* - provide documents for NP ballot by 10 Jun 2010.	WG1 project lead (Dickenson-US) and experts WG1 Secretariat AU: Dixon Hughes (to assist as expert) IT-014-09 for ballot response
12. Resolved that ISO/TC 215 approves the WG1 recommendation that the ISO/TC 215 Secretariat forward ISO/FDIS 21667 "Health Informatics: Health Indicators Conceptual Framework" to the ISO Central Secretariat for circulation as a FDIS ballot. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than July 12, 2010.	*ISO 21667 Health informatics framework for national health information systems* - provide final documents for FDIS ballot by 12 Jul 2010.	WG1 project lead (Pulcins-CA) and experts WG1 Secretariat AU: IT-014-09 for ballot response

Resolution	Further action	By
13. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 2.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat
14. Resolved that ISO/TC 215 approves the WG 2 recommendation that the ISO/TC 215 Secretariat forward" to the ISO Central Secretariat for circulation as a DIS ballot via ISO/HL7 Agreement. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 2010-06-10.	*ISO 13449 Clinical Genomics – Family History*. Finalise & submit draft specification for DIS ballot by 10 June	WG2 project lead (Kaufman) and experts WG2 Secretariat AU: IT-014 for ballot response
15. Resolved that ISO/TC 215 approves the WG 2 recommendation that the ISO/TC 215 Secretariat forward ISO 14199, "HI: The BRIDG domain analysis model for protocol-driven biomedical research" to the ISO Central Secretariat for circulation as a DIS ballot. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 2010-07-02.	*BRIDG domain analysis model for protocol-driven biomedical research* - provide documents for DIS ballot by 02 Jul 2010	WG2 project lead (CDISC – Iberson-Hurst) and experts WG2 Secretariat AU: IT-014 for ballot response
16. Resolved that ISO/TC 215 approves the WG 2 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of "IHE–Use Cases and Integration Profiles" for approval as a new work item targeting a Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than 2010-05-14 to be placed on the ISO/TC 215 balloting portal no later than 2010-05-28.	*IHE–Use Cases and Integration Profiles* - provide documents for NP ballot by 14 May 2010	WG2 project lead (Parisot-US/IHE) and experts WG2 Secretariat AU: IT-014-06 for ballot response
17. Resolved that ISO/TC 215 approves the WG 2 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of "Clinical Trial Registration and Results" for approval as a new work item targeting a International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than 2010-05-28 to be placed on the ISO/TC 215 balloting portal no later than 2010-06-14.	*Clinical Trial Registration and Results* - provide documents for NP ballot by 28 May 2010	WG2 project lead and experts WG2 Secretariat AU: IT-014 for ballot response
18. Resolved that ISO/TC 215 approves the WG 2 recommendation that the ISO/TC 215 Secretariat circulates the DTR ballot of ISO 13128 "Health informatics – Clinical Document Registry Federation" for approval as a Technical Report and that the document arrives at the TC Secretariat no later than 2010-06-04 to be placed on the ISO/TC web site no later than 2010-06-18.	*ISO/DTR 13128 Clinical Document Registry Federation* - provide documents for DTR ballot by 4 Jun 2010	WG2 project lead (Byoung-Kee Yi - KR) and experts WG2 Secretariat AU: IT-014-06 for ballot response
19. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 3.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat
20. Resolved that ISO/TC 215 approves the WG 3 recommendation to approve the following WG 3 officer for a second term, as follows: Heather Grain, Convenor	Update TC215 info to reflect appointments Ensure on-going attendance of officer is resourced	TC 215 & WG Secretariats AU: Heather Grain Standards Aust DoHA

Resolution	Further action	By
21. Resolved that ISO/TC 215 approves the WG 3 recommendation that the work item ISO/CD 13120 "Health informatics – A syntax to represent the content of medical classification systems" be renamed "Health informatics – A syntax to represent the content of classification systems in health care."	Renaming of work item	TC 215 Secretariat
22. Resolved that ISO/TC 215 approves the WG 3 recommendation that the ISO/TC 215 Secretariat circulates prEN ISO 13940-2 "Health informatics - System of concepts to support continuity of care - Part 2: Core process and work flow in health care" as a 2 month CD and that a document arrives at the TC Secretariat no later than 31 August 2010 to be placed on the ISO/TC web site no later than 15 September 2010.	*EN ISO 13940-2 System of concepts to support continuity of care - Part 2: Core process and work flow in health care* - provide documents for CD ballot by 31 Aug 2010	WG3 project lead (Mennerat -FR) and experts WG3 Secretariat AU: IT-014-02 for ballot response
23. Resolved that ISO/TC 215 approves the WG 3 recommendation that the ISO/TC 215 Secretariat forward ISO/CD 13119 "Health informatics – Clinical knowledge resources - Metadata" to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with CEN lead. A revised document, separate revisable figure files and a completed table of comments will arrive at the TC secretariat no later than 31 July 2010.	*ISO/CD 13119 Clinical knowledge resources – Metadata*. Provide documents for DTS ballot by 31 Jul 2010	WG3 project lead (Klein -SE) and experts WG3 Secretariat AU: IT-014-02 for ballot response
24. Resolution 24 was NOT approved (see section 22.2 below.)	n/a	n/a
25. Resolved that ISO/TC 215 approves the WG3 recommendation that ISO 28379 – "Health informatics – Common glossary for ISO/TC 215" be withdrawn from the ISO/TC 215 program of work.	*Common glossary for ISO/TC 215* – Advise ISO/CS it is withdrawn and update TC 215 work program	TC 215 Secretariat
26. Resolved that ISO/TC 215 approves the WG3 recommendation that the work item revision of ISO/TS 17117 "Health informatics – Criteria for the categorisation and evaluation of terminological systems" remain at preliminary stage.	*TS 17117* - WG3 recommendation to hold this update at preliminary stage be noted	TC 215 NMBs AU: IT-014-02 to note
27. Resolved that ISO/TC 215 approves the WG 3 recommendation that the ISO/TC 215 Secretariat circulates the DTR ballot of ISO 12300; Health informatics; Mapping of terminologies to classifications; for approval as a Technical Report and that the document arrives at the TC Secretariat no later than 31 May 2010, to be placed on the ISO/TC web site no later than 15 June 2010.	*ISO 12300 Mapping of terminologies to classifications* - - provide documents for DTR ballot by 31 May 2010	WG3 project lead (Grain -AU) and experts WG3 Secretariat AU: Grain leading IT-014-02 for ballot response
28. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 4.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat

Resolution	Further action	By
29. Resolved that ISO/TC 215 approves the WG 4 recommendation to approve the WG 4 officers as follows: - Lori Reed-Fourquet, Convenor - Luuc Posthumus , Vice Convenor - Elaine Sawatsky, Interim Secretary for the period of one year	Update TC215 info to reflect appointments Resource attendance of officers	TC 215 & WG Secretariats Appointed officers &/or their NMBs
30. Resolved that ISO/TC 215 approves the WG 4 recommendation that the work item ISO/DTS 14441-1 "Health Informatics - Security and privacy requirements for compliance testing of EHR systems - Part 1: Foundations" be renamed ISO/DTS 14441-1 "Health Informatics - Security and privacy requirements of EHR systems for use in conformity assessment - Part 1: Foundations."	Renaming of work item	TC 215 Secretariat
31. Resolved that ISO/TC 215 approves the WG 4 recommendation that the work item ISO/DTS 14441-2 "Health Informatics - Security and privacy requirements for compliance testing of EHR systems - Part 2: Protection profile for small-scale patient health record systems be renamed ISO/DTS 14441-2 "Health Informatics - Part 2: Protection profile for small-scale patient health record systems."	Renaming of work item	TC 215 Secretariat
32. Resolved that ISO/TC 215 approves the WG 4 recommendation to request the Secretariat to forward document ISO 20302 "Health informatics -- Health cards -- Numbering system and registration procedure for issuer identifiers" with an editorial correction to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than May 17, 2010.	Advise ISO/CS of editorial correction	TC 215 Secretariat
33. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 6.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat
34. Resolved that ISO/TC 215 approves the WG 6 recommendation that the work item #11238 "Health Informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances" be renamed "Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated information on substances."	*ISO 11238*– rename work item to emphasise regulatory context	TC 215 Secretariat

Resolution	Further action	By
35. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat to forward "prEN ISO 11238 Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated information on Substances" to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with ISO lead and in parallel in all JIC members and a revised document, separate revisable figure files and a completed table of comments to arrive at the TC secretariat no later than 1 July 2010.	*ISO 11238 IDMP – Data elements and structures for the unique identification and exchange of regulated information on substances* – provide documents for DIS ballot by 1 Jul 2010 Circulate as joint JIC ballot	WG6 project lead (Shepherd -UK) and experts WG6 Secretariat Joint ballot: TC215 Secretariat AU: IT-014-06-04 for ballot response
36. Resolved that ISO/TC 215 approves the WG 6 recommendation that the work item #11239 "Health informatics - Identification of medicinal products - Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration" be renamed #11239 "Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging".	*ISO 11239* – rename work item to emphasise regulatory context	TC 215 Secretariat
37. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat to forward "prEN ISO 11239 Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging" to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with ISO lead and in parallel in all JIC members and a revised document, separate revisable figure files and a completed table of comments to arrive at the TC secretariat no later than 1 July 2010.	*ISO 11239 IDMP – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging* – provide documents for DIS ballot by 1 Jul 2010 Circulate as joint JIC ballot	WG6 project lead (Shepherd -UK) and experts WG6 Secretariat Joint ballot: TC215 Secretariat AU: IT-014-06-04 for ballot response
38. Resolved that ISO/TC 215 approves the WG 6 recommendation that the work item #11240 "Health informatics – Identification of medicinal products – Data elements and structures to uniquely identify Units of Measurement" be renamed #11240 "Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of Units of Measurement".	*ISO 11240* – rename work item to emphasise regulatory context	TC 215 Secretariat

Resolution	Further action	By
39. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat to forward "prEN ISO 11240 Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of Units of Measurement" to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with ISO lead and in parallel in all JIC members and a revised document, separate revisable figure files and a completed table of comments to arrive at the TC secretariat no later than 1 July 2010.	*ISO 11240 IDMP – Data elements and structures for the unique identification and exchange of units of measurement* – provide documents for DIS ballot by 1 Jul 2010 Circulate as joint JIC ballot	WG6 project lead (Shepherd -UK) and experts WG6 Secretariat Joint ballot: TC215 Secretariat AU: IT-014-06-04 for ballot response
40. Resolved that ISO/TC 215 approves the WG 6 recommendation that the work item #11616 "Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs)" be renamed #11616 "Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information".	*ISO 11616* – rename work item to emphasise regulatory context	TC 215 Secretariat
41. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat to forward "prEN ISO 11616 Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of" to the ISO Central Secretariat for circulation as a DIS ballot via the Vienna Agreement with ISO lead and in parallel in all JIC members and a revised document, separate revisable figure files and a completed table of comments to arrive at the TC secretariat no later than 1 July 2010.	*ISO 11616 IDMP – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information* – provide documents for DIS ballot by 1 Jul 2010 Circulate as joint JIC ballot	WG6 project lead (Shepherd -UK) and experts WG6 Secretariat Joint ballot: TC215 Secretariat AU: IT-014-06-04 for ballot response
42. Resolved that ISO/TC 215 approves the WG 6 recommendation that the work item #11615 "Health informatics – Identification of Medicinal Products - data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information" be renamed #11615 "Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated medicinal product information".	*ISO 11615* – rename work item to emphasise regulatory context	TC 215 Secretariat
43. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat to forward to the ISO Central Secretariat "prEN ISO 11615 Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated medicinal product information" for circulation as a DIS ballot via the Vienna Agreement with ISO lead and in parallel in all JIC members and a revised document, separate revisable figure files and a completed table of comments to arrive at the TC secretariat no later than 1 July 2010.	*ISO 11615 IDMP – Data elements and structures for the unique identification and exchange of regulated medicinal product information* – provide documents for DIS ballot by 1 Jul 2010 Circulate as joint JIC ballot	WG6 project lead (Shepherd -UK) and experts WG6 Secretariat Joint ballot: TC215 Secretariat AU: IT-014-06-04 for ballot response

Resolution	Further action	By
44. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of the revision of TR 25257 "Health informatics – Business requirements for machine readable international coding for medicinal products" for approval as a new work item targeting a revised Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than 1 July 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 July 2010.	*TR 25257 Health informatics – Business requirements for machine readable international coding for medicinal products* – provide documents for NP ballot to revise existing TR by 15 Jul 2010	WG6 project lead (Ock-Hee Oh –KR) and experts WG6 Secretariat AU: IT-014-06-04 for ballot response
45. Resolved that ISO/TC 215 approves the WG 6 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of "Health informatics – A generic model for dose syntax" for approval as a new work item targeting a International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than 1 July 2010 to be placed on the ISO/TC 215 balloting portal no later than 15 July 2010.	*Generic model for dose syntax* - provide documents for NP ballot by 15 Jul 2010	WG6 project lead and experts WG6 Secretariat AU: IT-014-06-04 for ballot response
46. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG 7.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat
47. Resolved that ISO/TC 215 approves the WG 7 recommendation that the ISO/TC 215 Secretariat communicate to ISO Central Secretariat that WG7 in coordination with IEEE EMBS 11073 and other liaison groups, including Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PHD) Domain and the Continua Health Alliance, strongly desires to maintain the 11073 document titles and numbering scheme when IEEE approved work items are brought to ISO TC 215 for "fast track" processing.	Communicate concerns to ISO/CS about proposed changes to numbering of well-recognised 11073 series.	TC 215 Secretariat assisted by Convenor WG7
48. Resolved that ISO/TC 215 approves the WG 7 recommendation that the ISO/TC 215 Secretariat communicate to ISO Central Secretariat that WG7 in coordination with IEEE EMBS 11073 and other liaison groups, including Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PHD) Domain and the Continua Health Alliance, strongly desires to implement the PSDO [Partner Standards Development Organization] process so as to facilitate the timely joint consensus development that has been successfully employed for these joint documents.	Communicate with ISO/CS about desire to use IEEE PSDO agreement to fast-track 11073 series of device interface standards	TC 215 Secretariat assisted by Convenor WG7
49. Resolved that ISO/TC 215 approves the WG 7 recommendation that the ISO/TC 215 Secretariat communicate to ISO Central Secretariat that WG7 in coordination with IEEE EMBS 11073 and other liaison groups, including Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PHD) Domain and the Continua Health Alliance, strongly desires to include multiple document types within a series # (i.e. allow IS, TS, and TRs within 11073).	Communicate concerns to ISO/CS about proposed new rules affecting numbering within the well-recognised 11073 series.	TC 215 Secretariat assisted by Convenor WG7

Resolution	Further action	By
50. Resolved that ISO/TC 215 approves the WG 7 recommendation that the ISO/TC 215 Secretariat communicate to ISO Central Secretariat that WG7 in coordination with IEEE EMBS 11073 and other liaison groups, including Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PHD) Domain and the Continua Health Alliance, strongly desires to allow IS, TS & TRs under the PSDO Agreement.	Further actions relating to concerns about ISO/CS rule changes affecting 11073 series	TC 215 Secretariat assisted by Convenor WG7
51. Resolved that ISO/TC 215 approves the WG7 recommendation to request the ISO Central Secretariat and IEEE to resolve the current IEEE standard title issues in a timely manner. Be it further resolved that ISO/TC 215 WG7 is requesting that there be no publication of any 11073 standards that have been approved, and that all further projects be held back from submission for ISO processing until these issues are resolved, including the IEEE 11073 Health informatics – Personal health device communication – Device specialization – 11073-10404 Pulse oximeter (revision) 11073-10407 Blood pressure monitor 11073-10417 Glucose meter (revision) 11073-10418 INR analyzer 11073-10419 Insulin pump 11073-10420 Body composition analyzer 11073-10421 Peak expiratory flow monitor (peak flow) 11073-10472 Medication monitor	Further actions relating to concerns about ISO/CS rule changes affecting 11073 series	TC 215 Secretariat assisted by Convenor WG7
52. Resolved that ISO/TC 215 approves the WG 7 recommendation that subject to approval of IEEE and ISO CS staffs, resolve that the following standing process be enacted: 1) approved IEEE 11073 Project Authorization Request (PARs) are lodged onto the ISO TC 215 work programme as ISO/IEEE 11073 preNWIPs; 2) all ISO/IEEE 11073 preNWIPs are circulated to ISO TC 215 for a period of 30 days to allow for the nomination of contributing ISO experts; during pre and post meetings. 3) all IEEE 11073 drafts approved by the IEEE-SA Standards Board Review Committee, and previously notified as ISO/IEEE 11073 preNWIPs, will be accepted for fast-track FDIS.	Obtain approval from IEEE and ISO/CS for revised process for fast track processing of IEEE 11073 work as international standards	TC 215 Secretariat assisted by Convenor WG7
53. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG8.	Summary presentation by WG convenor to be available with minutes	WG Convenor TC 215 Secretariat

Resolution	Further action	By
54. Resolved that ISO/TC 215 approves the WG8 recommendation to ISO TC 215 that the ISO/TC 215 Secretariat circulates the NWIP ballot of "HL7 EHR-S Functional Model Release 2.0" for approval as a new work item targeting a joint ISO/HL7 International Standard and that the Form 4 and a document outline arrives at the TC Secretariat no later than June 10, 2010 to be placed on the ISO/TC 215 balloting portal no later than July 1, 2010.	*EHR-S FM Release 2* – provide documents for NP ballot by 10 Jun 2010.	WG8 project lead (HL7 – Dickinson) and experts WG8 Secretariat AU: IT-014-09 for ballot response
55. Resolved that ISO/TC 215 approves the WG8 recommendation to ISO TC 215 that the ISO/TC 215 Secretariat circulate the NWIP ballot of "HL7 PHR-S Functional Model Release 1" for approval as a new work item targeting a joint ISO/HL7 International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than June 10, 2010 to be placed on the ISO/TC 215 balloting portal no later than July 1, 2010.	PHR-S FM Release 1 – provide documents for NP ballot by 1 Jul 2010.	WG8 project lead and experts WG8 Secretariat AU: IT-014-09 for ballot response
56. Resolved that ISO/TC 215 accepts the reports from: Patient Safety and Quality Task Force, JIC Report, JTC1, Privacy Steering Committee.	Summary presentation by TF convenor to be available with minutes	PSQ TF Convenor TC 215 Secretariat
57. Resolved that ISO/TC 215 acknowledges the contributions of and thanks Julie Richards, Convenor of WG 1 Data Structure and Ross Fraser, Convenor of WG 4 Security, for their contributions to TC 215 during their years of participation.	Thanks – for minuting	TC 215 Secretariat (NMBs to note)
58. Resolved that ISO/TC 215 thank our host, ABNT, especially Márcia Elizabeth Marinho da Silva and Karina Ninzoli Luro and the Windsor Barra Hotel for their excellent meeting arrangements and social event, as well as their assistance throughout the meeting, which contributed to a successful and productive meeting.	Thanks – for minuting	TC 215 Secretariat (NMBs to note)
59. Resolved that ISO/TC 215 thanks the drafting committee of Sharon Stanford and Patricia Village.	Thanks – for minuting	TC 215 Secretariat
60. Resolved that ISO/TC 215 acknowledges and thanks the Observing country Singapore for the contribution of their members to the ISO/TC 215 Plenary meetings.	For noting in minutes	TC 215 Secretariat
61. Resolved that ISO/TC 215 approves that the next ISO/TC 215 Joint Working Group Meeting will be held in Rotterdam, Netherlands, 10–13 October 2010 and be it further resolved that a half day plenary meeting will be held in conjunction with the Joint Working Group Meeting.	Notice of meeting to be given NMBs & delegations to note dates + plan attendance	TC 215 Secretariat NMBs (Standards Australia & IT-014)

22.2 RESOLUTIONS NOT APPROVED

The following proposed resolution was not approved:

24. Resolved that ISO/TC 215 approves the WG 3 recommendation that the ISO/TC 215 Secretariat circulates the NWIP re-ballot of “Health informatics – Alert information in health records” for approval as a new work item targeting a TS and that the Form 4 and a document arrives at the TC Secretariat no later than 15 June to be placed on the ISO/TC 215 balloting portal no later than 30 June 2010."ISO/TC 215 approves that the next ISO/TC 215 Joint Working Group Meeting will be held in Rotterdam, Netherlands, 10–13 October 2010 and be it further resolved that a half day plenary meeting will be held in conjunction with the Joint Working Group Meeting.

Comment

The first NWIP (NP) ballot for this new work item closed on 5 May (put forward by Sweden with support from several European countries) with 14 in favour, 5 against and 6 abstentions; however, the required five experts had not been nominated, which means that the ballot failed.

Significantly, Canada, Japan, The Netherlands and UK were among those that had voted against the proposal. Additional experts were identified at the Rio meeting but discussion in joint session of WG1, WG3 and WG8 had indicated that much greater coordination with other work and a revised scope were required. Australia, Brazil, Germany and the US had all previously voted in favour of the work. While Australia accepted the argument that it would be better to allow the proposed work to begin in light of guidance given by the relevant WGs, the US, Brazil and Germany decided to join Canada, Japan and The Netherlands in voting against the proposal in the plenary (after the discussions a the WG sessions, the UK decided to move back from opposing to abstaining). With 6 in favour, 6 against and 5 abstaining, the required majority was not achieved. The supporters of the work were therefore asked to develop a revised proposal with a more appropriate and limited scope and appropriate arrangements for harmonisation and to resubmit for NP ballot when this is achieved.