INTERNATIONAL DELEGATES MEETING REPORT

Date	23 February 2015
Delegate(s) proposed by Projects Manager	Daniel Henzi
Standards Development Organsiation (SDO)	Standards Australia
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Delegate Details	*For a multi person delegation please provide details of the head of delegation only.*
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International Committee Details	ISO/TC 215 Health informatics (joint with CEN/TC 251), including opening/ closing plenary and meetings of: TC 215/CAG1, CAG2, CAG3, WG1, WG2, WG3, WG4, WG6, JWG1, JWG7 and TMTF. The following associated meetings were also attended ▪Joint Initiative Council (JIC) for global health informatics standardization ½ day planning session (Sun) + JIC Executive meeting (2 hrs Fri) ▪33rd Meeting of ISO-IEC-ITU-UN/ECE MOU/MG (held at ITU-T, Geneva on 2014-10-02 & 03) - representing ISO/TC 215 & JIC.
Is this a:	Technical Meeting	or	
	Is Australia P (Participating), O (Observing) or non-member of the international committee		P
Meeting Date and Venue Date	Sun 2014-10-04. JIC half day planning session
	Mon 2014-10-05 to Friday 10-09. TC 215 leadership meetings, opening plenary, 3 days of WG meetings and closing plenary. Fri 2014-10-09. JIC Executive Meeting
	Thu/Fri 2014-10-02 & 03 ISO, IEC, ITU-T, UN/ECE, OASIS MOU/MG mtg
Venue Details	DIN, Berlin, Germany (TC 215 & JIC). ITU-T, Geneva (MOU/MG).
Australian delegates	J Richard DIXON HUGHES (RDH), Head of delegation, expert and JIC Chair Heather GRAIN (HG), Convenor, ISO/TC 251/WG 3 Semantic content Also: Daniel HENZI (Standards Australia, ISO/TC 251/WG 1 secretariat)

Purpose of Meeting	The purpose of the TC 215 meeting was – to progress the work program comprising some 55 active projects and to review potential new projects in the field of health informatics, including joint work with other ISO/IEC technical committees.
	Australian involvement is significant in terms of monitoring and participating in relevant health informatics standards development work on behalf of IT-014 mirror committee, particularly through WG1 (Architecture, framework & models – where Standards Australia provides the secretariat), WG3 (Semantic content – where Heather Grain is the convenor), and in leadership roles (where Richard Dixon Hughes is a respected HoD, serving on CAG1 Executive Council, as an elected member of the CAG2 Coordination Group, as Chair of the JIC, as JTC1 liaison to TC215 and, on this occasion, attending the ISO/ITU/IEC/UN-ECE/OASIS MOU/MG deputising for the TC 215 chair.
	Other Australian experts Dr Trish Williams and Dr Vince McCauley attended as IHE International liaison officers (not as members of the Australian delegation), particularly contributing academic and health software industry viewpoints in relation to WG4 (security, safety and privacy) and JWG7 (risk management on networks of devices).
Attendees at the meeting	The following 21 P-members were represented at the TC 215 meeting by 132 registered delegates: Australia (2 delegates), Austria (2), Brazil (8), Canada (8), China (6), Denmark (3), Finland (2), Germany (14) Ireland (2), Italy (1), Japan (20), Korea (18), Malaysia (1), Mexico (3), Netherlands (6), Norway (1), Russia (2), Sweden (6), Switzerland (2), United Kingdom (4), United States (15).
	Liaison A organisations with separate delegates: Health on the Net foundation (1), IHE International (3), IHTSDO (1), INLAC (1)
	There were 9 other liaison participants from : DIN, ISO/TC 121, ISO/TC 247, ISO/IEC JTC 1, IEEE, EN13606 Association
	There were 11 non-delegate observers accompanying national delegations.
	The official welcome from DIN was given by Dr Erika Bohnsack (Head of Medical/Health sector standardization).
	Prof Dr Arno Elmer of Gematik gave an opening address *Health-telematics infrastructure in Germany.*
	Organisations represented at the MOU/MG meeting held the previous week in Geneva included: UN/CEFACT, ITU-T, OASIS, OAGi (remotely), GS1, SWIFT, CEN, ISO/TC 37, ISO/TC 46, ISO/TC 154, ISO/TC 184/SC 4, UNTDED, ISO/TC 215, ISO/PC 245.
	Other health informatics SDO's represented at JIC activities held in conjunction with the ISO/TC 215 meeting were: CEN/TC 251, HL7 International, CDISC, IHTSDO, GS1, IHE International and DICOM.

Key items discussed	**ISO/TC 215**. The main general topics addressed at the TC-level (CAG 1, CAG 2 and plenaries) included:
	• Difficulties faced by TC 215 in continuing in its peak role providing international recognition to core standards used in health informatics but produced by other standards development organisations. This is becoming increasingly difficult as key partner SDOs (HL7 International, CDISC, IHE International and DICOM) now make their standards freely available online, which is not compatible with the ISO business model.
	• In this regard, TC 215 took further steps to facilitate the definition and development of "meta-standards" or "master standards" that would call-up specific sets of other "recognised" standards to address use cases in identified domains. The scope of the CAG2 Coordination group was extended to give it a more pro-active role in defining domains and managing work (see Appendix A below).
	• Strengthening and revitalising the relationship between TC 215 and ITU-T (following very useful prior discussions at MOU/WG).
	• Problems being experienced with the two joint working groups of IEC/TC 25, ISO/TC 12, and TC 215 which were established to progress the ISO+IEC 80003-series of standards in the area of quantities and units for e-health.
	WG 1 Architecture, frameworks and models. Most TC 215/WG 1 meetings were held jointly with CEN/TC 251 WG 1 Data models. Across all sessions, 42 delegates from 15 countries participated in WG 1 work. Matters discussed included:
	• Work on the concurrent second edition of Parts 1 to 5 of ISO 13606 EHR communications was approved and the project is being re-started with a renewed call for experts. This is the main task for WG 1 in the coming year. The content of proposed changes was the subject of several working sessions.
	• Report-outs from sub-groups of 13606 experts, who had examined: integration of demographic information into 13606 communications, multi-patient EHR extracts, proposed 13606 mapping to an HL7 FHIR profile, progressing relationships between 13606 and CIMI, and potential 13606 role in EU FP7 SemanticHealthNet project.
	• The new CEN/TC 251 business plan, which focusses on the EC/EU as their main customer, while continuing to contribute to work of ISO and other health informatics SDOs. Specific areas to be progressed include 13606 (EHR communications), DCM (detailed clinical models), upcoming revision of 12967 (HISA. Health informatics – Service architecture), 13940 Contsys.
	• Overview and lessons emerging from collaborative projects on eHealth adoption and implementation (ANTILOPE), transatlantic exchange of summary records (Trillium Bridge) and the operation of the European Multi Stakeholder Platform (MSP) on ICT Standardisation in relation to global eHealth standards.
	• Proposals for a potential new work item to develop a meta-standard identifying the standards that are applicable to use cases in the public health domain, presented by Dr Anna Orlova (US).

	- Reports on progress of joint ISO/HL7 standards: 10781 (EHR-S FM); 16527 (PHR-S-FM); ISO/DTR 19669 (Re-usable component strategy for use case development) and review of HL7/FHIR support for EHR lifecycle events – led by Gary Dickinson (US). - Proposed disposition of negative votes and comments arising from successful CD ballot of *DTS 18864 .. [1]Quality Metrics for Detailed Clinical Models*, presented by Dr Sun Ju Ahn (KR). - Proposed Preliminary Work Item (PWI) for a standard on *"Meta Data for structured genomic sequencing report in EHR system"*, presented by Soo Yong Shin (KR) and subsequently accepted by TC 215.
	Joint WG1/WG3 projects. The following were the main topics discussed in joint session of WG1 and WG3. - ISO TS 18528 – Health Informatics standards functional classification. It was reluctantly agreed to recommend that the project be cancelled due to unavailability of a project leader. - SKMT (Standards Knowledge Management Tool) governance process and making the registration and harmonisation of health informatics standards, terms and definitions more effective. - ISO/FDIS 13940 System of concepts to support continuity of care (Contsys). After reconciliation of 123 pages of DIS ballot comments, 13940 is awaiting release as a parallel CEN/ISO FDIS ballot.
	WG 2 Systems and device interoperability. Across all sessions, 36 delegates from 10 countries and 5 liaison organisations participated in WG 2. Matters discussed are reported to have included: - ISO 14199 BRIDG model – submitted to DIS ballot (which closed in January 2015 and was successful). It was noted that HL7 has established a new Biomedical Research Integrated Domain Group to support future development and global implementation of BRIDG. - Metadata for medical information - a suggested New Proposal (NP) ballot item put forward to be led by Prof Youngseop (KR). The scope of the proposal was unclear and further information was requested, which has been circulated since the meeting. The connection of this proposed work to mainstream approaches needs to be explored. - ISO 22077-series of medical waveform standards. The results of voting and disposition of comments for Parts 1, 2 and 3 were discussed and recommendations prepared for the TC215 plenary. - ISO/TR 17522 .. Provisions for Health Applications on Mobile/Smart Devices. Results of voting and agreement to disposition of over 100 comments. Approved for publication by TC 215 plenary.

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[1] In this report, the words ***"Health informatics - "*** which appear in the titles of almost all standards products published by TC 215 have usually been abbreviated to ***".. "*** (i.e. two dots).

	- *ISO/AWI TR 20055: Person-owned document repository for PHR applications and health information exchange*. Following Change of title from "patient-owned" to "person-owned" was approved by TC 215. Revised scope and updated working draft to be produced by expert working group for April 2015 meeting. Presentation led by Byoung-Kee Yi (KR).
	- *ISO/DTS 21089 .. Trusted end-to-end Information flows*. Results of voting and disposition of comments from NP ballot discussed – led by Gary Dickinson (US).
	- *ISO 25720:2009 .. Genomic Sequence Variation Markup Language (GSVML)*. To be submitted for systematic review.
	- *ISO/DIS 17583 .. Terminology constraints for coded data elements expressed in ISO Harmonized Data Types used in healthcare information interchange*. Note that DIS ballot closed 2014-12-16.
	- Several other WG2 standards are coming up for systematic review including: ISO/HL7 27932:2009 (CDA), ISO/HL7 27951:2009 (CTS), ISO 17432:2004 (WADO)
	WG 3 Semantic content. Across all sessions, 22 delegates from 8 countries and 2 liaison organisations participated in WG 3. Heather Grain (AU), Convenor of WG3 reported that WG3 has noted the number and complexity of terminological resources used in healthcare continues to grow and even core resources such as SNOMED CT, LOINC and ICD are being adopted and implemented in a variety of ways, limiting the capacity for effective capture, sharing and interpretation of health information. Discussion in WG3 focussed on the need for standards to enable the quality of terminological resources and their implementation to be assessed and improved. In this regard TC 215 approved WG3 progressing the following 5 Preliminary Work Items (PWIs) with the intention of producing scope statements and working drafts for future consideration by TC 215: - Health informatics - Maturity levels for terminological resources in EHRs - Health informatics - Metadata requirements in healthcare - Health informatics - Terminology capacity assessment - Health informatics , Measurement of conformance in implementation of terminological resources - Update of ISO 13120:2013 Classification markup language (ClaML) Appendix A below provides more details on these 5 projects, which will be refined and progressed to new work item proposals through WG3 teleconferences in advance of the April 2015 meeting in San Francisco. Other matters discussed in WG 3 included: - Progressing and preparing for ballot: ISO/AWI TS 17117, ISO/DTS 16843-1, ISO/DTS 16843-2, ISO/PWI TS 16843-3

	• Final updates to the text of ISO/DTR 12310 (Principles and guidelines for the measurement of conformance in the implementation of terminological resources) prior to submission for publication as a TR.
	• The need for further traditional medicine informatics topics specific to TC 215 to be progressed by a separate domain-specific work group (see below for fuller coverage of this issue).
	• Continued improvement of processes for proposal, assessment and progression of new work in line with the spirit of ISO directives on having strong business cases and a realistic assessment of the prospects for proposed new work items.

WG 4 Security, Safety and Privacy. Across all sessions, 42 delegates from 15 countries participated in WG 4 (plus one joining remotely by Webex). Matters discussed are reported to have included:

- Planning progression of the following documents which were at ballot following systematic review and revision: ISO/DIS 27799; ISO/DIS 21298; ISO/DIS 21549-5; ISO/DIS 21549-7; ISO/CD 25237, ISO/DIS 17090-2.

- The proposed re-establishment of a project to consolidate various streams of work on data protection in trans-border flows of personal health information, presented by Luuc Posthumus (NL).

  Rather than proceed with the originally proposed NP ballot, TC 215 approval was obtained to add a PWI: *Health informatics - Principles and guidelines for protection of personal health information* to the WG4 work program, with a view to developing a single international standard encompassing the following existing standards:

  - ISO 22857:2013 .. Guidelines on data protection to facilitate transborder flows of personal health information

  - EN 14484:2003 .. International transfer of personal health data covered by the EU data protection directive - High level security policy

  - EN 14485:2003 .. Guidance for handling personal health data in international applications in the context of the EU data protection directive

- Collaboration with JWG7 on development of *IEC/TR 80001-2-8 Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC/TR 80001-2-2*; including the provision of a WG4 expert to review proposed mapping.

- Comments from DTS2 ballot of *ISO/TS 17975 .. Principles and data requirements for consent in the collection, use, or disclosure of personal health information*, (closed in August 2014) were presented by Elaine Sawatsky (CA) and resolved. On this basis, TC215 approved calling a 2-month 3rd DTS ballot.

- Comments from DTS ballot of *ISO/DTR 18638 .. Components of education to ensure health information privacy* [WG4]. DTR ballot, closed 2014-09-19 with 13 in favour, 2 (AR, UK) against. Australia was one of 5 voting in favour with comments. Comments from DTR ballot were addressed 2nd DTR ballot was proposed.

- Review of draft documentation for NP ballot to develop ISO/TS 20405 Health informatics - Framework of Event Data & Reporting Definitions for the Safety of Health Software. The need for this work was identified in ISO/TR17791:2013 .. Guidance on standards for enabling safety in health software. The work will be undertaken in collaboration with IEC/SC62A and JWG7 and take into account other activities on the safety of health software as reported in Appendix C. Discussion was led by the proposed project lead Grant Gillis (CA).
- Review of draft documentation for NP ballot for ISO/NP TS 17090-5 .. Public key infrastructure – Part 5: Authentication using healthcare PKI credentials led by Hideyuki Miyohara.

WG 6 Pharmacy and medicines business. Across all sessions, 43 delegates from 13 countries and 2 liaison organisations participated in WG 6 (plus four joining remotely by Webex). Matters discussed are reported to have included:

- The parallel CEN/ISO ballot for *ISO/DIS 17523 .. Requirements for electronic prescriptions*, which had been delayed by CEN ballot timing rules and would not close until 2015-02-11.

  Plans were made for the processing of responses prior to the April 2015 meeting. IHE representatives were invited to provide comments while the ballot was still open.

- A presentation by Jeremy Thorp (UK) on the *EU Guidelines on ePrescriptions Dataset for electronic exchange under the cross-border Directive 2011/24/EU*. He is the editor of these guidelines which are relevant to WG6's consideration of ISO 17523 and which are derived from previous work on epSOS. EU member state approval for the guidelines was anticipated in November 2014. They make reference to ISO 17523.

- Prof. Yasuyuki Hirose (JP) presented on WG3 work on *ISO/DTS 18062 .. Categorial structure for representation of herbal medicaments in terminological resources*. There are many harmonisation issues to resolve before the project can proceed to the next stage.

  Given the extent of the required changes, a second DTS ballot is likely to be required. Key overlaps noted by WG6 include IDMP standards, ISO 11238 and ISO/DTS 19844. TC 249 work on a standard coding system for decoction pieces (ISO/CD 18668-1) is also relevant.

- Review of current draft of *ISO/DTS 17251 .. Business requirements for the exchange of structured dose instructions for medicinal products* and recommending it move to parallel CEN/ISO DTS ballot.

- Progression of *ISO/DTS 19844 .. IDMP - Implementation Guide for ISO 11238 for Data Elements and Structures for the Unique Identification and Exchange of Regulated Information on Substances*, Review of NP ballot results was presented by project lead, Vada Perkins (US) and WG6 proposals to revise and submit to DTS ballot accepted by TC 215. Need for any 2nd DTS ballot will be decided at April 2015 meeting based on DTS response.

	- Progression of IDMP Implementation Guides for: ISO 11239 (project leader: Christopher Jarvis) and ISO 11615, ISO 11616 (Project leaders for both: Vada Perkins and Ilaria Del Seppia). Drafts were updated and approved by TC 215 to move to NP ballots.
	
	- The draft of *ISO/DTS 19256 .. Requirements for medicinal product dictionaries for clinical care* was updated taking into account comments about relationship to IDMP (as a regulatory, rather than clinical identifier) and further work on use cases. TC 215 approved the recommendation for it to proceed to parallel CEN/ISO DTS ballot with revised title (inclusion of words "for clinical care")
	
	- *ISO/AWI TS 19294 .. Data elements and structures for identification of extemporaneous and magistral (compound) pharmaceutical preparations without marketing authorisation* – reviewed and recommended for withdrawal from the TC 215 work program, which was accepted by TC215.
	
	- *ISO/AWI TS 19293 .. Requirements for a record of the dispense of a medicinal product* – progress review based on draft version circulated on 2014-08-23.
	
	- The need to revise *TR 22790 – Functional Characteristics of Prescriber Support Systems:2007*
	
	- Discussion on ICH/electronic Common Technical Document (eCTD). The original plan for fast-track adoption of HL7 RPS (Regulated Product Submissions) specification is no longer acceptable to ISO/CS. The alternative of proposing an ISO "meta" standard which includes the HL7 RPS R2 standard as normative reference, and provides guidance for implementation and/or conformance will be evaluated as a potential solution.
	
	- Further work on *ISO/AWI TR 14872 .. IDMP - Core principles for maintenance of identifiers and terms* will await the ballot results of the IDMP implementation guides before finalising the DTR for ballot.
	
	- At the request of Germany, it was noted that the title of *ISO/TS 16791:2014 Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers* will be further revisited at systematic review to clarify that the standard relates to GS1 identifiers.
	
	- Demonstrations/discussions of pharmaceutical support databases
	  - EDQM Standard Terms Database: Christopher Jarvis promised a link to a demo access for WG6 members noting that the database is under development.
	  - Global Ingredient Archival System (GInAS), was presented by Thomas Balzer, with a live demonstration by Larry Callahan. A link to a demonstration space was promised.
	  - International Non-Proprietary Name (INN) database published and maintained for pharmaceutical substances by WHO.
	
	- The contents of the proposed ISO publicity brochure on the IDMP series of standards.

	JWG 1 Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics). Across all sessions, 18 experts from 5 countries (China, Germany, Japan, Korea, USA) participated in JWG 1, which met concurrently with TMTF (see below) after an introductory joint session at which WG3, TMTF and JWG1 were all represented.
	JWG 1 matters discussed in are reported to have included:
	• Review and scope clarification for *ISO/CD 18668 TCM - Coding system of Chinese Medicine - Parts 1 to 3* (Part 1: Coding rules for decoction pieces; Part 2: Codes of decoction pieces; Part 3: Coding Rules for Chinese medicines in supply chain management).
	ISO/TC 249 (Traditional Chinese Medicine) is the administrative lead on these joint projects. On the recommendation of JWG1/TMTF, TC 215 resolved that that the definition of "Chinese Medicines" is to be clarified in relation to the parts of 18668 and that the domains of Kampo medicine, Korean medicine and other traditional medicines are not within the scope of the parts of this standard.
	Arrangements were agreed for joint balloting of these joint TCM standards in both TC 249 and TC 215.
	• Resolution of ballot procedure issues between JWG1, TC249 and TC215, with draft processes for joint publication to be documented and reviewed.
	• Management of progression by TC 215 of ISO 16843 Parts 1 to 4 on categorical structures for acupuncture points, acupuncture needling, moxibustion and meridian and collateral channels as JWG 1 projects.
	Traditional Medicine Task Force (TMTF). TMTF met concurrently with JWG1 at this meeting) after an introductory joint session at which WG3, TMTF and JWG1 were all represented.
	TMTF matters are reported to have included:
	• Arrangements for finalisation and publication of *ISO/TS 16277-1 .. Categorial structures of clinical findings in traditional medicine: Part 1 Traditional Chinese medicine, Japanese medicine and Korean medicine*, to include confirmation of additional final edits as requested by WHO.
	• Final update and progression to publication of *ISO/AWI DTS 18790-1 .. Profiling Framework and Classification for Traditional Medicine informatics standards development - Part 1: Traditional Chinese Medicine*.
	• The proposal by WG3 recommending that TMTF be considered as the core of a new domain-specific TC 215 work group addressing the health informatics aspects of various styles of traditional medicines.

| | **JWG 7** Joint ISO/TC 215 - IEC/SC 62A WG: Application of risk management to information technology (IT) networks incorporating medical devices.

Across all sessions, around 40 delegates from at least 13 countries participated in JWG 7.

A major topic of general interest to the global health informatics which was brought forward by JWG7 was the **report of the Health Software ad hoc group,** which was received and discussed in a joint meeting of WG1, WG2, WG4 and JWG 7. This was the conclusion of a 2-year review to review the state of health software safety standards and propose an architecture/framework for future work. Appendix C below contains a summary of key findings and recommendations from the review.

JWG7 is proposing the following pathway to apply the outcomes:

- Consideration of the draft report by IEC/SC62A at its meeting in Chicago in 2014-11.

- Confirming final report and recommendations for action at TC 215 meeting in April 2015.

- Considering development of an ISO guide to cover terms, concepts and framework from the report

- Considering utilising the 80001 series (now coming up for systematic review) - based on creating a new 80001-1 framework & overview standard and migrating the current 80001-1 to, say, 80001-1-1

Other matters discussed by JWG7 are reported to have included:

- Finalising content of IEC/TR 80001-2-8 (Guidance on standards for establishing the security capabilities identified in IEC/TR 80001-2-2) for DTR ballot (with updated DTR draft to be ready by mid-March).

- Content of NP ballot for new ISO/TR 80001-2-x to provide application guidance on the use of security assurance cases to demonstrate compliance with security requirements.

- Recommencement of work on second edition of IEC 62304 (Medical device software - Software life cycle processes), broadening focus on medical device Software to Health Software, aligning with the proposed framework in the health software report and considering splitting into two parts, one covering the development lifecycle and the other covering implementation, maintenance and use.

- Proposed systematic review, revitalisation and revision of 80001-1 and the 80001-2-series, to include fitting within the new framework for digital health safety, addressing feedback and experience from use of the first editions and making them more usable. |

	Other acknowledgements The sad passing in May 2014 of Dr Karin Kajbjer (a respected colleague and long-term member of the Swedish delegation) was marked with a brief reminder of her contributions to the field and a minute's silence. Many also expressed their condolences to Dr Gunnar Klein, her former partner. The great contribution over many years of Dr Bernd Blobel (Head of the German delegation) to TC 215, to TC 251, to HL7 and to health informatics as an academic was also marked with a short address and presentation. Bernd is retiring from travelling to health informatics standards meetings but still hopes to be active in a more passive role.
	JIC. Strategic discussion at JIC centred on carrying forward actions related to the evolving role of the JIC after 7 years of existence. The group had a good and productive discussion and agreed to the following areas of emphasis for the coming year: • Update of the JIC charter • Strategy refinement and a potentially more active role for the JIC • Leadership transition as Richard Dixon Hughes comes to the end of his period as chair, and identifying a more collaborative approach to resourcing the work of the JIC. More opportunities for joint work continue to be identified.
	ISO+IEC+ITU-T+UN/ECE+OASIS MOU/MG (on eCommerce standardization). A wide range of topics of concern to the wider IT standards community were discussed. Of particular value were side discussions with officers and office-bearers within ITU-T
Other Observations/Comments	**WG1 Secretariat**. The Standards Australia project manager assigned to provide the WG 1 secretariat unfortunately fell seriously ill on the night before the TC 215 meeting commenced and was in hospital for the entire meeting. The WG 1 convenor, vice-convenor and others covered for his absence and the WG was generous in being very understanding of the situation and expressing their best wishes for his speedy recovery. **Scope of ISO 13606 (EHRcom) Revision**. Australia has previously argued strongly that the scope of 13606 should not be significantly expanded. It appears that this position has been largely accepted. Preliminary proposals to explore moving some elements (ADL and reference archetypes) out of the standard so they can be available as complementary online content appear to be well-considered and generally acceptable but will need review as the project progresses. **Resignation of TC 215 Chair**. After the meeting but prior to the completion of this report, it became known that Prof Chris Chute (US) had resigned from the position of TC 215 Chair (one year before his term was due to expire). ANSI, the TC 215 secretariat national member body, has proposed Mike Glickman to take over as TC 215 Chair, subject to TMB approval. Mike's appointment would be widely acceptable to the TC 215 community and to Australian delegates and should be supported.

	Report of the Health Software Ad hoc Group. Health software is increasingly being regulated as a "medical device" but also has many unique characteristics that need to be taken into account to ensure an appropriately balanced safety regime is reflected in the relevant ISO and IEC standards. This major issue for the health IT industry and regulators was addressed in the report summarised of the Health Software ad hoc group a 2-year review (led by Neil Gardner, CA) to review the state of health software safety standards and propose an architecture/framework for future work. Appendix C below contains a summary of key findings and recommendations from the review. Further recommendations are expected from JWG7 at the April 2015 meeting after IEC/SC62A has also had an opportunity to review the findings.
	Proposed new WG for health informatics in traditional medicine (TM). On the recommendation of TC 215/WG3 and with support from the TMTF, TC 215 approved in principle the formation of a domain specific work group to work on health informatics standards for all types of traditional medicine. This approval is subject to being able to fill the positions of Convenor, Vice-convenor and Secretary and the identification of specific work items to be transferred to the proposed WG.
	The current structure whereby traditional medicine informatics matters are discussed in the TMTF and then managed to ballot through WG3 is no longer an efficient use of WG3 or TMTF time. Under ISO Directives and the ISO/CS e-Committees system, the TMTF can only be an internal TC 215 body and not a body of experts performing standards development work. It was considered that the time has come for TM informatics to have an appropriately recognised structure to which experts can be appointed by NMBs.
	Five TC 215 members (all from Europe) were concerned at the lack of prior discussion in CAG1 (Executive Council) and opposed the motion primarily on this ground.
	Given the existence of Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics), there does appear to be some potential for this to become disruptive. Issues appear to include uncertainty over the relationship with TC 249 Traditional Chinese Medicine and the role of JWG 1. The field and these relationships are still evolving and that the previous proliferation of domain WGs has only been addressed in the recent restructure of TC 215.

Key Items/Actions for Australia	**WG1 Secretariat**. With the resignation of Daniel Henzi from Standards Australia, Manjoo Lalwani will be taking over the TC 215/WG 1 secretariat. Richard Dixon Hughes as Head of Delegation and Heather Grain (WG3 Convenor) will provide Manjoo with any required advice on TC 215 matters.

13606 .. EHRcom [WG1]. Australia needs to confirm its experts to work on revision of 13606 parts 1 to 5) and contribute through IT-014.

12967 Health informatics – Service architecture. [WG1] Australia should support systematic review of this cornerstone 3-part suite of service architecture standards, considering SA HB 137, 138 and 321.

ISO/FDIS 13940 .. System of concepts to support continuity of care (Contsys). Australia submitted many comments in response to DIS ballot. IT-014 will need to provide response to upcoming parallel CEN/ISO FDIS ballot.

PWIs on use of terminological resources [WG3]. Heather Grain will be leading the upcoming PWIs on metadata for terminological resources, and the assessment of terminological resources and quality of their implementation. Other Australians with an interest should consider participation in the TC 215/WG3 monthly teleconferences developing these items for consideration at the April 2015 meeting of TC 215 in San Francisco. (For more details see Appendix B below).

Standards on safety of health software and report of the Health Software Ad hoc Group [JWG 7]. The outcomes of the recent review and the joint approach being adopted by ISO/TC 215 and IEC/SC 62A (Common aspects of electrical equipment used in medical practice) are to be noted and monitored by IT-014 and HE-003. (See Appendix C for a summary of the outcomes of the review).

Ensuring Australian has an informed, prepared position in relation to proposed WG on Traditional Medicine informatics. The recommendation for form this proposed new WG has been somewhat controversial. Australia has previously played a constructive role in supporting the inclusion of all styles of traditional medicine, particularly through HG's role as WG3 convenor and WG3's role in support of TMTF (Traditional Medicine Task Force). Further to earlier comments on this topic, some review of developments and consideration of the options prior to the San Francisco meeting in late April is suggested.

ISO/AWI TR 20055: Person-owned document repository for PHR applications and health information exchange [WG2]**.** Australia submitted comments during NP ballot (which closed on 2014-09-19) with RDH as named expert to assist with resolution of issues and preparation of draft.

Metadata for medical information [WG2].   The relationship between the proposed new WG2 work item being suggested for NP ballot by Korean interests and established approaches such as IHE/XDS, HL7+OMG RLUS and other ISO/CEN work on EHR query needs to be better understood and a constructive Australian position established before the April 2015 TC 215 meeting. |

	Other recent/upcoming ISO/TC 215 ballots include: • ISO/HL7 10781 EHR System – Functional model [FDIS closing 2015-03-29] • ISO/DTR 18638 Health Informatics –Components of education to ensure health information privacy [Second DTR ballot closing 2015-03-16] • ISO/DIS 21549-5 .. Patient healthcard data – Part 5: Identification data [DIS ballot closing 2015-02-25.] **Note**. AU was only NMB to vote negative at CD-stage. Australian comments appear to have been addressed. • ISO/HL7 16527 .. Personal Health Record System - Functional Model Release 1 [FDIS ballot awaited since mid 2014] • ISO/AWI TS 17117 .. Terminological Resources - Part 1: Characteristics [CD ballot awaited]. • ISO/DTS 18062 .. Categorial structure for representation of herbal medicaments in terminological systems [Second 2-month DTS ballot awaited] • ISO 25720:2009 .. Genomic Sequence Variation Markup Language (GSVML) [due for systematic review.] • ISO/HL7 27932:2009 .. Data exchange standards – HL7 clinical document architecture – Release 2. [due for systematic review.] • ISO/HL7 27951:2009 .. Common terminology services – Release 1. Due for systematic review [NB HL7 is now at CTS2]. • IEC/TR 80001-2-8 .. Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance – Guidance on standards for establishing the security [joint IEC/SC62A and TC 215 DTR ballot scheduled to start 2015-03] • ISO/TR 80001-2-8 .. Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance – Guidance on standards for establishing the security [parallel IEC/SC62A and TC 215 DTR ballot scheduled to start 2015-03] • IEC 82304-1 Health software -- Part 1: General requirements for product safety [overdue for parallel IEC/SC62A and TC215 ENQ/DIS ballot, planned to start 2015-02-15] •
Status of the work	**ISO/HL7 10781 .. EHR system – Functional model, Release 2.1** [WG1]. Release 2.0 of this cornerstone standard balloted in parallel with HL7 International with input from CEN, IHTSDO, CDISC and GS1 is now at ISO/FDIS ballot. HL7 work continues work to provide tooling support and it has been translated to Spanish, with others being considered. **Update of ISO 13606 .. EHRcom (all 5 parts)** [WG1]. Project recommenced in October 2014, resetting clock for up to 36 months. Progress will depend on availability of Dipak Kalra and a core group of active drafters. Australia to confirm nominated experts. **ISO 13940 .. System of concepts to support continuity of care (Contsys)** [WG3 (lead) & WG1]. Disposition of DIS comments complete. Updated text with ISO/CS awaiting combined ISO/CEN FDIS ballot.

ISO/HL7 16527 .. Personal Health Record System - Functional Model Release 1 [WG1]. HL7/ANSI edition published in May 2014. ISO/FDIS ballot of this work was deferred by ISO/CS pending resolution of joint publication issues but is expected to proceed soon.

ISO/DTS 16843-1 .. Categorial structure for representation of acupuncture - Part 1: Acupuncture points [WG3/JWG1/TMTF]. Approved for 3-month NP-DTS ballot (which closed on 2015-01-27).

ISO/DTS 16843-2 .. Categorial structure for representation of acupuncture - Part 2: Needling [WG3/JWG1/TMTF]. Approved for 3-month DTS ballot (which closed on 2015-02-02).

ISO/PWI TS 16843-3 .. Categorial Structure for representation of acupuncture - Part 3: Moxibustion [WG3/JWG1/TMTF]. Approved for NP ballot (which closed on 2015-02-05).

ISO/DIS 17090-2 .. Public key infrastructure - Part 2: Certificate profile [WG4]. 2nd DIS ballot passed 2014-11-18 with one negative (DK) and 18 comments to be resolved and discussed at April 2015 meeting.

ISO/DIS 17090-5 .. Public key infrastructure - Part 5: Authentication using Healthcare PKI credentials [WG4]. NP Ballot closing passed without objection 2015-02-07. Nominated Australian experts – Peter Williams, A/Prof Trish Williams.

ISO 17115:2007 Health informatics - Vocabulary for terminological systems [WG3]. Following systematic review, revision of this standard is approved as a joint CEN/ISO project incorporating update of EN 12264.

ISO/AWI TS 17117 .. Terminological Resources - Part 1: Characteristics [WG3] approved to proceed to a 2 month CD Ballot with updated text (due 2015-02-01).

ISO/DTS 17251 .. Business requirements for the exchange of structured dose instructions for medicinal products [WG6]. 2-month parallel CEN/ISO DTS ballot closed 2015-01-07 with no objections; resolution of comments to be discussed at April 2015 meeting.

ISO/DIS 17583 .. Terminology constraints for coded data elements expressed in ISO Harmonized Data Types used in healthcare information interchange [WG2]. DIS ballot closed 2014-12-16, resolution of comments to be discussed at April 2015 meeting.

ISO/TS 17975 .. Principles and data requirements for consent in the collection, use, or disclosure of personal health information. [WG4]. Following discussion and amendment of draft following second DTS ballot, TC215 approved a third DTS ballot, which closed on 2015-01-19**. Australia was the only NMB to vote negative** in this DTS3 ballot and will need to be prepared to discuss its position at the April 2015 meeting.

ISO/DTS 18062 .. Categorial structure for representation of herbal medicaments in terminological systems [WG3]. Approved to proceed to second 2-month DTS ballot on receipt of updated text (due 2014-12-07) including input from WG6 (due 2014-11-07).

ISO/DTS 18864 .. Quality metrics for detailed clinical models (DCM Quality Metrics) [WG1]. Passed CD ballot with 3 against, revised draft being prepared for discussion at April 2015 meeting.

	ISO/DTS 19256 .. Requirements for medicinal product dictionaries for clinical care (MPD) [WG6]. Parallel CEN/ISO DTS ballot closed 2015-01-04 with 13 in favour and 2 against (Australia, Russia). Resolution of comments to be discussed at April 2015 meeting.
	ISO/DTS 19844 .. IDMP - Implementation Guide for ISO 11238 for Data Elements and Structures for the Unique Identification and Exchange of Regulated Information on Substances [WG6]. 2-month parallel CEN/ISO DTS ballot of revised draft closed 2015-01-07 with 15 in favour and 1 (UK) against. Resolution of comments to be discussed at April 2015 meeting.
	ISO/AWI TR 20055 .. Person-owned document repository for PHR applications and health information exchange [WG2]. Passed NP ballot closing on 2014-09-19. Change of title approved by TC 215 at this meeting. Resolution of comments discussed, more precise scope and first WD being produced by project team for April 2015 meeting.
	ISO/NP TS 20405 .. Framework of Event Data & Reporting Definitions for the Safety of Health Software [WG4]. Passed NP ballot closing on 2015-02-05 without objection. Comments were also invited from IEC/62A. Nominated Australian experts – A/Prof Trish Williams, Kathy Dallest, Edmund Kienast.
	ISO/NP TS 20443 .. IDMP - Implementation Guide for ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information [WG6]. Parallel CEN/ISO NP ballot of passed 2015-01-07 without objection. Resolution of comments to be discussed at April 2015 meeting. [Note. There still seems to be some confusion over the ISO-numbering of this item]
	ISO/NP TS 20451 .. IDMP - Implementation Guide for ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information [WG6]. Parallel CEN/ISO NP ballot of passed 2015-01-09 without objection. Resolution of comments to be discussed at April 2015 meeting.
	ISO/AWI TS 21089 .. Trusted end-to-end information flows [WG2]. Passed NP ballot closing on 2014-08-26 for re-write of ISO/TR 21089:2009 following systematic review. Results of voting and disposition of comments discussed but not yet finalised. Acceptance of disposition anticipated to require 1 month ballot of WG.
	ISO/DIS 21298 .. Functional and structural roles [WG4]. Currently being upgraded from a TS (published:2008) to an IS following systematic review. Parallel CEN/ISO DIS ballot on revised text closed 2014-11-28, passing with 2 negatives (UK, NO) and 68 comments to be resolved.
	ISO/DIS 21549-7 .. Patient healthcard data – Part 7: Medication data [WG4]. Currently being revised following systematic review. Parallel CEN/ISO DIS ballot on revised text closed 2015-01-14, passing with 1 negative (JP) and 23 comments to be resolved.
	ISO/CD 25237 Health informatics – Pseudonymisation [WG4]. Currently being upgraded from a TS to an IS following systematic review. CD ballot on revised text closed 2014-12-04.
	ISO/DIS 27799 .. Information security management in health using ISO/IEC 27002 [WG4]. Following systematic review, DIS ballot on revised text closed 2015-02-13.

IEC 62304:2006 Medical device software -- Software life cycle processes [JWG7] – preparation of CD1 draft of revised new edition (targeting October 2015)

ISO/TR 80001-2-x Application of risk management for IT networks incorporating medical devices – Part 2-x: Application guidance – Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities [JWG7]. Parallel TC215 amd IEC/SC62A NP ballot closed 2015-02-07. Resolution of comments to be discussed at April 2015 meeting.

Documents recently completed or published by TC 215 include:

- ISO/TR 12300:2014 .. Principles of mapping between terminological systems [published 2014-11-10. Heather Grain (AU) was project leader]

- ISO/TR 12310 .. Principles and guidelines for the measurement of conformance in the implementation of terminological resources [TR finalised in Berlin and awaiting publication since 2015-01-23]

- ISO/TS 13131:2014 Telehealth services – Quality planning guidelines [published 2014-10-10, with Alan Taylor (AU) as final project lead].

- ISO/TR 14639-2:2014 .. Capacity-based eHealth architecture roadmap -- Part 2: Architectural components and maturity model [published 2014-10-10, with significant Australian input].

- ISO/TS 16277-1 .. Categorial structures of clinical findings in traditional medicine: Part 1 Traditional Chinese medicine, Japanese medicine and Korean medicine [final proof 2015-02-20]

- ISO 17090-4:2014 .. Public key infrastructure - Part 4: Digital Signatures for healthcare documents [published 2014-09-24]

- ISO/TR 17439:2014 .. Development of terms and definitions for health informatics glossaries [published 2014-11-14. Heather Grain (AU) was project leader]

- ISO/TR 17522 .. Provisions for health applications on mobile/smart Devices [approved DTR awaiting publication since 2014-10-14]

- ISO/TS 17938:2014 .. Semantic network framework of traditional Chinese medicine language system [published 2014-06-13]

- ISO/TS 17948:2014 Traditional Chinese medicine literature metadata [published 2014-07-14]

- ISO/TS 18790-1 .. Profiling Framework and Classification for Traditional Medicine informatics standards development - Part 1: Traditional Chinese Medicine [DTS finalised in Berlin and awaiting publication since 2015-01-06]

- ISO/TR 19231:2014 .. Survey of mHealth projects in low and middle income countries (LMIC) [published 2014-11-14]

- ISO 22600-1:2014 .. Privilege management and access control - Part 1: Overview and policy management [Published 2014-09-22]

- ISO 22600-2:2014 .. Privilege management and access control – Part 2: Formal models [published 2014-09-22]

	• ISO 22600-3:2014 .. Privilege management and access control - Part 3: Implementation [published 2014-09-22] • ISO/TR 28380-3:2014 .. IHE global standards adoption - Part 3: Deployment [published 2014-12-18] • IEC/TR 80001-2-5:2014 Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance –Guidance for distributed alarm systems [published 2014-12-17] • IEC/TR 80001-2-6:2014 Application of risk management for IT-networks incorporating medical devices – Part 2-6: Application guidance –Guidance for responsibility agreements [published 2014-11-20]
Other Stakeholders	In addition to the re-formed members of IT-014, it is suggested that potential recipients of this report include: • AIHW and the IT-000 mirror committee to ISO/IEC JTC1/SC32 Data management and interchange, in relation to extensions to ISO/IEC 11179 metadata for use in health. • HE-003 in relation to software safety and associated medical device topics. • HE-031 for issues related to traditional medicine

APPENDIX A – REVISED SCOPE FOR ISO/TC 215/CAG 2 COORDINATION GROUP

TC 215 approved the following revised scope for the ISO/TC 215/CAG 2 Coordination group, adding sub-points 2, 3 and 4 to the previous CAG 2 scope:

1. *To prioritise new work item proposals (NPs) with the goal of harmonizing work within TC 215 with the following objectives:*

    (a) *co-ordination of the development of health informatics standards;*

    (b) *harmonisation of existing and emerging health informatics standards to establish a global framework of consistent and common standards for health systems and health data (together with CAG3); and*

    (c) *development and maintenance of operational plans and the overseeing of their delivery; addressing TC logistics and expediting the standards development process, and*

2. *to create a framework of healthcare domains for which normative standards publications can be developed to define integrated systems of coherent and aligned health informatics standards from TC 215 and other Health Informatics SDOs to cover "end-to-end" management, interoperability, and use of health related data and information systems within each domain;*

3. *for each identified domain, to recommend to TC 215 a new or existing working group to undertake the development of such standard publications; and*

4. *to oversee and coordinate the process of developing such standards publications.*

During discussion, the UK requested that the following wording be included in the minutes before supporting the motion to adopt this resolution (TC 215 Resolution 2014:43), which then passed unanimously:

"The UK was concerned about the risk that existing standards might be adopted in full without due attention to the appropriateness of scope for the domain in question. In response, the Chair confirmed the intention for relevant working groups to apply their judgment in the selection of standards or relevant parts of standards, sensitive to issues of contextual dependency." The UK approved with the additional wording as listed."

APPENDIX B – PROPOSED WG 3 PRELIMINARY WORK ITEMS

The following preliminary work items (PWIs) were established for a range of topics recommended prior to the meeting and extended at the meeting by the national experts present. Their inclusion on the TC 215 work program as PWIs was accepted by TC 215 in final plenary.

Work will be undertaken on these work items to develop use case, confirm utility and priorities for development over the next 6 months in preparation for active work at the next face to face meeting in late-April 2015. Any Australian experts with an interest in participating in the work should contact Heather Grain (heather@lginformatics.com).

Maturity levels for terminological resources in EHRs

This work is aimed at an ISO Technical Specification (TS), which will be of value to national initiatives to assist in design and planning of requirements to progress terminology implementation safely and effectively. This will also enhance the ability to understand the roadway of development and maturity of individual systems and implementations. Specific use cases of this work item:

- Improve project scope and activities to delivery relevant terminology implementation across the health data continuum
- Enable assessment of current position on the maturity line and the priorities for further development to reduce risk and improve implementation and usability.

Metadata registry requirements in Healthcare

This proposed TS will define metadata registry extensions and clarification of ISO/IEC 11179 to meet the needs of data across the healthcare continuum from direct patient care to reported aggregate data. AIHW have already discussed this as an issue within IT-014 and Australian eHealth engagement is sought. It is also a known issue in the USA and Germany.

Terminology Capacity Assessment (targeting TS)

Many organisations are assessing which code system is relevant for use for a given purpose. This work will provide a mechanism for that evaluation. This proposed TS is seen as essential not only for individual healthcare organisations but also for state and national initiatives and data collections.

Revision of *ISO 13120 Syntax to represent the content of healthcare classification systems – Classification Markup language (ClaML):2013*

ISO 13120 is a recently developed international standard used by organisations including IHTSDO, WHO and many European nations to electronically publish health classifications.

The use of the existing standard has highlighted shortfalls and the need for some corrections, which will be undertaken in the proposed revision, which will also extend the standard to define representations for mapping content of such classifications.

Measurement of conformance in implementation of terminological resources

The final text of the technical report, *ISO/TR 12310 Health informatics, Principles and guidelines for the measurement of conformance in the implementation of terminological resources*, has been submitted to ISO/CS for review, approval and publication.

This new PWI aims to build on the concepts set out in that TR to create a normative set of conformance criteria and measures that can be used in assessing implementations which utilise terminological resources.

APPENDIX C – REPORT FROM THE JWG7 HEALTH SOFTWARE AD HOC GROUP – SUMMARY OF KEY OUTCOMES

In October 2012, ISO/TC 215, with agreement from IEC/SC 62A (Common aspects of electrical equipment used in medical practice), resolved:

- to establish a Health Software Ad hoc Group to create a report that provides guidance on the future development of health software work items that establishes: - guiding principles; common terms and definitions; and a development roadmap.

- the Group be convened for a period of two years from date of formation under the co-leadership of Sherman Eagles (US) and Neil Gardner (CA)

- the Group be coordinated with JWG7 and include members from ISO TC 215 and IEC SC62A.

- the Group adopt an approach consistent with the ISO TC 215 Common Terminology Initiative.

The focus of the Group's work for the first 12 months was on common concepts and definitions for health software safety in conjunction with development of *IEC 82304-1 Health software – Part 1: General requirements for product safety*.

This was also a year when national governments focussed on policy issues associated with the safety of health software and the challenges posed by its configurability, potential use across many platforms including mobile devices, diversity of suppliers outside the traditional medical device community and potentially short development/release cycles.

In particular, both the International Medical Device Regulators Forum (IMDRF) and the US federally mandated FDA Safety and Innovation Act (FDASIA) review recognized the complexity of this space and the need to adopt new approaches to protecting the safety of the public, while not stifling badly needed innovation in health care delivery enabled by health software systems.

Because health software is used in a complex socio-technical environment, in addition to considering characteristics of the software itself, standards for health software safety must also consider the people using the health software and the broader technical and information infrastructure within which the health software operates (including networks, security, servers, databases and integration with other software and systems).

The review built the findings of the earlier technical report ISO/TR17791:2013, which analysed and provided guidance on standards enabling health software safety. In particular, it confirms the finding that, while existing IEC medical device safety standards provided an excellent starting point for current ISO and IEC health software standards, these standards are not sufficient to address the full range of software safety needs.

The draft final report entitled *"Health Software and Health IT Safety Standards - Future State Architecture/Framework and Roadmap"* addresses the following final objectives:

- To **propose an overarching architecture/framework** that describes the desired future state for health software safety standards.

- To **map the content of existing standards** and any other emerging new sources of health software standards and best practices that major countries have adopted, **against the proposed framework**, and,

- Finally, to **develop a 'roadmap' for health software standards development** which builds on our existing standards assets and fills the highest priority gaps – i.e. by proposing new standards, extending the scope of existing standards to address the priority gaps and aligning definitions and concepts across each of the standards in this space as they come up for revision.

As guiding principles, it was determined that an effective architecture/framework guiding further development of standards for health software and health IT systems should:

- Address the full software product lifecycle and ensure any added burden is commensurate with risk;
- Recognize the broader socio-technical environment in which health software systems are implemented;
- Target the consumers of the standards – fostering their engagement, adoption, use and application;
- Leverage source standards by adding additional guidance and specificity;
- Be forward-looking and adaptable to changes in technology and how software is used; and
- Be agnostic as to whether software is regulated (but supportive of regulatory needs).

The proposed framework at its highest level includes four major components:

1. A **foundational set of standards** covering the key health software safety principles, concepts, definitions and common contexts for use of health software in a health IT system.

2. A set of **standards addressing the design and development of health software** (major portions of which could continue to apply to all medical devices) – e.g. updated version of IEC 62304 Medical device software – Software life cycle processes with expanded scope.

3. A set of **standards covering the configuration, integration and other implementation steps** in the lifecycle.   These would be new standards to address the increasing degree to which health software must operate within a complex health IT socio-technical environment involving significant integration with other systems and configuration to meet local business and workflow requirements.

4. A set of **standards covering the remaining steps in the lifecycle** including both the technical requirements for health software, and how the software will be used to support the clinical facets of the ongoing operation and ultimately the disposal aspects of health software.

The overarching focus in these standards is on patient safety.

Recommendations in relation to the proposed roadmap to implement the framework are:

1. Initiate a new standard or technical specification covering the common principles, concepts, and terms necessary for standards for optimizing the safety of health IT systems across their lifecycle in today's complex socio-technical environment.

2. Develop the revision of IEC 62304 to cover the scope required for health software.

3. Initiate a new standard or technical specification or adopt an existing standard covering the system engineering life cycle for health software and health IT systems.

4. Develop the revision of IEC 80001-1 (and its parts) to cover the content required for the Implementation and Use phases.

5. In the revision of ISO 27799, review the appropriate alignment with security components that are presently incorporated in several parts of IEC 80001-2.

6. Request that all new projects that impact the patient safety of health software or health IT systems provide an explanation on their NP form of how they fit in the framework.

There was general acceptance of the findings and recommendations. During discussion, Richard Dixon Hughes (AU) emphasised that they should draw on the existing mainstream software quality standards prepared by ISO/IEC JTC 1/SC 7 (Software & systems engineering) and other relevant global software SDOs and limit the amount of health-industry specific requirements to a minimum.