INTERNATIONAL DELEGATES MEETING REPORT

Date	17 July 2015		
Delegate(s) proposed by Projects Manager	Manjoo Lalwani		
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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, including opening/ closing plenary and meetings of: TC 215/CAG1, CAG2, CAG3, WG1, WG2, WG3, WG4, WG6, JWG1, JWG7 and TMTF. The following associated meeting was also attended ▪Joint Initiative Council (JIC) for global health informatics standardization ½ day planning session (Sun)		
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 2015-04-19. JIC half day planning session **Mon 2015-04-20 to Friday 2015-04-24**. TC 215 leadership meetings, opening plenary, 3 days of WG meetings and closing plenary.		
Venue Details	Marines' Memorial Club and Hotel, San Francisco (SFO), California, USA		
Australian delegates	J Richard DIXON HUGHES (RDH), Head of delegation, expert and immediate past-chair of the JIC Heather GRAIN (HG), Convenor, ISO/TC 251/WG 3 Semantic content Also: Manjoo LALWANI (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 93 active projects and to review potential new projects in the field of health informatics, including joint work with other ISO and 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 and RDH is active in projects as a nominated expert, • WG3 (Semantic content – where Heather Grain is the convenor), and • in leadership roles (where RDH and HG both serve on CAG1 Executive Council and the CAG2 Coordination Group, and RDH is Immediate-Past Chair of the JIC and is also ISO/IEC JTC1 liaison to TC215.)
Attendees at the meeting	The following 19 P-members were represented at the TC 215 meeting by 133 registered delegates: • Australia • Austria • Brazil • Canada • China • Denmark • Finland • Germany • Italy • Japan • Korea • Malaysia • Mexico • The Netherlands • Norway • Sweden • Switzerland • United Kingdom • United States A further 35 delegates represented liaison organisations (some of these delegates were also members of national delegations but were counted as representing their liaison organisation). Including delegates, observers, ISO/TC215 secretariat and the ISO/CS project director, the total attendance was 177 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: • **Change of TC 215 chair**. Following the resignation of Dr Chris Chute as TC 215 chair in late 2014, ANSI had proposed Mike Glickman (US) be appointed for an initial 3-year period to Dec 2017. His appointment was supported by the members of TC 215 and was approved by ISO/TMB prior to the meeting. By way of a resolution at the closing plenary, TC 215 expressed its sincere appreciation to Dr Chute for his many years of service and leadership on behalf of ISO/TC 215 and in the development of global health informatics standards worldwide.

- **1:1 meetings with TC 215 chair to discuss priorities and strategic direction**. Over the course of the meeting Mike Glickman held a series of one-on-one meetings with HoDs and WG conveners to identify priorities, issues and potential strategies. Both RDH and HG took the opportunity to participate, with the following being among the topics covered:
  - Strategic directions for WG 3; its methodology for identifying gaps and overlaps; and TC 215 processes to ensure consistent treatment of semantic content across application domains [HG]
  - Improving the rigour of NP project justification and prioritisation, use of PWIs and the role of CAG 02 coordination group.
  - Ensuring "bundling" pathways are not more complicated than they need to be and being clear where TMB agreement for arrangements with other SDOs is needed.
  - RDH insights as recent chair of JIC and continued opportunities for joint work and more effective engagement with the wider stakeholder community.
- **Opening address:** ***Health Care in the Information Age*** – by Dr Scott Young MD, Associate Executive Director, Clinical Care and Innovation, The Permanente Federation and Executive Director, Care Management Institute. He highlighted the way in which the ubiquitous use of ICT is starting to transform the way in which health care is being delivered within Kaiser-Permanente, the potential for further change and some of the issues needing to be addressed to transition clinical practice and patient/client engagement.
- **Peak role of TC 215**. Significant progress was noted in addressing difficulties faced by TC 215 in continuing its peak role of providing international recognition to core standards used in health informatics where these standards are produced by other SDOs (and particularly where partner SDOs have made the standards freely available online, which is not compatible with the ISO business model.)

  In this regard, TC 215 continues to progress the concept of developing "bundling standards", "meta-standards" or "master standards" that call-up and make normative reference to specific sets of other "recognised" standards to address use cases in identified domains.

  The TC 215 Chair and ISO/CS representative reported on positive discussions with members of the TMB over TC 215 specific needs and the passage of an ISO/TMB resolution, which acknowledges the existence of "challenges" faced by TC 215 in the health informatics sector and confirms that "special cases" may be referred to the TMB via ISO/CS. ISO policies on normative references continue to apply and, in some cases, agreements with other SDOs will be required.
- Following the major revision completed in 2013, it is again time for the TC 215 strategic business plan to be reviewed and updated. Volunteers are being sought. The two principal authors of the 2013 edition, RDH (AU) and Jeremy Thorp (UK) will assist but have indicated their preference not to lead the work.

- Problems continued to be experienced in progressing meaningful dialogue through the two TC 215 joint working groups established in conjunction with IEC/TC 25 and ISO/TC 12 to progress the ISO+IEC 80003-series of standards in the area of quantities and units for e-health (previously physiological quantities and/or telebiometrics)
- **Changes to ISO/IEC Directives and forms**. Changes coming into force on 1 May 2015 of particular interest to TC 215 include (a) the clarification of rules for proceeding directly to publication following approval of a DIS ballot; (b) closer alignment of CEN and ISO processes for VA projects (this impacts many TC 215 projects); (c) the need for better justification on positive NP/NWIP ballots; (d) tighter project progression criteria; (e) expanded P-member participation criteria; (f) proposed trials of increased use of electronic means of working; (g) the move to XML for publishing and the need to ensure that all material (including diagrams) is presented simply and in accordance with the rules
- **Changes to ISO systems**. Changes impacting TC 215 include the move to XML for publishing and the need to ensure that all material (including diagrams) is presented simply in accordance with the ISO rules and avoiding colour.
- **Thanks to Kaiser Permanente (KP) and sponsors.** TC 215 recorded its formal appreciation to KP and all hosts, sponsors and members of the planning committee for their hospitality and the arrangements for the 23rd meeting of ISO/TC 215.
- **Confirmation of TC 215 Work Group convenors and vice convenors.** The following appointments for 3 years from 2015-04 to 2018-04 were confirmed by TC 215 after nomination and election by their respective WGs and support from the TC 215 chair:
  - WG 2 Vice-convenor: Dr Byoung-Kee Yi (Korea/ KATS)
  - WG 3 Vice-convenor: Dr Anna Orlova (USA/ ANSI)
  - WG 6 Convenor: Mr. Christian Hay (Switzerland / SNV)
  - WG 6 Vice-convenor: Mr. Frits Elferink (Netherlands/ NEN)

  The position of WG 2 convenor remains vacant and discussions with potential nominees are continuing.

WG 1 Architecture, frameworks and models. Across all sessions, 27 delegates from 12 countries participated in WG 1 work with 2 others joining by Webex. Formal meetings of WG 1 took place on the Tuesday and Wednesday with the following matters among those discussed:

- **Completed documents awaiting publication.** It was noted that ISO publication of the following WG 1 documents, which passed their final ballot quite some time ago, was awaited:
  - *ISO/HL7 10781 EHR system functional model R2.0* (EHR-S FM) [ANSI/HL7 version was published Apr 2014]
  - *ISO/HL7 16527 PHR system functional model* (PHR-S FM)
  - *ISO/TS 13972 .. Detailed clinical models, characteristics and processes*

- **Development of second edition of *ISO 13606 .. [1]EHR communications* [EHRcom] - *Parts 1 to 5*.**

  The production of a 2nd edition of ISO 13606 started in 2012, was delayed and was re-initiated in 2014. It is now the main task for WG 1 and occupied some 50% of all WG 1 discussion at the SFO meeting, including a joint session with WG 4 on part 4 (Security). The work is being progressed in parallel by several task groups.

  The update of 13606 was addressed in a 'pre-meeting' with the Clinical Information Modelling Initiative (CIMI), which provided an opportunity for experts from both communities to share information with a view to harmonising CIMI and the revision of EN ISO 13606, particularly those parts concerned with archetypes. This facilitated progress in subsequent WG 1 discussion.

  The plan is to have a full CD draft of all 5 parts ready for ballot at the next TC 215 meeting in November. The approach includes keeping the existing scope, harmonising with other relevant work where possible and reducing the amount of reference material in the standard (e.g. the ADL language and some reference archetypes) and, instead, providing this material online.

  There are potentially significant changes to be reviewed in areas such as:

  - Simplification of the demographics package;
  - Alignment with and support for HL7/FHIR, ISO 18308 (EHR architecture requirements), ISO 21090 (Data types), ISO 27789 (Audit trails for EHRs), ISO/TS 14265 (Classification of purposes for processing personal health information), ISO/TS 21298 (functional and structural roles), ISO 22600 (Privilege management and access control).
  - Simplification of EHR_EXTRACT model (including changes to attributes and to RECORD_COMPONENT, FOLDER, COMPOSITION, ENTRY, CLUSTER, ELEMENT, LINK, FUNCTIONAL_ROLE, RELATED_PARTY, ATTESTATION_INFO, AUDIT_INFO and EXTRACT_CRITERIA.
  - Support of EHR access policies and access logs.

  WG 4 agreed to provide expertise PMAC, Audit trails for EHRs, Functional and structural roles and security and privacy issues in general, particularly in the update of Part 4.

  A pleasing aspect of this revision is the broad engagement with strong positive contributions, including some who had previously opposed the first edition (primarily from Europe).

  WG1 commended Prof Dipak Kalra and the expert teams for their work on the revision of 13606.

[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).

- ***International Workshop Agreement (IWA) on Community-based integrated health and care services for aged societies***. The joint proposal from JISC (JP) and BSI (UK) to progress an IWA on this topic was approved by ISO/TMB in Dec 2014 with the kick-off workshop to take place on 1 Jul 2015. The stated scope is broad and aims to establish principles of relevance to standards work on sustainable communities, ICT, medical devices, ambient assisted living, housing and built environment, ergonomic/ design and provision of various services. The Japanese are particularly keen to use the event to leverage their position, experience and solutions as the country with the most aged society on earth.

  Shigeru Miyake from Hitachi gave a presentation to suggest a related TC 215 work item: *"Information model and reference architecture for health guidance service"*, which was discussed. Material on the proposed IWA and the Hitachi proposal had been circulated for TC 215 comment by 30 Apr 2015 (see further comment under Australian actions below).

  TC 215/WG 1 approved Prof Stephen Kay (UK), as Chair of WG 1 attending the workshop on behalf of WG 1.

  The Hitachi suggestions are expected to be considered further at the next TC 215 meeting, by which time, work on the IWA should be well advanced.

- **EHR/PHR systems functional models and work in HL7 EHR WG**. In addition to providing an update on ISO publication, Gary Dickenson (US) stressed the role of functional profiles in applying the system functional models and briefed WG 1 on current HL7 EHR WG activities, including the development and release of tooling to support use of the EHR-S and PHR-S FMs, as well as noting:
  - *EHR-S FM – Release 3*. R3 development has commenced and includes aligning data requirements with HL7/FHIR resources [but was suspended at May 2015 HL7 WGM in Paris until there is more uptake of R2 profiles.]
  - *PHR-S FM – Release 2* is in development and will be aligned with EHR-S FM Release 2.
  - *Records Management/Evidentiary Support (RM-ES) Functional Profile* is being updated for use with EHR-S FM Release 2.
  - EHR System Usability; a functional profile is in development.
  - *ISO/NP TS 21089, Trusted end-to-end information flows*; HL7 is preparing a draft for TC 215 based on updating the existing ISO/TR 21089:2004.
  - FHIR Record Lifecycle Event Implementation Guide; to be included in FHIR DSTU-2 ballot
  - Vocabulary alignment across HL7 EHR, Security, CBCC (Community-based collaborative care) – particularly in relation to security, privacy and access control concepts.

  The EHR WG now holds 9 teleconferences each week addressing various topics, in which TC 215 experts are welcome to participate.

- ***ISO/NP TR 19669 .. Re-usable component strategy for use case development***. Project Lead, Gary Dickinson (US), gave a presentation which addressed progress in developing the underlying concepts through the S&I Simplification Work Group within the US Standards and Interoperability (S&I) Framework, which is sponsored by the ONC for Health IT within the US Government).

  Gary and others noted the challenges in using this work to produce a more internationally-aligned deliverable. Further considerable effort may yet be required but the project is working toward a TR, so it is not subject to the same progression rules as higher-consensus documents. Promised input from CEN work on use-case requirements is still pending. The next step is for WG 1 to receive and review a draft document prior to DTR ballot.

- **ISO/PWI TS 20428 .. *Metadata for describing structured genomic sequencing information in electronic health records***. The original proposal (form 4) was presented by Dr Soo Yong Shin (KR) and discussed. After confirming that the work would be done in conjunction with HL7 and had the active support of the Japanese delegation and Prof Jun Nakaya (who had led previous standards work in TC 215 and HL7), WG 1 supported the item being put up for NP ballot with the revised title above; this was approved by TC 215 and the item is now out for a 3-month NP ballot.

- **CEN Concurrent Use Initiative**. Prof Stephen Kay gave a brief update report given on the initiative, primarily focussing on the outcomes of the 6th Concurrent Use Workshop which took place in Mar 2015 in Lund, Sweden. Key themes included:
  - how to make the extensive work in 13940 ContSys more accessible to implementers and leverage it effectively as *"a comprehensive, conceptual basis for content and context in healthcare services, the foundation for interoperability at all levels in healthcare organizations and for development of information systems in healthcare."*
  - Implications for the next generation of 13606 EHRcom and 12967 HISA.
  - Tools and repositories that might be required to facilitate adoption and practical use of these standards.

  This was a segue into the HISA presentation which followed.

- ***ISO 12967 Health Informatics - Service Architecture [HISA] (Parts 1, 2 and 3)***. Pier-Angelo Sottile addressed plans for the systematic revision of this 3-part CEN/ISO standard, with the following being noted:
  - HISA is aimed at helping healthcare enterprises structure and evolve their information systems to deliver new benefits for themselves, their patients and staff.
  - It prescribes how to build an open and well-documented Service Architecture that enables enterprises to structure their information processes and systems to provide the required level of capability within a flexible framework for managing change.

- The revision will take into account recent CEN work on "concurrent use" by drawing more on ContSys and 13606 EHRcom [and also needs to take into account other significant initiatives and experience with HISA, including ISO/TR 14639, CIMI, HL7/FHIR and advances in service-oriented design]
- A more detailed proposal will be developed for circulation in Sep 2015, with a view to commencing work at the Nov 2015 TC 215 meeting in Switzerland.

- **Brazilian standards for hospital discharge summary and obstetric discharge summary.** Thais Abreu Maia gave a presentation on standards for electronic hospital discharge summaries and obstetric discharge summaries for use throughout Brazil. The standards, which are based on communication of ISO 13606 EHR extracts, were completed in Sep 2014, were open for national public consultation closing on 31 May. The hospital discharge summary includes information on:
  - Patient identification and characterization of hospitalization
  - Admission reason, relevant diagnoses, associated pathologies developed during hospitalization
  - Procedures performed; Clinical Summary ; Allergies and adverse reactions;
  - Prescription and orientation; Discharge instructions; Hospital discharge information; and
  - Attachments

  The obstetric discharge summary has similar content to the hospital discharge summary with the following key differences:
  - For a single admission there may be multiple records – one for the mother linked to records for one of more neonates (whereas a hospital discharge summary is for a single person).
  - The procedures and clinical summaries will include specific information required under the National Obstetric and Neonatal Care Policy, including details at birth, neonatal screening results, vaccinations and newborn care instructions.

- ***ISO/TR 14639-2:2014 .. Capacity-based eHealth architecture roadmap - Part 2: Architectural components***. The proposed discussion on how to progress this work was unable to take place due to the absence of Dr Marion Lyver because of illness; it will be addressed the next meeting in November.

  Stephen Kay raised a request from Dr. Alvin Marcelo who is based in the Philippines and co-chairs the Asia eHealth Informatics Network (AeHIN) for a normative coding of components in the 14639 framework (similar to that provided by the COBIT framework). The aim would be to support consistent use and comparison by those using and applying the framework. Following discussion, it was felt that the need and nature for such coding at the level of a TR was not immediately clear and decided to seek more information for consideration at the November meeting (noting there may be some synergy with Dr Lyver's potential proposals).

- ***ISO/DTS 18864 .. Quality Metrics for Detailed Clinical Models***. Discussion of the disposition of CD comments and the revised draft for DTS ballot was deferred to the next meeting because the project lead, Dr Sun Ju Ahn (KR), was unable to attend the SFO meeting.
- **Public health meta-standard.** There was nothing further on the suggested new work item to develop a meta-standard identifying the use case and standards applicable to the public health domain, which had been presented by Dr Anna Orlova (US) at the previous TC 215 meeting in Berlin.
- **Joint sessions with WG 4, WG 2 and JWG 7.** There was a joint session of JWG 7, WG 2, WG 4 and WG 1 hosted by JWG 7 to review and discuss the outcomes and future work flowing from the report of the Health Software ad hoc group [Covered under JWG 7].

  The same quarter was also the only time relevant experts were available for a joint session of WG 4 and WG 1 to discuss issues arising from the update of ISO 13606-4 (Security) – with it being agreed that the content of Part 4 would be similar but that specific details would need to be better aligned with other TC 215 standards.

Joint WG1/WG3 projects. The following were the main topics discussed in joint session of WG1 and WG3.

- **SKMT (Standards Knowledge Management Tool)**. Discussion focussed on governance processes and making the registration and harmonisation of health informatics standards, terms and definitions more effective.

  HG introduced an exercise aimed at selecting a “preferred definitions” for “health record” and key derivatives from the many definitions in SKMT for health records and related concepts. Some potential issues in aligning the SKMT definitions with the terms and definitive elements used in Contsys were noted and will be worked through by WG1, WG3 and the SKMT governance team between meetings.

  Immediately after the meeting, HG provided a discussion paper on the “Health record family of terms” for circulation to WG 1 as the basis for submitting comment on the preferred definition(s). [The paper was circulated on 24 Apr for comment to HG by 29 May].
- ***ISO/FDIS 13940 System of concepts to support continuity of care (Contsys).*** After reconciliation of 123 pages of DIS ballot comments, ISO 13940 was awaiting release as a parallel CEN/ISO FDIS ballot after extensive delays caused by problems rendering the concept model diagrams. [The problems have been overcome and the 2-month FDIS ballot opened on 2015-06-18].

  It was reassuring to see Contsys increasingly being referred to in the SFO meeting as a foundation resource and used in discussions about EHRcom, SKMT definitions and CIMI. This is to be encouraged.

WG 2 Systems and device interoperability. Across all sessions, 20+ delegates from at least 8 countries participated in WG 2, which currently has some 23 active work items. Items of note included:

- **Thanks to Mike Glickman** for 15 years service as convenor of WG 2 and congratulations on his appointment as TC 215 chair.
- ***ISO 14199 .. BRIDG model*** – DIS ballot closed in January 2015 with 100% approval from all voting P-members, with TC 215 approving its progressing directly to publication without an FDIS ballot.

  HL7 has established a new Biomedical Research Integrated Domain Group to support future development and implementation of BRIDG.
- **PWI for a proposed ISO/TR on a Trans-national health record.** TC 215 approved a preliminary work item (PWI) to enable WG2 to develop a project proposal and preliminary draft for NP ballot based on a submission from Il Kon Kim (KR). [It is considered important that the resulting NP proposal take into account other extensive work in this area and look to define and allocate appropriate standardization activities.]
- **ISO 11073-91064 and EN 1064 on Standard communication protocol – Computer-assisted electrocardiography.** Dr Alpo Värri (FI) reported on progress with the revision of these two parallel standards. The purpose of the revision is to keep the more useful and up-to-date parts of the standard more or less intact, remove or revise the outdated parts and add new, requested functionality including new long-term and stress-related ECG data formats and ECG annotations. Over 15 WebEx meetings have been held with considerable progress being made and specialist input from peak cardiology groups in the US and Europe.

  The draft text for DIS ballot is expected to be released progressively and be complete (including new sections) for review in September and approval for issue by TC 215 in November.
- **PWI for ISO/TS 22077-4 .. Medical waveform format – Part 4: Stress test electrocardiography.** Following on from recent approval of Parts 1 to 3 for publication, TC 215 approved a (PWI) for WG2 to commence work on a project proposal and preliminary draft for NP ballot as put forward by Satoshi Kobayashi (JP).
- **ISO 12052:2006 .. Digital imaging and communication in medicine (DICOM) including workflow and data management**. The future of this standard, which references the freely-available DICOM specification has been at the centre of discussions between ISO/TC 215 and ISO/CS and needs revision following systematic review. ISO/TC 215 accepted the WG 2 recommendation to update and revise the standard on a 36-month track with Harry Solomon and Kevin O'Donnell of DICOM as joint project leads. The revision will explore how the standard will relate to "bundling" for the medical imaging domain. Provided the required TMB approval is obtained, the outlook for this work is now positive.

- **Genomics markup language standards.** Proposals to progress work on the following standards for interchange of genomic data were reviewed by WG 2 and are being worked up as draft standards for NP ballots after the Nov 2015 TC 215 meeting in Switzerland.
  - *ISO 25720:2009 .. Genomic Sequence Variation Markup Language (GSVML)* - to be revised and enhanced as agreed by WG 2 following systematic review.
  - Proposed international standard on: *Omics markup language (OML)* – an extension of ISO 25720 to cover genomic sequence variations from both the molecular and the clinical application viewpoints.
  - Proposed international standard on: *Whole genome sequence markup language (WGSML)*.

  The lead for all 3 projects will be Prof Jun Nakaya (JP) who led the original development of ISO 25720 and it is understood they will be progressed with active engagement of HL7.

- **Proposals for PWIs on medical information search and retrieval**. Proposed resolutions to establish PWIs for the following work items were presented and considered by WG 2 but were not eventually progressed to vote in the closing plenary:
  - An ISO/TR on core metadata for medical information search
  - An ISO/TR on transformation rules for medical Information retrieval

  Both were proposed by Mr. Sungho Hong, Prof. Youngseop Kim and Mr. Yong-Hwan Lee (KR). As noted in the Australian report from the Oct 2015 TC 215 meeting in Berlin, the connection of this proposed work to mainstream approaches needs to be more clearly explained.

<u>The status of the following current WG 2 items was also noted</u>:

- *ISO/AWI TR 20055: Person-owned document repository for PHR applications and health information exchange*. Passed NP ballot in Sep 2014 and draft is understood to be still in preparation for DTR ballot [Acting WG 2 chair mistakenly reported to TC 215 that TR 20055 had passed DTR ballot and is in publication but this appears to be incorrect. RDH is one of the nominated experts and is seeking to reconnect with the project].
- *ISO/DTS 21089 .. Trusted end-to-end Information flows*. Preparation of DTS ballot draft is continuing – led by Gary Dickinson (US), who has also suggested it become part of the standards infrastructure framework to be used by CAG02 to classify and review proposed standards projects.
- *ISO/DIS 17583 .. Terminology constraints* [bindings] *for coded data elements expressed in ISO harmonized data types used in healthcare information interchange*. DIS ballot closed in Dec 2014 with 100% in favour and some 25 technical comments to be resolved (almost all from the UK). Required revisions were discussed in joint session of WG 2 and WG 3 with revised draft to be submitted for publication (without requirement for FDIS ballot).

- 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) but do not appear to have been discussed in any detail.
- Proposed CDA implementation guide for spirometry (translated from Spanish). There has been no action since the preliminary draft for this item was circulated in May last year. It was noted that it had been discussed in the January 2015 HL7/ IEEE/ ISO Devices meeting in San Antonio where Dr John Rhoads (US) was to review progress and evaluate how best to progress the work - and whether this might now be better done within HL7 or IHE, rather than ISO.

WG 3 Semantic content. Across all sessions, 22 delegates from 10 countries and 2 liaison organisations (IHTSDO and HL7) participated in WG 3, including one delegate attending by teleconference.

Heather Grain (AU), convener of WG 3 has provided a separate delegate report to Standards Australia, a copy of which is provided as Appendix B to this report. Her report is primarily focussed on developments in WG 3, highlights of which include:

- The outcomes of a very fruitful **review of the scope, terms of reference and conceptual framework for classification of WG 3 standards development work** was undertaken. The framework addresses needs across the different stages of development of terminological resources, and segmented the target domains into 5 general topic areas and 4 specific application domains. Based on the analysis, gaps in the available standards were able to be identified as the basis for new work, with project outlines for the following priority items being progressed by way of fortnightly teleconferences:
  - A multi-part ISO/TS series on **healthcare value domain content, provisionally segmented as follows:**
    - Part 1 Design and requirements
    - Part 2 Governance
    - Part 3 Quality assessment
  - An initial part of an ISO/TS on: **workforce for EHR semantic content implementation** – dealing with needs, roles and skills
- ***ISO 17115:2007 Health informatics - Vocabulary of terminological resources.*** Following systematic review, revision includes incorporating *EN 12264 Categorial structures for health care*; harmonizing with SKMT and reviewing categorial structures.
- ***ISO 13940 ContSys -*** Now at FDIS ballot [see WG 1 comments].
- ***ISO 13120:2013 .. Syntax to represent the content of healthcare classification systems* (Claml).** An NP ballot will be run for a revision to reflect implementation experience.
- ***ISO/DIS 16278 Categorial structures for terminological systems of human anatomy***. Approved for publication after successful DIS ballot and disposition of comments (including Australian comments).

- ***ISO/ AWI/DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems***. A joint session of WG 6 and WG 3 addressed many issues from DIS ballot arising from need to harmonise 18062 requirements and terminology with those used in other pharmacy standards (notably IDMP concept hierarchies). An agreed approach will see a revised document will go to DIS2 ballot. TC 215 approved seeking a maximum extension of the project timeline to 48 months.
- ***ISO 13582:2013 Sharing of OID registry information.*** TC 215 approved a WG 3 proposal for a minor revision to address issues encountered during implementation.

Terms and Definitions in the Family of Health Records. HG led discussion of user feedback process in joint WG 1/WG 3 session [as reported under WG 1].

WG 4 Security, Safety and Privacy**.** Across all sessions, some 24 delegates from 11 countries participated in WG 4 (including 3 joining remotely by Webex). Items of note included:

- ***ISO/NP TS 20405 Framework of event data and reporting definitions for the safety of health software***. Grant Gillis (CA) reported to a joint session of WG 4 and JWG 7 on progress, advising that this item had passed NP ballot in February and that a draft DTS for detailed discussion at the next TC 215 meeting is targeted for September. This work is expected to be relevant to Australia.
- ***ISO* PWI ISO/TR 14668 Alert information for risk management**. TC 215 approved the WG 4 proposal to remove this item from the work program.

  Some time back, the item was first proposed in conjunction with WG 3 under the title *"Guidelines for principles and desirable features of clinical decision support"* with the aim of building on Australian work in this area (with HG as co-lead) but this original approach was side-tracked by interests keen to propose a uniform set of alert symbolism and the work then lapsed when it failed to gain sufficient traction. It is likely that the original approach of elevating the previous Australian CDS work still has merit and may be considered separately by WG 3 in due course.
- ***ISO/TR 11633:2009 .. Information security management for remote maintenance of medical devices and medical information systems.*** This publication comprises two parts, which were systematically reviewed by WG 4:
  - Part 1: Requirements and risk analysis
  - Part 2: Implementation of an information security management system (ISMS).

  Hideyuki Miyohara (JP) reported that use of remote monitoring and maintenance is accelerating, which means that these specifications are of increasing relevance; however, they became dated when the ISO/IEC 27001 and 27002 standards which they draw on were

recently revised and more coverage of remote monitoring is needed. Upgrading Part 1 to ISO/TS is proposed and is reasonably straight forward, it is likely that Part 2, which provides an informative example, needs extensive revision and should remain an ISO/TR

TC 215 approved adding a PWI to the work program for upgrading Part 1 to an ISO/TS, with IEC/SC 62A to be advised and invited to participate. It is expected that a draft and form 4 will be ready for NP ballot after discussion at the Nov 2015 meeting.

WG 4 continues to consider the changes needed to Part 2, with a view to making a recommendation to the next TC 215 meeting.

- ***ISO/PWI ISO 20429 .. Principles and guidelines for protection of personal health information*.** TC 215 approved WG 4 recommendation to call NP ballot based on a 36 page draft, prepared by Luuc Posthumus (NL) which seeks to consolidate material in a single international standard encompassing the following existing documents:
  - *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*;

  and drawing on the updated 2013 OECD *Guidelines governing the Protection of Privacy and Transborder Flows of Personal Data*.

  Early positioning of this work relative to Australian circumstances will need meaningful engagement from IT-014 and experts on health information privacy in light of Australian information privacy regimes. It is potentially relevant to Australian participation in international exchange and use of personal health information.
- ***ISO 27799 .. Information security management in health using ISO/IEC 27002 (Second Edition).*** Publication of the second edition of this flagship standard has now been approved in principle by TC 215 following revision to reflect recent changes in the underlying ISO/IEC 27002 information security management standard. Changes arising from the joint ISO/DIS and IEC/CDV ballot (through IEC/SC 62A) are being incorporated, approved by WG4 and also circulated to JTC 1/SC27 and IEC/SC 62A for information.

  The first edition of ISO 27799 was developed with significant Australian input and gave rise to the local adoption AS ISO 27799-2011, which should now be revisited.
- **ISO 21298 .. Functional and structural roles**. This document, first published in 2008 as an ISO/TS, is being upgraded to a full international standard. In response to the DIS2 ballot, the UK remains opposed to a one size fits all standard' for functional structures and roles, given differences in national regimes, legal systems, local responsibilities and legal accountabilities. Norway submitted many comments concerned about mismatches with Contsys and reliance on potentially changing international data sets.

There was extensive discussion of the near impasse over the list of structural roles. No two countries will have same categorisation of clinical staff. From viewpoint of making the standard easier to use and acceptable to national programs, it would be preferable to have a few reasonably generic roles (and perhaps a few well recognised as being needed for special access security), whereas this is inadequate from the viewpoint of someone needing a "palette" of structural roles that can be used to provide a more fine-grained level of access.

A compromise was worked out during the meeting based on use of SNOMED CT personnel categories and this will form the basis of a further revision for DIS3 ballot expected to be issued mid-2015.

- WG4 participated in a joint meeting of several WGs led by JWG 7 to consider the proposed outcomes from the Ad Hoc Group on Health software final report [reported under JWG 7].
- There was a joint session with JWG7 to progress 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*.

The status of the following current WG 4 items was also noted:

- ***ISO 25237 .. Pseudonymisation.*** Updated text from the CD ballot for upgrade of ISO/TS 25237:2008 to a full international standard was agreed by WG 4 and will be the subject of a DIS ballot expected to open in July 2015. This should be of interest in Australia.
- ***ISO 21549 .. Health cards.***
  - ***Part 5: Identification data*****.** Revised 2nd edition of was approved for publication following successful DIS ballot.
  - ***Part 5: Medication data***. Work continues on resolving comments from DIS ballot for revised 2nd edition.
- **ISO 17090 .. Public key infrastructure** (series).
  - ***Part 2: Certificate profile*** **(revised 2nd edition)**. WG 4 accepted the proposed disposition of DIS ballot comments and TC 215 approved it moving to publication.
  - ***Part 5: Authentication using Healthcare PKI credentials.*** The NP ballot for this new part of the ISO 170790 series closed in Feb 2015. The disposition of comments was discussed and revised text is expected for a 2-month CD ballot in mid-2015.
- ***ISO/TS 17975 .. Principles and data requirements for consent in the collection, use, or disclosure of personal health information***. This ISO/TS was approved for publication following a successful third DTS ballot and resolution of comments (which mainly came from Australia and Norway and were addressed).

ISO/DTR 18638 .. Components of education to ensure health information privacy. More work is required to resolve 33 pages of comments from the second DTR ballot. Most of the comments came from Canada, Australia and the UK, with the WG 4 secretariat being tasked to follow up with UK over their negative vote and comments and to organise a teleconference between the project lead, Mee Jeong (KR) and those able to assist with comment resolution.

WG 6 Pharmacy and medicines business**.** Across all sessions, 55 delegates from at least 15 countries and 5 liaison organisations participated in person (plus 3 joining remotely by Webex). Matters discussed are reported to have included:

- ***ISO/DIS 17523 .. Requirements for electronic prescriptions***, Progress in resolving over 200 comments from the joint CEN/ISO DIS ballot was presented by Frits Elferink (NL). Some comments (including those from Australia and Germany) are still to be addressed before a revised draft is ready for a final FDIS ballot. TC 215 approved balloting the revised draft, expected to be ready by end-July but CEN may require up to 3 months for translation of the FDIS text, so the 2-mointh FDIS ballot will not be concluded in time for the TC 215 meeting in November. A German request for a second DIS ballot was not accepted by WG 6.

- ***ISO/DTS 19256 .. Requirements for medicinal product dictionaries for clinical care.*** On recommendation of WG 6, TC 215 approved the title of this work item being changed to: ***Health informatics - Requirements for medicinal product dictionary systems for clinical care***.

  The parallel DTS ballot of 2-month in CEN and ISO passed with significant comments. Clarification of the scope, relationship to IDMP and harmonisation of terminology with SKMT were addressed in joint session with WG 3. TC 215 approved the WG 6 resolution to submit a revised draft to a second DTS ballot (closing early August).

- **Identification of Medicinal Products (IDMP) projects.** WG6 devoted considerable time to progressing current work on IDMP projects, specifically the development and approval of IDMP implementation guides and the systematic review and updating of the underlying IDMP standards. The main developments are:

  - ***ISO/DTS 20440 .. IDMP – Implementation guide for ISO 11239*** *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*.

    Passed NP ballot in January with comments mainly from UK, which were reviewed by WG 6. On recommendation of WG 6, TC 215 approved revised draft being prepared and submitted for 2-month parallel ISO/CEN DTS ballot expected to commence in Jul/Aug 2015.

  - ***ISO/DTS 20443 .. IDMP – Implementation guide for ISO 11615*** *data elements and structures for the unique identification*

	and exchange of regulated medicinal product information. Joint with WG2: prEN [WG6N15-028 and WG6N15-029] Passed NP ballot in January with 99 pages of comments, mainly from UK, which were discussed in joint session by WG 6 and WG 2. On recommendation of WG 6, TC 215 approved revised draft being prepared and submitted for 2-month parallel ISO/CEN DTS ballot expected to commence in Jul/Aug 2015. - ***ISO/DTS 20451 .. IDMP - Implementation guide for ISO 11616*** data elements and structures for the unique identification and exchange of regulated pharmaceutical product information. The NP ballot passed with 98 pages of comments. Vada Perkins (US) presented the proposed approach to ballot reconciliation and issues relating to 'specified substances' and an annex on messaging were discussed. On recommendation of WG 6, TC 215 approved revised draft being prepared and submitted for 2-month parallel ISO/CEN DTS ballot expected to commence in Jul/Aug 2015. - ***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.*** The DTS ballot passed with 84 pages of comments (notably from UK, DK and US). Ilaria della Sepia (IT), Herman Diederik (NL) and Lawrence Callahan (US) explained the proposed resolution of comments and consequences for the document. The document is supported by a series of annexes, 4 of which have been completed and 6 more are in development. Following discussion, it was agreed to propose to TC 215 that ISO/TS 19844 proceed to publication with the existing 4 annexes and that a further ISO/CEN joint project be established to work on the first revision to include additional material. These proposals were accepted by TC 215 with the updated text expected to be with ISO/CS for publication in Aug 2015. - ***ISO 11238, ISO 11615 and ISO 11616***. The first revision of these standards is now required, with the publication dates to be synchronised with those for the respective implementation guides. TC 215 approved the WG 6 recommendation that documents be prepared for parallel ballots in ISO/TC 215 and CEN/TC 251 to establish them as PWIs for concurrent revision. - **IDMP roadmap.** A graphical representation was provided that allows a better understanding of the dependencies between the various IDMP projects. It was noted that, in the future, IDMP might need more frequent revision than the normal 5 years. - Joint workshops to progress ISO e-Dispense use cases and requirements for: HL7/FHIR prescription and dispense, HL7/IHE Medication statement, and HL7/FHIR Supply.

- **Proposed full day joint meeting of WG 6, HL7 Pharmacy WG and IHE Pharmacy WG.** This event was being planned for the last day of the May 2015 HL7 WGM being held in Paris and would include:
  - Updating each other on their current and proposed work on pharmacy standardization; and
  - Joint workshops to progress ISO e-Dispense use cases and requirements for: HL7/FHIR prescription and dispense, HL7/IHE Medication statement, and HL7/FHIR Supply.

The status of the following current WG 6 items was also noted:

- ***ISO/DTS 17251 .. Business requirements for the exchange of structured dose instructions for medicinal products.*** The project lead, Scott Robertson (US) presented changes arising from the successful DTS ballot and proposed new text to address unresolved comment reconciliations. A revised draft is to be circulated to WG 6 in Sep 2015, with a view to it being accepted for publication after review and discussion by WG 6 at the November TC 215 meeting in Switzerland.

- ***ISO/DTS 19293 .. Requirements for the record of the dispense of a medicinal product.*** This work item being led by Christian Hay has been placed on hold until the use cases and inputs from the EU Horizon 2020 openMedicine project can be leveraged. [He also gave a presentation on the openMedicine project – see below].

- ***ISO/TR 22790:2007 .. Functional characteristics of prescriber support systems.*** On the recommendation of WG 6, TC 215 approved the proposed revision of this TR being removed from the work program, as WG 6 does not currently have sufficient experts from vendors to support it. The outdated TR remains available and may be revised if interested experts from vendors can be found.

- ***ISO/TS 22224:2009 .. Electronic reporting of adverse drug reactions.*** This ISO/TS is up for revision following review [taking into account a report by Lise Stevens in Dec 2013 comparing it to ICSR reporting requirements in ISO/HL7 27953]. It appears that the only implementations of ISO/TS 22224 are in South Korea. Further feedback is awaited and has not yet been provided. WG 6 supported the continued for revision and the WG 6 secretariat will follow up with the WG 6 membership.

- **ISO/CEN NP/DTR ballot for "Health informatics - Medication Management concepts and definitions"**. On the recommendation of WG 6, TC 215 approved the calling of a parallel NP/DTR ballot for joint work with CEN/TC 251 on a TR to provide an overview of terms and processes relevant to al aspects of medication management. The ballot has been called and closes in early Aug 2015.

- **ISO/DTR 14872 Core principles for maintenance of identifiers and terms.** WG 6 accepted the proposal from the project lead, Lise Stevens (US) that this work remain on hold while the IDMP implementation guides are finalised, noting that WG 6 has until the end of 2016 to complete work on this joint ISO/CEN TR.
- ***ISO/DTS 18062 .. Categorial structure for representation of herbal medicaments in terminological resources*.** This item was discussed in joint session with WG 3 [and is reported under WG 3].

Short update presentations on the following were also given during the WG 6 sessions:

- *"Pharmacovigilance: Information systems and Services"* by Paolo Alcini, Head of Data Standardisation and Analytics, European Medicines Agency – outlining developments to support pharmacovigilance regulation in Europe.
- An update by Christian Hay on the EU Horizon 2020 programme openMedicines project, which was approved by the EC and commenced in January 2015. The main aim is to address the many challenges needing to be overcome to enable ePrescription and the communication of medicines information in cross-border settings. Solutions to most of the technical interoperability problems were demonstrated in the epSOS project; however, there are many regulatory and business practice issues that need to be overcome before such capability can be implemented across Europe. The project will address a range of use cases (such as product substitution) and is expected to leverage TC215 IDMP standards.
- *"Submission of information on medicinal products in the XEVPRM format in accordance with Article 57 of the EU pharmacovigilance legislation - Overview of achievements and next steps"* by Ms Ilaria Del Seppia, Scientific Administrator, Data Standardisation and Analytics, European Medicines Agency – addressing the data requirements for electronic submission, capture and storage of information on medicines marketed in the EU. Discussion particularly focussed on the transition to IDMP and packaging identification issues.
- *"EDQM Standard Terms Database" by Christopher Jarvis – providing an overview and demonstration of the use of the EDQM database, which is under development and may be freely accessed at: https://standardterms.edqm.eu/.*
- *"Cross Reference Tool Japan" by Ms Malin Jakobsson, Product Manager*, WHO Uppsala Monitoring Centre – outlining the issues arising in mapping between IDF codes used in Japan (including some Kampo medicinals and others without English equivalents) and DDE codes used in the VigiBase *and vigiAccess pharmacovigilance tool* used by the WHO.
- *"Overarching structure of IDMP standards and IDMP related issues"* by Mr Andreas Franken (BAH, Germany) presented an overview of the issues faced by small and medium enterprises in transitioning to new IDMP-based regulatory reporting environments for medicinal products.

JWG 1 Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics)**.** Across all sessions, 19 experts from 5 countries (China, Japan, Korea, Malaysia, USA) participated in JWG 1. Sessions were held jointly with the Traditional Medicine Task Force (TMTF) [see below]. The ISO/TC 249 secretariat was officially represented by Ivy Lee.

Matters discussed are reported to have included:

- ***ISO/NP TS 16843-3 Categorial structures for representation of acupuncture -Part 3: Moxibustion***. Following a successful NP ballot and in anticipation of the item being transferred from TMTF, JWG 1 gave instructions for progressing to a working draft to be available for JWG 1 review by end-Aug 2015. TC 215 approved the recommended transfer of the item from the TMTF to JWG 1.

  Work to be carried out on the draft included aligning the definitions of 'acupuncture' and 'acupuncture point' across parts 1, 2 and 3 (also covered by TMTF – see below) and these changes being reflected where the terms are used in the three parts.
- ***ISO/NP TS 16843-4 .. Categorial structures for representation of acupuncture -Part 4: Meridian and collateral channels***. ISO/TC 215 approved the JWG1 recommendation for a 3-month NP ballot targeting a TS (with TC 215 lead). This work item was transferred to JWG 1 from TMTF.
- ***ISO/CD 18668-2 TCM - Coding System of Chinese Medicines – Part 2: Codes of decoction pieces***. JWG 1 was reported to have agreed the disposition of NP ballot comments. A draft was agreed for progression to parallel CD ballot closing in Aug 2015 as a JWG 1 project with TC 249 lead.
- ***ISO/CD 18668-3 TCM - Coding System of Chinese Medicines – Part 3: Codes of Chinese Materia Medica***. NP ballot approved in Jan. A draft was agreed for progression to parallel CD ballots closing in Aug 2015 as a JWG 1 project with TC 249 lead.
- ***ISO/ CD 18668-4 TCM - Coding System of Chinese Medicines – Part 4: Codes of granule forms of individual medicines for prescriptions***. . NP ballot approved in Jan. A draft was agreed for progression to parallel CD ballot closing in Aug 2015 as a JWG 1 project with TC 249 lead.
- ***ISO/AWI 20333 TCM - Coding rules for Chinese medicines in supply chain management***. JWG 1 was reported to have agreed the disposition of NP ballot comments. TC 249 has launched parallel TC 249 and TC 215 CD ballots closing in Aug 2015.

<u>The status of the following JWG 1 items being progressed under TC 249 leadership was also noted</u>:

- ***ISO DTS 18790-1 .. Profiling framework and classification for traditional medicine informatics standards development – Part 1: Traditional Chinese medicine***. The final text was with ISO/CS undergoing publication review [and was published on 08 May 2015].
- ***ISO/DIS 18668-1 TCM - Coding System of Chinese Medicines – Part 1: Coding rules for decoction pieces.*** Parallel DIS ballot commenced in Mar 2015 and closed on 12 Jun.

Traditional Medicine Task Force (TMTF). Across all sessions, 18 experts from 5 countries (China, Japan, Korea, Malaysia, USA) are reported to have participated in the TMTF. Sessions were held jointly with JWG 1 [see above]. Ivy Lee from the ISO/TC 249 secretariat was present as ISO/TC 249 liaison representative.

Note: TC 249 and JWG 1 are concerned with Traditional Chinese Medicine, whereas the TMTF has a wider scope encompassing other forms of traditional medicine including Kampo and traditional Korean medicine as well as TCM. TMTF currently operates through WG 3.

The recommendation of WG 3 and the TMTF from the October 2015 TC 215 meeting in Berlin to form a separate TC 215 WG to address traditional medicine informatics has not yet been addressed by the TC 215 leadership [possibly due to the change of TC 215 chair].

Matters discussed in TMTF are reported to have included:

- ***ISO/NP TS 16843-1 Categorial structures for representation of acupuncture -Part 1: Acupuncture points***. Following a successful NP ballot, which closed in Jan 2015, an approach to reconciliation of comments was agreed with a view to revised draft being provided for DTS ballot in Jul 2015.
- ***ISO/DTS 16843-2 Categorial structures for representation of acupuncture -Part 2: Needling.*** Following a successful DTS ballot, which closed in Jan 2015, an approach to reconciliation of comments was agreed, with a view to revised draft (including updated graphics files) being provided for publication by end-Jun 2015.

  Work to be carried out on the drafts of parts 1 and 2 included aligning the definitions of 'acupuncture' and 'acupuncture point' across parts 1, 2 and 3 (also noted under JWG 1 – see above) and these changes being reflected where the terms are used in the three parts.
- ***ISO/NP TS 16843-3 Categorial structures for representation of acupuncture -Part 3: Moxibustion***. Following a successful NP ballot, TC 215 approved a TMTF recommendation that this item be progressed by JWG 1 [as noted under JWG 1 above].

  ISO/NP TS 16843-4 .. Categorial structures for representation of acupuncture -Part 4: Meridian and collateral channels. TMTF and JWG 1 agreed that this item originally proposed by TMTF would be progressed by JWG 1 and will now progress to NP ballot [as noted under JWG 1 above].

  ISO/PWI TS 16843-5 .. Categorial structures for representation of acupuncture -Part 5: Cupping. ISO/TC 215 approved a TMTF recommendation that this item be added to the WG3/TMTF work program as a preliminary work item (PWI) with documents to be provided for NP ballot by mid-Jul 2015.

<u>The status of the following item was also noted</u>:

- ***ISO/TS 16277-1 .. Categorial structures of clinical findings in Traditional Medicine: Part 1 Traditional Chinese, Japanese and Korean Medicine***. Was reported to be with ISO/CS awaiting publication by ISO/CS, which occurred on 23 Apr 2015.

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

31 delegates from 11 countries participated in most of the JWG 7-only sessions, with more attending the joint sessions with WG 1, WG 2 and WG 4. Significant matters discussed are understood to have included:

- **JWG 7 scope.** At its Nov 2014 meeting in New Orleans IEC/SC 62A agreed the revised scope for JWG 7 as originally agreed by TC 215 in Nov 2014, as follows:

  "Standardization in the area of health informatics and electrical equipment in healthcare where ISO/TC 215 and IEC/SC 62A have identified a need for joint standards development."

  It was noted that the JWG 7 leadership will work with the committee secretariats to update the WG title to reflect this approved scope.

- **Final report and recommendations of the Health Software ad hoc group**

  This work is of major interest to the global health informatics and medical devices communities. The updated final report and recommendations were received and discussed in a joint meeting of WG1, WG2, WG4 and JWG 7 at the April 2015 TC 215 meeting in San Francisco with a series of final recommendations being put to the TC 215 plenary.

  The draft findings of the review, which had been extensively discussed and accepted by ISO/TC 215 at its Oct 2014 meeting in Berlin, had been further refined following discussion at the Nov 2014 IEC/SC 62A meeting in New Orleans and through CIB ballots of IEC/SC 62A and SC 62D.

  There is now general acceptance of the outcomes, with some continuing opposition from interests associated with COCIR and some major medical equipment manufacturers – reflected in some of the comments submitted by the Netherlands and Germany through the CIB ballots.

  Appendix A below contains a further summary of key findings and recommendations from the review.

  Consideration of the recommendations by TC 215 concluded the 2-year review of health software with a focus on health software safety standards and resulted in a proposed architecture/framework for future work being accepted.

In consideration of the findings and recommendations in the report, TC 215 resolved:

- **to plan for the revision of the *IEC/ISO 80001-series***:
  - with its scope being expanded to "IT infrastructure incorporating medical devices or health software" from "IT networks incorporating medical devices";
  - to address risk management within the broader context of IT service management;

- to address necessary key properties and the socio-technical context of use (as identified in the health software report);
- to clarify that these standards address the implementation and clinical use of health IT systems;
- to explore the potential to apply systems engineering concepts to health IT life cycle processes,

with JWG 7 to develop proposals encompassing these requirements for consideration at the Nov 2015 TC 215 meeting in Switzerland.

- that the revision of ***IEC 62304:2006 Medical device software - Software life cycle processes*** should cover health software as recommended in the health software report, with JWG 7 to produce an updated draft ready for parallel CD ballot of TC 215 and IEC/SC 62A by mid-Oct 2015.
- to **consider incorporating the framework presented in the report in the next ISO/TC 215 business plan** and suggesting that IEC/SC 62A similarly consider incorporating it in the next iteration of the IEC/TC 62 business plan.

Other matters addressed by JWG7 included:

- ***IEC/TR 80001-2-8 Application of risk management for IT-networks incorporating medical devices - Guidance on standards for establishing the security capabilities identified in IEC/TR 80001-2-2.***

  On the recommendation of JWG 7, TC 215 confirmed its decision to submit an updated draft of IEC/DTR 80001-2-8 to DTR ballot planned to commence in Jun 2015, subject to the ballot draft including an updated map of requirements to the latest 2nd edition of ISO 27799, currently being prepared for publication.

- **Status and revision of the *IEC/ISO 80001-series.*** JWG 7 is progressing the systematic review, revitalisation and revision of foundation 80001-1 and 80001-2 series of standards, to include fitting within new frameworks for digital health safety, addressing feedback and experience from use of the first editions and making the standards more usable. The current documents in the 80001 (Application of risk management for IT-networks incorporating medical devices) series are:
  - *IEC 80001-1:2010 - Part 1: Roles, responsibilities and activities* [now due for systematic review].
  - *IEC/TR 80001-2-1:2012 - Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples*
  - *IEC/TR 80001-2-2:2012 - Part 2-2: Guidance for the communication of medical device security needs, risks and controls*
  - *IEC/TR 80001-2-3:2012 - Part 2-3: Guidance for wireless networks*
  - *IEC/TR 80001-2-4:2012 - Part 2-4: General implementation guidance for Healthcare Delivery Organizations*

- *IEC/TR 80001-2-5:2014 - Part 2-5: Application guidance - Guidance for distributed alarm systems*
- *ISO/TR 80001-2-6:2014 - Part 2-6: Application guidance - Guidance for responsibility agreements*
- *ISO/TR 80001-2-7:2015 - Application guidance - Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1*

and, the following still in preparation:

- IEC/DTR 80001-2-8 - Guidance on standards for establishing the security capabilities identified in IEC/TR 80001-2-2 [DTR ballot opened on 26 Jun 2015]
- IEC/NP TR 80001-2-9 Guidance on security assurance cases [passed NP ballot in Jun 2015 with CD now being prepared].

- **JWG 7 project teams to progress key initiatives**

  JWG 7 has formed two project teams to meet by teleconference to advance work required to implement outcomes of the health software report.. One team will advance NP(s) for new health foundation document(s) needed to integrate standards for health software and the other will address the proposals for the revision of the IEC 80001-series.

  Australian experts recognised for their contributions to the health software work included A/Prof Trish Williams, Kathy Dallest, and Dr Vince McCauley. Along with IT-014 chair, Richard Dixon Hughes and Edmund Keinast (NEHTA) they are continuing to contribute to the follow-up tasks needed to implement the associated TC 215 resolutions.

<u>The status of the following item was also noted</u>:

- ***IEC/CD 82304 -1 Health Software – Part 1: General requirements for product safety***. Progress has been slow since the CD ballot was completed in Feb 2014. Work has been deferred until completion of the health software review, with the delay being a source of concern to COCIR. Aiming for DIS ballot mid-2015. The existence of the work item has raised concerns among some concerned about potential impact on clinical innovation including the International Liaison of Pathology Presidents. IT-014 is well positioned to help ensure that all competing interests are addressed as the work progresses.

	JIC - Joint Initiative Council for Global Health Informatics Standardization Strategic discussion at JIC was led by the new chair, Don Sweete (CEO of IHTSDO) and centred on making a clear statement of common commitment and purpose and preliminary discussion of the steps needed to progress a potentially more active role for the JIC as the global body to which national governments and other agencies (sometimes global) could reach out to discuss and manage activities to ensure collaboration and interoperability between health informatics standards. This aim was summarised in the San Francisco declaration: *"The JIC will contribute to better global patient health outcomes by providing strategic leadership in the specification of sets of implementable standards for health information sharing."* All member SDOs (CDISC, CEN/TC251, DICOM, GS1, HL7, IHE, IHTSDO, ISO/TC215) were present along with the JIC Secretariat (IHTSDO), CAG 3 leadership team and an observer from IEEE. The focus of meeting was to discuss and agree strategic directions to meet the challenges for JIC and its membership, agreed next steps included: • Approval of the JIC Strategy and determining next steps to formalize the cooperative processes needed to get on with the work. • Developing a Business Plan covering a two-year period to be refreshed annually and include resource and funding requirements by all SDOs. • Completing an Interoperability Road Map for 2015-2017 that outlines key target achievement dates • Reviewing business models to drive the transformation of the JIC to enable achievement of the proposed new strategic direction • Completion and roll out of a new marketing and communications plan. RDH also reported on progress updating the JIC Charter, which was completed ready for execution in June. More opportunities for joint work continue to be identified.
Other Observations/Comments	**Disruptions due to illness and unavailability**. There were quite a few disruptions to the planned schedule of TC 215 and its WGs due to key personnel falling unexpectedly ill or being unable to attend, including: • Mike Glickman (TC 215 Chair), who was delayed due to injury and missed the JIC on Sunday and for the executive leadership meetings on the Monday (he participated for the rest of the meeting). • Beatriz de Faria Leao (WG 1 Vice Convener); Marion Lyver and Sun Ju Ahn (WG 1 project leads) – both unable to attend due to injuries. • Gary Dickenson (limited availability to present WG1 project work while acting as WG 2 convenor); **WG1 Secretariat**. The Standards Australia contribution of Manjoo Lalwani to provide the WG 1 secretariat was greatly appreciated by WG 1 and the wider TC 215 community.

Key Items/Actions for Australia	**WG1 Secretariat**. Manjoo Lalwani continues to service the TC 215/WG 1 secretariat. Richard Dixon Hughes as IT-014 Chair and Head of Delegation and Heather Grain (WG3 Convenor and IT-014 Vice-chair) will provide Manjoo with any required advice on TC 215 matters. **13606 .. EHRcom** [WG1]. Australia needs to be prepared to work on revision of 13606 parts 1 to 5 and contribute to the development of the CD through its experts and to the resulting DIS ballot though IT-014. ***IWA on Community-based integrated health and care services for aged societies.*** In addition to being discussed in WG 1 (see above), on 08 Apr 2015, the TC 215 secretariat sought initial comment (by 30 Apr 2015) on this proposed IWA and the associated Hitachi suggestion for TC 215 work on an *"Information model and reference architecture for health guidance service"*. In our response, Australia noted that, although linked, the IWA and the Hitachi proposal need to be addressed separately as they will have significantly different content on different time-lines and any work by TC 215 needs to support integration with existing e-health approaches. Australia supported the resolution for Prof Stephen Kay (UK), Chair of TC 215/WG 1 to attend the workshop on behalf of TC 215. Dr Isobel Frean, Head of BUPA aged care in Australia, who is known to IT-014 and has worked on related standards in the past, was also advised of these developments to explore the potential to draw on her knowledge and associations as the topic develops. In total, Australia submitted 11 pages of comment. IT-014 will be involved in reviewing feedback from the workshop and in developing a position on the Hitachi proposal for consideration at the next TC 215 meeting in Nov 2015. **ISO/FDIS 13940 .. System of concepts to support continuity of care (Contsys)**. Australia submitted many comments in response the DIS ballot, which closed in 2013. IT-014 now needs to respond to the recently released parallel ISO/CEN FDIS ballot by 18 Aug 2015. **ISO/PWI TS 20428 .. *Metadata for describing structured genomic sequencing information in electronic health records***. IT-014 now needs to respond to the recently released NP ballot by 17 Aug 2015. Australian input needs to take into account recent work by RCPA in Australia and NZ on the content and presentation of genetic test reports. **12967 Health informatics – Service architecture [HISA]**. [WG1] Australia should support systematic review of this cornerstone 3-part suite of service architecture standards, considering potential incorporation of work from and implications for SA HB 137, 138 and 321 and/or the potential for local adoption of the revised edition of 12967. **PWI on Trans-national health record.** Development of a new work item proposal by WG2 in this area needs to take into account current projects being initiated and contemplated in HL7 International, US/DHHS, US/ONC, EC/eHN and JIC following the US-EU Trillium Bridge project investigating the potential exchange of health summary information between the US and EU and between EU countries. It is in Australia's

	interests that work in these areas move toward a truly global perspective and avoid unnecessary overlap and duplication. As the proposal is developed, we should use our influence to encourage the development of a TR that defines and allocates appropriate standardization activities. **ISO/TS 13131:2014 .. Telehealth Services – Quality Planning Guidelines**. There was significant Australian input into this document, which was published in Dec 2014. It has since been suggested by several credible stakeholders that IT-014 should consider local adoption. **ISO/AWI TR 20055 .. Person-owned document repository for PHR applications and health information exchange.** As nominated expert on this WG 2 project, RDH needs to follow up with project lead, Prof Mr. Byoung-Kee Yi (KR) on plans for finalisation of document for DTR ballot. **PWIs on use of terminology capacity assessment** [WG3]. Heather Grain is leading work on PWIs to develop: • a multi-part series of ISO/TS PWIs on **healthcare value domain content** provisionally addressing: Design and requirements; Governance; and Quality assessment; and • The initial part of an ISO/TS on: **workforce for EHR semantic content implementation** – dealing with needs, roles and skills Other Australians with an interest should be informed of the opportunity to participate via fortnightly TC 215/WG3 teleconferences developing these items for consideration at the November 2015 meeting of TC 215 in Switzerland. **Review of the family of terms and concepts associated with "health records".** Heather Grain is leading this review on behalf of ISO/TC 215/WG 3, /WG 1 and the SKMT management committee to resolve and make recommendations concerning the many different definitions for terms such as "health record", "medical record" and "electronic health record" in international standards . This work is directly relevant to Australia, particularly if different definitions to those used in our existing AS2828-series emerge, in which case these documents should be modified to reflect international best practice. **Recent ISO/TC 215/WG 3 publications for IT-014 to consider considered for Australian adoption/ adaptation include:** • *ISO/TR 12300:2014 Health Informatics – Principles of mapping between terminological systems* • *ISO/TS 17439:2014 Health Informatics – Development of terms and definitions for health informatics glossaries* • *ISO/TR 12310:2015 Health Informatics – Principles and guidelines for the measurement of conformance in the implementation of terminological systems.* **Analysis of WG3 scope and intended new work items**. IT-014 to review, identify opportunities for constructive participation in the strategic standards projects identified by WG 3 and provide feedback to be requested of NMBs.

ISO/ AWI/ DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems. Given the significant place of herbal medicaments and Traditional Medicine education in Australia this work should be actively supported and reviewed both by IT-014 and by HE-031 (Traditional Chinese Medicine) and, when complete, it has been suggested that it should be considered for adoption in Australia.

ISO/NP TS 20405 .. Framework of event data and reporting definitions for the safety of health software. This is expected to be a significant contribution by TC 215 to the sensible, cost-effective management of health software safety. With the involvement of appropriate interests and experts through IT-014, it has the potential for parallel Australian development and/or adoption.

Australian experts nominated for the project are: A/Prof Trish Williams (ECU), Ms Kathy Dallest (UoQ) and Mr Edmund Keinast (NEHTA).

ISO 27799:2008 .. Information security management in health using ISO/IEC 27002 (2nd edition). Publication of the second edition of ISO 27799 has been approved in principle by TC 215. IT-014 should revisit the local adoption, AS ISO 27799-2011 in the light of changes to ISO 27799, ISO/IEC 27002 and also NEHTA work and government and industry guidelines on information security.

ISO 25237 .. Pseudonymisation. IT-014 to respond to DIS ballot expected to open in July 2015. This should be of interest for Australia as a potential direct-text adoption.

ISO/PWI ISO 20429 .. Principles and guidelines for protection of personal health information. IT-014 will need to consider how to respond to the TC 215/WG 4 NP ballot anticipated mid-year, in particular the extent to which it conforms to the APPs, professional guidelines on health information privacy, recent extensive work on health information privacy in Australia and previous work on AS 4400 (withdrawn). Contemporary issues such as the emergence of trans-border flows arising from use of cloud-based services are among the matters to be taken into account.

ISO 17090-2 .. Public key infrastructure - *Part 5: Authentication using Healthcare PKI credentials.* IT-014 response to proposed CD ballot is expected to be required soon. Peter Williams and A/Prof Trish Williams are nominated Australian experts.

ISO/TS 17975 .. Principles and data requirements for consent in the collection, use, or disclosure of personal health information. This ISO/TS is now proceeding to publication following a successful third DTS ballot, which resulted in many comments from Australia. Once published, it should be reviewed by IT-014 in conjunction with relevant Australian experts to determine whether or not it is suitable for Australian adoption and, if not, what changes might be proposed in any future revision or upgrade to a full international standard.

	ISO 21298 .. Functional and structural roles. [WG4] Australia was involved in the authorship of the original TS published in 2008. The revised draft IS is expected to circulated for a third DIS ballot once significant changes to the document are completed. IT-014 will need to consider the changes and the Australian response. ***ISO/DTS 19256 .. Requirements for medicinal product dictionary systems for clinical care.*** Australian response to second DTS ballot is required by early August 2015. ***ISO/DTS 20440, ISO/DTS 20443 and ISO/DTS 20451 - IDMP Implementation guides.*** Australian response to DTS ballot will be required in 2015Q3. Australia abstained on the NP ballots and should consider doing so again unless regulatory and/or industry stakeholders become actively involved. **ISO/CEN NP/DTR ballot for "Health informatics - Medication Management concepts and definitions"**. Australian response to NP ballot is required by early August 2015.. **Health informatics standards to support traditional medicine.**. Australia has an active role in the professional development and recognition of complementary and traditional medicine and has active practitioner communities, particularly in TCM, as reflected by the formation of committee HE-031. With the establishment of ISO/TC 249 and an increasing number of international ballots from both TC 215 and TC 249, it is recommended that relevant office bearers, experts and SA project managers of IT-014 and HE-031 confer on establishing a more effective process for providing Australian input to these ballots. **Standards on safety of health software and report of the Health Software Ad hoc Group** [JWG 7]. Following 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) to the upgrade of are to be noted and monitored by IT-014 and HE-003. (See Appendix A for a summary of the outcomes of the review). ***IEC/CD 82304 -1 Health Software – Part 1: General requirements for product safety***. IT-014 needs to contribute to this work and, I light of concerns of the ILPP and other clinical innovators to help ensure that all competing interests are addressed as the work progresses.
Status of the work	See the reports under each individual WG for information on the status of work items currently under development and for information about upcoming ballots. In addition, TC 215 has completed or published the following documents since mid 2014. • *ISO/HL7 10781 HL7 Electronic Health Records - System Functional Model, Release 2* (EHR-S FM R2). Following successful FDIS ballot, final documentation provided to ISO/CS on 2015-04-11 (release may be delayed while formatting issues resolved).

- *ISO/IEEE 11073-10442:2015 .. Personal health device communication - Part 10442: Device specialization - Strength fitness equipment*. Published 2015-03-02.
- *ISO/TR 12300:2014 .. Principles of mapping between terminological systems*. This was published 2014-11-10. Heather Grain (AU) was project leader. Potential for AU adoption.
- *ISO/TR 12310:2015 .. Principles and guidelines for the measurement of conformance in the implementation of terminological systems*. Published 2015-05-22. Potential for AU adoption.
- *ISO/TS 13131:2014 Telehealth services – Quality planning guidelines* Published 2014-10-10, with Alan Taylor (AU) as final project lead. AU adoption has been suggested.
- *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 16277-1:2015 .. Categorial structures of clinical findings in traditional medicine -- Part 1: Traditional Chinese, Japanese and Korean medicine*. Published 2015-04-23.
- *ISO/HL7 16527 .. HL7 Personal Health Record System Functional Model, Release 1* (PHR-S FM R1). Approved for publication with final documentation received by ISO/CS on 2015-04-01 (may be delayed while formatting issues resolved).
- *ISO 17090-4:2014 .. Public key infrastructure - Part 4: Digital Signatures for healthcare documents.* This part 4 was published 2014-09-24 as a first edition. Australia contributed significantly to various parts of ISO 17090 over the past 15 years or so. Plans for national adoption were overtaken by national eHealth initiatives but should be reviewed in light of emerging developments and needs.
- *ISO/TR 17439:2014 .. Development of terms and definitions for health informatics glossaries* Published 2014-11-14. Heather Grain (AU) was project leader. Could be considered for AU adoption although primarily affects standards development work.
- *ISO/TR 17522 .. Provisions for Health Applications on Mobile/Smart Devices*. Approved for publication with final documentation received by ISO/CS on 2015-06-18. A general descriptive work summarising the outcomes of preliminary online research into the subject (of limited value for AU adoption).
- *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 18790-1:2015 .. Profiling framework and classification for Traditional Medicine informatics standards development -- Part 1: Traditional Chinese Medicine*. Approved for publication with final documentation received by ISO/CS 2015-05-08.
- *ISO/TR 19231:2014 .. Survey of mHealth projects in low and middle income countries (LMIC)*. Published 2014-11-14. A general descriptive work summarising the outcomes of preliminary online research into the subject.

	• *ISO 22077-1:2015 .. Medical waveform format -- Part 1: Encoding rules*. This first part of a 3-part series was published on 2015-04-16 • *ISO/TS 22077-2 .. Medical waveform format - Part 2: Electrocardiography*. Approved for publication with final documentation received by ISO/CS 2015-06-25. • *ISO/TS 22077-3 .. Medical waveform format -- Part 3: Long term electrocardiography*. Approved for publication with final documentation received by ISO/CS 2015-06-25. Applicability of ISO 22077-series to AU is not presently known. • *ISO 22600-1:2014 .. Privilege management and access control - Part 1: Overview and policy management*; • ISO 22600-2:2014 .. Privilege management and access control – Part 2: Formal models; and • *ISO 22600-3:2014 .. Privilege management and access control - Part 3: Implementation*. The 3 parts of ISO 22600 were published together on 2014-09-22 having been upgraded from an ISO/TS. It is recognised as a significant standard that could possibly form the basis of a relevant AU standards publication, depending on national requirements. • *ISO/TR 28380-3:2014 .. IHE global standards adoption - Part 3: Deployment. Pu*blished 2014-12-18. Limited value in AU adoption. • *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; and • *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] Potential future AU adoption of IEC/ISO 80001-series, IEC 62304 and IEC 82305 deserves IT-014 (and HE-003) consideration. Several Australian experts continue to be involved in international work on these standards, which are being revised following systematic review and the health software report by JWG 7. IT-014 should consider whether any of these (or other current work items reported above) are suitable candidates for local adoption or adaptation..
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 – FINAL 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.

At the end of a two-stage process over 2 years, the Ad hoc Group presented its draft final report to the October 2014 meeting of ISO/TC 215 in Berlin with the findings and recommendations being generally accepted by the TC 215 community. The report was then presented to and discussed at the November 2014 meeting of IEC/SC 62A.

The draft final report was then circulated to the membership of IEC/SC 62A and IEC/SC 62D subcommittees for Committee Information Ballots (CIBs). In response to the IEC/SC 62A CIB, comments were provided by 6 NMBs (Germany, Japan, the Netherlands, Sweden, the United States and Portugal). The Netherlands, South Africa, Sweden and Portugal also responded with comments via IEC/SC 62D.

There was some concern, particularly from the Netherlands and Germany that adopting the recommendations in the draft report did not provide sufficient grounds for a sufficiently broad and cohesive approach and may lead to an plethora of overlapping standards. Others (and the parent committees) generally supported the report and its findings.

The Ad hoc Group took on board the feedback and prepared their final report, which was presented to and then finally accepted by TC 215 at the Apr 2015 meeting in San Francisco.

The final report now reflects feedback received during and following the Oct 2014 ISO/TC 215 and Nov 2014 IEC/SC 62A consultation and consideration of the comments received via the CIB ballots. In particular, the report's authors have taken on the need to build on and re-purpose the existing collection of health software standards, rather than to create any new standards.

The focus of the Group's work for the first 12 months was on common concepts and definitions for health software safety and was progressed in parallel with initial work on 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.

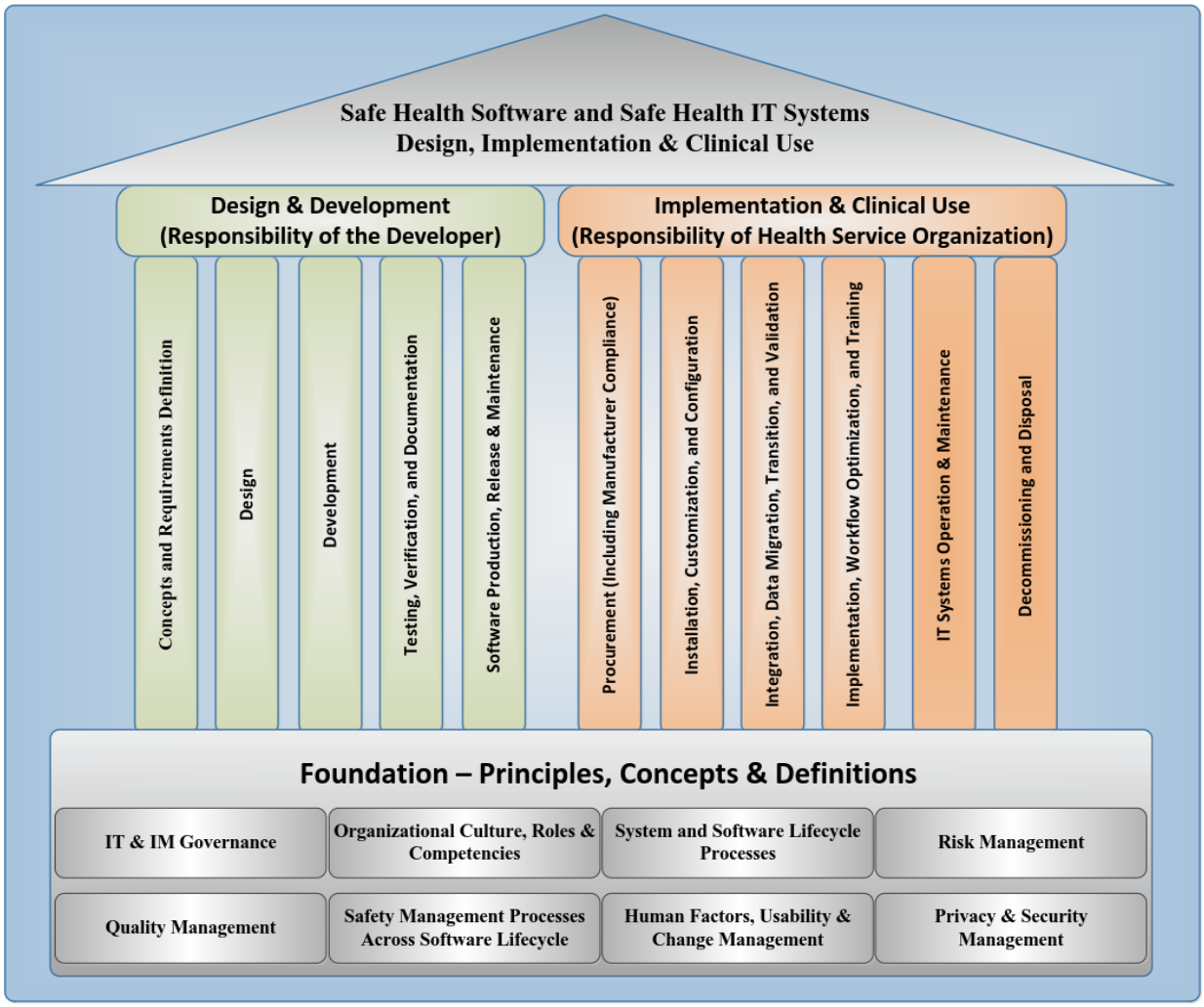
As guiding principles, it was determined that an effective architecture/framework guiding further development of standards for health software and health IT systems should:

- *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 safety (which includes but is broader than the provision of "patient safety" in "health care delivery organisations"). The way in which the framework will apply to various processes and activities are illustrated in the following figure (sourced from the final report of the ad hoc group):



Recommendations in relation to the proposed roadmap to implement the framework were considerably modified from those in the draft report and are now more operational and focussed on building on existing standards, as follows

- ***Recommendation 1*** [**in relation to foundational principles, concepts and definitions**] *Explore development of a document or documents addressing the common principles, concepts, and terms necessary for optimizing the safety of health software and health IT systems across their lifecycle in today's complex socio-technical environment; with JWG 7 preparing the draft NP form or forms necessary to propose this work for consideration at TC215 & SC62A's November 2015 meetings.*

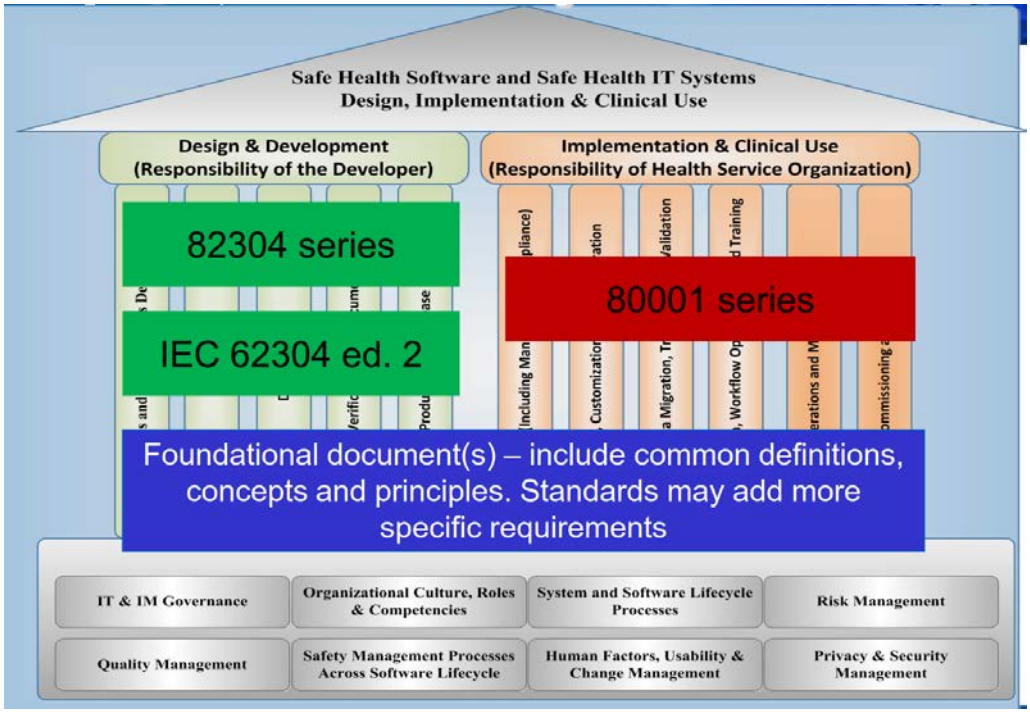
  Note: Once this is agreed upon by TC 215 & SC 62A, then with their mutual agreement this could be proposed to the respective standards management boards that this be considered as a policy document.

- ***Recommendation 2*** [**in relation to safety standards for health software design and development**]
  Develop the revision of IEC 62304 to cover the scope required for health software.

- ***Recommendation 3*** **[in relation to safety standards for health IT system implementation and support]**
  Prepare an NP or NP's for consideration at TC215 & SC62A's November 2015 meetings for broadening the scope of the 80001 series to cover the content required for the Implementation and Use phase (see section 3.3) by:
  - *expanding the scope from networks incorporating medical devices to IT infrastructure incorporating medical devices or health software*
  - *expanding the scope to address risk management within the broader context of IT service management*
  - *addressing the necessary key properties*
  - *addressing the socio-technical context of use*
  - *exploring the need for applying system engineering concepts to health IT life cycle processes.*

- ***Recommendation 4*** **[in respect of applying the framework]**
  That both TC215 and TC62 consider - incorporating the framework presented in this report into their upcoming business plans, and - requesting all new projects that directly address safety of health software or health IT systems to provide an explanation on their NP form as to how the proposed work aligns with the framework of the accepted report.

In the JWG 7 report to TC 215 plenary, the potential alignment of the framework to health software standards was illustrated as follows:



There was general acceptance of the findings and recommendations by TC 215

INTERNATIONAL DELEGATES MEETING REPORT

Date	26 April 2015		
Delegate(s) proposed by Projects Manager	Manjoo Lalwani		
Standards Development Organsiation (SDO)	ISO/TC215		
Delegate Details	*For a multi person delegation please provide details of the head of delegation only.*		
Name	Heather Grain		
Position/Title	CIO		
Company	eHealth education		
Postal Address	33 Thurso Sreet, Malvern East Vic 3145		
Email Address	h.grain@ehe.edu.au or heather@lginformatics.com		
International Committee Details	ISO TC215, WG3, CAG 1, CAG2, CAG3, WG1, WG6		
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	Type date (s) of meetings – Monday 20th April (CAG1, CAG2, CAG3) Tuesday 21st April Plenary (1 quarter), WG3 (3 quarters), Wednesday 22nd April WG3 (2.5 quarters) WG6 (1 quarter), WG1 (part of 1 quarter) Thursday 23rd April WG3 (4 quarters) Friday 24th April Team Meeting and Plenary		
Venue Details	Marines' Memorial Club and Hotel, San Francisco, USA		
Australian delegates	Heather Grain (Convenor ISO/TC 215/WG 3 Semantic content) Richard Dixon Hughes (Australian HoD)		
Purpose of Meeting	The TC is moving towards the development of a new approach to standards development – creation of ISO standards which indicate the 'bundle' of standards required for a specific use case – including standards produced by others such as HL7, IHTSDO, etc. With this requirement in mind WG3 reviewed it's Scope and identified gaps in standards required to support semantic content development, implementation and quality assessment generally but also for reference in such 'bundles'. The meeting also progressed a number of active work items detailed below.		

Attendees at the meeting	A detailed list of individual attendees is not required. Please provide details of countries represented by delegates/delegations and mention any special guests/speakers at the meeting(s). General: presentation from Dr Scott Young, Associate Executive Director , Clinical Care and Innovation, The Permanente Foundation (an organisation within the Kaiser Permanente group). In WG3: • USA, • Australia, • Brazil, • Japan • Korea, • China, • Malaysia, • Germany, • UK (via teleconference) • IHTSDO • HL7
Key items discussed	**WG3 Scope and Planning – Led by H. Grain (Australia)** The scope of the WG and terms of referenced were reviewed and not changed. A detailed framework of the scope of work for WG3 was developed and modified to a short summary. Full details will be further developed after the meeting. The Framework identifies the scope of semantic content in two axes: *Stages of Health Informatics* – Design, governance, implementation, and quality *Areas of Semantic Content* – General • Terminology Models and Structures • Data Specifications and metadata repositories • Terminology Content (Using terminology in healthcare systems) • Terminological Resources (code systems …) • Workforce Areas of Semantic Content – Specific Domains • Mapping • Glossary • Knowledge Representation • Big Data The diagram below shows the framework and indicates areas which have • Existing publications (green) • Current work (yellow) • Priority Developments (Red) • Other Developments (Purple) • Areas currently covered by others (Grey)

Existing publications and current work were put into the framework, gaps identified. Significant discussion occurred on the gaps and identification of priority work items needed to support eHealth by the countries and Liaison organisations present. A beginning on Form 4's and project outlines for the priority area work items was made. Additional discussion of potential work items (lower in priority at the moment) were identified. These are listed below. WG3 will continue to develop these materials via teleconference over the next few months.

Semantic Content area	*Stage of Use*			
	Design / Requirements	*Process / Governance*	*Implementation / Use*	*Quality*
Terminology Models / Structure	**IS (Conformance)**	**IS (conformance)**	TR - Guidance	
Data Specs	IS (Conformance)		IS (conformance)	
Terminology Content (use)	TS Design of value domain content	TS Governance of value domain content		TS Quality measures for value domain content
Terminology resources		TS Guidance	TS Terminology Implementation Maturity Model	
Workforce	TS – 1: Workforce Needs, Roles and Skills for eHR semantic content implementation		TS	TS
Mapping	TR - conformance	TR - conformance		TS Quality Assurance Measures for Maps in healthcare
Glossary	TS - conformance			TS - conformance
Knowledge representation	TS	TS	**Literature** Need to cover EHR	
Big Data	TR		TS	TS

Priority Work Areas (for which business cases are developed or in development)

Terminology Content (using terminologies in healthcare systems)

- TS – Part 1 Design of value domain content
- TS – Part 2 Governance of value domain content
- TS – Part 3 Terminology Implementation Maturity Model
- TS – Part 4 Quality measures for evaluation of value domain content

Workforce

- TS – Part 1 Workforce needs, roles and skills for EHR semantic content implementation.

	Work on future plan Workforce • TS – Part 2 Certification of semantic content competence in healthcare • TS – Part 3 Evaluation criteria for educational programs in semantic content for healthcare • TS – Part 4 EHR semantic content team workforce capacity evaluation Knowledge Representation • TS – Part 1 Design of knowledge representation for use in healthcare • TS – Part 2 Governance of knowledge representation resources for use in healthcare Big Data • TR – knowledge representation impacts upon big data • TS – How to go from data to information to minimize loss or change of meaning. • TS – Quality assessment of knowledge represented through big data
	Work Items **17115:2007 Vocabulary of Terminological Resources revision** – incorporating EN 12264 Categorial Structures for health care. This work is being coordinated and collaboration between the expert team to undertake the following activities: – Review of definitions and update after SKMT analysis and ontological review – Heather Grain (Australia) – Review of Categorial Structures to incorporate with the definition elements – Dr Y. Hirose (Japan), A. Orlova (USA) – Document to be prepared for committee review by the end of August for active discussion at the next meeting. This work item is being led by H. Grain and Y. Hirose. **13940 ContSys** – FDIS ballot in preparation –there have been significant formatting issues at ISO but these will hopefully be resolved shortly. **ISO 13120 Syntax to represent the content of healthcare classification systems (ClamI)** A new work item proposal came forward to revise this international standard to incorporate changes identified through use. This work is used widely in Europe to publish classifications in a manner suited to support 'ebook' use and database management of classification systems. This vote will come through to Australia where I recommend it be supported as the changes are highly functional and required to support usability. It is intended that updated documentation will be provided before the next meeting and that that meeting will be in a position to request a DIS ballot. Though I believe this work is of interest to Australia I am unaware of it being used in Australia.

	ISO/DIS 16278 Categorial structures for terminological systems of human anatomy submission for IS publication This work will go to publication after this meeting following modifications to definitions required to dispose comments – (including comments from Australia) Though internationally useful to support harmonised and consistent terminology development through terminology model consistency Australia does little of this type of activity. The standard could be adopted in Australia should it be determined that such activities are likely to be undertaken and therefore such adoption would be of value. ***ISO/ AWI/DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems*** Discussed with WG6 and WG3. This item has highlighted the lack of terminological principles in pharmacy based requirements which have not harmonised previously with terminology content for pharmacy (WG6). This work item has served to bring much greater understanding of these issues and needs. This meeting recognised that a terminology model (such as categorical structures) requires some alternative approaches and structures and needs to conform to existing definitions and processes in international terminology. It was agreed that the comment disposition be accepted and that the document go to a second DIS ballot. It was also agreed that potential new joint work item will be discussed further at the next meeting – this suggested item will provide guidance on the different information and terminology models and how they are used together. Given the significant place of herbal medicaments in the Australian healthcare system, and the strong place of Traditional Medicine education in Australia this work item should be actively supported and reviewed both by IT-014 and by HE-031 (Traditional Chinese Medicine). When complete this work should be adopted by Australia. ***ISO 13582:2013 Sharing of OID registry information*** This work item has proven highly useful in Europe and the Americas and this active use has identified a single correction needed for functionality. The document is presented for minor revision – modifying 'scopingOrganization' to required rather than mandatory throughout the document This means that scopingOrganisation will no longer always have to be present and conformant, but that when present musts be conformant. When this revision is changed IT-014 should consider whether adoption of this standard should be undertaken in Australia. **WG1: Terms and Definitions in the Family of Health Records** Heather Grain was asked to lead this discussion as the international leader of the Standards Knowledge Management Tool Glossary initiative of the JIC. This activity stemmed from clarification work undertaken in Australia and is based on a detailed ontological review of the terms used to describe different words associated with health records, including medical records, personal health records, electronic health records, digitized records and many variations of these terms. The document identifies suggested preferred definitions as well as the rationale behind that suggestion. WG1 members will review and provide comments upon this document with a view to establishing an international vote on updated suggestions and to be able to

	move those suggestions to preferred standard within the SKMT. This work is of direct interest to Australia. Should different definitions to those used in our existing AS2828 series these documents should be modified to reflect the decisions of this international voting. ***Traditional Medicine Taskforce*** Much of the work of this Taskforce is to progress a limited number of current work items, and to determine which work items should be led by the JWG1 of TC215 – this group is joint with TC249 Traditional Chinese Medicine. Specific items discussed at this meeting include: **ISO/DTS 16843 – Part 1 Categorial structures for representation of acupuncture – Part 1 Acupuncture points (body system)** This work item requires work in the definitions area which is being completed. The work item will be sent out for a 2 month DTS ballot as a result of this meeting. It is expected that the work item will begin ballot around 24th of October 2015. This work will therefore not be discussed at the next meeting in Bern in November. **ISO/DTS 16843 – Part 2 Categorial structures for representation of acupuncture – Part 2 Needling.** This work is progressing well and will be sent for a 2 month DTS ballot no later than 20th of July 2015. **ISO/DTS 16843 – Part 3 Categorial structures of representation of acupuncture – Part 3 Moxibustion** The meeting moved this work item from WG3 to JWG1. **JWG1 – Joint initiatives TC215 and TC249** This group met with the Traditional Medicine Taskforce Members. **ISO/PWI/16843-4, health informatics: Categorial structures for representation of acupuncture, Part 4: Meridian and collateral channels** This project is assessed to be a potential JWG1 project and is intended to be moved to JWG1.
	Published ISO/TR 12300 Health Informatics – Principles of mapping between terminological systems (H. Grain – Australia Project Leader) ISO/TR 17439 Health Informatics – common glossary metadata requirements and maintenance process (H. Grain – Australia Project Leader) ISO/TR 123100 Health Informatics – Principles and guidelines for the measurement of conformance in the implementation of terminological resources ISO/TS 17938 Health Informatics - Semantic network framework and coding of Traditional Chinese Medicine language system ISO/TS 17948 Health Informatics - Traditional Chinese medicine literature metadata ISO/TS 17939 Health Informatics - Profiling Framework and classification for traditional medicine informatics standards development – Part 1 Traditional Chinese Medicine

Other Observations/Comments	Include brief summary for items such as: • Publications for consideration for Australian adoption / adaption - ISO/TR 12300 Health Informatics – Principles of mapping between terminological systems - ISO/TR 17439 Health Informatics – Common glossary metadata requirements and maintenance process - ISO/TR 123100 Health Informatics – Principles and guidelines for the measurement of conformance in the implementation of terminological resources • Comments on other issues such as: - In WG3 Australia has very strong support of the community both in the general WG3 and also in the traditional medicine area. Our views are seriously considered and listened to – we therefore have significant influence in this area. • Australia's contribution at the meeting was well received, but coverage was inadequate to fully represent the interests of Australia, in particular activities in the Security WG. • The process of resolution processing for this meeting was a significant difficulty. Though WG3 provided our resolutions and questions on the Tuesday and Wednesday – we were given resolution wording on Thursday which was used to prepare the resolutions. These were reviewed early on Friday morning but at the meeting the ISO representative required changes. This was a poor process which confused the plenary and wasted considerable time. I am undertaking the development of a more specific written document of guidance on words and process which should alleviate this problem in future – my offer to produce such a document has been welcomed by TC215 secretary.
Key Items/Actions for Australia	Items Australian delegates have been asked to progress Lead the framework of standards for semantic content including preparation of outline documentation with WG3 and form 4's for each of the following • TS – Part 1 Design of value domain content • TS – Part 2 Governance of value domain content • TS – Part 3 Terminology Implementation Maturity Model • TS – Part 4 Quality measures for evaluation of value domain content • TS – Part 1 Workforce needs, roles and skills for EHR semantic content implementation • Leader of international glossary harmonisation work (not a formal work item but ongoing activity) • Leader of ISO 17115 revision

Items that may have impact on Australia including details information that aids Australian suppliers of goods and services in improving their export potential

- The set of new standards being developed are likely to be used to assess vendor products as they are all targeting compliance statements.
- These work items will also, or should, impact decision makers in healthcare and designers and users of data sets and data specifications of any type but particularly those in EHR implementations or data extracted from such implementations.

Recommendations, with reasons, for ay forthcoming voting, etc.

Review WG3 Framework and identify priorities for Australia

IT14, state jurisdictions and national Department of Health as well as ACHI, HIMAA and other professional bodies.

ISO 13120 Syntax to represent the content of healthcare classification systems (Claml)

A new work item proposal came forward to revise this international standard to incorporate changes identified through use. This work is used widely in Europe to publish classifications in a manner suited to support 'ebook' use and database management of classification systems. This vote will come through to Australia where I recommend it be supported as the changes are highly functional and required to support usability. It is intended that updated documentation will be provided before the next meeting and that that meeting will be in a position to request a DIS ballot. I understand that this work is not used to publish ICD-10-AM it may be used by eBook vendors and if to be relevant internationally for those using ICD-10-AM in other countries should be considered in Australia.

ISO/ AWI/DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems

This work impacts vendors and users of pharmacy concepts in systems and should be reviewed by our stakeholders in this area. It would be helpful to ensure that the community in Australia understand the differences between information model and terminology model and provide relevant comments. This work should be actively reviewed both by IT-014 and by HE-031 (Traditional Chinese Medicine). When complete this work should be adopted by Australia.

ISO 13582:2013 Sharing of OID registry information

This work item has proven highly useful in Europe and the Americas and this active use has identified a single correction needed for functionality. The document is presented for minor revision – modifying 'scopingOrganization' to required rather than mandatory throughout the document This means that scopingOrganisation will no longer always have to be present and conformant, but that when present musts be conformant.

	When this revision is changed IT-014 should consider whether adoption of this standard should be undertaken in Australia. Such adoption would support harmonisation between METeOR and HL7 repositories for example. **Terms and Definitions in the Family of Health Records** An International vote will be taken to which Standards Australia IT14 will be invited (through the SKMT governance process – not through the regular ISO voting system). This vote will include updated suggestions and voting to be able to move those suggestions to preferred standard within the SKMT. This work is of direct interest to Australia. Should different definitions to those used in our existing AS2828 series these documents should be modified to reflect the decisions of this international voting. **ISO/DTS 16843 – Part 1 Categorial structures for representation of acupuncture – Part 1 Acupuncture points (body system)** 2 month DIS ballot beginning 24th of October 2015.. This work should be considered from a terminology model perspective by IT-014 and by HE-031. In addition consideration by RACGP would be welcome as well as the Veterinary community as acupuncture is increasingly occurring in these environments. **ISO/DTS 16843 – Part 2 Categorial structures for representation of acupuncture – Part 2 Needling.** 2 month DIS ballot no later than 20th of July 2015. This work should be considered from a terminology model perspective by IT-014 and by HE-031. In addition consideration by RACGP would be welcome as well as the Veterinary community as acupuncture is increasingly occurring in these environments.
Status of the work	• **Review WG3 Framework and identify priorities for Australia – in development (not a balloted work item) –** to be discussed on monthly teleconferences and on a special day jointly with CEN mirror committee at the next joint meeting. • **Prepare Form 4 and Outline for each of the following to prepare them as PWIs –** next fact to face meeting to determine resources and priorities. o TS – Part 1 Design of value domain content o TS – Part 2 Governance of value domain content o TS – Part 3 Terminology Implementation Maturity Model o TS – Part 4 Quality measures for evaluation of value domain content o TS – Part 1 Workforce needs, roles and skills for EHR semantic content implementation

	• **17115:2007 Vocabulary of Terminological Resources** Current status Committee Draft to be prepared for CD ballot discussion at the next face to face meeting. • **ISO 13120 Syntax to represent the content of healthcare classification systems (ClamI)** revision proposal with intention for DIS ballot vote after the next face to face meeting. Comment disposition at the next face to face metting. • ***ISO/ AWI/DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems*** Completed DIS ballot – going out for a 2nd DTS ballot. To be actively discussed jointly with WG3 and WG6 at the next face to face meeting. • ***ISO 13582:2013 Sharing of OID registry information*** = current publication - minor modification to be prepared. No further discussion required. • **Terms and Definitions in the Family of Health Records –** not a conventional work item – but documentation prepared for term harmonisation and SKMT vote process prior to update and publication. Further discussion is highly likely at the next face to face meeting. • **ISO/DTS 16843 – Part 1 Categorial structures for representation of acupuncture – Part 1 Acupuncture points (body system)** current CD going out for DTS ballot. Will be discussed at the next face to face meeting. **ISO/DTS 16843 – Part 2 Categorial structures for representation of acupuncture – Part 2 Needling.** Currently CD going out to DTS ballot. – will be discussed at the next face to face meeting.
Other Stakeholders	• HE – 031 • AIHW • NEHTA • Each Jurisdictional Health Department and Department of Health. • HIMAA • ACHI