



International Delegates Meeting Report

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Date:	20 January 2016
Delegate(s) proposed by:	
Project Manager (PM)	Manjoo Lalwani
Standards Development Organisation (SDO)	Standards Australia
PMs email address:	manjoo;lalwani@standards.org.au

Delegate details:	<i>For multi-person delegation please provide details of the head of delegation only.</i>	
Name	J Richard DIXON HUGHES (HoD)	
Position/Title	Managing Director	
Company	DH4 Pty Limited	
Postal address	86 Cabramatta Road MOSMAN NSW 2088	
Email address	richard@dh4.com.au	

International Committee details:	ISO	TC 215 Health informatics, including opening/ closing plenary and meetings of: TC 215/CAG1, CAG2, WGs and Joint Initiative Council (JIC) for global health informatics standardization
Meeting/Committee type:	Technical Meeting	
Australian Participation:	P-Member	

Meeting date & venue:	
Date	02-11-2015 to 06-11-2015 (inclusive)
Venue details	Bern, Switzerland. Novotel Bern Expo plus: Swiss National Equestrian Centre, Curling Bahn Allmend, and the Armed Forces College.



<p>Australian delegates:</p>	<p>J Richard DIXON HUGHES (RDH), Head of delegation & expert – mainly at WG1 and WG6; also immediate past-chair of the JIC</p> <p>Heather GRAIN (HG) - Convenor, ISO/TC 215/WG 3 Semantic content</p> <p>A/Prof Trish WILLIAMS (TW), expert – mainly at WG4 and JWG 7</p> <p>Dr Vince McCAULEY (VMcC), expert – mainly at WG2 and JWG 7; also liaison officer for IHE International</p> <p>Peter WILLIAMS (PW), expert – mainly at WG3 – participation funded by Australian Governments' Health CIO Forum (HCIOF)</p> <p>Manjoo LALWANI (Standards Australia, ISO/TC 251/WG 1 secretariat)</p>
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<p>Purpose of meeting:</p>	<p>The purpose of the meeting was to progress the TC 215 work program comprising around 90 active projects and to review potential new projects in the field of health informatics, including joint work with other ISO and IEC technical committees.</p> <p>Australian involvement is significant in terms of monitoring and participating in relevant TC 215 health informatics standards development work on behalf of IT-014 mirror committee, particularly through:</p> <ul style="list-style-type: none"> • WG1 (Architecture, framework & models) – where Standards Australia provides the secretariat and RDH is active as a nominated expert, • WG3 (Semantic content) – where Heather Grain is the convenor and leader of several projects. • WG4 (Security, Safety & Privacy) – where Trish Williams is active as leader of several projects and several other Australians are nominated experts. • JWG 07 (Application of risk management to information technology (IT) networks incorporating medical devices) – where several Australians (including TW, VMcC and RDH) are active on the revision and restructure of health software risk management standards., which are likely to have global impacts on the regulation of health software and devices. • TC215 leadership roles - where RDH and HG both serve on TC 215/CAG01 Executive Council, CAG02 Coordination Group and participate in the Operations Advisory Group (OAG). RDH is also a member and former co-chair of the TC 215 Strategic planning task force and ISO/IEC JTC1 liaison to ISO/TC 215. • RDH served as Chair of the JIC for 2013 and 2014 (with Australian Government support) and continues his participation in the JIC Executive as immediate past chair and as one of the ISO/TC 215 representatives. <p>The meeting was significant because some of the items under discussion address identified Australian requirements, may be relevant for local adoption, are of interest to Australian jurisdictions as represented by the AHMAC/CIOF, are being worked on by Australian experts and/or are being implemented in Australian health care services and/or e-health systems that support them.</p>
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<p>Meeting attendees:</p>	<p>The following 22 P-members were represented at the TC 215 meeting by 154 registered delegates:</p> <ul style="list-style-type: none"> • Australia • Austria • Belgium • Brazil • Canada • China • Denmark • Finland • Germany • Ireland • Italy • Japan • Korea • Malaysia • The Netherlands • Norway • Russia • Spain • Sweden • Switzerland • United Kingdom • United States <p>A further 26 delegates represented 17 liaison organisations (many of these delegates were also members of national delegations but were counted as representing their liaison organisations).</p> <p>Including delegates, observers, ISO/TC215 secretariat and ISO Central Secretariat (ISO/CS) staff, the total attendance was 185.</p> <p>Official addresses on behalf of SNV, the hosts, were given by Markus Weber, CEO of SNV and Robert Hilty, a member of the SNV Board and principal SNV sponsor for the meeting.</p> <p>A presentation was also given to TC 215/OAG by Ms Laura Mathew, Editorial Programme Manager, ISO/CS on the drafting of ISO documents and making the most of ISO editorial/publication processes</p> <p>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.</p>
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<p>Key items discussed:</p>	<p>ISO/TC 215 – General (Plenary sessions, CAG 1, CAG 2 and OAG):</p> <ul style="list-style-type: none"> • Progression of the concept of “Reference Standards Portfolios” (RSPs) that normatively reference the work of other SDOs, in addition to ISO • Arrangements for review and update of the TC 215 strategic business plan – this was also on the agenda for all WGs • Proposed approaches to resolve issues with <i>ISO/IEC 80003-series: Quantities and units for telebiometrics/ e-health</i> • New convenor for TC 215/WG 2 Systems and device interoperability
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- ISO International Workshop Agreement: *IWA 18 Community-based integrated health and care services for aged societies*
- Scheduling of upcoming ISO/TC 215 meetings Changes flowing from 2015 edition of ISO/IEC Directives – particularly in relation to new work item proposals, Form 4 and the progression of projects Changes in ISO systems for publications and common problems to avoid
- Need for agreement between ISO and HL7 International^{®1} to be renewed

WG 1 Architecture, frameworks and models (joint with CEN/TC 251/WG i):

- Progressing coordinated development of Edition 2 of *ISO 13606 ..² EHR Communication (EHRcom) - Parts 1 to 5* (several sessions + resolutions)
- Establishing formal projects to update *ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3* (jointly with CEN/TC 251)
- Status of *ISO/DTS 18864, Health Informatics, Quality metrics for detailed clinical models*
- Status of *IWA 18* development and potential need for associated health informatics standards supporting work on aged societies
- Developments in European approaches to e-health standards
- Status of TC 251 Concurrent use initiative and e-health use case template
- Presentation by Elizabeth Keller [CA] summarising JIC work on a proposed “Standards Set” to support interchange of patient summaries
- Presentation by Jessica Rosenalv [SE] introducing a proposed work item on *business information analysis for healthcare* built around ContSys
- Status of proposed normative publication based on *ISO/TR 14649 .. Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model*.

[For joint sessions with:

- WG 2 (System and device interoperability) see notes below on WG 2.
- WG 3 (Concept representation) see notes below on WG 3.
- WG 4 (Security, safety and privacy) see notes below on WG 4.]

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² In this report, the words “Health informatics - ” which appear in the titles of almost all TC 215 publications have often been abbreviated to “..” (i.e. two dots). Three or more dots indicates a different or longer break in the text or a title.

WG 2 Systems and device interoperability

- Alternative pathways for future maintenance of *ISO 14199:2015 ... Biomedical Research Integrated Domain Group (BRIDG) Model* to reflect more frequent updates to the underlying CDISC/HL7 BRIDG model
- Discontinuation of previously proposed PWIs for ISO/TRs on:
 - *Core metadata for medical information search*
 - *Transformation rules for medical Information retrieval*
- Progression of *ISO/PWI TS 22077-4 .. Medical waveform format - Part 4: Stress test electrocardiography*
- Status of revision of *EN 1064:2005 Standard communication protocol - Computer-assisted electrocardiography (SCP ECG)* and the associated ISO standard: *ISO 11073-91064:2009*
- Status of *ISO/AWI TR 20055 .. Person-owned document repository for PHR applications and health information exchange*
- Status of approved revision/upgrade of *ISO/TR 21089:2004 .. Trusted end-to-end information flows* as an ISO/TS
- Withdrawal and reconsideration of previously approved *ISO/PWI for TR on Trans-national health records*
- Status and progression of systematic review and renewal of *ISO 12052:2006 .. Digital imaging and communication in medicine (DICOM)*
- Status and progression of RSP (“bundled standard”) for digital imaging domain
- Progression of *ISO/PWI on Omics Markup Language (OML)* to NP ballot - as extension and revision of *ISO 25720:2009 .. Genomic Sequence Variation Markup Language (GSVML)*
- Progression of *ISO/PWI for TR on Whole Genome Sequence Markup Language (WGSML)* to NP ballot.
- In joint session with WG 1 (Architecture, Frameworks and Models):
 - Introductory overview of *ISO/DTR 19669 Re-usable component strategy for use case development*
 - Progression of *ISO/DTS 20428 Health informatics, Metadata for describing structured clinical genomic sequence information in EHRs*
 - Importance of introducing the TC 215 community to HL7[®]/FHIR[®]
- In joint session with WG 3 (Semantic content), final resolution of comments prior to progression of *ISO/DIS 17583 .. Terminology constraints [bindings] for coded data elements expressed in ISO harmonized data types used in healthcare information interchange* to publication.

WG 3 Semantic content.

- Further development of the WG3 framework for analysis of community needs, gaps and overlaps and prioritization of WG 3 activities
- Progressing revision of *ISO 17115:2007 .. Vocabulary for terminological systems* - for DIS ballot after the May 2016 meeting
- Progressing revision of *ISO 13120:2013 .. Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClaML)* for DIS ballot after the May 2016 meeting
- Status of *ISO/AWI 17117-1 .. Terminological Resources - Part 1: Characteristics*, incorporating revision and upgrade of *ISO/TS 17117:2002*
- Progressing the following two high-priority items to NP ballot for ISO/TS:
 - *Healthcare terminology resource map quality measures (MapQual)*
 - *Metadata repository requirements in healthcare (MetReq)*
- Approaches for progressing approved but delayed PWIs on :
 - *Terminology implementation capability and maturity models – Part 1: Capability (TICMM1)*
 - *Value set definition – Part 1: Design and governance (VSD1)*
 - *Value set definition – Part 2: Quality measures (VSD2)*
- Possibility of PWIs to develop ISO/TS or ISO/TR documents addressing:
 - *Terminological systems for herbal medicines and formulas*
 - *Indications (efficacies) binding to herbal medicines and formulas*
- In joint session with WG 1 (Architecture, frameworks and models):
 - SKMT and the “health record” family of terms
 - Status of *ISO 13940 (ContSys)*
 - Proposed scope and content of the PWI on capabilities needed to work with clinical terminologies (*TermWorker*)
- In joint session with WG 6 (Pharmacy and medications business):
 - resolution of issues to progress *ISO/AWI DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems*
 - status of *ISO/DTS 19256 Health informatics – Requirements for medicinal product dictionary systems for health care*

[*ISO/DIS 17583* was discussed in joint session with WG 2 (System and device interoperability) as noted above for WG 2.]

[For joint session with JWG 1 Traditional Chinese medicine (informatics) and Traditional Medicine Taskforce (TMTF) see notes on JWG 1 below.]



WG 4 Security, Safety and Privacy

- Establishment of project *ISO/PWI TR 21332 .. TR Cloud computing security and privacy requirements for health information*
- Status and progression of *ISO/DIS 21549-7 .. Patient healthcard data-Part 7 Medication Ed2*
- Status and progression of *ISO/AWI 20429 .. Principles and guidelines for protection of personal health information (PHI)*
- Status and progression of *ISO/CD 17090-5 .. Public key infrastructure (PKI) - Part 5: Authentication using Healthcare PKI credentials*
- Establishment of project to revise *ISO/TR 11633-1:2009 .. Information security management for remote maintenance of medical devices and medical information systems – Part 1 Requirements and risk analysis* and upgrade it to an ISO/TS
- Status and progression of *ISO/DTR 18638 .. components of education to ensure health privacy*
- Initiation of PWI to revise *ISO/TR 11633-2:2009 .. Information security management for remote maintenance of medical devices and medical information systems - Part 2: Implementation of an information security management system (ISMS)*
- Establishment of project *ISO/PWI TR 21333 .. Privacy terms and definitions* (potentially based on HL7 Security and Privacy Ontology and Vocabulary)
- Status of revision and upgrade of *ISO/TS 25237:2008 .. Pseudonymization*
- Status and progression of revision of *ISO 21298 .. Functional and structural roles* and upgrade to an ISO standard
- Response to suggestion by ISO/IEC JTC 1/SC 27 that they assume responsibility for *ISO 27799 .. Information security management in health using ISO/IEC 27002*
- In joint session with WG 1 (Architecture, frameworks and models):
 - Progressing the revision of *ISO 13606 EHRcom Parts 4 and 5*
 - Status of upgrade of *ISO 21298 .. Functional and structural roles*
 - Presentation by Bernd Blobel [DE] suggesting formal approaches for deriving and harmonising information models within and across domains
- Report from liaison officer to ISO/TC 262 Security and resilience

[For joint session with JWG 7 (Application of risk management to IT networks incorporating medical devices) see notes below on JWG 7]

WG 6 Pharmacy and medicines business

- Status of *ISO/FDIS 17523 .. Requirements for electronic prescriptions*
- Status of *ISO/AWI TS 19293 .. Requirements for the record of dispense medicinal products*
- Outcome of joint meeting in May 2015 of WG 6 with HL7 Pharmacy and IHE Pharmacy SIG
- Presentation by José Costa Teixeira [IHE] on the *process of medication* - for inclusion in a potential ISO/TR
- Status of *ISO/NP DTR 20831 Medication management concepts and definitions*
- Resolution of comments and progression of *ISO/DTS 19256 .. Requirements for medicinal product dictionary systems for healthcare*
- Status, ballot reconciliation and progression of *ISO/DTS 17251 .. Business requirements for a syntax to exchange structured dose instructions for medicinal products*
- Status of *ISO/AWI TR 14872 .. IDMP - Core Principles for Maintenance of Identifiers and Terms*
- Production issues and progression of updates to *ISO/DTS 19844 .. Identification of Medicinal Products (IDMP) - Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances*
- Status and progression of updated Ed 2 of *ISO 11238 .. IDMP - Data elements and structures for the unique identification and exchange of regulated information on substances*
- Status and progression of the following 4 inter-related IDMP projects:
 - *ISO/DTS 20443 .. IDMP - Implementation Guide for ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information*
 - *ISO/NP 11615, update of ISO 11615:2012 .. IDMP - Data elements and structures for the unique identification and exchange of regulated medicinal product information to Ed 2*
 - *ISO/DTS 20451 .. IDMP – Implementation guide for ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*
 - *ISO/NP 11616 update of ISO 11616:2012 .. IDMP - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

- Status and progression of: *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*
- Withdrawal of *ISO/TS 22224:2009 . Health informatics - Electronic reporting of adverse drug reactions*

[For joint session with WG 3 (Semantic content) see notes above on WG 3]

JWG 1 Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics) plus Traditional Medicine Taskforce (TMTF)

- Status and progression of *ISO/NP TS 16843-1 .. Categorial structure for representation of acupuncture—Part 1: Acupuncture points*
- Expected publication of *ISO/DTS 16843-2 .. Categorial structures for representation of acupuncture -Part 2: Needling*
- Status and progression of *ISO/NP TS 16843-3 .. Categorial structures for representation of acupuncture -Part 3: Moxibustion*
- Status and progression of *ISO/PWI TS 16843-4 Categorial structures for representation of acupuncture -Part 4: Meridian and collateral channels*
- Presentation by Dr Li Haiyan on proposed project: *Classification of Traditional Chinese Medicine datasets*
- In joint session with WG 3 (Semantic content):
 - Progression of: *ISO/PWI TS 16843-05 Categorial structures for representation of acupuncture - Part 5 Cupping*
- Status and proposed approach for joint items being progressed under the leadership of TC 249 Traditional Chinese medicine (TCM):
 - *ISO/DIS 18668-1 TCM - Coding system of Chinese medicines – Part 1: Coding rules for Chinese medicines*
 - *ISO/CD 18668-2 TCM - Coding System of Chinese Medicine – Part 2: Codes of Decoction Pieces*
 - *ISO/ CD 18668-3 TCM - Coding System of Chinese Medicines – Part 3: Codes of Chinese Materia Medica*
 - *ISO/ CD 18668-4 TCM - Coding System of Chinese Medicine – Part 4: Codes of granule forms of individual medicinals for prescriptions (GFIMP)*
 - *ISO/CD 20333 TCM - Coding Rules for Chinese Medicines in Supply Chain Management*

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

- Activities of related AAMI Health IT (HIT) Committee, in particular, its plans to develop the following standards focussed on US requirements:
 - *AAMI HIT 1000 Application of risk management processes for health IT*
 - *AAMI HIT 2000 Application of quality management processes to HIT*



- *AAMI/UL 2800 Medical device interoperability safety standards* (to be developed by AAMI in collaboration with UL)
- Experiences with implementation and evaluation of *IEC 80001-1:2010 ... Part 1: Roles, responsibilities and activities* and the implementation guidance in various TRs that constitute Part 2 of *IEC 80001*
- Coverage of IS security management in ISO/IEC 80001-series and relationship to other initiatives such as HIMSS MDS2 (Medical Device Manufacturer Disclosure Statement for Medical Device Security)
- In joint session with WG 4 (Security, safety and privacy):
 - Resolution of comments on *IEC/DTR 80001-2-8 ... Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2*
 - Status and progression of *IEC/NP TR 80001-2-9 ... Part 2-9: Application guidance -- Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities*
 - Status and plans for a potential new health software foundation standard and revision of *ISO/IEC 80000-series*
- Outcomes from task groups and planning development of new “foundations” material on health software safety and its integration with revision of *IEC 80001-1 ... Part 1: Roles, responsibilities and activities* and the various TRs that constitute Part 2 of the *IEC 80001-series*
- Status and progression of *IEC/DIS 82304-1 Health software - Part 1: General requirements for product safety*
- Status and progression of *IEC/CD 62304 Medical device software - Software life cycle processes (Ed 2)*
- Plans to provide comment for systematic review on *ISO 14971:2007 Medical devices - Application of risk management to medical devices* to ISO/TC 210 (Quality management and corresponding general aspects for medical devices)
- Need for TC 215 liaison with recently formed IEC/TC 62 System Committee on Active Assisted Living (SyC-AAL)
- New IEC Advisory committee on security (ACSEC) – with support for Ben Kokx’ being nominated as IEC/TC 62 liaison officer to IEC/ACSEC
- JWG 7 interest in being part of the proposed revision of parts 1 and 2 of *ISO/TR 11633 .. Information security management for remote maintenance of medical devices and medical information systems* (a WG 4 project)
- Plans for out-of-cycle meetings and teleconferences to progress JWG 7 work items



JIC - Joint Initiative Council for Global Health Informatics Standardization

- Follow-up of members overdue in finalising their execution of updated JIC Charter
- Status of work on process for developing JIC Standard Sets
- Status and progression of the JIC Standard Set for Patient Summary – including relationship to EU/EC and HL7/Interpass activities
- Status and progression of work to aid adoption of universal Unique Device Identifiers (UDI)
- Planning for potential development of a JIC vendor user group
- Paper on Formal Standardization in Large-Scale e-Health Deployment from European e-Standards project
- JIC meetings for 2016

Confirm net benefit to Australia in participating:

Benefits of Australian participation include:

- Ability to understand better and to influence the direction of current and proposed TC 215 work items with some 16 projects coming to ballot prior to the next TC 215 meeting in May 2016 and many others at the PWI stage.
- Ability to pursue opportunities to promote the recognition and/or adoption of existing Australian work at international level, particularly in relation to aspects of identification, privacy and security, health software safety and services-oriented e-health interoperability.
- Ability to progress the interests of Australian jurisdictions (as reported from the AHMAC Health CIO Forum) in standards for the governance, management and use of clinical terminologies and coding systems, with Australia being accepted to lead the TC 215 work items most relevant to Australian needs in these areas. This work will support Australian initiatives to map commonly used interface terminologies to the Australian implementation of SNOMED CT[®] thereby enabling improved use of health information for shared clinical care, administrative and statistical reporting.
- Monitoring and participating in TC 215 work on security, safety, privacy and trans-border data flows that is potentially relevant to Australian practices and initiatives for sharing and use of health record information.
- Ability to monitor, participate in and influence the revision and restructure of ISO/IEC 80001-series and further development of health software risk management standards which are likely to have global impacts on the regulation of health software and devices. Many of the items under discussion in JWG 7 relating to this topic have direct relevance to Australia and its global markets and are actively supported by Australian experts, with some previous versions having been implemented in Australian settings.



- Promoting Australian expertise and leadership of standards related to eHealth software safety, security and privacy, ensuring that international developments are compatible with Australian best practice and are informed by Australian regulatory requirements.
- Opportunity to receive input and provide feedback on the operation of ISO/CS policies and systems as they affect Australian experts working on health informatics standards (which often involves the complexity of working across and reconciling the approaches of multiple SDOs – ISO, HL7, CEN, IHTSDO, GS1, IHE, DICOM, IEEE, Continua Alliance, ITU-T, CDISC, OASIS, W3C/IETF, JTC1 and others).
- Ability to promote Australia, its standards community and our commitment to best practice in international standardization and to influence the leadership of TC 215 to embrace harmonisation of the various e-health standards used in Australia and internationally and, where possible, support the use of TC 215 as a peak agent for the release of internationally agreed and harmonised specifications.
- Supporting the need for international standards that focus on policy, governance and functional best practice applicable to implementation of the eHealth agenda
- Improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice.
- Continuing to lead and promote the development and use of consistent terminology and an approved lexicon of terms and thesaurus for use across ISO and other health informatics standards.
- Supporting the proposed liaison between ISO/TC 215 and ISO/IEC Joint Technical Committee 1 (JTC 1) with a view to encouraging collaboration on IT standards affecting health care delivery and avoiding duplication of work.



Observations & comments:	
	<p>ISO/TC 215. The main general topics addressed at the TC-level (plenaries, CAG 1, CAG 2 and OAG) included:</p> <ul style="list-style-type: none"> <p>• Progressing the concept of “Reference Standards Portfolios” (RSPs – also referred to as “bundling standards” or “meta-standards”).</p> <p>In line with previous discussions and with the agreement of ISO/TMB, TC 215 is progressing the concept of RSP standards that will call-up and make normative reference to specific sets of “recognised” standards needed to address specific use cases in identified health informatics domains. The standards being referenced may include those of partner SDOs that are freely available online, publication of which by ISO is not compatible with the ISO business model. Research on the nature, contents and methodologies for developing RSPs has continued in parallel with a pilot project to create a reference standards portfolio specification in the area of “diagnostic imaging”. Feedback on initial activities was sought from CAG02, CAG01 and ISO/CS with inclusion of additional explanatory material and a need to embed normative references in normative requirements being suggested.</p> <p>• Update of TC 215 strategic business plan. Following the major revision completed in 2013, it is again time for the business plan to be reviewed and updated. Jeremy Thorp (UK) was appointed to lead an Ad-hoc task force. A “light touch” update of the 2013 plan is proposed, rather than another major revision.</p> <p>RDH will be involved in the task force as one of the main authors of the 2013 plan and HG as WG 3 convenor.</p> <p>• Status of work on ISO/IEC 80003-series: Quantities and units in e-health (and/or telebiometrics). Following further discussions between the TC 215 Chair and Secretariat with the leadership of ISO/TC 12 (Quantities and units) and with relevant ISO/CS and ANSI personnel, ISO/TC 215 concerns (shared by Australian delegates) about the content, direction and management of this work appear to have been accepted, with a survey to be conducted of all TC 215, ISO/TC 12 and IEC/TC 25 members to elicit whether there is still a need for work in the area and, if so, its content and how it should be managed.</p> <p>• Convenor of TC 215/WG 2 Systems and device interoperability. A one-month WG ballot would be held to approve the appointment of Mr Bron Kisler (USA) as convenor of WG 2. As Vice President, Strategic Initiatives for CDISC, Bron is a former Chair of the JIC and led work on the <i>ISO 14199 Biomedical Research Interchange Integrated Domain Group (BRIDG) model</i> standard. He is considered to be an excellent candidate worthy of Australian support when the ballot is released.</p> <p>• Processes for submission of publications. Changes in these processes require that by DIS/DTS ballot stage (and preferably earlier – WD or CD stage) updated text of drafts and all images/figures and all other electronic content must be submitted in the approved revisable format and are required to be checked by the TC 215 secretariat before materials are</p>



submitted to ISO/CS for publication. Authors need to be aware of these requirements.

- **Processes for approving new work items.** The need to use the new form 4, with more substantial justification of projects and, also, the requirement that all new work items to be balloted through the ISO balloting portal were noted. As TC 215 already ballots all new projects through the portal, removal of the option to accept them at committee meetings has little impact on TC 215. After discussion with the Chair, the proponents of several potential new TC 215 projects voluntarily withdrew their proposals for further consideration and justification (a positive development).
- **ISO/TC215 and Health Level 7 (HL7) pilot agreement.** This agreement is now overdue for revision, renewal and/or replacement, which may have implications for re-publication of HL7 work as ISO international standards but is not likely to affect the standing of *ISO/HL7 27931:2009* (HL7 v2.5), *ISO/HL7 27932:2009* (CDA r2), *ISO/HL7 27951:2009* (CTS1), *ISO/HL7 27953:2011* (ICSR), *ISO/HL7 21731:2014* (HL7 v3 RIM r4), *ISO/HL7 10781:2015* (EHR-S FM), *ISO/HL7 16527* (PHR-S FM).
- **Publication of freely available “adoptions”.** Existing TC 215 projects which involve the adoption, re-publication or referencing of significant bodies of normative material freely available on non-ISO websites which were blocked, have now been allowed to proceed but with the understanding that ISO/CS concerns will be addressed and relevant approvals obtained under the policies developed for “RSPs” and normative referencing. Under this dispensation, *ISO 14199:2015* (BRIDG) and *ISO/HL7 10781:2015* (EHR-S FM r2) have now been published, *ISO/HL7 16527* (PHR-S FM) is expected to be published soon and the systematic review of the existing *ISO 12052* (DICOM) and existing HL7 co-publications are expected to progress, while the broader concept of reference standards is progressed.
- **Need for introductory overview on HL7[®]/FHIR[®].** This was raised in several WGs and, given the involvement of Australian experts in the creation, management and ongoing development of FHIR, is something that the Australian delegation may be in a position to facilitate.

WG 1 Architecture, frameworks and models.

Across all sessions, around 36 delegates participated in WG 1 with some joining sessions by Webex. Meetings took place over 9 sessions on 3 days with most being conducted jointly with CEN/TC 251 WG i. The following points were noted:

- **ISO 13606 .. EHR communications [EHRcom] - Parts 1 to 5 – Second edition**
Work on production of the 2nd edition of ISO 13606 was re-initiated in 2014 after delays from its original commencement in 2012. It was the main task for WG 1 at the Bern meeting and occupied about 3 sessions, including part of a joint session with WG 4 on part 4 (Security).



The work is being actively progressed by several parallel task groups meeting at European venues and by teleconference. Despite some slippage, the broad engagement and associated team activity appear to be positive for progress.

Delivering promised harmonisation with HL7, limiting scope creep (in particular, avoiding any extension into an EHR repository and/or EHR query language standard) and concurrent publication of all 5 parts have been key issues for Australia.

Australia supported recent proposals from the 13606 project team to reduce size of the standard, with material such as the specification of the ADL archetype definition language being removed from the standard and maintained online by 13606 interest groups.

TC 215 accepted a WG 1 recommendation to move Part 1 (Reference model) and Part 2 (Archetype interchange specification) to CD ballot ahead of parts 3, 4 and 5. When this was questioned, the project lead confirmed that it was still the intention to publish all 5 parts of the 2nd edition simultaneously. The alignment and co-publication previously advocated by Australia may still be prejudiced by insufficient progress on parts 3, 4 and 5 and this risk will need to be monitored at the May meeting.

With a strong role in development of *openEHR* and tools for maintaining *openEHR* and ISO 13606 archetype repositories, Australia has considerable expertise to contribute to the review of 13606 but now little interest in adopting it per se. IT-014 needs to be prepared to engage with local experts when the time comes for review and comment.

- **ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3 – commencement of work on second edition**

Australia has a strong interest and expertise in the development, application and use of enterprise architectures, particularly those based on application of RM-ODP and SOA. HISA is also based on RM-ODP and is well accepted in Europe but needs to be better aligned with other approaches.

Relevant Australian activities include the work of NEHTA, DoH, jurisdictions and IT-014, which resulted in the high-level requirements being documented in *SA HB 137-2013 E health Interoperability Framework (eHIF)* and *SA HB 138-2013 E-health architecture principles (eHAP)* and, also, Australian contributions to *HL7/SAIF* and *ISO/TR 14639 eHealth architecture roadmap*. TC 215 has approved the joint development of a 2nd edition of 12967 with CEN/TC 251 under the Vienna Agreement being put to a 3-month NP ballot (which is now open). IT-014 and relevant Australian experts need to become engaged in responding to the NP ballot.

- **Potential to use SA HB 137 (eHIF) and SA HB 138 (eHAP) as the basis for international standards work.** Noting the proposed update of HISA, which is about to commence and the need for guidance on how to define and specify requirements for TC 215 RSPs and JIC Standards Sets for various domains, preliminary discussions have been held at recent TC 215 meetings on the possible contribution of *SA HB 137* and *SA HB 138* as the basis for possible international standards. While there has been some interest, without much greater awareness raising and development of the



concept, the opportunity for a well-structured approach to e-health specifications is likely to be overtaken by a range of less structured ad-hoc approaches promoted by each pilot project. Consideration needs to be given to these issues well before the May 2016 meeting in contemplation of making recommendations to improve strategic alignment and harmonisation of standards sets, including any possible role for the principles and approaches promoted in *SA HB 137* and *SA HB 138*.

- **ISO International Workshop Agreement: *IWA 18 Community-based integrated health and care services for aged societies*.** TC 215 has had some small involvement in developing *IWA 18* but there is considerable interest among the TC 215/IT-014 stakeholder community in the outcomes and implications. Organisations such as the Victorian Government and BUPA Australia have indicated their interest in being kept informed of developments. While some new standards may be needed to establish frameworks and principles for ensuring the needs of an “aged society” are met, it would be of general concern if there were to be any push to replicate standards in established core domains such as EHR, PHR, telemedicine and pharmacy to address the needs of an “aged society”, rather than ensuring that existing mainstream health informatics standards address these requirements or are upgraded to cover any additional needs. Proposals to TC 215 have been foreshadowed and need to be carefully scrutinised to ensure that they meet this principle.
- **European developments in e-health standards and the status of TC 251 Concurrent use initiative and e-health use case template.** These developments continue to be monitored with a view to trying to ensure that any resulting joint work for TC 215 fits into a genuinely international approach and that any aspects of potential benefit to Australia (e.g. our proposed adoption of *ContSys*) are considered.
- **Proposed Swedish work item on *business information analysis for healthcare*.** An Australian warning about attempting to standardise on a single generalised business modelling methodology for use in health care was raised. Informal advice on the key standardization principles to be addressed in progressing the potential requirement was given to Jessica Rosenalv [SE] with the offer of further advice, if required. The existence of such wide-ranging proposals is another reason for the frameworks set out in *SA HB 137 (eHIF)* and *SA HB 138 (eHAP)* to be brought forward for consideration and potential incorporation into TC 215 work.
- **Possible normative publication based on *ISO/TR 14649 .. Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model*.** While Australia has supported the concept in principle, resourcing appears to be a significant issue. Any further deliberation will await the provision of a definitive proposal (understood to be in the hands of Dr Marion Lyver, who was unable to be present in Bern).
- WG 1 and WG 2 agreed that they should schedule at least one joint session at upcoming TC 215 meetings to progress collaboration on joint work.

Australia continues to contribute information, expertise and secretarial support to progress WG 1 activities.

WG 2 Systems and device interoperability

Across all sessions, some 14 delegates from 5 countries and 1 liaison were reported to have participated in WG 2 with some 11 preliminary work items and 5 approved work items at various stages of development. WG 2 also manages ISO fast-track adoption of the ISO/IEEE 11073-series of device communication standards (with 6 parts currently being progressed). The following points were noted:

- The Australian delegation lacked the resources to participate fully in WG 2 but RDH, HG, PW and TW were present for some of the items.
- **Appointment of WG 2 convenor.** Bron Kisler has agreed to take on the position of WG 2 convenor following Mike Glickman becoming Chair of TC 215. He functioned as acting convenor for the Bern meeting pending ratification of his recommended appointment by WG ballot and approval by TC 215. Bron brings many strengths to the position and it is expected that his appointment should be widely supported.
- **ISO 14199:2015 ... Biomedical Research Integrated Domain Group (BRIDG) Model.** WG2 considered alternative pathways for future maintenance of this standard given that the recently published ISO standard encapsulates v3.2 but the underlying CDISC/HL7 BRIDG model is updated more frequently with version 4.0 already having HL7 approval. The options appear to be: 1) Reference BRIDG from the next edition and let the BRIDG process take over; 2) Update ISO 14199 to reflect major revisions of BRIDG every few years; 3) Bring all revisions through ISO; or 4) Seek some middle ground (as yet unspecified).
- **Withdrawal of potential preliminary work items.** Proposals from the Korean delegation for PWIs to produce ISO/TRs on the following were withdrawn.
 - *core metadata for medical information search*
 - *transformation rules for medical Information retrieval*

Following discussion with the TC 215 Chair, the previously approved PWI for an *ISO/TR on Trans-national health records* has also been withdrawn by the Korean delegation for reconsideration and possible resubmission. Australia supports the withdrawals.

- **ISO/TR 21089:2004 .. Trusted end-to-end information flows.** The NP ballot for revision and upgrade of this document to an ISO/TS has passed. The project lead, Gary Dickinson [US] has reached out to experts from various delegations including Australia for national input by 1 Feb 2016 prior to the next iteration of the draft which is to be circulated ahead of the next TC 215 meeting in May 2016.
- **ISO/NP TR 19669 .. Re-usable Component Strategy for Use Case Development.** Heavily based on US/ONC activities, preliminary draft was circulated for review prior to meeting, with further expert input being sought by early February. Australian input has been requested.



- **ISO12052:2006 .. Digital imaging and communication in medicine (DICOM).** As reported elsewhere, ISO/CS has allowed the review and update of the existing ISO 12052 DICOM standard to proceed. This will be undertaken as a separate project in parallel with the proposed preparation of the RSP (“bundled standard”) for clinical imaging domain, if and when that project has been approved by ISO/TMB.
- **Work on genomics topics.** Australian delegations have previously emphasised the need for work on the following standards to be broadly based, engaging with leading industry players and harmonised with related HL7 specifications. The project teams indicated that they are collaborating with each other and intend to abide by these principles – these aspects will be monitored in Australian responses to ballots.
 - ISO/PWI on *Omics Markup Language (OML)* - as extension and revision of *ISO 25720:2009 .. Genomic Sequence Variation Markup Language (GSVML)*. Approved to proceed to NP ballot.
 - ISO/PWI for TR on *Whole Genome Sequence Markup Language (WGSML)*. Approved to proceed to NP ballot.
 - *ISO/DTS 20428 Health informatics, Metadata for describing structured clinical genomic sequence information in EHRs.*
- **ISO/DIS 17583 .. Terminology constraints [bindings] for coded data elements expressed in ISO harmonized data types used in healthcare information interchange.** Australia has been monitoring the development of this work through WG 3 and the HL7/Vocab WG and supported the recommendation that it go to publication.
- WG 1 and WG 2 agreed that they should schedule at least one joint session at upcoming TC 215 meetings for collaboration on joint work.
- WG2 is planning to hold its traditional out-of-session meeting at the HL7 WGM in Orlando, Florida in the afternoon of Thursday, 14 Jan 2016.

Australia continues to monitor and contribute where possible to WG 2 activities.

WG 3 Semantic content

Across all sessions, 23 delegates from 9 countries and 2 liaison organisations (IHTSDO and HL7) participated in WG 3.

More detailed observations and comments on WG 3 activities are presented in Appendix A to this report, which is largely derived from the separate delegate report from Heather Grain, convener of WG 3. Items of particular interest to Australia include:

- Progression of *ISO/FDIS 13940 System of concepts to support continuity of care (Contsys)*. The HCIOF has allocated resources to assist with the possible local adoption of this standard once published.
- Potential Australian sponsorship of the following new work item proposals that are of particular interest to jurisdictions using SNOMED CT^{®3} as a

³ SNOMED[®] and SNOMED CT[®] are registered trademarks of IHTSDO (The International Health Terminology Standards Development Organisation).



reference terminology to enhance interoperability between different implementations of clinical terminologies:

- Proposed ISO/TS on: *Healthcare terminology resource map quality measures (MapQual)*; and
- Proposed ISO/TS on: *Metadata repository requirements in healthcare (MetReq)*.
- Progressing action on the previously approved TC 215 resolution to form a WG separate from WG 3 to replace the TMTF and focus on health informatics in traditional medicine (including working with JWG 1 and ISO/TC 249 on health informatics aspects of traditional Chinese medicine.

Australia will continue to contribute information, expertise and significant leadership effort to progress the WG 3 work program.

WG 4 Security, Safety and Privacy

Across all sessions, some 26 delegates from 12 countries participated in WG 4 (including 2 that joined remotely by Webex for specific items).

More detailed observations and comments on WG 4 activities are presented in Appendix B to this report, which is largely derived from the separate delegate report from A/Prof Trish Williams.

Several WG 4 work items are of potential interest to Australia and Australian work on privacy, security and safety in health is also potentially very relevant to several proposed new ISO/TC 215 projects.

Apart from the many items that were discussed and reported by A/Prof Williams, it was noted that, due to the absence of the project lead, there was no status report on *ISO/NP TS 20405 Health informatics - Framework of event data and reporting definitions for the safety of health software*, which is of potential interest to Australia.

A request had been received from ISO/IEC JTC 1/SC 27 (Information security) to assume responsibility for maintenance ISO 27799 as part of their desire to provide sector-specific guidance. The request failed to acknowledge, the need for extensive health sector input on issues affecting the security of health information, the existing collaboration between TC 215 and SC 27 or that the updated next edition of ISO 27799 which is awaiting publication addresses known concerns over alignment with ISO/IEC 27002. The issue was understood to be driven by the agenda of one particular NMB and a response prepared.

Australia continues to contribute information, expertise and significant leadership effort to progress projects underway and proposed on health information privacy.

WG 6 Pharmacy and medicines business

Across all sessions, some 47 delegates from at least 12 countries and 5 liaison organisations participated in WG 6 (including 3 joining remotely by Webex).

Matters discussed are noted above, with matters of particular note including:

- The breadth of representation in WG 6 and the closer communication between WG 6, HL7 Pharmacy and IHE Pharmacy SIG flowing from the joint meeting in Paris in May 2015 (on the last day of the HL7 WGM in Paris)

- The main activity continues to be the progressive development of the IDMP implementation guides, revisions to the underlying IDMP standards and the creation of code databases by affiliated organisations to support their use. This will continue to be the main focus for at least 12 months and has strong support from the US/FDA and input from ICH and EC/EMA.
- Preliminary proposals from the IHE liaison for a potential ISO/TR on the *process of medication*.
- Continuing need for further work to improve the expression in *ISO/AWI DTS 18062 Health informatics, Categorical structure for representation of herbal medicaments in terminological system* and its alignment with IDMP, so that it may progress to publication and perform as a normative specification that transcends its origins in support of East-Asian traditional medicines regulation and is capable of broader international application.
- The Australian delegation lacked the resources to participate significantly in WG 6 but RDH was present briefly for some of the items.

Australia continues to monitor and contribute where possible to WG 6 activities.

JWG 1 Joint ISO/TC 215 - ISO/TC 249 WG: Traditional Chinese Medicine (Informatics)

Across all sessions, some 17 delegates from 4 countries and 1 liaison organisation participated in the meetings of JWG 1 with all sessions being held jointly with the Traditional Medicine Task Force (TMTF). The ISO/TC 249 secretariat was officially represented by Ms Ivy Lee.

The Australian delegation has been seeking action on the previously approved TC 215 resolution to form a WG separate from WG 3 to replace the TMTF and focus on health informatics in traditional medicine (including working with JWG 1 and ISO/TC 249 on health informatics aspects of traditional Chinese medicine.

Australian coverage was limited to the joint session with WG 3. Key items reported from JWG 1 are noted above.

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

Across all sessions, at least 40 delegates from 13 countries and several liaison organisations participated in the meetings of JWG 7 (plus some on Webex).

More detailed observations and comments on JWG 7 activities are presented in Appendix C to this report, which is largely derived from the separate delegate report from Dr Vince McCauley, who is also an IHE liaison to JWG 7.

The main business of JWG 7 is focussed on:

- The revision, update and development of the *ISO/IEC 80001-series on Application of risk management to information technology (IT) networks incorporating medical devices*



	<ul style="list-style-type: none"> • Recognition/development of “foundation” standards and potential restructure of the 80001-series to address the recommendations of the recently completed TC 215/SC62A Health software safety report. Australian experts are participating in and leading some of the groups undertaking this work. • Finalising <i>IEC 82304-1 Health software - Part 1: General requirements for product safety</i> after DIS/CDV ballot – with an out-of-cycle meeting in Cape Town, South Africa in January 2016 (to be attended by Trish Williams). • Progressing development of <i>IEC/CD 62304 Medical device software - Software life cycle processes (Ed 2)</i>. A CD needs to be finalised and lodged for DIS ballot by mid-2016 to meet ISO target dates. <p>Australia continues to contribute information, expertise and significant leadership effort to progress JWG 7 work.</p>
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Key items/actions for Australia:	
	<ul style="list-style-type: none"> • Standards Australia to sponsor the following new work item proposals (with Heather Grain as proposed project lead for both): <ul style="list-style-type: none"> - ISO/TS on: <i>Healthcare terminology resource map quality measures (MapQual)</i>. Standards Australia is being asked to sponsor this work item. A draft document and Form 4 have been prepared. - ISO/TS on: <i>Metadata repository requirements in healthcare (MetReq)</i>. Standards Australia is being asked to sponsor this work item. A draft document and Form 4 have been prepared. • Australian experts and IT-014 to support the appointment of Mr Bron Kisler in the ballots for Convenor of WG 2 • Richard Dixon Hughes to: <ul style="list-style-type: none"> - contribute as core member of TC 215 strategic business plan task force – updating the TC 215 business plan - consult with project lead and review proposed drafts of <i>ISO/DTR 19669 Re-usable component strategy for use case development</i> from an Australian perspective - participate in drafting revision of <i>ISO/TR 21089:2004 .. Trusted end-to-end information flows</i> and its upgrade to an ISO/TS - contribute to documentation of processes for development of reference standards portfolios [CAG 02] and classification of standards [JIC] - provide any advice or feedback requested by proponents of proposed standard on business information analysis for healthcare [WG 1] • Standards Australia to continue support of secretariat for ISO/TC 215/WG 1 Architecture, Frameworks and Models (via Manjoo Lalwani). • Heather Grain to: <ul style="list-style-type: none"> - lead work on revision of <i>ISO 17115:2007 .. Vocabulary for terminological systems</i> - for DIS ballot after the May 2016 meeting



- finalise documentation and obtain sponsorship to enable the NP ballots on MapQual and MetReq to close before the May 2016 meeting.
- Convene regular teleconferences of WG 3 and its task groups to progress WG 3 work items for the next TC 215 meeting
- Provide WG 3 input to the TC 215 business plan
- Trish Williams to:
 - provide copies of *Australian Privacy Principles* (APPs) and other relevant documents for guidance of WG 4 and JWG 7 projects involvd with privacy and security
 - contribute to drafting WG 4 PWI for ISO/TR on *Cloud computing security and privacy requirements for health information*) and ensure it is compatible with APPs and other relevant legislation
 - participate in out-of-cycle Cape Town meeting of JWG 7 group finalising FDIS draft of *IEC 82504 Health software - Part 1: General requirements for product safety*.
 - advise on revised wording for *ISO/DTR 18638 .. Components of education to ensure health privacy*.
 - as joint leader, progress activities of JWG 7 task group defining a new foundation standard to underpin revision of ISO/IEC 80001-series and work on health software safety and risk management.
- Australian experts (Trish Williams, Kathy Dallest, Vince McCauley, Richard Dixon Hughes and Tony Cowan) to continue their contributions to work on revision of ISO/IEC 80001-series including new foundation standard on health software safety with Trish Williams to be joint lead of task force authoring new Foundations document.
- Dr Vince McCauley to continue participation in meeting of JWG 7 group finalising FDIS draft of *IEC 82504 Health software - Part 1: General requirements for product safety* – potentially including preparation for and input to out-of-cycle meeting in Cape Town (being attended by Trish Williams).
- IT-014 to consult with relevant Australian organisations and experts to consider justification and, where appropriate, arrange for preparation of project proposals for AU adoption of:
 - *ISO/TS 13131:2014 Telehealth services – Quality planning guidelines*, which was published 2014-10-10, led by Alan Taylor (AU).
 - *ISO 13940:2015 Health informatics - System of concepts to support continuity of care (ContSys)*, published 2015-12-16. Adoption is supported by HCIOF, which has allocated funds to assist.
 - *IEC 82304-1 Health software -- Part 1: General requirements for product safety* - expected to be published in 2016.
 - *ISO 21667 Health informatics - Health indicators conceptual framework (Ed.2)*, updating the existing adoption AS 21667-2012.
 - *ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3 (Ed. 2)*



- *ISO/IEC 80001 series (Application of risk management for IT-networks incorporating medical devices)* – as part of its current revision.
- Peter Williams to brief AHMAC/HCIOF on outcomes of TC 215 meeting in Bern and obtain feedback on the level of support for potential Australian adoptions.
- IT-014 Chair to monitor, consult within Australia and within TC 215 and JIC on whether and how to utilise the material in the following Standards Australia publications in the work of TC 215:
 - *SA HB 137-2013 E health Interoperability Framework (eHIF)*; and
 - *SA HB 138-2013 E-health architecture principles (eHAP)*.
- Among its other responsibilities, Australian delegation to the May 2016 meeting in Amsterdam should:
 - Monitor progress with revision of *ISO 13606 EHRcom* and if progress on parts 3, 4 and 5 is insufficient, suggest reallocation of project resources, to ensure concurrent publication of all 5 parts;
 - Progress rationalisation and progression of core standards for interoperability frameworks and their use to guide related standards development – particularly “reference standards portfolios”, “standards sets” and “bundling standards” within a domain;
 - Argue for any TC 215 standards on business information analysis in healthcare to be agnostic in relation to modelling methodologies or if this is not possible – to be compatible with mainstream approaches; and
 - Ensure WG 4 proposals for security and privacy of health information in cloud services are well integrated with projects being undertaken by ISO/IEC JTC 1/SC 38 Cloud computing and associated work with JTC 1/SC 27, particularly: *ISO/IEC NP 19086-4 IT - Cloud computing - Service level agreement (SLA) framework and Technology - Part 4: Security and privacy*.

Ballots requiring responses

Work on Australian responses to the following TC 215 ballots is expected to be needed prior to the May 2016 TC 215 meeting in Amsterdam:⁴

- *ISO 13606 .. Electronic health record communication (EHRcom)*
 - *Part 1: Reference model* and
 - *Part 2: Archetype interchange specification*

2-month CD ballot for second editions with TC 251 under Vienna Agreement (VA) after updated drafts supplied – scheduled for mid-January 2016. Involvement of local experts on openEHR/13606 tools recommended.

⁴ Most of these ballots were the subject of TC 215 resolutions but some were automatically generated as part of the ISO systematic review (SR) process. In some cases, it can be quite confusing when TC 215 or the relevant WG has resolved to work on or ballot an NP for an update, which is then pre-empted by an automatic SR ballot (e.g. ISO 11715).



- *ISO 12967 Health informatics – Services architecture (HISA)*
 - *Part 1 Enterprise viewpoint*
 - *Part 2 Information viewpoint*
 - *Part 3 Computational viewpoint*

3-month joint NP ballot to commence work on revised second edition under VA commenced late November 2015 and closes in February 2016.

Australian response to include at least one expert and be informed by recent work on *SA HB 137-2013 E-health Interoperability Framework (eHIF)*, *SA HB 138-2013 E-health architecture principles (eHAP)* and *NEHTA Interoperability Framework*.
- *ISO 21667 2010 - Health informatics - Health indicators conceptual framework*. 2-month systematic review opened in January and closes in March 2016. Australia has long-standing interest in this item – including having approved an identical adoption *AS 21667-2012*, which would also need to be revised to reflect any changes.
- *ISO TS 22077-4 - Medical waveform format - Pt 4 Stress test electrocardiography*. 2-month NP ballot opened in December 2015 and closes in February 2016.
- *Health informatics - OMICS Markup Language (OML)*. 3-month joint NP ballot under VA opened in January and closes in April 2016. An informed Australian response should engage with the wider genomics community.
- *Health informatics - Whole Genome Sequence Mark-up Language (WGSML)*. 3-month NP joint under the VA for an ISO/TR is planned to open in January and close in April 2016. An informed Australian response should engage with the wider genomics community.
- *ISO/IEEE11073-series of medical device/personal health device communication standards*
 - *Part 10419: Device specialization -- Insulin pump*
 - *Part 10424: Device specialization -- Sleep apnoea breathing therapy equipment (SABTE)*
 - *Part 10425: Device specialization -- Continuous glucose monitor (CGM)*
 - *Part 20601: Application profile -- Optimized exchange protocol (Ed 2)*

Fast track FDIS ballots for ISO acceptance of the these parts all close mid-January 2016.
- *ISO/IEEE11073-10101 .. Point-of-care medical device communication—Part 10101 Nomenclature*. Committee information ballot (CIB) for acceptance of *Amendment 1 (Additional definitions)* closes in February 2016 with some Australian comment proposed in relation to encouraging IEEE to move progressively toward compliance with ISO/IEC directives on terms and definitions.



- *ISO 21090:2011 Health informatics -- Harmonized data types for information interchange.* 6-month systematic review of this standard is expected to commence in January 2016. Early engagement with Grahame Grieve, the Australian expert who was the principal author, and with the global HL7/CDA, *openEHR*, ISO 13606 EHRcom and HL7/FHIR communities would be highly desirable to agree an appropriate path.
- *ISO 12052:2006 .. Digital imaging and communication in medicine (DICOM) including workflow and data management.* Subject to ISO/TMB approval of the approach, a 2-month CIB to progress an updated draft of the existing ISO 12052 standard and seek experts is tentatively planned to open in January/February 2016. Australia supports this approach as it is important that the widely-used DICOM standard continue to be recognised.
- *Healthcare terminology resource map quality measures (MapQual).* A 2-month NP ballot for an ISO/TS commenced in December 2015 and closes in January 2016 – with Australia to sponsor and support the work and provide a project leader (HG)
- *Metadata repository requirements in healthcare (MetReq).* A 2-month NP ballot for an ISO/TS commenced in January and closes in March 2016 – with Australia to sponsor and support the work and provide a project leader (HG).
- *ISO 17115 2007 - Health informatics -- Vocabulary for terminological systems.* Systematic review ballot on Edition 1 opened in October 2015 and closes in June 2016. Australia is supporting revision in line with preliminary work on a second edition already being drafted in WG 3
- *ISO/AWI IS 17117-1, Health informatics - Terminological Resources - Part 1: Characteristics.* 3-month CD ballot opened in early December 2015 and closes in February 2016 – with Australia to support.
- *ISO 16843-5 Health informatics - Categorical structures for representation of acupuncture-Part 5: Cupping.* Joint 2-month NP ballot with ISO/TC 249 TCM opened in December 2015 and closes in February 2016.
- *ISO/DIS 21549-7 Health Informatics – Patient healthcard data – Part 7: Medication.* A second DIS ballot was originally targeted to open in November 2015 but had not commenced at the time of writing.
- *ISO 11633-1 Health Informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis.*
2 month NP ballot for revised Edition 2 and upgrade to ISO/TS opened in mid-December and closes in February 2016. Comments suggested for the Australian ballot response include:
 - need for additional use cases for remoting monitoring of IT systems management;
 - need to change the term as the maintenance or monitoring system performance is intended not actual health monitoring
 - need for input from JWG7 from the medical devices perspective.



- *ISO/DIS 21298 Health Informatics – Functional and structural roles.* At its previous meeting in April 2015, TC 215 approved 2-month DIS3 ballot to finalise upgrade of *ISO/TS 21298*. DIS3 ballot will be held when updated draft and reconciliation of comments from previous ballot are provided, this needs to occur soon if the project is to avoid cancellation under the progression rules.
- *ISO/TS 19844 Health Informatics - Identification of Medicinal Products (IDMP) – Implementation guide for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances.*
 - 2-month joint DTS ballot under the VA for a revised Edition 2 for publication in 2016 and focussed on the updated Annexes E through K opened in mid-January and closes in March 2016;
 - A further 2-month j joint NP ballot under the VA to authorise work on Edition 3 for publication in 2017 is scheduled to open in mid-February and close in mid-April 2016.
- *ISO 17523 - Health informatics - Requirements for electronic prescriptions.* Originally approved by TC 215 at its April 2015 meeting and scheduled for August 2015, the joint 2-month FDIS ballot under the VA for *ISO 17523* eventually opened in mid-January and closes in March 2016. Stakeholders to be consulted include NEHTA and those involved with the NPDS.
- *ISO/IEC 80003-series: Quantities and units for telebiometrics/ e-health.* TC 215 national member bodies had the opportunity to respond to a questionnaire and comment on potential future directions of the troubled 80003-series via a 1-month CIB ballot that closed on 24 December 2015. Australia submitted detailed comments.
- *ISO/CD 18668-2 TCM - Coding System of Chinese Medicine - Part 2: Codes of Decoction Pieces.* Joint DIS ballot (under control of TC 249 TCM) anticipated in Feb/Mar 2016.
- *ISO/ CD 18668-3 TCM - Coding System of Chinese Medicines - Part 3: Codes of Chinese Materia Medica.* Joint DIS ballot (under control of TC 249 TCM) anticipated in Feb/Mar 2016.
- *ISO/ CD 18668-4, Coding System of Chinese Medicine – Part 4: Codes of granule forms of individual medicinals for prescriptions (GFIMP).* Joint DIS ballot (under control of TC 249 TCM) anticipated in Feb/Mar 2016.
- *ISO/CD 20333, Traditional Chinese Medicine -- Coding Rules for Chinese Medicines in Supply Chain Management.* Joint DIS ballot (under control of TC 249 TCM) anticipated in Feb/Mar 2016.



Status of the work:	
	<p>Recent & pending publications (since April 2015 meeting)</p> <ul style="list-style-type: none"> • <i>ISO/HL7 10781 Health Informatics – HL7 Electronic Health Records System Functional Model - Release 2 (EHR-S FM R2)</i>. Published 2015-07-31. • <i>ISO/HL7 16527 Health Informatics – HL7 Personal Health Record System Functional Model, Release 1 (PHR-S FM R1)</i>. Final copy to ISO/CS on 2015-04-01. • <i>ISO 13940:2015 Health Informatics – System of concepts to support continuity of care (ContSys)</i>. Published 2015-12-17. Noted as possible AU adoption. • <i>ISO/TS 13972:2015 Health Informatics - Detailed clinical models - characteristics and processes</i>. Published 2015-09-11. • <i>ISO/TR 17522:2015 Health Informatics – Provisions for Health Applications on Mobile/Smart Devices</i>. Published 2015-08-01. • <i>ISO 22077-1:2015 Health Informatics – Medical waveform format – Part 1: Encoding rules</i>. Published 2015-04-16. Applicability of ISO 22077-series to AU is not presently known. • <i>ISO/TS 22077-2:2015 Health Informatics – Medical waveform format – Part 2: Electrocardiography</i>. Published 2015-08-14. • <i>ISO/TS 22077-3:2015 Health informatics - Medical waveform format Part 3 : Long term Electrocardiography</i>. Published 2015-07-21. • <i>ISO 14199:2015 Health Informatics – Information models: Biomedical Research Integrated Domain Group (BRIDG) Model</i>. Published 2015-09-17. • <i>ISO/TS 13582:2015 Health informatics -- Sharing of OID registry information</i>. Published 2015-12-11. • <i>ISO/TR 12310:2015 Health Informatics – Principles and guidelines for the measurement of conformance in the implementation of terminological systems</i>. Published 2015-05-22. Potential for AU adoption. • <i>ISO 16278 Health Informatics – Categorical Structures for Terminological Systems of Human Anatomy</i>. Awaiting publication – expected 2016-02-01. • <i>ISO/TS 18790-1:2015 Health Informatics – Profiling framework and classification for Traditional Medicine informatics standards development - Part 1: Traditional Chinese Medicine</i>. Published 2015-05-08. • <i>ISO 17090-2 Health Informatics – Public key infrastructure - Part 2: Certificate profile</i>. Published 2015-11-16. To be considered in any revision of AS ISO 17090.2-2003 (as per aged standards review). • <i>ISO/TS 17975:2015 Health informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information</i>. Published 2015-09-18.



- *ISO 21549-5:2015 Health Informatics – Patient healthcard data - Part 5: Identification data.* Published 2015-09-16.
- *ISO/DIS 27799 Health Informatics – Information security management in health using ISO/IEC 27002.* Final text provided to ISO/CS in December 2015 with publication expected in coming months.
The local adoption, AS ISO 27799-2011 will need to be revisited (as per recent IT-014 aged standards review).
- *ISO/TS 19844:2015 Health informatics - Identification of medicinal products - Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances.* Published 2016-01-04.
- *ISO/TS 19256 Health informatics - Requirements for medicinal product dictionary systems for health care.* Final text submitted to ISO/CS for publication 2016-01-06.
- *ISO/TS 20440 Health informatics – 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.* Final text submitted to ISO/CS for publication 2016-01-11.
- *ISO/DTS 16843-2 Health informatics - Categorial structures for representation of acupuncture - Part 2: Needling.* Published 2015-12-08.

WG 1 projects

- *ISO 13606 .. Electronic health record communication (EHRcom).*
Revision of Parts 1 and 2 being progressed by project teams meeting regularly by teleconference and in Europe with view to updated drafts being submitted for CD ballot Feb 2016 and review of comments at May 2016 meeting. Revised drafts of parts 3, 4 and 5 continue to be prepared for review at the May 2016 meeting and CD ballot thereafter. It has been confirmed with the project lead that it is still intended to have all 5 parts of ISO 13606 Ed 2 submitted for joint DIS ballot at the same time.
- *ISO 12967:2009 Health informatics – Services architecture (HISA) Parts 1, 2 and 3.* Proposed Ed. 2 now open for joint NP ballot. Review of comments and approach planned for a dedicated session at the May 2016 meeting.
- *ISO/DTS 18864, Health Informatics, Quality metrics for detailed clinical models.* DTS ballot closed in Nov 2014, project lead promised updated draft document and disposition of comments for approval to publish (or re-ballot) at the May 2016 meeting.
- *IWA 18 Community-based integrated health and care services for aged societies.* The final revised report is to be made freely available by BSI in early 2016. Related WG 1 health informatics work items may arise during 2016. (Also see comments [above](#)).



- *Business information analysis for healthcare.* Potential work item proposed by Sweden is still at preliminary discussion stage but needs to ensure to focus on health informatics matters within TC 215 scope, rather than prescribing the use of any particular generic business analysis tool.
- *ISO/TR 14649 .. Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model.* Consideration of a proposal to upgrade to an ISO/TS is on hold until a preliminary draft and project justification is available.

WG 2 projects

- *ISO 14199:2015 ... Biomedical Research Integrated Domain Group (BRIDG) Model - Alternative pathways for future maintenance under discussion.*
- *ISO/PWI TS 22077-4 Health informatics - Medical waveform format - Part 4: Stress test electrocardiography.* 2-month NP ballot approved and in progress.
- *EN 1064:2005 Standard communication protocol - Computer-assisted electrocardiography (SCP ECG) and the associated ISO standard: ISO 11073-91064:2009.* Draft of proposed revisions not yet available.
- *ISO/AWI TR 20055 .. Person-owned document repository for PHR applications and health information exchange.* Project lead, Byoung-Kee Yi (KR), still reconciling comments and preparing revised draft for May 2016 meeting including consolidating and abstracting case studies.
- *ISO/NP TS 21089:2004 .. Trusted end-to-end information flows.* NP for upgrade of existing *ISO/TR 21089:2004* to ISO/TS approved in Jan 2015. Project lead Gary Dickenson (US) distributed working draft to experts for feedback by Feb 2016 to meet ISO posting deadline of 14 Mar. RDH needs to review and comment as the AU nominated expert.
- *ISO 12052:2006 .. Digital imaging and communication in medicine (DICOM) including workflow and data management.* To be revised in similar high-level form as Ed 1 in line with protocol agreed with ISO/TMB.
- RSP ("reference standards portfolio" or "bundled standard") for digital imaging domain. Once preliminary proposal approved by the TMB, work on this is to proceed in parallel with, but as a separate project to the revision of ISO 12052:2006. Draft of preliminary proposal still in preparation following circulation of concept documents among CAG 02 Coordination group.
- *Health informatics - OMICS Markup Language (OML).* 3-month joint NP ballot under VA approved and in progress. This new work will extend and replace *ISO 25720:2009 .. Genomic Sequence Variation Markup Language (GSVML).* See further comments [above](#).



- *Health informatics - Whole Genome Sequence Mark-up Language (WGSML)*. 3-month NP joint under the VA for an ISO/TR approved and is planned to run from January to April 2016. See further comments [above](#).
- *ISO/NP TS 20428 Health informatics, Metadata for describing structured clinical genomic sequence information in EHRs*. Mr. Soo-Yong Shin (KR) reported on progress in reconciling comments from NP ballot (closed Aug 2015) and providing updated DTS draft for May 2016 meeting. See further comments [above](#).
- *ISO/NP TR 19669 Re-usable component strategy for use case development*. Project lead Gary Dickenson (US) had distributed working draft to experts and invited feedback by 1 Feb 2016 with view to having a DTR for discussion at the next meeting in May 2016. RDH to review and respond as the AU nominated expert.
- *ISO 17583 .. Terminology constraints [bindings] for coded data elements expressed in ISO harmonized data types used in healthcare information interchange*. Approved to proceed to publication once final copy incorporating agreed changes from DIS ballot is provided (by mid-January).

WG 3 projects (see Appendix A for more details)

- *ISO 17115:2007 Health informatics - Vocabulary for terminological systems*. Integrated draft for Ed. 2 is being progressed for May 2016 meeting and potential DIS ballot thereafter. A systematic review ballot for *ISO 17115* has also been automatically triggered closing in March 2016.
- *ISO 13120:2013 Health informatics - Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClAML)*. A revised draft and reconciliation of NP ballot comments for Ed. 2 to be circulated before the May 2016 meeting for potential DIS ballot thereafter
- *ISO/AWI 17117-1 Health informatics - Terminological Resources - Part 1: Characteristics*. A draft of the updated work was received at the meeting and was circulated for a 3-month CD ballot on 30 November 2015.
- *Healthcare terminology resource map quality measures (MapQual)*. 2-month NP ballot for proposed ISO/TS approved and in progress. Australian sponsorship and leadership of the item is proposed.
- *Metadata repository requirements in healthcare (MetReq)*. 2-month NP ballot for proposed ISO/TS approved and in progress. Australian sponsorship and leadership of the item is proposed.
- *Value set definition – Part 1: Design and governance (VSD1)*. PWI documentation for an ISO/TS being progressed on WG 3 teleconferences.
- *Value set definition – Part 2: Quality measures (VSD2)*. PWI documentation for an ISO/TS being progressed on WG 3 teleconferences.
- *Workforce tasks and capability specification for semantic content (Termworkers)*. More focussed scope and PWI documentation for an ISO/TS being developed on WG 3 teleconferences.



- *ISO/TS 18062 Categorial structure for representation of herbal medicaments in terminological systems.* Following DTS2 ballot in October, approved for publication subject to completion of ballot reconciliation and significant editing, with results to be confirmed through a one-month review by WG 3 and WG 6 to confirm acceptability of final copy. Ballot reconciliation and updated draft with improved expression awaited.

WG 4 projects (see Appendix B for more details)

- *ISO/DIS 25237 Health informatics - Pseudonymization.* DIS ballot for Ed. 2 was still open until 05 Dec 2015. Proposals for finalisation expected at May 2016 meeting.
Existing AU adoption *ATS ISO 25237-2011* will need to be revisited in light of changes in the international edition.
- *ISO/TR 11633-1:2009 Health informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis.* 2-month NP ballot for update to ISO/TS approved and in progress. See comments [above](#).
- *ISO/PWI TR 11633-2:2009 Health informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 2: Implementation of an information security management system (ISMS).* PWI formally approved and registered for revision of existing ISO/TR 11633 Part 2 in parallel with revision and update of Part 1. Progress to NP ballot anticipated after May 2016 meeting.
- *ISO/NP 20429 .. Principles and guidelines for protection of personal health information.* WG 4 agreed scope amendments and work schedule for reconciliation of NP ballot comments with view to production of CD draft for review prior to May 2016 meeting and for ballot afterwards.
- *ISO/DTR 18638 Health informatics - Components of education to ensure health privacy.* Project originally registered in Jan 2013 is in risk of cancellation with very slow progress in producing a DTR for ballot. Plans to progress the work through regular teleconferences were agreed. Trish Williams (AU) will also edit the draft and advise on wording.
- *ISO/NP TS 20405 Health informatics - Framework of event data and reporting definitions for the safety of health software.* Project lead (Grant Gillis) was unable to be present. Updated working draft and reconciliation of comments from NP ballot are overdue.
- *ISO/DIS 21298 Health Informatics – Functional and structural roles.* Awaiting materials required for approved 2-month DIS3 ballot. This needs to occur soon if the project is to avoid cancellation under the progression rules.
- *ISO/PWI TR 21333 Health informatics - Privacy terms and definitions.* PWI formally approved and registered to progress an ISO/TR.

- *ISO/PWI TR 21332 Health informatics - Cloud computing security and privacy requirements for health information.* PWI formally approved and registered. Drafting of ISO/TR for May 2016 being progressed by scheduled teleconferences of a project team, which includes Trish Williams (AU).
- *SO/DIS 21549-7 Health Informatics – Patient healthcard data-Part 7: Medication.* Moved from 36 month to 48 month track. Updated documents for DIS2 ballot to be provided in November but the ballot does not yet appear to have opened.

WG 6 projects

- *ISO/DTS 19256 Health informatics - Requirements for medicinal product dictionary systems for health care.* Approved for publication following successful DIS2 ballot and acceptance of proposed edits.
- *ISO/TS 20440 Health informatics – 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.* Approved for publication following successful DTS ballot and agreement on final copy.
- *ISO/DTS 17251 Health informatics – Business requirements for a syntax to exchange structured dose instructions for medicinal products.* Approved for publication following successful DTS ballot and reconciliation of comments. Final copy due November 2015 is still awaited.
- *ISO/TS 22224:2009. Health informatics - Electronic reporting of adverse drug reactions.* Withdrawn from ISO catalogue with TC 215 approval.
- *ISO/TS 19844 Health Informatics - Identification of Medicinal Products (IDMP) – Implementation guide for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances*
 - Ed. 1 approved at previous meeting was published 2015-12-15.
 - 2-month joint DTS ballot with CEN/TC 251 under the Vienna Agreement (VA) for the second edition (2016) adding new Annexes E through K was approved and is now open, closing in March. Updated draft likely to be submitted for approval to publish at May meeting.
 - A further 2-month joint NP ballot under the VA to authorise work on the third edition (2017) has also been approved and is scheduled to open in February 2016.
- *ISO/NP 11238 Health Informatics - IDMP - Data elements and structures for the unique identification and exchange of regulated information on substances (Ed 2).* NP ballot closed in September. NP ballot reconciliation underway with revised draft also taking into account learning from parallel development of ISO/TS 19844 implementation guide. Revised working draft to be available for discussion and progression at May 2016 meeting.

- For:
 - *ISO/DTS 20443 Health Informatics - IDMP - Implementation Guide for ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information.*
 - *ISO/DTS 20451 Health Informatics - IDMP – Implementation guide for ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*
 - *ISO/NP 11615 Health Informatics - IDMP - Data elements and structures for the unique identification and exchange of regulated medicinal product information (Ed 2)*
 - *ISO/NP 11616 Health Informatics - IDMP - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (Ed. 2).*

All four documents passed DTS and NP ballots closing in September 2015. A synchronised process is being used for disposition of ballot comments with ballot reconciliations and updated working drafts to be circulated in time for consideration and progression at the May 2016 meeting.

- *ISO/AWI TR 14872 Health informatics - IDMP - Core Principles for Maintenance of Identifiers and Terms.* Project commenced in 2012/13 but set aside while IDMP implementation guides developed. Project lead, Lise Stevens (US), will have updated working draft and a draft resolution for DTR ballot available for the May 2016 meeting.
- *ISO/FDIS 17523 - Health informatics - Requirements for electronic prescriptions.* Joint 2-month FDIS ballot with CEN/TC 251 under the VA (originally approved by TC 215 in April 2015) has now commenced and it is likely this item will be approved for publication at the May 2016 meeting.
- *ISO/AWI TS 19293 - Health informatics - Requirements for the record of dispense medicinal products.* WG6 decided to reactivate the project (which has been dormant since the project was approved in October 2013). [However, it is noted final publication deadline is October 2015].
- *ISO/NP DTR 20831 Medication management concepts and definitions.* Expert team summarised progress since NP approved and registered in September and plan to have working draft of DTR ready for consideration at May 2016 meeting.

JWG 1 projects

- *ISO/NP TS 16843-1 Health informatics - Categorial structure for representation of acupuncture—Part 1: Acupuncture points.* DTS ballot closed September 2014. Ballot reconciliation and revised draft awaited and will be considered for publication at May 2016 meeting.
- *ISO/DTS 16843-2 Health informatics - Categorial structures for representation of acupuncture - Part 2: Needling.* Published 2015-12-08.

- *ISO/NP TS 16843-3 Health informatics - Categorical structures for representation of acupuncture - Part 3: Moxibustion.* Approved as new project in February 2015. NP ballot reconciliation and revised draft now required for approval to proceed to DTS ballot.
- *ISO/PWI TS 16843-4 Health informatics - Categorical structures for representation of acupuncture - Part 4: Meridian and collateral channels.* NP ballot closed 2015-09-15 with ballot results and decision awaited.
- *ISO/PWI TS 16843-05 Health informatics - Categorical structures for representation of acupuncture - Part 5 Cupping.* Joint 2-month NP ballot with ISO/TC 249 (TCM) approved and in progress.
- *Classification of Traditional Chinese Medicine datasets.* Potential JWG 1 work item and proposed form 4 presented by Dr.Li Haiyan. Regarded as a PWI at preliminary discussion stage.

[Note: the following joint projects are administered by TC 249 Traditional Chinese medicine (TCM).]

- *ISO/FDIS 18668-1 TCM - Coding system of Chinese medicines - Part 1: Coding rules for Chinese medicines.* At FDIS ballot closing Feb 2016.
- *ISO/CD 18668-2 TCM - Coding System of Chinese Medicine -- Part 2: Codes of Decoction Pieces.* Awaiting release of DIS ballot – expected Feb/Mar 2016.
- *ISO/ CD 18668-3, TCM - Coding System of Chinese Medicines -- Part 3: Codes of Chinese Materia Medica.* Awaiting release of DIS ballot – expected Feb/Mar 2016.
- *ISO/ CD 18668-4, Coding System of Chinese Medicine – Part 4: Codes of granule forms of individual medicinals for prescriptions (GFIMP).* Awaiting release of DIS ballot – expected Feb/Mar 2016.
- *ISO/CD 20333, Traditional Chinese Medicine -- Coding Rules for Chinese Medicines in Supply Chain Management.* Awaiting release of DIS ballot – expected Feb/Mar 2016.

JWG 7 projects (see Appendix C for more detail)

- *ISO/IEC 80001-series Application of risk management for IT-networks incorporating medical devices.*

Extensive revision of *80001-series* (including overlaps with *IEC 82304* and *IEC 62304* and incorporating new health software “foundations” requirements as per recent health software report) is occurring via regular teleconferences. All JWG 7 experts have been asked to sign on to at least one of the 3 teams progressing this work:

- Revision of existing 80001-1: Roles and responsibilities
- 80001 General Requirements – including overall structure & numbering of the 80001-series
- New Health Software Foundation document. Trish Williams (AU) is a co-lead on this team.



Recommendations and related project documentation were requested for review at the May 2016 meeting.

- *IEC/DIS 82304 Health software - Part 1: General requirements for product safety.* Joint DIS/CDV ballot closed the week of the Bern meeting. Out-of-cycle meeting taking place in Cape Town in January 2016 to resolve comments and plan completion of final draft (being attended by Trish Williams). Proposal and documentation for publication or FDIS ballot to be submitted to May 2016 TC 215 meeting and to IEC/SC 62A.
- *IEC/DTR 80001-2-8 Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2.* Approved to proceed to publication after final copy and disposition of comments confirmed by 1-month ballot of JWG 7 experts. Copy for publication requested by February 2016.
- *IEC/NP TR 80001-2-9 ... Part 2-9: Application guidance -- Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities.* NP ballot closed Feb 2015. Project team completed reconciliation of 100+ comments and working on CD draft for review and ballot as a DTR (further comments [below](#)).
- *IEC/CD 62304 Medical device software - Software life cycle processes (Ed 2).* Project team working on CD draft for delivery mid-year (further comments [below](#)). Project has already exceeded previous targets and its official deadline and will probably need to be cancelled and re-commenced. this would be best done when there is widely supported CD draft available.

Other recent TC 215 publications

- *ISO/IEEE 11073-10442:2015 .. Personal health device communication - Part 10442: Device specialization - Strength fitness equipment.* Published 2015-03-02.
- *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 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 to update national adoptions were overtaken by national eHealth initiatives but will be reconsidered by IT-014 following recent aged standards review.
- *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.



	<ul style="list-style-type: none">• <i>ISO/TS 17938:2014 .. Semantic network framework of traditional Chinese medicine language system.</i> Published 2014-06-13.• <i>ISO/TS 17948:2014 Traditional Chinese medicine literature metadata.</i> Published 2014-07-14.• <i>ISO/TR 19231:2014 .. Survey of mHealth projects in low and middle income countries (LMIC).</i> Published 2014-11-14. A general descriptive work summarising the outcomes of preliminary online research into the subject.• <i>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.</i> Published 2014-12-17.• <i>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.</i> Published 2014-11-20
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Other stakeholders:	<p>In addition to IT-014 and its nominating organisations, it is suggested that potential recipients of this report include:</p> <ul style="list-style-type: none">• In relation to the MetReq proposal:<ul style="list-style-type: none">- AIHW- the IT-xxx mirror committee to ISO/IEC JTC1/SC32 Data management and interchange,• HE-031 for issues related to traditional medicine• ACSQHC in relation to the work on safety of health software.
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* Abridged & edited in places for this appendix.

International Delegate's Meeting Report

Date	13th November 2015
Name	Heather Grain
Position/Title	Managing Director
Company	
Postal Address	Global eHealth Collaborative 33 Thurso Street, Malvern East, Vic. 3145
Email Address	heather.grain@gehco.org

Observations & comments:	<p>General.</p> <ul style="list-style-type: none"> • Working Group Strategy Review. Development and application of the WG3 framework for analysis and prioritization of working group activities to address community needs, which is led by Heather Grain, was noted and suggested for more consideration by other WGs. • Changes to ISO/IEC Directives and forms. The updated forms were reviewed and method of use explained. Improving the publication processes - detailed guidance was provided to the leadership specifically on issues identified by ISO SC editors. The tooling is not adequate to meet the needs of the health informatics standards community but is being improved. These sessions were very useful both for attendees and for the secretariat. • Changes to ISO systems. Discussion will be ongoing but improving use of the ISO portal for projects is to be implemented by WG3, with project specific pages being introduced. Requests have been made to the secretary to see how improved identification of current work can be communicated to the broad community. This is specifically to raise awareness in the health informatics and healthcare communities of the work items and their objective and use cases. <p>Joint WG1/WG3 projects. The following were the main topics discussed in joint session of WG1 and WG3.</p> <ul style="list-style-type: none"> • SKMT (Standards Knowledge Management Tool) and “health record” family of terms. HG reported on comments received on “preferred definitions” for “health record” and terms related to health record. This work used the many definitions in SKMT for health records and related concepts. EHR Definitions. Heather Grain presented an update on the comments received from WG1 and will prepare an updated harmonisation document taking those comments into consideration. This work is to be harmonised through the SKMT Governance Council (of the JIC). • ISO/FDIS 13940 System of concepts to support continuity of care (Contsys). Publishing problems are largely resolved and this work should be ready for publication in the next 3 months.
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Joint WG2/WG3 project. Progress on the following joint project with WG2 (Systems and device interoperability) was reviewed:

- **ISO/DIS 17583 .. Terminology constraints [bindings] for coded data elements expressed in ISO harmonized data types used in healthcare information interchange.** DIS ballot comment reconciliation was discussed and final comments resolved. These were largely issues of presentation. The work will be updated to reflect the changes agreed and go forward for publication.

Joint meeting of WG3 and WG6 (Pharmacy and medications business).

- **ISO/AWI DTS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems.** [To progress to publication after final review/edit as per entry below].

WG3 Semantic Content

- **Framework for classification of WG3 standards work.** The framework [which had been first presented at the April 2015 meeting in San Francisco] was further developed and discussed. Work items discussed at this meeting had been established on the basis of the WG framework gap analysis.

A detailed document outlining the framework and methodology used to produce it will be shared with the TC in December for further consideration by other working groups. WG3 will continue to review and update the framework as a means of identifying standards required.

In Publication:

- *ISO 16278 Health informatics - Categorial structures for terminological systems of human anatomy*
- *ISO 13940 Health informatics - System of concepts to support continuity of care (ContSys)*

Request to publish:

- **ISO TS 18062 Categorial structure for representation of herbal medicaments in terminological systems.** There were comments to be disposed. These were discussed and agreement on the best approach reached with experts from WG6. It was seen as vital that this work coordinate and harmonise with existing Pharmacy publications. It was agreed that these updates were satisfactory, and if combined with improved English expression would make the document suitable for publication. The TC accepted a request to publish following improvements to the expression.



Current work items:

- **ISO 17115:2007 .. Vocabulary for terminological systems.** The proposed revision of the terms in this document was discussed. The next step is to incorporate material from European work on categorial structures. It is intended that this be completed before the next meeting and at that meeting it is planned that this will come forward for DIS ballot.
- **ISO 13120:2013 .. Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClAML)** – Revision. This work identifies the requirements and representation for databases and other electronic forms of publication of classifications. It is used for ICD by WHO and many other countries and is therefore of direct interest to Australia as a consumer of these electronic formats. The modifications in this 2nd edition will reflect usage of the publication and are intended to make the work more generic and easier to use. A revised draft incorporating feedback from the recent NP ballot and discussions in Bern is to be circulated prior to the May 2016 meeting for consideration at that meeting and subsequent DIS ballot.
- **ISO/AWI 17117-1 Health informatics - Terminological Resources - Part 1: Characteristics**
(revising & upgrading: *ISO/TS 17117:2002 Health informatics - Controlled health terminology - Structure and high-level indicators*)
A draft of the updated work was received at the meeting and was subsequently circulated for CD ballot on 30 November 2015.

Proposals for New Work Items

These two work items were considered the highest priority under the WG3 planning framework. Both items are of direct interest and utility to Australian eHealth initiatives and to health informatics more generally. Peter Williams offered potential resourcing from within Australia.

- **Proposed ISO/TS on: Healthcare terminology resource map quality measures (MapQual).** Draft document and Form 4 have been provided. Standards Australia is being asked to sponsor the NP ballot for this work item, with leadership by Heather Grain. The business case was discussed and all countries present considered this to be a key piece of work and offered to provide expertise into the project.
- **Proposed ISO/TS on: Metadata repository requirements in healthcare (MetReq).** Draft document and Form 4 have been provided. Standards Australia is being asked to sponsor the NP ballot for this work item, with leadership by Heather Grain. The business case was discussed and all countries present considered this to be a key piece of work and offered to provide expertise to the project. Peter Williams indicated that material from AIHW would be available to assist in this project.



	<p>Preliminary Work Items (PWIs)</p> <p>The following preliminary work items previously approved by TC 215 are being progressed but do not yet have active resourcing. A diary of discussion topics for fortnightly WG3 teleconferences was established with times being scheduled for progression of each of the items.</p> <ul style="list-style-type: none"> • PWI for an ISO/TS on: <i>Terminology implementation capability and maturity models – Part 1: Capability (TICMM1)</i> • PWI for an ISO/TS on: <i>Value set definition – Part 1: Design and governance (VSD1)</i> • PWI for an ISO/TS on: <i>Value set definition – Part 2: Quality measures (VSD2)</i> • PWI for an ISO/TS on: <i>Workforce tasks and capability specification for semantic content (Termworkers)</i>. Joint discussion of this work item by WG1 and WG3 indicated that the scope of this PWI needs to be clarified and be more clearly focussed on those working with terminologies and classifications in healthcare. <p>There was also discussion of one or two potential new projects to develop ISO/TS or ISO/TR documents addressing:</p> <ul style="list-style-type: none"> • <i>Terminological systems for herbal medicines and formulas</i> • <i>Indications (efficacies) binding to herbal medicines and formulas</i> <p>Working drafts of the documents and Form 4s are expected to be available for WG3 review in February 2016 with the intention of seeking TC 215 approval at the May 2016 meeting to register them as PWIs.</p>
	<p>Joint meeting of WG 3 with the Traditional Medicine Taskforce (TMTF) and JWG1</p> <p>There were 4 countries represented along with the liaison from ISO/TC 249 (Traditional Chinese Medicine) at this joint session. [For the rest of the time, the TMTF met jointly with JWG 1]. The WG3 proposal to progress the following item to NP ballot was accepted by TC 215:</p> <ul style="list-style-type: none"> • <i>ISO/PWI TS 16843-05 Categorical structures for representation of acupuncture - Part 5 Cupping.</i>
<p>Key Items/Actions for Australia</p>	<p>New work items for sponsorship by Standards Australia:</p> <ul style="list-style-type: none"> • ISO/TS on: <i>Healthcare terminology resource map quality measures (MapQual)</i>. Standards Australia is being asked to sponsor this work item, with leadership by Heather Grain. A draft document and Form 4 have been provided. • ISO/TS on: <i>Metadata repository requirements in healthcare (MetReq)</i>. Standards Australia is being asked to sponsor this work item, with leadership by Heather Grain. A draft document and Form 4 have been provided.
<p>Status of the work</p>	<p>As reported in the main report.</p>



Other Stakeholders	<p>In addition to IT-014, it is suggested that potential recipients of this report include:</p> <ul style="list-style-type: none">• AIHW and the IT-000 mirror committee to ISO/IEC JTC1/SC32 Data management and interchange, in relation to MetReq• HE-031 for issues related to traditional medicine
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International Delegate's Meeting Report

Date:	6 th December 2015
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Delegate details:	
Name	Dr Trish Williams
Position/Title	Associate Professor
Company	Edith Cowan University
Postal address	14 Iandra Loop, Carramar, WA 6031
Email address	trish.williams@ecu.edu.au

Observations & comments:	
	<ul style="list-style-type: none"> • Brazilian proposal of <i>PWI for ISO/TR on Cloud computing security and privacy requirements for health information</i>. It was noted that the scope would address security and privacy requirements applicable to selecting suppliers of cloud services to process health information. • Proposed NWIP (from Japan) to revise <i>ISO/TR 11633:2009 Parts 1 & 2 on Information security management for remote maintenance of medical device and medical information systems</i>. These documents are based on application of the ISO/IEC 27000-series of information security standards and need to be updated to address changes in ISO/IEC 27001: 2005 and 27002:2005. There was discussion as to whether the scope of the work item was sufficiently clear and constrained due to the differing meanings of "remote maintenance" in the medical device and IT domains. There is also a need to involve JWG 7. • <i>ISO/NP 20429 Health informatics - Principles and guidelines for protection of personal health information (PHI)</i>. The current transborder standard [ISO 22857] is too complicated. Whilst it is proposed that the <i>ISO 20429</i> be based on the OECD principles, a revised privacy framework focusing on healthcare specifics was suggested. This item crosses over with JWG7 work, where it was proposed the Australian Privacy Principles be used as a practical basis. • <i>ISO/DTR 18638 Health informatics - Components of education to ensure health privacy</i>. Objections to this work item are largely due to poor communication of the content. The current draft needs significant rewording to address English language issues. • 82304-1 - Suggestion that a second part to this standard may be needed to address the specific application of security. Currently 82304 focusses on safety and demonstration of development processes to ensure safety. More discussion of this will be at the next out-of-cycle meeting at the comment resolution meeting.



	<ul style="list-style-type: none"> • JWG7 – New 80001 revision and new foundation standard task force. Australian experts are heavily engaged in this work and have been for the last 3 months with weekly meetings of the 8 topic groups with 2 Australian leads of the topic groups. – Tony Cowan and Trish Williams, with further engagement by Kathy Dallest and Vincent McCauley.
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Key items/actions for Australia:	-
	<p>In relation to WG 4 activities:</p> <ol style="list-style-type: none"> 1. Brazilian proposal of PWI for ISO/TR on <i>Cloud computing security and privacy requirements for health information</i>. The work needs to be compatible with the Australian Privacy Principles and EU legislation foundations. Trish Williams to work with preliminary drafting group by teleconference prior to May meeting in Amsterdam. 2. NWIP for <i>ISO 11633</i> updates (Japan). Australian comments on upcoming 2 month NP should include: <ul style="list-style-type: none"> - need for additional use cases for remoting monitoring of IT systems management; - need to change the term as the maintenance or monitoring system performance is intended not actual health monitoring - need for input from JWG7 from the medical devices perspective. 3. <i>ISO/NP 20429 .. Principles and guidelines for protection of PHI</i>. WG4 has been provided with Australian Privacy Principles as an exemplar. 4. <i>ISO/DTR 18638 .. Components of education to ensure health privacy</i>. Trish Williams will advise project team on wording before the work is reviewed again by WG 4. <p>In relation to JWG 7 activities:</p> <ol style="list-style-type: none"> 5. <i>82304-1 (Safety of health software)</i>. Comments from DIS ballot to be reconciled prior to and at out-of cycle-meeting in Cape Town in January 2016. Trish Williams will be attending self-funded to ensure that the health software domain is represented, as the group is dominated by delegates funded by the medical device manufacturing industry. 6. <i>Revision of ISO/IEC 80001-series including new foundation standard on health software safety</i>. Continuing engagement by Australian experts (Trish Williams, Kathy Dallest, Vince McCauley, Richard Dixon Hughes and Tony Cowan) with Trish Williams to be joint lead of task force authoring new <i>Foundations</i> document as part of 80001 revision.

Status of the work:	
	As reported in the main report.

International Delegate's Meeting Report

Date:	6 th December 2015
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Delegate details:	<i>For multi-person delegation please provide details of the head of delegation only.</i>
Name	Dr Vincent McCauley
Position/Title	Chief Medical Officer
Company	Emerging Systems Pty Ltd
Postal address	PO Box 508, ROZELLE, 2039
Email address	Vincent.McCauley@emerging.com.au

Confirm net benefit to Australia in participating:	<ul style="list-style-type: none"> The work in WG2 and JWG7 is relevant to Australia as industry is looking at trialling 82304-1 in 2016. Further, the influence of Australia is very important with regard to the revisions of 80001, as some jurisdictions (QLD and NSW) and major eHealth corporations (such as Telstra Health) are implementing or considering implementing, these standards as part of their approach to eHealth safety and clinical governance. These standard will also influence the new work in the USA (a major market partner) to develop requirements in these areas – <ul style="list-style-type: none"> - <i>AAMI HIT 1000 Application of risk management processes for health IT</i> - <i>AAMI HIT 2000 Application of quality management processes to Health IT</i> <p>Harmonization of requirements will facilitate entry of Australian products into the USA marketplace and a more competitive marketplace in Australia.</p>
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Observations & comments:	<ul style="list-style-type: none"> Revision of the ISO/IEC 80001-series. A consolidated report on progress was presented including the input from the various subgroups – including two chaired by Australians (Kathy Dallest and Trish Williams) – with input from Dr McCauley on clinical issues and Tony Cowan on Australian implementation experience. The progress achieved was due to a significant amount of work performed at several series of fortnightly teleconferences since the April 2015 meeting of ISO/TC 215 in San Francisco. <p>The treatment of privacy is a significant issue in the revision of the ISO/IEC 80001-series. Whilst this standard deals extensively with security its treatment of privacy is rudimentary. This was due to the belief when it was first written five years ago that privacy has major cultural determinants and hence consensus as part of an ISO document would be difficult to achieve. The need for more comprehensive coverage of privacy arose in the context of a discussion of Resolution 46 passed at the San Francisco meeting in</p>
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April that required JWG7 to “*explore development of a document addressing the sociotechnical context for Health IT & IM*”

At this meeting in Bern, Dr McCauley suggested that there was now a more mature and consistent approach to eHealth and privacy and proposed that the previous assumption of cultural diversity should be tested. This received general agreement. To that end the current Australian Privacy Principles (APPs) were distributed to JWG7 members for information and feedback. In particular, members were requested to inform the group if any of the APPs could not be supported. No issues with the APPs have been raised at or since the meeting. It thus appears that the APPs may form the initial guidance to eHealth privacy to be incorporated into the revised 80001 standards family.

- *IEC 82304-1 Health software - Part 1: General requirements for product safety* (colloquially known as “*Safety of health software*”). The DIS ballot closed immediately prior to this meeting. The document passed ballot but there are 200 plus comments including a number of negatives that need to be resolved. Work on resolving the comments has commenced by teleconference and it is the intention to have these fully resolved along with any resulting text changes by February in order for this document to be ready for publication as a Draft International Standard in time for the May ISO TC215 meeting.

There is some urgency in publishing this document to provide guidance for member countries formulating systematic approaches to eHealth software safety. Hence there will be an out of session meeting of the drafting sub-committee in Capetown in January 2016.

One of the negative votes suggested that security needs to be considered as part of this work. This was discussed in Bern and the potential for a second part to this standard to address the specific application of security appeared to have good support as a means to resolve this issue. Currently 82304-1 focusses on safety and demonstration of development processes to ensure safety and security was considered to be out of scope for the initial work. More discussion of this will take place at the next out-of-cycle meeting in Cape Town.

Two Australians – Prof. Trish Williams and Dr Vincent McCauley - have been part of the project team since its inception nearly three years ago.

- *IEC 62304:2006 Medical device software - Software life cycle processes* (colloquially known as “*Medical device software risk management*”). Drafting of the revised second edition is proceeding following an out of cycle meeting of the drafting sub-committee in Barcelona in October. Members of the drafting group indicated there was possibly an intention to extend the scope to general eHealth software. However the group has mainly medical device membership and little general Health software participation or expertise. There is also a risk that the revision of may have to deal with overlap and harmonisation of definitions with 82304, the 80001-series and proposed foundation standard.

It was agreed that further expertise would be sought via the IHE and HL7 ISO TC215 liaisons, An initial CD will be completed by May next year.



	<ul style="list-style-type: none"> • <i>IEC/DTR 80001-2-8 - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2 (colloquially: “security catalog for 80001 networks”).</i> This can now proceed to publication following completion of comment resolution (there were only 3 of substance). • <i>IEC/NP TR 80001-2-9 - Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities (colloquially “Safety case guidance for 80001”).</i> More than 100 comments were received at NP ballot but none from Australia. Collation of comments was only completed last week. A few contentious comments were discussed at the meeting and it appears some significant work is needed to reach consensus on this. • The ISO Online Browser platform (OBP) – for terms, standards etc is now available – see https://www.iso.org/obp/ui/
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Key items/actions for Australia:	
	<ul style="list-style-type: none"> • Revision of the <i>ISO/IEC 80001-series on the Application of risk management to IT networks containing medical devices.</i> Two of the subgroups reporting in to the Bern meeting were chaired by Australians (Kathy Dallest and Trish Williams) – with input from Dr McCauley on clinical issues and Tony Cowan on Australian implementation experience. Australians continue to be involved both through the subgroups and in leadership roles. The Australian APPs have been circulated to the project team and may form the basis of initial guidance on eHealth privacy to be incorporated into the revised 80001 standards family. • <i>IEC 82304-1 Health software - Part 1: General requirements for product safety.</i> Prof Trish Williams and Dr Vince McCauley will continue to be involved in finalising resolution of DIS ballot comments and progression of 82304 to publication or to FDIS ballot. • Trish Williams has circulated requested information on the APPs and other health information privacy regimes for consideration and use by JWG 7 in the revision of the ISO/IEC 80001-series and for consideration in the further development of the 82304-series.

Status of the work:	
	As reported in the main report.