Standards Australia Limited ABN 85 087 326 690
20 Bridge Street, Sydney NSW 2000
Telephone +61 2 9237 6000 Facsimile +61 2 9237 6010
www.standards.org.au

International Delegates Meeting Report

Date:	01 August 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:	For multi-person delegation please provide details of the head of delegation only.
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	Sun 01-05-2016. JIC half day planning session **Mon 02-05-2016 to Friday 06-05-2016** including TC 215 leadership meetings, opening plenary, 3 days WG meetings, and closing plenary.
Venue details	VU medisch centrum (VUmc) and Amstel Academie, De Boelelaan, Amsterdam, The Netherlands

Australian delegates:	J Richard DIXON HUGHES (RDH), Head of delegation & expert – mainly at leadership meetings and WG1; also immediate past-chair of the JIC Heather GRAIN (HG) - Convenor, ISO/TC 215/WG 3 Semantic content A/Prof Trish WILLIAMS (TW), expert – mainly at WG4 and JWG 7 Dr Vince McCAULEY (VMcC), expert – mainly at WG2 and JWG 7; also liaison officer for IHE International Manjoo LALWANI (Standards Australia, ISO/TC 251/WG 1 secretariat)

Purpose of meeting:	The purpose of the meeting was to progress the TC 215 work program comprising around 80 active projects and to review potential new projects in the field of health informatics, including joint work with other ISO and IEC technical committees. Australian involvement is significant in terms of monitoring and participating in relevant TC 215 health informatics standards development work on behalf of IT-014 mirror committee, particularly through: • WG1 (Architecture, framework & models) – where Standards Australia has been providing the secretariat (up to and including this meeting) 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 (including RDH and VMcC) 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. 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.

Meeting attendees:	The following 21 P-members were represented at the TC 215 meeting by 155 registered delegates: • Australia • Finland • Norway • Austria • Germany • Russian Federation • Brazil • Italy • Spain • Canada • Japan • Sweden • China • Korea • Switzerland • Czech Republic • Malaysia • United Kingdom • Denmark • The Netherlands • United States A further 37 delegates represented liaison organisations including IHTSDO, DICOM, GS1, IHE, JTC1, CDISC, COCIR, ICH, IEEE, ITU, WHO and several other ISO and IEC committees. Many of these delegates from liaison organisations were also members of national delegations but were counted as representing their liaison organisations. The total attendance of 195 also included delegates, observers, ISO/TC215 secretariat and ISO Central Secretariat (ISO/CS) staff. This meeting was also held jointly with the European CEN/TC251 Health Informatics committee and RDH was invited to observe a joint meeting of the two TC 251 WGs which were formed following a recent re-structure. Health informatics SDO's represented at JIC activities held in conjunction with the ISO/TC 215 meeting were: CEN/TC 251, HL7 International, CDISC, IHTSDO, GS1, IHE International and DICOM.

Key items discussed:	**ISO/TC 215 – General (Plenary sessions, CAG 1, CAG 2 and OAG):** • Status and progression of project to update the 2013 edition of the TC 215 strategic business plan (SBP). This included discussion of proposals for further minor revisions in the description (but not the substance) of the ISO/TC 215 scope. RDH has continuing involvement in the SBP task force and in progressing negotiations with the leadership of IEC/TC 62 and its subcommittees in relation to the scope issue. • Progression of the concept of "Reference Standards Portfolios" (RSPs) that normatively reference the work of other SDOs as well as ISO/IEC documents. The concept has been refined as part of the BSP activity and significant progress was made at this meeting on a project proposal and draft RSP for Clinical Imaging to pilot the RSP concept. • Positive developments through engagement with ISO/TC 12 and IEC/TC 25 to resolve concerns over work on the *ISO/IEC 80003-series: Quantities and*

	units for telebiometrics/ e-health. Following a ballot in the affected TCs, previous work on the *80003-series* is to be retired and a task force formed to ensure that the use of UCUM in clinical contexts is appropriately incorporated in ISO and IEC work on quantities and units. • Leadership renewals/vacancies: - TC 215/WG 1 Architecture, Frameworks and Models – seeking a Vice-Convenor - TC 215/WG 2 System and Device Interoperability. The appointment of Bron Kisler (USA) as convenor was confirmed - TC 215/WG 3 Semantic content - request for Australia to consider allowing Heather Grain to continue as convenor for a further 3-year term - TC 215/WG 4 Security, Safety and Privacy – nominations to be called for convenor - with Lori Reed-Fourquet (USA) likely to continue - Seeking secretariats for WG1 (being vacated by Manjoo Lalwani of Australia) and for WG 2, WG 3 and WG 4 (al being carried by the TC 215 secretariat). • Membership and role of ISO/TC 215 CAG 2 Advisory group. The membership of this group was increased to include all seven TC 215 WG and JWG convenors (in addition to the 5 elected members) and the quorum was increased from 5 to 7 members. • Formation of an additional TC 215 working group in the area of traditional medicine informatics and retire the Traditional Medicine Task Force (TMTF). • Scheduling of upcoming ISO/TC 215 meetings, with the following dates, venues and offers being noted: - 13-17 November 2016, Lillehammer, Norway - confirmed - with JIC Executive likely to meet on 18 November - 17-21 April 2017 (tentative), Hangzhou, Zhejiang Province, China - subject to formal invitation expected from SAC - 6-10 November 2017, Liverpool, United Kingdom - subject to formal invitation expected from BSI - April or May 2018 (dates tbc), Maringá, Paraná State, Brazil - subject to formal invitation expected from ABNT - October 2018 (dates tbc), Kuala Lumpur, Malaysia - subject to formal invitation expected from DSM - April or May 2019 - **a host for the 31st meeting is still being sought** - October or November 2019 (dates tbc), possibly Daegu (tbc), Korea - subject to formal invitation expected from KATS. • Changes in TC 215 processes and procedure flowing from the 2016 edition of ISO/IEC Directives. • A report on the activities of the JIC and specifically the work it is undertaking to identify standards needed to support an international sharing of patient summaries.

	WG 1 Architecture, frameworks and models (joint with CEN/TC 251/WG i): • Status and progression of work on coordinated development of Edition 2 of *ISO 13606 ..*[1] *EHR Communication (EHRcom) - Parts 1 to 5.* Parts 1 and 2 passed their recent CD ballot. The focus at this meeting was to have Parts 3, 4 and 5 ready for an 8-week CD ballot [which has commenced, closing on 15 Sep 2016]. • Status and progression of projects to update *ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3* (jointly with CEN/TC 251). All 3 parts passed NP ballot and work on the project has now commenced with a view to having preliminary drafts ready for the November meeting. • Status and progression of *ISO/DTS 18864, Health Informatics, Quality metrics for detailed clinical models.* The proposed disposition of comments was accepted. An updated version is to be prepared for review prior to approval for release to DTS ballot at the November meeting. • International interest and various developments in the area of patient summaries. • Noting the completion of *IWA 18:2016 Framework for integrated community-based life-long health and care services in aged societies*, and potential requests for related health informatics standards. • A short introductory HL7/FHIR tutorial was held in conjunction with WG2; it was agreed that a deeper understanding of FHIR would be beneficial to TC 215 experts and a longer workshop should be considered. • Status and progression of *ISO/DTR 19669 .. Re-usable Component Strategy for Use Case Development* - in conjunction with WG 2. The proposed draft was discussed and approval was given for the document to proceed to DTR ballot [which has commenced, closing on 14 Sep 2016]. • *Status and progression of ISO/DTS 20428 Metadata for describing structured clinical genomic sequence information in electronic health records* – in conjunction with WG 2. • Scope, status and progression of proposed project: *Health Informatics - Business and information needs analysis method in the Healthcare Enterprise*. • WG 1 secretariat. WG 1 was disappointed to be losing the services of Manjoo Lalwani and Standards Australia in providing the WG 1 secretariat. Manjoo was thanked by the Chair and the WG for her contribution. • WG 1 Vice-convenor. A call for nominations for Vice-convenor of WG 1 is to be issued. • European initiatives with an impact on e-health standards work.

[1] 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

The ability of the Australian delegation to cover activities in WG 2 was limited by the number of Australian delegates and competing priorities, hence WG 2 activities have only been partly covered in this and following sections of this report. Items addressed by WG 2 included:

- ISO/PWI for a Reference Standards Portfolio (RSP) in the Clinical imaging (CI)domain (see observations and comments for more on this significant activity).
- Current themes for WG 2 work:
  - Reference Standards Portfolio (RSP); Standards Set
  - Clinical Imaging (CI) and DICOM
  - Genomics
  - Interoperability – particularly the BRIDG Model & FHIR
  - Active coordination and communication with other WGs, external initiatives (e.g. HL7 Clinical Genomics), and standards organizations (GA4GH)
- Status and progression of *ISO/NP 21393 Health Informatics – Omics Markup Language (OML)*
- Status and progression of *ISO/NP 25720 Health Informatics – Whole Genomic Sequence Markup Language (WGML)*.
- Status and progression of *ISO/DTS 21089, Health Informatics – Trusted End-to-End Information Flows.*

  The proposed draft was discussed and TC 215 approved the document proceeding to DTS ballot [which has commenced, closing on 14 Sep 2016].
- Status and progression of *ISO/NP TS 22077-4, Health Informatics – Medical Waveform Format Part 4: Stress Test*
- Status and progression of *ISO/DTR 20055, Health Informatics – Person-owned document repository for PHR applications and health*
- Status and progression of joint work items with WG1:
  - *ISO/DTR 19669 .. Re-usable Component Strategy for Use Case Development* – see note under WG 1.
  - *ISO/DTS 20428 Metadata for describing structured clinical genomic sequence information in electronic health records*
- Establishment of *ISO/PWI TR 20841 Health informatics - Transnational Health Record*

  TC 215 approved project being registered as a PWI and proceeding to NP ballot when Form 4 and draft text provided by the project lead. The ballot does not yet appear to have commenced)

- Proposed ISO/PWI for a TR: *Health informatics--Clinically relevant data which a person daily generates*.

  TC 215 approved this project being registered as a PWI and proceeding to NP ballot when Form 4 and draft text provided by the project lead. The ballot does not yet appear to have commenced).

- Work items for future consideration. These include
  - Aspects of HL7/FHIR
  - BRIDG 4.0 and 4.1 (updating *ISO 14199:2015 … Biomedical Research Integrated Domain Group (BRIDG) Model*)
  - Clinical trial registration and results
- Need for more people and more countries, especially people with genomics expertise

WG 3 Semantic content.

Apart from a few observations provided elsewhere in this report most matters discussed in WG 3 are covered in Appendix A.

WG 4 Security, Safety and Privacy

The ability of the Australian delegation to cover activities in WG 4 was limited by the number of Australian delegates and competing priorities; hence WG 4 activities have only been partly covered in this and following sections of this report.

Nevertheless, TW attended WG 4 for some of the time and Appendix B contains information on some of the key topics that were discussed.

WG 6 Pharmacy and medicines business

Apart from a few observations provided elsewhere in this report most matters discussed in WG 6 are covered in Appendix C.

A diagram illustrating the projected phasing and timelines for work on the IDMP implementation guides and associated revisions of the underlying standards is provided as Appendix D.

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

The Australian delegation did not have sufficient resources to cover JWG1/TMTF work in any depth. Topics reported to have been covered and expected outcomes, were as follows:

- The potential formation of a separate Traditional Medicine working group within TC215. While some TC215 items relate to or include TM as a broad concept, the primary expertise lies in TCM and other specific local TM

	traditions and some within JWG 1 therefore question whether TC 215 has sufficient experts to cover the full field (particularly given that TCM has its own JWG). • Status and progression of *ISO/WD TS 16843-3 Categorial structures for representation of acupuncture- Part 3: Moxibustion*. TC215 approved the draft proceeding to DTS ballot • Status and progression of *ISO/WD TS 16843-4, health informatics: Categorial structures for representation of acupuncture, Part 4: Meridian and collateral channels*. TC215 approved the draft proceeding to DTS ballot • Status and progression of *ISO/NP 16843-5 Categorial structures for representation of acupuncture- Part 5: Cupping* This item passed DTS ballot and was discussed with a disposition of comments and revised draft to be considered for DTS ballot after the November meeting • Status and progression of the PWI on *Classification of Traditional Chinese Medicine datasets*. TC215 approved this document proceeding to NP ballot. • Status and progression of *Categorial structures for representation of processing Chinese materia medica* An updated draft is to be prepared and circulated for review and comment by TC215 WG/JWG leadership prior to being finalised and issued for NP ballot. **JWG 7 Joint ISO/TC 215 - IEC/SC 62A WG: Application of risk management to information technology (IT) networks incorporating medical devices** Apart from a few observations provided elsewhere in this report most matters discussed in JWG 7 are covered in Appendices B and C. **JIC - Joint Initiative Council for Global Health Informatics Standardization** • 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/Interpas activities – with reports from each of the working parties and refinement of the approach. • Status and progression of work to aid adoption of universal Unique Device Identifiers (UDI)

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 over 20 16 projects coming to ballot prior to the next TC 215 meeting in November 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 supports 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 the ISO/IEC 80001-series, IEC 82304-1 and related developments in health software risk management standards. These are likely to have global impacts on the regulation of health software and devices. Some jurisdictions (QLD and NSW) are now implementing the IEC 80001 standard. The proposed revision to the 80001-series and the creation of the new ISO 81001-series of foundational documents will impact medical devices (traditional and software based) from their manufacture through deployment and implementation, to retirement In Australia, the local health software industry is looking at trialling IEC 82304-1 in 2016. Further, the influence of Australia is very important with regard to the revisions of 80001. Many of the items under discussion in JWG 7 relating to these topics therefore have direct relevance to Australia and its global markets. • Promoting Australian expertise and leadership of standards related to Digital Health/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 Digital Health/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 Digital Health/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:	
	ISO/TC 215. The main general topics addressed at the TC-level (plenaries, CAG 1, CAG 2 and OAG) included: • **Update of TC 215 strategic business plan (SBP).** Under the leadership and principal authorship of Jeremy Thorp (UK), the ISO/TC215 Strategic Business Plan Task Force (SBP TF) had successfully completed the first phase of its work with the production of a revised draft ready for review and comment at the Amsterdam meeting. There were some suggestions for refinements, including a general desire to re-visit the description of the TC 215 scope to clarify that it extends from the point of information "capture". It was recognised that any such change would need to be discussed with other concerned parties including IEC/TC 62 and its subcommittees and, ultimately, approved by the TMB. Plans for relevant consultation on this particular matter were agreed and have been progressed since the meeting. Otherwise, the following points were noted: - Some actions from the 2013 SBP had been implemented, resulting in noticeable improvements. - No changes are proposed to TC 215's objectives or structure. - Continued improvements are possible by identifying and leveraging best practice in the management of WG and CAG activities within TC 215, including normalisation of meeting documentation and applying the planning framework developed by WG3 more widely. - Liaisons and partnerships need to be reviewed and managed more rigorously to ensure that they are both active and relevant. - ISO/TC 215 work program activities listed in the BSP would be updated, including clarifying and progressing examples of "RSPs" or "bundles". - The BSP should identify success factors and, where possible, related quantitative measures against which its achievement can be assessed more rigorously. - The BSP should promote: Improved governance and project management, greater engagement with eHealth stakeholder communities, and opportunities for cross-SDO collaboration on eHealth standardization. - The ISO/CS representative suggested that the main body of the SBP should be more externally focussed, with the internally-focussed material being relegated to annexes. Suggestions from the Amsterdam meeting and subsequent developments in relation to the scope statement are being incorporated into the SBP via a second phase of development, involving: - The project leader incorporating suggested changes into the next draft; - The next draft being circulated for a mandatory 4-week Committee

Internal Ballot (CIB) to obtain feedback via ISO/TC215 members - with WG experts and liaisons being encouraged to reply through their NMB or otherwise directly to the TC 215 secretariat;

- The CIB results being reviewed by the SBP TF with updates made as needed based on received comments;
- An updated draft final version of the SBP being posted for final TC215 member review no later than 1 October 2016; and
- Finalisation and acceptance of the SBP at the November 2016 plenary in Lillehammer.

RDH is a member of the task force (and one of the main authors of the 2013 plan). HG is involved as WG 3 convenor.

- **Progressing the "Reference Standards Portfolio" (RSP) concept – also referred to as "bundling".**

  Considerable discussion on the nature, contents and methodologies for developing RSPs has continued, notably in context of updating the TC 215 BSP and in establishing the pilot project on *"Reference standards portfolio for diagnostic imaging"*. Specific matters noted at this meeting included:

  - The draft document and new work item proposal for the pilot project had been posted and were discussed at some length at the meeting.
  - The pilot proposal needs to be completed and submitted as outlined in TMB Resolution 21/2015, preferably in time for the TMB meeting in June 2016.

    As required by TMB, TC 215 is to take RSP proposals to the TMB on a case-by-case basis explaining each proposal for external normative referencing, the additional value of identifying the RSP through an ISO standard and any maintenance details.
  - The documents for the pilot project would be further discussed, finalised and carried forward by the project team working though TC 215/WG 2.
  - TC 215/CAG 02 (Advisory group) recommended that the clinical imaging RSP be proposed as an ISO Technical Specification (TS), with a view to becoming a full international standard (IS) later but with some members preferring it should progress directly to an IS (which could be down-graded to a TS if required). The final recommendation from WG 2 and the Project Team approved by the TC 215 plenary was to aim for an IS.
  - Other projects and initiatives are being examined as potential candidates for or contributors to RSP "bundling" standards, thes include:
    - *ISO DTS 21089, Health informatics -Trusted-end-to-end workflow* as a framework for the bundle
    - The families of standards being established through the WG3 work program planning process
    - The work being done by the JIC on the standards needed to support international patient summaries – with the team seeking to be kept informed of developments.

- ***ISO/IEC 80003-series: Quantities and units for telebiometrics/ e-health***.

  The positive outcomes of engagement with ISO/TC 12 and IEC/TC 25 to resolve concerns over work on the *ISO/IEC 80003-series* were noted.

  Following a ballot in the affected TCs, previous work on this item is to be retired and a task force formed to ensure that the use of UCUM in clinical contexts is appropriately incorporated in ISO and IEC work on quantities and units.

  TC 215 is in the process of establishing a *Task Force on Quantities and Units to be used in e-health* (ISO/TC 215/TF 1) to identify relevant requirements and consult with ISO/TC 12 and IEC/TC 25 on a constructive approach to the issues.

- **Membership and role of ISO/TC 215 CAG 2 Advisory group**

  The membership of this key advisory group (which functions as a de facto executive committee) was increased to include all seven TC 215 WG and JWG convenors (raised from 4 convenors previously and in addition to 5 elected members). To accommodate this change, the quorum was increased from 5 to 7 members.

  The elected members were appointed in 2013 and have continued from year to year. As the elected appointments are nominally for a year at a time, it was also considered appropriate to seek nominations for all of the elected positions at this time.

  Richard Dixon Hughes is an elected member of the group and is willing to continue in that role if nominated and elected. He understands that his continuing in the role would be regarded favourably by the TC 215 leadership.

- **Formation of an additional TC 215 working group in the area of traditional medicine ™ informatics.**

  The formation of a separate WG for TM informatics was originally requested by WG 3 to avoid the double-handling of TM projects originating within TC 215, usually from the Traditional Medicine Task Force (TMTF), which does not have the standing to conduct standards development work.

  The move, which would see the activities of the TMTF subsumed by the new WG, was approved by TC 215 in October 2014 but has yet to be implemented.

  The TMTF largely exists to ensure that TC 215 work in TM informatics includes the interests of all TM disciplines, and not solely Traditional Chinese Medicine (TCM). The issue therefore has a geopolitical element, whereas the main interests of TC 215 members are to ensure that informatics work across TM fields is productive, as widely applicable as possible and well-coordinated both across TM traditions and with other work in health informatics (e.g. terminological frameworks and coding systems).

  Two nations, Korea/KATS and China/SAC have stepped forward with an offer to support the formation of a new ISO/TC215 TM WG with the resources required.

The TC 215 secretariat reported some lack of clarity form the affected delegates at the Amsterdam meeting regarding the need to form the new proposed TMTF-WG.

If the WG is to be formed, TC 215 secretariat will need to send out a background history document, put out a call for work items to be transferred to the WG; call for experts; call for leadership nominations and then issue leadership nominations via a CIB ballot.

Lisa Spellman (TC 215 Secretariat) and Mary Lou Pélaprat (ISO/CS) will work with the principals again in an attempt to clarify the issues and propose a way forward at the November meeting of TC 215 in Norway.

- **Proposal to allow ISO/DIS 17583 to expire.**

  The long-standing project ISO/DIS 17583, Health informatics, Terminology constraints for coded data elements expressed in ISO Harmonized Data Types used in healthcare information interchange ("Binding") was originated with strong HL7 involvement. It is a WG 3 project led by Ted Klein (HL7/US) with support from Heather Grain but was approaching its final limit date when it will automatically expire. The document is based on original HL7 work which was difficult to present effectively in the required ISO format.

  While the topic of termimnology binding is an essential one to be addressed by appropriate standards, is is unlikely that,this current version continues meet market need, especially considering the rise of HL7/FHIR, a reduction in the use and uptake of HL7 Version 3 (on which on was based), and a growth in the use of other approaches to managing terminology binding.

  After a review of options by WG 3, TC 215 resolved to:

  - Cancel the current ISO 17583 work item from its work programme at DIS ballot stage
  - Add a PWI to the work programme for a future project of similar content entitled *"ISO/PWI 17583, Health informatics-- Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange (Binding)"*;
  - Request ISO/CS to retain the same number (17583) for the PWI.

- **Changes in the ISO 2016 Directives**

  ISO/TC 215 was briefed on updates to the ISO Directives that are likely to impact its work, with the following highlights being particularly noted:

  - P-members must vote on systematic reviews otherwise they can get downgraded to O-members.
  - P members should be attending plenary meetings at least every other year and they should be sending comments by email otherwise they can be downgraded from P status
  - Justification supporting a NMB's approval of an NP ballot is now optional (the Australian delegation questioned this change as the measure had seemed appropriate - it appears that the piloting of this measure has not resulted in better support and greater market relevance as originally anticipated).

- NMB ballot NP responses must name an expert when submitting a positive vote (already required). If the expert is still to be advised when the vote closes and there is no expert within a maximum of 2 weeks, then the NMB will not be a participant in the project.
- Time for balloting and project progression is now counted in weeks not months.
- Joint working groups may now have co-convenors if twinning with a low or middle income country on the ISO development programme.
- Many TC 215 projects are joint with CEN/TC 251 under the Vienna Agreement (VA). When a DIS is approved within ISO and there are no substantive technical comments, the document can go directly to publication without an FDIS but this used not to be possible where CEN rules also applied. CEN is changing its approach and such documents under the VA agreement will be able to go directly to publication, by resolution of the relevant CEN/TC but an FDIS is still required if there are technical changes
- Resolutions must be posted within 48 hrs of the closing plenary.
- There is a new award, the ISO excellence award
- Any drafts that come to ISO/CS in 2016 have to apply the new drafting rules and the updated standard drafting templates. There is now a checklist for writers, the new template is now easier to use.
- Training sessions on the changes in the ISO Directives will be developed by the Secretariat and will be mandatory for TC 215 convenors, vice-convenors, and secretaries.

WG 1 Architecture, frameworks and models.

Across all sessions, around 22 delegates from 14 countries participated in core WG 1 activities (excluding experts who only participated in joint sessions – the total attendance across all sessions was almost double the core attendance). Meetings took place over 9 sessions on 3 days with most being conducted jointly with CEN/TC 251 WG i. The following are matters considered to deserve further comment:

- ***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 again the main task for WG 1 at the Amsterdam meeting and occupied about 3 sessions, including part of a joint session with WG 4 on part 4 (Security).

  As approved in the November 2015 meeting, Part 1 (Reference model) and Part 2 (Archetype interchange specification) proceeded to and have passed CD ballot. TC 215 has now accepted a WG 1 recommendation to move parts 3, 4 and 5 to CD ballot (which has now commenced), with previous concerns from Australia about the various parts getting out of step having now been allayed.

With a strong role in development of *open*EHR and tools for maintaining *open*EHR 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 is engaging with local experts as and when the time comes for review and comment.

- ***ISO 12967 Health informatics – Services architecture (HISA) - Parts 1, 2 and 3* – 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.

  The HISA standard 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 the jurisdictions, NEHTA, DoH, 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*.

  The proposed project passed the 3-month NP ballot under the Vienna Agreement with constructive input and RDH and Dr Zoran Milosevic being nominated as Australian experts to contribute to the work.

- **Potential to use *SA HB 137 (eHIF)* and *SA HB 138 (eHAP)* as the basis for international standards work**. Noting the proposed update of the HISA suite of standards, which has now commenced, and the need for guidance on how to define and specify requirements for TC 215 RSPs and JIC Standards Sets for various domains, further discussions have been held 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, there has also been some unexpected opposition to RM-ODP-based approaches. The opportunity for a well-structured approach to e-health specifications based on HISA, eHIP and eHAF should continue to be promoted as a worthwhile basis for relevant work, even if other less structured ad-hoc approaches are followed for some activities. The present priority is to apply as many of the principles as possible in the revision of the HISA standards.

- **Systematic Review of ISO 21667:2010 Health Indicators Conceptual Framework**

  The ISO timeline has been triggered for systematic review of this document which was strongly supported by engagement from Australia when initially developed (with a need to be compatible with national performance indicators). It was noted that it needs to be reviewed and that an Australian resource would be sought to provide leadership of the review. RDH is to report back to the November meeting.

- **Health Informatics - Business and information needs analysis method in the Healthcare Enterprise (BIA)**

  The issues raised by Australia and others at the previous meeting have largely been resolved by the proponents of this work being prepared to have it proceed as an IDSO/TR, rather than as a TS or IS.

- **ISO International Workshop Agreement: *IWA 18 Framework for integrated community-based life-long health and care services in aged societies***

  TC 215 had some small involvement in developing *IWA 18* but there was considerable interest among the TC 215/IT-014 stakeholder community in the outcomes and implications.

  Australian concerns have largely been met concerning the need to ensure that this work provided a general framework rather than prescribing particular standards for an "aged society" that replicate standards fin established core domains such as EHR, PHR, telemedicine and pharmacy. Proposals to TC 215 for supporting work have been foreshadowed and will be carefully scrutinised to ensure that they meet this principle.

- **Potential role of WG 1 in supporting work on patient summaries**

  As part of its strategic planning in relation to RSP/bundling WG 1 noted that it has a potential role (in conjunction with WG 2) in providing a platform for development and publication of peak standards and technical reports in the area of patient summaries. International interest and various developments in the area of patient summaries were noted as relevant to this role including the JIC work on a proposed "Standards Set" to support interchange of patient summaries, CEN/TC 251 discussions with the EU/EC and the next stages of US/EU and UK collaboration in the field.

- **Joint meetings of WG 1 and WG 2**. The two WGs agreed that they should schedule at least one and preferably more joint sessions at upcoming TC 215 meetings to progress collaboration on joint work.

WG 2 Systems and device interoperability

The Australian delegation lacked the resources to participate significantly in WG 2 but RDH was present for some of the items.

Across all sessions, a core of 20 delegates from 7 countries and 3 liaisons were reported to have participated in WG 2 and this was a considerable improvement on the numbers at the previous meeting in Bern. For sessions working on the Form 4 and draft outline for the pilot of the Reference Standards Portfolio (RSP) in the Clinical imaging domain, the numbers were significantly greater at 30 delegates from 10 countries and at least 3 liaisons (RDH participated in these sessions). The following were noted:

- **ISO/PWI for a Reference Standards Portfolio (RSP) in the Clinical imaging domain**.

  This was by far the most significant and well-attended WG 2 activity – resulting in the production of a Form 4 and draft outline for a pilot of the RSP

concept in the Clinical Imaging (CI) domain.

After consideration of the CAG 02 suggestion that the work be directed toward a TS, WG 2 recommended the PWI be put forward to NP ballot targeting an international standard (IS), which received TC 215 approval. The ballot for *ISO/NP 21860 Health Informatics -- Reference Standards Portfolio for Clinical Imaging (RSP-CI)* is open, closing on 09 Sep 2016.

- **ISO/IEEE 11073-series of device communication standards**. WG 2 manages ISO fast-track adoption of these standards brought across from IEEE at FDIS stage. 4 parts were published in the last 6 months, with 1 of the 37 current parts still in development within ISO.
- ***ISO12052:2006 .. Digital imaging and communication in medicine (DICOM)***. Just prior to the previous TC 215 meeting, ISO/CS gve permission for the review and update of the existing ISO 12052 DICOM standard to proceed. This is being undertaken as a separate project in parallel with the proposed preparation of the RSP ("bundled standard") for clinical imaging domain. Final details of the DICOM review are still awaited as the former project lead recently retired and is no longer available.
- **Work on genomics topics**. Australian delegations have previously emphasised the need for work by TC 215 on genomics standards to be broadly based, engaging with leading industry players and harmonised with related HL7 specifications. The project teams continue to assert that they are collaborating with each other and intend to abide by these principles. These aspects will continue to be monitored by Australia.

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

WG 3 Semantic content

Across all sessions, 18 delegates from 10 countries and 2 liaison organisations (IHTSDO and IHE International) 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.

Australian support is required to enable Heather to accept the request of WG 3 to continue as their convenor for a further 3 years.

WG 4 Security, Safety and Privacy

Across all sessions, some 27 delegates from 12 countries participated in WG 4 (including those that joined remotely by Webex for specific items).

Appendix B to this report includes more detailed observations and comments on WG 4 activities adapted from the separate delegate report from 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 again 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.

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 45 delegates from at least 14 countries and 4 liaison organisations participated in WG 6 (including some joining remotely by Webex).

Appendix C to this report includes more detailed observations and comments on WG 6 activities based on the separate delegate report from Dr Vince McCauley.

The main WG 6 activity has been the on-going development and update of the IDMP (Identification of Medicinal Products) standards and associated implementation guides, and the creation of code databases by affiliated organisations to support their use. Substantial progress has been made on IDMP and it has strong support from the US/FDA and input from ICH and EC/EMA.

As the uptake and use of IDMP progressively increases and the standards are being maintained to reflect implementation experience, WG6 is considering a number of strategies based on increasing the use and benefits from IDMP through outreach and synergies which can be achieved with it in various health IT domains. Disseminating information about IDMP is to be one of the strategic initiatives to be discussed further in at the Lillehammer meeting in November.

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 in a previous section of this report.

	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 draws from and extends the separate delegate report received from Dr Vince McCauley, who is also an IHE liaison to JWG 7. Australia continues to contribute information, expertise and significant leadership effort to progress JWG 7 work.

Key items/actions for Australia:	
	• Approval to be sought from Standards Australia for Heather Grain to continue as convenor of ISO/TC 215/WG 3 Semantic content for another 3-year term. • IT-014 to arrange for review of the final draft of the ISO/TC 215 Strategic Business Plan and the submission of comments in response to the mandatory CIB ballot expected in or around August 2016 • Consider re-nomination of Richard Dixon Hughes as a member of the CAG2 advisory group. In this role he had been able to demonstrate understanding of the broader standards development processes and procedures and is often able to highlight situations requiring consideration by the TC 215 secretariat and or ISO Central Secretariat. He understands that he continues to have the support of the TC 2i5 leadership for his continued contribution in this role. • Richard Dixon Hughes to - Continue to contribute as core member of TC 215 strategic business plan task force – finalising the TC 215 business plan - Report back at the next meeting of WG 1 and advise if Australia is able to lead the strategic review and update of *ISO 21667:2010 Health informatics -- Health indicators conceptual framework*. - Consult with project lead and review proposed drafts of *ISO/DTR 19669 Re-usable component strategy for use case development* from an Australian perspective - Participate as an expert in the revision of *ISO/TR 21089:2004 .. Trusted end-to-end information flows* and its upgrade to an ISO/TS - Contribute to work on TC 215 processes for development of reference standards portfolios [CAG 02] and classification of standards [JIC] - Participate in JWG7 teleconferences working on ISO/IEC 80001-series - Continue to assist TC 215 in constructively progressing the resolution of issues surrounding the standardizations of quantities and units use in e-health/Digital Health.

- Heather Grain to:
  - Continue to lead work on revision of *ISO 17115:2007 .. Vocabulary for terminological systems*
  - Continue progress work on the MapQual and MetReq projects.
  - Convene regular teleconferences of WG 3 and its task groups to progress WG 3 work items for the next TC 215 meeting
  - Continue providing WG 3 input to the TC 215 business plan

- Trish Williams, as joint leader - to 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 the new foundation standard on health software safety where Trish Williams is the joint project lead.
- IT-014 to continue to consult with relevant Australian organisations and experts to consider justification and, where appropriate, arrange for preparation of project proposals for AU adoption of relevant TC 215 standards publication, notably
  - *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 allocated funds to assist.
  - *IEC 82304-1 Health software -- Part 1: General requirements for product safety* – when it is finally published
  - *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.
  - Potentially, the IDMP standards for identification of pharmaceutical products and medicinal products and their application in regulatory environments.
- (Continuing on from a recommendation a previous report) IT-014 Chair to continue monitoring and consulting 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 November 2016 meeting in Lillehammer, Norway should promote 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.

Status of the work:	The status of current work items is reported under the relevant "observations and comments" for the relevant working group(s) – including those presented in the Appendices to this report and are not repeated in this section, which instead focusses on material recently published or submitted for publication.
	Recent & pending publications (since November 2015 meeting – excluding corrigenda) • *ISO/TS 13582:2015 Health informatics -- Sharing of OID registry information* Published 2015-12-15 • *ISO 13940:2015 Health informatics -- System of concepts to support continuity of care*. Published 2015-12-15. Noted as possible AU adoption. • *ISO 16278:2016 Health informatics -- Categorial structure for terminological systems of human anatomy*. Published 2016-03-01 • *ISO/HL7 16527:2016 Health informatics -- HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)* Published 2016-04-01 Review for possible AU adoption and/or profile. • *ISO/TS 16843-2:2015 Health informatics -- Categorial structures for representation of acupuncture -- Part 2: Needling*. Published 2015-12-15. • *ISO 17090-2:2015 Health informatics -- Public key infrastructure -- Part 2: Certificate profile*. Published 2015-11-15. To be considered alongside any revision of AS ISO 17090.2-2003 (as per aged standards review). • *ISO/TS 17251:2016 Health informatics -- Business requirements for a syntax to exchange structured dose information for medicinal products. Published 2016-06-16*. Review for possible AU adoption. • *ISO 17523:2016 Health informatics -- Requirements for electronic prescriptions*. Published 2016-06-01. Review for possible AU adoption. • *ISO/TS 19256:2016 Health informatics -- Requirements for medicinal product dictionary systems for health care*. Published 2016-05-26. • *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 2015-12-15. AU approach to IDMP needs to be discussed.

	• *ISO/TS 20440:2016 Health informatics -- Identification of medicinal products -- 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*. Published 2016-06-01, AU approach to IDMP needs to be discussed. • *ISO 27799:2016 Health informatics -- Information security management in health using ISO/IEC 27002*. Published 2016-07-01. Current Australian adoption of previous edition, AS ISO 27799-2011 now needs to be reviewed • *IEC/TR 80001-2-8:2016 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*. Published 2016-05-19. Review for possible AU adoption. • *ISO/IEEE 11073-10425:2016 Health informatics - Personal health device communication - Part 10425: Device specialization - Continuous glucose monitor (CGM)*. Published 2016-06-03. • *ISO/IEEE 11073-10424:2016 Health informatics -- Personal health device communication -- Part 10424: Device specialization -- Sleep apnoea breathing therapy equipment (SABTE)*. Published 2016-06-03. • *ISO/IEEE 11073-10419:2016 Health informatics -- Personal health device communication -- Part 10419: Device specialization -- Insulin pump*. Published 2016-06-03. • *ISO/IEEE 11073-20601:2016 Health informatics -- Personal health device communication -- Part 20601: Application profile -- Optimized exchange protocol*. Published 2016-07-12.

Other stakeholders:	In addition to the IT-014 membership, ACSQHC, TGA and AIHW are noted as having potential interests in medical device and health software safety issues and IDMP for pharmaceutical regulation.

APPENDIX A – REPORT* ON THE MEETING BY HEATHER GRAIN (CONVENER ISO/TC 215/WG 3)

* Abridged & edited in places for this appendix.

International Delegate's Meeting Report

Date	7 May 2016
Name	Heather Grain
Position/Title	Managing Director
Company	Global eHealth Collaborative
Postal Address	33 Thurso Street, Malvern East, Vic. 3145
Email Address	heather.grain@gehco.org

Observations & comments:

General - CAG 02, CAG 01 and OAG

- **RSP/Bundle projects**

A 'Bundle Project' or 'Reference Standards Portfolio" (RSP) is a standards publication which references relevant standards needed to achieve a specific task or use case. The key trial of this approach is the Clinical Imaging 'bundle'. This includes:

- HIT standards that need to be deployed when implementing interoperable clinical imaging applications in healthcare settings.
- Guidance to implement standards – based interoperable clinical imaging products in healthcare settings to support information exchanges
- Specifications for semantic, technical and functional components of interoperability
- Conformity criteria for testing and certification of clinical imaging products
- Implementation guidance.

Discussion on whether this work should be a TS as the prototype of a new approach, and it will be faster to market with this approach used. A common process in other committees is to publish a TS and when it is published move to review as an IS to take in learning from the initial work item.

Motion by Richard Dixon Hughes *that CAG 2 recommend that the bundle project work for Clinical imaging products be a TS with the potential to go to IS in the longer term*. Passed.

- **Work Group Framework and Gap Analysis**

I reported to CAG02 on the advances made by WG3 on Framework models for WGs and gap analysis, particularly the increase in active engagement which has resulted from that activity, including over subscription of experts (i.e. more than 5) to work items. This indicates a much higher indicator of relevance to national programs of the work being undertaken.

- **Other items.** Discussion of the following topics was also noted [and

these topics have been more fully covered in the main report above]:

- Status and progression of the TC 215 Strategic Business Plan (SBP)
- Changes to the ISO/IEC Directives and their impact on TC/WG operational activities and the need for training of operational personnel.

WG3 Semantic Content

- **WG3 Convenor**. The convenor's position currently occupied by Heather Grain will become vacant as of December 2016. The working group has asked her to continue in this role for a further 3-year term for the following reasons:
  - Heather has been instrumental in the re-development of the working group and focusing the projects undertaken on activities of national priority
  - Heather is establishing governance processes within the working group which better manage the workload and delivery of outcomes more effectively
  - Though there are now new attendees at the WG, none yet have the experience to undertake the role of Convenor – it is anticipated that this will no longer be a problem in 3 years' time.

  Standards Australia and IT-014 will be requested to confirm that this is acceptable to Australia. It is understood that such support does not imply acceptance in international delegations nor financial support to attend such meetings.
- **Working Group Strategic Framework.** WG 3 discussed the process for Framework review, which will be undertaken in 2018. The requirement to maintain and develop priority work was confirmed. It is intended to try and have a different project leader for each task so as not to overload any individual. Monthly calls on project status will occur for the whole working group and expert groups will have their own specific working calls to which the rest of the WG will be invited.
- ***ISO TR 21564 Health Informatics – Terminology Resource Map Quality Measures (MapQual)*** this work has defined the determinants of quality of maps and the meeting discussed relevant methodologies for measuring that quality as it applies to a specific use case.

  The expert group will be meeting regularly to push this work forward with a view to detailed CD for discussion and then ballot in November 2016
- ***ISO 17117-1 Health Informatics – Terminological Resources, Part 1 Characteristics*** **(TermChar)** This work item was presented to WG3 and WG1. There are a number of concepts which still require clarification and review of the proposed disposition will be undertaken by WG1 and WG3 members until the end of May then regular teleconferences will occur to resolve those issues. Whether resolved or not this work will be circulated for CD ballot at the end of July. If

there are outstanding issues these will be clearly identified in the document circulated.

- ***ISO 17117-2 Health Informatics – Terminological Resources, Part 2 Structure and High Level Indicators (TermStruc***) This is a preliminary work item which will target a TR. The work has not yet begun but will identify the relationship between characteristics to capacity of a terminological resource. This work measures the terminological resource, not the implementation of that resource
- ***ISO 17115:2007 Health informatics - Vocabulary of compositional terminological resources (VOTE)*.** Following systematic review, revision has been approved. This document will incorporate updated terms and definitions from 17117 and other more recent work, and incorporate *EN 12264 Categorial structures for health care*
- ***ISO 13120:2013 Syntax to represent the content of healthcare classification system*s (ClamI).** This is now a current work item. The update is incorporating requirements for representation of ICD-11 as well as existing classifications.

  Regular meetings on this work are occurring in Europe including contributions from WHO and many of the countries actively using this standard. It is intended that ICD-11 will be published in a manner compliant with this standard. It is expected that a CD draft will be ready for consideration by the November meeting.
- **Proposed ISO/TS on: *Health Informatics - Metadata Repository Requirements (MetaRep)***. The meeting including representatives working on *ISO/IEC 11179* within the ISO/IEC JTC 1/SC 32 community and the UK has also offered a project leader with background in *ISO/IEC 11179* work. It is intended that the experts meet regularly between this meeting and the November meeting to prepare an initial detailed draft and updated Form 4.

  The meeting discussed the scope of requirements for this work item and defined specific use cases known to be difficult with the current *ISO/IEC 11179* and beyond the scope of that work item. This document will reference other standards including *ISO/IEC 11179* and explain their relevance and only identify additional requirements where they are not covered elsewhere.
- ***ISO/DTS 18062 Health informatics - Categorial structure for representation of herbal medicaments in terminological systems***. A joint session of WG 6 and WG 3 addressed the remaining issues to harmonise this work with IDMP and a hopefully final review will be undertaken and completed by July in order to lead to publication. If there is any problem with meeting this deadline the Secretariat will discuss the time line with ISO central secretariat as the work is so nearly complete and there is a strong desire to complete and publish which has been approved.

- **ISO/PWI Health informatics - Semantic content workforce roles capabilities and specifications (TermSkills).** This work item will leverage the work done in Canada and other environments to determine an international approach to the skills needed to manage, use, make decisions, implement, create and maintain terminological systems and content in health record systems and associated reporting. A request has been made to seek leadership from Canada. Heather Grain has been an active contributor to the Canadian activity and is working on related projects in Australia.
- **Terms and Definitions in the Family of Health Records**. There was insufficient time for Heather to present the detailed activity which has occurred in this area. The focus at the meeting was on getting all the content related to the various types of health records added to SKMT then harmonisation activities will follow. A report on work undertaken was circulated with comments being requested from WG 1 and WG 3.

Other Preliminary Work Items (PWIs)

The following preliminary work items previously approved by TC 215 are being progressed but do not yet have active resourcing.

- **PWI for a TS on: *Terminology Implementation Capability and Maturity Models (TICCM).*** This work item focuses on the capability of systems which have implemented terminology in order to identify clearly the level of terminology implementation maturity of such systems. The capability of the system will be based upon the ability to use terminology capabilities identified in 17117 part 1. This work will progress as a background activity until a project leader is identified or when existing work items complete and free up resources to work on this item.
- **PWI for a TS on: Value Set Definition Design and Governance,** and
  PWI for a TS on: Value Set Definition Quality Measures for Value Domain Content
  These two proposed work items will bring together some material from existing standards, and combine it with work on the quality of value sets undertaken at HL7 in order to define requirements for data design and governance across healthcare and use cases and to measure the quality of that data representation.

	Other work WG3 is considering as preliminary work items include: • A PWI for a TS on: C*ategorial Structure for representation of decoction pieces*. The aim is for documents to be shared with a view to being ready for an NP ballot after the November 2016 meeting in Norway. • A PWI for a TS on: *Indication binding to herbal medicines and formulas* [it has more recently been suggested that this item be postponed to enable an initial draft to be considered at the April 2017 meeting in China. These two work items will be developed in conjunction with WG6 to ensure harmonisation with IDMP. **In Publication:** • *ISO/PRF TS 16843-1 Health Informatics - Categorial structures for representation of acupuncture - Part 1: Acupuncture points*
Key Items/Actions for Australia	• Consideration of WG3 Convenor status – recognising that there is no guarantee of support to attend meetings, I have been asked and am willing to stand as convenor for a further 3-year term if Australia, through IT-014 are supportive of this work.
Status of the work	As reported above.
Other Stakeholders	In addition to the re-formed members of IT-014, it is suggested that potential recipients of this report include: • AIHW and the IT-000 mirror committee to ISO/IEC JTC1/SC32 Data management and interchange, in relation to extensions to ISO/IEC 11179 metadata for use in health. • HE-003 in relation to software safety and associated medical device topics. • HE-031 for issues related to traditional medicine

APPENDIX B – COMMENTS* FROM REPORT BY Dr TRISH WILLIAMS

*Significantly edited, abridged & restructured for this appendix.

International Delegate's Meeting Report

Date:	10 June 2016

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

Key items discussed:	This report does not include some other outcomes and discussion listed in the minutes of WG 4 and JWG 7, and more specifically the progress of other WG4 standards not mentioned.

Observations & comments:	
	WG 4 Security, Safety and Privacy • ***ISO 27799:2016 Health informatics – Information security management in health using ISO/IEC 27002***. This joint standard developed with CEN under the Vienna agreement was at FDIS stage ballot closing on 17 May, a week or so after the Amsterdam meeting. [It passed FDIS ballot and was published on 1 July]. This is the second edition of this standard. The first edition published in 2008 was adopted as AS ISO 27799-2011 and was relied upon in the past as the basis for a number of health security documents produced by Australian professional associations. Australia had significant input into the final draft of this standard and our comments were all dealt with satisfactorily. IT-014 will now need to consider wat to do in relation to updating the Australian adoption. • ***ISO/NP TS 11633 Health Informatics- Information security management for remote maintenance of medical device and medical information systems Part 1: Requirements and risk analysis***. Ballot comment was presented and discussed. The comments submitted by Australia were addressed and it was noted that clarification of the scope and nature of remote maintenance processes contemplated had been provided. Specifically, safety is out of scope of this standard. Other countries supported the usefulness of the revisions with respect to protecting against increasing cyber security threats and the need for defined processes for remote access for medical devices, to avoid a significant avenue of potential

vulnerability.

- ***ISO/PWI TR 21333 Health informatics - Privacy terms and definitions*** This proposed work item is to be withdrawn from the work program, as there was a resolution and commitment from WG4 to put all definitions into SKMT, although this has not been consistently undertaken to date there is a commitment from WG4 to attend to this. Australia fully supported this resolution.
- ***ISO/DTR 18638 Health informatics - Components of education to ensure health privacy*.** This work item has been problematic because of the difficulty of adapting the underlying Korean work to reflect the practices and expression used in English-speaking culture. The working group for this has been expanded to work more directly on the document (Canada, USA x 3, Australia). At the meeting Australia and USA made further suggested revisions.

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

- **JWG7** Name. JWG 7 plans proposes to change its group name to *"Safe, effective and secure health software and health IT systems, including those incorporating medical devices"* to better reflect its scope. Such a change will require approval of both TC 215 and ISO/SC 62A.
- ***IEC/DIS 82304-1 Health software – Part 1: General requirements for product safety***. [This passed CDV/DIS stage in November 2015 and was being prepared for final FDIS ballot when extended project timeline expired in May 2016. Will continue as PWI until revised draft is available and then be fast-tracked to completion.].

  Australia had significant input in the writing and revision of this standard, and has provided the software industry and development perspectives for the standard, which otherwise tends to be dominated by medical device manufacturer interests. When published, Australia should consider direct text adoption of this standard.
- ***IEC 62304 Medical Device software – lifecycle processes*** is under revision and will change its scope and title to **Health software - Software lifecycle processes.** This reflects the changing environment and delineation between medical device software and other health software, including software as a medical device (SaMD). It is imperative that Australia engage with this new work (when it is reintroduced to the ISO work program). Revision suggestions are being sought by ballot until 02 September 2016.
- ***IEC/ISO 80001-series - Application of risk management for IT-networks incorporating medical devices.*** Work on the revision and creation of foundational standards for the next edition of the 80001-series has been underway for the past 9 months (following a 2-year review of software safety standards). This has resulted in two new work item proposals. The first is for a new standard to be entitled: ***Health software and health IT systems safety, effectiveness and security – Foundational principles, concepts and terms*.** This work is co-led by Trish Williams, with considerable input from other Australian experts: Richard Dixon Hughes, Vincent McCauley,

	Kathy Dallest and Tony Cowan. There was lengthy discussion at JWG7 on the future direction for 80001 in general, and presentation of what the future may look like for integration and use of medical devices, including software as a medical device. This included: - a clinical perspective (from Dr Vincent McCauley) - the work (and documents) from AAMI/UL2800 Medical Devices Interoperability and UL2900 Security(http://industries.ul.com/life-safety-and-security/cybersecurity-for-life-safety-and-physical-security-systems); - an overview of initiatives from the German DKE mirror committee; - a US perspective on decentralized networks and their impact on 80001; and - a presentation of the UK Health and Wellness Apps Code of Practice. All these documents are available on ISO TC215 JWG7 page. This is necessary to establish what the technical landscape in 4-5 years' time will look like. The standard will need to consider safety versus security, integrated and new architectures (bring your own mobile and medical device), and the connection to other intelligence sources and uses of patient collected data. The future standards will need to cater for adaptive and indeterminate systems. Where this overlaps with patient safety an increased focus on risk management will be needed particularly when reliance on Clinical Decision Support (CDS) is increased. Further, to date the 80001 series has focused on larger hospital environments and in future it will need to accommodate small health delivery organisations without dedicated IT and security staff, as well as app developers together with scalability optionality. • **The next meeting of JWG7** will be held on 5-7 October 2016 in Frankfurt, Germany in conjunction with IEC and following the 82304 meeting on 3-5 October

Key items/actions for Australia:	
	In relation to WG 4 activities: 1. *ISO/DTR 18638 Components of education to ensure health privacy*. Australian input offered (Trish Williams) to advise on wording before the work is reviewed again. Many objections to the work item are considered to arise from poor communication of the content. **In relation to JWG 7 activities:** **2.** Increased exposure of IEC 82304-1 is needed globally and Australia can socialize this standard by considering its adoption immediately after publication.

	3. Upcoming ballots on 62304, 81001-1, 80001-1-1, and 80001-2-9 in August and September are all applicable to Australia in the longer term, and work already undertaken by Australian delegates needs to be augmented by encouraging commenting by other stakeholders. 4. Australian delegates need to continue participation in 80001 revisions and foundational document co-leading. Australia has been the only country to provide strong and consistent clinical input into this work through Dr McCauley. As is common, the difficulty in meeting times outside of working meetings is problematic for Australian contributions.

Status of the work:	
	• WG4 - ISO 27799:2016 Health Informatics – Information security management in health using ISO/IEC 27002. Published 01 July following successful FDIS ballot. • WG4 - Work is continuing on : - *ISO/IS 20429 Health informatics, Principles and guidelines for protection of personal health information* (Netherlands lead) - *ISO/PWI TR Cloud computing security and privacy requirements for health information* (Brazil lead) - *ISO/TS 11633 Part 1 Health Informatics, Information security management for remote maintenance of medical devices and medical information systems -- Part 1: Requirements and risk* (Japan lead) - *ISO/TR 11633 Part 2 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)* (Japan lead) - *ISO/ TR 18638 Health informatics, Components of education to ensure health information privacy* (Korea) - *ISO/TS 20405 Framework of Event Data & Reporting Definitions for the Safety of Health Software* (Canada lead) • JWG7 – Proposed new title for JWG 7 to be submitted to 8-week ballot of TC 215 and IEC/SC 62A [closing 09 September 2016]. • JWG7 – *IEC 62304:2006 Health software – Software lifecycle processes* Returned to PWI stage after exceeding allowed development time. Draft of second edition and change of title to be prepared for NP ballot with CD attached [closing 2 September 2016]. • JWG7 – *IEC/DIS 82304-1 Health software - Part 1: General requirements for product safety*. Returned to PWI stage after exceeding allowed development time for release of FDIS in May 2016. Revision to be re-started once revised ballot draft is ready for review.

	• JWG7 – *ISO/NP 81001-1 Health software and health IT systems safety, effectiveness and security - Part 1: Foundational principles, concepts, and terms* To joint NP ballot of TC 215 and IEC/SC 62A closing 30 August 2016. • JWG7 – *IEC/ISO 80001-series - Application of risk management for IT networks incorporating medical devices* - *IEC/DTR 80001-2-9 … Part 2-9: Application guidance – Guidance on the use of security assurance cases to demonstrate confidence in IEC 80001-2-2 security capabilities*. To DTR ballot closing 29 July 2016 - *IEC 80001-1:2010 … Part 1: Roles, responsibilities and activities*. NP ballot closing 18 August 2016 for revision under alternative title: *IEC 80001-1-1, Safety, effectiveness and security in the implementation and clinical use of connected medical devices or connected health software – Part 1-1: Application of risk management*.

APPENDIX C – REPORT* ON THE MEETING BY Dr VINCE McCAULEY

* Abridged, edited and substantially modified for this appendix.

International Delegate's Meeting Report

Date:	10 July 2016

Delegate details:	
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

Observations & comments:	

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

- ***IEC 62304:2006 Health software – Software lifecycle processes.*** **D**rafting of the revised and re-titled second edition is proceeding but has been slowed by the illness of a key co-chair. Issues of scope remain under discussion - members of the drafting group indicated there is now an intention to extend the scope to general eHealth software but the group has mainly medical device membership and little general Health software participation or expertise. Attempts to enlist further software expertise via IHE and HL7 ISO TC215 liaisons have been only partially successful. Assuming a successful NP ballot to re-start the project, an initial CD should now be completed for discussion at the November 2016 ISO TC215 meeting in Norway.
- ***IEC/DIS 82304-1 Health software – Part 1: General requirements for product safety***. [There was general agreement on final changes required prior to FDIS ballot and publication; however, the project timeline expired at the end of May and project has yet to be re-started via an NP ballot].

  82304 drafting Co-chair, Peter Linders, spent a day in Brussels speaking to EC bureaucrats about their plan to develop an EC framework for regulation of healthcare software, which may be based on 82304.
- **Global Harmonisation Task Force**. This is a new group which is working to have consistent regulation of medical devices around the world. This group may take over some of the functionality of the International Medical Device Regulators Forum (IMDRF).
- ***ISO 14971:2007 Medical devices -- Application of risk management to medical devices*** (Second Edition – under periodic review). JWG 7 noted that this document, which was originally produced by ISO/TC 210 (Quality management and corresponding general aspects for medical devices), is

* Abridged & edited in places for this appendix.

being assessed for revision by a joint working group ISO/TC 210/JWG1 of TC 210 and IEC/SC 62A.

While IEC/SC 62A favours an update, ISO/TC 210 do not agree! A decision will be made at the TC210 meeting in Delft.

[It is noted that JWG 7 is working with SC 62A on the challenge of better aligning their flagship standards with the more widely accepted ISO approach to "risk management" defined in ISO 31000:2009 and ISO Guide 73:2009 but *ISO 14971* takes a different approach which does not align with the concepts and approaches in ISO 31000. There is potential for confusion and disagreements, which may impact JWG 7 work if not managed].

- **Scope and title of *ISO/IEC 82304-2***. This topic was raised for later more detailed consideration with the suggestion being that this part focus on: *"further security and validation detail and implementation guidance"*.
- ISO Focus magazine has an article on Medical Device safety: (http://www.iso.org/iso/home/news_index/news_archive/news.htm?Refid=Ref2055)

WG 6 Pharmacy and Medications Business.

- ***ISO 17523:2016 Health informatics — Requirements for electronic prescription***s. Approved for publication [published 01 Jun 2016.]
- ***ISO/TS 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 packagin***g. In publication following successful DTS ballot. [published 01 Jun 2016.].
- ***ISO/DTS 19293 Requirements for the record of dispense medicinal products***. At the request of WG 6, TC 215 approved seeking a 12-month extension for this project from 36 to 24 months.
- ***ISO/DTR 20831 .. Medication Management Concepts and Definitions***. Approved for submission to DTR ballot [closing 03 Aug 2016].
- ***ISO/HL7 27953:2011 .. Individual Case Safety Reports (ICSRs) in pharmacovigilance - Parts 1 and 2***. Both parts are to be recommended for renewal following reaffirmation of the underlying HL7 standard in the most recent HL7 ballot cycle. ISO systematic review initiated and closing on 05 Dec 2016.
- ***ISO/DTS 19844 ... IDMP – Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances*** [i.e. The IG for ISO 11238]

  Reconciliation of more than 400 NP ballot comments for the second edition of this document has now been completed. The document has been updated to reflect the agreed reconciliation of comments with an updated draft being circulated to WG 6 on 13 June. Review of the updated draft suggests that comments have been handled in an acceptable fashion.

* Abridged & edited in places for this appendix.

Comment submitters had until the end of May 2016 to review how their comments had been handled and lodge any concerns. Once all edits have been completed the document will be forwarded to ISO/CS for DTR ballot.

- ***ISO/DIS 11615:2012 … IDMP - Data elements and structures for the unique identification and exchange of regulated medicinal product information***. NP ballot for second edition of this standard closed in Sep 2015. 65 ballot comments were received. The reconciliation and proposed CD were reviewed by WG 6 and approved by TC 215 for release to DIS ballot [documents lodged with ISOI/CS in Jun 2016 but yet to be released]. Drivers for revision include alignment with the ISO/TS 20451 and ISO/TS 20433 implementation guides and practical experience with IDMP implementation.
- ***ISO/DIS 11616 ... IDMP – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information.*** NP ballot for second edition of this standard closed in Sep 2015. 38 ballot comments were received. The reconciliation and proposed CD were reviewed by WG 6 and approved by TC 215 for release to DIS ballot [documents lodged with ISO/CS in Jun 2016 but yet to be released]. Drivers for revision include alignment with the ISO/TS 20451 and ISO/TS 20433 implementation guides and practical experience with IDMP implementation.
- ***ISO/DTS 20443 … IDMP – Implementation Guide for ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information***. This TS is substantially ready for publication pending final checks for alignment with ISO/TS 20451 and the underlying Edition 2 of ISO 11615, currently out to DIS ballot. It is therefore affected by the need to align publication dates (see below). Current timeline for the project expires in Jan 2017.
- ***ISO/DTS 20451 ... IDMP – Implementation Guide for ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (PhPID).*** ***DTS*** ballot closed in Sep 2015. 72 ballot comments were received and reconciled after which this TS is substantially ready for publication pending final checks for alignment with ISO/TS 20443 and the underlying Edition 2 of ISO 11616, currently out to DIS ballot. It is therefore affected by the need to align publication dates (see below). Current timeline for the project expires in Jan 2017.
- **Aligning publication dates for IDMP standards and implementation guides**. It was noted that implementation guides ISO/TS 20451 and ISO/TS 20433 are substantially ready for publication but the updated second editions of the related standards to which these implementation guides apply (ISO 11615 and ISO 11616) cannot be published for at least another 6 months due to ISO process which requires an additional ballot round for an IS. If the implementation guides are published before the standards, they

* Abridged & edited in places for this appendix.

would be incompatible with any changes coming from the ballots for the underlying standards. The need for these to be harmonised will delay publication of all these documents until at least the next publication resolution at the next ISO meeting in Lillehammer with actual publication 4-6 months later (China meeting)

[See annotated diagram in Appendix D adapted from WG 6 presentation for proposed IDMP schedule].

- **Usage and maintenance of IDMP identifiers and codes.** US and European regulators have agreed to use the common terminology set managed by EDQM for medication dosage forms and administration routes. ISO is unable to provide facilities for terminology management. The EC has established a web site that provides the EDQM terminology internationally for free (see www.edqm.eu).

  This terminology will be referenced in the current draft of *ISO/DTR 20831 Medication management concepts and definitions*. It would useful if TGA and ADHA aligned their work with these approaches.

- **Safety symbols.** WG 6 proposes that new liaison be set up with TC145 SC 2/3 to standardise symbols in EMRs (TC145 does international symbols for dangers and warnings).

- ***Potential new work item - Use of IDMP in decision support systems.*** At its next meeting WG 6 will consider putting forward a project to address this question.

- **Raising IDMP awareness and promoting its use.**
  - ISO Focus magazine has an article on safe use of meds and the role of IDMP (http://www.iso.org/iso/home/news_index/news_archive/news.htm?Refid=Ref2056)
  - IDMP workshops are proving to be a success and further workshops are planned for the Lillehammer and Hangzhou meetings – targeting all TC 215 experts and others with involvement in medications management

- **Joint out-of-cycle WG 6 meeting in May 2017**. A joint meeting of TC 215/WG 6, IHE Pharmacy and HL7 Pharmacy will be held in conjunction with the HL7 Meeting scheduled for 2-7 May 2017 in Madrid.

- **Joint WG 3/WG 6 Projects.** The following joint project and potential joint projects were discussed in joint session of WG 3 and WG 6:
  - *ISO/DTS 18062 .. Categorial structure for representation of herbal medicaments in terminological systems*
  - Proposed PWI on: *Indications binding to herbal medicines and formulas*
  - Proposed PWI on: *Requirements for terminological systems on herbal medicines and formulas*.

- **HL7®/FHIR® (Fast HealthCare Interoperable Resources) for use in**

* Abridged & edited in places for this appendix.

	medications applications. Rik Smithies (HL7 UK) gave a presentation to WG 6 (and any others able to be present) on the key characteristics of HL7®/FHIR® and the application of this technology for interchange of medication information. It was noted that: - FHIR is a reboot of HL7 for the V2 use cases for mobile, web and more - FHIR is a set of XML or JSON resources linked by a REST API for accessing them - One of the first FHIR test apps was a FHIR Medications mobile app for patients - FHIR is based on "resources". The following resources have been defined in FHIR to address the exchange of information in medications management: Medication; Medication Order; Medication Administration; Medication Dispense; and Medication Statement - Other closely related FHIR resources include: Allergy; and Medical Device. - Interest in the use of FHIR is widespread and growing. Some notable highlights include: ▪ In the US, the HL7-backed Argonaut vendor consortium – Allscripts, Cerner, Epi, McKesson, Meditech etc – is investing heavily in FHIR and ONC is sponsoring three projects; ▪ In the UK, there are several implementations in the NHS; ▪ In Lithuania, the whole Health IT infrastructure is planning to be based on FHIR ▪ FHIR can be implemented using most contemporary web development environments. Open source libraries supporting FHIR include: UHN HAPI; HL7's JAVA; Furore .net API; Mohawk College etc

Key items/actions for Australia:	
	In relation to JWG 7 activities: 1. 80001 and 82304 should be considered for local adoption by IT-014 2. Australian experts need to engage with the current review of 80001 **In relation to WG 6 activities:** 3. The agreed terminology for medication dosage forms and routes by the USA and EC and published at www.edqm.eu should be strongly considered for adoption in Australia 4. The current phase of medication standards publication is nearing completion and planning for future work by WG6 will take place at the next meeting in Lillehammer, Norway

* Abridged & edited in places for this appendix.

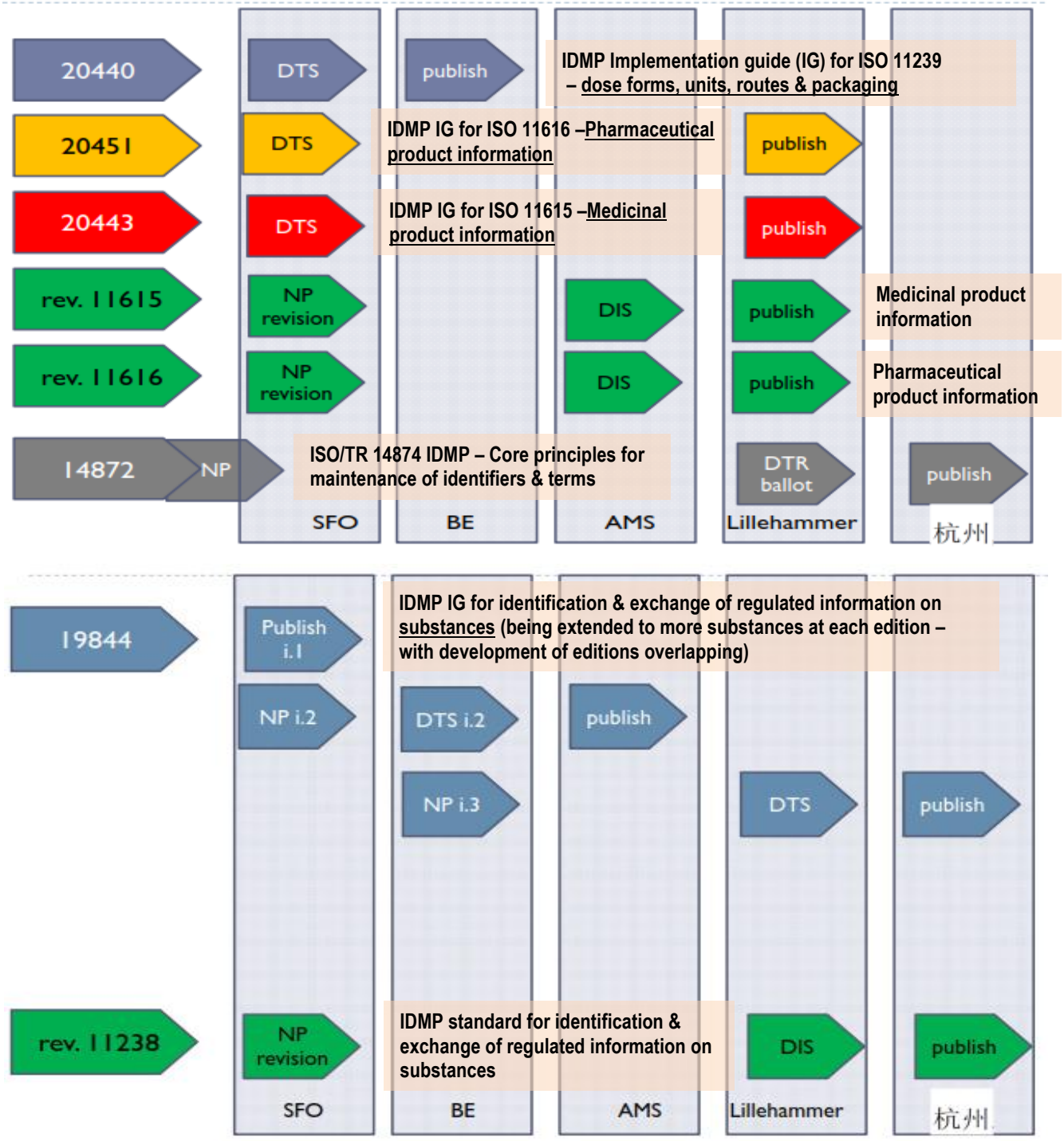
Status of the work:	
	As per the observations and comments above.

Other stakeholders:	• TGA • ADHA • HL7 Australia • IHE Australia

APPENDIX D – STATUS OF WG 6 WORK ON IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP)

* Abridged, edited and substantially modified for this appendix.

IDMP roadmap



* Abridged & edited in places for this appendix.

DUMPSTER

Formats for use:

SA Minutes Body Copy

Report_Bullet_1
- Report_Dash_2
  - Report_Da3

SA Minutes Table Text
- SA Minutes Table Text_L2
  - SA Minutes Table Text_L3

FROM CURRENT STATUS

	Recent & pending publications (since November 2015 meeting) *ISO/HL7 10781 Health Informatics – HL7 Electronic Health Records System Functional Model - Release 2* (EHR-S FM R2). Published 2015-07-31. *ISO/HL7 16527 Health Informatics – HL7 Personal Health Record System Functional Model, Release 1* (PHR-S FM R1). Final copy to ISO/CS on 2015-04-01. *ISO 13940:2015 Health Informatics – System of concepts to support continuity of care* (ContSys). Published 2015-12-17. Noted as possible AU adoption. *ISO/TS 13972:2015 Health Informatics - Detailed clinical models - characteristics and processes*. Published 2015-09-11. *ISO/TR 17522:2015 Health Informatics – Provisions for Health Applications on Mobile/Smart Devices*. Published 2015-08-01. *ISO 22077-1:2015 Health Informatics – Medical waveform format – Part 1: Encoding rules*. Published 2015-04-16. Applicability of ISO 22077-series to AU is not presently known. *ISO/TS 22077-2:2015 Health Informatics – Medical waveform format – Part 2: Electrocardiography*. Published 2015-08-14. *ISO/TS 22077-3:2015 Health informatics - Medical waveform format Part 3 :*

* Abridged & edited in places for this appendix.

	Long term Electrocardiography. Published 2015-07-21. *ISO 14199:2015 Health Informatics – Information models: Biomedical Research Integrated Domain Group (BRIDG) Model*. Published 2015-09-17. *ISO/TS 13582:2015 Health informatics -- Sharing of OID registry information*. Published 2015-12-11. *ISO/TR 12310:2015 Health Informatics – Principles and guidelines for the measurement of conformance in the implementation of terminological systems*. Published 2015-05-22. Potential for AU adoption. *ISO 16278 Health Informatics – Categorial Structures for Terminological Systems of Human Anatomy*. Awaiting publication – expected 2016-02-01. *ISO/TS 18790-1:2015 Health Informatics – Profiling framework and classification for Traditional Medicine informatics standards development - Part 1: Traditional Chinese Medicine*. Published 2015-05-08. *ISO 17090-2 Health Informatics – Public key infrastructure - Part 2: Certificate profile*. Published 2015-11-16. To be considered in any revision of *AS ISO 17090.2-2003* (as per aged standards review). *ISO/TS 17975:2015 Health informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information*. Published 2015-09-18.

* Abridged & edited in places for this appendix.

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.

* Abridged & edited in places for this appendix.

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 aqnd 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 **Error! Reference source not found.**.
- *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.

* Abridged & edited in places for this appendix.

- 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.

* Abridged & edited in places for this appendix.

- *ISO/NP TS 16843-3 Health informatics - Categorial 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 - Categorial 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 - Categorial 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 **Error! Reference source not found.**).
- *IEC/CD 62304 Medical device software - Software life cycle processes (Ed 2)*. Project team working on CD draft for delivery mid-year (further comments **Error! Reference source not found.**). 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 avaialble.

Other recent TC 215 publications

*ISO/IEEE 11073-10442:2015 .. Personal health device communication - Part 10442: Device specialization - Strength fitness equipmen*t. 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

* Abridged & edited in places for this appendix.

	informatics glossaries Published 2014-11-14. Heather Grain (AU) was project leader. Could be considered for AU adoption although primarily affects standards development work. *ISO/TS 17938:2014 .. Semantic network framework of traditional Chinese medicine language system*. Published 2014-06-13. *ISO/TS 17948:2014 Traditional Chinese medicine literature metadata*. Published 2014-07-14. *ISO/TR 19231:2014 .. Survey of mHealth projects in low and middle income countries (LMIC)*. Published 2014-11-14. A general descriptive work summarising the outcomes of preliminary online research into the subject. *IEC/TR 80001-2-5:2014 Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance –Guidance for distributed alarm systems*. Published 2014-12-17. *IEC/TR 80001-2-6:2014 Application of risk management for IT-networks incorporating medical devices – Part 2-6: Application guidance –Guidance for responsibility agreements*. Published 2014-11-20