# IT-014 Health Informatics Committee

Report

ISO/TC 215 Meeting – Mexico City, Mexico

21-26 April 2013

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Review: Richard Dixon Hughes
Collated by: Standards Australia

*With input from Australian Delegation:*

- *Richard Dixon Hughes (Head of Delegation)*
- *Michael Steine (Delegate)*
- *Alan Taylor (Delegate)*
- *Renato Iannella (Delegate)*
- *Naomi Ryan (WG1 Secretariat)*

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# 1. INTRODUCTION

The International Organization for Standardization (ISO) is the world's largest developer of standards. Although ISO's principal activity is the development of technical standards, ISO standards also have important economic and social repercussions. ISO is a network of the national standards institutes of 163 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland.

ISO develops health informatics standards through technical committee ISO/TC 215 Health Informatics, which conducts its activities through the following working groups (WGs) and other organisational units:

- CAG 1 - TC 215 Executive Council - responsible for executive leadership and strategy
- CAG 2 Coordination Group – reviews proposals for new work and coordinates working group activity and monitors progress of the work program
- WG 1 Architecture, Frameworks and Models [Secretariat: Australia]
- Public Health Taskforce (PHTF) reporting through WG 1
- WG 2 Systems and Device Interoperability
- WG 3 Semantic Content [Convenor: Heather Grain (Australia)]
- Traditional Medicine Task Force (TMTF) reporting through WG 3
- WG 4 Security, Safety and Privacy
- Patient Safety & Quality Task Force reporting through WG 4
- WG 6 Pharmacy and Medication Business
- WG 7 Devices (merged into WG 2 from September 2012)
- WG 8 Business Requirements for EHRs (merged into WG 1 from September 2012)
- Operations and Harmonization Committee – coordinates secretariat processes and reporting on TC 215 work program.
- CAG 3 Cross-SDO Coordination Group. Reports on progress of joint work items under the Joint Initiative Council for Global Health Informatics Standardization

The Plenary and Working Group Meeting of ISO/TC 215 Health Informatics was held from 21 to 26 April in Mexico City, Mexico and was attended by 5 Australian delegates (with funding assistance provided by the Department of Health and Ageing). In addition, Heather Grain participated by teleconference as an authorised Australian delegate in Working Group 3 Q4 on 21st April 2013, of which she is the convener.

ISO/TC 215's activities are mirrored in Australia by Standards Australia Technical Committee, IT-014 on Health Informatics.

The benefits that the Australian Healthcare Community derives from Australian representation at international meetings such as this one are significant and ongoing. It is recognised that it is vitally important to ensure that an Australian national position is

represented at such meetings. The most effective way of achieving this is to ensure that a delegation is comprised of the appropriate mix of skills and expertise in order that priority areas are comprehensively addressed.

ISO health informatics standards have tended to focus on policy, governance and functional best practice applicable to the eHealth agenda as opposed to the technical perspective found in HL7 and the content perspective of International Health Terminology Standards Development Organisation (IHTSDO). However, the formal relationships between each of these organisations are extended through regular meetings of their representatives through the Joint Initiative Council (JIC) resulting in increasing collaborative effort to harmonise standards development along a continuum that includes policy, governance, quality/safety and implementation pathways. As a result, ISO/TC 215 has provided an international forum in which key technical standards such as HL7v2.5, HL7v3 RIM, coordinated data types, HL7v3 CDA R2 and the CDISC BRIDG model are being jointly developed for acceptance as full international standards.

# 2. OBJECTIVES OF THE MEETING

Australia participates in international standards development activities in accordance with its obligations under World Trade Organisation (WTO) treaties. The overarching objectives are to benefit the Australian health system and wider community by:

- Improving Australian capacity to implement health informatics standards and e-health systems by expanding local knowledge and expertise based on international best practice.
- Promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing local health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different standards across domestic and international markets.
- Improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems.

Specific objectives for Australian engagement in international standardization via ISO/TC 215 (Health Informatics) include:

- Monitoring and influencing ISO/TC 215's strategic positioning and business model, encouraging it in leading collaboration with other global Standards Development Organisations (SDOs), and assessing and influencing its outputs so as to maximise Australia's capacity to ensure that our health information interchange and related requirements are supported unambiguously by international standards. A more global approach to standards development was a specific request to ISO from a range of national e-health programs, including Australia.
- Negotiating specific objectives for EHR, Personal Health Record (PHR) and health ICT safety standards.
- Progressing EHR Communication, Data Harmonisation, Subject of Care Identification, Provider Identification, and EHR/PHR Systems requirements standards into and through balloting, and assessing and contributing to other standards required for implementation of EHR and personal health record (PHR) applications.
- Advocating for consistency between major SDOs currently developing approaches to EHR interoperability, including consistency regarding data types, object constraint models, health information service architectures, and clinical information models and their representation.
- Facilitating consistency and collaboration between global SDOs in development and adoption of health informatics standards – including encouragement of and participation in harmonisation activities through the Joint Initiative Council (JIC) of ISO, CEN, HL7, IHTSDO, CDISC, GS1 and IHE International, with progress being reported

through the Cross-SDO Coordination stream at ISO/TC 215 meetings (ISO/TC 215/CAG 3).

- Leading development of consistent terminology and an approved lexicon of terms and thesaurus for use across all ISO health informatics standards.
- Progressing information security standards, including (where appropriate) encouraging finalization of standards on: Secure archiving of electronic health records; Security management in health using ISO/IEC 27002; Privilege management and access control (PMAC); Audit trails for electronic health records; Functional and structural roles; Information security management for remote maintenance of medical devices (guideline); Dynamic VPN access to health networks, and EN13606 Part 4 within ISO.
- Supporting the 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.

### Relevance to NEHTA programs

NEHTA has endorsed a range of Australian Standards derived from international standards work some of which were included in a National eHealth Standards Catalogue. A more recent review has identified many of potential relevance to the development of the Personally Controlled Electronic Health Record (PCEHR). As the implementation of PCEHR and other e health initiatives is based on a growing body of these standards, it is important that Australia continues to be involved in the international forums that develop, manage and maintain these, and other potentially relevant, health informatics standards.

ISO/TC 215 holds two full international meetings per year. The first (in April/May) is known as the “Plenary Meeting” because it includes plenary sessions in which formal resolutions are taken in addition to meetings of TC 215’s five domain-specific working groups.

The second meeting, (in September/October) is the “Joint Working Group Meeting” because it mainly comprises meetings of the working groups but, in recent years, has also included a smaller “mini-plenary” to progress urgent matters. The 2nd meeting of 2013 will be hosted by Australia in Sydney from 20-25th October enabled through funding from the Department of Health and Ageing.

The event is a true working meeting, not a conference, with many individual groups meeting to develop, discuss and improve ISO standards, processes and implementation guides and to determine the most effective way to meet the needs of the stakeholders – both those present at the meeting and those in the wider community of interest.

The meeting proper was preceded by a one-day working session of the Joint Initiative Council (JIC) executive and a day in which there was a JIC open forum and TC 215 leadership meetings. The Australian delegation also met on the evening before the official meeting commenced.

This particular Australian delegation had a good mix of skills but lacked the numbers to cover all aspects of the meeting.

# 3. MEETING AGENDA

The agenda for the ISO/TC 215 meeting (including Executive Council and other meetings on Sunday prior to the Opening Plenary) is provided in Appendix A.

There was also a closed meeting of the JIC Executive on Saturday, 20 April, which is not reflected on the ISO/TC 215 agenda.

# 4. RECOMMENDATIONS ARISING FROM THE MEETING

The principal issues / actions and recommendations identified by the Australian delegation at the April 2013 ISO/TC 215 meeting are summarised in this section. Alignment to the IT-014 Committee Structure is also listed.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **BPAH**<br>**Business Plan Ad Hoc Group**<br>**Finalisation of TC 215 Business Plan and related scope issues** | Richard Dixon Hughes (Australia) (RDH) and Jeremy Thorp (UK) chaired the TC 215 Business Plan Ad Hoc, which produced the Business Plan now approved by TC 215. RDH manages the master copy which now needs to proceed into the final ISO approval and publication process in parallel with resolution of TC 215 scope issues raised by some other technical committees.<br>**Action: Richard Dixon Hughes to work with TC 215 Secretariat in submitting final draft of TC 215 business plan for public review, any further formal acceptance and publication.**<br>**Action: Richard Dixon Hughes to confer with liaisons to IEC/TC 62 and ISO/TC 121 and work with JWG 7 Convener (Cooper), TC 215 Chair (Chute) and TC 215 Secretariat (Spellman) in negotiating a resolution to these issues.** | **Richard Dixon Hughes** |
| **CAG 1**<br>**Executive Council)**<br>**CAG 2**<br>**Coordination Group**<br>**Finalisation of project assessment criteria and processes & formation of CAG 2** | Richard Dixon Hughes has been leading a project on specification of more rigorous processes for TC 215 project prioritisation, which has been used to inform development of the TC 215 business plan. Now that the business plan has been approved and defines the business context and agreed high-level criteria, there is a need to finalise criteria and assessment processes (to be applied by the newly formed CAG 2 Coordination Group of which he is an initial member.<br>**Action: Richard Dixon Hughes to participate in finalisation of TC 215 assessment criteria and processes and establishment of CAG 2 Coordination Group.** | **Richard Dixon Hughes** |

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **CAG 2 Coordination Group**<br><br>**Better, more considered proposals for new standards work** | The quality of New Proposals presented during the Mexico meeting was uneven.<br><br>**Action: Australian delegations to upcoming TC 215 meetings should encourage stronger adherence to the requirements of the ISO/IEC Directives for new projects and IT-014 should vote against proposals that do not comply.** | **Australian TC 215 delegations**<br><br>**IT-014** |
| **Next ISO/TC 215 meeting in Sydney** | Potential delegates are seeking more information about the venue, accommodation, amenities and other activities in order to plan their attendance at the Sydney meeting in October. A structure should be considered for engaging with local volunteers and experts to assist in encouraging colleagues to attend and in welcoming and hosting delegates for the event. Synergies should also be sought with HL7 Australia conducting IHIC 2013 early the following week.<br><br>**Action: Consider formation of an organising group to support Standards Australia in hosting the October TC 215 meeting, encourage attendance and distribute additional information.** | **IT-014**<br><br>**Standards Australia**<br><br>**HL7 Australia** |
| **Operations & Harmonisation**<br><br>**Utility of the ISO/CS eCommittees system** | The usability of the ISO eCommittees web site should be improved.<br><br>**Action: Standards Australia should consult with recent new users of the ISO eCommittees website, prepare better guidance for new users and advise ISO on improvements in user help functions and support for navigating the system.** | **IT-014**<br><br>**Standards Australia** |
| **Report on JIC participation** | **Action: Richard Dixon Hughes to prepare separate consolidated report on JIC activities undertaken during April/May 2013.** | **Richard Dixon Hughes** |
| **JIC Leadership** | Despite secretariat staff shortages, JIC needs to progress work on its strategic priorities and the progression of joint work.<br><br>**Action: Richard Dixon Hughes as current Chair of JIC to work with Lisa Spellman and CAG 3 co-chairs (Newsham, Keller) to facilitate meetings by teleconference and progress key priorities, including action on LMIC, for consideration at the next face-to-face meeting of JIC in Sydney in October.** | **Richard Dixon Hughes** |
| **WG1**<br><br>**DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model** | Completion of the work item with detailed contributions for specified subsections.<br><br>**Action: Australian experts should continue to contribute and assist with completion of this item by next TC 215 meeting.** | **IT-014** |

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG1**<br><br>**DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model** | DTR 14639-2 is of potential interest and use to Australian health care providers, non-government organizations, government providers of aid, and the private sector in Australia. Additionally throughout the Asia Pacific region DTR 14639 parts 1 and 2 could be of substantial interest.<br><br>**Action: Following the publication of DTR 14639-2 a number of promotional activities will be need to be considered to promote the use of TR 14639 and associated ISO standards.** | **IT-014** |
| **WG 1**<br><br>**TS 13972 – Characteristics and Processes of Detailed Clinical Models** | The revised DTS 13972 will be sent out for a second ballot. It has been extensively reformatted and edited to take account of comments received. Further consideration will be required at the Sydney TC 215 meeting.<br><br>**Action: Australian experts to determine an approach on how to respond to the second DTS ballot.** | **IT-014-09**<br><br>**NEHTA CTI team** |
| **WG 1**<br><br>**DTS 18530 – Subject of Care (SOC) and Individual Provider Identification (GS1)** | Subject of Care and Provider identification via AICD is in important part of automation of processes during care delivery especially in the inpatient setting. For example it is heavily used in a closed loop medication management process.<br><br>GS1 is being adopted throughout Australia through the NPC however it may not be suitable in all settings.<br><br>**Action: IT-14-02 and IT-14-06-04 to review the DTS when available for suitability to Australia.** | **IT-014-02**<br><br>**IT-014-06-04** |
| **WG 1**<br><br>**NP Quality Metrics for Detailed Clinical Models** | This item is effectively an extension to ISO DTS 13972 on Detailed Clinical Models. It is likely to closely reference the structure and content of 13972. Given that Australia has some of the most extensive practical experience in quality metrics internationally, it is advisable that Australia actively participate in informing and shaping the final deliverable – whether a technical report or a technical specification.<br><br>**Action: Australia to provide expertise to inform the development of this new work item, no matter what the final targeted publication.** | **IT-014-09**<br><br>**NEHTA** |

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 1**<br><br>**ISO 13606 Electronic health record communication** | This will be a significant block of work to be undertaken over the next couple of years. There are many new or updated resources that will be taken into account in this revision. It will create a significant opportunity to harmonise activity from a variety of projects including, but not limited to, HL7's CDA, openEHR and the new CIMI project.<br><br>**Action: IT-014-09 to encourage and support Australian expert input to the revision of ISO 13606.**<br><br>**Action: IT-014-09 to monitor and participate in review of the proposed survey and all ISO 13606 documents.** | **IT-014-09** |
| **WG 1**<br><br>**Proposed NP TS 18528 – Functional Classification of Health Informatics Standards** | Australia should monitor and potentially actively contribute to the NP TS 18528 – Functional Classification of Health Informatics Standards, given our current work in IT-014-09 with the eHealth Architecture Framework, and the eHealth Maturity Model Classification. | **IT-014-02**<br><br>**IT-014-09** |
| **WG 1, WG 3**<br><br>**ISO/CD 13940 System of Concepts to Support Continuity of Care - CONTSYS** | It is critical for this work to be capable of practical application.<br>If implementation support is included, this work will be a useful resource to inform the NEHTA CI team, DCM, and specification development.<br>Alignment with IT-014-12 work on care management process modelling is also important.<br><br>**Action: Form taskforce of Australian experts to review and contribute to CONTSYS ballot response and to ensure that the standard is capable of practical implementation, is firmly grounded in clinical practice and can be implemented in specifications and by grassroots vendors.**<br><br>**Action: Monitor the progress of the CEN Convergence meetings to ensure that implementation support is grounding and informing the development of the CONTSYS standard.** | **IT-014-02**<br><br>**IT-014-06**<br><br>**IT-014-09**<br><br>**IT-014-12**<br><br>**IT-014-13**<br><br>**NEHTA**<br><br>**SA** |
| **WG 1, WG3**<br><br>**CEN WG1 Workshops - Convergence of 13606, CONTSYS and HISA** | The outcomes are relevant to Australia's viewpoint on these cornerstone standards and are also related to work being undertaken by IT-014-09, in conjunction with NEHTA re the eHealth Interoperability Framework (eHIF).<br><br>**Action: IT-014-09 should monitor and potentially actively contribute to this work, including considering its conclusions in relation to future iterations of the eHIF.** | **IT-014-09** |

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG2**<br>**DTS 13131 Telehealth Quality Criteria** | The CD ballot comments have not yet been reviewed and used to update the current draft.<br>**Action: Australia has offered to complete a review of comments, and prepare a new draft of TS 13131 for review at the TC215 Sydney meeting and include consideration of this item on IT-014-12 work plan.** | **IT-014-12**<br>**Alan Taylor** |
| **WG 2**<br>**ISO/TR 17522 Provisions for health applications on smart/mobile devices** | The topic is of particular relevance to the development of mobile access to eHealth applications by client, patients and provider. Standardisation is immature and there is little consensus on the best solution architecture. Australia would be well placed to leverage a well developed eHealth architectural framework to address these issues.<br>Although the topic is worthy of consideration the draft available to WG2 was of limited value, lacked a clear scope, analytical framework and purpose. A large number of negative comments can be expected.<br>**Action: Australia should provide a high level review of the draft when balloted, to assist the project leader moving forwards.** | **IT-014-12** |
| **WG 2**<br>**ISO/TR 17522 Provisions for health applications on smart/mobile devices** | The topic is worthy of consideration and could be useful to implementers both within Australia and the Asia Pacific.<br>Unfortunately the draft lacks an analytical framework, purpose, focus and rigor.<br>**Action: Australia should provide a high level review of the draft when balloted, to assist the project leader moving forwards.** | **IT-014-12** |
| **WG 2**<br>**DTR 2830-3 IHE adoption process Part 1 Process DTR 2830-3 IHE adoption process Part 2 Integration and Content Profiles** | ISO/TR 28380-1 IHE Global Standards Adoption – Process has been the subject of a DTR ballot. Comments have been collated and an amended draft will be prepared for publication.<br>ISO/TR 28380-2 IHE Global Standards Adoption - Integration and Content Profiles is ready to proceed to publication.<br>**Action: Ensure that State and Territory CIO's are aware of these publications when they are made available.** | **DoHA**<br>**State and Territory CIOs** |
| **WG 2**<br>**DTR 2830-3 IHE adoption process Part 3 Deployment** | ISO/N941 IHE Global Standards Adoption – Deployment. This report has been amended to take account of committee comments and will be circulated prior to submission to a three month DTR ballot.<br>**Action: Australian experts should continue to contribute and assist with completion of this item before the next TC215 meeting.** | **IT-014** |

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 3**<br><br>**12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems** | Australia can support this work item as NEHTA have developed Conformance Profiles for Terminologies and Mappings for AMT and SNOMED-CT.<br><br>**Action: Australia needs to decide whether to support this work item.** | **IT-014-02**<br><br>**NEHTA** |
| **WG 3**<br><br>**ISO TS 17439 STRUCTURE AND MAINTENANCE OF THE HEALTH INFORMATICS GLOSSARY** | **Action: Important for AU to follow and lead this work as foundational for terminology management.** | **IT-014-02** |
| **WG 3**<br><br>**TDR 12300 Principles of mapping between terminological resources** | Very important for AU to follow due to the requirements in local mapping terminologies with AMT (for example).<br><br>**Action: NEHTA and IT-014-02 to monitor this work item.** | **NEHTA**<br><br>**IT-014-02** |
| **WG 3**<br><br>**ISO/NP/TR 14668 GUIDELINES FOR PRINCIPLES AND DESIRABLE FEATURES OF CLINICAL DECISION SUPPORT** | This item is relevant to IT-014-13 work program on Clinical Decision support.<br><br>**Action: IT-014-13 to monitor progress.** | **IT-014-13** |
| **WG 6**<br><br>**ISO 16791 Requirements for machine-readable of medicinal product package identifiers** | The final draft of the ISO TS 16791 will be out for review around June. Recommend that Australia review to validate comments made during the DTS ballot are adequately resolved.<br><br>**Action: IT-014-06-04 to monitor for the release of the final draft for review by the informatics community.** | **IT-014-06-04**<br><br>**TGA**<br><br>**NEHTA** |
| **Public Health Task Force:**<br>**Business case for distribution of TR 14639- Parts 1 and 2** | Promotion of the TR 14639 reports will become the responsibility of national SDOs and their partners. The role of standards will become important to the provision of technical health implementation services and the delivery of health care services throughout the region.<br><br>**Acton: Australia should develop a national and regional approach to promotion of TR 14639.** | **IT-014** |

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **Public Health Task Force: Future Low Middle Income Countries (LMIC) related standards development and promotion** | Opportunities for collaboration with SDO initiatives to extend reach of eHealth standards to LMICs.<br><br>**Action: Collaboration opportunities should be explored between IT-014 and other SDOs in the area of standards education and liaison, especially to Australia's established regional partner nations.** | **IT-014** |
| **ISO/TC 215 Scope** | It is likely that some change in TC 215 scope may be required at the Sydney meeting.<br><br>**Action: Ensure that the Australian delegation reaches a position on a suitable TC 215 scope prior to their meeting.** | **IT-014** |

# 5. FUNDING SOURCE SUMMARY

In total, five Australians attended as representatives for the duration of this ISO/TC 215 meeting and one dialled in for one session. The funding source for these delegates is indicated in the table below.

| Funding Source | Number | Change from Previous Meeting |
|---|---|---|
| Full funding by employer: Private | 0 | 0 |
| Full funding by employer: States/Territories or National Initiatives (NEHTA) | 0 | 0 |
| Funding Assistance – DoHA through Standards Australia contract | 5 | -4 |
| Total: | **5** | **-4** |

The Australian delegation comprised:

- Richard Dixon Hughes (Head of Delegation)
- Michael Steine (Delegate)
- Renato Iannella (mentored position)
- Alan Taylor (mentored position)
- Naomi Ryan (WG1 Secretariat)
- Heather Grain (dialled in via teleconference from Australia for one quarter session)

# 6. ATTENDANCE

There were five Australians in attendance as representatives for the duration of this ISO/TC 215 meeting, as follows:

| |
|---|
| AT – Alan Taylor |
| MS – Michael Steine |
| NR – Naomi Ryan |
| RI – Renato Iannella |
| RDH – Richard Dixon Hughes |

| **Meeting** | **Sat 20th** | **Sun 21st** | **Mon 22nd** | **Tues 23rd** | **Wed 24th** | **Thurs 25th** | **Fri 26th** |
|---|---|---|---|---|---|---|---|
| WG 1 – Architecture, Frameworks & Models | | AT, NR | MS, AT, RDH, NR | AT, RDH, NR | AT, RDH, NR | AT, NR | |
| WG 2 - Systems & Device Interoperability | | | AT | | | | |
| WG 3 - Semantic Content | | | RI | RI | RI | | |
| WG 4 - Security, Safety and Privacy | | | | | | | |
| WG 6 - Pharmacy and Medicines Business | | | MS | MS | MS, RI | MS | |
| Traditional Medicine Taskforce | | | | | RI | | |
| JIC Executive | RDH | RDH | | RDH | | | RDH |
| JIC Open Forum | | RDH, MS, NR | | | | | |
| CAG 1 - Exec Council - invitation only | | RDH | | | | | |
| Operations Group | | NR, RDH | | | | | |
| CAG 3 Cross-SDO Coordination Group | | AT, NR | | | | | |
| Business Plan Ad Hoc (BPAH) group | | RDH | RDH | RDH | | RDH | |
| Public Health Task Force | | NR | RDH | | AT, RDH, NR | AT | |
| Plenaries | | RDH, RI, AT, MS, NR | | | AT | | RDH, RI, AT, NR |

# 7. POSITIONS HELD BY DELEGATES

The DoHA funded delegates were selected through an independent panel process jointly with NEHTA, DoHA and IT-014 facilitated by Standards Australia. The positions of these delegates (including leadership positions) are listed below.

| Working Group or Committee | Position | Status | Person |
|---|---|---|---|
| Australian Delegation | Head of Delegation (and ex-officio member of TC215 Executive Council) | Appointed | Richard Dixon Hughes |
| TC 215 – Task Force on project assessment & prioritization criteria | Leader – Role Incorporated into Ad Hoc on SBP | Appointed | Richard Dixon Hughes |
| ISO/IEC JTC 1 Liaison to TC 215 | Nominated JTC 1 Liaison Officer | Appointed by JTC 1 | Richard Dixon Hughes |
| Joint Initiative Council (Executive Meetings) | Chair for 2013+14 | Appointed by TC 215 | Richard Dixon Hughes |
| TC 215 Business Plan Ad Hoc (BPAH) | Co-Leader | Appointed by TC 215 | Richard Dixon Hughes |
| TC 215 | SKMT advisor and support (WG3 representative) | Appointed by the plenary | Heather Grain |
| TC 215/CAG 2 Coordination Group | Elected member | Appointed by TC 215 | Richard Dixon Hughes |
| ISO/TC 215 WG 1 Public Heath Task Force | National Expert | Lead on nominated sections for document drafting | Richard Dixon Hughes |
| ISO/TC 215 WG 1 Public Heath Task Force | Secretariat | Appointed | Standards Australia (IT-014 Program Manager) – Naomi Ryan |
| WG 1 – Architecture, Frameworks & Models | Secretariat | Appointed | Standards Australia (IT-014 Program Manager) – Naomi Ryan |
| WG 1 - Architecture, Frameworks & Models | ISO TS 13972 Health Informatics - Characteristics and Processes of Detailed Clinical Models<br>National Expert | Appointed | Richard Dixon Hughes |
| WG 1 - Architecture, Frameworks & Models | National expert nominated to contribute to several work items including DCMs and EHR-S FM | Nominated expert | Richard Dixon Hughes |
| WG 3 – Semantic Content (Terminology) | Convenor | Elected (to May 2013) | Heather Grain |
| WG 3 - Semantic Content | 12300 Principles of mapping between terminological resources,<br>ISO TS 17439 Structure and maintenance of the health informatics glossary<br>14668 Guidelines for principles and desirable features of Clinical Decision Support | Project leader and author | Heather Grain |

| Working Group or Committee | Position | Status | Person |
|---|---|---|---|
| WG 3 - Semantic Content | 12310 – Principles and guidelines for the measurement of conformance in the implementation of terminology systems.<br>ISO 17115:2007 Vocabulary for terminological systems (VOTE)<br>ISO 17117 Terminological resources Part 1 – Framework<br>ISO TS 16277-1 TS Health Informatics - Categorial structure of clinical finding in traditional medicine- Part 1: Traditional East Asian Medicine | Australian national nominated expert | Heather Grain |
| Traditional Medicine Task Force (TMTF) | National Expert | Australian national nominated expert | Heather Grain |

# 8. ADVISORY GROUP MEETINGS AND FORUMS

## 8.1 CAG 1 (EXECUTIVE COUNCIL) AND GOVERNANCE OF TECHNICAL COMMITTEE TC 215

| | |
|---|---|
| Australian Delegate Attendance | Richard Dixon Hughes (Australian HoD) |

### 8.1.1 BACKGROUND

The TC 215 Executive Council (EC) comprises the TC 215 Chair, the Head of Delegation for each country, and the Convenor and Vice-Convenor of each TC 215 Working Group. Its role is to consider issues of governance and process relevant to the TC.

Meetings of the Executive Council are chaired by the TC 215 Chair and are not generally open to delegates other than members of the Executive Council.

Within the recently revised TC 215 structure the Executive Council continues as a formally recognised advisory group, with the designation "CAG 1 Executive Council".

### 8.1.2 PROGRESS AT THIS MEETING

The EC met from 1330 to 1600 on Sunday 21 April, the day before the main TC 215 meetings commenced. Topics addressed, included:

- Developments arising from and since the September 2012 meeting in Vienna.
- Implementation of the TC 215 reorganization proposals and the TC 215 strategic business plan (SBP).

  Consideration of the business plan and related matters was a significant part of the meeting, which is reported further in Section 8.1.3 below
- Formation of the CAG 2 Coordination Group
- Leadership of working groups within TC 215
- Report from ISO Central Secretariat
- TC 215 meeting structure
- Calendar of future TC 215 meetings
- Updates from JIC

The Mexican delegation and its supporters were thanked for their considerable efforts in organising and hosting the meeting at relatively short notice.

Discussion of some topics during the scheduled CAG1, O&H and CAG 3 leadership meetings, was partly limited by the TC 215 Secretary becoming ill during the afternoon and having to leave the meetings for hospital treatment. Despite this setback, she made a good recovery and discussion of most topics was able to be continued during the week.

## Formation of TC 215 CAG 2 Coordination Group

The CAG 2 Coordination Group comprises the TC 215 Chair, the convenors of Working Groups 1 to 4, five elected members and the TC 215 Secretary. It is an advisory group tasked with using relevant assessment criteria to review and prioritize new work item proposals (NPs) with the goal of harmonizing work within TC 215 and, where appropriate, with other SDOs by working with CAG 3 and the JIC.

In addition to its harmonisation role, CAG 2 is to develop and maintain operational plans, oversee their delivery and work with the TC 215 WGs to expedite achievement of the TC 215 work program and business plan goals.

In accordance with approvals for implementing the recommendations of the ISO/TC 215 – Re-organisation Task Force Report, nominations were sought in March 2013 seeking candidates to serve as elected members of CAG 2. By the time of the CAG 1 meeting in Mexico City, the following five persons had been nominated as candidates for the five elected positions.

1. Mr. Javier Baltierrez (Mexico)
2. Mr. Richard Dixon-Hughes (Australia)
3. Mr. Christian Hay (Switzerland)
4. Mr. Michio Kimura (Japan)
5. Mr. Pier Angelo Sottile (Italy)

Following brief discussion and noting the breadth of skills and geographic coverage provided by the candidates offered, CAG 1 unanimously resolved to recommend their appointment to TC 215 plenary, which was subsequently approved at the plenary session.

An early task for CAG 2 will be to refine and communicate the criteria for assessment of new projects. It is anticipated this would build on the original work of Richard Dixon Hughes, the updated requirements of the ISO/IEC directives and the TC 215 business plan.

## Leadership of working groups within TC 215

Under its operating guidelines, TC 215 has had a long-standing principle that convenors of working groups should be limited to no more than two consecutive three-year terms. This was modelled on a similar requirement in the ISO/IEC directives for TC Chairs.

Several TC 215 working group office bearers have retired, become unavailable due to circumstances outside their control, or are coming up for retirement under the two-term rule.

The principal concern of the TC 215 leadership is to ensure adequacy and continuity and renewal of WG leadership and negotiations are continuing with potential candidates in relation to the various vacancies.

It is proving difficult to find the people and resources needed to fill vacancies as convenors and vice-convenors and to secure adequate continuity and resourcing for WG secretariats. This is becoming an increasing problem for TC 215, particularly in relation to the secretariats for WG 2 and WG 3 and several convenor/vice-convenor roles.

Part of the issue is that most potential candidates for these roles are dependent on funding from employers, national e-health programs or academic and research organisations and all of these sources are under considerable financial pressure in the current world-wide economic climate.

In considering this situation, there was discussion as to whether the self-imposed two-term rule should be retained or not, noting that, under the ISO/IEC Directives, there is no such restriction for WG leadership positions.

It was recognised that rotating such positions on a regular basis continued to be generally good practice and that it should continued to be pursued where possible. It was noted that ISO/CS supports moderate levels of leadership rotation as a means of stimulating commitment and vitality of committees. Nevertheless, there are many situations where longevity of WG conveners had also produced effective outcomes. It had not been a major issue as WGs were not intended to be formed as standing groups.

CAG1 resolved to recommend to TC 215 that WG convenors no longer be limited to two consecutive three-year terms.

During discussion, the contribution of Standards Australia and the Australian Government in providing a Secretariat for WG 1 was noted and greatly appreciated.

### Report from ISO Central Secretariat

Dr Mary Lou Pélaprat, the Technical Programme Manager at ISO/CS responsible for TC 215 provided some background on developments in ISO, particularly work on enhancing electronic services and changes in the next edition of the ISO/IEC Directives due for release in early May.

Key points from this and other presentations that Dr Pélaprat made during this TC 215 meeting are summarised in the report of the Operations and Harmonisation meeting in Section 8.2.3 below.

### TC 215 meeting structure

The meeting was reminded of the changes to the TC 215 meeting timetable that had been introduced at this meeting, particularly the opportunity for the host nation to have a more prominent role during the opening, the provision of extra time for WG activity and the changed schedule for submission and review of resolutions by national member bodies, with the closing plenary commencing later on the final day.

Some delegates were concerned that, when the preliminary leadership sessions are included, TC 215 meetings have now grown to 6 days for a plenary and 5 days for a working group meeting (with mini-plenary). It was suggested that the Sydney meeting be scaled back to commence on Monday with an early finish on the Thursday.

Ms Spellman noted that the 2013 schedules had been reviewed in detail at the Vienna closing plenary in September 2012 and that the duration of the meetings in Mexico City and Sydney had been reviewed, discussed and approved by TC 215 WG convenors and HODs as well as the plenary. She noted that the meeting schedule had not been "dictated" by the

Secretariat but, rather, it had been developed based on feedback from WG leadership, which had sought more time to progress the standards work.

Further input on these questions was sought throughout the week, recognising that the final timetable for the Sydney meeting would need to be a matter for the TC 215 Secretariat, the TC 215 Chair and Standards Australia.

The availability of a wiki for sharing draft resolutions and comments on them was greeted with encouragement, noting that more detail on this development would be provided to WG leaders at the subsequent Operation and Harmonisation session.

### Calendar for future TC 215 meetings

The Secretariat thanked the further countries that had expressed their interested in hosting TC 215 meetings in the coming years. Details of the proposed meeting calendar are provided in Section 8.1.4 below.

### Update from the JIC

As Chair of the JIC (Joint Initiative Council for Global Health Informatics Standardization), Richard Dixon Hughes provided a brief report on JIC activities, including summarising the outcomes of the planning work done on the previous day and the JIC executive meeting held that morning. In particular, he highlighted key areas of on-going work:

- Actions being taken to refine, prioritize and progress strategic actions identified at the JIC Strategic Workshop held at the September 2012 meeting in Vienna.
- Monitoring and reporting on the JIC joint work program. This was discussed in the CAG3 meeting later in the day (see Section 9.2 below).
- Thanks to Lisa Spellman (ISO/TC 215 and JIC secretariats) and Dr Mary Lou Pélaprat (ISO/CS) for their work on resolving issues surrounding the publication and potentially the maintenance of joint standards – notably for BRIDG and the EHR-S FM.
- Further discussions to take place during the week concerning the recommendations of the ISO/TC 215 Public Health Task Force for JIC activities and their potential relationship to the JIC's existing LMIC Initiative.
- Plans to progress other key strategic tasks, including: Update of JIC Charter and Bylaws; JIC communications and Web-presence; Re-engagement with stakeholders; progress in uptake and use of SKMT.

It was noted that JIC had considered but had decided not to mount an event in 2014 similar to the former Global Health IT Summit as a means of stakeholder engagement; however, opportunities would be sought to bring communities of interest together at other existing forums in coming years.

### 8.1.3 TC 215 BUSINESS PLANNING AND ORGANISATION

#### *8.1.3.1 Introduction*

Business planning, including periodic consideration of the relevance of working groups and their activities is a core responsibility of every ISO technical committee (TC). As part of this responsibility, the ISO/IEC Directives require each TC to maintain a strategic business plan (SBP) prepared in accordance with a standard ISO template. SBPs are publicly available documents that outline the business environment, scope, plans and activities of each TC.

#### *8.1.3.2 Recent progress*

TC 215 formed a Reorganization TF at the May 2010 meeting in Rio de Janeiro with an initial focus on achieving a more efficient organisation for TC 215 and also on updating the TC 215 strategic business plan. Since then:

- Initial consultation was carried out - including reviewing key principles and objectives and potential changes to scope and organisational structure of TC 215. An initial set of proposals for change were discussed at the Rotterdam meeting in October 2010.
- A report proposing a restructure of TC 215 was prepared and accepted in principle at the May 2011 plenary in Kuopio.

  The main organisational changes involved creating formal advisory groups to coordinate and prioritise work and reducing the number of standing working groups to four, while allowing for shorter-term domain WGs in areas such as pharmacy.
- At the further request of TC 215, the Reorganisation TF refined the operational aspects and prepared an updated report, along with specific recommendations for implementation.

  These recommendations for implementation were accepted in principle at the October 2011 TC 215 meeting in Chicago and ratified at the following (Vancouver) meeting in May 2012.

  TC 215 was then advised that some of its proposals were incompatible with changes being made by ISO, in particular, new systems for managing TC and WG participation. A series of negotiations between a TC 215 leadership group and ISO/CS eventually resulted in agreement on further updates to the Task Force report and associated recommendations for implementation.
- The final version 3.3 of the Reorganization Task Force Report and 31 associated recommendations for implementation were presented and approved at the September 2012 TC 215 meeting in Vienna, after which the TC 215 Reorganization Task Force was thanked for its work and retired.
- At the same meeting, Richard Dixon Hughes (Australia) and Jeremy Thorp (UK) were appointed to lead a Business Plan Ad Hoc group (BPAH) to focus on updating the TC 215 SBP. Other delegates interested in contributing were invited to put their names forward as members of the group and many expressed interest.

- Shortly after the Vienna meeting, the 31 specific recommendations for implementation of the proposed TC 215 organisation structure were circulated to TC 215 national member bodies for approval and comment via a letter ballot.
- As part of the process of preparing the SBP, the BPAH undertook to review and analyse responses to the letter ballot as well as addressing some residual issues relating to the names and scopes of TC 215 working groups.

  The letter ballot indicated strong support for the proposed restructure, but comments indicated that a further process of review, harmonisation and discussion was required to resolve some of the WG name and scope issues – particularly in relation to WG 1 and WG 2, which had been given the preliminary names: "Architecture" and "Systems and Device Interoperability" respectively.

In the period between the TC 215 September 2012 meeting in Vienna and the April 2013 meeting in Mexico City:

- The BPAH group corresponded by email and met by teleconference on five occasions in order to:
  - Consider the responses to the letter ballot on implementation of the TC 215 Reorganization Task Force report, and the names and scopes of TC 215 WGs;
  - Provide input during the preparation of the first discussion draft of the SBP;
  - Review and provide feedback on the first discussion draft of the SBP (v3.3); and
  - Review, suggest amendments and agree a final draft v3.4 for broader distribution to members of the TC 215 Executive Council (CAG 1) and WG secretaries.
- Updated WG titles and scopes were discussed and agreed (on 10 January) for inclusion in the draft SBP.
- A first discussion draft (v3.3) of the SBP was circulated to the BPAH for comment (on 7 February).
- After reconciliation of feedback and comments and follow-up of some WG scope issues, an updated v3.4 of the draft SBP was produced and circulated for BPAH consideration and approval at its fifth meeting on 28 February.
- A further version 3.4A, incorporating final BPAH suggestions, was circulated (on 2 March) to the BPAH and the wider TC 215 leadership group (Executive Council and WG Secretariats) with an invitation for comment and specific feedback being sought by means of a structured questionnaire.
- Input on the draft SBP continued to be received up to and into the commencement of the TC 215 meeting in Mexico City.

#### *8.1.3.3 Progress at this meeting*

Significant work was undertaken to communicate progress, obtain feedback, facilitate agreement and arrive at a draft final version of the TC 215 business plan at this meeting, including:

- A joint presentation by Jeremy Thorp and Richard Dixon Hughes to the Executive Council (CAG 1) on the process and progress up to that point, followed by discussion and consideration of the main areas to be resolved as part of the finalisation process, specifically:
    - The TC 215 scope statement and the relationship of TC 215 activity to the field of "health informatics";
    - The names and scopes of WG 1 and WG 2 (the others having all been agreed);
    - The rationale and appropriateness (or otherwise) of the specific objectives and timelines set out in the draft SBP; and
    - The proposed process for review, feedback, update and approval of a final draft business plan at the meeting.

  It was noted that TC 215 also needed to produce an updated policies and procedures document to replace the previous "TC 215 guidelines" and address operational matters needed to implement the SBP and various recommendations of the TC 215 Reorganization Task Force Report.
- Based on feedback from the earlier circulation of the v3.4A and from discussion at CAG 1 and with leaders in the TC 215 community, Richard Dixon Hughes produced an updated v3.5 of the SBP at the meeting with assistance from Jeremy Thorp.
- This v3.5 of the SBP was circulated around lunchtime on Tuesday 23 April to all delegates present at the TC 215 meeting in Mexico City for their review and feedback by late on Wednesday, 24 April with a view to acceptance at the closing plenary.
- Based on feedback from delegates, Richard Dixon Hughes and Jeremy Thorp incorporated further amendments to produce the draft final version of the business plan (SBP v3.6), which was then circulated with a proposed resolution for its adoption,.
- Action was taken to resolve differences over the names and scopes of WG 1 and WG 2, including discussions with the WG leaderships and a ballot of WG 1 experts in attendance at Mexico City. After a week of significant debate tinged with a modicum of personal acrimony, all matters related to WG titles and scopes were completely resolved. For the record:
    - The approved name of WG 1 is “Architecture, Frameworks and Models” with scope: "Standardization of frameworks, architectures, and their components in support of health and healthcare, including standardization of conceptual, logical, and functional requirements, process models and information models"; and
    - The approved name of WG 2 is “Systems and Device Interoperability” with scope: "Standardization of electronic exchange of information among health and healthcare systems, including information exchange within and among organizations and interoperability of devices".
- Reporting to and proposing a resolution at the closing plenary for adoption of v3.6 as the draft final version – to be processed for approval and publication. The resolution was passed.

- Detailed discussion and follow-up through the week in relation to objections from IEC/TC 62 (Electrical equipment in medical practice) and ISO/TC 121 (Anaesthetic and respiratory equipment) to the proposed revisions to the TC 215 scope statement and arranging for the continued management and resolution of this issue following the meeting, which is reported further in Section 8.1.3.4 below.

#### *8.1.3.4 TC 215 scope statement*

The currently approved scope for TC 215 as reflected on the ISO website is as follows:

> *"Standardization in the field of information for health, and Healt h Information and Communications Technology (ICT) to promote interoperability between independent systems, to enable compatibility and consistency for health information and data, as well as to reduce duplication of effort and redundancies.*
>
> - *The domain of ICT for health includes but is not limited to:*
> - *Healthcare delivery;*
> - *Disease prevention and wellness promotion;*
> - *Public health and surveillance;*
> - *Clinical research related to health service."*

In reviewing the TC 215 purpose and objectives, the Reorganization Task Force suggested an alternative scope. Although there would have been considerable problems in using the proposed scope, the suggestion stimulated further discussion as to whether the existing scope statement clearly expressed the area of activity addressed by TC 215.

Some of the issues with the current scope statement include the ambiguity in how the terms in the different lists are to be associated with each other, uncertainty as to the extent to which its activities are limited to specific purposes and the notion of "ICT for Health" being a list of clinical disciplines, often omitted when the scope is quoted.

The fact that the scopes of ISO/TC 215 and IEC/TC 62 overlap has already been recognised and is supported by the current joint collaboration through IEC/SC 62A/JWG 7, which appears to be working satisfactorily.

Unless resolved, the issues raised by IEC/TC 62 and ISO/TC 121 have the potential to cause extended delays in acceptance of a more appropriate statement of the TC 215 scope and also delay acceptance and publication of the TC 215 business plan, which depends on having an agreed scope statement.

After much debate and several changes along the way TC 215 finally resolved to adopt the following revised scope statement for TC 215 noting that it will need to be discussed with relevant TCs and will be subject to TMB approval:

> *"Standardization in the field of health informatics to facilitate the creation, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system"*

It has been suggested that there are concerns about this scope signalling a move by TC 215 to extend its activities into situations where data is created in a medical device (such as a scanner). The words "health system" are apparently also misinterpreted by

some as a reference to a piece of equipment or a network rather than having the intended meaning associated with the broader business or operational setting in which health and health-care services operate.

In providing this revised scope statement, TC 215 was not intending to extend its scope.

As the principal author of the TC 215 business plan and the person who facilitated most of the discussion about the scope of TC 215 and its working groups, Richard Dixon Hughes is working with Todd Cooper, who is the ISO/TC 215 co-chair of JWG 7, to assist the TC 215 secretariat and Chair resolve these issues. In particular, he was to meet with relevant liaison officers from TC 121 and IEC/SC 62A, when they gathered in Atlanta for a JWG 7 meeting ahead of the HL7 Working Group Meetings.

#### *8.1.3.5 Project approval and prioritization*

At the October 2011 meeting in Chicago, Richard Dixon Hughes was commissioned by Executive Council and TC 215 plenary to investigate and report at the May 2012 plenary meeting on possible methods of aligning the prioritisation, selection and approval of work items with TC 215 strategic objectives, This was to be done in collaboration with the TC 215 Reorganization Task Force.

He undertook an initial review and reported the results to the May 2012 meeting in Vancouver, noting that there was limited need for new measures but, rather, needs to consider more active enforcement of recent enhancements required by more recent versions of the ISO/IEC Directives. These initial findings also influenced the activities and governance processes proposed in the TC 215 business plan.

At the Vienna September 2012 meeting there was discussion regarding the documentation and balloting of new work items. Attention was drawn to the revised requirements flowing from the 2012 edition of the ISO/IEC directives, specifically the need to provide better, more considered proposals for new standards work including:

- more comprehensive documentation – preferably with a full draft of the proposed deliverable;
- greater attention to market relevance;
- evidence of an environmental scan to identify related and potentially overlapping work; and
- using the preliminary work item stage to develop proposals more thoroughly and communicate them more widely before putting them forward for NP ballot.

During this meeting in Mexico a small number of work items that are to proceed to NP ballot did not appear to have been subject to these quality control processes.

The processes for project assessment now need to also be taken to the next step, incorporated into TC 215 operating procedures and communicated to the TC 215 community.

### *8.1.3.6 Relevance to Australia*

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **BPAH**<br>**Business Plan Ad Hoc Group**<br><br>**Finalisation of TC 215 Business Plan and related scope issues** | Richard Dixon Hughes (Australia) (RDH) and Jeremy Thorp (UK) chaired the TC 215 Business Plan Ad Hoc, which produced the Business Plan now approved by TC 215. RDH manages the master copy which now needs to proceed into the final ISO approval and publication process in parallel with resolution of TC 215 scope issues raised by some other technical committees.<br><br>**Action: Richard Dixon Hughes to work with TC 215 Secretariat in submitting final draft of TC 215 business plan for public review, any further formal acceptance and publication.**<br><br>**Action: Richard Dixon Hughes to confer with liaisons to IEC/TC 62 and ISO/TC 121 and work with JWG 7 Convener (Cooper), TC 215 Chair (Chute) and TC 215 Secretariat (Spellman) in negotiating a resolution to these issues.** | **Richard Dixon Hughes** |
| **CAG 1**<br>**Executive Council)**<br><br>**CAG 2**<br>**Coordination Group**<br><br>**Finalisation of project assessment criteria and processes & formation of CAG 2** | Richard Dixon Hughes has been leading a project on specification of more rigorous processes for TC 215 project prioritisation, which has been used to inform development of the TC 215 business plan. Now that the business plan has been approved and defines the business context and agreed high-level criteria, there is a need to finalise criteria and assessment processes (to be applied by the newly formed CAG 2 Coordination Group of which he is an initial member.<br><br>**Action: Richard Dixon Hughes to participate in finalisation of TC 215 assessment criteria and processes and establishment of** | **Richard Dixon Hughes** |
| **CAG 2**<br>**Coordination Group**<br><br>**Better, more considered proposals for new standards work** | The quality of New Proposals presented during the Mexico meeting was uneven.<br><br>**Action: Australian delegations to upcoming TC 215 meetings should encourage stronger adherence to the requirements of the ISO/IEC Directives for new projects and IT-014 should vote against proposals that do not comply.** | **Australian TC 215 delegations**<br><br>**IT-014** |

### 8.1.4 FUTURE ISO/TC 215 MEETINGS

The currently proposed schedule for future IT-014 meetings is as follows:

| Dates | Location/comment | Meeting type |
|---|---|---|
| 21-25 Oct 2013 | Sydney Olympic Park, ANZ Stadium Sydney, Australia | 4 day WG plus ½ day mini-plenary |
| 19-24 May 2014 | Karuizawa Prince Hotel Karuizawa, Japan | 4 day WG plus full plenary (5 days) |
| 5-10 Oct 2014 | Berlin, Germany | 2 or 3 day WG plus ½ day mini-plenary Joint with CEN/TC 251 |
| Apr/May 2015 | Open – host sought | 2 or 3 day WG plus ½ day mini-plenary |
| Mid-Aug 2015 | Sao Paulo, Brazil – tentative, dates, facility tbc | day WG plus full plenary (5 days) |

Several other suggestions and offers to host TC 215 meetings have also been received, including one from Kaiser Permanente on behalf of the United States. Potential venues in Scotland have also been under consideration in relation to the meeting in April/May 2015.

An updated ISO/TC 215 meeting schedule will be posted in May or early June. Ms. Spellman commented that this outreach was going very well and that it is hoped to confirm the calendar planned through to the end of 2015.

The aim is to have meetings planned as far out as possible, at least for the next 3-4 years. Offers are presently being sought for 2016 and, potentially, 2017.

The demand is significant and increasing for more information about the October 2013 TC 215 meeting in Sydney and the options for accommodation, local transport, other nearby amenities, and other activities that could be undertaken in conjunction with a visit to Australia. Most delegates face the long travel times and need to organise their schedules and make travel arrangements early to get affordable fares. The more memorable and productive TC 215 (and HL7) meetings have also involved input from a small group of locally based volunteers, operating as a host committee, which would need to be organised to ensure a successful meeting. The need for attention to these matters is emphasised by the remote location of the site relative to other Sydney attractions and the relatively high cost structure in Australia (e.g. breakfast at the main venue hotels ranges from A$30 to $35, considerably more than the package deals available at other recent venues).

The event will also be followed by the International HL7 Interoperability Conference (IHIC 2013) with some delegates planning to be involved in both activities. Dialogue with HL7 Australia to maximise synergy and enhance the experience of delegates is also suggested.

#### *8.1.4.1 Relevance to Australia*

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **Next ISO/TC 215 meeting in Sydney** | Potential delegates are seeking more information about the venue, accommodation, amenities and other activities in order to plan their attendance at the Sydney meeting in October. A structure should be considered for engaging with local volunteers and experts to assist in encouraging colleagues to attend and in welcoming and hosting delegates for the event. Synergies should also be sought with HL7 Australia conducting IHIC 2013 early the following week.<br><br>**Action: Consider formation of an organising group to support Standards' Australia in hosting the October TC 215 meeting, encourage attendance and distribute additional information.** | **IT-014**<br><br>**Standards Australia**<br><br>**HL7 Australia** |

## 8.2 OPERATIONS AND HARMONIZATION

| | |
|---|---|
| Australian Delegate Attendance | Naomi Ryan (Secretariat WG 1)<br>Richard Dixon Hughes (Co-chair, Business Plan Ad Hoc) |

### 8.2.1 BACKGROUND

The Operations and Harmonization group (O&H) has traditionally coordinated secretariat processes and monitored the TC 215 work program, working with the TC 215 secretariat and the Executive Council in implementing ISO and TC 215 policy and improving TC 215 committee processes. O&H is led by the TC Secretary with a membership comprising the convener, vice-convener and secretariat of each of the TC 215 working groups, with others being invited as required.

Under the proposed structure of TC 215, the Coordination Group, formally designated CAG 2, has principal responsibility for prioritization of new work item proposals (NPs) and for making recommendations for coordinating standards development and managing the work program within TC 215.

An earlier proposal for CAG 2 to subsume the O&H role was been reviewed in light of the different functions and membership of the two groups; O&H meetings will continue to be convened by the ISO/TC 215 Secretariat at each TC 215 meeting for the purpose of coordinating and harmonising of operational activities and secretariat functions across all TC 215 working groups.

### 8.2.2 PROGRESS AT THIS MEETING

O&H discussions were particularly focussed on developments at ISO Central Secretariat (ISO/CS), their impacts on TC 215 activities and the ISO/CS facilities that might be used by TC 215 and its contributors to assist them in their work. These discussions were greatly facilitated by the participation of Dr Mary Lou Pélaprat from ISO/CS, who is normally able to attend one ISO/TC 215 per year.

While the substantive topics on the agenda were covered, the depth of O&H discussion and progression of some outcomes may have been adversely impacted as a result of the unavailability of Lisa Spellman, Head of the ISO/TC 215 Secretariat, who had fallen ill earlier in the day and had been admitted to hospital.

Matters addressed included:

- Effective use of ISO/CS facilities and eCommittees system.
- Anticipated impact of changes in the May 2013 edition of the ISO/IEC Directives.
- Calendar of future meetings (also discussed in other groups – see Section 8.1.4 above).
- Use of innovative tools for sharing and management of draft resolutions at the meeting.

### 8.2.3 USE OF ISO/CS FACILITIES AND ECOMMITTEES SYSTEM

#### *8.2.3.1 Background*

Effective communication is essential to ensure that those contributing to ISO/TC 215 and its working groups are effective. The ability to be aware of and to access current documents is an important aspect of communication within TC 215. This capability is now fully provided by the ISO/CS eCommittees system, with TC 215 having discontinued the use of its own separate document management system in 2011.

The facilities provided in the current ISO system, which has been upgraded since the last TC 215 meeting in Vienna includes:

- Document management to support all the work of technical committees within ISO;
- A resources area – which includes the ISO/IEC directives and ISO supplement available as free downloads; and
- Secure working areas for sharing and retrieval of project documents and to maintain personal details.

#### *8.2.3.2 Resources for registered users*

Convenors and WG secretaries were reminded that it is the principal responsibility of ISO national member bodies to maintain details of working group membership on the ISO eCommittees system and that neither they nor the TC 215 Secretariat have the administrative privileges to do this. It is therefore important that experts work closely with their national member bodies to ensure that their participation in working groups is properly recorded and effective.

Dr Mary Lou Pélaprat, ISO/TC 215 Technical Programme Manager at ISO/CS indicated that continual improvement of ISO's online presence and shared IT environment is being undertaken as part of the ISO "Simpler Faster and Better" strategic initiative.

Office bearers and project leaders are particularly encouraged to keep up-to-date with improvements in the capabilities of the eCommittees system and other IT-related services, which can be tracked through the new "ISO Connect" portal, available at: https://connect.iso.org to existing users of the eCommittees system and anyone else who registers for access.

ISO Connect provides the means of staying informed of ISO initiatives and changes to ISO services, with the ability to browse the site and also subscribe to updates on areas of interest. In particular, there is currently relevant information about:

- **The TMB Task Force on Seamless IT Environment (TFSITE)**. This TF aims to provide a more seamless IT environment for the standards development community within 12 months and also strategic guidance for the longer term. It is particularly focussed on the needs of NMBs that share the LiveLink content management platform.
- **The ISO Living Lab**. This is a performance improvement environment for evaluating changes in processes to support the "simpler, faster, better" philosophy through modelling of standardization processes and quantifying the impact of potential changes with a view to delivering increased value to ISO stakeholders. [Note: the Living Lab concept was initially developed to support innovation within Standards Australia and was subsequently taken up by ISO].
- Improvement of **electronic collaboration** to support more widespread and timely engagement in standards development.

  There is already a Webex tool which is available for free to support the progression of work between face to face meetings by contacting webconferencing@iso.org to secure a login for online WG and/or TC meetings. Access should not be offered to outsiders that are not registered experts or delegates of the relevant WG, SC or TC.
- Migration to XML-based publishing – which already supports enhancements that enable selective public access via the ISO Online Browsing Platform (OBP)
- A new, simpler, more flexible document template is being trialled and refined as an alternative to the current STD template; however, many NMBs have built editing and publishing capabilities around the existing outdated template, so transition may take some time. A more up-to-date, single font will also be adopted (Cambria).

#### *8.2.3.3 Other resources*

The following are among the "resources for standards development" are available to anyone following the links under the various headings in the "standards development" area of the ISO website:

- The latest version of the ISO/IEC Directives
  http://www.iso.org/iso/home/standards_development/resources-for-technical-work/iso_iec_directives_and_iso_supplement.htm

- IT Tools (ISO/TC Server and Portal) – including the "online browsing platform" for access to terms and definitions
  http://www.iso.org/iso/home/standards_development/resources-for-technical-work/iso_electronic_applications.htm
- Stages of standards development
  http://www.iso.org/iso/home/standards_development/resources-for-technical-work/stages_of_the_development_of_international_standards.htm,
  and
  http://www.iso.org/iso/home/standards_development/resources-for-technical-work/stages_table.htm

Clicking on "technical committees" within the "Standards Development" area provides a list of all technical committees with links to information about their scopes, business plans current publications and work plans (approved publications under development).

#### *8.2.3.4 Relevance to Australia*

While the eCommittees system may be comprehensive, for new delegates it is not easy or intuitive to use, and lacks any online help. Improvements to facilitate its use should be considered.

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **Operations & Harmonisation**<br><br>**Utility of the ISO/CS eCommittees system** | The usability of the ISO eCommittees web site should be improved.<br><br>**Action: Standards Australia should consult with recent new users of the ISO eCommittees website, prepare better guidance for new users and advise ISO on improvements in user help functions and support for navigating the system.** | **IT-014**<br><br>**Standards Australia** |

### 8.2.4 IMPACT OF CHANGES IN ISO/IEC DIRECTIVES

The May 2012 edition of the ISO/IEC Directives included significant updates to the requirements for documentation and ballot acceptance of new work item proposals (NP), including stronger approval criteria. Dr Pélaprat reiterated some of the key principles, including requirements for:

- Fully documented, robust information showing market relevance of a proposal – which must now be submitted on the latest (2012) version of the new work item proposal form (Form 4).
- Positive votes submitted by P members in an NP ballot must give a short justification for a ‘yes’ vote and nominate an expert to participate in the work or the vote is not counted.
- Approval of an NP ballot requires a majority of P members in favour and at least 5 experts.

- Members that vote against or abstain in an NP ballot may still nominate an expert but that expert does not count towards the minimum number of 5 from member bodies in favour of the proposal.
- Specified time for an enquiry (DIS) ballot is 3 months (rather than the previous 5 months); however, document preparation and release may still make the entire process up to 5 months.

Another edition of the ISO/IEC Directives was planned for release in May 2013, shortly after the TC 215 meeting. Key changes have already been foreshadowed and include:

- Clarification of the option to skip the CD Ballot stage. At the end of the preparatory stage documents may skip CD ballot and be submitted directly to DIS ballot if approved by a vote or one-month ballot of the TC membership.
- If a DIS passes ballot, there are no substantive objections or changes in content to be confirmed and the document is not being jointly developed with CEN under the Vienna agreement, the TC leadership has the option to recommend that TC 215 approve skipping the FDIS stage and go straight to publication.
- Form 4 (NWI ballot) is no longer required for revisions; a committee resolution is sufficient. A call for experts must be launched but there is no minimum number of active P-members required for revisions or amendments of existing standards.

### 8.2.5 TOOLS FOR SHARING AND MANAGEMENT OF DRAFT RESOLUTIONS

In its search for greater efficiency and transparency, the TC 215 secretariat arranged with Dr Andrew Grant and associates at Sherbrooke University to provide access to a TC 215 wiki service for circulating draft resolutions among delegates, WG leaders and the secretariat and receiving comments on them. All delegates were issued with user codes and passwords and given basic instruction on establishing and responding to discussion topics.

Some groups made more use of the facility than others and more experience is probably needed to integrate it more fully into the committee workflow. Australian delegations should encourage continuation, evaluation and improvement of the capability.

# 9. JOINT INITIATIVE COUNCIL (JIC)

## 9.1 JIC EXECUTIVE

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| Australian Delegate Attendance | Richard Dixon Hughes |

### 9.1.1 BACKGROUND

The Joint Initiative Council (JIC) for Global Health Informatics Standardization was established under a charter to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counter-productive standardization efforts through:

- Mutually agreed decision processes to meet needs for joint international standardization work;
- Coordinated standards strategies and plans, with the future goal of making all standards available through ISO;
- An integrated work program; and
- Focused, specific resolution of overlapping or counteracting standards within the participating SDOs existing work programs.

The standards development organisations (SDOs) that are currently members of the JIC are: ISO/TC 215, the European CEN/TC 251 health informatics committee, HL7, CDISC, IHTSDO, GS1 and now IHE International.

The TC 215 Secretariat also provides the secretariat for the JIC with some more information being available at: http://www.jointinitiativecouncil.org/.

### 9.1.2 PROGRESS AT THIS MEETING

Because of clashes with other headline meetings not all members of the JIC could be fully represented at the JIC meetings in Mexico City. Nevertheless, the meetings were productive. The following are among the various JIC activities that were undertaken in conjunction with ISO/TC 215, all of which involved Richard Dixon Hughes as Chair of the JIC for 2013 and 2014.

- Face-to-face meeting of available JIC Executive members, on Saturday, 20 April from 10:00 to 18:00 hours.

  The main aim of this meeting was to review the status of work on the 15 "strategic actions" identified by the JIC at its Vienna planning meeting and to provide time for members of the executive to progress some of the items in face-to-face breakout sessions.

  Most members of the JIC executive that were present in Mexico City had been able to participate by the end of the day.

Stephen Kay reported on progress of CEN workshops on concurrent use of ContSys, 13606 and HISA. During discussions it was noted that this would take some time but the resulting changes may have implications where this work and other associated standards are jointly published with ISO/TC 215 and other JIC SDOs

Considerable progress was achieved in defining and refining several of the strategic actions.

- Formal JIC Executive Meeting. This took place on Sunday, 21 April between 08:30 and 12:00, prior to the TC 215 leadership meetings. Topics addressed included:

  - Progress in establishing processes for updating reference calendar of relevant major health informatics/eHealth/HIT/HIS events on the JIC website. Engagement with member SDOs to contribute updated materials.

    Significant overlap of competing local, provincial, national, regional, international and commercial eHealth events is becoming a problem by fostering fragmentation of communication.

  - Feedback from recent reviews of joint projects, as covered in more detail under the report of the CAG 3 Cross-SDO Coordination Group at 9.2 below.

    There are positive signs that problems associated with differing publication formats and ongoing maintenance of joint standards are being overcome.

    There was discussion of the potential for JIC to draw on its experience to improve multilateral dealings among its member SDOs and with ISO as a producer and publisher of joint standards, noting that there are several different pathways (including PSDO and other types of agreements) for interaction with ISO, depending on the scale of shared interest.

  - Progress in populating SKMT to assist with harmonisation, communication and avoiding inconsistent replication of terms and definitions used across the various health informatics SDOs that are JIC members.

  - Presentation and discussion (led by Nicholas Oughtibridge of UK NHS) on current standards work having potential impacts as cornerstones for harmonization of standards work, specifically ContSys (Systems of concepts for the continuity of care), which is currently out for ISO DIS ballot and need genuine international engagement to be fully effective, and the CIMI project.

  - Progress with JIC strategic activities, including review of progress and decisions in relation to key priorities – update of the JIC charter and bylaws, enhancing JIC image and communication, the JIC joint work program, JIC activities in relation to low and medium income countries (LMICs), stakeholder interaction opportunities, and population of terminology via SKMT.

    A decision was taken that JIC would not seek to separately convene a major stakeholder engagement event similar to the former Global Health IT Summit (GHITS) series but would look to specific opportunities in relation to other events.

There was significant discussion of the need and strategies for LMIC engagement and JIC re-affirmed its in principle support for LMIC as a strategic priority, subject to role and capacity considerations.

- A series of meetings between the leadership of the JIC and the ISO/TC 215 Public Health Task Force (PHTF) in relation to the potential role of the JIC in progressing recommendations of the PHTF as part of the JIC's LMIC Initiative (see further detail in Sections 9.1.4, 9.2.4 and 12 below).
- A meeting convened by the US Office of the National Coordinator for Health IT (ONC) to brief leaders from the JIC and key SDOs on developments in trans-Atlantic eHealth collaboration, specifically the Trillium Bridge project, and the implications of these developments for eHealth standards work.
- Participation at a Health and Health IT industry function hosted by the US Ambassador at his residence, attended by Richard Dixon Hughes as JIC Chair and Australian Head of delegation and Lisa Spellman as Head of Secretariat for the JIC, ISO/TC 215 and the US-TAG to ISO/TC 215.
- Summary reports on JIC activities and progress, presented by Richard Dixon Hughes as JIC Chair at CAG 1, CAG 3 and the Closing Plenary.
- Convening and facilitation of the JIC Open Forum to provide an opportunity for ISO/TC 215 delegates to provide feedback and discuss current and potential JIC activities.

Shortly after the Mexico City meeting, it became known that Kim Osborne, who was supporting Lisa Spellman in providing secretariat services for the JIC, ISO/TC 215, and the US-TAG to ISO/TC 215, would be resigning effective 17 May. Unfortunately, this will limit Secretariat support, particularly to the JIC, in coming months.

As the Chair of the JIC, Richard Dixon Hughes received specific funding to participate in several conjoint activities on behalf of JIC, particularly the subsequent European E-health Week in Dublin on 13 to 15 May. More details of all JIC activities through the period and associated recommendations are to be provided in a separate report.

### 9.1.3 RELEVANCE TO AUSTRALIA

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
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| **Report on JIC participation** | **Action: Richard Dixon Hughes to prepare separate consolidated report on JIC activities undertaken during April/May 2013.** | **Richard Dixon Hughes** |

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| **JIC Leadership** | Despite secretariat staff shortages, JIC needs to progress work on its strategic priorities and the progression of joint work.<br><br>**Action: Richard Dixon Hughes as current Chair of JIC to work with Lisa Spellman and CAG 3 co-chairs (Newsham, Keller) to facilitate meetings by teleconference and progress key priorities, including action on LMIC, for consideration at the next face-to-face meeting of JIC in Sydney in October.** | **Richard Dixon Hughes** |

### 9.1.4 JIC LMIC INITIATIVE

One of the key JIC strategic actions is to progress e-Health standards activities of potential benefit to Low and Medium Income countries (LMICs). This initiative was commenced through joint workshops with IMIA and WHO in 2011 and has been particularly progressed by Don Newsham and Elizabeth Keller in their roles as co-chairs of the CAG3 Cross Coordination Group.

Elizabeth Keller and Don Newsham presented an updated proposal for progressing the JIC LMIC initiative. The timing for considering this matter coincides with a ISO/TC 215 Public Health Task Force (PHTF) white paper recommending that JIC initiate a series of actions to implement its key recommendations. As reported further in Sections 9.2.4 and 12 below, several meetings were convened during the week under the auspices of the JIC/CAG3 to discuss appropriate means of progressing the recommendations of the PHTF white paper. As a result of these meetings, there was general agreement on the following:

- Those PHTF recommendations appropriate to JIC and its member SDOs are being built into the JIC agenda.
- Others will be jointly progressed through other relevant agencies, funding bodies, SDOs and professional associations, particularly IMIA.
- The approach will include joint communication with significant international agencies working in the area including WHO and PAHO.

A small JIC task force being led by Don Newsham has been formed to explore the PHTF recommendations further and develop proposals for the October JIC and ISO/TC 215 meetings in Sydney.

## 9.2 CAG 3 CROSS-SDO COORDINATION MEETING

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| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)<br>Naomi Ryan (WG 1 secretariat)<br>Michael Steine, Renato Iannella, Alan Taylor |

### 9.2.1 BACKGROUND

The CAG3 - Cross-SDO Coordination Group, is constituted within TC 215 and makes recommendations to the JIC Executive on resolving gaps, overlaps or issues of counterproductive standardization between the SDOs that are members of the JIC.

### 9.2.2 PROGRESS AT THIS MEETING

At this meeting, the main focus of the CAG3 session was to provide an update and receive feedback on the status of joint projects and other key activities being tracked by the JIC, including the LMIC initiative.

This was followed by the JIC open forum, which provided the opportunity for more detailed consideration of current CEN and IHE activities focused on harmonization.

### 9.2.3 STATUS OF THE JOINT WORK PROGRAM

Prior to the meeting, the CAG 3 co-chairs, Don Newsham and Elizabeth Keller had reviewed and collated information on each of the joint projects on the current JIC Joint Work Program. The pre-meeting status of each item was reported to the meeting with input being sought from the project leads and other delegates.

As all the joint projects are also being progressed as ISO/TC 215 work items, their subsequent progression by the relevant TC 215 working groups is covered in the reports on the individual WGs. The following projects were discussed in relation to their status on the joint work program.

#### *9.2.3.1 ISO/HL7 DIS 10781 IS EHR System Functional Model Release 2.0*

Project lead: Gary Dickenson HL7.

An update was provided on the progress of this substantial work item being led by HL7 International. Following a six-way joint ISO/DIS and HL7/normative ballot, 630 comments were received. Because of the number of substantive changes a further ISO/DIS2 and HL7/normative ballot will be required. Harmonisation of these ballots is posing a challenge because of the different timescales and rules for voting and commenting on second round ballots in ISO, CEN and HL7 International. As JIC chair, Richard Dixon Hughes has been asked to assist in resolving these issues.

Previous issues relating to publication formats appear to have been resolved.

The work item was being progressed with discussion planned for WG1 later in the week.

#### *9.2.3.2 ISO/DTS 18530 TS Automatic identification and data capture marking and labelling - Subject of care and Individual Provider Identification*

Project lead: Christian Hay (GS1)

The main ISO/DTS ballot of this work is complete and resolution of comments was done by WG 1 at this Mexico meeting, with anticipation of resolving all negative votes and issues in the near future. (For more details, see Section 11.3.6 below)

After publication, now planned for August, the next step will be an implementation guide to be prepared jointly with HL7.

#### *9.2.3.3 ISO/PWI 14199 IS Biomedical Research Integrated Domain Group (BRIDG) Domain Analysis Model*

Unfortunately, because of a clash of dates with one of their major annual events, the CDISC leadership were unable to be present at the JIC and ISO/TC 215 in Mexico City. Don Newsham gave a status report on behalf of Bron Kisler, the project lead.

The BRIDG standard is a significant body of work, which is actively maintained by the clinical research community through the CDISC BRIDG committee.

The original project to publish the full BRIDG model as an ISO standard proved to be too complex and unworkable and would have always resulted in ISO having an out of date product. TMB cancelled the original project because of delays while attempting to resolve these issues. A revised approach based on the use of an "umbrella" standard has been developed with agreement being reached on the detailed arrangements for on-going maintenance and publication of the BRIDG model.

This will be reintroduced as new work item at this Mexico City meeting and, if approved, will proceed to DIS ballot.

#### *9.2.3.4 ISO/DTS 13972 Detailed clinical models, characteristics and processes (DCM)*

Project lead: William Goossen

The well-known background to this project was summarised. The project was commenced in 2008 and was originally intended to be a two-part full international standard; however, this was opposed by two countries and it was combined into a single document and downgraded to a technical specification after agreement with the countries that had opposed the original standard [one of which was Australia].

Following further significant revisions, six countries have now voted against the document in its first DTS ballot. Nevertheless, there were some substantial changes which proved to be unacceptable and the expert group consider that remaining issues should be satisfactorily resolved for a second DTS ballot, which is required given the level of comment and subsequent change.

The project was to be subsequently addressed in more detail by WG1 later in the week (see Section 11.3.5 below).

#### *9.2.3.5 ISO/DIS 13940 Health Informatics - System of concepts to support continuity of care (ContSys)*

Project lead: Nicholas Oughtibridge

This cornerstone standard which underpins harmonisation of concepts across a significant part of the health informatics arena is out for DIS ballot closing in a few weeks time and advice had been received that the technical content could not therefore be discussed in any detail at this meeting.

The standard and its relationship to other key health informatics standards was part of the material addressed in the JIC open forum (see Section 9.3) and there was also some discussion in WG 1 (see Section 11.3.8 below).

Although ContSys has traditionally been of interest to the ISO and CEN standards development community, it was noted that it is important that technical leaders in other SDOs be aware of this document and preferably be familiar with and have contributed to its content. It is the International Standard defining a large part of the system of concepts that should be used in most other Health Informatics standards. Failure to engage at this point potentially affects both the utility of this standard and the subsequent development and harmonisation of other health Informatics standards.

It was noted that engagement with other JIC members on this joint work item would be particularly welcome at this point before it eventually moves to FDIS ballot.

Other JIC SDOs were asked whether and how they could assist. IHTSDO indicated that it will investigate (Jayne (UK) to provide contacts). IHE profiles other standards but possibly needs to collaborate on naming conventions, particularly in relation to downstream implementation.

#### *9.2.3.6 Projects on hold*

Two approved items on the JIC Joint Work Program are presently on hold:

- ISO/NP 17537 IS Electronic Medical Record Clinical Research Functional Profile

  The underlying ISO project has been cancelled by ISO/TMB for a lack of progress and it remains suspended as an item on the JIC Joint Work Program until these issues have been resolved. More detail is provided in Section 11.2.2 below.

- ISO/PWI IS Clinical Trials Registration and Reporting (CTR&R)

  This work depends on resolution of issues surrounding approval and publication of the BRIDG model as an international standard. It will be started once BRIDG is complete or in its final stages of approval.

### 9.2.4 UPDATE ON JIC LMIC ACTIVITIES

Updates on work of importance to Low and Middle Income Countries (LMIC) and Clincal Information Modelling were provided by Elizabeth Keller, noting:

- Plans for JIC and PHTF leaders to meet this week with initial determination of what work items that can be accommodated by JIC members, given limited capacity.

- JIC is committed to progression of its LMIC Initiative in collaboration with the PHTF, subject to the identification of where items should best be undertaken.
- The outcomes of the joint IMIA/JIC meeting in 2011 on scope and mission and strategies for LMIC access, participation and use of standards, including:
    - Subsequent JIC commitments from its face-to-face meeting at HIMSS 2012;
    - in principle JIC support for the work of Dr Walter Suarez through the PHTF and for the PHTF white paper report; and
    - The meeting attended by Don Newsham in Yaoundé in Africa on behalf of JIC and the positive feedback received from that meeting.
- Further work of the JIC LMIC Initiative includes looking at the PHTF report, addressing recommendations in that report, noting the key technical standards opportunities and identifying we can assist from a JIC point of view.

During subsequent discussion, the following were also noted:

- Strong initial support from the WHO eHealth program and whether this levelof support can be revived.
- The growing focus on mHealth in LMIC and need to align activities and approaches to encompass this aspect more positively
- Support for JIC and PHTF collaborating on how to progress the PHTF recommendations in a concrete manner
- The high level of involvement and discussion of LMIC requirements at the first IHE World Summit. This included escalated interest of LMIC's in rapid implementation and vendors that operate in the open source community. A number of countries in Africa and Malaysia and Indonesia noted their support and there is a renewed opportunity for "harmonization".
- Existing SDO's working across LMICs and other countries have a critical opportunity to work with those countries, NGO's and donors and others on the ground to note and promote available standards. (use HL7 education and other SDO work and IMIA work to make available such support – key challenge now is HOW)
- The work needs to follow the money. Countries have limited means of funding to implement eHealth frameworks and mostly rely on donors. A lot of work is going on, but without knowledge of the SDO's and our work there is a disconnect with the standards work.

### 9.2.5 CIMI UPDATE

Nicholas Oughtibridge (UK NHS and member of the CIMI Executive Committee) provided an update on current CIMI work, noting:

- CIMI has identified a growing global library of open source clinical information models for representation of key clinical concepts at the micro level (variously based on CEMs, DCMs, CDA templates etc.)

- The aim is to have a cross platform/organisational representation of models that support: care pathways, continuity of care, record sharing and consistency of information representation so that it can be used seamlessly, retaining its context and meaning for applications such as clinical decision support. The required components to achieve this are:
    - a reference information model
    - agreed clinical terminology
    - at least one agreed representation for communicating the information (with an associated serialisation format)
    - rigorous metadata on the provenance of each model.
- Within CIMI it is agreed that a canonical common reference model is needed for clinical models to be comparable and potentially interoperable. CIMI is in the process of defining a reference model but there is no clear answer to the question "Is this CIMI reference model going to be adopted by any SDO?"

  CIMI work on reference models originates from ISO 13606 and openEHR and is focussed on representation of clinical information.
- For terminology, CIMI looks to SNOMED CT as the primary reference terminology of choice. LOINC is also approved and is being harmonised with SNOMED by IHTSDO. In the event of overlap, SNOMED will be CIMI's preferred terminology reference.
- Serialisation is potentially addressed through transformation of either ADL or UML representations. [For the less theoretically inclined, some consideration of serialisation based on HL7 technologies may be desirable.]
- The associated elements of the health informatics standards picture to ensure semantic interoperability and re-use of detailed clinical information models therefore involve standards at each of the following levels:
    - The conceptual level – which is defined by ContSys
    - The logical level – defined by SNOMED CT and CIMI Logical Reference Model.
    - The implementable level – 13606 EHRcom

It was noted that JIC should continue to track and follow the CIMI progress and plans.

## 9.3 JIC OPEN FORUM

### 9.3.1 BACKGROUND

The JIC is the Joint Initiative Council for Global Health Informatics Standardization – the current members of which are ISO/TC 215, CEN/TC251, HL7 International, CDISC, IHTSDO, GS1 and IHE International.

The Open Forum meetings are held to update the TC 215 community about the activities of the JIC.

### 9.3.2 ACTIVITY AT THIS MEETING

The JIC open forum at this meeting had the theme *"Harmonization, alignment and collaboration of health informatics standards – experiences and opportunities"* and commenced with two presentations on current harmonization activities being conducted by CEN and IHE, with the aims of:

- Informing experts of the existence of these current activities and related standards development work;
- Introducing discussion of practical realities, stakeholder requirements and the potential to learn from practical experience related to harmonization, alignment and collaboration of work on core health standards;
- .Providing other experts with opportunities to understand, contribute to and build on the activities of the CEN/EU and IHE camps in relation to core health informatics standards and their potential role as part of a backbone for other HI standards work; and
- Exploring how TC 215 and other JIC members can better leverage opportunities for alignment and sharing a common framework of core health informatics standards.

The presentations were informative and stimulated considerable interest; however, the time for detailed discussion was limited, despite running into extra time at the end of the day. In future, at least a full hour needs to be scheduled for the JIC Open Forum.

#### *9.3.2.1 CEN Workshops on concurrent use*

Stephen Kay spoke to the two workshops on concurrent use of the following CEN foundation standards, which are also published jointly with ISO/TC 215 under the Vienna Agreement:

- System of concepts to support continuity of care (EN ISO 13940, ContSys)
- Electronic health record (EHR) communication (EN ISO 13606, EHRcom)
- Health Informatics – service architecture (EN ISO 12967, HISA)

CEN/TC 251 has published the outcome of the second workshop, which was held in March, as a report: "Toward concurrent use of ContSys, 13606, and HISA: WG1 report from 2nd workshop (Madrid) 7th and 8th March 2013". This report addresses the concurrent use of models behind these three foundation standards and may be found at:
http://www.standard.no/Global/PDF/Helse/CEN-TC251_N2013028_N13-028_WG1_report_of_the_2nd_Madrid_Work.pdf

It was noted that this report is now a useful_resource. JIC was asked for input on what other SDOs can contribute with further discussions to be continued post meeting. This is an area Australia needs to consider further.

#### *9.3.2.2 First IHE World Summit*

Mike Nusbaum summarised some highlights of IHE's global activities and provided some observations from the IHE First World Summit, which had been held in Istanbul the previous week (16-17 April). With respect to the current status of IHE activities, he noted:

- The basic IHE product is the IHE Integration Profile. 135 of these integration profiles have now been produced for many domain areas including pharmacy, radiology, EHR document exchange and patient care devices.
- Local adoption is through global, regional and country level deployment coordination committees. Australia established its IHE deployment committee in 2009.

With respect to the First World Summit:

- It was conducted in the same location and at the same time as the IHE Europe Connectathon at which approximately 120 systems were tested against criteria for interoperability in the European context.
- In addition, 75 attendees from 21 countries specifically attended for the summit, which had the objectives of bringing representatives of the IHE community around the world to get to know each other, brainstorm and share experiences with each other and the IHE International leadership group.
- The summit was divided into a "panel track" for policy makers and those with a business interest in IHE (covering IHE Essentials, Implementing IHE, Marketing etc.) and a "developer track" for those with a more detailed technical interest in IHE integration profiles, their development and content.
- Hot topics and proposed future directions emerging from the Summit included:
    - The need for alignment with national /regional policy and infrastructure – the next summit will include government leaders [and potentially represents an opportunity for JIC and other SDOs to present a more united front].
    - Certification of vendor products to IHE Integration profiles – and associated issues of the relationship between product certification and the demonstration of interoperability through connectathons
    - Education and professional credentialing
    - The role of projectathons (like a connectathon but focussed on the needs of specific projects – such as the European epSOS profiles for exchange of patient data)
    - The need for active engagement and improved marketing, including the documentation of IHE success stories;
    - A commitment to further summits and other pathways to share best practices, learn and find common solutions

#### *9.3.2.3 Panel Session and General Discussion*

The limited time for panel discussion was dominated by a question relating to the need for clarity around copyright restrictions that may apply where an organisation has an existing standard that it publishes freely on the Internet that is proposed to become an ISO standard. It was noted that:

- Some organisations make their own work freely available, even though some of it is incorporated into an ISO standard (e.g. DICOM);

- In such cases there needs to be a bilateral agreement between ISO and the relevant organisation establishing how the intellectual property will be governed and used; and
- In these situations, the final document from ISO cannot be made freely available but the original document is their own so can provide to the public.

# 10. OPENING PLENARY

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| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)<br>Naomi Ryan (WG 1 secretariat)<br>Michael Steine, Renato Iannella, Alan Taylor |

## 10.1 TC 215 SECRETARIAT REPORT

Following an opening welcome by the Chairman, Dr Chris Chute, Lisa Spellman, Head of the ISO/TC 215 Secretariat conducted the official roll-call of attending members and liaisons and presented highlights from the formal written report of TC 215 Secretariat, which had been circulated with the meeting papers. Some successes have included:

- Migration to ISO eCommitttees. She thanked all TC 215 WGs for having completed the migration to the ISO eCommitttees system.
- The turn-around times for opening & closing ballots and other related tasks has been reduced.
- The secretariat has been able to resolve many outstanding issues by helping TC 215 contributors understand ISO processes and by facilitating discussion of residual issues with relevant staff at ISO/CS.
- Continuing work on raising the profile of ISO/TC 215 and the work of its experts is achieving some success.

Other matters discussed included the Secretariat's great appreciation of all the work performed by the Mexican host committee, and the new processes and timetable for submitting, commenting on and reviewing resolutions, including trialling a wiki for sharing information and comments on draft resolutions as they are being developed.

Lisa Spellman also thanked those who had helped look after her when she had been admitted to hospital the previous day, noting that her closer than expected encounter with the Mexican healthcare system had given her a first-hand appreciation of a system that looked to be in great shape.

## 10.2 PRESENTATIONS BY HOST NATION

Keynote presentations were given by representatives of two Mexican government agencies:

- Electronic Health Records, presented by Rafael Javier Montero Buenfil, Sub-director of Information Technology, Decentralization Institute of Public Health of the State of Campeche
- Electronic Medical Record for INR: benefits and reality for the patients, presented by Maria de Lourdes Zaldivar Martinez, Sub-director of Information Technology, INR (the National Rehabilitation Institute)

### 10.2.1 ELECTRONIC HEALTH RECORDS IN THE STATE OF CAMPECHE

Campeche is one of the states on the peninsular that forms the Southern edge of the Gulf of Mexico. It has a mixed urban/rural population of around 1 million people served by a decentralised state-run health service (INDESALUD) that operates 2 tertiary hospitals, 6 secondary hospitals and some 120 other facilities. A common standards-based EHR is being rolled out to support care delivery across both hospitals and primary/community care clinics.

INDESALUD aims to take account of regional and national plans, and avoid siloed projects. Use is made of DTR-10354, ICD-10, HL7 v3, LOINC classification, DICOM, and a Mexican personal identifier.

Standards implementation has not been easy, and it necessary to adjust and use standards appropriate to each facility type and level.

Benefits measured following implementation of the INDESALUD system include:

- improvements in throughput by 10%;
- a perception of quality improvement;
- reduced waiting times;
- one EHR per patient for all facilities., leading to reliable information, higher patient confidence.
- waiting times are now 6 to 8 minutes –(what this time represents was not indicated);
- health care protocols are better supported, management productivity improved.
- workers are more satisfied.
- data mining is now possible.

Main challenges have included a resistance to change from some older staff in particular, and the move from paper records was challenging. Initially there was little understanding of the need for standards and various medical groups to had special interests. The context of a limited budget, no clear national health care policy made these issues all the more challenging.

A change strategy that included consideration of political issues, promoted compromises, working directly with end users and including the trade unions assisted in resolution of many issues.

Next phases of this project will include the extension of coverage to more facilities and within facilities using WiMax technology, and fibre optic links. Telemedicine technology will support health care in rural areas.

### 10.2.2 ELECTRONIC MEDICAL RECORDS IN INR: BENEFITS AND REALITY FOR PATIENTS

The INR (Instituto Nacional de Rehabilitación) claims to be a unique service among Latin American nations in the extent of its provision of both short-term and long-term rehabilitation services arising from a wide range of causes. Some 10 million families

receive services from INR, which supports its operations via a federation of some 13 information systems that exchange information using HL7v3 technologies.

The INR EHR implementation comprises 13 sub-systems connected using HL7 Version 3. The EHR system provides for admissions and appointments, pathology, laboratory results, and PACs integration for a filmless environment. Payments by patients can now be made online through electronic banking. Nursing and operating areas have access to mobile devices. It is hoped that it will soon be possible to identify and track patients using a photo and barcode.

Benefits identified to date include reduced printing costs and patient waiting times reduces from 30 minutes to 15 minutes.

Issues encountered include a lack of ICT staff to support the implementation, inaccurate translation of the standards being used, difficulties creating interoperability between biomedical devices.

It was noted that isolated non-standard eHealth systems are still being built in Mexico.

# 11. WG 1 ARCHITECTURE, FRAMEWORKS AND MODELS

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| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)<br>Naomi Ryan (WG 1 secretariat)<br>Renato Iannella |

## 11.1 BACKGROUND

Working Group 1 covers topics around enterprise architectures, conceptual frameworks and information models specifically in relation to EHRs and associated business requirements.

Working Group 1 is chaired by Dr Stephen Kay (UK) and Naomi Ryan (Standards Australia) is currently providing Secretariat services. During this meeting Beatriz de Faria Leao from the Brazilian delegation was confirmed as co-convenor of WG1.

It had previously been resolved at the Vancouver meeting that Working Groups 1 and 8 would merge into one single group. This process was completed during the Mexico meeting. ISO/TC 215 formally resolved to adopt the following revised name for WG1 at this Mexico meeting: “Architecture, Frameworks and Models”.

The adoption of this name followed considerable discussion of the significance and transferability of useful meaning into other languages. (the word “ frameworks” does not translate well into Portuguese)

This ISO/TC 215 Mexico meeting also confirmed the following scope for WG1:

"Standardization of frameworks, architectures, and their components in support of health and healthcare, including standardization of conceptual, logical, and functional requirements, process models and information models".

## 11.2 RECENT ACTIVITY

### 11.2.1 PUBLISHED/IN-PUBLICATION STANDARDS

WG 1 has not submitted any standards documents for publication since the Vienna meeting, at which the prior publication of the following two documents was noted.

- ISO TR 14639-1: Capacity-based ehealth architecture roadmap Part 1 – Overview of national ehealth initiatives.

  This technical report was published in August 2012 and is available for CHF 162 from the ISO website.

  At the October 2012 meeting in Vienna, the Working Group proposed a resolution for ISO/TC 215 requesting ISO approval to make this technical report freely available to all countries given its utility to assist countries with ICT capacity-building and national e-health initiatives. This request has yet to be processed.

At his meeting, a similar resolution and business case were prepared for the purpose of seeking ISO approval to make Part 2 of this technical report freely available, once completed and published. Part 2 is a potentially an even more valuable document.

- ISO TR 13054 - Health Informatics: Knowledge Management of Health Information Standards - Published in July 2012.

### 11.2.2 CANCELLED PROJECTS

- ISO/TR 14639-2 Health informatics - Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model.

  This significant project is on the verge of being completed but was deregistered when the time for completion expired. TC 215 has approved it being reinstated and submitted for DTR ballot to approve its publication as a technical report as soon as final changes agreed at this meeting are incorporated.

- 17537, Electronic Health Records [EHR-CR] Clinical Research Functional Profile.

  The project was cancelled by ISO/TMB for a lack of progress. On suggestion that it be no further consideration be given to the project, WG 1 was informed that there continue to be stakeholders wishing to progress it and that the delays were apparently due to loss of key team members through misadventure.

  Australia previously raised concerns that this work was deviating from the accepted ISO/HL7 10871 EHR-S Functional Model standard as the basis for EHR systems profiles and the associated HL7 Clinical research profile. As a result of similar concerns among several TC 215 members, the project had been required to harmonise with other work outside Europe (specifically the ISO/HL7 EHR-S Functional Model and the associated HL7 Research Profile). It is unclear whether this requirement has reduced the original proponents' interest in the proposed ISO standard.

  Despite enquiries, no responses have been forthcoming from the relevant experts so WG 1 is not continuing with the project, even as a preliminary work item, until there is a clear indication that relevant experts are willing and available to progress it.

  ISO/CS has advised that TMB would need stronger justification before allowing an NP ballot to reinstate the project as an approved work item (AWI). This justification would need to identify why the project did not progress as planned in the first place, and that it would have renewed backing and high market relevance.

  The project remains suspended on the JIC Joint Work Program, pending clarification of its status with other relevant SDOs, notably CDISC, CEN and HL7.

### 11.2.3 WORK ITEMS IN PROGRESS

- ISO TR 14639-2 – Health Informatics - Capacity-based ehealth architecture roadmap Part 2 – architectural components & maturity model
- ISO TS 13972 Health Informatics – Characteristics and Processes of Detailed Clinical Models

- ISO/ DTS 18530 Health Informatics – Automatic identification and data capture marking and labeling - Subject of care and individual provider identification
- ISO/HL7 DIS 10781.2 - Health informatics Electronic health record system functional model [EHR-S FM] – Release 2
- ISO/HL7 NP 16527 - Health informatics – Personal health record system functional model [PHR- FM] – Release 1
- ISO/AWI TS 18528 - Functional classification of health informatics standards. This was approved as a new project and entered into the work program in January 2013.

## 11.3 PROGRESS AT THIS MEETING

WG 1 sessions at this meeting were typically well supported with some 30 to 45 delegates in attendance.

Not all WG 1 items considered during this meeting were able to be reported on in depth because relevant Australian experts also had to participate in other groups which had relevant items and activities on at the same time as WG 1 items.

### 11.3.1 NEW WORK ITEM PROPOSALS

Apart from recommending the reinstatement of "ISO TR 14639-2 – Health Informatics - Capacity-based ehealth architecture roadmap Part 2 – architectural components & maturity model" to the TC 215 work program, there were no proposals to ballot new work items arising from WG 1 at this meeting.

### 11.3.2 WG 1 OFFICE BEARERS

Dr Marion Lyver (Canada), who was the vice-convener of WG 1 and had formerly been the convener of WG8 before it was merged into WG 1, was retiring as vice convenor at this meeting. She was thanked for her considerable efforts and an election was held for her successor.

Nominations were called and Dr Beatriz Leao (Brazil), who had previously served as vice-convener of the former WG 8, was unanimously recommended as vice convenor, to replace Dr Lyver and her appointment was subsequently ratified by the TC 215 plenary meeting.

### 11.3.3 CONFIRMATION OF RECOMMENDED NAME FOR WG 1

There was considerable discussion of the names previously recommended by WG 1 (predominantly "Architecture") and alternatives put forward by the WG 1 convenors in response to feedback and suggestions from the Reorganisation Task Force and the Business Plan Ad Hoc group. The question of the recommended title for WG 1 was eventually resolved by means of preferential balloting resulting in "architecture, frameworks and models" being accepted

### 11.3.4 ISO TR 14639-2 - CAPACITY-BASED EHEALTH ARCHITECTURE ROADMAP PART 2 – ARCHITECTURAL COMPONENTS & MATURITY MODEL (EHAMM)

#### *11.3.4.1 Introduction*

This ISO Technical Report (TR) builds on the background information on national approaches and architectures for e health implementation in "ISO TR 14639-1 - Capacity-based ehealth architecture roadmap Part 1 – Overview of national ehealth initiatives" published in August 2012, by identifying each component from the Part 1 'Parthenon' diagram and providing the following details:

- a description of the architecture component,
- a definition of requirements to be addressed at each of Low/Medium/High levels of capability, plus
- identification of cross-references to, and dependencies on, other components.

Authors are contributing directly to an evolving document located at http://www.hiwiki.org/iso14639/index.php?title=Part_2_using_ISO_Template

#### *11.3.4.2 Progress to date*

This document, which is being progressed through collaboration with the PHTF, is almost complete with most sections having been drafted, checked, refined and harmonised.

Despite the large amount of work that has been taking place, the project was recently cancelled by ISO/CS because it had exceeded its time limit but, being a technical report, TC 215 was able reinstated it by means of a simple resolution, which was passed at the closing plenary.

It was noted that the following work on the document needs to be completed and that offers to help would be greatly appreciated:

- Re-ordering and checking of the Introduction, Scope and Overview to ensure that they meet ISO requirements and are still consistent with the document content and what had originally been drafted at the March 2011 meeting in Geneva (leads - Richard Dixon Hughes and Pier-Angelo Sottile).
- Review and additional material is being sought for sections 5.3.1 (General description of infostructure components), 5.3.2 (EHR & health information repositories), and 5.3.3 (Identification registries & directories) – authors/reviewers sought.
- Integration of standards referenced in Annex D into the capability statements in the main body of the document – additional contributions sought.
- Authoring of a section on standards and conformance infrastructure in section 5.4.
- Review of 5.2.3 (Primary care services) and 5.2.8 (Pharmacy services) to ensure that they are truly applicable to LMIC situations – Brazil to undertake.
- Review and checking the integration of sections related to national governance (section 5.1) – Alan Taylor suggested that it is possible an Australian expert could be found to finish this section.

Completion of this work will be overseen by Dr Marion Lyver (Canada).

#### *11.3.4.3 Proposed next steps*

It is aimed to complete outstanding work within 4 weeks and then go to ballot. The resolution agreed by the TC 215 plenary session stated that for ISO/TR 14639-2, Health informatics -- Capacity-based eHealth architecture roadmap -- Part 2: Architectural components and maturity model, ISO/TC 215:

- approves the recommendation of WG1 that this document be reinstated on the work programme and published as a Technical Report pending DTR ballot approval;
- instructs the project leader to provide the final version of the TR to the TC 215 secretary for DTR ballot no later than 30 May 2013.

#### *11.3.4.4 Relevance to Australia*

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG1 - DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model** | Completion of the work item with detailed contributions for specified subsections.<br>**Action: Australian experts should continue to contribute and assist with completion of this item by next TC215 meeting.** | **IT-014** |
| **WG1 - DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model** | DTR 14639-2 is of potential interest and use to Australian health care providers, non-government organizations, government providers of aid, and the private sector in Australia. Additionally throughout the Asia Pacific region DTR 14639 parts 1 and 2 could be of substantial interest.<br>**Action: Following the publication of DTR 14639-2 a number of promotional activities will be need to be considered to promote the use of TR 14639 and associated ISO standards.** | **IT-014** |

### 11.3.5 ISO TS 13972 – CHARACTERISTICS AND PROCESSES OF DETAILED CLINICAL MODELS

#### *11.3.5.1 Introduction*

The intent of this technical specification is to describe attributes and processes that will support development, verification and governance of high quality detailed clinical models (DCMs) from all sources.

The project leader and primary author is William Goossen (Netherlands).

Work commenced on the project in 2008, with the original aim of producing a two-part international standard.

#### *11.3.5.2 Progress to date*

Despite receiving a positive outcome at CD ballot, at the May 2012 ISO meeting, in the interest of consensus building, the project leader agreed to move the document back from an International Standard to a Technical Specification. As a result, the working group agreed to re-merge the first two of the components back together, with work on quality metrics to be progressed as a separate work item.

A consequence of changing the final publication format from IS to TS means that ISO TS 13972 is no longer being developed under auspice of the Vienna agreement.

The revised DTS 13972 was extensively reformatted following remerging from two separate documents and additional content regarding alignment with ISO 9000 processes was included.

The revised document was submitted to DTS ballot which resulted in its being passed but with six negative votes and around 150 comments. Australia supported the main thrust of the revision (from the previous DIS) and did not oppose the introduction of material related to ISO 9000 but was among those that voted negatively.

The comments received indicate the way in which the document was restructured has raised questions about its relationship to the ISO rules on conformity assessment and also resulted in a document that is more poorly structured, overly prescriptive, ambiguous and less digestible.

A joint session of WG 1 and WG 3 was held to discuss the outcomes of the DTS ballot and resolve the issues.

Several versions of an improved document with track changes had been prepared by the project lead and circulated among he nominated experts for comment. Specific revisions were proposed to address comments regarding scope, definition, ISO 9001 and the logical model.

Prior to the TC 215 Mexico meeting improved sections were submitted and discussed. In particular:

a) The linkage to ContSys has been strengthened.
b) Definitions, abbreviations and references have been improved.
c) Normative statements have been reduced in number, reducing duplication.
d) Chapters have been reordered, and all but one annex removed.

#### *11.3.5.3 Proposed future work*

ISO DTS 13972 will be submitted for a second DTS ballot to solidify support with only new comments being requested, for consideration at the Sydney TC 215 meeting.

Prior to balloting the text will be checked by a non-expert English speaker. Nicolas Oughtibridge offered to find a colleague within the UK NHS do this. Up to two weeks should be scheduled for this task.

#### 11.3.5.4 Relevance to Australia

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 1**<br><br>**TS 13972 – Characteristics and Processes of Detailed Clinical Models** | The revised DTS 13972 will be sent out for a second ballot. It has been extensively reformatted and edited to take account of comments received. Further consideration will be required at the Sydney TC 215 meeting.<br><br>**Action: Australian experts to determine an approach on how to respond to the second DTS ballot.** | **IT-014-09**<br><br>**NEHTA CTI team** |

### 11.3.6 ISO/ DTS 18530 HEALTH INFORMATICS – AUTOMATIC IDENTIFICATION AND DATA CAPTURE MARKING AND LABELING - SUBJECT OF CARE AND INDIVIDUAL PROVIDER IDENTIFICATION

#### 11.3.6.1 Introduction

This project is being led by Christian Hay (GS1) with a view to being published as an ISO Technical Specification. The project is also on the JIC Joint Work Program.

The intent is to create implementation guidelines on standards for identification and marking labelling for patients and care givers to enable Automatic Identification and Data Capture (AIDC) applications for care delivery process and other purposes, to assist in assuring patient safety. There is a strong focus on Subject of Care, but the Individual Provider also in scope; identification management is specifically not in scope.

This is part of ongoing work initiated from GS1 and will reference existing ISO/TC 215 technical specifications on identification. Specifically: ISO TS 22220 Identification of subjects of health care and ISO TS 25725 Provider identification.

#### 11.3.6.2 Progress to date

The goal has been to finalise this technical specification by the end of June 2013. As such a DTS ballot was conducted following the previous meeting in Vienna. The results of the ballot where as follows:

- 9 approvals
- 5 approvals with comment
- 2 rejections (coming from Germany and the Netherlands)
- 10 abstentions

Overall there were 62 comments, however the majority of these were in relation to the explicit references to GS1 in the specification and the lack of normative content,

Specifically, the main concern is that this apparently general specification for the application of technology in identification assumes the use of proprietary GS1 technologies and does not allow for substitution of alternative technologies. To meet the document's requirements, users must implement the GS1 system. The project lead, Christian Hay of GS1, recognised that this would indeed be the case.

To resolve this issue he recommended inclusion of the following text, which was based on text found in ISO 10685 to resolve a similar situation:

> 2) GTIN is the trademark identifier for trade items (which encompass both products and services) and is supplied by the GS1 System. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product/service identifier named. Equivalent products may be used if they can be shown to lead to the same results.
>
> **2** 

This was discussed but is unlikely to resolved the concerns raised by Germany. A proposal was also made to include reference to GS1 in the title of the specification to remove any ambiguity but was unclear whether the project lead is prepared to accept this approach.

Further agreements were made to resolve comments in relation to the absence of normative statements, these were primarily to use stronger and clearer imperatives “shall”, “should” etc… in the existing text to enable the implementers' conformance points to be seen clearly.

Noting the measures proposed to resolve previous concerns, it was agreed to progress to publication of this specification without a further DTS ballot.

#### *11.3.6.3 Proposed future work*

A new version of the draft TS addressing previous concerns is to be provided no later than 30 June 2013 to the WG1 secretary for WG1 circulation and review. If no comments are received or if received comments are satisfactorily addressed in the opinion of the WG1 Convenor, the final updated version will be provided to the TC215 Secretary no later than 20 July 2013 for publication no later than 31 August 2013.

#### *11.3.6.4 Relevance to Australia*

Australia voted in favour of the previous draft and has significant interest in the areas of subject of care identification and individual provider identification, aspects of which are addressed by this standard. While Australia is generally supportive of GS1 technologies and applies them widely, the implication that an apparently general standard creates a monopoly for them in these types of applications is a legitimate concern. The response to changes requested by some other national member bodies do need to be reviewed to ensure that they are adequate and do not misrepresent the context in which the standard is to be applied.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 1**<br><br>**DTS 18530 – Subject of Care (SOC) and Individual Provider Identification (GS1)** | Subject of Care and Provider identification via AICD is in important part of automation of processes during care delivery especially in the inpatient setting. For example it is heavily used in a closed loop medication management process.<br><br>GS1 is being adopted throughout Australia through the NPC however it may not be suitable in all settings.<br><br>**Action: IT-014-02 and IT-014-06-04 to review the DTS when available for suitability to Australia.** | **IT-014-02**<br><br>**IT-014-06-04** |

### 11.3.7 ISO EN 13606 ELECTRONIC HEALTH RECORD (TECHNICAL REVISION)

#### *11.3.7.1 Introduction*

Prof Dipak Kalra (UK) is the lead for this work item.

The intent of the revision to this five-part EHR communications standard is to update, harmonise and improve ISO13606 as a means of exchanging EHR extracts within a federation of distributed heterogeneous EHR systems. The five parts of the standard are:

- Part 1 – Reference Model – a comprehensive, generic model for communicating part or all of an EHR
- Part 2 – Archetype Specification – constraint-based approach for defining clinical models that are built from the reference model – adopted from openEHR
- Part 3 – Reference Archetypes and Term Lists – initial set of archetypes mapping to other relevant standards; as well as vocabularies supporting the reference model
- Part 4 - Security – measures to support access control, consent and auditability of EHR communications (this is managed by WG 4 rather than WG 1)
- Part 5 – Interface specification – message and service interfaces to enable EHR and archetype communication

This is a joint ISO/CEN work item but, because ISO 13606 originated as a European standard through CEN and is mandated for use in Europe, most of the work and pressure for change is expected to come from the CEN/TC 251 community. Nevertheless, much of the underlying technology parallels and draws on the archetype-based technologies used in openEHR, with the origins of both openEHR and ISO 13606 stemming from GEHR implementations nearly 20 years ago. Many regard the ISO 13606 extract to be a subset of the openEHR EHR specifications, which was originally developed by Australians. The openEHR tooling and specifications have evolved, largely driven by Australian expertise, and until recently 13606 implementations predominantly used openEHR tooling. However a more active 13606 community and specialised tooling has evolved in the past couple of years to support implementers.

The scope of each of the five parts will not be changed. Even though the five parts were originally achieved separately, they are now being reviewed together, rather than serially, to ensure harmonisation.

This will be a significant block of work to be undertaken over the next couple of years. There are many new and updated resources to be taken into account in this revision.

If the work is to be widely accepted, it will need to genuinely embrace the opportunity to harmonise activity from a variety of projects including, but not limited to, HL7 v3 RIM and CDA, openEHR and the new CIMI project.

#### *11.3.7.2 Progress to date*

The scope of the existing parts has been considered and it has been decided not to change the scope or try to do new things, such as extend the standard to define aspects related to EHR repositories and query/retrieval mechanisms.

While internal integrity of all 5 parts is the central theme, the need for ISO 13606 to work together with other standards as part of an end-to-end landscape is important, particularly new standards not around when the documents were originally developed. The following proposed issues were particularly noted.

- Part 1 Reference model
  - Modify data types to align with ISO 21090
  - Determine what alignment is appropriate for HL7 CDA and open EHR
- Part 2. Determine what is best course of action to take re language, whether to:
  - Replace v1.4 and adopt features of openEHR ADL v1.5, or
  - Remove all ADL content and refer to openEHR while keeping UML model in
  - Determine what alignment is appropriate with CIMI
- Part 3
  - Determine what archetype/DCM patterns to include. ContSys and CIMI are likely to be relevant.
  - Modify data types to align with ISO 21090
- Part 4. This will be done jointly with WG 4 and is being targeted to be elevated from the current TS to a full ISO international standard. In Europe, it is a full EN standard.
- Part 5. No key points for revision
- The need to consider the fidelity of end to end communication
- Questions of backward compatibility and ensuring the ability to continue using existing content
- Ensuring that multi-version EHR content and updated material is handled robustly
- Obtaining agreement on the identification and labelling of semantic content represented by archetypes – including node labelling and versioning of archetypes and instance identification. This could be considered unilaterally or in conjunction with CIMI.

The plan to organise SDOs to survey industry on their use of this standard was discussed. Australia indicated that both users and non-users of this standard could be contacted. A three month turn around for the survey was proposed. Specific matters discussed included:

- Including a question on why some respondents had decided not to use the standard
- Retaining a question on what other generic formats were actually being used, and why
- How to explore issues related to serialization formats

#### *11.3.7.3 Proposed future work*

The working group is seeking support of national member bodies in using the survey to gather experience and observations from implementers and use this as source for revisions of the specifications. This activity is targeted to occur prior to the next WG meeting in Sydney.

Once the survey is completed all revision of all five parts of ISO 13606 will be completed and will proceed to a ballot.

#### *11.3.7.4 Relevance to Australia*

Historically ISO 13606 has been shaped significantly by Australian input, as it is based on openEHR as it was nearly 10 years ago. While Australia has not adopted 13606 directly, there has certainly been an ongoing awareness and interest in whether it should.

Continued Australian involvement in openEHR, development of 21090 data types, expertise in archetype development, experience with NEHTA DCM development and CDA , and participation in the Clinical Information Modeling Initiative (CIMI) are just some of the areas where Australian experts can not only provide expertise to the harmonisation and enhancement of 13606, but significantly influence it's way forward.

This new revision of 13606 should be considered as a candidate for adoption by Australia and therefore should be monitored closely throughout all phases of development.

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG 1**<br><br>**ISO 13606 Electronic health record communication** | This will be a significant block of work to be undertaken over the next year or so. There are many new or updated resources that will be taken into account in this revision. It will create a significant opportunity to harmonise activity from a variety of projects including, but not limited to, HL7's CDA, openEHR and the new CIMI project.<br><br>**Action: IT-014-09 to encourage and support Australian expert input to the revision of ISO 13606.**<br><br>**Action: IT-014-09 to monitor and participate in review of the proposed survey and all ISO 13606 documents.** | **IT-014-09** |

### 11.3.8 ISO/CD 13940 SYSTEM OF CONCEPTS TO SUPPORT CONTINUITY OF CARE (CONTSYS)

#### *11.3.8.1 Introduction*

Nicholas Oughtibridge (UK) presented this joint project on behalf of CEN TC 251 WG1.

The proposed ISO 13940 System of concepts to support continuity of care (ContSys) exists in an earlier form as a European standard, which was fast tracked to DIS ballot in TC 215 based on a completed draft of the full document. The DIS ballot closed on 14 May.

ContSys relates to the conceptual (or "World") view of a health care enterprise within a health care system and identifies the conceptual components in this space, their characteristics, relationships and interactions.

ContSys is now an approved project on the JIC joint work program, recognising its important role as a foundation international standard naming many of the main concepts in the healthcare domain and identifying the relationships between them. As such, it is a framework on which many other standards, terms and definitions should be based – and it is important that it be correct and truly international in its application.

The goal is to try to achieve the review of ContSys within a 2 year ballot cyclefocussing on the processes and requirements for the representation of semantic content, but not on the content of systems which do so.

#### *11.3.8.2 Progress to date*

Some discussion of ContSys took place in a joint session of WG 1 and WG 3 at the TC 215 meeting in Mexico City but the amount of in-depth discussion that was possible was limited by ISO policies on the discussion of documents that are still out to ballot. Discussion was limited to an update on the project status and a discussion of future directions.

Closely linked to the development and refinement of ContSys is an activity being carried out by CEN/TC 251/WG 1 to reconcile the concepts and requirements for ‘Concurrent use’ of 3 complex foundation specifications that had been produced to satisfy different business requirements, yet were ‘designed’ to interoperate. These specifications are:

a) System of Concepts to Support Continuity of Care (ISO EN 13940, ContSys)
b) Electronic Health Record (EHR) Communication (ISO EN 13606, EHRcom)
c) Health Informatics - Service Architecture (ISO EN 12967, HISA)

The 3 specifications were originally produced in CEN TC 251 and then globalised by introducing them to ISO. The importance of this work has recently been recognised by some of the North American the standards community in North America and HL7 has committed to making appropriate contributions in attempt to ensure that the resulting standards meets international needs.

This work involves a series of ‘Concurrent use’ workshops. The first of these workshops was held in Rome in July 2012 and sought to re-understand the maturing and developing specifications afresh, and more importantly, to see how all three could be used together to make a contribution to interoperability within the combined scope.

The second ‘Concurrent use’ workshop was held in Madrid in March 2013. One explicit objective of the second workshop was to develop and formalise a method that would identify the inconsistencies between the specifications and proposals to fix (harmonise) them, whilst at the same time finding a way to ensure on-going convergence and facilitating concurrent use. An important consideration was to think about ‘implementation’ and the implications for both doing the work and achieving outcomes that would bring tactical and strategic benefits.

Stephen Kay gave presentations on the concurrent use workshop at the JIC Open Forum session (see Section 9.3.2.1 above).

#### *11.3.8.3 Proposed future work*

Comments and result of the DIS ballot of ISO/DIS ballot 13940 System of Concepts to Support Continuity of Care (ContSys) will be reviewed at the Sydney TC215 meeting in October 2013.

The CEN/TC 251/WG1 work on concurrent use of ContSys, ISO 13606 and HISA appears to be a potentially valuable exercise in attempting to bring together and characterise the roles of several of the main conceptual standards that affect systems architectures and interoperability. Others include the various architectural frameworks, clinical terminologies, the ISO/HL7 EHR-S functional model, HL7v3 RIM and the CIMI reference model.

#### *11.3.8.4 Relevance to Australia*

If implementation support is eventually included, this work may be a useful resource to inform the NEHTA Clinical Information team,DCM project and specification development activities more generally..

IT-014-12 also has an interest in using ContSys (expanding on the Wagner Care Model) for a proposed new 2012-14 project on Care Management process modelling where patient monitoring is involved. This is of considerable interest more generally, as the emphasis of Chronic Disease Management strategies, beyond conventional healthcare processes and systems, grows as one of the elements of national healthcare reform.

IT-014 established a specific joint project team which provided significant input for the recent DIS ballot and, while strongly supporting the need for ContSys, Australia has submitted a negative vote. The principal reason is to ensure that the conceptual framework laid out in this standard is properly reconciled with the other terminological resources already being deployed in the health Informatics standards space and are completely thought through from international (as distinct from a purely European) perspective.

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG 1, WG 3**<br><br>**ISO/CD 13940 System of Concepts to Support Continuity of Care - CONTSYS** | It is critical for this work be capable of practical application.<br><br>If implementation support is included, this work will be a useful resource to inform the NEHTA CI team, DCM, and specification development. Alignment with IT-014-12 work on care management process modelling is also important.<br><br>**Action: Form joint group of Australian experts to review and contribute to CONTSYS ballot response and to ensure that the standard is capable of practical implementation, is firmly grounded in clinical practice and can be implemented in specifications and by grassroots vendors.**<br><br>**Action: Monitor the progress of the CEN Convergence meetings to ensure that implementation support is grounding and informing the development of the CONTSYS standard.** | **IT-014-02**<br><br>**IT-014-06**<br><br>**IT-014-12**<br><br>**IT-014-13**<br><br>**NEHTA** |

### 11.3.9 NP - QUALITY METRICS FOR DETAILED CLINICAL MODELS

#### *11.3.9.1 Introduction*

This proposed work item has been anticipated for some years, having been removed from the initial scope of ISO TS 13972 on Detailed Clinical Models, but now initiated as a stand-alone work item. Prof Sun-Ju Ahn from South Korea is the project lead.

The intent is to define a set of quality metrics to evaluate Detailed Clinical Models objectively, including domains such as purpose and scope; stakeholder involvement; rigor of development; clarity and presentation; compliance to specifications; general methodology; metadata; and management and maintenance.

It is proposed that each metric will include: definition; objects of evaluation; evaluation method; and scoring. The metrics may be qualitative and quantitative.

This is a new work item that is effectively an extension to ISO DTS 13972 on Detailed Clinical Models. It is likely to closely reference the structure and content of 13972.

#### *11.3.9.2 Progress to date*

The project lead was unable to attend the Mexico TC 215 meeting and progress has been slow.

#### *11.3.9.3 Proposed future work*

The directions proposed for this item are not available at present. There could be an opportunity for Australian experts to assisting in progressing this item before the next TC 215 meeting in Sydney.

#### *11.3.9.4 Relevance to Australia*

Despite this being an immature knowledge domain, Australia has some of the most extensive international experience in quality metric measurement of Detailed Clinical Models and as such, should volunteer expertise to participate in and inform this work item, no matter what the final published outcome.

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG 1**<br>**NP Quality Metrics for Detailed Clinical Models** | This item is effectively an extension to ISO DTS 13972 on Detailed Clinical Models. It is likely to closely reference the structure and content of 13972. Given that Australia has some of the most extensive practical experience in quality metrics internationally, it is advisable that Australia actively participate in informing and shaping the final deliverable – whether a technical report or a technical specification.<br>**Action: Australia to provide expertise to inform the development of this new work item, no matter what the final targeted publication.** | **IT-014-06**<br>**NEHTA** |

### 11.3.10 17537, ELECTRONIC HEALTH RECORDS CLINICAL RESEARCH FUNCTIONAL PROFILE [EHR-CR] – STATUS

This project has been cancelled by ISO/TMB and further information on any proposed continuation is being sought (see comments in section 11.2.2 above).

### 11.3.11 ISO DIS 16527 PHR SYSTEM FUNCTIONAL MODEL (PHRS-FM)

#### *11.3.11.1 Introduction*

This project was presented by Gary Dickinson, who spoke to the project background, the current widespread use of the EHR-S FM (currently going to Release 2 – see section 11.3.12 below) and the relationship of PHR-S FM to the EHR-S FM.

This work is jointly balloted by ISO and HL7; while the work effort resides within HL7.

Any relevant work done on the Revision 2 of EHR S FM is planned to be reflected in the PHR S FM which will include more specific content related to consent management, personal health record management, telehealth, social networking, and mobile health.

#### *11.3.11.2 Progress to date*

The first joint ISO/DIS + HL7 normative ballot of the PHR-S FM specifications has closed. Ballot reconciliation has commenced with work proceeding via weekly teleconferences and planned for face-to-face discussion at the HL7 WGM coming up in Atlanta in early May.

The most significant issue arising from the international ballot was a negative vote from the UK, who want the specification downgraded to a TR. PHRs are virtually non-existent in the UK and so as there is not a market for this. UK did not agree to this as an international standard without having experience in this area. The UK position on this seems somewhat

extreme - seeking to deny others the benefit if an international standard because a technology is not used is unusual. It would also be difficult to reproduce the PHR-S FM in the form of a purely informative specification.

#### *11.3.11.3 Proposed future work*

Disposition of comments from first ISO/DIS + HL7/normative ballot is to be completed and an updated draft issued for joint DIS2 ballot prior to the Sydney meeting.

The document may need to be converted to ISO format before the second round pf balloting.

#### *11.3.11.4 Relevance to Australia*

Australian experts are maintaining a watching brief and participating when possible through HL7. There are no significant issues, actions or recommendations to report.

### 11.3.12 ISO DIS 10781-EHRSYSTEM – FUNCTIONAL MODEL (EHRS-FM) R2

#### *11.3.12.1 Introduction*

An overview of the progression of delivering Release 2 of the EHR Systems Functional Model (EHR S FM) as a joint HL7, ISO/TC 215 and CEN/TC 251 standard was provided by Gary Dickinson (USA), the project leader. International input is always actively being sought and is welcome to ensure that the EHR S FM has the widest applicability. Nevertheless, practical issues have resulted in most of the input and work being focussed on the USA and Canada. International implementations in The Netherlands, Ireland, Canada and UK have also been noted.

The standard is applied by developing functional profiles which are subsequently used for the assessing the capabilities of various types of EHR application systems (e.g. in the context of ambulatory care, long-term care or acute care).

Some of the main changes since the previous R1.1 (which was published as the original ISO/HL7 10781) include:

- Changes to the verb hierarchy (and associated verb use) to ensure consistent use of verbs – these changes have now been settled for this coming release;
- Wide-ranging and extensive inputs to Release 2 from over 20 key sources, including its use in producing functional profiles for various types of system assessment and certification;
- Significant reorganisation and expansion of the chapters – to include bringing in material in from other ISO standards on chain of trust for health records; and
- Growth in the number of conformance criteria from 983 in R1.1 to some 2,310 in R2.

#### *11.3.12.2 Progress to date*

The joint ISO/DIS + HL7 normative ballot of the EHR-S FM R2 specifications has closed and has resulted in a large number of comments as expected. Ballot reconciliation has

commenced with work proceeding via weekly teleconferences and planned for face-to-face discussion at the HL7 WGM coming up in Atlanta in early May.

It was pleasing to see all the affirmatives with 15 abstains and no negatives – a very positive reaction; however, a DIS2 ballot will be required because there will be substantive changes flowing from the HL7 and ISO/other ballots.

There will be a challenge integrating the next round of HL7 balloting with ISO/CEN. All of them need to be on the same page in terms of timing and comment submission and there are different rules. HL7 ballots only on 'changes' while ISO does not limit a DIS2 ballot in that manner – so an ISO change could upset the existing HL7 consensus.

It was noted that although an ISO ballot cannot constrain at this level, a note can be inserted to the ballot to indicate second DIS ballot and the status of the work item.

The previous issues in relation to formatting ar understood to have been overcome.

#### *11.3.12.3 Proposed future work*

Disposition of comments from first ISO/DIS + HL7/normative ballot is to be completed and an updated draft issued for joint DIS2 ballot prior to the Sydney meeting.

A means of aligning the next round of ballots needs to be discussed – possibly involving facilitation through the JIC.

#### *11.3.12.4 Relevance to Australia*

Australian experts were originally heavily involved in developing the EHR-S FM and are maintaining a watching brief and participating when possible through HL7; however, there has been limited interest in developing Australian conformance profiles for measuring the functional capabilities of EMR applications. There are no significant issues, actions or recommendations to report.

### 11.3.13 ONC – CROSS-INITIATIVE – S&I SIMPLIFICATION

#### *11.3.13.1 Introduction*

Work by one of the US-ONC's Standards and Interoperability (S&I) Framework work groups, the "Cross Initiative – S&I Simplification Work Group" was presented by Gary Dickinson at the September 2012 meeting of TC 215 in Vienna.

The group is intended to draw input from and cut across the multiplicity of approaches being used by different S&I work groups and SDOs in order to simplify the S&I use case and requirements outline, template and artefacts and make recommendations to all S&I WGs and Framework teams on common approaches. For further information see:
http://wiki.siframework.org/Cross+Initiative+-+S%26I+Simplification+WG/

#### *11.3.13.2 Progress to date*

At this TC 215 meeting, there was brief discussion of this activity to attempt to clarify what is being proposed, if anything, and what might eventuate.

Gary Dickenson indicated that he had brought the methodology forward for information. Possible outcomes include describing the methodology to do this, possibly via a TR.

A tool to do this is expected to be made available but there would be challenges with the US Government in making it widely available. There is a need to coordinate efforts and support others with the same need.

#### *11.3.13.3 Proposed future work*

Gary Dickenson expects to submit a draft NP for review at the Sydney TC 215 meeting in October.

#### *11.3.13.4 Relevance to Australia*

It appears that this work is at quite a high level and focussed on harmonising use-cases for patient/provider/information workflow rather than clinical content.

It may be useful for Australia to keep a watching brief on this work, although it is not likely to be reported further in ISO/TC 215 at this point.

### 11.3.14 ISO TS 18528 FUNCTIONAL CLASSIFICATION OF HEALTH INFORMATICS STANDARDS

#### *11.3.14.1 Introduction*

Technical Report ISO/TR 13054 provided background on the development and operation of the Standards Knowledge Management Tool (SKMT). It was published in 2012, following the May ISO meeting in Vancouver.

The proposed TS 18528 – Functional Classification of Health Informatics Standards Functional Classification of Health Informatics Standards provides the basis for refinement of the system of classification that has been used with the SKMT.

This work item is an extension of the previous TR 13054 (Knowledge management of health informatics standards) and development of the SKMT tool, which included significant Australian input. The SKMT has begun to be populated. New standards need to reference and use this tool.

#### *11.3.14.2 Progress to date*

This item is at an early stage of development. The intent is to produce a classification tool for standards that is useful to a broad set of users (such as implementers and policy makers), is intuitive and points to the right places.

The project is taking an empirical approach and is considering TR 1799 which is a bit abstract and old, a Generic Component Model Cube, and Canadian model from Infoway which is more sophisticated. A test questionnaire produced a small number of responses from WG1 members.

Initial design propositions include:

- base on European interoperability principles;
- use no more than 2 levels of hierarchy; and
- provide a harmonised glossary and maintained dictionary.

#### *11.3.14.3 Proposed future work*

Discussion of this project raised the following points for consideration by the project team:

a) There is a need to identify the primary users and business problem, particularly in LMIC settings.
b) Can the eHealth model contained in TR 14639-1 be a useful classification framework
c) Short cuts and different views should be possible.
d) The classification system must be tested on users.
e) The Australian eHealth Architectural Framework could be useful.

#### *11.3.14.4 Relevance to Australia*

SKMT is gaining increased awareness within the international community and is being referred to regularly in a range of activities both in Australia and overseas.

Australian experience would be valuable in providing a more useful health information classification of standards for on-going use, particularly as it is being incorporated in tooling such as SKMT. Recent work on e-health architecture framework (EHAF) being progressed by IT-014-09 as part of the e-health interoperability framework is also directly relevant.

| **Topic** | **Issue/Action and Recommendations for Australia** | **Suggested responsibility & alignment to IT-014** |
|---|---|---|
| **WG 1**<br><br>**Proposed NP TS 18528 – Functional Classification of Health Informatics Standards** | Australia should monitor and potentially actively contribute to the NP TS 18528 – Functional Classification of Health Informatics Standards, given our current work in IT-014-09 with the e-health Architecture Framework, and the e-health Maturity Model Classification. | **IT-014-02**<br><br>**IT-014-09** |

# 12. PUBLIC HEALTH TASK FORCE (PHTF)

| | |
|---|---|
| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)<br>Naomi Ryan (WG 1 secretariat)<br>Alan Taylor |

## 12.1 BACKGROUND

This Task Force was formed to progress a WHO-initiated body of work to develop a generalised high level enterprise architecture model for national eHealth systems, with major intention to provide developing countries with a mechanism for planning development of their future eHealth environments.

As part of this work, an initial survey tool was developed to understand the factors affecting various countries' state of readiness in eHealth and the results from applying it to a range of countries were considered in TR 14639-1. Australia, India, Brazil, Kenya and Canada were the countries which responded and were analysed in some depth.

A second part of TR 14639 is nearing completion, providing a maturity model and roadmap for development of eHealth capability within a health system.

The PHTF has a general interest in promoting eHealth standards and standardization for Low-to-Middle-Income-Countries (LMICs).

As part of this work, a further survey tool was developed to assess LMICs' state of readiness in eHealth and results from applying piloting it within a range of countries are still under consideration.

The PHTF originally reported to ISO/TC 215 through WG 8. However, with the reorganisation progressively coming into effect, is reporting through WG 1 from the September 2012 meeting onward.

## 12.2 RECENT ACTIVITY

### 12.2.1 CURRENT PUBLICATIONS

TR 14639 Part 1 has been published but is not yet freely available.

### 12.2.2 CURRENT WORK ITEMS

ISO/DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model is being completed and with the intent of obtaining agreement to publish pending DTR ballot approval.

It is intended that once ISO/DTR 14639-2 is published the PHTF will disband.

## 12.3 PROGRESS AT THIS MEETING

The ISO/TC 215 Public Health Task Force (PHTF) Report was presented by Walter Suarez. At the Plenary session of this TC 215 meeting it was resolved that ISO/TC 215:

- accepts the Public Health Task Force Report; and
- instructs the TC 215 Secretary to inform ISO Central Secretariat of this resolution and request a response by 15 May 2013 which can be conveyed to TC 215 and WG1 members with distribution of the report to follow immediately thereafter.

Walter Suarez reported on a WHO two day meeting Dec 2012 which led to the publishing of a WHO executive statement promoting the need to develop eHealth capacity. WHO is planning:

- production of guidelines for countries to establish e-health initiatives (policy level possibly) based on the recent forum;
- a global gateway for data standardisation and interoperability that will include links to information standards, country level policies and resources. A prototype is in rapid development; and
- a second forum on e-health planning and interoperability, in November 2013, in Bangkok

The members of the PHTF convened on the last day before the Plenary session to jointly work on completion of TR 14639 Part 2, develop a business proposal to ISO for free-of-charge access to TR 14639 Parts 1 and 2, discuss how support for the use of eHealth standards in LMIC settings can be promoted after the PHTF disbands, and discuss what form this work should take.

### 12.3.1 PROPOSED FUTURE WORK

The JIC recognises the value of the PHTF initiative. Appropriate vehicles will need to be found to continue the work commenced by PHTF. A multipronged strategy could include:

- JIC support for SDO activity in LMIC settings
- WHO activities – communicate between TC 215 and WHO as periodically as possible, learn about WHO activities, see how WHO can reach out to new countries
- New organisational forms - possibly through IMIA (International Medical Informatics Association) which has an agreement with WHO. As a professional society, IMIA has a standards, education and health informatics working groups. It is an association of 65 societies organized regionally. The Asia Pacific section has 13 members.
- There is a need to reach out to implementers. Health is a state funding matter and the sources of funding for eHealth and mHealth projects should be targeted for promotion of TR 14639 socialization.
- Coordination between TC 215 working groups developing items of relevance to LMIC settings will be important.

- Cooperation with other standards organisations is essential. (eg DICOM, the HL7 Africa initiative, the mHealth organisation and IHE).
- Discussions with large funding agencies and NGO implementers are needed.

Members of the PHTF present suggested that there are two ways the existing technical reports can be taken forwards:

1) A publication that is accessible and easier to market and read than the ISO format; and/or

2) Extension of the current technical reports into ISO standards.

#### *12.3.1.1 Relevance to Australia*

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **PHTF subcommittee: Business case for distribution of TR 14639-Parts 1 and 2** | Promotion of the TR 14639 reports will become the responsibility of national SDOs and their partners. The role of standards will become important to the provision of technical Health implementation services and the delivery of health care services throughout the region.<br>**Acton: Australia should develop a national and regional approach to promotion of TR 14639.** | **IT-014** |
| **Future LMIC related standards development and promotion** | Opportunities for collaboration with SDO initiatives to extend reach of eHealth standards to LMICs.<br>**Action: Collaboration opportunities should be explored between IT-014 and other SDOs in the area of standards education and liaison, especially to Australia's established regional partner nations.** | **IT-014** |

# 13. WG 2 SYSTEMS AND DEVICE INTEROPERABILITY

| | |
|---|---|
| Australian Delegate Attendance | Alan Taylor |

## 13.1 BACKGROUND

This ISO/TC 215 Mexico meeting confirmed the following name for WG2: “Systems and Device Interoperability”, and adopted the following scope for WG2: "Standardization of electronic exchange of information among health and healthcare systems, including information exchange within and among organizations and interoperability of devices".

Among other things, Working Group 2 deals with e-health messaging and communication standards submitted to ISO/TC 215 from other organisations such as HL7, IHE and CDISC as well as from the national member bodies.

It is the committee most closely involved with HL7 International's outreach into the international standards community and the forum through which HL7 standards including V2.x, V3 RIM, CDA and the HL7 HDF were progressed to become international standards.

## 13.2 RECENT ACTIVITY

### 13.2.1 CURRENT PUBLICATIONS

The following are publications produced by WG 2 (note – the large number of device standards to be migrated across from WG 7 are not included):

- 10159- Web Access Resource Manifest
- 12052 - DICOM
- 12974 - WADO - Web Services
- 13128 - Clinical Doc Registry Federation
- 17113 2 - Exchange of Information between HIS
- 17432 - DICOM WAPO
- 18232 - UID Length
- 21090 - Harmonized Data Types for Information Interchange
- 21731 - Pilot Project HL7 RIM Version 3
- 25720 - Genomic Sequencing Variation Markup Language
- 27790 - Document Registry Framework

- 27931 - HL7 Messaging Standard Version 2.5
- 27932 – HL7 Clinical Document Architecture

### 13.2.2 CURRENT WORK ITEMS

The following current work items were noted at this meeting:

- ISO 13131 - Quality Criteria for Telehealth
- ISO/TR 17522 Provisions for health applications on smart/mobile devices
- New Proposal New Proposal – Survey of mHealth Projects in LMIC
- ISO/TR 28380-3 - IHE Global Standards Adoption - Part 3
- ISO 14199 – CDISC-BRIDG Model
- ISO/TR 28380-1 - IHE Global Standards Adoption Part 1- Process
- ISO/TR 28380-2 - IHE Global Standards Adoption - Part 2
- ISO/HL7/DIS 21731-2 – Health informatics, HL7 v3.3 – Reference information model (RIM) – R 1-2, Release 4
- ISO/NP 12974 HI-WADO-Web-Services Web Access to DICOM persistent Objects by means of Web Services
- 17583: HI Terminology constraints (Binding) for coded data elements expressed in ISO harmonized data types used in healthcare information interchange

## 13.3 PROGRESS AT THIS MEETING

### 13.3.1 DTS 13131 QUALITY CRITERIA FOR TELEHEALTH

#### *13.3.1.1 Introduction*

This specific work item, DTS 13131, provides a generic “checklist” of considerations when implementing any clinical telehealth service.

Modifications of the draft document due to disposition of comments from Vancouver TC 215 meeting in May 2012 have not been completed, due to ill health of the project leader.

It was noted that the disposition of comments from Vancouver will be done soon.

It is then proposed to have an expert group agreement on this (during October) followed by WG2 ballot (during November) on whether it can proceed (during January) to a DTS ballot (with our without comments).

After that an assessment will be made as to whether revisions should be subject to a second DTS ballot or else move directly to publication.

New ISO rules on language to be used for quality management standards, and conformance testing, may need to be acknowledged or incorporated (including need for terms to be included in SKMT).

#### *13.3.1.2 Progress to date*

The current Project leader (Netherlands) has not undertaken an update of TS 13131 Telehealth Quality based on the comments received in the last ballot in March 2012.

The WG1 Chair suggested requesting Australia (Anthony Meader) to complete this work.

#### *13.3.1.3 Progress at this meeting and proposed future work*

After consultation with the Australian delegation an offer was made to the WG1 chair to provide assistance from IT-014-12 members led by Anthony Meader and Alan Taylor to complete a review of comments, and prepare a new draft of TS 13131 for review at the TC 215 Sydney meeting.

#### *13.3.1.4 Relevance to Australia*

This work item relates directly to numerous activities occurring nationally to roll out new telehealth services, catalysed by the new MBS item numbers for telehealth and by NBN inspired telehealth services growth ambitions. The availability of internationally recognised quality criteria will provide a "level playing field" for establishment of services by many different operators. It has been an ongoing international work item for IT-014-12 to contribute input to this document and also to provide a supporting national nominated expert (nominee Anthony Maeder).

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG2**<br>**DTS 13131 Telehealth Quality Criteria** | The CD ballot comments have not yet been reviewed and used to update the current draft.<br>**Action: Australia has offered to complete a review of comments, and prepare a new draft of TS 13131 for review at the TC 215 Sydney meeting and include consideration of this item on IT-014-12 work plan.** | **IT-014-12** |

### 13.3.2 ISO/TR 17522 PROVISIONS FOR HEALTH APPLICATIONS ON SMART/MOBILE DEVICES

#### *13.3.2.1 Introduction*

A draft of the CD of the TR from Korea was reviewed. The draft provides a brief discussion of selected mobile health use cases such as chronic disease, emergency transportation, nursing homes, access to radiology imaging etc. It includes a high level commentary on some of the applicable standards that may be appropriate to implement including XDS, the HL7 FHIR standard (draft), JSON and Web Services.

#### *13.3.2.2 Progress to date*

The draft is incomplete. The purpose and scope are unclear. It is unclear what the basis is for the selection of particular use cases. The proposed standards that could be useful in mobile settings are discussed at a high level only, and the basis for their selection is not immediately clear.

The discussion in WG2 mentioned the need to separate portal, acquisition and processing functions.

#### *13.3.2.3 Proposed future work*

ISO/DTR 17552, HI-Provisions for Health Applications on Mobile/Smart Devices, was narrowly approved during the Plenary for a three month DTR ballot as a proposed ISO Technical Report. ISO/TC 215. Australia abstained on the resolution..

#### *13.3.2.4 Relevance to Australia*

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 2**<br><br>**ISO/TR 17522 Provisions for health applications on smart/mobile devices** | The topic is of particular relevance to the development of mobile access to eHealth applications by client, patients and provider. Standardisation is immature and there is little consensus on the best solution architecture. Australia would be well placed to leverage a well-developed eHealth architectural framework to address these issues.<br><br>Although the topic is worthy of consideration the draft available to WG2 was of limited value, lacked a clear scope, analytical framework and purpose. A large number of negative comments can be expected.<br><br>**Action: Australia should provide a high level review of the draft when balloted, to assist the project leader moving forwards.** | **IT-014-12** |

### 13.3.3 NEW PROPOSAL – SURVEY OF MHEALTH PROJECTS IN LMIC

#### *13.3.3.1 Introduction*

A draft of the NP from Korea was reviewed. The draft provides a brief desk survey of selected mobile health implementations worldwide, mentions some use case, and discusses briefly the relevant standards and infrastructure.

#### *13.3.3.2 Proposed future work*

By a narrow margin the Plenary Session of TC 215 voted to support a NP for a Survey of mHealth Projects in Low and Middle Income Countries (LMIC) targeting as an eventual Technical Report, ISO/TC 215, as three month ballot. Australia and a number of other countries voted against progressing the draft at this time.

Advice given by Australia in WG2 was to consult further with WG1, especially the Public Health Taskforce, before proceeding to a NP ballot, to determine if application of DTR 14639-2 Health informatics — Capacity-based eHealth architecture roadmap — Part 2: Architectural components and maturity model to a review of selected mHealth projects has not yet been taken up by the project leader.

#### *13.3.3.3 Relevance to Australia*

The topic is worthy of consideration and could be useful to healthcare providers, and vendors both within Australia and the Asia Pacific.

Unfortunately the draft lacks an analytical framework, purpose, focus and rigor.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 2**<br><br>**ISO/TR 17522 Provisions for health applications on smart/mobile devices** | The topic is worthy of consideration and could be useful to implementers both within Australia and the Asia Pacific.<br><br>Unfortunately the draft lacks an analytical framework, purpose, focus and rigor.<br><br>**Action: Australia should provide a high level review of the draft when balloted, to assist the project leader moving forwards.** | **IT-014-12** |

### 13.3.4 ISO/DTR 28380-1 IHE GLOBAL STANDARDS ADOPTION, PARTS 1 TO 3

#### *13.3.4.1 Introduction*

Long overdue work on bringing to publication the following documents relating to IHE processes:

- *ISO/DTR 28380-1 Health informatics - IHE global standards adoption – Part 1: Process*
- *ISO/DTR 28380-2 Health informatics - IHE global standards adoption Part 2 - Integration and content profiles*

TR 28380-1 passed DTR ballot in 2007; TR 28380-2 passed DTR ballot in 2008; and all comments have been resolved. However, substantial delays in proceeding to publication have been concerned with the formatting of the documents.

As IHE has now become a full TC 215 Liaison A organisation, its documents can be published by ISO in IHE format, provided that ISO's first (four) introductory sections (Introduction, Scope, Normative references, Terms & Definitions) are included as an overlay. This should make the publication process much easier.

- *ISO/TR 28380-3 Health informatics - IHE Global Standards Adoption - Part 3:Deployment*

New work is now proposed for this third part with IHE being admitted to JIC, there seems to be more prospect that the ISO/DTR 28380-series will progress.

#### *13.3.4.2 Progress to date*

At this time, there are three Technical Reports that have been brought forward from IHE to ISO/TC 215.

- ISO/TR 28380-1 IHE Global Standards Adoption – Process has been the subject of a DTR ballot. Comments have been collated and an amended draft will be prepared for publication.
- ISO/TR 28380-2 IHE Global Standards Adoption - Integration and Content Profiles is ready to proceed to publication.
- ISO/N941 IHE Global Standards Adoption – Deployment. This report has been amended to take account of committee comments and will be circulated prior to submission to a three month DTR ballot

There is a great deal of interest in growing the collaboration between ISO/TC 215 and IHE International, and as a Category A Liaison, these opportunities increase.

#### *13.3.4.3 Relevance to Australia*

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 2**<br><br>**DTR 2830-3 IHE adoption process Part 1 Process**<br>**DTR 2830-3 IHE adoption process Part 2 Integration and Content Profiles** | ISO/TR 28380-1 IHE Global Standards Adoption – Process has been the subject of a DTR ballot. Comments have been collated and an amended draft will be prepared for publication.<br><br>ISO/TR 28380-2 IHE Global Standards Adoption - Integration and Content Profiles is ready to proceed to publication.<br><br>**Action: Ensure that State and Territory CIO's are aware of these publications when they are made available.** | **DoHA**<br><br>**State and Territory CIOs** |
| **WG 2**<br><br>**DTR 2830-3 IHE adoption process Part 3 Deployment** | ISO/N941 IHE Global Standards Adoption – Deployment. This report has been amended to take account of committee comments and will be circulated prior to submission to a three month DTR ballot.<br><br>**Action: Australian experts should continue to contribute and assist with completion of this item before the next TC 215 meeting.** | **IT-014** |

# 14. WG 3 SEMANTIC CONTENT

| | |
|---|---|
| Australian Delegate Attendance | Renato Iannella, Heather Grain (partly via teleconference on Monday 22nd April 2013) |

## 14.1 BACKGROUND

This working group focuses on the processes and requirements for the representation of semantic content, but not on the content of systems which do so. Over the last few months in teleconference the group has agreed that the general term for the area in which we work includes terminological resources (including terminologies, classifications, code systems etc.) and knowledge resources.

## 14.2 RECENT ACTIVITY

### 14.2.1 CURRENT PUBLICATIONS

The following documents have been recently published:

- ISO 13120 Syntax to represent the content of healthcare classification systems. Classification Markup Language (ClaML)
- ISO/TS 13582 Sharing of OID Registry Information
- EN ISO 13119 Clinical knowledge resources – metadata

### 14.2.2 CURRENT WORK ITEMS

| Number | Title | Status |
|---|---|---|
| 12310 | Principles and guidelines for the measurement of conformance in the implementation of terminological systems | PWI |
| 1828 | Categorial structure for terminological systems of surgical procedures (CEN EN) | FDIS - to ballot after this meeting |
| 17115 | Vocabulary for terminological systems | PWI |
| 13581 | Health informatics: Sharing of OID registry information | CD - in comment disposition |
| 13582 | Health informatics: Communication model and XML interface specification for OID registries | Awaiting 13581 |
| 17439 | Structure and maintenance of the health informatics glossary | In test |
| 12300 | Principles of mapping between terminological systems | DTR - to ballot after this meeting |
| 14668 | Guidelines for principles and desirable features of Clinical Decision Support | CD in preparation |
| 13119 | Clinical knowledge resources - metadata | At ballot |
| 18104 | Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems | At ballot |
| 13120 | Health informatics – A syntax to represent the content of classification systems in health care | DIS |
| 17117 | Terminological resources Part 1 – Framework | Preliminary work item |
| 16277-1 | Categorial structure of clinical finding in traditional | CD available |

| | | |
|---|---|---|
| | medicine- Part 1: Traditional East Asian Medicine | |
| 16843-1 | Categorial structures for representation of acupuncture Part 1: acupuncture points | NP passed ballot |
| 16843-2 | Categorial structures for representation of acupuncture Part 2: Needling | NP passed ballot |
| 17948 | ISO TS 17948 Health Informatics- Traditional Chinese medicine metadata | NP ballot comments disposed and new document ready for review |
| 17938 | ISO 17938 TS –health informatics- Semantic network framework and coding of Traditional Chinese Medicine language system. | NP ballot comments disposed and new document ready for review |
| 18062 | Categorial structures for representation of herbal medicaments in terminological systems | Initial draft awaiting comments |

## 14.3 PROGRESS AT THIS MEETING – CURRENT WORK ITEMS

The WG Convenor role is open for new nominations and will be discussed at the June teleconference. Australia needs to consider re-nomination of the current Convenor (Heather Grain).

The WG has suffered significantly from lack of Secretariat support. This has led to significant delays in project outcomes and inconsistencies and lack of clarity of project status and progress. Australia needs to consider this impact and make recommendations to remedy the lack of Secretariat support.

### 14.3.1 12310 – PRINCIPLES AND GUIDELINES FOR THE MEASUREMENT OF CONFORMANCE IN THE IMPLEMENTATION OF TERMINOLOGY SYSTEMS

#### *14.3.1.1 Introduction*

This work item was originally developed by Canada with support from Australia. It has been reviewed by both the ISO/TC 215 WG3 and HL7 Vocabulary communities and by IHTSDO Liaison. The work was not progressing so was cancelled until a leader with the time and resources to complete it could be found.

#### *14.3.1.2 Progress to date*

This item has been cancelled due to lack of progress.

#### *14.3.1.3 Proposed future work*

A decision will be made at the June teleconference meeting to progress this item to a New Project Ballot based on support from member countries

#### *14.3.1.4 Relevance to Australia*

This was a work item in which Australia (IT-014-02) members had expressed interest and to which NEHTA and Queensland Health provided comments.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 3**<br><br>**12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems** | Australia can support this work item as NEHTA have developed Conformance Profiles for Terminologies and Mappings for AMT and SNOMED-CT.<br><br>**Action: Australia needs to decide whether to support this work item.** | **IT-014-02**<br><br>**NEHTA** |

### 14.3.2 PREN ISO/DIS 1828 CATEGORIAL STRUCTURE FOR TERMINOLOGICAL SYSTEMS OF SURGICAL PROCEDURES

#### *14.3.2.1 Introduction*

This work item has come from Europe (CEN) and provides generally consistent structure to support comparison, mapping and development of terminological resources, including terminologies. It does not include content, but does represent the information model for generic representation of this information.

#### *14.3.2.2 Progress to date*

This item was not discussed at this meeting.

#### *14.3.2.3 Relevance to Australia*

This work and any similar work on categorial structures should be considered and used when developing health data collection and representation systems, when mapping or when considering the terminological resource which best suits a given need.

### 14.3.3 ISO 17115:2007 VOCABULARY FOR TERMINOLOGICAL SYSTEMS (VOTE)

#### *14.3.3.1 Introduction*

This item was originally published in 2007 but now needs considerable review and harmonisation of terms. The original content of VOTE was largely definition, which is no longer accepted for ISO standards. There is a need to both review the definitional content, and to provide a harmonious document which provides guidance for the structures and processes used in terminological resource development and definition.

#### *14.3.3.2 Progress to date*

The working group (WG3) made a resolution to combine ISO 15115:2007 Vocabulary of terminology with EN 12264:2005 Categorial structures for systems of concepts to have a single international ‘meta standard’ for Categorial Structures.

As such, EN 12264 is to be revised and prepare a working draft for circulation to WG3 by July 1st with revised draft and Form 4 ready for Sydney (01 September). An informal expert group will be created to contribute to the 17115 revision.

#### *14.3.3.3 Relevance to Australia*

This work is likely to assist Australian efforts to harmonise and improve health informatics terms and definitions as well as to support the development of terminological resources in general.

### 14.3.4 ISO/NP 13581: SHARING OF OID REGISTRY INFORMATION AND ISO/NP 13582: HEALTH INFORMATICS: COMMUNICATION MODEL AND XML INTERFACE SPECIFICATION FOR OID REGISTRIES

#### *14.3.4.1 Introduction*

These work items specify principles and processes that should be exhibited by developers and data administrators of OID (Object-Identifiers)-Registries and their applicant bodies. The primary target group for this document are those establishing OID-Registries and those (Industry, government bodies) using the services maintained by such organisations.

This project targets a Technical Report which:

- specifies procedures which are generally applicable to registration in the context of OID;
- provides guidelines for the establishment and operation of Registration Authorities; and
- provides guidelines for additional recommendations.

#### *14.3.4.2 Progress to date*

Australia has requested change of name for “ISO/PWI TR 13581 Guidance for maintenance of object identifiers (OIDS)” as it implies general maintenance of OIDs but should be scoped to OID Registries. As a result Australia should support the NWIP due soon for this project

#### *14.3.4.3 Relevance to Australia*

The issues which relate to sharing of OID registry information is an emerging one in Australia and therefore this item should continue to be watched by IT-014-02 and IT-014-06 who already have it on their international work programs.

### 14.3.5 ISO TS 17439 STRUCTURE AND MAINTENANCE OF THE HEALTH INFORMATICS GLOSSARY

#### *14.3.5.1 Introduction*

This work item represents procedures and guidelines including quality criteria for the development and maintenance of glossary content of the SKMT and is being tested through the updates and harmonisation activities being undertaken in conjunction with the review of 17115 (above).

#### *14.3.5.2 Progress to date*

There was agreement to go for Draft Technical Specification Ballot on this work item and a resolution for a name change to “Development of terms and definitions for the health informatics glossary”.

#### *14.3.5.3 Relevance to Australia*

This work is likely to assist Australian efforts to harmonise and improve health informatics terms and definitions as well as to support the development of terminological resources in general. The governance organisation allows a person to represent more than one organisation and therefore Heather Grain could represent IT-014 and WG3 thereby reducing overall resource requirements for Australia if this is desired.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 3**<br><br>**ISO TS 17439 STRUCTURE AND MAINTENANCE OF THE HEALTH INFORMATICS GLOSSARY** | **Action: Important for AU to follow and lead this work as foundational for terminology management.** | **IT-014-02** |

### 14.3.6 ISO TDR 12300 PRINCIPLES OF MAPPING BETWEEN TERMINOLOGICAL RESOURCES

#### *14.3.6.1 Introduction*

The benefits of data sharing and reuse are well known. That data should be collected once, and reused to the greatest extent possible is one of the key principles underpinning health informatics.

Mapping is the process of associating concepts from one terminological system to concepts in another terminological system and defining their equivalence in accordance with a documented rationale, and a given purpose. The terminological systems can be related (different versions of the same system) or completely different systems. The process identifies whether there is a relationship between the concepts, and if so, the level of meaning expressed by that relationship. It is a way to integrate different terminological systems used for different purposes – a bridge between them is required for interoperability and that bridge can be built through mapping. Thus different data sources can be compared and linked to enable the data to be exchanged between information systems. The end product (deliverable) of the process is a set of maps (relationships) between two terminological systems that defines the cardinality and degree of equivalence between concepts and rule set structures, and enables the automated translation between the terminological systems.

As an example in health care, data collected for communicating information about direct patient care (using clinical terminologies) can be reused for statistical and administrative reporting of morbidity data (using clinical classifications), by transforming the terminological representations into classification representations.

Maps are always built for a purpose. Skilled mapping personnel are required to ensure the quality and integrity of map development and mapping rules. The development of rules (either paper based or computer algorithms) that support conversion of data are crucial to standardize the process and create logical maps that a computer can use repeatedly to consistently convert data from one form to another.

This Technical Report provides guidance for organizations charged with creating or applying mappings to meet their business needs. It identifies issues and discusses both the potential in and the limitations of applying the maps. This Report does not provide information or guidance on the intellectual property rights of those who own the various terminologies or classifications.

This Technical Report also establishes and harmonizes the basic principles for developing, maintaining and using maps, and gives guidelines for good practice that underpin the mapping process.

#### *14.3.6.2 Progress to date*

Countries need to review the Disposition of Comments and return any feedback to the WG (Heather Grain is the Project Lead). If the feedback is resolved, then the item will go out for 2nd ballot - after changes from Disposition of Comments are applied.

#### *14.3.6.3 Relevance to Australia*

Though there are not likely to be major changes to the document this time, the input of interested parties in Australia needs to be actively sought.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 3**<br><br>**TDR 12300 Principles of mapping between terminological resources** | Very important for AU to follow due to the requirements in local mapping terminologies with AMT (for example).<br><br>**Action: NEHTA and IT-014-02 to monitor this work item** | **NEHTA**<br><br>**IT-014-02** |

### 14.3.7 ISO/NP/TR 14668 GUIDELINES FOR PRINCIPLES AND DESIRABLE FEATURES OF CLINICAL DECISION SUPPORT

#### *14.3.7.1 Introduction*

This project is based upon the Australian publication, HB 307-2007 Guide to the principles and desirable features of clinical decision support systems. International input is sought through this project to improve and internationalise the Australian work.
Progress to date

#### *14.3.7.2 Progress to date*

The New Project has been cancelled due to time limits. It will go forward as a new work item proposal while the draft is prepared.

Draft to be prepared and circulated to WG3 and WG1 in June; WGs to provide comments to ensure WD ready for NP in September four weeks before October meeting in Sydney.

#### *14.3.7.3 Relevance to Australia*

This is an Australian work item, with Australian leadership.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 3**<br><br>**ISO/NP/TR 14668 GUIDELINES FOR PRINCIPLES AND DESIRABLE FEATURES OF CLINICAL DECISION SUPPORT** | This item is relevant to IT-014-13 work program on Clinical Decision support.<br><br>**Action: IT-014-13 to monitor progress.** | **IT-014-13** |

### 14.3.8 ISO/CD 13940 HEALTH INFORMATICS – SYSTEM OF CONCEPTS TO SUPPORT CONTINUITY OF CARE

#### *14.3.8.1 Introduction*

This item defines the categories of concepts required to represent continuity of care and provides a mechanism to support selection of required elements for a given purpose, integration of functionality requirements and definitional components. This work originated in CEN and has been trialled in the UK and other countries.

#### *14.3.8.2 Progress to date*

Some discussion of ContSys was undertaken at Mexico in a joint session of WG 1 and WG 3, but this was limited due to the confusion over the ISO/TC 215 policies of concerning discussion documents out to ballot. (Further comments are provided in the report from WG 1 at Section 11.3.7).

#### *14.3.8.3 Relevance to Australia*

There has been considerable interest in this item in Australia as a mechanism which informs both PCEHR content and development as well as work on clinical data models.

### 14.3.9 PREN ISO/DIS 13120 – HEALTH INFORMATICS – A SYNTAX TO REPRESENT THE CONTENT OF CLASSIFICATION SYSTEMS IN HEALTH CARE

#### *14.3.9.1 Introduction*

Healthcare classifications are developed and distributed in a variety of informal formats, such as MS Word, with little consistency in approach between developers. Exchanging data from these systems or attempting to parse the informal text into a more formal structure, say for publishing purposes, presents many challenges because unwanted mistakes are easily made, and difficult to detect. For example, the accidental deletion of a tab can transform a sibling rubric into a parent. ASCII files with comma separated value fields is

another mechanism widely used for storing and transferring data, but as a solution here is limited by insufficient formal structuring capabilities.

In the interests of safely exchanging and distributing the content and hierarchical structure of healthcare classification systems, this International Standard presents a simple XML specification, ClaML, for exchange and distribution of healthcare classifications systems. XML is the chosen format for this International Standard as: a) XML provides the necessary structuring elements, and b) there are many readily available XML parsers in existence.

This International Standard builds on CEN/TS 14463:2002. In that CEN/TS 14463:2002 primary focus was to support electronic data processing. Assessment of CEN/TS 14463:2002 revealed the need to extend the areas for version control and maintenance within the Standard and this was supported by insight from the health informatics community who have been active in the implementation of this International Standard. This International Standard is intended to serve as the core representation from which all publication forms can be derived. It contains information of a depth sufficient to uniquely identify and describe the structure and relevant element of healthcare classification systems. This International Standard does not intend to prescribe to developers how healthcare classification systems should be structured.

Explain the meaning of the structuring elements. This International Standard is not meant to be a direct format for printing or viewing the content of a healthcare classification system. Views and prints shall be derived from this representation by post processing.

#### *14.3.9.2 Progress to date*

This item has now been published.

#### *14.3.9.3 Relevance to Australia*

This work is used extensively in Europe and should be reviewed by AIHW, DOHA and NEHTA IT-014 representatives to identify any specific concerns or issues relevant to Australia.

### 14.3.10 ISO 17117 TERMINOLOGICAL RESOURCES PART 1 – FRAMEWORK

#### *14.3.10.1 Introduction*

This is a major update to the existing publication on this topic. This document defines the characteristics of different types of terminological resources and assists in defining how they can be consistently described, governed and evaluated.

#### *14.3.10.2 Progress to date*

This item is a revision of ISO 17117:2002 Controlled health terminology – Structure and high-level indicators. The New Project was approved in 2009 but then cancelled due to failure to meet timelines.

A New Draft and Form 4 was presented for discussion and decision was to reinstate the item with enough supporting member countries. This item is a key dependency to many WG3 work items.

#### *14.3.10.3 Relevance to Australia*

There has been considerable interest in this item in Australia and the presentation has already been distributed to IT-014-02 and is an active item on their international work item list.

### 14.3.11 ISO TS 16277-1 TS HEALTH INFORMATICS - CATEGORIAL STRUCTURES OF CLINICAL FINDING IN TRADITIONAL MEDICINE-PART 1: TRADITIONAL EAST ASIAN MEDICINE

#### *14.3.11.1 Introduction*

This work uses the methodology consistent with western medicine to identify variations and requirements for the representation of traditional East Asian medicine.

#### *14.3.11.2 Progress to date*

The WG accepted a resolution to change name from “East Asian” to “Chinese, Japanese, Korean” which was a recommendation from the expert group.

The item will proceed to Draft Technical Specification (DTS) Ballot.

#### *14.3.11.3 Relevance to Australia*

There has been considerable interest in this item in Australia as a mechanism which informs both PCEHR content and development as well as work on clinical data models.

### 14.3.12 ISO/DIS 18104: HI – CATEGORIAL STRUCTURES FOR REPRESENTATION OF NURSING DIAGNOSES & NURSING ACTIONS IN TERMINOLOGICAL SYSTEMS

#### *14.3.12.1 Introduction*

This work item focused on the conceptual structures that are the basis of nursing terminologies in order to support interoperability. A major purpose of this initial International Standard was ‘to establish a nursing reference terminology model consistent with the goals and objectives of other specific health terminology models in order to provide a more unified reference health model.

#### *14.3.12.2 Progress to date*

Ballot for this item ended on 2013-01-23 and was approved.

Disposition and Revision (FDIS) for discussion and decision on progress to FDIS ballot was agreed by WG3.

### 14.3.13 ISO/AWI IS 16278 CATEGORICAL STRUCTURES TERMINOLOGICAL SYSTEMS HUMAN ANATOMY

#### *14.3.13.1 Introduction*

This work item defines the characteristics required to synthetically describe the organisation and content of human anatomy within a terminological system. It is intended primarily for use with computer-based applications such as clinical electronic health records, decision support and for various bio-medical research purposes.

#### *14.3.13.2 Progress to date*

The NWIP was positive with 5 experts nominated and a number of comments received. The item was discussed for progression to CD Ballot and agreed (under Vienna agreement).

A resolution was also made to correct the number of the work item and confirm the name as pre*EN ISO/AWI 1828 Categorical structures terminological systems of human anatomy.*

### 14.3.14 ISO 17583 HI TERMINOLOGY CONSTRAINTS [BINDING] FOR CODED DATA ELEMENTS EXPRESSED IN ISO HARMONIZED DATA TYPES USED IN HEALTHCARE INFORMATION INTERCHANGE

#### *14.3.14.1 Introduction*

This item is a joint project with WG2.

#### *14.3.14.2 Progress to date*

A number of issues from the ballot were discussed and guidance on possible solutions outlined with some requiring expert group resolution. .A second Committee Draft Ballot was requested (via WG2).

#### *14.3.14.3 Relevance to Australia*

Australia should contribute to second CD ballot.

## 14.4 PRELIMINARY AND NEW WORK ITEMS

### 14.4.1 ISO PWI – CONCEPTUAL FRAMEWORK FOR REPRESENTATION OF TREATMENT AND DIAGNOSTIC NON-CHEMICAL STIMULATION METHODS

Note for clarification: this work item is not a candidate for activity in Joint Working Group 10 since it is general to all forms of healthcare (i.e. not specific to traditional medicine) and will be undertaken within WG3.

#### *14.4.1.1 Introduction*

This work defines and clarifies the requirements for representation of the concepts for stimulation (non chemical) in all healthcare environments, traditional as well as western.

This has been identified as a significant gap in the current representations provided in terminological resources.

#### *14.4.1.2 Progress to date*

Comments have been requested and Form 4 to be circulated to WG3. Name change was not accepted but maybe requested in Sydney with New Project Ballot.

#### *14.4.1.3 Relevance to Australia*

Australia is to determine the priority of this item as well as process for obtaining relevant feedback.

### 14.4.2 ISO NP - HEALTH INFORMATICS: PROFILING FRAMEWORK AND CLASSIFICATION FOR TRADITIONAL MEDICINE INFORMATICS STANDARDS DEVELOPMENT PART 1: TRADITIONAL CHINESE MEDICINE (TMC)

#### *14.4.2.1 Introduction*

The target users of this piece of work are the TCM informatics standards developers, and users of TCM informatics standards. This work intends to provide assistance on the development and content of TCM standards related to health informatics. It was suggested that the target users also includes those who review TCM health informatics standards.

#### *14.4.2.2 Progress to date*

The Form 4 and Draft are ready for NP ballot and will be developed in parallel with ISO/AWI TS 18528 Informatics Standards Functional Classification (WG1). The issue as to the location of this item was resolved to be with TM-TF (and be reported through WG1).

#### *14.4.2.3 Relevance to Australia*

To be determined when the committee draft is available for review.

# 15. JWG 1 AND TRADITIONAL MEDICINE TASK FORCE

| | |
|---|---|
| Australian Delegate Attendance | No attendance was possible at this meeting |

## 15.1 BACKGROUND

This Task Force which reports through WG3 considers items concerning various types of Traditional Medicines such as Asian Traditional Medicines. It was formed to help resolve a perceived overlap between TC 215 and TC 249, in the area of TCM Informatics, and worked towards creation of ISO/TC 249/JWG1 between TC 215 and TC 249 to handle such items in the future.

Most current work items under the Task Force are focussed on Traditional Chinese Medicine (TCM) and are being progressed under the aegis of ISO/TC 249/JWG1 (JWG 1).

## 15.2 RECENT ACTIVITY

### 15.2.1 CURRENT PUBLICATIONS

### 15.2.2 CURRENT WORK ITEMS

- NP TS 16843-1 HI: Categorial structures for representation of acupuncture -- Part 1: Acupuncture points.
- NP TS 16843-2 HI: Categorial structures for representation of acupuncture -- Part 2: Needling.
- NP 18062 HI - Categorical structure for representation of herbal medicaments in terminological systems.
- PWI HI- Conceptual framework for representation of sites in body surface nonchemical stimulation;
- PWI HI, Conceptual framework for representation of treatment and diagnostic non-chemical stimulation methods.
- AWI TS 17948 HI - Traditional Chinese medicine literature metadata.
- AWI TS 17938 HI - Semantic network framework of Traditional Chinese medicine language system.
- NP TS 16277-1 HI- Structure of representation of clinical findings in traditional medicine - Part1: Traditional East Asian Medicine.
- ISO/PWI profiling framework and classification traditional medicine standards development. – Part 1 Traditional Chinese Medicine (New work item)

## 15.3 PROGRESS AT THIS MEETING

The following work was scheduled for JWG 1 at the Mexico City meeting and it was noted that active JWG 1 sessions were in train for several days but there was no Australian delegate provided to cover the activity. Topics scheduled on the agenda for detailed discussion included:

- ISO/PWI profiling framework and classification Traditional Medicine standards development. – Part 1 Traditional Chinese Medicine

  Progress of this item was reported through WG 3 – see Section 14.4.2 above.

- ISO/PWI Traditional Chinese Medicine – Categories of SNOTCM-CT
- ISO/AWI Coding system of Chinese Medicine – Part 1 Coding rules for decoction pieces [an AWI approved by TC 249 to be led by TC 249]

# 16. WG 4 SECURITY, SAFETY AND PRIVACY

| | |
|---|---|
| Australian Delegate Attendance | No Attendance at this meeting |

## 16.1 BACKGROUND

Working Group 4 defines standards for technical measures to protect and enhance the confidentiality, availability, and integrity of health information, and also accountability for users, as well as guidelines for security management in healthcare.

## 16.2 RECENT ACTIVITY

### 16.2.1 CURRENT PUBLICATIONS

### 16.2.2 CURRENT WORK ITEMS

| ISO Standard Number | Name of Standard | Type of Publication | Date | Comment |
|---|---|---|---|---|
| 21091 | Directory services | EN-IS | 13/08/2012 | Awaiting FDIS ballot |
| 27789 | Audit trails | EN-IS | 23/07/2012 | Awaiting FDIS registration |
| 22600-1 | PMAC-1 Overview & policy mgt | EN-IS | 16/08/2012 | Awaiting DIS ballot |
| 22600-2 | PMAC-2 Formal models | EN-IS | 16/08/2012 | Awaiting DIS ballot |
| 22600-3 | PMAC-3 Implementations | EN-IS | 16/08/2012 | Awaiting DIS ballot |
| 14441 | Compliance testing | TS | 14/09/2012 | Awaiting DTS/FDIS registration |
| 17090-1 | PKI-1 Overview dig.cert. sevices | IS | 17/06/2011 | SR ballot comments reviewed |
| 17090-2 | PKI-2 Certificate profile | IS | 17/06/2011 | SR ballot comments reviewed |
| 17090-3 | PKI-3 Policy mgt certific.authority | IS | 17/06/2011 | SR ballot comments reviewed |

To be discussed at this meeting and detailed listed in the sections below:

| ISO Standard Number | Name of Standard | Type of Publication | Date | Comment | Progress |
|---|---|---|---|---|---|
| 17090-4 | PKI-4 Signatures | IS | 13/06/2012 | NP ballot comments reviewed | Discuss updated DTS WG4-N532 |
| 17975 | Patient consent | TS | 15/06/2012 | NP ballot comments reviewed | Discuss updated DTS WG4-N533 |

| ISO Standard Number | Name of Standard | Type of Publication | Date | Comment | Progress |
|---|---|---|---|---|---|
| 17791 | Standards for safe health software | TR | 3/11/2011 | NP ballot comments reviewed | Discuss updated DTR WG4-N535 |
| 25238 | Classification of safety risks | TS | 17/09/2010 | SR ballot comments reviewed | |
| 27799 | ISM-H using ISO/IEC 27002 | IS | 17/09/2011 | SR ballot comments reviewed | Planning/preparing revision |
| 25237 | Pseudonymization | TS | 17/03/2012 | SR ballot comments received | Planning/preparing revision |
| 21298 | Functional & structural roles | IS | 17/03/2012 | Awaiting Rev.NP/DIS registr. | |
| 22857 | Trans-border flow ISO | IS | 30/11/2011 | DIS ballot comments reviewed | Discuss comments resolution and migration path |
| 16864 | Trans-border flow new | EN-IS | 10/03/2011 | NP ballot comments reviewed | |
| 16114 | EHR migration | TR | 26/02/2010 | NP ballot comments reviewed | WG4 comments expected |
| 13606-4 | EHR communication-4: Security | IS | 7/06/2012 | NP ballot ends 2012-09-04 | ??? |
| | Information Privacy Education | TR | 7/08/2012 | NP ballot ends 2012-11-07 | |

There is additional work with CEN on Health Cards as detailed below:

| | | | | |
|---|---|---|---|---|
| 21549-1 | Cards-General structure | EN-IS | 10/06/2011 | Awaiting FDIS registration |
| 21549-2 | Cards-Common objects | EN-IS | 28/06/2012 | DIS ballot ends 2012-11-28 |
| 21549-3 | Cards-Limited clinical data | EN-IS | 28/06/2012 | DIS ballot ends 2012-11-28 |
| 21549-4 | Cards-Extended clinical data | EN-IS | 28/06/2012 | DIS ballot ends 2012-11-28 |
| 21549-5 | Cards-Identification data | EN-IS | 17/06/2011 | Rev.NP ballot ends 2012-1015 |
| 21549-6 | Cards-Administrative data | EN-IS | 8/08/2012 | IS confirmed |
| 21549-7 | Cards-Medications | EN-IS | 17/09/2010 | Awaiting Rev.NP ballot |
| 21549-8 | Cards-Links | EN-IS | 8/06/2010 | IS published |
| 20301 | HC-General characteristics | IS | 16/08/2012 | DIS ballot ends 2012-11-16 |
| 20302 | HC-Numbering and issuer ID | IS | 17/03/2010 | |

## 16.3 PROGRESS AT THIS MEETING

There was no specific Australian delegate assigned to cover the output of this working group during this meeting.

### 16.3.1 REVISION OF PUBLISHED TS 21091 TO IS:HEALTH INFORMATICS – DIRECTORY SERVICES FOR HEALTH CARE PROVIDERS, SUBJECTS OF CARE AND OTHER ENTITIES

#### *16.3.1.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.1.2 Relevance to Australia*

No action required at this time.

### 16.3.2 DIS 27789 HEALTH INFORMATICS – AUDIT TRAILS FOR ELECTRONIC HEALTH RECORDS

Trust in electronic health records requires physical and technical security elements along with data integrity elements. Among the most important of all security requirements to protect personal health information and the integrity of records are those relating to audit and logging. These help to ensure accountability for subjects of care who entrust their information to electronic health record (EHR) systems. They also help to protect record integrity, as they provide a strong incentive to users of such systems to conform to organizational policies on the use of these systems.

Effective audit and logging can help to uncover misuse of EHR systems or EHR data and can help organisations and subjects of care obtain redress against users abusing their access privileges. For auditing to be effective, it is necessary that audit trails contain sufficient information to address a wide variety of circumstances.

Audit logs are complementary to access controls. The audit logs provide a means to assess compliance with organizational access policy and can contribute to improving and refining the policy itself. But as such a policy has to anticipate the occurrence of unforeseen or emergency cases, analysis of the audit logs becomes the primary means of ensuring access control for those cases.

#### *16.3.2.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.2.2 Relevance to Australia*

No action is required at this time.

### 16.3.3 DTS 14441 HEALTH INFORMATICS – SECURITY AND PRIVACY REQUIREMENTS FOR COMPLIANCE TESTING OF EHR SYSTEMS

#### *16.3.3.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.3.2 Relevance to Australia*

No action required at this time.

### 16.3.4 REVISION OF TS22600: PARTS 1-3 TO PRIVILEGE MANAGEMENT AND ACCESS CONTROL

#### *16.3.4.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.4.2 Relevance to Australia*

No action required at this time.

### 16.3.5 EN-ISO 27799 HEALTH INFORMATICS – INFORMATION SECURITY MANAGEMENT IN HEALTH USING 27002 (ISO/IEC JTC 1/SC 27 N10572 N10628)

#### *16.3.5.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.5.2 Relevance to Australia*

Currently IT-014-04 is undertaking a revision of HB 174 which is based on ISO 27799. The changes that result from both ISO 27002 and subsequently ISO 27799 may have an impact on this work, or at the least will require that IT-014-04 will need to review HB 174 when these standards are revised to ensure consistency and coverage.

SC 27 has some 700 comments on 27002 and some contentious items. So, since this will take a significant amount of time, WG4 decided to start review of 27799 before the revisions on 27002 are received.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4**<br><br>**EN-ISO 27799 Health Informatics – Information Security Management IN health using 27002 (ISO/IEC/JTC1/SC27 n10572 n10628)** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.6 ISO 21298 HEALTH INFORMATICS – FUNCTIONAL AND STRUCTURAL ROLES (N160)

This work item was started in 2003. A systematic review for ISO/TS 21298 Health Informatics – Functional and structural roles is currently on the work agenda. WG4 recommends to issue a new work item proposal targeting an International Standard. (Form 4 needs to be submitted to the ISO secretariat).

#### *16.3.6.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.6.2 Relevance to Australia*

No action required at this time.

### 16.3.7 ISO 17090-4 HEALTH INFORMATICS – PUBLIC KEY INFRASTRUCTURE – PART 4: DIGITAL SIGNATURES FOR HEALTHCARE DOCUMENTS (SYSTEMATIC REVIEW OF PARTS 1-3. TC215 –N960, WG4-N532)

ISO 17090 consists of four parts under the general title of 'Health Informatics – Public key infrastructure:

- Part 1: Overview of digital certificate services;
- Part 2: Certificate profile;
- Part 3: Policy management of certification authority; and
- Part 4: Digital signatures for healthcare documents.

Healthcare information is exchanged via many mediums. The Internet provides a highly cost-effective and accessible means of exchanging information, but it is also an insecure vehicle that demands additional measures be taken to maintain the privacy and confidentiality of information.

The proper deployment of digital certificates requires a blend of technology, policy and administrative processes that enable the exchange of sensitive data in an unsecured environment by the use of "public key cryptography" to protect information in transit and "certificates" to confirm the identity of a person or entity.

Interoperability of digital certificate technology and supporting policies, procedures and practices is of fundamental importance if information is to be exchanged between organizations and between jurisdictions in support of healthcare applications

Many countries are deploying digital certificates to support secure communications within their national boundaries. Inconsistencies will arise in policies and procedures between the certification authorities (CAs) and the registration authorities (RAs) of different countries if standards development activity is restricted to within national boundaries.

This Standard describes the common technical, operational and policy requirements that need to be addressed to enable digital certificates to be used in protecting the exchange of healthcare information within a single domain, between domains and across jurisdictional

boundaries. Its purpose is to create a platform for global interoperability. It specifically supports digital certificate enabled communication across borders, but could also provide guidance for the national or regional deployment of digital certificates in healthcare.

This standard supports the ability to interchange of digital signatures and the prevention of incorrect or illegal digital signatures by providing minimum requirements and formats for generating and verifying digital signatures and related certificates.

Furthermore, it defines the provable compliance with a PKI policy necessary in the domain of healthcare. This standard adopts long-term signature format to ensure integrity and non-repudiation in long-term electronic preservation of health information.

The standard conforms to ISO/ETSI standards for long-term signature formats to improve and guarantee interoperability in the healthcare field. There is no limitation regarding the data format and the subject the signature is created for.

#### *16.3.7.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.7.2 Proposed future work*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.7.3 Relevance to Australia*

The relevance of this item to Australia is in its review for consistency with Australia's approach to PKI and the National Authentication Services for Health (NASH). In the request for use cases for the Annex to the existing draft, to ensure alignment between the Australian approach and the proposed International Standard, NEHTA should be asked to contribute to the document and comments process.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4**<br>**ISO 17090-4 Health informatics – Public key infrastructure – Part 4: Digital signatures for healthcare documents** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.8 ISO 25237 PSEUDONYMIZATION (TC215 – N969)

Two interim calls to resolve comments were planned but did not occur. The intent is to progress this to a new International Standard; however the key problem is that we do not have a lead for the project.

#### *16.3.8.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.8.2 Proposed future work*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.8.3 Relevance to Australia*

It is very important, given the work Australia has already done on its own Pseudonymisation, that this review is consistent with the Australian standard. Dr Trish Williams will be listed as an expert on this work item (not lead).

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4<br>ISO 25237<br>Pseudonymization<br>(TC215 – N969)** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.9 ISO-DIS-22857 GUIDLINES ON DATA PROTECTION TO FACILITATE TRANS-BORDER FLOWS OF PERSONAL HEALTH INFORMATION (WG4-N534) AND ISO 16864 DATA PROTECTION IN TRANS-BORDER FLOWS OF PERSONAL HEALTH INFORMATION

As part of a systematic review, there is a plan is to merge the existing two CEN documents on this topic and the ISO 22857 documents into 16864. However, the correct processes to conclude the systematic review ballots needs to be concluded before this can occur.

ISO/DIS 22857 International health-related applications may require personal health data to be transmitted from one nation to another across national borders. This is very evident in telemedicine or when data are electronically dispatched for example in an email or as a data file to be added to an international database. It also occurs, but less obviously, when a database in one country is viewed from another for example over the Internet. That application may appear passive but the very act of viewing involves disclosure of that data and is deemed ‘processing’. Moreover it requires a download that may be automatically placed in a cache and held there until 'emptied' - this also is processing and involves a particular security hazard. This Standard seeks to draw on, and harmonise, data protection requirements relating to the transfer of personal health data across international boundaries as given in authoritative international documents. It also seeks to take into account a range of national requirements so as to avoid, as far as practicable, conflict between the requirements of this Standard and national specifications. This Standard applies, however, solely to transfer of personal health data across national borders. It explicitly does not seek to specify national data protection requirements. The creation of a set of requirements aimed at being acceptable to all countries, whether they be transmitting or receiving personal health data to/from other countries, inevitably means adopting the most stringent of requirements. This means that organisations in some countries would need to apply extra or more severe data protection requirements when transmitting to, or receiving personal health data from, other countries than might be necessary for handling such data

within their own boundaries. Although that might be the case, that does not mean that those extra or more severe requirements must be applied to solely national applications.

#### *16.3.9.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.9.2 Proposed future work*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.9.3 Relevance to Australia*

Australia should consider review of this work through IT-014-04 committee. Whilst these standards were previously EU centric the combining of the proposed combining of standards will see their wider applicability.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4**<br><br>**ISO-DIS-22857 Guidelines on data protection to facilitate trans-border flows of personal health information (WG4-N534) and ISO 16864 Data Protection in trans-border flows of personal health information** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.10 17975: HEALTH INFORMATICS – PRINCIPLES AND DATA STRUCTURES FOR CONSENT IN THE COLLECTION, USE OR DISCLOSURE OF PERSONAL HEALTH INFORMATION (WG4-N533)

This Technical Specification defines the different models of informational consent (i.e., consent to collect, use or disclose information) that are frequently used by organisations to obtain permission form subjects of care to process their personal health information. Requirements, arising from good practices, are specified for each model of consent. Adherence to these requirements will assure data subjects and parties that process personal health information that the consent to do so has been properly obtained and correctly specified.

#### *16.3.10.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.10.2 Proposed future work*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.10.3 Relevance to Australia*

Dr Trish Williams is the nominated Australian expert on this work item. There has been ongoing work via teleconferences on this over the last few months. Further review will be undertaken and an alignment where possible with Australia's various methods of consent reviewed. This standard is important as it provides a foundation for consent processes nationally and internationally.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4**<br>**17975: Health informatics – Principles and data structures for consent in the collection, use or disclosure of personal health information (WG4-N533)** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.11 ISO/DRT 16114 HEALTH INFORMATICS – SECURITY ASPECTS OF EHR MIGRATION (WG4-N488)

#### *16.3.11.1 Introduction*

At the previous TC 215 meeting, Pekka Ruotsalainen (Finland) reported that the task group responsible for progressing this item suggested that it be withdrawn and a new item proposed through negotiation with WG 1.

#### *16.3.11.2 Progress to date*

During a joint session of WG 1 and WG 4, there was discussion on proceeding with a new project addressing EHR migration – to be based on the earlier draft but with a broader scope than EHR security aspects of EHR migration.

Luuc Posthumus (Netherlands) led discussion on behalf of Pekka Ruotsalainen, who was not able to be present in Mexico City. Points noted included:

- A TR proposal was produced some years ago for migration of EHR systems. However, it was not possible to have this solely focussed on security. This project was therefore cancelled at the Vienna meeting.
- The content of the previously proposed draft TR is available to support a revised work item but, while it focuses on security aspects of EHR migration it could be extended to consider migration of EHRs in general.
- Pekka Ruotsalainen would not be able to lead the proposed new project, which would be most appropriately managed by WG 1, rather than WG 4.
- Members of WG 1 indicated that they could take on progressing the project as a preliminary work item but there was no one prepared and available to commit to being the project lead or to prepare the project proposal.

- Members were asked to form a group to consider preparing a project proposal for this work. Those interested in assisting are Walter Suarez, Marion Lyver, Dipak Kalra, and Mihoko Okada.

#### *16.3.11.3 Proposed future work*

A Project Leader and participating experts should be identified

Aim: to produce a completed Form 4 and TC resolution on the NP

#### *16.3.11.4 Relevance to Australia*

No action required at this time.

### 16.3.12 HEALTH CARDS

Since Australia is not looking at the adoption of health cards, there is no specific interest of action required at this time.

### 16.3.13 NP- MEDICAL INFORMATION PRIVACY OFFICER EDUCATION

#### *16.3.13.1 Progress to date*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.13.2 Proposed future work*

Not reported as no delegate provided to cover meetings of this WG.

#### *16.3.13.3 Relevance to Australia*

Australia needs to review this work to see if it has merit in the Australian context and if this is an area that is lacking internationally.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4**<br>**NP- Medical Information Privacy Officer Education** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.14 LIAISON WITH ISO/IEC JTC1/SC 2 INFORMATION TECHNOLOGY - SECURITY TECHNIQUES (WG4-N540)

This section is a report on the activities of ISO/IEC JTC 1/SC 27 in regard to projects that are of specific interest to ISO/TC 215 WG4. Please note the N-numbers cited are those of the IEC and ISO/TC 215:

I. Liaison statement to ISO/TC 215/WG 4 on Identity Management, Privacy Technology, and Biometrics: ISO/IEC JTC 1/SC 27/WG 1 and ISO/IEC JTC 1/SC 27/WG 5 would like to thank ISO/TC 215/WG 4 for their continued interest in their work.

II. WG 1 advises TC 215 that ISO/IEC 27002 is currently under revision and is expected to continue this revision process for a minimum of a further 12-months. Furthermore, ISO/IEC JTC 1/SC 27/WG 5 is pleased to pre-announce a Workshop on Privacy and Identity Management in Brussels on 22nd January 2013, which will be jointly conducted by ISO/IEC JTC 1/SC.

III. 27/WG 5 with ABC4Trust to reach out and discuss current projects and activities. Experts from Liaison Organisations are warmly invited to participate and are kindly requested to contact the ISO/IEC JTC 1/SC 27 Secretariat for more information.

#### *16.3.14.1 Current Projects:*

- ISO/IEC 29100 - Privacy Framework has been published on 2011-12-15.
- ISO/IEC 29101 - Privacy Architecture Framework remains on CD (Committee Draft) status.
- ISO/IEC 29115 l X.1254 - Entity Authentication Assurance Framework, common text project with ITU-T, will be submitted for an FDIS (Final Draft International Standard) ballot to National Bodies.
- ISO/IEC 29191 - Requirements for partially anonymous, partially un-linkable authentication will be submitted for a DIS (Draft International Standard) ballot to National Bodies.
- ISO/IEC 24760 - A Framework for Identity Management. Part 1 “Terminology and Concepts” has been published on 2011-12-15. Part 2 "Reference architecture and requirements" and Part 3 "Practice" will be further circulated as WDs (Working Drafts).
- ISO/IEC 29146 - A Framework for Access Management remains on WD status.
- ISO/IEC 29190 - Privacy Capability Assessment Model remains on WD status.
- ISO/IEC WD 27018 - Code of practice for data protection controls for public cloud computing services will remain on WD status.
- ISO/IEC NP 17922 l X.bhsm - Telebiometric authentication framework using biometric hardware security module has been accepted by ISO/IEC JTC 1/SC 27 as common text project with ITU-T, and will be made available as a first WD.
- ISO/IEC 24761 - Authentication context for biometrics has been confirmed after the 1st periodic pre-review and a technical corrigendum will be produced.
- ISO/IEC JTC 1/SC 27/WG 5 SD1 Roadmap will be further updated upon National Body (NB) comments.
- ISO/IEC JTC 1/SC 27/WG 5 SD2 – Part 1: Privacy References List is available via the website of JTC 1/SC 27 and will be further updated upon NB contributions.
- ISO/IEC JTC 1/SC 27/WG 5 SD3 Harmonized Vocabulary Effort will further be updated upon NB comments.

#### *16.3.14.2 New projects and study periods:*

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **WG 4**<br>**ISO/IEC WD 29190 – Privacy capability maturity model (not an ISO project, but from a liaison committee).** | To be reviewed in due course when formal minutes of meeting received. | |

### 16.3.15 DATA SEGMENTATION FOR PRIVACY PILOT (DS4P)

#### *16.3.15.1 Relevance to Australia*

Whilst relevant to Australia in the future, it is also being closely monitored through HL7 by the Australian delegation. There are no actions necessary at this time.

# 17. WG 6 PHARMACY AND MEDICINES

| | |
|---|---|
| Australian Delegate Attendance | Michael Steine |

## 17.1 BACKGROUND

The purpose of WG6 Pharmacy and Medicines Business is to establish standards in the domain of pharmacy and medication. This includes areas such as drug research and development, regulation, supply chain, usage and monitoring to improve the efficiency and interoperability of information systems affecting patient safety.

This working group provides appropriate domain expertise to ensure that the business requirements for international standards in this area are identified and met by one of the following routes:

- Co-operation with other organisations that develop standards to encourage the development to meet the identified requirements. In some cases this can lead to the adoption of such external standards by ISO in which case this working group is managing the resolution of possible comments and change requests;
- Co-operation with the other working groups of ISO/TC 215 "Health Informatics" as appropriate; to encourage, the development of new standards for this domain that may need to be co-ordinated with other health domains and cross-sector standards;
- Development of new standards and technical reports within the working group.

As much of the content is of relevance to Pharmaceutical regulators a number of the members present are either representatives of or are involved in the regulatory sector of the industry such as the European Medicines Agency (EMEA) or the US Food and Drug Administration (FDA).

Currently the leadership of WG 6 is:

- Convener: Christian Hay (GS1, Switzerland)
- Secretary: Shirin Golyardi (NEN, Netherlands)
- Vice Convenor: Frits Elferink (NEN, Netherlands)

## 17.2 RECENT ACTIVITY

### 17.2.1 CURRENT PUBLICATIONS

- ISO/TS 22224:2009 Health informatics -- Electronic reporting of adverse drug reactions
- ISO/TR 22790:2007 - Health informatics -- Functional characteristics of prescriber support systems
- ISO/TR 25257:2009 - Health informatics -- Business requirements for an international coding system for medicinal products

- ISO/HL7 27953-1:2011 - Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting
- ISO/HL7 27953-2:2011 - Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR
- ISO 11238:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO 11239:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO 11240:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement
- ISO 11615:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information
- ISO 11616:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

### 17.2.2 CURRENT WORK ITEMS

The following are new work items currently under consideration by the Working Group:

- prEN ISO 17253 Health Informatics - Requirements for electronic prescriptions
- ISO/NP Health informatics – Data elements and structures for identification of extemporaneous and magistral (compound) pharmaceutical preparations without marketing authorisation
- ISO/NP Health Informatics - Requirements for a record of the Dispense of a Medicinal Product
- ISO/NP Health Informatics - Requirements for Medicinal Product Dictionaries

The following are documents in development by the working group:

- ISO/DTS 16791 Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers
- ISO/DTR 14872 Health informatics — Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information
- ISO/DTS 17251 Health Informatics – Business requirements for a syntax to exchange structured dose information for medicinal products

## 17.3 PROGRESS AT THIS MEETING

At this meeting 15 nations where represented by their respective delgates, numbers where however lower than expected due to clashing dates with other similar standards activities. Prior to the meeting several teleconferences where held with the members to establish the agenda and to establish the esimated attendance and to ensure input from those that were unable to attend. During the Vienna meeting a number of new items were proposed and subsequently the WG worked on developing form 4's for the following NP's to be discussed during the meeting:

- Dispense Records;
- Compound Medication; and
- Drug Dictionaries.

It was recognised that there would be significant cross over between the scope of work of these items and that conducted by other SDO, namely HL7 and IHE, A joint meeting has been scheduled between the three agencies to coincide with the IHE meeting in Denmark in June. It was therefore proposed to have the Form4 and draft content ready for this meeting to socialise with IHE and HL7 the scope of the work and to ensure that any prior or current bodies of work can be harmonised.

The following sections outline the specific areas of activity conducted during this meeting:

### 17.3.1 ISO/DTS 17251 - BUSINESS REQUIREMENTS FOR A SYNTAX TO EXCHANGE STRUCTURED DOSE INFORMATION FOR MEDICINAL PRODUCT

#### *17.3.1.1 Introduction*

The syntax for a Dose Instruction is the full set of information that supports the correct administration of a medication to a patient in order for it to have its therapeutic effect. Within this set of information, there are a variety of different concepts represented, such as the amount of medication to be administered, the frequency with which it is to be administered etc. These are termed the component parts of the instruction, and they themselves may have attributes, or sub-types, within them.

A single "dose instruction" may be complex, and therefore may be split into a number of separate clauses: each clause can then be split into its component parts.

#### *17.3.1.2 Progress to date*

The current work item was approved in 2010, but the original proposer was not able to complete the work and it has been subsequently cancelled by the ISO central secretariat. As such Scott Robertson has developed a new work item proposal to restart this work and has also started work on a draft using content from the previous project.

Scott Robertson presented both the NP Form 4 document and his new working draft, it was discussed whether this project should be a JIC project, however as it is looking at consolidating existing work and not seeking to influence other SDO's it was felt at this time the JIC was not an appropriate place to conduct this work.

It was highlighted that this is not actually the structure (information model) but the business requirements. This project is targeted as bringing together existing work into a single view of what these requirements may be. Previously the older work item was to be based on the UK model, however this document was an actual specification and information model which is beyond the scope of this project. Therefore this work is targeted to being a conceptual model rather than an information model of Dose Syntax

Scott Robertson discussed the NCPDP standard developed in the US for Structured SIG, has been developed but not widely implemented or adopted. It is however recognised under Meaningful Use though. This standard has been tested against thousands of real scripts to parse out the free text to a 96% accuracy in the structure (although that level of granularity is overkill). The document is not freely available bt may be accessible to ISO and he will investigate it use as a potential source into this current proposal

The delegate from Ireland noted that the title referenced “syntax” implying a formal representation of the informationand therefore the NP will now be called “Health informatics – Requirements for the exchange of structured dose instructions for medicinal products”.

A presentation was also given by the Dutch on the current Dose Syntax system available in their national EMR, the complexities but also deficiencies of this system were noted.

#### *17.3.1.3 Proposed future work*

A new NP form 4 and new draft document were discussed and agreed on.under the new title: Health Informatics - Business requirements for the exchange of structured dose instructions for medicinal products.

WG6 agreed to proceed into NP ballot for 3 months to re-establish the work item, with the view of releasing a CD prior to the next meeting in Australia.

#### *17.3.1.4 Relevance to Australia*

NEHTA is developing a Dose Syntax model within its Medications Management program and it will be important to ensure harmonisation with what is presented in the CD once available for comments.

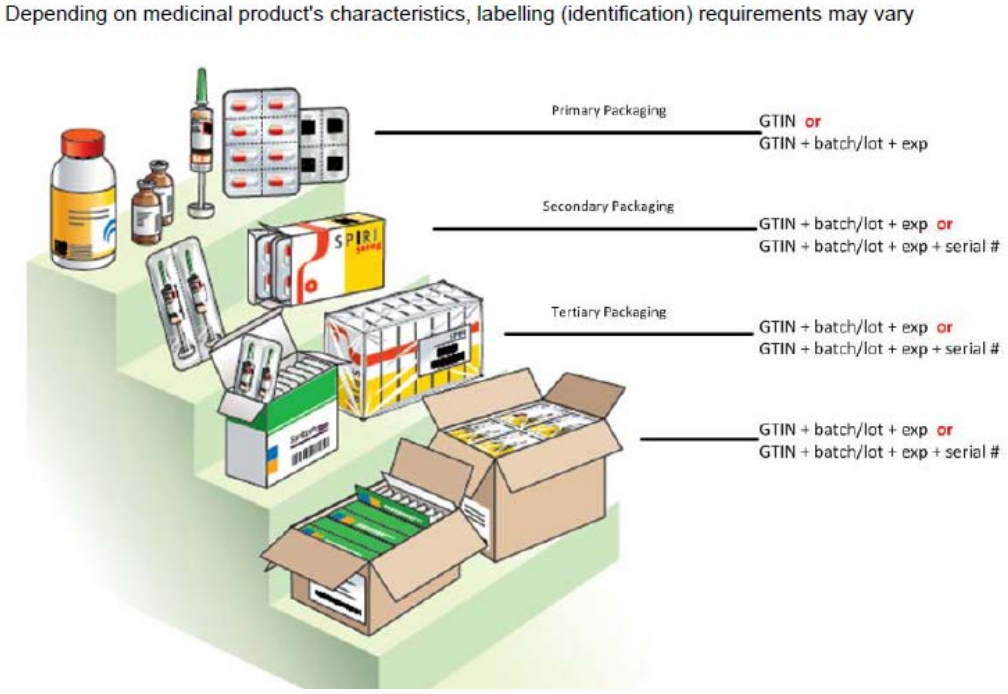
| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG 6**<br><br>**ISO 17251**<br>**Model for dose syntax** | A CD for ISO/DTS 17251 is expected for presentation at the next ISO meeting.<br>**Action: IT-014-06-04 and NEHTA to monitor and review the CD to once available to ensure alignment with Australian work in regards to Dose Syntax.** | **IT-014-06-04**<br>**NEHTA** |

### 17.3.2 ISO/CD 16791 - HEALTH INFORMATICS – REQUIREMENTS FOR INTERNATIONAL MACHINE-READABLE CODING OF MEDICINAL PRODUCT PACKAGE IDENTIFIERS

#### *17.3.2.1 Introduction*

This purpose of this Technical Specification will be to provide guidance on identification and labelling of medicinal products based on accepted principles of global best practice. The scope of this document is from the point of manufacture of packaged medicinal product to the point of dispensing. While this document outlines best practice guidance for Automatic Identification and Data Capture (AIDC) solutions for barcoding applications only, readers may consider the coding interoperability requirements for other AIDC technologies such as Radio Frequency Identification (RFID).

This work is largely focusing on barcoding using the GS1 General Specifications for using an identifier created using their GSRN (Global Service Relation Number) format. The purpose of the standard is not to replace local identifiers but to complement and assist data collection and interoperability by providing a standard mechanism of converting an identifier into a reusable object by other systems and devices that will have impact on process such as dispensing, labelling and device integration




#### *17.3.2.2 Progress to date*

Ballot resolution of comments was conducted.

Focus on the use of GS1 specifically and the discussion was on the resolution to revise the title to include specifically GS1 Germany who uses a different system to GS1 raised that there preference is that an ISO standard be open to all solutions ad providers, this was also raised as a concern by the Canadian delegate.

Australia also voted negative to the work and raised the comment that tea me of the document be changed to reflect the scope of GS1 users only.

Subsequently with unanimous support, a resolution was passed to amend title of this TS to read: "Requirements for international machine-readable coding of medicinal product package identifiers using the GS1 system".

The next item of discussion was the Australian comment recommending the change to this work item to be a Technical Report. Christian Hay outlined the background as to why this document was targeted to TS. The Australian comment highlighted the lack of the normative content.

Form a clearer view of what it is that this TS is aiming to standardise and express the associated normative requirements in a much more direct and less discursive manner. To the extent that this document has normative content, it would appear that this TS is setting requirements for systems or processes that use machine-readable coding, rather than the coding, as implied by the title.

Ensure that each of the detailed normative requirements actually addresses the subject of the standardization, otherwise consider whether this document should be a TR, rather than a TS.

This was discussed in depth, with agreement reached that the comment from Australia was valid, however it was maintained that the document should be TS and that efforts should be made to refine the normative.

Example of clauses 5.1 to 5.5 Re-work clauses 5.1 through 5.5 to provide much clearer normative statements that would permit their unambiguous application in conformance assessment. Table 1 in clause 5.6 might be the starting point for re-working these provisions.

If, on reflection, the objective is not to define requirements that can be used in this way, consider producing a TR on using IDMP and ICSR concepts within a GS1-based product medicinal product identification system.

It is unclear why these normative references have been given as the document does not make any normative reference to them. In fact, only ISO 11615 and ISO 11616 are referenced at all. These references are in the headings and introductory material for the informative Annexes A and C. If this TS is to achieve its goal, one might have expected it to make much stronger normative references to these standards and potentially include reference to 11238, as well.

There are other GS1 and JTC1/SC 31 standards that perhaps should have been referenced normatively but have not been.

#### *17.3.2.3 Proposed future work*

WG6 agreed to proceed into publication after the DTS comments are addressed fully and the final draft of the TS and disposition of comments are circulated in WG6 and TC for

ratification by August 31, 2013 with the goal of submission for publication by September 14, 2013.

The following items are the expected changes to be found in the final draft to be circulated:

- The title will be amended as: 'Health informatics – Requirements for international machine readable coding of medicinal product package identifiers using the GS1 system'.
- The project team will review the document further and reorganise the content so the normative statements are made visible.
- It was agreed to critically review existing references, their use in the text and move any not used normatively to the bibliography. Consider whether some of the syntactic elements defined in other standards should have been the subject of normative references.

#### *17.3.2.4 Relevance to Australia*

Under the National Product Catalogue the GTIN is utilised as the identifier for products and therefore this standard should be suitable for application locally. The draft previously had significant comments from interested parties in Australia which were in the negative towards publication, It is therefore important that the subsequent final draft is reviewed to ensure these comments are resolved to a satisfactory level.

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG 6**<br><br>**ISO 16791 Requirements for machine-readable of medicinal product package identifiers** | The final draft of the ISO TS 16791 will be out for review around June. Recommend that Australia review to validate comments made during the DTS ballot are adequately resolved.<br>**Action: IT-014-06-04 to monitor for the release of the final draft for review by the informatics community.** | **IT-014-06-04**<br>**TGA**<br>**NEHTA** |

### 17.3.3 MEDICINAL PRODUCT DICTIONARIES

#### *17.3.3.1 Introduction*

A drug dictionary is intended to unambiguously identify code and interpret medicines which includes standardised, consistent descriptions for each drug, facilitates seamless exchange and meets the needs and diverse requirements of different users and cater for new innovative products. It is the intent that a drug dictionary supplies an information model, relationships and underlying terminology to support the semantic understanding of medications and pharmaceuticals across all stakeholders such as prescribers, regulators, suppliers and vendors.

#### *17.3.3.2 Progress to date*

Prior to the meeting several teleconferences where held with the members to develop a draft Form for the NP on Drug Dictionaries. A document was provided prior to the meeting for review and subsequent discussion.

The scope of this project was defined in that Form 4 as:

*"The goal of this specification is to define the characteristics of and requirements for Medicinal Product Dictionaries.*

*This technical specification:*

- defines what is considered to be a medicinal product dictionary and what is not.
- describes the reasons for developing and maintaining medicinal product dictionaries. Use cases from information systems that support all kinds of processes, including decision support, dealing with medicinal products will clarify the desired purposes of medicinal product dictionaries.
- describes the requirements for medicinal product dictionaries that should be fulfilled to make a medicinal product dictionary suitable for each of the stated use cases and purposes."

A joint session with WG3 was also conducted to socialise the work item and obtain their input into the scope and nature of the project. Some specific comments raised during that session included:

- IHE added that scope should also state to support Decision Support Systems
- Discussion on scope determined that we should constrain to only items covered under IDMP or other items such as Traditional Medicine, if so WG3 work on herbal terminology may be of interest for this work, for a later stage.
- Question raised by JMA as to what qualifies a "drug". The point was noted in some countries an item may be a prescription medication, in others OTC and then again food in another. It was clarified it is only those items regulated by an authority such as JMA, FDA, TGA etc…

It was agreed that the project name should only a placeholder, as the document matures it will be refined to a Drug or Medicinal product information repository, but in principle WG3 supports the NP ballot to be launched.

#### *17.3.3.3 Proposed future work*

The work item shall proceed to NP ballot under Vienna Agreement (ISO lead), targeting a Technical Specification. The following timelines are expected

- Form 4 accompanied by an outline to ISO secretariat no later June 1, 2013;
- launch the NP ballot no later than June 14, 2013.

#### *17.3.3.4 Relevance to Australia*

Within Australia under NEHTA's AMT work there is already an underpinning model which could be interpreted as a Drug Dictionary. As this NP matures the scope of the proposed work item will need be monitored for its impact and relevance to any Australian initiatives. There is no action required to be taken at this time.

### 17.3.4 PR EN ISO 17523 REQUIREMENTS FOR ELECTRONIC PRESCRIPTIONS

#### *17.3.4.1 Introduction*

The goal of this work item is to create an international standard on electronic prescriptions. This standard shall describe the requirements that apply to existing and future electronic prescriptions which are part of health informatics systems throughout the world.

It is expected that only the general principles for electronic prescriptions and the content that facilitates the exchange and processing of an electronic prescription will be covered. The standard applies to healthcare outside hospitals (i.e. community based) as well as within.

The scope is constrained to the content of the prescription itself, to the roles of prescriber and dispensing pharmacist and to the scenario of prescribing medicinal products to be dispensed to human patients.

Other messages, roles and scenarios are out of scope of an international standard, because they are more or less country or region specific, due to differences in culture and in legislation of healthcare and reimbursement of care.

The way in which electronic prescriptions and dispensing messages are actually exchanged, or made available, falls outside the scope of this standard. Therefore it is expected that this standard will not contain an implementable specification of an electronic prescription (e.g. HL7 CDA)

#### *17.3.4.2 Progress to date*

At the previous meeting in Vienna the NP for this work item was approved. Subsequently a series of teleconference and work has been conducted in between meetings with input from a number of countries such as Sweden, Netherlands, Austria, Denmark and Singapore.

Frits Efernik of NEN (Netherlands) presented a committee developed over this time.

Additionally it was noted that a Technical report on eprescribing systems was developed in 2009 and it was discussed how the document should harmonise with this or had the world moved on since then. On June 10th in Holland there will be a joint meeting of WG6, HL7 and IHE Pharmacy group to discuss alignment on harmonisation.

It was discussed if certain components of an electronic prescription should be agreed on in the standard without providing an UML model. As this standard can be the basis for cross border interchangeable prescriptions it was expected to be fairly high level and conceptual but to achieve this interchangeable concept a certain level of detail will be necessary. The European project on e-invoicing (specifically TF4) can provide general input for this work.

The discussion on CD focused on that the content is currently very descriptive and needs to change focus from the patient to been the identification of the Subject of Care. This aligns with SKMT definition but also covers the concern that different identifiers and methods are used to identify a patient on a prescription. For example in Norway only identifier appears whereas in the Netherlands information such as Name, Address and Date of Birth

Main changes are:

- 4.3 The information components need to be included in the prescription.
- Patient will be renamed as subject of care (following prEN ISO 13940 HI – Continuity of care).
- Date of birth is not mandatory in all countries.
- The requirements need more clarifying texts. Examples will be added at the end showing different solutions fulfilling the requirements.

WG6 agreed to proceed into CD ballot of 3 months. The deadline for submission is 14th June. The CD ballot draft will be presented on the 10th June to IHE and HL7 and comments from these groups will be requested parallel to the CD ballot.

#### *17.3.4.3 Proposed future work*

Following the review of the CD during the meeting it was agreed that significant rework was required to get the document to the necessary level and some of the main changes noted are:

- The information components that need to be included in the prescription must be defined
- Patient will be renamed as subject of care (following prEN ISO 13940 HI – Continuity of care).
- Date of birth is not mandatory in all countries and should be removed
- The requirements need more clarifying text. Examples will be added at the end showing different solutions fulfilling the requirements.

WG6 agreed to proceed into CD ballot of 3 months and the deadline for submission of the draft to the ISO secretariat is 14 June. The CD ballot draft will be presented on the 10 June to IHE and HL7 and comments from these groups will be requested parallel to the CD ballot with the goal of having a definitive document targeted towards the Sydney TC215 meeting

#### *17.3.4.4 Relevance to Australia*

IT-014-06-04 is currently progressing a suite of standards on the Electronic Transfer of Prescriptions, which contains a specification for an electronic prescription. It is likely that we would seek that there be no contradiction between the ISO specification and any future Australian standard.

| Topic | Issue / Action / Recommendations for Australia | Recommended for Action by |
|---|---|---|
| **WG 6**<br><br>**ISO 16791 Requirements for machine-readable of medicinal product package identifiers** | The final draft of the ISO TS 16791 will be out for review around June. Recommend that Australia review to validate comments made during the DTS ballot are adequately resolved.<br><br>**Action: IT-014-06-04 to monitor for the release of the final draft for review by the informatics community.** | **IT-014-06-04**<br><br>**TGA**<br><br>**NEHTA** |

### 17.3.5 DISPENSE EVENT RECORD

#### *17.3.5.1 Introduction*

An electronic dispensing message contains information about the medicinal products to be supplied by the dispenser. An electronic dispensing message can be intended for the prescriber in the context of the cooperation between prescriber and dispenser, or for other suitably authorized healthcare practitioners in the context of the continuity of patient care.

The dispense event record is an important component of the chain of information custody in any prescribing episode or medications management system. It is important to note that the dispense event record may be synchronous with the prescribing event in the case where the prescriber and dispenser are the same.

#### *17.3.5.2 Progress to date*

Following the Vienna meeting this work item was agreed to be pursued as a new program of work to complement the work on Electronic Prescriptions. Between meetings several discussions were held and a Form 4 was drafted for discussions in Mexico.

The scope was discussed and it was decided that it shall include all medications including 'over the counter' dispensations and hospital pharmacy. The rationale behind this is that the purpose is to build a complete medication profile with the future vision of the WG is to have a multi-part standard on electronic prescriptions, dispense and administration record.

The scope in the Form 4 is as follows:

*"The scope of this specification is to define the information content for the capture of structured data of an event relating to the dispense of a Medicinal Product. The event includes any actual dispense, cancellation or other outcome that may have occurred at the time.*

*The contents of a dispensation record are the logical counterpart of an electronic prescription, however the scope of this standard is to include items which may be dispensed without the need for a prescription.*

*This specification intends only to capture the requirements and information content. It is not the intent to specify the exchange of the information in a message, although it is intended that this information content shall be used as the basis for the dispense information contained in any messaging event."*

A new title for the work item was also adopted: "Health Informatics - Requirements for a record of the Dispense of a Medicinal Product". This was taken as several countries had differing opinions on the actual meaning of the term Dispense record.

#### *17.3.5.3 Proposed future work*

The WG decided to proceed to NP ballot and this resolution was passed. Draft content for the NP ballot is required by June and this will be socialised with the corresponding members of the IHE and HL7 groups at the upcoming joint meeting in Denmark.

The intended project team: Michael Steine (Australia), Frits Elferink (Netherlands), Brendan Kernan and Jack Shanahan (Ireland), Chihiro Masuda (Japan), Andreas Franken

(Germany) and Scott Robertson (US). Michael Steine of Australia is currently slated as the project lead to progress this item through the NP Ballot stage.

#### *17.3.5.4 Relevance to Australia*

As with the Electronic Prescription work item, IT-014-06-04 is currently progressing a suite of standards on Electronic Transfer of Prescriptions, which contains a specification for an Dispense Record. It is likely that we would seek that there be no contradiction between the ISO specification and any future Australian standard.

There is no action at this point in time, however once a draft standard is available comments will be sort from the relevant stakeholders in Australia (IT-014-06-04, NEHTA, DOHA, PBS).

### 17.3.6 COMPOUND MEDICATION

#### *17.3.6.1 Introduction*

Compound Medications (or Extemporaneous) Medications, are those medicaments which are prepared from multiple ingredients and substances when no commercial form is available.

For the purposes of this working group the scope of the definition at this stage is any pharmaceutical product that is not registered by the relevant regulator (e.g. TGA, FDA, JMA) in the composition that is prescribed to the patient (this scope may change as the work item matures).

Although this makes up a small fraction of the overall number of prescriptions, currently many electronic systems handle Compound Medications inadequately and in a number of different ways. It is felt that this dilutes the ability for decision support systems to adequately process drug data related to the substances found in a Compound Medication and potentially poses a clinical safety risk to patients.

#### *17.3.6.2 Progress to date*

Following the Vienna meeting this work item was agreed to be pursued as a new program of work to complement the work on Electronic Prescriptions. Between meetings several discussions were held and a Form 4 was drafted for discussions in Mexico.

The scope was discussed and focused on the definition of compounding medicine with many countries indicating that some compound products may actually be regulated however others were not making the title ambiguous to what was and was not to be covered. The scope was amended accordingly following the resolution of the committee of the European ministers which contained an existing definition. After the meeting, it was noted that extemporaneous and magistral are synonymous. The intent is to address these as well as stock products (terminology from the EU document).

Therefore the following title has been adopted for the NP Ballot: “Health informatics – Data elements and structures for identification of extemporaneous and magistral (compound) pharmaceutical preparations without marketing authorisation.”

The scope was refined and is as follows:

*"The scope of this standard is to define the information model for the capture of strucutred data in relation to unlicensed Pharmaceutical preparations that are prepared without marketing authorisation.*

*Pharmaceutical preparations are medicinal products generally consisting of active substances that may be combined with excipients, formulated into a dosage form suitable for the intended use, where necessary after reconstitution, presented in a suitable and appropriately labelled container.*

*Pharmaceutical preparations may be licensed by the competent authority. Or they can be unlicensed and made to the specific needs of subjects of care according to legislation.*

*There are 2 categories of unlicensed pharmaceutical preparations:*

- *extemporaneous preparations, i.e. pharmaceutical preparations individually prepared for a specific subject of care or subjects of care group, supplied after preparation;*
- *stock preparations, i.e. pharmaceutical preparations prepared in advance and stored until a request for a supply is received.*

*This standard will specify the data structure for capturing the information of the unlicensed pharmaceutical preparations so that the underlying substances, ingredients and their strength and amounts are able to be identified at the level of granularity that is needed for prescription dispensing and decision support. Other information about the preparation where relevant such as preparation form, technique or instruction may also be captured."*

#### *17.3.6.3 Proposed future work*

The WG decided to proceed to NP ballot and this resolution was passed. Draft content for the NP ballot is required by June and this will be socialised with the corresponding members of the IHE and HL7 groups at the upcoming joint meeting in Denmark.

The intended project team: Michael Steine (Australia), Frits Elferink (Netherlands), Tomas Wennebo (Sweden), Andreas Franken (Germany), Vada Perkins and Scott Robertson (US). Michael Steine of Australia is currently stated as the project lead to progress this item through the NP Ballot stage.

#### *17.3.6.4 Relevance to Australia*

As with the Electronic Prescription work item, IT-014-06-04 is currently progressing a suite of standards on Electronic Transfer of Prescriptions, which contains a requirement to capture PBS Extemporaneous Items. It is likely that we would seek that there be no contradiction between the ISO specification and any future Australian standard.

There is no action at this point in time, however once the draft standard is available comments will be sort from the relevant stakeholders in Australia (IT-014-06-04, NEHTA, DOHA, PBS)

### 17.3.7 ISO/TR 14872 REQUIREMENTS FOR THE IMPLEMENTATION OF THE STANDARDS FOR THE IDENTIFICATION OF MEDICINAL PRODUCTS FOR THE EXCHANGE OF REGULATED MEDICINAL PRODUCT

#### *17.3.7.1 Introduction*

It had previously been established that there would be significant maintenance activities foreseen for the content captured by the standards in the IDMP suite and that these would constitute registration in ISO Terms.

The purpose of this Technical Report is to describe the maintenance requirements to support the implementation of the IDMP standards. Maintenance of controlled vocabularies is required to ensure that terms are kept up to date, through additions, modifications and retirements. Changes to the controlled vocabularies should only be made following suitable review and documented with a full audit trail. Secure publication in agreed formats is required to ensure the controlled vocabularies can be used on a continuous basis to meet legal compliance obligations.

The maintenance requirements envisaged within this Technical Report relate to processes that support the following activities:

- Initial creation of the controlled vocabularies;
- Continuous and ongoing maintenance of both the controlled vocabularies and the technical implementation of the structures in which they are made available in response to changes in the underlying concept models introduced through the standard revision procedures of ISO/TC 215 WG6 for the IDMP standards;
- Continuous and ongoing maintenance of the underlying definitions and concept model;
- Publication of change release documentation reflecting significant updates and additions;
- Continuous and ongoing maintenance of all of the controlled vocabularies, including controlled sub-vocabularies;
- Continuous and ongoing maintenance of non-preferred terms, synonyms and translations into multiple languages; and
- Up-to-date publication of the controlled vocabularies.

There is no necessary requirement that there should be a single maintenance organisation dealing with all the controlled vocabularies across the five IDMP standards. However, the maintenance organisation or organisations should work with other controlled vocabulary developers appropriately.

#### *17.3.7.2 Progress to date*

This document started out its life as a guide for the maintenance of the IDMP standard, initially by a third party agency acting as the ISO Registration Authority. As this is no longer likely, and alternative arrangements requiring joint activity between ICH members is likely to hold this role, the purpose of the document has become slightly uncertain and the current content in the draft would require significant rework to fit the new direction.

The development of this document cannot progress until an agreement is made by the ICH members on their approach to maintenance of the content captured using the IDMP standards. Mary Raphael of Canada informed the group that within ICH dialogue is on-going on how the maintenance of IDMP should be filled in. When the maintenance process is clear, the outcomes will be included in this DTR which will be used as communication towards the user communities.

At the moment, EMA is setting up the pharmacovigilance database to contain all adverse drug reactions from all EU member states. For this purpose, codes are needed identifying the specific reaction. This development is important to follow for the ISO/DTR 14872 document.

#### *17.3.7.3 Proposed future work*

The WG agreed to write a letter to Mr van Belkum, the rapporteur (convenor) of M2 of ICH, responsible for relationships with relevant SDOs to obtain a formal update and timelines in relation to the ICH efforts in this area.

At the previous TC 215 meeting in Vienna a resolution was passed to delay the presentation of a draft for ballot until December 2013 whilst the WG awaits this decision and this motion still standards until further information is presented by the ICH.

It may be the case that this document becomes irrelevant if adequate controls are developed outside of TC 215 by those agencies taking part in the maintenance activities.

#### *17.3.7.4 Relevance to Australia*

It is likely that IDMP standards will be adopted in Australia at some level, initially only by the TGA. Therefore the way in which the content of IDMP is controlled internationally is not only a concern for Australian regulators but also for agencies producing medications.

As the project is on hold until resolution by ICH there is currently no action.

# 18. CLOSING PLENARY

| | |
|---|---|
| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)<br>Naomi Ryan (WG 1 secretariat), Renato Iannella, Alan Taylor |

The closing plenary addressed the following agenda, with all resolutions being separately recorded in Appendix C below.

## 18.1 BACKGROUND

Resolutions for the plenary session are drafted by the working groups, task forces and other constituent bodies within TC 215 and typically follow wording set out in common templates circulated by the TC 215 Secretariat. The resolutions were circulated to national delegations for review shortly before the final plenary.

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

Reports from each working group presented at this Plenary Session are available on the TC 215Wiki (http://isotc.iso.org/livelink/livelink?func=ll&objId=8862396&objAction=browse&viewType=1) .Resolutions passed at this Plenary Session are listed in Appendix C.

#### *18.1.1.1 Plenary Issues of Relevance to Australia*

It was reported at the TC 215 Plenary that some concerns had been raised by other ISO committees regarding possible overlap of committee scope. Any change in TC 21 scope has the possibility of rippling through TC 215 Working group scopes, which could cause considerable debate.

The conduct of the TC 215 Plenary has room for improvement. Although the TC 215 chair was effective, and provided good guidance, there needs to be more clarity on when the taking of resolutions in block (to save time) is appropriate. Additional guidance on the process of taking amendments would be useful, and will improve the business efficiency of the plenary.

During this plenary resolutions were referred to by WG resolution number and by a TC 215 number, which caused some confusion. The TC 215 Wiki was used to post some resolutions, but was not used as a single source of truth during the plenary.

| Topic | Issue/Action and Recommendations for Australia | Suggested responsibility & alignment to IT-014 |
|---|---|---|
| **TC 215 Scope** | It is likely that some change in TC 215 scope may be required at the Sydney meeting.<br>**Action: Ensure that the Australian delegation reaches a position on a suitable TC 215 scope prior to their meeting.** | **IT-014** |
| **TC 215 Meeting Resolution Process** | The handling of resolutions and amendments is sometimes confusing or inconsistent and needs to improved before the next meeting in Sydney.<br>**Action: Agree early in the Sydney meeting a suitable and efficient process for handling resolutions and amendments.** | **IT-014** |
| **TC 215 Meeting Resolution Management** | Electronic management of resolutions and amendments to provide a single source of truth was ineffective at the Mexico plenary.<br>**Action: Agree and test a resolution submission, management and amendment process using the TC215 Wiki, prior to the Sydney meeting** | **IT-014** |

# APPENDIX A – MEETING AGENDA

# APPENDIX B – TC 215 – ACTIVE PROJECTS STANDARDS PUBLICATIONS UNDER DEVELOPMENT

# APPENDIX C – RESOLUTIONS AT CLOSING PLENARY

# APPENDIX D – ACRONYMS

| | |
|---|---|
| ACCC | Australian Competition and Consumer Commission |
| ACMA | Australian Communication and Media Authority |
| ACSQHC | Australian Commission on Safety and Quality in Health Care |
| ACTUG | Australian Clinical Terminology Users Group |
| ADL | Archetype Definition Language |
| AG | Advisory Group |
| AHIMA | American Health Information Management Association |
| AHMAC | Australian Health Ministers' Advisory Council |
| AHML | Australian Healthcare Messaging Laboratory |
| AIHW | Australian Institute of Health & Welfare |
| AIIA | Australian Information Industry Association |
| AMT | Australian Medicines Terminology |
| ANSI | American National Standards Institute |
| ArB | Architecture Review Board |
| AS HB | Australian Handbook |
| AS/NZS | Australian/New Zealand Handbook |
| AS/NZS ISO | International Standards adopted by Australia and New Zealand |
| AWI | Approved Work Item |
| CASCO | Conformity Assessment |
| CBCC | Community Based Collaborative Care Workshop |
| CCHIT | (US) Certification Commission for Health Information Technology |
| CD | Committee Draft (third stage in developing an ISO or IEC standard) |
| CDA | Clinical Document Architecture |
| CDISC | Clinical Data Standards Interchange Consortium |
| CDS | Clinical Decision Support |
| CDV | Committee Draft for Vote |
| CEN | European Committee for Standardization<br>(Comité Européen de Normalisation) |
| CIC | Clinical Interoperability Council Workgroup |
| CIS | Clinical Information Systems |
| COAG | Council of Australian Governments |
| DAFF | Department of Agriculture, Fisheries and Forestry |
| DAM | Domain Analysis Model (comprehensive model of a domain) |
| DCM | Detailed Clinical Model |
| DCOR, COR | (Draft) Corrigendum |

| | |
|---|---|
| DICOM | Digital Imaging and Communications in Medicine |
| DIISR | Department of Innovation, Industry, Science & Research |
| DIS | Draft International Standard (fourth stage in developing an ISO or IEC standard – the main opportunity for public input) |
| DoHA | (Australian Government) Department of Health and Ageing |
| DMP | Dossier Médical Partagé (Shared Medical Record) (France) |
| DSTU | Draft Standards for Trial Use (HL7 and ANSI) |
| EC | European Commission [the administrative arm of the EU] |
| ECCF | Enterprise Compliance and Conformance Framework |
| EFMI | European Federation of Medical Informatics |
| eHIF | E-health Interoperability Framework [Standards Australia & NEHTA] |
| EHR | Electronic Health Record |
| EHRS or EHR-S | Electronic Health Record System |
| ELGA | Austrian CDA Implementation Guide in Development |
| ELS | End Point Location Service |
| EMEA | European Medicines Agency |
| EN | European Standard (Européen Norm) |
| ETP | Electronic Transfer of Prescriptions |
| EU | European Union |
| FDAM | Final Draft Amendment |
| FCD | Final committee draft |
| FDIS | [ISO] Final Draft International Standard (for vote to publish) |
| GCM | Generic Component Model |
| GDP | Gross Domestic Product |
| GP | General Practitioner |
| GS1 | An international SDO – primarily in the supply-chain domain |
| HDF | HL7 Development Framework |
| HI | Health Identifiers |
| HIE | Health Information Exchange |
| HIMSS | Healthcare Information and Management Systems Society |
| HITSP | Health Information Technology Standards Panel |
| HL7 | Health Level Seven (International) |
| HL7 ELC | HL7 E-Learning Course |
| HPI | Healthcare Provider Identifier |
| HPI-I | Healthcare Provider Identifier for Individuals |
| HPI-O | Healthcare Provider Identifier for Providers |
| HSSP | Healthcare Services Specification Project [joint HL7/OMG] |
| ICH | International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use) |
| ICOGRADA | International Council of Graphic Design Associations |

| | |
|---|---|
| ICT | Information & Communications Technology |
| ICSR | Individual Case Safety Report [related to Medicines/Devices] |
| IDMP | Identification of Medicinal Products |
| IEC | International Electrotechnical Commission (an international SDO) |
| IEEE | Institute of Electrical & Electronic Engineers (US) (also an SDO) |
| IHE | Integrating the Healthcare Enterprise |
| IHI | Individual Healthcare Identifier |
| IHTSDO | International Health Terminology Standards Development Organisation |
| IS | International Standard |
| ISO | International Organization for Standardization |
| ISO/CS | ISO Central Secretariat |
| ITS | Implementable Technology Specifications |
| IXS | Identity Cross Reference Service |
| IT-014 | Standards Australia Committee IT-014 (Health Informatics) |
| ITU-T | International Telecommunications Union – Standards Division |
| JI | Joint Initiative on SDO Global Health Informatics Standardization |
| JIC | Joint Initiative Council<br>(responsible for governance of the JI – with current members being ISO/TC 215, CEN/TC251, HL7 International, CDISC, IHTSDO and GS1) |
| JTC | Joint Technical Committee |
| JTC 1 | ISO/IEC Joint Technical Committee 1 Information Technology |
| JWG | Joint Working Group [under the JI, unless otherwise specified] |
| JWG7 | Joint working group of IEC 62A and ISO/TC 215 |
| KPI | Key Performance Indicator |
| LB | Letter Ballot |
| LMIC | Low and Medium Income Countries |
| LOINC | Logical Observation Identifiers Names and Codes |
| LPO | Local PCEHR Officer |
| MBS | Medical Benefits Scheme |
| MDA | Model Driven Architecture |
| MM | Maturity Model |
| MSIA | Medical Software Industry Association |
| NASH | National Authentication Service for Health |
| NATA | National Association of Testing Authorities |
| NEHTA | (Australian) National E-Health Transition Authority |
| NH&MRC | National Health and Medical Research Council |
| NHIN | (US) National Health Information Network |
| NHS | (UK) National Health Service |
| NIH | (US) National Institutes of Health |
| NIST | National Institute of Standards and Testing |

| | |
|---|---|
| Normapme | European Office of Crafts, Trades and Small and Medium sized Enterprises for Standardisation |
| NMB | National Member Body [of ISO or CEN] |
| NP | New Work Item Proposal (current ISO/IEC abbreviation) |
| NPACC | National Pathology Accreditation Advisory Council |
| NSO | National Standards Office |
| NWIP | New Work Item Proposal (obsolete ISO/IEC abbreviation – see "NP") |
| OBPR | Office of Best Practice Regulation |
| OCL | Object Constraint Language |
| OID | Object Identifier |
| OMG | Object Management Group |
| ONC | Office of the National Coordinator for Health Information Technology |
| | (within US Department of Health and Human Services) |
| O&O | Orders and Observations Workgroup |
| OSI | Open Systems Interconnection |
| OTF | Organisation Task Force [ISO/TC 215] |
| OWL | Web Ontology Language |
| PACS | Picture Archive Systems |
| PAS | Patient Administration Systems |
| PDAM, DAM | (Proposed) Draft Amendment |
| PDF | Portable Document Format |
| PDTR, DTR | (Proposed) Draft Technical Report |
| PBS | Pharmaceutical Benefits Scheme |
| PCEHR | Personally Controlled Electronic Health Record |
| PHDSC | Public Health Data Standards Consortium |
| PHR | Personal Health Record |
| PHTF | Public Health Task Force |
| PIM | Platform Independent Model |
| PIP | Practice Incentive Payment |
| PIR | Post Implementation Review |
| PKI | Public Key Infrastructure |
| PM | Project Manager |
| PMBOK | Project Management Body of Knowledge |
| PMS | Practice Management System |
| PMTL | Project Management Team Leader |
| PoC | Point-of-Care |
| PSM | Platform Specific Model |
| RACGP | Royal Australian College of General Practice |
| RCPA | Royal College of Pathologists Australia |
| RHIO | (US) Regional Health Information Organisation |

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|---|---|
| RIMBAA | RIM Based Application Architecture |
| RIM | Reference Information Model |
| RIS | Radiology Information Systems |
| RLUS | Resource Locate Update Service (HSSP) |
| RM-ODP | Reference Model of Open Distributed Processing |
| SA | Standards Australia |
| SAIF | Services Aware Interoperability Framework |
| SBP | Strategic Business Plan [ISO & IEC] |
| SC | Subcommittee |
| SDO | Standards Development Organisation |
| SIG | Special Interest Group |
| SKMT | Standards Knowledge Management Tool |
| SLA | Service Level Agreement |
| SME | Subject Matter Experts |
| SMTP | Simple Mail Transfer Protocol |
| SNOMED | Systematised Nomenclature of Medicine |
| SOA | Service Oriented Architecture |
| SOAP | Simple Object Access Protocol |
| TC | Technical Committee |
| TCM | Traditional Chinese Medicine |
| TCP/IP | Transmission Control Protocol/Internet Protocol |
| TEAM | Traditional East Asian Medicine – This term, though inadequate is used to represent Traditional Chinese Medicine, Traditional Korean Medicine, Traditional Japanese Medicine. |
| TF | Task Force |
| TM | Traditional Medicine |
| TOGAF | The Open Group Architecture Framework |
| TR | Technical Report (an informative ISO or IEC standards publication) |
| TS | Technical Specification (a normative standards publication having a lower level of consensus than a full international standard) |
| UCUM | Unified Code for Units of Measure [Regenstrief Institute] |
| UML | Unified Modelling Language |
| UN | United Nations |
| VMR | Virtual Medical Record |
| W3C | World Wide Web Consortium |
| WD | Working Draft (second stage in developing an ISO or IEC standard) |
| WG | Working Group or Work Group |
| WGM | Working Group Meeting |
| WHO | World Health Organization |
| WI | Work Item |
| WTO | World Trade Organisation |

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|---|---|
| XDS | (IHE's) cross enterprise Data Sharing protocol |
| XML | Extensible Markup Language |