IT-014 Health Informatics Committee

Report

ISO/TC 215 Meeting – Vienna, Austria

22-26 September 2012

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Collated by: Standards Australia

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Contents

Contents .................................................................................................................................... 2
1. Introduction.......................................................................................................................... 3
2. Objectives of the meeting....................................................................................................... 4
3. Meeting agenda...................................................................................................................... 6
4. Recommendations arising from the meeting........................................................................ 6
5. Funding source summary........................................................................................................ 17
6. Attendance ............................................................................................................................ 18
7. Positions held by delegates................................................................................................... 19
8. Acronyms............................................................................................................................... 22
9. Detailed report on activities .................................................................................................. 27
  9.1 Executive Council (EC) and Technical Committee (TC) 215 Governance .................... 27
  9.2 Joint O&H / CAG 2 / CAG 3 Coordination meeting ..................................................... 36
  9.3 Joint Initiative Council Executive ................................................................................... 40
  9.4 JIC Open Forum ............................................................................................................... 43
  9.5 Opening Plenary ............................................................................................................... 47
  9.6 WG 1 Data Structure (incorporating WG 8 Business Requirements for EHR) ............ 49
  9.7 Public Health Task Force (PHTF) .................................................................................. 70
  9.8 WG 2 Data Interchange .................................................................................................... 74
  9.9 WG 3 Semantic Content .................................................................................................. 80
  9.10 Traditional Medicine Task Force .................................................................................. 93
  9.11 WG 4 Security, Safety and Privacy .............................................................................. 99
  9.12 WG 6 Pharmacy and Medicines Business ..................................................................... 116
  9.13 Joint Working Group 7 .................................................................................................. 130
  9.14 Closing Plenary ............................................................................................................. 130
  9.15 Background .................................................................................................................. 138
Appendix A – Meeting Agenda ................................................................................................. 139
Appendix B – ISO/TC 215 Standards and Approved Projects ................................................ 141
  B.1 TC 215 - Current Standards Publications .................................................................... 141
  B.2 TC 215 – Active projects - Standards publications under development ..................... 146
  B.3 TC 215 – Withdrawn standards publications .................................................................. 148
  B.4 TC 215 – Standards projects withdrawn or cancelled in last 12 months .................... 148
Appendix C – SKMT Background and Governance ................................................................... 149
Appendix D – Resolutions at closing plenary ............................................................................ 153
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 164 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:

- TC 215 Executive Council - responsible for executive leadership and strategy
- Public Health Taskforce (reporting through WG 1)
- WG 1 Data Structure [Secretariat: Australia]
- WG 2 Data Interchange
- WG 3 Semantic Content [Convenor: Heather Grain (Australia)]
- Traditional Medicine Task Force (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 working group activity, secretariat processes and TC 215 work program.

The Joint Meeting of ISO/TC 215 and CEN251 Health Informatics Working Groups was held from 22 to 26 September in Vienna, Austria and was attended by 9 Australian delegates (with funding assistance provided by the Department of Health and Ageing).

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 being 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 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’s.
- 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 and GS1 and the JIC Harmonisation stream at ISO/TC 215 meetings (ISO/TC 215 /WG9).

- 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 proposed liaison between ISO/TC 215 and ISO/IEC Joint Technical Committee 1 (JTC 1) with a view to encouraging collaboration on IT standards affecting health care delivery and avoiding duplication of work.

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 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 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 eight 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 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 and was able to cover most 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, 22 September, 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 September 2012 ISO/TC 215 meeting are summarised in this section. Alignment to the IT-014 Committee Structure is also listed.

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<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
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<tr>
<td>Executive Council – Implementation of new TC 215 organisation</td>
<td>Recommendations for restructure of TC 215 that were first put to the TC 215 plenary are to be circulated to P-members for approval in the near future. With Australia having two members on the Executive Council actively involved the proposed restructure, it is important that we participate in this ballot, preferably lending our support to the proposed changes. <strong>Action:</strong> Standards Australia and IT-014 to prepare response to the letter ballot on adoption of new TC 215 structure.</td>
<td>IT-014 Standards Australia</td>
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<td>Executive Council – Preparation of Strategic Business Plan (SBP) and project assessment criteria</td>
<td>The TC 215 work being led by Richard Dixon Hughes on identification and recommendation of more rigorous processes for project prioritisation are to be taken forward in the broader context of preparing an updated TC 215 Strategic Business Plan (SBP) in line with the ISO/IEC Directives. Richard and Jeremy Thorp (UK) have been asked to lead the SBP activity. <strong>Action:</strong> IT-014 to consider and contribute comments on the current e-health standards environment and needs for consideration in the TC 215 SBP. <strong>Action:</strong> Richard Dixon Hughes to progress TC 215 SBP activity with Jeremy Thorp and keep Standards Australia and IT-014 apprised of progress.</td>
<td>IT-014 Richard Dixon Hughes Standards Australia</td>
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<td>Joint Initiative Council (JIC) - Leadership</td>
<td>Richard Dixon Hughes (current Australian Head of Delegation to TC 215) has been nominated by the Chair of TC 215 as the preferred person to chair of the JIC on behalf of ISO/TC 215, when the JIC chair’s position rotates to TC 215 for 2013 and 2014. This possibility has been raised with, and supported by, Standards Australia and JSCHIS was announced at the May 2012 meeting in Vancouver and confirmed by plenary vote at this meeting. <strong>Action:</strong> (Continuing) Consider means whereby attendance of Richard Dixon Hughes at face-to-face meetings of the JIC executive can be supported through to 2014 (noting that many are likely to occur at TC 215 or HL7 meetings).</td>
<td>Standards Australia Richard Dixon Hughes</td>
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| **JIC** | Australia needs to consider the implications of support which needs to be provided to JIC activities, and the opportunity to leverage and influence activities. For example if the suggested summits are organised will they be supported, hosted, encouraged? As this community continues to emerge the opportunity to influence is significant, especially while an Australian is the Chair.  
**Action:** Determine any specific Australia objectives for engagement with JIC | IT-014 / DOHA |
| **JIC** | All National Member Body (NMB) countries were asked to consider hosting a future ISO/TC 215 meeting. In particular Australia was asked to confirm the status of holding a meeting in October 2013 in Sydney. This has been listed as ‘tentative’ for some time and planning needs to commence if this will be confirmed.  
**Action:** Standards Australia to follow up with the DoHA | Standards Australia  
DoHA |
| **Executive Council**  
**Health Informatics Standards Glossary and Knowledge Management Tool** | In relation to the ongoing development and usage of the Standards Knowledge Management Tool (SKMT) in ISO/TC 215 work and more broadly, it is recommended that:  
- Australia continues to support the development and promotes the usage of the SKMT  
- Australia assists in driving a greater level of awareness of the relationship between the various “meta-informatics” resources including SKMT, the HI wiki and other tools  
- Consideration be given to development of an Australian portal to provide easier access to Australian Standards  
**Action:** IT-014 to continue support for use of SKMT to inform our own definition developments in our documents, as well as our international contribution.  
**Action:** Consider development of an Australian standard-specific portal. | IT-014  
IT-014-01  
IT-014-02  
NEHTA |
| **WG 1**  
**CEN WG1 TR Enterprise Architecture within healthcare** | Issue: This new CEN WG1 work may be similar in nature to that which is being undertaken by IT-014-09, in conjunction with NEHTA re eHIF and certainly has the potential to overlap other TC 215 and HL7 work. The justification for it being done predominantly as a European project is unclear but before encouraging it being developed as a joint project, there is a need to ensure that it has the required level of market relevance and stakeholder support.  
**Action:** Australia should monitor this CEN work and for potential progression as a joint ISO/CEN project, noting potential overlap with our current work in IT-014-09 on the eHealth Interoperability Framework and other work within TC 215 and HL7. | IT-014-09 |
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| **WG 1**  
TS 13972 – Characteristics and Processes of Detailed Clinical Models | Issue: The revised DTS13972 is about to be sent out for ballot. It has been extensively reformatted following remerging from two separate documents and additional content regarding alignment with ISO 9000 processes included. While we supported the main thrust of the revision (from the previous DIS) and did not oppose the introduction of material related to ISO 9000, this has raised questions about the relationship between the ISO rules on conformity assessment and in the final outcome made for a document that is more poorly structured and less digestible. **Action:** Australian experts to determine an approach on how to respond to the DTS ballot. | IT-014-09 NEHTA CTI team |
| **WG 1**  
DTS 18530 – Subject of Care (SOC) and Individual Provider Identification (GS1) | Issue: Continued development and application of this GS1-led work on systems for automation of subject-of-care and provider identification is an international development of potential relevance to Australia. **Action:** Australia should continue to support the development and promote the usage of Subject of Care (SOC) and Individual Provider Identification standards as the work progresses. | IT-014 |
| **WG 1**  
CEN WG1 Report - Convergence of 13606, CONTSYS and HISA | Issue: This new CEN WG1 work appears to be a potentially valuable exercise in attempting to bring together and characterise the roles of the main conceptual standards that affect systems architectures and interoperability which was commenced with a recent 2-day workshop in Rome. 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). **Action:** IT-014-09 should monitor and potentially actively contribute this work, and including considering its conclusions in relation to future iterations of the eHIF. | IT-014-09 |
| **WG 1**  
ISO 13606 Electronic health record communication | The review of the 5 parts of ISO 13606 is just commencing with the NP ballots for simultaneous review and update of each of the 5 parts having been passed. All parts are 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. **Action:** IT-014-09 to encourage and support Australian expert input to the revision of ISO 13606. **Action:** IT-014-09 to monitor and participate in review of all ISO 13606 documents and actively encourage timely harmonisation with HL7, openEHR and CIMI activities. | IT-014-09 |
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<td><strong>WG 1, WG 3</strong>&lt;br&gt;ISO/CD 13940 System of Concepts to Support Continuity of Care - CONTSYS</td>
<td>This work is being fast tracked through CEN to go to joint DIS ballot ASAP. Although not yet widely known in Australia, its potential impact on e-health standards and specifications is significant. Recent additions appear to have made this project more academically focussed than the first version published as a European Standard. It is critical for this work be capable of practical application – this may no longer be the case. 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. <strong>Action:</strong> 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. <strong>Action:</strong> Monitor the progress of the CEN Convergence meetings to ensure that implementation support is grounding and informing the development of the CONTSYS standard.</td>
<td>IT-014-02&lt;br&gt;IT-014-06&lt;br&gt;IT-014-09&lt;br&gt;IT-014-12&lt;br&gt;IT-014-13&lt;br&gt;NEHTA</td>
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<td><strong>WG 1</strong>&lt;br&gt;NP EHR Clinical Research Profile</td>
<td>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. A compromise was agreed at the May 2102 meeting. A watching brief should be kept on this work, preferably with increased engagement with stakeholders involved in clinical research and trials. <strong>Action:</strong> IT-014-09 to keep a watching brief.</td>
<td>IT-014-09</td>
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<td><strong>WG 1</strong>&lt;br&gt;ISO DIS 10781 - EHR System Functional Model Release 2</td>
<td>Australia should continue to keep a watching brief on this work. The principal work is progressing through the HL7 EHR WG. <strong>Action:</strong> IT-014-09 should keep a watching brief on this work item, participating in the next ballot rounds when opened.</td>
<td>IT-014-09</td>
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<td><strong>WG 1</strong>&lt;br&gt;Proposed NP TS 18528 – Functional Classification of Health Informatics Standards</td>
<td>Issue: This new work item targeting a TS 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. <strong>Action:</strong> 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.</td>
<td>IT-014-02&lt;br&gt;IT-014-09</td>
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<td><strong>WG 1</strong>&lt;br&gt;ISO DIS 16527 PHR system functional model</td>
<td>Australia should keep a close watching brief on this work, with particular reference to its potential impact on future developments around the PCEHR. <strong>Action:</strong> IT-014-09 to keep a watching brief.</td>
<td>IT-014-09</td>
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| **WG 1 - PHTF**  
DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model | Issue: While much of the 14639-2 document has been completed in draft form detailed contributions for specified subsections are still required – including some from Australian experts – and detailed consolidated review and normalisation of the content is required.  
**Action:** Australian experts should continue to contribute and assist with completion of this item before the next TC215 meeting. | IT-014  
Richard Dixon  
Hughes  
Anthony Maeder |
| **WG 2**  
ISO 14199 BRIDG Model | Discussions are underway between the TC 215 secretariat, ANSI and ISO Central Secretariat to move standardization of BRIDG through ISO into an “Umbrella” model as has been used over the last 8 years for DICOM. If agreed, this will help ensure that the ISO standard references and provides a means for maintaining and establishing conformance with updated BRIDG specifications maintained by CDISC using agreed consensus processes and published online. This will overcome a problem of re-formatting established BRIDG content into an ISO standard that will always be several versions behind the latest BRIDG version. ISO/CS has some concerns over use of logos, governance and other issues. CDISC is in the process of preparing a response to ISO/CS questions in the hope of moving forward.  
**Action:** When and if it is released, IT-014 to review NP ballot proposal for revised approach to ISO standardization of BRIDG with a view to supporting the approach. | IT-014 |
| **WG 2**  
General use of umbrella model for frequently maintained material | Discussions have been continuing between the TC 215 secretariat, ANSI and ISO Central Secretariat to allow material that is maintained frequently and published online by approved third parties to be the subject of ISO standards, where the ISO standard would reference and provide a means for maintaining and establishing conformance with frequently updated third-party specifications published online. This is a generalisation of processes currently used with DICOM specifications and proposed for the CDISC/BRIDG model. Action on this more general proposal is currently on hold pending resolution of the TC 215  
**Action:** A watching brief should be kept as the implications for other cross standards adoption may have strong impact. | IT-014 |
| **WG 2 – DTS 13131**  
Telehealth Quality Criteria | The comment modifications arising from the CD ballot are being made and the item will soon be advanced to DTS ballot. The item is of potential interest for Australia due to recent new Medical Benefits Scheme (MBS) Telehealth items.  
**Action:** Continue active consideration of this item on IT-014-12 work plan, and contribute to DTS ballot in due course. | IT-014-12  
Anthony Maeder |
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<td><strong>WG 2</strong>  &lt;br&gt;Ability to publish HL7 and other standards in HTML/XML format</td>
<td>Progress was reported in obtaining ISO/CS agreement to the TC 215 recommendation that material originally published in HTML format by partner SDOs not be required to be re-formatted into hard-copy pdf documents when being published as an ISO standard. This is important for HL7 standards including the V3 RIM and EHR Systems Functional Model. A series of detailed provisions now need to be worked through to allow HTML/XML publication of these documents (including update of the agreement between ISO and HL7 for publication of HL7 documents). &lt;br&gt;&lt;br&gt;Action: IT-014 to note and track progress in achieving this outcome.</td>
<td>IT-014</td>
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<td><strong>WG 3</strong>  &lt;br&gt;12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems</td>
<td>This work item was originally developed some years ago by Canada with support from Australia but was cancelled following lack of a leader and progress. Sandra Stuart (USA) will be the new leader and an NP ballot proposal is to be prepared along with updated draft of previous document and circulated for comment among experts. &lt;br&gt;&lt;br&gt;Action: Return to active work items for review by IT-014-02 to ensure circulation to the community.</td>
<td>IT-014-02</td>
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<td><strong>WG 3</strong>  &lt;br&gt;1828 Categorial structure for terminological systems of surgical procedures</td>
<td>When current FDIS ballot complete and IS 1828 is published as a standard, consider relevance and reference inclusion in IT-014-02 work items such as update of the data development guide. &lt;br&gt;&lt;br&gt;Action: Include as reference for Data Development work item in IT-014-02.</td>
<td>IT-014-02</td>
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<td><strong>WG 3</strong>  &lt;br&gt;ISO 17115 Vocabulary of terminological systems (Review/update of existing standard)</td>
<td>This document (currently a preliminary work item reconciling existing ISO 17115 with EN 12264 and updating health informatics definitions to best practice) will be a useful resource for IT-014’s harmonisation of terms and definitions and will inform IT-014-02 and other communities in Australia to improve processes used to maintain terminological resources. &lt;br&gt;&lt;br&gt;Action: Include as reference for Data Development work item in IT-014-02 and ensure review of this work by IT-014-02.</td>
<td>IT-014-02</td>
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<td><strong>WG 3</strong>  &lt;br&gt;TDR 12300 Principles of mapping between terminological resources</td>
<td>This Technical Report provides guidance for organizations charged with creating or applying mappings to meet their business needs. Final comments from expert review have been incorporated and it will go out to ballot for acceptance as a TR after this meeting. Comments have been received in the past from members of IT-014-02. &lt;br&gt;&lt;br&gt;Action: Ensure circulation to IT-014-02 and NEHTA for comment.</td>
<td>IT-014-02 (already on the work program)</td>
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<td><strong>WG 3</strong>  &lt;br&gt;ISO/NP/TR 14668 Guidelines for principles and desirable features of clinical decision support</td>
<td>IT-014-13 have indicated that they wish to concentrate on HL7 issues in the CDS space. They need also to provide input to this ISO work as the intention was originally to harmonise these initiatives. Failure to progress this would be of concern. &lt;br&gt;&lt;br&gt;Action: IT-014 to request IT-014-13 to include review of ISO guidelines on its work program.</td>
<td>IT-014  &lt;br&gt;IT-014-13</td>
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<td><strong>WG 3</strong>&lt;br&gt;ISO/DIS 13120&lt;br&gt;A syntax to represent the content of classification systems in healthcare</td>
<td>This draft International Standard presents a simple XML specification, ClaML, for safely exchanging and distributing the content and hierarchical structure of healthcare classification systems, building on CEN/TS 14463:2002. Once the updated draft and comment disposition is seen by WG3 members it will be ready for FDIS ballot. This standard is used extensively in Europe and the draft should be reviewed by AIHW, DoHA and NEHTA. IT-014 representatives before finalisation at WG3 to identify any specific concerns or issues relevant to Australia.&lt;br&gt;&lt;br&gt;Action: IT-014 members, specifically AIHW, DoHA and NEHTA to be invited to provide feedback via WG3 experts before draft is circulated to be accepted via FDIS ballot.</td>
<td>IT-014 members&lt;br&gt;AIHW&lt;br&gt;DoHA&lt;br&gt;NEHTA</td>
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<td><strong>WG 3</strong>&lt;br&gt;- Traditional Medicine Task Force (TMTF):&lt;br&gt;TCM Informatic framework and classification for standards development</td>
<td>New preliminary work item to develop a generic framework for standards in TCM informatics compatible with ISO/TR 17118:2005. Action: Australia to support and contribute to new work item proposal via a nominated country expert (interim: Anthony Maeder), maintain watch on progress of the item, and communicate progress to other Standards groups in Australia (e.g. IHTSDO, TCM).</td>
<td>IT-014 Anthony Maeder</td>
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<td><strong>WG 3 (TMTF)</strong>&lt;br&gt;ISO TS 16277-1&lt;br&gt;Categorial structures of clinical findings in traditional medicine - part 1 traditional east Asian medicine</td>
<td>This work uses a methodology to identify variations and requirements for representing traditional East Asian Medicine in a way that is consistent with existing processes for Western Medicine. The draft document has been distributed to ISO experts and comments are also to be sought from the IT-014-02 community and the IT-014 traditional medicine liaisons from the Standards Australia community. Action: Standards Australia (IT-014 team) to distribute for comments.</td>
<td>IT-014-02 and Traditional Medicine liaisons</td>
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<tr>
<td><strong>WG 3 (TMTF)</strong>&lt;br&gt;ISO/NP TS 16843-1&lt;br&gt;Categorial structures for representation of acupuncture - part 1: acupuncture points</td>
<td>This work identifies the system components necessary to represent acupuncture points but does not specify the value domain of that representation, though examples are provided. Action: IT-014 to seek advice and determine priority for this work and obtain contacts to provide feedback.</td>
<td>IT-014&lt;br&gt;IT-014-02</td>
</tr>
<tr>
<td><strong>WG 3 (TMTF)</strong>&lt;br&gt;ISO/NP TS 16843-2&lt;br&gt;Categorial structures for representation of acupuncture - part 2: needling</td>
<td>China will lead this work identifying the system components necessary to represent acupuncture needling, but does not specify the value domain of that representation, though examples are provided. Action: IT-014 to seek advice and determine priority for this work and obtain contacts to provide feedback.</td>
<td>IT-014&lt;br&gt;IT-014-02</td>
</tr>
<tr>
<td><strong>WG 3 (TMTF)</strong>&lt;br&gt;ISO TS 17948&lt;br&gt;Traditional Chinese Medicine Metadata</td>
<td>This work identifies the types of metadata required to represent, index and retrieve literature on Traditional Chinese Medicine. Time is being given for all WG3 members to review the document and the comment disposition and to raise issues or problems prior to this item being sent to committee ballot. Action: IT-014 to seek advice and determine priority for this work and obtain contacts to provide feedback, preferably before the committee ballot.</td>
<td>IT-014&lt;br&gt;IT-014-02</td>
</tr>
<tr>
<td>Topic</td>
<td>Issue/Action and Recommendations for Australia</td>
<td>Suggested responsibility &amp; alignment to IT-014</td>
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<tr>
<td>WG 3 (TMTF) ISO TS 17938 Semantic network framework and coding of traditional Chinese medicine language system</td>
<td>This work identifies the language (keywords etc) to be used when describing traditional medicine literature and research. Both the current draft and comments received to date are with WG3/TMTF experts for further review. <strong>Action:</strong> IT-014 to seek advice and determine priority for this work and obtain contacts to provide feedback.</td>
<td>IT-014 IT-014-02</td>
</tr>
<tr>
<td>WG 3 Conceptual framework for representation of treatment and diagnostic non-chemical stimulation methods</td>
<td>This work item (currently at preliminary stage) will define and clarify requirements for representing concepts for non-chemical stimulation (e.g. massage, acupuncture) in all healthcare environments, traditional as well as western. The conceptual framework will address (1) location and (2) treatment. This has been identified as a significant gap in the current representations provided by terminological resources and will therefore be undertaken by WG 3, rather than through the JWG 10 liaison mechanism for TCM. <strong>Action:</strong> IT-014 to contribute to new work item proposal by supporting with a country expert (Heather Grain was suggested), maintain watch on progress of the item, and communicate progress to other Standards groups in Australia (e.g. IHTSDO, TCM).</td>
<td>IT-014 IT-014-02 Heather Grain</td>
</tr>
<tr>
<td>WG 4 Business planning task force</td>
<td>Issue: Dr Trish Williams invited to be on new business planning committee for WG4 following the ISO/TC 215 reorganisation to align WG4 work program. <strong>Action:</strong> For noting and approval of IT-014.</td>
<td>IT-014 Standards Australia</td>
</tr>
<tr>
<td>WG 4 Preparation for next ISO meeting (May 2013)</td>
<td>Issue: To ensure that Australia’s interests in the areas of security, privacy and patient safety are included and standards relevant to Australia are on the TC 215/WG 4 agenda for the forthcoming meeting. <strong>Action:</strong> Dr Trish Williams to be advised of any security privacy or patient safety standard inclusions or issues required for consideration at next ISO (WG4) meeting.</td>
<td>IT-014-04 Standards Australia IT-014</td>
</tr>
<tr>
<td>WG 4 ISO 27799 Health Informatics – Information Security Management in health using 27002</td>
<td>Issue: As the changes to ISO 27799 (based on ISO 27002) are developed, IT-014-04 should actively review and incorporate into HB 174, if possible. <strong>Action:</strong> IT-014-04 to monitor ongoing review and revision of ISO 27799 and ISO 27002.</td>
<td>IT-014-04</td>
</tr>
<tr>
<td>Topic</td>
<td>Issue/Action and Recommendations for Australia</td>
<td>Suggested responsibility &amp; alignment to IT-014</td>
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<tr>
<td><strong>WG 4</strong>&lt;br&gt;ISO 17090 Health informatics – Public key infrastructure</td>
<td>There are four parts to this PKI standard  &lt;br&gt;- Part 1: Overview of digital certificate services  &lt;br&gt;- Part 2: Certificate profile  &lt;br&gt;- Part 3: Policy management of certification authority  &lt;br&gt;- Part 4: Digital signatures for healthcare documents. Parts 1, 2 and 3 were published in 2008 and were submitted to systematic review in 2011. Part 3 has been reconfirmed without change; some minor revisions are being made to part 1 and part 2 is being updated. Part 4 is a new work item – with a draft being reviewed by WG4 following many comments and some concerns about the preliminary draft. ISO currently has it listed for accelerated delivery as an International Workshop Agreement (IWA).&lt;br&gt;&lt;br&gt;<strong>Action:</strong> The work on ISO 17090 should be reviewed in relation to Australian requirements and, particularly, harmonisation of Part 4 with the needs of the National Authentication Service for Health (NASH).</td>
<td>NEHTA review and feedback to IT-014-04 for escalation to ISO WG4</td>
</tr>
<tr>
<td><strong>WG 4</strong>&lt;br&gt;ISO TS 25237 Pseudonymization</td>
<td>This ISO/TS, first published in 2008, is undergoing systematic review and possible elevation to a full international standard. In 2011 it was adopted without change as Australian Technical Specification, ATS ISO 25237-2011. The document provides principles and requirements for privacy protection of personal health information by means of pseudonymization services. In line with the policy favouring international adoption where possible, Australian requirements need to be considered in the systematic review and update of ISO TS 25237.&lt;br&gt;&lt;br&gt;<strong>Action:</strong> Confirm Dr Trish Williams listed as expert on Pseudonymization work item to ensure consistency with Australian requirements.</td>
<td>Standards Australia IT-014-04</td>
</tr>
<tr>
<td><strong>WG 4</strong>&lt;br&gt;ISO-DIS-22857&lt;br&gt;ISO 16864&lt;br&gt;Trans-border flows of personal health information</td>
<td>With respect to:&lt;br&gt;- ISO-DIS-22857 Guidelines on data protection to facilitate trans-border flows of personal health information&lt;br&gt;- ISO 16864 Data Protection in trans-border flows of personal health information&lt;br&gt;&lt;br&gt;As part of a systematic review, there is a plan is to merge two existing CEN documents on this topic and ISO 22857 documents into ISO 16864. However, all the relevant systematic review ballots need to be concluded before this can occur.&lt;br&gt;&lt;br&gt;As Australia has a large group of transient and holidaying population, and given its large migrant populations, more engagement of IT-014 in these standards should be promoted. This is important as the standards are being combined.&lt;br&gt;&lt;br&gt;<strong>Action:</strong> Increased promotion among IT-014 committees and stakeholders with a view to identifying resources to assist with the review of these standards as they are collated into one standard.</td>
<td>IT-014 IT-014-04 IT-014-09</td>
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<tr>
<td>Topic</td>
<td>Issue/Action and Recommendations for Australia</td>
<td>Suggested responsibility &amp; alignment to IT-014</td>
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<td><strong>WG 4</strong>&lt;br&gt;TS 17975 Principles and data structures for consent in the collection, use or disclosure of personal health information</td>
<td>This Technical Specification is at working draft stage and defines different models of informational consent (i.e., consent to collect, use or disclose information) used to obtain permission form subjects of care to process their personal health information. Australian models and practices need to be represented in the standard. Action: Seek input on draft document to ensure it is consistent, useful and relevant to appropriate current practices used for Australian e-health initiatives, taking into account the full range of experience and situations encountered across the country.</td>
<td>IT-014-04&lt;br&gt;Lead: Dr Trish Williams</td>
</tr>
<tr>
<td><strong>WG 4</strong>&lt;br&gt;NP- Medical Information Privacy Officer Education</td>
<td>This item is contentious in WG4 as to whether or not it is the place of ISO WG4 to be developing educational standards. Action: Assess whether this is a work item that Australia should be contributing to and taking a lead on. Review and provide comment on the currently open ballot by 7 November, 2012.</td>
<td>IT-014-04</td>
</tr>
<tr>
<td><strong>WG 4</strong>&lt;br&gt;ISO/IEC WD 29190 – Privacy capability maturity model</td>
<td>The development of ISO/IEC WD 29190 – Privacy capability maturity model (referred to ISO/TC 215 from ISO/IEC JTC 1/SC27 may be relevant to the NESAF project and work on IT-014 standards arising from NESAF. Action: IT-014-04 to review ISO/IEC WD 29190 – Privacy capability maturity model for its applicability under the existing NESAF project on the IT-014-04 work program and more generally as a potential part of Australia’s e-health security framework.</td>
<td>IT-014-04</td>
</tr>
<tr>
<td><strong>WG 6</strong>&lt;br&gt;ISO 17251 Model for dose syntax</td>
<td>A CD for ISO/DTS 17251 is expected for presentation at the next ISO meeting. 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.</td>
<td>IT-014-06-04&lt;br&gt;NEHTA</td>
</tr>
<tr>
<td><strong>WG 6</strong>&lt;br&gt;ISO 16791 Requirements for machine-readable of medicinal product package identifiers</td>
<td>The DTS for ISO 16791 will be out for ballot around the new year. Recommend that Australia formulate an opinion on the suitability of the DTS for the Australian market. Action: IT-014-06-04 to monitor for release of the standard and assess impact on Australian market place.</td>
<td>IT-014-06-04&lt;br&gt;TGA&lt;br&gt;NEHTA</td>
</tr>
<tr>
<td><strong>WG 6</strong>&lt;br&gt;Identification of Medicinal Products (IDMP)</td>
<td>All 5 standards in the IDMP series will be published as full international standards in the coming months. Action: The TGA to understand suitability of the 5 standards for adoption in Australia. If any extension is required for the Australian market this may have to be realised through an Australian Standard.</td>
<td>TGA</td>
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<td>Topic</td>
<td>Issue/Action and Recommendations for Australia</td>
<td>Suggested responsibility &amp; alignment to IT-014</td>
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<tr>
<td>JWG 7</td>
<td>Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities</td>
<td>DoHA State and Territory CIOs</td>
</tr>
<tr>
<td>IEC 80001-1:2010</td>
<td>Part 2-1 Step by Step Risk Management of Medical IT-Networks Practical Applications and Examples</td>
<td></td>
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<tr>
<td>IEC TR 80001-2-1</td>
<td>Part 2-2 Guidance for the communication of medical device security needs, risks and controls</td>
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<tr>
<td>IEC TR 80001-2-3</td>
<td>This Standard and its associated Technical Reports address key issues of safety in complex Health IT networks incorporating Medical Devices.</td>
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<tr>
<td><strong>Action:</strong></td>
<td>Ensure that State and Territory CIO’s are aware of these recent publications.</td>
<td>Standards Australia</td>
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<tr>
<td><strong>Action:</strong></td>
<td>There is a need to identify or establish an appropriate Standards Australia mirror committee for JWG7 work items especially those related to Health Software safety.</td>
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<tr>
<td>JWG 7</td>
<td>This Technical report provides a comprehensive survey of issues related to the safety of Health Software and relevant International and National Standards work in this area. This publication provides very useful background for anyone undertaking work in this area.</td>
<td>Standards Australia</td>
</tr>
<tr>
<td>ISO TR17791</td>
<td>Action: Advertise the availability of this publication to relevant Government and Private sector groups such as the Safety and Quality Commission, DoHA, AMA, RACGP and the Private Hospitals Association as well as Health software developers through the MSIA, AIIA and ACIVA.</td>
<td></td>
</tr>
<tr>
<td><strong>JWG 7</strong></td>
<td>This is a standard which, when completed, may have far-reaching impact on the Healthcare industry. There needs to be adequate engagement with all affected Healthcare sectors and particularly the Health Software industry and the eHealth area within DoHA.</td>
<td>Standards Australia</td>
</tr>
<tr>
<td>IEC/ISO 82304-1</td>
<td>Action: Develop a plan to engage with Health CIOs at all levels. Plan for appropriate resourcing of attendance at out of session face-to-face meetings which will be used to “fast-track” development of this document.</td>
<td>DoHA MSIA</td>
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<tr>
<td>Health Software – General Requirements for Product Safety</td>
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<tr>
<td>E-Health standards for Low &amp; Medium Income Countries (LMICs)</td>
<td>Issue: Opportunities exist for collaboration with initiatives by HL7 International to extend reach of e-health standards to LMICs.</td>
<td>IT-014 Richard Dixon Hughes Anthony Maeder</td>
</tr>
<tr>
<td></td>
<td>Action: Collaboration opportunities should be explored between IT-014 and HL7 Australia in the area of standards education and liaison, especially to Australia’s established regional partner nations.</td>
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</tbody>
</table>
### Standards Knowledge Management Tool (SKMT) Governance Committee

The establishment of the SKMT Governance Committee means that IT-014, as a contributing member of the SKMT community may appoint a representative to this committee. This person may be an individual already on the committee or an additional person and should understand the principles of both the document and glossary elements of this tool and act as liaison between the SKMT Governance Committee of the JIC and Standards Australia IT-014. This committee identifies priorities for development of the web based tool, as well as providing oversight to term/definition harmonisation activities.

A copy of the governance terms of reference will be provided for circulation to IT-014 members.

**Action:** Identify IT-014’s representative to the SKMT Governance Committee.

**Note:** Should NEHTA formally decide to add their documents/terms and definitions to this tool, they two would be entitled to a representative.

<table>
<thead>
<tr>
<th>Suggested responsibility &amp; alignment to IT-014</th>
<th>NEHTA</th>
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</table>

### 5. FUNDING SOURCE SUMMARY

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

<table>
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<tr>
<th>Funding Source</th>
<th>Number</th>
<th>Change from Previous Meeting</th>
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<tr>
<td>Full funding by employer: Private</td>
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<tr>
<td>Full funding by employer: States/Territories or National Initiatives (NEHTA)</td>
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<td>Funding Assistance – DoHA through Standards Australia contract</td>
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<td>Total:</td>
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The Australian delegation comprised:

- Richard Dixon Hughes (Head of Delegation)
- Heather Grain (Delegate)
- Anthony Maeder (Delegate)
- Patricia Williams (Delegate)
- Vince McCauley (Delegate)
- Heather Leslie (Delegate)
- Michael Steine (Delegate)
- Erin Holmes (mentored position)
- Naomi Ryan (WG1 Secretariat)
6. ATTENDANCE

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

| AM – Anthony Maeder | NR – Naomi Ryan |
| EH – Erin Holmes | RDH – Richard Dixon Hughes |
| HG - Heather Grain | TW – Trish Williams |
| HL - Heather Leslie | VM – Vince McCauley |
| MS – Michael Steine |

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<tr>
<th>Meeting</th>
<th>Sat 22nd</th>
<th>Sun 23rd</th>
<th>Mon 24th</th>
<th>Tues 25th</th>
<th>Wed 26th</th>
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<td>WG 1 - Architecture</td>
<td>NR, EH, HL, RDH</td>
<td>NR, EH, AM, HL, RDH</td>
<td>HG</td>
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<td>WG 2 - Data Interchange</td>
<td>HG</td>
<td>AM, RDH</td>
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<td>WG 7 – Devices</td>
<td>RDH (Q2)</td>
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<td>Traditional Medicine Taskforce</td>
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<td>HG</td>
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<td>Exec Council - invitation only</td>
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<td>Operations &amp; Harmonisation</td>
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7. POSITIONS HELD BY DELEGATES

The DoHA funded delegates were selected through an independent panel process jointly with NEHTA, DoHA and HL7 Australia facilitated by Standards Australia. The positions of these delegates (including leadership positions) are listed below.

<table>
<thead>
<tr>
<th>Working Group or Committee</th>
<th>Position</th>
<th>Status</th>
<th>Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Delegation</td>
<td>Head of Delegation</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>TC 215 Organization Task</td>
<td>Members</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>Force</td>
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<td></td>
<td>Heather Grain</td>
</tr>
<tr>
<td>TC 215 – Task Force on</td>
<td>Leader – Role Incorporated into Ad Hoc on SBP</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>project assessment &amp;</td>
<td></td>
<td></td>
<td>Heather Grain</td>
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<tr>
<td>prioritization criteria</td>
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<tr>
<td>ISO/IEC JTC 1 Liaison to</td>
<td>Nominated JTC 1 Liaison Officer</td>
<td>Appointed by JTC 1</td>
<td>Richard Dixon Hughes</td>
</tr>
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<td>TC 215</td>
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<tr>
<td>Joint Initiative Council</td>
<td>Chair-elect (confirmed at this meeting)</td>
<td>Appointed by TC 215</td>
<td>Richard Dixon Hughes</td>
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<tr>
<td>(Executive Meetings)</td>
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<tr>
<td>TC 215 Ad Hoc on</td>
<td>Co-Leader</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
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<tr>
<td>Business Strategic Plan</td>
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<tr>
<td>TC 215</td>
<td>SKMT advisor and support (WG3 representative)</td>
<td>Appointed by the plenary at</td>
<td>Heather Grain</td>
</tr>
<tr>
<td>ISO/TC 215 WG 1 Public</td>
<td>National Expert</td>
<td>Lead on nominated sections</td>
<td>Richard Dixon Hughes</td>
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<tr>
<td>Health Task Force</td>
<td></td>
<td>for document drafting</td>
<td>Anthony Maeder</td>
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<tr>
<td>ISO/TC 215 WG 1 Public</td>
<td>Secretariat</td>
<td>Appointed</td>
<td>Standards Australia</td>
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<tr>
<td>Health Task Force</td>
<td></td>
<td></td>
<td>(IT-014 Program Manager) –</td>
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<tr>
<td>ISO/TC 215 WG 1 Public</td>
<td>ISO/WG 14639-2 Health informatics — Capacity-based</td>
<td>Appointed</td>
<td>Dr Vincent McCauley</td>
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<td>Health Task Force</td>
<td>ehealth architecture roadmap — Part 2: Architectural</td>
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<td></td>
<td>Diagnostics Chapter Author</td>
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<td>WG 1 - Architecture</td>
<td>Secretariat</td>
<td>Appointed</td>
<td>Standards Australia</td>
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<td></td>
<td></td>
<td>(IT-014 Program Manager) –</td>
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<td></td>
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<td></td>
<td>Naomi Ryan</td>
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<tr>
<td>WG 1 - Architecture</td>
<td>ISO TS 13972 Health Informatics - Characteristics</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
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<td>and Processes of Detailed Clinical Models National</td>
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<td>Evelyn Hovenga</td>
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<td></td>
<td>Expert</td>
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<td>Dr Heather Leslie</td>
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<td></td>
<td>National expert nominated to contribute to several</td>
<td>Nominated</td>
<td>Richard Dixon Hughes</td>
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<td></td>
<td>work items including DCMs and EHR-S FM</td>
<td>expert</td>
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<thead>
<tr>
<th>Working Group or Committee</th>
<th>Position</th>
<th>Status</th>
<th>Person</th>
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<tbody>
<tr>
<td>WG 2 – Data Interchange</td>
<td>ISO17583 - - “Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange” National Expert</td>
<td>Appointed</td>
<td>Dr Vincent McCauley</td>
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<tr>
<td>WG 2 – Data Interchange</td>
<td>ISO/DTS 13131 country expert</td>
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<td>Anthony Maeder</td>
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<tr>
<td>WG 3 – Semantic Content</td>
<td>Convenor</td>
<td>Elected (to May 2013)</td>
<td>Heather Grain</td>
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<td>WG 3 - Semantic Content</td>
<td>12300 Principles of mapping between terminological resources. ISO TS 17439 Structure and maintenance of the health informatics glossary 14668 Guidelines for principles and desirable features of Clinical Decision Support</td>
<td>Project leader and author</td>
<td>Heather Grain</td>
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<td>WG 3 - Semantic Content</td>
<td>12310 – Principles and guidelines for the measurement of conformance in the implementation of terminology systems. ISO 17115:2007 Vocabulary for terminological systems (VOTE) ISO 17117 Terminological resources Part 1 – Framework ISO TS 16277-1 TS Health Informatics - Categorial structure of clinical finding in traditional medicine- Part 1: Traditional East Asian Medicine</td>
<td>National expert nominated to the work item</td>
<td>Heather Grain</td>
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<td>WG 3 - Semantic Content</td>
<td>ISO17583 - - “Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange”</td>
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<tr>
<td>WG 4 - Security, Safety and Privacy</td>
<td>National experts sub-committee for ISO 17791 Health informatics – Guidance on Standards Enabling Safety in Health Software</td>
<td>Appointed by WG 4</td>
<td>Dr Trish Williams</td>
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<tr>
<td>WG 4 - Security, Safety and Privacy</td>
<td>National experts sub-committee for ISO/DTS 17975 Health Informatics – Principles and data structures for consent in the collection, use, or disclosure of personal health information</td>
<td>Appointed by WG 4</td>
<td>Dr Trish Williams</td>
</tr>
<tr>
<td>Working Group or Committee</td>
<td>Position</td>
<td>Status</td>
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</table>
| WG 4 - Security, Safety and Privacy | National experts sub-committee for ISO/PWI Health informatics - Information security management in health using ISO/IEC 27002 | Appointed by WG 4                      | Dr Trish Williams  
Dr Vincent McCauley |
| Traditional Medicine Task Force (TMTF) | National Expert                                                          | Australian national nominated expert    | Anthony Maeder, Heather Grain |
National experts sub-committee | Appointed                             | Dr Trish Williams  
Dr Vincent McCauley |
| Joint Working Group 7 | Specialist group to finalise 80001-2-x “Guidance for Responsibility agreements” in context of risk management of IT networks containing medical devices. | Appointed                             | Dr Vincent McCauley |
| Joint Working Group 7 | Member Ad Hoc group to develop overarching approach to Health Software Standards | Appointed by JWG 7                   | Dr Vincent McCauley |
# 8. ACRONYMS

<p>| <strong>ACCC</strong> | Australian Competition and Consumer Commission |
| <strong>ACMA</strong> | Australian Communication and Media Authority |
| <strong>ACSQHC</strong> | Australian Commission on Safety and Quality in Health Care |
| <strong>ACTUG</strong> | Australian Clinical Terminology Users Group |
| <strong>ADL</strong> | Archetype Definition Language |
| <strong>AG</strong> | Advisory Group |
| <strong>AHIMA</strong> | American Health Information Management Association |
| <strong>AHMAC</strong> | Australian Health Ministers’ Advisory Council |
| <strong>AHML</strong> | Australian Healthcare Messaging Laboratory |
| <strong>AIHW</strong> | Australian Institute of Health &amp; Welfare |
| <strong>AIIA</strong> | Australian Information Industry Association |
| <strong>AMT</strong> | Australian Medicines Terminology |
| <strong>ANSI</strong> | American National Standards Institute |
| <strong>ArB</strong> | Architecture Review Board |
| <strong>AS HB</strong> | Australian Handbook |
| <strong>AS/NZS</strong> | Australian/New Zealand Handbook |
| <strong>AS/NZS ISO</strong> | International Standards adopted by Australia and New Zealand |
| <strong>AWI</strong> | Approved Work Item |
| <strong>CASCO</strong> | Conformity Assessment |
| <strong>CBCC</strong> | Community Based Collaborative Care Workshop |
| <strong>CCHIT (US)</strong> | Certification Commission for Health Information Technology |
| <strong>CD</strong> | Committee Draft (third stage in developing an ISO or IEC standard) |
| <strong>CDA</strong> | Clinical Document Architecture |
| <strong>CDISC</strong> | Clinical Data Standards Interchange Consortium |
| <strong>CDS</strong> | Clinical Decision Support |
| <strong>CDV</strong> | Committee Draft for Vote |
| <strong>CEN</strong> | European Committee for Standardization (Comité Européen de Normalisation) |
| <strong>CIC</strong> | Clinical Interoperability Council Workgroup |
| <strong>CIS</strong> | Clinical Information Systems |
| <strong>COAG</strong> | Council of Australian Governments |
| <strong>DAFF</strong> | Department of Agriculture, Fisheries and Forestry |
| <strong>DAM</strong> | Domain Analysis Model (comprehensive model of a domain) |
| <strong>DCM</strong> | Detailed Clinical Model |
| <strong>DCOR, COR</strong> | (Draft) Corrigendum |
| <strong>DICOM</strong> | Digital Imaging and Communications in Medicine |
| <strong>DIISR</strong> | Department of Innovation, Industry, Science &amp; Research |</p>
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIS</td>
<td>Draft International Standard (fourth stage in developing an ISO or IEC standard – the main opportunity for public input)</td>
</tr>
<tr>
<td>DoHA</td>
<td>(Australian Government) Department of Health and Ageing</td>
</tr>
<tr>
<td>DMP</td>
<td>Dossier Médical Partagé (Shared Medical Record) (France)</td>
</tr>
<tr>
<td>DSTU</td>
<td>Draft Standards for Trial Use (HL7 and ANSI)</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission [the administrative arm of the EU]</td>
</tr>
<tr>
<td>ECCF</td>
<td>Enterprise Compliance and Conformance Framework</td>
</tr>
<tr>
<td>EFMI</td>
<td>European Federation of Medical Informatics</td>
</tr>
<tr>
<td>eHIF</td>
<td>E-health Interoperability Framework [Standards Australia &amp; NEHTA]</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>EHRS or EHR-S</td>
<td>Electronic Health Record System</td>
</tr>
<tr>
<td>ELGA</td>
<td>Austrian CDA Implementation Guide in Development</td>
</tr>
<tr>
<td>ELS</td>
<td>End Point Location Service</td>
</tr>
<tr>
<td>EMEA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EN</td>
<td>European Standard (Européen Norm)</td>
</tr>
<tr>
<td>ETP</td>
<td>Electronic Transfer of Prescriptions</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FDAM</td>
<td>Final Draft Amendment</td>
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<tr>
<td>FCD</td>
<td>Final committee draft</td>
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<tr>
<td>FDIS</td>
<td>[ISO] Final Draft International Standard (for vote to publish)</td>
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<td>GCM</td>
<td>Generic Component Model</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>GS1</td>
<td>An international SDO – primarily in the supply-chain domain</td>
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<tr>
<td>HDF</td>
<td>HL7 Development Framework</td>
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<td>HI</td>
<td>Health Identifiers</td>
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<tr>
<td>HIE</td>
<td>Health Information Exchange</td>
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<tr>
<td>HIMSS</td>
<td>Healthcare Information and Management Systems Society</td>
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<tr>
<td>HITSP</td>
<td>Health Information Technology Standards Panel</td>
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<td>HL7</td>
<td>Health Level Seven (International)</td>
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<td>HL7 ELC</td>
<td>HL7 E-Learning Course</td>
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<td>HPI</td>
<td>Healthcare Provider Identifier</td>
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<tr>
<td>HPI-I</td>
<td>Healthcare Provider Identifier for Individuals</td>
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<tr>
<td>HPI-O</td>
<td>Healthcare Provider Identifier for Providers</td>
</tr>
<tr>
<td>HSSP</td>
<td>Healthcare Services Specification Project [joint HL7/OMG]</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)</td>
</tr>
<tr>
<td>ICOGRADA</td>
<td>International Council of Graphic Design Associations</td>
</tr>
<tr>
<td>ICT</td>
<td>Information &amp; Communications Technology</td>
</tr>
<tr>
<td>ICSR</td>
<td>Individual Case Safety Report [related to Medicines/Devices]</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>IDMP</td>
<td>Identification of Medicinal Products</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission (an international SDO)</td>
</tr>
<tr>
<td>IEEE</td>
<td>Institute of Electrical &amp; Electronic Engineers (US) (also an SDO)</td>
</tr>
<tr>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
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<tr>
<td>IHI</td>
<td>Individual Healthcare Identifier</td>
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<tr>
<td>IHTSDO</td>
<td>International Health Terminology Standards Development Organisation</td>
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<td>IS</td>
<td>International Standard</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>ISO/CS</td>
<td>ISO Central Secretariat</td>
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<tr>
<td>ITS</td>
<td>Implementable Technology Specifications</td>
</tr>
<tr>
<td>IXS</td>
<td>Identity Cross Reference Service</td>
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<tr>
<td>IT-014</td>
<td>Standards Australia Committee IT-014 (Health Informatics)</td>
</tr>
<tr>
<td>ITU-T</td>
<td>International Telecommunications Union – Standards Division</td>
</tr>
<tr>
<td>JI</td>
<td>Joint Initiative on SDO Global Health Informatics Standardization</td>
</tr>
<tr>
<td>JIC</td>
<td>Joint Initiative Council (responsible for governance of the JI – with current members being ISO/TC 215, CEN/TC251, HL7 International, CDISC, IHTSDO and GS1)</td>
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<tr>
<td>JTC</td>
<td>Joint Technical Committee</td>
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<td>JTC 1</td>
<td>ISO/IEC Joint Technical Committee 1 Information Technology</td>
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<tr>
<td>JWG</td>
<td>Joint Working Group [under the JI, unless otherwise specified]</td>
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<td>JWG7</td>
<td>Joint working group of IEC 62A and ISO/TC 215</td>
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<td>KPI</td>
<td>Key Performance Indicator</td>
</tr>
<tr>
<td>LB</td>
<td>Letter Ballot</td>
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<td>LMIC</td>
<td>Low and Medium Income Countries</td>
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<tr>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes</td>
</tr>
<tr>
<td>LPO</td>
<td>Local PCEHR Officer</td>
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<tr>
<td>MBS</td>
<td>Medical Benefits Scheme</td>
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<tr>
<td>MDA</td>
<td>Model Driven Architecture</td>
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<tr>
<td>MM</td>
<td>Maturity Model</td>
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<tr>
<td>MSIA</td>
<td>Medical Software Industry Association</td>
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<tr>
<td>NASH</td>
<td>National Authentication Service for Health</td>
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<tr>
<td>NATA</td>
<td>National Association of Testing Authorities</td>
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<td>NEHTA</td>
<td>(Australian) National E-Health Transition Authority</td>
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<tr>
<td>NH&amp;MRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NHIN</td>
<td>(US) National Health Information Network</td>
</tr>
<tr>
<td>NHS</td>
<td>(UK) National Health Service</td>
</tr>
<tr>
<td>NIH</td>
<td>(US) National Institutes of Health</td>
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<tr>
<td>NIST</td>
<td>National Institute of Standards and Testing</td>
</tr>
<tr>
<td>Normapme</td>
<td>European Office of Crafts, Trades and Small and Medium sized Enterprises for Standardisation</td>
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<tr>
<td>NMB</td>
<td>National Member Body [of ISO or CEN]</td>
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<td>Acronym</td>
<td>Description</td>
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<tr>
<td>NP</td>
<td>New Work Item Proposal (current ISO/IEC abbreviation)</td>
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<td>NPACC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<tr>
<td>NSO</td>
<td>National Standards Office</td>
</tr>
<tr>
<td>NWIP</td>
<td>New Work Item Proposal (obsolete ISO/IEC abbreviation – see &quot;NP&quot;)</td>
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<td>OBPR</td>
<td>Office of Best Practice Regulation</td>
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<td>OCL</td>
<td>Object Constraint Language</td>
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<td>OID</td>
<td>Object Identifier</td>
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<td>OMG</td>
<td>Object Management Group</td>
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<td>ONC</td>
<td>Office of the National Coordinator for Health Information Technology (within US Department of Health and Human Services)</td>
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<td>O&amp;O</td>
<td>Orders and Observations Workgroup</td>
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<td>OSI</td>
<td>Open Systems Interconnection</td>
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<td>OTF</td>
<td>Organisation Task Force [ISO/TC 215]</td>
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<td>OWL</td>
<td>Web Ontology Language</td>
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<td>PACS</td>
<td>Picture Archive Systems</td>
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<td>PAS</td>
<td>Patient Administration Systems</td>
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<td>PDAM, DAM</td>
<td>(Proposed) Draft Amendment</td>
</tr>
<tr>
<td>PDF</td>
<td>Portable Document Format</td>
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<tr>
<td>PDTR, DTR</td>
<td>(Proposed) Draft Technical Report</td>
</tr>
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<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<td>PCEHR</td>
<td>Personally Controlled Electronic Health Record</td>
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<td>PHDSC</td>
<td>Public Health Data Standards Consortium</td>
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<td>PHR</td>
<td>Personal Health Record</td>
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<td>PHTF</td>
<td>Public Health Task Force</td>
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<td>PIM</td>
<td>Platform Independent Model</td>
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<td>PIP</td>
<td>Practice Incentive Payment</td>
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<td>PIR</td>
<td>Post Implementation Review</td>
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<td>PKI</td>
<td>Public Key Infrastructure</td>
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<td>PM</td>
<td>Project Manager</td>
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<td>PMBOK</td>
<td>Project Management Body of Knowledge</td>
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<td>PMS</td>
<td>Practice Management System</td>
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<td>PMTL</td>
<td>Project Management Team Leader</td>
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<td>PoC</td>
<td>Point-of-Care</td>
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<td>PSM</td>
<td>Platform Specific Model</td>
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<td>RACGP</td>
<td>Royal Australian College of General Practice</td>
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<td>RCPA</td>
<td>Royal College of Pathologists Australia</td>
</tr>
<tr>
<td>RHIO</td>
<td>(US) Regional Health Information Organisation</td>
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<td>RIMBAA</td>
<td>RIM Based Application Architecture</td>
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<td>RIM</td>
<td>Reference Information Model</td>
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<td>Description</td>
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<tr>
<td>RIS</td>
<td>Radiology Information Systems</td>
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<td>RLUS</td>
<td>Resource Locate Update Service (HSSP)</td>
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<td>RM-ODP</td>
<td>Reference Model of Open Distributed Processing</td>
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<td>SA</td>
<td>Standards Australia</td>
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<td>SAIF</td>
<td>Services Aware Interoperability Framework</td>
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<td>SBP</td>
<td>Strategic Business Plan [ISO &amp; IEC]</td>
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<td>SC</td>
<td>Subcommittee</td>
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<td>SDO</td>
<td>Standards Development Organisation</td>
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<td>Special Interest Group</td>
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<td>SKMT</td>
<td>Standards Knowledge Management Tool</td>
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<td>SLA</td>
<td>Service Level Agreement</td>
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<td>SME</td>
<td>Subject Matter Experts</td>
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<td>SMTP</td>
<td>Simple Mail Transfer Protocol</td>
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<td>SNOMED</td>
<td>Systematised Nomenclature of Medicine</td>
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<td>SOA</td>
<td>Service Oriented Architecture</td>
</tr>
<tr>
<td>SOAP</td>
<td>Simple Object Access Protocol</td>
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<td>TC</td>
<td>Technical Committee</td>
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<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
</tr>
<tr>
<td>TCP/IP</td>
<td>Transmission Control Protocol/Internet Protocol</td>
</tr>
<tr>
<td>TEAM</td>
<td>Traditional East Asian Medicine – This term, though inadequate is used to represent Traditional Chinese Medicine, Traditional Korean Medicine, Traditional Japanese Medicine.</td>
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<tr>
<td>TF</td>
<td>Task Force</td>
</tr>
<tr>
<td>TM</td>
<td>Traditional Medicine</td>
</tr>
<tr>
<td>TOGAF</td>
<td>The Open Group Architecture Framework</td>
</tr>
<tr>
<td>TR</td>
<td>Technical Report (an informative ISO or IEC standards publication)</td>
</tr>
<tr>
<td>TS</td>
<td>Technical Specification (a normative standards publication having a lower level of consensus than a full international standard)</td>
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<tr>
<td>UCUM</td>
<td>Unified Code for Units of Measure [Regenstrief Institute]</td>
</tr>
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<td>UML</td>
<td>Unified Modelling Language</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
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<td>VMR</td>
<td>Virtual Medical Record</td>
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<td>W3C</td>
<td>World Wide Web Consortium</td>
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<tr>
<td>WD</td>
<td>Working Draft (second stage in developing an ISO or IEC standard)</td>
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<td>WG</td>
<td>Working Group or Work Group</td>
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<td>WGM</td>
<td>Working Group Meeting</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WI</td>
<td>Work Item</td>
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<td>WTO</td>
<td>World Trade Organisation</td>
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<td>XDS</td>
<td>(IHE’s) cross enterprise Data Sharing protocol</td>
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<tr>
<td>XML</td>
<td>Extensible Markup Language</td>
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9. DETAILED REPORT ON ACTIVITIES

9.1 Executive Council (EC) and Technical Committee (TC) 215 Governance

| Australian Delegate Attendance | Richard Dixon Hughes (Australian HoD)  
Heather Grain (Convener WG 3) |

9.1.1 BACKGROUND

The TC 215 Executive Council comprises the TC 215 Chair, the Head of Delegation for each country, and the Convener and Vice-Convener 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 proposed TC 215 structure the Executive Council will continue as a formally recognised advisory group, with the designation "CAG 1 Executive Council".

9.1.2 PROGRESS AT THIS MEETING

The EC met from 1300 to 1600 on Sunday 23 September, the day before the main TC 215 meetings commenced. Most of the EC time was devoted to discussion of the TC 215 reorganisation and associated issues relating to the update of the TC 215 Strategic Business Plan (SBP) and alignment of its processes with those of ISO Central Secretariat (ISO/CS).

The Chair of ISO/TC 215, Dr Chris Chute, indicated his desire to get the new TC 215 organisation operational as soon as possible and outlined progress at further discussions that had involved himself, Lisa Spellman (TC 215 Secretariat), Jeremy Thorp (Chair, TC 215 Reorganisation Task Force), Richard Dixon Hughes (Chair, Assessment Criteria Group) and Dr Mary Lou Pélaprat of ISO/CS. The aim of these discussions was to resolve all of ISO/CS's remaining issues with the TC 215 organisation and to follow up on TC 215's need to produce joint publications with other SDOs effectively and efficiently.

The decision of HL7 to license its standards and other selected IP available free of charge was mentioned by Dr Chute as an important development which potentially changes the balance of interests in the environments in which TC 215 operates.

Bron Kisler, Chair of the Joint Initiative Council (JIC), and Don Newsham, Convenor of the Cross-SDO Coordination Group (CAG 3), provided a summary of the outcomes of the JIC strategic planning day, which had been held the previous day (Saturday, 22 September). These outcomes had also been presented to the JIC Open Forum on the Sunday morning, where there had been lively discussion. These outcomes were also presented to the closing plenary in summary form. Key strategic outcomes are summarised at 9.4.2 below.

It was noted that Richard Dixon Hughes had been nominated to become the independent chair of the JIC for two years commencing on 1 January 2013, when the role passes to
ISO/TC 215. His appointment was subsequently confirmed by resolution at the closing plenary.

Jeremy Thorp presented the work that was being undertaken to bring the reorganisation of TC 215 to a conclusion, highlighting the changes that were being made to accommodate the needs of ISO/CS, the status of the recommendations and proposals for its completion. Richard Dixon Hughes spoke briefly about the project assessment criteria and the need for these to be developed in the context of the updated TC 215 SBP.

There was considerable discussion around implementation of the final reorganisation proposals and the need to progress the SBP.

The TC 215 Chair asked Jeremy Thorp and Richard Dixon Hughes to lead an Ad Hoc group to progress the update of the TC 215 SBP, which they agreed to do. Other delegates interested in contributing were invited to put their names forward as members of the Ad Hoc group. A significant number of delegates indicated interest at various times – an email has been sent out to all delegates to ensure that none of those who wish to contribute are overlooked.

Further detail on TC 215 governance issues including finalising implementation of the new TC 215 organisation and the update of the SBP is provided at 9.1.3 below.

Dr Mary Lou Pélaprat, the Technical Programme Manager at ISO/CS responsible for TC 215 provided some background on ISO and the scale of its activities, before moving to more detailed advice on what is needed for TC 215 to progress its activities by getting maximum value from its relationship with ISO/CS and avoiding problems. Key points from this and other presentations that Dr Pélaprat made at various times during this TC 215 are summarised at 9.2.3 below.

Although identified and reinforced at meetings of TC215 since October 2011, many convenors did not appear to have taken to heart the requirement that work items not be put to ballot for acceptance until the items are fully worked up and ready to go, preferably with a full draft. WG 3 led by Heather Grain has followed this requirement since it was promulgated at the October 2011 meeting. New Proposals must be fully justified and properly documented ensuring that they are very robust. Information must also be provided to demonstrate the market relevance of a proposal.

At this meeting, further presentation and discussion of this topic generated considerably more questions than previously and hopefully this signals respect for the change in process. At the final plenary there were fewer new items coming forward which may mean that the requested changes in process are having effect. It was noted that this change does not necessarily mean that there will be less work for TC 215 in the long term, although that is one possibility, but that work will be better prioritised and justified and will not come forward as early in the process.

Potential arrangements for future ISO/TC 215 meetings were discussed, with the lack of a host for the next scheduled meeting in April/May 2013 becoming critical. As reported further at 9.1.4 below, some progress appears to have been made in resolving these issues over the period of the TC 215 meeting.
9.1.3 TC 215 ORGANISATION AND GOVERNANCE

9.1.3.1 Introduction

The Business Planning and Reorganization Task Force (TF) was formed at the May 2010 meeting in Rio de Janeiro with an initial focus on achieving a more efficient organisation for TC 215 and also to update the TC 215 strategic business plan (SBP).

9.1.3.2 Recent progress

After consultation around key principles and scope of TC 215, the TF developed proposals for the restructure of TC 215, which were accepted in principle at the May 2011 plenary in Kuopio, Finland.

As indicated in reports of Australian delegations to the TC 215 meetings in October 2011 (Chicago) and May 2012 (Vancouver), further proposals to implement the restructure were developed, presented and appeared to be generally accepted at these meetings. However, careful review of the records indicated that formal resolutions had yet to be passed to adopt many of the proposals.

The TC 215 restructure proposals have also been discussed at length with the ISO Central Secretariat since the October 2011 TC 215 meeting. ANSI, the US national member body responsible to ISO for the TC 215 Secretariat, has been assisting the TC 215 leadership in these discussions, which have focussed on concerns raised by ISO/CS, such as:

- A request to align proposed internal TC 215 organisational sub-groups more closely with the types of organisational entities allowed by the ISO/IEC Directives

  While largely a question of using appropriate names for the various groups, there were some aspects (such as cross-cutting working groups rather than subcommittees to manage other domain working groups) that TC 215 had to justify. Some proposed aspects had to be changed so that they could operate with current ISO systems.

- Minimising structures and processes unique to TC 215 to ensure that its operation and structure would be clear and understood by all national standards bodies and liaison organisations and could be represented within ISO's electronic support systems.

  While TC 215 will implement some additional internal processes, it must ensure that all interaction with national member bodies, ISO/CS and central systems are in accordance with the ISO/IEC Directives. Some measures originally proposed, such as having supplementary agreements with TC 215 national member bodies to clarify and encourage their involvement in TC 215 activities, were taken out to address this issue. Other procedural aspects originally proposed by TC 215 have been addressed by the most recent updates to the ISO/IEC Directives.

- Ensuring that TC 215 updates its strategic business plan (SBP). The current TC 215 business plan is obsolete and incomplete. Much of the strategic content of the TC 215 restructure report was considered by ISO/CS to be more relevant content for the SBP and will be re-used in that context.

- The need for TC 215 to follow proper process and obtain required approvals for things like proposed changes to the committee scope.
- Ensuring that proposed TC 215 processes continue to support national member bodies making final decisions (with appropriate notice) on committee matters and activities and that they not be supplanted by greater executive decision-making powers.

- The need to articulate and approve the proposed changes to TC 215 structure, ensuring that consequent changes to ISO/CS records and systems can be made by personnel that do not have direct knowledge of TC 215 and its activities.

9.1.3.3 Revised proposals

At the opening plenary, Jeremy Thorp, Chair of the TC 215 Reorganisation Task Force presented the outcomes of discussions with ISO/CS, noting that:

- ISO/CS was positive about TC 215 thinking creatively and strategically to clarify and refine its processes.

- TC 215's proposed approaches to ensuring its strategy, its portfolio of standards and proposed work items are reviewed more consistently, fit together and are relevant to stakeholder needs are supported by ISO and are consistent with overall ISO strategy and recent changes to the ISO/IEC Directives.

- TC215 needs to prepare an updated strategic business plan (quickly).

- Specific changes made to recommendations in the previous versions of the restructure report to satisfy ISO/CS and be compatible with the ISO Directives included:
  - Using the term "Working Group" (as defined in section 1.12 of the ISO/IEC Directives) to cover two TC 215 concepts – semi-permanent (cross-cutting) Working Groups (WG) and Working Group for a specific domain (WG-D) formed to progress a particular project or group of projects.
  - Designating the Executive Council (CAG 1), Co-ordination Group (CAG 2), and the Cross-SDO Harmonisation Group (CAG 3) as “groups having advisory functions within a committee” (as per section 1.13 of the ISO/IEC Directives). The ISO eCommittee system uses "CAG" to designate such advisory groups.
  - Designating any group formed to look at a precisely defined problem as an Ad hoc group (as per section 1.14 of the ISO/IEC Directives).
    Contrary to previous TC 215 practice, Ad Hoc groups (or Task Forces) may not run standards development projects (beyond preliminary planning). An approved project may only be run by a technical committee, subcommittee or working group.
  - Confirming that resolutions of the P-members of the TC is the means by which all TC215 decisions should be made (e.g. approving membership of the CAG2 Coordination Group).
  - Clarifying that membership of the TC is derived from NMBs, their appointed delegates and TC liaison representatives, and that “credentialed TC experts” are not automatically TC 215 delegates unless also nominated as delegates. Experts are nominated to WGs (or for specific work items) but this alone does not make them eligible to participate at the level of the TC 215 committee.
- Needs and priorities are to be based on considering input from “stakeholders” as well as “National Member Bodies” (as per current ISO 5-year strategic plan).
- NMBs are encouraged to act on behalf of developing countries (see 1.7 supplementary discussion on twinning arrangements).

Some of these changes will facilitate maintenance of TC215 information in the ISO Global Directory (linked with ISO web-site and eCommittee system).

- Specific resolutions need to be passed by TC 215 to bring the changes into effect.
- After discussion with the ISO/CS representative, it was agreed that the changes could be implemented by revising the existing TC 215 working group structure, rather than by replacing all TC 215 working groups and other units, which had been suggested as possibly being required. The simpler approach was accepted on the grounds that WG 1 through WG 4 will continue with similar scopes to those under which they presently operate.

9.1.3.4 Progress at this meeting

The TC 215 Chair and Secretary and others involved with the proposed reorganisation of TC 215 had hoped that the necessary resolutions to bring the new structure into effect could be passed in the final plenary session at this meeting. A group comprising Chris Chute, Lisa Spellman, Jeremy Thorp, Richard Dixon Hughes, Mary Lou Pélaprat and Sally Seitz drafted proposals and communicated with the working groups and national delegations throughout the meeting in an attempt to achieve this goal but, while substantial progress was made, there was insufficient time for national delegations and P-members not present to consider the changes. Nevertheless, the following were achieved:

- All working groups reviewed their title, scope and leadership arrangements within the context of the new structure, with preliminary proposals for revised WG titles, scopes and leadership arrangements being proposed for approval.
- An agreed set of final recommendations for implementation of the TC 215 revised structure were prepared, which would be put to ISO/TC 215 member bodies in a letter ballot being distributed shortly after the meeting.

The final set of 31 recommendations needed to be sufficiently specific to enable ISO/CS to unambiguously implement associated changes to the Global Directory entries.

- Agreement to form the TC 215 Ad Hoc Group on the Strategic Business Plan under the leadership of Mr. Richard Dixon Hughes and Mr. Jeremy Thorp to create a TC 215 SBP that reflects the TC 215 reorganization.

All TC 215 members were invited to participate in this work and any interested members were requested to inform the TC 215 Secretary as soon as possible.

- Agreement that the proposed scope of TC 215 (including amendments proposed in the reorganisation report would be re-visited as part of preparing the SBP.
- Agreement that proposals for implementing new ways of working would be incorporated into the both SBP and the implementation of the revised TC 215 organisation structure (specifically the new CAG 2 group)
9.1.3.5 Key outcomes

The following are among the key proposals from the reorganisation review agreed at the meeting for which approval is now being sought from TC 215 member bodies.

- Re-confirmation of the principles set out in the reorganisation report, following amendments that had been made to accommodate required terminology and other alignment with the ISO/IEC Directives.

- Consistent with a previous resolution at the May 2012 meeting in Vancouver, merging WG8 (Business Requirements for EHRs) into WG1 (Data Structures) with:
  - the WG1 name being revised to “Architecture” and its scope being modified to:
    "Standardization of architectures, frameworks and their components, including conceptual, logical and functional requirements, process models and information models in support of health and healthcare”, and
  - Standards Australia continuing as Secretariat.

- Merging WG7 (Devices) into WG2 (Data Interchange) with revised name “Systems and Device Interoperability” and modified scope:
  "Standardization in the field of electronic exchange of information between organizations and clinical and administrative systems, including interoperability of devices”

- Confirming that WG3 is retained with its existing name “Semantic Content” but with:
  - its scope being revised to:
    "To develop standards for representation of health concepts and data. These standards include:
    - formal models of representation and description of health concepts;
    - principles of their organization within terminological resources;
    - principles for governance and maintenance of terminological resources
    - the representation and management of knowledge; and
    - the use of terminological and knowledge resources in electronic health records and other systems”, and
  - Heather Grain to continue as convener.

- Confirming that WG4 is retained with its existing name “Security, Safety and Privacy” (to be updated on the ISO/CS database) and its existing scope:
  "To protect and enhance the confidentiality, availability, and integrity of health information; prevent health information systems from adversely affecting patient safety; protect privacy in relation to personal information; and ensure the accountability of users of health information systems."

- Confirming that WG6 is retained as a domain working group with its existing name “Pharmacy and Medicines Business” and its existing scope:
  "To establish standards in the domain of pharmacy and medication - research, development, regulation, supply, use and monitoring to improve
the efficiency and interoperability of information systems affecting patient safety.”

- Confirming that the Executive Committee continue as a Committee Advisory Group with the name “CAG 1 Executive Council” and scope:
  
  “To provide strategic and business leadership to the Committee. Formally, the Executive Council meeting is an advisory group to the Committee Chair. The following objectives are within scope for the Executive Council:
  - prioritizing … the development of health informatics standards
  - provide access and support for emerging and developing countries
  - planning, managing, evaluating the work of the committee.

- Establishing "CAG2 Co-ordination Group" to assimilate the functions of the informal operations and harmonization group, with proposed scope:

  “To prioritise new work item proposals (NPs) with the goal of harmonizing work within TC215 with the following objectives:
  a. co-ordination of the development of health informatics standards;
  b. harmonisation of existing and emerging health informatics standards to establish a global framework of consistent and common standards for health systems and health data (together with CAG3);
  c. development and maintenance of operational plans and the overseeing of their delivery; addressing TC logistics and expedition of the standards development process (specifically the WGs may identify standards which should be harmonized with another TC workgroup, technical committee or TC 215 liaisons, and will bring these to the CAG2 for consideration).”

- Establishing "CAG3 Cross SDO Coordination" to fulfil the role of "Joint Working Group" under the Joint Initiative Charter for Health Informatics SDO Standardization, with scope:

  “To plan, determine processes, and coordinate group that makes recommendations to the Joint Initiative Council (JIC) on resolving gaps, overlaps or issues of counterproductive standardization with the following objectives:
  a. to make recommendations to the JIC [CAG3 is also the external (Joint Initiative SDOs) coordination group for the TC215 Coordination Group (which is TC215 internally focused)].
  b. to harmonize existing and emerging health informatics standards to establish a global framework of consistent and common standards for health systems and health data (together with the CAG2)"

9.1.3.6 Project Prioritization Task Group

At the October 2011 meeting of TC 215, Richard Dixon Hughes was tasked with working in collaboration with the TC 215 Reorganisation Task Force to:

“... investigate and report at the Vancouver 2012 plenary meeting on the possible methods of aligning the prioritisation, selection and approval of work items with TC215 strategic objectives, including harmonisation …”
This work, to be undertaken in collaboration with the TC215 Task Force on Re-organisation and Business Planning, is aimed at identifying more detailed criteria for assessment of proposals for new standards work to contribute to implementation of the revised strategic business plan. His preliminary research on the topic was presented to the May 2012 meeting of TC 215 and with it being noted that:

- A need for more rigorous documentation, justification and assessment of proposals for new work by TC215 and a stronger role for the Chair, Secretariat and Advisory Groups in assessing and advising on new work item proposals – which aligns with ISO strategic directions and current changes to the Directives

- Goals can be largely achieved by more diligent use of existing rules, particularly with the changes recently introduced in the 9th Edition of the ISO/IEC Directives – published in April/May 2012

Subsequent work has highlighted the dependency on update and maintenance of the TC 215 SBP and its importance as the place where any criteria used in the assessment process should be documented and agreed.

Work on identification and recommendation of more rigorous processes for project prioritisation originally being led by Richard Dixon Hughes will now be taken forward in the broader context of preparing the updated TC 215 strategic business plan (SBP), with Richard Dixon Hughes becoming a co-leader of that activity.

**9.1.3.7 Relevance to Australia**

Australia has been supportive of the proposals to restructure TC 215 and ensure that its activities meet the needs of the wider stakeholder community. Gaining acceptance of the changes needs to be the current priority despite the roughness and diversity of expression in the details that have emerged from the various groups. The preparation of the TC 215 SBP represents the opportunity for further input on these issues.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
<th>Recommended for Action by</th>
</tr>
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<tbody>
<tr>
<td>Executive Council – Implementation of new TC 215 organisation</td>
<td>Recommendations for restructure of TC 215 that were first put to the TC 215 plenary are to be circulated to P-members for approval in the near future. With Australia having two members on the Executive Council actively involved the proposed restructure, it is important that we participate in this ballot, preferably lending our support to the proposed changes. <strong>Action</strong>: Standards Australia and IT-014 to prepare response to the letter ballot on adoption of new TC 215 structure.</td>
<td>IT-014 Standards Australia</td>
</tr>
</tbody>
</table>
Executive Council – Preparation of strategic business plan (SBP) and project assessment criteria

The TC 215 work being led by Richard Dixon Hughes on identification and recommendation of more rigorous processes for project prioritisation are to be taken forward in the broader context of preparing an updated TC 215 strategic business plan (SBP) in line with the ISO/IEC Directives. Richard and Jeremy Thorp (UK) have been asked to lead the SBP activity.

Action: IT-014 to consider and contribute comments on the current e-health standards environment and needs for consideration in the TC 215 SBP.

Action: Richard Dixon Hughes to progress TC 215 SBP activity with Jeremy Thorp and keep Standards Australia and IT-014 apprised of progress.

| IT-014 | Richard Dixon Hughes | Standards Australia |

9.1.4 FUTURE ISO/TC 215 MEETINGS

On coming to this meeting, potential locations and dates for future TC 215 meetings remained a concern, with many gaps in the forward program and no location for the next meeting, which would normally be held in April/May 2013.

Some offers were received during the meeting, including one from Mexico to host the next meeting, which would align with acceleration of their national program.

The secretariat is seeking confirmation of Australia's hosting of the following meeting in October 2013 almost every week and, with this having been agreed in principle for almost 12 months, any inability to carry through on our commitment at this point would be a major embarrassment and would also raise the question as to when we would be stepping forward to fulfil our commitment to next host a meeting as an active P-member of TC 215 (we last hosted in 2007).

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

<table>
<thead>
<tr>
<th>Dates</th>
<th>Location/comment</th>
<th>Meeting type</th>
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<tbody>
<tr>
<td>21-26 Apr 2013</td>
<td>Mexico – invitation accepted details tbc</td>
<td>4 day WG plus full plenary (5 days)</td>
</tr>
<tr>
<td>Oct 2013</td>
<td>Sydney, Australia still being confirmed</td>
<td>4 day WG plus ½ day mini-plenary</td>
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<tr>
<td>(14-18 or 21-25)</td>
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<tr>
<td>Apr/May 2014</td>
<td>Japan – tentative, details tbc</td>
<td>4 day WG plus full plenary (5 days)</td>
</tr>
<tr>
<td>Sep/Oct 2014</td>
<td>Berlin, Germany. Still open</td>
<td>2 or 3 day WG plus ½ day mini-plenary</td>
</tr>
<tr>
<td>Apr/May 2015</td>
<td>Open – host sought</td>
<td>2 or 3 day WG plus ½ day mini-plenary</td>
</tr>
<tr>
<td>Mid-Aug 2015</td>
<td>Sao Paulo, Brazil – tentative, dates, facility tbc</td>
<td>4 day WG plus full plenary (5 days)</td>
</tr>
</tbody>
</table>
9.2  JOINT O&H / CAG 2 / CAG 3 COORDINATION MEETING

| Australian Delegate Attendance | Heather Grain (Convener WG 3)  
|                               | Naomi Ryan (Secretariat WG 1 & WG 8)  
|                               | Richard Dixon Hughes |

9.2.1  BACKGROUND

The Operations and Harmonization group (O&H) has traditionally coordinated working group activities, secretariat processes and the TC 215 work program and works 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.

Under the proposed structure of TC 215, the Coordination Group (CG), formally designated CAG 2, is tasked with the prioritization of new work item proposals (NPs) with the goal of harmonizing work within TC215. It will also inherit the role of the Operations and Harmonization group (O&H).

The Cross-SDO Coordination Group, formally designated CAG 3, is constituted within TC 215 to make recommendations to the Joint Initiative Council 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, a joint session was convened to provide a forum for discussion of issues generally falling within the ambit of the existing O&H group and also those proposed to be dealt with under CAG 2 and CAG 3. The session was held from 1600 to 1830 on Sunday 23 September, following the JIC Open Forum and the Executive Council. There was no separate O&H meeting held at this particular WGM.

The following were among the topics covered:

- ISO/TC 215 operations processes & updates – including implications and issues flowing from greater use of the ISO/CS eCommittee system (see 9.2.3 below). Useful guidance was given to the community on the use of this tool.

  Work program updates, project processes and tools were also discussed. Heather Grain noted that WG 3 holds a monthly teleconference at which the statuses of its projects are reviewed.

- 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;

Using the preliminary work item stage to develop proposals more thoroughly and communicate them more widely before putting them forward for NP ballot.

It was also noted that positive (Yes) votes must be accompanied by reasons and the name of a nominated expert in order to be counted as a positive votes. The expert must be named before the close of voting, if the vote is to count. Other experts may be added at any time, including experts from national member bodies that abstain or vote negatively but obviously the existence of such experts would not contribute to acceptance of the work item.

The possibility of identifying sponsors for particular work items was discussed. Sponsors would commit to supporting a work item through the process.

- Systematic review processes.
- Update on ISO/TC 215 reorganization plan, forthcoming strategic business planning process and proposed new NP criteria. – with a brief presentation by Jeremy Thorp and input by Richard Dixon Hughes (reported at 9.1.3 above).
- Coordination and harmonisation of ISO/TC 215 work program, including new work items and joint work being progressed through JIC under the oversight of the CAG 3 cross-SDO Coordination group. Specific topics discussed included:
  - The need for ongoing collaboration and harmonization through both CAG2 and CAG3
    CAG2 deals with matters internal to TC 215 and result in projects being assessed for NP ballots and, if successful, their assignment to a particular TC 215/WG – to be managed through Lisa Spellman)
    CAG3 focuses on identification and monitoring of potential and agreed cross-SDO activities for reporting back to SDOs and JIC.
  - Brief mention of issues raised in JIC work program status check and JIC open forum (as most attendees were also in the JIC open forum)
  - Requests for comments and suggestions of potential joint SDO projects from ISO/TC 215 work program.
  - Feedback on the fact that all of those present in the JIC Open Forum had by resolution supported continuing holding the open forum at TC 215 meetings, even though it had been proposed at Executive Council that it be discontinued.
- Issues related to TC215 data entry and maintenance of material in the SKMT. Work items will no longer go to ballot without having had their details entered into the SKMT. The SKMT Governance Committee will address term harmonisation and general oversight of the tool. There are places on this committee for representatives of both TC 215 and of WG 3 and people are being sought to serve in these roles. Working groups were also requested to ensure that all projects consider the content of the SKMT glossary prior to development of new work.
Future meetings of TC 215 (see 9.1.4 above).

9.2.3 WORK PROCESSES AND THE ECOMMITTEE SYSTEM

9.2.3.1 Introduction

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 eCommittee system, with TC 215 having discontinued the use of its own separate document management system in 2011.

9.2.3.2 Progress at this meeting

Dr Mary Lou Pélaprat, Technical Programme Manager, ISO C/S, spoke at several sessions, including the Executive Council (CAG 1), the joint O&H/CAG 2/CAG 3 and the Opening Plenary, presenting on the updated ISO website and particularly changes arising from greater reliance on the eCommerce (LiveLink) document management system being used to support the work of technical committees within ISO.

These changes are having a significant impact on the way in which TC 215 operates, with the following points being particularly noted:

- ISO is an organisation operating on a global basis – with processes that need to work seamlessly for secretariats across the globe.

  The scale of this undertaking is emphasised by ISO now having 164 national member bodies, representing 5000 personnel; it has published 19,180 standards documents, and 625 liaison standards. There are 217 current Technical Committees with 3,354 technical bodies and 10,000 experts. The ISO member nations represent 98% of the world GNI, and 97% of the world’s population.

- ISO recently took the next step in the roll-out of its LiveLink eCommittee system with the system now being used to track and interact with all experts assigned to Working Groups (WGs) as well as delegates and liaisons appointed to technical committees (TCs) and subcommittees (SCs). Use of e-Committee is now mandatory for all WGs.

- Correct registration in the eCommittee system is now essential to receive notices and to access documents and information being distributed to all parties with an entitlement as a member of a TC, SC, WG, joint working group (JWG), committee advisory group (CAG) or task force (TF).

- The differences between delegates (to TCs) and experts (on WGs) were highlighted:

  **Delegates:**
  
  - Participate in the plenary meeting
  
  - Are appointed by a Participating Member Body (P-Member), an Observer or Correspondent Member Body or a Category A Liaison organization
  
  - Participate as members of a P-Member Body’s delegation and not as an individual, and only the Head of Delegation can vote on a committee resolution.
Experts:
- Participate in a working group (developing a standards publication)
- Are appointed by a Participating Member Body (P-Member) or Category A or D Liaison organization
- Work in an individual capacity in a working group
- Have a voice in achieving consensus for a project

- Access to e-committee information depends on being registered to all appropriate groups – otherwise relevant information will not be received.
- The capacity to add a person to the global directory or to change their access privileges is now solely exercised by the relevant national member bodies (NMBs) - ISO/TC secretariats and ISO/CS do not have the capability to do this – NMBs have the final say. The only exceptions are liaison representatives, who are added by ISO/CS.
- Key changes in the ISO/IEC directives in relation to new work need to be followed, specifically:
  - New Work Item Proposals (NPs) are to be fully documented as to market relevance of the proposal
  - Reasons need to be given for Yes votes on NP ballots; otherwise the vote is not counted.
- The ISO website has been significantly upgraded; delegates and experts need to be sure that they become familiar with how to access key features including:
  - The resource area – from which the ISO/IEC directives and ISO supplement can be obtained as a free download.
  - Details of the standards development process, including the normal pathways, development stages and some alternatives
  - The committee pages from where information on ISO/TC 215 and other committees may be found – including the P-members, O-members and liaisons, the committee structure, the committee’s most recent SBP, currently approved projects and lists of publications by committee
  - The use of the secure e-Committee working area for sharing and retrieval of project documents and to maintain personal details.

In conclusion, the importance of ensuring that all delegates and experts are properly registered by the Standards Australia Member Body User Administrator was noted.
9.3 JOINT INITIATIVE COUNCIL EXECUTIVE

Australian Delegate Attendance

Richard Dixon Hughes

9.3.1 BACKGROUND

The Joint Initiative Council (JIC) oversees processes 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 currently comprise 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/.

9.3.2 PROGRESS AT THIS MEETING

A feature of JIC activities at this meeting was a full-day working meeting of the JIC executive which considered JIC strategy for 2012-15. The outcomes of this strategic review were reported to the JIC Open Forum and summarised for the TC 215 Executive Council and the Closing Plenary.

The projects being coordinated by JIC were also discussed by the JIC executive, with key points being further elaborated during the JIC Open Forum and in the joint meeting of the CAG 2/CAG 3 coordination groups.

The outcomes of the strategic review and comments on the portfolio of projects are summarised in more detail under the JIC Open Forum at 9.4.2 below.

In addition to the matters being progressed as part of the overall JIC strategy, the following issues were among those generating widespread general discussion at the strategy session:

- The need to resolve and confirm the respective roles of the JIC executive and the Cross-SDO Harmonization and Coordination Group (currently constituted as ISO/TC 215/CAG3). In the final analysis, the following points were documented:
- Status of pending, proposed and approved work – and issues about who would be responsible for chasing up projects, keeping associated records up-to-date and reporting these outcomes to JIC.
• A requirement for the JIC to find more staff resources, if it is to be able to be effective in running an active harmonisation program—continuing the processes for identification, proposal, assessment, approval, monitoring and follow-up of joint work items.

The appointment of Richard Dixon Hughes as incoming chair of the JIC on behalf of ISO/TC 215 for the 2013 and 2014 years was announced at the Open Forum and joint meeting of CAG 2/CAG 3 and confirmed by resolution at the closing plenary.

9.3.3 RELATIONSHIP BETWEEN JIC AND ISO/TC 215

Given the close relationship between the Joint Initiative Council (JIC) and elements of ISO/TC 215, and the potential for confusion about the relationship, even among members of the JIC itself as the roles of the JIC and its members evolve, the JIC considered it valuable to summarise the current organisational arrangements that support the JIC through its relationship with TC 215. During discussion of these issues, copies of the original joint initiative (JI) charter were circulated for reference. The following were the key points noted at the meeting and subsequently presented at the JIC Open Forum and TC 215 meetings.

• As a health informatics SDO, ISO/TC 215 is an equal member of Joint Initiative Council along with CDISC, CEN/TC 251, GS1, HL7, IHE and IHTSDO.

• ISO/TC 215 has historically hosted JIC executive meetings and held JIC open forums at each of its face-to-face meetings; however some executive meetings and open forums have been held in conjunction with other events.

• ISO/TC 215 has traditionally volunteered to provide the secretariat for JIC. Accordingly, Lisa Spellman and her team provide secretariat services for both ISO/TC 215 and for the JIC; however, the JIC and its business is otherwise separate from ISO/TC 215 and its business.

• Committee Advisory Group 3 (CAG3) is an ISO/TC 215 advisory group specifically constituted to assist JIC with Cross-SDO (xSDO) coordination of JIC projects.

• CAG3 (identified as the "Joint Working Group" in the Charter signed by all Joint Initiative SDOs) is a planning, process determination and coordinating group that makes recommendations to the Joint Initiative Council on resolving gaps, overlaps or issues of counterproductive standardization in health informatics.

• While CAG3 is hosted by ISO/TC 215, it operates at the direction of the JIC to support JIC with a discussion, liaison, advisory and communication forum for achieving the goals set out in the Joint Initiative on SDO Global Health Informatics Standardization.

• The co-chairs of CAG3 are determined by the JIC under the Joint Initiative Charter to represent and address the full range of interests in standards coordination of all SDOs that are members of the JIC—presently CDISC, CEN/TC 251, GS1, HL7, IHE and IHTSDO, in addition to ISO/TC 215.

• Membership of CAG 3 includes chairs and nominated representatives of each of the JIC SDOs, with specific convenors and/or project leads being present as required for specific joint work items.
• CAG 3 is also open to other participants invited to attend by one of the SDOs participating in the JIC.

• CAG3 is not a decision body, but makes recommendations to the JIC.

• CAG 3 was previously constituted for convenience within ISO/TC 215 as Joint Working Group 9 (JWG 9) and registered as such with ISO/CS; however, this was incorrect as the group does not actually undertake standards development projects in its own right, which is the only reason for forming WGs and JWGs under ISO rules.

• All joint standards development projects being undertaken under the auspices of JIC are led by a nominated SDO and, if ISO/TC 215 is participating in the joint project, an ISO/TC 215 work group will be assigned to provide input or input and leadership of the project from the ISO/TC 215 perspective.

• Within ISO/TC 215, CAG 3 is also able to provide advice on external cross-SDO matters to the ISO/TC 215 CAG 2 Coordination Group (which is internally focused on ISO/TC 215 policy and coordination matters).

• To facilitate the flow of understanding and advice on external, cross-SDO matters from CAG 3 to TC 215 and facilitate practical coordination, the CAG 2 Coordination Group and CAG 3 may hold joint meetings as required, and the TC 215 Chair and ISO/TC 215 WG convenors are invited members of CAG 3.
9.4 JIC OPEN FORUM

9.4.1 BACKGROUND

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

The Open Forum meetings are held to update the TC215 community about the activities of the JIC.

9.4.2 ACTIVITY AT THE MEETING

The following general points were noted:

- Integrating the Healthcare Enterprise International (IHE) has been accepted as the seventh member of the JIC.
- Richard Dixon Hughes (Australia) is confirmed as Chair-elect of the JIC and will take over as Chair for a two-year term commencing 1 January 2013.
- All members of the JIC have now formally endorsed the use of SKMT and will establish the SKMT Governance Committee to oversee the registration and harmonisation of terms and definitions being used in health informatics standards.

A copy of the governance terms of reference are provided in Appendix C to this report and are also available in a separate document for circulation to IT-014 members.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards Knowledge Management Tool (SKMT)</td>
<td>The establishment of the SKMT Governance Committee means that IT-014, as a contributing member of the SKMT community may appoint a representative to this committee. This person may be an individual already on the committee or an additional person and should understand the principles of both the document and glossary elements of this tool and act as liaison between the SKMT Governance Committee of the JIC and Standards Australia IT-014. This committee identifies priorities for development of the web based tool, as well as providing oversight to term/definition harmonisation activities.</td>
<td>IT-014 NEHTA</td>
</tr>
<tr>
<td></td>
<td><strong>Action:</strong> Identify IT-014’s representative to the SKMT Governance Committee</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> Should NEHTA formally decide to add their documents/terms and definitions to this tool, they too would be entitled to a representative.</td>
<td></td>
</tr>
</tbody>
</table>

9.4.3 FEEDBACK ON JIC STRATEGIC PLANNING ACTIVITY

It was noted that the JIC had met on the Saturday, prior to the commencement of the ISO/TC 215 meeting for a full day planning session, attended by representatives of all seven members of the JIC.
The outcomes as reported at the JIC Open Forum were as follows:

9.4.3.1 Vision

The Vision and Purpose of the JIC was reviewed and updated to ensure that all members have a similar view.

**Vision:** speaking with one voice, facilitate achievement of coherent, coordinated and usable global health informatics standards providing value to member SDO’s and their constituencies.

9.4.3.2 Strategic goals

Strategic Goals were identified as including:

- Greater collaboration across SDOs;
- Coordinated standards approach, process and work programs;
- Resolution of overlapping and counteracting standards within and across participating SDO work programs;
- Make standards available through multiple SDO communities with preference to ISO. There may be multiple ballots but the end product of the JIC will produce ISO standards; and
- Greater communication and engagement with stakeholder communities.

9.4.3.3 SWOT analysis

The key points from the SWOT analysis were:

- **Strengths**
  - Purpose and mission
  - Commitment to xSDO collaboration; greater opportunity for xSDO coordination beyond one-to-one collaborations
  - Achieving standards convergence rather than divergence
  - Ability for SDOs and leadership to learn from one another
  - Relationship with ISO and support of ISO/TC 215

- **Weaknesses**
  - JIC does not develop standards directly
    (Rather, JIC provides leadership and coordination of standards development activities through its member SDOs – confirming the lead organisation and project leader from among its members)
  - Clear understanding and meeting of users needs is difficult to achieve
  - There are too many JIC activities brought forward from each of the members of the JIC, with varied expectations
  - Resources are limited and impacted by the need to deliver current work programs
- Communication and messaging

**Opportunities**
- Connecting with national standards collaboratives e.g. Canada, NEHTA
- Improve process and speed of standards delivery
- Educational summits
- Improved coordination of standards projects across global SDOs; aligning ballots
- Consolidated (single?) mechanism and experience for those reviewing and commenting on standards

**Threats**
- Coordinating with other key initiatives (e.g. CIMI) and stakeholder organizations (e.g. WHO, ITU)
- Promising too much and delivering too little
- Failure to achieve purposes in a timely manner
- Expectation management

The issue was not discussed of how to build collaboration between the members of the community as well as the leadership and to build understanding of purpose and scope.

**9.4.3.4 Follow-through actions**

Key actions for members of the JIC were identified and ‘owner’ organisations established. These were distributed as defined in table below

<table>
<thead>
<tr>
<th>Action</th>
<th>Owner Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managing status and addressing issues of current JIC work program</td>
<td>ISO</td>
</tr>
<tr>
<td>Communication including documentation of lessons learned and criteria for success</td>
<td>CDISC &amp; HL7</td>
</tr>
<tr>
<td>Bring a project through entire process from end-to-end documenting steps</td>
<td>CDISC</td>
</tr>
<tr>
<td>Understand what our respective customers want and need; identify common ground between SDOs</td>
<td>HL7</td>
</tr>
<tr>
<td>Explore harmonisation and value sets</td>
<td>IHSDO</td>
</tr>
<tr>
<td>Use and implementation of SKMT</td>
<td>ISO &amp; GS1</td>
</tr>
<tr>
<td>Standards for low and middle income countries</td>
<td>All</td>
</tr>
<tr>
<td>Understand shared view of standards impacting medical devices</td>
<td>IHTSDO</td>
</tr>
<tr>
<td>Resolution of distribution, publication and dissemination of joint standards e.g. IP, formatting</td>
<td>All</td>
</tr>
<tr>
<td>Affirm adapted chapter and by-laws across member SDOs</td>
<td>All</td>
</tr>
<tr>
<td>Assessment and impact with other key HI initiatives outside JIC e.g. CIMI</td>
<td>IHTSDO</td>
</tr>
<tr>
<td>Coordinate standards implementation and adoption across members SDO’s to reduce variability</td>
<td>IHE</td>
</tr>
</tbody>
</table>
• Collaborate to address quality criteria for testing and certification  
  IHE

• Concurrent use of architectures an frameworks  
  CEN

• Proactive analysis of SDO member’s standards to identify gaps (and synergies), 
  overlaps and counterproductive content and approaches in standards, choosing 
  top 5-6 potential JIC activities  
  All

Heather Grain raised the question of how the JIC will devolve cooperation and 
understanding down within their organisations in order to build actual cooperation and 
understanding. This question was addressed to some degree but is still an issue. Richard 
Dixon Hughes indicated that, in theory, there should be the release of some resources 
through improved productivity and reduction of overlaps. Heather Grain further noted that:

- Within the groups with which she is involved, specific work items are being actively 
  shared between IHTSDO and HL7 communities though the work items are ISO related. 
  This sharing occurs after the fact with HL7 activities.

- The process used in TC 215/WG 3 involves use of two different types of JIC 
  engagement:
  - Formal joint standards development process, where documents are jointly 
    balloted and published, and
  - Collaborative development of interested organisations where a single group 
    develops, ballots and publishes but actively seeks input from the other relevant 
    JIC member organisations during the process and considers the comments 
    received to be of equal weight and obligation to those of others (e.g. from 
    National Member Bodies).

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>JIC</td>
<td>Australia needs to consider the implications of support which needs to be provided to these activities, the opportunity to leverage and influence activities. For example if educational summits are organised will they be supported, hosted, encouraged. As this community emerges the opportunity to influence is significant, especially when we hold the position of chair. Action: Determine any specific Australia objectives for engagement</td>
<td>IT-014 / DOHA</td>
</tr>
</tbody>
</table>
9.5 OPENING PLENARY

The opening plenary is open to all members of national delegations and liaison representatives and is the official commencement of the standards development activities.

ISO/TC 215 Chair, Dr Chris Chute, opened the meeting. Delegates were welcomed to Vienna by the representatives of the Austrian hosts for the meeting – the Austrian Standards Institute, the Austrian Chamber of Industry (Wirkshaftskammer Österreich - WKÖ) and the Association of Management and IT Consultants, which had funded the meeting. It was noted that every business in Austria is required to be a member of WKÖ and that the Chamber has some 55,000 members.

The TC 215 Secretary, Lisa Spellman did a roll call of member nations and liaisons present. Attendance was noted from 23 P-members: Australia, Austria, Brazil, Canada, China, Czech Republic, Finland, Germany, Ireland, Italy, Japan, Republic of Korea, Malaysia, Mexico, The Netherlands, Norway, Russian Federation, Singapore, Spain, Sweden, Switzerland, United Kingdom of Great Britain, United States of America.

One O-member, South Africa, was also present.

Ms Kim Osborne has joined Lisa Spellman in the ISO/TC 215 secretariat at AHIMA and was introduced to the meeting. Sally Seitz of ANSI was also present to assist with the resolutions.

Mary Lou Pélaprat, Technical Programme Manager from ISO/CS with responsibility for TC 215, provided an update on the continuing evolution of the eCommittee system used by ISO for managing the work of its technical committees. The presentation was an abbreviated version of points she made to other leadership groups (see section 9.2.3 above) and particularly addressed the need for participants to be registered correctly by their national body as a TC 215 delegate or as a WG expert or both, in order to required documents circulated via the eCommittee system.

Richard Dixon Hughes asked for confirmation that observers and experts from other WGs were not precluded from being present in WG meetings – this was confirmed along with the right of WGs to seek advice from any expert to assist in their deliberations. It was noted that there will be more checking of voting credentials.

Dr Chute briefed the meeting on progress of the re-organisation of ISO/TC 215, noting that alignment appeared to have been achieved between a modified proposal for the reorganisation and ISO expectations and structures. Further work was foreshadowed to attempt to bring the reorganisation to finalisation by the closing plenary. All continuing WGs were requested to consider and update their scope statements.
Dr Chute also asked Jeremy Thorp and Richard Dixon Hughes to lead an Ad Hoc group to progress the update of the TC 215 Strategic Business Plan (SBP), which they agreed to do. A final draft is expected to be ready for approval by the next meeting. Other delegates interested in contributing were invited to put their names forward as members of the Ad Hoc group. A significant number of delegates indicated interest at various times – and an email has been sent out to all delegates to ensure that none of those who wish to contribute are overlooked.

It was noted that the SBP would be taking forward work on assessment and prioritisation of new projects – requiring proponents to establish market relevance within the context of the SBP and to provide more evidence of an effective environmental scan and having obtained engagement with and commitment from a spread of members and stakeholders.
9.6 WG 1 DATA STRUCTURE (INCORPORATING WG 8 BUSINESS REQUIREMENTS FOR EHR)

9.6.1 BACKGROUND

Working Groups 1 and 8 shared a common agenda and met together for all sessions of this meeting. This combined WG covers topics around Data Structures specifically in relation to EHRs (WG 1) and the Business Requirements for EHRs (WG 8).

Working Group 1 is chaired by Dr Stephen Kay (UK) and Working Group 8 is chaired by Dr Marion Lyver (Canada). Naomi Ryan (Standards Australia) is currently providing Secretariat services for both working groups.

9.6.1.1 Published/In Publication Standards

- ISO TR 14639-1: Capacity-based ehealth architecture roadmap Part 1 – Overview of national ehealth initiatives – was published in August 2012

  The Working Group proposed a resolution for ISO/TC 215 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.

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

9.6.1.2 Cancelled projects

- ISO TS 16555 Framework for National Health Information Systems - This work item was being led by WHO and based on the WHO Health Metrics Network. As WHO has advised they are unable to proceed with this work, the Working Group agreed to recommend that the work item be removed from the work program.

9.6.1.3 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


9.6.2 PROGRESS AT THIS MEETING

It had previously been resolved at the Vancouver meeting that Working Groups 1 and 8 would merge into one single group.

After considerable discussion the new combined group, to be known as ‘Working Group 1’ proposed that it should be re-named “Architecture”. The proposed scope statement agreed by the group at this Vienna meeting was: “Standardisation of architectures, frameworks and their components, including conceptual, logical, functional requirements, process models and information models in support of health and healthcare.”

A total of 45 delegates from 16 national member body countries attended the combined WG sessions.

9.6.2.1 New work item proposals

- ISO/TS 18528 – Functional Classification of Health Informatics Standards
- ISO/NP - Quality Metrics for Detailed Clinical Models

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

9.6.3.1 Introduction

This draft 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, 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

9.6.3.2 Progress to date

Significant Progress has been made towards completion of the draft document after the fact to face meeting that occurred following the May ISO meeting in Vancouver.

Draft Technical Report status:

- Introduction - nearly complete thanks to Richard Dixon Hughes & Pier Angelo Sottile
- Governance – largely contributed by Mexican delegation.
  - Contribution is very Mexico-specific and will need further revision to provide a broader perspective.
- Still 2 components needing authors
  - Health Process Domain Components – 13 components in total
    - 5 components still needing authors and yet to be completed
  - Foundation Components – eHealth Infostructure – 7 components in total
    - 2 yet to be completed
  - Foundation Components – ICT infrastructure – 5 components in total
    - 3 yet to be completed

Key Issues:

At present the major issue is identifying potential contributing authors for the remaining components but in general it appears that this work is proceeding efficiently.

Some concern was expressed that this Part 2 document may experience some of the issues faced by the publication of Part 1, such that a TR has a lower priority in the eyes of the ISO Secretariat, yet there is a recognised need in LMIC for this information to be published as soon as possible. This is part of a broader issue affecting other TRs within ISO and has been recognised by the Secretariat as needing attention.

Information was also provided on a newly published additional resource, the National eHealth Strategy Toolkit, published by WHO in conjunction with the International Telecommunication Union - http://www.itu.int/pub/D-STR-E_HEALTH.05-2012. It is described as “an expert, practical guide that provides governments, their ministries and stakeholders with a solid foundation and method for the development and implementation of a national eHealth vision, action plan and monitoring framework.” This toolkit was explained to be a higher level, and more generic document than ISO DTR 14639-2, yet complementary.

9.6.3.3 Proposed next steps

- Beatriz Leao expressed an intention to finish the current wiki-based document ready for DTR ballot in January, 2013. A resolution was proposed to this effect.
- Further PHTF meeting to be held immediately after the conclusion of the ISO Plenary on Wednesday, September 26, 2012.
- WHO is willing to organise a standards meeting in Geneva to coordinate (probably on December 3 & 4, 2012). Ramesh Krishnamurthy, who has taken over from Patrick Whitaker, will be the WHO liaison who will coordinate the meeting.

9.6.3.4 Relevance to Australia

Australian expertise contributed to this valuable work which is applicable not only in the LMIC context but also to a broader range of countries.

At this point in time it appears that this work is at risk of facing the same issues around publication as the Part 1 document. Australia is, and should be, advocating for ISO Secretariat to prioritise the publication process at least for this document and also explore
how this kind of work should best be progressed, including identifying a process outside
ISO if necessary.

Australia could canvas for additional expert authors to contribute to the remaining
components.

9.6.4 STANDARDS KNOWLEDGE MANAGEMENT

9.6.4.1 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.

9.6.4.2 Progress to date

Following on from this TR publication, the authors, Prof Andrew Grant (Canada) and
Heather Grain (Australia) are proposing to progress this work in two ways:

1. Enhancement of the current Standards Knowledge Management Tool, focussing on:
   a. Governance
   b. Expansion – make it available to Organisations or Jurisdictions, including
      adoption and usage within Australia
   c. Education

   Informatics Standards, including the following activities:
   a. Further literature research
   b. Empirical analysis of TC215 standards using CHI – interaction with working
      groups
   c. Development of a Standards Knowledge Management Classification
      i. Identify families of standards
      ii. Facilitate access and context understanding
      iii. Facilitate harmonisation
      iv. Enable gap analysis
      v. Support future generation of electronic tools
   d. Case example analysis (with GCM)
   e. Describing Classification Importance
      i. Classification enables location and clustering
      ii. ISO needs to provide some leadership

The Parthenon diagram from ISO DTR 14639, above, could be considered as an
underpinning ontology for this work.

9.6.4.3 Proposed future work

A Proposed New Work Item is being developed and will be made ready for balloting - TS
18528 – Functional Classification of Health Informatics Standards.
There is consideration of running a Workshop, possibly towards the end of November to inform this NP work.

Publication is targeting Autumn, 2013.

9.6.4.4 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.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>WG 1/8 Proposed NP TS 18528 – Functional Classification of Health Informatics Standards</td>
<td>Issue: This is a new work item targeting a TS but is an extension of the previous TR and development of the SKMT tool, which included significant Australian input. Action: 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.</td>
<td>IT-014-02 IT-014-09</td>
</tr>
</tbody>
</table>

9.6.5 REPORT: CEN WG1 - TR ENTERPRISE ARCHITECTURE WITHIN HEALTHCARE

9.6.5.1 Introduction
A report was provided by Frederik Endsleff (Denmark) & Pier Angelo Sotille (Italy) on a recently approved work item from CEN WG1 in which a Danish document is being extended and enhanced to provide an analysis of how standards can work together to support enterprise architecture (EA) within a healthcare context.

Currently this work item is an evolving TR investigating how EAs are used in the health domain, documenting what lessons can be learned, and includes a case study from Denmark.

9.6.5.2 Progress to date
The document is currently about 30 pages long, but needs extension and more examples from other jurisdictions, plus restructuring to ensure it is more generally applicable than the original Danish document.

The scope of standards being investigated includes HL7, CONTSYS, HISA, 13606, XDS, and there will be an analysis of how they relate to each other within a health EA context.

Work identified but yet to be completed:
• Mapping major standards to EA,
• Identifying how they relate to each other and including HISA, CONTSYS, & HL7
• Inclusion of more case studies.

The intent is explicitly not to create a new EA.

9.6.5.3 Relevance to Australia

Australia should keep a watching brief on this CEN TR. It may also inform work that is being undertaken by IT-014-09 in the eHealth Architecture Framework and Australia may also be able to inform the development of this CEN report.

<table>
<thead>
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<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG 1/8 CEN WG1 TR Enterprise Architecture within healthcare</td>
<td>Issue: This new CEN WG1 work may be similar in nature to that which is being undertaken by IT-014-09, in conjunction with NEHTA re eHealth Architecture Framework. Action: 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.</td>
<td>IT-014-09</td>
</tr>
</tbody>
</table>

9.6.6 ISO TS 13972 – CHARACTERISTICS AND PROCESSES OF DETAILED CLINICAL MODELS

9.6.6.1 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).

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 targeting 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 the 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.

9.6.6.2 Progress to date

At the May ISO meeting in Vancouver, the working group resolved to:
• Re-merge and re-sequence Parts 1 and 2 into a single document with duplicate material removed. This was achieved.
To include disposition of comments from the CD ballot. This was done, with the exception of a link to CONTSYS and explaining relationship to 13606, due to lack of expert advice being offered, so it was not included in draft DTS revision.

Identify and agree which content is appropriate to be documented in the specification as normative. Content that was identified as informative would be included as supportive material. Content that could not be agreed would be excluded and reviewed in the future when the approaches had some further understanding, convergence and agreement. This classification of content would be conducted during regular weekly teleconferences which were duly held. The revised document was distributed to the community of WG1 and WG8 for review. This was completed, as planned, during the month of August. No comments were received, which the author proposed was very positive and implied that the document was in good shape, ready for DTS ballot.

Once the revised document was ready and circulated to WGs 1 and 8 it was planned to submit it directly to DTS ballot.

During the period following the May 2012 ISO meeting, the project leader distributed an online poll seeking advice regarding suggested inclusion of ISO 9000 processes to underpin a significant part of the document – there were approximately 6 responses from within the expert group expressing positive support, with advice from Heather Leslie (Australia) that it may be too premature to pursue this approach any further than outlining how the ISO 9000 principles might apply to the DCM work – this concern was rejected.

Considerable rewriting of the document, including a detailed approach to align with the ISO 9000, process was included in the draft DTS document prior to distribution to the WGs. Unfortunately this has raised further issues with ISO Secretariat, yet to be resolved, that involve ISO Guide 83 - related to newly included content relating the DCM development to ISO 9000 quality processes. At the conclusion of the meeting it was still the intention of the WGs to submit the revised document to DTS ballot but unclear how this Guide 83 issue would be resolved and guidance was being sought from ISO Secretariat on how to progress this issue. Options include renaming or reframing the quality management processes more loosely or a major rewrite of the document, which may require not progressing directly to DTS as previously planned.

9.6.6.3 Proposed future work

- Resolve issues re ISO Guide 83 with ISO Central Secretariat
- Send out for draft DTS as soon as possible.
9.6.6.4 Relevance to Australia

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>WG 1/8 TS 13972 – Characteristics and Processes of Detailed Clinical Models</td>
<td>Issue: The revised DTS 13972 is about to be sent out for ballot. It has been extensively reformatted following remerging from two separate documents and additional content regarding alignment with ISO 9000 processes included. Action: Australian experts to determine an approach on how to respond to the DTS ballot.</td>
<td>IT-014-09 NEHTA CTI team</td>
</tr>
</tbody>
</table>

This specification has not had a smooth evolution. It started development targeting an International Standard and its ISO journey over the past 4 years has involved some significant changes from the initial intent and scope, including firstly splitting the draft into three components (Part 1 - Clinician engagement; repository and governance and patient safety; Part 2 – Attributes and metadata of a DCM; and Part 3 – Quality Metrics) and declaring some areas, such as transformations, out of scope for this initial block of work.

It is of interest to Australia because of DCM methodology that is underpinning the NEHTA’s standards development processes.

Australia has had four experts (Richard Dixon Hughes, Dr Heather Leslie, Dr Stephen Chu (NEHTA) and Prof Evelyn Hovenga) actively attempting to contribute to this item over the duration of this work to shape the document so that it is as inclusive of the wide range of models and modelling approaches, and especially ensuring that the work on, and experience gained from using, DCMs within Australia informs the final international specification.

There has not been a lot of collaboration within the expert group between formal ISO meetings and in general, there has been a distinct feeling of frustration amongst the Australian experts that it has not been easy for them to influence the general direction of the work. This is despite Australia now being one of the most practically experienced countries in clinical knowledge governance at national program level.

It has been the position of the Australian experts right from the initiation of this work, that the DCM domain is relatively immature and that the methodologies and processes are still in flux, hence our negative votes in previous ballots and our nomination of experts to try to influence and shape the work item in a positive way. This is reflected in our consistent request that the work item be targeting a lesser outcome – the Australian experts’ preferred position has always been a TR but we conceded with the demotion to a TS, pending the clear demarcation between normative and informative content.

Subsequent to the Vancouver ISO meeting, a series of meetings/teleconferences were arranged seeking consensus on normative versus informative content as agreed by the Working Group. Heather Leslie (Australia) attended the first face to face meeting in Vancouver, and three subsequent teleconferences. Good progress was made at those first four meetings with robust discussion occurring, despite small numbers. Circumstances prevented Heather and others from further participation at subsequent meetings but apparently the meetings continued – although we understand that towards the end only the leader and one other was in attendance. The project leader then declared that as the
sequence of meetings had concluded, the task of agreeing normative versus informative had also been completed. The Australian experts question this conclusion and are concerned that not all the content has been thoroughly reassessed by a group with a range of relevant expertise.

Private discussions with other WG members attending the Vienna meeting and with other experts indicate that there is some general concern about the lack of comments received from the WG distribution, including:

- few member bodies have the experience or expertise to make informed comments on both the previous CD ballot and the pending DTS ballot, and
- many WG attendees (and possibly this is reflected in NMBs as well) have little or no interest in the outcome of the ballot, although there is a general feeling that it would be desirable to have a reference document on DCMs of some sort available.

It appears a real possibility that this work item is progressing through the ISO processes:

- as a document that is not inclusive of all DCM methodology approaches; and
- with positive votes from NMBs who have little background or information to determine if the document is sound or not.

Australian experts have not made formal comments on the latest revision of the document as distributed to the working group in August, but will have an opportunity to respond formally in the upcoming DTS ballot.

Concerns that have been expressed by Australian experts scanning the DTS, and need to be investigated further before the DTS ballot, include:

- Content previously removed seems to have been re-included in the revised document, including statements which would imply that current Australian activity is not compliant with the specification, when in fact the Australian tooling and capability exceeds that described in the document;
- The ISO 9000 additions have altered the workflow and structure of the document so that the document is bulkier, less intuitive and more confusing;
- The demarcations between normative and informative statements have not been completed with adequate informed discussion and rigor;
- The document is not easy for a non-expert to read and understand – in terms of volume, use of jargon terms and inclusion of both conceptual (not based on any reference model) and logical (based on a nominated reference model) models in general discussion without always being explicit if the content refers to one, either or both types of models; and
- Potential reduction in significant amounts of contextual content within the document back considerably for purposes of clarity and to increase the ease of understanding.

Possible approaches for the Australian expert response to the pending DTS ballot:

- Continue to try to influence the whole document by extensive commenting within the DTS ballot process which is not likely to make much impact, or
- Respond to the DTS ballot by selectively focusing only on the areas that impact on the current work within the Australian environment and aiming to ensure that the Australian activity will be reflected adequately, thus accepting that it is not possible for the Australian influence on this DTS to be as much as may be desired by the experts.

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

9.6.7.1 Introduction

This project is being led by Christian Hay (GS1, via JIC) with a view to being published as an ISO Technical Specification.

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 safely. There is a strong focus on Subject of Care, but the Individual Provider also in scope; identification management is specifically not in scope.

There has been ongoing work initiated from GS1 and it will reference existing ISO/TC 215 technical specifications on identification - ISO TS 22220 Identification of subjects of health care and ISO TS 25725 Provider identification.

9.6.7.2 Progress to date

The patient ID/Caregiver ID project was supported by JIC members (including ISO) in April/May 2010 but was never actually formally balloted as an ISO project until entering formal ISO processes in January 2012.

In early September, 2012 it passed NP ballot. Comments will be resolved as soon as possible.

Completion is anticipated by the end of April 2013.

9.6.7.3 Relevance to Australia

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<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
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<tr>
<td>WG 1/8 DTS 18530 – Subject of Care (SOC) and Individual Provider Identification (GS1)</td>
<td>Issue: Continued development and application of the GS1 lead work on subject-of-care and provider identification is an international development of potential relevance to Australia. Action: Australia should continue to support the development and promote the usage of Subject of Care (SOC) and Individual Provider Identification standards as the work progresses.</td>
<td>IT-014</td>
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</table>
9.6.8 REPORT: CEN WG1 - WORKSHOP REPORT ON CONVERGENCE OF 13606, CONTSYS AND HISA

9.6.8.1 Introduction

Prof Stephen Kay presented a report on a recent CEN WG1 subcommittee meeting in Italy to investigate how 3 existing European standards can be applied effectively together: ISO 13606, CONTSYS and HISA.

The goals/outcomes of the meeting were to:
- Describe the issues related to concurrent use
- Map/extend the 3 standards as required
- Facilitate implementation guides
- Impute to revisionsFINALIZING OF WORK IN PROGRESS
- Identify opportunities for collaborative working within and across SDOs to develop an appropriate outcomes framework across all 3 standards.

They discovered that out of all the experts in the room, not one person knew the entirety of all three standards and so one of the major outcomes of the meeting was to achieve a common understanding of the three standards. In addition considerable work was done to identify overlap and unique attributes of each of the standards, resulting in some comparative tables and observations which were compiled in a report which has been distributed by email to WG1 members and input is sought from the broader community as to the next steps that might be deemed appropriate and useful.

A link to the report can be found here: http://www.ehealthinterop.nen.nl/publicaties/5117&details=true

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<tbody>
<tr>
<td>WG 1/8 CEN WG1 Convergence of 13606, CONTSYS and HISA</td>
<td>Issue: This new CEN WG1 work appears to be similar in nature to that which is being undertaken by IT-014-09, in conjunction with NEHTA re EHAF. Action: IT-014-09 should monitor and potentially actively contribute this work, and potentially include its conclusions in future iterations of the EHAF.</td>
<td>IT-014-09</td>
</tr>
</tbody>
</table>

9.6.9 ISO EN 13606 TECHNICAL REVISION

9.6.9.1 Introduction

Prof Dipak Kalra is the lead for this work item.

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

As ISO 13606 originated as a European standard through CEN and is mandated for use in Europe, this is a joint ISO/CEN work item with most of the work and pressure for change is expected to come from CEN/TC 251. However, 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.

At the recent Vancouver ISO meeting WG1 confirmed that the scope of each of the five parts should not be changed. However there are plans to align ISO 13606 with other ISO standards and HL7 standards including CDA, plus include learnings from other initiatives including openEHR (especially for part 1) and CIMI (for part 2).

9.6.9.2 Progress to date

All five parts of ISO 13606 are being revised simultaneously and have recently passed NP ballot.

Comments received during the NP ballot included a number of negative votes for the following reasons:

- Iran: is “using 13606 standard as communication pattern which was published in 2008 and the project is currently running and is under development, and since making changes on data types would impose cost on already developed project stages, thus making changes is not preferred.”

- Germany:
  - provided similar responses to their No vote on the original 13606 voting – suggesting more explanatory documentation.
  - no process to derive archetypes in a systematic way, no methodology predicting what archetypes may be needed
USA:
- “13606 describes transformation of original EHR record entry content into a set of exchange artefacts, anticipating that this transform will occur once outbound from the source/sending system and once again inbound to the receiving system. Not only does this Standard ignore end-to-end data/record fidelity issues inherent in this double transform scheme, it also offers no capability to ensure that the original author’s signature binding to EHR record entry content preserved in the exchange (alongside the new transformed content).“
  Proposed response: intent to expand the scope of the standard to embrace the US requirements to ensure that it keeps the intent of application for primary care.
- “ISO 13606 is intentionally positioned to capture constructs of privately-organised organisations and consortia. As made explicit in the NP, this includes openEHR and CIMI – both operating without benefit of an open consensus process, both eschewing SDO accreditation. Although not specifically mentioned in the NP, EuroRec is another interest at play in the formulation of ISO 13606 (as stated in open WG1/WG8 sessions in Vancouver). Please re-scope the Work Item to eliminate this dependency and remove related references.”
  Proposed response: Identified the difference between valid reference vs privileged relationship – every proposed contribution should be regarded as valid input, but not regarded as a deciding SDO or similar.

Norway:
- ISO 13606 is incompatible with Norwegian legislation and pointed out that there are problems with reusing information in a EHR extract.

There was discussion about the specification including EHR storage but consensus was that it would not be included in this scope, but proposed to have a separate NP to cater for this additional scope in the future, and perhaps identifying topics during the 13606 revision that will be relevant for the EHR storage extension. It was also noted that there is a possibility of including the EHR storage extension for consideration during the next revision of the HISA standard.

Dipak Kalra expressed a need people who have practical implementation experience of both ISO 13606 and openEHR to be involved in the development of the revision of this work item.
9.6.9.3 Proposed future work

Next steps:

- Confirm experts

- Request Member Bodies to launch information gathering exercise – what national and regional eHealth programmes and vendors/vendor associations using 13606

9.6.9.4 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.

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<tr>
<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
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<tr>
<td>WG 1/8 ISO 13606 Electronic health record communication</td>
<td>The 5 parts of ISO 13606 are all due for review. A NP for each of the 5 parts will be developed and all parts will be 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 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. Action: IT-014-09 to encourage and support Australian expert input to the revision of ISO 13606. Action: IT-014-09 to monitor and participate in review of all ISO 13606 documents.</td>
</tr>
<tr>
<td>Recommended for Action by</td>
<td>IT-014-09</td>
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9.6.10 ISO/CD 13940 SYSTEM OF CONCEPTS TO SUPPORT CONTINUITY OF CARE (CONTSYS)

9.6.10.1 Introduction

Nicholas Oughtibridge (UK) presented this 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 is being fast tracked (with substantial support) by TC215 having passed NP ballot with a DIS planned for June 2012 for ballot through to Jan 2013.

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.

The goal is to try to achieve the review of ContSys within a 2 year ballot cycle.

9.6.10.2 Progress to date

A Resolution was passed in Vancouver for Draft IS ballot submission no later than 30 June 2012 but the process has not been as smooth as first hoped. The document was also passed to BSi for a review of conformance to ISO template/style guide etc. and BSI have provided thorough feedback of adherence to template/style guide and identified improvements to the document. This feedback was too late for the experts to consider ahead of the Vienna ISO meeting and it will require the CONTSYS expert group to reflect the suggested changes in the draft IS.

The impact of this ‘detour’ is that the quality of the document has improved significantly; the amount of feedback provided by member bodies should be less; there will be a delay of over 3 months in the anticipated timings.

Previous concern regarding practical implementations appears to be under consideration now with the initiation of the CEN Workshop on Convergence of 13606, ContSys and HISA (as reported above).

9.6.10.3 Proposed future work

Prepare the document and send it out for DIS ballot as soon as possible.

9.6.10.4 Relevance to Australia

If implementation support is eventually included, this work may be a useful resource to inform the NEHTA CI team DCM and specification development.

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.

Australian involvement with the upcoming DIS process is advocated so that any mismatch of this methodology with our expectations (and any potential clash with the approach taken in our new IT-014-12 item) is determined early.

Others that have already expressed strong interest in this item, having contributed to previous consideration and discussion of the CD ballot and encouraging uptake of ContSys as a joint development under the auspices of the JIC, include IT-014-02, IT-014-06-06, IT-014-09 and IT-014-13.
If an appropriate level the support is to be found nationally, which may require further expert engagement beyond current IT-014 community, Australia should affirm its position of support. In this case it would also be desirable to assist with advancement of the item with additional expert active involvement as a joint exercise involving the relevant IT-014 subcommittees.

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<tr>
<td>WG 1/8, WG 3 ISO/CD 13940 System of Concepts to Support Continuity of Care - CONTSYS</td>
<td>This work is being fast tracked through CEN to go to joint DIS ballot ASAP. Although not yet widely known in Australia, its potential impact on e-health standards and specifications is significant. Recent additions appear to have made this project more academically focussed than the first version published as a European Standard. It is critical for this work be capable of practical application – this may no longer be the case. 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. <strong>Action:</strong> 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. <strong>Action:</strong> Monitor the progress of the CEN Convergence meetings to ensure that implementation support is grounding and informing the development of the CONTSYS standard.</td>
<td>IT-014-02 IT-014-06 IT-014-09 IT-014-12 IT-014-13 NEHTA</td>
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9.6.11 NP - QUALITY METRICS FOR DETAILED CLINICAL MODELS

9.6.11.1 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.

9.6.11.2 Progress to date

An initial Form 4 has been drafted and is being refined.

Discussion followed about the proposed publication target. Prof Sun-Ju is proposing a Technical Specification.

Heather Leslie (Australia) suggest that as there was still controversy about attributes and methodology for developing Detailed Clinical Models, then determining quality metrics around them was an even less mature knowledge domain – hence targeting a Technical Report about what practical implementations of existing quality metric measurement activity would be very useful. It is possible there is very little apart from the measurements occurring in the NEHTA Clinical Knowledge Manager actively implemented. This view was supported by Jamie Ferguson (KP/CIMI Executive, US) and Stephen Kay (CEN WG1, UK).

William Goossen and Jan Talmon (Netherlands) both strongly pushed for the final published output to be a Technical Specification.

The uncertain question at the heart of this issue is the unknown extent of quality metrics that can be normalised. This new work item will almost certainly reference ISO TS 13972, and given some of the issues already discussed previously about the revised 13972 document, there could be some further contentious issues that arise during the development of this project.

A straw poll of the WG found the group evenly divided – with approximately one third supporting publication as a technical report, one third favouring a technical specification and one third abstaining.

9.6.11.3 Proposed future work

A resolution was proposed to issue a NP ballot targeting a Technical Specification as requested by Sun-Ju.

The WG also requested Sun-Ju to investigate and send out supportive information including information on practical/concrete implementation activity on quality metric measurement as part of the NP ballot.

9.6.11.4 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.
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<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
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<tr>
<td>WG 1/8 NP Quality Metrics for Detailed Clinical Models</td>
<td>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. Given that Australia has some of the most extensive practical experience in quality metrics internationally and the difficult course that 13972 has taken, it is advisable that Australia actively participate in informing and shaping the final deliverable – whether a technical report or a technical specification. <strong>Action:</strong> Australia to consider voting for a technical report, given its longstanding preferred outcome for the 13972 work item to be demoted to a technical report. <strong>Action:</strong> Australia to provide expertise to inform the development of this new work item, no matter what the final targeted publication.</td>
<td>IT-014-09 NEHTA</td>
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</table>

9.6.12 17537, ELECTRONIC HEALTH RECORDS CLINICAL RESEARCH FUNCTIONAL PROFILE [EHR-CR] – STATUS

9.6.12.1 Introduction

This Project is being led by Mathias Poensgen (Germany) and Peter Knight (UK).

The project scope is to produce a profile of functional requirements for EHR systems being used to store electronic source data used for regulated clinical research. Such a profile will clarify the requirements to be met by EHR system developers, implementers and users when such systems are used for clinical research purposes and may be taken as the basis for qualification or certification activities.

The fundamental problem to be solved is that vendors of EHR systems, certification bodies, as well as users of EHR systems need a clear understanding of associated regulatory requirements to develop, certify, implement and maintain EHR systems to be used in clinical research in a compliant way and need to be able to distinguish these regulatory requirements from other requirements. The EHR-CR Functional Profile will clearly identify these regulatory research requirements in the context of how they pertain to EHR systems.

At the ISO meeting in Vancouver it became apparent that the project needed to harmonise with the EHR-S Functional Model. An expert group was established to commence resolution of the NP ballot comments.

9.6.12.2 Progress to date

Following the May ISO meeting, project the leaders have been holding teleconferences, but experiencing a lack of participation from project team and not as much progress has been made as was anticipated – so concerns were raised.
9.6.12.3  Proposed future work

Expert group consensus is that the work item should continue, but it was identified that the work item needs further time to allow the work to be completed.

9.6.12.4  Relevance to Australia

<table>
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<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
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</tr>
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<tr>
<td>WG 1/8 NP EHR Clinical Research Profile</td>
<td>Australia should keep a close watching brief on this work and ensure alignment with ISO 10871 EHR-S Functional Model standard. Action: IT-014-09 to keep a watching brief.</td>
<td>IT-014-09</td>
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</table>

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

9.6.13.1  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 9.6.14 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.

9.6.13.2  Progress to date

The PHRS-FM is currently undergoing a two way joint DIS ballot – the HL7 ballot closed 24 September, receiving several hundred comments; the ISO ballot is not yet scheduled but anticipated to be opened in October, 2012.

Reconciliation on the HL7 comments received so far is anticipated to commence very soon.

Proposed future work

Multiple functional profiles have been planned or proposed that will be conformant to the PHR Functional Model:

- Mobile Health (HL7 Mobile Health WG);
- Health Record Banks (HRBA);
- Tethered (Provider Based) PHRs; and
- Health Plan Based PHRs.
9.6.13.3 Relevance to Australia

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<tr>
<th>Topic</th>
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<tr>
<td>WG 1/8 ISO DIS 16527 PHR system functional model</td>
<td>Australia should keep a close watching brief on this work, in reference to its potential impact on the PCEHR development.</td>
<td>IT-014-09</td>
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<td>Action: IT-014-09 to keep a watching brief.</td>
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9.6.14 ISO DIS 10781-EHRS FM R2

9.6.14.1 Introduction

An overview of the significant work happening within HL7 to deliver 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.

Typically 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.

9.6.14.2 Progress to date

The HL7 ballot closed in May; the ISO International ballot closed during the ISO Vienna meeting.

9.6.14.3 Proposed future work

The second round of HL7 balloting is anticipated to open in early December, 2012, and at this point it is possible that the Joint International ballot may be ready to open in January 2013.

The regular series of weekly teleconferences will continue focused on the DIS ballot comment reconciliation.
There are also further plans for EHRS FM Release 3 development, including:

- Spreadsheet → tool based master;
  - e.g. using Enterprise Architect
- Hierarchy;
- Logical restructuring:
  - Data Requirements
  - Event Management
  - User interface, interactions, presentation, lists
  - Alerts, reminders, notifications
- HL7 function and Info model; and
- HL7 Tooling contract for R2 Functional Profiles.

### 9.6.14.4 Relevance to Australia

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<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
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<tr>
<td>WG 8 ISO DIS 10781 - EHR System Functional Model Release 2</td>
<td>Issue: Australia should continue to keep a watching brief on this work. The principal work is progressing through the HL7 EHR WG. Action: IT-014-09 should keep a watching brief on this work item, participating in the next ballot rounds when opened.</td>
<td>IT-014-09</td>
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### 9.6.15 REPORT: ONC - CROSS INITIATIVE – S&I SIMPLIFICATION

#### 9.6.15.1 Introduction

Presented by Gary Dickinson (US)

Under auspice of ONC's Standards and Interoperability Framework, the "Cross Initiative – S&I Simplification WG" is a "cross-cutting work group to simplify the use case and requirements outline, template and artefacts and make recommendations to all WGs and S&I Framework teams." [http://wiki.siframework.org/Cross+Initiative+-+S%26I+Simplification+WG](http://wiki.siframework.org/Cross+Initiative+-+S%26I+Simplification+WG)

Use case initiatives within the current scope include:

- Transitions of Care;
- Long-term coordination of care;
- Lab orders/Results;
- Electronic submission of Medical Documentation;
- Query Health;
- Data segmentation for Privacy;
- Public Health reporting; and
• Provider Directory.

The key objectives

• To identify a set of core components broadly applicable to, and re-usable in subsequent specification of, use cases

• Broadly stated, core components are Requirements, Events, Actions, Actors, Roles and Data Objects, that we:
  o find in common across use cases, scenarios and events; and
  o might re-use in a new use case scenario.

• To establish/maintain a core component registry

• To allow each use case Initiative to select core components applicable to their needs

• To identify new candidates for core components as each Use Case Initiative reaches consensus

• To identify candidates for Implementable data and software constructs.

Each use case has one or more scenarios with one or more events with one or more actions. Use Case Scenarios describe (resolve to): a set and sequence of actors taking actions; a progression of steps. Each initiative starts with Use Case Requirements. Use Cases resolve to a standard set of Core Components (detailed in the core Matrix).

Core matrix compiles and distils components from all S&I initiatives – for easy reference, organisation, comparison. So far 11 use cases with 30 multi-step scenarios.

Conveys uniform and integrated patterns of:

• Patient flow;

• Provider work/process flow; and

• Information flow.

9.6.15.2 Relevance to Australia

It appears that this work is at quite a high level and focussed on patient/provider/information workflow rather than clinical content. Where it refers to any clinical concepts it is still at very high level for example, only to the level of detail that is espoused in CCD, and so is not directly related to the DCM work being undertaken by the NEHTA CTI team.

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.

9.7 PUBLIC HEALTH TASK FORCE (PHTF)

9.7.1 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.

9.7.2 RECENT ACTIVITY

www.hiwiki.org provides a website for Task Force interactions and documents. Considerable email traffic also occurs between members of the group, and other external interested parties (e.g. group with overlapping interests in HL7 International, chaired by John Ritter).

WHO has not been able to sustain their leadership of this activity due to staff changes and restructuring, so more of the leadership responsibility has fallen to ISO/TC 215/WG 1 but the work has been particularly supported by Kaiser Permanente. Brazil, Canada, Mexico and USA have contributed major input since the last TC215 meeting. HL7 has developed its interests in LMIC in parallel and is engaged in a “free access to standards” education project. Liaison between HL7 and PHTF has occurred through joint group teleconferences and emails.

As insufficient DTR 14639-2 subtasks progressed to the point where they could be reviewed at this meeting, it was elected to hold a more general direction setting discussion.

9.7.2.1 Current publications

ISO/TR 14639-1 Health informatics — Capacity-based eHealth architecture roadmap — Part 1: Overview of national eHealth initiatives

9.7.2.2 Current work items

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

9.7.3 PROGRESS AT THIS MEETING

In addition to reporting progress in the WG 1 sessions, the PHTF convened a separate meeting to progress its items on the Wednesday afternoon (26th September 2012), following
the ISO/TC 215 closing plenary. Overall, the following topics were covered, as reported further in the following sections of this report:

- Revised eHealth Survey;
- WHO Update;
- Presentation on South African eHealth strategy; and

It was noted that a major limitation for the PHTF is unavailability of resourcing to engage with LMICs to conduct eHealth readiness surveys, and funding to hold meetings of the Task Force members to advance the work item, which is extensive and complex in scope and so needs the multiple contributors to align their thinking in detail.

9.7.4 REVISED E-HEALTH SURVEY

The revised e-health survey is an assessment tool that focuses on four priority areas of e-health capability: national ICT infrastructure; eHealth infostructure; patient services; governance and national ownership. There is also material on the use of public health standards including data exchange, communicable diseases, disease surveillance and the use of coding/terminologies, and messaging.

Data was extracted from online sources following an environmental scan.

The WHO Health Metrics Network has the best information in 69 country-specific profiles including eHealth, but lacks depth of detail in some areas. The survey needs to be expanded through cooperative data collection and extraction from other sources.

There is also a desire to develop a plan for coordinating assistance and support of LMICs wanting to develop their public health IT strategy.

9.7.5 WHO UPDATE

Planned Working Group on Health Data/ICT Standards Harmonisation Mon-Tue 3-4 Dec Geneva, may be preceded by a pre-meeting of SDOs on Friday 30 November which will give an opportunity to provide information and canvas support for PHTF work (and possibly also for PHTF members to meet if a sufficient number can attend). The meeting may also consider public health/surveillance standards with related indicators and health data reporting/visualization standards.

WHO is planning a review of countries' Public Health activity using “front line responders” including HIEs and other use cases (eg regional projects). They will develop a framework for health data standards deployment in developing countries and will form an inter-agency body to coordinate development and use of health data standards internationally. Deployment to countries with poor performance in public health indicators (as determined by WHO data centres) will be selected for intervention projects which may include eHealth components (eg diabetes, malaria, HIV/TB, maternal/infant). WHO has been working on a Handbook for Interoperability to try and get coherent data. WHO also is interested in contributing a background paper to inform the current work item. Their focus is very
strongly on the public health and health surveillance aspects of this area, and not specifically on EHR or messaging developments.

9.7.6 PRESENTATION ON SOUTH AFRICAN EHEALTH STRATEGY

Dr Rosemary Foster presented on the new South African eHealth strategy and associated developments

The South African Medical Research Council (MRC) recently conducted an “eHealth in Africa” survey of 10 countries in sub-Saharan Africa, based on the original survey used in ISO/TR 14639-1. This was undertaken using published literature from 2008 onwards, national MoH websites, and grey literature from Google Search. Three broad groups were noted: (1) no evidence of eHealth planning, (2) some planning but no implementation, and (3) both planning and implementation. WHO Global Observatory for eHealth and HMN planning for HIS was present in many of them from groups 2 and 3.

ICT Infrastructure progress is apparently linked with eHealth awareness and some associated planning and implementation. Most existing progress has been in specific areas of health care (e.g. infectious diseases). A 30 page report on this has been produced by MRC authored by Rosemary Foster and Chris Seebreghts, but needs to be cleared for distribution to PHTF.

ITU has also just conducted a survey of IT infrastructure in Africa and this information may be available on the ITU website.

9.7.7 ISO/DTR 14639 AND LMICS

9.7.7.1 Progress at this meeting

At the last TC 215/PHTF meeting (Vancouver May 2012) some subtasks in developing DTR 14639-2 further were allocated and it was expected that these would be reviewed at this meeting; however, insufficient progress had been made for this to occur.

Progress on this item was also presented in the main WG 1 meeting and the results of that consideration are reported at 9.6.3 above. The following points reflect PHTF deliberations on the broader strategic issues surrounding the technical report and LMIC activity more generally.

PHTF is a time limited group which will end when the TR has been produced. To carry this groundwork into realisation a partnership is needed between SDOs to coordinate access/availability and outreach. This could involve WHO Collaborating Centres or other already collaborating groups in certain geographic regions and would also need education on what standards are and how they can be used, with a 3-5 year horizon, which needs a curriculum and training package to be developed (including capabilities of users and experts in standards), then NGOs or CDC programme can help deliver. WHO can act as a gateway to help this happen, and support resulting entity/consortium.

DTR finalisation is needed by end of 2012, with missing sections to be crafted over the next month. The current draft can also be enhanced immediately using some materials offered at this meeting by various parties (e.g. the South African document). It needs stronger introductory section to give clearer scope and guidance (maybe an executive summary). Request to TC215/ISO will be made to extend project by one year to Dec 2013, to allow
completion of TR refinement and balloting. Possibility of World Bank and other international bodies involvement still needs to be explored. Regional collaboratives could be formed if global coverage is too great, or targeted partnerships (e.g. common language leverage such as Portuguese, French). To assist with adoption of the item, ISO will be requested to consider ways to make the resulting document available to LMICs fee free - this may require consideration of the HL7 model for free distribution, mentioned above.

9.7.7.2 Relevance to Australia

The eHealth enterprise architecture model developed in this item is generic, applying to HICs as well as LMICs, and so can be useful for planning and articulation of our own national strategies concerned with eHealth systems. It was developed with considerable Australian input and involvement (by Richard Dixon-Hughes and Anthony Maeder) and so Australian leadership in this area of international significance should be maintained until the work item is completed. Interaction with HL7 Australia (and via them with HL7 International) in the areas of LMIC standards education and liaison activities would also be justified by this orientation. Australia’s interest in continuing to contribute with expert input was reaffirmed. Australia’s ability to participate in eHealth related development projects in LMICs (eg Asia, Africa, South America) including our established Asia/Pacific established partner nations (eg Vietnam, Malaysia) and also AusAid supported projects related to healthcare, will be enhanced by our detailed knowledge and engagement in this topic.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHTF subcommittee: DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model</td>
<td>Completion of the work item with detailed contributions for specified subsections. <strong>Action:</strong> Australian experts should continue to contribute and assist with completion of this item by next TC215 meeting.</td>
<td>IT-014 Richard Dixon Hughes; Anthony Maeder</td>
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<tr>
<td></td>
<td>Opportunities for collaboration with HL7 initiatives to extend reach of eHealth standards to LMICs</td>
<td>IT-014 Richard Dixon Hughes; Anthony Maeder</td>
</tr>
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<td></td>
<td><strong>Action:</strong> Collaboration opportunities should be explored between IT-014 and HL7A in the area of standards education and liaison, especially to Australia’s established regional partner nations.</td>
<td>IT-014 Richard Dixon Hughes; Anthony Maeder</td>
</tr>
</tbody>
</table>

9.8 WG 2 DATA INTERCHANGE

9.8.1 BACKGROUND

Among other things, Working Group 2 "Data Interchange" (WG2) 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.

9.8.2 RECENT ACTIVITY

A significant amount of effort at the previous meeting was devoted to working up proposals to resolve increasing problems with ISO processes when processing documents being developed and maintained by TC 215 partner organisations, notably HL7, CDISC, DICOM and IHE.

Interim arrangements allowed HL7 documents to be effectively published in their original hyperlinked form but had expired. TC 215 is attempting to progress three significant measures in order to authorise further exploration of strategies to deal with the issues. The measures are:

(1) A proposed provision to allow the publishing of hyperlinked standards documents that originate from and are maintained by other SDOs in their original form within ISO covers and with ISO introductory material.

(2) Using an ISO head standard to reference normative content maintained externally by highly credible partner SDOs and giving conformance criteria for certification purposes and prescribing the means by which external content will be maintained. It represents a generalisation of the process used with DICOM and proposed for the BRIDG model.

(3) Specific measures to recommence work on publishing an ISO head standard around the BRIDG model material maintained by CDISC on behalf of BRIDG.

9.8.2.1 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
9.8.2.2 Current work items

The following current work items were noted at this meeting:

- ISO/DIS 13449 - Clinical genomics – Pedigree topic
- ISO/TR 28380-1 - IHE Global Standards Adoption Part 1- Process
- ISO/TR 28380-2 - IHE Global Standards Adoption - Part 2
- ISO/TR 28380-3 - IHE Global Standards Adoption - Part 3
- ISO 13131 - Quality Criteria for Telehealth
- ISO 14199 - BRIDG Model
- ISO/TR 17522 Provisions for health applications on smart/mobile devices

9.8.3 PROGRESS AT THIS MEETING

Working Group 2 convener, Michael Glickman (US), was unable to be present at the meeting and well known HL7 identity, George ("Woody") Beeler (US) did a good job of filling the role of acting convener, assisted by Vice-Convener Michio Kimura (JP) and the WG secretary Allison Viola (US - AHIMA). Attendance varied but ranged up to about 40.

Given the proposed merge of WG 7 (Devices) into WG 2, there was a joint meeting with WG 7 to draft a consolidated scope. The proposed change seems to have been accepted by both WGs at this stage.

Further effort at this meeting was devoted to negotiating with Dr Mary Lou Pélaprat of ISO/CS over the three key measures being proposed to handle documents being developed and maintained by TC 215 partner organisations. Informal indications were received that an approval was likely to allow the publishing of hyperlinked standards documents that originate from and are maintained by other SDOs in their original form within ISO covers and with ISO introductory material. A new XML publishing capability is being looked at to support this; however, the basic documents must be of appropriate quality. Those with responsibilities for progressing HL7 documents were encouraged by this – however, there is still a need for a new agreement to be established between ISO and HL7 International before HL7 again has the status to use these approaches.

There was some limited discussion of progress on the BRIDG Model, with the ball being back in the CDISC court to negotiate a series of questions from ISO/CS about the proposed approach. The paperwork has been prepared, referencing BRIDG ver3.2, to go forward as an NP ballot to reinstate the revised project once the approach is agreed. The hope was to go the NP ballot with attached CD in October 2012.

The more general measure of using an ISO head standard to reference normative content maintained externally by highly credible partner SDOs had not progressed and will probably need to be escalated within ISO when the issues are better understood.

Other WG 2 projects tracked, in most cases, progressed at this meeting included:

- ISO 13131 Quality measures for telehealth (see section 9.8.4 below)
- Clinical trials registration and reporting (CTR&R)
• ISO/TR 17522 Provisions for health applications on smart/mobile devices
  A draft of the CD of the TR from Korea was reviewed. The project leader will revise
  document to extend it to include devices used in lower, middle-income countries and to
  provide a framework for further standards to address the issues raised in the DTR.
  A revised DTR will be submitted to WG vote, including a vote on whether to seek
  approval from TC for a DTR ballot.

• ISO/HL7 DIS 13449 HI-Clinical genomics – Pedigree topic.
  This item was accepted on fast-track from HL7, passed unanimously and will be taken
  to IS publication. Comments received were resolved by reference to the HL7 WG for
  consideration in future revisions of the base standard.

• ISO CD 17583 - Terminology constraints [Binding] for coded data elements expressed
  in ISO harmonized data types used in healthcare information interchange
  CD ballot comments were reviewed and project leaders will reach out to DCM
  participants to align content, and to the UK voters to assure resolution of their votes.
  Project leaders will seek to revise document for a formal 30-day e-mail review by WG 2
  and vote on the disposition of comments, with possibility of subsequently proposing a
  resolution to TC 215 to approve for opening a DIS ballot.

• 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.

• New work on ISO/TR 28380-3 Health informatics - IHE Global Standards
  Adoption -Part 3:Deployment
  With IHE being admitted to JIC, there seems to be more prospect that the ISO/DTR
  28380-series will progress.

• As reported above, actions are proceeding on several fronts with some prospects of
  success to arrange a more satisfactory agreement between ISO and HL7 to replace the
  outdated HL7 pilot agreement and, as indicated above, obtain special approval to
  publish HL7 documents as ISO standards publications but largely in their original form.
  Projects affected are expected to include
    - Update of HL7 reference information model (RIM) standard (ISO/HL7 21731)
- Update of the HL7 Clinical Document Architecture (CDA) standard (ISO/HL7 27932)
- ISO 13499 Clinical genomics – pedigree topic. Unanimously approved for publication based on adoption of HL7 specifications, the documents are with ISO/CS awaiting publication
- Release 2 of the EHR-S FM (ISO/HL7 10781)
- PHR-S FM and profiles of the EHR-S FM and PHR-S FM.

9.8.4 DTS 13131 TELEHEALTH QUALITY CRITERIA

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

9.8.4.2 Recent events
Modifications of the draft document due to disposition of comments from Vancouver TC215 meeting in May 2012 have not been completed, due to ill health of the project leader.

9.8.4.3 Progress at this meeting and proposed future work
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).

9.8.4.4 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-14-12 to contribute input to this document and also to provide a supporting national nominated expert (nominee Anthony Maeder).
<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
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<tbody>
<tr>
<td>WG2 – DTS 13131 Telehealth Quality Criteria</td>
<td>The CD ballot comment modifications are being made and the item will soon be advanced to DTS ballot</td>
<td>IT-014-12</td>
</tr>
<tr>
<td></td>
<td><strong>Action:</strong> Continue active consideration of this item on IT-014-12 work plan, and contribute to DTS ballot in due course.</td>
<td>Anthony Maeder</td>
</tr>
</tbody>
</table>
9.9  WG 3 SEMANTIC CONTENT

9.9.1  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.

9.9.1.1  Current publications

There were no WG 3 documents published in the period between the last ISO/TC 215 meeting in Vancouver and this meeting.

9.9.1.2  Current work items

<table>
<thead>
<tr>
<th>Number</th>
<th>Title</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>12310</td>
<td>Principles and guidelines for the measurement of conformance in the implementation of terminological systems</td>
<td>PWI</td>
</tr>
<tr>
<td>1828</td>
<td>Categorial structure for terminological systems of surgical procedures (CEN EN)</td>
<td>FDIS - to ballot after this meeting</td>
</tr>
<tr>
<td>17115</td>
<td>Vocabulary for terminological systems</td>
<td>PWI</td>
</tr>
<tr>
<td>13581</td>
<td>Health informatics: Sharing of OID registry information</td>
<td>CD - in comment disposition</td>
</tr>
<tr>
<td>13582</td>
<td>Health informatics: Communication model and XML interface specification for OID registries</td>
<td>Awaiting 13581</td>
</tr>
<tr>
<td>17439</td>
<td>Structure and maintenance of the health informatics glossary</td>
<td>In test</td>
</tr>
<tr>
<td>12300</td>
<td>Principles of mapping between terminological systems</td>
<td>DTR - to ballot after this meeting</td>
</tr>
<tr>
<td>14668</td>
<td>Guidelines for principles and desirable features of Clinical Decision Support</td>
<td>CD in preparation</td>
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<tr>
<td>13119</td>
<td>Clinical knowledge resources - metadata</td>
<td>At ballot</td>
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<tr>
<td>18104</td>
<td>Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems</td>
<td>At ballot</td>
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<tr>
<td>13120</td>
<td>Health informatics – A syntax to represent the content of classification systems in health care</td>
<td>DIS</td>
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<tr>
<td>17117</td>
<td>Terminological resources Part 1 – Framework</td>
<td>Preliminary work item</td>
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<tr>
<td>16277-1</td>
<td>Categorial structure of clinical finding in traditional medicine- Part 1: Traditional East Asian Medicine</td>
<td>CD available</td>
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<tr>
<td>16843-1</td>
<td>Categorial structures for representation of acupuncture Part 1: acupuncture points</td>
<td>NP passed ballot</td>
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<tr>
<td>16843-2</td>
<td>Categorial structures for representation of acupuncture Part 2: Needling</td>
<td>NP passed ballot</td>
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<tr>
<td>17948</td>
<td>ISO TS 17948 Health Informatics- Traditional Chinese medicine metadata</td>
<td>NP ballot comments disposed and new document ready for review</td>
</tr>
<tr>
<td>17938</td>
<td>ISO 17938 TS –health informatics- Semantic network framework and coding of Traditional Chinese Medicine language system.</td>
<td>NP ballot comments disposed and new document ready for review</td>
</tr>
<tr>
<td>18062</td>
<td>Categorial structures for representation of herbal medications in</td>
<td>Initial draft awaiting</td>
</tr>
</tbody>
</table>
9.9.2 PROGRESS AT THIS MEETING

There were 11 Countries represented at this meeting with 33 attendees at the WG3 meetings over the two days. The working group reviewed the suggested scope information from the TC215 restructure documents and offered to the TC215 executive the following updated scope statement:

To develop standards for representation of health concepts and data.

These standards include:
- formal models of representation and description of health concepts;
- principles of their organization within terminological resources;
- principles for governance and maintenance of terminological resources;
- the representation and management of knowledge; and
- the use of terminological and knowledge resources in electronic health records and other systems.

Difficulties were also identified with ISO secretariat processes, believed to have come from the transfer of the secretariat. More than 200 errors in the project database were identified and are now being corrected; these affect not only the work of working group 3 but other groups as well. These issues generated considerable anxiety within the community, particularly in the traditional medicine group. Each issue was addressed by the convenor, Heather Grain (Australia) and actions identified.

9.9.3 12310 – PRINCIPLES AND GUIDELINES FOR THE MEASUREMENT OF CONFORMANCE IN THE IMPLEMENTATION OF TERMINOLOGY SYSTEMS

9.9.3.1 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.

9.9.3.2 Progress to date

Sandra Stuart of the USA is working on this document and will be the new project leader. A resolution was developed and a Form 4 completed to begin the process at this meeting.

Due to lack of time in resolution preparation this item was missed in the Working Group Resolutions.

9.9.3.3 Proposed future work

A complete draft and updated comment disposition is being prepared and this document will be circulated to the community in anticipation of ballot after the next meeting, unless a virtual agreement to ballot can be achieved.
9.9.3.4 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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
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</tr>
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<tr>
<td>WG3</td>
<td><strong>12310 Principles and guidelines for</strong></td>
<td>IT-014-02</td>
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<td><strong>the measurement of conformance</strong></td>
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<td><strong>terminological systems</strong></td>
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<td>Document expected to go out to comment</td>
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<td></td>
<td><strong>Action:</strong> Return to active work items for</td>
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<td></td>
<td><strong>review by IT-014-02 to ensure circulation</strong></td>
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<td><strong>to the community.</strong></td>
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9.9.4 PREN ISO/DIS 1828 CATEGORIAL STRUCTURE FOR TERMINOLOGICAL SYSTEMS OF SURGICAL PROCEDURES

9.9.4.1 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.

9.9.4.2 Progress to date
This document is currently out for FDIS ballot and was not discussed.

9.9.4.3 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.

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<tr>
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<th>Suggested responsibility &amp; alignment to IT-014</th>
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<td>WG3</td>
<td><strong>1828 Categorial structure for</strong></td>
<td>IT-014-02</td>
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<td><strong>terminological systems of surgical</strong></td>
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<td><strong>procedures</strong></td>
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<td>When ballot completes and the document is</td>
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<td></td>
<td><strong>published consider relevance and reference</strong></td>
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<td><strong>inclusion in IT-014-02 work items such as</strong></td>
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<td><strong>update of the data development guide</strong></td>
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<td><strong>Action:</strong> Include as reference for Data ****</td>
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<td><strong>Development work item in IT-014-02</strong></td>
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9.9.5 ISO 17115:2007 VOCABULARY FOR TERMINOLOGICAL SYSTEMS (VOTE)

9.9.5.1 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.

9.9.5.2 Progress to date

The meeting agreed to achieve the need to update VOTE through revision of “EN12264 Categorial structures for systems of concepts” and to identify ‘term families’, the definitions appropriate to each will be included in the final document and in this way the background information relevant to terminological resource standards included in EN12264 and the terms and definitions from the existing ISO 17115 will be reviewed and included. This new process will have three phases:

1. Revise normative content from EN12264 to identify TERM FAMILIES in addition to those in the existing ISO 17115.
2. Develop terms following directions provided in DTR 17439 Development of terms.
3. Prepare the New Work Item Proposal. Experts have been identified and include:
   i. Anne Casey
   ii. Ronald Cornet
   iii. Heather Grain
   iv. Yasuyuki Hirose
   v. Jean-Marie Rodrigues

In conjunction with this work item processes for the proposal and revision of terms and definitions are being tested.

The meeting reviewed both the processes and some of the terms. The preferred definition will be included in the resultant publication and, when confirmed by ballot on that document will go to the harmonization process via the JIC process.

The meeting confirmed quality criteria for definition assessment. Definitions should:

- use correct grammar and simple language;
- define the concept not including examples which should be in the notes area;
- be a single phrase; and
- be able to replace the term in a sentence.

9.9.5.3 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.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3</td>
<td>This document will be a useful resource to IT-014's harmonisation of terms and definitions and will inform the IT-014 and other communities in Australia to improve processes. Action: Include as reference for Data Development work item in IT-014-02 and ensure review of this work by IT-014-02</td>
<td>IT-014-02</td>
</tr>
</tbody>
</table>


9.9.6.1 Introduction

This work item specifies 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.

9.9.6.2 Progress to date

The ballot of this work item closed shortly before the meeting. A total of 27 countries voted and 4 countries provided over seventy (70) comments. Modifications will take into account the ISO data types. All comments will be able to reconcile after following up on those questions with the National Member Body from which they come, as the issue behind some of the comments is not clear.

Further discussion is required but it is believed that this can be accomplished in the teleconferences over the next month or two. Assuming that these discussions progress the comment disposition to complete this item will be prepared to go out to ballot by 1st of December 2012.

9.9.6.3 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.
9.9.7 ISO TS 17439 STRUCTURE AND MAINTENANCE OF THE HEALTH INFORMATICS GLOSSARY

9.9.7.1 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).

9.9.7.2 Progress to date

The Joint Initiative Council approved the SKMT (Standards Knowledge Management Tool) governance plan at this meeting. WG3 will play an advisory role in the governance and harmonisation of the SKMT content. Netherlands, Canada, Australia are three member bodies which have added terms/documents from their national standards or initiative infrastructures to the SKMT.

Some of the principles agreed to at this meeting include that:

- Poor definitions should be retired and the Work Group will be encouraged to sort out what terms should be retired or harmonized.
- Terminology guidelines should be followed. This includes the principle that origin of the definition should not influence the decision on preferred / retained definition. The quality of the definition should be the consideration.
- Status of the definition or document should be used when a WG is still working on a definition e.g. we have no preferred definition is available for categorical structures/terminological systems when our work is ready, a preferred definition will be created. The governance group will establish meeting times/processes (one of their terms of reference will set up meetings and work plans, etc.).

The issue of representation to the JIC SKMT Governance Committee was discussed. This requires consideration of representation of WG3, which is required to support liaison, advise and process development and of who will represent ISO/TC 215. It was the view of WG3 that the TC representative should provide a disparate view to that of WG3 and thereby improve the potential of the whole process. It was agreed that Heather Grain will represent WG 3 specifically.

9.9.7.3 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.
### ISO TDR 12300 PRINCIPLES OF MAPPING BETWEEN TERMINOLOGICAL RESOURCES

#### 9.9.8.1 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.
9.9.8.2  Progress to date
The meeting agreed to the disposition of comments and some minor modifications. The document will be forwarded to vote after this meeting. This work item is led by Heather Grain and Australia, including significant input from NEHTA staff.

9.9.8.3  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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3</td>
<td>This work will go out to ballot after this meeting. Comments have been received in the past from members of IT-014-02. Action: Ensure circulation to IT-014-02 and NEHTA for comment</td>
<td>IT-014-02 (already on the work program)</td>
</tr>
</tbody>
</table>

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

9.9.9.1  Introduction
This project is based upon the Australian publication, HB307-2007 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.

9.9.9.2  Progress to date
A report to WG3 and WG1 was made by Heather Grain which indicated that this work is currently delayed due to lack of resource availability but that the work should now progress and a draft will be made available by the end of the year. The restructuring of IT-014, to include working group IT-014-13 is hoped to assist with this work item. It is anticipated that a committee draft will be available before the end of the calendar year.

9.9.9.3  Relevance to Australia
This is an Australian work item, with Australian leadership.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3</td>
<td>IT-014-13 have indicated that they wish to concentrate on HL7 issues in this space. This is of significant concern as the intention was originally to harmonise these initiatives. Action: Include on IT-014-13 work program</td>
<td>IT-014 IT-014-13</td>
</tr>
</tbody>
</table>
9.9.10 ISO/CD 13940 HEALTH INFORMATICS – SYSTEM OF CONCEPTS TO SUPPORT CONTINUITY OF CARE

9.9.10.1 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.

9.9.10.2 Progress to date
A report from Nicholas Oughtibridge (BSI) was provided to WG’s 1, 8 and 3. The project lead sent documents to the ISO Secretariat in June. At the same time the documents were sent to BSI who have provided valuable feedback. At the meeting the experts have not yet had time to process all of this feedback.

9.9.10.3 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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3 System of Concepts to Support Continuity of Care</td>
<td>The community should be aware that this item will be put forward to FDIS ballot. Action: IT-014 should be aware of the need to provide a vote on this work item.</td>
<td>IT-014</td>
</tr>
</tbody>
</table>

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

9.9.11.1 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.

9.9.11.2 Progress to date

This item has progressed slowly due to lack of resources in the leadership. Germany have provided additional resources and the disposition of comments has now been undertaken and this work item is now ready for FDIS ballot, once the draft and comment disposition is seen by the WG3 members. This standard is a XML and metadata structure designed to work with classifications. The disposition of comments will be discussed at the teleconferences and resolution to go to ballot is dependent upon the WG agreeing with the comment disposition.

9.9.11.3 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.

<table>
<thead>
<tr>
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<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3</td>
<td>Assess the priority and usage of this work item in Australia</td>
<td>IT-014 members, AIHW, DOHA, NEHTA</td>
</tr>
<tr>
<td></td>
<td>Action: IT-014 members, specifically AIHW, DOHA and NEHTA</td>
<td></td>
</tr>
</tbody>
</table>

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9.9.12 ISO 17117 TERMINOLOGICAL RESOURCES PART 1 – FRAMEWORK

9.9.12.1 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.

9.9.12.2 Progress to date

A very clear and well-structured presentation was provided by Takeshi Imai. The draft document has been circulated to experts on 6th September for review. A definition of terminological resources is offered in this document. Other highlights included:

- Data entry with requirements was presented – some required, some optional in the list. It was suggested that this be termed data capture, as not all data is entered by an individual.
- Data aggregation for statistical analysis was also covered with some required, some optional in the list.

This work should be reviewed to evaluate the structure against the agreed criteria for definitions discussed by WG3.

It was suggested that an introductory paragraph or section be added that describes the use of this standard as it relates to electronic health records. The candidate definition in the ReVote standard in process could be considered. Classification is a terminological resource with the additional characteristics of mutual exclusiveness and exhaustiveness. Define at the characteristic level.

9.9.12.3 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.

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

9.9.13.1 Introduction

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

9.9.13.2 Progress to date

A status update was provided by Dr. Kyungmo Park. A new title was proposed to provide consistency of titles within WG3 products. The title agreed was - *Categorial structures of clinical findings in traditional medicine part 1: Traditional East Asian Medicine*. 
This work item draft document has been distributed to the list of experts and will be shared with the IT-014-02 community and identified traditional medicine liaison individuals in the Australian Standards Australia community for their input.

9.9.13.3 **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.

<table>
<thead>
<tr>
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<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3</td>
<td>Comments are being sought</td>
<td>IT-014-02 and Traditional Medicine liaison</td>
</tr>
<tr>
<td>Categorial structures of clinical findings in traditional medicine - part 1 traditional east Asian medicine</td>
<td>Action: Distribute for comments</td>
<td></td>
</tr>
</tbody>
</table>

9.9.14 **PRELIMINARY WORK ITEMS**

9.9.14.1 **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.

9.9.14.2 **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.

9.9.14.3 **Progress to date**

Now that the status of the item has been clarified a draft will be prepared prior to the next meeting.

Note: IT-014-02 have discussed this item and consider it to be highly relevant to Australian systems and needs.

9.9.14.4 **Relevance to Australia**

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

9.9.15.1 Health informatics: Profiling framework and classification for traditional medicine informatics standards development Part 1: Traditional Chinese Medicine (TMC)

9.9.15.1.1 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.

9.9.15.1.2 Progress to date

This item was presented for the first time at the meeting and received considerable support due to the clear need made obvious throughout the meeting.

A committee draft should be available before a new proposal for a preliminary work item was agreed.

9.9.15.1.3 Relevance to Australia

To be determined when the committee draft is available for review.
9.10 TRADITIONAL MEDICINE TASK FORCE

9.10.1 BACKGROUND

This Task Force subcommittee of WG3 considers items concerning various types of Traditional Medicines such as Asian Traditional Medicines. It was formed to help resolve a perceived overlap between TC215 and TC249, in the area of TCM Informatics, and was intended to work towards creation of a JWG between TC215 and TC249 to handle such items inclusively in the future. Most current work items under the Task Force are focussed on Traditional Chinese Medicine (TCM) probably due to the lack of countries with other forms of TM regularly attending TC215 meetings.

9.10.2 RECENT ACTIVITY

The group has evolved over the past few TC215 meetings and is in the final stages of the process of forming a JWG with TC249 in the area of TCM Informatics (currently a WG of TC249). This JWG will cover only TCM, and the Task Force (as a subcommittee of WG3) will need to continue to exist as it has other forms of TM within scope. An election for co-convenor of the JWG from TC215 is currently underway, to be concluded by October 2012, after which it is expected that ISO will establish the JWG formally. Initial leadership of the Task Force by Korea was recently replaced by Malaysia, and some work items formerly led by Japan have been replaced by China and Korea. The Task Force now appears in a position to function as a normal standards document development group and is initiating new PWIs as a result.

9.10.2.1 Current publications

No current publications.

9.10.2.2 Current work items

- 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.
9.10.3 Progress at this meeting

A review of task force discussions and activities was provided by Dr Khadzir. A discussion occurred at the request of the TMTF to consider whether the TMTF (Traditional Medicine Task Force) continues to be organized directly under ISO/TC 215 or remains in WG3 ISO/TC 215. WG3 agreed that the TMTF should be left as “status quo” meaning that this group will continue to be aligned with and report to WG3, but that this situation should be regularly reviewed, particularly to consider the content of work being discussed which currently strongly aligns with activities in WG3.

The meeting was informed that JWG10/TC215 and JWG6/TC249 will be two separate organizations but function as one and having same co-convenors. (In effect it will be physically 1 group with 2 different names and reporting lines, and terms of reference will determine how to deal with any abnormal situations). This JWG will only deal with agreed projects on health informatics in TCM. The implication is that the Task Force will need to continue to exist to deal with TC215 TM projects not transferred to the JWG.

During the meetings of the TMTF meeting issues arose which warranted additional discussion and clarification with WG3. A discussion was held between members of the TMTF with the ISO Central Secretariat, represented by Mary Lou Peleprat and the ISO/TC 215 Secretary, Lisa Spellman about process issues of concern involving work item advancement and program management. It was noted by WG3 that similar issues have occurred with other work items of the WG. It was stated in the meeting by Ted Klein that there were data integrity problems in the ISO database and/or ISO/TC 215 Secretary documentation sources recently discovered which have affected the advancement of selected work items from the TMTF and other areas. After discussion with the TMTF the ISO Central Secretariat it was agreed that the projects will go forward with the time clock restarted as at this meeting. The current list of experts must be documented and reviewed in order for all countries to reconfirm the expert list.

Japan withdrew officially via email their secretarial support for TMTF at this meeting, China agreed to provide secretarial support for the Task Force. Malaysia continues to chair the Task Force.

The meeting was informed that there was only one nomination for co-convenor in JWG6/TC249. However, there were three nominations for co-convenor in JWG10/TC215 and ballot will close in early October. Until then, all related work will continue within the Task Force and handover to the JWG will be anticipated at the next TC215 meeting.
9.10.4 PROGRESS OF PROJECTS

9.10.4.1 NP: CONCEPTUAL FRAMEWORKS FOR NON-CHEMICAL BODY SURFACE STIMULATION

Two closely linked new proposed work items will be put to TC215 WG3 on body surface non-chemical stimulation, dealing with (1) location and (2) treatment. Although widely used in TM and TCM (e.g. for acupuncture, moxibustion), this topic is not exclusively confined to those areas (e.g. massage). Consequently these items were assessed as not confined in scope to TM Task Force and similarly not appropriate as JWG items, and so they needed to be processed as WG3 items.

9.10.4.1.1 Relevance to Australia

Australian support for the proposal and interest in contributing to these items was confirmed (as it had been previously expressed), as it was considered that now Australian TCM practitioners are on a common registration scheme for medical providers, there may be a need for PCEHR to incorporate TCM terminology in the future. Heather Grain was reported by the project lead as having been previously offered as interim expert from Australia to contribute to these work items.

9.10.4.2 NP: TCM Informatics framework and classification for standards development

A proposal from China was presented to develop a generic framework for TCM Informatics standards development, aligned with the model proposed in ISO/TR 17119:2005 Health informatics profiling framework and Classification Matrix (HIPF). It was deemed beneficial to be able to discuss TCM informatics standards in the same language and with the same concepts as other Health Informatics standards, which in the longer term could help make e-Health software compatible/extensible across Western and Traditional medicines. A similar situation applies in Allied Health. This could also help to ensure consistency between ISO and other agencies concerned with TCM informatics, such as WHO. It might also enable input on a wider front to an emerging discussion to create SNO-TCM as an extension of SNOMED-CT.

9.10.4.2.1 Relevance to Australia

Australian support for the proposal and interest in contributing to this item was expressed, as it was considered that now Australian TCM practitioners are on a common registration scheme for medical providers, there may be a need for PCEHR to incorporate TCM terminology in the future. Anthony Maeder offered himself as interim expert from Australia to contribute to this work item.
### Topic: Conceptual frameworks for non-chemical body surface stimulation

<table>
<thead>
<tr>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>New proposed work item to develop a conceptual framework for (1) location and (2) treatment</td>
<td>IT-014 Heather Grain</td>
</tr>
<tr>
<td>Action: Australia to support contribute to new work item proposal as a nominated country expert (nominated: Health Grain), maintain watch on progress of the item, and communicate progress to other Standards groups in Australia (e.g. IHTSDO, TCM).</td>
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</tr>
</tbody>
</table>

### Topic: Traditional Medicine Task Force subcommittee: TCM Informatics framework and classification for standards development

<table>
<thead>
<tr>
<th>Issue/Action and Recommendations for Australia</th>
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</tr>
</thead>
<tbody>
<tr>
<td>New proposed work item to develop a generic framework for standards in TCM informatics compatible with ISO/TR 17118:2005</td>
<td>IT-014 Anthony Maeder</td>
</tr>
<tr>
<td>Action: Australia to support contribute to new work item proposal as a nominated country expert (interim: Anthony Maeder), maintain watch on progress of the item, and communicate progress to other Standards groups in Australia (e.g. IHTSDO, TCM).</td>
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9.10.4.3 **ISO/NP TS 16843-1 Health Informatics – Categorial structures for representation of acupuncture – Part 1: Acupuncture points**

**9.10.4.3.1 Introduction**

This work identifies the system components necessary to represent acupuncture but does not specify the value domain of that representation, though examples are provided.

**9.10.4.3.2 Progress to date**

In addition to the issues noted above during the TMTF meeting Japan requested a change in the lead for this work item. Japan will provide an expert and intends to send an e-mail to withdraw the lead for this project and nominate new experts.

**9.10.4.3.3 Relevance to Australia**

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

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<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
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</tr>
</thead>
<tbody>
<tr>
<td>WG3 Categorial structures for representation of acupuncture - part 1: acupuncture points</td>
<td>Action: Determine priority and contacts to provide feedback,</td>
<td>IT-014 IT-014-02</td>
</tr>
</tbody>
</table>

9.10.4.4 **16843-2 Categorial structures for representation of acupuncture Part 2: Needling**

**9.10.4.4.1 Introduction**

This work identifies the system components necessary to represent acupuncture - needling, but does not specify the value domain of that representation, though examples are provided.
9.10.4.4.2 Progress to date
In addition to the issues noted above China will lead this project:
ISO NP 18062 –Categorical structure for representation of herbal medicaments in terminology systems.
Designated experts are from China, Germany, Holland, Japan, UK, Korea.

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

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<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG3 Categorial structures for representation of acupuncture - part 2: needling</td>
<td>Action: Determine priority and contacts to provide feedback.</td>
<td>IT-014 IT-014-02</td>
</tr>
</tbody>
</table>

9.10.4.5 ISO TS 17948 Health Informatics- Traditional Chinese medicine metadata

9.10.4.5.1 Introduction
This work identifies metadata required to represent literature on traditional Chinese medicine.

9.10.4.5.2 Progress to date
There was some confusion about the process for preparation and sharing of both the document and the comment disposition document. To ensure that all with interest in this item has the opportunity for review and comment time will be given for all WG members to review the document and the comment disposition and to raise issues or problems prior to this item being sent to committee ballot.

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

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
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</thead>
<tbody>
<tr>
<td>WG3 Traditional Chinese Medicine Metadata</td>
<td>Action: Determine priority and contacts to provide feedback.</td>
<td>IT-014 IT-014-02</td>
</tr>
</tbody>
</table>
9.10.4.6 ISO 17938 TS –health informatics- Semantic network framework and coding of Traditional Chinese Medicine language system. (CT MLS)

9.10.4.6.1 Introduction

This work identifies the language (keywords etc.) to be used when describing traditional medicine literature and research.

9.10.4.6.2 Progress to date

An update was proved at the meeting. The document was sent out three (3) weeks ago but not the disposition of comments. The current draft and the disposition will be forwarded after this meeting.

9.10.4.6.3 Relevance to Australia

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

<table>
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<tr>
<th>Topic</th>
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</tr>
</thead>
<tbody>
<tr>
<td>WG3 Semantic network framework and coding of traditional Chinese medicine language system</td>
<td>Action: Determine priority and contacts to provide feedback</td>
<td>IT-014 IT-014-02</td>
</tr>
</tbody>
</table>

9.10.4.7 ISO NP18062 Health informatics – Categorial structures for representation of herbal medicaments in terminological systems

9.10.4.7.1 Introduction

This work defines the structures required to represent herbal medicaments.

9.10.4.7.2 Progress to date

Comments were requested from the Working Group as well as a request for a clearer title for this work.

9.10.4.7.3 Relevance to Australia

Australia is to determine the priority of this item as well as process for obtaining relevant feedback.
9.11 WG 4 SECURITY, SAFETY AND PRIVACY

9.11.1 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.

9.11.2 RECENT ACTIVITY

As part of the ongoing management of the workgroup it was decided that to schedule a roadmap discussion for the WG4 program for the next (Spring-May) meeting. A preliminary discussion will take place for a cross section of international experts and will include Ross Fraser (Canada), Bernd Blobel (Germany), Trish Williams (Australia), Lori Reed-Forquet (USA), Pekka Ruotsalainen (Finland), Hideku Myohara (Japan), Lucc Posthumas (Netherlands). Preliminary meeting set for October 22, 8am ET, noon UTC.

There was a special tribute to Alessandra Pastorino – “Remembering our dear colleague and Italian HOD who passed away shortly following our May meeting in Vancouver. Alessandra was an active and energetic contributor to ISO/TC 215 WG4 and CEN TC251 WG3. We will miss her deeply”.

9.11.2.1 Current publications

<table>
<thead>
<tr>
<th>ISO Standard Number</th>
<th>Name of Standard</th>
<th>Type of Publication</th>
<th>Date Published</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>27809</td>
<td>Measures for safe health softw</td>
<td>TR</td>
<td>11/07/2007</td>
<td>TR Published</td>
</tr>
<tr>
<td>11633-1</td>
<td>ISM remote maintenance-1: Risk</td>
<td>TR</td>
<td>6/11/2009</td>
<td>TR Published</td>
</tr>
<tr>
<td>11633-2</td>
<td>ISM remote maintenance-2: Impl</td>
<td>TR</td>
<td>6/11/2009</td>
<td>TR Published</td>
</tr>
<tr>
<td>11636</td>
<td>Dynamic on-demand VPN</td>
<td>TR</td>
<td>27/11/2009</td>
<td>TR Published</td>
</tr>
<tr>
<td>21547</td>
<td>EHR archiving - Principles</td>
<td>TS</td>
<td>2/02/2010</td>
<td>TS Published</td>
</tr>
<tr>
<td>21548</td>
<td>EHR archiving - Guidelines</td>
<td>TR</td>
<td>26/01/2010</td>
<td>TR Published</td>
</tr>
<tr>
<td>14265</td>
<td>Classification of purposes</td>
<td>TS</td>
<td>28/10/2011</td>
<td>TS Published</td>
</tr>
</tbody>
</table>

TS 14265 “Classification of Purposes for processing of personal health information” was published on 10-28-2011.

9.11.2.2 Current work items

<table>
<thead>
<tr>
<th>ISO Standard Number</th>
<th>Name of Standard</th>
<th>Type of Publication</th>
<th>Date</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>21091</td>
<td>Directory services</td>
<td>EN-IS</td>
<td>13/08/2012</td>
<td>Awaiting FDIS ballot</td>
</tr>
<tr>
<td>27789</td>
<td>Audit trails</td>
<td>EN-IS</td>
<td>23/07/2012</td>
<td>Awaiting FDIS registration</td>
</tr>
<tr>
<td>22600-1</td>
<td>PMAC-1 Overview&amp;policy mgt</td>
<td>EN-IS</td>
<td>16/08/2012</td>
<td>Awaiting DIS ballot</td>
</tr>
<tr>
<td>22600-2</td>
<td>PMAC-2 Formal models</td>
<td>EN-IS</td>
<td>16/08/2012</td>
<td>Awaiting DIS ballot</td>
</tr>
<tr>
<td>22600-3</td>
<td>PMAC-3 Implementations</td>
<td>EN-IS</td>
<td>16/08/2012</td>
<td>Awaiting DIS ballot</td>
</tr>
</tbody>
</table>
To be discussed at this meeting and detailed listed in the sections below:

<table>
<thead>
<tr>
<th>ISO Standard Number</th>
<th>Name of Standard</th>
<th>Type of Publication</th>
<th>Date</th>
<th>Comment</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>17090-4</td>
<td>PKI-4 Signatures</td>
<td>IS</td>
<td>13/06/2012</td>
<td>NP ballot comments reviewed</td>
<td>Discuss updated DTS WG4-N532</td>
</tr>
<tr>
<td>17975</td>
<td>Patient consent</td>
<td>TS</td>
<td>15/06/2012</td>
<td>NP ballot comments reviewed</td>
<td>Discuss updated DTS WG4-N533</td>
</tr>
<tr>
<td>17791</td>
<td>Standards for safe health software</td>
<td>TR</td>
<td>3/11/2011</td>
<td>NP ballot comments reviewed</td>
<td>Discuss updated DTR WG4-N535</td>
</tr>
<tr>
<td>25238</td>
<td>Classification of safety risks</td>
<td>TS</td>
<td>17/09/2010</td>
<td>SR ballot comments reviewed</td>
<td></td>
</tr>
<tr>
<td>25237</td>
<td>Pseudonymization</td>
<td>TS</td>
<td>17/03/2012</td>
<td>SR ballot comments received</td>
<td>Planning/preparing revision</td>
</tr>
<tr>
<td>21298</td>
<td>Functional &amp; structural roles</td>
<td>IS</td>
<td>17/03/2012</td>
<td>Awaiting Rev.NP/DIS registr.</td>
<td></td>
</tr>
<tr>
<td>22857</td>
<td>Trans-border flow ISO</td>
<td>IS</td>
<td>30/11/2011</td>
<td>DIS ballot comments reviewed</td>
<td>Discuss comments resolution and migration path</td>
</tr>
<tr>
<td>16864</td>
<td>Trans-border flow new</td>
<td>EN-IS</td>
<td>10/03/2011</td>
<td>NP ballot comments reviewed</td>
<td></td>
</tr>
<tr>
<td>16114</td>
<td>EHR migration</td>
<td>TR</td>
<td>26/02/2010</td>
<td>NP ballot comments reviewed</td>
<td>WG4 comments expected</td>
</tr>
<tr>
<td>13606-4</td>
<td>EHR communication-4: Security</td>
<td>IS</td>
<td>7/06/2012</td>
<td>NP ballot ends 2012-09-04</td>
<td>???</td>
</tr>
<tr>
<td></td>
<td>Information Privacy Education</td>
<td>TR</td>
<td>7/08/2012</td>
<td>NP ballot ends 2012-11-07</td>
<td></td>
</tr>
</tbody>
</table>

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

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

Luuc Posthumus reported that CEN WG3 is no longer active. Luuc will remain the liaison to CEN regarding the work of ISO WG4.

General discussions to establish a preliminary working committee to develop a revised roadmap for WG4 for the work program in 2013 and for the scope and to align with the new business plan for WG4. The meeting will be October 22, 2012 8am ET, noon UTC. Ross Frazer, Bernd Blobel, Pekka, Hide Myohara, Luuc Posthumus, Lori Reed-Forquet and Trish Williams are on this working committee.

The WG4 “Security, Safety and Privacy” scope will be amended to include defining health informatics security and privacy protection standards to:

- protect and enhance the confidentiality, availability, and integrity of health information;
- prevent health information systems from adversely affecting patient safety;
- protect privacy in relation to personal information; and
- ensure the accountability of users of health information systems.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG4 Business Planning task force</td>
<td>Dr Trish Williams was invited to be on new business planning committee for WG4 following the ISO/TC 215 reorganisation to align WG4 work program. Action: For noting and approval of IT-014</td>
<td>IT-014 Standards Australia</td>
</tr>
<tr>
<td>WG4 Preparation for next ISO meeting (May 2013)</td>
<td>To ensure that Australia’s interests are included and standards relevant to Australia are on the agenda for the forthcoming meeting. Action: Advise on any security (WG4) standard inclusions or issues required for next ISO meeting.</td>
<td>IT-014-04 Standards Australia IT-014 Contact is Trish Williams</td>
</tr>
</tbody>
</table>

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

9.11.4.1 Progress to date

This item is awaiting FDIS ballot. As such no further discussion was planned for this meeting.

9.11.4.2 Relevance to Australia

No action required at this time.
9.11.5 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.

9.11.5.1 Progress to date
This item is a waiting FDIS registration. No further discussion was planned for this meeting.

9.11.5.2 Relevance to Australia
No action is required at this time.

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

9.11.6.1 Progress to date
This item is awaiting publication.

9.11.6.2 Relevance to Australia
No action required at this time.

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

9.11.7.1 Progress to date
This item is awaiting DIS ballot. There was no discussion required at this meeting.

9.11.7.2 Relevance to Australia
No action required at this time.
9.11.8 EN-ISO 27799 HEALTH INFORMATICS – INFORMATION SECURITY MANAGEMENT IN HEALTH USING 27002 (ISO/IEC JTC 1/SC 27 N10572 N10628)

9.11.8.1 Progress to date

This item is under systematic review. Further discussion with Liaisons for alignment with 27002 SM-health is required. Systematic Review ballot comments have been reviewed and this meeting needed to look at the planning/preparing revision required.

Revision planning and drafting

This standard is under the systematic ballot review cycle. Currently, since this standard is based on ISO 27002 the plan that WG4 should take is to wait until the revisions to IS 27002 are completed. The meeting of ISO/IEC JTC 1/SC 27 in Rome 22-27 October will result in an update of ISO 27002. This will be distributed in early November and ISO working group to discuss the revisions in relation to ISO 27799 on Nov 19th 8am ET.

There is concern that waiting for the actually revised document will result in a prolonged and delayed work plan on this item. WG4 should begin a review of the content of ISO 27799 to identify the major areas that will require revision, whether or not these appear in the revised ISO 27002.

There is a proposal that WG4 initiate some of the work in preparation for this work based on WG4’s own review.

The areas identified initially that will require revision:

- Consent and purpose of use;
- Patient safety as a factor in risk assessment and risk management;
- Revisit discussion on should v shall;
- Informational consent;
- Audit trail;
- Review terminology e.g. subject of care;
- Compare risk section with current 27001/27002/27005; and
- Focus was on individual organisations more focus on national systems integration.

9.11.8.2 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 ISO27799 may have an impact on this work, or at the least will require that IT-014-04 will need to review HB174 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.
### 9.11.9 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).

#### 9.11.9.1 Progress to date

This item is under systematic review (SR). The SR ballot is now awaiting NP/DIS registration. There was a discussion on changing the title to something that reflects the contextualisation of the DIS. The issue is the scope and abstract of what the standard is for. Currently this is not sufficiently definitive or informative as to what you would use the document for. There was no further discussion about this item at this meeting.

#### 9.11.9.2 Relevance to Australia

No action required at this time.


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.

9.11.10.1 Progress to date

For Parts 1 and 2, revisions submitted for FDIS Ballot and clarification pending for NP resolutions.

Part 1: This requires a minor revision as below following the 2011 Systematic Review of ISO 17090-1 (in TC215 N895) and TC 215 Resolution 21 taken at the 20 October 2011 Meeting in Chicago. The following changes shall be made to the text:

- Amend title of section 6.3 by adding the underlined text "Healthcare-specific needs and the separation of authentication from data encipherment"
- Change the last sentence in section 6.3 to read: "If keys are used for data encryption, a form of key management is necessary to prevent data loss if the decryption keys are not available."
- Delete from section 7.3 the sentence "Essential step before the private key operation is the use of a cryptographic hash function." along with the following three
paragraphs. Replace with more succinct text: "This operation uses the private key and a one-way mathematical function known as a hashing algorithm, to produce a hash (a very large number) from the original message. The hash function has the property that it is computationally infeasible to produce the original message or private key from the hash. This hash is sent with the message. The recipient then uses the sender's public key to perform the same operation on the message and compare the resultant hash with the one sent with the message. If the two are identical, then the recipient can have a level of confidence that the message was sent by the source that claimed to have sent it."

- Delete from section 7.4 the fourth paragraph discussing storage on a floppy disk as well as deleting the phrase "stored on one of these devices" from the fifth paragraph.
- Remove from section 8.1.4 the phrase "on a floppy disk or on other media" and replace it with "on other removable media".

This will be submitted for FDIS balloting no later than September 26, 2012.

Part 2: The standard will be revised based on the comments received on the 2011 Systematic Review of ISO 17090-2 (in TC215 N896) and from the TC215 Resolution 22 taken at the 20 October 2011 Meeting in Chicago. The following members of WG4 have committed to complete this revision:

Experts:
- Lori Reed-Fourquet, US
- Ross Fraser, CA
- Bernd Blobel, DE
- Luuc Posthumus, NL
- Hideyuki Myohara, JP

There will be a two-month CD-ballot once this is completed. This is expected to be ready for immediate CD balloting no later than September 26, 2012.

**Part 3** affirmed for republication

**Part 4** The NP ballot comments have been reviewed and a draft update WG4-N532 discussed.

The updated draft was discussed at meeting (Hideyuki Myohara) and is to be revised.

9.11.10.2 Proposed future work

Part 1 needs a resolution to get this published as ISO 21549-1 following the systematic review of Health Informatics – Patient Healthcare Data Part 1: General Structure.

TC 215 noting comments received on 2011 systematic review of ISO 17090-2.
Next setups – harmonise definitions between all parts – working draft will be moved to CD or DIS ballot. Then it is to be given to WG4 for comment by Oct 15 where it will be circulated for 1 month. The responses will be due on Nov 15th. On Jan 15 it is aimed to circulate for a 2 month review. Before this occurs, there is a need to review (particularly chapter 3) and request more information for annex in terms of use cases from other countries. By April 2013, it may then be ready for a formal ballot.

No resolution required at this time.

### 9.11.10.3 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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG4:</td>
<td>This PKI standard is under review. Action: This standard should be reviewed in relation to the National Authentication Service of Health (NASH) to ensure harmonisation.</td>
<td>NEHTA review and feedback to IT-014-04 for escalation to ISO WG4.</td>
</tr>
</tbody>
</table>

#### 9.11.11 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.

### 9.11.11.1 Progress to date

Systematic review (SR) ballot comments received. This item is under discussion for revision planning.

### 9.11.11.2 Proposed future work

NP ballot targeting an International Standard under the Vienna agreement with ISO lead on Pseudonymization; to facilitate this, the secretariat will require a Form 4 and accompanying draft no later than 1 October 2012. This new item will review SR ballot comments and revision planning.

### 9.11.11.3 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).
<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WG4 ISO 25237 Pseudonymization (TC215 – N969)</strong></td>
<td>Ensure consistency in new Pseudonymization standard. Action: Note Dr Trish Williams listed as expert on new work item on Pseudonymization to ensure consistency with the Australian Standard.</td>
<td>Standards Australia IT-014-04</td>
</tr>
</tbody>
</table>

**9.11.12 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.
9.11.12.1 Progress to date
This item is currently at DIS Ballot. The comments have been reviewed and at this meeting was comments resolution and migration path were discussed.

9.11.12.2 Proposed future work
DIS-ballot comment resolution and strategy for migration to: 16864 Transborder ISO/CEN (WG4-N538) was discussed. Prepare disposition of comments from DIS ballot and updated document for distribution to WG4 by November 2102, with responses due December 31, 2012.

ISO 16864 Data Protection in trans-border flows of personal health information. WG4 is preparing a working draft from updated 22857 and NP ballot comments. Distribute to WG4 for comment by November 30, 2012, with responses due December 31, 2012.

9.11.12.3 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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
</tr>
</thead>
<tbody>
<tr>
<td>WG4 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</td>
<td>As Australia has a large group of transient and holidaying population, and given its large migrant populations, more engagement of IT-014 in these standards should be promoted. This is important as the standards are being combined. Action: Increased promotion and allocation of committees to review these standards as they are collated into one standard.</td>
<td>IT-014 IT-014-04</td>
</tr>
</tbody>
</table>

9.11.13 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.
9.11.13.1 Progress to date
The NP ballot comments have been reviewed. The new working draft was discussed. There is a need to distinguish between operationalized consent and what people can see based on the consent and those who are consent maintainer as this relates to storage of consent. Other specific aspects that were discussed specifically were ‘Relation to purpose of use and denial – and assumed consent.

9.11.13.2 Proposed future work
Action Item #1: Changes from workgroup discussion will be circulated at end of October.
Action Item #2: Nov 22 13.00 UTC teleconference to discuss changes
Action Item #3: Changes March 15, 2013

9.11.13.3 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.

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<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
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<tr>
<td>WG4 17975: Health informatics – Principles and data structures for consent in the collection, use or disclosure of personal health information (WG4-N533)</td>
<td>Opportunity to ensure Australian models and practices are represented in the standard. Action: Review for consistency and usefulness to the Australian e-health initiatives and current practices required.</td>
<td>IT-014-04 Lead: Dr Trish Williams</td>
</tr>
</tbody>
</table>

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

9.11.14.1 Introduction
Update from Pekka Ruotsalainen task group on this item reported that it is suggested that this item is withdrawn and a new item is proposed through negotiation with WG1/WG8. A joint session with WG1 is planned to be held during the next ISO meeting and this draft is planned to be used to create a new work item discussion on preparing a new project with a broader scope than EHR migration security aspects.
9.11.14.2 Progress to date
The NP ballot comments have been reviewed; there have been no additional comments since the Chicago meeting in 2011. It is expected that there should either be general discussion on document progression or withdrawal of this document from the work program.

9.11.14.3 Proposed future work
Resolution: Regarding ISO/TC 215 16114 Health Informatics – Security aspects of EHR migration. It is/was requested that this project be cancelled from the program of work with the intention that a New Work Item Proposal will be submitted at a later time with a broader scope in cooperation with other working groups.

Action Item #1: WG1/8 interest will be polled for interest
Action Item #2: Prepare preliminary NP for discussion in first 2013 meeting with the intent that a New Work Item Proposal with a broader scope will be submitted in the future;

9.11.14.4 Relevance to Australia
TC 215 agreed that ISO 16114 be withdrawn from the TC 215 Program of Work.
No action required at this time.

9.11.15 HEALTH CARDS

9.11.15.1 Progress to date
The ISO/TC 215 Task Group on Health Cards does not have a specific workgroup meeting in Vienna. There was no session specifically planned for this meeting to discuss the various multiple parts of the ISO 21549 series of standards. The status of the parts is:

1. 21549-1 Patient Health Card Data Part 1 General Structure: The editorial changes were confirmed in Rotterdam. This is currently awaiting publication following the editorial corrections. **21549-1 General Structure revised document was rejected by the Central Secretariat during the publication process. Request for corrections has been made from the document editors.**


Action Item #2: Revision to be provided back to Central Secretariat from Health Card Task Group.

2. 21549 Parts 2, 3, 4: - DIS ballot ends 2012-11-28
4. 21549-6 Cards-Administrative data: The IS has been confirmed.
5. 20301 HC-General characteristics: DIS ballot ends 16th November, 2012
6. FDIS 21549-7 Health informatics -- Patient health card data -- Part 7: Medication:
This has had a number of comments received pertaining to the medication sections, and Ian Shepherd has been assisting with comment resolution.
21549-7 Set up teleconference to review the revisions.

Reorganisation: Proposal to move Health Cards to WG2. Concerns remain in work group because the remaining work is based on security and it depends on what the use is of the card. In many European countries it is used for identification and authentication, whereas Brazil use it for identification only.

9.11.15.2 Relevance to Australia
Since Australia is not looking at the adoption of health cards, there is no action required at this time.

9.11.16 NP- MEDICAL INFORMATION PRIVACY OFFICER EDUCATION

9.11.16.1 Progress to date
No Discussion scheduled for Education of Privacy Officers as the ballot for this item remains open until November 7, 2012.

9.11.16.2 Proposed future work
Assistance may be required in formulating this draft and comment resolution.

9.11.16.3 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.

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<tr>
<td>WG4 NP- Medical Information Privacy Officer Education</td>
<td>This item is contentious in WG4 as to whether or not it is the place of ISO WG4 to be developing educational standards. Action: Assess whether this is a work item that Australia should be contributing to and taking a lead on. Review and provide comment on the currently open ballot by November 7th, 2012.</td>
<td>IIT-014-04</td>
</tr>
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</table>

9.11.17 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:


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.

Below is a short summary of the activities at the recent meeting on the different projects; the respective new documents will be provided upon their availability. The next meeting of ISO/IEC JTC 1/SC 27/WG 5 is scheduled in October 2012 in Rome, Italy. WG 5 would welcome comments and contributions to be sent in by 22nd of September 2012.

9.11.17.1 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 29191 - Requirements for partially anonymous, partially un-linkable authentication will be submitted for a DIS (Draft International Standard) ballot to National Bodies.
- 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.

9.11.17.2 New projects and study periods:

• NP on Identity Proofing. A New Work Item Proposal on Identity Proofing has been initiated.

• NP and SP on Privacy Impact Assessment. A New Work Item Proposal (NP) Privacy Impact Assessment – Methodology has been initiated. A respective Study Period (SP) was extended to assess the need for further projects on the topic.

• SP on security evaluation of anti-spoofing techniques for biometrics. has been initiated jointly with ISO/IEC JTC 1/SC 27/WG 3.

• SP on documentation of data deletion principles for personally identifiable information in organisations has been initiated.

• SP on Personal Information / Privacy Management Systems has been extended to develop a new work item proposal on controls for implementing the ISO/IEC 29100 privacy principles in the context of an information security management system as defined in ISO/IEC 27001.

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<tr>
<td>WG4 / ISO/IEC WD 29190 – Privacy capability maturity model (not an ISO project, but from a liaison committee).</td>
<td>The development of the ISO/IEC WD 29190 – Privacy capability maturity model may be relevant to include in the NESAF project. Action: IT-014-04 to review ISO/IEC WD 29190 – Privacy capability maturity model for its applicability to the existing NESAF project under IT-014-04 work program.</td>
<td>Enter IT-014-04</td>
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</tbody>
</table>
9.11.18 DATA SEGMENTATION FOR PRIVACY PILOT (DS4P)

Walter Suarez gave a presentation on the DS4P project which is running through The Standards and Interoperability Framework (S&I) in collaboration with Health Level 7 (HL7). This is about tagging for sensitive information so that a continuity of confidentiality and disclosure can be managed.

In the US the S&I initiative funded by the government to support this and to produce the standards to support the use cases for data segmentation.

Data segmentation refers to the process of sequestering from capture, access or view personal health information this is perceived by a legal entity or individual as being undesirable to share. This definition does not account for the multiple permutations of segmentation in the healthcare context – i.e. the granularity.

The group has identified a set of (mainly HL7) standards that fulfil the requirements. Currently a pilot is running to test how the data can be segmented and sent out and according to a permitted authorisation.

9.11.18.1 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.
9.12  WG 6 PHARMACY AND MEDICINES BUSINESS

9.12.1  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)

9.12.2  RECENT ACTIVITY

- Activities of WG6 have been dominated by two major pieces of joint ISO/CEN work for the last couple of years – the Identification of Medicinal Products (IDMP) and the Individual Case Safety Report (ICSR) series of standards. The ICSR standards were published last year and the IDMP suite is reaching an advanced stage in the publication cycle with the 5 documents at FDIS awaiting publication this year.

- During the meeting May 2012 meeting in Vancouver a New Convenor, Christian Hay of Switzerland, commenced his two year term. The new convenor has set a task to refocus the WG on its future activities and an ongoing engagement model with WG members now that the ICSR and IDMP work is complete.

- After not meeting in Chicago 2011 and following a disappointing attendance at Vancouver in May, several teleconferences have been conducted with WG members to
construct the agenda for this meeting including development of the NP Requirements of Electronic Prescriptions and to clarify the status on some long standing work items and it now appears that under the new convenor the WG is refocused and eager to progress.

9.12.2.1 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 27953-2:2011 - Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR

9.12.2.2 Current work items

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

- ISO/NP Health Informatics - Requirements for electronic prescriptions

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

The following are documents awaiting publication by ISO:

- ISO/FDIS 11238 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO/FDIS 11239 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/FDIS 11240 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement

• ISO/FDIS 11615 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information

• ISO/FDIS 11616 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

9.12.3 PROGRESS AT THIS MEETING

The previous meeting of WG6 was poorly attended with a number of key participants missing due to last minute cancellations. Fortunately this meeting was far better attended with 14 member nations present.

Prior to the meeting several teleconferences where held with the members to establish the agenda and to establish the estimated attendance and to ensure input from those that were unable to attend. A SWOT analysis was conducted on the subjects identified as potential future work items at the previous meeting in Vancouver and a short list for discussion at this meeting was determined. The new topics for discussion were:

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

Subjects such as Administration Records, Clinical Trials and Reimbursement which were previously mentioned as potential work items were deferred as there was no substantial motivation for progressing these as new work items at this time.

During this meeting the NP for the Requirements of Electronic Prescribing was also presented as well as an update on other work items currently in progress.

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

9.12.4.1 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.
9.12.4.2 Progress to date

This Technical Specification was originally proposed in Rio 2010 by the UK delegation based on the work they had been developing around Dose Syntax for the NHS. However progress on ISO/DTS 17251 has been minimal to date. A draft to the identified experts was expected by the end of April 2012, which was to include an updated timeline to complete the project within the original 36 month development track.

Informal discussions in IHE, HL7, and NCPDP have identified shared goals and potential alignment of work efforts, however there has not been any formal collaboration between the groups and therefore progress at ISO has stalled as it was expected the contents of the DTS would be generated through this channel. It became clear following updates from members of the HL7 and IHE Pathology groups present in Vienna though that there was uncertainty as to the scope of the ISO document.

Since the Vancouver meeting there has been a debate whether this is a statement of business requirements for a Dose Syntax Model or is it an actual specification of the model.

9.12.4.3 Proposed future work

If the document is to become a requirements specification there will need to be significant rewrite as the initial source document from the UK is based on the model implantation from the UK. Stepping back to a requirements document and preparation of a CD will take a further 6 months and will be presented at the next meeting. Scott Robertson of Kaiser Permanente (representing ANSI) will co-ordinate the preparation of this draft for the next meeting planned in Mexico.

As the work item is already a year old so the group needs to plan towards a ballot in the next 12 months.

9.12.4.4 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.

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<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
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<tr>
<td>WG 6 ISO 17251 Model for dose syntax</td>
<td>A CD for ISO/DTS 17251 is expected for presentation at the next ISO meeting. 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</td>
<td>IT-014-06-04 NEHTA</td>
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9.12.5 ISO/CD 16791 - HEALTH INFORMATICS – REQUIREMENTS FOR INTERNATIONAL MACHINE-READABLE CODING OF MEDICINAL PRODUCT PACKAGE IDENTIFIERS

9.12.5.1 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.

Depending on medicinal product’s characteristics, labelling (identification) requirements may vary

9.12.5.2 Progress to date

The NP was adopted at Rotterdam in October 2010 and Pat Gallagher was nominated as the expert from Australia. The work was scheduled to be fast tracked to publication however was behind schedule and a resolution was passed at the previous meeting in Vancouver to
proceed with a one year extension. During this time a CD has been available for review with the only substantial issue coming from Germany who opposes the use of GS1’s GTIN explicitly in the document.

This issue arises as they currently use a different identifier than the GTIN within the German marketplace. As such they queried the practice of naming a system like GTIN in an ISO standard and it was discussed other similar instances exist inside TC215 and other ISO committees such as UCOM and HL7.

Despite this the WG agreed to the resolution that the project proceed to DTS Ballot and that the draft to be available to ISO by 15th December 2012

9.12.5.3 Proposed future work

Once available for comment the DTS Ballot will require review and comment and will be subsequently reviewed at the next WG 6 meeting.

9.12.5.4 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 will have to be reviewed to understand if there are any potential local impacts or requirements not adequately reflected in the current version.

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<tr>
<td>WG 6 ISO 16791 Requirements for machine-readable of medicinal product package identifiers</td>
<td>The DTS for ISO 16791 will be out for ballot around the new year. Recommend that Australia formulate an opinion on the suitability of the DTS for the Australian market. Action: IT-014-06-04 to monitor for release of the standard and assess impact on Australian market place.</td>
<td>IT-014-06-04 TGA NEHTA</td>
</tr>
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9.12.6 IDMP SERIES OF STANDARDS

9.12.6.1 Introduction

The standards for the Identification of Medicinal Products (IDMP) is a joint project under the JIC between ISO, CEN, HL7, CDISC, IHTSDO and GS1 that will support the activities of medicines regulatory agencies worldwide. These include a variety of regulatory activities related to development, registration and life-cycle management of medicinal products as well as pharmacovigilance and risk management. The IDMP series of standards comprises:

- ISO/DIS 11615 Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated Medicinal Product information
• ISO/DIS 11616 Health informatics – Identification of Medicinal Products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
• ISO/DIS 11238 Health Informatics - Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on substances
• ISO/DIS 11239 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/DIS 11240 Health informatics - Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement

9.12.6.2 Progress to date
The FDIS Ballot reconciliation has been completed and at the previous meeting in Vancouver a resolution was passed to publish these items. They are currently at ISO and publication should be in the next month or two.

9.12.6.3 Proposed future work
As the documents are ready for publication there is none, however the maintenance issue and subsequent work item ISO/TR 14872 (see Section 9.12.11) is still open

9.12.6.4 Relevance to Australia
It is likely that IDMP standards will be adopted in Australia at some level, initially only by the TGA.

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<tr>
<td>WG 6 Identification of Medicinal Products (IDMP)</td>
<td>All 5 standards will be published as full international standards in the coming months. Action: The TGA to understand suitability of the 5 standards for adoption in Australia. If any extension is required for the Australian market this may have to be realised through an Australian Standard.</td>
<td>TGA</td>
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</tbody>
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9.12.7 DRUG DICTIONARIES

9.12.7.1 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.

9.12.7.2 Progress to date

At the Vancouver meeting as delegate from the Ministry of Health Holdings in Singapore provided a detailed presentation of ongoing work into the Singapore Drug Dictionary (SDD).

The Singapore Drug Dictionary work was well regarded by the WG members and a similar ISO standard was considered a possible new work item which was evaluated by the committee and recommended to be explored as a potential NP at this meeting.

The delegates from the US and Europe in particular were quite supportive at the meeting of creating a NP for Drug Dictionaries. It was however highlighted by those involved in the IDMP development that essentially the IDMP is a drug dictionary already. It was noted that the scope of the SDD and IDMP were quite different which raised the question of what the scope of an International Standard for a DD might look like.

It was decided that a NP be drafted to capture the proposed scope and definition by the next meeting so that this can be discussed.

9.12.7.3 Proposed future work

A NP for Drug Dictionaries will be drafted for presentation at the next ISO WG6 meeting. This work will be led by Dutch, Irish and US delegates.

9.12.7.4 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.

9.12.8 EPRESCRIPTION

9.12.8.1 Introduction

The goal of this NP 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)

9.12.8.2 Progress to date

CEN has previously published a standard with similar scope ENV 13607 (2000) Health informatics - Messages for the exchange of information on medicine prescriptions.

This standard is out of date, and the rationale for a European standard is reaffirmed by the recent EU directive on the application of patients’ rights in cross-border healthcare. This directive demands that prescriptions of authorized medicinal products that are issued in any Member State can be dispensed in compliance with its national legislation.

As such at the Kuopio WG meeting in 2010 the Netherlands moved to have this NP created and the subsequent document was balloted and presented at this meeting.

9.12.8.3 Proposed future work

NP was balloted and a Committee draft is expected to be presented to the WG at the next meeting. This work is being led by the Netherlands.

9.12.8.4 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.

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

9.12.9 DISPENSE EVENT RECORD

9.12.9.1 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.

9.12.9.2 Progress to date

At the Vancouver meeting and prior to Vienna, several teleconferences were held with the members to perform a SWOT analysis on the subjects identified as potential future work for the WG. Dispensing was one of the key areas highlighted, given that the WG had already begun a work item in regards to Electronic Prescriptions and there was a close bind between the two activities. It was also felt that the requirements of dispensing may impact on the requirements for prescribing and the projects could not be performed properly with mutually exploring both.

Additionally, the superseded ENV 13607 (2000) Health informatics - Messages for the exchange of information on medicine prescriptions, publication also covered dispense messaging in its scope and therefore would not be able to be adequately replaced by an Electronic Prescription standard alone.

9.12.9.3 Proposed future work

At this meeting the WG agreed that a NP be drafted to capture the proposed scope and definition by the next meeting so that this can be discussed further with a view to presenting this as a resolution at the next plenary.

Australia, Austria, Ireland and the Netherlands all agreed to participate in the development of this NP.

9.12.9.4 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 the NP is available comments will be sought from the relevant stakeholders in Australia (IT-014-06-04, NEHTA, DOHA, PBS).
9.12.10 COMPOUND MEDICATION

9.12.10.1 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.

9.12.10.2 Progress to date

At the Vancouver meeting and prior to Vienna, several teleconferences where held with the members to perform a SWOT analysis on the subjects identified as potential future work for the WG. Compound Medication was one of the key areas highlighted. It was felt discussed that many of the member nations had struggled with this concept and guidance from ISO would be of high value to the international community.

Additionally given that the WG had already begun a work item on Electronic Prescriptions and that there would be a requirement to handle Compound Medication in Electronic Prescriptions.

It was also felt that with the publication of IDMP standards these may form the reference model for which to outline the structure(s) required for capturing Compound Medications correctly.

9.12.10.3 Proposed future work

At this meeting it was decided that a NP be drafted to capture the proposed scope and definition by the next meeting so that this can be discussed further with a view to presenting this as a resolution at the next plenary. This work shall be led by Ireland, Austrian, UK and Dutch members.

9.12.10.4 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 NP is available comments will be sort from the relevant stakeholders in Australia (IT-014-06-04, NEHTA, DOHA, PBS)


9.12.11.1 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.
9.12.11.2 Progress to date

Initially it was felt that a requirement for a Registration Authority to manage the ongoing maintenance of the IDMP standards beyond publication existed. A Registration Authority is a formally established relationship between ISO and an external agency (the Registration Authority) that is created when an International Standards developed by ISO technical committees require, with a view to their updating or implementation, a competent body which is given the responsibility of maintaining lists of codes under international standards and issuing new codes to those wishing to register them.

It was previously discussed in the WG that a number of benefits and concerns could be found with the ISO Registration Authority approach. These included established methods for the oversight and accountability of RAs, dispute resolutions with RA's and funding arrangements for RA's through ISO. There were also a number of perceived negatives such as the agility of an RA and stability of the model due to issues such as inflationary pressures. Alternate approaches to an RA such as a designated agency filling the RA role without any binding (or financial assistance) to ISO could also be established by the consumers of the standard.

- It was generally agreed that the IDMP standards should not go down the path of having the RA at the moment purely on a maturity argument, as there are a number of issues with establishing the requirement for an RA now without knowing what the dynamics of the environment will be in 2-3 years time when agencies like EMEA, FDA and TGA have adopted IDMP locally. Once the standards are endemic it will be clearer what the function and role of IDMP maintenance will require.

- At the Kuopio meeting in 2011 there was no resolution to start the ISO Registration Authority process and as such the IDMP standards documents were not updated to reflect the requirement for a Registration Authority prior to publication.
Therefore as 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.

9.12.11.3 Proposed future work

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.

A resolution was passed at this meeting to delay the presentation of a draft for ballot until December 2013 whilst the WG awaits this decision. It may be the case that this document becomes irrelevant if adequate controls are developed outside of TC215 by those agencies taking part in the maintenance activities.

9.12.11.4 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.
9.13 JOINT WORKING GROUP 7

9.13.1 BACKGROUND

Joint WG7 is supported by a liaison between IEC 62A, TC215 and ISO/TC 215. There is some overlap with TC215 WG4 as increasingly there is a move to the standardisation of health software and consideration of its security and patient safety risks. This working group is important as the delineation between medical devices and its integrated software becomes less delineated.

JWG7 has carriage of three areas of standardisation:

(a) Standards for the safety of health IT networks that incorporate Medical devices – the 80001-x series

This is a multi-part standard of which the initial base standard and specialised areas have been completed. Work contains on further specialised Technical Reports as noted below

(b) Health Software safety standards ISO TR17791 and IEC/ISO 82304-1"

(c) Development of an overarching approach to Health Software Architecture

9.13.2 RECENT ACTIVITY

In addition to the projects listed below, the JWG7 meeting discussed the proposal of a task group to work on the architecture of standards going forward given the work being done on ISO17791 and perhaps this is a time to look at software standards that look at health software. This needs to include lifecycle and implementation, integration, configuration and ongoing maintenance. This includes the wider physical connection across the globe. This would consider but not include legislative requirements which vary per country. The intent is to look at the development of an overall architecture of standards, however but first it makes sense to look at definitions first and then second step to consider the overall architecture.

JWG7 has also been struggling with defining the scope of 82304 and its relationship to the Medical; Device standards that IEC 62A has previously published. A significant amount of time has been spent on discussing the meanings of defined terms in 82304 which have been used inconsistently across IEC and ISO standards.

Performing work out of session via Wikis, email and TCs has proven difficult due to the large number of countries actively participating and the difficulties with reconciling the IEC and ISO TC215 approaches.

Steady progress has been made with the 80001 standards family and a number of new parts have been authorised for publication.

A new ad-hoc group to consider the development of an overarching standards approach to Health Software architecture had its first TC immediately prior to the Vienna meeting.
9.13.2.1 Current publications

- ISO TR80001-2-1 – “Step by step risk management of Medical IT Networks. Practical applications and examples.”
- ISO TR80001-2-2 – “Guidance for the communication of medical device security needs, risks and controls”

9.13.2.2 Current work items

- ISO TR 17791 Guidance on Standards enabling safety in Health Software
  Status: NP Ballot
- IEC/ISO 82304-1 Health Software – Part 1: General requirements for product safety
  Status: NWIP draft
  Status: Passed Final ballot – approved for publication at this meeting
  Status: CD draft nearing completion
  Status: NWIP Ballot resolution in progress

9.13.3 PROGRESS AT THIS MEETING

For the first time, there was a stream dedicated to JWG7. Whilst this introduced new challenges in terms of delegate allocation, it ensured that there was significant progress.

9.13.4 ISO 17791 HEALTH INFORMATICS – GUIDANCE ON STANDARDS ENABLING SAFETY IN HEALTH SOFTWARE (DTR TC215 N1063, WG7 N313, WG4 N535)

9.13.4.1 Introduction

While the benefits of health informatics for patient safety are increasingly accepted, there are risks of inadvertent and adverse events caused by health software solutions and these risks are becoming more apparent. As increasingly sophisticated health software solutions are deployed that provide higher levels of decision support and integrate patient data between systems, across organizational lines, and across the continuum of care, the patient safety benefits increase along with the risks of software induced adverse events.
9.13.4.2 Progress to date

This work item has been under development for 18 months and is now nearing completion. It provides a comprehensive review of available standard’s publications related to Health Software safety.

Comment resolution on this project was performed during the meeting on the following two documents:

- Doc. 215/WG 7 N313, ISO DTR 17991
- Doc. 215/WG 7 N314, Compilation of IEC 62A comments on ISO/DTR 17991, with proposed resolutions for consideration in Vienna

9.13.4.3 Proposed future work

Regarding revision of ISO 17791 approves WG4 recommendation to issue a DTR ballot targeting a technical specification no later than 1 December 2012.

Action Item #1: Two teleconferences on 16th and 30th October, 2012, 8am WT (12.00 UTC) to resolve final agreements.


9.13.4.4 Relevance to Australia

Australia is involved heavily with this work item given the current focus on the development of health software and the new e-health system and Personally Controlled Electronic Health Record (PCEHR). In addition, this work is significant to Australia as we are in the best informed position to influence its development. In the reconciliation of comments those of Australia were not reconciled satisfactorily at the IEC 62A meeting. Subsequently, it is vitally important that Australia is represented at the forthcoming teleconferences to rectify this and to ensure that Australia’s interests are represented. There is also concern that other meetings held by IEC 62A have Australian representation. From liaison with the IEC committee at Standards Australia it is apparent that this group is not involved in this work item.
### ISO 17791 Health Informatics – Guidance on standards enabling safety in health software (DTR TC215 N1063, WG7 N313, WG4 N535)

Given the lack of suitable representation by the IEC committees on this work item, it is imperative that Australia has representation for this item.

This publication provides very useful background for anyone undertaking work in this area. Its publication needs to be advertised to relevant Government and Private sector groups such as the Safety and Quality Commission, DoHA, AMA, RACGP and the Private Hospitals Association as well as Health software developers through the MSIA, AIIA and ACIVA.

**Action:** Consideration of support for the expert volunteers to attend the out of cycle IEC 62A meetings.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue/Action and Recommendations for Australia</th>
<th>Suggested responsibility &amp; alignment to IT-014</th>
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<td>JWG7</td>
<td>Given the lack of suitable representation by the IEC committees on this work item, it is imperative that Australia has representation for this item. This publication provides very useful background for anyone undertaking work in this area. Its publication needs to be advertised to relevant Government and Private sector groups such as the Safety and Quality Commission, DoHA, AMA, RACGP and the Private Hospitals Association as well as Health software developers through the MSIA, AIIA and ACIVA.</td>
<td>IT-014 (endorsement of importance) Standards Australia (support for continuing engagement with IEC 62A)</td>
</tr>
</tbody>
</table>

**9.13.5 ISO 82304-1 HEALTHCARE SOFTWARE SYSTEMS PART 1 GENERAL REQUIREMENTS (TC215 N1028, WG4-N532)**

The NP was developed to have the project organized as a joint project between IEC/SC 62A and ISO/TC 215 (with IEC lead) to connect the two Committees on this neighbouring field and to benefit from the substantially complementing expertise. The NP was circulated as 62A/732/NP in IEC and as TC215/N858/NP in ISO.

This work builds on and extends the work of IEC62A in publishing safety standards for Medical Devices. An initial approach led by the IEC members in which “Medical Device” was replaced by “Health Software” in an existing Medical Device standard proved unacceptable. This has however, served to highlight the significant areas of confusion and contention related to the definitions of “Medical Device”, “Health Software” and related terms across different Standards publications and international boundaries as well the different approaches to regulation in different domains.

Health software products are comprised solely of software, no electrical equipment is included as part of the product. These products are intended to be used with general purpose computing equipment and are intended by their manufacturer to aid in the diagnosis, treatment, or monitoring of a patient; or to aid in compensation or alleviation of disease, injury or disability. Some, but not all, health software can contribute to a hazard. Accordingly, risk management process is required for all health software. For those health software that can contribute to a hazard, additional requirements are needed to ensure safety. Testing of the finished product is not, by itself, adequate to address the safety of these health software, requirements for the processes by which the health software system is developed are necessary.

Whether health software has to meet legal regulatory requirements is a matter of national legislation. This standard makes no attempt to determine whether health software is or should be regulated. Whether health software can contribute to a hazard is not dependent on legislation, but on how the health software is used in its environment. The requirements...
in this standard are necessary to identify and control potential RISKS that may occur when using the health software.

Dr Patricia Williams and Dr Vincent McCauley are the nominated Australian National Experts for this project.

9.13.5.1 Progress to date

This work item has been renamed to reflect debate and definitions of terms agreed at the previous meeting. The planned out of session teleconferences that were to be have been held to resolve remaining issues of definition, did not occur. In particular the different definitions of “Health Software” in TR17791 and 82304 had not been resolved.

A proposed disposition of comments on the Working Draft of 82304-1 had been developed out of session by a select group, mainly from IEC 62A, which did not include many ISO nominated National experts, including those from Australia. Many comments including those from Australia, Canada and the USA had not been adequately resolved and the proposed disposition was not agreed.

Dr. Patricia Williams requested to write a few sentences about inclusion of scheduling and other software for the scope to sent. “In an increasingly integrated e-health environment, this report includes in its scope and definition that health software includes patient administrative systems. Medical practice management software, designed to manage clinical, financial and operational processes to improve practice efficiency and maximize patient care, may include administrative systems such as appointment scheduling and resources management, whether or not such software is integrated into clinical systems (completed at meeting).

9.13.5.2 Proposed future work

A teleconference is to be held in late October of the National experts to attempt to resolve remaining comments and edit and approve the text of a first Committee draft (CD1). All National experts are to meet in Delft, Holland 25-27 March, 2013 to resolve comments on CD1 and develop and agree a second Committee draft (CD2) to be completed by April 30, 2013.

Work to be done before the CD1 is to be published:

- Amend to software only health software products
- Currently only covers lifecycle activities of concept to rel
- Does not covers integration, configuration, decommissioning etc
- Harmonisation of the descriptions of health software is required
- 82304-1 = Reconcile differences in definitions of health software in 17791 – software developed specifically for the purpose for maintaining and improving health of individual persons
• 17791 = software used in the health sector that can have an impact on the health
and healthcare of a subject of care.

Outstanding:
• Validation 0 needs its own clause as not part of clause 4.4 in lifecycle
• Rationalize add elements on borrowing of processes and requirements from
standards applicable to regulated medical device domains. This includes adapting
definitions
• Publish CD1 (IEC notations for DIS FDIS etc)
• Timing of next steps:
  o CD 1 Oct 31
  o 2CD 30-04-2013
  o CCDV 31-01-2014
  o DEC 31-01-2015
  o PPUB
• Project schedule discussed with opportunity to have 2 full project group meetings.
• CD1 31-10-12 – suggested Face to face meeting of experts in Delft 25-27 March
full project team meeting. (national experts)

Discussion of CD2 will take place at the JWG7 meeting to be held in conjunction with the ISO
TC215 meeting in Mexico in May 2013.
A further meeting of National experts will held in September 2013 at either the ISO TC 215
meeting in Sydney or the IEC meeting in China. It is proposed that the final draft text should
be available by 31 Jan. 2014 with a completed Standard to be published by 31 Jan. 2015

9.13.5.3 Relevance to Australia

Internationally agreed Standards for safety of Health Software would be an important step
forward. The rejection by a majority of ISO members of a previous attempt three years ago to
develop an ISO publication in this area, demonstrated how difficult it is to develop such
Standards in the international arena. Australia is in a strong position to provide appropriate
expertise to influence the content of the proposed standard so that it is able to form the basis
of future developments in this area in Australia. Australia’s position that the issues in safety
for Health software are significantly different to those in considering safety for medical
devices, has received strong support from Canada and the USA. However, it is vital that
Australia continues to have adequate representation at the out of session face-to-face
meetings that are planned to take this work item forward if a non-EEC view of this area is to
be given adequate weight.

Australia has two experts on this work item. This work item, together with IS17791, is
becoming increasingly important as the basis for the evolution of medical devices and their
relationship to the software that is increasingly integral to their performance. Given the predominance of telehealth and its associated devices in Australia, (to name but one area of significance), it is imperative that Australia is fully engaged and involved in the development of these standards. There are two meetings to be held of JWG7 with IEC out of cycle with the ISO meetings in 2013. These are: Delft 25-27 March 2013 and possibly China in September 2013. There is concern by the Australian delegation that work in this area is being driven predominantly by a select group in the IEC (that does not have Australian representation in it). Further, that the IEC committee does not have sufficient expertise in the health software facet of this work.

<table>
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<tr>
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</thead>
</table>
| JWG7  | Given the related nature of this standard to ISO17791 and other developing standards in this area, it is imperative that Australian health software representation is provided. At present these are Delft 25-27 March 2013 and possibly China in September 2013. Action: Funding is provided for attendance at the out of cycle IEC meetings (given that the other Standards Australia IEC 62A liaison committee is not engaged with these items). | Standards Australia  
DoHA |
## 9.14 CLOSING PLENARY

| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)  
|                              | Heather Grain (WG 3 convener)  
|                              | Naomi Ryan (WG 1 secretariat)  
|                              | Heather Leslie, Michael Steine, Vince McCauley, Erin Holmes, Trish Williams, Anthony Maeder |

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

1. Opening of meeting Dr. Chris Chute
2. Roll Call of ISO/TC 215 Delegates Ms. Lisa Spellman
3. Adoption of agenda Dr. Chris Chute
4. Appointment of the Drafting Committee Ms. Lisa Spellman
7. Re-Organization Interim Report Mr. Jeremy Thorp  
   Mr. Richard Dixon Hughes
8. Joint Initiative Council (JIC) Report Mr. Bron Kisler, JIC Chair
9. Reports from Working Groups WG conveners  
   a) WG 1- Data structures  
   b) WG 8 - Business requirements for EHR  
   c) WG 2 – Data Interchange  
   d) WG 3 – Semantic content  
   e) WG 4 – Security, safety and privacy  
   f) WG 6 – Pharmacy and medicines  
   g) WG 7 – Devices  
   h) Joint WG 7 (with IEC/62A) – Application of risk management for IT-networks incorporating medical devices
10. Future meetings Ms. Lisa Spellman
11. Other Business Dr. Chris Chute
12. ISO/TC 215 Secretariat nomination of Dr. Christopher Chute for a second term Ms. Lisa Spellman
13. Approval of Meeting Resolutions Ms. Lisa Spellman
14. Adjournment (Close of meeting) Dr. Chris Chute

On this occasion, the closing plenary did not include liaison reports as these are for the annual plenary in the first half of the year, where there is more time to consider them).
9.15 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.
## Appendix A – Meeting Agenda

### Sunday 23 September 2012

- **7:30 – 18:00**: Registrations. Please look for signs in the lobby to direct you to registration.
- **09:00 – 12:00**: Joint Intimate Council (JIC) Open Forum: open to all.
- **13:00 – 15:00**: TC215 A02 Chairman’s Executive Council: Heads of delegations, convenors, vice-convenors and invited guests.
- **16:00 – 18:30**: TC215 A02 Operations & Harmonization and A03 IEC Cross-ISO Harmonization & Coordination: Convenors, vice-convenors, secretaries and invited guests.

### Monday 24 September 2012

- **7:30 – 17:00**: Notice for check-in at registration to pick up your badge. No one will be admitted to any of the meetings without a badge.
- **8:30 – 9:30**: Opening Plenary in Rooms 4 & 5 – direction signs will be posted.
- **9:30 – 10:00**: Refreshment Break
- **10:00 – 12:15**: Joint plenary.
- **12:15 – 13:30**: Lunch – available for purchase in the Chamber Cafeteria (CASH ONLY) and nearby restaurants.
- **13:30 – 14:30**: Advisory Council.
- **14:30 – 14:45**: Refreshment Break
- **14:45 – 17:00**: Open Plenary Sessions in Rooms 4 & 5.

### Tuesday 25 September 2012

- **7:30 – 17:00**: Registration.
- **9:00 – 10:30**: Plenary.
- **10:30 – 11:00**: Refreshment Break.
- **11:00 – 12:15**: Joint meeting.
- **12:15 – 13:30**: Lunch – available for purchase in the Chamber Cafeteria (CASH ONLY) and nearby restaurants.
- **13:30 – 15:30**: Joint meeting.
- **15:30 – 16:00**: Refreshment Break.
- **16:00 – 17:00**: Joint meeting.

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**Note**: For any further information, please contact [delegates@tc215.org](mailto:delegates@tc215.org) with your request.
## Appendix B – ISO/TC 215 Standards and Approved Projects

### B.1 TC 215 - CURRENT STANDARDS PUBLICATIONS

As at 6 November 2012, TC 215 had 111 current standards publications, as follows:

<table>
<thead>
<tr>
<th>Standard and/or project</th>
<th>Title</th>
<th>Stage</th>
</tr>
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<tbody>
<tr>
<td>ISO 1828:2012</td>
<td>Health informatics -- Categorial structure for terminological systems of surgical procedures</td>
<td>60.6</td>
</tr>
<tr>
<td>ISO/TR 18307:2001</td>
<td>Health informatics -- Interoperability and compatibility in messaging and communication standards -- Key characteristics</td>
<td>60.6</td>
</tr>
<tr>
<td>ISO 18308:2011</td>
<td>Health informatics -- Requirements for an electronic health record architecture</td>
<td>60.6</td>
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<tr>
<td>ISO 18812:2003</td>
<td>Health informatics -- Clinical analyser interfaces to laboratory information systems -- Use profiles</td>
<td>90.6</td>
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<tr>
<td>ISO 20301:2006</td>
<td>Health informatics -- Health cards -- General characteristics</td>
<td>90.92</td>
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<tr>
<td>ISO 20302:2006</td>
<td>Health informatics -- Health cards -- Numbering system and registration procedure for issuer identifiers</td>
<td>90.6</td>
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<tr>
<td>ISO/TR 20514:2005</td>
<td>Health informatics -- Electronic health record -- Definition, scope and context</td>
<td>60.6</td>
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<tr>
<td>ISO/TR 21089:2004</td>
<td>Health informatics -- Trusted end-to-end information flows</td>
<td>60.6</td>
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<tr>
<td>ISO/IEEE 11073-10415:2010</td>
<td>Health informatics -- Personal health device communication -- Part 10415: Device specialization -- Weighing scale</td>
<td>60.6</td>
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<tr>
<td>ISO 21090:2011</td>
<td>Health informatics -- Harmonized data types for information interchange</td>
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<td>ISO/TS 21091:2005</td>
<td>Health informatics -- Directory services for security, communications and identification of professionals and patients</td>
<td>90.92</td>
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<td>ISO/TS 21298:2008</td>
<td>Health informatics -- Functional and structural roles</td>
<td>90.6</td>
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<tr>
<td>ISO/TS 21547:2010</td>
<td>Health informatics -- Security requirements for archiving of electronic health records -- Principles</td>
<td>60.6</td>
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<tr>
<td>ISO/TR 21548:2010</td>
<td>Health informatics -- Security requirements for archiving of electronic health records -- Guidelines</td>
<td>60.6</td>
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<tr>
<td>ISO 21549-1:2004</td>
<td>Health informatics -- Patient healthcard data -- Part 1: General structure</td>
<td>90.92</td>
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<tr>
<td>ISO 21549-2:2004</td>
<td>Health informatics -- Patient healthcard data -- Part 2: Common objects</td>
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<tr>
<td>ISO/IEEE 11073-10417:2010</td>
<td>Health informatics -- Personal health device communication -- Part 10417: Device specialization -- Glucose meter</td>
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<tr>
<td>ISO 21549-4:2006</td>
<td>Health informatics -- Patient healthcard data -- Part 4: Extended clinical data</td>
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<td>ISO 21549-5:2008</td>
<td>Health informatics -- Patient healthcard data -- Part 5: Identification data</td>
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<td>ISO 21549-6:2008</td>
<td>Health informatics -- Patient healthcard data -- Part 6: Administrative data</td>
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<td>ISO 21549-7:2007</td>
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<td>Health informatics -- Patient healthcard data -- Part 8: Links</td>
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<td>ISO 21667:2010</td>
<td>Health informatics -- Health indicators conceptual framework</td>
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<tr>
<td>ISO/TR 21730:2007</td>
<td>Health informatics -- Use of mobile wireless communication and computing technology in healthcare facilities -- Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices</td>
<td>60.6</td>
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<tr>
<td>ISO/HL7 21731:2006</td>
<td>Health informatics -- HL7 version 3 -- Reference information model -- Release 1</td>
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<td>ISO/TS 22220:2011</td>
<td>Health informatics -- Identification of subjects of health care</td>
<td>60.6</td>
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<tr>
<td>ISO/TR 22221:2006</td>
<td>Health informatics - Good principles and practices for a clinical data warehouse</td>
<td>60.6</td>
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<tr>
<td>ISO/TS 22224:2009</td>
<td>Health informatics -- Electronic reporting of adverse drug reactions</td>
<td>60.6</td>
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<tr>
<td>ISO/TS 22600-1:2006</td>
<td>Health informatics -- Privilege management and access control -- Part 1: Overview and policy management</td>
<td>90.92</td>
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<td>ISO/TS 22600-3:2009</td>
<td>Health informatics -- Privilege management and access control -- Part 3: Implementations</td>
<td>90.92</td>
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<td>ISO/TS 22789:2010</td>
<td>Health informatics -- Conceptual framework for patient findings and problems in terminologies</td>
<td>60.6</td>
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<td>ISO/TR 22790:2007</td>
<td>Health informatics -- Functional characteristics of prescriber support systems</td>
<td>60.6</td>
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<td>ISO 22857:2004</td>
<td>Health informatics -- Guidelines on data protection to facilitate trans-border flows of personal health information</td>
<td>90.92</td>
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<td>ISO/TS 25237:2008</td>
<td>Health informatics -- Pseudonymization</td>
<td>90.6</td>
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<td>ISO/IEEE 11073-10420:2012</td>
<td>Health informatics -- Personal health device communication -- Part 10420: Device specialization -- Body composition analyzer</td>
<td>60.6</td>
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<td>ISO/TS 25238:2007</td>
<td>Health informatics -- Classification of safety risks from health software</td>
<td>90.6</td>
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<td>ISO/TR 25257:2009</td>
<td>Health informatics -- Business requirements for an international coding system for medicinal products</td>
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<td>ISO 25720:2009</td>
<td>Health informatics -- Genomic Sequence Variation Markup Language (GSVML)</td>
<td>60.6</td>
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<td>ISO/TS 27527:2010</td>
<td>Health informatics -- Provider identification</td>
<td>60.6</td>
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<td>ISO/TS 27790:2009</td>
<td>Health informatics -- Document registry framework</td>
<td>60.6</td>
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<td>ISO 27799:2008</td>
<td>Health informatics -- Information security management in health using ISO/IEC 27002</td>
<td>90.92</td>
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<td>ISO/TR 27809:2007</td>
<td>Health informatics -- Measures for ensuring patient safety of health software</td>
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<td>ISO/HL7 27931:2009</td>
<td>Data Exchange Standards -- Health Level Seven Version 2.5 -- An application protocol for electronic data exchange in healthcare environments</td>
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<td>ISO/HL7 27932:2009</td>
<td>Data Exchange Standards -- HL7 Clinical Document Architecture, Release 2</td>
<td>60.6</td>
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<td>Standard and/or project</td>
<td>Title</td>
<td>Stage</td>
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<td>ISO/IEEE 11073-10421:2012</td>
<td>Health informatics -- Personal health device communication -- Part 10421: Device specialization -- Peak expiratory flow monitor (peak flow)</td>
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<td>ISO/HL7 27951:2009</td>
<td>Health informatics -- Common terminology services, release 1</td>
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<td>ISO/HL7 27953-1:2011</td>
<td>Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting</td>
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<td>ISO/HL7 27953-2:2011</td>
<td>Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR</td>
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<td>ISO/TS 29585:2010</td>
<td>Health informatics -- Deployment of a clinical data warehouse</td>
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<td>IEC 80001-1:2010</td>
<td>Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities</td>
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<td>Application of risk management for IT-networks incorporating medical devices -- Part 2-2: Guidance for the communication of medical device security needs, risks and controls</td>
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<td>Health informatics -- Personal health device communication -- Part 10471: Device specialization - Independant living activity hub</td>
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<td>Health informatics -- Personal health device communication -- Part 10472: Device specialization -- Medication monitor</td>
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<td>ISO 10159:2011</td>
<td>Health informatics -- Messages and communication -- Web access reference manifest</td>
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<td>Health informatics -- Point-of-care medical device communication -- Part 30200: Transport profile -- Cable connected</td>
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<td>Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless</td>
<td>90.6</td>
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<td>Health informatics -- Point-of-care medical device communication -- Part 30400: Interface profile -- Cabled Ethernet</td>
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<td>Health informatics -- Standard communication protocol -- Part 91064: Computer-assisted electrocardiography</td>
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<td>ISO/TS 11073-92001:2007</td>
<td>Health informatics -- Medical waveform format -- Part 92001: Encoding rules</td>
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<tr>
<td>Standard and/or project</td>
<td>Title</td>
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<td>Electronic Health Record-System Functional Model, Release 1.1</td>
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<td>Health informatics -- Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis</td>
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<td>ISO/TR 11633-2:2009</td>
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<td>Business requirements for health summary records -- Part 1: Requirements</td>
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<td>Business requirements for health summary records -- Part 2: Environmental scan</td>
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<td>60.6</td>
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<td>Health informatics -- Service architecture -- Part 3: Computational viewpoint</td>
<td>60.6</td>
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<td>Knowledge management of health information standards</td>
<td>60.6</td>
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<tr>
<td>ISO 13119:2012</td>
<td>Health informatics -- Clinical knowledge resources -- Metadata</td>
<td>60.6</td>
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<tr>
<td>ISO/TR 13128:2012</td>
<td>Health Informatics -- Clinical document registry federation</td>
<td>60.6</td>
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<td>ISO 13606-1:2008</td>
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<td>90.92</td>
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<td>90.92</td>
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<td>Standard and/or project</td>
<td>Title</td>
<td>Stage</td>
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<tr>
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<td>ISO/TS 14265:2011</td>
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<td>Health informatics -- Interoperability of telehealth systems and networks -- Part 2: Real-time systems</td>
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<td>ISO/TS 16058:2004</td>
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<td>Health informatics -- Personal health device communication -- Part 10404: Device specialization -- Pulse oximeter</td>
<td>60.6</td>
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<td>ISO 17090-1:2008</td>
<td>Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services</td>
<td>90.92</td>
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<td>ISO 17090-3:2008</td>
<td>Health informatics -- Public key infrastructure -- Part 3: Policy management of certification authority</td>
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<td>Health informatics -- Vocabulary for terminological systems</td>
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<td>Health informatics -- Controlled health terminology -- Structure and high-level indicators</td>
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<td>Health informatics - Health informatics profiling framework</td>
<td>60.6</td>
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<td>Health informatics -- Messages and communication -- Web access to DICOM persistent objects</td>
<td>90.93</td>
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<td>Health informatics -- Personal health device communication -- Part 10407: Device specialization -- Blood pressure monitor</td>
<td>60.6</td>
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<td>ISO 18104:2003</td>
<td>Health informatics -- Integration of a reference terminology model for nursing</td>
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<td>ISO 18232:2006</td>
<td>Health Informatics -- Messages and communication -- Format of length limited globally unique string identifiers</td>
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<td>ISO/IEEE 11073-10408:2010</td>
<td>Health informatics -- Personal health device communication -- Part 10408: Device specialization -- Thermometer</td>
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</table>
B.2 TC 215 – ACTIVE PROJECTS - STANDARDS PUBLICATIONS UNDER DEVELOPMENT

As at 6 November 2012 TC 215 had 49 standards publications under development, as follows:

<table>
<thead>
<tr>
<th>Standard and/or project</th>
<th>Title</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/HL7 DIS 10781</td>
<td>Electronic Health Record-System Functional Model, Release 2.0 (EHR FM)</td>
<td>40.6</td>
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<tr>
<td>ISO/IEEE 11073-10406</td>
<td>Health informatics -- Personal health device communication -- Part 10406: Device specialization -- Basic electrocardiograph (ECG) (1- to 3-lead ECG)</td>
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<td>ISO/IEEE DIS 11073-10417</td>
<td>Health informatics -- Personal health device communication -- Part 10417: Device specialization -- Glucose meter</td>
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<td>ISO/IEEE DIS 11073-10418</td>
<td>Health informatics -- Personal health device communication -- Part 10418: Device specialization -- International Normalized Ratio (INR) monitor</td>
<td>40.99</td>
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<td>ISO/DTR 12300</td>
<td>Health informatics - Principles of mapping between terminological systems</td>
<td>30.6</td>
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<tr>
<td>ISO/FDIS 13120</td>
<td>Health informatics -- Syntax to represent the content of healthcare classification systems -- Classification Markup Language (ClaML)</td>
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<td>ISO/DTS 13131</td>
<td>Health Informatics -- Quality criteria for services and systems for telehealth</td>
<td>30.99</td>
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<td>ISO/HL7 DIS 13449</td>
<td>Health informatics -- Clinical genomics pedigree topic</td>
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<td>ISO/DTS 13582</td>
<td>Health Informatics -- Sharing of OID registry information</td>
<td>30.99</td>
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<td>ISO/DIS 13940</td>
<td>Health informatics -- System of concepts to support continuity of care</td>
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<td>ISO/DTS 13972</td>
<td>Health informatics -- Detailed clinical models, characteristics and processes</td>
<td>30.2</td>
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<tr>
<td>ISO/DTS 14441</td>
<td>Health informatics -- Security and privacy requirements of EHR systems for use in conformity assessment</td>
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<tr>
<td>ISO/AWI TS 16223</td>
<td>Health Informatics - Standards convergence to promote EHR interoperability</td>
<td>20</td>
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<tr>
<td>ISO/NP TS 16277-1</td>
<td>Health Informatics - Structure of representation of clinical findings in traditional medicine -- Part 1: Traditional East Asian Medicine</td>
<td>10.99</td>
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<td>ISO/CD 16278</td>
<td>Health informatics -- Categorial structure for terminologies of human anatomy</td>
<td>30.6</td>
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<td>ISO/NP TS 16279</td>
<td>Health Informatics - Alert information in health records</td>
<td>10.99</td>
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<td>ISO/HL7 DIS 16527</td>
<td>Personal Health Record System Functional Model, Release 1 (PHRS FM)</td>
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<td>ISO/AWI TS 16791</td>
<td>Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers</td>
<td>20</td>
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<td>ISO/DIS 17090-1</td>
<td>Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services</td>
<td>40.99</td>
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<td>ISO/CD 17090-2</td>
<td>Health informatics -- Public key infrastructure -- Part 2: Certificate profile</td>
<td>30</td>
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<td>ISO/AWI 17090-4</td>
<td>Health informatics -- Public key infrastructure -- Part 4: Digital Signatures for healthcare documents</td>
<td>20</td>
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<td>Title</td>
<td>Stage</td>
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<td>Health informatics -- Structure and maintenance of the health</td>
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<td>ISO/AWI 17523</td>
<td>Health informatics -- Requirements for electronic prescriptions</td>
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<td>ISO/CD 17583</td>
<td>Health informatics -- Terminology constraints for coded data</td>
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<td>care information interchange</td>
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<td>ISO/AWI TR 17791</td>
<td>Health informatics - Guidance on Standards for Enabling Safety in</td>
<td>20</td>
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<tr>
<td></td>
<td>Health Software</td>
<td></td>
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<td>ISO/AWI TS 17938</td>
<td>Health informatics -- Semantic network framework of traditional</td>
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<td>Chinese medicine language system</td>
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<td>ISO/AWI TS 17948</td>
<td>Traditional Chinese medicine literature metadata</td>
<td>20</td>
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<tr>
<td>ISO/AWI TS 17975</td>
<td>Health informatics -- Principles and data structures for consent in</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>the collection, use, or disclosure of personal health information --</td>
<td></td>
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<tr>
<td></td>
<td>Patient consent</td>
<td></td>
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<td>ISO/AWI TS 18062</td>
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<td>20</td>
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<td>Health informatics -- Categorical structures for representation of</td>
<td>40.2</td>
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<td>ISO/NP TS 18530</td>
<td>Health Informatics -- Automatic identification and data capture</td>
<td>10.99</td>
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<td>marking and labelling - Subject of care and individual provider</td>
<td></td>
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<td>ISO/DIS 20301</td>
<td>Health informatics -- Health cards -- General characteristics</td>
<td>40.2</td>
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<td>ISO/FDIS 21091</td>
<td>Health informatics -- Directory services for healthcare providers,</td>
<td>50.2</td>
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<td>40.99</td>
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<td>40.2</td>
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<td>40.2</td>
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<td></td>
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<tr>
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<td>40.2</td>
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<td></td>
<td>Part 3: Implementations</td>
<td></td>
</tr>
<tr>
<td>ISO/DIS 22857</td>
<td>Health informatics -- Guidelines on data protection to facilitate</td>
<td>40.6</td>
</tr>
<tr>
<td></td>
<td>trans-border flows of personal health data</td>
<td></td>
</tr>
<tr>
<td>ISO/FDIS 27789</td>
<td>Health informatics -- Audit trails for electronic health records</td>
<td>50</td>
</tr>
<tr>
<td>ISO/DTR 28380-2</td>
<td>Health informatics -- IHE global standards adoption -- Part 2:</td>
<td>30.99</td>
</tr>
<tr>
<td></td>
<td>Integration and content profiles</td>
<td></td>
</tr>
</tbody>
</table>
### B.3 TC 215 – WITHDRAWN STANDARDS PUBLICATIONS

As at 6 November 2012, TC 215 had published 8 standards publications that were later withdrawn, as follows:

<table>
<thead>
<tr>
<th>Standard and/or project</th>
<th>Title</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/TS 18308:2004</td>
<td>Health informatics -- Requirements for an electronic health record architecture</td>
<td>95.99</td>
</tr>
<tr>
<td>ISO/TS 21667:2004</td>
<td>Health informatics -- Health indicators conceptual framework</td>
<td>95.99</td>
</tr>
<tr>
<td>ISO/TR 21730:2005</td>
<td>Health informatics -- Use of mobile wireless communication and computing technology in healthcare facilities -- Recommendations for the management of unintentional electromagnetic interference with medical devices</td>
<td>95.99</td>
</tr>
</tbody>
</table>

### B.4 TC 215 – STANDARDS PROJECTS WITHDRAWN OR CANCELLED IN LAST 12 MONTHS

As at 6 November 2012, TC 215 has 5 standards publications withdrawn or cancelled in the last 12 months, as follows:

<table>
<thead>
<tr>
<th>Standard and/or project</th>
<th>Title</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/DIS 11073-92001</td>
<td>Health informatics -- Medical waveform format -- Part 92001: Encoding rules</td>
<td>40.98</td>
</tr>
<tr>
<td>ISO/HL7 CD 13972-1</td>
<td>Health Informatics -- Detailed Clinical Models -- Part 1: Quality processes regarding detailed clinical model development, governance, publishing and maintenance</td>
<td>30.98</td>
</tr>
<tr>
<td>ISO/HL7 CD 13972-2</td>
<td>Health Informatics -- Detailed Clinical Models -- Part 2: Quality attributes of detailed clinical models</td>
<td>30.98</td>
</tr>
<tr>
<td>ISO/CD 14199</td>
<td>Health Informatics: The BRIDG Domain Analysis Model for Protocol-driven biomedical Research</td>
<td>30.98</td>
</tr>
<tr>
<td>ISO/DTR 28380-1</td>
<td>Health informatics -- IHE global standards adoption -- Part 1: Process</td>
<td>30.98</td>
</tr>
</tbody>
</table>
Appendix C – SKMT Background and Governance

Standards Knowledge Management Tool    SKMT
Prepared by:  Andrew Grant (Canada) and Heather Grain (Australia)
March 2012

1.  INTRODUCTION

This document explains the background to the Standards Knowledge Management Tool and defines the requirements, Draft Terms of Reference and procedures for the JIC SKMT Governance Committee as well as procedures for SDO content administration and maintenance

2.  BRIEF BACKGROUND

The SKMT grew from a web based software tool initially intended to support the HIPF (Health Informatics Profiling Framework) ISO 215 TR 17199 around 2005. It also, under the auspices of WG8 around 2007, acquired the need to be a database of ISO 215 published and developing standards. At about the same time collaborative work with WG3 decided that the tool should enable a harmonised Health Informatics vocabulary. The need for a database of documents (now extended to standards products including documents) for the ISO 215 TC and for a harmonised vocabulary has been subsequently endorsed by the Joint Initiative council around 2009. Funding for development of the web based tool has been obtained from the Canada Institute for Health Information supplemented by Canada Infoway to add their terms, and by the World Health Organisation as part of an initiative to enable health information system developers and users to have easier access to knowledge about standards. Voluntary resources have also been provided to develop and support the tool.

3.  SOME GENERAL PRINCIPLES

Open Access: The tool is designed to give easy access to the whole health informatics community and beyond thus promoting standards awareness, ease of access and raising the image of the standards community. Registration for reading is open to all.

The tool maintains metadata of:
- products – usually documents
- terms used in documents/products.

Document Publisher Control of Content: Access for and editing of content by designated members of each SDO, jurisdictions or organisations who control their own material is determined by each SDO. Thus a designated person has control of all content relating to that organisation.

Example of process used in ISO/CEN:

In ISO 215 and CEN 251, terms are defined within standards documents, hence it is essential that both the document and its assigned terms are entered into the tool. This supports harmonisation of concepts in subject domains. In other cases, terms may also be separately defined by SDOs, jurisdictions or organisations, in this case they are usually associated to a single glossary document controlled by that organisation. Therefore in all cases terms are related to the documents (including glossary documents) or products which use or define them. No term has an owner, but do have users who are defined through the relationship of the term to the document/products in the Tool.

Term Harmonisation: Terms should have a single definition where practical. Where more than one definition is required the context in which the specific definition applies must be indicated in order to clarify intended use. The principle that term definitions be harmonised and improved can be supported by the glossary functionality of the SKMT. The relationships between definitions and documents are not changed as a result of this process, rather the process supports update and improvement of definitions over time moving towards consistency and clarity.
4. BEST PRACTICE AND USER SUPPORT
The SKMT content needs to be continuously kept up-to-date to well serve both the needs of the SDOs and consumers.

**Example of process used in ISO 215:**
Working groups should be responsible for delegating persons to enter and update content including all documents in development once accepted as a new work item. This needs to be monitored at the time of balloting so that balloting cannot take place unless the item and relevant definitions are recorded in the tool. The organisations will be automatically asked to review editing access permission on a 6-monthly basis.

To support users the tool provides:
- a user guide,
- a short video showing overall functions of the tool and
- access to rapid user support available from the home screen and there is an FAQ section.
- web based training sessions can be requested as can personal demonstrations at relevant SDO meetings.

5. SKMT GOVERNANCE COMMITTEE
There is a need to ensure continuity and appropriate process to the governance and ongoing improvement of the SKMT. This includes the comprehensive functionalities of the tool as well as the need to harmonize terms and definitions. There is often more than one definition for a term, and some definitions are poorly structured. A sub-group (SKMT Governance Committee) reporting to the JIC and with ISO 215 WG3 (Semantic Content) advising them would be responsible for administering SKMT functionality and term harmonisation.

**Objective**
The objective of the SGC is to support ongoing improvement of the SKMT as an accessible knowledge resource about health informatics standards and products, published and in development, and also the content of the Glossary of the SKMT and member organisations of the JIC in their engagement with the SKMT and term harmonisation processes.

**Terms of Reference**
The SGC reports to the JIC 6 monthly and receives advisory terminological support from ISO WG3 – Semantic Content. The SGC will:
- maintain and communicate the SGC Operational Principles,
- provide oversight to SKMT content management processes
- identify and prioritise changes required to processes and tooling to improve the quality of content in the Glossary and the ability to support governance processes.
- review and maintain product and term/definition entry and maintenance guidelines
- receive term harmonisation proposals from members of the JIC community and determine how these will be processed by the member organisations to achieve agreed harmonisation (through term generation, retirement and/or context declaration) and identification of preferred definition/s in context.
- Establish and maintain the operating procedures of the SGC.

**Membership**
The SGC should be a small group of people, in order to support ease of operation. Where possible, representatives should with some understanding of term/definition best practice. Individuals may represent more than one group, in order to keep the group as small as practical.

Representative areas are the groups who need to be represented in the SGC.
- a representative of each member of the JIC. This member is responsible for liaison with their organisation in order to support representation of their information in the tool, and term harmonisation processes.
- a representative of national bodies or other organisations which are contributing to the SKMT (such as WHO)
- a representative of the SKMT administrative group – currently CRED.
- a representative of ISO WG3 to provide liaison and advisory support.
The chair of the group is to be elected by the members.

One individual may represent more than one of the representative groups.

**SGC Operational principles include:**

More than one definition of the same term is possible provided the context that merits variation in definition is clearly defined in that term’s metadata.

Historically several definitions of the same term have been tolerated and have been reported in the tool. Some definitions of the same term are very similar; others are more or less adequate. In these cases poor term definitions need to be retired.

Respect for and use of the term entry guidelines.

Harmonisation process does not consider the origin of a definition, rather the quality of the definition and whether it is fit for purpose.

Usage of definitions. Where an SDO has used a definition (i.e. that definition is published or used in their document/tools) that organisation will be asked to contribute to harmonisation (agreed definition processes) to either agree on a single preferred definition, or to assert context relevant to their specific environment.

There are four statuses of term definitions (consistent with metadata specifications from ISO 11179):

- pending – prior to publication of the term and standards document containing this new term;
- candidate - published but waiting for SGC review;
- preferred - endorsed by the SGC either as it is the only definition and is correctly structured or it is a definition which has completed harmonisation and were required ballot of harmonisation;
- retired by the SGC – the definition is still present in the glossary but only when requested. The link to documents in which this definition is used is maintained to support document review at a later time.

Much of the SGC activity can be achieved virtually. The aim, also to accommodate the current backlog, is to systematically review batches of terms in collaboration with the different organisations responsible for term introduction.

The harmonisation is aided by functionalities of the SKMT.

**Functionalities of the SKMT**

The SKMT records major standards product metadata: including, publisher (SDO), working group, progression status and date, introduction, scope. It has optional fields yet under exploited for hyperlinks, descriptions of use context and possible improvement.

For terms and definitions, the SKMT records links to standards documents/products, definitions and context where required per definition, source, status and date of status allocation, rational for change, notes and examples, with optional possibility to hyperlink to other information.

The functions include extensive search options with the possibility to move between terms and documents and vice versa, reports, editing support and documentation update. It includes also tools to support the SGC.

Current and future developments include the introduction of a standard document classification, visual navigation support that can identify clusters and hence supports gap identification, collaborative editing and critique tools, bank of use case scenarios and standards users’ education.

**SKMT Current Governance, Management and Continuing Development**

The SKMT activity reports to the JIC. It is managed by a small team of ISO 215 experienced contributors,

Andrew Grant, professor and director CRED (Collaborative research for effective diagnostics), part of the Université de Sherbrooke faculty of Medicine WHO collaborating centre whose health informatics group is responsible for programming and technical support.
The CRED accepts to host and continue to develop the SKMT until end 2016 (excepting force major). Subsequently this relationship with the Université de Sherbrooke is expected to continue as a first option. If required however an alternative host will be solicited (possible candidates: Canada Institute of Health Information; or WHO) and the tool, including source code and reasonable assistance, will be transferred without charge.

Heather Grain, Associate Professor and chair of Standards Australia’s Health Informatics Committee and Convener ISO/TC 215 WG3 volunteering through Llewelyn Grain Informatics responsible for health informatics consultancy, education, research and development is co-lead. Whereas maintenance is low cost, the financial grants received to date and welcome in the future enables continuous evolution of the tool and its potential to serve not only standards developers but also standards implementers worldwide and the health informatics community at large.

**Associated Documents**

ISO/TC 215 DTR Development of Terms and Definitions for the Health Informatics Glossary
ISO/TC DTR 13054 Knowledge Management of Health Informatics Standards

One individual may represent more than one of the representative groups.
Appendix D – Resolutions at closing plenary

The resolutions approved at the closing plenary follow directly as the body of this Appendix.
N1092 – Resolutions from the 18th Meeting of ISO TC215, Health Informatics
26 September 2012, Vienna Austria

1. [WG1-R1] Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG1

   Approves the recommendation of WG1 that the work item be withdrawn from the ISO/TC215 work program based on the request of WHO’s project lead.
   Instructs the Secretary to process withdrawal from the TC215 program of work.
   Abstain: Malaysia

   Approves the recommendation of WG1 that the published Technical Report be made available free of charge on a priority basis to all countries based on the following rationale:
   ▪ This report is a potentially important resource for countries, especially Low and Middle Income Countries (LMIC), in the implementation of their national eHealth policies
   Instructs its Secretary to inform ISO Central Secretariat of this resolution and request a response by 30 November 2012 which can be conveyed to TC 215 and WG1 members.
   Abstain: Malaysia

   Approves the recommendation of WG1 to issue a DTR ballot
   Instructs the project lead to provide the text of ISO/DTR with final disposition of NP comments to the TC215 secretary no later than 15 January 2012:
   Instructs its Secretary to issue a DTR ballot immediately upon receipt of the documents

   Approves the recommendation of WG 1 to issue a DTS ballot;
   Instructs the project lead to provide the text of ISO/DTS 13972 and the final disposition of comments document to the TC 215 Secretary no later than 30 September 2012;
   Instructs its Secretary to issue a DTS ballot immediately upon receipt of the documents.
   Abstain: Malaysia
   Approves the recommendation of WG 1 to issue a DTS ballot; 
   Instructs the project lead to provide the text of ISO/DTS 18530 and the final disposition of comments document to the TC 215 Secretary no later than 31 October 2012; 
   Instructs its Secretary to issue a DTS ballot immediately upon receipt of the documents. 
   Abstain: Malaysia

7. [WG1-R7] Regarding eCommittee website—Resolved that ISO/TC215 
   Approves the recommendation of WG 1 to combine WG1 and WG8 eCommittee sites (and all documents held within) into one location within the ISO/TC215 eCommittee 
   Instructs the TC 215 Secretary to complete this no later than 30 November 2012; 
   Abstain: Malaysia

   Approves the WG 1 recommendation to issue a NP ballot targeting a technical specification; 
   Instructs the ISO/TC 215 Secretary to coordinate with the WG 1 Secretary to circulate a NP ballot with attached Form 4 and documentation, with the project lead, Sun-Ju Ahn, no later than 31 December 2012. 
   - Positive: Brazil, Republic of Korea, Canada, Mexico, Japan, Netherlands, Italy, Singapore, Austria, China 
   - Negative: Sweden, United States 
   - Abstain: Australia, Ireland, Germany, Russian Federation, United Kingdom, Finland, Malaysia, Norway

9. Resolved, that ISO/TC215 accepts the report of WORK GROUP 2

    TC215 noting the report of WG2 and the intent of WG2 to reactivate ISO 28380-, requests that the TC215 Secretary inform ISO/CS of this intent. 
    TC215 further instructs its secretary to submit the text of ISO DTR 28380-1 to TC215 for a 3 month DTR ballot immediately following it activation by ISO/CS. 
    Abstain: China, Malaysia
11. Resolved, that ISO/TC215 accepts the report of WORK GROUP 3

12. [WG3-R1] Regarding ISO/DTS 13582: Health informatics: Sharing of OID registry information

Resolved that ISO/TC 215:

- Approves the disposition of the CD ballot comments agreed to at the Vienna WG 3 meeting and that the project should proceed to DTS ballot;
- Instructs the PL/WG convener to provide the updated text of ISO/TS 13582 and the final disposition of comments document to the TC 215 Secretary no later than December 1st 2012;
- Instructs the TC 215 Secretary to submit the text to ISO Central Secretariat for TS balloting no later than 15th December 2012.

Abstain: Singapore

13. [WG3-R2] Regarding the SKMT Governance Committee positions defined in the SKMT Governance document, the ISO TC215 representative and the WG3 liaison and advisory support representative—Resolved that ISO/TC215

- Request nominations from the working groups for the ISO/TC215 representative, and
- Accept the nomination of Heather Grain to the WG3 position.

Abstain: Finland


- Approves the change of name of this project to Principles of mapping between terminological resources.
- Approves the disposition of DTR ballot comments agreed to at the Vienna WG 3 meeting and that the project should proceed to DTR ballot;
- Instructs the PL/WG convener to provide the updated text of ISO/DTR 12300 and the final disposition of comments document to the TC 215 Secretary no later than 30th October 2012;
- Instructs the TC 215 Secretary to circulate the text for DTR balloting no later than 15th November 2012. Abstain: Singapore

15. [WG3-R4] Regarding prEN ISO/DIS 13120 – Health informatics – A syntax to represent the content of classification systems in health care – Resolved that ISO/TC 215

- Approves the disposition of the DIS ballot comments subject to WG 3 approval of disposition and document at an upcoming teleconference meeting, and that the project should proceed to FDIS ballot at that time.
- Instructs the PL/WG convener to provide the updated text of ISO/FDIS 13120, revisable figure files and the final disposition of comments document to the TC 215 Secretary no later than 31st December 2012;
- Instructs the TC 215 Secretary to submit the text to ISO Central Secretariat for FDIS balloting no later than 15th January 2013. Abstain: Singapore

Approves the WG 3 recommendation that the name of this work item be changed to Health informatics – Categorial structures of clinical findings in Traditional Medicine: Part 1: Traditional East Asian Medicine.

Approves the disposition of the NP ballot comments agreed to at the Vienna WG 3 meeting and teleconferences of WG3 and that the project should proceed to CD ballot;

Instructs the PL/WG convener to provide the updated text of ISO/CD 16277-1, revisable figure files and the final disposition of comments document to the TC 215 Secretary no later than 16th November 2012;

Instructs the TC 215 Secretary to submit the text to ISO Central Secretariat for CD balloting no later than 2nd December 2012. Abstain: Singapore


Approves the WG 3 recommendation that a new project based on EN12264 Categorial Structures for Systems of Concepts be added to the TC 215 Program of Work as a Preliminary Work Item which will include relevant content from ISO 17115 which will subsequently be withdrawn.

Instructs the TC 215 Secretary to inform ISO Central Secretariat of this decision and add the project to the TC 215 Program of Work.

Abstain: Singapore


Approves the disposition of the NP ballot comments subject to WG3 approval of disposition and document at upcoming teleconference meeting, and that the project should proceed to CD ballot at that time;

Instructs the PL/WG convener to provide the updated text of ISO/CD 17948, revisable figure files and the final disposition of comments document to the TC 215 Secretary no later than 31 December 2012;

Instructs the TC 215 Secretary to ballot ISO/CD 17948 for a two month CD balloting no later than 15th January 2013.

Abstain: Singapore

Resolved that ISO/TC 215

Approves the disposition of the NP ballot comments subject to WG3 approval of disposition and document at upcoming teleconference meeting, and that the project should proceed to CD ballot at that time;

Instructs the PL/WG convener to provide the updated text of ISO/CD 17938, revisable figure files and the final disposition of comments document to the TC 215 Secretary no later than 31 December 2012;

Instructs the TC 215 Secretary to ballot ISO/CD 17938 for a two month CD balloting no later than 15th January 2013.

Abstain: Singapore


Resolved that ISO/TC215

Approves the WG 3 recommendation that the above mentioned project be added to the TC 215 Program of Work as a Preliminary Work Item; and

Instructs the TC 215 Secretary to inform ISO Central Secretariat of this decision and add the project to the TC 215 Program of Work.

Abstain: Singapore


Noting that ISO TC215 approved the disposition of the CD ballot comments agreed to at the WG3 meeting in Vancouver May 2012 and that ISO TC215 resolved that the project should proceed to DIS ballot

Instructs the Project Lead / Working Group Convenor to provide the updated text of ISO/DIS 13940 and the final disposition of comments document to the TC215 secretary no later than 8 October 2012

Instructs the TC215 secretary to submit the text to ISO CS for DIS ballot no later than 22 October 2012. Unanimous approval
22. **Resolved, that ISO/TC215 accepts the report of WORK GROUP 4**


   TC 215, noting the report from WG 4 and the request that ISO 16114 be withdrawn from the TC 215 Program of Work and the intent that a New Work Item Proposal with a broader scope will be submitted in the future;

   TC 215 agrees that ISO 16114 be withdrawn from the TC 215 Program of Work.

   The TC 215 Secretary is instructed to contact ISO Central Secretariat and request the withdrawal of this project from the TC 215 Program of Work. Abstain: Malaysia, Singapore

24. **[WG4-R2] Regarding ISO 17090-1, Health informatics - Public Key Infrastructure - Part 1: Overview of digital certificate services - Resolved that ISO/TC 215**

   TC 215, noting the comments received on the 2011 Systematic Review of ISO 17090-1 as contained in TC 215 N 895 and TC 215 Resolution 21 taken at the 20 October 2011 Meeting in Chicago agrees that ISO 17090-1 shall undergo a minor revision. The following changes shall be made to the text:

   - Amend title of section 6.3 by adding the underlined text "Healthcare-specific needs and the separation of authentication from data encipherment"
   - Change the last sentence in section 6.3 to read: "If keys are used for data encryption, a form of key management is necessary to prevent data loss if the decryption keys are not available."
   - Delete from section 7.3 the sentence "Essential step before the private key operation is the use of a cryptographic hash function." along with the following three paragraphs. Replace with more succinct text: "This operation uses the private key and a one-way mathematical function known as a hashing algorithm, to produce a hash (a very large number) from the original message. The hash function has the property that it is computationally infeasible to produce the original message or private key from the hash. This hash is sent with the message. The recipient then uses the sender’s public key to perform the same operation on the message and compare the resultant hash with the one sent with the message. If the two are identical, then the recipient can have a level of confidence that the message was sent by the source that claimed to have sent it."
   - Delete from section 7.4 the fourth paragraph discussing storage on a floppy disk as well as deleting the phrase "stored on one of these devices" from the fifth paragraph.
   - Remove from section 8.1.4 the phrase "on a floppy disk or on other media" and replace it with "on other removable media".

   TC 215 instructs the Project Editor to submit the revised text to TC 215 Secretary for FDIS balloting no later than September 26, 2012.

   Abstain: Malaysia, Singapore

TC 215, noting the comments received on the 2011 Systematic Review of ISO 17090-2 as contained in TC 215 N 896 and TC 215 Resolution 22 taken at the 20 October 2011 Meeting in Chicago, agrees that ISO 17090-2 shall be revised. The following P-members of TC 215 commit to this revision:

Experts:
1. Lori Reed-Fourquet, US
2. Ross Fraser, CA
3. Bernd Blobel, DE
4. Luuc Posthumus, NL
5. Hideyuki Myohara, JP

TC 215 further agrees that the revised text of ISO 17090-2 as prepared by TC 215/WG 4 in response to the comments contained in TC 215 N 896 be circulated to TC 215 members for a two-month CD-ballot. The Project Editor is requested to submit the text of ISO 17090-2 and disposition of systematic review comments to the TC 215 Secretary for immediate CD balloting no later than September 26, 2012.

Abstain: Malaysia, Singapore


TC 215 approves the WG 4 recommendation to issue ISO 17791 for DTR ballot; and

Instructs the PL/WG convener to provide the secretariat with a text for DTR ballot no later than 1 December 2012;

Instructs the TC 215 Secretary to issue a DTR ballot immediately upon receipt of the text.

Approves the disposition of NP ballot comments as agreed by the project team subject to final review of both WG4 and JWG7 and that the project should proceed to DTR ballot;

Instructs the PL/WG convener to provide the updated text of ISO/DTR 17791 and the final disposition of comments document to the TC 215 Secretary no later than 1 December 2012;

Instructs the TC 215 Secretary to coordinate with the IEC/SC 62A Secretary to circulate the text for a three month DTR ballot immediately upon receipt, but no later than 15 December 2012.

Abstain: Malaysia, Singapore

27. [WG4-R5] Regarding NP Health Informatics - Pseudonymization—Resolved that ISO/TC215

TC 215 approves the WG 4 recommendation to issue a NP ballot targeting an International Standard under the Vienna agreement with ISO lead on Pseudonymization;

Requests the WG 4 convener to provide the secretariat with a Form 4 and accompanying draft no later than 1 October 2012;

TC 215 instructs the TC 215 Secretary to issue a NP ballot immediately upon receipt of the text.

Abstain: Malaysia, Singapore
28. [WG4-R6] Regarding communication to JTC1/SC27 —Resolved that ISO/TC215

TC 215, noting the report from WG 4, instructs the TC 215 Secretary to contact JTC 1/SC 27 to:

- Acknowledge the receipt of and thank them for the Liaison Statement dated 30 July 2012;
- Apologize that TC 215 couldn’t respond to the 22 September 2012 response date for contributions to the next JTC 1/SC 27 meeting as the TC 215 meeting was held September 24-26 and the document didn’t reach us in time;
- Inform JTC 1/SC 27 that ISO 27799, Health informatics -- Information security management in health using ISO/IEC 27002 is currently under revision, and as such, TC 215 is very much interested in revisions of the 27000 series especially the revisions of ISO/IEC 27001, Information technology – Security techniques – Information security management systems - Requirements and ISO/IEC 27002, Information technology – Security techniques – Code of practice for information security controls; and

Abstain: Malaysia, Singapore


TC 215, noting the report from WG 4 that the liaison between TC 215 and ISO/IEC JTC 1/SC 27 is not functioning as optimally as WG 4 would like and that the revision of ISO 27799, Health informatics -- Information security management in health using ISO/IEC 27002 is dependent on ISO/IEC JTC 1/SC 27 standards;

Nominates Mr. Ross Fraser, CA, as liaison representative from TC 215 to ISO/IEC JTC 1/SC 27 as Mr. Fraser is not only an active participant in WG 4 but also well versed in the parts of the ISO/IEC JTC 1/SC 27 Work Program relative to TC 215.

The TC 215 Secretary is instructed to inform ISO Central Secretariat and ISO/IEC JTC 1/SC 27 of this nomination. (Pending Mr. Fraser's endorsement by the SCC)

Abstain: Malaysia, Singapore


TC 215, noting the comments received on the 2010 Systematic Review of ISO 21549-1 as contained in TC 215 N 846 and TC 215 Resolution 30 taken at the 13 October 2010 Meeting in Rotterdam agrees that ISO 21549-1 shall undergo a minor revision. The following changes shall be made to the text:

- Foreword: The title of Part 7 was changed to "Medication data".
- 2 Normative references: The dated references were updated to the last editions.
- 5 Basic data object model for a healthcare data card - Patient healthcare data object structure: The title of Part 7 was changed to "Medication data" in text, in the Figure 1 and elsewhere in Clause 5.7.
31. Resolved, that ISO/TC215 accepts the report of WORK GROUP 6

32. [WG6-R1] Regarding ISO/DTS 167911 Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers—Resolved that ISO/TC215 Approves the recommendation of WG6 that the project proceed DTS ballot; 
Instructs the project lead to provide the DTS text of ISO/DTS 16791 and the final disposition of comments document to the TC 215 Secretary no later than 15 December 2012; 
Instructs the TC 215 Secretary to submit the text to ISO Central Secretariat for DTS balloting immediately upon receipt.
Abstain: China, Japan, Malaysia

33. [WG6-R2] Regarding 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 —Resolved that ISO/TC215 Approves the recommendation of WG6 that the project proceed DTR ballot; 
Instructs the project lead to provide the DTR text of ISO/DTR 14872 and the final disposition of comments document to the TC 215 Secretary no later than 15 December 2013; 
Instructs the TC 215 Secretary to submit the text to ISO Central Secretariat for DTR balloting immediately upon receipt.
Abstain: China, Japan, Malaysia

34. [WG6-R3] Thanking the host of the joint ISO/TC 215 & CEN/TC 251 WG meetings—Resolved that ISO/TC215 Approves the recommendation of WG 6 to thank the WKO and Austrian Standards Institute for hosting the joint ISO/TC 215 and CEN/TC 251 WG meetings in Vienna.
Abstain: China, Japan, Malaysia
35. Resolved, that ISO/TC215 accepts the report of WORK GROUP 7


   Noting that the following work item was accidentally included in the list of work items to be removed from the work program in Resolution 40-Vancouver 2012

   ISO/IEEE NP 11073-10422   Health informatics — Personal health device communication — Devic specialization — Urine analyzer — Part 10422

   ISO/TC 215 agrees with the WG 7 recommendation that this work item be restored to the work program of ISO/TC 215 as a preliminary work item; and

   Reiterates that IEEE has been invited to submit this revised standard for Fast Track ballot and adoption by ISO/TC 215 in accordance with the ISO–IEEE Partner Standards Development Organization agreement.

37. [WG7-R2] Regarding the cancellation of ISO/IEEE Projects as to the TC215 Program of Work—Resolved that ISO/TC215

   Noting that the following work items are not on the work program of IEEE and are not active projects within WG 7

   ISO/PWI TR 11073-92205   Health informatics — Medical waveform format — Part 92205: Physiological report, HL7 CDA R2
   ISO/PWI TR 11073-92206   Health informatics — Medical waveform format — Part 92206: Conversion from SCP-ECG format

   ISO/TC 215 agrees with the WG 7 recommendation that these work items should be withdrawn from the ISO TC 215 Program of Work; and

   Instructs the TC 215 Secretary to inform the ISO Central Secretariat of this decision and request the withdrawal of these projects from the program of the technical committee.

   Abstain: China, Singapore


   Noting that the following work item has been published by IEEE and was approved for advancement for Fast Track ballot in Resolution 75-Kuopio 2011

   ISO/IEEE NP TR 11073-00103   Health informatics — Personal health device communication — Technical report — Part 00103: Overview

   ISO/TC 215 instructs the ISO/TC Secretary to liaise with IEEE and facilitate the initiation of the Fast Track ballot of this standard.

   Abstain: China, Singapore

Resolved that ISO/TC215

Noting that IEEE has published an amendment to the following ISO/IEEE standard

ISO/TC 215 agrees with the WG7 recommendation that this amendment be added to the work program as a revision of the 2010 standard; and

Invites IEEE to submit the amended standard for Fast Track ballot and adoption by ISO/TC 215 in accordance with the ISO–IEEE Partner Standards Development Organization agreement.

Abstain: China, Singapore

40. [WG7-R5] Regarding the Addition of Five IEEE Documents as Listed to the TC215 Program of Work—Resolved that ISO/TC215

Noting that Resolution 41-Vancouver 2012 agreed to add the following revisions to the work program of ISO/TC 215 and invited IEEE to submit these documents for Fast Track ballot upon their completion:

ISO/IEEE 11073-10101  Health informatics -- Point-of-care medical device communication -- Part 10101: Nomenclature

ISO/IEEE 11073-10201  Health informatics -- Point-of-care medical device communication -- Part 10201: Domain information model

IEEE 11073-10404  Health informatics – Personal health device communication – Device specialization – Pulse Oximeter

ISO/IEEE 11073-20101  Health informatics — Point-of-care medical device communication — Part 20101: Application profiles — Base standard

IEEE 11073-20601  Health informatics – Personal health device communication – Application profile – Optimized Exchange Protocol

ISO/TC 215 instructs the Secretary to take the actions necessary to register these work items appropriately on the official work program of the technical committee.

Abstain: China, Singapore

Noting that Resolution 42-Vancouver 2012 approved the circulation of the following work item for Fast Track ballot and that a ballot document was provided to the ISO Central Secretariat on 5 April 2012
ISO/IEEE DIS 11073-10417 Health informatics — Personal health device communication — Part 10417: Device specialization — Glucose meter

ISO/TC 215 requests the Secretariat to work with the ISO Central Secretariat to ensure the initiation of the Fast Track ballot of this work item.

Further noting that Resolution 42-Vancouver 2012 also added the ongoing IEEE amendment of this document to the work program of the technical committee as a future revision and invited IEEE, upon the completion of the amendment to submit the document for Fast Track revision.

ISO/TC 215 instructs the ISO/TC 215 Secretary to take the actions necessary to register this planned revision on the official work program of the technical committee.

Abstain: China, Singapore


Noting that the Periodic Review of the following documents closed in 2008


ISO/TC 215 instructs the Secretary to issue the Form 21 for these documents, informing ISO TC 215 and ISO Central Secretariat of the results of the Systematic Reviews of these documents.

Abstain: China, Singapore
43. [WG7-R8] Regarding the Addition of ISO/IEEE 11073-30200 to the TC215 Program of Work—

Resolved that ISO/TC215

Noting that an amendment of this standard has been published by IEEE,

ISO/TC 215 agrees with the WG 7 recommendation that a revision of ISO/IEEE 11073-30200 be added to the work program of the technical committee; and

Invites IEEE to submit the amended standard for Fast Track ballot and adoption by TC 215 as a revision of the 2004 standard in accordance with the ISO–IEEE Partner Standards Development Organization agreement.

Regarding the Addition of Five New IEEE Work Items to the TC215 Program of Work

Abstain: China, Singapore

44. [WG7-R9] Regarding the Addition of Four Projects to the TC 215 Program of Work—Resolved that

ISO/TC215

Noting that Resolution 45-Vancouver 2012 agreed to add the following new IEEE work items to the work program of the technical committee and invited IEEE to submit these documents for Fast Track ballot upon their completion:

IEEE 11073-10413 Health informatics – Personal health device communication – Device specialization – Respiration rate monitor
IEEE 11073-10419 Health informatics – Personal health device communication – Device specialization – Insulin pump
IEEE 11073-10441 Health informatics – Personal health device communication – Device specialization – Cardiovascular Fitness and Activity Monitor
IEEE 11073-10442 Health informatics – Personal health device communication – Device specialization – Strength Fitness Equipment

And further noting that these documents have not been registered on the official work program of the technical committee.

ISO/TC 215 instructs the Secretary to take the actions necessary to register these work items on the official work program of the technical committee.

Abstain: China, Singapore
45. [WG7-R10] Regarding the Cancellation of ISO/IEEE 11073-10443 from the TC215 Program of Work—Resolved that ISO/TC215

*Noting* that the following work item, which was to be added to the work program of ISO/TC 215 according to Resolution 45-Vancouver 2012, has been cancelled by IEEE

IEEE 11073-10443 Health informatics – Personal health device communication – Device specialization – Physical Activity Monitor

*ISO/TC 215 agrees* with the WG 7 recommendation that this work item should not be added to the work program of the technical committee.

Abstain: China, Singapore


*Noting* that IEEE has begun work on an amendment to the following standard


*ISO/TC 215 agrees* with the WG 7 recommendation that a revision of ISO/IEEE 11073-10471 be added to the work program of the technical committee; and

*Invites* IEEE, upon completion of the amendment, to submit the amended standard for Fast Track ballot and adoption by TC 215 as a revision of the 2010 standard in accordance with the ISO–IEEE Partner Standards Development Organization agreement.

Abstain: China, Singapore

47. [WG7-R12] Regarding the Addition of Three IEEE Work Items to the TC215 Program of Work—Resolved that ISO/TC215

*Noting* that IEEE has begun work on the following work items

IEEE 11073-10423 Health informatics – Personal health device communication – Device specialization – Sleep Quality Monitor

IEEE 11073-10424 Health informatics – Personal health device communication – Device specialization – Sleep apnea breathing therapy equipment

IEEE 11073-10425 Health informatics – Personal health device communication – Device specialization – Continuous Glucose Monitor (CGM)

*TC 215 agrees* with the WG 7 recommendation that these items should be added to the work program of the technical committee; and

*Invites* IEEE, following their completions, to submit these new standards for Fast Track ballot and adoption by TC 215 in accordance with the ISO–IEEE Partner Standards Development Organization agreement. Abstain: China, Singapore
48. [WG7-R13] Regarding the Addition of Seven Specific IEEE Work Items to the TC215 Program of Work—Resolved that ISO/TC215

Noting that IEEE 11073 have the following projects in the submission process:

- 11073-10301-1 Health informatics – Point-of-care medical device communication – Part 10301-1: Device specialization – Infusion pump – General
- 11073-10302-1 Health informatics – Point-of-care medical device communication – Part 10302-1: Device specialization – Physiologic monitor – General
- 11073-10303-1 Health informatics – Point-of-care medical device communication – Part 10303-1: Device specialization – Ventilator – General
- 11073-20201 Health informatics – Point-of-care medical device communication – Part 20201: Application profile – Polling mode
- 11073-20202 Health informatics – Point-of-care medical device communication – Part 20202: Application profile – Baseline asynchronous mode
- 11073-20301 Health informatics – Point-of-care medical device communication – Part 20301: Application profile – Optional package, remote control
- 11073-20401 Health informatics – Point-of-care medical device communication – Part 20401: Application profile – Common networking services

TC 215 agrees with the WG 7 recommendation that, if added to the work program of IEEE, these items will be added to the work program of the technical committee; and

Invites IEEE to submit these new standards, upon their completion, for Fast Track ballot and adoption by TC 215 in accordance with the ISO–IEEE Partner Standards Development Organization agreement.

Abstain: China, Singapore

49. [WG7-R14] Regarding a New Project on Spirometry—Resolved that ISO/TC215

TC 215 agrees with the WG 7 recommendation that an ISO/HL7 New Work Item Proposal for the development of a standard for spirometry test reports go forward under the Vienna Agreement with an ISO lead. This NP is to be submitted for consideration by ISO/TC 215 and CEN/TC 251 no later than 15 December 2012 and upon approval of the new work the Joint Initiative Council will be asked to facilitate the coordination across SDO’s.

Abstain: China, Singapore

Noting that the proposed reorganization plan for ISO/TC 215 envisions the disbanding of ISO/TC 215/WG 7

TC 215 agrees with the WG 7 recommendation that, upon the disbanding of the WG, the ISO/TC 215 Secretary and IEEE appoint a project leader to manage future processing of IEEE 11073 standards by ISO/TC 215 in accordance with the ISO–IEEE Partner Standards Development Organization agreement.

Abstain: China, Singapore


TC 215 resolves that a New Work Item Proposal to initiate a revision of ISO 11073-91064:2009 (Ed. 1) under the Vienna Agreement with a CEN lead be prepared and submitted to the TC 215 and CEN/TC 251 Secretariats no later than 15 December 2012.

Abstain: China, Singapore

52. Resolved, that ISO/TC215 accepts the report of Joint WORK GROUP 7

53. [JWG7-R1] Regarding JWG7 Secretary – Resolved that ISO/TC 215

Approves the JWG7 recommendation to nominate the following individual as JWG 7 secretary:

Mr. Joe Lewelling (USA)

Abstain: China, Malaysia, Singapore

54. [JWG7-R2] Regarding Health Software Ad hoc group – Resolved that ISO/TC 215

Approves the creation of a Health Software Ad hoc group to create a report that provides guidance on the future development of health software work items that establishes:

1. Guiding principles
2. Common terms and definitions
3. Development roadmap

The group shall be convened for a period of two years from the date of formation and shall have the following co-leaders:

- Sherman Eagles (US)
- Neil Gardner (CA) [pending confirmation by Standards Council of Canada]

The Group shall be coordinated with JWG7 and include members from ISO TC 215 and IEC SC62A.

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

   Notes that IEC has the lead;
   Approves the disposition of DTR ballot comments agreed to at the JWG7 Vienna meeting and that the project should proceed to final TR publication;
   Instructs the PL/WG convener to provide the updated text of the TR and the final disposition of DTR comments to the IEC/SC62A and ISO/TC 215 Secretaries no later than 31 October 2012;
   Instructs the ISO/TC 215 Secretary to coordinate with the IEC/SC62A Secretary on the publication of the TR no later than 15 November 2012


   Approves the JWG 7 recommendation to issue a Joint NP ballot targeting a technical report to be developed with ISO/TC215 lead;
   Instructs the PL/WG convener to provide the updated working draft text of the TR to the IEC/SC62A and ISO/TC 215 Secretaries no later than 31 October 2012;
   Instructs the ISO/TC 215 Secretary to coordinate with the IEC/SC 62A Secretary to circulate a Joint NP ballot with ISO/TC215 lead no later than 15 November 2012


   Approves the disposition of NP ballot comments as agreed by the project team and that the project should proceed to CD ballot;
   Instructs the PL/WG convener to provide the updated text of IEC/ISO CD 82304-1 and final disposition of comments document to the TC 215 Secretary no later than 30 November 2012;
   Instructs the TC 215 Secretary to coordinate with the IEC/SC 62A Secretary to circulate the text for a three month CD ballot immediately upon receipt, but no later than 15 December 2012.


   Approves the JWG 7 recommendation to issue a Joint NP ballot targeting a technical report to be developed with ISO/TC215 lead;
   Instructs the PL/WG convener to provide a draft document to the TC 215 Secretary no later than 30 November 2012;
   Instructs the ISO/TC 215 Secretary to coordinate with the IEC/SC 62A Sec to circulate a Joint NP ballot with an attached draft, with ISO/TC215 lead no later than 15 December 2012

Resolved that ISO/TC 215  

Approves the JWG 7 recommendation that the above mentioned project be added to the TC 215 Program of Work as a Preliminary Work Item; and  

Instructs the TC 215 Secretary to inform ISO Central Secretariat of this decision and add the project to the TC 215 Program of Work.

60. Regarding the Use of SKMT—Resolved that ISO/TC215  

TC 215 instructs all TC 215 Project Editors to examine the SKMT for relevant glossary terms early in the drafting process, and where appropriate, consider using terms and definitions already entered into the SKMT. For each project ensure that all relevant metadata is entered into SKMT prior to forwarding for ballot.  

Unanimous

61. Regarding the TC 215 Reorganization Plan—Resolved that ISO/TC215  

TC 215 instructs its Secretary to post the TC 215 Reorganization Plan and the resolutions regarding the Reorganization Plan (with the editorial modifications discussed at this meeting including the preliminary status of WG titles and scopes) as TC 215 N-numbered documents to the TC 215 site on eCommittee no later than 12 October 2012.  

The TC 215 Secretary is further instructed to initiate a fifteen day letter ballot for the approval of the TC 215 Reorganization Document and Reorganization Resolutions by that same date. The results of this ballot will be addressed by TC 215.  

Unanimous


TC 215 establishes the TC 215 Ad Hoc Group on the Strategic Business Plan under the leadership of Mr. Richard Dixon Hughes and Mr. Jeremy Thorp. The Ad Hoc Group is tasked with creating a TC 215 Business Plan that reflects the TC 215 reorganization including finalization of the WG titles and scopes currently listed as preliminary in the TC 215 Reorganization Plan. All TC 215 members are invited to participate in this work. Any interested members are requested to inform the TC 215 Secretary as soon as possible.  

Unanimous

63. Regarding Endorsement of TC 215 Chair—Resolved that ISO/TC215  

TC 215, noting the nomination by the TC 215 Secretary of Dr. Chris Chute for another three-year term as TC 215 Chair, endorses recommendation. TC 215 instructs its Secretary to notify ISO Central Secretariat of this decision.  

Endorsement by Acclamation
64. Regarding Endorsement the JIC Chair—*Resolved that ISO/TC215*

TC 215, *noting* the TC 215 Chair’s appointment of Mr. Richard Dixon Hughes to be the independent Chair of the Joint Initiative Council (JIC) on this position rotating to TC 215 for 2 years from 2013-01-01.

Unanimous

65. Regarding Future Meetings—*Resolved that ISO/TC215*

TC 215 *notes* the following TC 215 meeting calendar:

<table>
<thead>
<tr>
<th>Days</th>
<th>Dates</th>
<th>Month</th>
<th>Location</th>
<th>Status / Comments</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>23-26</td>
<td>September</td>
<td>Vienna, Austria</td>
<td>Confirmed</td>
<td>Two day WG with ½ day Mini-Plenary</td>
</tr>
<tr>
<td>2013</td>
<td>21-26</td>
<td>April</td>
<td>Mexico</td>
<td>Invitation accepted, details forthcoming</td>
<td>Four day WG meeting with full day Plenary for a five total days</td>
</tr>
<tr>
<td>2013</td>
<td>TBD</td>
<td>2 or 3rd week Oct 2013</td>
<td>Sydney, Australia*</td>
<td>*Tentative</td>
<td>Two or Three day WG with ½ day Mini-Plenary</td>
</tr>
<tr>
<td>2014</td>
<td>TBD</td>
<td>April / May</td>
<td>Japan*</td>
<td>*Tentative</td>
<td>Four day WG meeting with full day Plenary for a five total days</td>
</tr>
<tr>
<td>2014</td>
<td>TBD</td>
<td>Sept / Oct</td>
<td>Berlin, Germany</td>
<td>Open</td>
<td>Two or Three day WG with ½ day Mini-Plenary</td>
</tr>
<tr>
<td>2015</td>
<td>TBD</td>
<td>April / May</td>
<td>OPEN – Host sought</td>
<td>Open</td>
<td>Two or Three day WG with ½ day Mini-Plenary</td>
</tr>
<tr>
<td>2015</td>
<td>Mid-August</td>
<td>August</td>
<td>Sao Paolo, Brazil*</td>
<td>*Tentative</td>
<td>Four day WG meeting with full day Plenary for a five total days</td>
</tr>
</tbody>
</table>

66. Appreciation: TC 215 WG 7 and WG 8 Chairs and Secretaries—*Resolved that ISO/TC215*

*Noting* that WG 7 and WG 8 will be disbanded under the TC 215 reorganization, TC 215 *expresses* its gratitude to Ms. Patty Krantz, WG 7 Chair, Mr. Joe Lewelling, WG 7 Secretary, Ms. Marian Lyver, WG 8 Chair, and Ms. Naomi Ryan, WG 8 Secretary, for their excellent leadership and guidance to the working groups over the years.

*
67. Appreciation: JIC Chair—Resolved that ISO/TC215

TC 215 expresses its gratitude and appreciation to Mr. Bron Kissler, JIC Chair, for his excellent leadership and guidance to the JIC.

68. Appreciation: Mary Lou Pelaprat, ISO Central Secretariat—Resolved that ISO/TC215

TC 215 expresses its gratitude and appreciation to Ms. Mary Lou Pelaprat, ISO Central Secretariat, for her support during this meeting and throughout the year to TC 215. Without her, the work of TC 215 would not progress as well as it does.

69. Appreciation: Meeting Host—Resolved that ISO/TC215

TC 215 expresses its appreciation to the Austrian Standards Association (OS) for hosting this meeting and the lovely cocktail reception on Monday evening. TC 215 especially thanks Mr. Martin Prager for his assistance in the planning of this meeting and all events.

70. Appreciation: TC 215 Chair and Secretary—Resolved that ISO/TC215

TC 215 expresses its gratitude to the TC 215 Chair, Mr. Chris Chute, and its Secretary, Ms. Lisa Spellman, for their excellent leadership and guidance during the meeting and throughout the year.

71. Remembrance

TC 215 expresses its condolences to the family of Ms. Alessandra Pastorino. Ms. Pastorino was a vital part of the TC 215 delegation and her expertise and kindness will be missed by all.