IT-014 Health Informatics Committee

Report

ISO/TC 215 Meeting – Sydney, Australia

21-25 October 2013

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Collated by: Standards Australia

With input from Australian Delegation:

- Richard Dixon Hughes (Head of Delegation)
- Michael Steine
- Alan Taylor
- Celine De Sousa (WG1 Secretariat)
- Kathy Dallest
- Peter Williams
- Stephen Chu
- Heather Grain
- Edmund Kienast
- Heather Leslie
- Cathy Richardson
- Anthony Maeder
- Tanya Wordsworth
- John Barned
- Andre de Wolf
## Contents

1. INTRODUCTION ........................................................................................................ 4
2. OBJECTIVES OF THE MEETING .................................................................................. 6
3. MEETING AGENDA ....................................................................................................... 8
4. RECOMMENDATIONS ARISING FROM THE MEETING ................................................ 9
5. FUNDING SOURCE SUMMARY ................................................................................... 15
6. ATTENDANCE ............................................................................................................... 16
7. POSITIONS HELD BY DELEGATES ............................................................................ 17
8. DETAILED REPORT ON ACTIVITIES ......................................................................... 19
   8.1 EXECUTIVE COUNCIL (EC) AND TECHNICAL COMMITTEE (TC) 215 GOVERNANCE .......... 19
   8.2 JOINT O&H / CAG 2/ CAG 3 COORDINATION MEETING ................................................... 20
   8.3 JOINT INITIATIVE COUNCIL EXECUTIVE ................................................................ 22
   8.4 JIC OPEN FORUM .................................................................................................. 22
9. OPENING PLENARY ..................................................................................................... 25
10. WG 1 ARCHITECTURE, FRAMEWORKS AND MODELS ............................................ 25
   10.1 BACKGROUND ........................................................................................................ 26
11. PUBLIC HEALTH TASK FORCE (PHTF) ................................................................. 43
   11.1 BACKGROUND ....................................................................................................... 43
   11.2 RECENT ACTIVITY ................................................................................................ 43
12. WG 2 SYSTEMS AND DEVICE INTEROPERABILITY .................................................. 45
   12.1 BACKGROUND ....................................................................................................... 45
   12.2 RECENT ACTIVITY ................................................................................................ 45
13. WG 3 SEMANTIC CONTENT ....................................................................................... 52
   13.1 BACKGROUND ....................................................................................................... 52
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
  - ISO/TC215 CAG1
  - ISO/TC215 CAG2
  - ISO/TC215 CAG3
- WG 1 Architecture Frameworks and Models [Secretariat: Australia]
- WG 2 Systems and Device Interoperability
- 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 Medicines Business
- JWG 7 (joint with IEC62A) Application of risk management for IT-networks incorporating medical devices
- Operations and Harmonization Committee – coordinates working group activity, secretariat processes and TC 215 work program.

The Working Group Meeting of ISO/TC 215 Health Informatics was held from 21 to 25 October in Sydney, Australia and was attended by 14 Australian delegates.

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 April/May) is known as the “Plenary Meeting” because it includes plenary sessions in which formal resolutions are taken in addition to meetings of TC 215’s five domain-specific working groups.

The second meeting, (in September/October) is the “Joint Working Group Meeting” because it mainly comprises meetings of the working groups but, in recent years, has also included a smaller “mini-plenary” to progress urgent matters.

The 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 Monday prior to the Opening Plenary) is provided in Appendix A.
4. RECOMMENDATIONS ARISING FROM THE MEETING

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

<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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</table>
| SKMT Harmonisation Proposals | IT-014 need to determine the process we should use to:  
• respond to requests for harmonisation both from an international perspective and as it might impact content of our own standards documents.  
• to represent proposals from IT14 document harmonisation projects | IT-014-02 to advise IT-014 |
| WG1- DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model | There has been significant contribution to the development of this Technical Report to date.  
**ACTION:** Encourage a broader range of Australian experts to provide feedback to the TR ballot. | IT-014 |
| WG1- DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model | DTR 14639-2 is of potential interest and use to Australian health care providers, non-government organizations, government providers of aid, and the private sector in Australia. Additionally throughout the Asia Pacific region DTR 14639 parts 1 and 2 could be of substantial interest. The  
**ACTION:** Following the publication of DTR 14639-2, Australia could consider strategies that will support the authors in making the both technical reports accessible to LMIC. | IT-014 |
| WG 1 Proposed NP TS 18528 – Functional Classification of Health Informatics Standards | 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.  
**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 e-health Architecture Framework, and the e-health Maturity Model Classification  
**ACTION:** Australia should participate by contributing terms and definitions from the e-Health Architecture Framework, and the e-Health Maturity Model Classification to SKMT. | IT-014-02 IT-014-09 |
| WG 1 CEN WG 1 TR Enterprise Architecture within healthcare | Issue: This work may be similar in nature to that which is being undertaken by IT-014-09, in conjunction with NEHTA re EHAF.  
**Action:** Australia should monitor and potentially actively contribute to this publication, given the recent experience current work in IT-014-09 with the eHealth Architecture Framework. | IT-014-09 |
<table>
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<tr>
<th>WG 1</th>
<th>ISO 13606 Electronic health record communication</th>
<th>This new revision of 13606 will create a significant opportunity to harmonise activity from a variety of projects and should be considered as a candidate for adoption by Australia and therefore should be monitored closely throughout all phases of development. 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 the proposed survey and all ISO 13606 documents.</th>
<th>IT-014-09</th>
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<tr>
<td>WG 1, WG 3</td>
<td>ISO/CD 13940 System of Concepts to Support Continuity of Care - CONTSYS</td>
<td>Action: Form joint group of Australian experts to review and contribute to CONTSYS ballot response and to ensure that the standard is capable of practical implementation, is firmly grounded in clinical practice and can be implemented in specifications and by grassroots vendors. Action: 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-014-12 IT-014-13 NEHTA</td>
</tr>
<tr>
<td>WG 1</td>
<td>NP Quality Metrics for Detailed Clinical Models</td>
<td>ACTION: Australia to actively participate and provide feedback to this new work item.</td>
<td>IT-014-09</td>
</tr>
<tr>
<td>NWIP - RE-USABLE COMPONENT STRATEGY FOR USE CASE DEVELOPMENT, ADAPTATION AND IMPLEMENTATION</td>
<td>This work is new and evolving, thus effectively a research project, however only targeting a Technical Report. ACTION: When voting for the NWIP Australia should consider whether this work item is an appropriate ISO activity or whether this should be better documented as an informative white paper about a specific project or academic publication.</td>
<td>IT-014-09</td>
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<tr>
<td>Public Health Taskforce (PHTF)</td>
<td>ACTION: Support work of PHTF to disseminate the standard and other products and ensure equitable availability to NMBs and others who have need for the guidance ACTION: Australia to actively participate in a possible Public Health/Research domain working group</td>
<td>IT-014</td>
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<td>Health informatics — Quality criteria for services and systems for telehealth</td>
<td>This item is out for ballot. When comments are received the Australian lead will provide comment disposition and revised text for an early publication.</td>
<td>IT-014-12 Chair to assist</td>
<td></td>
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<tr>
<td>DTR 28380 3 Health informatics, Messages &amp; communication – IHE Global Standards Adoption – Part 3: Deployment – Process</td>
<td>ISO/TR 28380-3 Health Informatics, Messages &amp; communication – IHE Global Standards Adoption – Part 3: Deployment – Process has been the subject of a DTR ballot. Comments have been collated and an amended draft will be prepared for publication. Action: Ensure that State and Territory CIO’s are aware of these publications when they are made available.</td>
<td>Department of Health State and Territory CIOs</td>
<td></td>
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<tr>
<td>WG 2</td>
<td>ISO/CD 17583 - Health informatics: Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange</td>
<td>Australia should contribute to second CD ballot.</td>
<td>IT-014 committees and secretariat</td>
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<tr>
<td>WG 2</td>
<td>ISO/DTR 19231, Health informatics, Survey of mHealth projects in low to middle income countries (LMIC)</td>
<td>Australia should request that ISO/TC215 working group chairs assign an experienced expert to mentor project leads of new proposals in order to obtain the best quality work items for publication.</td>
<td>IT-014 committees and secretariat</td>
</tr>
<tr>
<td>WG 2</td>
<td>12.2.10. ISO/TR 17522 provisions for health applications on smart/mobile devices</td>
<td>Australia should request that ISO/TC215 working group chairs assign an experienced expert to mentor project leads of new proposals in order to obtain the best quality work items for publication.</td>
<td>IT-014 committees and secretariat</td>
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<td>The draft technical report is coming from a low base. Considerable effort would be required to deal with the comments received by the project lead. However the report has a high potential value. <strong>ACTION:</strong> IT-014-12 and the delegation lead should discuss the value of Australian involvement.</td>
<td>Australian Head of Delegation, IT-014-12 Chair</td>
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<td><strong>Publications of TC 215 originating in WG3 - Australian consideration of adoption/adaption needs</strong></td>
<td>IT-014-02 to provide recommendations to IT-014 and prepare project documentation if required.</td>
</tr>
<tr>
<td>WG 3</td>
<td>12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems</td>
<td>This work item supports Australian as well as international quality of terms and definitions as well as term harmonisation and SKMT entries. It is already a work item for international oversight at IT-014-02.</td>
<td>IT-014-02 – already on international work program with Australian Lead</td>
</tr>
<tr>
<td>ISO TR 12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems</td>
<td>This work is seen as relevant to Australia both nationally and in local healthcare providers who need to be cognisant of and apply the principles included in this document.</td>
<td>IT-014-02 active international work item</td>
<td></td>
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<tr>
<td>ISO 17115 Vocabulary of terminological systems (Review)</td>
<td>Active participation will improve knowledge of these processes in Australia and ensure our requirements for terminological representation are consistently met.</td>
<td>IT-014-02 active work program</td>
<td></td>
</tr>
<tr>
<td>WG 3</td>
<td>Guidance for maintenance of object identifiers</td>
<td>The publication of the Sharing of OID Registry Information document is of value to Australia and should be reviewed, particularly by IT-014-06 and AIHW. In general the existing publication is likely to be sufficient to meet our needs. It is recommended, unless IT-014-06 or AIHW suggest otherwise and provide leadership, that this project be cancelled.</td>
<td>IT-014-06 AIHW</td>
</tr>
<tr>
<td>WG 3</td>
<td>SKMT governance representation</td>
<td>This work item supports Australian as well as international quality of terms and definitions as well as term harmonisation and SKMT entries. It is already a work item for international oversight at IT-014-02.</td>
<td>IT-014-02 – already on international work program with Australian Lead</td>
</tr>
<tr>
<td>WG 3</td>
<td>Categorial structure for the representation of physical external stimuli</td>
<td>This item can be reviewed and contributed to by IT-014-02, however additional input from physiotherapists, and other allied health professionals would be a significant advantage.</td>
<td>IT-014-02 to include on their international work program Standards Australia to seek input from relevant associations, if not at IT-014 level, then at this specific work item level.</td>
</tr>
<tr>
<td>WG 3</td>
<td>Categorial structures for terminological systems of human anatomy</td>
<td>It is recommended that this document be actively reviewed for ballot, and supported in Australia</td>
<td>IT-014-02 active work program</td>
</tr>
<tr>
<td>TDR 12300</td>
<td>Principles of mapping between terminological resources</td>
<td>This work item originated from Australian requests and is active in IT-014-02 international work program. This work item has been requested as a priority by Nehta staff.</td>
<td>IT-014-02 – already on work program and lead by Australia</td>
</tr>
<tr>
<td>WG 3</td>
<td>Guidelines for principles and desirable features of clinical decision support</td>
<td>Based upon initial Australian publication this has received considerable international interest.</td>
<td>IT-014-13 already on work program lead by Australia</td>
</tr>
<tr>
<td>System of Concepts to Support Continuity of Care</td>
<td>Australia provided input to this document, and we need to ensure that we monitor and review the updated documents.</td>
<td>IT-014-02 IT-014-06 IT-014-09 IT-014-12</td>
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<tr>
<td>Terminological resources Part 1 Characteristics</td>
<td>Active item for IT-014-02 contribution and review. To be included in the listed international work program for this group.</td>
<td>IT-014-02</td>
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<tr>
<td>Categorial structures of clinical findings in traditional medicine - part 1 traditional east Asian medicine</td>
<td>Input from Australian experts in this topic is to be encouraged and support of IT-014-02 to provide guidance on categorial structure and system requirements should be considered, though not core to IT-014-02 there are advantages to Australia in providing general support.</td>
<td>IT-014-02 oversight but not active contribution Coordination with Standards Australia’s Traditional Chinese Medicine Committee.</td>
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<tr>
<td>WG 3</td>
<td>ISO/AM 18104 Categorial structure for representation of nursing diagnosis and nursing actions in terminological systems</td>
<td>Circulate disposition of comments to nursing representatives for advice regarding adoption/adaption.</td>
<td>IT-014-02</td>
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<tr>
<td>Category</td>
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<td>Categorial structures for representation of acupuncture - part 1: acupuncture points</td>
<td>That these items be supported by Australia when voting is undertaken. That IT-014-02 and the SA Traditional Medicine Committee both provide oversight on the content.</td>
<td>IT-014-02 Standards Australia Traditional Medicine Committee.</td>
<td></td>
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<tr>
<td>WG 3</td>
<td>Semantic network framework and coding of traditional Chinese medicine language system</td>
<td>Input from Australian experts in this topic is to be encouraged and support of IT-014-02 to provide guidance on categorial structure and system requirements should be considered, though not core to IT-014-02 there are advantages to Australia in providing general support.</td>
<td>IT-014-02 oversight but not active contribution Coordination with Standards Australia's Traditional Chinese Medicine Committee.</td>
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<tr>
<td>WG 3</td>
<td>Categorial structures for representation of herbal medicaments in terminological systems</td>
<td>Include in list of international work items for active oversight.</td>
<td>IT-014-02</td>
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<tr>
<td>WG 4</td>
<td>17975: Health informatics – Principles and data structures for consent in the collection, use or disclosure of personal health information (WG4-N533)</td>
<td>Australia provide support to author Elaine Sawatsky.</td>
<td>IT-14-04 to support as it relates to privacy/confidentiality (Trish Williams)</td>
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<tr>
<td>ISO/DTS 17251</td>
<td>Business requirements for the exchange of structured dose instructions for medicinal products</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 IT-014-06-06 IT-014-13</td>
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<tr>
<td>WG 6</td>
<td>ISO 17253 Requirements for Electronic Prescriptions</td>
<td>This work item is relevant to ETP and medication management programs in Australia. IT-014-06-04, IT-014-06-06, IT-014-13, NEHTA and jurisdiction medication management programs to monitor and comments on the draft.</td>
<td>IT-014-06-04, IT-014-06-06, IT-014-13, NEHTA and jurisdiction medication management programs</td>
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<td>WG 6</td>
<td>NP 'Health informatics – Identification of Medicinal Products (IDMP) – Core Principles for Maintenance of Identifiers and Terms'</td>
<td>A NP Ballot for 'Health informatics – Identification of Medicinal Products (IDMP) – Core Principles for Maintenance of Identifiers and Terms' is to be held. Action: IT-14-06-04 and Department of Health to determine a position on the work item and decided whether to support, oppose or abstain from voting on the NP.</td>
<td>IT-014-06-04 Department of Health</td>
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</table>
Action: IT-14-06-04 and Department of Health to determine a position on the work item and decided whether to support, oppose or abstain from voting on the NP. |
| IEC 80001-1:2010 Application of risk management for IT-networks incorporating medical devices series of standards, IEC 62304 medical device software and IEC 82304 Healthcare software systems | These series of standards have a wide applicability to developers and users of medical devices and software in Australia.
Medical device software is becoming increasingly useful in mobile health device deployments and consumer settings.
It is important that the whole IT-14 community be understands the importance of these standards. |
| IT-014-06-04 Department of Health | IT-014 examine the range of IT-14 sub-committees that should provide input to and comment on these sets of standards. |
5. FUNDING SOURCE SUMMARY

In total, 14 Australians attended as representatives for the duration of this ISO/TC 215 meeting. The Department of Health funded the entire meeting. However, delegates were not funded to attend as this meeting was held in Australia.

The Australian delegation comprised:

- Richard Dixon Hughes (Head of Delegation)
- Michael Steine
- Alan Taylor
- Celine De Sousa (WG1 Secretariat)
- Kathy Dallest
- Peter Williams
- Stephen Chu
- Heather Grain
- Edmund Kienast
- Heather Leslie
- Cathy Richardson
- Anthony Maeder
- Tanya Wordsworth
- John Barned
- Andre de Wolf
6. ATTENDANCE

There were 14 Australians in attendance as representatives for the duration of this ISO/TC 215 meeting, as follows:

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<td>CR</td>
<td>AM</td>
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<tr>
<th>Meeting</th>
<th>Mon 21st</th>
<th>Tues 22nd</th>
<th>Wed 23rd</th>
<th>Thurs 24th</th>
<th>Fri 25th</th>
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<tbody>
<tr>
<td>WG 1 – Architecture, Frameworks and Models</td>
<td>HL</td>
<td>TW, AM, HL, AT</td>
<td>TW, HG, HL, AT</td>
<td>TW, AM, HL, AT</td>
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<td>WG 2 - Data Interchange</td>
<td>TW, AT, SC</td>
<td>AM, AT</td>
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<td>WG 3 - Semantic Content</td>
<td>HG, TW, CR</td>
<td>HG, TW, AM, CR</td>
<td>HG, TW, CR</td>
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<td>WG 4 - Security, Safety and Privacy</td>
<td>AW</td>
<td>AW</td>
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<td>WG 6 - Pharmacy and Medicines Business</td>
<td>MS, SC, JB</td>
<td>MS, SC, JB</td>
<td>JB</td>
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<td>JWG 7 Application of risk management for IT-networks incorporating medical devices</td>
<td>KD, AT, EK</td>
<td>KD, EK</td>
<td>KD, AM, AT, EK</td>
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<td>Traditional Medicine Taskforce</td>
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<td>JIC Executive</td>
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<td>JIC Open Forum</td>
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<td>Exec Council - invitation only</td>
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<td>CAG 1</td>
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<td>CAG 2</td>
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<td>CAG 3</td>
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<td>Operations Group</td>
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<tr>
<td>Business Organisation Task Force</td>
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<tr>
<td>Plenary</td>
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</tbody>
</table>

16
7. POSITIONS HELD BY DELEGATES

Some Australian delegates hold appointed positions at ISO/TC 215. 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 Force</td>
<td>Members</td>
<td>Appointed</td>
<td>Richard Dixon Hughes, Heather Grain</td>
</tr>
<tr>
<td>TC 215 – Task Force on project assessment &amp; prioritization criteria</td>
<td>Leader – Role incorporated into Ad Hoc on SBP</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>ISO/IEC JTC 1 Liaison to TC 215</td>
<td>Nominated JTC 1 Liaison Officer</td>
<td>Appointed by JTC 1</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>Joint Initiative Council (Executive Meetings)</td>
<td>Chair-elect (confirmed at this meeting)</td>
<td>Appointed by TC 215</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>TC 215 Ad Hoc on Business Strategic Plan</td>
<td>Co-Leader</td>
<td>Appointed</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>TC 215</td>
<td>SKMT advisor and support (WG3 representative)</td>
<td>Appointed</td>
<td>Heather Grain</td>
</tr>
<tr>
<td>WG 1 - Architecture, frameworks and models</td>
<td>Secretariat</td>
<td>Appointed</td>
<td>Standards Australia (IT-014 Program Manager) – Celine De Sousa</td>
</tr>
<tr>
<td>WG 1 - Architecture</td>
<td>National expert nominated to contribute to several work items including DCMs and EHR-S FM</td>
<td>Nominated expert</td>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>WG 1 - Architecture, frameworks and models</td>
<td>National expert nominated to contribute to Detailed Clinical Models processes; Expert contributing to Quality Metrics for Detailed Clinical Model, Alerts, ISO 13606 Review</td>
<td>Nominated expert</td>
<td>Heather Leslie</td>
</tr>
<tr>
<td>WG 3 – Semantic Content (Terminology)</td>
<td>Convenor</td>
<td>Elected</td>
<td>Heather Grain</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>Working Group or Committee</td>
<td>Position</td>
<td>Status</td>
<td>Person</td>
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</tr>
<tr>
<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>
</tr>
<tr>
<td>Traditional Medicine Task Force (TMFT)</td>
<td>ISO17583  - - “Health informatics – Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange”</td>
<td>National Expert</td>
<td>Australian national nominated expert</td>
</tr>
<tr>
<td>JWG 7 Application of risk management for IT-networks incorporating medical devices</td>
<td></td>
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</tbody>
</table>
8. DETAILED REPORT ON ACTIVITIES

8.1. Executive Council (EC) and Technical Committee (TC) 215 Governance

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
<th>Richard Dixon Hughes (Australian HoD)</th>
</tr>
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<tr>
<td></td>
<td>Heather Grain (Convenor WG3)</td>
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</table>

8.1.1. BACKGROUND

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

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

Within the proposed TC 215 structure the Executive Council will continue as a formally recognised advisory group, with the designation "CAG 1 Executive Council".

8.1.2. PROGRESS AT THIS MEETING

8.1.3. TC 215 ORGANISATION AND GOVERNANCE

8.1.3.1. 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).

8.1.3.2. Progress at this meeting

The Chair announced that discussions are ongoing regarding the recognition of standards and similar documentation produced by other SDOs which will reduce the need to re-publish through ISO processes. The current re-publication process generates issues of content ownership as well of timely publication and management.

Further work must be done to establish how the objectives might be met.

8.1.3.3. Key outcomes

8.1.3.4. Project Prioritization Task Group

8.1.3.5. Relevance to Australia

This activity is likely to lead to improved standards and improved availability. This process should be encouraged and watched.
8.1.4. FUTURE ISO/TC 215 MEETINGS

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>
</tr>
</thead>
<tbody>
<tr>
<td>Apr/May 2014</td>
<td>Japan – 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,</td>
<td>4 day WG plus full plenary (5 days)</td>
</tr>
</tbody>
</table>

8.2. JOINT O&H / CAG 2 / CAG 3 COORDINATION MEETING

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celine De Sousa (Secretariat WG 1)</td>
</tr>
<tr>
<td>Richard Dixon Hughes</td>
</tr>
<tr>
<td>Heather Grain (Convenor WG3)</td>
</tr>
</tbody>
</table>

8.2.1. 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.

8.2.2. PROGRESS AT THIS MEETING

8.2.2.1. SKMT Governance

The SKMT Governance Committee is a committee of the Joint Initiative Council which has been established to:

- manage SKMT governance
- establish and process term/definition harmonisation proposals
- other requirements related to SKMT that are asked of it by the JIC.
The SKMT Governance Committee has now had 5 meetings and members provide representation for:

- ISO TC215
- HL7
- GS1
- IHE
- IHTSDO
- CEN
- CDisk

The following activities are being undertaken as a first priority:

- Identification of internal processes for content maintenance and management. IHE in particular is considering improved automated methods and tools for content management.

- Three trial harmonisation proposals have been provided to allow each organisation to develop and test processes for:
  
  o Terms with single definitions which require only acceptance, review to meet quality definition requirements
  
  o Family of term definition harmonisation – single work item. This is where a single existing work item (eg professionals and providers – the terms and definitions in this area are being undertaken through the ‘System of Concepts for Continuity of Care – ContSys) is already covering the content of the harmonisation proposal.
  
  o Family of term definition harmonisation - general – which covers broad scope and is of interest to all parties not covered by existing work item (e.g. Health records).

- It was recommended that the CAG 02 consider the following mechanisms to provide comments to harmonisation proposals back to the SKMT governance committee:
  
  o Terms with single definitions – returned to the relevant committee to provide comments (in this case to pharmacy)
  
  o Family of term definition (single work item) – suggest that the test harmonisation proposal be considered as part of the relevant work item
  
  o CAG 02 determine the scope of distribution of the proposal – but it is suggested that the proposal be circulated to National Member Bodies and WG members to solicit comments.

WG3 will provide a single page set of guidelines for comments.

8.2.3. WORK PROCESSES AND THE ECOMMITTEE SYSTEM

8.2.3.1. 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.

<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>SKMT Harmonisation Proposals</td>
<td>IT-014 need to determine the process we should use to:</td>
<td>IT-014-02 to advise IT-014</td>
</tr>
<tr>
<td></td>
<td>• respond to requests for harmonisation both from an international perspective and as it might impact content of our own standards documents.</td>
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<td></td>
<td>• to represent proposals from IT14 document harmonisation projects</td>
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</table>

8.2.3.2. Progress at this meeting

8.3. JOINT INITIATIVE COUNCIL EXECUTIVE

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
<th>Richard Dixon Hughes</th>
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</thead>
</table>

8.3.1. 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/.

8.3.2. PROGRESS AT THIS MEETING

8.3.3. RELATIONSHIP BETWEEN JIC AND ISO/TC 215

8.4. JIC OPEN FORUM
8.4.1. 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. (From HL)

8.4.2. ACTIVITY AT THE MEETING

Project updates on:

- EHR Functional Model
- Multiple NMBs offering translations – some exist for R1 and others proposed for R2
- ISO DTS 18530 Automatic ID and data capture marking and labelling
- Should be ready for publication, in editorial review process at ISO CS since early August 2013
- DIN raised a claim against the focus on GS1.
- ISO 14199 BRIDG
  Passed, as of today. 8 for, 3 against, 16 abstentions. Those who voted negatively still thought the standard had market relevance
- ISO PWI Clinical Trials – Registration and Reporting
- Planned as a NWIP post BRIDG
- ISO DTS 13972 Detailed Clinical models
  8 in favour, 4 in favour with comments, 2 disapproval with comments (willing to change to positive if comments resolved), 14 abstentions
- ISO DIS 13949 CONSYS
  DIS approved – 17 in favour; 4 disapprove – AU, DK, UK, US but supportive of the project
  Confusion re comments submitted from US, combined with HL7 comments. Needs further coordination to explore clear commenting from SDOs vs NMBs
- ISO DTS xxxx Health Informatics Standards Functional Classification
- SKMT Governance committee has been appointed, undergoing consolidation re processes/methodology – intent for term harmonisation

Potential new work items proposed:

- Dipak Kalra raised issue for ISO/EN 13606 EHR Communication
  - Originally 13606 work was intended to be aligned from ODP point of view. Not looking for procedural method to achieve it, but a ‘hearts and minds’ engagement esp those who are not using 13606 eg EHR FM, Structured document template development, archetypes/templates, CDA alignment
  - RDH – already a joint ballot with CEN, so should be on the JIC agenda
- Mike Nusbaum - IHE Int and HL7 Int have reconfirmed MOU
  - Activities with PHTF profiles
  - Pseudonymisation
- LMIC update
Recommendations from the PHTF Report and discussions with IMIA, JIC

- IMIA has agreed to take on education/training and curriculum development for LMICs
- Next step to be a focus on priorities and action plan around building leadership and technical capacity in LMICs for eHealth, with key word being ACTION.
9. OPENING PLENARY

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
<th>Richard Dixon Hughes (Head of Delegation)</th>
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<tr>
<td>Celine De Sousa (WG 1 secretariat)</td>
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The opening plenary is open to all members of national delegations and liaison representatives and is the official commencement of the standards development activities.

The delegates were welcomed to Australia by Mr Adrian O’Connell, General Manager Operations of Standards Australia, which were the Host of the TC215 Sydney meeting. Mr Paul Madden Deputy Secretary and Chief Information and Knowledge Officer from the Commonwealth Department of Health who were the sponsors of the event also welcomed the delegates followed by a warm welcome by the Australian Head of Delegation, Richard Dixon-Hughes.

The TC 215 Secretary, Lisa Spellman did a roll call of member nations and liaisons present. Attendance was noted from 16 P-members: Australia, Brazil, Canada, China, Denmark, Finland, Germany, Italy, Japan, Republic of Korea, Malaysia, Mexico, The Netherlands, Sweden, Switzerland, United Kingdom of Great Britain, United States of America.

The secretary also reminded participants to check with the WG secretary or convenor this week to make sure that they are listed on the member list for their WG. The secretariat cannot add experts and delegates, only their national member body can do this. Please contact Lisa with any questions.
10. WG 1 ARCHITECTURE, FRAMEWORKS AND MODELS

<table>
<thead>
<tr>
<th>Australian Delegate Attendance</th>
<th>Richard Dixon Hughes (Head of Delegation)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Celine De Sousa (WG 1 secretariat)</td>
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<tr>
<td></td>
<td>Heather Leslie</td>
</tr>
<tr>
<td></td>
<td>Catherine Richardson</td>
</tr>
<tr>
<td></td>
<td>Kathy Dalleet</td>
</tr>
<tr>
<td></td>
<td>Tanya Wordsworth</td>
</tr>
<tr>
<td></td>
<td>Alan Taylor</td>
</tr>
<tr>
<td></td>
<td>Larry Singer</td>
</tr>
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<td></td>
<td>Peter MacIsaac</td>
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10.1. BACKGROUND

Working Group 1 covers “Standardization of frameworks, architectures, and their components in support of health and healthcare, including standardization of conceptual, logical, and function requirements, process models and information models.”

Dr Stephen Kay (UK) is the WG Convenor, Beatriz DeFaria Leao (Brazil) is WG Vice Convenor and Celine De Sousa (Standards Australia) is providing Secretariat services.

In addition, in attendance were:

- Stan Huff, leader of the Clinical Information Modelling Initiative, participated in the 13606 revision workshop
- Peter Williams, very first convenor of WG1 in attendance

10.1.1. Published/In Publication Standards

ISO TS 13972 Health Informatics – Characteristics and Processes of Detailed Clinical Models was approved at this meeting and is to be sent for publication, following final inclusion of comment resolutions.

10.1.2. Cancelled projects

None.

10.1.3. Work items in progress

Three work items were discussed in detail during this meeting.

- ISO IS 13606 - all 5 parts are under revision and targeting publication as a full international standard
- Closure activity – sunsetting of the PHTF task force

10.1.3.1. In ballot (and not able to be discussed in detail)
Short reports on 3 work items were provided, but were not discussed in detail due them being in mid-ballot

- ISO TR 14639-2 – Health Informatics - Capacity-based ehealth architecture roadmap Part 2 – architectural components & maturity mode

10.1.4. PROGRESS AT THIS MEETING

The Working Group was well attended by 46 attendees from 14 National Member Bodies.

10.1.4.1. New work item proposals

Two new work items were proposed and accepted by Working Group for future work:

- Reusable component strategy for use case Development
- Quality Metrics for Detailed Clinical Models

10.1.5. CONVERGENCE OF 13606, CONTSYS AND HISA

A CEN group has met on three occasions to consider harmonisation and convergence between the following 3 standards:

- ISO 13606 Health informatics -- Electronic health record communication – Parts 1 to 5
- ISO/CD 13940 System of concepts to support continuity of care (ContSys)
- ISO 12967 Health informatics -- Service architecture -- Parts 1 to 3

The first meeting in July 2012 established a basic and shared understanding amongst the group of all 3 standards and to consider how people use all three specifications together.

The second meeting in March 2013 developed a formalised template for concurrent use. A report from this meeting can be found at http://www.standard.no/Global/PDF/Helse/CEN-TC251_N2013028_N13-028_WG1_report_of_the_2nd_Madrid_Work.pdf.

The third and most recent meeting was held in August 2013 and created an outcome framework – the report is not yet available.

The group is planning to meet in early 2014 in conjunction with SemanticHealthNet.

An animated explanation about Concurrent Use of 13606, ContSys and HISA has been developed and published on YouTube - http://youtu.be/pLfQGhw5uf8

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

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

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

Leadership has been provided by the Primary Health Task Force.

10.1.6.2. Progress to date

This Technical Report was on the verge of completion but was deregistered when the time for completion expired. At the last meeting in Mexico it was reinstated and final changes incorporated.

It was sent out for CD ballot on October 1, 2013 and the ballot is due for completion of March 1, 2014.

There has been considerable discussion about the barriers for access by Low to Medium Income Countries to both parts of the TR 14639. ISO has not been able to support making these standards available for free to countries who are not easily able to access this report as it requires modification to policy about its business plan.

10.1.6.3. Proposed next steps

Awaiting ballot completion and resolution of comments.

10.1.6.4. Relevance to Australia

<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>WG1- DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model</td>
<td>There has been significant contribution to the development of this Technical Report to date. &lt;br&gt;&lt;br&gt; <strong>ACTION:</strong> Encourage a broader range of Australian experts to provide feedback to the TR ballot.</td>
<td>IT-014</td>
</tr>
<tr>
<td>WG1- DTR 14639-2 Health informatics — Capacity-based ehealth architecture roadmap — Part 2: Architectural components and maturity model</td>
<td>DTR 14639-2 is of potential interest and use to Australian health care providers, non-government organizations, government providers of aid, and the private sector in Australia. Additionally throughout the Asia Pacific region DTR 14639 parts 1 and 2 could be of substantial interest. The &lt;br&gt;&lt;br&gt; <strong>ACTION:</strong> Following the publication of DTR 14639-2, Australia could consider strategies that will support the authors in making the both technical reports accessible to LMIC.</td>
<td>IT-014</td>
</tr>
</tbody>
</table>
10.1.7. ISO TS 18528 FUNCTIONAL CLASSIFICATION OF HEALTH INFORMATICS STANDARDS

10.1.7.1. Introduction

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

The proposed TS 18528 – Functional Classification of Health Informatics Standards provides the basis for refinement of the system of classification that has been used with the SKMT. This work item is an extension of the previous TR 13054 (Knowledge management of health informatics standards) and development of the SKMT tool, which included significant Australian input. The SKMT has begun to be populated. New standards need to reference and use this tool.

The project leaders and primary authors are Heather Grain (Australia) and Andrew Grant (Canada).

It is intended that this Technical Specification will support reliable detection of pertinent documents and standards by non-expert users and support inter-disciplinary dialogue for harmonisation and analysis.

10.1.7.2. Progress to date

The major progress that has happened since the Mexico meeting is that a process for SKMT Governance has been put in place, commencing with a Governance Committee representing a range of SDOs - ISO TC 215, GS1, CEN 251, CDISC, IHTSDO, IHE and HL7. An approach has also been designed for harmonisation of existing SKMT and new health informatics terms which is being tested and refined with the Governance Committee members.

10.1.7.3. Proposed future work

This item is approved as a Technical Specification. At present the work informing the specification is being undertaken. This will need to be documented and brought back for approval. Timelines are unclear at this point.

Proposed work includes research into strategies for publication of available standards with SDOs and using the approach outlined above for the next 3-6 months to gather practical experience in harmonising terms using one identified community, using the expert group to analyse and consult more broadly, and then to take this refined approach forward to other ISO communities.

10.1.7.4. 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.
10.1.8. REPORT: CEN WG1 - TR ENTERPRISE ARCHITECTURE WITHIN HEALTHCARE

10.1.8.1. Introduction

A report was provided by Frederik Endsleff (Denmark) on a CEN-led effort to develop an analysis of how standards can work together to support enterprise architecture within a healthcare context. Currently this work item is an evolving TR, primed by the Danish Capital Region experience, investigating how EAs are used in the health domain, documenting what lessons can be learned, and what a comprehensive ‘health platform’ should be able to support. It includes case studies from Denmark and Italy.

10.1.8.2. Progress to date

It was reported that there has been little progress since the last report in September 2012. At that stage the document was 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 how they relate to each other within a health EA context. The intent is explicitly not to create a new EA.

10.1.8.3. Relevance to Australia

Australia should keep a watching brief on this CEN TR.
10.1.9. ISO TS 13972 – CHARACTERISTICS AND PROCESSES OF DETAILED CLINICAL MODELS

10.1.9.1. Introduction

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

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

Work commenced on the project in 2008, with the original aim of producing a two-part international standard. The work item has had a tortuous gestation, including:

- Despite receiving a positive outcome at CD ballot, at the May 2012 ISO meeting, in the interest of consensus building, the project leader agreed to move the document back from an International Standard to a Technical Specification.
- A consequence of changing the final publication format from IS to TS means that ISO TS 13972 is no longer being developed under auspice of the Vienna agreement.
- The revised DTS 13972 was extensively reformatted following remerging from two separate documents and additional content regarding alignment with ISO 9000 processes was included.
- The revised document was submitted to DTS ballot which resulted in its being passed in early 2013 but with six negative votes and around 150 comments. Australia supported the main thrust of the revision (from the previous DIS) and did not oppose the introduction of material related to ISO 9000 but was among those that voted negatively.

10.1.9.2. Progress to date

Following the Mexico meeting the DTS was sent for second DTS ballot. This ballot only allowed comment on the changes that were incorporated or initiated at the Mexico meeting.

The DTS technically passed the ballot with no substantive comments.

During the meeting there was discussion and resolutions made for all of the unresolved comments.

The Working Group resolved that after the disposition comments and addition of a compliance clause, the DTS be submitted for publication, anticipated in early 2014.

10.1.9.3. Relevance to Australia

Australian experts have actively contributed to this specification because of experience and active information modelling that has been conducted by NEHTA, contributing to the PCEHR, and for clinical system development by the Northern Territory Department of Health. The intent was to try to ensure that the Australian expertise and experience was reflected in the final specification.

The resulting specification that will now be published has not been the result of a systematic enquiry of international best practice, nor is there evidence of the methodology by which the specification was developed, for example, an environmental scan. It has not
been easy for the Australian experts to contribute to building an international publication that positively incorporates local expertise and experience. Unfortunately the Australian experts have been forced into the unsatisfactory position of having to consistently vote negatively and contribute significant editorial and whole of document feedback to each document draft.

It has been the Australian expert position for some years that the first publication for this knowledge domain would be better targeted as a Technical Report. The Australian position, along with a number of national member bodies with direct experience in building DCMs was part of the reason that the original International Standard was downgraded to an International Specification, and while there was considerable NMB pressure to target a Technical Report, this was not supported by the majority of NMBs.

It remains the opinion of the Australian experts that while the document to be published is helpful, primarily as an informative document identifying useful principles, the content is not evidence-based, consensus-based or inclusive enough to warrant status as an International Specification, despite the inclusion of normative statements. It is anticipated that in years to come, a revision of this work item should be able to draw on a more mature knowledge domain and more opportunities for establishment of a consensus approach to the design, development, maintenance and governance of detailed clinical models.

10.1.10. Revision of ISO EN 13606 Electronic Health Record Extract – Parts 1-5

10.1.10.1. Introduction

Professor Dipak Kalra is leading this revision work item.

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

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

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

The scope of each of the five parts will not be changed. Even though the five parts were originally achieved separately, between 2007 and 2010, the intent is that they 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 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, CIMI, ISO 21090, ISO 10781, ISO 18308, ISO DTS 13972, ContSys and HISA.

10.1.10.2. Progress to date

In June 2013 a questionnaire was sent to NMBs about use of 13606. There were 20 responses from 12 countries, including input from industry, healthcare, university sectors, ministry and the EN 13606 Association. The level of detail in responses varied considerably and many described why 13606 was not in use.

It was noted by Prof. Kalra that most NMBs did not have a dissemination channel to sound out who may have used 13606. The responders were mostly part of the ‘friends and families’ of 13606 and thus ‘like-minded’. He raised the issue that it is difficult for ISO or other SDOs to have information about the uptake and use of published standards.

Findings from the Questionnaire included:

- Uncontroversial Recommendation – to include a Normative XML schema in the revision
- Controversial – the RecordComponent hierarchy – views that it was too strict or needed further constraint.
- There was a steep learning curve in order to successfully use a generic information model – a need was identified for more guidance and worked examples
- Overwhelmingly, main reason for non-use is prior decision to use CDA
- Suggestions:
  o RM should be radically simplified (or produce a lightweight version for easy early adoption) for key use cases, and offer an enrichment pathway for downstream use
  o Support queries
  o Facilitate mapping to CDA and openEHR
  o Clearer guidance re distributed versioning
  o Workflow management to support cross-enterprise communication
  o Generic entry is generally supported
- Desire to understand how to work with:
  o Existing Projects – eg epSOS
  o Other Technology – eg IHE XDS registry/repository

10.1.10.3. Proposed future work

Key Work Items identified during the workshop discussion:

- Identify Modelling patterns – Stan Huff (US, CIMI)/Nicolas Oughtibridge UK, ContSys)/Heather Leslie (Australia, openEHR)
- Identification of models – needs further refinement, including input from recent openEHR research
• Explore harmonisation with ISO 21090 data types – consider the proposal to constrain the data types down to those relevant for use in an EHR, then further constrain to remove data types that would be represented by a reference model.
• Consider revision of the EHR component hierarchy

10.1.10.4. 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 at this point, 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.

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<th>Topic</th>
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<tr>
<td>WG 1</td>
<td>ISO 13606 Electronic health record communication</td>
<td>This new revision of 13606 will create a significant opportunity to harmonise activity from a variety of projects and should be considered as a candidate for adoption by Australia and therefore should be monitored closely throughout all phases of development. 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 the proposed survey and all ISO 13606 documents.</td>
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10.1.11. ISO/CD 13940 SYSTEM OF CONCEPTS TO SUPPORT CONTINUITY OF CARE (CONT SYS)

10.1.11.1. Introduction

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

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

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 intent is to describe how healthcare is delivered, rather than define the informatics, and to provide an overarching view of healthcare from which component such as clinical models, formal logical models and an implementable platform will work and be coherent to achieve interoperability.

ContSys is an approved project on the JIC joint work program, recognising its important role as a foundation international standard naming many of the main concepts in the healthcare domain and identifying the relationships between them. As such, it is a framework on which many other standards, terms and definitions should be based – and it is important that it be correct and truly international in its application.
The goal is to try to achieve the review of ContSys within a 2 year ballot cycle focusing on the processes and requirements for the representation of semantic content, but not on the content of systems which do so.

10.1.11.2. Progress to date

The latest DIS ballot closed on 14 May, 2013 and was approved. Australia was one of four NMBs to vote negatively, along with Denmark, UK and US, yet all were still supportive in principle of the project. There were 494 comments received.

As a result of disposition of comments, there are some significant changes with only four concepts untouched. Two concepts were deleted and there were 131 concepts with changes (including the addition of 14 new concepts).

Key themes identified in the comments:

- Need for initial and ongoing harmonisation of terms with SKMT
- Need for harmonisation with a logical model such as 13606 or HL7. The decision has been made that there will be no activity in this area as ContSys is not intended to be directly translated into models but to represent concepts in healthcare.
- Tone of the document needed to be rephrased to be informative rather than normative.
- Document reorganised to reduce the introduction and move previous extra material to an Annex.

10.1.11.3. Proposed future work

The current document, updated to include changes resulting from ballot comments, and reflects the team’s latest agreed text. It has been noted that there may be inconsistencies in definitions and UML modelling, and between document and diagrams, which need further review.

The team are confident there will be a final draft document ready for next step in January, 2014. Options initially considered were to re-ballot DIS or move forward with FDIS ballot.

10.1.11.4. Relevance to Australia

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

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

It appears that there is pushback from the ContSys team that the intent is not to support direct implementation in systems, however if this is not the case, then this work runs the risk of being purely academic and not useable within electronic health records.
### 10.1.12. NP - QUALITY METRICS FOR DETAILED CLINICAL MODELS

#### 10.1.12.1. Introduction

Commencement of this work item is dependent on the completion of the ISO TS 13972 specification on detailed clinical models. It will build on the principles identified in 13972 by identifying how DCMs can be validated as quality models.

The proposal was accepted at the Vienna meeting Sep 2012 and a draft document was circulated in April 2013 for comment.

#### 10.1.12.2. Progress to date

To date, 13 metrics have been identified. A possible pattern for a metric includes a definition, an evaluation target, an evaluation method and an evaluation result. Consideration will be given to transforming principles identified in TS 13972 into 1:n concrete measures.

Feedback from 13972 experts included:

- Make it more simple and easy to use
- Scoring needs to be unambiguous – for example, pass or fail
- Removed: the discussion about quality theory
- Included: Introduction on ‘Purpose of quality measurement of DCM’

To date, this work has been guided by Stan Huff (USA, CIMI), Dipak Kalra (UK, 13606), Heather Leslie (Australia, openEHR) and William Goossens (Netherlands, DCMs).

#### 10.1.12.3. Proposed future work

Next steps include alignment with the final published version of ISO TS 13972 followed by distribution to the WG experts in November, 2013 and CIMI experts in January, 2014.

#### 10.1.12.4. Relevance to Australia

Australian experts have provided significant feedback to the development of the ISO TS 13972 work and it makes sense to continue this involvement. Experience from development of clinical information models in the NEHTA CKM has already been contributed to this specification. It is definitely in Australian’s interest to continue to participate and provide feedback, ensuring that Australian processes are included and best practice learnings from

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<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
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<tr>
<td>WG 1, WG 3</td>
<td>Action: Form joint group of Australian experts to review and contribute to CONTSYS ballot response and to ensure that the standard is capable of practical implementation, is firmly grounded in clinical practice and can be implemented in specifications and by grassroots vendors. Action: 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-014-12 IT-014-13 NEHTA</td>
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international collaboration implemented in the NEHTA CKM. In many ways there is more potential for this work to be more valuable than the 13972 publication as the scope will be clearer and outcomes will be less ambiguous.

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<tr>
<td>WG 1 NP Quality Metrics for Detailed Clinical Models</td>
<td>ACTION: Australia to actively participate and provide feedback to this new work item.</td>
<td>IT-014-09</td>
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10.1.13. ISO DIS 16527 PHR SYSTEM FUNCTIONAL MODEL (PHRS-FM)

10.1.13.1. Introduction

This project was presented by Gary Dickinson.

In a similar way to the EHRS 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.

10.1.13.2. Progress to date

As a ballot is currently underway this work item could not be discussed in detail.

Ballot Status:
- The 2nd HL7 ballot was completed in September and reconciliation is underway, similarly targeting corrections and clarification and no substantive changes.
- Joint ISO ballot also underway

There are currently no functional profiles either planned or in progress.

10.1.13.3. Proposed future work

Awaiting results of Joint ballot.

10.1.13.4. Relevance to Australia

Australian experts are maintaining a watching brief and participating when possible, mainly through HL7.

10.1.14. ISO DIS 10781-EHRS FM R2

10.1.14.1. Introduction

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

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

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

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

10.1.14.2. Progress to date

As a ballot is currently underway this work item could not be discussed in detail.

Ballot Status:

- The 2nd HL7 ballot was completed in May and reconciled in July. It was balloted targeting only corrections and clarifications, aiming for no substantive changes.
- A joint JIC ballot (2nd DIS) is currently underway. The ballot opened on October 3 and will close on December 3, 2013.

It was also noted that there had been development of tooling support. A Phase 1 development was complete and Phase 2 had been contracted and was in progress, which would enable the creation and maintenance of Functional Profiles.

There are currently 16 functional profiles either planned or in progress.

10.1.14.3. Proposed future work

Awaiting results of Joint ballot.

10.1.14.4. Relevance to Australia

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

10.1.15. ALERTS - POTENTIAL NP ON HEALTH INFORMATICS - ALERT INFORMATION FOR RISK MANAGEMENT AND ISO/PWI TR 14668 GUIDELINES FOR PRINCIPLES AND DESIRABLE FEATURES OF CLINICAL DECISION SUPPORT SYSTEMS


**10.1.15.1. Introduction**

Dr Rikard Lövström (Sweden) presented about this proposed work item on alerts. He has presented it on at least two other occasions, at the Rotterdam and Kuopio meetings. There appears to have been little progress.

There were at least four working groups present during this report, indicating the wide impact of alerts within the domain of health informatics.

There was not a lot of support for the general notion of the proposal as presented. The potential breadth and depth of the subject, need to understand alerts within a given context, and potential implications in all working groups present is indicative that the approach proposed was too general and needed to target some specific issues in a coordinated method.

Concern was also expressed about the potential published output – is it a visual alert indicator, a classification, a report, or a profile? What is the scope - drug-drug interaction vs public health alert vs device related alert?

The general meeting consensus was that work needed to be done in order to identify specific components that could be proposed as work items

An advisory group of volunteers was formed to support Rikard further exploring how to progress this potentially important work

Heather Leslie (Australia) volunteered as a member of the advisory group.

**10.1.16. NEW WORK ITEM: RE-USABLE COMPONENT STRATEGY FOR USE CASE DEVELOPMENT, ADAPTATION AND IMPLEMENTATION**

**10.1.16.1. Introduction**

This new work item proposal, targeting a Technical Report, was presented by Gary Dickinson (US) and offers a methodology for Use Case development and implementation, building from a common repository of re-usable core components. Core components are Requirements, Events, Actions, Actors, Roles and Data Objects, that:

- Are found in common across Use Cases, Scenarios and Events;
- Might be re-used in a new Use Case Scenario.

It is based on the US S&I Initiatives and originates from the S&I Simplification Working Group - [http://wiki.siframework.org/Cross+Initiative++S%26I+Simplification+WG](http://wiki.siframework.org/Cross+Initiative++S%26I+Simplification+WG)

The key objectives are:

- To identify a set of Core Components broadly applicable to – and re-usuable in subsequent specification of – Use Cases
- To establish/maintain a Core Component Registry
- To allow each Use Case Initiative to select (re-use) Core Components applicable to their needs or create anew
- To identify new Core Components candidates as each Use Case Initiative reaches consensus
• To identify Implementable Data and Software Constructs fulfilling Core Component requirements

The proposal reflects work done to distil use case components from existing S&I initiatives – currently there are 16 use cases that have been created comprising 36 multi-step scenarios.

10.1.16.2. Progress to date

A framework for Use Case Development has been designed and considerable work has been completed to establish a core Matrix for core components of 16 use cases and register these within the US Health Information Knowledgebase (USHIK).

There is also some work under way to develop tooling to support the methodology.

10.1.16.3. Relevance to Australia

This work item is symptomatic of a current trend within ISO to publish work that could quite rightly not belong as part of the standards process. This work is documenting a methodology to achieve an identified end. However the question has to be asked whether this actually belongs within the ISO framework. As an informative Technical Report, it could equally be published and valued as a white paper or academic publication. The notion of re-usability is appealing and resonates with the work recently completed around detailed clinical models, but there is no other work of a similar nature that has been identified and so the actual standardisation component is not clear – it is just documenting how one group approaches this issue of re-use of Use Cases.

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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>NWIP - RE-USABLE COMPONENT STRATEGY FOR USE CASE DEVELOPMENT, ADAPTATION AND IMPLEMENTATION</td>
<td>This work is new and evolving, thus effectively a research project, however only targeting a Technical Report. <strong>ACTION:</strong> When voting for the NWIP Australia should consider whether this work item is an appropriate ISO activity or whether this should be better documented as an informative white paper about a specific project or academic publication.</td>
<td>IT-014-09</td>
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10.1.17. REPORT: ISO/TR 17791. PATIENT SAFETY

An update on eSafety standards was presented by Don Newsham and Grant Gillis (Canada).

Ballot comments were received and dispositioned post-Mexico and a final version for publication was sent to ISO TC 215 Secretariat by August 30. Publication expected in November/December

In Canada, COACH will publish the inaugural edition of eSafety Guidelines on November 5. This will include:
• Robust elaboration of safety principles
• Best practices based method leveraging international standards
• Two case studies to profile application
• Trial implementation completed with 8 organisations

Future Considerations:
• Monitoring and Reporting Standardisation
  o Opportunity to consider an international effort on defining data values and sets for eHealth factors/formats in safety-related incidents (adverse events, near-misses and unsafe conditions etc)
  o A number of current national examples on patient safety data reporting:
    • Canada (CIHI) Canadian Medication Incident Reporting system) has a contributing factors approach
    • USA (AHRQ) has common data formats approach
• An international data standard, given the increasing global market of HI solutions, would allow for global eSafety reporting analysis and reporting with such results as:
  o Greater opportunities for reporting and sharing
  o Wider opportunities for analysis and comparison, and
  o More rapid diagnosis and resolution of IT-related safety issues
• Path forward on eSafety factor/format data values and sets and associated analysis and reporting standard
  o Identify interested experts to work with Canada
  o Multiple working groups
  o Dialogue on value proposition, scope and components
  o Build consensus towards a draft NP for formal consideration in Japan.

Further discussion included:
• Suggestion re liaison in TC 210 re adverse event reporting from devices

A group volunteered to participate including 4 Australians experts. In addition Australian input related to the standardisation of date values and sets related to adverse events is also to be considered.

10.1.18. REPORT: QUALITY REPORTING PUBLIC HEALTH

An introduction to an IHE initiative about the Quality Reporting and Public Health domain was presented by Lori Reed-Forquet.

Initially formed in 2007, it is intending to address information exchange and EHR content standards necessary to share information relevant to quality improvement in patient care, clinical research and public eHealth monitoring, particularly related to repurposing clinical data for these ‘secondary’ uses.

Examples of profile supplements that have been published include:

• Newborn Admission Notification Information (NANI) - describes the content needed to communicate a timely newborn admission notification to public health
• Vital Records Death Reporting (VRDR) - defines a Retrieve Form for Data Capture (RFD) content profile that will specify derivation of source content from a medical summary document, by defining requirements for form filler content and form manager handling of the content.
• Birth and Fetal Death Reporting (BFDR) - describes the content and format to be used within the pre-population data part of the Retrieve Form Request transaction from the RFD.
• Early Hearing Care Plan (EHCP) - assists with the early detection, documentation of and intervention for hearing loss by enabling electronic communication of care plan content and instructions as part of the Public Health Early Hearing Detection and Intervention (EHDI) Program.
• Physician Reporting to a Public Health Repository-Cancer Registry (PRPH-Ca) - defines the data elements to be retrieved from the EMR and transmitted to the cancer registry or to a healthcare provider.

• Healthy Weight (HW) - captures and communicates information for managing and monitoring healthy weight among clinical and public health surveillance systems.

Attendees were encouraged to participate in the QRPH activity by becoming an IHE International member and participating in the domain committee work, or by non-members participating in the comment period.

Further details can be found at: www.ihe.net/Quality_Research_And_Public_Health/
11. PUBLIC HEALTH TASK FORCE (PHTF)

| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation)  
|                              | Heather Leslie  
|                              | Peter Macisaac  
|                              | Alan Taylor  
|                              | Anthony Maeder  
|                              | Larry Singer |

11.1. 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.

Following the Mexico meeting the PHTF was advised that it was not possible to make ISO TRs 14639-1 and 14639-2 available to LMIC for free. It was suggested that the PHTF create a brochure and associated white paper as a means to promote the TRs through NMBs and other organisations.

In addition, a document was prepared by Gunnar Klein, entitled Global Access to Health Standards, on behalf of the PHTF and distributed to WG1. In this document, it was proposed that ISO should approach a donor community in co-operation with WHO to investigate the feasibility of obtaining yearly resources to ‘buy’ the 14639 reports from ISO to allow free global access.

11.2. RECENT ACTIVITY

11.2.1. Current publications

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

11.2.2. Current work items
11.2.3. PROGRESS AT THIS MEETING

Current Chair of ISO TC215, Chris Chute attended the working group meeting. He stated that he had been instructed by ISO that the proposal from PHTF as articulated in Gunnar Klein’s document was not possible and should not be raised further as discussion on the ISO Business plan ‘is out of scope’.

As soon as the final report has been delivered, the PHTF will be ‘sunsetted’.

Discussion followed regarding:

- Any new adhoc group looking to marketing and dissemination of our services to the broader community - perhaps reporting to CAG1
- LMIC and promotion of standards by different business model – to be considered how it may be taken forward at different level within TC215 in the future
- Public Health domain – has not had a separate or distinct existence within TC but is represented by a number of activities in different WGs. Possibilities include:
  - WG1 could be a place for new work items related to Public Health – reuse/secondary use of data or ‘public health’.
  - Walter Suarez suggested a separate Public Health domain WG, in similar manner to Pharmacy. Would need to put forward a substantial body of work.

A formal thankyou was entered into the minutes for the work of the PHTF.

11.2.3.1. Relevance to Australia

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| Public Health Taskforce (PHTF) | ACTION: Support work of PHTF to disseminate the standard and other products and ensure equitable availability to NMBs and others who have need for the guidance  
ACTION: Australia to actively participate in a possible Public Health/Research domain working group | Suggested responsibility & alignment to IT-014 |
12. WG 2 SYSTEMS AND DEVICE INTEROPERABILITY

Australian Delegate Attendance
Alan Taylor, Anthony Maeder, Stephen Chu

12.1. 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.

12.2. RECENT ACTIVITY

12.2.1. Current publications

Recent publications include:

- ISO TR 13128:2012 (Ed. 1) Health Informatics, Clinical document registry federation [DTR]
- ISO 10159:2011 (Ed. 1) Health informatics -- Messages and communication -- Web access reference manifest
- ISO/HL7 21731:2006 (Ed. 1) Health informatics, ISO/HL7 v3 - Reference information model [RIM] -R1

12.2.2. Preliminary work items

Preliminary work items include:

- Clinical trials - Registration and reporting [CTR&R] This project will start once BRIDG [14119] is underway
- Spirometry: - A new work item proposal may be forthcoming following translation of an existing Spanish standard.

ISO TR21089:2004, Health Informatics, Trusted End-to-End Information flows has been proposed as a new project to ISO/TC215.

Discussion took place on the value of a possible new proposal for a medical search engine specification.

12.2.3. Current work items

The following current work items were noted at this meeting:

- ISO/NP DTR 19231 Survey of mHealth projects in low to middle income countries (LMIC)
12.2.4. Cancelled projects

New Proposal ISO 12974 Web access to DICOM persistent objects by means of web services extension of the retrieve service [WADO web service]. Following discussion at DICOM meeting during HL7 in Phoenix this item has been cancelled from TC215 work program.

ISO/HL7/DIS 13449 Health informatics, Clinical genomics pedigree topic has been cancelled from TC215 work program because no update has been received from the project lead for 12 months.

12.2.5. PROGRESS AT THIS MEETING

12.2.6. Health informatics — Quality criteria for services and systems for telehealth

12.2.6.1. Introduction

This technical specification describes quality requirements for telehealth services. These requirements deal with:

• development of quality criteria for telehealth using a systematic approach;
• quality management by the telehealth service provider, health or healthcare organization of telehealth processes;
• quality aspects and criteria for the telehealth process that impact care recipients or clients;
• quality aspects and criteria related to facilities, equipment and devices for telehealth;
• quality aspects and criteria related to the use and management of information, communications and applications used in telehealth services.

12.2.6.2. Progress at this meeting and proposed future work

The previous project leader (Netherlands) has been unable to complete a full revision of DTS 13131 based on the comments received in the last ballot in March 2012. Following discussion at the last ISO/TC215 meeting in Mexico City, Australia (Alan Taylor) has completed a full revision of the draft and provided it to the WG2 secretariat and Chair for a second DTS ballot.

12.2.6.3. Proposed future work

Following receipt of comments in January 2014, the WG2 Chair recommended that the revised item proceed directly to publication.

12.2.6.4. Relevance to Australia

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

<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>Health informatics — Quality criteria for services and systems for telehealth</td>
<td>This item is out for ballot. When comments are received the Australian lead will provide comment disposition and revised text for an early publication.</td>
<td>IT-014-12 Chair to assist</td>
</tr>
</tbody>
</table>

12.2.7. ISO/DTR 28380-3, Health Informatics, Messages & communication – IHE Global Standards Adoption – Part 3: Deployment,

12.2.7.1. Introduction

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

- ISO/DTR 28380-1 Health informatics - IHE global standards adoption – Part 1: Process
- ISO/DTR 28380-2 Health informatics - IHE global standards adoption Part 2 - Integration and content profiles
TR 28380-1 passed DTR ballot in 2007; TR 28380-2 passed DTR ballot in 2008; and all comments have been resolved. However, substantial delays in proceeding to publication have been concerned with the formatting of the documents.

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

12.2.7.2. Progress at this meeting

This Part 3 technical report describes the general methodology to analyze interoperability requirements in support of a use case to produce the selection and combination of the relevant Profiles specified in TR28380-2. It is illustrated by applying this methodology to a small number of examples. It also identifies and proposes a high-level quantification of the benefits gained by the use of a profile based specification of interoperability. The report also discusses the approach to effectively test interoperability from the specific of the standards and profiles, up to the level of business use cases.

It was resolved to propose to ISO/TC215 that this technical report advance to publication.

12.2.7.3. Proposed future work

The project lead will provide the disposition of comments, final text and revisable graphics files to the WG2 Secretary no later than 30 November 2013.

12.2.7.4. Relevance to Australia

<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>DTR 28380 3 Health Informatics, Messages &amp; communication – IHE Global Standards Adoption – Part 3: Deployment – Process</td>
<td>ISO/TR 28380-3 Health Informatics, Messages &amp; communication – IHE Global Standards Adoption – Part 3: Deployment – Process has been the subject of a DTR ballot. Comments have been collated and an amended draft will be prepared for publication. Action: Ensure that State and Territory CIO’s are aware of these publications when they are made available.</td>
<td>Department of Health State and Territory CIOs</td>
</tr>
</tbody>
</table>

12.2.8. ISO/CD 17583 - Health informatics: Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange

12.2.8.1. Introduction

This was a joint work item with WG3. It was decided at the ISO/TC215 Mexico meeting to request a further ballot.

12.2.8.2. Progress at this meeting

It was resolved to recommend to ISO/TC215 that this item proceed to a DIS ballot.
12.2.8.3. **Proposed future work**

The project lead will provide the disposition of comments, and updated text to the TC215 secretary by 7 April, 2014 for subsequent DIS ballot by 14 April 2014.

12.2.8.4. **Relevance to Australia**

<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>WG 2</td>
<td>ISO/CD 17583 - Health informatics: Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange</td>
<td>Australia should contribute to second CD ballot.</td>
</tr>
</tbody>
</table>

12.2.9. **ISO/DTR 19231, Health informatics, Survey of mHealth projects in low to middle income countries (LMIC)**

12.2.9.1. **Introduction**

Following the Mexico City meeting this new proposal was balloted. This item passed by a simple majority approving placement on the ISO/TC215 work program. This document is targeted to be a TR but was balloted as an NP to gather feedback to inform item development and to invite NMB participation. Three NMBs identified experts to work on the item and this information is listed in the ballot results results.

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

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

12.2.9.2. **Progress at this meeting**

The substantial number of comments made during the ballot process were not disposed of correctly or fully. The Working Group voted to progress the draft report to publication. This is a poor quality report, which will be of limited value to the intended audience.

12.2.9.3. **Proposed future work**

The project lead will provide the disposition of comments, and updated text to the WG2 secretary no later than December 15, 2013 for submission for publication by submit to ISO/CS for TR publication by February 15, 2014.
### 12.2.9.4. Relevance to Australia

<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>WG 2 ISO/DTR 19231, Health informatics, Survey of mHealth projects in low to middle income countries (LMIC)</td>
<td>Australia should request that ISO/TC215 working group chairs assign an experienced expert to mentor project leads of new proposals in order to obtain the best quality work items for publication.</td>
<td>IT-014 committees and secretariat</td>
</tr>
</tbody>
</table>

### 12.2.10. ISO/TR 17522 provisions for health applications on smart/mobile devices

#### 12.2.10.1. Introduction

Following the Mexico City meeting this new proposal was balloted

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

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

#### 12.2.10.2. Progress at this meeting

The purpose and scope of the draft are unclear which possibly contribute to the large number of comments (approximately 100) being received.

#### 12.2.10.3. Proposed future work

The project lead will provide the disposition of comments, and updated text to the WG2 secretariat as soon as possible. The WG2 chair suggested that the project lead seek the help of other experts, including those from Australia to revise the technical report. The Australian delegates advised they would seek guidance from the delegation lead.

The advice of experts in IHE and HL7 reference architectures would also be important.

#### 12.2.10.4. Relevance to Australia

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

Unfortunately the draft lacks an analytical framework, purpose, focus and rigor.
12.2.10. ISO/TR 17522 provisions for health applications on smart/mobile devices

**Issue/Action and Recommendations for Australia**

Australia should request that ISO/TC215 working group chairs assign an experienced expert to mentor project leads of new proposals in order to obtain the best quality work items for publication.

**Suggested responsibility & alignment to IT-014**

IT-014 committees and secretariat

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12.2.11. PROGRESS AT THIS MEETING

**Mobile Health Survey**

Outcome of an international survey of mobile health requirements was reported at WG2 meeting. Twenty-eight countries responded to the survey with 3 negatives votes. Australia submitted a number of comments which would need to be resolved. Inputs from Australia commenters are required.

WG2 experts will continue to review comments and propose comment dispositions and to bring disposition recommendation for WG2 review and decision.

**Standardisation of Spirometry Report**

Report from WG4: a Spanish spirometry report specification is available and is currently in use in Spain. It is unclear whether the specification is for sending spirometry report as CDA document.

The Spanish document will need to be translated into English for it to be reviewed and suitability for adoption evaluated. Australian delegates had suggested that Australia might be able to provide translation resources to help with this work.

Once translation is completed, it was proposed that the document would be passed to HL7 to determine whether additional work would be required.
13. WG 3 SEMANTIC CONTENT

Australian Delegate Attendance
Heather Grain

13.1. 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.

In particular WG3 considers terminological and semantic requirements which cross over the interests and responsibilities of individual terminological resource providers (e.g., IHTSDO, WHO, LOINC and others). The terms of reference of WG3 are 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.

13.1.1. Current publications

Publications in the last 12 months:

<table>
<thead>
<tr>
<th>ISO 13120</th>
<th>Health informatics, Syntax to represent the content of healthcare classification systems, Classification Markup Language (ClaML)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 13582</td>
<td>Health informatics, Sharing of OID Registry information</td>
</tr>
<tr>
<td>EN ISO 1828</td>
<td>Categorial Structure for Terminological Systems of Surgical Procedures</td>
</tr>
<tr>
<td>EN ISO 13119</td>
<td>Health informatics -- Clinical knowledge resources -- Metadata</td>
</tr>
</tbody>
</table>

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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>
</thead>
<tbody>
<tr>
<td>Publications of TC 215 originating in WG3</td>
<td>IT-014-02 to provide recommendations to IT-014 and prepare project documentation if required.</td>
<td>IT-014-02</td>
</tr>
</tbody>
</table>
13.1.2. Current work items

The following current work items were noted at this meeting:

- ISO/AWI TS 17439 Health Informatics – Common glossary metadata requirements and maintenance process
- ISO TR 12310 Health Informatics, Principles and Guidelines for the Measurement of Conformance in the Implementation of Terminology Systems
- ISO/AWI TR 12300 Health informatics, Principles of mapping between terminological systems
- ISO/AWI 18104 Health Informatics, Categorial structure for representation of nursing diagnosis and nursing actions in terminological systems
- ISO/AWI 13940 Health informatics, System of concepts to support continuity of care (ContSys)
- ISO/CD DTS 17938 Health Informatics, Semantic network framework and coding of Traditional Medicine language system
- ISO/AWI DTS 17948 Health Informatics, Traditional medicine literature metadata
- ISO/AWI TS 16843-1 Health informatics, Categorial structures for representation of acupuncture, Part 1: Acupuncture points (body system)
- ISO/AWI TS 16843-2 Health informatics, Categorial structures for representation of acupuncture, Part 2: Needling
- ISO/AWI TS 18062 Health informatics, Categorial structure for representation of herbal medicaments in terminological systems
- ISO/PWI TR 13581 Guidance for maintenance of object identifiers (OIDS)
- ISO / PWI 19239 Categorial structure for the representation of physical external stimuli
- ISO/NP TS 18790-1 Health Informatics, Profiling Framework and Classification for Traditional Medicine informatics standards development – Part 1: Traditional Chinese Medicine (To be handled in JWG1)
- EN ISO/CD 16278 Health Informatics, Categorial structures for terminological systems of human anatomy
- ISO CD-DTS 17583 Health Informatics, Terminology constraints for coded data elements expressed in ISO Harmonized Data Types used in healthcare information interchange [Binding]
- ISO/NP TS 17117-1 Health Informatics, Terminological resources, Part 1: Characteristics
13.1.3. PROGRESS AT THIS MEETING

13.1.4. ISO TR 12310 – PRINCIPLES AND GUIDELINES FOR THE MEASUREMENT OF CONFORMANCE IN THE IMPLEMENTATION OF TERMINOLOGY SYSTEMS

13.1.4.1. Introduction

This publication provides guidance on preparation of quality definitions for health informatics standards, but also supports the processes of the SKMT.

13.1.4.2. Progress to date

This item passed ballot but comments were only received on Tuesday of the meeting so not discussed in detail. The intention is to prepare comment disposition and revised draft for IT14/2 review and WG3 review and to submit for publication prior to the next ISO TC215 meeting.

13.1.4.3. Relevance to Australia

<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>WG 3</td>
<td>This work item supports Australian as well as international quality of terms and definitions as well as term harmonisation and SKMT entries. It is already a work item for international oversight at IT-014-02.</td>
<td>IT-014-02 – already on international work program with Australian Lead</td>
</tr>
</tbody>
</table>

13.1.5. ISO TR 12310 – PRINCIPLES AND GUIDELINES FOR THE MEASUREMENT OF CONFORMANCE IN THE IMPLEMENTATION OF TERMINOLOGY SYSTEMS

13.1.5.1. Introduction

This work item is to define a framework of good practices for EHR terminology maintenance. The scope of the work includes:

- governance models and practices
- high level processes, and
- requirements for managing change for keeping EHR terminology standards and associated reference material clinically and / or technically relevant and valid

The scope of this item will not include a definition of the detailed processes for performing EHR terminology maintenance.

13.1.5.2. Progress to date

A complete draft of this document has been prepared, comments disposed and the document has been sent to ISO central secretariat.
13.1.5.3. Proposed future work

This document is expected to come out to ballot shortly and IT14/02 should be asked to provide guidance to IT14 on the comments to be provided.

13.1.5.4. Relevance to Australia

This work will inform and contribute to the existing IT-014-02 work item on terminology in local systems.

<table>
<thead>
<tr>
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<th>Issue/Action and Recommendations for Australia</th>
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</tr>
</thead>
<tbody>
<tr>
<td>ISO TR 12310 Principles and guidelines for the measurement of conformance in the implementation of terminological systems</td>
<td>This work is seen as relevant to Australia both nationally and in local healthcare providers who need to be cognisant of and apply the principles included in this document.</td>
<td>IT-014-02 active international work item</td>
</tr>
</tbody>
</table>

13.1.6. ISO 17115:2007 VOCABULARY FOR TERMINOLOGICAL SYSTEMS (VOTE)

13.1.6.1. Introduction

This document originally represented a glossary and basic explanatory information for terminological resources. The content is now quite outdated, and the intention is to:

- review all definitions - using the SKMT glossary harmonisation process and include those relevant in the updated version of this document
- add details from EN 12264:2005 (also now outdated) to indicate the principles of categorial structures for systems of concepts.

This work underpins much of the other work being undertaken by the WG.

13.1.6.2. Progress to date

Agreed methodology was discussed and additional leadership established to progress this work within the WG.

This is considered a priority work item for the WG to be discussed and advanced at teleconference calls.

This work is now entitled: Categorial Structures for Systems of Concepts.

13.1.6.3. Relevance to Australia

Updating these documents provides a sound, standards basis for interoperability between systems and between concept representation systems. It should be actively supported and advanced.
ISO 17115 Vocabulary of terminological systems (Review)

Active participation will improve knowledge of these processes in Australia and ensure our requirements for terminological representation are consistently met.

Suggested responsibility & alignment to IT-014

IT-014-02 active work program


13.1.7.1. Introduction

This work item was intended to extend the work of Sharing of OID Registry Information. It was proposed and lead by German representatives. It was intended to include:

- processes for content management and maintenance
- identification of inter organisational communication and collaboration.

13.1.7.2. Progress to date

Following publication of ISO 13582 Health Informatics, Sharing of OID Registry Information which this word was to extend, discussion determined that:

- the original proposers no longer have the bandwidth nor the urgent need for this work item. This results in no project leader being available.
- the publication has met most of the initial requirements.

WG3 members felt that this work item was of value but less important than other current work items. It was suggested the National Member Bodies review this work and provide guidance back to WG3 to provide leadership, or recommend cancellation.

13.1.7.3. Relevance to Australia

WG 3 Guidance for maintenance of object identifiers

The publication of the Sharing of OID Registry Information document is of value to Australia and should be reviewed, particularly by IT-014-06 and AIHW. In general the existing publication is likely to be sufficient to meet our needs. It is recommended, unless IT-014-06 or AIHW suggest otherwise and provide leadership, that this project be cancelled.

IT-014-06 AIHW

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

13.1.8.1. Introduction

This publication provides guidance on preparation of quality definitions for health informatics standards, but also supports the processes of the SKMT.
13.1.8.2. Progress to date

This item passed ballot but comments were only received on Tuesday of the meeting so not discussed in detail. The intention is to prepare comment disposition and revised draft for IT14/2 review and WG3 review and to submit for publication prior to the next ISO TC215 meeting.

13.1.8.3. Relevance to Australia

<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>WG 3 SKMT governance representation</td>
<td>This work item supports Australian as well as international quality of terms and definitions as well as term harmonisation and SKMT entries. It is already a work item for international oversight at IT-014-02.</td>
<td>IT-014-02 – already on international work program with Australian Lead</td>
</tr>
</tbody>
</table>

13.1.9. ISO/PWI 19239 CATEGORIAL STRUCTURE FOR REPRESENTATION OF PHYSICAL EXTERNAL STIMULI

13.1.9.1. Introduction

Previously called non-chemical stimulation this work item originated in Traditional Medicine, but relates much more broadly and is considered a whole of healthcare work item.

This item seeks to define high level categories for representing non-chemical stimulation, orders, methods and devices. This includes concepts which impact allied health, such as physiotherapy.

The potential uses for this conceptual framework are to:

1) support developers of new terminology systems concerning any form of non-chemical stimulation;
2) support developers of new detailed content areas of existing terminology systems concerning procedures to ensure conformance;
3) facilitate the representation of non-chemical stimulation procedures using a standard core model in a manner suitable for computer processing;
4) provide a conceptual framework for the generation of compositional concept representation;
5) facilitate the mapping and improved semantic correspondence between different terminologies by proposing a core specification for physical stimuli;
6) provide a core model to describe physical stimuli, and facilitate improved semantic correspondence with information models;
7) provide a new method for researchers to conduct relevant research, and ideas for the development of physical stimuli disciplines.
13.1.9.2. Progress to date

This item is now in active development. There was considerable discussion on how to represent concepts in a manner which is clear and consistent, particularly the need for consistent and understandable definitions and terms.

13.1.9.3. Relevance to Australia

Given the significant use of physiotherapy and other physical stimuli in Australian healthcare there is a need to ensure that this work meets our requirements.

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<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>WG 3</td>
<td>Categorial structure for the representation of physical external stimuli</td>
<td>This item can be reviewed and contributed to by IT-014-02, however additional input from physiotherapists, and other allied health professionals would be a significant advantage.</td>
</tr>
</tbody>
</table>

13.1.10. ISO/NP TS 18790-1 PROFILING FRAMEWORK AND CLASSIFICATION FOR TRADITIONAL MEDICINE INFORMATICS STANDARDS DEVELOPMENT - PART 1: TRADITIONAL CHINESE MEDICINE

13.1.10.1. Introduction

This work item is not being covered in WG3 but has been taken on by JWG1 - in conjunction with TC 249 Traditional Chinese Medicine.

13.1.11. ISO/DIS 16278 CATEGORIAL STRUCTURES FOR TERMINOLOGICAL SYSTEMS OF HUMAN ANATOMY

13.1.11.1. Introduction

This takes European standard EN 15521:2007) forward into the international environment. The document represents high level requirements for representation of human anatomy.

13.1.11.2. Progress to date

Document has been sent for DIS ballot.

13.1.11.3. Relevance to Australia
It is essential that this work be consistent with SNOMED CT and other terminological systems. However this should not require significant input from Australia.

<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>WG 3 Categorial structures for terminological systems of human anatomy</td>
<td>It is recommended that this document be actively reviewed for ballot, and supported in Australia</td>
<td>IT-014-02 active work program</td>
</tr>
</tbody>
</table>

13.1.12. ISO TDR 12300 PRINCIPLES OF MAPPING BETWEEN TERMINOLOGICAL RESOURCES

13.1.12.1. Introduction

This item identifies the core components and issues associated with mapping. In this document mapping refers to the establishment of semantic comparability between terminologies and classifications. The work is written to be relevant for any terminological resources. It includes information about how to map, definitions of terms used. Essential criteria needed to undertake a mapping exercise. Quality assessment processes and risks and opportunities relevant to the use cases for mapping.

13.1.12.2. Progress to date

This item completes ballot on the 22nd of November 2013. Comments will be circulated to IT-014-02 for comment and contribution.

13.1.12.3. Relevance to Australia

Australia currently has disparate terminological systems being used which will require mapping to support migration to SNOMED CT-AU or in the situation where vendors chose to maintain legacy systems to support semantic interoperability via maintained mappings.

Mapping will also need to be considered where classifications such as ICD-10-AM/ACHI are used for funding and epidemiological purposes. Mapping between versions e.g. ICD-10-AM 7th edition and 8th edition is already common practice.

Mapping between disparate systems requires skill and this standard would be an important tool in providing understanding to those undertaking this activity within Australia.

<table>
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<tr>
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<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>TDR 12300 Principles of mapping between terminological resources</td>
<td>This work item originated from Australian requests and is active in IT-014-02 international work program. This work item has been requested as a priority by Nehta staff.</td>
<td>IT-014-02 – already on work program and lead by Australia</td>
</tr>
</tbody>
</table>
13.1.13. ISO/NP/TR 14668 GUIDELINES FOR PRINCIPLES AND DESIRABLE FEATURES OF CLINICAL DECISION SUPPORT

13.1.13.1. Introduction
This item provides general principles for assessment of clinical decision support systems and projects. It is based upon the work undertaken in IT-014-02 some years ago. It has been shared with IT-014-13 who agreed that it should be continued.

13.1.13.2. Progress to date
This item has not progressed. H. Grain is the leader and has not had resources to update and forward the new draft, also was disinclined to continue unless IT-014-13 were in agreement. The intention is to prepare this and have the draft available for comment of IT-014-13 by the end of January 2014 and for WG 1, 3 and 4 for discussion at the meeting in May. If the comment disposition is agreed this item could be agreed for publication in May.

13.1.13.3. Relevance to Australia

<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>WG 3</td>
<td>Based upon initial Australian publication this has received considerable international interest.</td>
<td>IT-014-13 already on work program lead by Australia</td>
</tr>
</tbody>
</table>


13.1.14.1. Introduction
The purpose of this standard is to define the generic concepts needed to achieve continuity of care. Continuity of care is an important aspect of quality and safety in healthcare with semantic interoperability a basic requirement for continuity of care. The concepts that are needed for these should represent both the content and context of the healthcare service.

This work aims to provide a comprehensive, conceptual basis for content and context in healthcare services. It should be the foundation for interoperability at all levels in healthcare organizations and for development of information systems in healthcare.

In practice this standard should be used whenever information in healthcare is specified as a requirement. This will cover all levels of specifications in the development of:
- business or clinical reference models as a common basis for interoperability on international, national and local levels;
- information systems and
- information for specified types of clinical processes.
13.1.14.2. Progress to date

This meeting received presentations on the comments received and some comment disposition was discussed. The Authors were keen to progress the work to publishing quickly, however updated diagrams within the document are needed and there is a strong need to get HL7 and IHTSDO input. That being the case, it was agreed, after considerable negotiation undertaken by WG3 convenor that:

- HL7 and IHTSDO would be specifically asked for their input.
- Comment disposition will be completed and published for community review and comment.
- Document update will be made available for comment and review (expected by February 2014).
- For detailed discussion and review at the meeting in April 2014 with a view to final ballot after that.

13.1.14.3. Relevance to Australia

This work is highly relevant to Australia as it supports interoperability of systems at all levels of healthcare. Our interoperability standards can be informed by it locally, from a jurisdictional perspective and nationally.

<table>
<thead>
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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>System of Concepts to Support Continuity of Care</td>
<td>Australia provided input to this document, and we need to ensure that we monitor and review the updated documents.</td>
<td>IT-014-02, IT-014-06, IT-014-09, IT-014-12</td>
</tr>
</tbody>
</table>

13.1.15. ISO 17117 TERMINOLOGICAL RESOURCES PART 1 – FRAMEWORK

13.1.15.1. Introduction

The characteristics of a terminology influence its utility and appropriateness in clinical applications. This Draft International Standard defines universal and specialised characteristics of health terminological resources that make them fit for the purposes required of such systems. It refers only to terminological resources that are primarily designed to be used for clinical concept representation or to those parts of other terminological resources designed to be used for clinical concept representation.

Categorisation of healthcare terminological systems according to the name of the system may not be helpful and has caused confusion in the past. Section 4 and 5 below supports categorisation according to the characteristics and functions of the terminological resources rather than the name.

The main purpose of the entire revision work (both Part1 and Part2) enable users to assess whether a terminology has the characteristics or provides the functions that will support their specified requirements. The focus of this document (Part1) is to define characteristics and functions of terminological resources in healthcare that can be used to identify different
types of them for categorization purpose, not according to the names. Requirements for
and evaluation criteria of terminological resources in health care are described in Part 2,
both of which are tightly related to the characteristics of terminological resources and
functions that they can provide.

13.1.15.2. Progress to date

This work has had leadership changes during the last 12 months but is now progressing.
There was active discussion of this work item and a draft will be prepared, but initial work
will focus on content required from ISO 17115 (described above).

The new proposal documentation and working draft is to be submitted to the Technical
Committee secretariat by mid- November 2013.

The comments received when this work item was previously active were managed in the
first draft.

13.1.15.3. Relevance to Australia

Elements of this work have already been found useful in Australia to terminological
definition, implementation and educational initiatives and should be followed closely and
contributed to where possible.

<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>Terminological resources Part 1 Characteristics</td>
<td>Active item for IT-014-02 contribution and review. To be included in the listed international work program for this group.</td>
<td>IT-014-02</td>
</tr>
</tbody>
</table>

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

13.1.16.1. Introduction

This work item represents a standardised high level model for representation of clinical
findings in traditional medicine specific domains that can harmonise with western medicine
structures and form a basis for the development of classifications and other terminological
systems.

13.1.16.2. Progress to date

Name change: Traditional Chinese Medicine, Traditional Japanese Medicine and
Traditional Korean Medicine. The name change is to make clear that this covers the three
traditions.

This work is proceeding well and represents categories such as disease patterns and their
relationship to diagnosis and other concepts with which western medicine are familiar. At
this meeting the proposal was offered for a consistent mechanism for the representation of context and this work suggested the use of superscripts as a mechanism, e.g., disease pattern™.

13.1.16.3. Relevance to Australia

It is important that this work be carefully harmonised with categorial structures in Western medicine in order to support consistent terminology development and comparability. In Australia, a major provider of traditional Chinese medicine education and user of traditional Chinese medicine this is particularly important and our leadership in this area is of value to our relationship with other countries in our region.

<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>Categorial structures of clinical findings in traditional medicine - part 1 traditional east Asian medicine</td>
<td>Input from Australian experts in this topic is to be encouraged and support of IT-014-02 to provide guidance on categorial structure and system requirements should be considered, though not core to IT-014-02 there are advantages to Australia in providing general support.</td>
<td>IT-014-02 oversight but not active contribution Coordination with Standards Australia’s Traditional Chinese Medicine Committee.</td>
</tr>
</tbody>
</table>

13.1.17. ISO/AWI 18104 HEALTH INFORMATICS, CATEGORIAL STRUCTURE FOR REPRESENTATION OF NURSING DIAGNOSIS AND NURSING ACTIONS IN TERMINOLOGICAL SYSTEMS

13.1.17.1. Introduction

Terminology development in nursing has been motivated by multiple factors including:

- implementation of computer-based systems in clinical settings,
- quest for reimbursement for nursing services delivered,
- documentation of nursing contributions to patient care outcomes,
- teaching students, and
- enhancing the body of nursing knowledge.

Nursing terminologies, in either paper-based or computer-based form, have been designed as enumerated classifications and implemented both as interface terminologies at the point of care and as administrative terminologies to examine nursing data across settings. At the present time, many standardized terminologies exist and no single standardized terminology is complete for the domain in terms of breadth or granularity.

Moreover, there is currently no concept-oriented terminology that integrates the domain concepts of nursing in a manner suitable for computer processing.

Among the remaining major challenges are the development of a reference terminology model that supports the representation of nursing concepts and the integration of the reference terminology model with other models for the health-care domain. This work is based upon the original CEN work to identify categorial structures which focus specifically
on the conceptual structures that are represented in a reference terminology model rather
than in other types of information models. Moreover, toward the goal of integration with
other health-care models, the reference terminology models for nursing.

Diagnoses and nursing actions in this International Standard reflect attempts at
harmonisation with evolving.

13.1.17.2. Progress to date
This item is out at ballot (closing December 8th).

13.1.17.3. Relevance to Australia
Interest in this work has been expressed by nursing communities in Australia. When
complete it will be reviewed by IT-014-02.

<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>WG 3</td>
<td>Circulate disposition of comments to nursing representatives for advice regarding adoption/adaption.</td>
<td>IT-014-02</td>
</tr>
</tbody>
</table>


13.1.17.4.1. Introduction
These two work items are closely related so discussed together.

The purpose of this Technical Specification is to specify categorial structures within the
subject field of acupuncture by defining a set of domain constraints for use within
terminological resources.

This Technical Specification describes a concept system detailing a domain constraints of
sanctioned characteristics, each composed of a semantic link and an applicable
characterizing category.

The potential uses for this conceptual framework are to:
• support developers of new terminology systems concerning acupuncture needling;
• support developers of new detailed content areas of existing terminology systems
  concerning acupuncture needling procedures to ensure conformance;
• facilitate the representation of acupuncture needling procedures using a standard core
  model in a manner suitable for computer processing;
• provide a conceptual framework for the generation of compositional concept
  representation of acupuncture needling;
• facilitate the mapping and improved semantic correspondence between different
  terminologies by proposing a core specification for acupuncture needling;
• provide a core model to describe the structure of acupuncture, and facilitate improved
  semantic correspondence with information models;
• provide a tool for acupuncture text mining, database construction, ancient documents processing and wide area of acupuncture information collection and processing
• provide a new method for researchers to conduct relevant research, and ideas for the development of Acupuncture disciplines.

Part 1: covers acupuncture points - the anatomy associated with acupuncture.

Part 2: covers the processes and equipment used for acupuncture needling.

13.1.17.4.2. Progress to date

These items had early difficulties associated with documentation and changes in secretariat. These problems have now been resolved, and the draft documentation updated. These work items are of particular interest as they are the first major work being undertaken by a collaborative leadership from the traditional medicine community.

This meeting agreed to submit these items for new work item - reinstatement ballot.

This work is being reviewed to ensure a cohesive approach with existing western medicine concepts for body systems, procedures and devices / instruments. Such integration of concepts is considered essential for interoperability and particularly for decision support systems which cover both western and traditional medicine. A long standing area of interest in the Australian clinical community.

13.1.17.4.3. Relevance to Australia

This work supports computerised data collection, representation, analysis and knowledge acquisition related to traditional medicine. Given Australia’s strong educational engagement in this area and the need for integration with western medicine representational systems it would seem relevant that we support and actively monitor these work items.

<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>Categorial structures for representation of acupuncture - part 1: acupuncture points</td>
<td>That these items be supported by Australia when voting is undertaken. That IT-014-02 and the SA Traditional Medicine Committee both provide oversight on the content.</td>
<td>IT-014-02 Standards Australia Traditional Medicine Committee.</td>
</tr>
</tbody>
</table>

13.1.17.5. ISO 17938 TS – health informatics- Semantic network framework and coding of Traditional Chinese Medicine language system. (CT MLS)

13.1.17.5.1. Introduction

This pair of documents identify a system to support literature searching and identification similar to that provided through the National Library of Medicine (USA) Medical Subject Headings system (Mesh) for western medicine.
13.1.17.5.2. **Progress to date**

Comment dispositions were received and reviewed. These items were approved for publication.

13.1.17.5.3. **Relevance to Australia**

The academic community, particularly those universities and educational organisations providing Traditional Chinese medicine education should be informed of this work and encouraged to use it.

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>WG 3 Semantic network framework and coding of traditional Chinese medicine language system</td>
<td>Input from Australian experts in this topic is to be encouraged and support of IT-014-02 to provide guidance on categorial structure and system requirements should be considered, though not core to IT-014-02 there are advantages to Australia in providing general support.</td>
<td>IT-014-02 oversight but not active contribution Coordination with Standards Australia’s Traditional Chinese Medicine Committee.</td>
</tr>
</tbody>
</table>

13.1.17.6. **ISO NP18062 Health informatics – Categorial structures for representation of herbal medicaments in terminological systems**

13.1.17.6.1. **Introduction**

It should be noted that this is not a traditional medicine only work item though it is informed by that community.

This technical specification will:

- specify the concepts in the field of herbal medicament
- clarify the relationships amongst concepts as well as between concepts and terms (thus providing the components for description logic)
- provide the underpinning required to support consistency and interoperability for the terms and their designating concepts in terminological systems

Herbal medicaments are made of single natural material.

13.1.17.6.2. **Progress to date**

This is an active work item with draft currently in development. It was not discussed in detail at the meeting. A draft document is expected to be available for discussion at the next ISO meeting.

13.1.17.6.3. **Relevance to Australia**

Herbal medicines are widely used not only in traditional medicine but in consumer based medication. It is known that some of these medications can have serious adverse effects when taken with western medicines. It is for this reason that Australia should ensure the integrated nature of the end result of this work item.
<table>
<thead>
<tr>
<th>Topic</th>
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</table>
| **WG 3**  
**Categorial structures for representation of herbal medicaments in terminological systems** |

<table>
<thead>
<tr>
<th>Issue/Action and Recommendations for Australia</th>
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<tr>
<td>Include in list of international work items for active oversight.</td>
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<tr>
<th>Suggested responsibility &amp; alignment to IT-014</th>
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<tr>
<td>IT-014-02</td>
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</table>
14. WG 4 SECURITY, SAFETY AND PRIVACY

14.1. 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.

14.2. RECENT ACTIVITY

14.2.1. Current publications

14.2.2. Current work items

The following current work items were noted at this meeting:

- ISO/TR 18638 Health Informatics, component of education to ensure health privacy:

  Comments mainly related to definitions. Advised that definitions to be obtained from either recent ISO standards or SKMT Glossary. If definitions are not at SKMT Glossary to be added there.

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

14.2.3.1. Progress to date

Part1-3: comments revised and integrated, Moved for FDIS Ballot, with Part 2 under condition to fix some figures and 1 added clarification.

14.2.3.2. Relevance to Australia

High relevance, about managing access to data that crosses policy borders so across healthcare organisation boundaries which is applicable to eHealth initiatives across Australia.

14.2.4. ISO 21298 HEALTH INFORMATICS – FUNCTIONAL AND STRUCTURAL ROLES (N160)

14.2.4.1. Progress to date

Comments processed, however discussion whether UK activities should inform this spec. Progressed for CD ballot.
14.2.4.2. **Relevance to Australia**

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

14.2.5.1. **Progress to date**
Comments from different countries discussed, moved to DIS Ballot. Issue is that some countries did not grasp difference between general Digital Signature standard and this one specific for Healthcare documents. Suggested to add explanation of difference in Scope. DIS Ballot could resolve this.

14.2.5.2. **Proposed future work**

14.2.5.3. **Relevance to Australia**
Relevant for all eHealth initiatives involving signed clinical documents.

14.2.6. 17975: HEALTH INFORMATICS – PRINCIPLES AND DATA STRUCTURES FOR CONSENT IN THE COLLECTION, USE OR DISCLOSURE OF PERSONAL HEALTH INFORMATION (WG4-N533)

14.2.6.1. **Progress to date**
Many comments received.

14.2.6.2. **Proposed future work**
Document needs to apply to all countries, needs to be written to fit for all countries despite varying legislations. Editorial changes required as well. Australia and UK to support author to progress.

14.2.6.3. **Relevance to Australia**
Relevant (e.g. PCEHR).

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td><strong>WG 4 17975</strong>: Health informatics – Principles and data structures for consent in the collection, use or disclosure of personal health information (WG4-N533)</td>
<td>Australia provide support to author Elaine Sawatsky.</td>
<td>IT-14-04 to support as it relates to privacy/confidentiality (Trish Williams)</td>
</tr>
</tbody>
</table>
14.2.7. HEALTH CARDS

14.2.7.1. Progress to date

14.2.7.2. Relevance to Australia
Not relevant, Healthcare cards not used in Australia.
15. WG 6 PHARMACY AND MEDICINES

15.1. 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 Convener: Frits Elferink (NEN, Netherlands)

15.2. RECENT ACTIVITY

15.2.1. Current publications

15.2.2. Current work items

- ISO/TS 22224:2009 Health informatics -- Electronic reporting of adverse drug reactions
- ISO/TR 22790:2007 - Health informatics -- Functional characteristics of prescriber support systems
During the meeting it was discussed to review the following publications to review if more recent publications by TC215 and other SDO's had an impact on the documents. The following TC215 documents have been identified as requiring review.

- ISO/TS 22224 Health informatics – Electronic adverse drug reactions:
The review should be in the view of ICSR standards, in particular part 1. Lise Stevens of the FDA (US) agreed to review the TS and provide a recommendation to the WG concerning the document. Part of the consultation process of the WG and the user community should be the check of any recommendations which elaborate the use of a standard(s) instead of the TS 22224. Mrs Stevens will report back to WG6 in the second half of December 2013.

- ISO/TR 27090 Health informatics – Functional characteristics of prescriber support systems:
The work on e-prescriptions should refer to this TR (not normative), but does not replace that report. The TR will be reviewed by Ms Lenoria Grandia of NEN (Netherlands) and IHTSDO in the light of the NP 'Requirements for Medicinal Product Dictionaries'. She agreed to provide a recommendation to the WG concerning the future of the TS in the second half of December 2013.

15.2.3. Current work items

The following are documents in development by the working group:

- ISO/DIS 19294 Health informatics – Data elements and structures for identification of extemporaneous and magistral (compound) pharmaceutical preparations without marketing authorisation
- ISO/DIS 19293 Health Informatics - Requirements for a record of the Dispense of a Medicinal Product
15.2.4. PROGRESS AT THIS MEETING

At this meeting 13 nations and 4 SDO’s (HL7, IHE, IHTSDO and GS1) were represented by their respective delgates, 22 attending in person with 7 connecting remotely via teleconference.

In the last meeting 4 possible new topics were discussed:

- ‘electronic patient leaflets’,
- ‘mobile authentication services’,
- ‘administration record’ and
- ‘look-alike, sound-alike medicines’.

The question was raised if a higher-level strategy is needed before a certain topic is chosen to follow up as possible NP. The proposed topic ‘administration record’ could fit in the current work programme. Other ideas should remain on hold and for further discussion, since not clearly in TC 215 WG 6’s scope.

A number of possible new topics was also discussed.

- ‘recall or disposal of medicinal products’, e.g. ‘expired drugs’ is an interesting direction to explore further and may focus on controlled substances (disposal) or any medicinal product (recall).
- ‘lifecycle of the medicinal product’ (risk management), which includes processes to monitor marketed medicinal products,
- ‘batch/lot information’ to be provided by the manufacturer to regulators for batch releases (e.g. biologicals, vaccines),
- ‘medicinal product shortage’, which includes alert systems when potential shortage are noticed on the market.

At this stage though given the available resources and scope of the current work program, there were no resolutions made by the WG to progress any of the 4 new topics from the previously or those identified in the brainstorming session at this meeting.

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

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

- ISODTS 19256 Health Informatics - Requirements for Medicinal Product Dictionaries
- IDMP rules for maintenance (previous "ISO/DTR 14872 "Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information") (document N13-043)
- ISO/DTS 16791 Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers using the GS1 System
- ISO/DTS 17251 Health Informatics – Business requirements for a syntax to exchange structured dose information for medicinal products
- ISO/DIS 17253 Health Informatics - Requirements for electronic prescriptions
15.2.5.1. 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.

15.2.5.2. Progress to date

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

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

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

There was a resolution then that agreed to proceed into NP ballot for 3 months to re-establish the work item, with the view of releasing a committee Draft prior to the next meeting in Australia. Subsequently the NP ballot was held and passed with positive result with mainly editorial comments.

In regard to the scope statement, the following comments were discussed and reconciled:

- The primary use case is more than the prescriber-to-patient, e.g. computable exchange of information. This was agreed and appropriate wording will be added.
- Unstructured dose instructions are not within the scope. It was agreed to consider where information about the unstructured instructions can be included, e.g. an informative annex.
- It was agreed that the instruction information can be used in the communication to multiple entities and therefore the document should be comprehensive for the patient. This comment will be incorporated and revised throughout the document.
- the statement about the identification of terms as patient and/or caregiver is not clear. These terms should be represented separately and it was agreed to extend the definition with additional wording.
15.2.5.3. Proposed future work

Next step is circulating the draft disposition of the NP ballot comments in WG6 after approval by the project team.

Most discussion focused on the planning for the project now that the NP ballot had passed. In regards to the ongoing project team, Mr Robertson indicated that he knows interested experts who are not nominated by their respective NMB and it is planned that Mr Robertson will work with those nominated in the NP response to work out a plan and schedule for engagement around the Committee Draft.

Before the next ISO meetings in May, the draft DTS document plus disposition of comments will be distributed in WG6 for approval of launching the DTS ballot; otherwise the WG agreed that no resolution is required at the moment for this item.

An updated draft is planned to be circulated to WG6 in February 2014 for further review.

A final draft is expected to be ready for May 2014 meeting in Japan and the first Technical Specification will be ready for ballot in northern hemisphere summer in 2014.

15.2.5.4. 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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue / Action / Recommendations for Australia</th>
<th>Recommended for Action by</th>
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<tbody>
<tr>
<td>ISO/DTS 17251 - Business requirements for the exchange of structured dose instructions for medicinal products</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 IT-014-06-06 IT-014-13</td>
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</tbody>
</table>

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

15.2.6.1. 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.

15.2.6.2. Progress to date

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

The document was then recommended to be moved to publication with the final document to the TC215 document in September. There has however been an unexpected Publication delay for ISO/DTS 16791 as DIN (Germany) had submitted a claim in regard to title of this DTS and its content focussing on GS1. In its response sent to TC 215 Chair, WG6 leadership stressed that the process has been followed correctly, reconsolidating all comments with approval of DIN representative in the last meeting, including the proposal for a title change.

Subsequent DIN comments regarding the document were submitted however this was after the ballot deadline and submitted too late.

15.2.7. MEDICINAL PRODUCT DICTIONARIES

15.2.7.1. 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.

As defined in the Form 4 NP proposal the goal of this specification is to define the characteristics of and requirements for Medicinal Product Dictionaries. Specifically the technical specification:

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

In the previous meeting in Mexico, it was agreed that the project name should only be a placeholder, as the document matures it will be refined to a Drug or Medicinal product information repository in spite of this it was agreed to progress the NP to ballot after the meeting.

The NP ballot was conducted and passed with what was largely a positive result and some comments.

Many comments address the scope, purpose and justification of the proposed document, which was expected based on the Mexico discussion.

Some of the comments regarding this included:

- The scope statement needs to be more precise; not only describe what dictionaries do, but also define what a MPD is (a database?), based on (clinical) use cases. It is concluded that the direction of the scope is that MPD is hierarchically describes medicines on a different level of detail, not including the technical implementation aspects.
- Depending of the usage of the dictionaries, the kind of requirements (technical, functional, informational, safety, quality, etc.) will be determined.
- Terms and definitions need to be cross-checked with the SKMT.
- Traditional medicine is out of scope. This domain should be referenced appropriately with some link to TC 215 WG 3 work and TC 249. There is an overlap which should not be contradictory. This will be noted explicitly in the scope statement. Most of the other comments were editorial in nature and can be reconciled by different wording in the committee draft document.

15.2.7.3. Proposed future work

Next step is circulating the draft disposition of the NP ballot comments in WG6 after approval by the project team.

Most discussion focused on the planning for the project now that the NP ballot had passed. In regards to the ongoing project team. Given the nature of this project and uncertain scope engagement by the nominated experts is very important. Interested experts, who are not nominated for this project, can contact the WG leadership.

The project group will start with working on the scope statement and provide the WG a 1st draft document for comment. Before the next ISO meetings in May, a matured DTS draft will be provided for discussion. Depending on the level of maturity, WG 6 may approve launch of DTS ballot.

15.2.7.4. Relevance to Australia

Australia is more advanced in work done on this topic and is in a strong position to provide expertise and important guidance to the project team.
Within Australia under NEHTA’s AMT work there is already an underpinning model which could be interpreted as a Drug Dictionary. As the CD 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.

15.2.8. prEN ISO 17523 Requirements for electronic prescriptions

15.2.8.1. Introduction

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

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

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

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

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

15.2.8.2. Progress to date

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

Following the review of the CD during the Mexico meeting (May 2013) it was agreed that significant rework was required to get the document to the necessary level and some of the main changes noted are:

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

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

Subsequently the document passed CD ballot with a number of comments and the draft disposition of the technical CD ballot comments was discussed and reconciled during this meeting. The following items were discussed in detail:

- Allergies and drug sensitivities should be included, but this element will be optional.
- Reason for prescription can be provided within the prescription under the condition that this element remains optional. This element can for example be used to track ‘off-label’ prescribing.
- The suggestion having 2nd CD ballot was rejected due to time restrictions for the project.
- Medication safety is suggested to be included explicitly in the scope statement. If “medication safety” would be considered as in the scope of this document, other mandatory elements would be needed to support the medication safety. Although all our standards intent to support patient safety, WG 6 does not consider this as part of the scope. Some wording will be included in the introduction of the standard.
- Paragraph 4.5.4: will be optional so it can be used according to different national legislations.
- Paragraph 4.6: the prescription elements will be renamed to make the understanding of them more explicit and aligned to standard terminology (SKMT)

### 15.2.8.3. Proposed future work

WG6 agreed that no resolution is needed at this moment regarding the document and the next step is circulating the draft disposition of the CD ballot comments in WG6 after approval by the project team.

Before the next ISO meetings in May, the draft DIS document plus disposition of comments will be distributed in WG6 for approval of launching the DIS ballot.

### 15.2.8.4. 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 time but after the next meeting in Japan and the availability of the DIS document for ballot this item should be reviewed by NEHTA and IT-14-06-04.
15.2.9. prEN ISO/DTS 19293 Health informatics – Requirements for a record of the Dispense of a Medicinal Product

15.2.9.1. 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.

The scope as specified in the NP Form 4 for this project is as follows:

“The scope of this specification is to define the information content for the capture of structured data of an event relating to the dispense of a Medicinal Product. The event includes any actual dispense, cancellation or other outcome that may have occurred at the time. The contents of a dispensation record are the logical counterpart of an electronic prescription, however the scope of this standard is to include items which may be dispensed without the need for a prescription. This specification intends only to capture the requirements and information content. It is not the intent to specify the exchange of the information in a message, although it is intended that this information content shall be used as the basis for the dispense information contained in any messaging event.”

15.2.9.2. Progress to date

Following the Vienna meeting this work item was agreed to be pursued as a new program of work to complement the work on Electronic Prescriptions. Between meetings several discussions were held and a Form 4 was drafted for discussions in Mexico. At this time a new title for the work item was also adopted: “Health Informatics - Requirements for a record of the Dispense of a Medicinal Product”. This was taken as several countries had differing opinions on the actual meaning of the term Dispense record.

The NP ballot was conducted and passed with what was largely a positive result and some comments which largely came from an Australian delegate in relation to clarification of the scope. The question was largely if the TS would deliver a set of requirements or a conceptual information model, which was clarified that in alignment with the ePrescription
work item the scope is to produce requirements. It was also agreed that the scope statement should be as limited as possible; ‘universally’ will be replaced by ‘care setting agnostic’ (no geographical reference).

The content in terms of developing the Committee draft was also discussed and several documents such as the HL7 Dispense record and NCPDP documents will be considered as relevant input. It was also discussed that the goal of the TS is not to reproduce the content of already available documents, but is seeking to provide use case specific requirements, harmonizing the work which is already available.

15.2.9.3. Proposed future work

The intended project team was nominated as Michael Steine (Australia), Frits Elferink (Netherlands), Brendan Kernan and Jack Shanahan (Ireland), Chihiro Masuda (Japan), Andreas Franken (Germany) and Scott Robertson (US). Although Michael Steine (of Australia) is mentioned as proposed project leader this was in an interim capacity (as the primary author of the NP) until this meeting and a new lead needs to be identified.

WG6 consider who can take over this role Several members indicated considering if they can contribute actively in this work item (Mr Barned, Chu and Ms Stevens). Ms Stevens will also look if a colleague can take a more active role. Also, representation from the retail pharmacy vendors would be valuable. Mr Chu will take this back to the IHE Pharmacy WG to see if active involvement by them is feasible. The WG agreed to have Mr Hay as project lead (placeholder) while these actions are followed up.

This may hinder the development of the committee draft between now and the next meeting in May however the goal is for a document to be ready for discussion.

15.2.9.4. 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 a Dispense Record. It is likely that we would seek that there be no contradiction between the ISO specification and any future Australian standard.

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

15.2.10. prEN ISO/NP 19294 Health informatics — Data elements and structures for identification of extemporaneous and magistral (compound) pharmaceutical preparations without marketing authorised

15.2.10.1. 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.

15.2.10.2. Progress to date

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

The document passed the NP ballot with minimal comment and the scope is confirmed as:

“To define the information model for the capture of structured data in relation to unlicensed Pharmaceutical preparations that are prepared without marketing authorisation. Pharmaceutical preparations are medicinal products generally consisting of active substances that may be combined with excipients, formulated into a dosage form suitable for the intended use, where necessary after reconstitution, presented in a suitable and appropriately labelled container. Pharmaceutical preparations may be licensed by the competent authority. Or they can be unlicensed and made to the specific needs of subjects of care according to legislation”.

There are 2 categories of unlicensed pharmaceutical preparations:
- extemporaneous preparations, ie. pharmaceutical preparations individually prepared for a specific subject of care or subjects of care group, supplied after preparation;
- stock preparations, ie. pharmaceutical preparations prepared in advance and stored until a request for a supply is received.

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

There was one technical comment in the NP ballot relating to need and driver for the standard which came from a delegate who had not been tracking the project in detail previously. It was discussed how this item had been raised by a number of member countries as an area of concern and this was reinforced by members from the US, Europe and Asia. It was also discussed that several existing projects and documents were reviewed to understand the scope and nature of the project prior to the development of the Form 4. It was therefore decided that the Technical Comment requesting that the NP be replaced by an Environmental Scanning and Needs analysis exercise was non-persuasive.
It was discussed that this TS will be complementary to the IDMP standards: EN ISO 11615 and 11616; this means that the level of requirements should be consistent with these two standards so that Medicinal products which are NOT regulated and NOT within the scope of the IDMP standards are within the scope of the present TS.

Concerning the modelling, to support successful information exchange in relation to the unique identification and characterization of Medicinal Products, the use of HL7 Common Product Model (CPM) and Structured Product Labeling (SPL) messaging aspects are followed as the IDMP standards do. Subject specific experts (e.g. pharmacists) will be invited to provide input to fill in the specific elements. The dependencies between this work and other items will be considered in detail when the work will have progressed and documents available for comparison.

The only other anomaly in the NP Ballot was that Russia abstained from voting however nominated an expert to participate in the project.

15.2.10.3. Proposed future work

The intended project team: Michael Steine (Australia), Frits Elferink (Netherlands), Tomas Wennebo (Sweden), Andreas Franken (Germany), Vada Perkins and Scott Robertson (US). Michael Steine of Australia is currently slated as the project lead.

The working group agreed that no resolution is needed at this moment. Next step is circulating the draft disposition of the NP ballot comments in WG6 after approval by the project team and the project team will start with investigating which existing work should be used as the basis for the 1st draft document with a goal for presenting this at the Japan meeting in May.

15.2.10.4. 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 draft standard is available comments will be sort from the relevant stakeholders in Australia (IT-014-06-04, NEHTA, Department of Health, PBS).

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

15.2.11.1. 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.

15.2.11.2. Progress to date

This document started out its life as a guide for the maintenance of the IDMP standard, initially by a third party agency acting as the ISO Registration Authority. As this is no longer likely, and alternative arrangements requiring joint activity between ICH members is likely to hold this role. In light of this a new NP was drafted and presented during this meeting.

This document highlighted that it is a key requirement for IDMP to be successful that a global Regulatory Authority/Competent Authority (RA/CA) processes pertaining to the review, approval, registration, listing and post market surveillance of human pharmaceutical products exists which covers:

- Premarket: IND phase through pre-licensure approval
- Post market: Expedited and non-serious reporting, including Phase IV studies

Due to relationship with regulatory processes the maintenance support model needs to be flexible to accommodate requirements in different jurisdictions while maintaining a reusable and consistent approach that can be applied globally for each IDMP standard.
The current thinking is now that a federated service delivery model is proposed for IDMP maintenance including a set of core principles that can be used as evaluation criteria to determine potential services. Collaboration is a core principle. Maintenance organisations will need to evaluate existing processes to determine the best approach based upon IDMP standard type (e.g. Substances):

- creation of new terms
- reconciliation/mapping of existing terms
- audit trail throughout the lifecycle
- maintenance and dissemination, increasing deprecated (retired) terms
- data exchange

The question was raised if safety alerts should be included as part of these processes; WG6 comes to the conclusion that this is not the case. This also can support the traceability for compliance and pharmacovigilance purposes.

In all regions maintenance processes exist today. By strengthen the collaboration between the existing maintenance and regulatory organisations, we can choose, evaluate and improve indicators to achieve better quality. But this is out of scope of the proposed TR. The proposed TR merely outlines the guiding principles for a Maintenance Organisation. A good example is GInAS for Substances.

This proposed TR does not define the maintenance processes as such. These will vary by region, but the core principles on identifiers and terms should be universal. Maintenance organisations should however comply to ISO/TR 12309:2009 and the core principles:

- Governance and due process;
- Openness and transparency;
- Impartiality and balance;
- Sustainability and responsiveness; and
- Safety

15.2.11.3. Proposed future work

In developing a maintenance TR, interaction with other SDO’s: essential to leverage with the terminology related SDO’s, participation by ICH should be reinforced again. While the new NP document is in ballot, the key regulators can define/refine their evaluation criteria or questions for engaging with maintenance organisations.

WG6 agreed to move this item to NP ballot with the changed title and Ms Stevens as project lead. The title will be changed to: ‘Health informatics – Identification of Medicinal Products (IDMP) – Core Principles for Maintenance of Identifiers and Terms’.

This ballot will take place in parallel with the proposed NP ballot for the implementation guide for EN ISO 11238 - Substances. All interested stakeholders can also submit their comments through the formal NP ballot through the national NMB’s.

15.2.11.4. 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. There
does not appear to be any specific reason why Australia would choose to vote against this NP but as there is currently no clear movement towards IDMP then as an NMB we may choose to abstain.

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<td>WG 6 NP 'Health informatics – Identification of Medicinal Products (IDMP) – Core Principles for Maintenance of Identifiers and Terms'</td>
<td>A NP Ballot for ‘Health informatics – Identification of Medicinal Products (IDMP) – Core Principles for Maintenance of Identifiers and Terms’ is to be held. Action: IT-14-06-04 and Department of Health to determine a position on the work item and decided whether to support, oppose or abstain from voting on the NP.</td>
<td>IT-014-06-04 Department of Health</td>
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15.2.12.1. Introduction

Implementation guides have been written to assist the end users with the implementation of the 5 published ISO IDMP standards. They were prepared within the ICH community and ready for a broader stakeholder review. The 5 IDMP standards are as followed:

- 11238 – Substances
- 11239 – Pharmaceutical dose forms, units of presentation, routes of administration and packaging
- 11240 – Units of Measurement
- 11615 – Medicinal Product Information
- 11616 – Pharmaceutical Product Information

The assumption is that the guidelines will be balloted as ISO Technical Specifications and include:

- Recommendations about how the content for each data element is to be represented in an XML-based data exchange format: e.g., HL7 (SPL) Structured Product Labelling (HL7 being not mandatory);
- Recommendations about minimum or maximum data element conformance (e.g., required, optional and repeatability) based upon the use case for data exchange, e.g., foreign or domestic data exchange;
- Recommendations concerning use of terminology value sets for coded values.

It was emphasized and agreed that it is essential that the content of the implementation guides are actually tested within the real practice and not being theoretical exercises.

15.2.12.2. Progress to date

This NP is to develop the first of these in relation to Substances and during the meeting a title change was agreed to: ‘Health informatics – Identification of Medicinal Products (IDMP) – Implementation Guide for EN ISO 11238 Data Elements and Structures for the Unique Identification and Exchange of Regulated Information on Substances’.
During this meeting the WG agreed to move the implementation guide on EN ISO 11238 - Substances to NP ballot with Mr Vader Perkins of the FDA as project lead.

15.2.12.3. Proposed future work

WG6 members can send their comments on the available document (part of N13-044) to Mr Perkins by 18th November. This ballot will take place in parallel with the proposed NP ballot for ISO/DTR 14872. The timeframes for the development of ISO/TS are bit longer than proposed; two ballots are required – NP and DTS ballots.

It is expected the other 4 implementation guides corresponding the IDMP standards will follow as NP’s after the next ISO meeting.

15.2.12.4. 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. There does not appear to be any specific reason why Australia would chose to vote against this NP but as there is currently no clear movement towards IDMP then as an NMB we may choose to abstain.

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16. JWG 7 Application of risk management for IT-networks incorporating medical devices

Australian Delegate Attendance  Alan Taylor, Anthony Maeder

16.1. BACKGROUND

16.2. RECENT ACTIVITY

16.2.1. Current publications

- IEC 80001-1:2010 Application of risk management for IT-networks incorporating medical devices Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples
- IEC 80001-1:2010 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

16.2.2. Preliminary work items


16.2.3. PROGRESS AT THIS MEETING

16.2.4. IEC 80001-1 Ed. 1.0 (2010-10-27), Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities

16.2.4.1. Introduction

This item is a subset of IEC 80001-1 Ed. 1.0 (2010-10-27), Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities.

16.2.4.2. Progress to date

IEC 80001-1 Ed. 1.0_CIB_ROV passed TC215 committee internal ballot approving a one year stability extension before formal review of the item begins.
16.2.4.3. Proposed future work

The project lead will review comments received during the ballot.


16.2.5.1. Introduction

This item is a subset of IEC 80001-1 Ed. 1.0 (2010-10-27), Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities.

16.2.5.2. Progress to date

It was resolved to propose to ISO/TC215 to proceed to three-month CD comment under IEC lead, instructs the JWG7 secretary to coordinate the schedule [as needed] with the IEC primary point of contact and in schedule coordination with IEC, and the project lead provides the disposition of comments and committee draft text to the JWG7 secretary no later than 15 December 2013;

16.2.5.3. Proposed future work

The project lead will provide the disposition of comments and committee draft text to the JWG7 secretary no later than 15 December 2013.

16.2.6. IEC / AWI TR 80001-2-6 Application risk management for IT-networks incorporating medical devices- Guidance for responsibility agreements

16.2.6.1. Introduction

This Technical Report provides guidance on implementing Responsibility Agreements, which are described in IEC 80001-1 as used to establish the roles and responsibilities among the stakeholders engaged in the incorporation of a Medical Device into an IT-Network in order to support compliance to IEC 80001-1. Stakeholders may include Responsible Organizations, IT suppliers, Medical Device manufacturers and others. The goal of a Responsibility Agreement is to these roles and responsibilities should cover the complete lifecycle of the resulting Medical It-Network.

16.2.6.2. Progress to date

It was resolved to propose to ISO/TC215 that this item proceeds to the publication of a technical report and the JWG7 secretary to coordinates [as needed] with the IEC primary point of contact when the project lead provides the disposition of comments, and final text.

16.2.6.3. Proposed future work

This item will be published.

16.2.7. IEC / NP TR 80001-2-7 Application of risk management for IT-networks incorporating medical devices – Part 2-7: Guidance for Healthcare Delivery Organizations (HDOs) on how to self assess their conformance with IEC 80001-1
16.2.7.1. Introduction

This TR provides guidance for Healthcare Delivery Organizations on assessing how well they have implemented processes conformant with IEC 80001-1:2010.

This document:

- defines a process reference model (PRM) comprising a set of processes, described in terms of
  process purpose and outcomes that demonstrate coverage of the requirements of IEC 80001-1.
- defines an exemplar process assessment model (PAM) that meets the requirements of ISO/IEC 15504-2 for process assessment and that supports the performance of an assessment by providing indicators for guidance on the interpretation of the process purposes and outcomes as defined in the IEC 80001-1 PRM and the process attributes as defined in ISO/IEC 15504-2;
- provides guidance, by example, on the definition, selection and use of assessment indicators.

A PAM comprises a set of indicators of process performance and process capability. The indicators are used as a basis for collecting the objective evidence that enables an assessor to assign ratings. The PAM in this document is directed at assessment sponsors (HDOs) and competent assessors who wish to select a model, and associated documented process method, for assessment (for either capability determination or process improvement). It can be used by:

a) responsible organisations in the assessment of the risk management process for the Medical IT network, spanning planning, design, installation, device connection, configuration, use/operation, maintenance and device decommissioning.
b) responsible organisations to ensure that medical device manufacturer and other IT providers make available documentary information applicable to the technology being incorporated into the IT network.

16.2.7.2. Progress to date

It was resolved to propose to ISO/TC215 that the revised text be circulated as a committee draft for comment for a two-month period in schedule coordination with IEC.

16.2.7.3. Proposed future work

The project lead will provide the disposition of comments and final text to the JWG7 secretary no later than 6 January 2014.

16.2.8.1. Introduction

This part of IEC 80001 provides guidance for the application of the framework outlined in IEC 80001-2-2. Managing the RISK in connecting Medical Devices to IT-networks requires the disclosure of security-related capabilities and RISKS. IEC 80001-2-2 presents a framework for this disclosure and the security dialog that surrounds the IEC 80001-1 Risk Management of IT network connection. IEC 80001-2-2 presents an informative set of common, high-level security-related capabilities that are useful in terms of gaining an understanding of the user needs. This document addresses each of the Security Capabilities and identifies security controls to be considered and RISKS that lead to the controls. Intended Use and local factors determine which exact capabilities will be useful and also the security controls required to establish the capability. This report is intended to be useful to:

a) Health Delivery Organizations (HDOs),
b) Medical Device manufacturers (MDMs), and
c) IT vendors

16.2.8.2. Progress to date

It was resolved to propose to ISO/TC215 to proceed to new proposal ballot with an IEC lead.

16.2.8.3. Proposed future work

Further work is subject to the outcome of the new proposal ballot.

16.2.9. IEC 62304 2nd edition, transfer of work item from ISO/TC 210 to ISO/TC 215

16.2.9.1. Introduction

It is proposed to ISO/TC215 that for the planned revision of IEC 62304, Medical device software – Life cycle processes, pending ISO/TC 210 the revision work be transferred from ISO/TC 210 to ISO/TC 215.

16.2.9.2. Progress to date

It was proposed that ISO TC 215 add this item to its work programme for development by JWG7 under IEC lead with the revised title “Health software – Software life cycle processes” (2nd ed.).

16.2.9.3. Proposed future work

Further work is subject to the agreement of ISO/TC210 to the transfer of work.

16.2.10. IEC / CD 82304-1 Healthcare software systems - Part 1: General requirements - General implementation guidance for healthcare delivery organizations
16.2.10.1. Introduction

At the IEC/TC 62 meeting in Brussels in 2009, a concern was raised that software standards for Health IT /Standalone Software may use a different risk model to ISO 14971 and that manufacturers might in the future be required to follow two different risk models and development processes for the same software. At the Brussels meeting, the IEC/TC 62 CAG tasked a small group to investigate extending the scope of IEC 60601-1 to include standalone software.

The extension developed by the small group was opposed by the majority of the National Committees, but most of them agreed that standalone software should be covered by an new product level standard for standalone software and reuse IEC 62304 in respect of software development processes.

This proposed new standard consequently addresses Health Software and includes requirements that would be sufficient for software that is a medical device, while not constraining its scope to only those software products that are regulated as medical devices.

The New Work Item Proposal (NWIP) has been developed as a joint project between IEC/SC 62A and ISO/TC 215 (with IEC lead) to benefit from the combined expertise of the two committees.

16.2.10.2. Progress to date

Working draft (WD7.0) has been prepared on the basis of WD6.3, incorporating changes based on comments by the national members to IEC and ISO after CD1 (62A/839/CD and ISO/TC 215/1115, respectively) as well as enrichments proposed by members of the project team following very constructive discussions. WD7.1 includes updates as agreed at the progress call on 15 October 2013. WD7.1.1 has a few slight corrections.

It was resolved to propose to ISO/TC215 that the name of this item be changed:

- FROM: Healthcare software systems -- Part 1: General requirements
- TO: Health software – Part 1: General requirements for product safety

It was also resolved that the JWG7 secretary coordinate [as needed] with the IEC primary point of contact and instructs the project lead to provide the disposition of comments from the 1st committee draft and updated text to the JWG7 secretary no later than 1 December 2014.

16.2.10.3. Proposed future work

The JWG7 secretary will provide these items to the TC 215 Secretary no later than 10 December 2014 circulation of a second committee draft ballot no later than 15 December 2014.
### 16.2.11. Relevance to Australia

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<td>IEC 80001-1:2010 Application of risk management for IT-networks incorporating medical devices series of standards, IEC 62304 medical device software and IEC 82304 Healthcare software systems</td>
<td>These series of standards have a wide applicability to developers and users of medical devices and software in Australia. Medical device software is becoming increasingly useful in mobile health device deployments and consumer settings. It is important that the whole IT-14 community be understands the importance of these standards.</td>
<td>IT-014 examine the range of IT-14 sub-committees that should provide input to and comment on these sets of standards.</td>
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17. CLOSING PLENARY

| Australian Delegate Attendance | Richard Dixon Hughes (Head of Delegation) |

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

17.1. BACKGROUND

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

Contentious issues tend to be raised and discussed during WG sessions or, at the latest, when the proposed resolutions are circulated to the national delegations with consensus on most matters being achieved by negotiation before they are presented to the plenary. Under this process, while some items are contested on the floor of the plenary, it is normal for the vast majority of resolutions to be passed.
Appendix A – Meeting Agenda
A final schedule with meeting rooms listed will be provided at check-in registration

### MONDAY 21 OCTOBER 2013 | Operations Meetings

**ANZ Stadium – Please enter through Gate L – see map on last page**

*Signs for registration and meeting rooms will be clearly posted.*

*Please remember to check-in at registration to pick-up your badge. No one will be admitted without a badge.*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:30 – 17:00</td>
<td>Registration – Enter through ANZ Gate L and look for signs to ISOTC215 Registration.</td>
</tr>
</tbody>
</table>

*There is no lunch provided on Monday so please eat before you arrive for Monday afternoon meetings. Thank you.*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:30 – 14:00</td>
<td>Committee Advisory Group 2 (CAG02) - TC215 coordination: Nominated members, WG convenors and invited guests.</td>
</tr>
<tr>
<td>14:30 – 16:00</td>
<td>Committee Advisory Group 1 (CAG01): TC215 Executive Council: Heads of delegation, conveners, vice-conveners and invited guests. Meeting room location provided at Registration.</td>
</tr>
<tr>
<td>16:00 – 16:15</td>
<td>Break</td>
</tr>
<tr>
<td>16:15 – 17:30</td>
<td>Operations &amp; Harmonization (O&amp;H): TC215 chair and TC secretary, WG convenors, vice-convenors, WG secretaries and invited guests. Meeting room location provided at Registration.</td>
</tr>
</tbody>
</table>

### TUESDAY 22 OCTOBER 2013 | WG MEETINGS DAY 1

*Signs for registration and meeting rooms will be clearly posted.*

*Please remember to check-in at registration to pick-up your badge. No one will be admitted without a badge.*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00 – 17:00</td>
<td>Registration – Enter through ANZ Gate L and look for signs to ISOTC215 Registration.</td>
</tr>
</tbody>
</table>

**Q2**

11:00 – 12:30

<table>
<thead>
<tr>
<th>WG1 Agenda N1304</th>
<th>WG2 Agenda N1305</th>
<th>WG3 Agenda N1306</th>
<th>WG4 Agenda N1307</th>
<th>WG6 Agenda N1308</th>
<th>JWG1 Agenda N1309</th>
<th>TMTF Agenda: N1311</th>
<th>JWG7 Agenda N1310</th>
</tr>
</thead>
</table>

*A final schedule with meeting rooms listed will be provided at Registration check-in.*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:30 – 13:30</td>
<td>Lunch is provided on site</td>
</tr>
</tbody>
</table>

**Q3**

13:30 – 15:00

<table>
<thead>
<tr>
<th>WG1</th>
<th>WG2</th>
<th>WG3</th>
<th>WG4</th>
<th>WG6</th>
<th>TMTF/JWG 1/Other</th>
<th>JWG7</th>
</tr>
</thead>
</table>

*A final schedule with meeting rooms listed will be provided at Registration check-in.*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00 – 15:30</td>
<td>Break</td>
</tr>
</tbody>
</table>

**Q4**

15:30 – 17:30

<table>
<thead>
<tr>
<th>WG1</th>
<th>WG2</th>
<th>WG3</th>
<th>WG4</th>
<th>WG6</th>
<th>TMTF/JWG 1/Other</th>
<th>JWG7</th>
</tr>
</thead>
</table>

*A final schedule with meeting rooms listed will be provided at Registration check-in.*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>17:45 – 18:45</td>
<td>CAG03 and JIC Open Forum - Room: TBD</td>
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</tbody>
</table>
### WEDNESDAY 23 OCTOBER 2013 | WG MEETINGS DAY 2

A final schedule with meeting rooms listed will be provided at check-in registration

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td><strong>08.00 – 17:00</strong></td>
<td>Registration desk - Please look for signs</td>
</tr>
<tr>
<td><strong>Q1 9:00 – 10:30</strong></td>
<td>WG1 Agenda N1304, WG2 Agenda N1305, WG3 Agenda N1306, WG4 Agenda N1307, WG6 Agenda N1308, JWG1 Agenda N1309, TMTF Agenda N1311, JWG7 Agenda N1310</td>
</tr>
<tr>
<td><strong>10:30 – 11:00</strong></td>
<td>Break</td>
</tr>
<tr>
<td><strong>Q2 11:00 – 12:30</strong></td>
<td>WG1, WG2, WG3, WG4, WG6, TMTF/JWG 1/Other, JWG7</td>
</tr>
<tr>
<td><strong>12:30 – 13:30</strong></td>
<td>Lunch is provided on site</td>
</tr>
<tr>
<td><strong>Q3 13:30 – 15:00</strong></td>
<td>WG1, WG2, WG3, WG4, WG6, TMTF/JWG 1/Other, JWG7</td>
</tr>
<tr>
<td><strong>15:00 – 15:30</strong></td>
<td>Break</td>
</tr>
<tr>
<td><strong>Q4 15:30 – 17:30</strong></td>
<td>WG1, WG2, WG3, WG4, WG6, TMTF/JWG 1/Other, JWG7</td>
</tr>
<tr>
<td><strong>17:45 – 18:45</strong></td>
<td>Social event- Standards Australia cocktail reception hosted onsite - details provided at registration and the opening plenary.</td>
</tr>
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</table>
### THURSDAY 24 OCTOBER 2013 | WG MEETINGS DAY 3

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Details</th>
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</thead>
<tbody>
<tr>
<td>08.00–17:00</td>
<td>Registration – Please look for signs</td>
</tr>
<tr>
<td>Q1 9:00–10:30</td>
<td>WG1 Agenda NXXX</td>
</tr>
<tr>
<td>10:30–11:00</td>
<td>Break</td>
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<tr>
<td>Q2 11:00–12:30</td>
<td>WG1</td>
</tr>
<tr>
<td>12:30–13:30</td>
<td>Lunch is provided on site</td>
</tr>
<tr>
<td>Q3 13:30–15:00</td>
<td>WG1</td>
</tr>
<tr>
<td>15:00–15:30</td>
<td>Break</td>
</tr>
<tr>
<td>Q4 15:30–17:30</td>
<td>WG1</td>
</tr>
</tbody>
</table>

*Resolutions are due to secretariat staff by 16:00 and even earlier is welcome and appreciated!*
### FRIDAY 25 OCTOBER 2013
Delegation meetings and closing plenary

<table>
<thead>
<tr>
<th>Time</th>
<th>Delegation</th>
<th>Delegation</th>
<th>Delegation</th>
<th>Delegation</th>
<th>Delegation</th>
<th>Delegation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delegation meetings 8:00 – 10:30</td>
<td>Delegation 1</td>
<td>Delegation 2</td>
<td>Delegation 3</td>
<td>Delegation 4</td>
<td>Delegation 5</td>
<td>Delegation 6</td>
</tr>
<tr>
<td>Room</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>10:30 – 11:00</td>
<td>Break</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11:00 – 12:30</td>
<td>Closing plenary</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:30 – 13:15</td>
<td>Lunch provided on site</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13:15 – 14:30</td>
<td>Closing plenary</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>15:00 – 18:30</td>
<td>JIC Executive Council</td>
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</tr>
</tbody>
</table>

Thank you to Standards Australia and to all TC215 members for participating!

*Please plan to join ISO/TC215 in Karuizawa, Prince Hotel West, Karuizawa, Japan 19 to 23 May 2014. Please see N1276 for Japan Calling Notice of Meeting details*
Directions to Sydney Olympic Park from the Sydney Airport or Central Business District:
— Please see N1257– Important Travel and Hotel Info Visitors to Australia ISOTC215 Meeting 21-21 Oct 2013 for information on trains and taxis from Sydney Airport.
— The address of the venue is: ANZ Stadium, Edwin Flack Ave, Sydney Olympic Park, Australia

www.sydneyolympicpark.com.au
Appendix B – ISO/TC 215 Standards and Approved Projects
WORK GROUP 1: DATA STRUCTURE

### Preliminary work items

<table>
<thead>
<tr>
<th>WG</th>
<th>ISO / WD</th>
<th>ISO Title</th>
<th>PLs</th>
<th>Current Stage</th>
<th>Stage desc at time of this report</th>
<th>As of this date</th>
<th>If currently in ballot: date open</th>
<th>If currently in ballot: date closes</th>
<th>Other key info</th>
<th>SKMT Status - Has data been entered?</th>
<th>Resolutions</th>
</tr>
</thead>
</table>
|    | ISO / AWI TS 18528 | Health informatics, Functional classification health informatics standards | Mr. Andrew Grant (CAN) | 20.00 | 2013-10-13: Has been submitted to JIC for coordination. On Sydney Agenda; DTS ballot will be next step. | 2013/10/13 | NP results N1064
Mexican City 12 |
|    | ISO / PRF TS 18530 | Health informatics, Automatic identification and data capture marking and labeling - Subject of care and individual provider identification | Mr. Christian Hay (GS1) | 50.00 | 2013-10-13: Final has been submitted to ISO CS for publication preparation. | 2013/10/13 | JIC; 2012-09-04: NP Ballot closed, item passed, results N1049. NP Form 6 posted as N1116. //Vancouver 10; Vienna 6 Mexico City 13 |
|    | prEN ISO/ DTS 13972 | Health informatics, Detailed clinical models- detailed clinical models, charateristics and processes | Mr. William Goossen (NEN) | 30.60 | 2013-10-13: 2nd DTS closed 2013-09-18. I've not uploaded the 2nd DTS results yet as I have a few open questions w/ISOCS, but the item did pass and I sent the PL the ROV. | 2013/10/13 | (1) Name changed. (2)Vancouver R4: Parts 1 & 2 publish as single TS w/content of the former parts placed in new document, and Pts 1 & 2 merged new name: TS, Vancouver 4; Vienna 5 Mexico City 14 |
| ISO / HL7 / DIS 16527 | Personal Health Record System Functional Model, Release 1 (PHRS FM): | Mr. G. Dickinson (US) | 40.93 - Decision for 2nd DIS | 2013-10-13: In 2nd DIS ballot. | 2013/10/13 | 2013-09-03 | 2013/12/03 | NP ROV N1128 Updated ROV w/ Mexico R16-N1245 | Vancouver 49 & 50. Mexico City 16 |
| ISO / DIS 13940 | System of concepts to support continuity of care [ContSys] | Mr. Nicholas Outbridge (BSI) | 40.60 | 2013-10-13: Passed DIS - DIS ROV initial prelim combined ISO/CEN=N1200. Updated ROV w/post-decision to be filed after next "ad hoc" ballot that is planned by PL per email from Nick O on 13 June 2013. Over 600 comments were received on CD ballot so project team working to dispose; on Australia WG1 agenda for review and discussion | 2013/10/13 | 2013/10/02 | 2014/01/03 | N1200=Prelim ISO-CEN DIS ROV | Chicago 12. |

**Cancelled / Withdrawn**


**Published Standards**

<p>| ISO/ TR 14639:1-2012 | Health informatics, Capacity-based eHealth architecture roadmap part 1: Overview of national initiatives [eHealth Enterprise] | 60.60 | Published 2012-08-08 - congratulations! | 2012/08/01 | | | Kuopio 84 Chicago 31 Vancouver 51 |
| ISO/ TR 14292:2012 | Health informatics, Personal health records, Definition, scope and context | - | 60.00 | Published 2012-03-09 - congratulations! | 2012/08/01 | | | Kuopio 85 |
| ISO/TR 13054-1:2012 | Knowledge management of health information standards, Part 1 | - | 60.60 | Published standard. Congratulations! Next review is in 2016. | 2012/08/01 | | | Chicago 30 |
| ISO/NP TS 16555 | Framework for National Health Information Systems | Mr. R. Krishnamurthy (WHO) | 10.99 | Vienna R2: To withdraw 16555 from work program. | 2012/11/21 | | | Vienna 2 |</p>
<table>
<thead>
<tr>
<th>WG</th>
<th>ISO #</th>
<th>ISO Title</th>
<th>PLs</th>
<th>Current Stage</th>
<th>Stage desc at time of this report</th>
<th>As of this date</th>
<th>If currently in ballot: date open</th>
<th>If currently in ballot: date closes</th>
<th>Other Key Info</th>
<th>Other Key Info</th>
<th>SKMT Status</th>
<th>Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>PWI</td>
<td>PWI - Clinical trials - Registration and reporting [CTR&amp;R]</td>
<td>Mr. Bron Kisler, CDISC</td>
<td>00.00</td>
<td>This project will start once BRIDG [14199] is underway</td>
<td>2013/10/13</td>
<td></td>
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<td>Rotterdam 6 Kuopio 20</td>
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<tr>
<td>2</td>
<td>PWI</td>
<td>Vienna R49: Spirometry: [WG7-R14] Regarding an NP on</td>
<td>Mr. Alpo Varri (FIN)</td>
<td>2013-09-09: Is slated for discussion in Sydney. Alpo Varri coordinating.</td>
<td>2013/10/13</td>
<td></td>
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<td></td>
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<td>Vienna 49</td>
<td></td>
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<tr>
<td>2</td>
<td>ISO/NP DTR 19231</td>
<td>Survey of mHealth projects in low to middle income countries (LMIC)</td>
<td>Mr. IL. Kon Kim (Korea)</td>
<td>10.60 - NP Close of voting</td>
<td>2013-10-13: Passed NP-DTR ballot - ROV posted as N1264.</td>
<td>2013/10/13</td>
<td></td>
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<td>NP ROV=</td>
<td>Mexico City R27</td>
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<td>2</td>
<td>ISO / DTR 17522</td>
<td>Health informatics, Provisions for Health Applications on Mobile / Smart Devices [TR]</td>
<td>Mr. IL. Kon Kim (Korea)</td>
<td>30.60 - CD/DTR Close of voting</td>
<td>2013-10-13: DTR ROV posted as N807 WG2 ISOTC215 N1265. Passed DTR.</td>
<td>2013/10/13</td>
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<td>NP ROV=</td>
<td>Mexico City R21</td>
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<tr>
<td>2</td>
<td>ISO/NP TS 22077-2</td>
<td>Health informatics, Medical waveform format Part 2: Electrocardiography</td>
<td>Mr. Masaaki Hirai (Japan)</td>
<td>10.20 -</td>
<td>2013-09-10: NP ballot closed 2013-09-29. Have not yet uploaded final results because the item is short three experts - two were named and three are required. We are contacting the NMBs that voted in support to try to find three additional experts. Item to be discussed and resolved in Sydney in Oct 2013.</td>
<td>2013/10/13</td>
<td></td>
<td></td>
<td>NP ROV=</td>
<td>Mexico City R20</td>
<td></td>
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<tr>
<td>2</td>
<td>ISO/NP TS 22077-3</td>
<td>Health informatics, Medical waveform format Part3 : Long term Electrocardiography</td>
<td>Mr. Masaaki Hirai (Japan)</td>
<td>10.20 -</td>
<td>2013-10-13: NP ballot closed 2013-09-29. Have not yet uploaded final results because the item is short three experts - two were named and three are required. We are contacting the NMBs that voted in support to try to find three additional experts. Item to be discussed and resolved in Sydney in Oct 2013.</td>
<td>2013/10/13</td>
<td></td>
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<td>NP ROV=</td>
<td>Mexico City R20</td>
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<td></td>
<td>ISO / CD 17583</td>
<td>Health informatics, Terminology constraints [Binding] for coded data elements expressed in ISO harmonized data types used in healthcare information interchange - joint w/WG3 - WG2 lead</td>
<td>Mr. Beeler, Mr. Klein (US)</td>
<td>30.99</td>
<td>2013-09-10: WG2 is lead. Moved from 36 to 48 month track. DIS draft &amp; disposition of NP comments expected by Sydney.</td>
<td>2013/10/13</td>
<td>Vancouver 11;</td>
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<td></td>
<td>ISO / DTS 13131</td>
<td>Health informatics, Quality criteria for services and systems for telehealth [DTS]</td>
<td>Mr. Alan Taylor (AUS)</td>
<td>30.20</td>
<td>2013-10-13: In DTS ballot as N1283.</td>
<td>2013/10/13</td>
<td>Kuopio 23</td>
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<tr>
<td>Number</td>
<td>Standard/Reference</td>
<td>Description</td>
<td>Date</td>
<td>Status</td>
<td>Responsible Person</td>
<td>Next SI</td>
<td>SI Details</td>
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<td>2</td>
<td>ISO / NP 12974</td>
<td>Web access to DICOM persistent objects by means of web services extension of the retrieve service (WADO web service)</td>
<td>10.60</td>
<td>2013-01-25: Per discussion at DICOM meeting @ HL7 in Phoenix - cancelled from TC215 work program.</td>
<td>-</td>
<td>-</td>
<td>WG2: Please provide update. NP ballot closed 2008-10-13; results N655; is this Chicago Res 77? Test was due 29 Feb 2012. Will be cancelled if status not provided soon.</td>
<td>Chicago ?</td>
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<td>2</td>
<td>ISO / HL7 / DIS 13449</td>
<td>Health informatics, Clinical genomics pedigree topic</td>
<td>40.60</td>
<td>2013-01-25: No action or update received for 12 months; has been cancelled from TC215 work program.</td>
<td>Amon Shabo, IBM</td>
<td>2013/01/30</td>
<td>Last results N878</td>
<td>Kuopio 21</td>
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<tr>
<td>2</td>
<td>ISO TR 13128:2012 (Ed. 1)</td>
<td>Health Informatics, Clinical document registry federation (DTR)</td>
<td>60.60</td>
<td>TR published in June 2012 - congratulations!</td>
<td>-</td>
<td>-</td>
<td>2012/07/16</td>
<td>Kuopio 22</td>
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<td>2</td>
<td>ISO 10159:2011 (Ed. 1)</td>
<td>Health informatics -- Messages and communication -- Web access reference manifest</td>
<td>60.00</td>
<td>International Standard Published</td>
<td>-</td>
<td>-</td>
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<td>2</td>
<td>ISO/HL7 21731:2006 (Ed. 1)</td>
<td>Health informatics, ISO/HL7 v3 - Reference information model (RIM) - R1</td>
<td>90.60</td>
<td>Published. Next SI is 2014</td>
<td>Gary Dickinson</td>
<td>-</td>
<td>-</td>
<td>External reference: HL7 RIM R1-2003</td>
<td>Chicago 5</td>
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**Published Standards**

- **ISO 10159:2011 (Ed. 1)**: Health informatics -- Messages and communication -- Web access reference manifest. Published in June 2012.
- **ISO/HL7 21731:2006 (Ed. 1)**: Health informatics, ISO/HL7 v3 - Reference information model (RIM) - R1. Published in 2012.
<table>
<thead>
<tr>
<th>Work Group 3: Semantic content</th>
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</table>

### Preliminary work items

<table>
<thead>
<tr>
<th>ISO/PWI 19239</th>
<th>Health informatics, Conceptual framework for representation of treatment and diagnostic non-chemical stimulation methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/PWI 13581</td>
<td>Health informatics, Guidance for maintenance of object identifiers (OIDS) (with WG2)</td>
</tr>
<tr>
<td>ISO/PWI TR 12310</td>
<td>Health informatics, Principles and guidelines for the measurement of conformance in the implementation of terminological resources</td>
</tr>
<tr>
<td>EN ISO/PWI 12264:2005</td>
<td>Health informatics, Categorial structures for systems of concepts</td>
</tr>
<tr>
<td>ISO/NP TR 14668</td>
<td>Health informatics, Clinical decision support</td>
</tr>
<tr>
<td>EN ISO 12381</td>
<td>Time standards for healthcare specific problems</td>
</tr>
</tbody>
</table>

### Items requested for reinstatement

<table>
<thead>
<tr>
<th>3</th>
<th>ISO/PWI 19239</th>
<th>Health informatics, Conceptual framework for representation of treatment and diagnostic non-chemical stimulation methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>ISO/PWI 13581</td>
<td>Health informatics, Guidance for maintenance of object identifiers (OIDS) (with WG2)</td>
</tr>
<tr>
<td>3</td>
<td>ISO/PWI TR 12310</td>
<td>Health informatics, Principles and guidelines for the measurement of conformance in the implementation of terminological resources</td>
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</table>

### ACTIVE WORK ITEMS

<table>
<thead>
<tr>
<th>3</th>
<th>prEN ISO/CD 16278</th>
<th>Health informatics, Categorial structures for terminological systems of human anatomy (EN 15521: 2007 Categorial structure for terminologies of human anatomy)</th>
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| W G | ISO # | ISO Title | PLs | Current Stage | Stage desc at time of this report | As of this date | If currently in ballot: date open | If currently in ballot: date closes | COMMENTS COLUMN FOR WG3 CALLS | TC Secretary Reply | Other key info | SKMT Status | Resolutions |
|-----|-------|-----------|-----|--------------|----------------------------------|---------------|-------------------------------|-------------------------------|---------------------------------|-----------------|---------------|-------------|-------------|-------------|
| 3   | 19239 | ISO/PWI 19239 | Health informatics, Conceptual framework for representation of treatment and diagnostic non-chemical stimulation methods | Prof Hirose (Japan) | 00.00 - PWI | 2013-10-13 | Per HG, NP ballot to be prepared for Sydney with proposal to change title to ‘Categorial Structure for the representation of physical external stimuli’ | 2013/10/13 | 2013-06-28: TC215 secretary requested an ISO number for item tracking. Task complete. | Vancouver 20 |
| 3   | 13581 | ISO/PWI TR 13581 | Health informatics, Guidance for maintenance of object identifiers (OIDS) (with WG2) | Mr. Kai Heitmann (DIN) & Mr. Ted Klein (US) | 20.00 | 2013-10-13 | Per HG, Form 4 and WD to be prepared for Sydney. / Lisa requested reinstatement to TC215 work program and this has been completed. HG will contact Kai regarding status | 2013/10/13 | Name to be considered as NP prepared | 2013-06-28: Originally closed in 2009, ISOCS cancelled. Reinstatement requested. |
| 3   | 12310 | ISO/PWI TR 12310 | Health informatics, Principles and guidelines for the measurement of conformance in the implementation of terminological resources | Ms. Sandy Stuart (US) & Ms. Beverly Knight (CAN) | 20.00 - Reinstated to work program | 2013-10-13 | Sandy Stuart has checked in with questions so the work progress is expected to resume. | 2013/10/13 | 2013-06-30: Lisa has submitted Request for reinstatement to ISO-CS. | Mexico City 38 |
| 3   | 12264:2005 | EN ISO/PWI 12264:2005 | Health informatics, Categorial structures for systems of concepts | Ms. Anne Casey (UK) | 00.00 - PWI | 2013-10-13 | Form 4 & WD to be provided in Sydney. / HG to send info so LS can request an ISO number to ensure tracking and avoid confusing this project with others that have similar sounding titles | 2013/10/13 | Working Draft to be prepared for circulation to informal expert group towards NP decision in Sydney | Vienna R17, [WG3-R6] an NP based on EN12264 Categorial Structures for Systems of |
| 3   | 14668 | ISO/NP TR 14668 | Health informatics, Clinical decision support | Ms. Heather Grain? (Australia) | 00.00 - PWI | 2013-10-13 | Potential project, reviewing with WG4 6 Sept : HG working on a draft | 2013/10/13 | | Vienna 17 Mexico City 39 |
| 3   | 12381 | EN 12381 | Time standards for healthcare specific problems | CEN TC215 WG2 | 00.00 - PWI | 2013-10-13 | To be discussed in October for next steps. | 2013/10/13 | JIC view? | 2013-06-06: I moved this to preliminary since 1st time seeing this. |

### ACTIVE WORK ITEMS

<p>| 3 | prEN ISO/CD 16278 | Health informatics, Categorial structures for terminological systems of human anatomy (EN 15521: 2007 Categorial structure for terminologies of human anatomy) | Dr Park (Korea) | 30.60 - close of CD voting | 2013-10-13 | I requested and received an extension so this must stay on schedule - DIS text &amp; CD disposition of comments must be submitted to me by 5 Nov 2013 or ISO will cancel this. DIS &amp; CD disposition w/export group for sign off by 15 August - for DIS decision in Sydney. - 6 Sept: Check and see if was sent - HG, AC, LS | 2013/10/13 | Submitted. Name and number confirmed with ISO central secretariat. Needs project lead | N780 - voting results (2010-05-26); approved as WD. | 2012-03-02, approved N950. | Kuopio 28, Mexico City 40 |</p>
<table>
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<tr>
<th>W G</th>
<th>ISO #</th>
<th>Title</th>
<th>PLs</th>
<th>Current Stage</th>
<th>Stage desc at time of this report</th>
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<th>If currently in ballot: date closes</th>
<th>COMMENTS COLUMN FOR WG3 CALLS</th>
<th>TC Secretary Reply</th>
<th>Other key info</th>
<th>SKMT Status</th>
<th>Resolutions</th>
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<tbody>
<tr>
<td>3</td>
<td>NPO T5</td>
<td>17117-1</td>
<td>Dr Imai (Japan)</td>
<td>10.99</td>
<td>2013-10-13: Dr. Imai going to do some more work on the draft and target to submit before or in Sydney for review and discussion.</td>
<td>2013/10/13</td>
<td></td>
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<td></td>
<td>2013-06-26: Lisa notified WG3 that the request for reinstatement is complete.</td>
<td>2011-05-13: RWIP results posted N842.</td>
<td>Kuopio 40, Mexico City 36</td>
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<tr>
<td>3</td>
<td>NPO T5</td>
<td>18790-1</td>
<td>Dr. Haiyan Li (China)</td>
<td>10.60</td>
<td>2013-10-13: Passed NP - NP ROV posted as N1266.</td>
<td>2013/10/13</td>
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<td>Mexico City</td>
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<tr>
<td>3</td>
<td>AWI T5</td>
<td>16277-1</td>
<td>Dr. Kyungmo Park (Korea)</td>
<td>30.20</td>
<td>2013-10-13: Passed DTS - ROV N1275S. on Sydney WG3 agenda for review and discussion.</td>
<td>2013/10/13</td>
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<td>Chicago 11; Vienna 16; Mexico City N29</td>
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<td>3</td>
<td>DT5</td>
<td>17439</td>
<td>Ms. Heather Grain (Australia)</td>
<td>30.20</td>
<td>2013-10-13: Name change passed; DTS ballot opened as N1239 and closes 2013-10-20.</td>
<td>2013/10/13</td>
<td>2013/08/07</td>
<td>2013/10/20</td>
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<td>Mexico City 35</td>
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<tr>
<td>3</td>
<td>FDIS</td>
<td>18104</td>
<td>MS. Anne Casey (UK-BSI)</td>
<td>50.20</td>
<td>2013-10-13: In FDIS and proof sent to PL for review.</td>
<td>2013/10/13</td>
<td>2013/10/03</td>
<td>2013/12/04</td>
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<td>Kuopio 38; Vancouver 22; Mexico City 37</td>
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<tr>
<td>3</td>
<td>NPO T5</td>
<td>16843-1</td>
<td>Dr. Kyungmo Park (Korea)</td>
<td>10.99</td>
<td>2013-10-13: Dr Park provided an update - draft text and form 4 for review prior to end in Sydney. These docs have been uploaded to WG3 project folder for this item. is on Sydney agenda.</td>
<td>2013/10/13</td>
<td></td>
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<td>2013-06-28: Request for reinstatement complete. PL</td>
<td>Kuopio 40, Mexico City</td>
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<td>3</td>
<td>NPO T5</td>
<td>16843-2</td>
<td>Dr. Cui Meng, (China)</td>
<td>10.99</td>
<td>2013-10-13: PL has submitted NP draft, a completed form 4 and disposition of previous comments. These items uploaded as N087 and available for WG3 review.</td>
<td>2013/10/13</td>
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<td>2013-06-28: Req for reinstatement complete. Timeline update requested from PL. WG3 - please provide update for next steps to record on this work program. Working draft posted for review.</td>
<td>Kuopio 40; Mexico City 34</td>
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<td>3</td>
<td>CD</td>
<td>17583</td>
<td>Mr. G. Beeler and Mr. Ted Rein (US) - Joint w/WG2 - WG2 lead</td>
<td>30.99</td>
<td>2013-10-13: DIS draft &amp; NP disp comments are behind schedule but are expected for Sydney. WG2 is the lead on this item.</td>
<td>2013/10/13</td>
<td></td>
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<td>Significant comments to be resolved by expert group - for repeat CD ballot after Sydney</td>
<td>2011-07-08: NP results posted N857. CD results N1058.</td>
<td>Kuopio 24</td>
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<td>3</td>
<td>ISO/DTS 17938 Semantic network framework and coding of Traditional Chinese Medicine language system</td>
<td>Prof Meng (China)</td>
<td>30.99 - awaiting final text</td>
<td>2013-10-13: AC has requested sign off by expert group by 12 September. // 2013-09-06: HG going to check w/PL to see if this is on schedule to be completed by deadline</td>
<td>2013/10/13</td>
<td>DTS ballot closed 8 June ROV: passed (2 negative votes - DIN, KATS) Disposition of comments posted Awaiting revised Draft for review before Sydney towards TS Resolution at Chicago 13</td>
<td>2013/10/13</td>
<td>DTS ballot closed 8 June ROV: passed (1 negative vote - DIN) Disposition of comments posted Awaiting revised Draft for review before Sydney towards TS Resolution at Chicago, Vienna 18, Mexico City 30</td>
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<tr>
<td>3</td>
<td>ISO/AWI DTS 17948 Health Informatics -- Traditional Chinese medicine literature metadata</td>
<td>Prof Meng (China)</td>
<td>30.99 - awaiting final text</td>
<td>2013-10-13: AC has requested sign off by expert group by 12 September. // 2013-09-06: HG going to check w/PL to see if this is on schedule to be completed by deadline</td>
<td>2013/10/13</td>
<td>DTS ballot closed 8 June ROV: passed (1 negative vote - DIN) Disposition of comments posted Awaiting revised Draft for review before Sydney towards TS Resolution at Chicago 13; Vienna 18; Mexico City 31</td>
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<tr>
<td>3</td>
<td>ISO/AWI TS 18062 Health informatics, Categorical structure for representation of herbal medicaments in terminological systems</td>
<td>Prof Hirose (Japan)</td>
<td>20.00 - np approved and registered</td>
<td>2013-10-13: Revised working draft in preparation. WG6 to be included in review when draft ready. Awaiting final text</td>
<td>2013/10/13</td>
<td>Revised draft will be circulated to the expert group and further comments addressed in time for circulation to WG3 and WG6 before October meeting</td>
<td>2013/10/13</td>
<td>DTS ballot closed 12-03-20, results N934. Proposed as probable for new JWG10 [TCM] work Chicago 9</td>
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<td>1</td>
<td>ISO / DIS 13940 System of concepts to support continuity of care [ContSys] - Joint w/WG3; WG1 in lead</td>
<td>Mr. Nicholas Outibridge (BSI)</td>
<td>40.60 - In CD ballot</td>
<td>2013-10-13: Passed DIS - DIS ROV initial prelin combined ISO CEN-N1200. Updated ROV w/post-decision to be filed after next &quot;ad hoc&quot; ballot that is planned by PL per email from Nick O on 13 June 2013. Over 600 comments were received on CD ballot so project team working to dispose; on Australia WG1 agenda for review and discussion</td>
<td>2013/10/13</td>
<td>N1200=Prelin ISO-CEN DIS ROV</td>
<td>2013/10/13</td>
<td>N711 - voting results (2009-06-18)</td>
<td>Kuopio 29; Vancouver24; Vienna 21</td>
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**Published Standards**

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<td>3</td>
<td>ISO 13520 Health informatics, Syntax to represent the content of healthcare classification systems, Classification Markup Language (CiML)</td>
<td>Published 2015 - to start review in 2015</td>
<td>Keept on work program to ensure early review (2015) - suggested project lead to be user of the standard Vienna 15</td>
</tr>
<tr>
<td>3</td>
<td>ISO 13582 Health informatics, Sharing of OID Registry information</td>
<td>60.00 - Is published</td>
<td>N711 - voting results (2009-06-18)</td>
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<tr>
<td>3</td>
<td>EN ISO 1828 Categorical Structure for Terminological Systems of Surgical Procedures</td>
<td>60.60 - Is published 2012-09-12</td>
<td>2011-10-13: DIS vote results Kuopio 39</td>
</tr>
<tr>
<td>3</td>
<td>EN ISO 13119 Health informatics -- Clinical knowledge resources -- Metadata</td>
<td>60.60 - Is published 2012-10-26</td>
<td>Congratulations!</td>
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## Working Group 4: Privacy, Safety, and Security

### Preliminary work items [PWI]

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<tr>
<th>ISN #</th>
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<th>Next Due Date</th>
<th>If currently in ballot: date open</th>
<th>If currently in ballot: date closes</th>
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<th>SKMT Status</th>
<th>Resolutions</th>
<th>Start Date</th>
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<td>Machine ID for patients</td>
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<td>DW checking if this should remain on PWI</td>
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<td>2013/09/10</td>
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### Active work items [AWI]

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<th>If currently in ballot: date open</th>
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<th>SKMT Status</th>
<th>Resolutions</th>
<th>Start Date</th>
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<tbody>
<tr>
<td>4</td>
<td>ISO/TR 14668 Alert information for risk management</td>
<td>Mr. R. Lövström</td>
<td>0.00</td>
<td>Discussion in process; WebEx has been held and to be discussed in Sydney</td>
<td>2013/10/13</td>
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<td>Discuss in Sydney</td>
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<tr>
<td>4</td>
<td>EN-ISO 27799 Information security management in health</td>
<td>Mr. R. Fraser (CAN)</td>
<td>0.00</td>
<td>Revision of 27799 HI - Information security management in health using ISO/IEC 27002</td>
<td>2013/10/13</td>
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<td>Discuss in Sydney</td>
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### Notes
- Revisions of ISO 21298:2008, Health informatics, Functional structure and roles
- Revision of ISO/AWI TR 21298:2008, Health informatics, Functional structure and roles
- ISO/CD 17090-2: Health informatics - Public Key Infrastructure - Part 2: Certificate profile
- ISO/AWI 25237: Health informatics, Pseudonymization 25237:2008 | New work item -
Still need both next line? Yes I migrated to the this since it has


Health informatics, Patient healthcard data – Part 3: Limited clinical data - (Ed 2) Mr. I. Emelin (GOST R Experts) 50.00 - DIS approved for FDIS 2013-09-09: ISO/CS expects to open FDIS 2013-09-12 and close 2013-11-13. 2013/10/13 2013/08/15 FDIS expected to open 2013-09-12 FDIS expected to close 2013-22-13 This is a revision of ISO 21549-3:2004 2011-11-02: N807 NP vote results; approved as CD 2013-03-14: ISO registered @ 20.00 Vancouver 28 Mexico City 40

Health informatics, Patient healthcard data – Part 4: Extended clinical data - (Ed 2) Mr. I. Emelin (GOST R Experts) 50.00 - DIS approved for FDIS 2013-09-09: ISO/CS expects to open FDIS 2013-09-12 and close 2013-11-13. 2013/10/13 2013/08/15 FDIS expected to open 2013-09-12 FDIS expected to close 2013-22-13 This is a revision of ISO 21549-5:2004 2011-11-02: N808 NP vote results; approved as CD 2013-03-14: ISO registered @ 20.00 Vancouver 50 Mexico City 50

Health informatics, Patient healthcard data-Part 5: Identification data - NP for the revision of 21529-5:2008 Mr. I. Emelin (GOST R Experts) 30.20 - in CD ballot N260 opened on 2013-08-21 and closes 2013-10-21. 2013/10/13 2013-08-21 2013/10/21 This is a revision of 21549-5:2008; ISO-IEC w/ISO as lead 2013-03-14: ISO registered @ 20.00 Vancouver 19 Mexico City 46

Health informatics, Patient healthcard data-Part 7: Medication Mr. I. Emelin (GOST R Experts) 20.00 - NP registered on WP This item is behind. Draft by 2013/08/01. Will circulate 2013/09/05. Sent email to follow up on status 2013/09/06 // 2013-09-09: text for CD ballot no later than 2014-03-01. 2013/10/13 2013/08/01 2013-03-14: ISO registered @ 20.00 Vancouver 10

Health informatics - Principals and data requirements for consent in the collection, use or disclosure of personal health information Ms. T. Sawatsky (EIC) 30.20 - in CD/DTS ballot 2013-10-13: CD ballot results: Did not pass DTS ballot. 2013/10/13 10/10/2013, on agenda for Sydney NP form 6 N975 Mexico City 42 - Title Mexico City 43

Health Informatics, Data protection in trans-border flows of personal health information Mr. L. Posthumus (NEN Experts) 20.00 - NP registered on WP 2013-09-10: ISO 16864 to replace ISO 22857. Migration path discussed in Vienna | NP ROV is N759. NOTE approaching DIS limit date of 2013-11-12. NOTE: Will be automatically cancelled by ISO CS if this does not keep moving forward. 2013/10/13 Discuss in Sydney 2013-02-13: IECOS granted request for a Track 3 extension of 48 months 2011-03-24: NP.V05 vote results - N903 - revised voting results (2013-11-02), approved as WD. NP ROV form 6 is 759 2011-11-02, N904 NP vote results; approved as CD 2013-03-14: ISO registered @ 20.00 Vancouver 11 Mexico City 51 Do I still need this since it has migrated to the next line? Yes I still need both

Guidelines on data protection to facilitate trans-border flows of personal health data Mr. L. Posthumus (NEN Experts) 50.00 - DIS approved for FDIS 2013-09-10: in ISO CS FDIS prep. ISO 16864 replace ISO 22857. 2013/10/13 Discuss in Sydney Secretary filed an extension - extended to 2013-10-30; DIS opened by ISO/CS: 2011-06-28; closed 2011-11-28 - Passed 17/18 - Committee Decision 2013-03-14: ISO registered @ 20.00 Vancouver 11 Mexico City 51

Health informatics – Health cards – General characteristics Mr. M. Tachida (JISC_JTC1) 50.00 - registered for FDIS 2013-09-10: IECOS opened FDIS ballot 2013-09-02, closes 2013-11-03. 2013/10/13 2013/09/02 2013/11/03 Revision of ISO 20301:2006 2011-11-02: N808 NP vote results; approved as a CD; DIS ROV 8844 Chicago 50 Mexico City 46

ISO/CS expects to open FDIS 2013-09-12.

ISO/CS opened FDIS ballot 2013-09-02, closes 2013-11-03.

ISO/CS granted request for a Track 3 extension of 48 months.

Juliet Haddock
| No. | ISO/TS 14441 | Health informatics, Security and privacy requirements for compliance testing of EHR systems -- Part 1: Foundation | Mr. R. Fraser (CAN) | 60.00 - on hold | Mexico City 42; DTS copy to Secretary by 30 April. 24 May 2013 need the following: (1) Completed text ready for publication (2) Native graphic files for any graphics that are not able to be easily manipulated in the document. sent f/u email 2013/05/28 & 2013/06/08 // 2013-06-06: Need document text. Lori Sent email to follow up on status 2013/05/06 2013-09-09; DW still waiting for final text from PL. This is far behind schedule and risks ISO cancellation if no movement. | 2013/10/13 2013/12/31 | - | VA: ISO Lead CEN/TC 251 voting results; approved as WD | Chicago 27 Vienna 30 Mexico City 41 |
| No. | ISO/TS 20302 | Health Informatics - Health cards - Numbering and issuer identification | Mr. M. Yoshida (Japan) | 50.20 - in FDIS | 2013-10-13: In FDIS closes 2013-12-11. 2013/10/13 2013/10/10 2013/12/11 | Due to Secretary 2013/06/02 | Mexico City 47 |
|---|---|---|---|---|---|---|
ISO 17090-3:2008
HI -- Public key infrastructure -- Part 3: Policy management of certification authority
Mr. R. Fraser (CAN) 60.60 - In SR
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<td>Preliminary work items [PWI]</td>
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<tr>
<td>1 &amp; 4</td>
<td>ISO / WD 13806-4</td>
<td>Health informatics, EHR Communication Part 4 - Security (Doing jointly w/WG1)</td>
<td>Mr. D. Kalra (BSI)</td>
<td>20.20 - WD started</td>
<td>NP N1054 passed, results w/form 6 posted as N1134; Text in development &amp; disp comments. (Transferred to WG 1 - DONE 2013/06/07</td>
<td>2013/06/07</td>
<td>WG 1 Lead</td>
<td>NP ballot closed 2012-09-04; passed, results N1054; Updated w/form 6 as N1134</td>
<td>Mexico City 13</td>
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<td>Potential NP on EHR migration WG 1 Lead</td>
<td>2013/06/27</td>
<td>WG 1 Lead</td>
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**Active work items [AWI]**
### Work Group 6: Pharmacy & Medicines

#### Preliminary work items [PWI]

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<th>As of this date</th>
<th>If currently in ballot: date open</th>
<th>If currently in ballot: date closes</th>
<th>Other key info</th>
<th>SKMT Status</th>
<th>Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>No ISO # yet</td>
<td>Possible PWI: Medical alert information</td>
<td>Possible joint project with other WGs. WG6 not in the lead.</td>
<td>2013/10/13</td>
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<td></td>
<td>IDMP implementation guidances</td>
<td>are proposed as NWIP at SYD meeting (5 or 6 TS).</td>
<td>2013/10/13</td>
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#### Active work items

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<tr>
<th>#</th>
<th>ISO/TS 19293 - 19294</th>
<th>Title</th>
<th>PLs</th>
<th>As of this date</th>
<th>If currently in ballot: date open</th>
<th>If currently in ballot: date closes</th>
<th>Other key info</th>
<th>SKMT Status</th>
<th>Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>ISO/NP TS 19293</td>
<td>TS-Health informatics, Requirements for a record of the Dispense of a Medicinal Products</td>
<td>Michael Steine <a href="mailto:michael.steine@bt.com">michael.steine@bt.com</a></td>
<td>10.99</td>
<td>2013-10-13: Passed NP ballot - ROV is N1271</td>
<td>2013/10/13</td>
<td>Mexico City R62</td>
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<tr>
<td>6</td>
<td>prEN/ISO TS 19294</td>
<td>IS - Health informatics, Data elements and structures for identification of extemporeous and magistral (compound) pharmaceutical preparations without marketing authorisation</td>
<td>Michael Steine <a href="mailto:michael.steine@bt.com">michael.steine@bt.com</a></td>
<td>10.99</td>
<td>2013-10-13: Passed NP ballot - ROV is N1272</td>
<td>2013/10/13</td>
<td>Mexico City R63</td>
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<tr>
<td>6</td>
<td>prEN / ISO/NP TS 17251</td>
<td>Health informatics, Business requirements for a syntax to exchange structured dose information for medicinal products [TS]</td>
<td>Michael Steine <a href="mailto:michael.steine@bt.com">michael.steine@bt.com</a></td>
<td>10.99</td>
<td>2013-10-13: Passed NP ballot - ROV is N1269</td>
<td>2013/10/13</td>
<td>Kuopio 54; Mexico City 58</td>
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<td>6</td>
<td>prEN ISO/TS NP 19256</td>
<td>Health informatics, Requirements for medicinal product dictionaries</td>
<td>Lenora Grandia (NEN)</td>
<td>10.99</td>
<td>2013-10-13: Passed NP ballot - ROV is N1267</td>
<td>2013/10/13</td>
<td>Mexico City R61</td>
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This is NOT a pure WG6 work Item; it is lead by another WG.

IDMP implementation guidances are proposed as NWIP at SYD meeting (5 or 6 TS).
<table>
<thead>
<tr>
<th>No.</th>
<th>Task</th>
<th>Description</th>
<th>Status</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>6</td>
<td>prEN /ISO / CD 17523</td>
<td>Health informatics, Requirement for electronic prescriptions</td>
<td>30.60</td>
<td>2013-10-03: CD ROV N1268. Please note item is approaching deadline. DIS text must be submitted to TC215 Secretary by 2013-12-01. This item passed CD ballot w/many comments – 27 pages worth. This item is proceeding jointly with CEN251 so falls under the Vienna Agreement and as such, the CEN ROV is included with these results. This item and its results are on the TC215 WG agenda for review and discussion at the upcoming TC215 meeting in Australia. Following review and discussion, the PL is asked to inform the TC215 Secretary if a 2nd CD will occur or if this will proceed to DIS. Until such time, this item is posted as a preliminary result. Thank you.</td>
</tr>
<tr>
<td>6</td>
<td>ISO/DTS 16791</td>
<td>Health informatics, Requirements for international machine-readable coding of medicinal product package identifiers using the GS1 system (using the GS1 system added per Mexico R59)</td>
<td>50.00</td>
<td>2013-09-09: Final TS documents have been submitted to ISO CS for publication preparation.</td>
</tr>
<tr>
<td>6</td>
<td>ISO/DTS 16791</td>
<td>Health informatics, Requirements for international machine-readable coding of medicinal product package identifiers using the GS1 system (using the GS1 system added per Mexico R59)</td>
<td>50.00</td>
<td>2013-09-09: Final TS documents have been submitted to ISO CS for publication preparation.</td>
</tr>
<tr>
<td>6</td>
<td>ISO / NP TR 14872</td>
<td>Health informatics, Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information [TR]</td>
<td>10.98</td>
<td>Has been automatically cancelled by ISO/CS - item has been on the program too long</td>
</tr>
<tr>
<td>6</td>
<td>ISO / NP TR 14872</td>
<td>Health informatics, Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information [TR]</td>
<td>10.98</td>
<td>2013/09/09: DTR text was due 15 Dec 2012 per Vienna R 33. (WG6-R2) - not yet received by TC sec. Project delayed per Shirin; WG6 secretary working w/PL &amp; convenor. (Behind schedule, tentative for Mexico City)</td>
</tr>
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WG 6
N1316_WG6_Master TC215 Work Program_as of 2013-10-13.xlsx
<table>
<thead>
<tr>
<th>No.</th>
<th>Standard Code</th>
<th>Standard Title</th>
<th>Details</th>
<th>Published Date</th>
<th>Project Details</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>ISO/FDIS 11238</td>
<td>HI- Identification of medicinal products - [IDMP] - Data elements and structures for the unique identification and exchange of regulated information on substances</td>
<td>L. Callahan (ANSI Experts)</td>
<td>60.00</td>
<td>Congratulations - International Standard was published 2012-10-26</td>
<td>2012/11/21</td>
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<td>6</td>
<td>ISO/FDIS 11239</td>
<td>HI- Identification of medicinal products - [IDMP] - 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</td>
<td>R. Granados Martin (AENOR ISO Experts)</td>
<td>60.00</td>
<td>Congratulations - International Standard was published 2012-10-26</td>
<td>2012/11/21</td>
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<td>6</td>
<td>ISO/FDIS 11240</td>
<td>HI- Identification of medicinal products - [IDMP] - Data elements and structures for unique identification and exchange of units of measurement</td>
<td>C. Gesauer (DIN Experts)</td>
<td>60.00</td>
<td>Congratulations - International Standard was published 2012-10-26</td>
<td>2012/11/21</td>
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<td>6</td>
<td>ISO/FDIS 11615</td>
<td>HI- Identification of medicinal products - [IDMP] - Data elements and structures for the unique identification and exchange of regulated medicinal product information</td>
<td>T. Buxton (EMEA)</td>
<td>60.00</td>
<td>Congratulations - International Standard was published 2012-10-26</td>
<td>2012/11/21</td>
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<td>6</td>
<td>ISO/FDIS 11616</td>
<td>HI- Identification of medicinal products - [IDMP] - Data elements and structures for unique identification and exchange of regulated pharmaceutical product information</td>
<td>L. Grandia (IM SDO)</td>
<td>60.00</td>
<td>Congratulations - International Standard was published 2012-10-26</td>
<td>2012/11/21</td>
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Note: Per WG6 Vienna report: WG6 is preparing a plan for the ongoing maintenance of the IDMP standards.

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Note: Per WG6 Vienna report: WG6 is preparing a plan for the ongoing maintenance of the IDMP standards.
### Preliminary work items

<table>
<thead>
<tr>
<th>WG</th>
<th>ISO #</th>
<th>ISO Title</th>
<th>PLs</th>
<th>Stage # at time of this report</th>
<th>Stage desc at time of this report</th>
<th>As of this date</th>
<th>If currently in ballot: date open</th>
<th>If currently in ballot: date closes</th>
<th>Other ISO info</th>
<th>Other key info</th>
<th>Entered in SKMT?</th>
<th>Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>JWG7</td>
<td>IEC / ISO / PWI 80001-2-x</td>
<td>IEC / ISO / PWI 80001-2-x: Application of risk management for IT-networks incorporating medical devices – Part 2-x: Guidance on standards for establishing the security capabilities identified in IEC/TR 80001-2-2, ISO TC215</td>
<td>0.00</td>
<td>Added to ISO/TC215 work program</td>
<td>2013/09/10</td>
<td>PWI IEC lead/TR 8001-2-x, to be added to TC215 work program</td>
<td>No</td>
<td>Mexico City 65</td>
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<tr>
<td>JWG7</td>
<td>IEC / CD 82304-1</td>
<td>Healthcare software systems - Part 1: General requirements - General implementation guidance for healthcare delivery organizations</td>
<td>Ms P Krantz, Mr P Linders</td>
<td>30.99</td>
<td>2013-09-11: Per SE: Schedule was revised in IEC to provide for a 2nd CD which is expected by 31 October 2013. A further revision of the schedule is currently being considered by the IEC SMB. CD2 2013-12, CDV 2014-11, FDIS 2015-06</td>
<td>2013/09/10</td>
<td>2013-09-11: Per SE: Schedule was revised in IEC to provide for a 2nd CD which is expected by 31 October 2013. A further revision of the schedule is currently being considered by the IEC SMB. CD2 2013-12, CDV 2014-11, FDIS 2015-06</td>
<td>No</td>
<td>Vancouver 3</td>
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<tr>
<td>JWG7</td>
<td>IEC 80001-1 Ed. 1.0</td>
<td>IEC 80001-1 Ed. 1.0 (2010-10-27), Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities</td>
<td>Mr T Cooper, Mr S Eagles</td>
<td>2010-10-03: IEC 80001-1 Ed. 1.0 passed TC215 committee internal ballot (CIB) approving extension.</td>
<td>2013/10/03</td>
<td>2013-10-03: IEC 80001-1 Ed. 1.0 passed TC215 committee internal ballot (CIB) approving extension.</td>
<td>No</td>
<td>Kuopio 88</td>
<td>Kuopio 90</td>
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<tr>
<td>JWG7</td>
<td>IEC 80001-1 2010-10-27</td>
<td>Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities</td>
<td>Mr T Cooper, Mr S Eagles</td>
<td>60.60</td>
<td>Published 2010-10-27</td>
<td>2013/10/03</td>
<td>2013-10-03: IEC 80001-1 Ed. 1.0 passed TC215 committee internal ballot (CIB) approving extension.</td>
<td>No</td>
<td>Kuopio 88</td>
<td>Kuopio 90</td>
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<tr>
<td>JWG7</td>
<td>IEC/TR 80001-2-3:2012</td>
<td>Part 2-3: Guidance for wireless networks</td>
<td>Dr. P. Raymond, Mr. R. Hampton</td>
<td>60.60</td>
<td>Published 2012-07-10</td>
<td>2012/09/08</td>
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<td>No</td>
<td>Kuopio 88 Kuopio 90</td>
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<tr>
<td>JWG7</td>
<td>IEC/TR 80001-2-4:2012</td>
<td>Application risk mgmt for IT-networks incorp med-devices-Part 2-4: General implementation guidance for healthcare delivery organisations</td>
<td>Dr. M. Baker (UK NHS)</td>
<td>60.60</td>
<td>Published 2012-12-03</td>
<td>2013/01/02</td>
<td></td>
<td>N1317: Combined IEC &amp; ISO ROV DTR ballot. DTR results</td>
<td>N1226 N1257 No Kuopio 92 &amp; 93, Vancouver 2, Vienna 55</td>
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### Preliminary work items

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<tr>
<th>ISO 20000-2-x</th>
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<th>Stage desc at time of this report</th>
<th>Other ISO Info</th>
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<tbody>
<tr>
<td>IEC 80001-2-x</td>
<td>Application of risk management for IT-networks incorporating medical devices – Part 2: Guidance on how to self-assess their conformance with IEC 80001-1</td>
<td>0.00 Preliminary research work being done at the Regulated Software Research Group, Dundalk Institute of Technology, Ireland</td>
<td>2012/08/16</td>
</tr>
</tbody>
</table>

- Resolved that ISO/TC215 approves the ISO/TC215-IEC/SC62A Joint Working Group 7 (JWG7) recommendation that IEC 80001-2-x, Application of risk management for IT-networks incorporating medical devices – Part 2: Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1” be added to the work program of ISO/TC 215 as a new preliminary work item to be jointly developed between ISO/TC 215 and IEC/SC62A within JWG7. And be it further resolved that, upon the future receipt from JWG7 of a Form 4 and initial working draft for this project, the ISO/TC 215 Secretariat shall circulate the NWIP for approval as a new work item targeting a technical report.


### Active work items

#### JWG7 ISO 82304-1

- **ISO 82304-1**
  - **No** Healthcare software systems - Part 1: General requirements (General implementation guidance for healthcare delivery organizations)
  - **10.00-20.00** JWG working on comment resolution in Vienna and next draft text. Also may meet w/WG4 in Vienna to discuss.
  - 2012/08/08
  - 2011-10-04: NP passed closed
  - V83: Regarding ISO/NP 82304, Healthcare software systems-Part 1: General requirements – Resolved 215-Notes the positive results of the NP ballot and instructs the ISO/TC215 Secretary to add to the TC work program and assign the project to JWG7.

#### JWG7 IS 80001-2-x

- **IS 80001-2-x**
  - **No** Application of risk management for IT-networks incorporating medical devices – Part 2: Guidance on distributed alarm systems
  - **10.00** 2012-05-25: NP ballot opened each in ISO & IEC. Ballot will close before Vienna and is on Vienna agenda for review and comment disposition
  - 2012/08/08
  - 2012-05-24
  - N108E: DTR NP text

#### JWG7 IEC/CD TR 80000-2-1

- **IEC/CD TR 80000-2-1**
  - **No** Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples
  - **30.00-60.00** Published 2012-07-10
  - 2012/08/08

#### JWG7 IEC/CD TR 80000-2-2

- **IEC/CD TR 80000-2-2**
  - **No** Part 2-2: Guidance for the communication of medical device security needs, risks and controls
  - **30.00-60.00** Published 2012-07-10
  - 2012/08/08

---

For more information, please refer to N1317_JWG7_Master_ISO TC215 Work Program as of 2013-10-13.xlsx - Past Notes.
| JWG7 | IEC/CD TR 80001-2-3 | 80001-2-3 | No | Part 2-3: Guidance for wireless networks | | Published 2012-07-10 | 2012/08/08 | 2012-05-24 | 2012-08-26 | Approves the disposition of NP ballot comments agreed to at the JWG 7 meeting and that the project should proceed to DTR ballot; Instructs the PL/WG convener to provide the updated text of the DTR and the final disposition of NP comments to the IEC/SC62A and ISO/TC 215 Secretaries no later than 1 June 2012; Instructs the ISO/TC 215 Secretary to coordinate with the IEC/SC62A Secretary to circulate a DTR ballot no later than 15 June 2012 | Unknown, please update |
|-----|------------------|----------|----|-----------------------------------------||                       |          |                                      |   |                                        | Kuopio 92 & 93, Vancouver 2 |
| JWG7 | DTR 80001-2-4 | 80001-2-4 | No | Application risk mngmt for IT networks incorp med devices - Part 2-4: General implementation guidance for healthcare delivery organizations | Dr. Maureen Baker (UK NHS) | 40.20 | 2012-05-24: NP ballot opened each in ISO & IEC. Ballot will close before Vienna & is on Vienna agenda for review and comment disposition | 2012/08/08 | | | Unknown, please update | Kuopio 88, Kuopio 90 |

**Part 2-3: Guidance for wireless networks**

Published 2012-07-10

2012/08/08

2012-05-24

2012-08-26

Approves the disposition of NP ballot comments agreed to at the JWG 7 meeting and that the project should proceed to DTR ballot; Instructs the PL/WG convener to provide the updated text of the DTR and the final disposition of NP comments to the IEC/SC62A and ISO/TC 215 Secretaries no later than 1 June 2012; Instructs the ISO/TC 215 Secretary to coordinate with the IEC/SC62A Secretary to circulate a DTR ballot no later than 15 June 2012

Unknown, please update

Kuopio 88, Kuopio 90
Appendix C – Resolutions at closing plenary
RESOLUTIONS FROM ISOTC215 COMMITTEE ADVISORY GROUP 1 (CAG01)

2013 Resolution 71 [CAG1-R1] "Stakeholder Needs and Interest Assessment and Evaluation Task Force"
--- ISO/TC 215 resolves to create a new task force, titled "Stakeholder Needs and Interest Assessment and Evaluation Task Force" to solicit stakeholder requirements with a particular emphasis on NMB functional needs. TC215 appoints Mr. Stephen Kay (UK) and Mr. Don Newsham (Canada) to form the TF and recruit additional volunteers as a first order of business.
--- The Task Force is asked to form and meet no later than 15 February 2014 and provide a status report at the May 2014 CAG01 meeting.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 72 [CAG1-R2] approval for TC215 chair to lead feedback to ITU
--- ISO/TC215 resolves to establish an advisory group under the responsibility of the ISO/TC215 Chair, Dr. Christopher G. Chute, to continue communication with the ITU and ISO/TC12 regarding the scope and the importance of previous informatics work with the new initiatives of ITU in eHealth telecommunications. The members of this advisory group will be chosen by the Chair.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 73 [CAG1-R3] acknowledge complaint from DIN regarding ISO/DTS 16791 and ISO/DTS 18530
For ISO/DTS 16791, Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers using the GS1 system, ISO/TC 215
--- approves the CAG1 recommendation to amend the title as: 'ISO/DTS 16791, Health informatics -- Requirements for international machine-readable coding of medicinal product package identifiers';
--- approves the addition of an appropriate disclaimer note concerning trademarks in accordance with the Dir Pt 2;
--- instructs its Secretary to notify ISO/CS of the amended title and disclaimer no later than 15 November 2013.

For ISO/DTS 18530 Health Informatics -- Automatic identification and data capture marking and labelling - Subject of care and individual provider identification
--- approves the addition of an appropriate disclaimer note concerning trademarks in accordance with the Dir Pt 2;
--- instructs its Secretary to notify ISO/CS of the disclaimer no later than 15 November 2013

Discussion: None; Opposed: None; Abstentions: None; Motion carries
RESOLUTIONS FROM THE ISO/TC215 OFFICE OF THE SECRETARIAT

2013 Resolution 74 [TC215-R1] appointment of ISO/TC215 work group leadership slate
ISO/TC215 approves the slate of ISOTC/215 convenors and vice convenors that were nominated by their work group members and approved for appointment by the TC215 chair.

WG2
— Convenor: Mr. Michael Glickman, United States
— Vice-convenor: Mr. Michael Nusbaum, IHE International

WG3
— Convenor: Ms. Heather Grain, Australia
— Vice-convenor: Still open – seeking nominations

WG4
— Convenor: Ms. Lori Reed-Fourquet, United States
— Vice-convenor: Mr. Hideyuki Miyohara, Japan

WG1:
— The term of Mr. Stephen Kay (UK) WG1 convenor concludes in 2013. A similar nomination, election and appointment process will be conducted with the eventual appointment of the individual as the first order of business in Japan in May 2014.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 75 [TC215-R2] Appreciation
— ISO/TC215 expresses its sincere appreciation to our Australian hosts and sponsors for the excellent meeting arrangements and hospitality during the 20th Meeting of ISO/TC215.

Discussion: None; Opposed: None; Abstentions: None; Motion carries
RESOLUTIONS WG1: ARCHITECTURE, FRAMEWORKS AND MODELS

Note: WG1 Resolutions were voted on as a block. For all Resolutions the vote was as follows:

Discussion: None; Opposed: None; Abstentions: None; Motion carries for all

2013 Resolution 76 [WG1-R1] prEN/ISO/DTS 13972 submission for TS publication
For prEN/ISO/DTS 13972, Health informatics - Detailed clinical models, characteristics and processes, ISO/TC215
— approves the disposition of the ISO/DTS 13972 ballot comments agreed to at the Sydney WG 1 meeting and confirms that the project lead ascertains the disposition comments are carried out;
— instructs the PL/WG convener to provide the updated text of ISO/TS 13972 and the final disposition of comments document to the WG1 Secretary no later than 10 January 2014;
— instructs the WG1 secretary to provide the updated text of ISO/TS 13972, and the final disposition of comments document to the TC 215 Secretary no later than 17 January 2014.
— instructs the TC 215 Secretary to submit to ISO CS for TS publication no later than 1 February 2014.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 77 [WG1-R2] ISO/PWI Reusable component strategy for use case development submission for NP ballot
For ISO/PWI, Reusable component strategy for use case development, ISO/TC215
— approves the recommendation of WG1 to proceed to NP ballot;
— instructs the project leader to provide a completed form 4 and text to the WG1 secretary no later than 28 October 2013; instructs the WG1 secretary to provide a completed form 4 and text to the TC215 secretary no later than 5 November 2013;
— instructs the TC215 Secretary to launch an NP ballot no later than 1 December 2013.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

For ISO/PWI, Health Informatics Quality Metrics for Detailed Clinical Models, ISO/TC215
— approves the recommendation of WG1 to proceed to NP ballot;
— instructs the project leader to provide a completed form 4 and text to the WG1 secretary no later than 1 December 2013.
— instructs the WG1 secretary to provide a completed form 4 and text to the TC215 secretary no later than 7 December 2013.
— instructs the TC215 Secretary to launch an NP ballot no later than 24 December 2013.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

— Thanks the leads and members of the PHTF and acknowledges the significant work done by the Task Force in preparing and delivering its final report.

— Sunsets the Public Health Task Force as of 24 October 2013;

— and recommends that TC215 consider the creation of a new ad-hoc group, perhaps under CAG1, to work in alignment with JIC LMIC Initiative and IMIA Standards for Health Care Informatics Working Group, and to be directed to pursue education, communication and outreach strategies directed primarily to Low and Middle Income Countries (LMICs) aimed at advancing their level of awareness and understanding of ISO TC215 standards, increasing their involvement and participation in ISO TC215, and promoting the adoption and implementation of ISO TC215 standards in LMICs.

Discussion: None; Opposed: None; Abstentions: None; Motion carries
RESOLUTIONS WG2: SYSTEMS AND DEVICE INTEROPERABILITY

**Note:** WG2 Resolutions were not voted as a block.

**2013 Resolution 80 [WG2-R1] ISO/PWI DTS Health Informatics, Trusted End-to-End Information flows – submission as Preliminary Work Item (PWI)**

- approves the WG2 recommendation to add ISO/TR 21089:2004, *Health Informatics, Trusted End-to-End Information flows* as a preliminary work item to the ISO/TC215 WG 2 work program;
- instructs the TC215 secretary to request ISO/CS add this item to the ISO/TC215 WG 2 work program no later than 15 November 2013.

**Discussion:**
- Mr. Luuc Posthumous (NEN) made the request to ensure that ISO/TC215 WG4 is involved. There was verbal agreement for this from the floor and no opposition or additional comment.

**2013 Resolution 81 [WG2-R2] ISO/DTR 28380-3 submission for TR publication**

- approves the WG2 recommendation to advance for TR publication;
- instructs the project lead to provide the disposition of DTR comments, final text and revisable graphics files to the WG2 Secretary no later than 30 November 2013;
- instructs the WG2 secretary to provide these items to the TC215 Secretary by 15 December 2013;
- instructs the TC215 Secretary to submit to ISOCS for TR publication by 15 January 2014

**Discussion:** None; **Opposed:** None; **Abstentions:** None; **Motion carries**

**2013 Resolution 82 [WG2-R3] ISO/DTR 19231 submitted for a TR ballot**

For ISO/DTR 19231, *Health informatics, Survey of mHealth projects in low to middle income countries (LMIC)*, ISO/TC 215
- agrees with WG2 recommendation to submit ISO/NP 19231 for TR ballot;
- instructs the PL to provide the disposition of NP/DTR comments, updated text and revisable files for any visuals to the WG2 secretary no later than December 15, 2013;
- instructs the WG2 secretary to provide these items to the TC215 secretary by January 15, 2014;
- instructs TC215 Secretary to open a TR ballot by February 15, 2014

**Opposed:** None; **Abstentions:** Australia, Sweden, Switzerland; **Motion carries**
**2013 Resolution 83 [WG2-R4] ISO/CD 17583 submitted for DIS ballot**

For ISO/CD 17583 - Health informatics: Terminology constraints for coded data elements expressed in ISO harmonized data types used in healthcare information interchange

ISO/TC 215
- agrees with WG2 recommendation to submit ISO/CD 17583 for DIS ballot;
- instructs the PL to provide the disposition of NP comments, updated text to the WG2 secretary no later than **1 April 2014**;
- instructs the WG2 secretary to provide these items to the TC215 secretary by **7 April, 2014**;
- instructs TC215 Secretary to submit to ISO/CS for DIS ballot by **14 April 2014**.

*Opposed:* None  *Abstentions:* Netherlands, Malaysia  **Motion carries**
RESOLUTIONS WG3: SEMANTIC CONTENT

Note:  WG3 Resolutions were not voted as a block.

2013 Resolution 84 [WG3-R1] ISO/DIS 13940 conditional FDIS submission
For ISO/DIS 13940, Health informatics – System of concepts to support continuity of care [ContSys],
   — ISO/TC215 approves the submission for FDIS ballot subject to the following conditions being met:
   — Comment disposition and revised draft has been posted for more than 6 weeks but the WG seeks input
     from HL7 and IHTSDO liaisons no later than 6th December 2013 and these additional comments are to be
     discussed by the WG1 and WG2 by 12th of December 2013;
   — This joint meeting determines that the document may proceed to FDIS ballot at that time.
   — Note: WG has until 13 December 2014 to submit disposition of DIS comments and final FDIS draft to
     TC215 secretary to submit to ISO/CS for FDIS ballot and of course can submit earlier if possible.
Discussion: None;  Opposed: None;  Abstentions: Canada, Netherlands, United Kingdom;  Motion carries

2013 Resolution 85 [WG3-R2] ISO/DTS 16277-1 name change
For ISO/DTS 16277-1, Health Informatics, Categorial structures of clinical findings in Traditional Medicine - Part
1: Traditional Chinese, Japanese and Korean Medicine, ISO/TC 215
   — approves the change of name of this project
   — FROM:  
     Health Informatics, Categorial structures of clinical findings in Traditional Medicine - Part 1:  
     Traditional Chinese, Japanese and Korean Medicine
   — TO:  
     o Health informatics, Categorial structures of clinical findings in Traditional Medicine - Part 1:  
     Traditional Chinese Medicine; Traditional Japanese Medicine; and Traditional Korean Medicine.
Discussion: None;  Opposed: None;  Abstentions: Canada, Finland, Mexico, Netherlands, United Kingdom
Motion carries

2013 Resolution 86 [WG3-R3] ISO/DTS 17938 submission for TS publication
For ISO/DTS 17938 Health informatics – Semantic network framework of Traditional Chinese Medicine
language system, ISO/TC 215
   — approves the WG3 recommendation to submit ISO/DTS 17938 for TS publication;
   — instructs the project leader to provide the disposition of DTS comments, updated text of ISO/DTS
     17938 and revisable graphics files to the WG3 convenor for review and approval no later than 20
     December 2013;
   — instructs the project leader / convenor to provide these items to the TC 215 Secretary no later than 24
     December 2013;
   — instructs the TC 215 Secretary to submit TS materials to ISO/CS for TS publication no later than 15
     January 2014.
Discussion: None;  Opposed: None;  Abstentions: Canada, Finland, Netherlands, Mexico, United Kingdom
Motion carries
2013 Resolution 87 [WG3-R4] ISO/DTS 17948 submission for TS publication
For ISO/DTS 17948 Health informatics – Traditional Chinese Medicine literature metadata, ISO/TC 215
— approves the WG3 recommendation to submit ISO/DTS 17948 for TS publication;
— instructs the project leader to provide the disposition of DTS comments, updated text of ISO/DTS 17948 and reversible figure files to the WG3 convenor for review and approval no later than 20 December 2013;
— instructs the project leader / convenor to provide these items to the TC 215 Secretary no later than 24 December 2013;
— instructs the TC 215 Secretary to submit TS materials to ISO/CS for publication no later than 15 January 2014.
Discussion: None; Opposed: None; Abstentions: Canada, Finland, Netherlands, Mexico, United Kingdom
Motion carries

2013 Resolution 88 [WG3-R5] ISO/DTS 17439 progress to conditional TS publication
For ISO/DTS 17439, Health informatics – Common glossary metadata requirements and maintenance process, ISO/TC 215
— approves the publication of the TS subject to the following conditions being met:
— the WG will post the comment disposition and revised draft no later than 30 November 2013;
— WG will submit disposition of comments and revised TS draft for review on the WG3 ISO eCommittee web site for at least 6 weeks from the date of posting and notification;
— Note: WG3 has until 1 December 2014 to submit disposition of TS comments and final TS draft to TC215 secretary to submit to ISO CS for publication and earlier if possible.
Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 89 [WG3-R6] ISO/NP 16843-1 submission for NP ballot
— approves the WG3 recommendation to submit for NP (reinstatement) ballot;
— instructs the project leader to provide complete form 4 and NP text to the WG convenor for review and approval no later than 1 February 2014;
— instructs the project leader to provide these items to the TC215 Secretary by 7 February 2014;
— instructs the TC215 Secretary to launch an NP ballot by March 1st 2014.
Note: 16843-1 and 16843-2 were voted as a block with the same results as listed below.
Discussion: None; Opposed: None; Abstentions: Canada, Finland, Mexico, Netherlands, United Kingdom
Motion carries
2013 Resolution 90 [WG3-R7] ISO/DIS 16843-2 submission for NP ballot


— approves the WG3 recommendation to submit for NP (reinstatement) ballot;
— instructs the project leader to provide complete form 4 and NP text to the WG convenor for review and approval no later than 1 February 2014;
— instructs the project leader to provide these items to the TC215 Secretary by 7 February 2014;
— instructs the TC215 Secretary to launch an NP ballot by 1 March 2014.

Note: 16843-1 and 16843-2 were voted as a block with the same results as listed below.

Discussion: None;  Opposed: None;  Abstentions: Canada, Finland, Mexico, Netherlands, United Kingdom

Motion carries

2013 Resolution 91 [WG3-R8] ISO/PWI 13581 cancel from ISO/TC215 WG3 work program

ISO TC215

— approves the request to cancel ISO/PWI TR 13581 Guidance for maintenance of object identifiers (OIDs) from the ISO/TC215 WG3 work program

Discussion: None;  Opposed: None;  Abstentions: None

Motion carries
RESOLUTIONS WG4: SECURITY, SAFETY AND PRIVACY

Note: WG4 Resolutions were not voted as a block.

2013 Resolution 92 [WG4-R1]: ISO/22600-1 submitted for FDIS ballot
For ISO/FDIS 22600-1, Health Informatics – Privilege management and access control part 1: Overview and policy management, ISO/TC215
- approves WG4 recommendation to progress to FDIS ballot;
- instructs the project leader to submit the disposition of DIS comments, updated DIS text to the WG4 secretary no later than 2013-10-25;
- instructs the WG4 secretary to submit these items to the TC215 secretary no later than 2013-11-04;
- instructs the TC215 Secretary to submit to ISO/CS for FDIS ballot no later than 2013-11-18;
Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 93 [WG4-R2]: ISO/22600-2 submitted for FDIS ballot
- approves WG4 recommendation to progress to FDIS ballot;
- instructs the project leader to submit the disposition of DIS comments, updated DIS text to the WG4 secretary no later than 2013-10-25;
- instructs the WG4 secretary to submit these items to the TC215 secretary no later than 2013-11-04;
- instructs the TC215 Secretary to submit to ISO/CS for FDIS ballot no later than 2013-11-18;
Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 94 [WG4-R3]: ISO/22600-3 submitted for FDIS ballot
For ISO/FDIS 22600-3, Health Informatics – Privilege management and access control part 3: Implementation, ISO/TC215
- approves WG4 recommendation to progress to FDIS ballot;
- instructs the project leader to submit the disposition of DIS comments, updated DIS text to the WG4 secretary no later than 2013-10-25;
- instructs the WG4 secretary to submit these items to the TC215 secretary no later than 2013-11-04;
- instructs the TC215 Secretary to submit to ISO/CS for FDIS ballot no later than 2013-11-18;
Discussion: None; Opposed: None; Abstentions: None; Motion carries
2013 Resolution 95 [WG4-R4]: ISO/DIS 17090-2 submission for DIS Ballot
- approves WG4 recommendation to progress to DIS ballot;
- instructs the project leader to submit the disposition of comments, updated text to the WG4 secretary by 25 October 2013;
- instructs the WG4 secretary to submit these items to the TC215 secretary by 4 November 2013;
- instructs the TC215 Secretary to submit to ISO/CS for publication by 18 November 2013.
Discussion: None;  Opposed: None;  Abstentions: None;  Motion carries

2013 Resolution 96 [WG4-R5]: ISO 17090-4 submission for DIS ballot
- approves WG4 recommendation to progress to DIS ballot;
- instructs the project leader to submit the disposition of CD comments, updated DIS text to the WG4 secretary no later than 18 November 2013;
- instructs the WG4 secretary to submit these items to the TC215 secretary by 19 November 2013;
- instructs the TC215 Secretary to submit to ISO/CS for DIS ballot by 3 December 2013.
Discussion: None;  Opposed: None;  Abstentions: None;  Motion carries

For ISO/AWI NP 21298, Health informatics, Functional structure and roles, ISO/TC 215
- approves WG4 recommendation to progress to CD Ballot;
- instructs the project leader to submit the disposition of comments, updated text files to the WG4 secretary no later than 1 November 2013;
- instructs the WG4 secretary to submit these items to the TC215 secretary by 8 November 2013;
- instructs the TC215 Secretary to launch a CD ballot by 22 November 2013;
Discussion: None;  Opposed: None;  Abstentions: None;  Motion carries

2013 Resolution 98 [WG4–R7]: ISO/21549-7 submission for CD ballot
For ISO/21549-7, Health Informatics – Patient healthcard data Part 7: Medication, ISO/TC215
- approves WG4 recommendation to progress to CD ballot;
- instructs the project leader to submit the disposition of NP comments, updated CD text to the WG4 secretary no later than 25 October 2013;  instructs the WG4 secretary to submit these items to the TC215 secretary by 4 November 2013;
- instructs the TC215 Secretary to launch a CD ballot by 18 November 2013.
Discussion: None;  Opposed: None;  Abstentions: Brazil, Canada, Finland, Italy, Sweden, Switzerland, US
Motion carries
RESOLUTIONS WG6: PHARMACY AND MEDICINES BUSINESS

Note: WG6 Resolutions were not voted as a block.

2013 Resolution 99 [WG6-R1] prEN/ISO/DTR NP 14872 submission for NP ballot
For prEN/ISO/DTR PWI 14872, Health informatics – Identification of Medicinal Products (IDMP) – Core Principles for Maintenance of Identifiers and Terms,
ISO/TC 215
- approves the WG6 recommendation to proceed to NP ballot under Vienna Agreement (ISO lead);
- instructs the project lead to provide the complete form 4 and NP text to the WG6 secretary no later than 9 December 2013;
- instructs the WG 6 secretary to provide these items to the TC 215 Secretary no later than 17 December 2013;
- instructs the TC 215 Secretary to launch an NP ballot no later than 24 December 2013.

Discussion: None; Opposed: None; Abstentions: Malaysia Motion carries

For prEN/ISO/DTS PWI Health informatics – Identification of Medicinal Products (IDMP) – Implementation Guide for EN ISO 11238 Data Elements and Structures for the Unique Identification and Exchange of Regulated Information on Substances
ISO/TC 215
- approves the WG6 recommendation to proceed to NP ballot under Vienna Agreement (ISO lead);
- instructs the project lead to provide the complete form 4 and NP text to the WG6 secretary no later than 9 December 2013;
- instructs the WG 6 secretary to provide these items to the TC 215 Secretary no later than 17 December 2013;
- instructs the TC 215 Secretary to launch an NP ballot no later than 24 December 2013.

Discussion: None; Opposed: None; Abstentions: Malaysia Motion carries
RESOLUTIONS FROM ISO/TC215 JWG1: INFORMATICS OF TRADITIONAL CHINESE MEDICINE (PROVISIONAL)

Note: JWG1 Resolutions were not voted as a block.

2013 Resolution 101 [JWG1-R1] ISO/NP TS 18790-1 for submission as JWG1 project
For ISO/NP TS 18790-1, Health informatics -- Profiling Framework and Classification for Traditional Medicine informatics standards development -- Part 1: Traditional Chinese Medicine,
ISO/TC 215
– agrees with the assessment by JWG1 co-convenors that this can progress as a JWG1 project;
– agrees that Dr. Michael Hammes from ISO/TC249 will join the project team as an expert;
– agrees that the PL of ISO/PWI 18790-1 will submit the disposition of NP comments and revised WD to the JWG1 secretary no later than 31 December 2013;
– agrees that the JWG1 secretary will submit these items to the TC249 secretary for review no later than 7 January 2014.
Discussion: None;  Opposed: None;  Abstentions: Brazil, Canada, Finland, Netherlands, Mexico, United Kingdom
Motion carries

2013 Resolution 102 [JWG1-R2] ISO/WD IS 18668-1 from ISO/TC249 as a JWG1 project
– agrees with the assessment by JWG1 co-convenors that this can progress as a JWG1 project;
– agrees that TC215/JWG1 will call for experts from TC215/WG3 and WG6 by 1 December 2013.
Discussion: None;  Opposed: None;  Abstentions: Brazil, Canada, Finland, Netherlands, Mexico, United Kingdom
Motion carries

2013 Resolution 103 [JWG1-R3] ISO/PWI IS 18668-3 from ISO/TC249 as a JWG1 project
– agrees with the assessment by JWG1 co-convenors that this can progress as a JWG1 project when this item completes it NP ballot;
– agrees that TC215/JWG1 will call for experts from TC215/WG3 and WG6 no later than 30 days after completion of NP ballot.
Discussion: None;  Opposed: None;  Abstentions: Brazil, Canada, Finland, Mexico, Netherlands, United Kingdom
MOTION CARRIES
RESOLUTIONS JWG7: APPLICATION OF RISK MANAGEMENT TO INFORMATION TECHNOLOGY NETWORKS INCORPORATING MEDICAL DEVICES

Note: JWG7 Resolutions were not voted as a block.


ISO/TC215
- approves the JWG7 recommendation to proceed to NP ballot with an IEC lead
- Instructs the JWG7 secretary to coordinate the schedule with the IEC primary point of contact
- in schedule coordination with IEC, instructs the PL to provide the complete form 4 and NP text to the JWG7 secretary no later than 15 November 2013;
- instructs the JWG7 secretary to provide these items to the TC 215 Secretary and IEC no later than 1 December 2013;
- instructs the TC 215 Secretary and IEC SC 62A Secretary to launch the respective NP ballots no later than 15 December 2013.

Discussion: None; Opposed: None; Abstentions: None; Motion carries

2013 Resolution 105 [JWG7- R2] IEC/WD 80001-2-5 submission for CD for comment
- approves the JWG7 recommendation to proceed to three-month CD comment under IEC lead
- Instructs the JWG7 secretary to coordinate the schedule [as needed] with the IEC primary point of contact
- in schedule coordination with IEC, instructs the PL to provide the disposition of WD comments and CD text to the JWG7 secretary no later than 15 December 2013;
- instructs the JWG7 secretary to provide these items to the TC 215 Secretary and IEC SC 62A Secretary no later than 15 December 2013;
- instructs the TC 215 Secretary and IEC SC 62A Secretary to circulate the respective CDs for comment no later than 20 December 2013.

Discussion: None; Opposed: None; Abstentions: Malaysia; Motion carries

For the planned revision of IEC 62304, Medical device software – Software Life cycle processes, pending ISO/TC 210 decision to transfer the work item, ISO TC 215

– agrees to add this work item to its work programme for development by JWG7 under IEC lead

Discussion:

Canada: Mr. Don Newsham (HOD)
   — Thinks the title change makes sense; defer the title change until further feedback is collected
   — Friendly amendment is to strike the title from the 2nd clause – and this is accepted
   — This is to communicate back to TC210
   — It is important to have the same title for the sake of clarity

JWG7 (US): Mr. Sherman Eagles (co-convenor for IEC/62A)
   — Thinks title change already occurred in IEC 62a,
   — Could negotiate if – to re-phrase – makes this agnostic and if there is a need to address and if this is transferred
   — Re-state: agrees to add this work item for development

JWG7 (US): Mr. Todd Cooper (co-convenor for TC215)
   — Should appear with title as on 62a work program
   — Keep the door open when have these two items IF this ends up being transferred

Discussion: As noted;  Opposed: None   Abstentions: Malaysia   Motion carries

2013 Resolution 107 [JWG7- R4] ISO/TR 80001-2-7 submission as a CD for comment


- agrees to circulate the revised draft as a CD for comment for a two-month period,
- in schedule coordination with IEC, instructs the PL to provide the disposition of NP comments, final text to the JWG7 secretary no later than 6 January 2014;
- instructs the JWG7 secretary to provide these items to the TC 215 and IEC 62A Secretaries no later than 10 January 2014;
- instructs the TC 215 and IEC/SC 62A Secretaries to circulate the draft for a two month comment period by 15 January 2014.

Discussion: None;  Opposed: None;   Abstentions: Malaysia;   Motion carries
2013 Resolution 108 [JWG7- R5] ISO/DTR 80001-2-6 submission for TR publication


- approves the JWG7 recommendation to proceed to TR publication
- instructs the JWG7 secretary to coordinate [as needed] with the IEC primary point of contact
- in coordination with IEC, instructs the PL to provide the disposition of DTR comments, final text and any visuals as revisable graphics files to the JWG7 secretary no later than 5 January 2014;
- instructs the JWG7 secretary to provide these items to the TC 215 Secretary no later than 15 January 2014;
- instructs the TC 215 Secretary to submit items to ISO/CS for publication no later than 15 February 2014.

Discussion: None; Opposed: None; Abstentions: Malaysia; Motion carries


- approves the JWG7 recommendation to launch a 2nd CD for a 3 month ballot
- instructs the JWG7 secretary to coordinate the schedule [as needed] with the IEC primary point of contact;
- in schedule coordination with IEC, instructs the PL to provide the disposition of comments from the 1st CD and updated text to the JWG7 secretary no later than 1 December 2013;
- instructs the JWG7 secretary to provide these items to the TC 215 Secretary no later than 10 December 2013;
- instructs the TC 215 Secretary to submit items to circulate the 2nd CD for ballot no later than 15 December 2013.

DISCUSSION
- There was a request from the floor for Todd to describe in a bit more detail, so he added the following:
  o The changes are essentially about who instructs who to do what
  o Includes two components including a name change which was approved in the CD ballot but was never formally put to a vote to the TC

OUTCOMES OF DISCUSSION
— To continue with the work and the Resolution as stated, but to hold the title change for now
— Strike the first bullet about the title change

Discussion: As noted Opposed: None; Abstentions: Malaysia Motion carries
# Appendix D – Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
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<tr>
<td>ACMA</td>
<td>Australian Communication and Media Authority</td>
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<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
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<tr>
<td>ACTUG</td>
<td>Australian Clinical Terminology Users Group</td>
</tr>
<tr>
<td>ADL</td>
<td>Archetype Definition Language</td>
</tr>
<tr>
<td>AG</td>
<td>Advisory Group</td>
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<tr>
<td>AHIMA</td>
<td>American Health Information Management Association</td>
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<tr>
<td>AHMAC</td>
<td>Australian Health Ministers’ Advisory Council</td>
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<tr>
<td>AHML</td>
<td>Australian Healthcare Messaging Laboratory</td>
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<tr>
<td>AIHW</td>
<td>Australian Institute of Health &amp; Welfare</td>
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<tr>
<td>AIIA</td>
<td>Australian Information Industry Association</td>
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<td>AMT</td>
<td>Australian Medicines Terminology</td>
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<td>ANSI</td>
<td>American National Standards Institute</td>
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<tr>
<td>ArB</td>
<td>Architecture Review Board</td>
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<tr>
<td>AS HB</td>
<td>Australian Handbook</td>
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<tr>
<td>AS/NZS</td>
<td>Australian/New Zealand Handbook</td>
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<tr>
<td>AS/NZS ISO</td>
<td>International Standards adopted by Australia and New Zealand</td>
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<tr>
<td>AWI</td>
<td>Approved Work Item</td>
</tr>
<tr>
<td>CASCO</td>
<td>Conformity Assessment</td>
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<tr>
<td>CBCC</td>
<td>Community Based Collaborative Care Workshop</td>
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<tr>
<td>CCHIT</td>
<td>(US) Certification Commission for Health Information Technology</td>
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<tr>
<td>CD</td>
<td>Committee Draft (third stage in developing an ISO or IEC standard)</td>
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<tr>
<td>CDA</td>
<td>Clinical Document Architecture</td>
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<td>CDISC</td>
<td>Clinical Data Standards Interchange Consortium</td>
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<td>CDS</td>
<td>Clinical Decision Support</td>
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<tr>
<td>CDV</td>
<td>Committee Draft for Vote</td>
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<tr>
<td>CEN</td>
<td>European Committee for Standardization (Comité Européen de Normalisation)</td>
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<tr>
<td>CIC</td>
<td>Clinical Interoperability Council Workgroup</td>
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<td>CIMI</td>
<td>Clinical Information Modeling Initiative</td>
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<td>CIS</td>
<td>Clinical Information Systems</td>
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<tr>
<td>COAG</td>
<td>Council of Australian Governments</td>
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<tr>
<td>DAFF</td>
<td>Department of Agriculture, Fisheries and Forestry</td>
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<tr>
<td>DAM</td>
<td>Domain Analysis Model (comprehensive model of a domain)</td>
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<tr>
<td>DCM</td>
<td>Detailed Clinical Model</td>
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<tr>
<td>DCOR, COR</td>
<td>(Draft) Corrigendum</td>
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<tr>
<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>DIISR</td>
<td>Department of Innovation, Industry, Science &amp; Research</td>
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<tr>
<td>DIS</td>
<td>Draft International Standard (fourth stage in developing an ISO or IEC standard – the main opportunity for public input)</td>
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<tr>
<td>DMP</td>
<td>Dossier Médical Partagé (Shared Medical Record) (France)</td>
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<tr>
<td>DSTU</td>
<td>Draft Standards for Trial Use (HL7 and ANSI)</td>
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<tr>
<td>EC</td>
<td>European Commission [the administrative arm of the EU]</td>
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<tr>
<td>ECCF</td>
<td>Enterprise Compliance and Conformance Framework</td>
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<td>EFMI</td>
<td>European Federation of Medical Informatics</td>
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<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>
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<tr>
<td>ELGA</td>
<td>Austrian CDA Implementation Guide in Development</td>
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<td>ELS</td>
<td>End Point Location Service</td>
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<tr>
<td>EMEA</td>
<td>European Medicines Agency</td>
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<tr>
<td>EN</td>
<td>European Standard (Européen Norm)</td>
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<td>ETP</td>
<td>Electronic Transfer of Prescriptions</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDAM</td>
<td>Final Draft Amendment</td>
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<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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<tr>
<td>GCM</td>
<td>Generic Component Model</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<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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<tr>
<td>HI</td>
<td>Health Identifiers</td>
</tr>
<tr>
<td>HIE</td>
<td>Health Information Exchange</td>
</tr>
<tr>
<td>HIMSS</td>
<td>Healthcare Information and Management Systems Society</td>
</tr>
<tr>
<td>HITSP</td>
<td>Health Information Technology Standards Panel</td>
</tr>
<tr>
<td>HL7</td>
<td>Health Level Seven (International)</td>
</tr>
<tr>
<td>HL7 ELC</td>
<td>HL7 E-Learning Course</td>
</tr>
<tr>
<td>HPI</td>
<td>Healthcare Provider Identifier</td>
</tr>
<tr>
<td>HPI-I</td>
<td>Healthcare Provider Identifier for Individuals</td>
</tr>
<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>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
</tr>
<tr>
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</tr>
<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>
</tr>
<tr>
<td>IHI</td>
<td>Individual Healthcare Identifier</td>
</tr>
<tr>
<td>IHTSDO</td>
<td>International Health Terminology Standards Development Organisation</td>
</tr>
<tr>
<td>IS</td>
<td>International Standard</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>ISO/CS</td>
<td>ISO Central Secretariat</td>
</tr>
<tr>
<td>ITS</td>
<td>Implementable Technology Specifications</td>
</tr>
<tr>
<td>IXS</td>
<td>Identity Cross Reference Service</td>
</tr>
<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>
</tr>
<tr>
<td>JTC</td>
<td>Joint Technical Committee</td>
</tr>
<tr>
<td>JTC 1</td>
<td>ISO/IEC Joint Technical Committee 1 Information Technology</td>
</tr>
<tr>
<td>JWG</td>
<td>Joint Working Group [under the JI, unless otherwise specified]</td>
</tr>
<tr>
<td>JWG7</td>
<td>Joint working group of IEC 62A and ISO/TC 215</td>
</tr>
<tr>
<td>KPI</td>
<td>Key Performance Indicator</td>
</tr>
<tr>
<td>LB</td>
<td>Letter Ballot</td>
</tr>
<tr>
<td>LMIC</td>
<td>Low and Medium Income Countries</td>
</tr>
<tr>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes</td>
</tr>
<tr>
<td>LPO</td>
<td>Local PCEHR Officer</td>
</tr>
<tr>
<td>MBS</td>
<td>Medical Benefits Scheme</td>
</tr>
<tr>
<td>MDA</td>
<td>Model Driven Architecture</td>
</tr>
<tr>
<td>MM</td>
<td>Maturity Model</td>
</tr>
<tr>
<td>MSIA</td>
<td>Medical Software Industry Association</td>
</tr>
<tr>
<td>NASH</td>
<td>National Authentication Service for Health</td>
</tr>
<tr>
<td>NATA</td>
<td>National Association of Testing Authorities</td>
</tr>
<tr>
<td>NEHTA</td>
<td>(Australian) National E-Health Transition Authority</td>
</tr>
<tr>
<td>NH&amp;MRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>NMB</td>
<td>National Member Body [of ISO or CEN]</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>NP</td>
<td>New Work Item Proposal (current ISO/IEC abbreviation)</td>
</tr>
<tr>
<td>NPACC</td>
<td>National Pathology Accreditation Advisory Council</td>
</tr>
<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>
</tr>
<tr>
<td>OBPR</td>
<td>Office of Best Practice Regulation</td>
</tr>
<tr>
<td>OCL</td>
<td>Object Constraint Language</td>
</tr>
<tr>
<td>OID</td>
<td>Object Identifier</td>
</tr>
<tr>
<td>OMG</td>
<td>Object Management Group</td>
</tr>
<tr>
<td>ONC</td>
<td>Office of the National Coordinator for Health Information Technology (within US Department of Health and Human Services)</td>
</tr>
<tr>
<td>O&amp;O</td>
<td>Orders and Observations Workgroup</td>
</tr>
<tr>
<td>OSI</td>
<td>Open Systems Interconnection</td>
</tr>
<tr>
<td>OTF</td>
<td>Organisation Task Force [ISO/TC 215]</td>
</tr>
<tr>
<td>OWL</td>
<td>Web Ontology Language</td>
</tr>
<tr>
<td>PACS</td>
<td>Picture Archive Systems</td>
</tr>
<tr>
<td>PAS</td>
<td>Patient Administration Systems</td>
</tr>
<tr>
<td>PDAM, DAM</td>
<td>(Proposed) Draft Amendment</td>
</tr>
<tr>
<td>PDF</td>
<td>Portable Document Format</td>
</tr>
<tr>
<td>PDTR, DTR</td>
<td>(Proposed) Draft Technical Report</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>PCEHR</td>
<td>Personally Controlled Electronic Health Record</td>
</tr>
<tr>
<td>PHDSC</td>
<td>Public Health Data Standards Consortium</td>
</tr>
<tr>
<td>PHR</td>
<td>Personal Health Record</td>
</tr>
<tr>
<td>PHTF</td>
<td>Public Health Task Force</td>
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<tr>
<td>PIM</td>
<td>Platform Independent Model</td>
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<tr>
<td>PIP</td>
<td>Practice Incentive Payment</td>
</tr>
<tr>
<td>PIR</td>
<td>Post Implementation Review</td>
</tr>
<tr>
<td>PKI</td>
<td>Public Key Infrastructure</td>
</tr>
<tr>
<td>PM</td>
<td>Project Manager</td>
</tr>
<tr>
<td>PMBOK</td>
<td>Project Management Body of Knowledge</td>
</tr>
<tr>
<td>PMS</td>
<td>Practice Management System</td>
</tr>
<tr>
<td>PMTL</td>
<td>Project Management Team Leader</td>
</tr>
<tr>
<td>PoC</td>
<td>Point-of-Care</td>
</tr>
<tr>
<td>PSM</td>
<td>Platform Specific Model</td>
</tr>
<tr>
<td>RACGP</td>
<td>Royal Australian College of General Practice</td>
</tr>
<tr>
<td>RCPA</td>
<td>Royal College of Pathologists Australia</td>
</tr>
<tr>
<td>RHIO</td>
<td>(US) Regional Health Information Organisation</td>
</tr>
<tr>
<td>RIMBAAS</td>
<td>RIM Based Application Architecture</td>
</tr>
<tr>
<td>RIM</td>
<td>Reference Information Model</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>RIS</td>
<td>Radiology Information Systems</td>
</tr>
<tr>
<td>RLUS</td>
<td>Resource Locate Update Service (HSSP)</td>
</tr>
<tr>
<td>RM-ODP</td>
<td>Reference Model of Open Distributed Processing</td>
</tr>
<tr>
<td>SA</td>
<td>Standards Australia</td>
</tr>
<tr>
<td>SAIF</td>
<td>Services Aware Interoperability Framework</td>
</tr>
<tr>
<td>SBP</td>
<td>Strategic Business Plan [ISO &amp; IEC]</td>
</tr>
<tr>
<td>SC</td>
<td>Subcommittee</td>
</tr>
<tr>
<td>SDO</td>
<td>Standards Development Organisation</td>
</tr>
<tr>
<td>SIG</td>
<td>Special Interest Group</td>
</tr>
<tr>
<td>SKMT</td>
<td>Standards Knowledge Management Tool</td>
</tr>
<tr>
<td>SLA</td>
<td>Service Level Agreement</td>
</tr>
<tr>
<td>SME</td>
<td>Subject Matter Experts</td>
</tr>
<tr>
<td>SMTP</td>
<td>Simple Mail Transfer Protocol</td>
</tr>
<tr>
<td>SNOMED</td>
<td>Systematised Nomenclature of Medicine</td>
</tr>
<tr>
<td>SOA</td>
<td>Service Oriented Architecture</td>
</tr>
<tr>
<td>SOAP</td>
<td>Simple Object Access Protocol</td>
</tr>
<tr>
<td>TC</td>
<td>Technical Committee</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>UCUM</td>
<td>Unified Code for Units of Measure [Regenstrief Institute]</td>
</tr>
<tr>
<td>UML</td>
<td>Unified Modelling Language</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>VMR</td>
<td>Virtual Medical Record</td>
</tr>
<tr>
<td>W3C</td>
<td>World Wide Web Consortium</td>
</tr>
<tr>
<td>WD</td>
<td>Working Draft (second stage in developing an ISO or IEC standard)</td>
</tr>
<tr>
<td>WG</td>
<td>Working Group or Work Group</td>
</tr>
<tr>
<td>WGM</td>
<td>Working Group Meeting</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WI</td>
<td>Work Item</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organisation</td>
</tr>
<tr>
<td>XDS</td>
<td>(IHE’s) cross enterprise Data Sharing protocol</td>
</tr>
<tr>
<td>XML</td>
<td>Extensible Markup Language</td>
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