

IT-014 Health Informatics Committee

Executive Supplementary Report

ISO Meeting

Rotterdam, Netherlands, October 2010



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Collated by: Standards Australia

With input from Australian Delegation and other employer funded Australians at the meeting:

- *Richard Dixon Hughes (Head of Delegation)*
- *Heather Grain (Delegate)*
- *Evelyn Hovenga (Delegate)*
- *Heather Leslie (Delegate)*
- *Anthony Maeder (Delegate)*
- *Klaus Veil (Delegate)*
- *Andrew Caswell (WG8 Secretariat)*

INTRODUCTION

ISO (International Organization for Standardization) 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 148 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland.

The International Organization for Standardization (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 organizational units:

- TC 215 Executive Council - responsible for executive leadership and strategy
- WG 1 Data Structure
- WG 2 Data Interchange
- WG 3 Semantic Content [Convenor: Heather Grain (Australia)]
- Traditional Medicine Task Force (reporting through WG 3)
- WG 4 Security, Safety and Privacy
- Patient Safety & Quality Task Force (reporting through WG 4)
- WG 6 Pharmacy and Medication Business
- WG 7 Devices
- WG 8 Business Requirements for EHRs [Secretariat: Australia]
- Operations and Harmonization Committee – coordinates working group activity, secretariat processes and TC 215 work program.

In May 2010, the TC 215 Executive Council also formed a Business Planning and Reorganization Task Force to review and report back in one year on TC 215's strategic direction, its business plan and its organisation structure – with Richard Dixon Hughes and Heather Grain both being active members.

In addition, TC 215 hosted a face-to-face meeting of the Joint Initiative Council (JIC) and the JIC Harmonization Open Forum at which collaborative projects potentially involving several JIC members are discussed, approved and tracked. The current members of the JIC are: ISO/TC 215, CEN/TC 251, HL7 International, CDISC, IHTSDO and GS1.

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 e-health agenda - as opposed to the technical perspective found in HL7 and the content perspective of 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.

OBJECTIVES OF THE MEETING AGENDA AND LOGISTICS

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 eight domain-specific working groups.

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

The Joint Working Group Meeting for 2010 was hosted by NEN, the ISO national member body for The Netherlands and covered four days from 10 to 13 October in accordance with the agenda below. A full day of TC 215 leadership and information-sharing meetings was held at Novotel Rotterdam, Brainpark Hotel on the Sunday with the following three days taking place in the Congress Centre of Erasmus University, located within a few minutes walk from the hotel.

The meeting was attended by between 150 and 200 delegates from 18 participating member countries (compared with 16 at the May 2010 meeting in Rio de Janeiro, Brazil) and included representatives of liaison organisations including TC 249 TCM, IHTSDO, GS1, WHO, ICH, JTC1, CDISC and IEEE.

Being held in Europe most sessions were held jointly with the European CEN/TC 251 Health Informatics committee and its four working groups.

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 number of concurrent sessions and the unavailability of experts in some of the TC 215 subject areas make it difficult for a small delegation to effectively follow the issues and to influence change in all of the active areas.

Agenda

ISO/TC 215 & CEN/TC 251 Health Informatics										
10-13 October 2010										
Rotterdam, Netherlands										
Sunday Schedule is in NOVOTEL Rotterdam Brainpark Hotel										
10-oct	0830-1100	Executive Council Meeting (HOD's - Convener's - Vice Convener's) (includes lunch) Room: Rotterdam								
	1130-1330	Formatting Class by ISO/ICS for WG leadership Room: Rotterdam								
	1400-1900	Joint Initiative Open Forum, Open to all JWG attendees								
	1930-1830	Joint Initiative Open Forum session on software as Medical Devices –Open to all JWG attendees –Room: Rotterdam								
Monday-Tuesday-Wednesday Schedule at Erasmus University										
MONI-OPEN PLENARY (Forum room)										
Mon	0900-1000	Coffee Break								
	1000-1015	WG Lict	215-WG-1/8/261-WG-1	215- WG2	215-WG-3/261-WG-2	215-WG-4/261-WG-3	215-WG6	215-WG-7/261-WG-4	Task Forces	Additional RM
		ROOM	FORUM (58)	Lund (29)	Heidelberg (31)	Rochester (32)	Sanlander (32)	Aberdeen (27)	Auckland	
11-oct	1016-1216		Welcome-Agenda Proposed New Ways of Working Published Standards/Br Framework for Nat'l Health Enterprise Architecture	Welcome-Agenda Review CDISC-BRIDG Status Clinical Trials Reg NWP review	Welcome-Agenda Review minutes Update 12300 Revision of 17117 18104 Revision	Welcome-Agenda Review Patient Safety and Quality Task Force	Welcome-Agenda Review Update of 10886 Ballot recuts TR26267	IEEE 11073 meeting report IEEE 11073 PHD meeting report	DCM Meeting Only	Invite
	1216 - 1316	LUNCH (O&H meeting)								
	1316 - 1600	Joint with WG 6 Generic Model for Dose Syntax IDMP Update 14838 1&2 HN Mgmt HI 13064 14189 BRIDG	Genomics - Pedigree Topo IS 13448	OID discussion 13681 and 13662 13118 Metadata 17116 BR discussion	DT3 14441 Security & privacy req. of EHR for use in conformity assessment	Joint session with WG 1 Generic model for dose syntax Update on IDMP	Report of European 'Health' standards Review of work plans (215/WG7 & 261/WGIV)	Traditional Medicine Task Force	Re-Organization Task Force Meeting Jeremy Thorp, chair	
	1600 - 1616	Coffee Break								
	1616 - 1700	Use Case Template for HI projects 16223 Standards Convergence 15872 DCM	Work Item Status IHE Use Cases and Integration profiles work	TR for Glosceary Database 12310/12676 Term Sys 16278 H-A term sys	TR 18114 Security aspects of EHR migration	ISO/TR 14872	Continuation of topics	JIC Harm session as agenda		
	1700-1800	RA meeting with Atsuko								
		JIC Harm session as agenda								
Tuesday Schedule										
12-oct	0800-1030	WG Lict	215-WG-1/8/261-WG-1	WG2	215-WG-3/261-WG-2	215-WG-4/261-WG-3	WG6	215-WG-7/261-WG-4	Task Forces	
		ROOM	FORUM (58)	Lund (29)	Heidelberg (31)	Rochester (32)	Sanlander (32)	Aberdeen (27)	Auckland	
	0900-1030		Begin at 0830 15808 /18308 EHR 13872 DCM 14292 PHR 10731 R2	Telehealth TS 13131	TMTF feedback	TF Health Cards 26238 Clarick-3R	ICSR #27965-1 2nd DIS comments review	ISO/IEC JWG7 83001-4 Update (network risk management) 26238 Clarick-3R	Patient ID Meeting	
	1030-1046	Coffee Break								
	1046-1216	NWP PHR Sys FM 14296 Data Purposes Health Summary Req Bus Req	WADO-Web Services IS12974	16277-1 Clinical Findings in TM prEN ISO 18228 19120 Syn medical classification 13046-1 &2 Continuity of Care	27788 EHR Audit trails 22867 Data protection in trans-border flow	ICSR #27963-2 2nd DIS comments review	DCM update MFER NWP/ IEEE 11073 draft standards rvw	JIC Harm session as agenda		
	1216 - 1316	LUNCH ContSys1 and 2 coordination meeting								
	1316 - 1600	TS 21081 Directory Services Enablers of CDSS	Document Registry Federation TR 13128 Reference Model/Terminology Binding Rules Discussion IS2190 Data Types	Joint meeting W06 1-3-8 CDSS-Alerts and user interface	CEN/TC261/WG III Formal meeting	Formal WG6 meeting	IHE ICE-PAC Rapid Device conffg Update on FEF (EN14271) Ballot review Standalone SW & MDD	JIC Executive Session		
	1600 - 1616	Coffee Break								
	1616 - 1700	Continuity of Care & Resolutions	New Business, Review of Resolutions and WG closing Plenary	Review Resolutions Consider other business Dates of future meetings.	ISO/TC215/WG 4 Formal meeting	Formal WG6 meeting Closing and WG resolution development Due at 1030	Educational/Primer materials Resolutions	JIC Executive Session		
	1700-1800	Canadian Delegation Meeting	Australia Delegation Meeting	Japan Delegation Meeting	Brazil Delegation meeting	Netherlands Delegation meeting	US Delegation Meeting	UK Delegation Meeting		
	1800-2000	Rotterdam City Hall Social Event -								

Wednesday Schedule										
13-oct	0730 - 0845	215-WG-1/8/261-WG-1	WG2	215-WG-3/261-WG-2	215-WG-4/261-WG-3	WG6	215-WG-7/261-WG-4	Task Forces		
	0845 - 0900	FORUM (58)	Lund (29)	Heidelberg (31)	Rochester (32)	Sanlander (32)	Aberdeen (27)	Auckland		
	0900 - 1030	Closing and WG resolution development Due at 1030	Callope Meeting Jeremy Thorp	Closing and WG resolution development Due at 1030	Closing and WG resolution development Due at 1030	OPEN	Closing and WG resolution development Due at 1030	Open		
	1030-1046	Coffee Break								
	1046 - 1216		Callope Meeting Jeremy Thorp			OPEN	Closing and non-resolution topics	JIC Harm session as agenda		
	1046 - 1216	Resolutions review/collated by the TC secretariat								
	1216 - 1316	Lunch and Resolution Distribution to all HOD's at 1215								
	1315 - 1500	Mini-Plenary 1315-1700 Room: FORUM								Mini-Plenary cannot begin until all resolutions are done, checked and accepted.
	1500 - 1515	Coffee Break								
	1515 - 1700	Mini-Plenary 1315-1700								

RECOMMENDATIONS ARISING FROM THE MEETING

The principal issues / actions and recommendations identified by the Australian delegation at the October 2010 ISO TC 215 Meeting in Rotterdam are summarised in this section.

Topic	Issue/Action and Recommendations for Australia	Alignment to IT014 Structure
Executive Council Meeting	<p>Ongoing maintenance of evolving standards and standardized code sets are issues facing some TC 215 groups. ISO rules provide two types of structures to assist in this area:</p> <ul style="list-style-type: none"> • Maintenance Agency – maintains normative elements that require regular maintenance in a standard - such as code system content. • Registration Agency which registers items such as OIDs in a database. <p>Maintenance agencies must be an ISO national member body or a standardization organisation that performs the function on behalf of a NMB.</p> <p>A Maintenance Agency may be required for some of the pharmaceutical identification standards.</p> <p>IT-014 needs to understand and work within this framework.</p>	IT-014, its subcommittees and Standards Australia
Business Planning & Organization Task Force	<p>The task force reported on its work and presented its Interim Report designed to:</p> <ul style="list-style-type: none"> • provide an agreed description of scope and objectives for TC 215 • identify potential organisational models • propose a process for the appraisal of these models, including appropriate assessment criteria <p>IT-014 needs to ensure that the business plan and on-going organisation will address Australian needs effectively.</p>	IT-014, Richard Dixon Hughes & Heather Grain (as TF members)
Formatting Class	<p>Instructions from the ISO Central Secretariat on the preparation and format of standards documents were relayed to WG conveners, vice conveners and secretariats. This included advice on the drafting of titles, provisions, scope, conformance criteria, normative references self referencing, clauses, subclauses with and without titles, paragraphs and hanging paragraphs, notes, examples and lists.</p> <p>ISO have implemented their concept database which is available at www.cdb.iso.org.</p> <p>Existing tools and information for drafting of standards (including the SKMT glossary management tool) should be more widely used. Groups seeking terms and definitions for TC215 will first seek existing definitions from the SKMT, then check the ISO tool:</p> <p>IT-014 and Standards Australia will need to consider whether we should adopt the same procedure – SKMT first, then ISO concept database.</p>	IT-014, its subcommittees and Standards Australia editorial staff

Joint Initiative Council Harmonisation	<p>In order to be more open, inclusive and informative, the JIC now has three types of meetings</p> <ul style="list-style-type: none"> • Open Forum - where issues are openly discussed and open to the whole community • Harmonisation Track – where specific issues of harmonisation between the members are discussed and open to the whole community • Council Meeting - which is the only closed meeting. <p>A new web site for the Joint Initiative Council (holding a registry of all JIC projects, Inventory of policies and record of all meetings and agendas has been established and can be found at: www.jointinitiativecouncil.org. The website replaces the JWG/JIC website formerly managed by Standards Australia on behalf of ISO/TC 215/WG9.</p> <p>IT-014 and TC 215 Delegates will need to become more familiar with the working of the JIC and consider how best to utilise its facilities.</p>	IT-014 and ISO TC 215 Delegation Members
Working Group 1	<p>All of this group's working sessions were held jointly with WG8 – where most of the document progression is detailed. However, the following document was progressed through to its final stages:</p> <ul style="list-style-type: none"> • FDIS 21667 "<i>Health indicators conceptual framework</i>". <p>Once published, Australia will need to consider this standard for local adoption.</p>	IT-014-09
Working Group 2 Communications Topics	<p>This group is working on several joint initiatives including:</p> <ul style="list-style-type: none"> • BRIDG V3.0.2 currently out for DIS ballot • NWIP "<i>Clinical Trials Registration & Reporting</i>" • NWIP "<i>HL7 V3 Reference Information Model - Maintenance Release Process</i>" <p>The two foundation TRs on IHE process and profiles (of interest to Australia) had still not progressed but another person was appointed to facilitate their finalization.</p> <p>As much of the WG2 work draws on HL7, IHE, CDISC work or is in areas where Australia has not been active, WG2 engagement has been a lower priority for Australia – except for the area of telehealth; however, closer attention is warranted to ensure joint work is completed.</p>	IT-014 IT-014-06 and sub-groups
Working Group 2 Telehealth	<p>WG2 is also progressing two documents of interest in the area of telehealth:</p> <ul style="list-style-type: none"> • TS "<i>Quality Criteria for Services and Systems in Telehealth</i>" • NWIP for a TR "<i>Provisions for Health Applications on Mobile/Smart Devices</i>" 	IT-014-12
Working Group 3	<p>Work in this group progressed as indicated below:</p> <ul style="list-style-type: none"> • ISO/NP TR12300 <i>Mapping of terminologies to classifications</i> <p>This work is led by Australia and is out to ballot.</p>	IT-014-02 have oversight of this project

	<ul style="list-style-type: none"> • <i>ISO/TS 17117 Criteria for the categorisation and evaluation of terminological systems</i> This work is a review of the existing TS and targets an IS with the title: Health Informatics - Terminological resources Part 1 – Characteristics Part 2 – Requirements Part 3 – Criteria for evaluation • <i>Revision of ISO 18104:2003 Integration of a reference terminology model for nursing</i> Issues discussed related to the need to clarify specific concepts within this work item, as well as the title of the work item. • <i>System of concepts for the continuity of care - ContSys</i> This is a CEN work item in two parts: - Part 1 - Basic concepts - Part 2 - Health care process and workflow. <p>Several IT-014 subcommittees (see next column) are engaged in contributing to and monitoring these projects.</p>	<p>IT-014-02 and NeHTA</p> <p>IT-014 (particularly members representing nursing organisations)</p> <p>IT-014-06, IT-014-09 and NeHTA</p>
<p>Working Group 4</p>	<p>The documents below were the focus of the group's attention during the meeting:</p> <ul style="list-style-type: none"> • <i>ISO DIS2 21091, "Health informatics: Directory Services for healthcare providers, subjects of care and other entities"</i> This is of concern to some Australian experts who have implemented systems in this area. Wider discussion warranted. • <i>ISO Publication TS14265, "Classification of Purposes for processing personal health information"</i> • <i>NWIP IS "Health informatics — Data Protection in trans-border flows of personal health information"</i> • <i>ISO Withdraw TS 25238, "Classification of Safety risks from health software"</i> • <i>ISO SYSREV TS 22600 Health informatics -- Privilege management and access control part 3:Implementations</i> <p>The WG also received and discussed a report from the TC 215 delegation to the meeting of the ISO/TMB Privacy Steering Committee (PSC) held in Berlin in the week before the Rotterdam meeting. It appears that ISO is keen to coordinate activities in the area to address broader privacy protection issues in collaboration with privacy commissioners.</p> <p>The WG also dealt with recommendations of the Health Cards TF in relation to the update, renewal and republication of various health card standards.</p> <p>The work of WG4 and associated sub-groups is relevant to Australia as we move forward on privacy and security issues associated with the PCEHR and with identification management in healthcare. Greater local engagement is sought.</p>	<p>IT-014 IT-014-04 and NeHTA</p>

<p>Working Group 6</p>	<p>This group held several joint sessions and only its own projects are reported here. Three projects were progressed towards publication:</p> <ul style="list-style-type: none"> • <i>ISO FDIS 27953-1 "Health informatics – Pharmacovigilance – Individual case safety report [ICSR] – Part 1: The framework for adverse event reporting"</i> • <i>ISO FDIS 27953-2 "Health informatics – Pharmacovigilance – Individual case safety report – Part 2: Human pharmaceutical reporting requirements for ICSR"</i> • <i>ISO DTR 14872 "Health informatics – Requirements for the implementation of the standards for the identification of medicinal products [IDMP] for the exchange of regulated medicinal product information"</i> <p>Two New Work Items Proposals were also generated:</p> <ul style="list-style-type: none"> • <i>NWIP TS "Health informatics – Requirements for international machine-readable coding of medicinal product package identifiers"</i> • <i>NWIP TS "Health informatics – Business requirements for a syntax to exchange structured dose information for medicinal products",</i> <p>Australia does not have a group active on the ICSR and IDMP work and will need to find appropriate experts to assist in determining its support (or otherwise) for these latter two.</p>	<p>IT-014 and NeHTA</p>
<p>Working Group 7</p>	<p>This group is not specifically monitored by Australia. Its final recommendation was to present a Preliminary New Work Items for International Standards on the following IEEE 11073 projects:</p> <ul style="list-style-type: none"> • <i>11073-10419 Health informatics - Personal health device communication- Device specialization - Insulin pump</i> • <i>11073-10420 Health informatics - Personal health device communication - Device specialization - Body composition analyzer</i> • <i>11073-10421 Health informatics - Personal health device communication - Device specialization - Peak expiratory flow monitor (peak flow)</i> • <i>11073-10418 Health informatics - Personal health device communication - Device specialization - INR analyzer</i> • <i>11073-10413 Health informatics - Personal health device communication- Device specialization - Respiration rate</i> • <i>11073-10443 Health informatics - Personal health device communication- Device specialization - Physical activity monitor</i> 	<p>IT-014 generally with input on specific issues via leadership of IT-014-06 IT-014-09 IT-014-12</p>

Working Group 8	<p>The working group had several significant presentations, but three work items were brought forward for progression:</p> <ul style="list-style-type: none"> • DTR 14639 <i>“Capacity-based e-health architecture roadmap – Part 1:Environmental scan”</i> Richard Dixon Hughes and Anthony Maeder have made significant contributions to parts 1 and 2 of DTR 14639. • TR 13054 <i>“Knowledge Management of health information standards”</i> Heather Grain is Australian lead and draws on IT-014-02 expertise to moderate differences. • TR 14292 <i>“Personal health records – definition, scope and context”</i> Relevant to PCEHR and similar information communication involving privacy consent. <p>Australia has significant commitment to WG8 through the secretariat and associated close relationship with WG1. The 3 projects being progressed warrant careful monitoring. TR 13054 is of particular significance to Australia and has potential impact across the whole health informatics space.</p>	<p>IT-014, IT-014-09 and NEHTA</p> <p>Standards Australia as WG8 secretariat</p> <p>IT-014 and IT-014-02 (Heather Grain) on TR 13054 and vocab management</p>
Traditional Medicine Task Force	<p>The task force met separately to WG3 for a half day.</p> <p>Attendance at the meeting of a formal representative and Liaison from the Traditional Medicine TC of ISO from China was welcome and the meeting was constructive. This is an enormous step forward.</p> <p>Two new work items were developed and presented:</p> <ul style="list-style-type: none"> • <i>Categorical structures for representation of acupuncture – Part 1 – Acupuncture points</i> • <i>Categorical structures for representation of acupuncture – Part 2 – Needling</i> <p>Other work in preparation includes</p> <ul style="list-style-type: none"> • <i>Traditional herbal medicine – Part 1 – General Principles</i> • <i>Traditional herbal medicine – Part 2 – Japan</i> • <i>Traditional herbal medicine – Part 3 – Korea</i> <p>IT-014 needs to consider how we gain experts to contribute appropriately to these work items and the priority of this work to Australia.</p>	IT-014

FUNDING SOURCE SUMMARY

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

Funding Source	Number
Full funding by employer: Private	0
Full funding by employer: States/Territories or National Initiatives (NeHTA)	0
Full funding – DOHA through Standards Australia contract	7
Total:	7

The overall Australian delegation in Rotterdam was considerably smaller than the 11 we had in Rio de Janeiro because there were no NeHTA representatives as the meeting was not co-located with HL7 on this occasion.

ATTENDANCE DETAILS

The DOHA funded delegates were selected through an independent panel process jointly with NEHTA, DOHA, HL7 Australia and Standards Australia.

Attendee	Position (held at the meeting)	Funding Source	Working Group or Committee
Richard Dixon Hughes	Head of Delegation	Standards Australia via the DoHA Funding Agreement	Executive Council JIC Harmonisation, WG8, WG1, (WG4 and WG7)
Heather Grain	Delegate	Standards Australia via the DoHA Funding Agreement	Executive Council WG3 (as convener), JIC Harmonisation and Traditional Medicine Task Force
Evelyn Hovenga	Delegate	Standards Australia via the DoHA Funding Agreement	WG1, WG6 and Traditional Medicine Task Force (WG8)
Heather Leslie	Delegate	Standards Australia via the DoHA Funding Agreement	WG1 (WG8)
Anthony Maeder	Delegate	Standards Australia via the DoHA Funding Agreement	WG4 and JIC Harmonisation
Klaus Veil	Delegate	Standards Australia via the DoHA Funding Agreement	WG2 and JIC Harmonisation (WG7)
Andrew Caswell	Delegate	Standards Australia via the DoHA Funding Agreement	WG8 (Secretariat)