

MINUTES - JIC Executive Session

Thursday 20 March 2014 | 16.00 hrs US-CT (UTC-5)

Richard Dixon Hughes, Chair | Lisa Spellman, Secretary

1. Welcome, roll call

2. Agenda approval, minutes from last meeting

Minutes of meeting held by teleconference on 2014-02-20 were approved after amendment of the attendance record to note that Robert Stegwee attended the meetings in October 2013 and on 2014-01-14.
 Moved: Chuck Jaffe; seconded: Bron Kisler. Abstain: Kevin O'Donnell and Harry Solomon.

3. New business, other agenda topics

- Welcomed newest member organization DICOM Standards Committee and its two member representatives:
 - Harry Solomon: Co-chair, DICOM
 - o Kevin O'Donnell, Toshiba, Chair WG10, the Strategic Work Group has the responsibilities for ISO; IHE
- DICOM major topic of current interest: ISO Business Model issue

4. Review of action items from 20 February 2014 meeting

(a) DICOM application for JIC membership

Action / Task> Send notification letter to DICOM. <Status> Complete

(b) JIC project application from Dr. Andrew Grant for ISO/DTS 18528

Action / Task> HL7, IHE, GS1 and IHTSDO to name resource by the next JIC meeting in March 2014.

Action / Task> - Secretariat to send a reminder letter to JIC members to name their resources <Status> Complete

- A project to do with the classification of standards which is complementary to the work that has been underway for some years to establish a consolidated database (SKMT) to capture uses of terms
- The Task Force has been able to ramp up and expert representatives of JIC members are sought to participate and/or liaise with the ISO/DTS 18528 project team

Action /Task> Ask Heather and Andrew to reach out to new DICOM members

5. ISO global business model - Vancouver #13

- Update regarding next steps

— **Per Sydney Resolution #72:** The Advisory group has been named and has accepted. Lisa sent notification to ISO/CS that Resolution was passed and an advisory group was named.

Vancouver 2012 Resolution 13.) Regarding the Establishment of an Ad Hoc Group on the Rapidly Evolving Health Informatics Standards Field and the Work of ISO TC 215 – Resolved that ISO/TC 215 - Convenes an Ad Hoc Group (AHG): to advise the Secretary in relation to discussions with the ISO Central Secretariat regarding issues associated with the rapidly evolving heath informatics standards field and the work of ISO/TC215 in regards to alternative methods of publishing and incorporating material from other approved SDOs working in the

health informatics field; these discussions be based on draft resolutions as A and B below as the basis for initial discussions with the ISO Central Secretariat; and To be chaired by Mike Glickman

- ISO and ANSI had asked TC215 to not put forward the Public Health Standards (free licensing) proposal at the Sydney meeting that was submitted by Gunnar Klein because they felt that questioning the ISO business model was not within the scope of a TC. TC215 did comply and did not present the proposal at the Plenary, however, doing so was with the understanding that ISO/CS was willing to consider other possible options including developing a model for "recognized" standards. However, this consideration was removed so TC215 then chose to pursue the option of invoking Vancouver Resolution 13. ISO/CS was notified that this was our intention. ISO/CS acknowledged and asked that TC215 work with ANSI on the next steps.
- Chris Chute, Mike Glickman, Todd Cooper and Lisa Spellman held a conference call with Joe Tretler and Steve Cornish of ANSI. Steve and Joe seemed to understand the global trend in the health informatics community which is moving towards free availability of standards and that TC215 will become irrelevant if we cannot determine a model for moving this forward
- Chris Chute was in Geneva in early March 2014 and was able to meet with ISO/CS staff and will provide a brief status report.

Chris Chute gave an update to the March JIC meeting.

- ANSI and ISO are negotiating and have asked us not to share the parameters of that discussion and he hopes that we can share a more specific details to address this particular problem; a coherent catalog
- Chris had a meeting in Geneva with Kevin McKinley (Deputy Secretary-General), Trevor Vyze (Director Standards Development), Henry Cuschieri (ITTF), and Nicolas Fleury (Director Marketing and Communications).
- ISO/CS is aware that healthcare is as much as 20% of the economy and a significant area of key accomplishments in standardization
- ISO has heard the concern and is interested in progressing discussions. We are beyond the initial stage of "No comments from TCs on the ISO business model".
- The key issue has been that while ISO has one-on-one arrangements with Partner SDOs (PSDOs) supporting joint publication, with IEEE being the leading example, the terms of these agreements have all involved both parties having a common interest in selling the standards to sustain their businesses. The arrangements with CDISC, DICOM and now HL7, which provide free online access to the core standards material, are all outside the traditional PSDO model.
- Timeline: There is not a specific timeline to resolve the current issue but its importance is recognized by ANSI as well as ISO/CS.
- Status of projects: The bad news is that the non-partner SDO arrangements are on hold, this includes
 - o CDISC; ISO/14199; DICOM; HL7
- Current state: Establishing the initial framework for the conversation;
- Concept of "recognized" standards; a harmonious and coherent catalogue to facilitate coordination; issue is around the revenue model, we will need to identify a financial alternative to be able to co-brand
- Once some of these initial issues are resolved, since ANSI holds the secretariat, they have asked that a small task force from the US manage this for the moment.
- Question: What will be the forum for these discussions? Reply: Yes, JIC is the forum

- Question: Sounds like there are two categories:
 - o standards developed de novo
 - o those would be the "Recognized" category
- ANSI appears to understand the issue and concerns in health IT and were sympathetic and supportive of us trying to respectfully work through the process

6. EU/US work item update

— Moved to March per Catherine Chronaki request

Action / Task> Catherine to provide update and comments on developments in Europe

- Catherine gave a brief update of next steps and asked if the JIC would be interested to engage
- Her main guestions about RX-NORM and LOINC
- EU-US Discussion with Lisa Spellman Follow-up from Lisa Spellman regarding potential collaboration ISO-HL7-EU-US-Trillium Bridge etc
- They are looking at two things:
 - 1. An immediate objective to identify elements to put forward as working items HL7, ISO, IHE
 - 2. Use as a basic core

7. Update on recent MOU between UK and US

Lisa Spellman

- The US has recently signed an agreement with the UK similar to the EU/US agreement
- The UK-US agreement is different from the EU-US MOU there are some differing details

Action / Task> See if Steve Kay and/or Robert Stegwee can provide an update on the recent MOU between UK-US

Action / Task> Steve Kay will enquire and see if he can provide an update on the recent MOU between UK-US

8. ISO IEC 80003 series (Quantities and Units) and related ITU work - status update

Lisa Spellman

- Two new JWGs have been formed
 - 1. Between IEC/TC 25/JWG 1 and TC215: IEC has the administrative lead
 - 2. Between ISO/TC12 and ISO/TC215: TC12 has the administrative lead
- Call for experts for both JWGs went out as TC 215/N1401

Lisa reported that the "call for experts" from ISO/TC 215 members to serve on the two ISO/IEC 80003 JWGs closed on 14 February 2014. ROV were included in this March meeting packet.

Chris Chute and Richard Dixon Hughes elaborated on the underlying issues, with Richard noting his discussions in Geneva with mid-level ITU-T project officers responsible for the corresponding work in ITU, who appeared to share ISO/CS and TC 215 concerns that this work is being driven by a small clique and is at cross purposes to mainstream needs. While a growing need for telebiometric identification standards is recognized and may be applicable to remote delivery of services via eHealth, the proposed 80003-series of standards, which have been approved as ISO/IEC work items, do not specifically address this need - but rather a diverse range of issues related to OIDs used

for quantities and units and safe levels of exposure to various physical phenomena - work which has no particular reason to be part of a set of standards for quantities and units in "eHealth".

[Richard DH notes that the "explosion of OIDs" – with anyone being able to get them from anyone and assign them to anything, with very low probability of resolving has recently been raised in some other forums as an interoperability issue, which may become a de facto reason for work on these standards. This may be an issue that the new JWGs could usefully pursue – but in a wider context of semantically "labeling" quantities and units of measure for expression in any context – not just eHealth.]

9. Engagement between health informatics and medical devices communities

Chris Chute/Lisa Spellman

- Last year, IEC/TC 62 (Electrical equipment in medical practice) and ISO/TC 121 (Anaesthetic and respiratory equipment) challenged a proposed re-wording aimed at clarifying the TC 215 scope as part of the TC 215 business planning process.
- TC 62 is a strong and well established standards committee with major industry support. There is a long-standing active JWG SC 62A/JWG 7 (Application of risk management to information technology (IT) networks incorporating medical devices), that has been managing standards of mutual interest.
- Although TC 215 progressed its business plan under the previous scope, the underlying issues are broader and are associated with potential further overlaps and industry's desire for consistency, particularly insofar as standards may affect the costs of regulatory compliance.
- Some in the health informatics community have been concerned that over-regulation of software applications used in health care will stifle innovation and the public interest and be a barrier to market entry.
- Constraint of TC 215 scope may limit its potential effectiveness as a vehicle for collaborative publication of work with
- A meeting between chairs of the relevant committees and some of their key advisors is scheduled to take place in Washington DC on March 17.

Action / Task> Chris Chute/Lisa Spellman to update on outcomes/progress of discussions and potential impact on areas such as interoperability, terminology, functional model and safety/security standards in the health informatics domain.

- Chris reported a very successful meeting
- One simple change, replacing "creation" with "coherent and aligned" would allay their concerns and misunderstanding.
- The view of those TC 215 representatives at the meeting in person and by dial-in was that we should recommend TC 215 accept this change as we care about standards at the interface and the ecosystem around it.
- A meaningful level of trust and goodwill appears to have been established, along with agreement on better future communications, which will hopefully hold us all in good stead for the future.
- The next key issue to be resolved is an agreed title and scope for IEC/SC62A/JWG 7

10. Olympics proposal status update

Mike Nusbaum/Others

- It is moving forward, albeit more slowly than had hoped, but Mike has had some productive conversations
- Almost complete slide deck was to be circulated by Mike on a CONFIDENTIAL basis for feedback.

— It had been noted that what is really needed is a home for this idea so that it has a coordinating group and some funding to support the activity so that it can move forward

At this meeting: (a) comments on proposed slide deck as circulated, (b) updates on further developments, if any, and (c) actions to progress;

Action / Task> Mike to circulate draft slide deck for confidential consideration and feedback. **Status>** Slide deck circulated – feedback sought.

Action / Task> JIC members are asked to think of possible ways to help support including seeing if they can find some support within their organization and nation. **Status>** Open. Need for an action group noted.

- Canada has been the stalking horse to date. Mike and Lisa have discussed US involvement with preliminary sounding out of ONC and any official approach being via the US-TAG, possibly running a webinar too drive interest in the USA. Australia is another possible target.
- Jane requested something more for SDOs as well this would be very helpful. Others agreed.
- The aim should be to demonstrate the value of the work we (the wider JIC membership) do as SDOs
- Richard noted the importance of corporate involvement and compatibility with wider Olympic sponsorship arrangements corporate sponsorships (and broadcast rights) sustain the Olympic business model.
- GE remains a potential cornerstone corporate participant.
- The importance of keeping it confidential until ready to discuss was noted.
- Steve Kay didn't think that the UK would be interested.

<action/Task> Lisa will ask Mike to send information to DICOM and answer any question

11. CAG03: Any work program updates as needed Elizabeth Keller, Don Newsham

 Prior to the February meeting, Don had confirmed to Richard DH that he and Elizabeth would be ringing around the projects in order to compile the normal report for the meeting in Japan.

Don raised a question about how the impacts of the ISO/TC215 discussions with ANSI and ISO/CS re the ISO business model should be addressed. During discussion it was confirmed that:

- The main dimension of the work on-hold is the co-publication of joint documents
- In response to a question from Becky, it was also noted that there are potential problems with progressing the balloting of joint documents
- It was confirmed that all joint projects remain on the joint program but their status and issues with their progression will continue to be tracked through the JIC, whether progressed through ISO or otherwise.

12. Calendaring Lisa Spellman

- Japan: JIC is scheduled to meet on the Friday 23 May 2014 after the TC215 closing plenary
- Berlin: it is presently planned that JIC meet Friday 10 October following TC215 closing plenary
- The Friday afternoon meeting timeslot for Japan had been previously discussed and agreed (e.g. see December 2013 minutes)
- In both cases, the Friday scheduling worked best for host facilities

- Discussed holding a planning session in Berlin either earlier in the week (say Monday morning) or at another location in the evenings or on the weekend (as the DIN premises being used for TC215 are not open at those times). Christian Hay had agreed to investigate GS1 sponsorship of an alternative venue for the weekend.
- There was discussion indicating that holding the JIC late Friday afternoon is problematic and is causing travel problems for some. It was requested to see if the Japan and Berlin JIC meetings could be moved to one of the evenings during the week.

(a) Face-to-face JIC meeting in Japan

<Note> Lisa followed up with the Japan Host Committee and it is not possible to make changes to the schedule so the JIC will meet on Friday following the closing plenary as discussed at previous JIC meetings.

— Unless anyone claims the October 2015 timeslot, IHTSDO will claim those dates ???

<action / Task> Move calendaring (including preparation of the draft 2015 calendar) to the start of the next meeting.

(b) Face-to-face JIC meeting and planning session in Berlin

It was asked if the additional strategic planning session could be held on Monday morning or on an evening during the week. There is an IHTSDO meeting in Barcelona commencing shortly after the Berlin TC 215 meeting. Lisa does not believe the DIN facilitates are available in the evening,

<Action / Task> Berlin: Christian Hay is looking to see if GS1 could provide a meeting location so Lisa will ask him to expand his question to the other evenings of the week.

13. New business

14. Wrap

The meeting concluded at 5:15pmCT

Potential topics for future meetings

- 1. CEN outcomes/proposals arising from ContSys + ISO 13606 + HISA harmonisation & transatlantic impacts
- 2. CIMI outcomes/proposals arising from CIMI
- 3. All progress in implementation & use of SKMT
- 4. HL7 update on FHIR role and impact on harmonization of standards
- 5. After 20 years what are the core eHealth standards that are actually implemented today?

Attendance roster

			25-Oct-13	9-Dec-13	29-Jan-14	20-Feb-14	20-Mar-14
Catherine	Chronaki	HL7				Α	Υ
Chris	Chute	TC215	Y		Υ	Y	Υ
Richard	Dixon Hughes	TC215	Y	Υ	Υ	Y	Υ
Mike	Glickman	CDISC	Y	Υ	Y	Y	Υ
Shirin	Golyardi	CEN251	Y				

Christian	Hay	GS1	Υ				Sent regrets
Chuck	Jaffe	HL7				Y	Y
Stephen	Kay	CEN251	Υ	Υ			Y
Elizabeth	Keller	CAG03	Υ	Υ	R	А	
Bron	Kisler	CDISC	Υ	Υ			Y
Becky	Kush	CDISC			Y	Y	Y
Jane	Millar	IHTSDO	Υ	Y	Y	Y	Y
Don	Newsham	CAG03	Υ	Y	R	А	Y
Mike	Nusbaum	IHE	Υ	Y	Y	Y	
Kevin	O'Donnell	DICOM					Υ
John	Quinn	HL7	Υ	Y			
Harry	Solomon	DICOM		n/a	n/a	n/a	Y
Lisa	Spellman	Secretary	Υ	Υ	Υ	Y	Y
Robert	Stegwee	CEN251	Υ	Υ	Υ		Y
Beatriz	de Faria Leão	Observer	Υ				
Gary	Dickenson	Observer	Υ				