



Joint Initiative on SDO Global Health Informatics Standardization

Joint Working Group (WG9) SDO Harmonization

Meeting Minutes

Meeting 6

Held at the ISO TC 215 and CEN TC 251 Working Group Meeting
Istanbul
12 October 2008

CEN Co-Chair	HL7 Co-Chair	ISO Co-Chair	Secretariat
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1 Welcome and introductions

Don Newsham, co-chair of the Joint Working Group (JWG), welcomed over ninety attendees to the sixth meeting of the JWG. Countries represented at the meeting were Austria, Australia, Brazil, Canada, China, Denmark, Finland, France, Germany, Hong Kong, Japan, Korea, Malaysia, New Zealand, Russia, The Netherlands, Sweden, Turkey, United Kingdom, and the United States. The following Standards Development Organization (SDOs) and organizations were represented at the meeting: CEN TC 251, CDISC, HL7, ICH, IHTDSDO, ISO TC 215, and JTC1.

Don Newsham reported that the Joint Working Group was established in August 2007 under the Joint Initiative Charter. The JWG has held five open meetings at standards meetings hosted by ISO TC215, CEN TC 251 and HL7. There are now almost 190 people on the JWG list. The JWG has an operational Secretariat and there is a website at www.global-e-health-standards.org for access to public information about the Joint Initiative and JWG meetings.

It was further reported that the Joint Initiative Council (JIC) has been meeting regularly by teleconference since its last face to face meeting at Gothenburg in May to approve projects on the joint work program and to address challenges identified by the JWG. The JIC has developed and approved policies and procedures for Joint Initiative task groups and for the nomination of further international SDOs to the JIC.

2 Opening of the meeting

a. Confirmation of the agenda

The agenda was confirmed, with the addition of an item at item 8 proposed by Gary Dickinson on the path to simplification.

b. Confirmation of minutes from JWG Meeting 5 – September 2008, Vancouver

The minutes of meeting 5 were accepted.

c. Actions

See item 10.

3 SDO Work Program Harmonization

a. Joint SDO work program inventory, version 2.1

1. SKMT use / registration / term entry / follow-on discussion from Vancouver

The Joint SDO work program inventory, version 2.1 currently holds over 200 active work items under development in the four SDOs participating in the Joint Initiative (CEN TC 251, ISO TC 215, HL7 and CDISC). It was pointed out that there are approximately 40 active CDISC work items to be added. The next step is the analysis of the inventory.

Marion Lyver spoke about the ISO TC 215 Working Group 8 work on the Standards Knowledge Management Tool (SKMT), which is a web-based tool developed to manage the Common Glossary and Standards meta-data. It was reported that the SKMT design took account of the ISO 17119 Health Informatics Profiling Framework, the Zachman Framework and the Canadian Advisory Committee on Health Infostructure framework (ACHI). The SKMT project lead, Andrew Grant is in discussion with Mark Shafarman and Bernd Blobel regarding approaches to classification of standards for the associated new work item on

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Knowledge Management of Health Information Standards, which is at ISO NWIP ballot until late November. Comment was requested from National Member Bodies in the ballot on the Knowledge Management of Health Information Standards work item, in particular, the outline document and project scope.

The Common Glossary project lead by Heather Grain will set out a process for entry, review and harmonization of terms used in health informatics Standards. Ongoing resourcing for the Glossary needs further investigation.

It was queried how the process within SDOs to maintain the Glossary and Standards meta-data would be linked to a process across SDOs.

b. Updates /SDO Work program harmonization issues

1. European Union ESO Mandate project update

Melvin Reynolds stated that the project report had been updated as a result of discussions held at HL7, and is currently out for comment (refer to www.ehealth-INTEROP.nen.nl for further information about the report). The Joint SDO work program inventory was used as the basis for an analysis of standards, based on a keyword approach. It was concluded that any information management approach has to be developed with the end user or procurement purposes in mind, utilizing a usable, structured set of keywords. A dynamic, accessible knowledge management tool such as the SKMT would be beneficial and ensure that currency is maintained.

2. Input to SDO Work Program Task Force on approach

Charlie McCay noted that HL7 has been focusing on projects, products and workgroups and the process and forms required to manage these, with links via URLs to information held in a repository. This will allow an accurate up-to-date view of projects and their status (preliminary / active / published). It would be helpful to have this type of information available across SDOs via a central tool which also sends out notifications about work item activity.

It was noted that providing access to information about published Standards, and work items was an important initiative, and that each SDO needs a repository to manage standards information

It was noted that there are several elements to be explored by the task force, for instance, the tooling, the information / meta-data provided about standards, approaches to classification of standards, the process for access and other process issues.

The task force will be convened to analyse the work program, and others will be added to the task force (see also action 5.1).

4 Joint Work Program – Status, Review and Discussion

a. 13606 and HL7 Version 3 implementation guide

It was reported that a Joint Initiative task group template has been submitted to the JIC for approval.

b. Data Types

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Grahame Grieve reported that the joint project had now closed at DIS ballot in ISO/TC 215, with both the HL7 and CEN ballots already closed. He reported that the HL7 ballot passed, and that there were some negative ballot submissions from the editors. The ISO ballot received positive votes, and many detailed comments, which will be distributed to ISO and HL7 members for review. It was reported that there was a total of 374 detailed lined items to review, some of these significant.

Grahame raised a number of options to move forward:

1. Now that the ISO DIS ballot has passed, that draft could be published as is without going to FDIS, noting that there are known flaws to be addressed;
2. The editorial team could make editorial corrections and re-ballot the document as FDIS and DSTU;
3. HL7 could send the data types document to a normative ballot and the document could proceed to ISO FDIS

The intention is to seek feedback on progress from ISO TC 215 WG 2 at this meeting, and to form a resolution.

The following matters were raised:

- HL7 has a 4 month process both for DSTU(not normative) or normative Standards, if the document went back to DSTU, then that would take a TSC decision (TSC meets weekly)
- A new ballot may open new issues, and those with issues could do a profile in the expectation that these comments could be considered in the next release.
- It would be useful to achieve a simultaneous publication of the same technical content at CEN, ISO and HL7, and to keep maintenance also in synchronization.

There was general and strong support for the project team to make changes and work towards a combination of options 2 and 3 in early 2009.

c. Pharmacovigilance and identification of medicinal products

Ian Shepherd, noting that this work was formally requested of CEN TC 251 and ISO TC 215, reported that ICH had developing guidelines for regulation and licensing of pharmacovigilance products, for human use. ISO TC 215 was asked to extend countries involved in the work, with the work items largely in use in the US, Japan and Europe. Ian identified that issues encountered in the project were in two categories: firstly, scope, in that it would be time consuming to cover all possible uses outside the licensing and regulation domain; secondly, being in the licensing area, the project is impacted by national differences in legislation for registering of medicines. He further reported that WG6 have been responsible for these projects for two years, which has involved changes of personnel, and some re-education of new personnel. It was reported that twenty to thirty different organizations were involved in the development of these work items to ensure compatibility with broader work. It was expected that some work items would be sent for ballot after this meeting.

d. Glossary

It was reported that a Joint Initiative task group template has been submitted to JIC for approval.

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e. Entity Names Harmonization

It was reported that a Joint Initiative task group template needs to be developed for submission to the JIC for approval.

f. Units of Measure

Melvin Reynolds reported that there is a project underway in ISO/TC 215 Working Group 6 on Units of Measure, and also a new work item being discussed in Working Group 3 regarding the methodology for maintenance and publication of units of measure. It was noted that the Regenstrief Institute produces an informal publication on Units of Measure which is mandated in HI7 Version 3.

Melvin Reynolds reported that he has held follow-up discussion on Units of Measure after Vancouver, seeking assurances there is alignment between the two work items. Areas of infrastructure, registration and maintenance need to be understood and the need for formal governance processes and a host organization for UCUM were identified.

It was noted that there is interest from CDISC, and HL7 also in this work, and that an ISO lead was needed.

The relationship with IHTSDO work was queried, and it was reported that IHT had provided some information from the SNOMED CT perspective on units of measure. The possibility of having both an ISO Standard and a IHTSDO Standard, leading to Intellectual Property issues, was raised.

g. Identification of other potential joint work items

Don Newsham raised the representation and exchange of clinical data through archetypes, templates and bindings to terminology as a potential area of joint work. It was noted that ISO TC 215 Working Group 1 has an agenda item on detailed clinical models scheduled for this week's working group meeting, and that this work will build on the work undertaken in Scotland and The Netherlands on clinical data requirements.

It was reported that HL7 have working groups for vocabulary and templates, looking at the appropriate use of clinical models, and that the Clinical Interoperability Council is drawing in clinical requirements for interoperability.

Mark Shafarman noted that this matter is related to the harmonisation between 13606, and HI7 V 3.

Action 6.1 JWG Convenor to schedule update report on detailed clinical modeling work for JWG Meeting 7

5 Standardization processes

a. Joint Initiative Task Group Processes

Don Newsham referred to the JIC Policy and Procedures version 5. The JIC has approved this policy and procedure, which was based on the Charter, and incorporates the principles of harmonization from the Charter. The document includes the current lists of agreements between SDOs that are in force for working in the Joint Initiative task group. The approved Policy and Procedure sets out how SDOs work together in a joint initiative task group, and is a simplified version of the

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draft detailed processes for common / harmonized standards development released for comment to JWG members earlier in the year.

A query was raised about how the process would allow the addition of another SDO to the joint task group.

Charlie McCay asked that the Joint Initiative Task Group templates be published on the website before they go to the JIC for approval.

Action 6.2 JWG secretariat to load the Joint Initiative Task Group templates proposals to website prior to submission to the JIC.

6 Harmonization Needs and Issues

It was stated that issues of maintenance, versioning and co-ordination of balloting would be covered in the discussion, and also issues surrounding intellectual property and referencing other standards.

The following issues were raised:

- How should revisions of published standards be managed to avoid multiple publications in different SDOs?
- The need to address timing of updates to standards.
- The need to have a fixed update cycle
- Should all balloting occur in the host SDO i.e. in one community?
- The need to have a stopping point, and allow countries to develop a profile
- There has been a lot of goodwill to date to deal with these issues. ISO has an inherently limited process ie DIS, FDIS, while HL7 can go through an unlimited process. Can we ask for comments to be limited in scope and defer management to a later release?
- In the device communications projects, the joint working group, using the goodwill principle, shared documents and jointly viewed documents with circulation restricted during development to the ballot group. One SDO managed the ballot process and accepted input to ballot processes from others signed up to the ballot group. The standard went straight to publication in the other SDOs as there were no further changes required.
- Is there a need for a stopping process in place i.e. if new comments come in, they are addressed in the next ballot cycle.
- In the Vocabulary area, there is a need to harmonize between ISO and HL7 i.e. discussion is held in two places which leads to two documents: one technical and one procedural, both referencing the other document. This is a cohesive answer to the two parts of the problem, and not a joint work item. There will need to be a ballot hosted by 1 SDO with other SDOs contributing, with both documents being balloted simultaneously.
- Which template should be used for Standards developed jointly?
- The need to need to have some joint documents made available electronically. With a deeply technical document, navigation and hyperlinks would be helpful.

It was noted that the guidelines for referencing other Standards varied between SDO, and that the lead SDO's guidelines should be followed.

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It was further noted that concerns related to Intellectual Property, for instance, how much of a Standard could be quoted in another document, would depend on the legislative framework under which an SDO operates.

In summarising the discussion, Don Newsham suggested that the primary approach is through good will, and that a singular ballot should be hosted and managed by one SDO and all SDOs can contribute to that ballot.

Action 6.3 Bev Knight to provide an update report to JWG Meeting 7 on the Vocabulary documents being developed as separate technical and procedural documents and balloted simultaneously.

7 Communications

The Joint Working Group website is at www.global-e-health-standards.org

8 Other Business

Gary Dickinson spoke briefly on the path to simplification for analysis of standards to address the large number of standards publications and projects.

Action 6.4 JWG Convenor to schedule an out of session review of Gary Dickinson's proposal on a path to simplification and provide an update report to JWG Meeting 7.

9 Next JWG Meetings

1. HL7 (Orlando) - 11 January 2009, after international affiliates meeting (4.30pm to 6.30pm)
2. ISO TC 215 / CEN TC 251 Meeting (Edinburgh) - April 2009

10 Actions

Number	Action	Responsibility
3.4	Update the decision tree diagram for discussion at May JWG meeting. 2008/05/30 Jeremy Thorp noted that some examples to work through would be of assistance in updating and simplifying the decision tree. Carried 2008/09/14 Carried. 2008/10/12 Carried	Jeremy Thorp
4.1	Report back on gaps and overlaps found in the joint SDO work program inventory. 2008/09/14 Carried. 2008/10/12 Carried	Melvin Reynolds
4.2	Submit items of overlap, duplication or other issues to JWG secretariat. 2008/09/14 Carried. 2008/10/12 Carried	Members of ISO/TC 215, CEN/TC 251, HL7, CDISC
4.5	Submit the Joint initiative task group template for the Entity Name Harmonization project to the JIC for approval and inclusion on the joint work program. 2008/09/14 Carried. 2008/10/12 Carried	Heather Grain and Grahame Grieve
4.6	Submit the Joint initiative task group template for the Units	Ray Simkus,

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	of Measure project to the JIC for approval and inclusion on the joint work program. 2008/09/14 Carried. 2008/10/12 Carried	Gunnar Klein, Robert Owens and Grahame Grieve
5.1	Establish a taskforce to explore issues and propose next steps for standards analysis 2008/10/12 Mark Shafarman and Gary Dickinson added to taskforce Carried	Don Newsham, Melvin Reynolds and Charlie McCay, and other volunteers
5.2	Forward to the TSC process issues raised by Grahame Grieve in regard to the date types project. 2008/10/12 Carried	Charlie McCay
5.3	Forward to JWG Secretariat for circulation, details of the process for registration and entry of terms to the glossary via the SKMT 2008/10/12 Carried	Heather Grain
5.4	Forward issues related to multiple releases of a Standard to the JIC for discussion and decision making 2008/10/12 Completed	JWG Convenor
6.1	Schedule update report on detailed clinical modeling work for JWG Meeting 7	JWG Convenor
6.2	JWG secretariat to load the Joint Initiative Task Group templates proposals to website prior to submission to the JIC	JWG Secretariat
6.3	Provide an update report to JWG Meeting 7 on the Vocabulary documents being developed as separate technical and procedural documents and balloted simultaneously.	Bev Knight
6.4	Schedule an out of session review of Gary Dickinson's proposal on a path to simplification and provide an update report to JWG Meeting 7.	JWG Convenor