



Joint Initiative on SDO Global Health Informatics Standardization

Joint Working Group (JWG)

Joint Initiative Processes - DETAIL

Detail of Joint Initiative processes and processes for for common / harmonized standards development (Normative Standards)

DRAFT FOR COMMENT

Version 2.1, 24 April 2008

CEN Co-Chair	HL7 Co-Chair	ISO Co-Chair	Secretariat
Melvin Reynolds	Charles Jaffe	Don Newsham	Elizabeth Hanley
MelvinR@AMS-Consulting.co.uk	cjaffe@hl7.org	DonNewsham@SierraSystems.com	Elizabeth.hanley@standards.org.au

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)*

Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)

Detailed Joint Initiative Processes for common / harmonized Standards development (Normative Standards)

Introduction

“The Joint Working Group is responsible for developing, testing and using effective decision processes for international standardization needs; and developing common processes for harmonization in accordance with participating SDO processes.” (Charter, version 8, August 2007)

To this end and building on the Overview of SDO Processes and Common / Harmonized standards Development Processes (Normative Standards) where comparison of the three founding SDO processes was highlighted, this document underpins the building of a set of common harmonization processes which will support the activity, approach and goals of the Joint Initiative Council (JIC) and Joint Working Group (JWG).

These processes will evolve over time based on the best practices and procedures of participating SDOs, the learnings from experience and work on various joint standards development projects, and are informed by contributions from standards experts world-wide who are involved in health informatics standardization.

As Joint Initiative processes evolve, these will be founded on consistent and commonly accepted principles of standards development : **openness, transparency, consensus** , and on the agreed principles of global health informatics harmonization, as set out below.

Principles of harmonization

- Openness, transparency, global awareness and flexibility
- A clear requirement for development of the standard
- A singular set of standards and tests to address a singular business need
- One SDO leading the joint standards development project in collaboration with other participating SDOs
- Coordinated and timely engagement of the relevant community of expertise in development of content and resolution of issues
- Mutual recognition and endorsement of standards developed through the Joint Initiative

(Charter, version 8, August 2007)

The processes identified below are solely targeted on Joint Initiative activities, addressing collaborative activities and processes where relevant, that apply within individual SDOs. This is not meant to be a comprehensive listing of all participating SDOs' processes, but only those that are germane to and focused on collaboration in and co-ordination of common harmonized standards development.

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)
Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)*

Detailed Joint Initiative Processes for Common / Harmonized Health Informatics Standards Development

Process Stage	Process Detail	Comments	Related Forms / Documents / Templates
Preliminary	<ol style="list-style-type: none"> 1. JWG Co-Chairs review ISO/CEN/HL7 Work Program Inventory for identification of potential overlaps, duplications, or conflicting standardization 2. Any participating SDO, through the JIC member or through any SDO convenor or technical chair, may identify an issue of potential overlap, duplication or conflicting standardization 3. Until such time as a standards map is available, JWG Secretariat will list all preliminary standards work items of all participating SDOs in a separate section of the Work Program Inventory 	When and as available (not presently underway) a Standards Map (roadmap of what global standards are needed within health informatics) will be developed, including scanning and analysis of new requirements in any country.	ISO/CEN/HL7 Work Program Inventory
Proposal - Joint Project Proposal for work items	<ol style="list-style-type: none"> 1. Any SDO convenor or technical chair including JWG co-chairs, may submit a Joint Project Proposal. Joint project proposals may be for “new” or “existing” projects and may be at initial, working or committee draft balloted stage 2. Completed Joint Project Proposal templates should be forwarded to the JWG Secretariat. 	JWG Work Program covers all Joint Projects that are submitted and approved by JIC (with status noted).	Joint Project Proposal template must indicate <ul style="list-style-type: none"> - resourcing / funding requirements and availability - whether existing working draft is available reference standards and version
Assessment / Decision making, and Approval	<ol style="list-style-type: none"> 1. JWG Secretariat records all Joint Project Proposal submissions. 2. JWG Co-Chairs apply decision tree and JWG Secretariat documents results. 3. Apply Decision tree assessment: <ol style="list-style-type: none"> a. Requirements review b. Assess if this is a harmonization requirement (gap, overlap, counter-productive issue) c. Assess if existing standard applies d. Assess if there should be an 	All new Joint Project proposals, whether new project, adoption or new joint activity follow an accepted (and regularly refined) decision tree (see below) JIC decisions and directions are	Joint Project Proposal template Decision Record

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)*

Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)

	<p>international standard or standard(s) do exist (resolve duplications if identified)</p> <ul style="list-style-type: none"> e. Assess if there is an SDO to undertake work, if it is on their work program and if it can be fast tracked f. Assess if the proposed new standard would fit the purpose g. Assess lead SDOs ability to satisfy resourcing and funding requirements h. Assessment results for this Joint Project Proposal may be <ul style="list-style-type: none"> i. One SDO develops and all / multiple SDOs agree to adopt ii. Joint Proposal accepted into Joint Work Program and a Task Group is formed is identified to undertake joint development iii. It is not accepted onto the Joint Work Program iv. Joint Project Proposal is returned for more information i. JWG brings to JIC for approval the direction set from a - f. above. j. JIC reviews, determines lead SDO, assesses and approves resourcing / funding approach as indicated in the Joint Project Proposal, approves work item's inclusion on the Joint Work Program, and identifies either an existing SDO WG or TC for the work item or identifies a Task Group (including experts) for the joint work item. 	<p>communicated to all Joint Initiative SDOs through their respective JIC members.</p> <p>NOTE: JWG communications (agendas, minutes, status reports, etc) are provided and shared with each SDO Secretariat and with JWG attending members</p>	
--	---	---	--

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)*

Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)

<p>Development – Joint adoption (of an existing standard) - no actual standards development required</p>	<p>For proposed Joint (adoption) Projects that are assigned to or undertaken by a particular SDO</p> <ol style="list-style-type: none"> 1. Project schedule is identified and status is reported at JWG meetings. 2. Agreements in force between SDOs (Vienna Agreement, HL7/ISO Agreement) are the first choice of vehicle for adoption. 3. A single version of the standard is the desired target for multi-SDO adoption. In addition, that single version target is for an ISO/TC215 standard. Where additional requirements are identified in adopting SDOs, negotiation on inclusion in future releases is undertaken and the originating SDO is deemed responsible for any agreed changes. Where requirements cannot be satisfied or not satisfied in a timely manner, implementation guides are an option to be considered in place of multiple versioning. 4. Mapping of the Standard considered for adoption, to other standards within adopting SDOs, if requested and agreed upon by multiple SDOs and their experts, may become a Joint Project, undertaken by a Task Group. 5. Implementation Guidelines if requested and agreed upon by multiple SDOs and their experts, may become a Joint project, undertaken by a Task Group. 	<p>Development includes balloting, of a singular Standard by one SDO, and adoption by other SDOs.</p> <p>This includes work items that are already underway in a specific SDO, and also proposed joint work items that are assigned to or undertaken by a particular SDO.</p>	
<p>Development – New joint project development, approval and adoption - For work items (existing or new) that are approved by JIC, with Task Groups identified</p>	<ol style="list-style-type: none"> 1. Once approved by JIC, the lead SDO shall: <ol style="list-style-type: none"> a. Identify the WG/TC and appoint a Task Group chair (as determined at JIC);, b. Host the Task Group (within a WG/TC) 2. All participating SDOs shall: <ol style="list-style-type: none"> a. Appoint a co-chair to the Joint Project Task Group; b. Call for, identify and/or approve experts to participate; c. Host any required Task Group meetings at the appropriate WG/TC meetings 3. Co-Chairs shall: <ol style="list-style-type: none"> a. Organize TG meetings; b. Schedule TG meetings, to be held 	<p>Jointly developed (with expert engagement) coordinated, balloted, dispositioned and published Standard in ISO/TC215 and other SDOs, as required, <u>in a common timeframe.</u></p>	

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)*

Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)

	<p>at any participating SDOs meeting, or as necessary in out-of-cycle meetings, provided two months notice is announced to the TG and/or at a JWG meeting;</p> <ul style="list-style-type: none"> c. Notify both lead SDO and JWG Secretariat of any TG meeting arrangements in a timely manner; d. Identify other SDO working groups / committees that should for coordination and communication purposes be involved in this Joint Project; e. Table project scope, plan and source of funding information, with the JWG Secretariat and at the next JWG meeting following JIC approval; f. Provide an update report at all JWG meetings on the project plan, schedule, other WG/TC liaison or meeting needs, status of drafts, and ballot resolution issues. <p>4. JWG Secretariat shall post on the JWG website Joint Work Program project information including work item project plans, schedules, (including ballot schedules) and other public documents related to development of the work item.</p> <p>5. Development of the joint work item is undertaken by the Task Group (TG), as identified in their plan, including:</p> <ul style="list-style-type: none"> a. Resourcing undertaken as identified in the Joint Project Proposal template and agreed upon by the JIC; b. Determining a detailed project scope, plan and ballot schedule; c. Developing working drafts; d. Reviewing content at TG meetings; e. Managing working drafts and version control; f. Communicating to TG experts. <p>6. Issues of development and ongoing engagement for development shall be addressed with the JWG Co-Chairs and at the JWG meetings, where recommendations for resolution may then</p>		
--	---	--	--

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)*

Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)

	be forwarded to the JIC.		
Engagement	<ol style="list-style-type: none"> 1. Initial Committee Draft (CD) ballots are undertaken in accordance with lead SDO timeframes and are undertaken by: <ol style="list-style-type: none"> a. Separate ballots in each participating SDO; b. Using a common CD document for the ballot <ol style="list-style-type: none"> i. ISO Document template to be the default, unless otherwise agreed upon. c. Determining a common end-date (common by month at least, exact date preferable); d. Using a common comment template (from the lead SDO, unless otherwise agreed upon). 2. Each SDO shall: <ol style="list-style-type: none"> a. Use their own voting rules and directives to govern balloting; b. Accumulate ballot votes; c. Accumulate comments in the common comment template; d. Forward the ballot votes and comments to the JIC Secretariat. 3. JIC Secretariat shall collate the votes and comments into a single vote results document and forward these to all participating SDOs, the JWG Secretariat and to the joint work item TG co-chairs. 4. Comment dispositioning shall be: <ol style="list-style-type: none"> a. Done by the TG (and initially the work item lead) and in accordance with the lead SDOs policy and directives for disposition of comments; b. Posted on the lead SDO website and sent to the JWG Secretariat for posting on JWG website; c. Issues / negative votes for further resolution are handled at the next JWG or lead SDO meeting (whichever is soonest). 5. Repeat committee draft balloting may be necessary if substantial changes are done after the first / previous draft ballot. If so, processes shall be repeated as above. 		
Enquiry	<ol style="list-style-type: none"> 1. DIS, ENQ and Membership ballots shall be undertaken in the same manner as 		

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)*

Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)

	<p>above, excepting that</p> <ol style="list-style-type: none"> a. DIS, ENQ and Membership ballots should be fully synchronized in start and end dates, and use common comment templates. 2. All other processes are similar to CD ballot / development stage above. 		
Approval	<ol style="list-style-type: none"> 1. FDIS, EN and HL7 final approval are undertaken in same manner as enquiry stage with fully synchronized start and end dates (excepting HL7 if necessary) 		
Publication	<ol style="list-style-type: none"> 1. Each SDO publishes the common Standard (using common document template – fronted by the individual SDOs cover sheet). 2. Each SDO retains individual copyright on the common Standard which is applied from the start of CD balloting. 3. The resulting publication will include a reference to the SDOs participating in the Joint Work Item (common reference to be developed) in the “preface or foreward”. 4. Upon publication, if a Task Group was established for the Joint Work Program work item, then it will be dissolved. 	Standards Maintenance is the purview of each SDO	Common reference template paragraph

*Detailed Joint Initiative Processes for common / harmonized Standards Development
(Normative Standards)
Draft for comment (Agenda item 4 b ii, JWG Meeting 30 May 2008)*

Standards Decision Tree

Version 1.0 - Jeremy Thorp, August 2007

