



Joint Initiative on SDO Global Health Informatics Standardization

Joint Working Group (JWG)

Joint Initiative Processes - OVERVIEW

**An overview of SDO processes
and processes for
common / harmonized standards development
(Normative Standards)**

DRAFT FOR COMMENT

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(normative Standards)*

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

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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).

This document provides a high level overview of founding Standards Development Organizations (SDO) formal procedures, and proposes high level processes for common / harmonized health informatics standards development. For information on procedures specific to CEN, ISO and HL7, the reader should refer to each SDOs policy and procedures documents.

An accompanying Joint Initiative Processes document provides details on the processes for common / harmonized health informatics standards development.

Principles of harmonization

The Joint Initiative on SDO Global Health Informatics Standardization released a Charter in August 2007, agreed by the three founding members of the Joint Initiative: HL7; ISO TC 215 and CEN 251. This Charter, version 8, sets out a number of principles applicable to the joint initiative.

- 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)

REFERENCES

CEN/CENELEC *Internal Regulations, Part 2: Common Rules for Standardization Work*, 2006

HL7 *Co-Chair Handbook*, 2006

ISO/IEC *Directives, Part 1*, 2007

SO *Supplement*, 2001

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**High Level Process Map for common / harmonized Standards development
(Normative Standards)**

Process Stage	CEN TC 251	ISO TC 215	HL7	Recommendation
Preliminary	Preliminary Questionnaire (PQ/UQ)	Preliminary work item (PWI)	Refer to HDF	Follow individual preliminary processes and JWG review of ISO / CEN / HL7 Work Program Inventory (until standards map work is completed)
Proposal, Assessment / Decision making	New work item proposal	New work item proposal (NP / NWIP) vote and nomination of experts	Project statement	Joint Project Proposal template submitted to JWG; JWG applies decision tree and assesses all information for JIC direction;
Approval		Vote and Nomination of Experts	TSC Approves Project Statement	JIC determines lead SDO, resourcing, joint Task Group assignment; approved work item added to Joint Work Program
Development	Working Draft	Working Draft (for NP without document)	Working draft	Task Group (TG) established and project scope and plan set; TG maintains / develops Working Draft; TG reports status to each JWG meeting against timelines
Engagement	Working draft	Committee Draft (CD)	Committee Ballot (30 days – within Committee)	CD balloted through lead SDO and other SDOs; All experts contribute comment to coordinated CD ballot; TG resolve comments and distribute disposition through lead SDO and to

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Process Stage	CEN TC 251	ISO TC 215	HL7	Recommendation
				JWG; Issues /negative votes brought to next JWG/lead SDO meeting (whichever soonest)
Enquiry	Enquiry (ENQ) (5 months)	Draft International Standard (DIS) (5 months)	Full Membership Ballot (30 days)	Synchronized DIS ballot through all participating SDOs; All experts contribute comment to DIS ballot; TG review all comments and distribute disposition through lead SDO and JWG; Resolution of issues and negative votes brought to JWG /lead SDO meeting (whichever soonest)
Approval	Final Vote (FV)	Final Draft International Standard (FDIS) (3 months)	HL7 TSC approves as HL7 Standard (and forwarded for ANSI approval)	If document passes DIS ballot, ballot, conduct FDIS through participating SDOs in accordance with SDOs procedures for final vote.
Publication	EN	International Standard (IS)	HL7 Standard approved by ANSI	Publish through all participating SDOs.
Maintenance		Systematic review ballot (6 months) Options for Standards are: confirmation / amendment / withdrawal.		