SDO Plan of Action
for
Global Health Informatics Standards

SDO Harmonization Model
and
SDO Global Liaison Group
(Initial Terms of Reference)

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V0.2, Initial Working Draft, July 30, 2006

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1. Introduction

It is readily apparent to health informatics standards development organizations (SDO's) that transformational change is underway like no time previous. This transformational change is being applied both to the business of health care and in turn to the enabling health informatics systems and tools and to the business of standards developments. A common focus on better information for better health provides the lever for much transformational change. Underlying and enabling this focus are health information standards and underlying the standards are the development organizations that plan, coordinate, develop, and adopt standards.

SDO's and associated member countries are placing a priority on changing the way standards are being developed, adopted and coordinated.

- ISO/TC1215 has been reviewing its roles, function, priorities, and business models over the last 18 months with an increasing focus on aggregating, facilitating, harmonizing and orchestrating available standards, with production of standards as a lower or last level of responsibility
- CEN TC251 under its' new leader Kees Molenaar is actively updating its priorities, focus and work program targets
- HL7 has a strong international affiliates program and is collaborating to investigate new methodologies and its overall HL7 work program
- Together all three of these SDO's are undertaking a specific harmonization work effort on an EHR communication reference model and implementation guide
- A key focus of the health information technology leaders from Canada, US, England and Australia agreed to collaborate on adoption of standards as one of their first key focus areas. Common international standards was strongly noted to help simplify procurement and deployment of health information technology solutions.
- Individually these same countries and many others with national health information initiatives such as Korea, Japan, New Zealand, Netherlands, Sweden, Norway, Denmark, Germany, France, South Africa, Turkey and others have place a priority on their health information standards programs in support of country wide health development and transformation needs.

The drivers of change for SDO's today come from the national health information initiatives and their associated purchasers and implementers of systems and the suppliers of those systems. These "national programs", their leaders and their constituents are the communities that SDO's must serve to retain relevance and value.

The goal of most standards programs today is enabling "interoperability". Globally based standards that enable information system interoperability are required by system purchasers and suppliers alike. No longer is system functionality the only or major criteria. No longer are systems independent. And no longer are health informatics initiatives at all levels from community to state to national levels, implemented as islands of information and associated services.

To make interoperability a reality there must be one standard for one health business need with one test. That is the goal of harmonization among all standards development organizations.

Three specific health informatics focused SDO's have already recognized the need for commonality and harmonization in standards. While the frequent saying amongst all standards users is often about "so many standards to choose from', it is quite apparent to ISO TC215, CEN TC251 and HL7 that there are too many and potentially competing standards to choose from for our purchaser and supplier communities.

A worthy and early discussed set of objectives to make progress on one standard for one health business need with one test includes:

- rationalizing the overlaps and gaps in health informatics standards,
- developing an accountable work plan that meets demonstrated market and health business needs and
- coordinating developments, programs and activities while maintaining individual roles, mandates and responsibilities.

During several of the recent ISO TC215, CEN TC251 and HL7 meetings the leadership of these SDO's have meet and undertaken targeted discussions on peer to peer harmonization. Specific discussions were held at the April 2006 ISO TC15 meetings in Jeju Korea with all three SDO's, at the May 2006 HL7 meetings in San Antonia, both for a targeted work item (13606) and generally for SDO harmonization and further at the June 2006 CEN TC251 meetings in Lund, Sweden. The harmonization impetus also comes from the emerging new business model of ISO TC215 (draft v01. available from David Rowlands or the ISO TC215 Secretariat).

This paper provides the starting points for a more structured approach to SDO harmonization and aligns with the business model directions of TC215. It is being developed to support transformational change in the way business is conducted amongst an initial small set of SDO's for health informatics globally, with the full objective of being inclusive, open, and transparent.

SDO's are in the best position to orchestrate the harmonization work necessary, including the coordination, leadership, communication, strategizing and planning of harmonization. The actual delivery of a harmonized standard is difficult, substantial and sensitive work requiring specific funding, full time work and expert resources. Such "delivery work" may best be undertaken within or through a specific SDO or within and through resources funded by one or more national programs.

Recognizing the challenges of harmonization, with thoughtful review and refinement and with enthusiastic openness to work and learn together through collaborative action, the results of harmonization will enable a much needed transformation in global health informatics standards – all to achieve better information for better health.

The next meeting and target in-person discussion on this paper will be the joint ISO and CEN meetings in Geneva in October, 2006

2. SDO Harmonization Model

Harmonization is defined as "*to bring into agreement or harmony*". In our standards world an Industry Canada definition based on Agreement for International Trade identifies harmonization as *making identical or minimizing the differences between standards or related measures of similar scope.* CEN TC251 identified harmonization as *the prevention or elimination of differences in the technical content of standards having the same scope, particularly those differences that may cause hindrances to trade.*

Harmonization among multiple standards may also be defined as having multiple levels, perhaps best identified through a continuum of harmonization. Such levels may include:

- Mutual Recognition
- Rationalization of purpose
- Rationalization of scope
- Mutual alignment and rationalization of standard content
- Consolidation to one standard

The choice of degree of harmonization is one of the necessary steps in a model of SDO harmonization.

The following table provides a high level model for SDO harmonization.

WHO	WHAT	WHEN
SDO's that participate in harmonization include all peer SDO's that: - Are international in scope - Are member country based and governed	Harmonization is the rationalization of SDO work programs and resources towards achieving one standard for one business problem with one test - one standard means a single	SDO Harmonization working meetings will take place at minimum – twice annually

- Have a formal standards development process - Have products that are formal (normative) standards - Focused only on health informatics related standards (health - data, process, technology or organization) Founding SDO's include ISO TC215, CEN TC251, HL7 and others as may fit the above criteria Other SDO's that encompass some but not all criteria will have full access to all SDO harmonization information	agreed normative specification - one business problem means the single purpose for the standard that is fully grounded in the global health care agendas, plans and programs - one test means that compliance with the standard can be singularly and independently tested SDO harmonization will be undertaken based on this model and an agreed terms of reference that will be bi-annually reviewed and updated. SDO harmonization will evolve over time	

WHERE	**WHY**	**HOW**
Harmonization work will be undertaken at a rotated roster of individually hosted SDO meetings in a member country. Specific time and location for the meeting will be arranged by the Group Administrative Support service with the hosting member country	Harmonization of SDO work programs and resources and the achievement of one standard for one health problem with one test is needed - to achieve interoperability, both functional and semantic and for health information, businesses, and information systems - to enable effective, efficient, quality, safe information systems and related tools - to meet the mandate for health care transformational change being undertaken by the many "national programs" - to leverage standards developers expertise and time and to acquire and sustain the required people and funding resources - to provide a focus point for overall coordination of global health information standards If harmonization is achieved	SDO Harmonization will take place by: - identifying global standardization needs, opportunities, and constraints including, as required, the health business informational, functional and interoperability requirements of key targeted information systems - identifying the broad "map" of standards required to address global and member body health business needs, priorities and mandates and, as required, the standards available, their use and their technical feasibility - involving "customers" or "purchasers" of standards including national ehealth programs and "suppliers"

	standards will be produced with greater timeliness, ease, efficiency, relevancy, responsiveness, coordination, direct use, buy-in and sustainability	of health information system / software - identifying areas of unnecessary overlap, areas of alignment or change and areas of new development with associated responsibility - negotiating and coordinating among SDO's for cross-referencing each others standards and for rationalizing among competing standards that have the same content to ensure that only one standard is identified and referenced by other standards - assessing level / degree of harmonization or whether harmonization is feasible or simple choice needs to be made - clarifying issues associated with divergent approaches to standardization in specific domains and assist "purchasers" and "suppliers" in making informed choices. - identifying opportunities and commitments to rationalize or share resources in the development of standards - developing concrete work programs and acquiring funding through SDO member national programs and/or identifying and assigning SDO resources to undertake specific harmonization actions Harmonization will take place through an open, transparent, consensus based approach.

3. Terms of Reference

Preamble

This document, initially agreed upon at a meeting of founding SDO's on *[date]* provides the working terms for the business and structure of the SDO Global Health Informatics Liaison Group.

Name

SDO Global Health Informatics Liaison Group

Purpose

The SDO Global Health Informatics Liaison Group (Group) is a harmonization group with the mandate to rationalize health informatics SDO work programs and resources towards achieving one standard for one business problem with one test

Scope

The Group shall limit the scope to health informatics normative standards developed or planned to be developed and adopted through formal standards processes by SDO member countries.

Changes in scope can be accommodated by consensus

Definitions

Standards

…

Responsibilities

The SDO Global Health Informatics Liaison Group shall:

- identify global standardization needs, opportunities, and constraints including, as required, the health business informational, functional and interoperability requirements of key targeted information systems
- identify broad "map" of standards required to address global and member body health business needs, priorities and mandates and, as required, the standards available, their use and their technical feasibility
- involve "customers" or "purchasers" of standards including national ehealth programs and "suppliers" of health information system / software
- identify areas of unnecessary overlap, areas of alignment or change and areas of new development with associated responsibility
- negotiate and coordinate among SDO's for cross-referencing each others standards and for rationalizing among competing standards that have the same content to ensure that only one standard is identified and referenced by other standards

- assessing whether harmonization is feasible or level / degree of harmonization or whether a simple choice needs to be made
- clarify issues associated with divergent approaches to standardization in specific domains and assist "purchasers" and "suppliers" in making informed choices.
- identify opportunities and commitments to rationalize or share resources in the development of standards
- develop concrete work programs and acquire funding through SDO member national programs and/or identify and assign SDO resources to undertake specific harmonization actions

Membership

The founding members of the Group are ISO TC215, CEN TC251, and HL7.

Additional SDO's that meet the following criteria may participate at any time.

- SDO is an internationally based and recognized standards development organization
- SDO is member country based and governed
- SDO has a formal standards development process
- SDO has products that are formal (normative) standards
- SDO is focused only on health informatics related standards (health - data, process, technology or organization)

Individual Group members are the Chair, Vice Chair and Working Group Convenors of each SDO.

An Executive of the Group will be established to coordinate business and provide direction between Group meetings. The Executive will be made up of the Chairs and Vice Chairs of the SDO's.

Other SDO's that encompass some but not all criteria will have full access to all Group information.

Principles of Operation

The Group will operate under a published set of principles, which may be amended from time to time by agreement of the Group members. The operations of the Group will be based broadly on ISO processes and the new ISO TC215 business model. The Group will operate with a global interest first and foremost.

Administrative Support

The Group will be supported by the ISO TC215 Secretariat.

Meeting Procedures

The Group will conduct meetings as follows:

- Meet on a semi-annual basis or more often at the call of the Chair
- Meetings will be scheduled at least six months in advance;
- Agendas and appropriate supporting documentation will be distributed two months in advance of each meeting;

- Agendas will be set with input from the members, but at the final discretion of the Chair. Items to be considered for the Agenda may be submitted to Secretariat;
- Where necessary the agenda may be broken into parallel sections for input, information sharing and development of recommendations (by topic or work program component)
- Meetings will be held at such dates, times and locations as determined by a rotation amongst SDO members to coincide with normal SDO meetings.
- Ad-hoc meetings may, from time to time, be required, and where possible, these will be arranged by video conference, telephone conference, or via such means as to minimize time demands on the Group members;
- Meetings will be conducted by the Chair, or the Chair's designate;
- Minutes of each meeting, and decisions made, will be recorded and will be distributed to all attendees and all Members. Finalized minutes and decisions will be posted on a website and available to each SDO website.
- Conveners can identify one alternate to attend on their behalf.
- Responsibilities of the Group, and its operating principles and processes, will be open to continuous re-evaluation by its members.
- The Group will elect its' own chair.

Decision Making

Wherever possible, all decisions of the Group will be made by consensus. Where this is not possible, a vote will be called by the Chair, whereby:

- Each member on the Group has one vote
- A majority vote will carry the decision

Accountability

The Group does not supersede individual SDO accountabilities, mandates or roles nor supersede bi-lateral SDO agreements or processes

4. Initial Harmonization Work

While the first tasks of harmonization include the identification of needs, availability, alignment, overlaps and targeted actions it is reasonable to initiate early action on well known and agreed upon standards where harmonization would be particularly and clearly necessary. Parallel action on both the work and the process of harmonization amongst the SDO's builds agreement, ensures processes are meaningful and practical and uses early learnings to influence and simplify working processes.

Additional standards for early harmonization work beyond the following may also be suggested by any of the SDO leaders participating in the harmonization planning.

- **13606 EHR Communication**: Substantial efforts have been made towards harmonisation of 13606 and HL7 v3 since 2002, but it is not clear exactly how each of these five part-standards should be implemented alongside the implementation of HL7 version 3 standards (i.e. how 13606 can be adopted within an HL7 version 3 computing environment). It is to address this that a joint Implementation Guide project is being proposed and harmonization work is already underway to address this requirement
- **Health Summary Records**: Common data is and will be required to populate health summary records (also known by many names including continuity of care record, the UK's Care Record Summary (CRS), NEHTA specifications, IHE XDS, etc). ISO TC215 WG8 has initiated work on the Health Summary Record and harmonization work will be required.
- **GPICs**: A range of system to system messaging applications exist (pathology, radiology, patient administration, referral and discharge) and within those messaging standards harmonization requirements exists (ie GPICs)