

Introductory letter to the ISO Technical Management Board (ISO TMB) and the World Standards Cooperation (WSC)

From the CEN Advisory Board for Health Standards (ABHS)

'Proposal for Global Health Technical Advisory Group (GH TAG)'

Background

The CEN Advisory Board for Health Standards (ABHS) commented in May 2006 on the Recommendations of the Final Report of the WSC Health Technologies Task Force (HTTF) dated January 2006. In its response, the ABHS proposed the setting up of an advisory global strategic standards group that integrates (at least) all six standardization bodies (ISO/IEC/ITU-T and CEN/CENELEC/ETSI) to coordinate and integrate standards work programmes in the health sector.

The attached proposal elaborates on the possible title, terms of reference, goals, constitution and mode of operation of the advisory group.

The proposal is based on the experiences of the CEN ABHS, which has now been established for almost two years, but takes into consideration the existence of the dormant ISO/IEC JTAG 1, the recommendations of the WSC HTTF and the wider remit of a global group.

In broad terms, the proposal suggests the setting up of a global technical advisory group with membership along the lines of the membership of the HTTF. In effect, the new TAG could take the best elements of both JTAG 1 and HTTF and form an entirely new TAG with a remit and constitution consistent with the needs of global health standardization today.

The proposal focuses on the first two recommendations of the HTTF, namely:

- 1) Strengthen the dialog between ISO/IEC/ITU-T, the WHO¹ and the GHTF²
- 2) Foster cooperation among the globally relevant standardization organizations and SDOs.

The last three recommendations of the HTTF were considered to be recommendations that would primarily be implemented by standardization organizations, rather than a TAG, although some elements of these recommendations (e.g., recommendation 4, the risk management proposal) could be included in the work of the GH TAG.

At its recent meeting on 21-22 November 2007, the ABHS approved the attached proposal for presentation to the ISO TMB and the WSC for consideration.

Respectfully submitted on behalf of the ABHS

¹ WHO = World Health Organization

² GHTF = Global Harmonization Task Force, a global group of regulatory and industry members focussing on harmonization of global regulations for medical devices

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Proposal for Global Health Technical Advisory Group (GH TAG)

Justification for proposal

This proposal is driven by the need to coordinate the standards-writing activities of not only ISO/IEC/ITU-T, but also CEN/CENELEC/ETSI with that of SDOs¹ (such as AAMI, ASTM, IEEE, HL7, etc.), in order to prevent duplication of effort, unnecessary overlap, costly delays, and to develop only those standards necessary for accessing healthcare technology, for supporting harmonized legislation on a global basis and for safety/public interest reasons. In order to achieve this, effective communication between stakeholders is necessary, as well as a means of identifying and prioritizing work items. Especially important for the future will be liaisons with health informatics to enable interoperability of equipment, and – due to convergence of technologies – the effective functioning of joint task forces and committees. New fields like tissue engineering, minimally invasive and robotic surgery and nanotechnology are very fast moving, and future standardization needs are likely to be different than at present, and to require shorter timescales.

The intention of this proposal is to respect the different structures, procedures and methods of working of the various groups involved in health standardization, but to work collaboratively wherever possible. There is a need to identify and foster best practices amongst stakeholder groups as well as to make recommendations for promoting and streamlining standardization processes in relation to the health sector.

Title

It is proposed that the title of the advisory group could be 'Global Health Technical Advisory Group (GH TAG)'. The title reflects the intention that it should be global in nature. 'Global' was chosen rather than 'World' to reduce confusion with either the WSC or the WHO.

Terms of reference

The purpose of the GH TAG is to foster cooperation and communication between stakeholders in order to make the best possible use of limited resources, and to enable standardizers to produce the standards that are needed for removing barriers to trade, for supporting harmonized legislation on a global basis and for safety/public interest reasons. In addition, the GH TAG can operate as an advisory group to the ISO TMB as needed.

Definition of stakeholders

Stakeholders: Standards organizations², SDOs, NSBs, industry consortia, users of standards (industry, regulators, purchasing authorities, healthcare professionals, and (indirectly), patients and others).

Goals

1. To improve coordination between standardization stakeholders
 - To identify where current joint projects need strengthening and encourage the development of clear rules for the operation of joint working groups;

¹ SDOs = Standards Development Organizations, for the purpose of this paper, intended to mean organizations that develop standards, but are not ISO/IEC/ITU or CEN/CENELEC/ETSI.

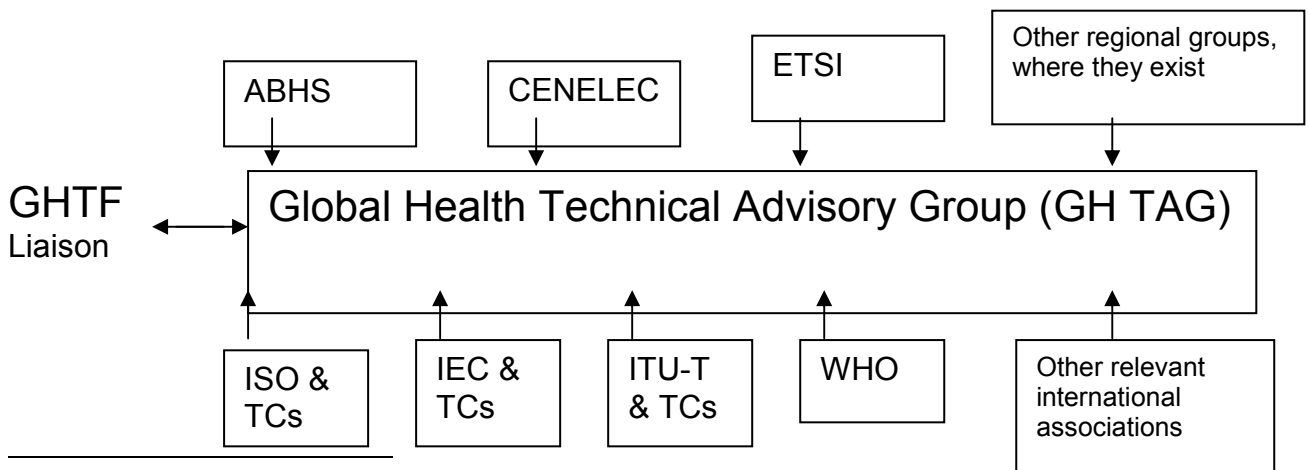
² Standards organization, for the purpose of this paper, intended to mean ISO/IEC/ITU or CEN/CENELEC/ETSI.

- To provide a forum where jurisdictional problems of overlap can be highlighted and discussed through negotiation and cooperation;
 - To connect with regulatory agencies through international structures such as the GHTF, in order to assess and clarify regulatory and other user needs for standards and to develop strategies for implementation;
 - To foster the establishment of a single point of contact within standards organizations and SDOs to provide information on current work programs in the health sector;
 - To deliver appropriate observations and requests to relevant international standards organizations and SDOs;
 - To advise on standards matters to relevant decision bodies;
 - To provide advice to the ISO TMB, acting as the health sector voice.
2. To determine key priority items in the health work program
- To encourage a clear and harmonized presentation of the respective standardization programs;
 - To map the existing standardization programs and priorities in the medical fields;
 - To optimize the transparency and the timeliness of priority work items, especially at the stage of initiation of new work;
 - To encourage the establishment of a database of health standards for each standards organization and SDOs, with their title, scope, summary of content and status.
3. To improve the compatibility, communication and interactions between different technical areas
- To promote the incorporation of the risk management approach in the standardization process;
 - To reduce duplication or divergence of work amongst TCs on a 'management by exception' basis.

Constitution

It is intended that all stakeholders should be able to participate in the GH TAG. Specifically, these should include representatives of ISO/IEC/ITU-T and the WHO; the GHTF; regional groups such as the ABHS, CEN/CENELEC/ETSI (and others, e.g., Asia/Latin America), NSBs and TCs. SDOs, e.g., AAMI, ASTM, IEEE, HL7, industry associations and consortia, e.g. IHE, GS1, and other relevant professional and patient user groups would be welcome to participate if they wish. A starting point would be to invite the membership of HTTF³

See Schematic below:



³ See HTTF 010-6 2006-01-30 'Final report – World Standards Cooperation Healthcare Technology Task Force (January 2006) for a list of members.

Figure 1. Schematic representation of proposed GH TAG membership

Mode of operation

Structure

ISO should provide a platform for the GH TAG to meet, but the other standards organizations and groups (see above) would be welcome to be full members of the group. In this role, the GH TAG could be viewed as the voice of the health sector. The GH TAG could provide advice to the ISO TMB when requested, and likewise receive requests from the ISO TMB to provide information.

This proposal is based on the successful model in CEN, where the ABHS provides sector input to the CEN Technical Board, but CENELEC, ETSI, the European Commission and others are nevertheless invited members of the ABHS. There is thus no obligation for invited members such as CENELEC or ETSI to adopt the recommendations of the ABHS, and no interference with the structure or authority of these members. Likewise, agenda items are on an 'advice as needed or requested' basis, such that well-functioning liaisons and TCs do not come to the attention of the ABHS.

Frequency

It is suggested that, once established, the GH TAG could meet once per year, with one or two *interim* meetings via teleconference, as successfully used by the HTTF. However, in the 1st or 2nd year, it may be deemed necessary to meet twice per year.

Chair/Secretariat

It is suggested that one of the participating organizations could provide the secretariat (this could be a standards organization, an SDO, NSB, industry association or consortia member) and Chair for a period of three years, and then it should move to another stakeholder.

Set up of the GH TAG

It is suggested that, in the first instance, nominations are sought for a Steering Group to consider the details of the initial title, terms of reference, goals and mode of operation, in order to make adjustments as necessary to this original proposal. Nominations can then be sought for Secretariat, Chairman, members, etc., however the membership of the HTTF would be a good starting point.

Liaison with the GHTF

It has been noted that recently the GHTF is taking a greater interest in liaison with standards programs, and this is to be enthusiastically welcomed since standardization is an important pillar that undergirds many regulatory systems. It is often difficult to separate standardization and regulatory processes in a highly regulated sector such as medical technologies. The GHTF has established a Memorandum of Understanding with both ISO/TC 210 and ISO/TC 194; has recently accepted liaison status with IEC; and has appointed a Standards Rapporteur (Dr Carl Wallroth) to inform the GHTF Steering Committee on ISO/IEC standards matters likely to impact on the work of the GHTF. A strong liaison would be desirable between the GHTF and the GH TAG. The GHTF could provide an active input to the GH TAG in, e.g., the following areas:

- Advise on standards that may be used to demonstrate compliance with basic principles of quality, safety and function, as described in the various GHTF guidelines;
- Identify new standards needed for global harmonization of regulation;
- Advise on prioritization of the work program for medical devices in relation to regulatory needs;

- Identify and draw attention to deficiencies in standards (both published and under development), including notifying when an acceptable 'state of the art' is not being maintained;
- Work with the GH TAG to ensure the published standards in the GHTF 'Essential Principles' document are up-to-date and complete;
- Notify inconsistencies between requirements in related standards.