

Advisory Board for Healthcare Standards (ABHS)

Terms of Reference

1 Mission

The Mission of the Advisory Board for Healthcare Standards (ABHS) is to provide strategic and well-informed advice on matters relating to Healthcare Standardization in the European Economic Area (EEA) to CEN and CENELEC and their Technical Boards (BTs).

2 Vision

- To become **the** reference advisory body for CEN and CENELEC and National Standards Bodies (NSBs) on European healthcare standardization;
- To ensure a coherent relationship between healthcare standardization and regulation;
- To ensure standardization in the healthcare sector remains start-of-art, especially when referenced into regulation;
- To ensure healthcare standards* are "fit for purpose", e.g. relevant, right and realistic for the target audience (stakeholders and standard users).

* NOTE Other standardization deliverables (by any means) are considered to be included (e.g. Technical Specifications, guides, Technical Reports, webpages, etc.).

3 Strategy

3.1 General

The ABHS is to accomplish its Mission by:

- 1) acquiring an overview on all existing standards affecting/covering the healthcare sector;
- 2) determining stakeholders' requirements and identifying areas that are not sufficiently covered (gap analysis);
- 3) identifying where relevant stakeholders are not properly represented in the various standardization activities;

- 4) ensuring that standards are developed at the most appropriate level using the Vienna and Dresden Agreements where applicable;
- 5) ensuring European standardization interests are adequately represented at the international level.

3.2 Function

The ABHS is set up under the auspices of CEN and CENELEC.

When appropriate, ABHS will prepare and submit advice to the relevant Technical Board(s) for endorsement and dissemination to the appropriate Technical Committees (CEN/TCs or CENELEC TCs).

3.3 Terms of Reference

3.3.1 Purpose

The purpose of the ABHS is to *inter alia*:

- 1) provide advice on matters of strategic importance to the healthcare sector referred to it by relevant stakeholders, including advice on the allocation of new work proposals and identification of weaknesses in the coverage of standards used to provide a presumption of conformity with EU legislation;
- 2) promote a coherent understanding of CEN and CENELEC and EU Commission decisions within the healthcare sector;
- 3) provide an interface between all stakeholders influencing EU healthcare standardization;
- 4) where there is no appropriate CEN or CENELEC Technical Body, promote the use of relevant international standards, and propose solutions to monitor international work including recommendations as to possible relationships with EU legislation;
- 5) encourage standardization work be undertaken at the most appropriate level;
- 6) consider means to provide unified European input to international work and maintain necessary liaisons;
- 7) establish and maintain participation with relevant industry and professional European and international organizations, especially clinical, patient or other healthcare providers/organizations, or those who have a legitimate interest in standardization in healthcare;
- 8) consider matters of strategic importance to standardization referred to CEN and CENELEC by the European Commission, e.g. establishment of mandates for standards in the healthcare sector, input to EC initiatives such as the Digital Agenda, Lead Market Initiative, etc.;
- 9) analyze strategic developments and issues in healthcare, especially future challenges relating to the development of new and advanced technologies including overlaps with other sectors that may transcend the healthcare sector;

- 10) analyze strategic developments and issues relating to regulation and standardization, as they may impact the standardization process or prioritization of work, including interfaces with the European Commission, Medical Device Experts Group (MDEG), the International Medical Device Regulators Forum (IMDRF) and National Health Authorities;
- 11) mediate and propose solutions to coordination issues, including those between Technical Committees and Working Groups, if requested.

3.3.2 Composition

- Chair and Vice chair (collectively appointed by the CEN and CENELEC Technical Boards)
- Competent Authorities
- CEN-CENELEC Healthcare Consultant(s)
- CEN and CENELEC representatives
- CEN and CENELEC Technical Committee chairmen and secretaries
- European and international organizations (e.g. European Pharmacopoeia, ISO, IEC, ITU, etc.)
- European Commission, EFTA
- National Standards Bodies
- National Health Authorities
- European trade associations, federations and market partners, health insurers (public and private), and organizations for patients/users related to healthcare (market partners would include e.g. IHE, HL7, Continua Alliance)
- Other relevant individuals and groups at the discretion of the ABHS (e.g. Notified Bodies)

The chairmanship alternates between CEN and CENELEC. The ESO not holding the chairmanship nominates a Vice chair. Chair and Vice chair are appointed for a period of three years. The Chair or Vice chair, respectively, nominated by CEN will act as CEN Sector Rapporteur.

The total number of participants should be limited to those able to provide an effective and proactive input in order to maintain a workable-sized group. As a guide, any organization should limit delegates to three.

It is important that adequate commitment is made available from the CEN-CENELEC Management Centre (CCMC) as well as the ABHS Secretariat to provide professional coordination and technical support.

To meet the identified needs, the ABHS will appoint a Chairman's Advisory Group (CAG) and/or Task Forces or Interest Groups as necessary (see 3.4 and 3.5, respectively).

3.3.3 Mode of operation and meeting frequency

It is envisaged that the ABHS will meet one to two times per year at a location agreed between the members. There should be at least one meeting per year. The meeting length should not be more than two days.

It may be desirable to have meetings focused on different topics or to engage and concentrate on particular interests. For example, focuses might include interfaces between health informatics/medical devices; electromedical/software issues; regulatory interfaces; Quality Management Systems in healthcare establishments, etc. These could be accompanied with presentations by acknowledged experts in the area and discussion.

A Chairman's Advisory Group may be set up with membership as defined in 3.4.

Task Forces (TF) or Interest Groups (IG) will be established if needed, with membership to be determined by the ABHS. It is envisaged that any such group or priority topic will have several individuals appointed to take responsibility for identifying useful liaisons, obtaining necessary information and taking all actions needed to progress the matter to resolution. TFs will be disbanded when their work is finished and no ongoing need is identified. TF and IG conveners should deliver reports at least three weeks prior to the ABHS plenary meetings in order to allow review and comment.

Final agreement of proposed solutions, papers, reports or recommendations concerning any issues should be confirmed by the ABHS, either at a regular meeting or by correspondence if deemed necessary.

The ABHS can:

- Initiate investigations:
 - Create ABHS/IG (Interest Groups, permanent), e.g.:
 - Environment
 - e-health
 - Communication and education
 - Create ABHS/TF (Task Forces, temporary) on a specific matter with an anticipated completion date:
 - Numbering will follow the format 2011-01, 2011-02, etc.
 - Participants to be regular members of ABHS or temporary members for a specific TF on invitation
- Organize workshops on a case-to-case basis on a specific topic insofar as the workshop is meant to help ABHS accomplish its Mission. Unnecessary duplication of work with existing initiatives (like those of a body of the European Commission) shall, however, be avoided.

3.4 Chairman's Advisory Group (CAG)

3.4.1 Function

It is envisaged that the CAG will have, amongst other possible functions, the following roles:

- assist the ABHS Chairman in the organization of the ABHS and TFs/IGs;
- assist the ABHS Chairman to determine the need for additional meetings and/or cancellation of meetings, and to determine agenda items;
- identify urgent needs and react to these;
- identify and follow strategic developments in the healthcare sector;
- establish, when necessary, TFs/IGs and identify potential TF/IG members;
- review the overall progress of the standardization work on a regular basis;
- evaluate any emerging challenges which impact the standardization system and to propose solutions;
- communicate with members of the ABHS and/or other relevant partners to ensure transparency and provide needed information;
- assist the CEN-CENELEC Management Centre (CCMC) in any matters arising related to the healthcare sector.

If a TF or IG is set up by the CAG, the full ABHS membership should be given the opportunity to agree and to nominate TF or IG members, or to oppose setting up the TF or IG if they think it would be poor use of resources.

3.4.2 Composition

The CAG should comprise those invited by the Chairman but will be documented and reported to the members of the ABHS.

3.4.3 Meeting frequency

The CAG will communicate whenever possible by electronic means, but may meet between ABHS meetings. Meetings will be notified beforehand to the membership of the ABHS.

3.5 Task Forces/Interest Groups (TFs/IGs)

3.5.1 Function

TFs/IGs may be set up by the ABHS or *ad hoc* by the CAG, in order to look in detail at specific issues delegated to the TF/IG by the ABHS. The scope and objectives shall be agreed and clearly stated when the TF/IG is created.

3.5.2 Composition

A TF/IG might consist of selected experts from within the ABHS and/or the healthcare sector in a wider sense.

TFs/IGs are to be accountable to the ABHS, and should make recommendations to appropriate decision-making bodies only after approval of ABHS, which may be done by correspondence. Reports and ongoing progress of TF/IG meetings should be made available to the ABHS in a transparent and regular manner.