

BUSINESS PLAN
CEN/TC 140
IN VITRO DIAGNOSTIC MEDICAL DEVICES
(IVD MDs)

EXECUTIVE SUMMARY

Business environment

- Europe represents about 32 % of the worldwide market of IVD MDs;
- Number of application sectors (hospitals, medical or clinical laboratories, doctors' surgeries, private homes, etc.)
- Parties involved in the standardization:
 - Industry of IVD MDs (manufacturer)
 - Operators of the various application sectors (users)
 - Health authorities

Benefits

The standards developed by CEN/TC 140 support the uniform implementation of the requirements of the European Directive 98/79/EC on "In vitro diagnostic medical devices". They will be revised in the near future to support the essential requirements of the IVD Regulation 2017/746 on "In vitro diagnostic medical devices".

Since the foundation of CEN/TC 140 about 397 standards have been adopted.

Priorities

To make available European standards related to:

- Labelling and performance evaluation;
- Quality systems for IVD MDs;
- Quality management in the medical laboratory;
- Reference systems;
- Specimen containers;
- Staining in biology;
- IVD MDs for self-testing; and
- Use of external quality assessment schemes.

1 BUSINESS ENVIRONMENT OF CEN/TC 140

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of CEN/TC 140, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

In vitro diagnostic medical devices used to be subject to different laws, regulations and administrative provisions in the Member States of the European Union with regard to safety, health protection, performance characteristics and authorization procedures. The Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices contributes to the further development of the European internal market, the free movement of goods, the removal and prevention of trade barriers. In addition, it ensures a uniform level of protection to patients, users and third parties in the European Member States. This New Approach Directive, in particular its essential requirements, are supported by European Standards which are mandated by the European Commission and EFTA.

On May 5, 2017 the EU commission published the IVD Regulation 2017/746 on "In vitro diagnostic medical devices". In contrast to the Directive 98/79/EC, where a translation in national law was mandatory, Regulation 2017/746 is valid immediately in the European Union. The transition period for the new regulation ends on 26 May 2022. While the Regulation is published and in force, several underlying processes need to be defined in more detail.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of CEN /TC 140:

The standards being developed in CEN/TC 140 may be used by hospitals, medical laboratories, biobanks, and healthcare settings, as well as by manufacturers and government agencies. There are seven large multinational manufacturers of IVD products that command nearly 85% of the global market. Moreover, several thousand smaller companies exist that have niche markets or are start-up enterprises.

In 2015 the total Medical device (IVD + MD) market made sales worth more than US\$140 billion and is expected to grow by about 25 % in the next 5 years.

According to the Advanced Medical Technology Association (AdvaMed)¹:

- "IVDs save patient lives through early detection. Occult blood screening of high-risk individuals over the age of 40 can reduce colorectal cancer deaths by about one-third. Routine prenatal screening for hepatitis B infection in high-risk groups can prevent as many as 1,400 cases of chronic liver disease per 100,000 women screened.
- IVDs improve health through prompt diagnosis. Rapid bacterial test systems can reduce the mortality rate associated with infection by 45%. Urine tests, which predict the development of kidney disorder in insulin-dependent patients with diabetes, can reduce the need for kidney dialysis or transplantation by up to 63%.

¹ "In vitro diagnostics: Medical Tests that Save Lives and Reduce Health Care Costs," Advanced Medical Technology Association (AdvaMed) IVD Fact Sheet.

- IVDs help manage existing conditions – and their costs. Tests that monitor the effectiveness of certain antibiotic therapies can aid in reducing the duration of drug therapy and shorten hospital stays by more than four days, saving more than US\$2 million annually in hospital costs for every 500 patients.
- Compact blood glucose monitoring devices enable patients with diabetes to control insulin levels, thereby reducing the risk of kidney failure, blindness, heart attack, and amputation.
- IVDs help healthcare providers improve productivity and reduce costs. Tests to analyse cardiac enzyme levels allow early diagnosis of heart attack, thereby reducing hospitalisation days by more than 500,000 per year and saving US\$182 million annually. Rapid bedside blood testing in the emergency room can cut turn-around time and may reduce time in the ER for an estimated 17% of patients.”

2 BENEFITS EXPECTED FROM THE WORK OF CEN/TC 140

The standards developed by CEN/TC 140:

- Assist manufacturers of IVD products to demonstrate fulfillment of the applicable Essential Requirements of the Directive 98/79/EC and provide manufacturers, notified bodies, test houses with a clear route to CE marking;
- Assist manufacturers of IVD products to demonstrate fulfillment of the applicable requirements of the IVD Regulation 2017/746 on In vitro diagnostic medical devices, and provide manufacturers, notified bodies, test houses guidance to CE marking;
- Contribute to the elimination of trade barriers and favour the global market; and
- Provide agreed test methods and improve the quality of testing.

3 PARTICIPATION IN CEN/TC 140

All CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF CEN/TC 140 AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The objectives of CEN/TC 140 are to develop and maintain up to date standards and to:

- Develop standards that are also accepted by ISO, possibly by means of the Vienna Agreement for a joint adoption;
- Develop standardized performance test procedures; and
- Promote uniformity and clarity in understanding by adoption of standardized terminology.

4.2 Identified strategies to achieve the CEN/TCs defined objectives

European Standards which have been mandated by the European Commission and EFTA with regard to Directive 98/79/EC as well as IVD Regulation 2017/746 and which therefore are related to the manufacture of IVD MDs are prepared with highest priority. Non-mandated, user-related

standards are as far as possible prepared in the framework of the Vienna Agreement under ISO lead.

The work of the TC and its WG(s) is done at meetings and by correspondence. Electronic means for the distribution of documents are used.

The standardisation projects, which are adopted in the work programme are allocated to the Working Group(s). If required, Joint Working Groups and ad hoc groups will be arranged at TC level and Working Group level respectively.

CEN/TC 140 is in liaison with:

- Biobanking and BioMolecular resources Research Infrastructure (BBMRI-ERIC);
- European Commission (EC);
- European Federation of Clinical Chemistry and Laboratory Medicine (EFLM);
- European Association for Professions in Biomedical Science (EPBS);
- European Society of Pathology (ESP);
- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC);
- Japanese Industrial Standards Committee (JISC); and
- European trade association representing the medical technology industries, from diagnosis to cure (MedTech Europe).

CEN/TC 140 also established liaisons with:

- ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems", with regard to various standards projects prepared under the Vienna Agreement under CEN lead or ISO lead; and
- ISO/TC 276 "Biotechnology", to coordinate the development of relevant biobanking standardization work.

4.3 Environmental aspects

Since this Technical Committee is focused on IVD MDs according to Directive 98/79/EC and in the upcoming years to the IVD-Regulation 2017/746 on in vitro diagnostic medical devices", environmental aspects are of minor importance. Environmental aspects are being considered in e.g. the selection of test methods. In the case that environmental aspects become a matter, example e.g. for the disposal of materials or toxic substances, they will be considered in the respective standards.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

The availability of experts in the field of IVD MDs and financial support is limited. Drafting of standards on a continuous basis and in an appropriate time schedule is achieved only by sufficient participation of all stakeholders and sufficient government and industrial finance. Therefore, the voluntary power of the industry must be supported by means of mandates in order to achieve successful continuity of the standardization work.

Working and coordinating a work item with international standards development groups tends to slow down the timeline for reaching a final document. This delay is justified when the document is harmonized and acceptable to a broader group of stakeholders, for example ISO and CEN.