

BUSINESS PLAN

CEN/TC 332

LABORATORY EQUIPMENT

EXECUTIVE SUMMARY

The standardization work of CEN/TC 332 covers equipment for laboratories involved in chemical, physical and biological work. In general, equipment for laboratories can be divided into 3 main sections:

- laboratory glass and plastics ware,
- laboratory metrological and other electrical and non-electrical devices,
- laboratory furniture, fittings and fixtures.

Figures given in literature about the size of the total worldwide market for this equipment differ a lot, but can be estimated to be about 41 billion \$ in 2014. Europe represents about one third of the world market.

CEN/TC 332 deals with all the 3 sections of this equipment. The emphasis is on the standardization in the field of laboratory equipment, with respect to principles and to materials of construction, performance, dimensions and testing, as well as to terms and definitions for use in connection therewith. Since its establishment in 1997, CEN/TC 332 has developed and published 47 European Standards, Technical Reports and Specifications for laboratory equipment.

The standards give the manufacturer guidance in respect of product safety liability, performance requirements requested by users and legal authorities and decrease the number of sizes and dimensions to be manufactured thus reducing the costs.

The standards give the user practical help in handling and calibrating the equipment thus meeting specified quality criteria and they assure the compatibility of equipment and materials from different manufacturers. They give guidance in the establishment of measurement's uncertainty budgets.

The standards support legal authorities and manufacturers by specifying technically detailed requirements to fulfil basic legal requirements. The standards are basis for the legal verification of measuring instruments and for national regulations in the fields of occupational health and safety at the work place. The standards serve test houses involved in metrological and safety testing in the accreditation process and in the documentation of worldwide acknowledged test procedures.

The standards serve other TC's developing test standards, e. g. for materials testing, analytical procedures and techniques as well as non-chemical and non-laboratory measurements.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

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 this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

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- laboratory glass and plastics ware,
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- laboratory furniture, fittings and fixtures.

CEN/TC 332 deals with all the 3 sections. The standards developed serve the producers of lab equipment as well as the users of the equipment in the laboratories. They are from importance for all institutions running a laboratory, may they be large international companies running laboratories for research and quality control around the world, may they be small or medium sized companies or governmental authorities operating on a more national level or may the laboratories serve for educational purposes such as schools and universities.

In the context of quality management systems such as ISO 9000 and laboratory accreditation, e. g. in accordance with ISO/IEC 17025, users of equipment ask for practical guidance on how to perform quality assurance for measuring equipment and how to estimate uncertainty of measurement.

In respect of regulatory obstacles, national verification laws, labour safety (occupational health), consumer and environmental protection as well as the related laws and directives (partly in development, e. g. for metrology in Europe) shall be considered during the standards development process. The harmonization of metrological standards serving the official verification of instruments results in a high impact on competitiveness. The world level impact of the TC 332 standardization work is given by the close cooperation with ISO/TC 48 and its liaison partners such as ICG, WMO, WHO and others, and with regional standardization organizations like ASTM and with related Technical Committees, especially in the fields of biotechnology and of in vitro diagnostic laboratory instruments.

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 the CEN /TC:

Figures given in literature about the size of the total worldwide market differ a lot, but can be estimated to be about 42 billion \$ in 2015. Regarding the size of the market for glassware and related apparatus, figures are confidential and not publicly available. Total market evaluations exist, e. g. by Frost & Sullivan, and can be purchased for about 3.000 US \$. An estimate of the market value for laboratory goods of the categories in section 1 above, in the EC alone, is at least 4,2 billion \$ (in 2013).

Manufacture of laboratory equipment in general, is technologically, highly innovative with about 2000 small and medium sized businesses worldwide, where the exchange of information and co-operations influence the degree of innovation. More details about products, product groups, manufacturers and institutions involved can be found free of charge on the web pages of scientific organizations such as DECHEMA (www.achema.de).

The worldwide market for metrological equipment, other than glass, can be expected to expand significantly with increased demand for food, pharmaceutical and medical quality control and accreditation, and environmental monitoring. A future quantitative growth of market for laboratory glassware can be expected in South American, African and Asian countries. A growth of market in North America and Europe can only be expected in qualitative and not in quantitative terms.

Since the foundation of CEN/TC 332 in 1997, 45 European Standards and 1 Technical Specification (CEN/TS) and 1 Technical Report (CEN/TR) have been developed and published. Current and up-to-date ISO/TC 48 standards are adopted as EN ISO standards without modification.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

The standards give the manufacturer guidance in respect of product safety liability, performance requirements requested by users and legal authorities and decrease the number of sizes and dimensions to be manufactured thus reducing the costs.

The standards give the user practical help in handling and calibrating the equipment thus meeting specified quality criteria and they assure the compatibility of equipment and materials from different manufacturers. They give guidance in the establishment of measurement's uncertainty budgets.

The standards support legal authorities and manufacturers by specifying technically detailed requirements to fulfil basic legal requirements. The standards are basis for the legal verification. The standards serve test houses involved in metrological and safety testing in the accreditation process and in the documentation of worldwide acknowledged test procedures.

The standards serve other TC's developing test standards, e. g. for materials testing, analytical procedures and techniques as well as non-chemical and non-laboratory measurements.

The standards support environmental protection and sustainable development, e. g. by marking of materials on the products as important prerequisite for the recycling of products or materials.

3 PARTICIPATION IN THE CEN/TC

All the 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 THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

Based on the business environment and the considerations mentioned above, CEN/TC 332 has developed the following objectives and strategic directions for its future work:

Development of European Standards and Technical Specifications as laid down in the scope of the TC and in the fields described above. Adoption of International Standards as European Standards via Vienna Agreement without modification.

The elimination of trade barriers in the fields of legal metrology is a primary requirement of industry. Several national authorities and the European Community are developing Measuring Instrument Directives or appropriate regulations and the standards can serve the fulfillment of the essential requirements of these directives or regulations, if they include laboratory instruments.

A second important objective is the support of clinical and diagnostic laboratories in the fields of quality assurance of measurement equipment. In addition the standards are important for the control mechanisms of WTO and WCO policies and especially for the financial income of governments if taxation is based on measurement (e. g. oil, food and beverage industries).

A third objective is the support of sustainable development and environmental protection during manufacture and use of laboratory equipment.

4.2 Identified strategies to achieve the CEN/TC.s defined objectives.

Working in parallel with CEN under ISO lead for the whole scope of ISO/TC 48 which mainly corresponds to CEN/TC 332/WG 1 *Glass and plastics devices including volumetric instruments*. Only in exceptional cases working in parallel under CEN lead for devices to be decided individually for each work item. As DIN undertakes the secretariat of ISO/TC 48 and of CEN/TC 332 in addition, overlap of work will be avoided by standards development with parallel voting in accordance with the Vienna agreement in the whole scope of ISO/TC 48.

As some general laboratory equipment is also used in medical and biotechnological laboratories co-operation with CEN/TC 140, ISO/TC 212 and CEN/TC 233 already exists at national and regional levels.

4.3 Environmental aspects

Laboratory work is very often connected with the handling of hazardous substances. For safety reasons and to fulfill occupational health requirements laboratories need sophisticated air ventilation and conditioning systems (HVAC's) and circumferential exhaust air equipment such as fume cupboards. This equipment contributes considerably to the energy use and energy balance of the laboratory and of whole lab buildings.

Consequently, the standardization work for this equipment concentrates to join safety aspects with energy efficiency. As example, EN 14175-6 has been developed to reduce the air consumption of fume cupboards and during the development procedure of the whole standard series 14175 all measures have been undertaken to reduce the air velocity in fume cupboards. Fume cupboards in accordance with EN 14175 can work with about 40 % lower air consumption than formerly designed fume cupboards nevertheless supplying the same safety level. WG 4 of TC 332 will strive for similar approaches, if developing a standard for laboratory HVAC systems.

"Sustainable laboratories" have been an item of discussion in some European countries and in US in the last years. These discussions have been initiated e. g. by EPBD (European performance of buildings directive) and its national implementations. The emphasis here lays on architectural aspects of buildings (lab buildings) which is outside the scope of TC 332. Nevertheless TC 332 examines whether contributions in the fields of terminology, of energy efficiency and by technical building equipment, especially of exhaust air equipment, can be supplied.

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

The experts of TC 332 have to be aware, that the scope of the TC is limited to terminology, specification and testing of laboratory equipment and its materials, and that it is not the task to develop methods of laboratory measurement and analytical techniques or to specify how to perform measurements on special samples. Thus, TC 332 develops terminology, testing and product standards and not process standards. General advice on the proper handling of equipment or on qualification, validation, calibration and testing of equipment may be given.

Advice on the safe handling of the equipment by laboratory personal shall be avoided or limited, because aspects of occupational health and compulsory safety regulations for laboratories usually are the responsibility of national legislation and national executive authorities. Thus, standards specifying safety requirements have to address in the first line equipment manufacturers.

6 WORKING STRUCTURE

In order to achieve the objectives stated above, CEN/TC 332 “Laboratory equipment” decided to create Working groups to deal with different aspects of standardization activity.

- WG 1: Glass and plastic devices including volumetric instruments
- WG 2: Fitting and Fixtures
- WG 4: Fume cupboards and associated ventilation
- WG 6: Emergency Safety Showers
- WG 7: Micro process engineering