BUSINESS PLAN

ISO/TC 48
Laboratory equipment

EXECUTIVE SUMMARY

The standardization work of ISO/TC 48 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 50 billion $ in 2016.

ISO/TC 48 was established in 1947 mainly for the standardization of laboratory glassware and deals at the time being with all the three sections of this equipment. The emphasis is on product standards for laboratory devices and apparatus, with respect to principles and to materials of construction, performance, dimensions and testing, as well as to terms and definitions used in connection therewith.

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 asssure 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. 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; cross-referencing, e. g. by ISO/TC 212, ISO/TC 28 and ISO/TC 47.

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.

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TC's) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TC's to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF THE ISO/TC

2.1 Description of the Business Environment

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

The standardization work of ISO/TC 48 covers equipment for laboratories involved in chemical, physical and biological work. In general, the equipment 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.

ISO/TC 48 (established in 1947 mainly for the standardization of laboratory glassware) deals at the time being with all the three sections. Only apparatus and devices constructed for personal safety of persons working in laboratories are excluded from the scope of TC 48. Most standards developed are product standards and 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 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 competitivity. The world level impact of the TC 48 standardization work is given by the close cooperation with liaison partners such as ICG, WHO, WMO and others, and with regional standardization organizations like CEN, especially in the fields of legal metrology and of in vitro diagnostic laboratory instruments.

2.2 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 ISO/TC:

Figures given in literature about the size of the total worldwide market differ a lot, but can be estimated to be about 50 billion $ in 2016. Regarding the size of the market for glassware and related apparatus, figures are confidential and not publicly available.

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.

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 ISO/TC 48 in 1947, many of the 110 International Standards published have been adopted as national standards, e. g. in China, Egypt, India, Russian Republic and in almost all European countries. Since the establishment of the European Technical Committee CEN/TC 332 in 1997, all TC 48 standards are adopted as EN ISO standards without modification.

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/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 asssure 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; cross-referencing, e. g. by ISO/TC 212, ISO/TC 28 and ISO/TC 47.

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.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Countries/ISO members bodies that are P and O members of the ISO committee

4.2 Analysis of the participation

Manufacturers, users of the equipment, research institutions and governmental authorities are well represented as experts in TC 48 and in its three subcommittees. Regarding active membership, there has been in the past 20 years an emphasis on experts from European countries.

In order to avoid a decrease of acceptibility of the TC 48 standards to the wider international market, considerable and successful efforts have been undertaken during the last years to return to a more active participation of National Standardization Organisations and experts from non-European countries, especially from America and Asia. Now TC 48 is more global and has the opportunity to spread the standardization work and the usage of TC 48 standards.

5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

Based on the business environment and the considerations mentioned above, ISO/TC 48 has developed over the decades the following objectives and strategic directions for its future work:

Development of International Standards and Technical Reports as laid down in the scope of the TC and in the fields described above. Adoption of the developed International Standards as national or regional standards, e. g. as European Standards by CEN 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 fullfilment 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, gas, food and beverage industries).

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

5.2 Identified strategies to achieve the ISO/TC's defined objectives

Working in parallel with CEN under ISO lead for the whole scope of ISO/TC 48. 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.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

Taking into account that the use of instrumentalized analytical methods such as spectroscopy and chromatography increased considerably during the last 3 decades the scope of ISO/TC 48 has been widened in 2005 from "laboratory glassware and related equipment" to laboratory equipment in general.

The experts of TC 48 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 48 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.

Since 2003 the secretariat of Subcommittee 5 "Quality of glassware" is vacant and no active standardization work is performed. Most International Standards in responsibility of SC 5 are up to date and represent the state of art, but it is important to find a successor with back-up by a National ISO Member Body to continue the secretariat work.

Many countries in the world act as importers of laboratory equipment and have limited own manufacturing facilities. Thus, it is quite understandable, that the number of actively participating countries in TC 48 is limited. Nevertheless, TC 48 would welcome and encourage any additional member.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 Structure of the ISO committee

7.2 Current projects of the ISO technical committee and its subcommittees

7.3 Publications of the ISO technical committee and its subcommittees

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work