



ISO/TC 212 Strategic Business Plan 2019

ISO/TC 212 Clinical laboratory testing and *in vitro* diagnostic test systems

Executive summary

ISO/TC 212 addresses the discipline of clinical laboratory medicine through a focus on quality management, reference measurement systems, *in vitro* diagnostic (IVD) products, antimicrobial susceptibility testing, molecular diagnostics, and risk management. The main fields of interest include laboratory measurement of quantities in specimens of biological origin, testing the susceptibility of antimicrobial agents against bacteria, competence and accreditation, safety and risk management in the laboratory, point-of-care self-testing, and product labeling and validation. The worldwide market for technical committee deliverables ranges from high-technology testing sites, to resource-limited sites, to home testing. A benefit already realized through ISO/TC 212's work is the availability of standards for medical laboratories for implementing quality management systems based on ISO 9001, e.g., ISO 15189. The new standards are intended to promote a common, harmonized, international approach to the quality management of medical laboratories and for all aspects of operation, from patient preparation and identification to the collection and examination of clinical specimens. The primary objective of the technical committee in its current work is to broaden the application of the quality system in medical laboratories, the IVD industry, and related off-site clinical testing to improve health care worldwide. ISO/TC 212 is designed to address the global clinical laboratory community needs of all its stakeholders.

ISO/TC 212 Deliverables

ISO/TC 212 develops Standards, Technical Specifications, and Technical Reports. The primary product is a standard, which is a normative document developed according to consensus procedures. Standards are approved by the ISO membership and P-members of the responsible committee in accordance with the ISO/IEC Directives. Adoption of a standard as a means for compliance with respective legislation is voluntary.

1 Introduction

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure forming part of a major review of business. It aligns the ISO work programme with the expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, identifies the measurable benefits expected from the availability of International Standards, and ensures 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 and other ISO deliverables: [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 164 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 do not have the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable that bridges 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.

Over the past two decades, the development of a global economy has affected the health care field in a number of ways. More countries have experienced economic expansion and have increased resources to spend on health care. Globalization resulting in open markets, open political systems, and access to communication technologies have prompted people to travel at higher rates than ever before. It is estimated that 15 000 individuals cross national borders every minute. This mobility also means that diseases that were previously isolated to specific geographic areas now affect people around the globe within 24 hours. These travelers are potential patients in the global health care system, and their increased mobility creates a greater demand for global quality medical care that is harmonized and standardized. These factors and an international drive for harmonization and standardization in the clinical laboratory field have

combined to increase the demand for quality health care, the availability of quality medical products, and the need for health care practitioners to have a common basis to discuss a patient's condition and test results.

Consequently, the level of medical laboratory testing and corresponding use of IVD products continues to expand worldwide. IVD devices use fluids, tissue specimens, or excretions from the human body to detect, diagnose, manage, or prevent medical conditions. IVD products include reagents for the chemical and physical analysis of material derived from the human body, equipment such as clinical chemistry and hematology analyzers used to automate the analyses, portable instruments used to carry out self-testing, such as blood glucose monitors, and kits, such as home pregnancy tests. IVD devices are used in almost every part of the health care system, as well as in non-health care settings, e.g.:

- Medical/clinical laboratories, hospital operating rooms, emergency rooms, and at the patient's bedside;
- Physicians' offices, walk-in clinics, pharmacies, and surgery centers
- Medical laboratories that conduct large-volume testing for physician clinics and hospitals
- Private homes, childcare centers, senior centers, health clubs, and other locations where patients may spend time

The IVD market is a relatively small segment of the overall medical products market, representing less than 3% of total health care spending, but it has experienced significant growth over the past 30 years. The worldwide market for IVD devices grew from roughly US \$450 million in 1970 to US \$60 billion in 2016. A period of maturation and consolidation has slowed this growth significantly, but a wave of technology-driven change is poised to transform the nature of the market and the role of clinical diagnostics in medicine. It is projected that these changes will lead to a compound annual growth rate of approximately 5% to 7% from the present to 2023. Relevant stakeholders in this field include laboratories, manufacturers, professional societies, government agencies, customers of medical/clinical laboratory services, including clinicians, hospitals, patients, payers [e.g., national health systems, national governments, insurance companies, health maintenance organizations (HMOs)], and accreditation and certification organizations.

Regulatory authorities, manufacturers, and laboratory accreditation agencies are increasingly using international standards to assure the safety and effectiveness of IVD devices. For example, in the European Union Directive 98/79/EC of the European Parliament and Council on *In Vitro* Diagnostic Medical Devices stipulates that a product needs to comply with essential requirements before being admitted to the market. Compliance with these essential requirements is presumed if the product has been developed and manufactured according to certain, harmonized European Norms (EN) developed by the European standards bodies, i.e., European Committee for Standardization (CEN) and European Committee for Electrotechnical Standardization (CENELEC). The U.S. Food and Drug Administration (FDA) is also moving toward the increasing use of standards to support regulations.

In addition, there has been an increase in the development of accreditation and certification programs for medical/clinical laboratories. The purpose of accreditation and certification is to ensure that the medical/clinical laboratory is operating according to a recognized quality management system. Certification means an institution meets requirements, while accreditation demonstrates competency. Interest in accreditation and certification has been prompted by a

number of factors, including health and safety issues in the medical/clinical laboratory, the development of quality system standards by ISO/TC 176 and ISO/TC 210, and the transport and investigation of specimens across borders for testing (e.g., specimens transported from the West Coast of the United States to Japan for rapid testing in automated laboratories).

2.2 Quantitative Indicators of the Business Environment

The following objective, quantitative indicators describe the business environment in order to provide adequate information to support actions of the ISO/TC:

The standards being developed in ISO/TC 212 may be used by thousands of hospitals, clinical/medical laboratories, and health care settings worldwide, as well as by manufacturers and government regulatory agencies. Several large manufacturers of IVD devices command nearly 85% of the global market, and several thousand smaller companies have niche markets or are start-up enterprises.

According to “*In vitro* diagnostics: Medical Tests that Save Lives and Reduce Health Care Costs,” an Advanced Medical Technology Association (AdvaMed) IVD fact sheet:

- IVDs save patient lives through early detection. Occult blood screening of high-risk individuals over 40 years of age can reduce colorectal cancer deaths by about one third. Routine prenatal screening for hepatitis B infection in high-risk groups can prevent up to 1400 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%.
- IVDs help manage existing conditions and their costs. Tests that monitor the effectiveness of antibiotic therapies can help reduce 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 health care providers improve productivity and reduce costs. Tests to analyze cardiac enzyme levels allow early diagnosis of heart attack, thereby reducing hospitalization days by more than 500 000 per year and saving US \$182 million annually. Rapid bedside blood testing in the emergency room (ER) can shorten turnaround time and may reduce time in the ER for an estimated 17% of patients.

2.3 Environmental Trends

2.3.1 Technical Advances

As an environmental trend, technical advances and their integration are expected to have a great impact on the field of laboratory medicine in the next decade. These advances include artificial intelligence, big data, and Internet of Things. The newest technologies need time to evolve, adapt, and mature. When technologies reach a level of maturity suitable for harmonization/standardization, groups like ISO/TC 212 become important in providing that global alignment.

2.3.2 Medical Laboratory Regulations

More countries throughout the world are using ISO 15189 to accredit laboratories instead of implementing new regulations. Other standards are likely needed to set global benchmarks in areas that may not meet essential, safety, or performance requirements.

2.3.3 IVD Industry Regulations

Global harmonization of IVD regulations supported by international standards is continuing. Australia, Brazil, and China, as well as other countries, implemented regulations that encourage use of standards. The Asian Harmonization Working Party (AHWP) and Pan African Harmonisation Working Party (PAHWP) support adoption of harmonized regulations in Asia and Africa per the standards-based Global Harmonization Task Force (GHTF) model. In October 2011, The International Medical Device Regulators Forum (IMDRF) replaced the GHTF to promote global harmonization.

The EU IVD Regulation (IVDR), which replaces the current EU IVD Directive (IVDD), was published in May 2017. Until the IVDD is officially repealed in May 2022, both legislations remain in force. Increased regulatory oversight, more stringent requirements for manufacturers, and increased supervision of notified bodies are expected. Adoption of ISO/TC 212 standards for regulatory purposes is mixed. The European Commission has adopted 13 standards developed by ISO/TC 212 under the Vienna Agreement to support the current IVD Directive. The US FDA does not currently recognize any ISO/TC 212 standards. Data on adoption by other countries are needed.

3 Benefits expected from the work of the ISO/TC

As mentioned above, it is expected that the worldwide volume of testing in the medical/clinical laboratory and international trade in IVD products will continue to grow by at least 5% annually over the next five years. While there is a significant amount of literature available on topics within the scope of the technical committee, there remains the need for comprehensive, harmonized standards for IVD products that facilitate their use in the laboratory environment, in homes, and other locations where testing is provided or available. By addressing this need, ISO/TC 212 will improve the quality of testing, thus improving the quality of health care. Economic globalization affects the health care industry in general and laboratory testing in particular. ISO/TC 212's documents will facilitate the manufacture and availability of quality laboratory testing products through reduced barriers to trade and harmonization of product quality requirements worldwide. The globally renowned human genome sequencing project is completed and will lead to extraordinary opportunities and new advances in medical/clinical laboratory testing. ISO/TC 212 documents will have worldwide benefit in this dynamic environment. Specific benefits include:

- Reduction in medical errors
 - Greater compliance with regulations
 - Reduction in regulatory barriers to trade
 - Improved quality of laboratory specimens
 - Faster time to market for IVD products
 - Laboratory results that meet clinical/medical needs for optimal patient care
 - Response to both existing and potential public health and safety concerns
 - Cost-effective operations of health care systems
- Harmonization of CEN and ISO standards to provide consistent and effective guidance to the international clinical laboratory field
 - Greater harmonization of national regulations to provide international standardization of practice
 - Support for implementation and distribution of standards such as ISO 13485, ISO 14971, ISO 15189, and ISO 35001

4 Representation and participation in the ISO/TC

4.1 Membership

[Countries/ISO member bodies that are P and O members of the ISO committee](#)

4.2 Analysis of the participation

ISO/TC 212 liaises with other ISO or IEC technical committees, as well as with other international organizations, and enjoys excellent cooperation and information exchange with CEN/TC 140. At present, ten ISO/TC 212 projects are proceeding with CEN/TC 140 participation, under terms of the Vienna Agreement. ISO/TC 212 supports the broadest possible participation of ISO member bodies. Although ISO/TC 212 assigns high priority to developing standards for developed technologies, it recognizes that the special needs of countries in development must also be considered. ISO/TC 212 could benefit from greater participation from government agencies, professional societies, and user groups; countries in the regions of Southeast Asia, Africa, the Middle East, and Eastern Europe; and organizations that accredit medical/clinical laboratories.

4.3 Relevant Stakeholders

Relevant stakeholders include health care providers and patients, health care management, employees and suppliers of medical laboratories, non-laboratory testing sites (e.g., physician offices, ambulatory and field clinics, ambulances, pharmacies, patient homes), IVD companies, vaccine and pharmaceutical manufacturers, laboratory accreditation bodies, government regulatory authorities and other standards development organizations, medical research centers, public health institutes and biobanks, metrology institutes and reference measurement laboratories, laboratory medicine professional societies and industry trade associations, and third-party health care payers. It is recognized that medical laboratories, point-of-care testing users, IVD manufacturers, and regulatory authorities are the key stakeholders for many of the documents developed by ISO/TC 212.

5 Objectives of the ISO/TC and strategies for their achievement

5.1 Defined objectives of the ISO/TC

ISO/TC 212 is committed to:

- Developing standards that are relevant to the intended users
- Achieving the highest quality standards that meet medical needs for patient care
- Focusing on global harmonization of scopes, approaches, terms and definitions at the technical level and at the level of national/regional regulations, and standards to facilitate conformance to those regulations
- Providing a forum for all IVD testing stakeholders to reach consensus on international standards
- Developing standards and guidelines that improve the quality of IVD examinations and ensure that results meet medical needs for both commercially purchased and laboratory-developed tests
- Developing standards and guidelines to ensure IVD device safety
- Developing standards and guidelines that reduce technical barriers to trade
- Developing standards to drive innovations and promote their adoption

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

ISO/TC 212 will implement the following strategies:

- Select new projects using the breadth and depth of the expertise gathered in ISO/TC 212; focus on horizontal standards; address topics that are generally applicable to all IVD devices; and limit the activities of ISO/TC 212 to a level that corresponds to the resources that are available (i.e., time and funds of the delegates).
- Assign high preference to standards for developed technologies and to those that meet minimum performance goals or specifications; take the potential cost of implementation of a standard into consideration; and solicit New Work Item ideas only according to perceived needs, which should be fully explained and supported by evidence.
- Globalize regional standards that have a global impact.

5.3 Resulting action plan

ISO/TC 212 will implement the following action plan:

- To strengthen the need for effective and optimal use of the limited resources of ISO/TC 212, it is highly recommended that a P-member, through the Secretariat, circulates a planned New Work Item Proposal to the Technical Committee before a plenary meeting to allow a general discussion before the voting procedure is started (following the plenary meeting).
- To globalize important regional standards, ISO/TC 212 should seek the cooperation of CEN/TC 140 to:
 - Conduct regular joint reviews, by the secretariats of the Technical Committees, of all current and future Work Items.
 - Propose, by the Secretariats, potential joint projects to ISO/TC 212's technical board and, if acceptable, to the CEN/TC 140 (*In Vitro* Diagnostic Medical Devices) secretariat and to the management of CEN/TC 140;
 - Attempt to codevelop, under the Vienna Agreement, as many standards mandated by the European Commission to CEN/TC 140 as possible.

6 Factors affecting completion and implementation of the ISO/TC work programme

Many of ISO/TC 212's standards relate directly or indirectly to the European legislations (IVDD and IVDR), to U.S. FDA regulations, and to regulations of other countries. It is important to ensure that these standards support the regulations and that, where standards exist, they be aligned. It has been found that assignment of the appropriate individuals to a work item is critical. Inclusion of all stakeholders is key to efficient completion of the projects. For example, ISO/TC 212 has a responsibility to ensure participation and contributions from relevant parties such as practitioners, patients, government regulators, and the IVD industry. Finding suitable and committed volunteers starts with the appropriate selection of the work item itself. Coordinating a work item with other international standards development groups tends to increase the time it takes to obtain a final-stage document, but this delay is justified when the document is harmonized and acceptable to a broader group of stakeholders, e.g., ISO and CEN. Active efforts to publicize and raise awareness of ISO/TC/212 and to recruit qualified P-members are desirable.

7 Structure, current projects and publications of the ISO/TC

This section provides an overview of ISO/TC 212's structure, scope of the existing working groups, and information on existing and planned standardization projects and publications of ISO/TC 212 and its working groups.

Information on ISO online

The link below is to the TC's page on ISO's website:

[ISO TC 212 on ISO Online](#)

Click on the tabs and links on this page to find the following information:

- About (Secretariat, Committee Manager, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
- Meetings
- Tools
- Work programme (published standards and standards under development)

Structure of the ISO committee

TC/212 consists of five working groups (WGs):

- WG 1: Quality and competence in the medical laboratory
- WG 2: Reference systems
- WG 3: *In vitro* diagnostic products
- WG 4: Microbiology and molecular diagnostics
- WG 5: Laboratory biorisk management

The working groups ensure that ISO/TC 212 projects are consistent with the Strategic Business Plan (SBP) outlined here, follow the ISO Code of Conduct, address market needs, and are within the scope of ISO TC/212. On a periodic basis, a Strategic Business Plan Drafting Team is convened, composed of members from each working group and the Secretariat. The Drafting Team, which reflects a geographic and professional balance of ISO/TC 212 members:

- Identifies needs, objectives, and priorities of ISO/TC 212 stakeholders.
- Defines goals and metrics to track success.
- Develops effective strategies to achieve defined goals.
- Justifies the existence of ISO/TC 212 and describes its role in the ISO/IEC community.

Reference information

[Glossary of terms and abbreviations used in ISO/TC Business Plans](#)

[General information on the principles of ISO's technical work](#)