

STRATEGIC BUSINESS PLAN – ISO/TC 336

Executive summary

- 1. Laboratory infrastructure is important across multiple industries including agriculture, environmental protection, food safety, healthcare, and to mitigate and adapt to climate change.
- 2. Currently, there is no international Laboratory Design Standard; ISO/TC 336 shall:
 - a. postulate global standards so that efficient laboratory function, quality, safety is met;
 - b. embed Environment, Health and Safety (EHS) in the design process to construct laboratories that are cost and energy efficient with minimal environmental impact and provide high standards for the health, wellbeing and safety of laboratory personnel;
 - c. ensure laboratories adjust to changing demands and advances in technology and can be disassembled at the end of their useful life and the material reused or recycled;
 - d. play an important role in meeting challenges articulated in UN Sustainable Development Goals (SDGs) and help countries to deliver the SDGs faster, at an affordable cost with reduced risk and address climate change in support of the ISO London Declaration;¹
 - e. incorporate relevant regulatory and voluntary standards requirements from around the world as an integral component of laboratory design.
- 3. ISO/TC 336 will benefit all countries by providing consistent and standardised recommendations and guidelines for planners, designers, builders, and laboratory owners. Many countries already have regulations, standards and compliance codes for work health, safety, and the environment. ISO/TC 336 shall allow those who do not have their own national laboratory design standards, especially those in developing and emerging economies constrained by lack of resources and technical expertise, to either adopt the standards in their entirety or to develop national standards consistent with the ISO standard. For those countries who have existing laboratory design standards, ISO/TC 336 will provide an opportunity to review and identify potential gaps in the design process and make improvements.
- 4. ISO/TC 336 shall encourage design and construction of next generation of energy efficient laboratories with sustainable construction practices in mind whilst ensuring high standards of health, safety and wellbeing of all laboratory users. The aim should be to implement suitable passive and active engineered solutions to eliminate or minimise the environmental impact of energy intensive and contaminating processes.
- 5. Laboratory Design requires multidisciplinary teams. ISO/TC 336 shall incorporate best practices by assembling expertise from across the laboratory design and construction community and with extensive internal and external liaisons.
- 6. ISO/TC 336 activities shall:
 - a. incorporate terminology and classification of laboratory design and consider health, safety, personnel wellbeing, energy efficiency, environmental impact, functionality, flexibility and lifecycle effect;
 - b. utilize digital and automation technologies for better data reliability, facilities management, environment control, low carbon emissions and security of workspaces, relevant infrastructure.

¹ https://www.iso.org/ClimateAction/LondonDeclaration.html

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 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/TCs 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: <u>ISO</u> (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of <u>IEC</u> (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of <u>ITU</u> (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 <u>Technical Committees</u> 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 also offers 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 336, Laboratory Design

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the Laboratory Design and Construction sector related to the scope of ISO/TC 336.

The scope of ISO/TC 336, available here <u>https://www.iso.org/committee/8581603.html</u>, is:

Standardization in the field of laboratory design including site selection, design of space and integration of services with the objective to provide functional, safe, energy efficient and sustainable laboratories considering the health and wellbeing of laboratory users, environmental impact, the practical division of experimental and support areas and layouts plus model selection of integrated laboratory equipment.

It includes standardization of apparatus and devices for personnel safety, health, environmental protection and energy saving that are an integral part of the laboratory.

Standardization of devices and furniture for laboratory purposes, with respect to principles of construction, performance, dimensions and testing are covered by ISO/TC 48 and are excluded from the scope of ISO/TC 336.

Excluded:

- ISO/TC 48 (Laboratory equipment);
- ISO/TC 212 (Clinical laboratory testing and in vitro diagnostic test systems);
- ISO/CASCO;
- IEC/TC 66 (Safety of measuring control and laboratory equipment);
- ISO/TC 209 (Clean rooms).

Laboratories impact all sectors of the economy and are essential for operational and R&D activities in many areas including pharmaceuticals, agriculture, food, consumer products, healthcare, education, energy production, law enforcement, manufacturing, environmental protection and waste management. Currently, there is no international standard on the design of a healthy, safe and sustainable laboratory.

Countries lacking in resources, in a framework of standards and in national codes can experience poor responses to outbreaks of disease, such as Avian Influenza (H5N1), Middle East Respiratory Syndrome (MERS), Ebola virus, severe acute respiratory syndrome (SARS), and Coronavirus (COVID-19). An international laboratory design standard will support low-resource environments by providing voluntary guidance so that all countries can achieve functional and safe laboratories which consider other aspects such as cost-effectiveness, efficiency and sustainability.

The main reason for implementing ISO standards is to improve quality by introducing best achievable practices into industries. ISO Standards are voluntary and ISO has no power to enforce them. However, many countries choose to adopt them in their regulatory framework in sectors such as health, safety and the environment, bringing benefits for the population and country as a whole. This also makes a clear impact on meeting the United Nations (UN) Sustainable Development Goals (SDGs).

Implementing ISO standards improve quality by introducing best practices into industries. Laboratory Design Standards should provide safe, reliable and internationally recognised laboratory infrastructure to emerging economies enhancing their ability to meet market, environmental and societal needs and hasten the achievement of the UN Sustainable Development Goals (SDGs) as envisaged by the 2030 Agenda for Sustainable Development².

In 2015, to attain a sustainable and poverty-free world by 2030, the SDGs were adopted by 193 countries. These 17 targets, in areas such as health, gender, jobs, and poverty reduction, are part of a comprehensive global agenda to end poverty in a single generation. ISO/TC 336 should enable countries to address a wide range of global issues and contribute to these SDGs.

International Stakeholders: contribution to the UN Sustainable Development Goals (SDGs).

ISO/TC 336 should enable countries to address a wide range of global issues and reach the UN Sustainable Development Goals:

- 1: No Poverty
- 2: Zero Hunger
- 3: Good Health and Well-being
- 6: Clean Water and Sanitation
- 7: Affordable and Clean Energy
- 8: Decent Work and Economic Growth
- 9: Industry, Innovation and Infrastructure
- 13: Climate Action
- 17: Partnerships to achieve the Goal



More details on the United Nations High-level Political Forum on Sustainable Development (HLPF) website: <u>https://sustainabledevelopment.un.org/</u>

ISO/TC 336 will provide a standardised approach on laboratory health and safety, energy efficiency, environmental impact and regulatory compliance issues at an early stage in the laboratory design process.

ISO/TC 336 shall formulate standards that:

- provide a common understanding of technical terminology, definition, and scope of standards used in the laboratory design process;
- create a framework and tools that embed Environment, Health and Safety (EHS) in the design process to construct laboratories that are cost and energy efficient with minimal environmental impact and provide high standards for the health, wellness and safety of laboratory workers;
- ensure flexibility by designing sustainable (modular & prefabricated) laboratories that adjust to changing demands and can be disassembled at the end of their useful life and the material reused or recycled.

² <u>https://www.unido.org/sites/default/files/files/2021-04/LP_publication_22042021_FINAL.pdf</u>

 ISO/TC 336 Work Programs shall aim to develop standards that support the ISO London Declaration (<u>https://www.iso.org/news/ref2726.html</u>) that pledges ISO to support governments and industry to tackle climate change and accelerate their transition to net zero by incorporating key elements of climate science in every new standard that is created and also retrospectively bearing in mind these requirements for all existing standards as they are revised.

2.2 Quantitative Indicators of the Business Environment

Potential worldwide benefits from Laboratory Design ISO/TC 336 activities are massive.

Target 9.5 of UN Sustainable Goal 9 to build resilient infrastructure, promotes inclusive and sustainable industrialization and foster innovation states:

"Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending."

In recognition of the importance of Science and Technology research and development (R&D) for economic development and competitiveness, both private and public sectors are investing considerable sums across multiple industries including, agriculture, environmental protection, food safety, healthcare, and mitigation of and adaption to climate change.

It is estimated that in high income countries, annual research spending as a share of GDP is over 2%, equal to over USD1 trillion. If only 5% of this is allocated to laboratory infrastructure, this is equivalent to annual spending USD50 billion³,⁴.



³ https://ourworldindata.org/grapher/research-spending-gdp?tab=chart

⁴ https://ourworldindata.org/grapher/gross-domestic-product?tab=chart



3 Benefits expected from the work of the ISO/TC

Work of ISO/TC 336 will:

- strengthen innovations in Laboratory Design and provide standards and guidelines for the design of different types of laboratories;
- promote improved understanding of laboratory design principles and safe work methods to eliminate or minimize the risk of harm to laboratory personnel;
- provide technical information to support the creation of laboratory environment conditions to minimize the adverse impact on the health, safety and wellbeing of laboratory personnel;
- provide technical information and guidance to support the protection of the laboratory and its environment to promote energy efficiency and reduce emissions;
- enable interaction, discussion and collaboration between diverse stakeholders at international, regional and national levels;
- ensure participation of developing countries and through active liaison with international agencies (e.g. UNIDO) safeguard their interests in the laboratory design standards development process;
- assist countries to deliver the UN sustainable development goals at a faster pace, lower cost, reduced risk and address climate change in support of the ISO London Declaration;
- allow laboratory design principles and methods to be known on an international scale, which in turn will have a positive public health and safety impact by reducing risks of accidents, and adverse impact on health, safety and wellbeing from imported designs, technology and equipment;
- the economy will benefit positively from laboratory owners and operators who understand the principles and methods of laboratory design for better management of health and safety, construction, acceptance, operation and functionality.

4 Representation and participation in the ISO/TC

4.1 Membership

Countries/ISO member bodies that are P (Participant) and O (Observer) members of the ISO/TC 336 committee can be viewed at: <u>ISO - ISO/TC 336 - Laboratory design</u>

4.2 Analysis of the participation

Since its establishment, ISO/TC 336 has attracted confirmed involvement of 35 countries, 16 'P' members and 19 'O' members.

Currently developing countries are underrepresented and the Committee shall:

- pursue to grow their participation and ensure their interests are taken into account in the laboratory design standards development process; to enable this, a category A liaison has been established with UNIDO, a United Nations agency that promotes industrial development for poverty reduction, inclusive globalization and environmental sustainability;
- utilise hybrid virtual and in person meetings to enable increased participation from all members;
- liaise with ISO/DEVCO Committee on developing country matters.

ISO/TC 336 values the participation by its P and O members, liaison with ISO and IEC TCs and UNIDO. The Committee shall encourage the participation of O members to a greater degree by becoming P members and seek to attract more of the world's laboratory design experts to participate in the work program.

ISO/TC336 Laboratory Design: Participation

Involment of 35 countries spread across all regions, 16 'P' members and 19 'O' members, blue and orange respectively.



Developing countries under represented.



- Developing countries interests taken into account in the laboratory design standards development process with category A liaison with UNIDO, a UN agency that promotes industrial development for poverty reduction, inclusive globalization and environmental sustainability.
- Advice and assistance from ISO/DEVCO Committee on developing country matters will be sought.

United Nations Conference on Trade and Development https://unctad.org/topic/least-developed-countries/map

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

5.1 Defined objectives of the ISO/TC 336

The outputs of the International Technical Committee on laboratory design will promote the development and implementation of international standards on laboratory design and provide:

- a) standards for the design of various types of laboratories and allow laboratory design principles and methods to be known on an international level in order to prevent incidents, injuries and disease impacting health, safety and wellbeing;
- b) professional references for scientific laboratory facilities and environmental conditions, and technical support to verify the data reliability of research and testing laboratories;
- c) technical requirements on laboratory environment conditions (including indoor air quality) to prevent adverse impact on the health and wellbeing of laboratory personnel;
- d) technical requirements on environment protection in order to promote energy saving and reduce emissions.

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

Priority of ISO/TC 336 shall be to develop standardized terminology to ensure a common understanding of the scope and objectives of the TC followed by work programs to develop various ISO deliverables (International Standards, Technical Specifications, etc.).

To reach its priorities/objectives, ISO/TC 336 has defined the following strategies:

- develop standards and documents that are based on identified market needs and that are consistent, concise as well as easy to understand, use, and implement;
- attract experts with deep knowledge who are also aware of the business and market needs;
- maintain a high level of participation from all stakeholder groups to ensure latest developments are incorporated and market needs are addressed;
- identify and address issues related to gaps and overlaps;
- create new working groups as the market need arises to develop new needed standards;
- coordinate with other technical committees, groups, and organizations to ensure that the development of standards is as efficient as possible.



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

Successful delivery of planned objectives and targets of ISO/TC 336 will require:

- a. a common understanding of the objectives of ISO/TC 336;
- b. high quality communication with other ISO and IEC TCs;
- c. access to specialists across multiple disciplines; a balance of expertise will be needed to maintain coverage of wide array of specialisms involved in Laboratory design across all regions;
- d. use of working practices and tools such as on-line meetings to attract and motivate participation of highly experienced but time poor leading specialists.

The challenges ISO/TC 336 will potentially face are:

- a. different time zones for virtual meetings and travel costs for face to face meetings;
- b. liaison with other technical committees to avoid overlap.
- c. potential lack of experts, and the prospects for a suitable range of experts to participate in the TC's work program;
- d. diverse laws and regulations in place;
- e. difficulties to get funding.

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

Information on ISO online

The link below is to the ISO/TC 336's page on ISO's website: <u>ISO - ISO/TC 336 - Laboratory design</u> 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)

Reference information

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

General information on the principles of ISO's technical work