



STRATEGIC BUSINESS PLAN – ISO/TC 336

Executive summary

1. Laboratories impact all sectors of the economy and are essential for operational and R & D activities in many sectors including pharmaceuticals, agriculture, food, medicine, energy production and law enforcement but there are no recognised international standards on any major aspect of Laboratory Design.
2. Purpose of setting up ISO/TC 336: Laboratory Design:
 - a) to provide unified global standards for laboratory design;
 - 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, wellness and safety of laboratory workers;
 - c) ensure flexibility by designing 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.
3. ISO/TC 336 stakeholders include laboratory owners (including governments, scientific agencies, universities and many industrial sectors) designers, constructors, users, operators and entire society.
4. Worldwide potential benefits from ISO/TC 336: Laboratory Design are massive. For example, life science industry in California (USA) supported over 1.4 million jobs generating USD 372 billion in 2019¹ and clinical laboratories in USA contributed over USD 106 billion in total economic output, supporting over 688,000 jobs, generating USD 44 billion in wages and paying more than USD 14 billion in state and federal taxes². **(WE NEED VERIFIABLE REFERENCES FROM OTHER COUNTRIES/REGIONS)**
5. ISO/TC 336 will postulate a globally agreed definition of Laboratory Design as applied to the practices, activities and products for the laboratory design and construction sector, and interpretation of what constitutes good Laboratory Design practice.
6. A large number of voluntary and regulatory laboratory design guidelines and standards are being developed by various countries, regions and sectors but few are applicable to the whole sector. They could benefit international standards development and ISO/TC 336 shall seek to utilise them to accelerate development of globally agreed laboratory design standards.
7. ISO/TC 336 aims to consolidate innovations in Laboratory Design and empower 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.
8. ISO/TC 336 shall convene experts from across the laboratory design and construction community and include extensive internal and external liaisons to take expertise in sustainability and other arenas into Laboratory Design in a way that can be incorporated into best practices.

¹ [Life Science Industry in California Generates \\$372 Billion Annually, Providing 1.4M Jobs](#)

² [ACLA Economic Impact of Clinical Labs](#)

9. ISO/TC 336 international standards development work program will encompass the following activities:
- a) Terminology and classification of laboratory design;
 - b) Planning and designing laboratories;
 - c) Safety and health standards for laboratory design;
 - d) Energy saving and environmental protection standards for laboratory design;
 - e) Digital laboratory design standard;
 - f) Mobile laboratory design standard;
 - g) Technical requirements for different kinds of laboratory design.

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: [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 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 Laboratory Design and Construction sector related to the scope of ISO/TC 336.

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

Standardization in the field of laboratory design including site selection, design of internal layout of space and integration of services with the objective to provide functional, safe, energy efficient and sustainable laboratories taking into account the health and wellness of laboratory workers, environmental impact, the practical division of experimental and support areas and layouts plus model selection of laboratory furniture.

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);*
- 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 sectors including pharmaceuticals, agriculture, food, medicine, energy production and law enforcement but there are no recognised international standards on any major aspect of Laboratory Design.

Global lack of adequate laboratory capacity, especially in low-resource environments, has clearly highlighted challenges presented by current climate change, environmental impact and public health concerns. Response to outbreaks of zoonotic disease like Avian Influenza (H5N1), Middle East Respiratory Syndrome (MERS), Ebola virus, Severe Acute Respiratory Syndrome (SARS), and Coronavirus (COVID-19) has been impeded in many countries by lack of efficient, sustainable and cost-effective laboratories. Undeniably there is a massive global demand for developing such laboratory infrastructure.

The main reason for implementing ISO standards is to improve quality by introducing best 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).

* This will be replaced with the final version of the scope discussed, adopted by the committee and approved by TMB.

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 P 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
- 13: Climate Action
- 17: Partnerships to achieve the Goal



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

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 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 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;

ISO/TC 336 Work Programs shall aim to develop standards that support the ISO London Declaration (<https://www.iso.org/news/ref2726.html>) 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

Worldwide market benefiting from Laboratory Design ISO/TC 336 are massive. For example, in 2019 life science industry in California (USA) supported over 1.4 million jobs generating USD 372 billion and clinical laboratories alone had a significant impact on the U.S. economy contributing over USD 106 billion in total economic output, supporting over 688,000 jobs, generating USD 44 billion in wages and paying more than USD 14 billion in state and federal taxes.

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 methods on a global scale in order to avoid the occurrence of accidents impacting safety;
- provide technical requirements on laboratory environment conditions in order to minimize the adverse impact on the health of laboratory personnel and insure their wellbeing;
- provide technical requirements on laboratory environment protection in order to promote energy saving and emission reduction;
- 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;
- empower 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.

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:

Countries/ISO member bodies that are P and O members of ISO/TC 336

4.2 Analysis of the participation

In its first year of existence ISO/TC 336 has attracted confirmed involvement of 33 countries, 15 'P' members and 18 'O' members.

Currently developing countries are underrepresented and the Committee shall:

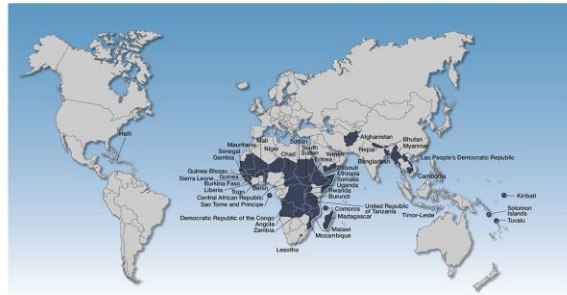
- pursue to grow their participation and ensure their interests are taken into account in the laboratory design standards development process; to enable this, a category A liaison has been established with UNIDO, a United Nations agency that promotes industrial development for poverty reduction, inclusive 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/TC 336 Laboratory Design: participation.

involvement of 33 countries spread across all regions, 15 'P' members and 18 '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

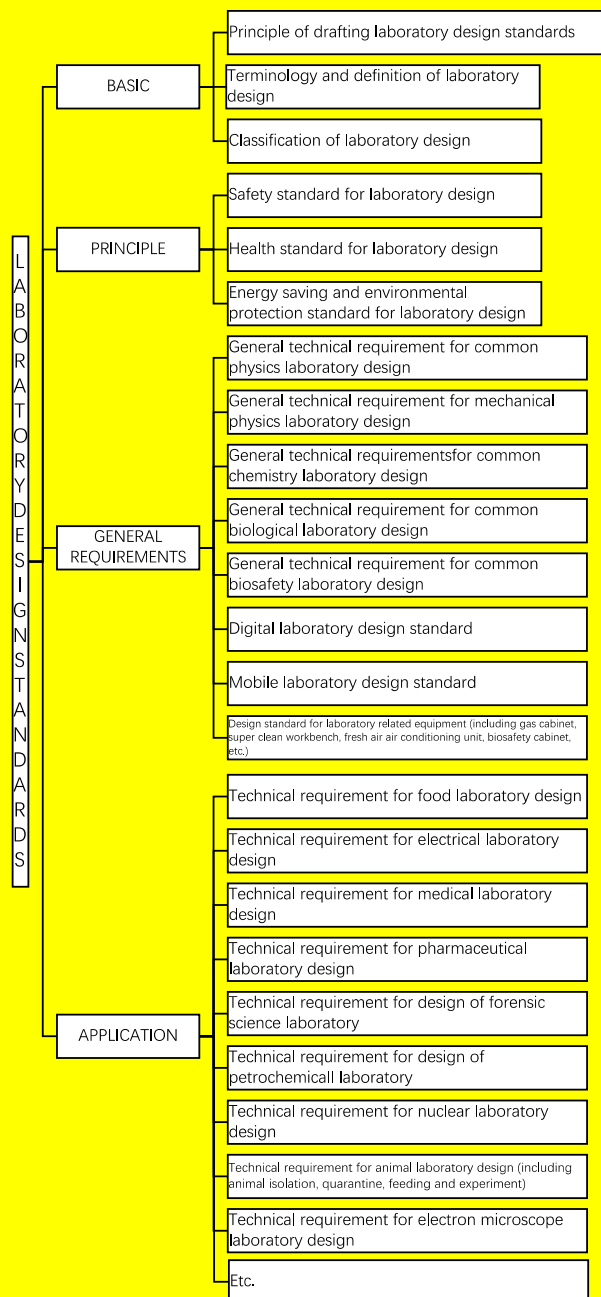
5.1 Defined objectives of the ISO/TC

ISO/TC 336 will elaborate a package of International Standards in laboratory design sector including aspects as bellow:

- a) Terminology and classification of laboratory design ;
- b) Planning and designing laboratories;
- c) Safety and health standards for laboratory design;
- d) Energy saving and environmental protection standards for laboratory design;
- e) Digital laboratory design standard;
- f) Mobile laboratory design standard;
- g) Technical requirements for different kinds of laboratory design.

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

First priority of ISO/TC 336 shall be to develop standardised 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.).



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.

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

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

[ISO TC 336 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)

Reference information

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

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