International Organization for Standardization
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Международная организация по стандартизации

FORM 1:
PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY

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Proposer SAC	**ISO/TS/P** 280

A proposal for a new field of technical activity shall be submitted to the ISO Central Secretariat, which will assign it a reference number and process the proposal in accordance with the ISO/IEC Directives Part 1, Clause 1.5. The proposer may be a member body of ISO, a technical committee, subcommittee or project committee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the ISO/IEC Directives Part 1, Annex C.

Proposal (to be completed by the proposer)

Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover). Laboratory Design

Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned).

Standardization in the field of laboratory design including site selection and design planning, the functional division of experimental areas, the determination of scientific and technological processes, layouts and design of furniture, and the scientific design of the facility taking into account environmental conditions and impact.

Excluded:

- IEC/TC 64 (Electrical installations and protection against electric shock);
- IEC/TC 81 (Lightning protection);
- IEC/TC 66 (Safety of measuring, control and laboratory equipment);
- IEC/TC 85 (Measuring equipment for electrical and electromagnetic quantities).

Once the new TC is established, liaisons with other relevant ISO technical committees will be established, including ISO/TC 48（laboratory equipment）, ISO/TC 212 （Clinical laboratory testing and in vitro diagnostic test systems）and CASCO as well as relevant IEC technical committees (IEC/TC 45(Nuclear instrumentation), IEC/TC 62 (Electrical equipment in medical practice), IEC/TC 65 (Industrial-process measurement, control and automation), IEC/TC 76 (Optical radiation safety and laser equipment) and IEC/TC 104 (Environmental conditions, classification and methods of test).

Note: the TC will support the contribution of the laboratory design industry to UN Sustainable Development Goals and enable countries to address a wide range of global issues including eradication of hunger and poverty, health, climate change and economic development.

☒ **The proposer has checked whether the proposed scope of the new committee overlaps with the scope of any existing ISO committee**

☐ **If an overlap or the potential for overlap is identified, the affected committee has been informed and consultation has taken place between proposer and committee on**

i. **modification/restriction of the scope of the proposal to eliminate the overlap,**
ii. **potential modification/restriction of the scope of the existing committee to eliminate the overlap.**

☐ **If agreement with the existing committee has not been reached, arguments are presented in this proposal (under question 7) as to why it should be approved.**

Proposed initial programme of work. (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subject proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.)

The new TC will stipulate technical design requirements for a diverse range of laboratories with different functions and responsibilities. It will include, but not limited to:

1. site selection and design planning;
2. layouts and design of furniture (e.g workbenches, fume hoods, safety showers, biological safety cabinets, etc);
3. electrical, water and gas supply systems, drainage, fire prevention, HVAC, auto-control and decoration;
4. laboratories featuring bio-safety, constant temperature and humidity, and other special laboratories;
5. laboratory safety, staff health, environmental protection, and energy saving;
6. Smart laboratory (use of new technologies such as big data, cloud computing, block chain, etc. to empower laboratories, e.g. increase the depth and width of services provided to clients, improve the servicing level during the consulting, design and maintenance phases.).

Initial Work Programme over 3 to 5 years will develop and prepare common design requirements for different types of laboratories and submit international standards (IS): “General Specification of Technical Requirements for Laboratory Design” and “Technical Requirements for Smart Laboratory Design”.

The programme will:

a. build the framework for drafting “General Specification of Technical Requirements for Laboratory Design”;
b. classify laboratory types and define terminology;
c. clarify the principles of laboratory design requirements for various disciplines and acceptance requirements of laboratory functions;
d. clarify the technical design requirements for laboratories utilizing digital technologies for building management and environmental control;
e. prepare IS “General Specification of Technical Requirements for Laboratory Design”;
f. prepare IS “Technical Requirements for Smart Laboratory Design”.

Based on categorization of laboratory types and framework of the “Technical Requirements of Laboratory Design”, future Work Programme over a period of 3 to 5 years will develop the technical requirements for design of various types of laboratories, e.g. food and agricultural product, medical, pharmaceutical, petrochemical, university etc.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient).

Combined with “Proposed initial programme of work”.

A listing of relevant existing documents at the international, regional and national levels. (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)

1. There are no recognised international standards on any major aspect of Laboratory Design. Many countries have formulated national building, safety and laboratory design regulations and guidelines but no global systematic standards on laboratory design that can be widely applied across the world have been developed.
2. China has released some national standards related to laboratory design and construction.
3. Standards Australia/New Zealand has issued a Laboratory design and construction Standard (AS/NZS 2982:2010).
4. Standards and guidelines of relevance to the work of the proposed TC from China and other countries are listed in Annex 1.

Country/ Organization	Standard headlines	Laboratory category
Australia/New Zealand	AS/NZS 2982:2010 Laboratory design and construction	General laboratory / specialized laboratory
China	GB50346 Biosafety Laboratory Building Specification	Biology laboratory
China	GB19489 Laboratory - General Requirements for Biosafety	Biology laboratory
China	GB/T27476.1 Safety of Testing Laboratory	Testing Laboratory
China	JGJ 91-93 Design code for scientific experiment buildings.	Scientific research laboratory
China	GB/T 32146.1-2015 Technical requirements of design and construction for inspection and testing laboratory- Part 1:general specification	Testing laboratory
China	GB/T 32146.2-2015 Technical requirements of design and construction for inspection and testing laboratory- Part 2:Electrical laboratory	Testing laboratory
China	GB/T 32146.3-2015 Technical requirements of design and construction for inspection and testing laboratory- Part 3:Food laboratory	Testing laboratory

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. (The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

The mission of the proposed TC is to set up a series of standards on technical requirements for the design and construction of different types of laboratories, and develop standards of smart laboratories based on digital technologies. At present, there is no ISO TC or SC covering laboratory design. ISO17025 and ISO TC48 mention laboratories but do not cover laboratory design. ISO17025 merely refers to laboratory environment and equipment and is limited to a broad quality management requirement. ISO TC48 is limited to standards for laboratory equipment and glassware and has no conflict with the standards to be drafted by the proposed new TC.

A listing of relevant countries where the subject of the proposal is important to their national commercial interests.

Laboratories are a key component supporting both private and public sectors in a sustainable economy, including agriculture and healthcare. The outcomes and outputs of the proposed TC should be of interest to a great number of countries, including those in developed and emerging economies. It would enable countries to address a wide range of global issues and reach the UN Sustainable Development Goals (SDGs)including eradication of hunger and poverty, health, climate change and economic development.

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)

1.Internal parties: these are all committees named above.

a. ISO committees: ISO/TC 48, ISO/TC 212 and CASCO;

b. IEC committees: IEC/TC 45, IEC/TC 62, IEC/TC 64, IEC/TC 65, IEC/TC66, IEC/TC 81, IEC/TC 76, IEC/TC85 and IEC/TC 104.

2.External organizations:

a. Union Internationale des Laboratoires Indépendants (UILI);

b. European Federation of National Associations of Measurement, Testing and Analytical Laboratories (EUROLAB).

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).

The setting up of laboratory design TC and establishment of laboratory design standards will benefit organizations and groups as follows:

1. Laboratory owners (including governments, scientific agencies and enterprises, etc.):

   Laboratory owners will understand the principles and methods of laboratory design for better management of laboratory design, construction, acceptance and operation. The investment budget will have a reference basis; construction cost will be better controlled; investment risk will be lowered; project quality can be better evaluated; construction cycle will be shortened; capital usage efficiency will be raised;

2. Laboratory designers:

   Laboratory designers will understand the principles and methods of laboratory design, and will have standards to follow and verify by, make fewer design faults and ensure laboratory design to be more scientific and professional; laboratory environmental facility will be improved in terms of safety, energy conservation, environmental friendliness, as well as impacts on human health and well-being.

3. Laboratory constructors:

   Laboratory constructors will have construction and acceptance standards to refer to; the construction quality will be raised; technology advancement will be promoted; the industry will be further regulated.

4. Laboratory users:

   Laboratory users will understand the principles and methods of laboratory design; stakeholders can communicate with each other in a more informed way and evaluate laboratories based on common standards, making laboratory use, operation and management more scientific and regulated. Smart laboratories will allow more functions and add value by integrating technologies of big data, cloud computing and internet of things, etc.

5. Laboratory operators:

   Laboratory operators will understand the principles and methods of laboratory design, which will facilitate the maintenance of laboratories; Smart laboratories will enable the remote digital control of laboratory operation and facilitate reliable, efficient and convenient maintenance.

6. Society:

   The society will be able to cultivate more professional personnel in the field of laboratory design; a more sound and fair development of laboratory design and construction both home and abroad will be facilitated; more energy-saving and environmental-friendly design will promote the sustainable development of the society; the premium laboratories will inspire the creativity of researchers and promote the advancement and development of technologies. Smart laboratories will facilitate technological progress, product quality improvement, data recognition as well as international trade.

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

If the proposal is accepted, China is willing to undertake the work of secretariat of the new TC and will provide all necessary resources including financial and human resources as well as facility supports.

A partnership agreement between China and France at committee level is foreseen.

Purpose and justification for the proposal. (The purpose and justification for the creation of a new technical committee shall be made clear and the need for standardization in this fieldshall be justified. Clause C.4.13.3 of Annex C of the ISO/IEC Directives, Part 1 contains a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)

The rationale for setting up laboratory design TC is as follows:

1. Laboratories serve as the foundation for technological progress and product quality assurance and play a pivotal role in social and economic development. Worldwide, the laboratory construction volume is rising year by year, with trillions of USD invested into construction of new laboratories and renovation of existent ones. However, on a global scale there is no standard on design of various types of laboratories that project owners, designers, users and quality supervision authorities can refer to, resulting in a number of problems in laboratory construction worldwide;

2. Lack of systematic laboratory design standards is the fundamental cause of frequent occurrence of laboratory accidents impacting laboratory safety and occupants' health, some of which may also seriously jeopardize public health (such as BSL – 3 and BSL - 4 laboratories);

3. Currently there are no internationally agreed systematic standards on laboratory design and construction. The existing ISO laboratory quality management standard (ISO/IEC 17025:2017 (Section 6.3: Facilities and environmental conditions) recognizes that robust and quality outputs from laboratories are dependent on their facilities and environmental conditions but does not provide any guidance on laboratory design.

4. In recent years, there is an increasing demand from Chinese market for various types of laboratories, with hundreds billions of Chinese RMB invested each year in laboratory construction. In the process, the standards system of laboratory design and construction in China have been gradually established. Now China has not only developed laboratory design standards, but also laboratory construction and acceptance standards, with the corresponding standards for laboratory environmental facilities being established along the way. China's laboratory design standards system not only covers the general planning of laboratory, experiment procedure, layout, electrical and water supply, drainage, heating, ventilation and air purification, furniture, fire prevention, safety, energy efficiency and environmental protection. During the standards compilation, experts and scholars integrated new technologies, materials and processes proven technically and economically effective in practice into the standards, which has greatly improved the level of laboratory construction in China, and provided support to the economic and social development. By setting up the laboratory design TC, China is willing to harness its accumulated experience and work together with other ISO member countries on the development of ISO laboratory design standard, in order to benefit other countries around the world;

5. It has been shown in many cases that, as a result of unhealthy laboratory of environment, the researchers working in laboratories developed diseases such as lung cancer, leukemia and brain cancer. The underlying causes of these problems are the lack of laboratory design standards on health.

6. Environmental protection, energy efficiency and emissions reduction in laboratory construction will be given more prominence, addressing climate change issues and meeting sustainable development goals.

7. Lack of standards on Smart laboratories that integrate facilities and instrumentation has adversely impacted the generation and utilization of quality laboratory data.

The establishment of laboratory design TC will:

1. promote the development and implementation of international standards on laboratory design;
2. provide standards for the design of various types of laboratories and allow laboratory design principles and methods to be known on a global scale in order to avoid the occurrence of accidents impacting safety and health;
3. provide professional references for ensuring scientific laboratory facilities and environmental conditions, and technical support to guarantee the data reliability of research and testing laboratories;
4. provide technical requirements on laboratory environment conditions in order to minimize the adverse impact on the health of laboratory personnel;
5. provide technical requirements on environment protection in order to promote energy saving and emission reduction;
6. provide technical requirements on the intelligent data retrieval and processing, in order to facilitate global data sharing;
7. provide technical requirements on data traceability, in order to ensure the truthfulness of data, and thus facilitate the R&D innovation and improvement of product quality;
8. provide technical requirements on smart laboratory, in order to the facilitate the mutual data recognition among laboratories, promote the technological progress and development of international trade.

Signature of the proposer
SAC

Further information to assist with understanding the requirements for the items above can be found in the Directives, Part 1, Annex C.

ANNEX 1

Planning principles / laws, standards and regulations from various countries:

Australia / New Zealand

1. AS/NZS 2982:2010 Laboratory design and construction
2. AS/NZ 2243 Safety in Laboratories Series:
    a. AS/NZ 2243.1:2005 Planning and Operational Aspects
    b. AS/NZ 2243.2:2006 Chemical Aspects
    c. AS/NZ 2243.3:2010 Microbiological safety and containment
    d. AS/NZS 2243.4:2018 Safety in laboratories - Ionizing radiations
    e. AS/NZ 2243.5:2004 Non-ionizing radiations – Electromagnetic, sound and ultrasound
    f. AS/NZ 2243.6:2010 Plant and equipment aspects
    g. AS/NZ 2243.7:1991 Electrical aspects
    h. AS/NZ 2243.8:2014 Fume cupboards
    i. AS/NZ 2243.9:2009 Recirculating fume cabinets
    j. AS/NZ 2243.10:2004 Storage of chemicals

Switzerland

1. Labor Law (ArG), its regulations and the guidelines
2. "Law on the safety of technical equipment and devices" (STEG)
3. "Regulation on the safety of technical equipment and devices" (STEV)
4. "Ordinance on the protection of workers against endangerment by micro-organisms" (SAMV)
5. Inclusion Ordinance (ESV) No. 814.912, Ordinance on the Handling of Organisms in Closed Systems
6. Ordinance on the handling of organisms in the environment (release ordinance, FrSV)
7. Radiation Protection Ordinance No. 814.554, Ordinance on the handling of open radioactive radiation sources

Federal Coordination Commission for Occupational Safety (EKAS)

1. EKAS - Guideline No. 1871 Chemical laboratories
2. EKAS - Guideline No. 6501 acids and alkalis
3. EKAS - Guideline No. 1825 Flammable liquids
4. EKAS Guideline No. 6508 Involvement of occupational physicians and other occupational safety specialists
5. EKAS - Guideline No. 6512 Work equipment
6. EKAS 6807 Checklist: Maintenance of ventilation and air conditioning systems (RLT systems)
7. SUVA - Directive "Explosion Protection - Principles, Minimum Requirements,

Zones"
8. SUVA- Fact sheet No. 33038 "Internal transport of easily combustible liquids"
9. SUVA - Guideline no. 1864.d Guidelines for cold rooms and freezers
10. SUVA 67001 Traffic routes for persons
11. SUVA 67009 Noise at work
12. SUVA 67012 floors
13. SUVA 67013 Handling of solvents
14. SUVA 67032 Storage shelves and drawer cabinets
15. SUVA 67045 Cleaning and maintenance of buildings
16. SUVA 67054 Compressed air
17. SUVA 67068 Gas cylinders
18. SUVA 67070 Vibrations at work
19. SUVA 67071 Storage of easily combustible liquids
20. SUVA 67072 Doors and gates
21. SUVA 67083 Static electricity. Explosion risks when handling flammable liquids
22. SUVA 67084 Acids and alkalis
23. SUVA 67089 Load transport by hand
24. SUVA 67091 Personal Protective Equipment
25. SUVA 67132 Explosion risks (Explosion protection document for SMEs)
26. SUVA 67142 storage and stacking
27. SUVA 67149 Dealing with microorganisms
28. SUVA 67157 Escape routes
29. SUVA 67171 Technical noise protection measures
30. SUVA 67189 Stop the tripping and falling accidents when cleaning buildings
31. SUVA 84040 Eight vital rules for the maintenance of machinery and equipment
32. SUVA 84042 5 + 5 vital rules in dealing with electricity
33. SUVA Limits at the workplace
34. SUVA 86048 Acoustic limit and guide values

EN standards

1. EN 12128 "Biotechnology - Laboratories for research, development and analysis – Containment levels of microbiological laboratories, areas of risk, localities and physical safety requirements".
2. EN 14056 "Laboratory furniture - Recommendations for design and installation"
3. EN 14175 "Fume cupboards " (part 1 to 7)
4. EN 13150 Workbenches for laboratories - Dimensions, safety requirements and test methods
5. EN 13792 Colour coding of taps and valves for use in laboratories
6. EN 14470 Fire safety storage cabinets (part 1 and 2)
7. EN 312 Particleboards - Specifications
8. EN 15154 Emergency safety showers (part 1 to 4)
9. EN ISO 14644 Cleanrooms and associated controlled environments (part 1 to 15)

France

1. NF X 15-206 " Laboratory fume cupboards - Threshold for confinement test"
2. NF X 15-211 " Laboratory equipment - Recirculatory filtration fume cupboard - General, classification, requirements"
3. NF X 15-221 " Emergency safety showers - Permanently plumbed-in body showers for sites other than laboratories"

Germany

1. DIN 12980 Laboratory installations - Safety cabinets and glove boxes for cytotoxic substances and other CMR drugs "

China

1. GB50346 Biosafety Laboratory Building Specification
2. GB19489 Laboratory - General Requirements for Biosafety
3. GB/T27476.1 Safety of Testing Laboratory
4. JGJ 91-93 Design code for scientific experiment buildings.
5.GB/T 32146.1-2015 Technical requirements of design and construction for inspection and testing laboratory- Part 1: general specification
6.GB/T 32146.2-2015 Technical requirements of design and construction for inspection and testing laboratory- Part 2: Electrical laboratory
7.GB/T 32146.3-2015 Technical requirements of design and construction for inspection and testing laboratory- Part 3: Food laboratory
8.GB/T 37140-2018 Technical requirements acceptance specification for inspection and testing laboratory