International Organization for Standardization
Organisation internationale de normalisation
Международная организация по стандартизации

STRATEGIC BUSINESS PLAN – ISO/TC 121 (REVISED 2021)

Executive summary

The main field of technical activity is the preparation of International standards for equipment used:

- to administer anaesthetic agents and medical gases to a patient,
- to deliver the correct gaseous anaesthetic agents and medical gases to a device or a patient,
- to conduct excess and expired gases safely away from a patient and operating room staff,
- to monitor a patient,
- to administer respiratory therapy and care.

The titles and scopes of the Subcommittees of ISO/TC 121 are as detailed below:

ISO/TC 121/SC1, Breathing attachments and anaesthetic machines
Standardisation of the particular requirements for basic safety and essential performance of medical devices and their accessories for dispensing, delivery and removal of medical and anaesthetic gases and vapours. This includes anaesthetic gas delivery systems, anaesthetic breathing systems and any related monitoring equipment, alarm systems and protection devices. It also covers the conveying of excess anaesthetic gases to an appropriate place of discharge.

ISO/TC 121/SC2, Airways and related equipment
Standardisation of the particular requirements for basic safety and essential performance of medical devices and their accessories that connect to or are inserted into the airways of patients, including those devices that provide the interface between the patient and atmosphere or gas from a supply device.

Examples include tracheal and tracheostomy tubes, supralaryngeal and oropharyngeal airways, laryngoscopes, connectors, breathing system tubing, respiratory therapy tubing, nebulizers, breathing filters, suction catheters, fire-activated oxygen shut off devices.

ISO/TC 121/SC3, Respiratory devices and related equipment used for patient care
Standardisation of the particular requirements for basic safety and essential performance of medical devices and their accessories intended for ventilatory support, delivery of respiratory gases and related monitoring of patients. This includes dosing and conditioning of the gases supplied to or inhaled by the patient. These medical devices can be intended for use in specific, particular or defined healthcare environments, including home healthcare environments. These medical devices are generally active, reusable electromedical equipment (i.e. durable) with accessories that mainly are for single-patient use. ISO/TC 121/SC 3 is also responsible for the biological evaluation of gas pathways in all environments. Further, ISO/TC 121/SC 3, in co-operation with IEC/TC 62 Subcommittees utilizing Joint Working Groups, is responsible for the standardisation of the horizontal requirements for basic safety and essential performance of medical electrical equipment used in:

- emergency medical services;
- home healthcare environments;
- alarm systems in all environments; and
- physiological closed-loop control in all environments.

ISO/TC 121/SC4, Vocabulary and semantics
Coordination of the establishment and maintenance of a standardized vocabulary of terms, definitions and their associated semantics for anaesthetic and respiratory equipment, so that they are used consistently across ISO/TC 121, Anaesthetic and respiratory equipment and its associated Subcommittees, Joint Working Groups and Working Groups.

These vocabularies and associated semantics can include terminology for:

- standards development;
- human-device interface;
- labeling;
- communication of health informatics data.

ISO/TC 121/SC6, Medical gas supply systems
Standardisation of the particular requirements for basic safety and essential performance of systems that supply medical gas in healthcare, homecare, medical transport and emergency facilities including terminal unit outlets as well as their accessories and connected supply units. These systems include stationary, mobile and portable production, storage, and supply systems for medical gases and stationary vacuum supply systems such as: medical gas pipeline systems, vacuum and gas scavenging pipeline systems, medical gas cylinder supply systems, oxygen concentrators and transportable oxygen (liquid/gas) supply systems, and associated control devices.

ISO/TC 121/SC8, Suction devices
Standardisation of the particular requirements for basic safety and essential performance of suction devices that regulate the level of vacuum (negative) pressure applied to a patient undergoing medical or surgical treatment in healthcare, homecare, transport and field facilities. These include electrically and manually powered suction devices as well as those devices powered by a positive pressure gas source or central pipeline vacuum system. Also included are requirements for suction tubing and connectors.

These suction devices do not include:

- central pipeline vacuum systems;
- anaesthetic gas scavenging disposal systems;
- central pipeline plume extraction systems;
- accessories such as suction ends and catheters.

The main benefit provided by the standards of ISO/TC 121 is to foster the provision of equipment that will maximize patient and user safety via informative labeling, correct interconnection, avoidance of misconnection, minimization of pneumatic, physiological, environmental and electrical hazards and ensuring satisfactory clinical performance.

The main priority of ISO/TC 121 is to ensure as far as possible the safety of the patient and the user, the provision of appropriate and adequate device function and to provide a basis for testing, certification and regulation of devices within its scope.

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 165 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:

ISO/TC 121 was formed to prepare international standards for equipment used in inhalational anaesthesia and respiratory care. The equipment includes devices to secure and care for the airway of the patient; equipment to administer the correct gaseous anaesthetic agents and medical gases at controlled flow and pressure to the device or the patient and conduct excess and exhaled gases safely away from the patient and operating room staff; equipment to monitor some physiological parameters of the patient, and equipment for use in respiratory therapy and care.

Respiratory care equipment comprises a broad range of devices, some e.g. lung ventilators, intended to initiate or maintain the breathing of patients who cannot breathe spontaneously or to assist those who can do so only with difficulty, others intended to supply therapeutic gases and medication via inhalation.

Patient monitoring devices are intended to measure/indicate critical physiological and equipment parameters for patients undergoing anaesthesia and respiratory care, to guide, inform and warn the healthcare provider about the condition of the patient or the performance of the device. The rapid development of electronic and computer technologies and their application to medical devices means that a growing proportion of the work programme is related to increasingly sophisticated devices. Interoperability with computerized systems to populate electronic medical records, implement clinical decision support, and integrate devices in the clinical environment to enable care automation to improve patient safety, reduce costs, and accelerate innovation is becoming increasingly important. This trend will continue, but so will the existence of a market, especially in countries with limited infrastructure, for simple, mainly mechanical or electromechanical devices. Globally, healthcare budgets are under pressure, and it is important that device costs are not needlessly increased by excessive requirements.

Innovation, particularly fresh design and marketing approaches, is a feature of the medical device industry, and ISO/TC 121 standards are framed in such a way that such development is not stifled or excluded. Assessment and monitoring of patient parameters and device performance, coupled with the provision of relevant alarm and protection systems will continue to expand. Litigation following patient injury is rapidly increasing in some parts of the world, and the safety and satisfactory performance or failure of ‘standardised’ devices is being used increasingly by prosecutors and defendants to support their legal arguments.

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:

The prime objective of ISO/TC 121 is to ensure as far as possible the safety of the patient undergoing anaesthesia and/or respiratory therapy and care. Other major safety-related aims are to safeguard the operator of the equipment, to ensure connectability and compatibility between devices and to ensure devices are supplied with proper labeling, appropriate instructions for use and technical performance data. In view of these aims, factors such as the structure, size and value of the market, percentage of gross domestic product and other financial parameters are of relatively low importance to ISO/TC 121 and are consequently not detailed here.

3 Benefits expected from the work of the ISO/TC

The work of ISO/TC121 will help to ensure the provision of equipment that will maximize patient and user safety and usability through the provision of safety features, legible and informative labeling, including instructions for use and performance data. Such equipment will be designed for optimal clinical performance and function and will interconnect correctly with minimal possibility of misconnection.

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

Active participants in ISO/TC 121 include clinicians, academics, manufacturers, professional societies, test house and certification body staff and government and regulatory staff. Most of the active member bodies are from developed regions of the world, but the TC is cognizant of the needs of countries with limited infrastructure where the correct operation and maintenance of sophisticated equipment may be unreliable or absent. Liaison relationships with the World Federation of Societies of Anaesthesiology, the World Health Organization and other bodies help to address this.

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

5.1 Defined objectives of the ISO/TC

To prepare and maintain standards and other ISO deliverables concerning anaesthetic and respiratory equipment for which a need has been demonstrated. The standards and deliverables have one or more of the following functions:

- to ensure as far as possible the safety of the patient and the user;
- to ensure as far as possible appropriate and adequate device performance and function;
- to reduce unnecessary variation;
- to foster interconnectability and compatibility of devices;
- to provide a basis for testing, certification and regulation of devices;
- to provide a basis for comparison and assessment of devices;
- to assist clinicians and purchasers in the selection and purchase of devices;
- to minimize obstacles to international trade.

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

To develop new ISO standards and deliverables or to adopt (modified or unchanged) specifications prepared by other organizations.

The technical work programme is divided between the various subcommittees with projects of interest to more than one subcommittee being handled by ISO/TC 121, by joint meetings of the relevant subcommittees or by ad hoc meetings of appropriate experts. ISO/TC 121 acts as the management committee to coordinate the activities of the subcommittees. Each subcommittee

has autonomy and sets its own priorities and targets within principles set by ISO/TC 121. The technical work of most subcommittees is carried out in working groups for which the subcommittee has administrative control.

Significant cooperation and joint work is taking place with IEC/TC 62 on projects that are based on the principles of the IEC 60601 series of standards on Medical electrical equipment. New and updated joint working group projects are being assigned numbers in the IEC/ISO 80601 series. With some exceptions (e.g. vocabulary), three types of standards are prepared:

- those specifying performance requirements;
- those specifying performance parameters to be disclosed by the manufacturers, together with appropriate test methods by which the disclosed parameters are to be measured;
- dimensional and design specifications.

As most of the types of devices addressed by ISO/TC 121 publications are expected to remain in clinical use, a significant portion of ISO/TC 121 future work will be the periodic review and updating of its portfolio of publications.

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

No significant factors are affecting completion and implementation of the ISO/TC 121 work programme at this time.

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 121 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