Draft business plan ISO/TC 170

BUSINESS PLAN
ISO/TC 170
Surgical instruments

EXECUTIVE SUMMARY

Established in 1977, ISO Technical Committee 170 (ISO/TC 170) has developed and published standards for non-active surgical instruments. These are instruments that typically can be re-sterilized and reused many times during the product lifecycle. Such instruments are used by surgeons in the sterile surgical field to manipulate various tissues in the body. Many of the types of surgical instruments under the purview of this committee remain state of the art, despite having been in use for well over 100 years and not having changed substantially since their original development and introduction.

Surgical intervention is standard practice in the treatment of many diseases, maladies and injuries. The multi-billion dollar global market for surgical instruments remains large and growing. Modern surgery is performed not only in developed countries but increasingly also in developing countries. Hundreds of millions of surgical procedures are performed annually, with this number expected to grow as a consequence of increasing access to surgery across the globe as well as to demographic factors such as ageing populations and rising incidences of chronic illness. ISO/TC 170 Standards may serve as basis for agreements and contracts in business relationships throughout the world and are therefore of particular importance to stakeholders in an expanding global market.

Standardization of design, materials and performance testing all aim to increase quality in the delivery of healthcare as well as to improve patient outcomes and population health. ISO/TC 170 standards address and establish factors of safety, quality, longevity and functional performance of surgical instruments. In developing, reviewing, publishing and governing these standards, ISO/TC 170 aims to contribute to the satisfaction of three primary needs: the safety and welfare of the patient, the confidence of the surgeon/practitioner in the products, and the facilitation of global trade and market access. The work performed by the Technical Committee (TC) is therefore expected to benefit a variety of healthcare stakeholders, including patients, surgeons, hospitals and healthcare facilities, instrument manufacturers, regulators and governmental agencies, payers and insurance companies, testing facilities and academic/research institutions.

ISO/TC 170 has 10 participating members (P-members) and 23 observing members (O-members) and oversees 5 published standards. Two standards are currently under revision. The Technical Committee's purpose is to maintain the present range of standards and to develop new standards to address unmet and/or emerging needs.

As with other TCs under the International Standards Organization, TC 170 recognizes that there are certain obstacles which can detract from the Committee's efficiency and the completion of its work. Key among these are:

1) Infrequent assessment and communication of committee strategic goals and objectives;
2) Limited number of available experts (stakeholders) who participate new projects;
3) Inadequate expert input and consensus building at early stages of project development; and
4) Non-uniform participation and voting practices among P-members.
   These obstacles are explained further in Clause 6

To mitigate these obstacles and their effects, the Committee pledges to:

1) frequently assess and communicate TC goals and objectives;
2) avoid and/or address duplication of work;
3) address the potentially limited number of available experts (stakeholders) by providing alternative ways to participate
4) encourage opportunities for expert input and consensus building at preliminary work item (PWI) stage of project development; and
5) encourage more sustained and uniform participation and voting practices among P-members.

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. This helps 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 140 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 170

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 170 sets and maintains standards for medical devices which are used during surgical operations. Examples are such as forceps, graspers, retractors, scalpels and scissors. This includes, but is not limited to General, Pediatric, Urological, Gastrointestinal, and plastic surgery instruments such as open, endoscopic, laparoscopic and robotic surgery instruments and (hemostatic) surgical energy devices.

The products within the scope of these standards comprise a broad range, from integrated, technically sophisticated systems such as those for minimally invasive surgery, to comparatively simple products, such as a scalpel, and further, to components and/or materials (such as stainless steels). ISO/TC 170 is also responsible for developing test methods, specifications, and performance standards for these devices.

On the supply side, manufacturers and suppliers of surgical instruments comprise a mix of multinational corporations, some large or mid-size, as well as small manufacturers. Innovation is being driven by manufacturers across the size spectrum. Some manufacturers enjoy dominant market shares in certain regional markets, but as a whole the market remains mostly fragmented. Recently there has been some degree of regional consolidation, due in part to economic factors resulting from by the Covid-19 pandemic, but also to rollout and implementation of tighter regulatory controls, like those specifically arising from the new European Medical Device Regulations (EU MDR).

Major technologies used in the production of surgical instruments include the processing of materials like stainless steels by means of hot or cold forging, machining, turning, joining, laser and waterjet cutting, casting, metal and plastic injection molding, stamping, pressing, heat treating, grinding, polishing, etc. as

well as galvanic surface preparation and the application of specialty coatings. While the manufacture of handheld surgical instruments traditionally required, and still requires, a significant amount of hand craftsmanship, automated and software-driven manufacturing technologies such CNC machining, but also robotics, and 3D printing, are increasingly finding application in the production of surgical instruments.

On the demand side, ISO/TC 170 standards cover products required by and supplied directly to purchasers, like medical practitioners in hospitals, clinics and ambulatory surgical centers, among others, around the globe. Competition is strong, not only at the producer level but also at the end user level. Technology developments and trends in interoperative visualization, robotics, miniaturization and energy-driven hemostasis continue to create and drive shifts from traditional "open" surgical procedures to less invasive or minimally invasive endoscopic, or keyhole, procedures.

2.2 Quantitative Indicators of the Business Environment

The following quantitative indicators describe the business environment and provide underlying information that may be used to support actions of the ISO/TC.

The market for surgical instruments is a global one, consisting of medical practitioners both inside and outside of hospitals/health care facilities and manufacturers across geographic regions. In 2022, the annual global volume of surgical instrument sales surpassed $5 billion[1]. Measuring the value of standardization work against its benefits, in terms of total sales, total employment or total international trade, makes particular sense when the programme of work is directed to the development of "standards for typical products or families of products". For instance ISO/TC 170 has developed and published only five standards, despite those standards being applicable to a total range of approximately 15,000 different products.
Nowadays, surgical instrument manufacturers use a quality management system in which a master file relates to an entire relevant product category, i.e. family of similar products.

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

ISO/TC 170 standards address safety, quality, longevity and functional performance. The Technical Committee expects to satisfy three needs: the safety and comfort of the patient, the confidence of the surgeon/practitioner in the product, and the facilitation of global trade and market access.
Standards on performance requirements as well as performance testing directly support safety and comfort of the 'end-users', the patients, and create confidence of the surgeons in the surgical instruments that they use.

International Standards also serve in commercial agreements and business contracts throughout the world and are therefore vital for an expanding the global market. Clear requirements and universal definitions facilitate negotiation and avoid disputes between suppliers and buyers by allowing proper and consistent characterization of medical devices.

[1] https://www.grandviewresearch.com/industry-analysis/surgical-equipment-market#:~:text=Report%20Overview,9.4%25%20from%202023%20to%202030 .

The standards produced by ISO/TC 170 also help the manufacturer to show conformity with relevant regulatory requirements resulting in:

- Reduced time for regulatory review;
- Better understanding of the types of information needed to evaluate the safety and/or effectiveness of devices; and
- Agreed and clearly documented technical requirements for global harmonization.
- ISO/TC 170 standards are used by many manufacturers and regulatory bodies:
- In the specification of materials and components that are used in the manufacture and assembly of surgical instruments;
- As a means of validation of test methods;
- In the evaluation of surgical instrument performance;
- In the determination of conformity with existing specifications;
- In the development of guidance documents;
- In clearance or approval of marketing applications; and
- For quality management purposes.

Due to increasing requirements from international regulatory authorities, ISO/TC 170 develops and revises International Standards concerned with the materials and processes required for manufacturing, reprocessing and use of surgical instruments. Groups which benefit directly or indirectly from ISO/TC 170 Standards include patients, surgeons, health service providers, material suppliers, manufacturers, scientists and engineers.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Countries/ISO members bodies that are P and O members of the ISO committee

https://www.iso.org/committee/53648.html?view=participation

4.2 Participation

ISO/TC 170 has 10 P-members and 23 O-members. Most active member bodies are from the developed countries. ISO/TC 170 encourages all member bodies to evaluate periodically both their participation and voting practices.

It is desirable to have each member body identify experts that represent all of the following stakeholder categories:

A. Industry and commerce:

- Manufacturers, which make and sell surgical instruments and provide support to those who use them;
- Suppliers, who provide services or the materials or parts from which surgical instruments are made; and
- Trade associations

B. Government:
- Government organizations and agencies; and
- Regulatory authorities, which evaluate surgical instruments for safety and effectiveness in the pre- and post-market

C. Consumers:
- Patients, on whom surgical instruments are used in the course of surgical procedures;
- Purchaser, Healthcare centers, which buy, store and use surgical instruments; and
- Surgeons, who select and surgically employ them

D. Labour:
- Trade unions, which represent manufacturers and users of surgical instruments; and
- Employees

E. Academic and research bodies:
- Academic and research communities, which invent, educate and conduct research on surgical procedures and instruments used therein

F. Standards application:
- Testing facilities, which test finished systems, devices, components, and materials, to evaluate device safety and effectiveness;
- Accreditation bodies; and
- Standards development organizations, governmental or independent

G. Non-governmental organization (NGO)
- Non-profit independent organizations active in humanitarian, educational, health care, public policy, social, human rights, environmental, and other areas to effect changes according to their objectives

It is believed that through active and informed participation by as many body experts as is reasonably practicable that ISO/TC 170 is best able to achieve the various stakeholder benefits outlined in Clause 3.

4.3 Analysis of the participation

ISO/TC 170 has 10 P-members and 23 O-members. Although annual meetings have regularly taken place over the past decade, P-membership and active participation in meetings and balloting in some cases has diminished to the point that the committee now lacks sufficient participation to meet ISO Organization rules.

In order to achieve its objectives, personal representation of the member bodies must comprise all interested parties. The interested parties can include surgeons (user community), industry, regulatory authorities and research community. Unfortunately, in ISO/TC 170 the personal representation of the member bodies does not comprise all the parties named here, but mostly consists of representatives of manufacturers. Outreach efforts to mitigate/correct this circumstance at the member level have been

made by the committee leadership. In addition, waivers on achieving balloting requirements have been requested at the TMB organization level.

The leadership and membership of the committee regards its autonomy as essential and is therefore resolved to finding a lasting solution to the challenge of insufficient member participation, including measures such as converting O-members to P-members.

5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

ISO/TC 170 develops and elaborates standards for surgical instruments, covering terminology, specifications and requirements as well as methods of tests for all types of instruments. These International Standards shall provide a basis and good infrastructure for the global market for surgical instruments, improve the safety and comfort of the patient, increase the confidence of the surgeon in the product, and the facilitation of global trade and market access.

5.2 Identified active measures to achieve defined objectives of the ISO/TC

The active measures used to achieve the objectives of the committee include:
1) Holding annual meetings and, if necessary, interim meetings;
3) Encouraging the TC to identify respective strategies for completing work; and
4) Developing committee level strategies to overcome obstacles which detract from efficiency and the completion of work.

Committee Meetings
The work of the TC is conducted by holding physical face-to-face and web-based meetings, typically on an annual basis. Documents are provided through the ISO/TC ISO documents Platform.

TC Strategies to Address Key Obstacles which Detract from Efficiency and Completion of Work

To address obstacles which could detract from efficiency and completion of the work, ISO/TC 170 follows the practices of TC 150 and has identified the following strategies:

1) More Frequent Assessment and Communication of TC Goals and Objectives:

ISO/TC 170 will annually discuss and develop short, medium, and/or long-term goals and objectives as continual changes in technology and regulations can be expected and as new fields of activity are developed, ISO/TC 170 will do the following actions.

Action Items:
- Revise TC Goals and Objectives in the Strategic Business Plan on regular basis.
- Encourage the recruitment of new experts to help reassess strategic goals.

2) Addressing the Limited Number of Available Experts (Stakeholders) by Providing Alternative Ways to Participate:

To increase available expert participation, ISO/TC 170 will continue to facilitate the use of interim teleconferences and web-based meetings. At their annual meetings, such technology can also be used. In addition, ISO/TC 170 has outlined the following action items to achieve the goal of receiving more balanced input from each stakeholder category, in the work conducted by the TC working groups. The near-term goal of this effort is to identify areas in which stakeholder attendance may be lacking, if any. The longer-term goal of this effort is to identify practical ways to obtain input from these stakeholder groups.

Action Items:

- As part of the meeting minutes for each annual meeting or interim teleconference or Web based meeting, ISO/TC 170 to document the name of each expert, their corresponding P-member body, and the stakeholder group to which they belong.
- From the information provided in the annual meeting and interim meeting minutes, ISO/TC 170 will produce a report after each annual meeting, which will detail, for each P-member body, the experts who attended and the stakeholder groups to which they belong. This report will also detail which stakeholder group(s) that were and were not in attendance for consideration by TC Chair and Committee manager.

3) Encouraging Opportunities for Expert Input and Consensus Building at Preliminary Work Item (PWI) Stage of Project Development:

ISO/TC 170 encourages each subcommittee and working group to adopt procedures to identify projects early at the PWI stage; thus, allowing for the required intensive expert input and consensus building prior to initiating the formal balloting process and timeline. Chairs and convenors should encourage members to identify PWIs during committee meetings.

Action Items:

- In the committee and working group agendas, under “New Business,” encourage members to identify preliminary work items early.
- When projects are identified, create multiple opportunities where experts from key stakeholder groups are able to provide the required input and build consensus prior to initiating the formal balloting process and timeline.

6 OBSTACLES WHICH DETRACT FROM EFFICIENCY AND COMPLETION OF THE ISO/TC WORK PROGRAM

The obstacles which detract from efficiency and completion of the work program may include the following:

- Infrequent assessment and communication of committee strategic goals and objectives;
- Limited number of available experts (stakeholders) who participate in working group (WG) meetings;
- Inadequate expert input and consensus building at early stages of project development; and
- Non-uniform participation and voting practices among P-members.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

This section gives an overview of the ISO/TC's structure, scope, current status of projects under development, and publications. All of this information is updated regularly and is available on ISO's website, ISO Online.
The link below is to the TC's page on ISO's website:
ISO/TC 170 on ISO Online

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

- About (Secretariat, Secretary, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
- Meetings
- Tools
- Work program (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