# STRATEGIC BUSINESS PLAN
# ISO/TC 150 Implants for surgery

## EXECUTIVE SUMMARY

Established in 1971, ISO/TC 150 has developed standards for non-active and active medical devices which are implanted in the body either permanently or temporarily for therapeutic or diagnostic purposes. Non-active implants are intended to replace or repair worn-out or damaged parts of the body or even to allow for aesthetic restoration or enhancement. Active implants provide therapeutic electrical stimulation and/or sense biological signals.

The healthcare market for implants is global, large and growing. It involves tens of millions of devices in millions of patients and these numbers are expected to multiply due to the ageing population.

The scope of the committee includes complete non-active and active implantable medical device systems and their instruments, components, and materials. Further explanation and examples of the range of products covered are included in Clause 2.1.

ISO/TC 150 has 24 participating members (P-members) and 22 observing members (O-members) and has developed over 173 International Standards. It is responsible for maintaining the present range of standards and developing new standards to address unmet needs.

ISO/TC 150 standards address safety, quality, longevity and functional performance. Their purpose is to improve patients' welfare and quality of life, the healthcare professionals' confidence in product quality, and the facilitation of global trade and regulation. The Technical Committee's (TC's) work is therefore expected to benefit patients, industry, surgeons, healthcare centers, government regulators, testing facilities and academic and research communities. The developed standards support the UN Sustainable Development Goals (SDG) and in particular SDG 3 (Good health & well-being).

One of the main purposes of the ISO/TC 150 Strategic Business Plan is to highlight key obstacles and strategies to overcome them.

Key obstacles which detract from efficiency and completion of work include:
1) Insufficient assessment and communication of committee strategic goals and objectives;
2) Duplication of standards;
3) Lack of continuity in project leadership;
4) Non-uniform participation and voting practices among P-members.

These obstacles are explained in Clause 6.

Our strategies to overcome the obstacles outlined above include:
1) Sufficient assessment and communication of TC and subcommittee (SC) goals and objectives, including Potential Ideas for Preliminary Work Items;
2) Avoiding and addressing duplication of standards;
3) Improving the continuity in project leadership;
4) Encouraging more uniform participation and voting practices among P-members.

These strategies are explained in Clause 5.2.

# 1 INTRODUCTION

## *1.1 ISO technical committees and business planning*

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is important and forms part of a major review of business. The aim is to align the ISO work program with expressed business environment needs and trends, and to allow ISO/TCs to prioritize among different projects. This helps 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. The latter is the responsibility of IEC (International Electrotechnical Committee). Most of the Telecommunications Technologies 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 167 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). The parity representation of National Standards Bodies in ISO fora provides an unrestricted recognition of these International Standards by the World Trade Organization members as instruments to regulate products, processes and services. 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 ISO/TC 150

## *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 ISO/TC 150, and can influence how the relevant standards development processes are conducted and the content of the resulting standards.

ISO/TC 150 (Implants for Surgery) produces and maintains the standards for nearly all types of implants used in surgery. Its work benefits patients, industry, surgeons, healthcare centers, government regulators, testing facilities and academic and research communities.

The range of products covered by the scope of the committee includes complete non-active and active implantable medical device systems and their instruments, components, and materials. Examples of these products are outlined below.

Non-active implants describe those implants that do not have a specific electrically powered aspect to them. Examples of non-active implants are orthopaedic joint replacements; nails, screws, and plates for osteosynthesis; interbody fusion devices for stabilization of the spine; breast implants; neurosurgical implants; cardiovascular stents, cardiac valves, and vascular grafts.

Implants whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy are considered active implants. Examples of active implants are cardiac pacemakers, drug-delivery devices, neurostimulators, cochlear implants, and ventricular assist devices.

ISO/TC 150 also produces standards on topics such as: extracorporeal systems such as equipment for renal replacement therapy; tissue engineered medical implants whose function relies on the interaction of a non-biological scaffold and biologically active constituents; implant retrieval; and implant coatings.

The medical implants market, in general, is characterized by a large number of manufacturers and suppliers, none of which clearly dominate the market. There are also many small to medium size enterprises, which have been hotbeds for innovation. This business environment has led to consolidation and market concentration by mergers, acquisitions and globalization, as companies expand their product portfolio and acquire market share. This process has also been fueled by the higher demands on medical services and logistics and increasing cost. Major manufacturers in the industry include those of orthopedic, cardiovascular, neurosurgical, and other devices, as well as their supporting industries.

Major customer groups for the final implants and associated devices under consideration are hospitals, surgeon groups, and individual physicians. The end-user of an implant (i.e. the patient) is rarely the one who purchases the implant or even decides which implant should be used. Usually this is decided by the physician. However, the internet and other readily available information sources have led to a much better informed patient population. Increasingly, patients are asking for evidence of safety and effectiveness and thus sharing in the decision on choice of implant. Compliance with widely respected standards is very persuasive from the patients' and physicians' point of view.

New technologies (such as miniaturization, advanced electronics, new materials, additive manufacturing and antimicrobial surfaces) have enormous impacts on the need for ISO/TC 150 standards. The changes in technology may relate to the implants, resulting in better function or longevity, or may affect situations that at first glance appear remote from the implant. Examples of these technologies include imaging systems and the production of customized implants. Advanced imaging technologies, such as MRI, can affect the function of already implanted devices and must be taken into account. Customized production of implants for individual patients may become common and these may range from CAD/CAM “made to measure” machining of hip joint replacements, additively manufactured (3D printed) implants and instruments, and replacement organs using cell culture of the patient’s own tissues on an artificial substrate.

Patients interact with various forms of non-medical technology in daily life (such as airport security scanners, anti-theft devices and mobile phones) and this may affect the safety and effectiveness of their implanted device(s). When appropriate, the effects of these non-medical technologies on implants are considered in standards development.

More and more companies are producing implants and more countries are making or importing them. The regulatory environment and complying manufacturers benefit from international harmonization especially

through ISO standards. This adds important commercial and sometimes politically sensitive aspects to the work of ISO/TC 150 and its standards development.

### *2.2 Size of the Business Environment*

The healthcare market for implants is global, large and growing. It involves tens of millions of devices in millions of patients and these numbers are expected to multiply due to the ageing population. This growth is amplified further by the increased usage of implants in the developing world as devices become affordable and their technology more accessible. Orthopaedic and cardiovascular implants represent the largest share of the current market.

## 3 BENEFITS EXPECTED FROM THE WORK OF ISO/TC 150

ISO/TC 150 standards address safety, quality, longevity and functional performance. Their purpose is to improve patients' welfare and quality of life, the healthcare professionals' confidence in product quality, and the facilitation of global trade and regulation. The TC's work is therefore expected to benefit patients, industry, surgeons, healthcare centers, government regulators, testing facilities and academic and research communities.

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 facilitate the negotiation and avoid disputes with customers by allowing proper characterization of medical devices.

The standards produced by ISO/TC 150 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 150 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 medical devices;
- As a means of validation of test methods;
- In the evaluation of device 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.

## 4 REPRESENTATION AND PARTICIPATION IN ISO/TC 150

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

### *4.2 Participation*

ISO/TC 150 has 24 P-members and 22 O-members. Most active member bodies are from the developed countries. ISO/TC 150 encourages all member bodies to periodically evaluate their participation and voting practices.

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

**A. Industry and commerce:**
- Manufacturers, which make and sell implants and provide support to those who use them;
- Suppliers, who provide services or the materials or parts from which they are made; and
- Trade associations

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

**C. Consumers:**
- Patients, who need implants;
- Healthcare centers, which buy and store them for delivery to patients; and
- Surgeons and other healthcare professionals, who select and surgically install them

**D. Labour:**
- Trade unions; and
- Employees

**E. Academic and research bodies:**
- Academic and research communities, which invent, educate and conduct research on implants

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

**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 through the active and informed participation by each member body expert that ISO/TC 150 is able to achieve the various stakeholder benefits outlined in Clause 3.

# 5 OBJECTIVES OF ISO/TC 150 AND STRATEGIES FOR THEIR ACHIEVEMENT

## *5.1 Defined objectives of ISO/TC 150*

ISO/TC 150 develops standards for active and non-active medical devices which are implanted in the body either permanently or temporarily for therapeutic, diagnostic or monitoring purposes. These implants are intended to replace, repair, or stimulate defective or worn-out or damaged parts of the body or even to allow for aesthetic restoration.

ISO/TC 150 standards address issues such as safety, quality, and performance to facilitate improvement in the patients' welfare and quality of life, the healthcare professionals' confidence in product quality, and, global trade and regulation.

## *5.2 Identified strategies to achieve ISO/TC 150's defined objectives*

The strategies used to achieve the objectives of the committee include:

a) Investigate how to meet in the future within ISO/TC 150 (physical vs. web based vs. hybrid, frequency of meetings, etc.)
b) A committee structure which divides work into Technical Committee WGs, and Subcommittees, and their corresponding WGs;
c) Communicate TC and SC Goals and Objectives in the Strategic Business Plan; and
d) Developing committee level strategies to overcome obstacles which detract from efficiency and the completion of work.

**a) Committee Meetings**

Pre-Covid 19, ISO/TC 150 and its SCs met annually in physical face-to-face meetings. During Covid 19 this had changed to web based meetings. Both have advantages and disadvantages, and hybrid involving both has its own challenges, too. The committee's approach about this is still fluid at this time, the subject of much

discussion, and therefore the member bodies as well as the delegates and experts involved will be consulted for their preference.

**b) Committee Structure**

Outlined below is the committee structure. Clause 7 also provides links to the ISO/TC 150 website that includes ISO/TC 150's structure.

The committee structure comprises ISO/TC 150 working groups (WGs), subcommittees (SCs), and their corresponding WGs. The WGs of ISO/TC 150 address standards that apply to one or more device specific topics and are therefore considered horizontal in nature. Regarding the SCs, the materials SC is horizontal in nature; whereas the other SCs cover product specific fields. To provide efficient working structures, all of the SCs have corresponding WGs. WGs may be temporary in nature if they have a small number of standards in development; or, they may be more permanent if they are responsible for many standards.

The active ISO/TC 150 working groups include:

- JWG 1 *Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications*
- WG 7 *Fundamental standards*
- WG 10 *Use and retrieval of surgical implants*
- WG 12 *Implant coatings*
- WG 13 *Absorbable implants*
- WG 14 *Models of tissues for mechanical testing of implants*
- WG 15 *Neurosurgical Implants*
- WG 16 *Antimicrobial properties of implants*

The subcommittees include:

- SC1 *Materials*
- SC2 *Cardiovascular implants and extracorporeal systems*
- SC4 *Bone and joint replacement*
- SC5 *Osteosynthesis and spinal devices*
- SC6 *Active implants*
- SC7 Tissue-engineered medical products (TEMPs)

**c) Individual TC and SC Strategies for Allocating and Completing Work**

Clause 7 provides links to the ISO/TC 150 website that includes the ISO/TC's scope, current status of all projects under development, and publications. Outlined below are the identified future strategies or future work items for the TC and each SC that are not identified on the website.

JWG 1 *Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications*
Currently no future strategies beyond development of ISO 5092 *Additive manufacturing for medical — General principles — Roadmap to safe and effective additively manufactured implants* (currently in "accepted work item" stage).

WG 7 *Fundamental standards*
Future work items include:

- Consider a revision of the standard on Implants for surgery -- Cleanliness of orthopedic implants -- General requirements (ISO 19227) once the revision of the standard on Non-active surgical implants -- General requirements (ISO 14630) is completed.

WG 8 *Breast Implants*
No future strategies beyond finishing the revision of ISO 14607 *Non-active surgical implants - Mammary implants - Particular requirements.*

WG 10 *Use and retrieval of surgical implants*
No future strategies beyond maintenance of the documents allocated to WG 10.

WG 12 *Implant coatings*
Development of a scratch test method to determine coating adhesion specific to implant coatings.

WG 13 *Absorbable implants*
Development of a new umbrella document for standards specific for absorbable materials and implants: ISO/PWI 16683 – Implants for surgery – General guidelines and methodologies for assessment of implantable absorbable materials and devices.

WG 14 *Models of tissues for mechanical testing of implants*
Future work items include:

- *Review and possible revision of ISO 19213 Implants for surgery — Test methods of material for use as a cortical bone model*

WG 15 *Neurosurgical Implants*
No future strategies beyond completion of revision of ISO 7197 *Neurosurgical implants — Sterile, single-use hydrocephalus shunts*.

WG 16 *Antimicrobial properties of implants*
WG 16 was newly formed in March 2021.
Future work items include:

- *Development of terminology document for antimicrobial properties of implants*
- *Development of individual in vitro antimicrobial test methods and elution test methods*

SC 1 *Materials*
SC 1 covers non-biologically derived materials for use in implants for surgery. These materials include metals, polymers and ceramics.
ISO/TC 150/SC 1 is working on several preliminary work items:

In WG 3, Ceramics

- ISO/PWI 4403, *Implants for surgery - Test method for flexural strength of porous bioactive ceramics under in vivo mimicking circumstances*
- ISO/PWI 18531, *Implants for surgery — Calcium salt based bioceramics — Characterization of hardening bone paste materials*
- ISO/PWI 13175-3, *Implants for surgery — Calcium phosphates — Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes*
- ISO/PWI 6232, *Implants for surgery —Test method for torsional strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline*
- ISO/PWI 13356-1, *Implants for surgery – Zirconia ceramics – Part 1: Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*
- ISO/PWI 13356-2, *Implants for surgery – Zirconia ceramics – Part 2: Name to be defined (ATZ ceramic)*

In WG 4, Metals

- ISO/PWI 15374, *Implants for surgery — Requirements for production of forgings*

In WG 5 Plastics

- ISO/PWI 5834-2, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms*
- ISO/PWI 14949, *Implants for surgery — Two-part addition-cure silicone elastomers*
- ISO/PWI 5833, *Implants for surgery — Acrylic resin cements*
- ISO/PWI xxxx, *Accelerated test method to evaluate delamination resistance of ultra-high molecular weight polyethylene used for orthopaedic implants*

SC 2 *Cardiovascular implants and extracorporeal systems*
SC 2 covers cardiac valves, including transcatheter valves and repair devices; vascular prostheses, with a current emphasis on vascular stents; blood gas exchangers; renal replacement and detoxification, including guidance for the preparation and quality management of fluids for haemodialysis and related therapies and extracorporeal systems for blood purification; vascular device-drug combination products; cardiovascular absorbable implants; and cardiac occluders.
Future strategies include:

Within SC2/ WG5 there is close collaboration with IEC SC62D/MT20 whose remit is to prepare international standards and other publications to support safety and performance for equipment used in renal replacement therapy;

- IEC 60601-2-16: Medical electrical equipment - Part 2-16: Particular requirements for the

safety of haemodialysis, haemodiafiltration and haemofiltration equipment
- IEC 60601-2-39: Medical electrical equipment - Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment
- IEC/ISO 62653: Guidelines for the safe use of medical products in dialysis treatment
- In addition, work is also ongoing on as yet un-numbered technical report dealing with the design principles and validation methods for the maintenance of microbial control for non-disposable fluid paths of dialysis equipment
- It is likely that in the future there will be need to integrate the requirements detailed in ISO 8637-2 with those in IEC 60601-2-16 as blood lines are becoming increasingly integrated into the latter

SC 4 *Bone and joint replacement*
SC 4 covers the field of orthopaedic 'repair' by replacement of bones and joints. This includes mainly dimensions, requirements and test methods for hip and knee joints or parts of them.
Future strategies and work items include:
- It is the intention to develop standards for other joint replacements, and under wider clinical conditions. This may include patient, surgical, and device related factors.
- An effort will be made to include performance requirements within joint replacements standards.
- In the longer term, standards determining the mechanical and tribological performance of earlier interventions, such as osteochondral grafts to repair cartilage, will need to be developed.

In addition to the above, SC4 is committed to tackling duplication in standards. Thus far SC4 has created 6 TFG for tackling duplications. Over the next few years, we will continue to create new TFG to tackle other duplications we have identified in our standards.

SC 5 *Osteosynthesis and spinal devices*
SC 5 covers the orthopaedics device area responsible for general osteosynthesis (fixing fractures with plates, screws, nails and wires) and spinal implant devices. Areas of clinical development and research currently include such products as spinal fixation devices, spinal stabilization devices, spinal disc replacements, and intervertebral body fusion devices.
Future strategies and future work items include:
- Developing umbrella standards and specifications for the device categories listed above.
  - For osteosyntheses (WG1), this included consolidating bone screw standards into one umbrella specification to replace:
    - ISO 6475 - Implants for surgery — Metal bone screws with asymmetrical thread — Requirements and mechanical test methods
    - ISO 9268 - Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions
    - ISO 5835 - Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions
  - For spinal devices (WG2), this includes the continued development of:
    - Newly Published: ISO 23089-2:2021 Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements — Part 2: Spinal intervertebral body fusion devices
    - Registered and in Progress: ISO 23089-1:YYYY Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements — Part 1: Thoracolumbar Pedicle Screw Systems
    - Upcoming: ISO 23089-TBD:YYYY Implants for surgery — Pre-clinical mechanical assessment of spinal implants and particular requirements — Part 3: Total Disc Replacements

SC 6, Active implants
SC 6 covers active implantable medical devices that rely for their functioning on a source of energy or any source of power other than that directly generated by the human body or gravity.
Future work items include:
- A revision of ISO 14708-1:2014, Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
- A revision of ISO 14708-3:2017, Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators
- A revision of ISO 14117:2019, Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices

SC 7 *Tissue-engineered medical products*
SC 7 covers general requirements and performance of tissue engineered medical products with the exclusion of gene therapy, transplantation and transfusion.
Future strategies include:

- To assist SC 1 with development of standards related to materials used in or with TEMPs

ISO/TC 150/SC 7 is working on several preliminary work items:
WG1 Management of Risk

- ISO/PWI xxxx, Tissue engineered medical products – Characterization and evaluation of recombinant collagen as a starting material for TEMPs
- WG 1 intends to initiate work items to supplement umbrella document TS 21560:2020 General requirements for tissue engineered medical products

WG 3 Tissue engineered medical products for skeletal tissues

- ISO/PWI xxxx, Tissue engineered medical products – Test method for Cell Attachment for Bioceramics – Part 1: Seeding on Dense Bioceramic Scaffolds
- ISO/PWI xxxx, Tissue engineered medical products – MRI evaluation of cartilage – Part 2: Pre-clinical evaluation of regenerative knee articular cartilage

**d) TC Strategies to Address Key Obstacles which Detract from Efficiency and Completion of Work**
To address each of the obstacles which detract from efficiency and completion of the work (Clause 6), ISO/TC 150 has identified the following strategies:

1) **Sufficient Assessment and Communication of TC and SC Goals and Objectives, including Potential Ideas for Preliminary Work Items:** ISO/TC 150 and its subcommittees periodically discuss and develop short, medium, and/or long-term goals and objectives, with input from their respective WGs. As there are continual changes in technology and new fields of activity are developed, ISO/TC 150 and its subcommittees perform the following actions.

   **Action Items:**
   - Hold a meeting for the TC and each SC at least once a year
     - to discuss and develop short, medium, and/or long-term goals and objectives, with input from their respective WGs. The agenda shall include an item titled: “Assessment of Goals and Objectives”
     - to identify, discuss and assess potential ideas for preliminary work items to be added to the work program. The agenda shall include an item titled: “Identification of and Discussion on Potential Ideas for Preliminary Work Items”
   - Develop an action plan and identify a task leader for each goal and objective and each preliminary work item agreed upon during this meeting.
   - Communicate TC and SC Goals and Objectives in the Strategic Business Plan in Clause 5.2 c).
   - Encourage the recruitment of new experts to help reassess strategic goals.

2) **Avoiding and Addressing Duplication of Standards:** ISO/TC 150 has taken additional steps to achieve the goal to minimize and avoid duplication of standards. In 2015, ISO/TC 150 established a Task Force (TF) to assess the current and future risk of duplication of standards and the efficiency implications regarding them. The specific aim of the TF was to identify potential solutions, which were agreeable to members of ISO/TC 150 to be optionally implemented. The TF includes the TC 150 Chair and Secretary; SC Chairs and Secretaries; one representative from each P-members country; and, a representative of the ISO Central Secretariat. Over the course of two years, the TF finalized a guidance document titled, “Guidance for Avoiding Duplication of Work” (“Guidance”, included as Attachment 1).

   In 2017, ISO/TC 150 implemented the “Guidance” developed by the TF. The “Guidance” contains recommendations to address each “Standard that Duplicates” and minimize future duplication. As the “Guidance” contains only optional recommendations for how to address each “Standard that Duplicates” and minimize future duplication, the ISO/TMB agreed that it is not a “Committee Specific Procedure.” The recommendations outlined in this “Guidance” are for consideration by ISO/TC 150 and its SCs to avoid the duplication of work that affects some (not all) of its committees. The TF work continues to support the large effort to implement the above through the TC and SCs.

   ISO/TC 150 and its SCs set up multiple task forces which compare individual duplicating standards and recommend ways to deal with the existing duplication. ISO/TC 150 and its SCs then take resolutions to

address the existing duplication upon consideration of the recommended plan.

ISO/TC 150 desires to ensure that users have as much relevant information as possible in a single standard and has worked to develop procedures to avoid or minimize the duplication of standards and duplication of effort. In order to minimize the duplication of effort and to conserve resources, the ISO/TC 150 itself as well as its subcommittees cultivate co-operation and liaisons with other ISO and IEC committees (e.g., ISO/TC 261 Additive Manufacturing, ISO/IEC JTC 1 Information Technology, IEC 62B Diagnostic imaging equipment).

ISO/TC 150 benefits from a working relationship with the European standards committee CEN/TC 285 Non-active surgical implants. As far as possible, the Vienna Agreement is applied with either CEN or ISO leading as appropriate.

ISO/TC 150 has had an increasing number of interactions with ASTM F04 Medical and surgical materials and devices, which have led to a common goal to avoid future duplication and address existing duplication between both committees. To support this a joint ISO/TC 150/ASTM F04 workshop on duplication was held in June 2022.

**Action Items:**
- Continue to implement in the TC and SC's the guidance document titled, "Guidance for Avoiding Duplication of Work" (Attachment 1).
- Continue to cultivate co-operation and liaisons with related standards development organizations.
- Continue to look for opportunities to disseminate information about ISO/TC 150's activities to avoid and address duplication (e. g. by setting up a ISO/TC 150 LinkedIn page)
- Encourage TC and SCs leadership to identify a member within each WG to assist with oversight of duplication efforts

3) **Improving the Continuity in Project Leadership:** ISO/TC 150 and its subcommittees recommend the following action item to address any unexpected turnover or absence of project leaders. In addition, we encourage the convenors and secretaries to continually monitor the effectiveness of the work item co-leaders and, when issues arise, identify appropriate project leaders to accomplish the task.

**Action Item:**
- Each WG should identify co-leaders who coordinate and take shared responsibility for each work item.

4) **Encouraging More Uniform Participation and Voting Practices among P-Members:** ISO/TC 150 and its subcommittees will encourage all member bodies to actively engage in the work of each WG and to provide constructive input through nominated experts. ISO/TC 150 will encourage member bodies to vote "abstain" unless their nominated experts are actively participating in meetings and providing constructive input throughout the development of work items. To address issues that arise from inactive P-members, ISO/TC 150 has identified the following action items. The aim is to develop proposals to encourage more uniform participation and voting practices amongst the member bodies by identifying/developing training materials to better educate member bodies. (Note that the first item is based on Clause 1.7.4 and 1.7.5 of the ISO/IEC Directives – Part 1, 2022).

**Action Items:**
- In each annual meeting, request ISO/TC 150 and each of its SCs determine and report as part of their meeting minutes:
  - If any P-member has been persistently inactive by failing to attend two successive committee meetings (in person, virtually or by correspondence) and failing to have any Expert(s) appointed to the technical work, or
  - If any P-member has failed to vote on over 20 % (and at least 2) of the questions formally submitted for voting on the committee internal balloting (CIB) within the committee over one calendar year; or
  - If any P-member has failed to vote on an enquiry draft or final draft International Standard prepared by the respective committee, or on a systematic review ballot for a document under the responsibility of the committee.
- Review the past two years of voting in ISO/TC 150 and each of its SCs to determine which member bodies are voting "disapproval" or "approval" and providing comments; voting "approval" without comment; and, voting "abstain." This information will be included as part of their meeting minutes.
- For each committee internal ballot within ISO/TC 150 and each of its SCs include language to explain

that the default voting option should be to “Abstain” instead of “Approval”, if expert stakeholders of any P-member did not have an opportunity to do a critical analysis of the ballot content. Also, the committee manager of ISO/TC 150 will communicate to ISO/CS a recommendation to the ISO/TMB to include such language in other ballots (DIS, FDIS, SR).

- ISO/TC 150 will communicate with P-members who have been consistently voting “Approval without comments” to inform them of the merits of voting “Abstain”, and the potential problems associated with voting “Approval” without critical analysis of the ballot content.

# 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 include the following:

1) Insufficient assessment and communication of committee strategic goals and objectives;
2) Lack of coordination among multiple standards developing bodies working independently on the same subject;
3) Lack of continuity in project leadership; and
4) Non-uniform participation and voting practices among P-members.

**1. Insufficient Assessment and Communication of Strategic Goals and Objectives**

Often ISO/TC 150 and its subcommittees spend their time either reacting to unsolicited proposals or maintaining the current range of standards and do not take sufficient time to discuss and develop short, medium, and/or long-term strategic goals and corresponding objectives.

It is through the discussion of these goals that committees are able to identify gaps in areas of unmet need either for the entire group or individual stakeholders. Once the gaps have been identified, goals and corresponding focused objectives can be developed, including potential ideas for preliminary work items.

Once the focused objectives have been developed, new experts may need to be recruited.

ISO/TC 150, its working groups and subcommittees, have identified that a strategic objective is to periodically assess and communicate TC and SC goals and objectives (Clause 5.2).

**2. Duplication of standards**

Duplication of standards on the same subject matter must be avoided or minimized. Although the ISO/IEC Directives clearly indicate to avoid duplication, such duplication still occurs both among technical committees within ISO and IEC as well as among different standards developing bodies. Duplication of standards leads to confusion when standards are written on the same subject matter as they may contain different or conflicting information. Such standards, over time, may “grow apart” as each may be revised independently. Duplication wastes valuable resources including those needed to develop standards in areas of unmet need.

ISO/TC 150 has identified the implementation of the “Guidance” in the TC and SCs as a strategic objective to achieve the goal of avoiding the duplication of work (Clause 5.2). In addition, the TC and SCs have developed and will continue to cultivate co-operation and liaisons with related standards development organizations (Clause 5.2).

**3. Lack of continuity in Project Leadership**

Parts of the committee have been affected by mergers and acquisitions of manufacturers or changes in employment causing interruptions or inconsistent participation by project leaders. To address this issue, some working groups have intentionally identified more than one project leader for each work item. By identifying co-leaders for each work item, the continuity of the developing projects is maintained through changes of employment or roles to allow for participation and progress to be made at each committee meeting. ISO/TC 150 and its subcommittees recommend that each working group identify co-leaders for each work item to prepare for unexpected turnover in project leadership as a strategic objective (Clause 5.2).

**4. Non-Uniform Participation and Voting Practices among P-members**

It is the right and responsibility of each member body to vote in accordance with its goals and objectives. ISO/TC 150 and its subcommittees will encourage all members to actively engage in the work of the committee and provide constructive input through nominated experts. Some member bodies are voting “approval” on draft standards without actively participating in meetings or providing constructive input on work items. If members vote “approval” on ballot items for which they have little to no expertise, they create an ISO process

which is biased to favor all new proposals. In such a process, well considered “disapproval” votes may carry less weight in committee discussions. Such member body “disapproval” votes that include constructive criticisms and suggestions for improvements, when faced with a significant number of “approval” votes, may struggle to instigate the necessary revision or persuade that a re-balloting at the same stage of development is necessary.

Rather than voting “approval” in such a situation, a member body should, by default, vote “abstain” based on the ISO directives. This is appropriate even if it means that on multiple ballots on a particular topic, member bodies would end up repeatedly voting “abstain”. Therefore, ISO/TC 150 encourages member bodies to vote “abstain”, if their expert stakeholders did not have an opportunity to do a critical analysis of the ballot content.

In addition, some P-members inactivity, either by lack of direct participation in technical committee/subcommittee meetings or by lack of correspondence; failing to appoint experts to the technical work; failing to consistently submit and informed vote on committee internal ballots, enquiry drafts (DIS), or final draft International Standards (FDIS) has limited the effectiveness of the committee around the world. ISO/TC 150 has identified strategic objectives to achieve the goal of encouraging more uniform participation and voting practices among P-Members (Clause 5.2).

**Conclusion**

To address each of the obstacles which detract from efficiency and completion of the work program, ISO/TC 150 has summarized the strategies mentioned in this section in Clause 5.2 above.

# 7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF ISO/TC 150

This section gives an overview of ISO/TC 150'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 150 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***