



STRATEGIC BUSINESS PLAN

ISO/TC 106¹

EXECUTIVE SUMMARY

Modern dentistry is much greater in scope, more complex and has a greater scientific base than ever before. Today's general practice includes minimal invasive therapies, adhesive aesthetic restorations, complex periodontal care, removable and fixed orthodontics, endodontic "root canal" therapy, minor oral surgery, and fixed or removable or implant supported prosthetic treatment. Prevention of oral diseases plays a major role. Furthermore, dental practice equipment follows ergonomic demands and must today also comply with national or international regulations concerning safety and environmental aspects. Infection prevention and control regulations have been considerably tightened, which has direct impact on dental practise. Dental products in general are in most countries regarded as medical devices and must comply with relevant national or international regulations. Finally, the dental market is becoming increasingly sophisticated with digital technologies including artificial intelligence.

The global dental industry is a small subset of the medical specialty groups for general healthcare but is considered a highly lucrative, desirable, and competitive market. Prior to COVID, it was predicted that the scale of the global dental market would be US\$37 billion worldwide. The global dental market was for the 2021 financial year forecasted to be worldwide US\$36.32 billion. There was a market decline of 7.6% in 2020, compared to 2019. The compound annual growth rate (CAGR) for the period 2022-2029 is projected to be 7.4%. Dental consumables make up 80% of the market, and the remaining 20% is dental equipment².

The key benefits already realized or expected from the work of ISO/TC 106 are:

- Improvements in the quality of products on the market.
- Improvements in the quality of care provided to patients.
- Reduction of barriers to trade in a growing international market.
- Protection of the health and safety of dental patients and users.
- Uniformity of terminology used in dentistry.
- Improvement of sustainability together with protecting the environment in line with UN Sustainable Development Goals, including waste management, without compromising healthcare benefits.
- To contribute to the limitation or reduction of greenhouse gas emission and thus reducing dentistry's contribution to climate change.

¹ This document has been revised in 2023 to account for the ISO TMB Action Plan linked to the London Declaration.

² Data sources from Fortune Business Insights: <https://www.fortunebusinessinsights.com/dental-market-106251>

ISO/TC 106 has the following objectives:

- To develop international standards that are congruent with the scope of the Committee.
- To revise or withdraw all other standards that are the responsibility of TC106 as per ISO periodic review procedures.
- To develop standards that stay current and evolve as the practice of dentistry evolves.
- To develop standards that make the best possible use of available scientific data.
- To develop standards, which take environmental aspects and those of sustainability into account as well as the challenges of limitation or reduction of greenhouse gas emissions.
- To be vigilant in harmonizing standards for similar types of products.
- To develop standards based upon function, utilization, and safety/environmental requirements rather than only on chemical and/or physical properties.
- To ensure that the composition of working groups is balanced and includes the best experts as well as representation from all stakeholders.
- To ensure that vested interests never dictate the development of dental standards.

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's needs and trends, and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: [ISO](#) (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of [IEC](#) (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of [ITU](#) (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the [International Standard](#).

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its [Technical Committees](#) are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF THE ISO/TC 106

2.1 *Description of the Business Environment*

The following political, economic, technical, regulatory, legal and social dynamics define the business environment of the industry sector, impacting products, materials, disciplines or practices related to the scope of this ISO/TC 106, and may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

Modern dentistry is much greater in scope, more complex and has a greater scientific base than ever before. Today's general practice includes minimal tooth invasive therapies, adhesive aesthetic restorations, complex periodontal care, removable and fixed orthodontics, root canal therapy, minor oral surgery, and fixed or removable or implant supported prosthetic treatment. Prevention of oral diseases plays a major role. Furthermore, dental practice equipment follows ergonomic demands and must today also comply with national or international regulations concerning safety and environmental aspects. Infection prevention and control regulations have considerably been tightened, which has direct impact on dental work and standards development. Dental products in general are in most countries regarded as medical devices and must comply with relevant national or international regulations. Finally, the dental market is becoming increasingly sophisticated with digital technologies providing 3D imaging, CAD/CAM milling and 3D printing of e.g. crowns and bridges. Recently, new technologies based on artificial intelligence entered the market and relevant standards are being developed in this area.

The global dental industry is a small subset of the medical specialty groups for general healthcare but is considered a highly lucrative, desirable, and competitive market. The multi-national nature of the dental industry and a high degree of regulatory oversight create the need for the development of international standards (for more details see below).

ISO TC/106 is developing standards with which manufacturers can comply to ensure that the dental products used in dentistry are safe for humans and for the environment and fit for their intended purpose. The public is increasingly concerned about the quality and safety of dental products that are placed into their bodies. Consequently, virtually all over the world, so-called medical devices, which includes most dental products, are subject to strict national or international legal regulations defining sets of essential requirements to be fulfilled before the medical device can be placed on the market. Standards are an important and legally recognized tool to show conformity with these requirements.

The ageing of the population, occurring in most developed countries, is another factor that influences the dental market. Many people will maintain good health to a greater age but will require some assistance for physical impairment, including dental rehabilitation, which will lead to changes in dental practice.

The exponential increase in the use of implants osseointegrated in the jaws e.g., as a foundation for the replacement of missing teeth has led to the development of new products and techniques. Dental implants are now integrated into many dental practices and the number of implants placed annually is increasing dramatically; this trend is expected to continue for some time. The same is true for dental CAD/CAM technologies. These include digital impression taking, computational design of the restorations and finally the manufacture of the restoration by 3D grinding or 3D

printing. These new developments are also reflected in a plethora of new dental products, and the ISO TC/106 has accordingly created a new subcommittee for this expanding area.

Public acceptance and appreciation of the importance of good oral health for optimal function, as well as the ability to create the best possible appearance, are important influences on the industry. They explain the interest in oral care and preventive materials, such as toothpaste and other fluoride containing products. There is also an increasing desire for aesthetic dentistry, which involves tooth-coloured restorative materials such as polymers, polymer-ceramic composites, and ceramics, as well as tooth-whitening products. Finally, minimal invasive concepts for longer-lasting restorations have been developed and have led to new treatment concepts based on adhesive dentistry.

Populations in developing economies/economies in transition present major oral healthcare challenges in terms of large patient numbers, disease patterns and healthcare resources. Their significant requirements currently differ from those of developed economies and will continue to develop and expand.

In line with the view of the World Dental Federation (FDI), protection of the environment and sustainable oral healthcare, including waste management, are the provision of equitable, ethical, high-quality, inclusive, and safe care with appropriate, effective and efficient use of resources. Through this, the healthcare opportunities of current and future generations are respected and protected by actively minimising negative environmental impacts. This includes sound waste management. In this context, ISO Guides 82 (Guidelines for addressing sustainability in standards) and 84 (Guidelines for addressing climate change in standards) are respected.

The relevant stakeholders include dentists, other providers of health care (private and public), dental industry and trade organizations, patients and consumers, government agencies, regulatory authorities, and certification organizations.

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 dental industry's manufacturing base is relatively small in global terms. It is, however, multi-national and consists of a few very large companies and a larger number of small companies. Dental products are generally of high added value so that the market, although small, is lucrative. In contrast, the market for oral care products used by the public is very large.

The following indicators are intended to provide quantitative information that demonstrates the scale of the industry in which ISO/TC 106 operates. The following data are based on available information from the International Dental Manufacturers (IDM) or from the internet and are the best estimates available.

- Prior to COVID, it was predicted that the scale of the global dental market would be US\$37 billion worldwide. The global dental market was forecasted for the 2021 financial year to be worldwide US\$36.32 billion. There was a market decline of 7.6% in 2020, compared to 2019.
- In 2016, the dental implants market was estimated at approximately US\$13 billion in the US alone, with Europe being the largest market, and further growth rates are expected. The

major factors expected to drive the market are the increased awareness of the benefit of good oral health and the resulting demand for optimally functioning and aesthetic tooth restorations.

- The global bioceramics market is forecasted to reach US\$27.3 billion by 2025, growing at a CAGR of 7.0% from 2017 to 2025. Bioceramics are used in dental applications such as dental implants and restorations.
- The global dental consumables market is projected to reach US\$55,584 million in 2023. The compound annual growth rate (CAGR) for the period 2022-2029 is projected to be 7.4%. Dental consumables make up 80% of the market, and the remaining 20% is dental equipment. Dental consumables include oral hygiene products, implants, orthodontic components, and a variety of materials for the restoration and maintenance of oral health.
- There are about 15 major international dental companies with annual sales ranging from approximately US\$200 million to US\$2 billion. The rest of the industry is comprised of 3,500 to 4,000 smaller companies worldwide. Recently, a large number of companies from the CAD/CAM sector has stepped into the dental market.
- The World Health Organization estimates that there are 1.9 million dentists and other dentistry personnel worldwide, although there is a wide variation in dentist to population ratio.
- Dental products are manufactured as medical devices and are subject to strict national or international legal regulations varying between countries and defining sets of essential requirements that must be met before a medical device can be placed on the market. Standards produced by ISO/TC 106 are recognized tools to demonstrate conformity with these requirements and contribute to improved quality of products and protection of the health and safety of dental patients, users, and the environment.

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

The key benefits already realized or expected from the work of ISO/TC 106 are:

- Improvements in the quality of oral products on the market.
- Improvements in the quality of oral care provided to patients.
- Reduction of barriers to trade.
- A growing international market with an increasing number of countries producing/using oral products.
- Provision of applicable and reliable tests for prediction of clinical performance.
- Protection of the health and safety of dental patients, users, and the environment.
- Uniformity of terminology used in dentistry.
- Provision of tools for the conformity with legal requirements.
- Improvement of sustainability in line with UN Sustainable Development Goals, including waste management, without compromising healthcare benefits.
- To contribute to the limitation or reduction of greenhouse gas emission and thus reducing dentistry's contribution to climate change.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Countries/ISO member bodies that are P and O members of ISO/TC 106

Representation of countries/ISO member bodies of ISO/TC 106 is shown in Table 1.

4.2 *Analysis of the participation*

The membership of TC 106 comprises 31 P-members and 16 O-members (Table 1). All countries with a significant dental industry are well represented within the Committee. Among P-members, two-thirds are developed countries with advanced economies and one-third are developing countries and countries with economies in transition. Active participation is reasonably balanced as all the major players in the industry are represented, but there could be a bias towards the European point of view in voting matters since European countries constitute over 60% of the TC 106 membership.

In recent years, increasing activities were observed in several Asian countries and ISO/TC 106 annual meetings have been organized in China, Hong Kong, Japan, Korea and Thailand. Furthermore, ISO/TC 106 standards have gained increasing importance in the US. Participation from South America is low. There is little participation from Africa; this lack of participation can probably be explained by the lack of a major dental industry.

Table 1: Member countries of ISO/TC 106 <developing countries not participating as much... NTS.>

Region	Advanced economies		Developing economies/ economies in transition	
	P members	O members	P members	O members
Africa	1	-	-	-
America	2	-	1	2
Asia	3	1	4	1
Europe	16	6	1	6
Middle East	-	-	2	-
Oceania	1	-	-	-

ISO/TC 106 works in close cooperation with its European counterpart, CEN/TC 55. The work programs of both committees have been fully aligned with the standards developed by ISO/TC 106 being simultaneously adopted by CEN/TC 55 under the Vienna Agreement.

ISO/TC 106 has liaisons with other ISO Committees as follows:

- IEC/TC 62 Medical equipment, software and systems
- ISO/TC 150 – Implants for surgery
- ISO/TC 150/SC 7 - Tissue-engineered medical products
- ISO/TC 156 – Corrosion of metals and alloys
- ISO/TC 159/SC 1 – General ergonomics principles
- ISO/TC 159/SC 3 – Anthropometry and biomechanics
- ISO/TC 170 – Surgical instruments

- ISO/TC 194 – Biological and clinical evaluation of medical devices
- ISO/TC 210 – Quality management and corresponding general aspects for medical devices
- ISO/TC 215 – Health informatics
- ISO/TC 217 – Cosmetics
- ISO/TC 304 - Healthcare organization management

ISO/TC 106 is also in liaison with:

- European Commission (EC)
- FDI World Dental Federation (FDI)
- Federation of the European Dental Industry (FIDE)
- International Association for Dental Research (IADR)
- International Dental Manufacturers (IDM)
- World Customs Organization (WCO)
- World Health Organization (WHO)

Further to these liaisons, ISO/TC 106 has formalized an agreement with the FDI World Dental Federation (FDI), in which FDI endorses the use of ISO standards for dental practise. Furthermore, close cooperation between the two organizations will help towards priorities of ISO/TC 106.

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

5.1 *Defined objectives of the ISO/TC*

ISO/TC 106 has the following objectives:

To develop international standards that are congruent with the scope of the Committee, which is standardization in oral care including terms and definitions, performance, safety and specification requirements of dental products and clinically relevant laboratory test methods, all of which contribute to improved global health.

- To revise or withdraw all other standards that are the responsibility of TC106 as per ISO periodic review procedures.
- To develop standards that stay current and evolve as the practice of dentistry evolves.
- To develop standards that make the best possible use of available scientific data.
- To be vigilant in harmonizing standards for similar types of products.
- To develop standards based upon function, utilization, and safety/environmental requirements rather than on chemical and/or physical properties.
- To develop standards, which take environmental aspects and those of sustainability into account as well as the challenges of limitation or reduction of greenhouse gas emissions.
- To continue to ensure that the make-up of working groups is balanced and includes the best experts as well as representation from all stakeholders.

- To ensure that vested interests never dictate the development of dental standards.

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

The strategies adopted to reach the above objectives include the following:

- Develop more international experts and provide support.
- Maintain, develop, and if necessary, add to the current liaisons.
- Continue to work in close co-operation with CEN/TC 55 and make maximum use of the Vienna agreement processes to develop common documents.
- Ensure that new work item proposals are justified in terms of market need, patients' safety and environmental aspects and to avoid any overlap with existing standards or those in preparation/revision.
- Critically review existing standards and revise or withdraw as justified.
- Encourage educational initiatives in dental schools, dental professional organizations and dental industrial settings to promote better knowledge, understanding and appreciation of the value of dental standards.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

Regarding the completion of ISO work items, the major factor that may have an effect is the availability of financial resources to support the participation of delegates. In the current economic climate, the member countries and technical experts are very sensitive to the cost of voluntary participation, which could lead to difficulty in ensuring sufficient involvement. This is a continual problem, which makes it essential that the work programme be relevant.

The overall planning of the schedule of meetings may at times be problematic for countries having a small number of delegates wishing to participate in working group meetings that run concurrently. Due to the growing number of working group meetings, it is not always possible to arrange the overall timetable to avoid conflicts amongst experts sitting in the various sub-committees and working group meetings of interest to the member bodies.

In early 2020, the COVID-19 pandemic and the resulting stay-at-home orders led to significant changes in the way people work. Where ISO/TC106 once held international standards meetings on an annual basis in person, the TC suddenly had to adapt to a virtual environment to conduct business. This brought both challenges and opportunities. Examples of how the mandatory use of video conferencing as a means of communicating was challenging for some included learning a new technology, the stability of personal internet service, concerns about active engagement by participants in various time zones, and the quality of the meeting without disruptions, to name a few. That being said, it also brought opportunities for those who never had the opportunity, such as those from developing countries, to participate in standards meetings due to restrictions and cost of travel

to in-person meetings. Those members now were on a level playing field in the development of standards with their fellow member bodies. The future of standards development is ever evolving; however, this unique time had a profound impact on how work is completed.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC 106

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 Structure of the ISO committee

The structure of TC 106 is outlined in Table 2. All decisions taken by the subcommittees are reported to at the TC 106 Plenary session, which takes place at the end of the annual TC106 meeting.

Furthermore, TC 106 has installed a Chairman's Advisory Group (CAG), which meets at the beginning of the TC 106 annual meeting and at least 3 more times (quarterly) throughout the year. This ensures mutual information sharing of the subcommittees and avoids possible conflicts or overlap between the subcommittees. General points of interest are discussed, coordinated, and agreed upon such as external liaison requests, definition of subcommittee scopes or New Work Item Proposals and any other new activities.

Table 2: ISO/TC 106 Structure

<u>ISO/TC 106</u>	Dentistry
<u>ISO/TC 106/SC 1</u>	Filling and restorative materials
<u>ISO/TC 106/SC 2</u>	Prosthetic materials
<u>ISO/TC 106/SC 3</u>	Terminology
<u>ISO/TC 106/SC 4</u>	Dental instruments
<u>ISO/TC 106/SC 6</u>	Dental equipment
<u>ISO/TC 106/SC 7</u>	Oral care products
<u>ISO/TC 106/SC 8</u>	Dental implants
<u>ISO/TC 106/SC 9</u>	Dental CAD/CAM systems

All SC's have several WGs (approximately 51 WGs and 5 ad hoc committees total), on different subtopics, under the umbrella of ISO TC 106, three Working Groups have been established taking care of overarching topics:

- WG 10 – Biological evaluation
- WG 12 - Dental implant surgical guide

- WG 13 - Dentistry — Artificial intelligence (AI) based 2D X-ray analysis — Data generation, data annotation and data processing

7.2 Standards and/or projects under the direct responsibility of:

(Click on filters to view standards under development or published standards)

[ISO/TC 106](#)

[ISO/TC 106/SC 1](#)

[ISO/TC 106/SC 2](#)

[ISO/TC 106/SC 3](#)

[ISO/TC 106/SC 4](#)

[ISO/TC 106/SC 6](#)

[ISO/TC 106/SC 7](#)

[ISO/TC 106/SC 8](#)

[ISO/TC 106/SC 9](#)

Information on ISO online

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

[**ISO TC 106 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 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**](#)