International Standards in Dentistry

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This invited commentary describes the development of dental standards activity, how it functions within ISO, and the challenges it faces.

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Editor-in-Chief

Although specifications for materials such as gold and silver alloys have a long history,[1] the need for a wide range of standards is relatively modern. Traditionally, craftsmen depended on their skills to select appropriate materials from a limited range, and the technology for testing them was lacking. The development of science and the emergence of the industrial revolution created the need for standards that could meet requirements, specifications, guidelines, or characteristics and that could be used consistently to ensure that materials and products were suitable for their intended use. Standards activity also began to embrace processes and services. Without these, materials and devices might fail to function as intended, have variable and undefined properties, perform incorrectly, and be potentially hazardous. Today, the characteristics of a vast array of products are influenced by standards. As clinicians we assume that a dental bur will fit a handpiece or that an impression material is both accurate to a defined level and non-hazardous to our patients and the dental team. The field of standards preparation is complex and this paper principally focuses on the work of the International Organization for Standardization (ISO), the world's largest developer of voluntary international standards. Reference is also made to those bodies with which it liaises.

The preparation of standards has a long and complex history, which, in its broadest sense, may include legal requirements enacted by the state. Standards are usually prepared for voluntary adoption, although a government may give them legal authority. Their preparation typically involves manufacturers, trade associations, learned societies, and standards bodies so as to develop a balanced approach.

Whenever a special interest group is involved solely in writing a standard there is a risk of their bias influencing the outcome by excessive emphasis on their specialist views or a desire to manipulate markets. For example, there was a significant difference of opinion in the 1870s in the United States between steel manufacturers and a railroad company that wished to use a standard for steel rails it had developed. An engineer and a prosthodontist may have very different views on the design of a clinical instrument such as a torque wrench.

It, therefore, became evident toward the end of the 19th century that qualified, multidisciplinary bodies were required to identify needs and prepare and maintain standards, with a remit to achieve a consensus agreement between producers and end users. The authors also needed to work within a defined framework to ensure that the process was fair. The writing of a standard is, however, a complex process, as it requires an understanding of its aims and objectives, the feasibility of its development, its applicability, and the cost of its application. A standard, once written, also requires regular maintenance.

The formation of the International Association for Testing Materials (IATM) was followed in the USA by the creation of an American section in 1898, a forerunner of ASTM International[2] (Table 1). In Britain, the Council of the Institution of Civil Engineers formed a committee in 1901 to consider standardizing iron and steel sections, a body that eventually evolved into the British Standards Institution (BSI) in 1931, being officially recognized in 1942 as the sole organization for issuing national standards.

The industrialized wars of the 20th century saw a growing interest by governments in standards development for the vast quantities of products they were purchasing, and the state has continued to refer to defined standards in its decisions. In recognition of the need for an independent national standards framework, most countries gradually introduced their own responsible bodies, although the roles of other organizations can still be significant. The involvement of professional societies and trade associations in the preparation of guidelines and standards has been considerable, either in their own right or by contributing to the work of the national standards body. In the United States the American National Standards

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Table 1 Abbreviations

ADA	American Dental Association
ANSI	American National Standards Institute
ASTM	ASTM International (formerly known as the American Society for Testing and Materials)
BSI	British Standards Institution
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
EC	European Commission
ETSI	European Telecommunications Standards Institute
FDI	FDI World Dental Federation
FIDE	Federation of the European Dental Industry
IADR	International Association for Dental Research
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
WCO	World Customs Organisation
WHO	World Health Organization

Institute (ANSI) serves as administrator and coordinator of the US private sector's voluntary standardization system and currently accredits some 200 of these standards developers. The American Dental Association, for example, began work in this field in the early part of the 20th century and develops and publishes standards for which it has a team of 40 voting members and 60 working groups. The standards on titanium produced by the ASTM are familiar to many prosthodontists.[3]

While there is a tendency to think of standards as pertaining to materials or devices, there is increasing interest in processes; for example, the comprehensive ISO 9000 series of standards is concerned with quality management. The digitization of dentistry is requiring consideration to be given to computer-aided design/computer-assisted manufacture (CAD/CAM) technology, computer software, and digital imaging, and dental informatics is now a significant area in standards development. Similarly, the interest of some legislatures in tracing the use of individual surgically implanted devices will need the development of terminology, systems, and standards for doing so.

With international trade ever-expanding, it became important to make standards global. This meant that it was possible for internationally recognized standards to be written that could be suitable for a wide range of markets. The worldwide cooperation that this required also enhanced standards quality and stimulated the development of international bodies, which required their own networks to maximize interdependence. The ISO committee concerned with dentistry (ISO/TC 106) has particular links with the FDI World Dental Federation (FDI), World Health Organization (WHO), International Association for Dental Research (IADR), Federation of the European Dental Industry (FIDE), and World Customs Organization (WCO).

International Organization for Standardization

A group of 65 delegates from 25 countries met in London in 1946 to consider the future of international standardization, and in 1947 the ISO officially came into existence. Initially, the organization comprised 67 groups, called technical committees (TCs), each of which focused on a specific subject. Currently, there are 289 TCs, which are numbered consecutively in order of creation, dentistry being TC 106. There is also a joint technical committee with the International Electrotechnical Commission (IEC). Prosthodontists with an interest in screwed joints may like to note that TC1 is titled Screw Threads.

The ISO is based in Geneva, Switzerland, and is the world's largest developer of voluntary international standards, with members from 161 countries and a staff of about 150. It collaborates with more than 700 international, regional, and national organizations.

TC 106 (dentistry) was established in 1962 and has as its scope standardization in oral health care, including:

- Terms and definitions
- Performance, safety, and specification requirements of dental products
- Clinically relevant laboratory test methods, all of which contribute to improved global health.

The committee has 27 participating countries and 17 observer countries (Table 2) and is arranged in a hierarchical fashion with 9 subcommittees (SCs) and 1 working group (Table 3), whereas the subcommittees themselves have working groups established to address specific topics. The total number of published ISO standards related to the TC and its subcommittees is 168, as of 2014—including updates.

The committee is involved in identifying the need for new standards and, upon agreement by international consensus, preparing these new standards using an ISO-defined schedule. Existing standards also need to be reviewed and, when necessary, revised on a regular basis. The committee has a strong international membership, with colleagues drawn from industry, academic and clinical dentistry, and dental technology. Members work via email most of the year, then gather for a 1-week annual meeting in a different country each year. These meetings have tight

schedules based around individual working groups, which report upwards through their subcommittees to TC 106 itself. Working groups from different subcommittees sometimes also meet jointly to explore topics of mutual interest, for example, terminology and dental implants.

TC 106 also liaises with several other TCs as well as with the European Commission (EC), FDI, FIDE, IADR, WHO, and WCO.

Principles of Standard Development

The ISO has four key principles for standard development [4]:

1. ISO standards respond to a need in the market, usually in the form of requests from industry, consumer groups, or others involved in the field.
2. ISO standards are based on global expert opinion. This is the basis of the TC's activities, which include the standard's scope, key definitions, and content.
3. ISO standards are developed through a multistakeholder process.
4. ISO standards are based on a consensus-based approach.

Stages of Standard Development

The development of an international standard reflects an agreement between ISO and its member bodies. Such standards may be implemented by incorporation into national standards in different countries or used as written.

The process of developing a standard follows an agreed procedure comprising six steps, with the work being carried out by ISO technical committees and subcommittees.[5]

1. Proposal stage. The process of developing an international standard begins with confirmation that such a standard is needed. It is common for suggestions made informally in working groups (WGs) and SCs to be initially explored by these groups. This can result in a clearer understanding of the project and its parameters, an indication of likely support and resolution of any major concerns. A new work item proposal (NP) is then prepared and submitted for vote by the members of the relevant TC or SC to determine whether this proposal should be included in the work program.

A proposal is accepted if a majority of the P-members of the TC/SC votes in favor and at least five P-members declare their commitment to participate actively in the project. A project leader responsible for the work item would normally be appointed at this stage.

Table 2 ISO/TC 106 Participating and Observing Countries (Standards bodies)

Participating countries	Observing countries
Australia (SA)	Argentina (IRAM)
Austria (ASI)	Belarus (BELST)
Belgium (NBN)	Brazil (ABNT)
Canada (SCC)*	Cuba (NC)
China (SAC)	Czech Republic (UNMZ)
Finland (SFS)	Greece (ELOT)
France (AFNOR)	Hong Kong (ITCHKSAR)**
Germany (DIN)	Hungary (MSZT)
India (BIS)	Malaysia (DSM)
Iran, Islamic Republic of (ISIRI)	Poland (PKN)
Ireland (NSAI)	Romania (ASRO)
Israel (SII)	Serbia (ISS)
Italy (UNI)	Slovakia (SUTN)
Japan (JISC)	Syrian Arab Republic (SASMO)
Korea, Republic of (KATS)	Tunisia (INNORPI)
Mongolia (MASM)	Turkey (TSE)
Netherlands (NEN)	Ukraine (DTR)
Norway (SN)	
Portugal (IPQ)	
Russian Federation (GOST R)	
Saudi Arabia (SASO)	
Spain (AENOR)	
Sweden (SIS)	
Switzerland (SNV)	
Thailand (TISI)	
United Kingdom (BSI)	
United States (ANSI)	

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Table 3 TC 106 Subcommittees and Working Group

Subcommittee/ Working group*	Title
ISO/TC 106/WG 10	Biological evaluation
ISO/TC 106/SC 1	Filling and restorative materials
ISO/TC 106/SC 2	Prosthodontic materials
ISO/TC 106/SC 3	Terminology
ISO/TC 106/SC 4	Dental instruments
ISO/TC 106/SC 6	Dental equipment
ISO/TC 106/SC 7	Oral care products
ISO/TC 106/SC 8	Dental implants
ISO/TC 106/SC 9	Dental CAD/CAM systems

* Subcommittees also have their own working groups.

Table 4 ISO Liaising Organizations—TC 106

Name	Abbreviation
European Commission	EC
FDI World Dental Federation	FDI
Federation of the European Dental Industry	FIDE
International Association for Dental Research	IADR
World Customs Organization	WCO
World Health Organization	WHO

2. Preparatory stage. The preparation of a working draft of the standard is usually entrusted to a group of experts appointed by the TC/SC and chaired by the project leader. This is usually an iterative process until the group is satisfied that the best technical solution has been achieved. This first committee draft would then be forwarded to the group's parent committee for development of an agreed-upon document in the committee stage.

3. Committee stage. When a first committee draft is available, it is registered by the ISO Central Secretariat and circulated for comment and, if required, voting, by the P-members of the TC/SC. This process may involve preparation of several committee drafts in succession before consensus is reached on the technical content. The text is then finalized for submission as a draft international standard (DIS).

4. Enquiry stage. The ISO Central Secretariat circulates the DIS to all ISO member bodies for voting and comments within a period of 3 months. The DIS can be approved for submission as a final draft international standard (FDIS) if there is a 2/3 majority of P-members and not more than 1/4 of the votes cast are negative. If not approved, the text is returned to the originating TC/SC for further development, following which a revised document will again be circulated for voting and comment as a DIS.

5. Approval stage. This stage is optional, as the leadership of the committee preparing the standard can decide to proceed to publication if the DIS approval criteria are met.

More usually the FDIS is circulated to all ISO member bodies by the ISO Central Secretariat for a final Yes/No vote within 2 months. Additional technical comments are no longer considered at this stage but are retained for future discussion when revising the standard. The text is approved as an international standard using the same voting criteria as at the enquiry stage. If rejected, the document is referred back for further work based on the submitted comments.

6. Publication stage. Following approval of an FDIS, only minor editorial changes, if and when necessary, are made in the text. This is then sent to the ISO Central Secretariat for publication as an international standard.

FDI World Dental Federation

The FDI, which was founded in 1900, occupies a role as the principal representative body for more than 1 million dentists worldwide and has a very wide range of activities. It has official relations with the WHO and links with other major entities, being one of the organizations with which TC 106 liaises (Table 4). The FDI has been active in standards development since before ISO/TC 106 was established, a process in which it was involved. All nine existing FDI specifications were subsequently adopted as ISO standards in 1966, and in 1977 agreement was reached on responsibilities for standards.[6]

European Committee for Standardization

The European Committee for Standardization (CEN) was officially created as an international nonprofit association in 1975, with a mission to foster the European economy in global trading, the welfare of European citizens, and the environment.

CEN is a major provider of European standards and technical specifications, and is the only recognized European organization for the planning, drafting, and adoption of European standards with the exceptions of electrotechnology (CENELEC) and telecommunication (ETSI). CEN has a wide range of committees including TC 55 Dentistry.

CEN and ISO signed the Vienna Agreement in 1991, which aimed to prevent duplication of effort when preparing standards and to maximize efficiency in the processes. Consequently, new standards developments are jointly planned between the two bodies, and the agreement supports coordination, technical cooperation by correspondence, cross-representation at meetings, and adoption of the same text as both an ISO standard and a European standard.

A European standard (EN) has a unique status because it is also required to be used as a national standard in each of the member countries, with any conflicting national standards being withdrawn.

World Health Organization

This organization's constitution came into force in April 1948, and it has an extensive range of activities, including the preparation of standards embracing, for example, food safety, health metrics, medical devices, health statistics, and health information systems. The organization has recognized that there is a need for a global nomenclature system for naming medical devices that could be used in a wide range of tasks and is currently working on an extensive project to develop this. The parallels with some areas of TC 106 activity underline the importance of ongoing liaison.

Future Developments

International standards can bring a range of benefits, including enhanced customer satisfaction, cost savings, access to new markets, increased market share, and environmental benefits. There will therefore be a growing need for standards development and maintenance with pressures to make these global, whenever possible. This will require increasing collaboration, particularly across traditional boundaries between disciplines, and perhaps the emergence of new bodies such as the International Medical Device Regulators Forum (IMDRF). This is an international voluntary group of medical device regulators building on the work of the Global Harmonization Task Force on Medical Devices (GHTF), with representatives from medical device regulatory authorities in Australia, Brazil, Canada, China, the European Union, Japan, and the United States, together with the WHO.

The needs of the various stakeholders will have to be reconciled because industry, health care professionals, and researchers may have differing views. This is important in emerging technologies where the premature development of standards can restrict innovation, while a less structured arrangement can result in inferior goods, incompatibility between systems, and a lack of criteria against which to judge products.

Pressures to expand data collection for a wider range of clinical activities, the digitization of dentistry, including the replacement of physical artifacts with digital analogues, computer-controlled fabrication techniques, robotic devices, and dental informatics, will all create challenges if dental care professionals are to work effectively in an increasingly complex environment.

Standards development may be seen by some as an astringent environment, yet it will be increasingly important in the care of our patients and an area in which support from the dental care professional will continue to be essential.

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George Zarb Receives CDA Medal of Honour

The Canadian Dental Association recently awarded Dr George Zarb, IJP editor-in-chief, the CDA Medal of Honour. The highest award the association confers, the Medal of Honour is given to a dentist in recognition of a lifetime of outstanding service and professional achievement to the benefit of the dental profession, the dental community, and society at large, and to whom significant change can be attributed. The breadth and scope of achievement are significant factors in granting this award, as are the individual's contributions to the goals and objectives of CDA. Dr Peter Doig, CDA president, is shown with Dr Zarb *(right)* during presentation of the award at the CDA Executive Meeting in April in Ottawa, Ontario, Canada.