DENTAL MATERIALS 27 (2011) 619–621

available at www.sciencedirect.com

ScienceDirect

journal homepage: www.intl.elsevierhealth.com/journals/dema

Editorial Review

International dental standards—Order out of chaos?

ARTICLE INFO

Keywords:
International standards
Research methodology
Dental materials
Oral and craniofacial biomaterials

ABSTRACT

The history, scope, structural components, generation, and purpose of international dental standards are concisely surveyed by three researchers active in standards development.

Significance: Standards have an important role to play within dental materials research alongside more specialist scientific instruments and methods. For all that are concerned with the wider business and safety issues of manufacture, marketing, selection and use of dental biomaterials and devices, knowledge of the vital role of standards is indispensable.

> *"A good student reverences books;*
> *a better student is more critical of them!"*

This dictum is also applicable to our appreciation and use of national and international standards. At one extreme there are dental material researchers who totally ignore such standards, at the other are investigators who treat them as the final word in research methodology. The aim of this Editorial Review is to promote understanding, informed discussion and appropriate use of international standards in the conduct and reporting of research on dental materials and devices.

There are several interrelated topics to be considered, including the history, definition, scope, structural components, generation, several uses and main purpose of dental standards. The last topic (purpose) addresses the question: What are Standards for? In the view of the late Dr. John Stanford, former Chairman of ISO/TC106:

> "Standards serve a variety of market-perfecting purposes. They provide the basis for comparison of products and establish consistent terminologies through standard definitions, measures, and test procedures. They promote compatibility of products used in systems, thereby reducing the ranges of variety of products. Not only do they assure desired qualities and performance levels, they reduce low quality by providing consumers with an easy check on individual producer quality claims, thereby increasing consumer welfare. As a result, standards can enhance the overall image of industry. The use of standards increases buyer confidence about product quality and in turn may very well increase overall demand for the product, reflecting buyer preference regarding quality. Standards provide for transfer of technologies throughout industry and facilitate introduction of innovation by reducing market and technical risks. They provide the industry with an important marketing tool". [1]

The leading current standards are from the *International Standards Organization* (ISO) and *ASTM International*, known prior to 2001 as the *American Society for Testing and Materials* (ASTM). The ASTM was formed in 1898 by chemists and engineers from the Pennsylvania Railroad. At the time of its establishment, the organization was known as the American Section of the *International Association for Testing and Materials*.

The ISO is the world largest standards developing organization. It was born from the union of two organizations – the ISA (*International Federation of the National Standardizing Associations*), established in New York in 1926, and the UNSCC (*United Nations Standards Coordinating Committee*), established in 1944. Aiming "to facilitate the international coordination and unification of industrial standards", the new organization, ISO, officially began operations on 23 February 1947. Since then, ISO has published more than 18,500 International Standards, ranging from standards for activities such as agriculture and construction, through mechanical engineering, to medical and dental devices, to the newest information technology developments.

In addition to ISO and ASTM standards, the *American Dental Association* (ADA), the accredited dental standards body of the *American National Standards Institute* (ANSI), also publishes dental standards.

A description is perhaps more useful than a formal *definition* of a Standard. Dental Standards are documents designed to assess relevant properties of a product to see whether it meets acceptable requirements for safe and effective use. The *scope* of products addressed by dental standards includes

devices, such as hand-held instruments, equipment and curing lights (powered polymerization activators), as well as oral care products and a wide range of oral biomaterials for direct and indirect restorations. The latter include laboratory materials. In recent years ISO/TC106 has expanded its activities into new technologies such as dental implants and CAD/CAM and is addressing environmental issues such as amalgam waste as well as infection control. In developing these standards this committee is increasing emphasis on clinical relevance and product performance in order to address the needs of the clinician and the consumer. One useful distinction is between '*vertical*' and '*horizontal*' standards. The former denotes a standard concerned, for example, with a specific material type. The latter specifies test methods, such as assessment of color stability (ISO standard 7491 or ANSI/ADA standard 80), that can be applied 'across the board' to many different materials such as resin-composites and denture materials when exposed to light and water.

Within each Standard document, the first priority is to state the *scope* of that standard (for example, the particular *class or classes* of dental cements under consideration), also followed by necessary *definitions*. Other key *components* are *normative references* to associated foundational standards, commonly including those that address biological safety requirements. This means that biological safety can often be considered separately from physical, mechanical and chemical properties, etc. Major sections on property *requirements* then follow. These embody minimum *performance limits* (for example, strength values in MPa). The question of *sampling* is usually addressed, followed by the major sections on *Test Methods*. These vital methodological sections describe exactly how test specimens are to be fabricated, followed by exact measurement procedures including the equipment required (often illustrated with diagrams), control of environmental parameters, number (n) of repeat measurements and the *treatment of results*. The final sections of Standards deal, where appropriate, with presentational and marketing issues: *Packaging, marking and information to be supplied by the manufacturer* as well as *Manufacturer's instructions and information for the user*.

How are dental standards *generated?* In respect of ISO dental standards, there has been since 1963 an overseeing ISO *Technical Committee* (TC), namely ISO/TC106, which has published more than 150 dental standards. This is administered by a Secretariat, currently held by Canada, through its standards organization (SCC). TC106 is currently divided into seven *Sub-Committees* (SC), each with their own Secretariat, that are further divided into *convenor*-led *Working Groups* (WG), which produce drafts of one or more standard documents. When these drafts have reached a definitive status they are released for voting and comments by the national bodies represented in TC106. The work of TC106 is divided between an intensive 6-day annual conference and communication between participants throughout the year.

Approximately 25 nations are Participating ('P') Members of ISO/TC106, each appointing expert voting delegates to the respective SCs and WGs. Eighteen other countries have 'Observer' ('O') status, without voting rights. Thus an important difference exists between the international, yet relatively 'closed' nature of the delegate groups, and the completely open nature of the international scientific community. The overall expertise within ISO/TC106 is drawn from the industrial, technical and business sectors and includes academic and clinical scientists, representatives of government agencies, testing laboratories, consumer associations, and non-governmental organizations.

This complex mix of nations and professional expertise often requires a high degree of diplomacy in securing agreement about issues of test methods and test limits within a particular WG or SC. It is quite common for divergence of judgment to arise about such matters and compromise solutions have to be found by majority vote. The resulting standards documents bear no trace of the intensive discussions that often precede publication. Certainly, intense and protracted intellectual effort goes into the creation and revision of standards. ISO standards generally reflect the status of the commercial market. It is extremely rare for a test limit to be set that would exclude a material already established on the market. When this has happened it sometimes precipitates a round of lobbying by the industrial companies affected to get this changed.

Standards documents and their production are not directly intended to involve original research, although this depends upon the definition of 'research'. It is common for 'round-robin' inter-laboratory testing to take place within WGs, to help establish performance-limits for particular properties of a given class of material or device. One major constraint is that the test-methods developed should not be more complex or sophisticated than is strictly necessary. The resources required should be available to reasonably equipped international test-houses. Hence, to our knowledge, no test methods require the use of equipment such as scanning electron microscopes, X-ray tomography or NMR spectrometers, even though use of such instrumentation is well represented in leading-edge dental materials science. A further constraint is that the time-scale of measurements is restricted. This is so that Test Houses can complete the required measurements within a reasonable time period. For example, ISO 4049 requires water-sorption and solubility measurements to be conducted over a period of 7 days immersion (excluding conditioning and re-conditioning). However, in original research, as distinct from product testing, much longer immersion periods over several months are often necessary. This is governed by the inherent physico-chemical behavior of materials, rather than by the urgencies of business time-lines. Thus the application of standards 'to the letter' is sometimes one step further removed from clinical reality than is the best available *in vitro* research.

Using the distinction recently made by Dr. Jack Ferracane between 'State of the art' and 'Standard of care' [2] dental standards are more orientated to the latter concept, whereas original research is more orientated to the former.

It follows that Standards should be used intelligently. Regulatory use requires their application to the letter, whereas in pure research there may – and sometimes must – be creative extension of the standards methodologies. Moreover, Standards are not designed to establish which is the 'best performing' material for a given clinical application. At the lowest level they are designed to exclude unsafe and poorly performing materials from the market. Nevertheless, where suitable standards – or component methods – are available, their use and citation is to be encouraged by researchers. Since so many well-researched and clinically relevant stan-

dards are now available either from the ISO website (iso.org) or through national standards bodies (e.g. ABNT, in Brazil) it is apparent that their appropriate use should be expected in research involving their scope of application. In the USA, existing standards are used in evaluation of dental products for clinicians in the *Professional Product Review* (available by subscription from ADA) and for development of new clinically relevant test methods for such evaluations. As a result, editors of dental publications may request whether standards have been used in research studies involving new or existing technologies.

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8 April 2011

0109-5641/$ – see front matter

doi:10.1016/j.dental.2011.04.004