'Few dentists realise how many international dental standards are involved in a routine root canal procedure.'

International dental standards

International dental standards are vital in maintaining the safety and quality of both the products and materials used by dental professionals and the many oral health products used by members of the general public, yet many dentists will be unaware of the role standards play in their daily practice. In this article, **Derek W. Jones** *outlines the vital work of the International Standards Organization and highlights how standards pervade nearly every dental procedure.*

With millions of dental products sold worldwide, the development of international dental standards is important to assure the safety and quality of those products. The dental committee of the International Standards Organization (ISO/TC 106) has already developed some 156 dental standards. International standards facilitate international trade in dental products and manufacturing, which has now reached €10 billion annually; these standards help to make available a wider range of dental products around the world. ISO dental standards play a vital role in contributing to the quality and safety of products used by dental healthcare professionals in dental treatments as well as the oral hygiene products used on a daily basis by the public.

The ISO/TC 106 committee has 46 member countries (25 actively participating and 21 observing). In addition to the full technical committee there are seven sub-committees and some 44 working groups, which have input and participation from close to 300 international dental experts from the member countries. ISO's dental standards committee works closely with the European Union, illustrated by the fact that a total of 123 ISO standards were accepted (as EN ISO standards) by the European Standards Committee CEN/TC 55 as of August 2006. In addition, the ISO committee also collaborates with the World Dental Federation (FDI) and the World Health Organization (WHO).

HOW MANY DENTAL STANDARDS?

Few dentists realise how many international (ISO) dental standards are involved in a routine root canal procedure. The use of materials and equipment involved in this one procedure are covered by more than a dozen ISO dental standards to clean, shape and seal the root canal.

Leaning over the patient in the dental chair, illuminated by a dental light which complies with the ISO standard and with the sound of the drill and the suction equipment – both pieces of equipment which may comply with the international standard, the dentist's thoughts are no doubt far away from the ISO standards for the equipment, devices and materials which ensure the quality and safety of the procedure.

What may be more surprising to many dentists is the fact that more than 20 ISO dental standards, involving definitions, codes and designations, materials, devices and equipment, are used for the production and placement of an anterior jacket crown. An ISO designated system is used to record the location of each tooth in a patient's dental chart and shaping the preparation for the crown requires a variety of instruments conforming to ISO standards.

In addition to performance standards, extensive coding systems are used to classify rotary instruments, with limits for bore sizes and dimensions for discs, wheels and cutting burs. ISO standards have been developed for impression materials, die materials, casting alloys for copings as well as for ceramic materials. The various materials used are also covered by ISO biocompatibility tests and in order to comply with ISO specifications, the metal used for the coping has to also conform to the standard for corrosion. The luting cements used to seal the crown in place are also covered by ISO standards. If the product you are using has a statement on the package that it meets the relevant ISO

'Some 40 documents for standards development were being voted on by member body countries of ISO/TC 106 during a three-month period May-July 2007.'

standard, the company's product must have been evaluated to comply with the various specifications.

STANDARDS DEVELOPMENT ACTIVITY

Many dentists would be surprised at the level of standardisation activity of the ISO/TC 106 dental committee program. An indication of this level can be gained by the fact that some 40 documents for standards development were being voted on by member body countries of ISO/TC 106 during a three-month period May-July 2007. Surprisingly, this level of activity is fairly typical for the workload of the ISO/TC 106 dental committee. The publication of an ISO Standard requires that 75% of the member bodies (countries) casting a vote must support the document. The year 2007 should see the first international standard ever to be published for an orthodontic device. This standard is ISO 21606, which deals with orthodontic elastics. The orthodontic elastics covered in this standard comprise elastic bands, chains, links, thread and ligatures used in orthodontics both inside and outside the mouth in conjunction with fixed and removable appliances. The ISO standard for orthodontic elastics was developed as a result of the difficulty often encountered by clinicians in making meaningful comparisons between different elastomeric products when using the information currently available from manufactures and suppliers.

An important ballot was conducted during April-June 2007 for a technical specification dealing with corrosion of dental amalgam. The development of this technical specification was the result of worldwide demand for test methods to determine acceptability of dental amalgams for oral restorations in relation to corrosion and mercury vapour release. Test methods for corrosion have previously been standardised in the document ISO 10271 for dental metallic materials in general, however, these tests methods are not suitable for amalgam due to the formation of precipitates during the test; furthermore, ISO 10271 does not cover measurement of mercury vapour release during corrosion of amalgam.

It should be noted that a 'technical specification' is a precursor in the development of some standards, in cases where insufficient data is available to develop an international standard. An ISO technical specification requires approval of two thirds of the members of the committee casting a vote. A technical specification is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an international standard, or withdrawn. The ISO/TS 17576 corrosion document is entering its second three-year term; if it is confirmed it must be reviewed again in three years time when it MUST be either transformed into an international standard or withdrawn.

Balloting was also taking place in June-July 2007 for a draft international standard for denture base polymers (DIS 20795-1). This international standard classifies denture base polymers and co-polymers and specifies their requirements and the test methods used to determine the requirements. A committee draft for denture soft lining materials was also voted on in May 2007.

An important standard dealing with codification and data exchange (ISO/FDIS 16059) was balloted with the vote terminating in May 2007. As long ago as 1983, FDI, WHO and ISO adopted a system that would serve as a basis for the digital coding of oral health care: the 'oral status and intervention index' (OSI index). One of the purposes of codification is to facilitate information exchange regardless of the language. Communication can be enhanced by the use of standardised abbreviations or codes, allowing the interpretation and transmission of a message. This international standard (ISO/FDIS 16059) defines the elements of syntax, including the structure and associated content, for the purpose of coded data exchange and the need for harmonising existing and future codifications.

Another very important draft standard being balloted during June-July 2007 was a revision of ISO/DIS 3950, a standard used by most of the 800,000 dentists worldwide. This document deals with the designation system for teeth and areas of the oral cavity. The increasing use of computers to store information, together with the increasing necessity for the communication of dental information by wire, printed documentation and orally, has required that new basic elements be taken into consideration for drawing up a designation system for teeth. The system described in this international standard was originally drawn up by FDI, and approved by WHO and the technical committee ISO/TC 106 in order to satisfy the following requirements:

a) Simple to understand
b) Easy to pronounce in conversation and dictation
c) Readily communicable to print or by wire
d) Easy to translate into computer 'input'
e) Easily adaptable to standard charts used in general dental practice.

This ISO/DIS is a draft circulated for comment and approval; this second edition will cancel and replace the 23-year-old first edition of ISO/DIS 3950, which has been technically revised.

A standard for single-use cartridges for local anaesthetics, as well as a large number of standards dealing with hand-

'Dental standardisation involves a diverse range of stakeholders: dental professionals, dental manufacturers, government agencies and the ultimate consumer – the patient...'

held instruments, were being balloted with closing dates in June 2007. A total of nine standards dealing with rotary instruments and handpieces, as well as a further seven standards for the number coding systems for rotary instruments and standards for excavators and explorers, were also voted on in June-July 2007. The important items of dental office equipment, the operating light (ISO/FDIS 9680), the important draft standard for the revision of amalgam separators (ISO/DIS 11143), a standard dealing with the general requirements for dental units (ISO/7494-1), a standard for compressor systems and a standard dealing with the curing lights for resin systems (ISO/10650-1) all came up for voting in May-June 2007.

Many dentists will be pleased to know that a standard for materials to be used for dental equipment surfaces (ISO 21530), which are very important in the modern dental office, was balloted in June 2007. All surfaces used for external and touchable parts of dental equipment, which require disinfecting since they can be contaminated by aerosols, splatters and droplets in normal use, should be capable of undergoing disinfection without deterioration or discoloration when using relevant disinfection agents recommended by the manufacturer of the dental equipment.

A very important standard dealing with the quality of microbial dental treatment water was balloted to determine if it would be included in the work program of ISO/TC 106. Hopefully this work will be implemented as a new work item, since it is a topic of growing public interest. The committee draft dealing with dentifrices (ISO/CD 11609) was circulated for comment and voting to participating member body countries with a deadline of April 15 2007. This ISO standard specifies requirements and test methods for the physical and chemical properties, and for the marketing and/or labelling for daily use by the public with a toothbrush to promote oral hygiene. It is anticipated by the ISO committee that guidelines on implied efficacy of dentifrices for the prevention or control of oral conditions will be published as an FDI technical report.

The increasing use of implants in modern dental treatment requires standards to be developed to address this trend. A document dealing with the performance of hand torque instruments for the clinical tightening of screwed components in endosseous dental implants was balloted with a closing date of April 18 2007. This standard will specify testing procedures for determining the repeatability of the torque developed by hand torque instruments.

Arguably the ISO standards developed for preclinical evaluation of biocompatibility test methods can be regarded as the most important contribution to clinical dentistry. On August 1 2007 a ballot was scheduled to be concluded dealing with the draft standard for biocompatibility test methods (ISO/DIS 7405) for dental materials. This international dental standard has to be used in conjunction with the more general 'Biological evaluation of medical devices' series of standards (ISO 10993). The ISO/DIS 7405 document contains special tests, for which ample experience exists in dentistry and which acknowledge the special needs of dentistry. Only those test methods that are supported by sufficient published data have been included. The committee noted that in recommending the test methods, the need to minimise the use of animals was given a very high priority. The committee pointed out that it is essential that the decision to undertake tests involving animals be reached only after a full and careful review of the evidence indicating that other types of tests cannot achieve a similar outcome. It was further emphasised that in order to keep the number of animals required for tests to an absolute minimum, consistent with achieving the objective indicated, it may be appropriate to conduct more than one type of test in the same animal at the same time, eg pulp and dentine usage tests and pulp capping tests. In accordance with ISO 10993-2 these tests shall be performed both in an efficient and humane way.

From the above it can be seen that in a very short period of three months, 40 ISO standards important to the practice of dentistry will have been voted upon. At the meeting of ISO/TC 106 held in Beijing in 2006, a total of 13 new work items were either commenced or were proposed by the seven sub-committees. These items were a shear bond strength test for adherence to tooth structure, orthodontic brackets and tubes, a shade conformity system for ceramics, the possible consolidation of three hydrocolloid impression material standards into one document, laser welding materials and CAD/CAM systems, work on denture adhesives and calibration of ceramic ovens. Work commenced on dental floss, tooth whitening products and fluoride varnishes, and the standardisation of torsional loads applied to implants and the design of implant screws are also under consideration.

PARTICIPATION IN DENTAL STANDARDISATION

Dental standardisation involves a diverse range of stakeholders: the dental professionals, dental manufacturers, government healthcare regulatory agencies and the ultimate consumer – the patient.

The ISO/TC 106 dentistry committee provides a forum for the dental industry, for professional bodies, academic dentistry and consumers – to produce

'In accordance with ISO strategies, environmental issues are also examined in the development of dental standards.'

standards governing the practice of dental treatment and the manufacture of reliable and safe products. Participation by stakeholders in the development of dental standards generates an information flow between manufacturers, the dental profession, and government regulators.

A large percentage of dentists and other dental professionals as well as the general public are not generally aware of the existence or the details contained in the 156 ISO dental standards that have been produced to enhance the quality of the dental treatment. Clearly these international standards are extremely important given that some 90% of the population worldwide suffers at some time in their lives from dental disease requiring clinical treatment and a high proportion of this population also use oral hygiene products.

In developed countries, oral health is improving with a decline in dental caries, particularly in children. But because people are living longer, increased retention of teeth has resulted in greater demand for dental treatment. Modern dentistry is thus greater in scope and has more possibilities than in the past, with less removal of tooth structure by drilling and by the increased use of adhesive aesthetic fillings, periodontal care, root canal therapy, minor surgery, orthodontics and implants. Reflecting the future trends in dental treatment, the scope of ISO/TC 106 is likely to increase to incorporate areas such as tissue engineering tissue scaffolding and bone growth.

THE DENTAL INDUSTRY

The market for dental products for which ISO standards are developed is relatively small in relation to that for healthcare in general and is a highly competitive market, globally estimated at approximately €10 billion annually, with the consumable product segment totalling €8.6 billion.

Excluding equipment, the global market for dental products is estimated to be growing at 4.5% to 5.9% annually, which amounts to an annual growth of €470-550 million. The market for oral hygiene products in the US alone reached over €3 billion in the year 2000 and the best-selling tooth bleaching brand in the US market had sales of €130 million in 2004, up 5.2% from the previous year. There are ten major international dental companies with annual sales ranging from €200 million to €1.7 billion. The rest of the industry is made up of 3,500 to 4,000 smaller companies worldwide. Around 600,000 dental implants are used annually throughout the world. The implant industry is made up of about four or five large companies and around 200 smaller manufacturers. The worldwide dental implant market in the year 2005 was about €1 billion and is estimated to grow to €2.4 billion by the year 2010.

The number of people employed in the dental manufacturing and supply industry is estimated to be between 40,000 and 60,000 and there are between 700,000 and 800,000 dentists throughout the world, although the number of dentists per capita varies widely in different regions. In developed countries, typically the ratio is about one dentist to 2,000 to 3,000 people. However, in some developing countries there may be only one dentist to over a million people. In developed countries, the daily use of fluoride toothpaste and a tradition of brushing teeth is common practice. In many developing countries however, although toothbrushes and toothpaste conforming to ISO standards are often available in urban areas through western multinationals and national suppliers, they are simply too expensive for the poor. Traditional teeth cleaning methods such as chewing sticks or twigs and natural remedies like ash are better than nothing, but cannot compare with fluoride toothpaste. ISO/TC 106 has recently initiated the revision of the ISO standard for toothpaste to address the question of bulk containers used for supervised tooth brushing programmes in schools and public health programmes in developing countries.

THE FUTURE STANDARDISATION PROGRAMME

The ISO dental technical committee has established an *ad hoc* group to review the future scope of the work programme of ISO/TC 106, which currently covers standardisation of terminology and methods of testing, and specifications applicable to materials and equipment used in all branches of dentistry. The *ad hoc* group is giving greater emphasis to the criteria for performance thresholds and the longevity of restorative materials, as well as the use of imaging systems software and clinical record-keeping software. The group also looks at questions of consumer safety and product effectiveness. In accordance with ISO strategies, environmental issues are also examined in the development of dental standards and any change in the scope of ISO/TC 106 has to be approved by the ISO technical management board.

CONCLUSIONS

In future there will be greater emphasis on the performance and quality of dental products based on consumer needs, testing methods, terminology and properties that ensure safety and reliability. Several thousand dental products are manufactured and exported worldwide; ISO standards are a major factor in facilitating international trade in dental products.

'Dental standards play a vital role in society by contributing to the quality and safety levels of products used in dental treatments and by the general public.'

Developed countries have a responsibility to play a role in the development of international standards in this vital area. Dental standards play a vital and important role in society by contributing to the quality and safety levels of products used in dental treatments and by the general public. ISO/TC 106 is addressing the needs of the current and future standardisation of products and considers ISO standards a necessary requirement for the dental profession and patients worldwide.

Derek W. Jones,
Chair ISO/TC 106, Dentistry

This article is based upon a paper written by D. W. Jones which appeared in the February 2007 issue of ISO Focus – the magazine of the International Organization for Standardization *Volume 4, No. 2 pages 8-11, and is reproduced here with the permission of ISO Central Secretariat (www.iso.org). Editorial enquiries: gasiorowski@iso.org. A one-year subscription costs 158 Swiss francs. Subscription enquiries: sales@iso.org.*

DOI: 10.1038/bdj.2007.837

About the author

Derek Jones obtained his BSc and PhD from the University of Birmingham, United Kindgom and is currently Professor Emeritus of Biomaterials, Dalhousie University, Canada. He has been involved with standards development for the past 36 years. He is currently Chair of ISO/TC 106 for the term of 2005-2010 and was Secretary of ISO/TC 106/SC 1, Dental filling and restorative materials, from 1979 to 1997, and Chair of ISO/TC 106/SC 1 from 1998-2005. He is a Chartered Chemist (C.Chem) and a Fellow of the Royal Society of Chemistry (FRSC), the Institute of Ceramics (F.I.Ceram), Institute of Materials (FIM) and Biomaterials Science and Engineering (FBSE). He has done research on a wide range of material properties and has authored and co-authored over 290 papers and abstracts and written sections in eight books. He holds two patents on biomaterials and has received numerous awards for his work in the dental field.

Erratum

Clinical performance of reinforced glass ionomer restorations placed in UK dental practices (*BDJ* 2007; **203:** E2)

It has been brought to our attention that in the above online research paper (*BDJ* 2007; **203:** E2) and its accompanying research summary (*BDJ* 2007; **203:** 40-41), author Stuart Cripps' name was printed in error as 'S. Phipps'. The authors should therefore read 'F. J. T. Burke, C. Siddons, S. Cripps, J. Bardha, R. J. Crisp and B. Dopheide'.

The corresponding author wishes to apologise to Dr Cripps and to readers for this error and any inconvenience that may have been caused.

DOI: 10.1038/bdj.2007.838