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International Standards and the Dental Practitioner

Abstract: The relationship between dental practice and international standards is described together with an account of the way in which standards are drafted and published. The United Kingdom participates in the process through the British Standards Institution, which is a Member Body of the International Standards Organization and the European Standards Committee. Some of the standards relevant to dental practice are quoted to demonstrate their importance. The principles of the regulatory processes used in Europe in relation to the Medical Device Directive and CE marking are discussed.

Clinical Relevance: International Standards for dental materials, instruments and equipment form an integral part of dental practice, as they assist the dentist and his/her patients by setting minimum properties for materials and ensure safety and interchangeability of equipment.

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Splash out!

So your turbine handpiece is clapped out and you decide to buy that luxury high speed, fibre optic, ball-race piece of kit that you saw at the recent exhibition. It arrives and without a second thought you connect it to your unit and run it up without it shattering your eardrums.

Why does it connect directly to your old tubing connector? Why is it not deafening? Well, it's because it conforms to International Standards – the coupling dimensions and the limit on noise emission are all specified in International Standards and all reputable manufacturers comply with these. So the standards are good for you and good for the manufacturers in promoting and selling their products.

What are International Standards?

There are over 150 International Standards dealing with dental equipment, instruments, materials and terminology. The catalogue lists every material and instrument that you use in practice and much of the equipment, from handpieces and burs to the dental unit and light. There is also a series of standards dealing with healthcare products such as toothbrushes, floss and toothpaste.

The two principal purposes of International Standards are:

- To protect the consumer, in this case the dentist and the patient, from inferior products; and
- To facilitate international trade for manufacturers so that only one set of requirements applies for every country.

The Standards are formulated by experts in the field and published by the International Standards Organization (ISO) in Geneva. The experts and their efforts are co-ordinated by a Technical Committee numbered 106 (TC 106), which has the responsibility for management of the standards process.

Now it starts to get a bit arcane! The principal members of TC 106 are national standards bodies such the British Standards Institution (BSI), the American National Standards Institute (ANSI), Japan Industrial Standards Committee (JISC), Association Française de Normalisation (AFNOR) and so on; there are 27 participating members.

Each standards body has a series of 'mirror' committees that monitor and contribute to the standards process. BSI has six dental committees consisting of nominees from organizations such as the British Dental Trade Association (BDTA), British Dental Association (BDA) and the British Society for Restorative Dentistry (BSRD).

Each national standards body nominates its delegation that attends the TC meeting. The delegation will be composed of scientists, dentists, manufacturers and standards personnel. These people will be appointed for their expertise in particular fields – polymeric materials, metals, burs, instruments, and so on. The organization of the TC work programme is delegated to Sub-Committees (SC) that deal with product groups (Restorative materials, Equipment, Implants, etc), which in turn are broken down into individual products that are considered by specialist Working Groups (WG) that are responsible for the basic

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Stage	Purpose	Action by ISO
Preliminary stage	Identification of the product(s) to be standardized – properties, test methods	Sub-Committee (SC) approval, nomination of WG Convenor and members
New Work Item Proposal	Summary of intended standard	Vote by Member Bodies
Working draft (WD)	Draft standard written by WG including test methods	Document confined to WG
Collaborative testing to support the writing of the WD	Verification of test methods Setting performance limits	Data confined to WG
Committee Draft (CD)	Comment by Sub-Committee members	Circulated within SC members only
Draft International Standard (DIS)	Public consultation	Circulated to Technical Committee members
Final Draft International Standard (FDIS) Publication	Editorial checking	Circulated to Technical Committee members

Table 1. Stages in the drafting and publication of an International Standard.

- Film thickness of luting materials
- Working time (self-cure materials)
- Setting time (self-cure materials)
- Sensitivity to ambient light (light-cure materials)
- Depth of cure (light-cure materials)
- Flexural strength
- Water sorption and solubility
- Shade and colour stability after irradiation and water sorption
- Radio-opacity
- Packaging, marking and instructions and information to be supplied by the manufacturer

Table 2. Properties specified in ISO 4049.

drafting of the individual standards.

Each standard is taken through a series of drafting stages to ensure proper consultation with interested parties (Table 1). The WG writes a Working Draft (WD) over a period of two or three years, which is usually supported by its own testing of products to set performance limits. When ready, the WD becomes a Committee Draft (CD) which receives comments from outside the WG. Assuming general agreement, the CD is redrafted to take account of comments and criticism to become a Draft International Standard (DIS), which is a public document and is open for anyone to pass comment.

The WG then completes the drafting and final checking stage of Final Draft International Standard (FDIS), which again is sent out for vote after which the completed standard is published.

Much criticism has been made about the length of time these standards take to publish from start to finish and ISO has streamlined its procedures to attempt to deal with the problem.

Standards are consensus, state of the art documents and require majority votes from national standards bodies in order to progress. If this majority is not achieved or many technical problems are raised, the draft can be set back a stage for redrafting.

Examples of International Standards

Probably the two International Standards that a general dental practitioner will see quoted most are ISO 4049, Polymer-based restorative and luting materials, and ISO 9917, Dental cements. These two standards cover the vast majority of tooth-coloured materials and include the composites, glass ionomers of all types, lining and luting cements. If a manufacturer is claiming compliance of the material with a standard, you will find a statement to this effect in the instructions for use.

Other standards covering restorative materials include ISO 24234 Dental amalgam, ISO 6876 Endodontic materials, and ISO 20795-1 Denture base polymers. ISO 3630, with its several parts, deals with the plethora of endodontic instruments and was the standard that originally prescribed the size designation and colour coding of reamers and files.

In ISO 4049 you will find the minimum performance limits for composites and polymeric luting materials. This standard was first published in 1978 and two revisions have been completed (1988 and 2000), with the third and latest currently out for vote at the DIS stage. In this standard you will find tests for many properties and I have listed these in Table 2. As the materials have improved, so the minimum values for many of these properties have increased. In 1978 the minimum flexural strength was 50 MPa, whereas in the current draft it is 80 or 100 MPa.

When tests are proposed for standards they need to have a track record of success in research. The test methods for these properties have been established for many years and produce reliable results in laboratories around the world. It is no use having a really special and complicated test if only one laboratory is tooled up to perform it.

At the next stage comes the setting of performance limits. These are the values for each property that the material under test must equal or exceed. These values are not dreamt up by the WG in a darkened room as *targets* for materials to reach. This is another misconception about standards. The process involves characterizing the materials that are clinically successful with a series of tests. Having determined the performance of these as a group, it is then possible to judge whether a new material is good enough to join the group. Now, if someone has been clever and invented a new material, then there will not be a standard for it, because standards cannot predict developments; they are always looking back. So, for example, there is currently no standard for CAD/CAM systems.

Are standards clinically realistic?

Another criticism that is levelled at laboratory tests is whether they are clinically realistic, that is whether they measure failure in the way that the material will fail clinically. Standard tests and performance limits avoid this argument by taking an established group of materials, such as one that all dentists would accept as being successful, and applying the series of reliable tests to this.

However, not all important properties can be determined. There might not be agreement on an appropriate laboratory test. This particular problem has caused difficulty in adhesion testing and in the determination of polymerization shrinkage. Then, even with an acceptable test, there might not be agreement on an appropriate performance limit. Whilst there is general agreement that polymerization shrinkage of composites is an important property and should be as low as possible, it is impossible for experts to agree on how low is acceptable.

If a performance limit cannot be agreed, an agreed test method for the property might be published as a Technical Specification so that the user can compare data from individual manufacturers determined by the same test.

The use of standards in regulatory processes

Complying with standards is a voluntary matter unless the standard is incorporated into legislation. ISO publishes the standards but then, somewhat strangely, has no interest in whether they are used or how they are used.

Various national regulatory bodies exist and many of these prescribe that materials and equipment marketed in their countries shall meet International Standards. The most relevant to us in the UK is the European Commission and I will deal with this in some detail.

The European dimension

European standards (European Norms, EN) are published by the Comité Européen de Normalisation (CEN) under the authority of the European Commission. The CEN dental standards committee, TC 55, for the most part adopts ISO dental standards without technical changes under a joint drafting and voting arrangement called the 'Vienna Agreement'. These joint standards are labelled EN ISO (number). BSI is committed to publishing ENs without change and so most dental standards are labelled BS EN ISO (number).

The European consumer is assured as to the quality of all goods marketed in Europe by their being labelled with the 'CE mark'. This mark is part of a mandatory European marking system for certain products to indicate their conformity with the Essential Requirements (ER) set out in European Directives. To permit the use of a CE mark on a product, proof that the item meets the relevant requirements must be documented. Manufacturers may elect to claim compliance with ENs, which simplifies the process, or may set their own standards. Sometimes, this is achieved using an external test house, which evaluates the product, or otherwise by an internal company self-certification process. In any case, manufacturers or their agents have to issue an 'EC-Declaration of Conformity' indicating that they declare that their product complies with the standards they nominate.

This process is scrutinized by a 'Notified Body', which is part of the EU certification system. At the other end of the chain are the 'Competent Authorities' which set guidance on requirements and are usually national government agencies. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the Competent Authority for medical devices.

Dental materials, instruments, equipment and implants fall into the generic group of 'Medical devices' and thus are subject to the appropriate requirements of the EU Medical Devices Directive (MDD). This Directive requires that devices shall, amongst other things:

- Be designed and manufactured in such a way as to guarantee the characteristics and performance when used for the intended purpose of the device;
- Not compromise the clinical condition or the safety of patients, or the health and safety of users;
- Not create any risks that are not acceptable in the context of the benefits of their use;
- Be accompanied by the information needed to use it safely taking into account the training and knowledge of the potential users;
- Be traceable after use.

You will be familiar with the registration of dental laboratories that is required by the MDD in relation to the manufacture of 'custom made devices', ie devices that are designed and manufactured for a particular patient.

The MDD also provides rules for the classification of medical devices based on risk and intended use. Manufacturers have the responsibility for classifying their device(s) according to the rules. In order to assist manufacturers, CEN TC 55 has published a Technical Report (TR 12401) that gives guidance on classification. In essence, the higher the risk, the more stringent are the ERs that apply. A low risk dental device, for example, is gingival retraction cord, whereas filling materials are considered to be of high risk.

In order to support the MDD, CEN TC 55 has published four 'horizontal' standards that are mandated by the European Commission. These deal with generic groups of materials, namely instruments, equipment, materials and implants (EN 1639–EN 1642) and reference each EN ISO standard and its relationship to the appropriate ERs.

In addition, each dental EN

product (or 'vertical') standard has an Annex added to it after the ISO standard has been approved and this specifies the ERs that the standard supports.

Conclusion

I hope that this article has given you an insight into the workings of ISO, CEN and BSI. I suppose that many dentists will take such workings for granted or may not even realize how everything they do involves standards of many types before they even think of complying with such things as national clinical guidelines.

Certainly, the manufacturers do not take anything for granted and they have this myriad of regulations to deal with in some way or other to get their products to you. In Europe and, to a certain extent, in the Far East, things are very complicated.

It is fashionable in some quarters to claim that Europe in general is over-regulated, and you might give some thought as to whether you want things standardized and reliable or whether you would prefer an unregulated 'free for all'! You could indicate your support by ensuring that everything you buy complies with a BS EN ISO standard.

Suffice it to say, we are where we are and someone has to do the dirty work of drafting standards and keeping an eye on the regulators.

I would like to finish by paying tribute to my colleagues on BS committees and who have been with me for many years on the UK Delegations to ISO and CEN. Without the huge unpaid and somewhat unseen effort that these people make, I think that the standard of care that we provide for our patients would be diminished. Think about joining us – all are welcome!

References

Standards referred to in the text, published by the British Standards Institution, 389 Chiswick High Road, London W4 4AL. (Note: undated standards references require reference to the most recent revision).

1. BS EN ISO 20795-1, *Dentistry – Denture base polymers.*
2. BS EN ISO 3630-1, 2, 3 *Dentistry – Root-canal instruments.*
3. BS EN ISO 4049, *Dentistry – Polymer-based filling, restorative and luting materials.*
4. BS EN ISO 6875, *Dental equipment – Dental patient chair.*
5. BS EN ISO 6876, Dentistry – *Dental root canal sealing materials.*
6. BS EN ISO 7494-1, *Dentistry – Dental units – Part 1. General requirements and test methods.*
7. BS EN ISO 9917-1, *Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements.*
8. BS EN ISO 9917-2, *Dental water-based cements – Part 2: Light activated cements.*
9. BS EN ISO 23964, *Dentistry – Dental handpieces – Coupling dimensions.*
10. BS EN ISO 24234, *Dentistry – Mercury and alloys for dental amalgam.*

Standards referred to in the text published by Comité Européen de Normalisation (CEN), Rue de Stassart 36, B-1050 Brussels, Belgium.

1. EN 1639, *Dentistry – Medical devices for dentistry – Instruments.*
2. EN 1640, *Dentistry – Medical devices for dentistry – Equipment.*
3. EN 1641, *Dentistry – Medical devices for dentistry – Materials.*
4. EN 1642, *Dentistry – Medical devices for dentistry – Implants.*
5. CEN/TR 12401, *Dentistry – Guidance on the classification of dental devices and accessories.*

Medical Device Directive

1. 93/42/EEC Council Directive of 14 June 1993 concerning medical devices (O.J. L. 169 from 12.07.1993, page 1-43), as amended by Directive 2007/47/EC.

Websites

1. British Standards Institution **www.bsi-global.com**
2. Comité Européen de Normalisation **www.cen.eu/cenorm**
3. International Standards Organization **www.iso.org**
4. Medicines and Healthcare Products Regulatory Agency **www.mhra.gov.uk**

Abstract

HOW SUCCESSFUL ARE YOUR RESIN-BONDED BRIDGES?

An update on resin-bonded bridges.
Barber MW, Preston AJ. *European Journal of Prosthodontics and Restorative Dentistry* 2008; **16**: 2–9.

I was astounded to read in this paper that it is 35 years since Rochette first described the resin-retained bridge (RRB), now a mainstay of many restorative treatments for the replacement of missing teeth with minimal intervention. This excellent paper provides a comprehensive review of the indications, advantages, longevity, design and clinical procedures currently being taught. These have seen significant change and development since Rochette's first description of the techniques with perforated mesh wings.

Key learning points from the paper are that RRBs require minimal, or at best no tooth preparation; they may be the most cost-effective and least expensive method of tooth replacement when compared to all the alternatives, especially in view of the little clinical time required; that, having supragingival margins, they are good for periodontal health; a single bonded retainer 'wing' is preferable to a fixed-fixed double wing design; RRBs should generally only replace one tooth; the latest studies using the most recent developments (and these are continuing) show significant success rates; following laboratory cleaning they can be successfully rebounded should they debond in clinical use, although it is wise to diagnose the reason for debonding first.

The authors also detail the current clinical procedures including design, preparation, laboratory procedures, try-in and cementation.

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CPD ANSWERS

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1. A, C, D	**6.** A, C
2. B, D	**7.** A, C
3. A, C, D	**8.** A, D
4. A, B, C	**9.** A, B
5. C, D	**10.** A, B