

## **Annex: Standards Developed by ISO/TC 106**

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**TC/106 - Biocompatibility:** Arguably the ISO standards developed for preclinical evaluation of biocompatibility test methods can be regarded as the most important contribution to clinical dentistry. The evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008) specifies test methods for the evaluation of biological effects of medical devices used in dentistry. It includes testing of pharmacological agents that are an integral part of the device under test. ISO 7405:2008 does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body. 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, which are supported by sufficient published data, have been included. The test methods aim to minimize the use of animals. 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. In accordance with ISO 10993-2 these tests shall be performed both in an efficient and humane way. Discussions regarding the lead concentration that is leached from dental ceramics have concluded that this is very low and is not significant because it is less than the concentration accepted for drinking water limits (i.e. WHO 25ppb).

**TC/106 - Preventive Sealants:** The standard ISO 6874:2005 specifies requirements and test methods for polymer-based materials intended for sealing pits and fissures in teeth. The standard covers both self-cured and external-energy-activated materials. Dental “preventive” sealants are thin polymer coatings that are applied to the occlusal (chewing) surfaces of the posterior (back) teeth to protect them from dental caries (tooth decay). Most tooth decay in children and teens occurs on these surfaces. Sealants protect from tooth decay by keeping bacteria and food (pellicle formation) out of these grooves. Permanent molars are the most likely to benefit from sealants. The polymer resin is applied following etching of the tooth enamel. Alternatively, a glass polyalkenoate sealant material may be used which chemically bonds to the calcium in the tooth surface.

### **Sub Committee #1 Filling and Restorative Materials (& Orthodontics):**

**Polymer based restoratives:** The standard ISO 4049:2009 specifies requirements for dental polymer-based (composite) restorative materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of cavities in the teeth. Recent modifications to the standard have included the use of such materials as “luting agents” (used to seal the space between restorative components such as inlays, crowns and bridges and the tooth). A standard dealing with polymerisation shrinkage of filling materials, ISO/CD 17304, is under development.

**Dental Cements:** In the early days of dental standards development the various types of cements such as zinc phosphate, glass polyalkenoate, zinc polycarboxylate, zinc oxide/eugenol each had their own standard specification. However, a decision was made to combine as many cement standards as possible into one single standard (horizontal standard). The result was “Water-based cements -- Part 1: Powder/liquid acid-base cements, ISO 9917-1:2007” this specifies requirements and test methods for powder/liquid acid-base dental cements intended for permanent cementation, lining and restoration. The standard is applicable to both hand-mixed and capsulated cements for mechanical mixing. The standard also specifies limits for each of the properties according to whether the cement is intended for use as a luting agent, a base or liner or as a restorative material. However, ISO 9917-1:2007 is not intended to address resin-modified water-based cements.

**Resin Modified Cements:** In 2010 work was completed on a standard specification for cements (resin modified cements) in which setting is achieved by a combination of an acid-base reaction and polymerization (ISO 9917-2:2010). The polymerization component of the reaction may be activated by mixing different components (chemically activated) or through application of energy from an external source (photo-initiation). Manufacturers are requested to note that this standard specification is closely related to ISO 4049 and ISO 9917-1. Consideration therefore has to be given as to which is the most appropriate international standard by which to evaluate any individual commercial dental cement product. The polymer-based luting materials covered by ISO 4049:2009 are intended for use in the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges. This international standard does not cover those polymer-based luting materials that have an “adhesive” component within the structure of the material.

**Adhesive components:** A new standard for polymer-based luting materials containing adhesive components ISO/NP 16506 is now under development. This new standard will address, testing for water sorption, solubility and flexural strength (according to ISO 4049).

**Zinc Oxide/Eugenol Cements:** Work has been completed in the revision of the standard for zinc oxide/eugenol cements (ISO 3107:2011). This standard covers non-water-based zinc oxide/eugenol cement suitable for use in restorative dentistry for temporary cementation of inlays, crowns and bridges and for use as a base underneath other restorative materials. It also covers the use of zinc oxide/eugenol as a temporary restoration, which will ultimately be replaced after a short time by a permanent restoration. In addition the standard also covers the non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation. The test methods specify the method to determine the acid-soluble fraction of arsenic that may be present as a trace element in the zinc oxide, which should be no more than 2 mg/kg.

**Dental Amalgam:** The standard ISO 24234:2004 – Mercury and alloys for dental amalgam was the first edition of a combined (amalgam and mercury) standard. Revision of ISO 24234 has commenced, one proposed change aims to remove the use of bulk mercury. The ISO 24234:2004 standard specifies the requirements and test methods for alloys and for mercury suitable for the preparation of dental amalgam, together with the requirements and test methods for that amalgam and the requirements for packaging and marking with instructions concerning mercury. It is applicable to alloys supplied in the form of either a powder in bulk, or a powder compressed to form a tablet, or a powder in pre-dosed capsules. The revision will be applicable to dental mercury supplied either in pre-dosed sachets, or in pre-dosed capsules. It is not applicable to alloys intended for use with liquid metals that are not mercury. Work is commencing on technical specification -Amalgam Corrosion Test Methods, ISO/NP TS 17988.

**Adhesion to Tooth Structure:** The technical specification ISO/TS 11405 emphasizes the importance of adhesion in restorative dentistry. It is very important that information on the performance of materials claiming to bond to tooth structure should be made available to the dentist. In the absence of comparative clinical trials, much emphasis is placed on laboratory assessment of bond strength. It is recognized that laboratory tests cannot predict the exact clinical behaviour of these materials, however, such tests may be of value in batch quality control. The standardization of laboratory test methods will better allow the correlation between laboratory testing and clinical performance to be realized. Work is continuing on this difficult task aiming to up-grade the existing Technical Specification (ISO/TS 11405) to a standard. This Technical Specification gives guidance on substrate selection; storage and handling as well as essential characteristics of different test methods for quality testing of the adhesive bond between restorative dental materials and tooth structure, i.e. enamel and dentine. It specifies two bond strength measurements tests (tensile and shear), a test for measurement of marginal gaps around fillings and a micro-leakage test, as well as giving recommendations on clinical usage tests for such materials. It also presents some specific

test methods for bond strength measurements. A standard specification for adhesion is now under development ISO/CD 29022 Adhesion -Notched-edge shear bond strength test. The aim of ISO 29022 is to establish a simple and easy to use method to document a claim that a material adheres to tooth substance.

**Root Canal Sealing Materials and Points:** Endodontic treatment, involves a dental procedure in which the diseased or damaged pulp (core) of a tooth is removed and the inside areas (the pulp chamber and root canals) are filled and sealed. The standard for dental root canal sealing materials (ISO 6876) has undergone revision. The previous version (ISO 6876:2001) was significantly revised. This international standard specifies requirements and test methods for root canal sealing materials, which set with and without the assistance of moisture and are used for permanent obturation of the root canal, with or without the aid of obturating points. It is applicable only to sealers intended for orthograde use, i.e. a root filling placed from the coronal aspect of a tooth. Root canal obturating points ISO 6877:2006 specifies the dimensions and compositional requirements for prefabricated metal or polymeric points or cones suitable for use in the obturation of the dental root-canal, but not for support of a coronal restoration. It also specifies numerical systems and a colour coding system for designating the sizes. Dental root-canal obturating points are marketed sterilized or unsterilized. ISO 6877:2006 covers the physical attributes expected of such products as supplied. Requirements for sterility are not included, and any claim that the product is sterile is the responsibility of the manufacturer. The standard Dental absorbent points ISO 7551:1996, specifies requirements and test methods for “absorbent” points used in endodontic procedures. A new project is being developed (ISO/NP 17681) dealing with “Thermo-plasticized Root-Canal Obturating Materials”.

**Orthodontics:** The important area of orthodontics had the first ever-international standard published in 2006; this was for orthodontic wires (ISO 15841). This standard was developed as a result of the difficulty encountered by clinicians in making meaningful comparisons between wires using the information that was currently available from manufacturers and suppliers. This standard specifies requirements and test methods for wires to be used in fixed and removable orthodontic appliances. It includes preformed orthodontic archwires but excludes springs and other preformed components. The standard gives detailed requirements concerning the presentation of the physical and mechanical properties of orthodontic wires, the test methods by which they can be determined, as well as packaging, and standardized labeling information. The second international standard (ISO21606: 2007) developed for orthodontic materials and devices covered elastics, elastomeric bands, chains, links and ligatures used both inside and outside the mouth in conjunction with fixed and removable orthodontic appliances. A third important standard for brackets and tubes for use in orthodontics (ISO/FDIS 27020) has now been completed. This allows dentists in making meaningful comparisons between various brackets or tubes available on the market based strictly on the information currently available from manufacturers and suppliers. This standard details the methods to compare the functional dimensions of orthodontic brackets and tubes, and the test methods by which they can be determined, as well as standardized packaging and labeling information. A new project (ISO/NP 17192), "Test methods for shear bond strength of adhesives for orthodontic attachment" is being undertaken.

## **Sub Committee #2 Prosthodontic Materials:**

**Denture Resilient linings for short-term use:** ISO 10139-1, specifies requirements for the physical properties, test methods, packaging, marking and manufacturer's instructions for denture lining materials suitable for short-term use. The standard for resilient linings for dentures for long-term use (ISO 10139-2) was approved and published in 2009. This standard specifies requirements for softness, adhesion, water sorption and water solubility as well as for packaging, marking and manufacturer's instructions for soft denture lining materials suitable for long-term use. These materials may also be used for maxillofacial prostheses. Consideration is being given to harmonizing parts 1 and 2 of ISO10139: 2009 in a future revision into a single standard. Concerns have been expressed about the leakage of phthalate esters from some denture soft liners however; the scientific literature indicates that some 3-6 thousand PPM of phthalate is leached from denture soft linings in 14 days. This indicates that the phthalate leached from a

denture lining may only be about one tenth of the acceptable daily intake (ADI).

**Impression Materials:** The work on the revision of elastomeric impression materials and hydrocolloid impression materials (ISO/DIS 21563) is progressing. The revision of elastomeric impression materials (ISO 4823) is aiming to develop a more performance- oriented standard as well as developing a working time test method that can include very high viscosity putty materials. **Aqueous impression materials based on agar**, (ISO 1564:1995), specifies requirements for physical properties and other characteristics of this class of impression materials and tests for determining compliance with those requirements. It also specifies requirements with respect to the manufacturer's instructions, and the essentials for packaging, labelling and marking.

**Metallic Materials:** Laser welding; ISO 28319:2010 specifies requirements and test methods for laser welding, in the dental laboratory, of materials suitable for use in metallic restorations and appliances.

**Metallic Materials for Fixed and Removable Dental Restorations and Appliances:** ISO 22674, is currently being revised. The reasons for undertaking the revision included clarification of the intended uses of various alloys, consideration of modern processing techniques, revision of the measurement technique for Young's modulus, and harmonization with ISO 10271. The requirement for beryllium will not be changed in the revised document. Possible improvements in the future could address the questions the use of modern processing techniques such as CAD/CAM machining and laser sintering.

**Corrosion test methods for metallic material:** ISO 10271:2011 provides test methods and procedures to determine the corrosion behaviour of metallic materials used in the oral cavity. It is intended that the test methods and procedures in ISO 10271:2011 be referred to in the individual International Standards specifying such metallic materials. However, ISO 10271:2011 is not applicable to instruments and dental amalgam and appliances for orthodontics. The work on metallic corrosion test methods (DIS 10271) is progressing. Developing a test procedure to evaluate the corrosion behaviour of metallic materials in dentistry is complicated due to the diversity of the range of materials involved, as well as the wide range of applications and the variation of the environment to which they are exposed to. In addition variation occurs between devices and within the same device during the exposure time. The type of corrosion behaviour or effect may also vary with exposure time. For these reasons, it is not possible to specify a single test capable of covering all situations, nor is it a practical proposition to define a test for each situation. Because of this ISO 10271 gives detailed protocols for test methods, which have been found to be of merit as evidenced by considerable use. The revised version of ISO 10271 includes two new test methods. A time-dependent corrosion test has been added to supplement the static immersion test, since the corrosion rate of most dental alloys is not constant over time. For example, alloys that have corrosion resistance due to passive films, such as titanium alloys, may have relatively high corrosion when first placed in a corrosive environment as evaluated by the static immersion test; however, as the thickness and integrity of the passive film increases with time, the corrosion may decrease significantly. The aim of the time dependent corrosion test is to provide information on the corrosion rate of a dental alloy with time.

**Colour Determination:** An important and challenging new work item that has been proposed concerns the development of a test method for the determination of shade conformity of commercial aesthetic filling materials with their cross-referenced commercial shade guides. The aim is to include composite, glass ionomer, and resin-modified glass ionomer and compomer materials in this standard. A wide range of restorative and filling materials are marketed having shades for various aesthetic needs. It is important for the dentist to be able to select the correct colour of these materials (hue, value and chroma) in order to ensure the best aesthetic performance of these materials. When a dentist selects the shade of a restorative

material, the shade of the tooth being restored is first checked with a shade guide and the shade guide tab which is then used to select the appropriate restorative material. Unfortunately what often happens is that the colour of the restorative material is different to the shade guide tabs to which it was cross-referenced. Thus a standard test to determine shade conformity between each material and a cross-referenced shade guide tab is desirable. This work is also relevant to ceramic and ceramic fused to metal crown and bridge materials. A technical report (ISO/TR 28642:2011), “Dentistry-Guidance on Colour Measurement” has been developed. This valuable report identifies three types of topics related to shade conformity and interconvertibility of monochromatic and polychromatic tissues and materials related to the discipline of dentistry; it describes visual and instrumental methods for assessment of these topics. ISO/TR 28642:2011 suggests interpretation of the findings through colour difference thresholds, and provides guidelines for future standardization related to dental shade conformity and interconvertibility. It also includes guidelines related to colour vision of persons undertaking visual colour assessment and instructions for reporting of colour and colour difference assessments.

**Denture base polymers:** ISO 20795-1:2008 classifies denture base polymers and copolymers and specifies their requirements. It also specifies the test methods to be used in determining compliance with these requirements. It further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for use of these materials. Furthermore it applies to denture base polymers for which the manufacturer claims that the material has improved impact resistance. It also specifies the respective requirement and the test method to be used.

ISO 20795-1:2008 applies to denture base polymers such as those listed below:

- poly(acrylic acid esters);
- poly(substituted acrylic acid esters);
- poly(vinyl esters);
- polystyrene;
- rubber modified poly(methacrylic acid esters);
- polycarbonates;
- polysulfones;
- poly(dimethacrylic acid esters);
- polyacetals (polyoxymethylene);
- copolymers or mixtures of the polymers listed above.

**Orthodontic base polymers:** ISO 20795-2:2010 is applicable to orthodontic base polymers and copolymers used in the construction of both active and passive orthodontic appliances and specifies their requirements. It also specifies test methods to be used in determining compliance with these requirements. ISO 20795-2:2010 further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for use of these materials.

**Polymer-based crown and bridge materials:** ISO 10477:2004 classifies polymer-based dental crown and bridge materials and specifies their requirements. It also specifies the test methods to be used to determine compliance with these requirements. ISO 10477:2004 is applicable to polymer-based dental crown and bridge materials for laboratory-fabricated permanent facings or anterior crowns that may or may not be attached to a metal substructure. It also applies to polymer-based dental crown and bridge materials for which the manufacturer claims adhesion to the metal substructure without macro-mechanical retention such as beads or wires. ISO 10477:2004 is not applicable to polymer-based materials that are used to make crowns, veneers or repairs in the operator, nor does it cover the application of those materials to stress-bearing areas of posterior teeth.

**Ceramic materials:** ISO 6872:2008 specifies the requirements and the corresponding test methods for dental ceramic materials for fixed all-ceramic and metal-ceramic restorations and prostheses. Metal-ceramic dental restorative systems, ISO 9693-1:2012 specifies test methods for determining the compatibility of metallic and ceramic materials used for dental restorations by testing the composite structure. The requirements given in ISO 9693-1:2012 are applicable to metallic materials and ceramics when used in combination, and are not applicable to either metallic materials or ceramics when used alone. A compatibility tests for metal-ceramic and ceramic-ceramic restorative systems is being developed (ISO 9693-2). This International Standard aims to specify test methods to determine the compatibility of metallic and ceramic materials used for dental restorations by testing the composite (metal/ceramic) structure. Five test methods: (1) shear bond testing; (2) Schwickerath Test; (3) incisor loading; (4) fatigue loading of cemented, supported discs; and (5) thermal shock resistance will be evaluated. It should be noted that this International Standard only applies to the metallic materials and ceramics when used in combination, and compliance may not be claimed for either metallic materials or for ceramics alone.

**Furnace Temperature Calibration:** A very important aspect of achieving the correct colour of ceramic restorative crowns and bridges relates to the control of the firing temperature. The temperature control of the furnace can also affect the strength of such structures. A test for dental furnace temperature control is being developed (ISO/DIS 13078) using a separate thermocouple, which should minimize errors of colour/translucency and structures, which may exhibit inferior strength resulting in clinical failures. This international standard aims to level the existing differences between dental furnaces ex-factory by means of a final adjustment to be carried out by manufacturers in a standardized way using an external thermocouple or by using the silver test at 961 degrees C.

**Investment Materials and Die materials:** The role of investment materials in the accuracy of precision casting of inlays, crowns, denture frameworks and bridges is vital. "Casting investments and refractory die materials", ISO 15912:2006 is applicable to dental casting, brazing and refractory investments and refractory die materials, regardless of the nature of the binding system or the particular application. ISO 15912:2006 classifies investments into types according to their intended use and classes according to the burnout procedure recommended by the manufacturer. ISO 15912:2006 specifies requirements for the essential physical and mechanical properties of the materials and the test methods used to determine them. ISO 15912:2006 also includes requirements for the information and instructions which accompany each package. The work on revision of investments used for precision casting (ISO 15912:2006) is close to completion in the form of an amendment which provides a requirement and test method to ensure compensation of the thermal contraction of a cast alloy by adequate expansion of the casting investment material. Consideration is now also being given to revising the standard for gypsum products (ISO 6873). The revision of ISO 6873:1998 would consider the possibility of addressing the fabrication of model bases and CAD/CAM dies.

**Casting and Baseplate Waxes:** This standard ISO 15854:2005 is applicable to dental casting wax and to dental baseplate wax. It specifies the classification of, and requirements for, dental casting wax and baseplate wax together with the test methods to be employed to determine compliance with these requirements.

**Polymer-based Die Materials:** ISO 14233:2003 gives compositional, performance, user-information, packaging and marking, and testing requirements for polymer-based die materials used in dentistry. It is applicable to die materials having a polymeric matrix as their principal constituent. Polymer-based die materials are used in the dental laboratory mainly to produce casts from dental impressions for the manufacture of fixed or removable restorations.

## **Sub Committee #3 Terminology:**

**Vocabulary for developing standards:** ISO 1942:2008 (80 pages) provides definitions for a number of concepts specific to dentistry in the interest of facilitating development and comprehension of standards, and to improve communication with the *Fédération Dentaire Internationale*, the World Health Organization and other interested organizations. Annex A to ISO 1942:2008 provides additional information that can be helpful to users of the document. A revised version ISO DTS 11942 has been produced which however, will not be published but will be available for internal use only within ISO TC 106. The aim will be to permanently assign the identification number 11942.

**Terminology of oral implantology:** ISO/CD 16443 is currently under development in conjunction with Sub Committee #8.

**Dental equipment -- Graphical symbols:** ISO 9687:1993. The 153 symbols specified are to be used on the appropriate piece of equipment and in documents pertaining to dental equipment pieces, e.g. in instructions for use. The symbols are selected specifically for all kinds of dental equipment. The majority of them are taken from the relevant IEC and ISO International Standards. This standard is undergoing revision.

A number of Technical Reports have been produced involving digital codification.

**Designation system for teeth and areas of the oral cavity:** ISO 3950:2009 provides a valuable system for designating teeth or areas of the oral cavity using two digits.

**Digital coding of oral health and care:** ISO/TR 13668:1998.

**Application of OSI clinical codification:** The classification and coding of dental products, ISO/TR 15300:2001.

**Digital codification of dental laboratory procedures:** ISO/TR 15599:2002 provides a code of dental laboratory procedures which is digital so as to render it language-independent. This makes it convenient to use as a basic reference for existing or future dental codes, and ensures their compatibility through simple softwares, which is the fundamental goal of the exercise. In addition the digital code is intended to provide, as a result of built-in indexing functions:

- 1) the identification and traceability of dental prostheses and materials, epidemiology and forensic dentistry, investment planning, teaching, research, industry, insurance systems, social services and regulatory authorities;
- 2) the creation of performing databases for the field evaluation of materials, design and construction techniques of dental prostheses, and their effects, wanted or unwanted;
- 3) the possibility of communication between the dental professions, dental industry and trade, on both qualitative and quantitative scales.

One of the purposes of codification is to facilitate information exchange regardless of the language.

**Communication** can be enhanced by the use of standardized abbreviations or codes, allowing the interpretation and transmission of a message. The international standard (ISO/16059:2007) defines the elements of syntax, including the structure and associated content, for the purpose of coded data exchange and the need for harmonizing existing and future codifications.

Classification and codification of oral anomalies -- Part 1: Structure of the classification, ISO/NP 16202-1, and Part 2, Developmental disturbances of teeth, ISO/NP 16202-2 under development.

**Designation System for Teeth:** The standard for 'Designation System for Teeth and Areas of the Oral Cavity' has now been completed; this second edition will cancel and replace the 23-year-old first edition of ISO 3950, which has been technically revised.

**Classification of Caries and Cavities:** The committee is planning to commence on a new work item dealing with the development of a classification of both caries and types of cavity in teeth. The progressive use of a more conservative approach and minimal intervention in modern dental practice necessitates this important initiative. The development of an ISO standard for dental caries is long overdue and would play a very important role in the development of the practice of conservative dentistry worldwide. The hope is to collaborate with FDI in developing this very important standard.

## **Sub Committee #4 Dental Instruments:**

Work is continuing dealing with revising the standard for periodontal probes. This covers two ISO standards, ISO/WD 21672-1 Periodontal probes - Part 1: General requirements, and ISO/WD 21672-2 Periodontal probes – Part 2: Designation. New work is being undertaken for the functional designation of extraction forceps (DIS 9173- 2) and design and dimensions (DIS 9173-3) and consideration is being given to new work item covering Jacquette scalers as part 4 of ISO 13397. A further new work item is being considered for rubber dam punches and rubber dam bracket forceps. Handpieces are extremely important instruments in the dental office. Appropriate standards are required in order to ensure their safety and acceptable function. A revision of the standard “Handpieces and motors” (ISO/14457:2009) is aiming to address this need. This revision has combined four existing dental handpiece standards in one standard. In addition it includes angled handpieces for prophylactic purposes. Consideration is being given to an important corrosion test versus life cycle test. A series of basic standards on dental rotary instruments are being produced which constitute an important link between the standards on dental rotary instruments and those on dental handpieces. The international standard (ISO/DIS 1797-1) specifies shanks for rotary instruments used in dentistry and gives measurement methods for the verification of the dimensions. A quality control requirement ensures a high quality level.

**Shanks for rotary instruments -- Part 1: Shanks made of metals,** ISO 1797-1:2011 specifies shanks for rotary instruments used in dentistry and gives measurement methods for the verification of dimensions.

**Rotary instruments Shanks made of plastics** ISO 1797-2 1992, Specifies four types. Gives measurement methods for the verification of dimensions. Includes quality control requirements.

**Shanks for rotary instruments:** ISO/DIS 1797-3, Shanks made of ceramics is under development.

**Rotary instruments -- Nominal diameters and designation code number:** ISO 2157:1992. Specifies relevant characteristics of working parts of rotary instruments, e.g. burs, laboratory burs, grinding instruments, diamond instruments, mandrels, etc. Does not cover the diameters of root canal instruments.

**Root-canal instruments -- Part 1: General requirements and test methods,** ISO 3630-1:2008 specifies general requirements and test methods for root-canal instruments used for endodontic purposes, e.g. enlargers, shaping and cleaning instruments, condensers, and accessory instruments. In addition it covers general size designations, colour coding, packaging and identification symbols.

**Dental root-canal instruments Part 2: Enlargers,** ISO 3630-2:2000 Specifies relevant characteristics.

**Endodontic instruments -- Part 2: Enlargers,** ISO/DIS 3630-2 (2011) under development.

**Root-canal instruments -- Part 3: Condensers, pluggers and spreaders,** ISO 3630-3:1994, Specifies requirements and test methods for pluggers and spreaders, used to condense root-canal filling materials. Includes, additional to standard sizes, a secondary size system referred to as "taper size". These "taper size" sizes are identifiable by tapers, which vary with instrument size. This standard is currently being revised.

**Root canal instruments -- Part 4: Auxiliary instruments,**ISO 3630-4:2009 specifies requirements and test methods for hand-held or mechanically operated instruments for performing root canal procedures not cited in ISO 3630-1, 3630-2, 3630-3 or 3630-5. ISO 3630-4:2009 specifies requirements for size, product designation, safety considerations, instructions and labelling.

**Endodontic instruments -- Part 5: Shaping and cleaning instruments,** ISO 3630-5:2011.

**Rotary instruments -- Burs -- Part 1: Steel and carbide burs,** ISO 3823-1:1997.

**Rotary bur instruments -- Part 2: Finishing burs,** ISO 3823-2:2003 specifies dimensional and other relevant requirements for the 17 most commonly used shapes of steel and carbide finishing burs, including a quality control and specifications for labelling of these instruments.

**Dental handpieces, Coupling dimensions,** ISO 3964:1982. Specifies the nominal dimensions and tolerances of the swivel-type coupling used between the dental handpieces and their driving mechanisms. It is not applicable to the older "slip-joint" coupling and restricted to mechanically coupled handpieces of the slow or medium speed types.



**Number coding system for rotary instruments -- Part 1: General characteristics**, ISO 6360-1:2004 presents a number coding system for dental rotary instruments and accessories, and provides guidance with regard to its interpretation and use. ISO 6360-1:2004 specifies the code numbers for materials used for the working parts of instruments, the coating and the binding of abrasives for instruments. This three-digit number forms the first group of three digits in the 15-digit overall number. ISO 6360-1:2004 further specifies the code numbers for shanks, handles, or bore diameter of unmounted instruments, and for the overall lengths of instruments. This three-digit number forms the second group of three (two plus one) digits in the 15-digit overall number. Several examples of complete 15-digit identification numbers are given to demonstrate the number coding system, including examples of three (additional) optional digits (16 to 18) for diamond instruments.

**Number coding system for rotary instruments, Part 2: Shapes**, ISO 6360-2:2004 specifies the code numbers for the shapes of all dental rotary instruments and for several accessories used in connection with these instruments. This three-digit number for shape description forms the third group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1.

**Number coding system for rotary instruments -- Part 3: Specific characteristics of burs and cutters**, ISO 6360-3:2005 specifies the code numbers for specific characteristics of burs, finishing burs, cutters and surgical instruments, which refer to the type of tothing on the working part of the instrument. This three-digit number appears in the locations 10 to 12 of the 15-digit overall number and forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and 6360-2.

**Number coding system for rotary instruments -- Part 4: Specific characteristics of diamond instruments**, ISO 6360-4:2004 specifies the code numbers for specific characteristics of rotary diamond instruments and diamond-coated discs for use in dentistry. This three-digit number forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2. ISO 6360-4:2004 also gives a three-digit number which in addition to the 15-digit code number may be used to provide additional information for diamond instruments and diamond-coated discs, at the discretion of the manufacturer.

**Number coding system for rotary instruments -- Part 5: Specific characteristics of root-canal instruments**, ISO 6360-5:2007 specifies the code numbers for specific characteristics of root-canal instruments. This three digit number appears in the locations 10 to 12 of the 15-digit overall number and forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2.

**Number coding system for rotary instruments, Part 6: Specific characteristics of abrasive instruments**, ISO 6360-6:2004 specifies the code numbers for specific characteristics of rotary abrasive instruments used in dentistry. This three-digit number forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2. ISO 6360-6:2004 is also applicable to dental polishers, which are considered as abrasive instruments.

**Number coding system for rotary instruments -- Part 7: Specific characteristics of mandrels and special instruments**, ISO 6360-7:2006 specifies the code numbers for specific characteristics of mandrels and special instruments such as bone cutters, implant burs, trephines, wax scrapers and polishers. This three-digit number forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2.

**Dental explorers**, ISO 7492:1997, Specifies the dimensions and performance requirements for dental explorers. Replaces the first edition.

**Rotary instruments -- Diamond instruments -- Part 1: Dimensions, requirements, marking and packaging**, ISO 7711-1:1997. Specifies dimensional and other relevant requirements for the 14 most commonly used shapes of dental diamond instruments, including a quality control for these instruments.

**Rotary diamond instruments -- Part 2: Discs**, ISO 7711-2:2011 specifies requirements for diamond discs used commonly in the dental laboratory for the cutting of dental materials, such as metals, ceramics, plastics or gypsum. In addition, ISO 7711-2:2011 selects five specific shapes with their specific dimensions.

**Diamond rotary instruments, Part 3: Grit sizes, designation and colour code**, ISO 7711-3:2004 specifies the designation, colour code and grit sizes for diamond rotary instruments which are used commonly in a dental surgery. It applies to all types of dental diamond rotary instruments independent of type and shape. NOTE: Attention is drawn to ISO 6360, which specifies a number coding system for the identification of dental rotary instruments of all types.

**Dental handpieces -- Part 1: High-speed air turbine handpieces**, ISO 7785-1:1997. No abstract.

**Dental handpieces -- Part 2: Straight and geared angle handpieces**, ISO 7785-2:1995. Specifies requirements and test methods for straight and geared angle dental hand instruments for application to patients. Contains also specifications on manufacturer's instructions, marking and packaging.

**Dental rotary instruments -- Laboratory abrasive instruments**, ISO 7786:2001.

**Dental rotary instruments, Cutters Part 1: Steel laboratory cutters**, ISO 7787-1:1984. Specification of the dimensional and other requirements, that are considered important to ensure the interchangeability of these instruments, for the nine most commonly, used steel cutters. Other characteristics of cutters, for example spiralled blades or cross-cut, are not included. Attention is drawn to ISO 6360, which specifies a 15 digit number for the identification of all types of these rotary instruments.

**Dental rotary instruments -- Cutters -- Part 2: Carbide laboratory cutters**, ISO 7787-2:2000.

**Dental rotary instruments -- Cutters -- Part 3: Carbide laboratory cutters for milling machines**, ISO 7787-3:1991. Specifies the dimensional and other requirements for the three most commonly used cutters with nominal sizes 010, 015, 023, such as cylindrical cutters for side cutting only.

**Dental rotary instruments -- Cutters -- Part 4: Miniature carbide laboratory cutters**, ISO 7787-4:2002. This part of ISO 7787 specifies the shape and dimensional characteristics, number of blades, type of tothing and run-out for the ten most common miniature carbide laboratory cutters, which are predominantly used in the dental laboratory.

**Sterile injection needles for single use**, ISO 7885:2010 gives dimensional and performance requirements for sterile injection needles for single use which are used in dental cartridge syringes complying with ISO 9997 for injection of dental local anaesthetics. It further specifies requirements with respect to their packaging, labelling and colour coding. It does not cover needles for special applications or techniques. Only the materials used for the construction of the needle tubing are specified.

**Test methods for rotary instruments**, ISO 8325:2004 specifies methods for measuring the dimensional characteristics, neck strength and surface roughness of dental rotary instruments, such as burs, cutters, polishers, diamond and abrasive instruments. ISO 8325:2004 does not provide test methods for the characteristics of materials used for dental rotary instruments. NOTE: For testing of these characteristics, see the respective product standards. ISO 8325:2004 is not applicable to dental root-canal instruments (see ISO 3630-1).

**Hose connectors for air driven dental handpieces**, ISO 9168:2009 is applicable for achieving reliable interchangeability between hoses from dental units and dental handpieces. ISO 9168:2009 specifies four types of hose connector for use between air driven dental handpieces and the flexible hoses of the dental unit which supply the handpieces with water, air and light, and provide for exhaust.

**Extraction forceps, Part 1: General requirements and test methods**, ISSpecifies the following nominal bore diameters in order to achieve interchangeability between discs and wheels. Diameters in mm: 1,6; 1,8; 2,2; 3,0 9173-1:2006 specifies the general performance requirements for dental extraction forceps.

**Extraction forceps, Part 2: Designation**, ISO 9173-2:2010 specifies designation of extraction forceps.

**Extraction forceps, Part 3: Design and dimensions, ISO/CD 9173-3** under development.

**Dental hand instruments, reusable mirrors and handles, ISO 9873:1998.**

**Dental cartridge syringes, ISO 9997:1999.**

**Dental rotary instruments -- Bore diameters for discs and wheels, ISO 10323:1991.** Specifies the following nominal bore diameters in order to achieve interchangeability between discs and wheels. Diameters in mm: 1,6; 1,8; 2,2; 3. This standard is under revision.

**Dental handpieces -- Dental low-voltage electrical motors, ISO 11498:1997.** Gives requirements and test methods for dental low-voltage electrical motors used in connection with dental handpieces. It also contains specifications on manufacturer's instructions, packaging and marking. Refers to IEC 601-1, the basic standard on safety of medical electrical equipment.

**Single-use cartridges for local anaesthetics, ISO 11499:2007** gives specific performance requirements for single-use dental cartridges of 1,8 ml and 2,2 ml nominal capacity, for use with local anaesthetics. It specifies tests for leakage, plunger movement, extractable volume and underfilling, and lists general overall dimensions to ensure that the cartridge will fit dental cartridge syringes complying with ISO 9997. Labelling requirements are also specified. This standard is under revision.

**Dental handpieces -- Dental air-motors, ISO 13294:1997.**

**Mandrels for rotary instruments, ISO 13295:2007** specifies the requirements, the packaging and marking characteristics for mandrels suitable for discs and polishers used in dentistry. ISO 13295:2007 uses the system of coding laid down in ISO 6360, which specifies a 15-digit number for the identification of dental rotary instruments of all types.

**Periodontal curettes, dental scalers and excavators -- Part 1: General requirements, ISO 13397-1:1995.** Specifies the general material and performance requirements for periodontal curettes, dental scalers and excavators.

**Dentistry -- Periodontal curettes, dental scalers and excavators -- Part 2: Periodontal curettes of Gr-type, ISO 13397-2:2005** specifies the designs and dimensions for Gr-type periodontal curettes.

**Periodontal curettes, dental scalers and excavators -- Part 3: Dental scalers -- H-type, ISO 13397-3:1996.** Gives the dimensions for H-type dental scalers.

**Periodontal curettes, dental scalers and excavators -- Part 4: Dental excavators -- Discoid-type, ISO 13397-4:1997.**

**Periodontal curettes, dental scalers and excavators -- Part 5: Jacquette scalers, ISO/AWI 13397-5** under development.

**General requirements for instruments and related accessories used in dental implant placement and treatment, ISO/FDIS 13504** under development.

**Handpieces and motors, ISO/DIS 14457** under development.

**Dental elevators -- Part 1: General requirements, ISO 15087-1:1999.**

**Dental elevators -- Part 2: Warwick James elevators, ISO 15087-2:2000.**

**Rubber dam technique -- Part 2: Rubber dam clamp forceps and elevators -- Part 3: Cryer elevators, ISO 15087-3:2000.**

**Dental elevators -- Part 4: Coupland elevators, ISO 15087-4:2000.**

**Dental elevators -- Part 5: Bein elevators, ISO 15087-5:2000.**

**Dental elevators -- Part 6: Flohr elevators, ISO 15087-6:2000.**

**Dental tweezers -- Part 1: General requirements, ISO 15098-1:1999.**

**Dental tweezers -- Part 2: Meriam types, ISO 15098-2:2000.**

**Dental tweezers -- Part 3: College types, ISO 15098-3:2000.**

**Dental handpieces -- Air-powered scalers and scaler tips, ISO 15606:1999.**

**Rubber dam technique -- Part 1: Rubber dam punch, ISO/CD 16635-1.**

**Rubber dam technique -- Part 2: Rubber dam clamp forceps, ISO/CD 16635-2.**

**Graphical symbols for dental instruments, ISO 21531:2009** presents a series of graphical symbols for dental instruments. They are set out particularly for this area of dentistry or corresponding specific areas within dentistry. General symbols are taken from relevant ISO, IEC or other international documents. Several new symbols presented by manufacturers or users have been added.

**Reusable cartridge syringes intended for intra-ligamentary injections, ISO 21533:2003** specifies requirements and test methods for reusable cartridge syringes intended for intra-ligamentary injections. It specifies requirements for dental cartridge syringes only with ISO metric thread sizes, and only intended for intra-ligamentary injections. However, imperial thread sizes are considered in an informative annex.

**Rotary polishers, ISO 21671:2006** specifies the dimensions and other requirements for the most commonly used polishers which are used at the working place of the dentist and/or in the dental laboratory. ISO 21671:2006 is applicable to unmounted and mounted polishers.

**Periodontal probes -- Part 1: General requirements, ISO/FDIS 21672-1.**

**Periodontal probes -- Part 2: Designation, ISO/DIS 21672-2.**

**Dental handpieces -- Electrical-powered scalers and scaler tips, ISO 22374:2005** specifies requirements and test methods for electrical-powered scalers and scaler tips, including piezo, ferrostrictive and magnetostrictive type ultrasonic scalers, operated as stand-alone items or connected to dental units, for use on patients. It also contains specifications on manufacturers' instructions, marking and packaging.

## **Sub Committee #6 Dental Equipment:**

The quality and safety of the equipment used by the dental professional is extremely important.

**Operator's stool (ISO 7493:2006)** is currently being considered for adoption or revision. The objectives of this International Standard are to ensure that the design and functioning of the operator's stool in the dental office will be such as to enable the dental operator to perform his or her work effectively and safely, to minimize the muscular and skeletal stresses, particularly in shoulders and spine, that arise during the performance of the work, and to allow freedom of movement without undue muscular activity. The standard covers recommendations to manufacturer on the design of operator's stools, as well as requirements for the manufacturer's instructions for use. For purposes of ISO 7493:2006, the term "dental operator" includes dentists, dental assistants and dental hygienists.

**Operating lights (ISO 9680:2007)** aims to provide the dentist and his staff with means to enable them to work with optimum visual ease and comfort, i.e. a visual acuity of 90 % to 100 % according to zone, without adversely affecting their perception of colour or causing excessive fatigue. This standard is undergoing revision. Significant technical changes are contemplated including the possible effects of operating lights on potential premature curing of light- curable composites.

**Quality of water** in the dental unit is extremely important. A technical specification (ISO/TS 11080:2009) has been published for essential characteristics of test methods for the evaluation of treatment methods intended to improve or maintain the microbiological of dental unit procedural water. Further work is now proceeding with part 2 dealing with a test method to evaluate treatment methods intended to improve or maintain the microbiological quality of the dental unit procedural water. A further new work item being worked on deals with central dental suction source equipment.

**Amalgam capsules: ISO 13897:2003** specifies requirements and test methods for pre-dosed capsules and for reusable capsules used for mixing dental amalgam alloys and mercury.

**Test methods for evaluating microbiological treatment methods for dental unit procedural water: ISO/AWI 16954** is under development.

**Materials used for dental equipment surfaces -Determination of resistance to chemical disinfectants: ISO 21530:2004** specifies test methods for determining the resistance to chemical disinfectants of all materials used for external surfaces of dental equipment intended for such disinfection. Three test methods are specified: an immersion test, a spray test and a contact test. The choice of test method to be used is left to the discretion of the party conducting the testing. ISO 21530:2004 does not address the bactericidal,

virucidal and fungicidal effectiveness of the disinfectants. ISO 21530:2004 does not provide for testing the possible detrimental effects of applied stress on the resistance of test materials to the test reagents.

**Plant area equipment - Part 1: Suction systems:** ISO/TS 22595-1:2006 is applicable to dental suction equipment in the plant area, used to source suction for the dental equipment specified in ISO 10637. In addition ISO/TS 22595-1:2006 gives recommended guidelines for performance as well as test procedures for dental suction equipment including suction machines, amalgam separators, filters, valves, pipes, fittings and exhaust requirements. ISO/TS 22595-1:2006 is limited to the performance of the suction system at the suction line connection point.

**Dentistry -Plant area equipment - Part 2: Compressor systems:** ISO/TS 22595-2:2008 applies to compressor units for dental air and specifies quality requirements for dental air, fittings, pipe lines and valves in the plant area, used to source compressed air for the dental units, dental instruments and technical dental lab equipment. ISO/TS 22595-2:2008 gives recommended guidelines for performance as well as test procedures for compressor units for dental air with at least a compressor motor set including compressor head, air receiver, air dryer system, condensed water tap, pressure switch, valves, pipes, fittings and quality requirements for dental air.

**Information system on the location of dental equipment in the working area of the oral health care provider:** ISO 4073:2009 specifies an information system for the location of items of dental equipment that are used at the working place of the team of the oral health care provider where examination, treatment and other clinical procedures, with the patient directly involved, are carried out. The identification system provides the means of giving general information about the presence of items and of describing relevant characteristics concerning dimensional flexibility and adaptability of the items and parts of their accessories. In addition, ISO 4073:2009 provides definitions for general terms used in the area of dental equipment.

**Patient chair:** ISO 6875:2011 is applicable to all patient chairs, regardless of their construction, and regardless of whether they are operated manually, electrically or by other means, or as a combination of these. ISO 6875:2011 specifies requirements, test methods, manufacturer's information, marking and packaging.

**Dental amalgamators:** ISO 7488:1991 specifies the requirements, recommendations and test methods for the dental amalgamators used in the dental office as well as requirements for the manufacturer's instructions for use.

**Dental units -Part 1: General requirements and test methods:** ISO 7494-1:2011 specifies requirements and test methods for dental units, regardless of whether or not they are electrically powered. ISO 7494-1:2011 also specifies requirements for manufacturer's instructions, marking and packaging.

**Dental units -Part 2: Water and air supply:** ISO 7494-2:2003 specifies requirements and test methods for the materials, design and construction of the water and air supply within dental units in order to ensure that the compressed water and air supplied via the dental unit are of appropriate quality. It includes provisions for the prevention of retraction of oral fluids into the water supply of the dental unit. ISO 7494-2:2003 does not address prevention of contamination and/or proliferation of hazardous microorganisms (for example bacteria, viruses) in the dental unit. This standard is under revision.

**Mercury and alloy mixers and dispensers:** ISO 8282:1994. Specifies requirements and test methods for devices used for dispensing dental amalgam alloys and/or mercury. Includes the dispensing portion of devices which dispense the correct portions of alloy and mercury as well as mix the amalgam in a single, continuous operation. Does not specify requirements and test methods for the efficacy of mixing.

**Operating lights:** ISO 9680:2007 specifies requirements and test methods for operating lights used in the dental office and intended for illuminating the oral cavity of patients. It also contains specifications on manufacturers' instructions, marking and packaging. ISO 9680:2007 applies to operating lights that are intended to be permanently fixed to the ceiling, or to the wall or to the floor. (ISO 9680 is under revision.)

**Dental equipment -High- and medium-volume suction systems:** ISO 10637:1999.

**Powered polymerization activators -Part 1: Quartz tungsten halogen lamps:** ISO 10650-1:2004 specifies requirements and test methods for powered polymerization activators in the blue wavelength region intended for chair-side use in polymerization of dental polymer-based materials. ISO 10650-1:2004 applies to powered tungsten-halogen lamps and rechargeable battery-powered tungsten-halogen polymerization activators. ISO 10650-1:2004 is not applicable to powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances. ISO 10650-1:2004 takes priority over IEC 60601-1:1988 where specified in the individual clauses of this International Standard.

**Powered polymerization activators -Part 2: Light-emitting diode (LED) lamps:** ISO 10650-2:2007, specifies requirements and test methods for powered polymerization activators with light-emitting diodes (LED) in the blue wavelength region intended for chair-side use in polymerization of dental polymer-based restorative materials. ISO 10650-2:2007 is not applicable to powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances.

**Essential characteristics of test methods for the evaluation of treatment methods intended to improve or maintain the microbiological quality of dental unit procedural water:** ISO/TS 11080:2009 provides guidelines for type test methods for evaluating the effectiveness of treatment methods intended to improve or maintain the microbiological quality of procedural water from dental units and other dental equipment under laboratory conditions.

**Amalgam separators:** ISO 11143:2008, specifies requirements and test methods for amalgam separators used in connection with dental equipment in the dental treatment centre. It specifies the efficiency of the amalgam separators in terms of the level of retention of amalgam based on a laboratory test and the test procedure for determining this efficiency. It also includes requirements for the safe functioning of the amalgam separator, for marking, instructions for use, operation and maintenance.

**Connections for supply and waste lines:** ISO 11144:1995, specifies requirements for the layout of the connections to the supply and waste lines for dental equipment, dental units, apparatus and devices, both as concerns the building plumbing and as mutually related to each other. Also lays down the relative positions, centres and minimum dimensions to accommodate the water, waste-water and suction supply lines, and adjacent spaces destined for electrical lines and compressed air lines for dental services. Covers requirements for all types of dental units and dental treatment centres.

**Test methods for evaluating microbiological treatment methods for dental unit procedural water:** ISO/AWI 16954 is currently under development.

**Electrical Safety:** A series of nine standards in the ISO 80601 series deal with requirements for basic safety and essential performance of dental equipment, IEC 80601-2-60.

## **Sub Committee #7 Oral Hygiene Products:**

**Manual toothbrushes:** General requirements and test methods; ISO/20126.2 has now been completed. Significant discussion has taken place concerning manual and power toothbrushes that could be sterilized. It has been agreed that a statement be considered indicating that if a manufacturer recommends sterilization of their toothbrush, the toothbrush must still meet all of the physical requirements of the standard after sterilization.

**Manual toothbrushes:** Resistance of tufted portion to deflection; ISO 22254:2005 specifies a test method for determining the resistance of the tufted portion of manual toothbrushes to deflection. This International Standard is applicable to toothbrushes having a conventional flat trim design and may not be applicable to toothbrushes with other designs. The results obtained with this International Standard may not correspond to consumer perceptions of the stiffness of toothbrush bristles.

**Powered toothbrushes:** General requirements and test methods, ISO 20127:2005 specifies requirements and test methods for the physical properties of powered toothbrushes in order to promote the safety of these

products for their intended use. Specifically excluded are other types of powered oral hygiene devices (such as powered inter-dental brushes) and manual toothbrushes.

**Manual inter-dental brushes:** ISO 16409:2006 specifies requirements and test methods for performance criteria for manual inter-dental brushes with a round cross-section of the brush head. It also specifies the accompanying information, such as the manufacturer's instructions for use and labelling of the packaging. ISO 16409:2006 is not applicable to powered inter-dental brushes, manual toothbrushes, dental floss, tapes, and strings, nor is it applicable to inter-dental cleaners that do not include filaments.

**Denture adhesives:** ISO 10873:2010 classifies denture adhesives used by wearers of removable dentures; it also specifies requirements, test methods and instructions to be supplied for the use of such products. ISO 10873:2010 is applicable to denture adhesives for use by the public and excludes the dental lining materials prescribed or applied by dental professionals. ISO 10873:2010 does not specify qualitative or quantitative requirements for freedom from biological hazards. For assessing possible biological hazards, see ISO 7405 and ISO 10993-1.

**Dentifrices:** Requirements, test methods and marking, ISO 11609:2010 specifies requirements for the physical and chemical properties of dentifrices and provides guidelines for suitable test methods. It also specifies requirements for the marking, labelling and packaging of dentifrices. ISO 11609:2010 applies to dentifrices, including toothpastes, destined to be used by the public on a daily basis with a toothbrush to promote oral hygiene.

**Oral rinses:** ISO 16408:2004 specifies physical and chemical requirements and test methods for oral rinses. It also specifies the accompanying information such as manufacturer's instructions for use, marking and/or labelling requirements. ISO 16408:2004 is not applicable to other delivery systems (e.g. mouthsprays, foams, powders). It is not intended to describe regulatory aspects, e.g. methods of prescription. ISO 16408:2004 is not applicable to oral rinses available by prescription only.

**Oral rinses:** A new work item "Screening method for erosion potential of oral rinses" ISO 28888 has commenced. The standard will relate to the screening method only. An ad hoc group has been proposed to deal with analysis of fluorides to focus the efforts of three working groups on this topic.

**Dental bleaching products:** ISO 28399 was only published in 2011 however; the working group is already considering a new or modified erosion method to be included in a future revision.

**Wear of Teeth:** The technical report; Guidance on testing of wear -Part 1: Wear by tooth-brushing, ISO/TR 14569-1:2007 provides guidelines for test methods for the assessment of resistance to wear by tooth brushing for materials used for the preparation of artificial teeth as well as for veneering of crowns and bridges. Another technical report; ISO/TS 14569-2:2001, Part 2: deals with wear by two- and/or three body contact.

**Integrated dental floss and handles:** ISO 28158:2010 is applicable to integrated dental floss and handles for manual use. It does not include dental floss and handles, which contain a continuous supply of dental floss, or dental floss and handles to which the floss is subsequently added. ISO 28158:2010 does not specify specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks.

**Products for external tooth bleaching:** ISO 28399:2011 specifies requirements and test methods for external tooth bleaching products. These products are intended for use in the oral cavity, either by professional application (in-office tooth bleaching products) or consumer application (professional or non-professional home use of tooth bleaching products). It also specifies requirements for their packaging, labelling and instructions for use.

The following tooth bleaching products are not covered by ISO 28399:2011:

- those intended to change colour perception of natural teeth by mechanical methods (e.g. stain removal) or using restorative approaches, such as veneers or crowns;
- auxiliary or supplementary materials (e.g. tray materials) and instruments or devices (e.g. lights) that are used in conjunction with the bleaching products.

## **Sub Committee #8 Dental implants:**

Around 600,000 dental implants are used annually throughout the world. The dental implant industry is made up of about 4 or 5 large companies and around 200 smaller manufacturers. The worldwide dental implant market in the year 2005 was about one billion euro and was estimated to grow to 2.4 billion Euros by the year 2010. The increasing use of implants in modern dental treatment requires standards to be developed to address this trend.

**Implants -- Clinical performance of hand torque instruments:** ISO 11953:2010 describes a classification system for hand-held torque wrenches intended for clinical use. It specifies their performance requirements in terms of accuracy and reproducibility for the clinical tightening of screwed components. Test methods are described, and marking and labelling requirements specified. This standard specifies testing procedures for determining the repeatability of the torque developed by hand torque instruments, this is very important for the quality of dental treatment involving implants. Screw-retained joints are used widely in dental implant systems and for their integrity depend on the creation and maintenance of an appropriate clamping force. Failure of such joints is a documented clinical problem, which can have significant impact on treatment outcomes. Manually operated, suitably calibrated torque wrenches or devices are widely employed in dental implant treatment to tighten screwed joints and should be capable of providing the desired torque in a consistent manner. There is, however, some evidence that this might not always be the case. The ISO 11953 standard has, been developed to facilitate the availability of devices that meet necessary clinical requirements and help ensure successful clinical outcomes.

**Implants -- Dynamic fatigue test for endosseous dental implants:** ISO 14801:2007, specifies a method of fatigue testing of single post endosseous dental implants of the transmucosal type and their pre-manufactured prosthetic components. It is most useful for comparing endosseous dental implants of different designs or sizes. While it simulates the functional loading of an endosseous dental implant body and its pre-manufactured prosthetic components under “worst case” conditions, ISO 14801:2007 is not applicable for predicting the *in vivo* performance of an endosseous dental implant or prosthesis, particularly if multiple endosseous dental implants are used for a prosthesis.

**Preclinical evaluation of dental implant systems -- Animal test methods:** ISO/TS 22911:2005, concerns animal tests relevant to the functional assessment of dental implant systems, using both macroscopic and microscopic parameters. It is intended for use only when risk analysis indicates a need for additional information that only animal testing can provide.

**Guidelines for developing dental implants:** ISO/TR 11175:1993, provides general principles and concepts relevant to the production of a given type of dental implant; however, it does not aim to define the ideal dental implant. The guidelines include technical aspects and biological aspects.

**Contents of technical file for dental implant systems:** ISO 10451:2010 specifies requirements for the contents of a technical file to demonstrate the fulfilment of regulatory requirements for a dental implant and any prefabricated part thereof that remains in the mouth after surgery.

**Torsion test of implant body/connecting part joints of endosseous dental implant systems:** ISO/TS 13498:2011 establishes a method to determine the torsional yield strength and maximum torque of the implant body/connecting part joints of endosseous dental implant systems. This test is most appropriate for evaluating new types of joints and connecting parts, as well as new materials. ISO/TS 13498:2011 provides a protocol for torsional loading of an implant body/connecting part joint. It is not however, applicable for predicting the *in vivo* performance of an endosseous dental implant system and it is not derived from observations of clinical failure.

**Implantable materials for bone filling and augmentation in oral and maxillofacial surgery -- Contents of a technical file:** ISO 22794:2007 applies to implantable materials, whether resorbable or non-resorbable, used as dental devices for filling and augmenting bones in oral and maxillofacial surgery. Products that are essentially pure (greater than 90 %) hydroxyapatite are not covered by this International



Standard. Evaluation includes the physico-chemical, mechanical, biological and clinical aspects and behaviour of these implantable dental materials.

**Membrane materials for guided tissue regeneration in oral and maxillofacial surgery -- Contents of a technical file:** ISO 22803:2004, this standard deals with membrane materials for guided tissue regeneration in oral and maxillofacial surgery. It details the requirements for a technical file on the evaluation of the chemical, physical, mechanical, biological and clinical aspects and behaviour of membrane materials, whether resorbable, partially resorbable or non-resorbable, which are used:-

- a) for guided tissue regeneration in oral and maxillofacial surgery to correct a morphological defect or abnormality,
- b) in contact with teeth and/or dental implants,
- c) for prevention of epithelial migration in periodontal surgery,
- d) for the augmentation of bone prior to the planned insertion of dental implants,
- e) and/or for augmentation of bone for stabilization of dental prostheses.

This International Standard is not applicable to materials whose primary intended use is to deliver a medicinal product, autografts and allografts, or materials intended to act through pharmacological, immunological or metabolic means. ISO 22803:2004 is currently undergoing revision.

**Minimal dental implant data set for clinical use:** ISO/CD 16498, is currently under development.

### **Sub Committee #9 CAD/CAM Systems:**

Computer aided design combined with computer aided machining is becoming increasingly popular in dentistry. The laser mapping of a cavity preparation can be fed to a computer controlled milling machine, which can then machine an inlay, crown or bridge structure. Various glass -infiltrated alumina, and zirconia ceramics are used in CAD/CAM systems to manufacture dental fixed crown and bridge frameworks or for implant systems. There is clearly a need to develop standardized criteria for the various dental CAD/CAM systems. However, standardization of the many aspects and uses of dental CAD/CAM systems and materials presents many challenges due to the complexity of the process and the need for a wide range of expertise in the standards writing process. The first CAD/CAM standard has been produced (ISO 12836) describing test methods for the assessment of the accuracy and reproducibility of digitization devices for CAD/CAM systems for indirect dental restorations. The three test procedures are involved: - 1) "Sphere", limited to the upper part of the specimen, in order to apply standard procedures for single crown measurements. 2) "Swiss cross" (bracket shaped specimen) in order to simulate inlay type shaped cavities, and 3) a "Multi-unit" specimen, consisting of two full coverage dies with distances of 30 mm, being designed to simulate a 3-unit bridge digitizing process. The accuracy and reproducibility of intra- and extra-oral surface digitization devices for hard and soft tissue and dental implant system components is required in order to determine their efficacy. In the future the newly created Sub Committee number 9 will address various other aspects of dental CAD/CAM applications.

*Note: - The status of the above international standards, technical reports or technical specifications can change due to the result of voting by member bodies and the introduction of new or modified standards.*