Date	CEN/TC 55 N 551
2009-02-25	Dentistry

REPORT OF THE SECRETARIAT

January 2008 – February 2009

1 CEN structure

30 National Members: Participating Members (P-members, 27 EU + 3 EFTA countries)
Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom.

CEN's National Members are the National Standards Organizations of 30 European countries. There is only one member per country. They have voting rights in the General Assembly and Administrative Board of CEN and provide delegations to the Technical Board which defines the work programme. It is the responsibility of the CEN National Members to implement European Standards as national standards, to distribute and sell them and to withdraw any conflicting national standards.

17 Affiliates
Affiliates are the national standards bodies of the accession countries to the European Union: Albania, Armenia, Bosnia-Herzegovina, Croatia, Egypt, The Former Yugoslav Republic of Macedonia, Georgia, Israel, Jordan, Lebanon, Republic of Moldova, Montenegro, Russia, Serbia, Tunisia, Turkey, Ukraine.

In 2008 **two new affiliates** were accepted: Georgia, Lebanon.

Affiliates may apply for full member ship of the European Union in the coming years by meeting certain criteria. The most important criteria is the adoption of European Standards as national standards.

CEN Central secretariat
New office and meeting rooms for CEN and CENELEC
In January 2009 CEN Central Secretariat moved into new office rooms in the new CEN/CENELEC Meeting Centre in Brussels:

CEN Management Centre
Avenue Marnix 17
B – 1000 Brussels

Up to now, CEN has published over 10.000 European Standards of which over 2.000 documents are harmonised standards. Harmonized standards have been developed to support European legislation through the New Approach.

CEN currently has 377 active Technical Committees and 30 active CEN Workshops.

January 2009: Creation of **new** CEN/TC 392 *Cosmetics* (Secretariat: NEN).

[redacted]
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2 CEN/TC 55 Dentistry

Chairman Prof. Dr. H. Kappert, Liechtenstein
Secretary Dr. H.-P. Keller, DIN

Working Groups of CEN/TC 55

WG 3 Classification

Convenor: Prof. *K. Dermann*, Germany

WG 4 Preclinical biological evaluation and testing

Convenor: Dr. *A. Hensten*, Norway

WG 5 Nomenclature and coding system for medical devices used in dentistry

Convenor: Prof. *P. Calfon*, France

WG 6 Dental alloys

Convenor: Prof. *H. Kappert*, Liechtenstein

WG 7 Steering Committee

Convenor: Dr. *P. Jacobsen*, UK

WG 8 Occupational risk assessments related to dental materials

Convenor: Prof. *U. Örtengren*, Sweden

and

Joint Working Group with CEN/TC 162/WG 11/PG 8 Mouthguards

Convenor: Prof. *B. Avery*, UK; meeting: 2008-03-12 in London. After this meeting no meeting report was distributed until today. The proposal to exclude Type 1 made-to-measure (custom made) mouthguards from the scope of prEN 15912 "Mouthguards for use in sports – Safety requirements and test methods" was ignored. The project leader developed the text for final prEN voting without asking the experts of the JWG. The assessment of the CEN consultant is negative (see document N 549).

3 Ratified European Standards (Stage 64)

Document N 545 gives an overview of about **126 European Standards** published by CEN/TC 55 Dentistry. Since the last TC 55 Plenary meeting in February 2008 the following five European Standards, and one Amendment were published:

EN ISO 3630-1:2008 Dentistry — Root-canal instruments — Part 1: General requirements and test methods (ISO 3630-1:2008)

EN ISO 6872:2008 Dentistry — Ceramic materials (ISO 6872:2008)

EN ISO 7405:2008 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008)

EN ISO 11143:2008 Dentistry — Amalgam separators (ISO 11143:2008)

EN ISO 20795-1:2008 Dentistry — Base polymers — Part 1: Denture base polymers (ISO 20795-1:2008)

EN ISO 3823-2:2003/Amd.1:2008 Dentistry — Rotary bur instruments — Part 2: Finishing burs — Amendment 1 (ISO 3823-2:2003/Amd.1:2008)

4 Harmonized standards EN 1639 to EN 1642

The second revision of EN 1639 to EN 1642 is currently under development. In September 2008 the following draft European Standards were distributed by CEN/CMC:

prEN 1639:2008	Dentistry — Medical devices for dentistry — Instruments
prEN 1640:2008	Dentistry — Medical devices for dentistry — Equipment
prEN 1641:2008	Dentistry — Medical devices for dentistry — Materials
prEN 1642:2008	Dentistry — Medical devices for dentistry — Dental implants

All changes introduced by Directive 2007/47/EC were included in these draft standards.

The first revisions of EN 1639 to EN 1642 were published by CEN/CMC in June 2004. In September 2005 the titles of these standards were published in the Official Journal of the European Union (Commission Communication C 240/2, 30.9.2005, page 6) and therefore approved as harmonized standards for the European Directive 93/42/EEC for Medical Devices.

5 Healthcare consultants (for medical devices)

Richard Mellish, Robert Virefleau, Tony Wilkes.

6 Regulatory environment of CEN/TC 55

Note of the secretariat: The following information in this clause is based on my actual knowledge. It is intended to provide a common discussion base at the next TC 55 Plenary meeting.

6.1 Medical Device Directive (MDD) 93/42/EEC amended by Directive 2007/47/EC

On the 21 September 2007 the new Directive 2007/47/EC of the European Parliament and the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, was published in the Official Journal of the European Union (Directive 2007/47/EC – OJ L247/21.9.07).

Directive 2007/47/EC entered into force twenty days after publication. Member States must adopt and publish by the 21 December 2008 the laws, regulations and administrative provisions necessary to comply with the Directive. They must apply those measures from 21 March 2010.

Between 8 May and 2 July 2008 the European Commission services consulted stakeholders on the revision of the legal framework for medical devices ("recast"). A public consultation a public consultation in the form of a questionnaire was prepared.

6.2 General Service Directive 2006/123/EC

On the 27th December 2006 the directive on general services was published in the Official Journal of the European Union. The directive aims to break down barriers to trade in the field of services across the European Union.

Excluded are healthcare services.

6.3 EC Directive on patients rights in cross-boarder healthcare

As part of the Renewed Social Agenda, the Commission adopted on 2. July 2008 a proposal for a directive to facilitate the application of European patients' rights in relation to cross-border healthcare.

This Directive will provide a clear framework for cross-border care with the following goals:
- Patients have the right to seek healthcare abroad and be reimbursed up to what they would have received at home.
- Member States are responsible for healthcare provided on their territory.
- The Directive will facilitate European cooperation on healthcare (e.g. development of European reference networks, patients will have easier access to highly specialised care).
- Heath technology assessment.
- Activities in the field of "e-Health" will also be strengthend.

This healthcare services directive will be applicable e.g. to dental treatment, e.g. provided by the dentist to a patient.

European Standards Organizations launch joint project on interoperability of eHealth standards
CEN, CENELEC, and ETSI, the three European Standards Organizations (ESOs) launched the joint project ‘eHEALTH-INTEROP’, which will address the requirements of the European Commission mandate on standardization in the field of e-health. This mandate (M/403) aims to provide a consistent set of standards to address the needs of this rapidly-evolving field for the benefit of future healthcare provision. The project will have two phases. In phase 1, a team of appointed experts reporting to the ESOs will examine the portfolios of existing standards from the many different organizations in the sector, including international formal bodies and industry standards consortia. Analysis of sector needs and recommendations for specific standards development will subsequently be carried out in full consultation with other international partners and a work programme will be produced that reflects the need for coherent, cost-effective, and secure provision of electronic healthcare services.
Phase 2, in 2009 and 2010, will see the execution of that work programme. Detailed work on the project is due to start early in March 2008 with the completion of phase 1 foreseen for September 2008. This will be followed by public consultation on the draft work programme and final reporting to the European Commission: a conference will fully discuss possible solutions.

6.4 Restriction of the use of Hazardous Substances in Electrical and Electronical Equipment Directive (RoHS) 2002/95/EEC

The current Directive on Restriction of Hazardous Substanzes (RoHS), 2002/95/EEC, restricts placing on the market equipment containing six substances: cadmium, lead, mercury, haxavalent chromium, and polybrominated biphenyl- and polybrominated diphenyl-ether (e.g. used as flame retardants): Cd, Pb, Hg, Cr6+, PBBs, PBDEs

The European Commission and Directorate General (DG) Environment are reviewing the scope of the Directive and the current exemptions from its requirement. A report from ERA suggested that medical devices should be included in the classification. Currently medical devices are outside the scope of this Directive in Europe, but in China (1 March 2007), Japan and Korea (2008) they are included into the corresponding environmental laws, which causes problems for global trade.

An early message from the review was that the continued blanket exclusion of medical devices from the scope of RoHS was possible, but not likely. Therefore implications for certain materials and usages like sensors, detectors and electrodes, lifetime buy components

and leaded solder are under discussion. The component sector of the electronics industry, notably the printed circuit board (PCB) producers, make changes to accommodate Directive 2002/95/EC in its current scope, including the move to lead free solder for PCBs.

A proposal for changes in the RoHS Directive will be made in early 2007. The proposed implementation date for medical devices is 2012. Problems are expected for dental X-ray systems where lead is used for shielding purposes.

6.5 EC-Regulation 1907/2006 Registration, Evaluation and Authorisation of Chemical Substances Directive (REACH)

The European Commission Regulation 1907/2006 for the control of chemical substances, known as REACH (from Registration, Evaluation, Authorization of Chemicals) entered into force on 1 June 2007 and includes medical devices.

Registration at the new European Chemicals Agency in Helsinki is required for manufacturers and importers of chemical substances. For each substance manufactured or imported in quantities of 1 t or above per year a registration is required. In addition downstream users are also included in the REACH system. Downstream users may be any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oil and lubricants in other industrial processes. They are required to consider the safety of their uses of substances, based primarily on information from their suppliers, and to apply risk management measures. In particular they will have to check that their use(s) are “covered” by the safety data sheets, i.e. that they use a substance within the conditions described in the exposure scenarios in safety data sheets.

Commercially working persons (e.g. dentists, dental technicians) are now in the regulatory system. They are only allowed to use a chemical substance if it has a clearance statement from their supplier for the intended purpose.

The registration is only necessary for products higher than 1 t per year. However, in addition it is necessary for dangerous substances. Therefore it might be difficult to get the authorisation of the agency for the registration of dental amalgam.

6.6 Inland Transport of Dangerous Goods Directive 2008/68/EC

In September 2008 the new Directive on the Inland Transport of Dangerous Goods 2008/68/EC was adopted. Therefore the existing two Directives 94/55/EC on transport of dangerous goods by road and 96/49/EC on transport of dangerous goods by rail will be repealed (end of June 2009). In addition, the new Directive gives provisions for inland waterways.

6.7 Global Harmonized System (GHS) for the Classification and labelling of hazardous substances: New labels in 2011

In 2008 labelling of dangerous products must be performed according to the United Nations Global System for the Classification and Labelling of hazardous substances. The national application is dated for 1.1.2011. From this date dangerous substances will be labelled worldwide with the same symbols:
Hazard information code (e.g. H 224) (earlier: risks, R-Sätze): physical-chemical properties and ecotoxicological data;
Precuationary information code (e.g. P 201), (earlier: safety, S-Sätze): information concerning storage, safety measures;
GHS-safety data sheet (former: EG-Sicherheitsdatenblatt).

These labelling requirements should be investigated for some dental products (e.g. dental amalgams, etching gels, adhesives, disinfection agents, …).

6.7 EC Cosmetics Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

The European Commission has launched on 12 January 2007 a consultation round for stakeholders in the field of cosmetics, to come to a simplified and modern regulatory framework for the industry, which avoids unnecessary costs. This new framework should replace the existing EU Cosmetics Directive from 1976, which has become a “patchwork” of almost 50 amendments without coherent terminology.

Moreover, many provisions appear in the wrong context and the detailed regulation of individual substances used for cosmetics has proven very complex, resource-intensive and difficult to administer. This renders compliance more onerous and costly than necessary for the industry, which is world leader in this field. The consultation round will end in March this year and must lead to a new framework by 2010 at the latest. The existing provisions on the ban and phasing-out of animal-tests for cosmetic products by 2009/2013 are not going to be part of this exercise.

The SCCP (Scientific Committee on consumer Products) discusses the safety of chemical substances. It discussed the use of Triclosan as a preservative in cosmetic products taking into account the new documentation of resistance development by certain micro-organisms and cross-resistance.

Under the cosmetics directive fall general dental OTC products (over the counter products) such as toothpaste, oral rinses, tooth brushes, interdental brushes, (some) bleaching agents.

6.8 European Nickel Directive

Nickel-Directive from 1994 intended to protect from direct and indirect contact of the skin with products containing nickel.

This directive includes jewellery made from non-precious alloys containing nickel.

6.9 General Product Safety Directive 2001/95/EC (GPSD)

This general directive is for ensuring consumer product safety. This includes all general consumer products not covered by a specific sectoral directive.

This includes e.g. child use and care articles, general software like virus scanner, cigarette lighters, magnetic toys, …

Clause 11 of GPSD describes the establishment of a Community Rapid Information System (RAPEX) on consumer products. This system includes also general dental consumer products, e.g. toothpaste.

In 2007 several warnings for toothpaste were issued. Some product posed a chemical risk because
- of diethylene glycol (DEG),
- the colouring (see ingredients) is not in the list of colourings approved for cosmetic products under the Cosmetics Directive 76/768/EEC,
- bacterial problems.

New warning required for magnetic toys placed or made available on the market, shall display a warning about the health and safety risk they pose.

6.10 Directive on the quality and safety of Human Tissues and Cells (2004/23/EC)

The European Directive 2004/23/EC on the quality and safety of Human Tissues and Cells reassures that tissues and cells sourced from any European Union Member State will meet uniform standards for quality and safety as to their donation, procurement, testing, processing, preservation, storage and distribution. Additionally the origins of all donated tissue and cells must now be traceable. A European-wide coding system, which will be in place by 1 September 2008, will be an important element in ensuring this traceability.

6.11 Proposed new Directive on quality and safety of organ donation

In May 2007 the European Commission adopted a Communication proposing actions for closer cooperation between Member States in the field of organ donation and transplantation, and announcing plans for a European Directive on quality and safety of organ donation.

A European Directive on quality and safety of organ donation, based on Article 152 of the EC Treaty, would create common standards for quality and safety at every stage of the transplant process across the Community, without affecting organ donation rates in the EU. This proposal will complement the cooperation approach set out in the action plan.

The Directive, expected to be proposed in 2008, would establish oversight authorities in Member States, a common set of quality and safety standards and a system to ensure the traceability and the reporting of serious adverse events and reactions. It would also establish inspection and control measures, and incorporate a mechanism to characterise organs, so that the transplant teams can undertake the appropriate risk assessment.

6.12 EC Pharmaceutical Directive Pharmacopoe

New in 2007: Clinical investigations for children required for drugs intended for children.

In dentistry during the treatment of children the usage of drugs for the alleviation of pain and anaesthetic sedation is a common practice. However, the drugs used had no clinical investigations performed on children.

Drugs used in dentistry are e.g. local anaesthetica,
adstringents for blood (e.g strings used during impression of teeth),
biological active implant materials,
resorbable suture materials,
fluoride varnishes for protection of teeth.

6.13 Machinery Directive 2006/42/EC

The revised European Directive for machinery (2006/42/EC) has been approved. The current machinery directive (98/37/ED) is applicable until 28th December 2009, after which Member States must apply the provisions of the revised directive.

The Machinery Directive is applicable e.g. for handpieces, instruments and equipment used by dental technicians (i.e. all products with a movable part which are not medical devices and which are not considered as electrical devices according to the low voltage directive) and for suction machines and compressors in the dental plant area near the dental office.
This includes cutting machines used in dental CAD/CAM centres.

6.14 Low voltage Directive 2006/95/EC

The Low Voltage Directive 2006/95/EC on health and safety aspects of electrical equipment operating within certain ranges was published in 2006.

In dentistry this directive includes e.g. light curing devices used by the dental technician in the dental laboratory for light curing of acrylic materials, e.g. for dental prostheses, orthodontic appliances (not to confuse with the CE-marking according to the MDD of light curing devices used by the dentist for filling materials). These devices are CE-marked in accordance with the low voltage directive.

6.15 Directive 1995/5/EC Radio & Telecom Terminal equipment, equipment and mobile phones

This Directive is applicable e.g. for dental equipment with
- RF transmissions from digital sensors used in intraoral X-ray,
- photos from intraoral cameras,
- wireless communication (WLAN) networks in the dental office.

6.16 Personal Protective Equipment Directive 89/686/EEC of 21. December 1989 on the approximation of the laws of the Member States relating to personal protective equipment

The European Commission has published on 17 July 2006 guidelines on the personal protective equipment (PPE) Directive, providing guidance on how to apply Directive 89/686/EEC on personal protective equipment.

The guidelines were drawn up jointly by the Enterprise and Industry Directorate-General, the member states, European industry, European standardisation experts and the approved bodies. They also include a new PPE categorisation system with categories ranging from I (low risk) to III (high risk).

Dental personal protective devices are e.g. mouth guards for sports activities, safety glasses for protection of dentist's eye, mouth masks for the dentist, gloves.

6.17 Construction Products Directive (CPD), 89/106/EEC

The Construction Products Directive (CPD) came into force in 1989, as a legislative measure to create the internal market in Europe. This year marks the 20th Anniversary of the CPD, and provides a perfect opportunity to revisit this legislation, its outcomes, and the future prospects.

Because Member States' regulatory efforts in construction usually concentrate on works – including building and civil engineering structures – rather than directly on products, the Essential Requirements in this directive are written for works. These requirements therefore call for an interpretation based on the concept of 'intended use', when it comes to the essential characteristics of products. The directive also makes conformity with technical specifications (i.e. standards) compulsory, whereas other directive provide optional means of compliance.

Amalgam separators which are installed away from the dental treatment centre, e.g. in the cellar, fall under the construction products directive.

6.18 Directives for pressure devices

The safety of pressure equipment in the European Union is regulated by three directives:
1. Simple Pressure Equipment Directive 97/404/EEC (SPVD);
2. Pressure Equipment Directive 97/23/EC (PED);
3. Transportable Pressure Equipment Directive 99/36/EC (TPED).

The SPVD and PED are *New Approach* directives, whilst the TPED implements certain elements of the New Approach (e.g. conformity assessment modules) but essentially transposes United Nations regulations on transportable pressure equipment into European law.

The European Commission has an objective to revise the European pressure equipment legislation before the end of 2008.

The pressure devices used for compressors fall under the pressure devices.

6.19 Directive 97/43/EURATOM, Directive 96/29/EURATOM (Protection from X-rays)

This directive is applicable to the following dental devices:
For X-ray devices e.g. intraoral films or digital X-rays, panoramic X-rays, cephalometric X-rays, digital volume tomographs.

6.20 European Directive 2003/10 EC Noise protection at the working place

Directive of 6 February 2003 about protection and safety and health of working persons:

Mindestvorschriften zum Schutz von Sicherheit und Gesundheit der Arbeitnehmer vor der Gefährdung durch physikalische Einwirkungen (Lärm), Amtsblatt der Europäischen Union L 42 vom 15. Februar 2003, S. 38. Diese RL ist in Deutschland durch die Lärm- und Vibrations-Arbeitsschutzverordnung umgesetzt. Dafür gibt es ISO 9612. Verordnung zum Schutz der Beschäftigten vor Gefährdungen durch Lärm und Vibrationen (Lärm- und Vibrations-Arbeitsschutzverordnung – Lärm-VibrationsArbSchV) vom 6. März 2007, BGBl. I, S. 261

6.21 Packaging and Packaging Waste Directive 94/62/EC

Directive 94/62/EC aims to harmonize measures concerning the management of packaging and packaging waste. This will provide a high level of environmental protection, strengthen the internal market, and reduce distortion, obstacles to trade, and restriction of competition within the European Community. To this end, this directive lays down measures aimed at preventing the production of packaging waste as well as reusing and recycling packaging, as well as other forms of recovering packaging waste. The goal, of course, is to reduce the final disposal of such waste.

Harmonized standards EN 13427 to EN 13431 support this Directive.

This Directive applies to the packaging of all dental materials and devices.

7 CEN/TC 55 documents in the European voting procedures

7.1 Parallel voting procedure

In 2008 all documents distributed by ISO/TC 106 *Dentistry* as Draft International Standards (DIS) or Final Draft International Standards (FDIS) were distributed under the parallel voting procedure in accordance with the Vienna Agreement (VA).

Because there is no advantage in transposing an International Technical Specification (TS) or an International Technical Report (TR) into a European Technical Specification or a European Technical Report (still each CEN member body can decide if they want to transpose it into a national document or not) all ISO documents which are intended for publication as Technical Specification or as Technical Report are not in the parallel voting procedure.

7.2 Unique Acceptance procedure (UAP)

In 2008 this voting procedure (intended for the transposition of published ISO standards) was not used.

8 Harmonisation of work programme between CEN/TC 55 and ISO/TC 106

The Business Plan of CEN/TC 55 was approved by BT C 160 in 1999. In the meantime additional work items were approved by ISO/TC 106. Therefore the work programme of CEN/TC 55 was updated at the Plenary meeting 2008 in Brussels. Today the work programme of all CEN and ISO committees is available on the internet. This is a great help for the coordination of the work programme. The actual version of the work programme downloaded from the internet (2008-01-18) is listed for

— CEN/TC 55 Dentistry in document N 546
— ISO/TC 106 Dentistry in document N 547

In order to harmonise the work programme of CEN/TC 55 with the work programme of ISO/TC 106 the following actions are necessary.

8.1 Deletion of existing work items

The following work items should be deleted from work programme of CEN/TC 55:

— 00055242 EN ISO 21672 Dentistry – Periodontal probes

Reason: ISO/TC 106/SC 4/WG 8 decided to replace this work item by 00055295 (prEN ISO 21672-1) and 00055296 (prEN ISO 21672-2) Periodontal probes – Part 1: General requirements and Part 2: Designation.

— 00055285 EN ISO 16409 Dentistry – Oral hygiene products – manual interdental brushes

Reason: ISO/TC 106/SC 7/WG 5 decided to prepare an amendment for ISO 16409. This work item is already listed as WI 00055293.

8.2 Addition of new work items

The following work items should be added to the CEN/TC 55 work programme:
— ISO/CD 3630-2 Dental root-canal instruments – Part 2: Enlargers (ISO/TC106/SC4/WG 9);
— ISO/CD 3630-4 Dental root-canal instruments – Part 4: Auxiliary instruments (ISO/TC106/SC4/WG 9);
— ISO/CD 3630-5 Dental root-canal instruments – Part 5: Shaping and cleaning instruments (ISO/TC106/SC4/WG 9);
— ISO/AWI 13017 Magnetic attachments (ISO/TC106/SC2/Ad-Hoc WG 22);
— ISO/CD 21563 Hydrocolloid Impression Materials (ISO/TC106/SC2/WG 7);

— ISO/CD 80601-2-60 Medical electrical equipment – Part 2-60: Particular requirements for basic safety and essential performance of dental equipment (ISO/TC106/SC6/WG 9);
— ISO/CD 29474 Fluoride varnishes (ISO/TC 106/SC 7/WG 8);

CEN/TC 55 is requested to adopt separate resolutions for the addition of these work items.

For the adoption of these resolutions a weighted voting is required (as for the approval of European Standards).

8.3 Systematic review for European Standards

The alerts displayed in PROJEX-ONLINE showed that a systematic review for European Standards should be performed (document N 548). However, all indicated TC 55 standards were developed at the ISO level where a systematic review is also performed.

In order to avoid two voting systems for the systematic review process TC 55 expressed already on 2003-02-04 by resolution 3 the concern with regard to the lack of progress in the harmonisation of timing of the respective review procedures.

In the following years no review at the European level was necessary. Due to changes in the ISO systematic review procedure (now first review after 3 years, than 5 years time period) the harmonisation of the review procedures is no longer available.

In order to avoid confusion it is proposed to confirm all European Standards indicated in document N 548 by a Plenary resolution.

If the systematic review process at the ISO level indicates that a revision is necessary, the Vienna Agreement is automatically applied and a parallel ISO/CEN voting procedure is performed.

9 CEN BOSS

The CEN system and the rules of standardization are described in CEN BOSS (CEN Business Operations Support Systems) which is publicly available and directly accessible on the following web page:

http://www.cen.eu/boss/

10 Livelink

In order to have all documents of CEN/TC 55 available on the internet the document server Livelink is used. Access for all registered member bodies of CEN/TC 55 is possible from the following web page (pass word protected):

http://www.din.de/livelink

The server is also used by all working groups of CEN/TC 55.

11 Business plan

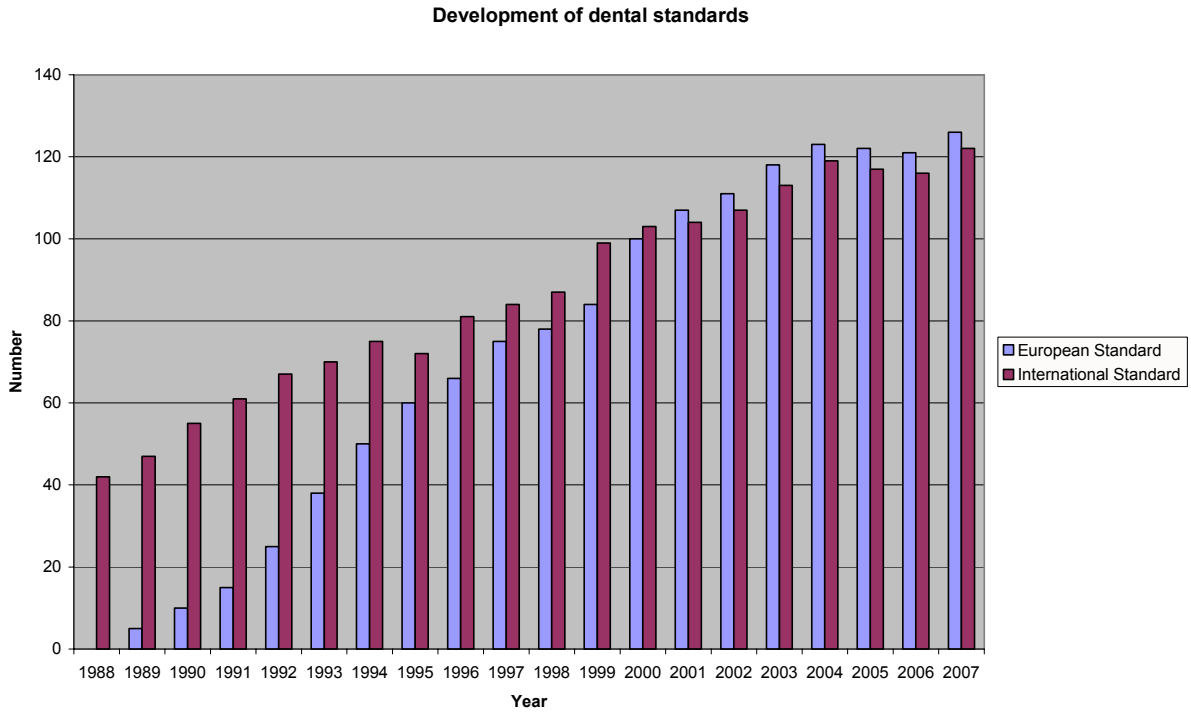
New: CEN BT modified in January 2009 the CEN/TC Business Plan template by adding an environmental section.

CEN/TC 55 received on 2004-02-12 a letter from Mr. Plissart (Director Standards Development) with the request to update the Business Plan. WG 7 discussed the revision of the Business Plan at the meeting on 2004-02-16.

CEN/TC 55 reviewed the proposal of WG 7 at the Plenary meeting on 2004-02-17. The revised document was distributed as document N 450. The revised Business Plan was published.

12 Work progress of CEN/TC 55

The work progress of CEN/TC 55 in the last decade is shown in this diagram:



13 Any other business

The Secretary thanks the Chairman, the Convenors and all experts of CEN/TC 55 for their outstanding support.

Yours sincerely

H-P Keller

Dr. H-P Keller
Secretary CEN/TC 55