BUSINESS PLAN

CEN/TC 55
DENTISTRY

EXECUTIVE SUMMARY

Scope
Standardization of terminology, test methods and specifications applicable to materials, implants, instruments, appliances and equipment used in all branches of dentistry.

Business Environment
- Europe represents a significant part of the world dental market;
- Relatively small, but lucrative market;
- High competition on the market;
- High innovative market (new products first in dentistry);
- Parties involved: FIDE, ADDE, ERO, CED, FEPPD, Public Authorities, Consumers;
- CEN/TC 55 operates in close cooperation with ISO/TC 106 Dentistry.

The following European laws are relevant to the work of CEN/TC 55:

((Regulation xx = REGULATION (EC) No xx))

Basic (Conformity Assessment, CE-marking):
— Decision 768/2008 New Legislative Framework (NLF) for the marketing of products
— Regulation 765/2008 Accreditation/market surveillance relating to the marketing of products

Medical Devices:
— Directive 93/42/EEC Medical devices
— Regulation proposal 2012: Proposal for a Regulation on medical devices (replacing 93/42/EEC)
— Regulation 207/2012 Electronic instructions for use of medical devices
— Regulation 722/2012 Medical devices manufactured utilising tissues of animal origin
— EC Recommendation 2013/172 Medical Devices – Unique Device Identification (UDI)

Specific:
— Directive 89/686 Personal protective equipment
— Directive 2001/83/EC Medicinal products
— Directive 2003/10/EEC Noise protection for employees
— Directive 2004/12/EC Packaging and packaging waste
— Directive 2004/108/EEC Electromagnetic compatibility
— Directive 2006/42 EC Machinery
— Directive 2006/95 EC Electrical equipment designed for use within certain voltage limit
— Directive 2011/65/EU Restriction of hazardous substances in electronic equipment
— Directive 2012/19/EC Waste Electrical and Electronical Equipment
— Directive 2013/59 EURATOM Protection from exposure to ionizing radiation
— Regulation 1907/2006 REACH
(Registration, Evaluation, Authorisation and Restriction of Chemicals)
— Regulation 1394/2007 Advanced therapy medicinal products (gene, somatic cells, tissue)
— Regulation 1272/2008 CLP
(Classification, labelling and packaging of substances and mixtures, amending 1907/2006)
— Regulation 1223/2009 Cosmetic products
— Regulation 3113/2013 WEEE (Waste electrical and electronic equipment)
— Regulation 535/2014 Clinical trials on medicinal products for human use

Benefits

To define the necessary standards to be used to perform the desired level of commercial interoperability in Europe, considering its very significant position in the international market.

- Since 1990, more than 140 European standards were adopted,
- Confidence of consumers in respect of quality and health benefits,
- The need of manufacturers for a fast access to the European Market.

Priorities

- Priority 1:

  The first priority of TC 55 has been to develop semi-horizontal standards for the four most common areas of dentistry: instruments, equipment, materials and dental implants. This has been fullfilled, and the second revision of these standards was successfully completed. For the future the task is the review and, if necessary, the updating of ENs 1639 to 1642.

- Priority 2:

  The second priority of TC 55 has been the development of dental product and product related standards, including specific requirements and corresponding test methods. This has been partially fulfilled and the resulting task is the development and maintenance of a comprehensive portfolio of European dental product standards, and other deliverables, in response to perceived need. The standards will be based on the corresponding ISO standards, without change wherever possible.

1 BUSINESS ENVIRONMENT OF THE CEN/TC 55

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of CEN/TC 55, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

TC55 was established in 1973 with the principal objective of contributing to public health by the development of dental product standards. Conformity with these standards by manufacturers would ensure that the medical devices used in dentistry are safe and fit for their intended purpose. Standards are now developed and written to support the requirements of the Medical Devices Directive 93/42/EEC of 14 June 1993. The Technical Committee does not develop standards to meet anticipated technological advances but responds to the existing market place.

The relevant stakeholders include the dental profession, dental technicians, providers of health care (public and private), dental industry and trade organisations, patients and consumers, regulatory authorities, Notified Bodies, certification organisations, test houses and the European Commission.

The multi-national nature of the dental industry underlines the need for the development of International Standards. CEN/TC 55 works in close cooperation with its international counterpart, ISO/TC 106. The work programmes of both committees have been fully aligned with the work being undertaken by ISO/TC 106 under the Vienna Agreement, thereby ensuring common requirements internationally, both within and outside Europe.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of CEN/TC 55:

The dental industry manufacturing base is relatively small in global terms. It is, however, multi-national consisting of a mix of large and small undertakings. Dental products are generally of high added value so that the market, whilst small, is lucrative. In contrast, the market for oral hygiene products used by the general public is very large.

Number of practising dentists in Europe (CED 2014):	340.000 approx.
Number of dental technicians in Europe: (FEPPD 2014):	210.000 approx.
Total sales values in Europe (ADDE 2014):	6.200 Mio € approx.

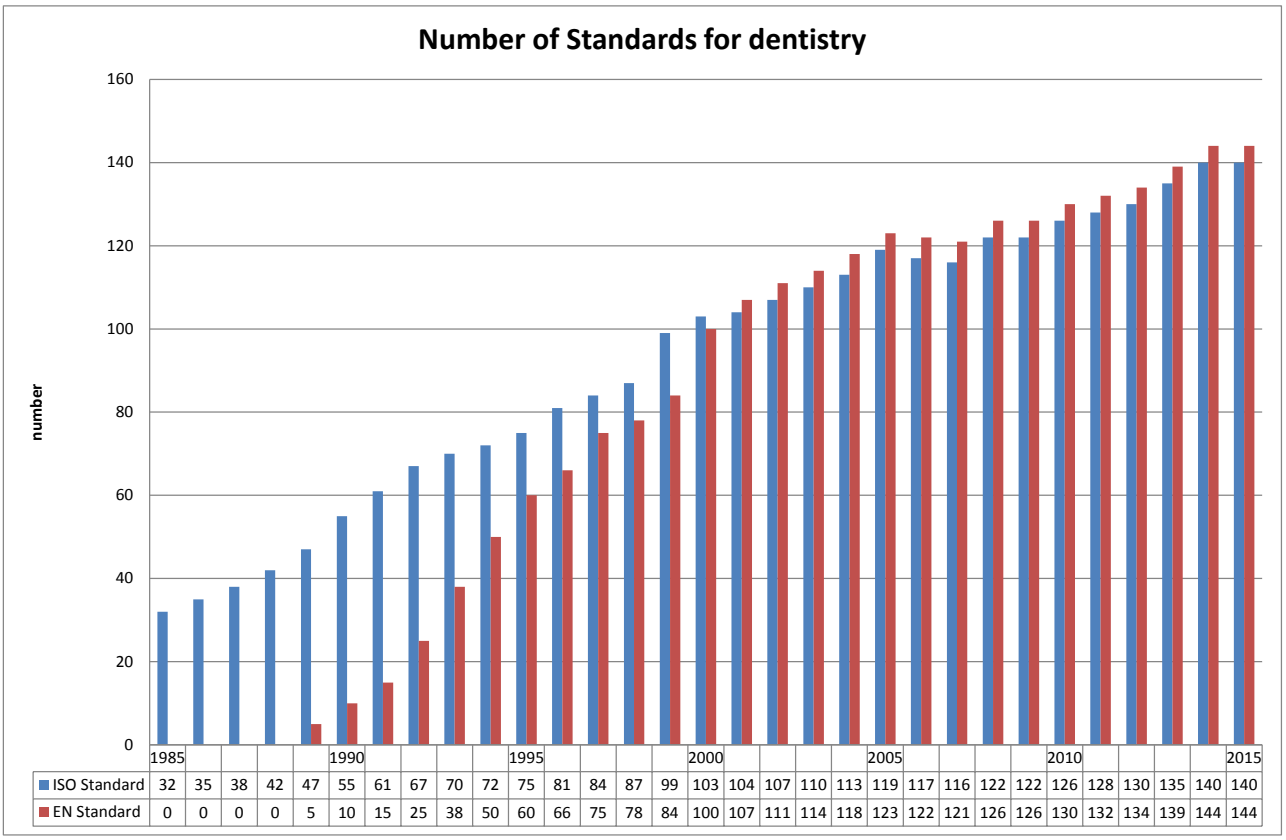
Many product standards developed by CEN/TC 55 are used for conformity assessment procedures in accordance with Directive 93/42/EEC. They are the basis of certification for manufacturers for products in order to access the market.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 55

The standards developed by CEN/TC 55:

- assist manufacturers to demonstrate fulfillment of the applicable Essential Requirements of the Medical Device Directive and provide manufacturers, Notified Bodies and test houses with a clear route to CE marking;
- contribute to the elimination of trade barriers and favour the global market in particular by the application of the Vienna Agreement with ISO/TC 106;
- support Small and Medium Enterprises;
- provide agreed test methods;
- consider environmental aspects;
- promote improvement in the quality of products on the market; and, indirectly improvements in the quality of care provided for patients.

In 1990 European member bodies had many different national standards for dental products. Naturally these standards had different requirements and test methods. Therefore only national markets were possible for dental products. The adoption of over 140 European Standards have assisted in the creation of a single European market.



	1985				1990					1995					2000					2005					2010				2015
ISO Standard	32	35	38	42	47	55	61	67	70	72	75	81	84	87	99	103	104	107	110	113	119	117	116	122	122	126	128	130	135	140	140
EN Standard	0	0	0	0	5	10	15	25	38	50	60	66	75	78	84	100	107	111	114	118	123	122	121	126	126	130	132	134	139	144	144

3 PARTICIPATION IN THE CEN/TC 55

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC 55

The objectives of CEN/TC 55 are to develop and maintain a comprehensive portfolio of European dental product standards, and other deliverables, in response to perceived need. The standards are to be based on the corresponding ISO standards, without change wherever possible. In addition specific goals are:

1. The review and, if necessary, the updating of ENs 1639 to 1642;

2. To encourage the rationalization and amalgamation of product standards wherever possible;

3. To provide a source of expertise and information on dental matters related to standards or otherwise, including consideration of specific topics referred by the Commission, CEN and others when required.

4.2 Identified strategies to achieve the CEN/TC 55s defined objectives

The work programmes of CEN/TC 55 and ISO/TC 106 have been aligned. European Dental Standards shall be, as far as practicable, the corresponding standards developed by ISO/TC 106. These shall be subject to the parallel voting procedure with ISO lead according to the Vienna Agreement. The CEN experts contribute to the work at ISO. This allows for proper consideration of European requirements at the International level without duplication of effort.

4.3 Environmental aspects

The documents developed by CEN/TC 55 consider the potential impacts of a product that can occur during all stages of its life cycle, e.g. environmental aspects involving the design, operation, dismantling and disposal. These impacts range from slight to significant; however safety aspects (Medical Device Directive) will always have priority over environmental aspects.

CEN Guide 4 is used for informative purposes, e.g. assessment of dangerous substances. For dental electronic equipment (e.g. dental units, dental handpieces) Directive 2011/65/EU "Restriction of hazardous substances in electronic equipment" is considered.

The dental harmonized standards allow compliance with Regulation 207/2012 electronic instructions for use reducing the use of paper.

Reduction of chemical waste contamination is achieved by adhering to REACH.

We recognize the increase in clinical waste from, eg, single use items, and TC 55 needs to address this matter in collaboration with national regulatory agencies.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 55 WORK PROGRAMME

Resources and continued motivation of all parties concerned are crucial factors for the successful work of CEN/TC 55. The necessary expertise is anticipated and has so far been found.

No constraints on the completion of the CEN/TC 55 work programme can be foreseen provided the present range and depth of expertise available to the TC and its WGs can be maintained. The

work programme is complex and it requires participants with broad-based expertise and detailed knowledge of the dental sector.