



Date

2009-03-30

CEN/TC 55 N 562

Report

of the Plenary meeting of

CEN/TC 55 Dentistry

held on 2009-03-03

in Bratislava

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1 Opening of the meeting

The Director of the Slovak Standards Institute (SUTN), Ms. I. Zelinova, explained the task and work of SUTN. She welcomed all experts of CEN/TC 55 to SUTN in Bratislava.

The Chairman, Prof. H. Kappert, opened the meeting and thanked SUTN for the impressive work performed in the last years. He thanked Ms. Zelinova and all staff members for the organisational preparation of the TC 55 Plenary and working group meetings.

The Secretary distributed the attendance sheet and referred to the assignment of exploitation rights.

2 Roll call of delegates

The delegates introduced themselves. Delegations from eight member bodies were present (see Annex A for details). The leaders of the delegations were:

Belgium:	Dr. P. Helderweirt
France:	J. Mercier
Germany:	Prof. K. Dermann
Italy:	Prof. C. Paganelli
Norway:	Dr. A. Hensten
Slovakia	L. Neischl
Sweden	Prof. U. Ortengren
United Kingdom:	T. Prodger

Liaison representatives from the following three organisations were present:

ERO:	Prof. P. Calfon
FEPPD:	H. Dohalova
NORMAPME:	J. Schwichtenberg

3 Adoption of the agenda

The proposed draft agenda, document CEN/TC 55 N 543, was adopted.

Resolution 1

4 Appointment of the Resolution Committee

T. Prodger, Prof. K. Dermann and Mr. J. Mercier volunteered to assist the Secretary in drafting the resolutions.

Resolution 2

5 Report of the Chairman

The Chairman, Prof. H. Kappert, reported about the various activities of CEN/TC 55 in 2008. European Standards are now prepared for about 500 million people in the European Union.

The Chairman referred to document N 542 with the report of the Chairman given at the last ISO/TC 106 Plenary meeting held on 2008-10-04 in Gothenburg (Sweden).

The meeting showed again the excellent relation between CEN/TC 55 and ISO/TC 106.

6 Report of the secretariat

Dr. H.-P. Keller presented the report of the secretariat (document N 551). Since the last Plenary meeting (February 2008) five European Standards and one amendment were published by CEN/TC 55. Today there are 126 published European Standards for dentistry (see document N 551).

The new CEN/Committee CEN/TC 392, *Cosmetics*, is of great importance for several TC 55 standards, e.g. toothpaste, toothbrushes, interdental brushes, oral rinses, bleaching agents. Therefore TC 55 decided to request a liaison with CEN/TC 392.

Resolution 3

The new proposed EC Directive on patients rights in cross-boarder healthcare is of great importance for CEN/TC 55. Therefore TC 55 decided to request a liaison with the CEN/WG on interoperability of eHealth standards.

Resolution 4

7 Report of CEN activities

7.1 Report from CEN Central Secretariat

The responsible Technical Officer in the Healthcare Department of CEN, Mrs. A. van Groote, was not present.

The secretary reported that CEN had moved to a new office building in January 2009.

7.2 Report from CEN Healthcare Consultant

The CEN healthcare consultant, Mr. R. Virefleau, informed the Plenary meeting that due to conflicting meetings it was not possible for him to attend the Plenary meeting of CEN/TC 55. His comments were given to prEN 1639 to prEN 1642 under the heading of CEN.

The secretary reported that in 2008 Mr. T. Wilkes was appointed as new healthcare consultant, increasing the number of consultants from two to here.

8 Report of liaison organizations

8.1 Liaison report from ISO/TC 106 Dentistry

The 43rd meeting of ISO/TC 106 and its subcommittees took place during the week 29. September to 4. October 2008 at Gotenburg in Sweden. Good progress was made at these meetings, as a result of some 42 working group meetings. About 300 delegates and experts from 20 countries were present. An overview about the structure and the work programme of ISO/TC 106 is given in document N 547. The modified scope of TC 106 was noted (document N 541).

The next meeting of ISO/TC 106 will be held from 4. to 10. October 2009 in Osaka, Japan. The website for the 2009 meeting of ISO/TC 106, which will take place in Osaka, Japan on October 5-10, 2009, was launched on 1. March 2009. Information regarding the meeting venue and hotel as well as general and tourist information for Japan are currently available at <http://iso.tc106-osaka.jp>.

8.2 Liaison report from FIDE

Prof. Paganelli reported that L. Sanin was not able to attend the meeting. Therefore he reported about the activities of FIDE. FIDE has no problems with standardisation.

8.3 Liaison report from NORMAPME

The liaison representative of NORMAPME, Mr. J. Schwichtenberg, gave an oral report of the activities of NORMAPME (European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardization).

8.4 Liaison report from FEPPD

The liaison representative of FEPPD, Ms. H. Dohalova, referred to document N 550 with the report on the activities of FEPP (Fédération Européenne Des Patrons Prothésistes Dentaires). She expressed the concern of FEPPD about increasing health risks for dental technicians caused by adverse skin reactions with base polymers.

8.5 Liaison request from ERO

The liaison representative of ERO, Prof. P. Calfon, referred to document N 552 with the report about the activities of ERO, the European Regional organization of FDI. The annual meeting was held in September 2008 in Stockholm. The British dental association joined the ERO.

ERO expressed several problems for discussion within dentistry and for improvements of dental standards. The proposals were discussed in full length. The request for risk assessment of the final product was considered. It is difficult to include the final product risk assessment in a specific product standard.

It could be possible to include this request in the SC 8 standards describing the content of the Technical Documentation. A separate chapter in this standards identifying specific risk assessment questions could be added.

9 Report, deliberation and decision about the activities of the Working Groups

9.1 WG 3 Classification

The convenor of WG 3, Prof. K. Dermann, reported about the activities of WG 3 "Classification". The Technical Report CEN/TR 12401 was distributed for final voting within CEN/TC 55. The preliminary voting result was positive with no negative votes.

9.2 WG 4 Preclinical biological evaluation and testing

The convenor of WG 4, Dr. Hensten, reported that no meeting of WG 4 "Preclinical biological evaluation and testing" was held. He reported about the excellent progress made by ISO/TC 106/WG 10 "Biological evaluation of dental materials". ISO 7405 was published in december 2008. He congratulated the convener of ISO/TC 106/WG 10, Prof. Schmalz, for the excellent job performed.

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

The convenor of WG 5, Dr. P. Calfon, reported that no meeting of WG 5 "Nomenclature and coding system for medical devices used in dentistry" was held.

The general designation system for teeth and areas of the oral cavity was revised and the final document was forwarded as ISO/FDIS 3950 to Geneva.

He identified the need for a working group meeting in 2010.

9.4 WG 6 Dental alloys

The convenor of WG 6, Prof. H. Kappert, reported that no meeting of WG 6 "Dental alloys" was necessary. He reported about the publication for ISO 22674 "Metallic materials for fixed and removable restorations and appliances" in November 2006.

Currently it is unclear, if ISO 22674 is adopted in other parts of the world (e.g. US, Japan). The international adoption process should be observed.

9.5 WG 7 Steering Committee

The report of the convenor of WG 7, Dr. P. Jacobsen, was presented as document N 553. A meeting of WG 7 "Steering Committee" was held on 2009-03-02 in Bratislava.

The report of WG 7 was approved.

Resolution 5

Based on the proposed actions from WG 7, CEN/TC 55 decided to forward the following four revised prENs for FprEN-voting as the harmonised EN standards:

a) FprEN 1639 Dentistry – Medical devices for dentistry – Instruments

Resolution 6

b) FprEN 1640 Dentistry – Medical devices for dentistry – Equipment

Resolution 7

c) FprEN 1641 Dentistry – Medical devices for dentistry – Materials

Resolution 8

d) FprEN 1642 Dentistry – Medical devices for dentistry – Dental implants

Resolution 9

No working group meeting in 2010 is necessary.

9.6 WG 8 Occupational risk assessment related to dental materials

The convenor of the WG 8, Prof. U. Örtengren, reported about the meeting of the Group WG 8 "Occupational risk assessment related to dental materials" on 2009-03-02 in Bratislava (document N 554).

The report of WG 8 was approved.

Resolution 10

The Plenary and the liaison partner FEPPD requested WG 8 to prepare a new work item proposal until 2008-12-31 for a European Technical Report for "Guidelines for handling methacrylate-based materials in the dental laboratory".

Resolution 11

10 Acknowledgement of the work of relevant adjacent committees

10.1 CEN/TC 102 Sterilizers for medical purposes

Mr. T. Prodger referred to document N 555 with the report about the activities of CEN/TC 102 "Sterilizers for medical devices".

10.2 CEN/TC 162 Protective clothing including hand and arm protection and lifejackets

CEN/TC 162 *Protective clothing including hand and arm protection and lifejackets* developed in 2007 the draft European Standard prEN 15712 "Mouthguards for use in sports – Safety requirements and test methods". A meeting of the Joint Working Group with CEN/TC 162/WG 11/PG 8 Mouthguards was held on 2008-03-12 in London. After the meeting on 2008-03-12 in London no meeting report was distributed. The project leader developed the text for final prEN voting without asking the experts of the JWG. The assessment of the CEN consultant in 2009 is negative (see document N 549).

CEN/TC 55 discussed the situation and decided to draw the attention of CEN/BT to the intransparent working procedures of TC 162/WG 11/PG 8 on Mouthguards. The draft for final voting as FprEN 15912 "Mouthguards for use in sports – Safety requirements and test methods" was developed without considering the borderlines between the two European Directives for medical devices and personal protective equipment. The proposal to exclude Type 1 made to measure (custom made) mouthguards from the scope of prEN 15912 was disregarded although the testing of this Type of mouthguards is not possible.

CEN/TC 55 requests CEN/BT to disapprove the final voting of prEN 15912.

Resolution 12

10.3 CEN/TC 204 Sterilization of medical devices

The liaison representative, Mr. T. Prodger, referred to document N 556 with the report about the activities of CEN/TC 204 "Sterilization of medical devices".

10.4 CEN/TC 205 Non-active medical devices

No information about the work of CEN/TC 205 "Non-active medical devices" was available.

10.5 CEN/TC 206 Biological evaluation of medical devices

The liaison representative, Dr. A. Hensten, reported about the development within CEN/TC 206 "Biocompatibility of medical and dental materials and devices". CEN/TC 206 will meet in conjunction with the next ISO/TC 194 "Biological evaluation of medical devices" meeting in April 2009 in China.

10.6 CEN/TC 216 Chemical disinfectants and antiseptics

Prof. C. Paganelli, reported about the work of CEN/TC 216 "Chemical disinfectants and antiseptics". Currently the committee considers veterinary problems.

10.7 CEN/TC 251 Health informatics

The liaison representative, Prof. C. Paganelli, referred to document N 557 with the report about the activities of CEN/TC 251 "Health informatics". The last joint working group meeting has been held in Delft in February.

10.8 CEN/CLC TC 3 Quality management and corresponding general aspects for medical devices

Mr. T. Prodger reported that the work of CEN/TC 257 "Terminology, symbols and information provided with medical devices" was transferred to CEN/CLC TC 3 and CEN/TC 257 was disbanded.

10.9 CEN/TC 258 Clinical investigation of medical devices

The report of the liaison representative to CEN/TC 258 "Clinical investigation of medical devices", Dr. P. Jacobsen, was presented as document N 558.

10.10 CEN/TC 285 Non-active surgical implants

The secretariat of CEN/TC 258 "Non-active surgical implants" was changed from NEN to DIN.

10.11 CEN/TC 316 Medical devices utilizing tissues

The work of CEN/TC 316 "Medical devices utilizing tissues" was transferred to ISO. The transposition of the three European standards into International Standards was now published as ISO standard in ISO/TC 194/SC 1.

10.12 CEN/TC 347 Methods for analysis of allergens

The liaison representative, Dr. Hensten, reported about CEN/TC 347 "Methods for analysis of allergens". A new standard for the release of nickel from the surface of jewellery metals is under preparation. TC 347 has four working groups and each working group can decide, if medical devices are included in their work or not.

11 Decision about specific work items in the CEN/TC 55 work programme

The actual work programme of CEN/TC 55 (document N 546) was compared with the actual work programme of ISO/TC 106 (document N 547).

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

a) 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.

Resolution 13

b) 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.

Resolution 14

The comparison of the work programme of ISO/TC 106 and CEN/TC 55 showed that the following work items were missing in the European work programme. TC 55 decided their introduction into the work programme.

The following work items should be added to the CEN/TC 55 work programme:

1. As pre-adoption of a potential future new work item:

a) ISO/CD 3630-2 Dental root-canal instruments – Part 2: Enlargers (ISO/TC106/SC4/WG 9);

Resolution 15

2. As adoption of the WI:

a) ISO/CD 3630-4 Dental root-canal instruments – Part 4: Auxiliary instruments (ISO/TC106/SC4/WG 9);

Resolution 16

b) ISO/CD 3630-5 Dental root-canal instruments – Part 5: Shaping and cleaning instruments (ISO/TC106/SC4/WG 9);

Resolution 17

c) ISO/AWI 13017 Magnetic attachments (ISO/TC106/SC2/Ad-Hoc WG 22);

Resolution 18

d) ISO/CD 21563 Hydrocolloid Impression Materials (ISO/TC106/SC2/WG 7);

Resolution 19

e) 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);

Resolution 20

f) ISO/CD 29474 Fluoride varnishes (ISO/TC 106/SC 7/WG 8);

Resolution 21

The development of the corresponding European Standards is transposed to ISO/TC 106.

In addition the requirements of the systematic review were discussed. TC 55 confirmed the following existing European Standards.

WI 00055119: EN ISO 4823:2000, *Elastomeric impression material*

WI 00055118: EN ISO 8325:2004, *Test methods for rotary instruments*

WI 00055140, EN ISO 13897:2004, *Amalgam capsules*

WI 00055150, EN ISO 6360-1:2004, *Number coding system for rotary instruments — Part 1: General characteristics*

WI 00055155, EN ISO 6360-6:2004, *Number coding system for rotary instruments — Part 6: Specific characteristics of abrasive instruments*

WI 00055191, EN ISO 16408:2004, *Oral hygiene products — Oral rinses*

WI 00055232, EN ISO 7711-3:2004, *Dentistry — Diamond rotary instruments — Part 3: Grit sizes, designation and colour code*

WI 00055207, EN ISO 10477:2004, *Polymer-based crown and bridge materials*

WI 00055219, EN ISO 21530:2004, *Materials used for dental equipment surfaces —*

Determination of resistance to chemical disinfectants

Resolution 22

12 Discussion of working experience with the document server system Livelink

TC 55 discussed the working experience of 2008 concerning document distribution via the DIN Livelink server. No problems were encountered.

13 Any other business

The secretary informed the Plenary that new environmental requirements are under preparation by CEN, e.g. for a revised business plan.

14 Place and date of next CEN/TC 55 meeting

The next CEN/TC 55 Plenary meeting is scheduled for 23. February 2010 in Brussels. Meetings of Working Group 5 and WG 8 are scheduled for 22. February 2010.

Resolution 23

15 Approval of resolutions

All resolutions were approved during the meeting. The final editorial formulation of the resolutions will be prepared by the resolution committee.

16 Closure of the meeting

The Chairman thanked all the delegates for their attendance and their excellent contributions to the discussions, SUTN for the excellent organisation and hosting of the meetings and closed the session.

Annex A – List of participants (CEN/TC 55, Bratislava, 2009)

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