Date	CEN/TC 55 N 459
2005-02-09	Dentistry

REPORT OF THE SECRETARIAT

February 2004 – January 2005

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1 CEN National Members, Affiliates and Partner Standardization Bodies

28 participating members (P-members)
Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom

6 Affiliates
Albania, Bulgaria, Croatia, Romania, The former Yugoslav Republic of Macedonia, Turkey

5 Partner Standardization Bodies
Egypt, Russia, Serbia and Montenegro, Tunisia, Ukraine

2 Chairman Dr. M. Stümke, Germany

3 Secretary Dr. H.-P. Keller, DIN

4 Constitution

WG 2 Clinical evaluation and investigation on medical devices used in dentistry
Convenor: Dr. *P. David*, France

WG 3 Classification
Convenor: Prof. *G. Øilo*, Norway

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. *C. Howard*, UK

[redacted]
SECRETARIAT DIN DEUTSCHES INSTITUT FÜR NORMUNG e.V.
Mailing address: 75172 Pforzheim · Alexander-Wellendorff-Str. 2
Tel: + 49 72 31 91 88 - 19 · Fax: + 49 72 31 91 88 33 · E-Mail: hans-peter.keller@din.de

5 Ratified European Standards (Stage 64)

Document N 455 gives an overview about **122 European Standards** published by CEN/TC 55 Dentistry.

Since the last TC 55 Plenary meeting in February 2004 the following 16 European Standards were published:

EN 1639:2004	Dentistry — Medical devices for dentistry — Instruments
EN 1640:2004	Dentistry — Medical devices for dentistry — Equipment
EN 1641:2004	Dentistry — Medical devices for dentistry — Materials
EN 1642:2004	Dentistry — Medical devices for dentistry — Dental implants
EN ISO 1562:2004	Dentistry — Casting gold alloys (ISO 1562:2004)
EN ISO 3107:2004	Dentistry — Zinc oxide/eugenol and zinc oxide/non-eugenol cements (ISO 3107:2004)
EN ISO 6360-1:2004	Dentistry — Number coding system for rotary instruments — Part 1: General characteristics (ISO 6360-1:2004)
EN ISO 6360-4:2004	Dentistry — Number coding system for rotary instruments — Part 4: Specific characteristics of diamond instruments (ISO 6360-1:2004)
EN ISO 6360-6:2004	Dentistry — Number coding system for rotary instruments — Part 6: Specific characteristics of abrasive instruments (ISO 6360-6:2004)
EN ISO 7711-3:2004	Dentistry — Diamond rotary instruments — Part 3: Grit sizes, designation and colour code (ISO 7711-3:2004)
EN ISO 8325:2004	Dentistry — Test methods for rotary instruments (ISO 8325:2004)
EN ISO 10477:2004	Dentistry — Polymer-based crown and bridge materials (ISO 10477:2004)
EN ISO 13897:2004	Dentistry — Amalgam capsules (ISO 13897:2003)
EN ISO 16408:2004	Dentistry — Oral hygiene products — Oral rinses (ISO 16408:2004)
EN ISO 21530:2004	Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants (ISO 21530:2004)
EN ISO 24234:2004	Dentistry — Mercury and alloys for dental amalgam (ISO 24234:2004)

6 Beryllium in dental alloys

CEN/TC 55 notes with great pleasure the distribution of the following documents:

1. Draft Amendment for ISO 6871-1:1994/DAmd 1
Dental base metal casting alloys – Part 1: Cobalt-based alloys
Begin of voting: 2004-06-25
End of voting: 2004-11-25
Status: Approved.

2. Draft Amendment for ISO 6871-2:1994/DAmd 1
Dental base metal casting alloys – Part 2: Nickel-based alloys
Begin of voting: 2004-06-25
End of voting: 2004-11-25
Status: Approved.

3. Draft Amendment for ISO 9693:1999/DAmd 1
Metal-ceramic dental restorative systems
Begin of voting: 2004-09-08
End of voting: 2005-02-08
Status: Open.

4. Publication of EN ISO 16744:2003 Dentistry — Base metal materials for fixed dental restorations (ISO 16744:2003).

These four documents require now (see e.g. 5.1.2 of EN ISO 16744:2003-12-15):

> The alloy shall not contain more than 0,02 % mass fraction of beryllium.

and are now in accordance with

> **Resolution 6** of CEN/TC 55, adopted on 2002-02-26:
>
> It is the opinion of CEN/TC 55 that beryllium in dental alloys poses a serious hazard to health. The use of beryllium containing alloys should therefore be avoided whereever possible. CEN/TC 55 is aware that alternatives to beryllium containing alloys exist. For these reasons, CEN/TC 55 recommends that the maximum permitted Beryllium content is 0,02 % by mass in all dental alloy standards.

Conclusion
We consider this development concerning the beryllium content in dental alloys as an excellent example of the good relationship between CEN/TC 55 and ISO/TC 106.

7 Revision of EN 1639 to EN 1642

The (first) CEN enquiry was distributed by CEN/CMC on 2002-08-19 with deadline 2003-02-18. The result of voting was positive (18 approval, 1 disapproval). The comments received were discussed by CEN/TC 55/WG 7. The revised documents were forwarded to CMC on 2003-08-15. The positive assessment from the CEN consultant Mr. Virefleau was received on 2003-09-02. The (second) CEN enquiry for the formal vote review was distributed on 2003-11-20 with deadline 2004-01-20. The result of the formal vote review was positive (19 approval, 1 disapproval).

Therefore the standards EN 1639 to EN 1642 were published by CEN/CMC in June 2004.

We congratulate the convener and the experts of WG 7 to the excellent work performed.

8 TC 55 documents in the European voting procedures

8.1 Parallel voting procedure

In 2004 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.

8.2 Unique Acceptance procedure (UAP)

In 2004 this voting procedure was used for one published ISO standard:
— ISO 13897 Dentistry – Amalgam capsules.

In 2005 this voting procedure is used for the following four published ISO standards:
— ISO 4073 Dental equipment – Items of dental equipment at the working place – Identification system
— ISO 7494-1 Dentistry – Dental units – Part 1: General requirements and test methods
— ISO 10650-1 Dentistry – Powered polymerization activators – Part 1: Quartz tungsten halogen
— ISO 22803 Dentistry – Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file

Reason: The specific document was already at the DIS stage (or published) when the new work item was approved by CEN/TC 55.

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

The Business Plan of 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 2004 in Brussels. Today the work programm 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 (2005-02-09) is listed for

— CEN/TC 55 Dentistry in document N 457
— ISO/TC 106 Dentistry in document N 458

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

9.1 Deletion of existing work items

The following work item should be deleted from the TC 55 work programme:

— 00055192 ISO/AWI 16409-1 Oral hygiene products – Part 1: Manual interdental brushes

Reason: The number of the work item was changed from ISO 16409-1 to ISO 16409.

9.2 Addition of new work items

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

— ISO/NP 10139-2 Dentistry – Soft lining materials for removable dentures – Part 2: Materials for long-term use (ISO/TC 106/SC 2/WG 10);
— ISO/CD 11143 Dentistry – Amalgam separators (ISO/TC 106/SC 6/WG 2);
— ISO/CD 14801 Dentistry – Fatigue test for endosseous dental implants (ISO/TC 106/SC 8/WG 4);
— ISO/CD 16409 Dentistry – Oral hygiene products – Part 1: Manual interdental brushes (ISO/TC 106/SC 7/WG 3);
— ISO/AWI 21606 Dentistry – Orthodontic elastics – (ISO/TC 106/SC 1/WG 14)
— ISO/DIS 3665 Photography – Intra-oral dental radiographic film – Specification (ISO/TC 42)

TC 55 is requested to adopt separte 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).

10 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.cenorm.be/boss

11 Livelink

In order to have all documents of TC 55 available on the internet the document server Livelink is used. Access for all registered member bodies of 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.

12 Business plan

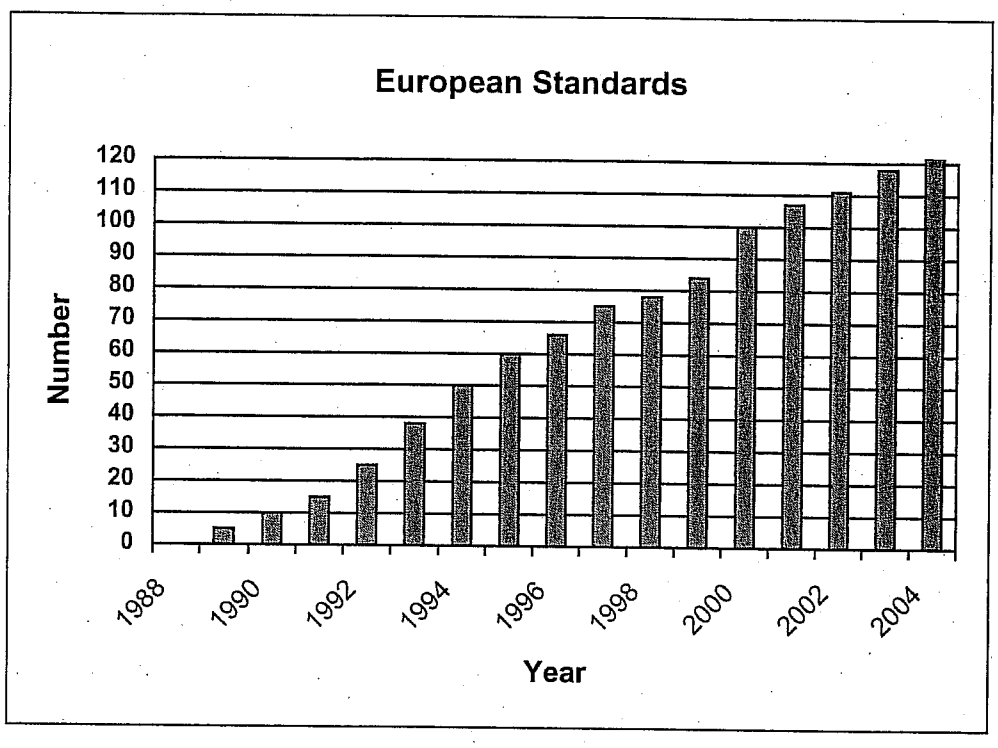
TC 55 did receive on 2004-02-12 a letter from Mr. Plissart (Director Standards Development) with the request to update the Business Plan. WG 7 discussed the revision of the Business Plan at the meeting on 2004-02-16.

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.

TC 55 is waiting for an answer from CEN/CMC and/or for the publication of the Business Plan.

13 Work progress of CEN/TC 55

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



Please note that TC 55 published in 2004 a total number of 16 European Standards. However, the total number of European Standards increased only by 4 (from 118 to 122 European Standards). We consider this fact as proof that the strategy of CEN/TC 55 (whenever possible, to combine several existing standards into one standard) is working.

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

2004-09-04	ISO / TC106 N 910 "Dentistry"

ISO / TC 106 Meeting - Plenary Session, Chiang Mai, 04 September 2004 (# 10) Report of the Chairman of CEN / TC 55 - Dentistry

As announced at the last meeting in Sydney, the number of CEN P-members has increased by six, in partly fulfillment of the requirements for their accession to the EU on January 1st 2004:

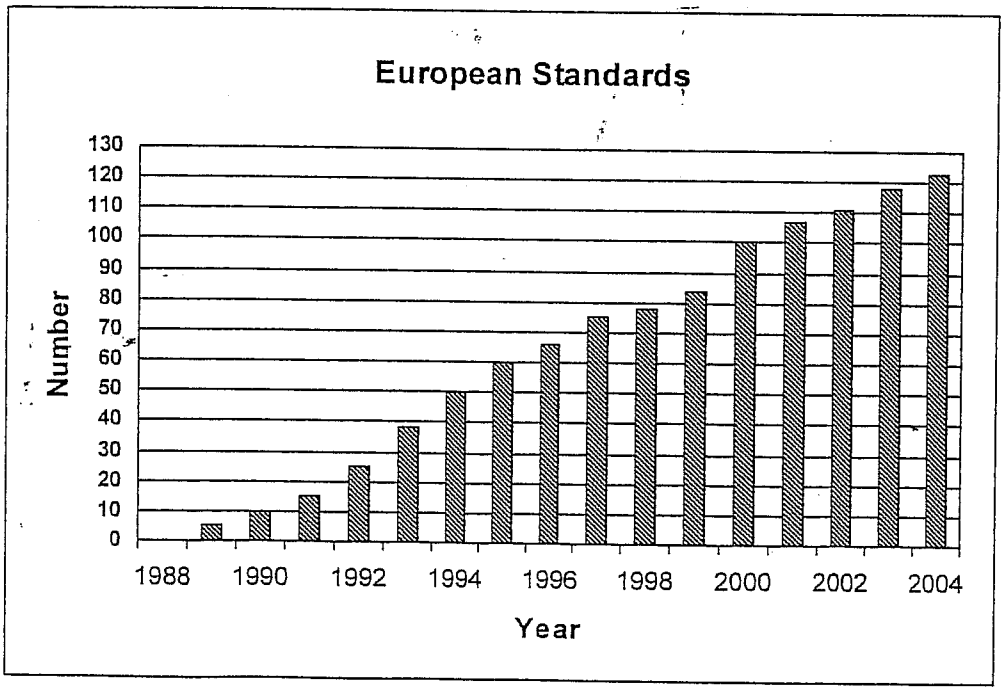
28 CEN National Members (P-members)

Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom

[new members as of 2004-01-01]

This enlargement in membership will be a challenge for CEN /TC 55. However, it is a chance for ISO /TC 106 with regard to the acceptance of International Standards for dentistry by at least 28 European countries.

Again it is to be reported that the number of European Standards, being developed under the parallel voting procedure with ISO in the lead, is increasing steadily:
As of July this year 118 ISO Standards have been accepted as EN ISO Standards by CEN / TC 55.



SECRETARIAT DIN DEUTSCHES INSTITUT FÜR NORMUNG e.V.
Mailing address: 75172 Pforzheim · Turnplatz 2
Tel: + 49 72 31 91 88 - 19 · Fax: + 49 72 31 91 88 33 · E-Mail: hans-peter.keller@din.de

In addition to that, the four Harmonized European Standards EN 1639 (Instruments), EN 1640 (Equipment), EN 1641 (Materials) and EN 1642 (Dental Implants) have been revised and published, and the Technical Report CEN/TR 12401 (Guidance on the classification of dental devices and accessories) has been updated.

Since the Business Plan of TC 55 dates back to 1999, the revision of the Business Plan was discussed at the meeting of WG7 and the work programme of CEN/TC 55 was updated and harmonized with the work programme of ISO / TC106 at the 2004 Plenary meeting in Brussels.

Today the work programmes of all CEN and ISO committees are available on the internet.

Access for all registered member bodies of 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.

The next meeting of CEN/TC 55 is scheduled for 14th and 15th February 2005 in Brussels, and we would be honored if the chairman or the secretary of ISO/TC 106 could join us.

Dr. Manfred Stümke
Chairman of CEN/TC55

[redacted]
SECRETARIAT DIN DEUTSCHES INSTITUT FÜR NORMUNG e.V.
Mailing address: 75172 Pforzheim · Turnplatz 2
Tel: + 49 72 31 91 88 - 19 · Fax: + 49 72 31 91 88 33 · E-Mail: hans-peter.keller@din.de

Document: ISO/TC 106 N913

Our Ref.: ISO/TC 106

Date: 8 February 2005

Direct tel.: +1 613 523 1770
Direct fax : +1 613 523 7736
E-mail: nmartel@cda-adc.ca

To the members of ISO/TC 106 – Dentistry

Dear Member,

Preliminary Information – Rome 2005

This is to inform you that the next meeting of ISO/TC 106 will be hosted by Italy and will take place in Rome, from September 26 to October 1, 2005.

The venue will be at the following address:

Sheraton Golf Parco dé Medici
Viale Parco dé Medici 167
00148 ROME
TP: + 39 06 65288
TFX: + 39 06 65287060

More information will be distributed as soon as it becomes available.

Kind regards,

Nathalie Martel
Secretary, ISO/TC 106

European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardisation
Bureau Européen de l'Artisanat et des Petites et Moyennes Entreprises pour la Normalisation
Europäisches Büro des Handwerks und der Klein- und Mittelbetriebe für die Normung

Report on the activities of the NORMAPME in 2004

The NORMAPME founded together with the FEPPD a international mirror group of experts for the standardise sector. This group maintains contact with similar experts in both organisations across Europe. This works like a mirror committee for SMEs where experts discuss items on the TC 55 agenda. Members also collect opinion from their national association or network. In order to present these opinions to CEN/ TC 55 the experts uses this panel of technical expert advisors, the list is above.

The group:
Jurgen Schwichtenberg Normapme
Paolo Battaglia Italy
Jean Jacques Herremans Belgium
Charles Samit France
Rob Maters The Netherlands
Peter Thomsen Germany
Graham Findlay UK

Normally the group maintains email contact however land mail and fax are also used. Questionnaires are sometimes used to establish member opinion. In addition to the email contact the Group tries to meet four times a year, the last meeting was held on 7th January 2005.

The experts reported in January 2005 that they have attended 52 meetings concerning standardisation issues in dentistry over the past year.

Below you will find a summary of the main issues currently being discussed in the mirror group:

- work in the field of monomers
- work towards banishing nickel from dental alloys
- develop horizontal and generic standards for instructions for use
- continue to develop a quality management standard applicable SME`s
- continue to work towards a specific occupational standard in this sector

Last year CEN/TC 55 plenary already discussed the problems of dental base materials. We now got a information from the Netherlands that the SME's have to follow very strict environment requirements for the use of these materials. Therefore the NORMAPME again ask to aid in the relevant standard that

monomer and polymer shall be in one capsule in which they are mixed.

In order to have a 'comprehensive' view of developments in this field the experts also follows the CEN Healthcare Forum.
To support the experts in this work The NORMAPME Healthcare Forum meets quarterly and works effectively with the UEAPME Healthcare Forum and the CEN Healthcare Forum (ChEF). The next NORMAPME Healthcare Forum will take place on 18th April 2005.

Brussels, February 2005

Fédération Européenne et
Internationale des Patrons
Prothésistes Dentaires

REPORT 2005

FEPPD POSITION PAPER

In 2004 FEPPD sent out a member survey to ask its 26 member organisations which problems occur during using dental materials and producing custom made medical devices.
The outcome of this questionnaire has been evaluated by FEPPD's Technical Working Group.

The majority of countries are asking to assist them in helping to comply with the Medical Devises Directive so that they can minimise patients' health risks.

The material manufacturers offer safety data sheets and instructions for use for all available products. Our members (the custom-made device manufacturers) have to comply with these instructions for use to be able to hand out the Certificate of Conformity (MDD). They also need to comply with these standards to be able to place their Medical Devices on the market. (To meet the essential requirements of ~~Article~~ 1).
ANNEX
These instruction standards do not regulate the content, the structure and the risks (health and environment) for use.

The goal we wish to achieve is to make sure that high value materials certificated by the industries will not lose their quality during the manufacturing procedure in the dental laboratories.

Therefore the FEPPD proposes and emphasises the importance to standardize not only the products and their test methods but also the instructions for use. A next step could be creating generic and horizontal standards for using all dental products.

Jürgen Schwichtenberg
President FEPPD

asbl FEPPD – Rue Jacques De Lalaing 4 – B-1040 Brussels – Belgium
Tel. +32 (0)2 231 05 73 – Fax +32 (0)2 230 50 27 – E-mail : feppd@kmonet.org – Website : www.feppd.org
Delta Lloyd Bank – B-1210 Bruxelles - Nr. 635-4849201-28

Adopted agenda CEN TC 55 WG 5
14th February 2005

1. Opening of the meeting (10:00)
2. Roll call of delegates
3. Adoption of the agenda
4. Appointment of the Resolution Committee
5. Report of P. Calfon on ISO 1942
6. Report of C. Paganelli on GMD
7. Discussion about terminology and classification of the domain
8. Identification of concepts, definitions and terms needing harmonization
9. Proposal of harmonization to be submitted to GMDN and ISO
10. Any other business
11. Approval of resolutions
12. Closure of the meeting

DENTISTRY - NOMENCLATURE AND CODING SYSTEM FOR MEDICAL DEVICES USED IN DENTISTRY.

REPORT OF MEETING
BRUXELLES 14th February 2005

Le comité membre français :

AFNOR

Association
Française de
Normalisation
11 avenue Francis de Pressensé
93571 Saint-Denis La Plaine Cedex
France
Tél. : +33 (0)1 41 62 80 00
Fax : +33 (0)1 49 17 90 00
http://www.afnor.fr

Convenor : Dr Philippe Calfon (France)

The meeting was chaired by Dr Philippe Calfon.

1 Opening of the meeting

The meeting was opened at 9:00 a.m.

2 Roll call of experts

The list of the attendees is attached to this report.

3 Approval of the draft agenda (Document CEN 55_5_N16)

The draft agenda, document CEN 55_5_N16, was modified upon the request of Pr Gudbrand Oilo suggesting that, since Pr. Corrado Paganelli is the liaison officer with CEN TC 257 and the appointed expert of the maintenance agency, it would be preferable that Pr. Paganelli gives a report regarding GMDN. The modified and adopted agenda is attached to this report.

Resolution 1

4 Appointment of the drafting committee

Pr. Klaus Dermann (D), Pr. Peter Jacobsen (UK) and Mr. Jacques Mercier (F) were appointed to the Drafting Committee.

Association reconnue
d'utilité publique
Comité membre français
du CEN et de l'ISO
Siret 775 724 818 00015
Code NAF 751 E

5 Report from Dr. Philippe Calfon on ISO 1942

A brief presentation was projected and will be available on the livelink. Dr. Calfon presented the scope, purpose and method of ISO 1942, insisting on the need to be consistent with ISO terminology rules that are very strict in this field. ISO 1942 is at DIS 2 stage, and has been sent to central secretariat for ballot. The document need to be circulated and used by experts in order to be improved according to the imputs of the users of the document. It is important that this document obtain a positive vote to be published, a tremendous work has been done by ISO TC 106 SC 3 to review the comments from DIS 1 and there is a risk that this work can be deleted from the ISO program because of the time limit. An extensive discussion took place about the need of a terminology standard, a resolution expressing that need was adopted.

Resolution 2

6 Report from Pr. Corrado Paganelli on GMDN

Pr. Paganelli explained the task of the GMDN Maintenance Agency and it's Expert Team. GMDN M.A. answers to questions from the users of GMDN, is entitled to remove term or to add new term to the GMDN. A proposal of "collective terms" that can serve as describers for notified bodies is developed within ISO under the reference PR 15133.
Pr. Paganelli informed the WG that he received a letter from the Chairman of GMDN M.A. asking him to resign from his mandat as expert for dental devices, the need for such an expert within the GMDN M.A. was expressed by the WG and a resolution was adopted .

Resolution 3

7 Discussion about harmonization of terminology between GMDN and ISO 1942

Since the reviewed ISO 1942 is not published yet, it was decided to pospound the work on harmonization, the comparaison of the two document will show if there is a need of an harmonization.

8 Future work

No supplementary future work was identified.

7 Any other business

Pr. Hans-Peter Keller mentioned the fact that DIN has published a terminology standard for dental implants and will propose the adoption of this standard by CEN.

8 Approval of resolutions

The resolutions 2 and 3 were phrased by the drafting comitee as follows:

RESOLUTION 2:

WG 5 of TC 55 has noted the existence of GMDN and recognizes that it is intended to facilitate data exchange for regulatory purposes. This document, therefore, does not fulfil the requirements of an ISO standard for terminology in the field of dentistry. WG5 commends to CEN TC 55 the awaited revision of ISO 1942 and its adoption as a European standard.

RESOLUTION 3:

WG5 notes with concern the end of Pr. Corrado Paganelli appointment as expert for the dental field within GMDN Expert Team of Maintenance Agency. The WG recommends to TC 55 that a letter be written to the Chairman of Maintenance Agency proposing suitable candidates.

A proposal of letter to be sent to GMDN M.A. is attached.

9 Date and place of the future meeting

WG5 will decide the need of a meeting next year depending on the publication of ISO 1942.

10 Closure of the meeting

The meeting closed at 16:00.

Respectfully submitted

Dr Philippe Calfon

Proposal of letter from TC 55 to GMDN M.A.

Pr. Paganelli reported to TC 55 that his term of office on the Expert Team of GMDN Maintenance Agency has been ended, and that "another candidate" would be appointed.

TC 55 regrets the need for this rotation in view of Pr. Paganelli's expertise and commitment in this field, and asks if this decision could be reviewed. TC 55 would strongly support his continuation in this role.

However, TC 55 is not clear as to how "another candidate" from dentistry will be selected and would draw your attention to the liaison between TC 55 and TC 257. Therefore, TC 55 would like the Maintenance Agency to consider other dental devices experts who are involved in both TC's. These experts are Pr. Gudbrand Oilo and Pr. Klaus Dermann, and TC 55 would ask you to consider appointing one of these persons if it is impossible for Pr. Corrado Paganelli to continue. We attach brief resumes of the two proposed candidates for your information.

REPORT ON TC204 ACTIVITIES

A lot of work has gone into the joint revisions on the series EN550/ISO11135 – Ethylene oxide sterilisation, EN552/ISO11137 – Radiation sterilisation and EN554/ISO11134 – Moist heat sterilisation. Much of TC204's work involves ISO TC198.

ISO 17665

The standard with the most impact on dentistry is the moist heat sterilisation standard and this has caused a lot of controversy. There have been hundreds of pages of comment which was surprising given that this process is well established and understood. The DIS has just been through the ISO voting procedure and it narrowly received approval with 5/22 members voting against. This gave a 21.75% disapproval vote which was close to the 25% needed to reject the draft. The 5 countries that registered disapproval votes were Australia, Austria, France, Sweden and Switzerland. The comments from Canada were very much against the draft although they voted approval. There are still some 40 pages of comments to be addressed. The standard was written to cover moist heat sterilisation regardless of its application and there is doubt as to whether or not this is workable in areas as diverse as equipment manufacturers and healthcare facilities. There are also concerns that the standard is inadequate to support the Medical Devices Directive and that the requirements are not specific thus open to interpretation. Some doubts exist on the methodology as well. There are similar concerns in CEN although the DIS has passed the parallel enquiry. It will be left to TC198 and TC204 to see if the differences can be settled at this late stage perhaps through the use of additional supporting guidance.

The ethylene oxide standard has also run into problems although it has passed the ISO voting procedure at the DIS stage. There are concerns about the technical applicability of Annex A which is a normative annex and proposes the use of a 'bioburden-approach' method for development and validation purposes rather than an absolute bioburden approach. This annex may be deleted to gain approval of the remainder of the document.

The series of standards on radiation sterilisation have been progresses to the DIS stage and approval given although there are still a number of comments to be reviewed.

Work has been carried out to prepare a draft for a standard on low temperature steam/formaldehyde sterilisation but this has been cancelled due to its over-running the 3 year timeframe allowed by CEN. TC204 will be sending a resolution and a revised text to get the work reinstated.

The following standards have been ratified:

EN ISO 14160 – *Sterilisation of single-use medical devices of animal origin – Validation and routine control of sterilisation by liquid chemical sterilants.*

EN ISO 14937 – *general requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices* (including the corrigenda already approved by ISO). presso di ratifica

prEN ISO 17664 – *Information to be provided by the manufacturer for the reprocessing of resterilisable devices.*

prEN 13824 – *Aseptic processing of liquid medical devices – Requirements.*

EN 556 – *Requirements for medical devices to be labelled sterile.* Supersedes EN556/A1.

EN 556-1 - *Requirements for medical devices to be labelled sterile – Pt 1 Requirements for terminally sterilised medical devices.*

Report prepared by T E Prodger
02/05

Report to CEN TC 55 on CEN TC 251 Health Informatics

TC 251 documents are available on the web site (http://www.centc251.org/).

Next joint working group meeting will be held on 12-13 May in Berlin: I would like to step out of this position as liaison, as Informatics is not going to be main interest of my organization in the future.

Report to CEN TC 55 on CEN TC 216 Disinfectant

TC 251 documents are available on the web site http://comelec.afnor.fr/cen/t72len

Next joint working group meeting will be held on 11-12 April in Delft: I would like to step out of this position as liaison, as Disinfectant is not going to be main interest of my organization in the future.

Report to CEN TC 55 on GMDN

The document has been published as :

- CEN Report, CR14230:2001 titled ' Global medical device nomenclature for the purpose of regulatory data exchange'
- ISO Technical Specification, numbered ISO TS 20225:2001.

You can order the GMDN CD-ROM by BSI at http://www.gmdn.org/order2.xalter

I had been nominated expert for the Maintenance Agency. But I have received a letter by Maurice Freeman asking me to step out to rotate the responsibility of Expert Team (ET) dental device consultant to another candidate.

CEN TC 257 has prepared prTR 15133 "Nomenclature – Collective terms and codes for groups of medical devices" including some collective terms (the previous so called subcategories) as mandated by the Commission mainly to identify the skills of Notified bodies.

Sincerely

Corrado Paganelli Dental Clinic - University of Brescia - Pza Spedali Civili I-25100 Brescia Italy
fax +39.030303194 mobile +39.335 293501 e-mail paganell@master.cci.unibs.it paganell@med.unibs.it

European Dental Industry
Kirchweg 2, D-50858 Köln
Tel: 049/221/50 06 87-12
Fax: 049/221/50 06 87-21
www.fide-online.org

Excerpt from Regulatory Affairs report to FIDE Executive Committee and General Assembly 13 May 2004 Vienna

Item 6: Regulatory Affairs

REACH –Ms. Sanin

In June 2003, FIDE urged companies and member associations to send comments within the Public Internet Consultation hosted by Directorate-General Enterprise & Directorate-General Environment of the European Commission.

Along with other interested parties, FIDE asked for the exclusion of medical devices form the REACH program, in order to avoid a double regulation for those products.
Following the Public consultation, the REACH programme was presented in its final draft to the European Parliament in October 2003.
Even if we failed in excluding medical devices, the information sent by industry enabled improvements to the proposal, such as:

- ☑ a simplification of requirements and a reduced burden for downstream users.
- ☑ as far as the registration of substances by their identified uses is concerned, downstream users will have the right to insist that their use of a substance is identified by their supplier through the declaration of a range of identified uses for that particular substance; unless they prefer to carry out and submit their own Chemical Safety Assessment to the European Agency, for reasons of commercial confidentiality.
- ☑ No preliminary Chemical Safety Reports
- ☑ No registration and evaluation for polymers
- ☑ Lighter registration for substances produced between 1-10 tonnes
- ☑ Simplification of requirements for preparations (CSA will have to be performed only for substances above certain concentration limits)
- ☑ Etc.

We have recently been informed by our colleagues of the cosmetics sector (COLIPA Italian Member) of the existence of a European organization called DUCC (**D**ownstream **U**sers of **C**hemicals **Co**-ordination group), which was founded following

European Dental Industry
Kirchweg 2, D-50858 Köln
Tel: 049/221/50 06 87-12
Fax: 049/221/50 06 87-21
www.fide-online.org

the publication of the European Commission *white paper on the "Strategy for a Future Chemicals Policy"*.

The objective of creating this co-ordination group was:

- to offer a platform for Associations with similar goals and objectives
- to come together and create a unified and effective voice with the specific concern of the applicability of the future Chemicals Policy.

DUCC represents a variety of Associations in its membership and has developed a series of position papers addressing specific aspects of the REACH program, identifying the concerns of downstream users and suggesting concrete proposals to address them. These views (a better workability) have been successfully presented to the European Commission and the European Parliament and both institutions welcome the DUCC initiative and appreciate it as the common voice for many 'users' of chemicals.

Linda Sanin