

## REPORT

FIDE was represented at the CEN/TC Plenary meeting by Ms. Linda Sanin, UNIDI.

After role call of delegates and adoption of the proposed agenda, the resolution committee was appointed.

### **Report of the Chairman** – *Manfred Stumke*

#### **Report given at the last ISO/TC 106 Plenary Meeting in Chiang Mai**

Attached document ISO/TC 106 N910

### **Report of the Secretariat** – *Hans-Peter Keller*

Attached document CEN/TC N459

### **Report of liaison organizations:**

#### **Report of ISO/TC 106** – *Natalie Martel, Secretary*

A letter was distributed by the CEN/TC 55 Secretariat on behalf of N. Martel, concerning preliminary information with regard to the next ISO/TC 106 meetings in Rome from September 26 to October 1 2005. More information will be distributed as soon as available

#### **Report of FIDE** – *Linda Sanin*

Ms. Sanin informs CEN/TC 55 members of the recent involvement of FIDE in the study panel on the interference between new generation MRI equipment (magnetic resonance imaging) and implants. The study panel was set up by Eucomed (representing implants industry) and Cocir (representing MRI equipment industry). The initiative came from the British MHRA, which expressed concerns with regard to new generation MRIs (power up to 9.3 Tesla) currently under development.

On one hand MRI devices are having more and more power, due to the increased expectations of professionals; on the other hand, more and more patients are benefiting from implantable devices, which have a potential to interact with MRI if such imaging technique is deemed appropriate for diagnosis.

The objective of this study panel should be that to develop further guidance for users and – considering the lack of compatibility testing standards and harmonized standards – eventually to encourage the development of standards.

Ms. Sanin informs participants that she has no further information at the time being, as the first meeting will take place on February 23<sup>rd</sup>. Ms. Sanin will send a brief report to the CEN/TC 55 Secretariat after the above meeting for distribution to its members.

Further, Ms. Sanin gives some general information concerning the next ISO/TC 106 meetings to be held in Rome. She informs participants that soon Delegates will be able to register to the meeting through an *ad hoc* web site.

#### **Report of NORMAPME** – *J. Schwichtenberg*

See attached NORMAPME document concerning environmental problems linked to dental base materials and current legislation. Normapme asks to add in the relevant standard “..that monomers and polymers shall be in one capsule in which they are mixed”.

#### **Report of FEPPD** – *Jean Jacques Herremans*

See attached FEPPD document concerning the proposal to standardize not only dental products and their test methods, but also the instructions for use, especially as far as health and environmental risks are concerned. They also propose to develop horizontal standards dealing with general instructions for use for all dental products.

## **Report of CEN/TC 55 Working Groups**

### **WG2 – Clinical evaluation and investigation on medical devices used in dentistry**

#### **Convenor: P. David**

The WG did not meet this year. Philip David announces his resignation as an expert of CEN/TC 55 and from the convenorship of WG2. Further he also steps out of the role of liaison member for TC 258 – Clinical investigation of medical devices and TC 316 medical devices utilizing tissues. This last TC seems to not exist anymore. As far as the liaison position with TC 258 is concerned, Mr. Jacobsen (UK delegation) offers to step in.

### **WG3 – Classification**

#### **Convenor: G. Oilo**

The WG did not meet this year. There was a follow up of last year's Resolution concerning the reclassification of dental Curing lights

### **WG4 – Preclinical biological evaluation and testing**

#### **Convenor: A. Hensten**

In accordance with the Vienna Agreement there was no meeting as an ISO WG is already dealing with the same issue.

### **WG5 Nomenclature and Coding system for medical devices used in dentistry**

#### **Convenore: P. Calfon**

Report attached.

### **WG6 – Dental Alloys**

#### **Convenor: H. Kappert**

In accordance with the Vienna Agreement there was no meeting as an ISO WG is already dealing with the same issue.

Mr. Kappert gave a brief report on the activity of the ISO/TC 106 SC2 in Chiang Mai.

## **Acknowledgement of the work of relevant adjacent committees**

### **CEN/TC 102 Sterilizers for medical purposes**

Dr. Keller reported that EN 13060 – Small steam sterilizers has been published in 2004.

### **CEN/TC 204 Sterilization of medical devices**

Liaison member: Mr. T Prodger

Report attached.

### **CEN/TC 216 Chemical disinfectants and antiseptics**

Liaison member: Prof. Paganelli

Report attached.

### **CEN/TC 251 Health informatics**

Liaison member: Prof. Paganelli

Report attached.

### **CEN/TC 257 Terminology, symbols and information provided with medical devices and SC1 identification, coding, nomenclature and regulatory data set.**

Liaison member: Prof. Paganelli

Report attached.

**Information about REACH and possible effects on dentistry**

The Chairman reports there is no information available. Ms. Sanin – FIDE – informs TC 55 that FIDE has been dealing with REACH for a short period but, at the time being, no up to date information is available. However, Ms. Sanin will send an excerpt of FIDE's report concerning the issue to the CEN/TC 55 Secretariat.

**Any other business**

1. The four semi-horizontal standards have been published in 2004, but the harmonization process is delayed;
2. P. Calfon informs TC55 that the French Dental Association is willing to develop a standard concerning surfaces of dental offices. He asks other delegations if there are similar intentions in other countries.

**Appointment of new Chairman**

Dr. M. Stumke has been Chairman of CEN/TC 55 for ten years already. However, in accordance with CEN rules TC 55 must appoint a new chairman. CEN/TC 55 Secretariat proposes Mr. H. Kappert of the German Delegation.

TC 55 members agree unanimously.

**Place and date of next CEN/TC 55 meeting**

20/21 February 2006

The meeting closed at 4:00 PM