

## LIAISON REPORT CEN/TC 55 – ERO CEN/TC55 Annual Plenary Meeting – Bratislava – 2<sup>nd</sup> and 3<sup>rd</sup> March 2009

### **CEN TC55 WG8 – Assessment of dental materials-related occupational risks – 02.03.09**

CEN TC55 WG 8 was set up in continuation of the Task Force created in 2007 to assess the risks associated with the use of polymers in dental laboratories. Following the preparatory work conducted by the Task Force, CEN TC55 decided that the occupational risks related to dental materials could be investigated by a working group set up specifically for that purpose, whose first task would be to draft a report on polymer-related risks. A questionnaire was sent out to all European institutions that represent dental laboratories (CEN-TC55-WG8\_N0028). The answers are currently being processed.

The WG work report (CEN-TC55-WG8\_N0029), a letter of information from the WG convenor to the WG members (CEN-TC55-WG8\_N0030) and the minutes of the WG meeting held on 2<sup>nd</sup> March 2009 (CEN-TC55-WG8\_N0031) are provided in the appendices.

Experts on methacrylate resins are now needed to conduct further investigations, and the ERO is encouraged to provide expertise.

### **CEN TC55 WG7 – Steering Committee – 02.03.09**

The Harmonised European Standards have been amended in conformity with the new recommendations laid out in the revised Medical Devices Directive. More specifically, the annexes ZA required by the Directive have been drafted for each standard. Annex ZA is essential, as it specifies the correlation between the Essential Requirements set out in the new Directive 2007/47/EC and the clauses of the standard. This makes the standard easier to read and understand, and facilitates the work of the notified bodies, as well as that of manufacturers in carrying out their conformity procedures.

Various documents in relation with the work of WG 7 are provided in the appendices. They are identified by the expression "WG7" in their title (CEN-TC55-WG7\_N0217, CEN-TC55-WG7\_N0218, CEN-TC55-WG7\_N0240), and they describe the work conducted since the last meeting.

### **CEN TC55 – Plenary meeting – 03.03.09**

The report from the secretary Hans-Peter Keller (DIN) is provided in the appendices (CEN-TC55\_N551). Item 6 is of particular interest, as it gives a comprehensive explanation on how European regulations are set through the New Approach Directives, and the impact of these Directives on standardisation. The reading of this report is highly recommended to apprehend the domain.

The minutes of the meeting held on 3<sup>rd</sup> March 2009 are also appended (CEN-TC55\_N0562).

### **CEN TC55 WG5 – Codification**

I have asked for this working group – which I will be heading in 2010 – to organise a meeting so that a Global Codification project drafted by ISO TC 106 SC3 may be presented. This project results from the revision of the COSI (Codification of Oral Status and Interventions) which was adopted by FDI and WHO years ago.

## **ERO**

In my capacity as liaison officer between CEN TC 55 and the ERO, I presented a report on the activities of the ERO (CEN\_TC55\_N0552) at the TC 55 plenary meeting, and insisted on the need of introducing a Final Product Risk Assessment in European standards, as a result of the questions arising from the possibility of lead leaking in imported dental prosthesis.

## **CED**

The CED has applied to establish a partnership liaison with CEN TC55 (CEN-TC55-N0563).

## **Mouthguards**

This standardisation work falls outside the scope of CEN TC55 as it is related to protective equipment. It seems that the project is badly written, lacks clarity and cannot be published in its current form (CEN-TC55\_N0549).

## **Appended documents**

The documents appended to this report give additional information for a better understanding of standardisation activities and of the European regulatory environment that influences them.

Documents CEN TC55 N0555 to 558 are reports from other liaison officers who follow the work conducted in other committees (sterilisation, clinical trials, and so on).

The next TC 55 and TC 55 WG meetings are scheduled on 22-23 February in Brussels.

Dr Philippe Calfon

A handwritten signature in black ink, appearing to read 'Calfon', with a long horizontal stroke extending to the right.