Report meeting CEN TC 55 WG7 - 7 APRIL 2014, BRUSSELS

Revision of the MDD 93/42/EEC and the four horizontal EN standards

Background

It had been agreed that the revised Medical Device Regulation would indicate the revision of the four harmonised standards (EN1639, 1640, 1641 and 1642). When this was available, WG7 would commence the revision, subject to approval of the TC. The WG reconfirmed this decision.

Notwithstanding the TC policy agreed in 2013 that revision of the four harmonised standards would be deferred until advice from CEN was available, AFNOR had submitted a NWIP proposing revision of EN 1642 including test methods and performance limits. This proposal was at odds with the long established policy of the TC that CEN would not introduce test methods or requirements that were not published by ISO.

The four horizontal EN standards have historically represented all ISO standards within the dentistry field. According to the convener, it was a method to introduce and adopt ISO Dentistry standards within Europe.

The French New Work Item Proposal (NWIP) on revision of EN1642 has though been approved in voting. Even though there were very few of the 33 member countries that voted on the proposal, the result showed that a majority of the cast votes supported the proposal (only UK and Sweden voted against the proposal).

Discussion

The meeting was attended by 15 members from five countries and chaired by Dr P H Jacobsen, UK.

The Chairman summarised the current status of the revision of the MDD 93/42/EEC. It was currently being revised in accordance with a large number of comments made on the draft.

There was a long discussion about the status and future of the NWIP.

France and Germany wanted the revision work to start immediately on EN1642 while United Kingdom and Sweden tried to delay it until the Medical Device Regulation (MDR) is adopted and there are guidelines available on how to interpret the requirements.

France and Germany pointed out the particular problem in the implant field that no limits had been proposed for certain properties and this would inhibit the drafting of Annexe ZA for EN 1642. They claim that no test method will be accepted without limits from now on.
Especially the France delegation had a different philosophy regarding the EN standards considering the standards not as horizontal but vertical standards.

The convener of CEN TC55/WG7 explained that the main issues for WG7 was that the General Safety and Performance Requirements (the old ER) had been extended to 19. Annexes Z of all European harmonised standards would need to address these Requirements and any standards cited to fulfil the GSPRs would need to include performance limits. In addition it was likely that only dated standards could be cited in harmonised standards. It was also proposed that each element of the GSPRs would need to be addressed. For example, if a GSPR included “design and manufactured” then both “design” and “manufactured” would need to be covered. Guidance was expected from CEN on how to write Annexes Z but the CEN consultant working on this had stopped because of the controversy. The convener doubted that the revision could be finished within the time limits because of the large changes that need to be done.

France and Germany still considered it advantageous to initiate the revision work on one of the four harmonized standards now to practice for the upcoming work that has to be done.

Sweden suggested the performance limits to be added in the ISO 14801 standard by TC106/SC8/WG4 (Dental Implants: mechanical testing) and not in the EN standard.

It was eventually agreed to recommend to the TC that a Project Group would be established within WG7 to draft the revision of EN 1642. The Secretary would circulate the MBs of WG7 asking for nominations to thePG. French proposed the Project Leader for the PG and this was Professor Brigitte Grosgogeat. It was noted that the closing date for the project, including PrEN vote, was January 2017.

Conclusion

- It was decided to re-confirm the three harmonized standards EN1639,1640 and 1641 to make them stay un-revised.

- A Project group within CEN TC55/WG7 will start to work on the French proposal and has to finalize the standard within three years.

Report meeting CEN TC 55 Plenary meeting - 8 APRIL 2014, BRUSSELS

22 delegates from 7 member bodies were present

Adoption of the agenda
The proposed draft agenda, document CEN/TC 55 N 702, was adopted.
Decision 1

Appointment of the Decision Committee
Mr. T. Prodger, Prof. K. Dermann and Prof. P. Calfon volunteered to assist the Secretary in drafting the decisions.
Decision 2

Report of the Chairman
The Chairman, Mr. J. Nille, reported about the various activities of CEN/TC 55 in 2013. European Standards are now prepared for more than 500 million people in the European Union. The Chairman referred to document N 699 with the report of the Chairman given at the last ISO/TC 106 Plenary meeting held on 2013-10-05 in Incheon (Korea).

Report of the Secretariat
Dr. H.-P. Keller presented the report of the secretariat (document N 709). Since the last Plenary meeting (April 2013) 12 European Standards, one CEN Technical Report and one Amendment were published by CEN/TC 55. Today there are 139 published European Standards for dentistry (document N 706). The secretary mentioned the difficulties in applying the Vienna Agreement to the work programme of ISO/TC 106. Due to several rule changes at ISO the coordination of the work is now more difficult.

Report from CCMC Environmental Help Desk
No report form the CCMC Environmental Help Desk was received. The CCMC Environmental help desk is responsible for e.g. CCMC Environmental approach and CCMC Life Cycle approach concept and
a) integration of environmental aspects in European Standards;
b) tools and solutions.
If there is a special request Ms. Bénédicte is always willing to attend future Plenary meetings of CEN/TC 55.
Dr. Hensten informed TC 55 that the current opinions on dental amalgam, which were requested from the two European Commission's Scientific Committees, Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) and Scientific Committee for Health and Environmental Risks (SCHER).

Report of liaison organizations
Liaison report from ISO/TC 106 Dentistry
The secretary reported that Ms. S. Lefébvre could not attend the meeting. The 49th meeting of ISO/TC 106 and its subcommittees took place during the week 30th September to 5th October 2013 in Incheon (Korea, South). Due to the excellent meeting organisation good progress was made at these meetings, as a result of some 40 working group meetings. More than 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 707. The next meeting of ISO/TC 106 will be held from 14th to 20th September 2014 in Berlin (Germany).

Liaison report from FIDE

Because Ms. L. Sanin could not attend the meeting a written report about the activities of FIDE (European Dental Industry) was presented as document N 715.
In order to support the statements of FIDE the following documents were presented:
a) FIDE Statement on the risk classification of medical devices containing nanomaterials on the basis of an assessment of their health effects: document N 714;
b) Market Surveillance on dental and bone fillers: document N 713.

Liaison report from FEPPD

The liaison representative of FEPPD, Ms. H. Dohalova, reported about the activities of FEPPD (Fédération Européenne Des Patrons Prothésistes Dentaires) and referred to document N 712. The secretary explained that additional clarification between FEPPD and CEN is needed in order to maintain FEPPD as a European liaison organisation (see document N 711).

Liaison report from ERO

The liaison representative of ERO, Prof. P. Calfon, reported about the activities of ERO (European Regional organization of FDI). No written report was available.
The secretary explained that additional clarification between ERO and CEN is needed in order to maintain ERO as a European liaison organisation (see document N 711).

Liaison report from CED

The liaison representative of CED, Dr. J. Nagaba, reported about the activities of CED (Council of European Dentists). No written report was available.

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

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 published in 2009. No WG 3 meeting was necessary in 2013. WG 3 is waiting for the new regulation of the MDR and the revised classification rules.

WG 4 Preclinical biological evaluation and testing

The convenor of WG 4, Dr. A. Hensten, reported about the activities of WG 4 "Preclinical biological evaluation and testing". He reported about the excellent progress made by ISO/TC 106/WG 10 "Biological evaluation of dental materials" at the 2013 meeting in Incheon (document N 720). ISO 7405 was published in December 2008. An amendment describing "positive control material" for ISO 7405 was published in July 2013. No WG 4 meeting was necessary in 2013. As a new work item the functional use of dental implants is discussed. Sample preparation of nanomaterials is discussed with ISO/TC 194/WG 17. The effects of BPA and the biological aspects of light curing lamps with high UV radiation are considered.

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

Prof. Calfon reported about the activities of WG 5. He referred to the Dutch proposal for a new work item (document N 704) "Diagnostic terms and codes for dentistry". This proposal can also be discussed within ISO/TC 106/SC 3/WG 2. No WG 5 meeting was necessary in 2013. The situation with UDI was discussed. From September 2014 UDI is required for class III medical devices.

WG 6 Dental alloys

The secretary reported on behalf of the convenor of WG 6, Dr. J. Lindigkeit, about the activities of WG 6 "Dental alloys". The revision of ISO 22674 "Metallic materials for fixed and removable restorations and appliances" is currently at the DIS stage.
No WG 6 meeting was necessary in 2013.

WG 7 Steering Committee

The convenor of WG 7, Dr. P. Jacobsen, reported about the meeting of WG 7 "Steering Committee" on 2014-04-07 in Brussels (document N 719). The main task was the discussion of the status and content of the draft of the new MDR regulations. The report of WG 7 was approved.
Decision 3

CEN/TC 55 discussed the current situation (e.g. systematic review) with the four harmonized
standards EN 1639 to EN 1642. The following procedure was accepted:
EN 1639:2009 , Dentistry — Medical devices for dentistry — Instruments: Confirmation.
Decision 4
EN 1640:2009 , Dentistry — Medical devices for dentistry — Equipment: Confirmation
Decision 5
EN 1641:2009 , Dentistry — Medical devices for dentistry — Materials: Confirmation
Decision 6
EN 1642:2011 , Dentistry — Medical devices for dentistry — Dental implants:
Revision. A Project group within CEN TC55/WG7 will start to work on the French proposal and has to finalize the standard within three years.

French proposal for revision of EN 1642 and result of voting
CEN/TC 55 Dentistry discussed the French proposal for revision on EN 1642 (document N 700) and noted the voting result (document N 710), which was acceptance of the revision proposal. WG 7 established a project group for discussing the working drafts. In order to allow participation from experts the secretariat was asked to prepare a call for experts to the member bodies (document N 722).

WG 8 Occupational risk assessment related to dental materials

The convenor of WG 8, Prof. U. Ortengren, reported about the activites of WG 8 "Occupational risk assessment related to dental materials. The CEN Report CEN/TR 16384 “Dentistry – Guidelines for handling methacrylate-based materials in the dental laboratory” was published in January 2013. No WG 8 meeting was necessary in 2013. Currently participation with ISO/TC 106/WG 10 is planned.

Dutch proposal for a possible new work item

The Dutch delegation leader presented a proposal for a possible new work item on “Diagnostic terms and codes for dentistry” (document N 704). The proposal is suitable for countries with a good developed health care system. The descriptive way of diagnosis opens the market for dental software. Currently ACTA is using the system. CEN/TC 55 discussed the possibilities. Prof. Calfon explained that France adopts a new classification of medical treatment, especially in dentistry, in the next months.
The Dutch delegation will analyse the discussion and prepare a revised proposal.

Acknowledgement of the work of relevant adjacent committees

CEN/TC 102 Sterilizers for medical purposes
The liaison representative, Mr. T. Prodger, referred to document N 717 with the report about the activities of CEN/TC 102 "Sterilizers for medical purposes". EN ISO 15883, Washer disinfectors, Part 5: Test methods for soil, had encountered difficulties for preparing a standardised test soil because each country defends its own testsoil preparation. As solution all soils are accepted, provided that is has certain adhesive properties.

CEN/TC 204 Sterilization of medical devices
The liaison representative, Mr. T. Prodger, reported about the activities of CEN/TC 204 "Sterilization of medical devices". Nearly all activities are now transferred to the ISO level of ISO/TC 198. The only remaining standards are EN 556. EN ISO 11135 EO needs a longer transition period than the usual 6 months. The transition period was expanded to 36 months.

CEN/TC 205 Non-active medical devices
The liaison representative, Mr. T. Prodger, reported about the activities of CEN/TC 205 "Nonactive medical devices" (document N 716)
In addition to the revision of the following parts of EN 455 "Medical gloves for single use"prEN 455-2 "Part 2: Requirements and testing for physical properties";
prEN 455-3 "Part 3: Requirements and testing for biological evaluation"
a CEN/TR "Medical and examination gloves – Guidance for proper selection, correct use, care and maintenance" was proposed. However, the project is delayed. This report could be of interest to CEN/TC 55/WG 8.

CEN/TC 206 Biological evaluation of medical devices
The liaison representative, Dr. A. Hensten, reported about the activities of CEN/TC 206 "Biological evaluation of medical devices". The CEN committee works closely together with ISO/TC 194.
A new working group ISO/TC 194/WG 17 "Nanomaterials" was established. ISO 10993-6 has 5 annexes. FDI recognizes only 4 annexes. They like to see different formats to fit regulatory purposes. The next meeting is scheduled for 26th April 2014 in Japan.

CEN/TC 216 Chemical disinfectants and antiseptics
The liaison representative, Mr. T. Prodger, reported about the work of CEN/TC 216 "Chemical disinfectants and antiseptics". Work continues on disinfectants for medical instruments.

CEN/TC 251 Health informatics
No information was available about the ongoing activities of CEN/TC 251 Health Informatics.

CEN/CLC TC 3 Quality management and corresponding general aspects for medical devices. Activities of CEN/CLC TC 3 Quality management and corresponding general aspects formedical devices:ISO 13485 is under revision. Currently the DIS is out for voting.The document is intended to replace ISO 9001. Therefore no longer certification

according to ISO 9001 is needed/allowed.

Can a company in future still have two quality management certificates, e.g.
a) ISO 9001
b) ISO 13485
or is this no longer allowed?
Many dental companies distribute medical devices, but also products which are not considered as medical devices (e.g. products for the dental laboratory such as investment materials, laboratory instruments, etc.).

CEN/TC 258 Clinical investigation of medical devices
The liaison representative, Dr. P. Jacobsen, reported about the activities of CEN/TC 258 "Clinical investigation of medical devices". ISO 14155 was published in January 2011. Revision of ISO 14155 is foreseen due to new regulatory plans for clinical investigations of medical devices.

CEN/TC 285 Non-active surgical implants
The next meeting of ISO/TC 150 "Surgical implants" is scheduled in September 2014 in Seoul in Korea. CEN/TC 285 "Non-active surgical implants" is looking for a meeting place.

CEN/TC 316 Medical devices utilizing tissues
The new title of CEN/TC 316 is "Medical products utilizing cells, tissues and/or their derivatives". The scope contains now human and animal products.

CEN/TC 347 Methods for analysis of allergens
The liaison representative, Dr. Hensten, reported about CEN/TC 347 "Methods for analysisof allergens". Switzerland has taken over the secretariat for CEN/TC 347 (third change of secretariat). TC 347 has three working groups.

CEN/TC 392 Cosmetics
The liaison representative, Dr. P. Helderweirt, reported about CEN/TC 392 "Cosmetics". In November 2009 regulation (EC) No 1223/2009 on cosmetic products was issued (document N 592). It shall apply from 11 July 2013.
He attended the Plenary meeting in February 2014 in Brussels. The secretariat was transferred from NEN to AFNOR with X. Peguy as new secretary. The committee is focussing on analytical methods for microbial loads. Report Plenary meeting CEN/TC 55 on 2014-04-08 in Brussels page 12 of 20

CEN/TC 403 Aesthetic surgery devices
Prof. Calfon reported about the activities of CEN/TC 403 "Aesthetic surgery services". The prosed new service standard received a Type A deviation from AFNOR. Dentistry should be excluded from the scope of CEN/TC 403.

CEN/TC 424 Care services for cleft lip and/or palate
A new work item proposal from Bulgaria for the creation a new committee "Care services for cleft lip and/or palate" was issued in 2013 and approved. The first meeting of CEN/TC 424 was held on 4th/5th September 2013 in Vienna
CEN/TC 55 was concerned about these activities, because in most countries there are

specialised services for babies having a palatal cleft. The activities of EUROCLEFT were discussed. The next Plenary meeting is scheduled for 28 April 2014 in Sofia (Bulgaria).

Decision about specific work items in the CEN/TC 55 work programme
The actual work programme of CEN/TC 55 (document N 708) was compared with the actual work programme of ISO/TC 106 (document N 707). The following work items were added to the CEN/TC 55 work programme:
NOTE: Approval of work items is now handled via the PROJEX database. For information clarity the following work items were approved at the Plenary for addition to the work programme of CEN/TC 55:
ISO/WD 19023, Dentistry - Orthodontic anchor screws (ISO/TC 106/SC 1/WG 17);
Decision 7
ISO/CD 17509, Dentistry -Torque transmitter for handpieces
(ISO/TC 106/SC 4/WG 13),
Decision 8
ISO/WD 19448, Dentistry - Analysis of fluoride concentration in aqueous solutions by use of fluoride-ion selective electrode (ISO/TC 106/SC 7/WG 8);
Decision 9
ISO/WD 14801, Dentistry -Implants - Dynamic fatigue test for endosseous dental implants (ISO/TC 106/SC 8/WG 4);
Decision 10
ISO/WD 19421, Dentistry - Endosseous uncoated metal dental implants
(ISO/TC 106/SC 8/WG 3);
Decision 11
ISO/AWI 18675, Dentistry- CAD/CAM machinable zirconia blanks
(ISO/TC 106/SC 9/WG 5);
Decision 12
ISO/CD 18739, Dentistry- Terminology of process chain for CAD/CAM systems
(ISO/TC 106/SC 9/WG 2);
Decision 13
ISO/AWI 18845, Dentistry -CAD/CAM systems -Accuracy of machined indirect restorations -Test methods and marking (ISO/TC 106/SC 9/WG 4);
Decision 14

Discussion of working experience with the document server system Livelink
CEN/TC 55 discussed the working experience of 2013 concerning document distribution via the DIN Livelink server. No problems were encountered. 13 Place and date of next CEN/TC 55 meeting. The next CEN/TC 55 Plenary meeting is scheduled for 21 April 2015 in Brussels.
Decision 15
Approval of decisions
All decisions were approved during the meeting. The final editorial formulation of the decisions will be prepared by the decision committee.

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