Standard developments in Dentistry

Asbjørn Jokstad
Science manager FDI
1920 1930 1940 1950 1960 1970

FDI

ISO

NIOM

TC106 Dentistry

ADA

Evaluation programs

ASTM, ANSI, BSI, DIN, AFNOR ….

Australia DMRL … DSC
ADA

- 1919: Surgeon general request on assessment of amalgam
- 1942: Bureau of standards, Research commission
- 1955: Clinical testing of dental caries preventives. Report of a conference to develop uniform standards and procedures
- 1971: Cvar & Ryge, USPHS system
- 1977: ADA specification no. 27 for direct filling resins. JADA 94:1191-4
- 1979: ANSI/ADA document no 41 for recommended standard practices for biological evaluation of dental materials

1986: ADA acceptance program for dentin adhesive materials and enamel and dentin adhesive materials. JADA 112:707-9

1989: Revised ADA guidelines for submission of composite resin materials for posterior restorations.


FDI – Recommendations for trials

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1990: Good manufacturing practices, including quality assurance for dental materials Int Dent J 40:253-6
ISO

Nongovernmental

National standardization bodies – one from each country

70% of these are national standards bodies

Several hundred technical committees

ISO standards

• Mandatory
• Voluntary

Standards governs availability of products
ISO

- TC 106 Dentistry [1959]
- TC106/FDI joint WG - toothpaste [1985]
- TC106/FDI joint WG - biological testing [1986]
- TC 194 Biological evaluation of medical and dental materials and devices [1988]
  - Biological evaluation of medical devices ISO 10993-1/-12
ISO TC 106 Dentistry

- SC 1 Filling and restorative materials
  - 14 WG
- SC2 Prosthodontic materials
  - 20 WG
- SC3 Terminology
  - 4 WG
- SC4 Dental Instruments
  - 10 WG
- SC6 Dental Equipment
  - 8 WG
- SC7 Oral hygiene products
  - 4 WG
- SC8 Dental Implants
  - 5 WG
1958 Contact whether the FDI specifications could be considered as ISO standards

Result of liaison was establishment of TC106 Dentistry in 1963

1966 Adoption of all 9 FDI specifications as ISO standards

1966 Several Joint working groups formulated

Joint working groups disbanded

1967 Adoption of all 9 FDI specifications as ISO standards


Biological test methodology & clinical evaluations: FDI (Ottawa)

1984: TR 7405

Biologic evaluation of dental materials

1985: JWG Toothpaste & Biologic testing

1987: FDI (Ottawa)
FDI - CDP

- WG 1 Clinical testing protocols (M Tyas) Completed 1990
  - Mjör, Reich, Subramaniam, Harcourt, Krishnan, Weber
- WG 2,
- WG 3,
- WG 4,
- WG 5
- WG 6 Status and informative reports (Mjör → PL Fan)
- WG 7 Prevention and dental protection during sports activity (Bogopolsky)
- WG 8 Emergencies in dental practice and revision of medical history forms (RG Woods)
  - Woods, Amerena, VanAmerongen, David, Duxbury, Franz, Petersen, Ratnanesan, Uji, Voss, Wagner
- WG 9 Multi-country clinical trials on materials performance (J Reese)
FDI - CDEP

- WG 1
- WG 2
- WG 3
- WG 4
- WG 5
- WG 6
- WG 7 Forensic dentistry (Swinburn)
- WG 8 Impact of changing disease trends on dental education
- WG 9 Marketing (Masalin)
- WG 10 Delivery of oral health care to the elderly patient (Nordahl)
- WG 11 Distance learning (Anneroth)
- WG 12 Quality assurance → Commission project 93-6 (Olsen)
- WG 13 Computerised diagnostic systems in dentistry (Matheis)
- WG 14 Preregistration and postgraduate practice training (Stanley)
- WG 15 Participatory continuing dental education (Caffesse) → Commission project 93-12 (DL Allen)
- WG 16 Flexibility in the dental curriculum (Sanz)
FDI - CORE

- WG 1
- WG 2 Orofacial neoplasms (Johnson)
- WG 3 Promoting oral health: guidelines for Das (Cohen)
- WG 4 Reasons for toothloss (Croxson)
- WG 5 Oral health needs of the elderly (Ettinger)
- WG 6 Topical & systemic antimicrobial agents in periodontology
- WG 7
- WG 8
- WG 9 Developmental defects of enamel index (DDE index) (Clarkson)
- WG10 Saliva (Sreebny)
- WG11 Oral health in the handicapped (Rule)
- WG12 Nutrition and oral health (Midda)
- WG13 Evaluation of clinical trials of agents and procedures to prevent caries and periodontal disease (S Moss)
- Review of methods of identification of high caries risk patients (Hunter)
FDI INCORPIT, Intercommission group on relations between the profession, trade and industry

- Guidelines for evaluation programmes for dental products. 1989
- Guidelines for dental dealers. 1989
- Guidelines for post-marketing surveillance and performance evaluation. 1989
- Handling of Hazardous wastes. 1989
- Equipment maintenance. 1987
FDI – Joint work groups

- JWG 1- TC106: Toothpastes (D Lange)
  - Barolet, David, Franz, Josefowicz, König, Ohashi, Pearson, Takac, Weaver
- JWG2 -TC106: Biological evaluation of dental materials (H Stanley)
  - Lia, deMoraes, Meurman, Murphy, Pearson, Reese, Rodrigues, Martin, Tyas, Valdrigi
- JWG 5 –Effects on flying and diving of drugs (Rohweder)
- JWG 9 – Economic factors in delivery of services (Backer)
- JWG10 – Periodontal health services (Pilot)
- JWG11 WHO (PAHO): Establishment of criteria for classification of dental products and their importation and exportation in Latin America (D Del Rio)
  - Adler
- JWG12 Monitoring oral health in adolescents (Carlson)
- JWG13 Educational programs for teaching (Gomez)
- JWG14 – WHO: Oral manifestations of HIV/AIDS (Cutress)
- JWG15 International collaboration for oral health research, ICOHR (Løe)
- JWG -TC106/TC42: Revision of ISO 3665 for intraoral radiographic films
CEN

- TC55 Dental products
- TC205 Non-active medical devices
- TC206 Biocompatibility and biological safety of medical and dental materials and devices 1989

From 1988:
- Class I Good manufacturing practice (GMP)
- Class 2: GMP + EN + test
- Class 3: GMP + EN + pharmaceutical evaluation
1977: Tentative work to establish European standard

Standstill until 85: Present ISO standards as CEN as soon as possible


1993: Certification system for Medical-technical equipment
Standards require

1. Sponsoring body, e.g. NDA or governmental agency
2. Recognised standards for certification
3. Testing laboratory for checking quality and products after acceptance
4. Recognised standards for advertising and promoting products