Standard developments in Dentistry

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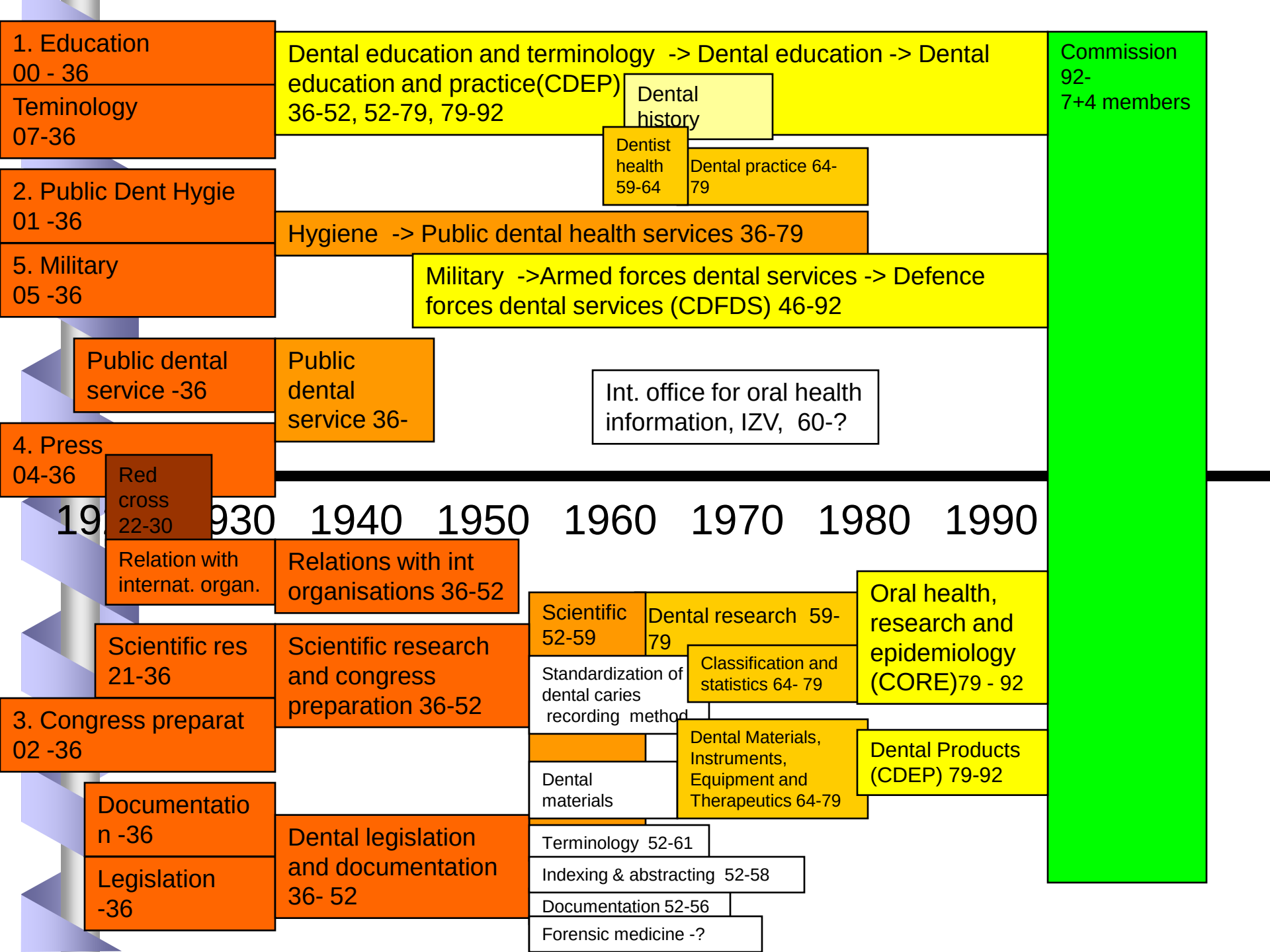
Science manager FDI


1. Education
00 - 36
Teminology
07-36
Dental education and terminology -> Dental education -> Dental education and practice(CDEP)
36-52, 52-79, 79-92
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Dentist health 59-64
Dental practice 64-79
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92-
7+4 members
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05 -36
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Public dental service 36-
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Classification and statistics 64- 79
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Dental Products (CDEP) 79-92
Dental materials
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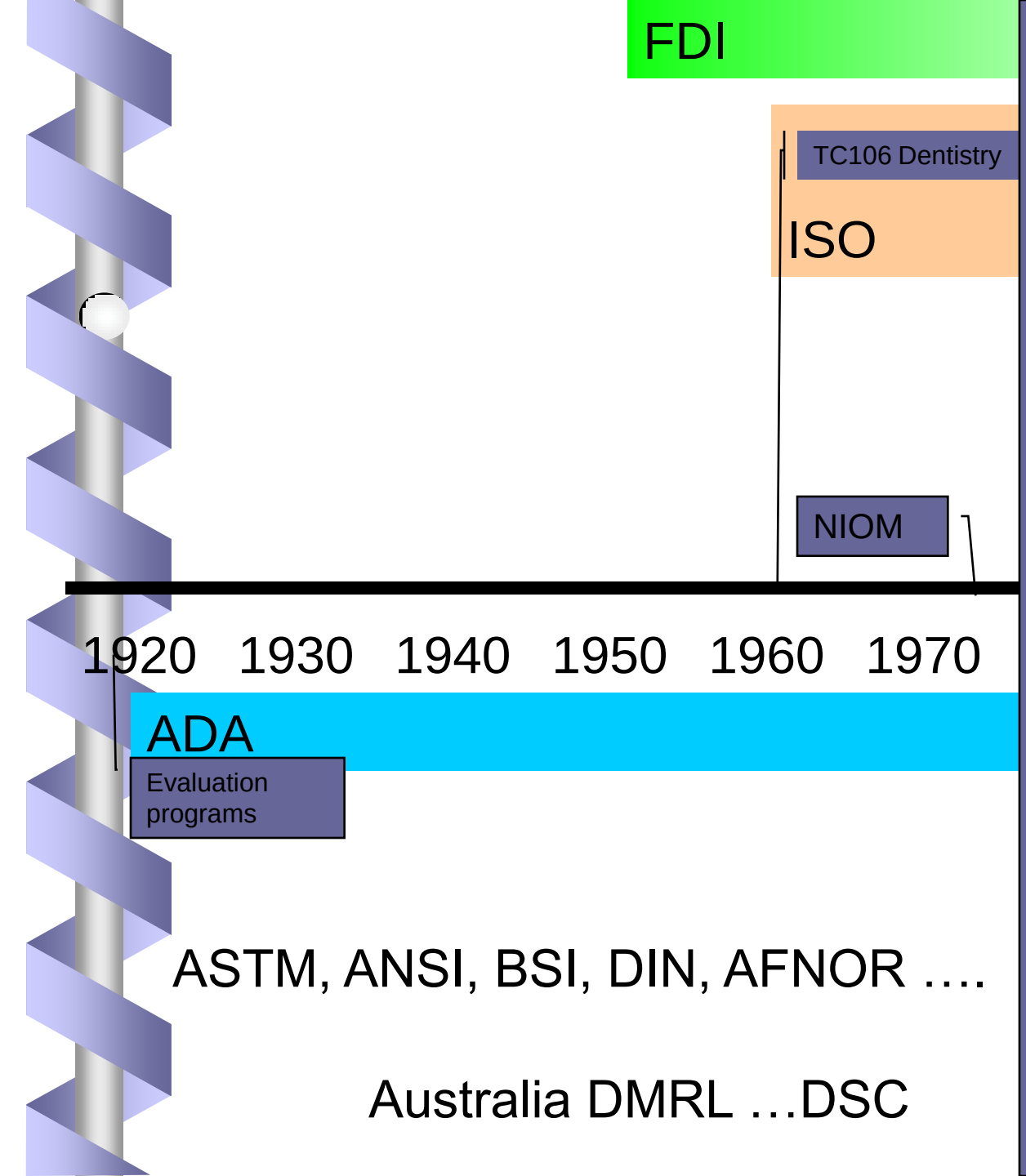
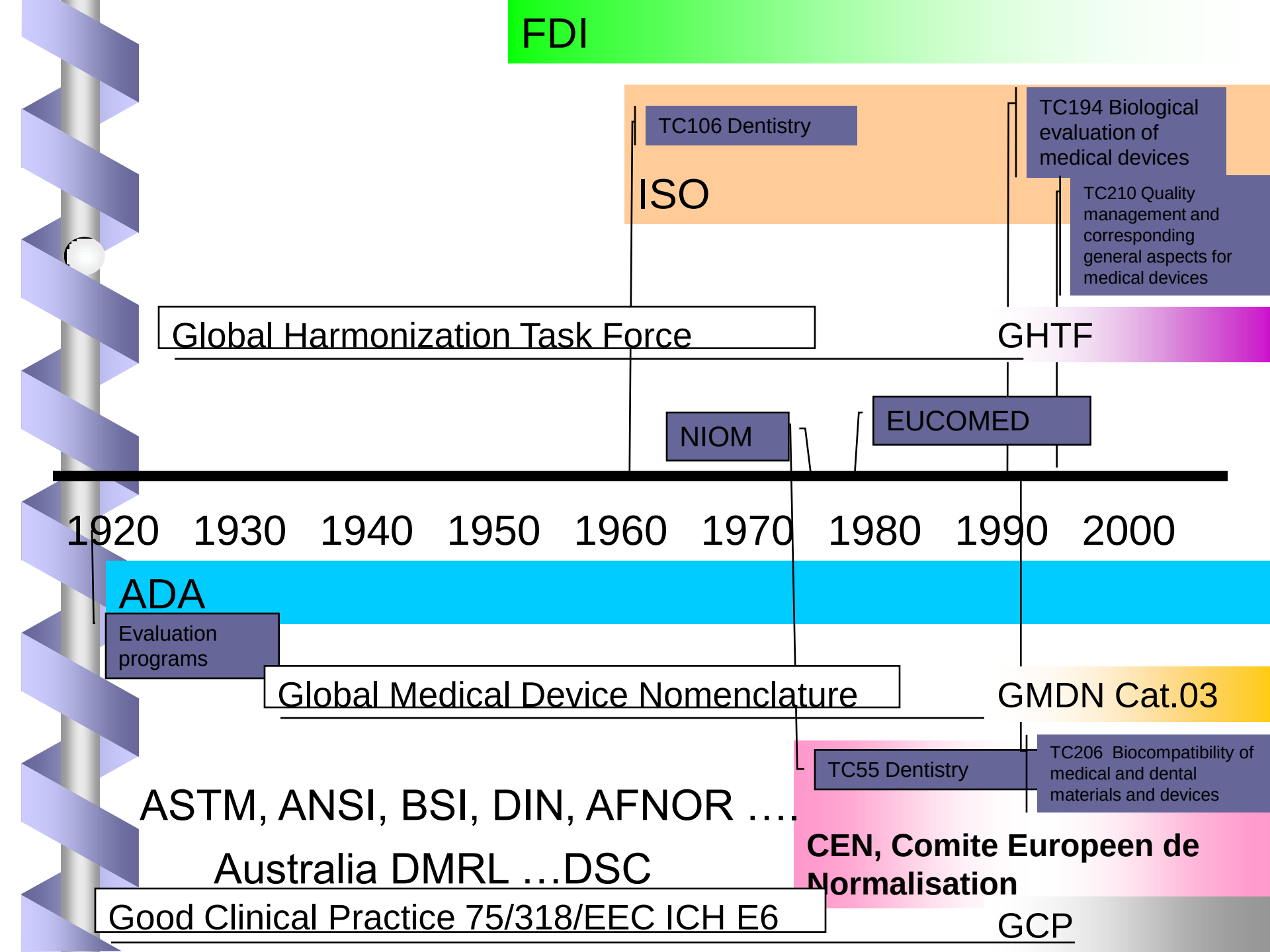

FDI
TC106 Dentistry
ISO
NIOM
1920
1930
1940
1950
1960
1970
ADA
Evaluation programs
ASTM, ANSI, BSI, DIN, AFNOR ….
Australia DMRL …DSC


FDI
TC106 Dentistry
ISO
TC194 Biological evaluation of medical devices
TC210 Quality management and corresponding general aspects for medical devices
Global Harmonization Task Force
GHTF
NIOM
EUCOMED
1920 1930 1940 1950 1960 1970 1980 1990 2000
ADA
Evaluation programs
Global Medical Device Nomenclature
GMDN Cat.03
TC55 Dentistry
TC206 Biocompatibility of medical and dental materials and devices
ASTM, ANSI, BSI, DIN, AFNOR ….
Australia DMRL …DSC
CEN, Comite Europeen de Normalisation
Good Clinical Practice 75/318/EEC ICH E6
GCP

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
- 1972: Recommended standard practices for clinical evaluation of dental materials and devices. JADA 84:388-90.
- 1973: Guidelines for reporting clinical trials. JADA 87:557.
- 1977: ADA specification no. 27 for direct filling resins. JADA 94:1191-4
- 1978: Clinical evaluation of dental materials. USPHS Publ 1980.
- 1979: ANSI/ADA document no 41 for recommended standard practices for biological evaluation of dental materials

ADA

- 1981: Expansion of the acceptance program for dental materials, instruments and equipment: composite resin materials for occlusal class I and II restorations. JADA 102:349-50.
- 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.
- 1991: Revised ADA guidelines for evaluation of dentin and enamel adhesive materials.
- 1994: Revised ADA guidelines for evaluation of dentin enamel adhesive materials.

CoC, Committee on commissions

1960 1965 1970 1975 1980 1985 1990 1995 2000

INCOGUDET

Commission on Dental Materials, Instruments, Equipment and Therapeutics 64-79

INCORPIT (Intercomm group on relations between the profession, trade and industry)

CDP, Commission on Dental Products 79-92

CORE, Commission on oral health, research and epidemiology 79-92

CDEP, Commission on Dental Education and Practice 79-92

CDFDS, Commission on Defence Forces Dental Services 79-92

FDI Commission 92-

Chairman (Mjör)

CDP chm (Woods)

CORE chm (Moss)

CDEP chm (Allen)

Scient.progrm comm (Djukanovic)

IADR rep (Naylor)

Who repr (Barmes)

Section of Defence

FDI – Recommendations for trials

- 1967: Principal requirements for controlled clinical trials. (Recommended randomisation, adequate sample size and attrition loss). Int Dent J 17:93-103
- 1973: Ethical policy regarding the use of human subjects in clinical research. Int Dent J 23: 641
- 1974: Acceptance programs for dental materials and devices. Int Dent J 24:372-5
- 1975: Classification of epidemiological studies of dental caries and definitions of releted terms. (FDI Technical report no 3.) Int Dent J 25:79-87
- 1977: Recommended format for protocol for clinical research programs. Clinical comparison of several ant and post rest mat. Int Dent J 27:46-59
- 1977: Principal requirements for controlled clinical trials in periodontal diseases. (FDI Technical report no 4.) Int Dent J 27:62-76

FDI – Recommendations for trials

- 1980: Recommended standard practices for biological evaluation of dental materials. Int Dent J 30:140-8 (FDI Technical report no 9.)
- 1982: Principal requirements for controlled clinical trials of caries preventive agents and procedures. Int Dent J 32:293-308 (FDI Technical report no 1, 3. Edit.)
- 1982: Recommendations for clinical research protocols for dental materials. Int Dent J 32:403-23 (FDI Technical report)
- 1990: Good manufacturing practices, including quality assurance for dental materials Int Dent J 40:253-6

ISO

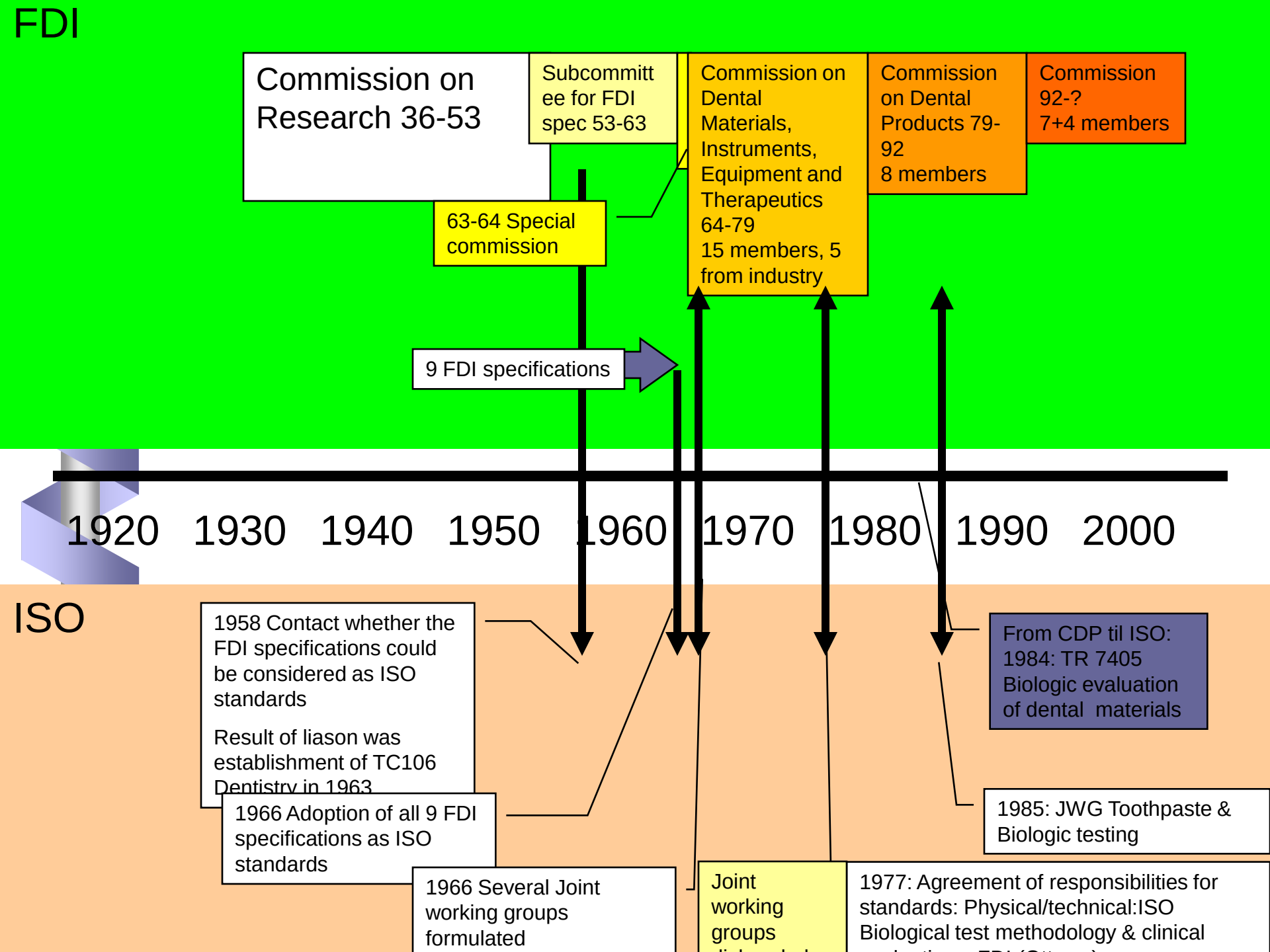
- Nongovernmental
- National standardization bodies – one from each country
- 70% of these are national standards bodies
- Several hundred technical committees
- ISO standards
  - Mandatory
  - Voluntary
- Standards governs availability of products

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


FDI
Commission on Research 36-53
Subcommittee for FDI spec 53-63
Commission on Dental Materials, Instruments, Equipment and Therapeutics 64-79 15 members, 5 from industry
Commission on Dental Products 79-92 8 members
Commission 92-? 7+4 members
63-64 Special commission
9 FDI specifications
1920
1930
1940
1950
1960
1970
1980
1990
2000
ISO
1958 Contact whether the FDI specifications could be considered as ISO standards
Result of liason was establishment of TC106 Dentistry in 1963
From CDP til ISO: 1984: TR 7405 Biologic evaluation of dental materials
1966 Adoption of all 9 FDI specifications as ISO standards
1985: JWG Toothpaste & Biologic testing
1966 Several Joint working groups formulated
Joint working groups
1977: Agreement of responsibilities for standards: Physical/technical:ISO Biological test methodology & clinical

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)
- WG10 Delivery of oral health care to the elderly patient (Nordahl)
- WG11 Distance learning (Anneroth)
- WG12 Quality assurance → Commission project 93-6 (Olsen)
- WG13 Computerised diagnostic systems in dentistry (Matheis)
- WG14 Preregistration and postgraduate practice training (Stanley)
- WG15 Participatory continuing dental education (Caffesse) → Commission project 93-12 (DL Allen)
- WG16 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

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

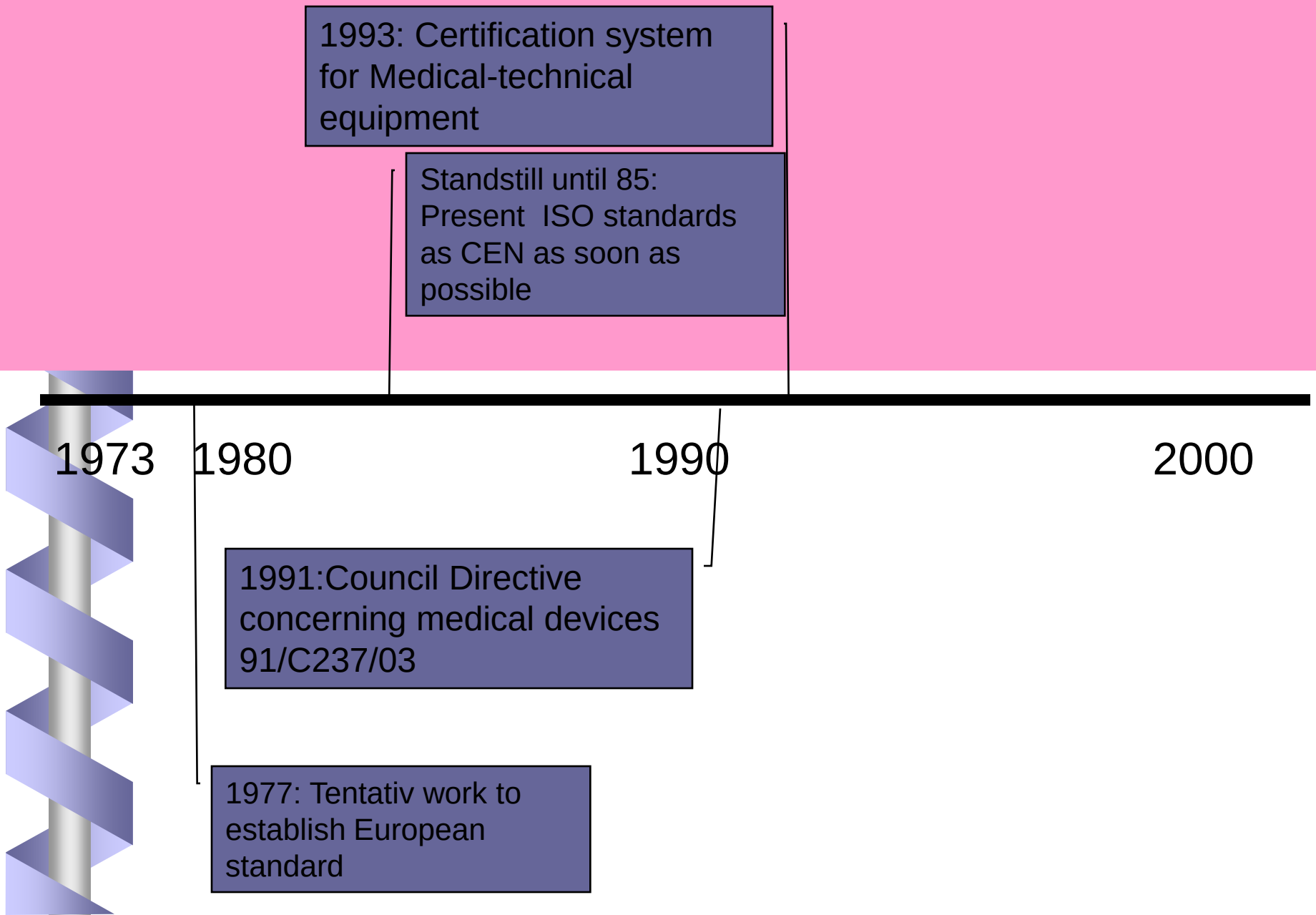
CEN

- 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

CEN


1993: Certification system for Medical-technical equipment
Standstill until 85: Present ISO standards as CEN as soon as possible
1973
1980
1990
2000
1991:Council Directive concerning medical devices 91/C237/03
1977: Tentativ work to establish European standard

Standards require

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