

INTERNATIONAL STANDARDIZATION OF TECHNICAL PRODUCTS IN MEDICAL PRACTICE

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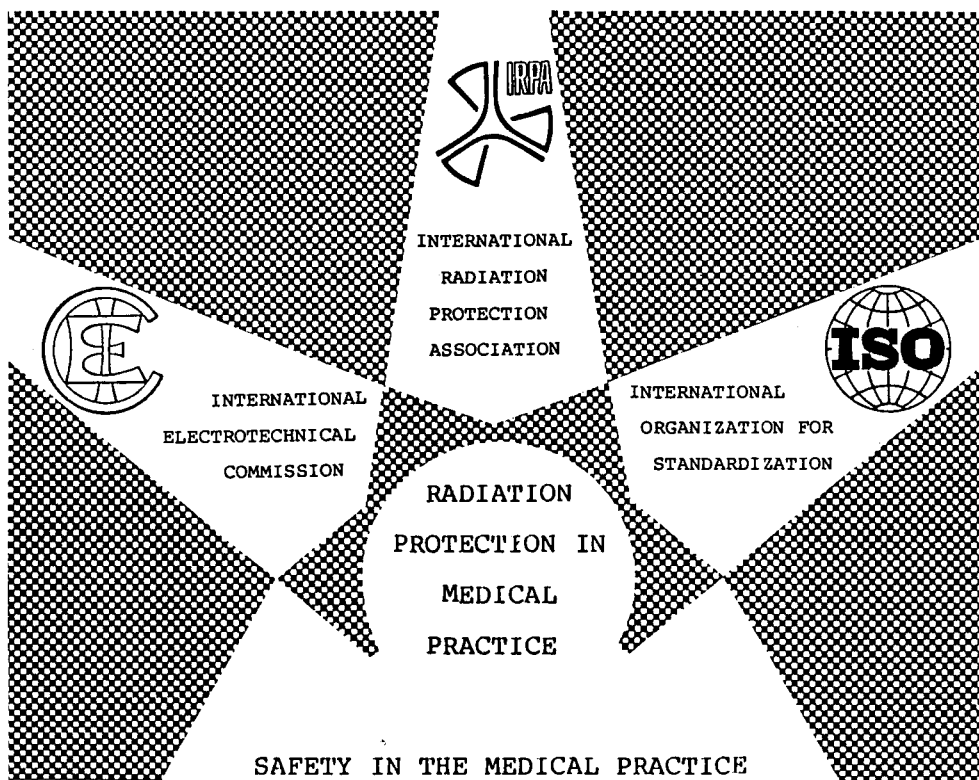
International Standardization of Technical products is mainly performed by the two non-governmental international organizations:

the International Electrotechnical Commission
and the International Organization for Standardization

Both organizations are active in a wide variety of subjects, whereby the activities of the IEC are confined to subjects related to the use of electricity and to phenomena arising from the presence of electricity, such as electrostatic charges.

Both organizations are concerned with aspects of protection against various kinds of radiation, whereby either radioactive materials are involved or the radiation is deliberately produced or the technical products concerned have to be protected against a radiation.

One of the important areas in which both organizations are involved is the safety in the medical practice or more precise the safety of patients and operators due to the use of technical products in the medical environment.



Technical Committees concerned with radiation are for example:

- IEC TC 3 Graphical symbols
- IEC TC 13 Electrical measuring equipment
 - Transducers with electrical output
- IEC TC 27 Industrial electroheating equipment
- IEC TC 29 Electroacoustics
- IEC TC 45 Nuclear instrumentation
- IEC TC 59 Performance of household electrical appliances
 - Microwave appliances
- IEC TC 61 Safety of household and similar appliances
 - Household microwave ovens; Ultraviolet and infrared lamps
- IEC TC 76 Laser equipment
- ISO/TC 85 Nuclear energy
- ISO/TC 135 Non-destructive testing

Within the IEC following Technical Committees are dealing with equipment, devices, accessories or system aspects related to the use or presence of electricity in the medical practice:

- IEC TC 1 Terminology
 - Radiology and radiological physics; Electrobiology
- IEC SC 14D Small special power transformers
 - Safety transformers
- IEC SC 29D Ultrasonics
 - Hearing aids; Ultrasonic diagnostic equipment; Ultrasonic therapeutic equipment
- IEC SC 45B Health physics instrumentation
- IEC TC 61 Safety of household electrical appliances
 - Ultraviolet and infrared radiating appliances
- IEC TC 62 Electrical equipment in medical practice
- IEC TC 64 Electrical installations of buildings
 - Installations in medically used rooms
- IEC TC 66 Electronic measuring equipment
 - Clinical laboratory equipment
- IEC TC 76 Laser equipment
- IEC TC 77 Electromagnetic compatibility between electrical equipment
 - including networks
- IEC CISPR International special committee on radio interference

Following ISO Technical Committees are concerned with equipment, devices, accessories, measuring procedures for medical use and bioengineering including surgical, radiological and dental applications, that are related to electricity or radiation:

- ISO/TC 76 Transfusion equipment for medical use
- ISO/TC 84 Syringes for medical use and needles for injections
- ISO/TC 85 Nuclear energy
 - Radiation protection, personal dosimeters
- ISO/TC 94 Personal Safety
 - Protective clothing and equipment
- ISO/TC 97 Computer and information processing
- ISO/TC 106 Dentistry
- ISO/TC 121 Anaesthetic equipment and medical breathing machines
- ISO/TC 136 Furniture
 - Hospital furniture
- ISO/TC 150 Surgical implants
- ISO/TC 172 Optics and optical instruments
- ISO/TC 173 Technical aids for disabled and handicapped persons

For their activities in the medical field the two organizations have made an agreement in the form of 'Guidelines for the collaboration between ISO and IEC in the field of safety aspects of medical electrical equipment'

Liaisons exist also with other non-governmental and governmental organizations working in fields of common interest.

Among those ICRP and ICRU should be mentioned and among the governmental organizations the International Organization for Legal Metrology, OIML. The OIML is concerned with the procedures for legally enforced calibration of instrumentation used in the health care.

At present, work in the IEC involving aspects of radiation protection in medical electrical equipment is done for:

Medical electron accelerators,	Publication 601-1-1 (1980)
High frequency surgical equipment,	Publication 601-1-2 (1982)
Short wave therapy equipment,	Publication 601-1-3 (1982)
Ultrasonic therapy equipment,	Publication 601-2-5 (1984)
Microwave therapy equipment,	Publication 601-2-..(1984), (earlier 62D(Central Office)18)
Baby incubators,	Document 62D(Central Office)24, March 1983
Gamma beam teletherapy equipment,	Document 62C(Central Office)26, January 1984
Therapeutic X-ray generators,	Document 62B(Central Office)49, February 1984
High voltage generators of diagnostic X-ray generators,	Documents 62B(Central Office)50 and .., June 1982 and ... 1984
Capacitor discharge X-ray generators,	Document 62B(Secretariat)80, ... 1984 (earlier: 62B(Secretariat)70)
Dignostic X-ray equipment, General requirements for protection against ionizing radiation,	Document 62B(Secretariat)91, ... 1984 (earlier: 62B(Secretariat)81)
Ultrasonic medical diagnostic equipment,	Document 62D(Central Office)..., ... 1984 (earlier: 62D(Secretariat)31)

Information on current activities in IEC TC 62 can be obtained by requesting the submission of the Occasional Report from the Secretariat of IEC TC 62; POB 630121; D - 2000 Hamburg 63 .

Title and Scope of Technical Committee No 62 of the IEC are:

Electrical equipment in medical practice

To prepare international standards concerning the manufacture, installation and application of electrical equipment used in medical practice. This also concerns surgery, dentistry and other specialities of the healing art.

Note.- This scope includes systems, equipment's and accessories which are within the scope of other Technical Committees; attention will be confined to aspects in which special requirements for medical use arise, particularly as regards safety.

The IEC works through the National Committees of its member countries. At meetings of the Technical Committees the National Committees are represented by delegations. At meetings no final decisions are made as to the content of a standard to be published. At meetings the decisions of the Technical Committee

are confined to questions of procedure, how and when the drafts will be circulated for comments or balloting.

International safety standards are developed according to the IEC Report, Basic aspects of the safety philosophy of electrical equipment used in medical practice, Publication 513 (1976).

In order to aim at generally useful and acceptable international standards it is important that all interested people or groupes within a country are involved in commenting on, and the decision making about, the draft international standard developed. It is evident that the influence a National Committee will have upon the development of an international standard depends on the prospect of the final international standard being accepted and used in the country.

The desired contribution at the national level can normally only be reached if the structures of the national participation ensure the input from the interested groups and parties concerned in that country. In this connection the need for liaisons at the national level to related activities in the different international organizations and different Technical Committees of IEC and ISO is evident.

In order to care for good international standards on technical products in the medical practice, the national member organizations of the International Radiation Protection Association should be adequately represented with respect to the necessary requirements for the desired radiation protection in the relevant committees of the national bodies being the members of IEC and ISO.

The addresses of the National Committees of the IEC as well as those of sources of supply of Publications of the IEC can be obtained from the Information Officer; IEC Central Office; 3, rue de Varembe; CH - 1211 Genève 20 .