INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) AND RADIATION SAFETY REQUIREMENTS FOR MEDICAL X-EQUIPMENT

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INTRODUCTION

The International Electrotechnical Commission (IEC) came into being in 1904. Its object is to facilitate the coordination and unification of national electrotechnical standards.

In 1966, the Technical Committee No. 62 of the International Electrotechnical Commission was established. Its first meeting was held in May 1968. The scope of the Technical Committee No. 62 of the IEC was defined as follows: "To prepare international recommendations 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".

The major task of IEC TC 62 is to reach an international concensus on the requirements for manufacture, installation, use and maintenance of electrical equipment used in medicine. One on the most important aspects is safety of the patients and users of the equipment. This means protection against electric hazards, radiation hazards, mechanical hazards and hazards that have to do with the particular kind of effects an electrical equipment is intended to produce.

The work of IEC TC 62 started with X-ray equipment because an urgent need for international harmonization in this field was apparent.

IEC TC 62 Sub-committee B deals with X-ray equipment operating up to 400 kV and accessories, and Sub-committee C with high energy equipment and equipment for nuclear medicine.

LIASONS WITH INTERNATIONAL ORGANIZATIONS

The Central Office of the IEC in Geneva, Switzerland, maintains liason with the following international organizations in the field of electrical equipment in medical practice:

ICRP	International Commission on Radiological Protection (particularly with Committee 3 on External Exposure)
ICRU	International Commission on Radiation Units and Measurements
IAEA	International Atomic Energy Agency
IFMBE	International Federation for Medical and Biological Engineering
IFIP	International Federation for Information Processing (particularly with Committee 4, Information Processing in Medicine)
WHO	World Health Organization
SIC	Société Internationale de Cardiologie
FDI	Fédération Dentaire Internationale
OIML	Organisation Internationale de Métrologie Légale
ISO	International Standards Organization, particularly with Committees:
	/TC 42 Photography
	/TC 85 Nuclear Energy
	/TC106 Dentistry
	/TC121 Anaesthetic equipment and medical breathing machines
	/TC150 Implants for Surgery

IEC PUBLICATIONS ON RADIATION PROTECTION

In 1973 IEC Publication 407: Radiation Protection in Medical X-ray equipment 10 kV to 400 kV was published. In 1975 this was supplemented by publication 407A: Radiation protection in dental X-ray equipment.

At the present time a new publication 601, supplement A to part 1 is in preparation to be published. It deals with the radiation safety of medical X-ray equipment and is a part of publication 601 that deals with the general philosophy of the safety of electrical medical equipment.

The purpose of this paper is to present some main features of this new standard.

SCOPE OF THE NEW STANDARD

This document concerns the radiation protection of diagnostic X-ray equipment including computed tomography (CT) and dental equipment. High voltage generators and X-ray therapy equipment are covered by separate standards.

CATEGORIES OF EQUIPMENT

All diagnostic equipments are devided into categories according to the imaging arrangements as follows:

Radioscopy and radiography with spot film device

Radiography
- image receptive areas, FID or both variable
- image receptive area and FID fixed

Radioscopy
- direct
- indirect

Special purpose X-ray equipment

Special purposes X-ray equipment are listed separately:
- mass chest survey
- transportable, radiography
- transportable, for indirect radioscope
- mammography
- therapy simulator
- reconstructive tomography
- diagnostic, above 200 kV
- dental, with intraoral receptor
- dental, panoramic tomography
- dental, panoramic radiography with intraoral X-ray tube
- cephalometric radiography

OBJECT OF THE STANDARD

The object of this standard is to protect both patient and staff from unwanted radiation. The philosophy of ICRP has been followed as closely as possible.

TECHNICAL ASPECTS

In the following some technical aspects of this new standard are discussed.

Filtration

Recommendation of ICRP are respected. However, the user may remove or add special filters.

Alignment of radiation beam

Limitation of the radiation beam to a minimum is an important factor affecting both the image quality and the radiation dose. Therefore, exact requirements concerning the alignment of the X-ray field are given.

Leakage radiation

KERMA in air from leakage radiation: max 0.87 mGy (=100 mR) in one hour is allowed at 1 m distance from the focal spot.

Focal spot to skin distance

This is limited to minimum 0.38 m.

Radioscopy

During radioscopy maximum KERMA rate allowed is 50 mGy (=5.7R) per minute. The apparatus shall be operable only on this condition.

Material between the patient and image receptor

Maximum absorption values are specified as follows:

Cassette holder Film changer Spot film device	max 1.0 mm Al equivalent
Patient support	max 1.5 mm Al equivalent
Cradles	max 2.0 mm Al equivalent

Normal operation location

In this document models are given for calculating the radiation dose received by the operator of the equipment assuming a normal operation location for each type of X-ray equipment.

CONCLUSIONS

Recommendations of the ICRP have been used as a basis for setting up the requirements of the IEC standards according to which compliance of an equipment or device can be tested and verified.

The new standard is of basic importance for the manufacture and installation of X-ray diagnostic equipment. Its aim is to ensure adequate protection of the public as well as personnel using ionizing radiation.

REFERENCES

1. Radiation protection in medical X-ray equipment 10 kV to 400 kV. Publication 407. International Electrotechnical Commission. Geneva 1973.
2. Radiation protection in dental X-ray equipment. Publication 407A. International Electrotechnical Commission. Geneva 1975.