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Medical electrical equipment - Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

医用电气设备 第一部分：安全通用要求

三．并列标准 诊断 X 射线设备辐射防护通用要求

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Foreword

This Standard is identical to the International Electrotechnical Commission IEC 601-1-3:1994 “Medical electrical equipment - Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment” (first edition).

The purpose of developing this Standard is to provide uniform general requirements for radiation protection in medical diagnostic X-ray equipment, to meet the needs of international trade, technical and economic exchanges, and adoption of development of international standards.

This Standard is implemented in conjunction with GB 9706.1-1995 “Medical electrical equipment - Part 1: General requirements for safety” (hereinafter referred to as the General Standard).

Annexes AAA, BBB, and CCC in this Standard are for information only.

To ensure the applicability of terms, the terms appearing in this Standard are explained as follows.

Installation instructions are also referred to as assembling instructions. Significant zone of occupancy is also referred to as significant zone of occupancy of space occupying area. Beam applicator, in some cases, is also referred to as a beam emitter or beam concentrator. Primary protective shielding is also referred to as the primary protective screen. Maker is also known as the manufacturer or producer. Beam limiting device is also known as the beam limiter.

This Standard was proposed by National Medical Products Administration.

This Standard shall be under the jurisdiction of National Technical Subcommittee 1 on Medical X-ray Equipment and Appliances of Standardization Administration of China.

Drafting organization of this Standard: Liaoning Medical Device Test Institute.

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Medical electrical equipment

Part 1: General requirements for safety

3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 Scope

This Collateral Standard applies to medical diagnostic X-RAY EQUIPMENT and to sub-assemblies of such EQUIPMENT.

1.202 Object

The object of this Collateral Standard is to establish general requirements for protection against IONIZING RADIATION in medical diagnostic X-RAY EQUIPMENT, in order that the DOSE EQUIVALENT to the PATIENT, the OPERATOR and other staff can be kept as low as reasonably achievable.

Some of the requirements in this Collateral Standard include variations for different types of X-RAY EQUIPMENT. This is intended to widen the scope within which the Collateral Standard can be applied usefully without addition or modification, especially in respect of types of X-RAY EQUIPMENT that are commonly used in MEDICAL DIAGNOSTIC RADIOLOGY.

The requirements in this Collateral Standard apply mainly in respect of X-RADIATION after its generation. Requirements for the control of the electrical energy used to generate X-RADIATION, which is also an important aspect of RADIATION PROTECTION, are included in GB 9706.1 “Medical electrical equipment - Part 1: General requirements for safety” and in Particular Standards for the safety of the EQUIPMENT concerned.

1.203 Relationship to other standards

1.203.1 GB 9706.1

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