

Translated English of Chinese Standard: GB9706.12-1997

www.ChineseStandard.net → Buy True-PDF → Auto-delivery.

Sales@ChineseStandard.net

GB

NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.50
C 43

GB 9706.12-1997

idt 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**

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

Issued on: June 28, 1997

Implemented on: September 01, 1998

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the PRC**

Table of Contents

Foreword.....	4
IEC foreword.....	5
SECTION 1: GENERAL.....	7
1 Scope, object and relationship to other standards	7
1.201 Scope.....	7
1.202 Object.....	7
1.203 Relationship to other standards	7
2 Terminology and definitions.....	10
2.201 Defined terms.....	10
2.202 Qualifying conditions for defined terms	10
2.203 Composition of reference materials	11
2.204 Degrees of requirement and miscellaneous terms (omitted).....	11
2.205 RADIATION QUANTITIES and units.....	11
4 General requirements for tests.....	11
4.201 Compliance	11
6 Identification, marking and documents.....	12
6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts	12
6.1.201 Marking requirements	12
6.1.202 General requirements	12
6.8 ACCOMPANYING DOCUMENTS	12
6.8.201 References in subclauses	12
6.8.202 General requirements	13
SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	14
29 X-RADIATION	14
29.201 RADIATION QUALITY	14
29.202 Limitation and indication of the extent of the X-RAY BEAM	20

29.203 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA	25
29.204 LEAKAGE RADIATION	29
29.205 FOCAL SPOT TO SKIN DISTANCE.....	33
29.206 ATTENUATION of the X-RAY BEAM.....	34
29.207 PRIMARY PROTECTIVE SHIELDING.....	35
29.208 Protection against STRAY RADIATION.....	39
Annex AAA (informative) Recommendations for the protection against STRAY RADIATION.....	49
Annex BBB (informative) Index of defined terms	53
Annex CCC (informative) Normative references to ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and ASSEMBLING INSTRUCTIONS	56
Table 208a -- Application categories	38
Table 208b -- Requirements for PRIMARY PROTECTIVE SHIELDING	39
Figure 201 -- Zone of extra-focal radiation.....	45
Figure 202 -- Discrepancies in visual indication of the X-RAY FIELD	46
Figure 203 -- Discrepancies in covering the IMAGE RECEPTION AREA	46
Figure 204 -- Testing for STRAY RADIATION (under-table tube with X-RAY BEAM horizontal)	47
Figure 205 -- Testing for STRAY RADIATION (under-table tube with X-RAY BEAM vertical).....	47
Figure 206 -- Testing for STRAY RADIATION (over-table tube with X-RAY BEAM horizontal)	48
Figure 207 -- Testing for STRAY RADIATION (over-table tube with X-RAY	

BEAM vertical).....48

Figure 208 -- Example of presentation of data on STRAY RADIATION....49

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.

Main drafters of this Standard: He Yuhua, Wang Shoumin, Xia Lianji, Li Chuan, Shen Hua.

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

This is an excerpt of the PDF (Some pages are marked off intentionally)

Full-copy PDF can be purchased from 1 of 2 websites:

1. <https://www.ChineseStandard.us>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Select your country (currency), for example: USA (USD); Germany (Euro).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Tax invoice can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with download links).

2. <https://www.ChineseStandard.net>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Add to cart. Only accept USD (other currencies - <https://www.ChineseStandard.us>).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with PDFs attached, invoice and download links).

Translated by: Field Test Asia Pte. Ltd. (Incorporated & taxed in Singapore. Tax ID: 201302277C)

About Us (Goodwill, Policies, Fair Trading...): <https://www.chinesestandard.net/AboutUs.aspx>

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: <https://www.linkedin.com/in/waynezhengwenrui/>

----- The End -----