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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 9706.5-2008

**Medical electrical equipment -- Part 2-1: Particular requirements
for the safety of electron accelerators in the range 1 MeV to 50
MeV**

(English Translation)

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Foreword

All the technical contents of this Part are mandatory.

The safety serial standards of Medical Electrical Equipment consist of the following two parts.

--- Part 1.General Requirements for the Safety;

--- Part 2.Particular Requirements for the Safety.

This Part is the Particular Requirements for the Safety; which is the Part 5 of GB 9706.

This Part equivalently adopts IEC 60601-2-1.1998 Medical Electrical Equipment - Part

2-1.Particular Requirements for the Safety of Electron Accelerators in the Range

1MeV to 50MeV and its Amendment No.1.2002.

For the benefit of use, this Part made the following editorial modifications.

--- Delete the Foreword, Introduction and Annex BB of IEC 60601-2-1.1998 Medical

Electrical Equipment - Part 2-1.Particular Requirements for the Safety of

Electron Accelerators in the Range 1MeV to 50MeV; add this Foreword;

--- The Annex L of this Part is normative, thereof, the mentioned "Annex L in the

General Standard" refers to Annex L of GB 9706.1-2007.The Annex AA of this

Part is informative.

--- For other international standard quoted in the standard, if they have been converted into Chinese standards, this Part replaces the corresponding international standard number by the national standard number; the corresponding relationship is listed in the Annex L.

This Part replaced GB 9706.5-1992 Medical Electrical Equipment - Particular Requirements for the Safety of Medical Electron Accelerators in the Range 1MeV to 50MeV.

Compared with GB 9706.5-1992, this Part has the major technical changes as follows.

--- Use through combination of GB 9706.1-2007. According to the requirements of this General Standard, this Part made the corresponding modifications;

--- Add the parallel standards, such as IEC 60601-1-14, YY 0505;

--- There are many revision and deletion against the marking requirements of the control devices and instruments; such part contents in the original standard have been included in GB/T 18987-2003;

--- Add the requirements for the instruction manual;

--- Make more revision and deletion against the requirements for the technical specification;

--- Propose more detailed requirements for the moving parts;

--- Add and modify the requirements for ionizing radiation;

--- Equivalently adopt the content of Amendment No.1.2002 of IEC 62601-2-1.set the leakage limit for the total limit beam system (see 29.3.1.1 of this Part in details);

--- Add the requirements for the abnormal operation and fault conditions;

--- Delete the requirements for the components and assemblies;

--- Add and modify the drawing;

--- Add the Annex L (Informative).

The Annex L, Annex AA of this Part are informative.

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of Technical Sub-Committee for Standardization of Radiotherapy, Nuclear Medicine and Radiopharmaceutical Equipment of National Technical Committee for Standardization of Medical Electrical Equipment (SAC/TC 10/SC 3).

Drafting organization of this Part. Beijing Institute of Medical Device Testing.

Chief drafting staffs of this Part. Liu Yi, Sun Zhuohui, Wang Peichen, and Song Lianyou.

This Part was first-time published in November of 1992; this time is the first-time revised.

1 Scope and Object

This Part establishes requirements to ensure the IONIZING RADIATION safety and enhanced electrical and mechanical safety of ELECTRON ACCELERATORS, and specifies tests to check compliance with those requirements.

2 Terminology and Definitions

Term used where the features of a system can be modified only by physically removing and re-routing wires.

For a particular design of device or EQUIPMENT, test by the MANUFACTURER to establish compliance with SPECIFIED criteria.

4 General Requirements for Tests

Three grades of TYPE TEST and two of SITE TEST procedures are SPECIFIED in clause 29 of this Particular Standard. Their requirements are as follows.

5 Classification Replacement.

EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in clause 6. This includes.

6 Identification, Marking and Documents

Where the requirements of this item are wholly or partly met by the nature of the installation, compliance at installation should be checked by inspection; the results

should be included in the SITE TEST report.

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