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

GB 9706.15-2008

**Medical electrical equipment -- Part 1: General requirements for
safety. 1 -- Collateral standard: Safety requirements for medical
electrical systems**

(English Translation)

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Foreword

The full technical content of this Part of GB 9706 is mandatory.

"Medical electrical equipment" safety series standard consists of two parts.

- Part 1.General requirements for safety;
- Part 2.Particular requirements for safety.

Part 1 includes, in addition to this Part, other standards.

- GB 9706.1 Medical electrical equipment - Part 1.General requirements for safety;
- YY 0505 Medical electrical equipment - Part 1-2.General requirements for safety - Collateral standard. Electromagnetic compatibility - Requirements and tests;
- GB 9706.12 Medical electrical equipment - Part 1.General requirements for safety - 3.Collateral standard. General requirements for radiation protection in diagnostic X-ray equipment;

This Part is Part 15.

This Part equivalently adopts IEC 60601-1-1:2000 "Medical electrical equipment - Part 1-1.General requirements for safety - Collateral standard. Safety requirements for medical electrical systems".

The main difference between this Part and IEC 60601-1-1 is that if the international standards referenced in the standard have been converted into Chinese standards, then this Part replaces the referenced international standard number with the corresponding Chinese standard number.

This Part replaces GB 9706.15-1999 "Medical electrical equipment - Part 1. General requirements for safety - 1. Collateral standard. Safety requirements for medical electrical systems".

As compared with GB 9706.15-1999, the main changes in this Part are as follows.

- The terms and definitions have been adjusted accordingly;
- ADD some requirements for accompanying documents of a system (6.8.201);
- The contents of continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS (Clause 19) have been adjusted accordingly;
- ADD some requirements for connections (56.3.201);
- Delete some requirements for protection of wiring (59.201);
- The contents of Annex BBB have been adjusted.

Annexes CCC and EEE of this Part are normative annexes. Annexes AAA, BBB, DDD, and FFF are informative annexes.

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee 10 on Medical Electrical Equipment of Standardization Administration of China (SAC/TC 10).

This Part was drafted by Shanghai Testing and Inspection Institute for Medical Devices.

Main drafters of this Part. He Jun, Huang Jiahua, Lu E.

The previous edition replaced by this Part is as follows.

- GB 9706.15-1999.

Medical electrical equipment Part 1.General
requirements for safety - 1.Collateral standard.

Safety requirements for medical electrical systems

SECTION ONE - GENERAL

1 Scope and object

This Part applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.201.It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

2 Terminology and definitions

In this Collateral Standard, terms printed in small capitals are used in accordance with their definitions in GB 9706.1.

Connection, electrical or otherwise, including those intended to transfer signals and/or power and/or substances.

3 General requirements

MEDICAL ELECTRICAL EQUIPMENT shall comply with the requirements of GB 9706.1 and its relevant particular standards.

Compliance is checked by inspection of appropriate documents or certificates.

After installation or subsequent modification, the SYSTEM shall be in compliance with the requirements of this Collateral Standard.

6 Identification, marking and documents

A SYSTEM (including a modified SYSTEM) shall be accompanied by documents containing all the data necessary for safe and intended use.

These documents shall include.

10 Environmental conditions

A power supply from another equipment for EQUIPMENT in a SYSTEM shall be specified by the manufacturer.

16 ENCLOSURES and PROTECTIVE COVERS

Parts of non-medical electrical equipment in the PATIENT ENVIRONMENT that, after removal of covers, connectors, etc., without the use of a TOOL, may be contacted by the OPERATOR during routine maintenance, calibration, etc., shall operate at a voltage not exceeding 25 V a.c.

17 Separation

The terminals of each of these parts are connected together during the test.

The test voltage is chosen from Table 5 of GB 9706.1-2007.

22 Moving parts

See informative note in Annex AAA.

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