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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.229-2021

Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

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Foreword

GB 9706 "Medical Electrical Equipment" is divided into the following parts.

---Part 1.General requirements for basic safety and basic performance;

---Part 1-3.General requirements for basic safety and basic performance Parallel standard. Radiation protection of diagnostic X-ray equipment;

---Part 2-1.Specific requirements for the basic safety and basic performance of electron accelerators with an energy of 1MeV to 50MeV;

---Part 2-2.Special requirements for the basic safety and basic performance of high-frequency surgical equipment and high-frequency accessories;

---Part 2-3.Special requirements for basic safety and basic performance of shortwave treatment equipment;

---Part 2-4.Special requirements for the basic safety and basic performance of cardiac defibrillators;

---Part 2-5.Special requirements for the basic safety and basic performance of ultrasonic physical therapy equipment;

---Part 2-6.Special requirements for the basic safety and basic performance of microwave therapy equipment;

---Part 2-8.Special requirements for the basic safety and basic performance of therapeutic X-ray equipment with an energy of 10kV to 1MV;

---Part 2-11.Special requirements for the basic safety and basic performance of gamma beam therapy equipment;

---Part 2-12.Special requirements for the basic safety and basic performance of intensive care ventilators;

---Part 2-13.Special requirements for the basic safety and basic performance of the anesthesia workstation;

---Part 2-16.Specific requirements for the basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;

---Part 2-17.Special requirements for the basic safety and basic performance of automatic control brachytherapy after-installation equipment;

---Part 2-18.Specific requirements for the basic safety and basic performance of endoscopic equipment;

---Part 2-19.Special requirements for basic safety and basic performance of infant incubators;

---Part 2-22.Special requirements for basic safety and basic performance of laser equipment for surgery, plastic surgery, treatment and diagnosis;

---Part 2-24.Specific requirements for the basic safety and basic performance of infusion pumps and infusion controllers;

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---Part 2-28.Special requirements for the basic safety and basic performance of medical diagnostic X-ray tube components;

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---Part 2-36.Special requirements for the basic safety and basic performance of in vitro lithotripsy equipment;

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Require;

---Part 2-54.Special requirements for the basic safety and basic performance of X-ray photography and fluoroscopy equipment;

---Part 2-60.Special requirements for basic safety and basic performance of dental equipment;

---Part 2-63.Special requirements for the basic safety and basic performance of extraoral imaging dental X-ray machines;

---Part 2-65.Special requirements for the basic safety and basic performance of intraoral imaging dental X-ray machines;

---Part 2-66.Special requirements for basic safety and basic performance of hearing equipment and hearing equipment system.

This part is part 2-29 of GB 9706.

This section was drafted in accordance with the rules given in GB/T 1.1-2009.

This part replaces GB 9706.16-2015 ``Medical Electrical Equipment Part 2.Special Requirements for the Safety of Radiotherapy Simulators'', and

Compared with GB 9706.16-2015, the main technical changes are as follows.

---Chapter number and order are revised in accordance with the content of IEC 60601-2-29.2008 (see.201.1~201.17);

---Modified some terms and definitions (see.201.3).

This part uses the redrafting law to amend and adopt IEC 60601-2-29.2008 "Medical Electrical Equipment Part 2-29.Radiation Therapy Mode"

Specific requirements for the basic safety and basic performance of the proposed aircraft.

The technical differences between this part and IEC 60601-2-29.2008 and the reasons are as follows.

---Regarding normative reference documents, this section has made adjustments with technical differences to adapt to my country's technical conditions and adjustments.

The situation is collectively reflected in the chapter "Normative Reference Documents", and the specific adjustments are as follows.

* Replace IEC 61217 with GB/T 18987-2015, which is equivalent to adopting international standards.

This section has made the following editorial changes.

--- Deleted some informative "Notes";

---The term index at the end of the international standard text has been deleted.

Introduction

The requirements determined in this section serve as the manufacturer's basis for the design and manufacture of radiation therapy simulators. This section does not attempt to determine

For its optimal performance requirements, its purpose is to determine those currently considered essential for the safe operation of such ME equipment

Design features. This article sets a limit for the degradation of ME equipment performance. When the limit is reached, the ME equipment is considered to be in a fault state. example

For example, when a component fails, the interlocking action needs to be triggered correspondingly to prevent the continued operation of the ME equipment.

Medical Electrical Equipment Part 2-29.

Basic safety and basic performance of radiation therapy simulator

Dedicated requirements