ICS 11.040.50
CCS C 43

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.103-2020

Replacing GB 9706.12-1997

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment

Issued on: December 24, 2020 **Implemented on: May 1, 2023**

Issued by: State Administration for Market Regulation, China National Standardization Administration

Table of Contents

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 energy from 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 short-wave 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 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 basic safety and basic performance of anesthesia workstations;

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

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

---Part 2-18: Specific requirements for 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 basic safety and basic performance of infusion pumps and infusion controllers;

---Part 2-25: Special requirements for basic safety and basic performance of electrocardiograph;

---Part 2-26: Specific requirements for the basic safety and basic performance of EEG machines;

---Part 2-27: Special requirements for basic safety and basic performance of ECG monitoring equipment;

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

---Part 2-29: Specific requirements for the basic safety and basic performance of radiotherapy simulators;

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

---Part 2-37: Special requirements for the basic safety and basic performance of ultrasonic diagnostic and monitoring equipment;

---Part 2-39: Specific requirements for the basic safety and basic performance of peritoneal dialysis equipment;

---Part 2-43: Special requirements for the basic safety and basic performance of interventional X-ray equipment;

---Part 2-44: Special requirements for the basic safety and basic performance of X-ray computed tomography equipment;

---Part 2-45: The basic safety and basic performance of mammography equipment and mammography stereotaxic devices

Claim;

--- Part 2-54: Specific 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: Specific 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 1-3 of GB 9706:

This section was drafted in accordance with the rules given in GB/T 1:1-2009:

This part replaces GB 9706:12-1997 ``Medical Electrical Equipment Part 1: Safety General Requirements III: Parallel Standard Diagnostic X

General Requirements for Radiation Protection of X-ray Equipment:

Compared with GB 9706:12-1997, the main technical changes in this part are as follows:

---Adjusted in accordance with the standard structure of GB 9706:1-2020, while paying attention to the radiation protection of all diagnostic X-ray equipment

Use requirements and introduce the concept of risk management;

---The calibration of dosimetry has been added (see 5:2:2);

---The general requirements for radiation dose information, dose instructions, clinical protocols, deterministic effects and the

Risk (see 5:2:4);

---In the radiation management, dosimetry instructions, automatic control systems and scattered radiation reduction have been added (see 6:4:5, 6:5, 6:6);

---The imaging performance adds the requirements of system performance, nominal focus value, radiation detector or X-ray image receiver (see 6:7:2,

6:7:3, 6:7:4);

---The X-ray tube voltage waveform is added to the radiation quality (see 7:2);

---Modified the value of the half-price layer of X-ray equipment (see 7:1, 29:201:2 in the:1997 edition);

--- Deleted the test method of the correspondence between the X-ray field and the image receiving surface (see 29:203:4 in the:1997 edition);

--- Deleted the attenuation test of the residual radiation (see 29:207:2 of the:1997 edition):

This part uses the redrafting law to amend and adopt IEC 60601-1-3:2013 Medical Electrical Equipment Part 1-3: Basic Safety and Basic Safety

The general requirements for this performance are collateral standards: radiation protection of diagnostic X-ray equipment:

The technical differences between this part and IEC 60601-1-3:2013 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 Chapter 2 "Normative Reference Documents", and the specific adjustments are as follows:

* Replace IEC 60601-1:2012 with GB 9706:1-2020 which is modified to adopt international standards;

* Replace ISO 497 with GB/T 19764 which is equivalent to adopting international standards;

* Replace IEC 60366 with YY/T 0063-2007 which is equivalent to adopting international standards: