CCS C43

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.268-2022

Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

医用电气设备 第2-68部分：电子加速器、轻离子束治疗设备和放射性核素射束治疗设备用的X射线图像引导放射治疗设备的基本安全和基本性能专用要求

Issued on: May 18, 2022 **Implemented on: June 1, 2025**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 18 May 2022 by the National Medical Products Administration and takes effect on 1 June 2025.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It is classified under Chinese classification C43.

The entire technical content of this document is mandatory. This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules of Standardization Documents" drafted. This document is part 2-68 of Medical Electrical Equipment. The following parts of the "Medical Electrical Equipment" series of standards have been published.

--- Part 1: General and side-by-side requirements;

--- Part 2: Specific requirements. This document uses the redrafted law to modify and adopt IEC 60601-2-68.2014 "Medical Electrical Equipment Part 2: Electron accelerators, light Basic safety and fundamentals of X-ray image-guided radiotherapy equipment for ion beam therapy equipment and radionuclide beam therapy equipment Capability-Specific Requirements". The technical differences between this document and IEC 60601-2-68.2014 and their reasons are as follows.

--- Regarding normative reference documents, this document has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustment. The situation is reflected in the chapter "Normative References", and the specific adjustments are as follows. * Replacing IEC 60601-1.2005/AMD1.2012 with GB 9706.1-2020 which is modified to adopt international standards; * Replacing IEC 60601-1-3.2008 with GB 9706.103-2020 which has been modified to adopt international standards; * Replacing IEC 60601-2-1.2009 with GB 9706.201-2020 which has been modified to adopt international standards; * Replacing IEC 60601-1-6.2010/AMD1.2013 with YY/T 9706.106-2021 which has been modified to adopt international standards; * Replacing IEC 60601-2-44.2012 with GB 9706.244-2020 which has been modified to adopt international standards; * Replace IEC 61217.2011 with GB/T

18987-2015 which is equivalent to adopting international standards; * Added YY 9706.102-2021 and ISO 12052.2017; * Moved IEC 60976.2007, IEC 61262-7.1995 into references; * Removed IEC 61223-3-5.2004, IEC 62274.2005, IEC 62083.2009, IEC 60731.2011, IEC 60601-2-4. 2010 and IEC 62396-1.2012. The following editorial changes have been made to this document.

--- Deleted some informative notes;

--- Deleted the term index at the end of the International Standard text. Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This standard is approved by the National Technical Committee for Standardization of Medical Electrical Appliances, Radiotherapy Nuclear Medicine and Radiation Dosimetry Equipment Sub-Technical Committee (SAC/ TC10/SC3) centralized management.

Introduction

Medical electrical equipment safety standards, also known as the 9706 series of standards, consist of general standards, side-by-side standards, specific standards, guidelines and interpretations.

---General standard. Medical electrical equipment should be generally applicable to safety standards, that is, equipment that meets the definition of medical electrical equipment should meet this Basic standard requirements.

--- Side-by-side standard. Medical electrical equipment should be generally applicable to the safety standards, but in most cases only limited to some specific functions or special Only devices that are sexual are required to meet the requirements of such standards.

---Special standard. a safety standard applicable to a certain type of medical electrical equipment, and not all medical electrical equipment has special standard.

--- Guidance and interpretation. application guidance and interpretation of the relevant requirements in the standards involved. In the "Medical Electrical Equipment" series of standards, in addition to the published standards and this document, the planned standards are as follows.

--- Part 2-64: Particular requirements for basic safety and basic performance of light ion beam medical electrical equipment. This document relates to X-ray image-guided radiation for electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment Particular requirements for basic safety and essential performance of therapeutic equipment. This document modifies and supplements GB 9706.1-2020. Modern radiation therapy utilizes information collected from various imaging modalities prior to initiation of treatment to develop treatment plans. imaging provides the target information

about the location and other anatomical characteristics of the region, so that a treatment plan can be formed that provides the optimal dose distribution, and the treatment effect is The best chance to anticipate and minimize side effects. However, due to the constant movement of the target/critical structures in the body, when trying to manage radiation Difficulties arose. For example, in body parts that move with respiration, during exposure to the radiation beam throughout any given fraction, the target/critical Structures may change position or shape. Additionally, a course of treatment may last for multiple days, during which time the target volume/patient may shrink or grow and/or or move. Therefore, the precise location of the target volume/critical structure may change between the imaging of the treatment plan and the actual execution of the treatment. image guide Radiation therapy (IGRT) combines planar or volume imaging during radiation therapy sessions to adjust treatment based on patient anatomy and patient location. treatment implementation. This allows the operator and/or the external beam beam (EBE) to use imaging information such as target location, critical organs and/or other references feature) to adjust radiation beam exposure to compensate for anatomical changes including internal organ motion and/or uncertainty in treatment placement. accurate The improved accuracy and accuracy allow higher radiation doses to irradiate the target area, reducing the effect of radiation on healthy cells at the edge. IGRT is often associated with Use in conjunction with other monitoring equipment. This document establishes the requirements for manufacturers to design and build X-ray IGRT equipment (X-IGRT) beg. This document covers the use of IGRT for the purposes of EBE (e.g. electron accelerators, medical light ion beam equipment or radionuclide beam therapy equipment) safety parts of kilovolt (kV) and megavolt (MV) X-ray imaging devices with known geometry. It covers EBE and X-ray Communication and relationship aspects between imaging devices. The X-ray imaging device can be connected to the EBE, or not directly connected but in the same radiation shield region, and is only used with EBE. This document applies to X-ray-based IGRT equipment used indoors for IGRT purposes. This document does not apply to non-applications Standard CT scan setup for IGRT. However, if the CT scanning device is aimed at IGRT, it can be used indoors with linear (electron) accelerators. (linac), this document applies. When conducting a hazard analysis, the manufacturer should consider relevant diagnostic criteria. For example, with regard to the diagnosis of The quality of the image display device used has been specified in IEC documents (eg YY/T 0910.1-2013). However, due to the use of IGRT Such high requirements may or may not be required, and manufacturers themselves specify those requirements for use with their X-IGRT devices. This document addresses the safety of image acquisition, image analysis, data transfer and treatment replanning or EBE/patient repositioning. this document Involves devices for real-time X-IGRT, online X-IGRT and offline X-IGRT. X-IGRT equipment is also associated with the following current standards.

---YY 0637-2013 "Safety Requirements for Medical Electrical Equipment Radiation Therapy Planning System";

---GB/T 18987-2015 "Radiation Therapy Equipment Coordinate System, Movement and

Scale";

---YY 0721-2009 "Safety of Radiotherapy Recording and Verification System for Medical Electrical Equipment";

---IEC 60976.2007 "Functional Characteristics of Medical Electron Accelerator for Medical Electrical Equipment";

---IEC /T R60977.2008 "Guidelines for Functional Characteristics of Medical Electron Accelerators for Medical Electrical Equipment";

--- This document may cause revisions to some of the above-mentioned standards. This document is devoted to the security part of the main functions of X-IGRT. In order not to hinder progress, it does not involve emerging technologies in the field, but also The hope is to define a way to achieve X-IGRT security. Medical Electrical Equipment Part 2-68: Electron Acceleration devices, light ion beam therapy equipment and radionuclide beams X-ray image-guided radiation therapy for treatment equipment Particular requirements for essential safety and essential performance of equipment 201.1 Scope, Purpose and Related Standards Except as follows, Chapter 1 of the General Standard applies. 201.1.1 Scope replace. This document specifies the basic safety and basic requirements of X-ray image-guided radiation therapy (X-IGRT) equipment for external beam beam equipment (EBE). performance. This document covers kilovolts (kV) and megavolts for image-guided radiation therapy (IGRT) purposes with a known geometric relationship to the EBE (MV) Safety of X-ray Imaging Devices. It covers aspects of communication and relationship between EBE and X-ray imaging devices. X-ray imaging The device may be connected to the EBE, or not directly connected but in the same radiation shielding area and intended for use with the EBE only. This document deals with real-time X-IGRT, online X-IGRT and offline X-IGRT devices. It covers methods to reduce over-reliance on X- IGRT External Beam System (X-IGRTEBS) Risk Approach. For example, the manufacturer provides an interactive interface for the user to positive interaction. If a chapter or article is specifically intended to apply to the X-IGRTEBE system, the content of that chapter or article will be explained. If this is not the case, then this chapter or clause applies only to X-IGRT equipment. This document contains type tests and field tests, respectively applicable to manufacturers and certain installation aspects of the X-IGRTEBE system, expected achieve. * In normal use, by properly licensed or qualified personnel, by persons with specific medical applications, such as static radiation Therapeutic and moving beam radiation therapy, the skill of the operator required to achieve specific clinical purposes; * Carry out maintenance according to the recommendations in the instruction manual; * Comply with periodic quality assurance performance and calibration checks by qualified personnel. Note. In this document, all installation information refers to the installation in the responsible party's premises. 201.1.2 Purpose replace. The purpose of this document is to establish specific essential safety and essential performance requirements for X-IGRT equipment and X-IGRTEBE systems. 201.1.3 Tied standards Replenish. This document