CCS C43

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.264-2022

Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

医用电气设备 第2-64部分：轻离子束医用电气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**

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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 2-64 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 translation method to modify and adopt IEC 60601-2-64.2014 "Medical Electrical Equipment Part 2-64: Light Ion Beam Medical Electrical Equipment" Particular requirements for basic safety and basic performance of gas equipment. The technical differences between this document and IEC 60601-2-64.2014 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 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 60601-1-2.2014 with YY 9706.102-2021, which is an international standard; * Replace IEC 61217.2011 with GB/T 18987-2015 which is equivalent to adopting international standards; * Removed IEC 60601-2-11.2013 and ISO /IEC 14165-321.2009. The following editorial changes have been made to this document.

--- Under.201.10.2.101.3.1.7, in order to correspond to the content under the serial number

of the previous items in this section, the "d) B-level field test

--- is implemented. The corresponding serial number of "one-time irradiation" is revised to

e), the corresponding serial number of "e) B-level field test

--- step" is revised to

f), and "f) B-level field test Test

--- Step "Corresponding serial number is modified to

d), and the order is adjusted;

--- 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 document is set up by the National Medical Appliances Standardization Technical Committee of the State Drug Administration for Radiotherapy, Nuclear Medicine and Radiation Dosimetry Backup Technical Committee (SAC/TC10/SC3) centralized.

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 2-68: Medical electrical equipment Part 2: Electron accelerators, light ion beam therapy equipment and radionuclide beam therapy Particular requirements for the basic safety and basic performance of X-ray image-guided radiotherapy equipment used in radiotherapy equipment. This document relates to the basic safety and essential

performance of light ion beam medical electrical equipment (hereinafter referred to as ME equipment) for the treatment of patients special request. This document modifies and supplements GB 9706.1-2020. When using light ion beam ME equipment for radiation therapy, if the ME equipment is not delivering the required dose to the patient, or the ME equipment The design of the device does not meet electrical and mechanical safety standards and may expose the patient to danger. If ME EQUIPMENT is not properly blocked The ME EQUIPMENT may also present a hazard to nearby persons due to improper radiation protection or improper design of the treatment room. This document establishes requirements that manufacturers of light ion beam equipment for radiotherapy should meet during the design and construction phases; this document does not Try to define the best performance requirements for these devices. The purpose of this document is to identify those that are currently considered safe operation of this type of ME EQUIPMENT Design features necessary for the performance of this document; this document sets limits for the reduction in performance of ME EQUIPMENT, exceeding the limits is considered a fault condition, and And the subsequent operation of the ME EQUIPMENT is prevented by the action of the interlock. To ensure that equipment maintains basic performance and avoids unsafe conditions,.201.10 includes limits for interlocking actions that prevent, Interrupt or terminate irradiation. For each requirement, type tests are specified to be carried out by the manufacturer, or field tests that must not be carried out by the manufacturer test. It can be understood that, before installation, the manufacturer can provide proof of conformity only for type testing. Data obtained from field trials It should be added to the random file in the form of a field test report by the field tester of the ME EQUIPMENT during installation. The standard closely related to this document is IEC 62667, which is currently under development. This standard is a light The performance testing of ion beam ME equipment specifies the test method and report format, the purpose is to provide a uniform implementation method. IEC 62667 The appendix provides a format for expressing the values of the properties measured according to the specified method. Medical Electrical Equipment Part 2-64. Basic safety and light ion beam medical electrical equipment Specific requirements for basic performance 201.1 Scope, Purpose and Related Standards Except for the following, Chapter 1 of the general standard 1) applies. 201.1.1 Scope replace. This document specifies the basic safety and essential performance of light ion beam medical electrical equipment (hereinafter referred to as ME equipment) used for the treatment of patients special request. If a chapter or subclause is specifically intended to apply only to ME EQUIPMENT or ME SYSTEM, the relevant content of that chapter or subclause will be stated. if not If this is the case, then this clause or clause applies to ME EQUIPMENT and ME SYSTEMS. This document contains type tests and field tests for manufacturers of light ion beam ME EQUIPMENT and certain installation aspects, respectively, that equipment.

--- Medical practice intended for human radiation therapy, including those operating parameters that can be automated by programmable electronic subsystems (PESS) control

selection and display,

--- In normal use, the light ion radiation beam with single nuclear energy of 10MeV/n~500MeV/n is delivered, and expected

--- During normal use, under the authorization of the appropriate licensed or qualified personnel, by operators with the required skills for the specific medical application. The author's operation, to achieve the prescribed clinical purpose, and to be consistent with the recommendations in the instructions for use,

--- Requires regular performance quality assurance and calibration checks by qualified personnel.

Note 1: In this document, all references to installation refer to installation in the responsible party's premises.

Note 2: In this document, all references to absorbed dose refer to the absorbed dose in water.

Note 3: See YY 9706.268 for information related to X-ray image guidance.

Note 4: GB/T 18987 provides guidance on ME EQUIPMENT motion, scale marking, zero position and positive direction of motion (see.201.7.4.101). 201.1.2 Purpose replace. The purpose of this document is to establish basic safety and basic performance specifications for light ion beam ME equipment with energies ranging from 10MeV/n to 500MeV/n. requirements and specify the tests for compliance checking for these requirements. NOTE. Adoption of this document helps ensure that ME EQUIPMENT. maintain patient safety during ME EQUIPMENT movement and in the event of a mains failure; Delivery of preselected radiation types, mononuclear energy, light ion species and absorbed doses; Utilize light ion beam conditioning devices, etc., to deliver a preselected light ion beam to the patient without causing unnecessary damage to the patient, operator, other personnel or the environment risks of. 1) The general standard refers to GB 9706.1-2020 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Basic Performance".

1 Scope

YY 9706.264 is the mandatory Chinese standard for light ion beam therapy equipment, the proton and carbon ion systems now operating at several Chinese centres. Ion beams deposit their dose at a defined depth and stop, which is the therapeutic advantage and the safety problem in one: an error in energy or in the delivery chain moves the dose peak somewhere it was not intended, and there is no exit dose to reveal the mistake. The standard sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the beam delivery and its monitoring, the interlocks, the accuracy of the delivered dose distribution and the fault