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PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国医药行业标准

YY 0637-2013/IEC 62083: 2009

Replace YY 0637-2008

Medical electrical equipment—Requirements for the safety of radiotherapy treatment planning systems

医用电气设备

放射治疗计划系统的安全要求

(IEC 62083: 2009, IDT)

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Foreword

This Standard is drafted according to the rules specified in GB/T 1.1-2009

The Standard will replace YY0637-2008 *Medical Electrical Equipment – Requirements for the Safety of Radiotherapy Treatment Planning Systems*; compared with YY0637-2008, the main technical changes of the Standard include:

— Added 3.2 Abbreviations;

— Deleted Chapter 3 of the primary standard;

— Divided 8.1 of the primary standard into 7.1 and 7.2 of the Standard;

— Deleted Chapter 14 of the primary standard;

The Standard is identical to IEC62083: 2009 *Medical Electrical Equipment – Requirements for the Safety of Radiotherapy Treatment Planning Systems*.

Our national documents in consistent with the international documents referenced normatively in the Standard are as follows:

For convenience, the Standard is modified as follows:

--- Modified the “international standard” to “the Standard”;

---Replaced the comma “,” with a decimal point “.”;

--- Deleted the foreword of international standards;

Please note that some content of the Document may involve any patent. The issuing authority of the Document will not undertake the responsibility of identifying these patents.

The Standard was proposed by China Food and Drug Administration.

The Standard is under the jurisdiction of National Standardization Technical Committee of Medical Appliances Radiotherapy and Technical Committee of Nuclear Medicine and Radiation Dosimetry Equipment (SAC/TC10/SC3).

The Standard is mainly drafted by: Beijing Institute of Medical Device Testing, Shandong Shinva Medical Instrument Co., Ltd. and Shanghai Song’s Lab Science and Technology Development Co., Ltd.

The main drafters of the Standard: Song Lianyou, Wang Peichen, Yin Xiaohui and Cao Guogang.

The Standard was first issued in 2008.

Introduction

A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device, usually a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM that is used to simulate the application of RADIATION to a PATIENT for a proposed RADIOTHERAPY TREATMENT. It usually, but not necessarily, provides estimates of ABSORBED DOSE distribution in human tissue using a particular algorithm or algorithms. These estimations, referred to in this International Standard as ABSORBED DOSE distributions, are used by a QUALIFIED PERSON in planning a course of RADIOTHERAPY.

The output of an RTPS is used by appropriately QUALIFIED PERSONS as important information in RADIOTHERAPY TREATMENT PLANNING. Inaccuracies in the input data, the limitations of the algorithms, errors in the TREATMENT PLANNING process, or improper use of output data, may represent a safety HAZARD to PATIENTS should the resulting data be used for TREATMENT purposes. This standard defines requirements to be complied with by MANUFACTURERS in the design and construction of an RTPS in order to provide protection against the occurrence of such HAZARDS.

SPECIFIC types of input data and calculation algorithms are not addressed in this standard. These are dependent on many factors, such as available technology, RESPONSIBLE ORGANIZATION preference, and the type of TREATMENT being planned. However, this standard establishes the safety requirements that are common to algorithms. it also establishes the minimum requirements for the contents of the ACCOMPANYING DOCUMENTS that will permit the OPERATOR to make informed choices during the TREATMENT PLANNING process.

Generally, an RTPS is not used in the presence of PATIENTS, so it is not MEDICAL ELECTRICAL ,EQUIPMENT as defined by IEC 60601-1. Consequently, this standard is written in an , independent format rather than as a particular standard to IEC 60601-1.

Relationship to other standards

The BASIC SAFETY of hardware, such as for protection against electric shock and fire, and for -'assuring ELECTROMAGNETIC COMPATIBILITY requires that these subjects be addressed by the MANUFACTURER through compliance with an appropriate standard, depending upon the nature and environment of the hardware used for the RTPS. See

Annex A for hardware safety standards.

A RTPS is principally a software application for medical purposes. IEC 62304 applies (see Clause 14).

IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero position and the direction of movement with increasing value. The means of applying IEC 61217 are SPECIFIED in appropriate clauses and subclauses of this standard.

IEC 62366 applies (see Clause 16).

Medical electrical equipment—Requirements for the safety of radiotherapy treatment planning systems

1 Scope

This Standard applies to the design, manufacture and some installation aspects of a radiotherapy treatment planning systems(RTPS)

- for use in RADIOTHERAPY TREATMENT PLANNING in human medical practice;
- that imports data either through input by the OPERATOR or directly from other devices;
- that outputs data either in printed form for review or directly to other devices;
- and which is intended to be
- for NORMAL USE, under the authority of appropriately licensed or QUALIFIED PERSONS, by OPERATORS having the required skills and training;
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
- used within the environmental and electrical supply conditions SPECIFIED in the technical description.

2 Normative references

The articles contained in the following documents have become this document when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this document.

GB 9706.17-2009 Medical electrical equipment - Part 2: Particular requirements for the safety of gamma beam therapy equipment (IEC 60601-2-11: 1997, IDT)

IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-2-1:2009, Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

IEC/TR 60788:2004, Medical electrical equipment - Glossary of defined terms

IEC 60950-1, Information technology equipment - Safety - Part 1: General requirements

IEC 61000-4-1, Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series

IEC 61000-4-2, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test

IEC 61000-4-3, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

IEC 61000-4-4, Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

IEC 61217, Radiotherapy equipment - Coordinates, movements and scales

IEC 62304, Medical device software - Software life cycle processes

IEC 62366:2007, Medical devices - Application of usability engineering to medical devices

ICRU Report 42:1987, Use of Computers in External Beam Radiotherapy Procedures with High Energy Photons and Electrons

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE See the Index of defined terms for a full list of terms used in this standard and their source.

3.1.1

ANATOMY MODELLING

process of establishing the PATIENT ANATOMY MODEL

3.1.2

BRACHYTHERAPY SOURCE MODEL

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