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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0721-2009

Medical electrical equipment - Safety of radiotherapy record and verify systems

医用电气设备 放射治疗记录与验证系统的安全

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Foreword

This standard is identical with IEC 62274.2005 "Medical electrical equipment - Safety of radiotherapy record and verify systems." For ease of use, this standard made the following editorial changes.

--- Deleting IEC 62274.2005 Foreword;

--- For other international standards quoted in the standard, if it has converted to our standards, this section replaces the corresponding international standards by the national number Standard. Appendix A of this standard is a normative appendix. This standard was proposed by the State Food and Drug Administration. This standard by the National Radiological medical treatment appliances Standardization Technical Committee, the Technical Committee of nuclear science equipment Medical and radiation dose (SAC/TC10/SC3) centralized. This standard was drafted. Beijing Medical Device Testing. The main drafters of this standard. Hu Jia, Feng Jian, Goofy, Chen Jing, Xu Yan. YY 0721-2009/IEC 62274.2005

Radiation treatment records and verification system (RVS) is a programmable medical electrical systems (PEMS) or subsystem, to help preventing Subsystem only medical electron accelerators, gamma-rays or other radiation therapy treatment device device error parameters, and record all treatment order segment. If the (machine) the current parameters with preset parameters do not match, RVS verified these parameters to prevent the machine running. In the recording and verification Process inaccuracies and erroneous data will pose a security risk to the patient. In order to provide protection against such security risk, This standard defines the manufacturers to follow when designing and building RVS requirements. YY 0721-2009/IEC 62274.2005 Medical electrical equipment - Security radiotherapy record and verify systems

1 Scope and purpose

YY 0721 is the mandatory Chinese standard for the safety of radiotherapy record and verify systems, the software that holds a patient's prescription, transfers the parameters to the

treatment machine and checks that what is about to be delivered matches what was planned. It is the last barrier before the beam is switched on, and the catastrophic radiotherapy accidents on record have generally involved a mismatch that a record and verify system either failed to catch or was bypassed to overcome. The standard sets the requirements such a system has to meet, covering the integrity of the data it holds and transfers, the checks it performs, the handling of overrides and the audit trail. Being a YY standard without the /T suffix, compliance is compulsory in China.

1.1 Scope This standard applies to the medical field radiotherapy record and verify systems (RVS) the design, manufacture and installation of certain aspects. This Kinds of recording and verification system (RVS).

a) providing a definition of the treatment machine or setting data display; manually enter data or import data directly from other devices;

b) controls the equipment operation;

c) recording data throughout the treatment period;

d) intended for. 1) under the authority of the appropriate license or have qualified personnel staff, having relevant technical and trained operators are Often used; 2) in accordance with the instructions of recommendations for maintenance; 3) used in the technical specifications under the environmental conditions and supply conditions described. This standard does not address the treatment of the implementation of dynamic ray beam.

Note. The implementation of dynamic beam treatment may be described in future versions of the standard. However, it is directed to certain specific aspects connected with or other radiation therapy equipment RVS and connected to a network system, and make With the communication protocol.

1.2 Purpose This standard applies to any RVS, RVS and provides characteristics, relevant documentation and software testing requirements. Hardware security Requirements not included in this standard, because the hardware security requirements vary with different hardware itself (see

1.3.1 and Appendix A Section on hardware requirements). This standard does not apply to user-developed and only RTPS own use, but developers are encouraged to use this standard in the development and use. If such RTPS was developed by those who can not directly control its use by other users to use, and a description of this system is suitable for use, then Developers will be considered for the manufacturer and must comply with this standard.

1.3 Relationship with other standards

1.3.1 Hardware Security Standard This standard does not include hardware security requirements, such as to prevent electrical shock, fire, and electromagnetic compatibility of

hardware security. Safety requirements in accordance with the manufacturer Hardware environment and characteristics RVS use a separate statement of compliance with applicable relevant standards (standards for hardware security, see Appendix A).

1.3.2 software safety standards IEC 60601-1-4 (see 4.1) all chapter shall apply. The risk of using IEC 60601-1-4, the manufacturer should take into account the errors that may occur when using the RVS in.

Note. IEC 60601-1-6 describes the use of the wrong risk management process.

1.3.3 GB/T 18987 GB/T 18987 "Radiotherapy equipment Coordinates, movements and scales," apply. GB/T 18987 for use in the present standard applicable When the article explained.

1.3.4 Other criteria Because RVS likely to contain relevant information and other medical patient data, and confidentiality and security of electronic patient information recording phase YY 0721-2009/IEC 62274.2005