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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 1650-2019

**X-ray based image-guided radiotherapy equipment -
Performance characteristics and test methods**

X射线图像引导放射治疗设备性能和试验方法

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009. Please note that some of the contents of this document may involve patents. The issuing organization of this document is not responsible for identifying these patents. This standard was proposed by the State Drug Administration. This standard is divided into the Technical Committee of Radiotherapy, Nuclear Medicine and Radiation Dosimetry Equipment of the National Medical Electrical Equipment Standardization Technical Committee. (SAC/TC10/SC3) is under the jurisdiction. This standard was drafted. Beijing Medical Device Inspection Institute, Jiangsu Ruier Medical Technology Co., Ltd., Medical Branch (Beijing) medical equipment Limited company. The main drafters of this standard. Wang Peichen, Ren Dazhi, Hou Yaofang, Xie Soldier, Fu Dongshan, Zhang Jizhuang, Song Lianyou, Zhang Xin, Feng Jian, Jiao Chunying. X-ray image guided radiotherapy equipment Performance and test methods

1 Scope

YY 1650 sets the performance characteristics and test methods for X-ray based image-guided radiotherapy equipment, the imaging built into a linear accelerator to verify patient position before treatment. It specifies what has to be measured and how: the geometric accuracy of the image relative to the treatment isocentre, the image quality achieved, and the additional imaging dose the patient receives. The whole justification for tight treatment margins is that the position is verified each session, so an image guidance system whose registration is off by millimetres silently defeats the plan it is supposed to protect. Where YY 9706.268 covers the safety of such equipment, this document covers what it must achieve. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the requirements and test methods for X-ray image guided radiotherapy (hereinafter referred to as X-IGRT) equipment. This standard applies to electronic accelerators, light ion beam therapy equipment and X-IGRT equipment for radionuclide beam therapy equipment.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article. Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB 15213-2016 Medical electron accelerator performance and test methods

IEC 60601-2-68.2014 Medical electrical equipment - Part 2-68. Electron accelerators, light ion beam therapy equipment and radiation Special requirements for basic safety and basic performance of X-ray image-guided radiotherapy equipment for use with sex nuclear beam therapy equipment

3 Terms and definitions

The following terms and definitions defined in GB 15213-2016 and IEC 60601-2-68.2014 apply to this document.

3.1 Image guided radiotherapy image-guidedradiotherapy IGRT A radiation therapy process. An image of the target area and its surrounding anatomy at the time of treatment to determine the therapeutic beam in the patient relative to The position of the target zone is predetermined to make the necessary corrections to the predetermined position of the beam relative to the target zone. [GB 15213-2016, definition 3.8]

3.2 Image reconstruction imagereconstruction A method of processing the acquired data into an image data set that can be used for analysis. [IEC 60601-2-68.2014, definition.2011.3.210]

3.3 Image registration imageregistration A method of mapping or mapping a point in a set of image data sets with a corresponding point in another set of image data sets. [IEC 60601-2-68.2014, definition.2011.3.211]

3.4 KV X-IGRT device kilovoltageX-IGRTequipment X-IGRT equipment using kV X radiation. [IEC 60601-2-68.2014, definition.201.3.213]

3.5 Megavolt X-IGRT device megavoltageX-IGRTequipment X-IGRT equipment using megavolt X radiation. YY 1650-2019 Image-guided radiotherapy equipment of X-ray-based - Performance characteristics and test methods ICS

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