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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 16362-2010

Replacing GB 16362-1996

Requirements for quality assurance and radiological protection for patients in teletherapy

远距治疗患者放射防护与质量保证要求

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Standardization Administration of China

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Foreword

4,5,6 this standard are mandatory, the rest are recommended. Rules of the draft standard is based on the preparation of GB/T 1.1-2009 "Standardization Guide Part 1. Standard structure and write." This standard replaces GB 16362-1996 "external beam radiation therapy in patients with radiation health protection standards." This standard compared with GB 16362-1996, the main changes are as follows:

--- Teletherapy unit will be renamed using the unit to carry out long-range radiation therapy unit (hereinafter referred to as radiotherapy units), amended on Its requirements, the introduction of the "Radiation treatment regulations," and supporting standards in terms of radiation conditions on the unit personnel, equipment and Claim;

--- Modify the general requirements for teletherapy patient protection, the introduction of the relevant provisions of GB Z179-2006;

--- Will merge the relevant provisions require radiation therapy equipment, radiation therapy and operating requirements for radiation dose measurement requirements for Quality assurance requirements;

--- Increased requirements on the quality of radiotherapy simulators and other auxiliary equipment control;

--- Increased the radiation treatment planning system quality control requirements;

--- Added Appendix A, Appendix B. This standard is proposed and administered by the People's Republic of China Ministry of Health. This standard by the People's Republic of China Ministry of Health is responsible for interpretation. This standard was drafted. Shandong Academy of Medical Sciences Institute of Radiation Medicine. The main drafters of this standard. Song Gang, Lu Feng, Deng Daping, Zhu Jianguo, Chen Yingmin, Li

Hailiang, Cheng Yufeng, LIU Li-ping. This standard replaces the standards previously issued as follows:

--- GB 16362-1996. Teletherapy radiological protection and quality assurance requirements of patients

1 Scope

GB 16362 covers external beam radiotherapy - the linear accelerators, the medical gamma units, the X-knife and the gamma-knife that deliver a prescribed dose to a tumour from outside the body, where the margin between an effective treatment and an injury is narrow and the errors are systematic rather than random. Clause 4 fixes the conditions the radiotherapy unit must satisfy before it treats anyone: a protection and quality control organisation headed by the director of radiation oncology, verified dosimetry instruments, a justification assessment made by an oncologist holding at least an intermediate qualification, written information to the patient on the risk, and working interlocks with anti-crushing protection on the door. Clause 5 follows the patient through treatment - the plan countersigned by an oncologist and a medical physicist, the estimate of the dose to organs outside the target, the caution required for children and pregnant women, the immobilisation during X-knife and gamma-knife irradiation, and what is to be recorded when a source fails to return to its shielded position. Clause 6 is the quality assurance programme: validated planning software, acceptance testing after installation and after a key repair, an annual status test, stability testing against the acceptance baselines, the daily-weekly-monthly-annual schedule of checks, and participation in the TLD postal dose comparison. Issued on 14 January 2011, in force since 1 May 2011, replacing GB 16362-1996. This page is published from the official record of the standard and from its published table of contents. The full clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This standard specifies the teletherapy in patients with quality assurance and protection of basic principles and requirements. This standard applies to the medical electron accelerators and medical gamma-ray devices for external beam therapy and X, gamma-ray stereotactic put Radiation therapy (hereinafter referred to as X knife, gamma knife) and other teletherapy Practice, practice does not apply to the treatment of deep X-ray therapy machine.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 17856 radiotherapy simulator performance and test methods

GB 18871 ionizing radiation protection and safety of radiation sources basic standards

GB/T 19046 Medical Electron Accelerator acceptance tests and periodic inspection procedures GB Z126 Medical Electron Accelerator health protection standards GB Z161 Medical gamma beam teletherapy protection and safety standards GB Z168 X, gamma-ray head of stereotactic surgical treatment of radiation protection standards GB Z179 basic requirements for medical exposure Radiological Protection GB Z/T 201.1 radiotherapy treatment rooms - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Teletherapy teletherapy Between the radiation source to skin distance is greater than 50cm in vitro radiation beam radiation therapy.

3.2 Teletherapy quality assurance qualityassuranceinteletherapy Implementation teletherapy, in order to ensure the accuracy of the location and geometry of the target dose of irradiation to reduce the radiation dose to normal tissues and organs, Exposed personnel to prevent a series of measures taken by mistake irradiation formed.

4 Basic Principles

4.1 units to carry out long-range radiation therapy (hereinafter referred to as radiotherapy units) shall comply with national regulations and relevant radiation treatment radiation Other personnel and equipment conditions and requirements supporting standard treatment prescribed.

4.2 Radiotherapy Unit shall establish radiological protection and quality control management organizations, radiation oncologists, medical physicists and radiotherapy technicians and other personnel Medical technicians to implement protection and quality control measures in their work, and to assume corresponding responsibilities.

4.3 radiotherapy units should be in accordance with GB 18871 and GB Z179 requirements, develop system of protection of patients and radiotherapy quality assurance program, and Staff engaged in teletherapy protection of patients undergoing regular training and quality control to ensure that from the management system and quality control procedures Radiation therapy is implemented correctly.

4.4 radiotherapy units should be equipped with appropriate protection of patients and quality control testing equipment, and in accordance with the provisions of verification or calibration on a regular basis, get together Grid certificate. After detection equipment within the validity period after major repairs may involve measurement scale, should be re-verification or calibration.

4.5 for patients with prior radiation therapy, radiation oncologists should be more than

mid-level professional and technical qualifications by-Example legitimacy sentence Off. Only when the advantages outweigh the disadvantages, the order for radiation therapy, and should take the largest relative benefits of treatment options, and each case treated Process data archiving. Radiation oncologist before radiation therapy should be informed in writing of the possible risks of patients or their families.

4.6 Radiation therapy should be strictly controlled indications, benign try not to use radiation therapy, radiation therapy to strictly control sensitive benign disease Disease in vitro radiotherapy.

4.7 radiotherapy apparatus (including radiation therapy simulation and other auxiliary equipment), places and the environment should be consistent with GB 18871, GB Z126, GB Z161, GB Z168, GB Z/T 201.1 and other relevant radiological protection standards, should ensure that the interlock system to work properly, the door should have anti-extrusion protection And forced manual measures.

4.8 radiotherapy unit to deal with possible implementation of radiotherapy failure or mistakes, development of contingency plans, and training and emergency drills.

5 Patient protection requirements

General requirements

5.1 teletherapy patient protection should comply with the relevant provisions of GB Z179. It should develop detailed radiotherapy treatment planning based on clinical findings

5.2 before radiation therapy, including the type of radiation therapy, the target tissue dose fractionated Cloth, split mode, the treatment cycle. For radiation treatment planning of orders to be checked, signature recognition and archiving. Intermediate professional treatment plan should be And technical qualifications more radiation oncologists and medical physicists who co-signed.

5.3 developing radiation therapy plans for addressing the absorbed dose outside the target vital organs were estimated by lesions, including the use of Organ shield, including appropriate technologies and measures to protect the normal tissues and organs, to ensure treatment requirements under the premise that it is reasonable to It reached the lowest possible level.

5.4 Unless there are good reasons and obvious on clinical indications, pregnant or may become pregnant women and children should be careful using radiation therapy. in Radiation therapy for pregnant women should be carried out to implement any more careful treatment planning, so that the embryo or fetus suffered radiation dose is minimized.

5.5 In the course of treatment, patients should be regularly checked and analyzed to adjust the treatment plan as required changes in condition, pay close attention to in vitro Radiotherapy radiation damage effects that appear with possible radiation injury, to take the