

Translated English of Chinese Standard: YY0637-2013



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

YY 0637-2013 / IEC 62083:2009

Replacing 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 replaces YY0637-2008 *Medical Electrical Equipment – Requirements for the Safety of Radiotherapy Treatment Planning Systems*. Compared with YY0637-2008, the main technical changes of this Standard are as follows:

- Add 3.2 Abbreviations;
- Delete Chapter 3 of the previous standard;
- Split the 8.1 of the previous standard INTO 7.1 and 7.2 of this Standard;
- Delete Chapter 14 of the previous standard.

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

Our national documents that are consistent with the international documents of the Normative References of this Standard are as follows:

[Translator: NIL here]

For ease of use, this Standard is modified as follows:

- Modify the “international standard” to “this Standard”;
- Replace the comma “,” with a decimal point “.”;
- Delete the foreword of international standard.

Please note that some contents of this Document may involve patents. The issuing authority of this Document does not undertake the responsibility of identifying these patents.

This Standard was proposed by the State Food and Drug Administration.

This Standard shall be 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).

Main drafting organizations of this Standard: Beijing Institute of Medical Device Testing, Shandong Shinva Medical Instrument Co., Ltd., and Shanghai Song's Lab Science and Technology Development Co., Ltd.

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This Standard was first-time issued in 2008.