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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0291-2016

Replacing YY/T 0291-2007

**Environmental requirements and test
methods for medical X-ray equipment**

医用 X 射线设备环境要求和试验方法

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Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

Compared with YY/T 0291-2007, the major technical changes of this Standard are as follows:

- it adds in the normative references JTG B01-2014, *Technical Standard of Highway Engineering*;
- it adds the clause of terms and definitions;
- it modifies the expression of environment grouping (see 4; and see 3 of 2007 edition);
- it modifies the expression of requirements (see 5; and see 4.1, 4.2 and 4.3 of 2007 edition);
- it modifies the expression of special circumstances (see 6.3; and see 5.1 of edition 2007);
- it modifies the expression of test sequence (see 6.1.2; and see 5.2.2 of 2007 edition);
- it modifies the expression of test content (see 6.2; and see 5.2.3 of edition 2007);
- it modifies the expression of environment test methods (see 6.2; and see 5.3 of 2007 edition);
- it modifies the expression of requirements for recovery time and requirements for power supply adaptability (see Table A.1; and see Table A.1 of 2007 edition);
- it adds the environment test sequence chart Annex B as an informative annex.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuer of this document shall not be held responsible for identifying any or all such patent rights.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of Subcommittee 1 on Medical X-ray Equipment and Tools of National Technical Committee 10 of Standardization Administration of China (SAC/TC 10/SC 1).

The drafting organizations of this Standard: Liaoning Medical Device Test Institute, Shanghai Siemens Medical Device Co., Ltd.

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Environmental requirements and test methods for medical X-ray equipment

1 Scope

This Standard specifies the environment grouping, requirements and test methods for medical X-ray equipment (hereinafter referred to as equipment).

This Standard applies to medical X-ray equipment.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition dated applies to this document. For undated references, the latest edition of the referenced documents (including all amendments) applies to This Standard.

GB 9706.1-2007, *Medical electrical equipment – Part 1: General requirements for safety*

GB 9706.3-2000, *Medical electrical equipment – Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

GB 9706.18-2006, *Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray equipment for computed tomography*

GB 9706.24-2005, *Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices*

GB/T 10149-1988, *Terminology and symbol for medical X-ray equipment*

GB/T 14710-2009, *Environmental requirement and test methods for medical electrical equipment*

JTG B01-2014, *Technical Standard of Highway Engineering*

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB/T 10149-1988 apply.

After test, the fasteners of equipment shall not become loose, which shall be tested in accordance with the test items specified in product standard.

5.2.4 Power supply adaptability

5.2.4.1 The power supply of equipment is set at 110% and 90% of rated working voltage, supply frequency 50 Hz \pm 1 Hz (if necessary). Maintain the voltages for at least 15 min and then test the relevant test items specified in product standard.

5.2.4.2 For equipment having special requirements for power supply frequency and voltage, its working range of frequency and voltage can be specified otherwise in product standard.

6 Test methods

6.1 Test procedure and test sequence

6.1.1 Test procedure

Each test normally includes the following procedures:

- a) pretreatment (if necessary);
- b) initial detection (if necessary);
- c) test;
- d) intermediate detection (if necessary);
- e) recovery (if necessary);
- f) final detection.

6.1.2 Test sequence

When multiple tests are conducted for the same equipment, tests shall be normally conducted in the following sequence:

- a) rated working low temperature test;
- b) low temperature storage test;
- c) rated working high temperature test;
- d) high temperature storage test;
- e) rated working damp heat test;
- f) damp heat storage test;

Under the condition of normal package of equipment, equipment shall be fixed to the rear part of truck in accordance with the sign "UP" location. The load of truck during test is 1/3 of the rated load.

Test can be conducted using truck or transportation test apparatus.

After test, test whether equipment fasteners become loose and conduct test items in accordance with product standard.

6.2.4 Power supply adaptability test

This test is normally conducted during rated working low temperature test and rated working high temperature test. During test, connect the power cord of equipment to an adjustable power supply; maintain the output frequency of the adjustable power supply at the rated product frequency; set voltages at 110% and 90% of rated product voltage; maintain the voltages at least 15 min; and then conduct relevant test items specified in product standard.

6.3 Special circumstances

Consider the following circumstances:

- a) climatic environment test only applies to those parts or components which may be subjected to the climatic conditions simulated by test;
- b) equipment shall be placed in test chamber unpackaged, in the ready-for-use state, at a normal working position;
- c) equipment accessories shall be tested along with equipment, unless they are specified otherwise in product standard;
- d) the components which can be detached without using tools shall be detached and tested along with major parts;
- e) if test can't be conducted without disassembling and reassembling, the time intervals between treatment and test and between test and detection shall be decided in accordance with the time of equipment handling, assembling and debugging;
- f) if equipment (such as large equipment or equipment having special requirements for service environment) is inappropriate for some environment test items (such as rated working low temperature test, rated working high temperature test, rated working damp heat test and so on), the manufacturer shall provide specific test requirements and indicate in product standard;
- g) if product standard has special requirements for environment test conditions, they shall be implemented as specified in product standard. When it is impossible to test the whole machine, product standard shall specify which key parts or components are to be tested;

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