# YY

PHARMACEUTICAL INDUSTRY STANDARD

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# YY/T 0310-2015

**Replacing YY 0310-2005**

# General specifications for X-ray equipment for computer tomography

X 射线计算机体层摄影设备通用技术条件



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**Issued by: China Food and Drug Administration**

# Table of Contents

# Foreword

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

This Standard replaces YY 0310-2005 *General specifications for X-ray equipment for computed tomography*.

Compared with YY 0310-2005, the main technical changes are as follows:

- Modified the description of application scope, including CT scanner which provides image data for radiation treatment planning;
- Added YY 0505 and YY/T 0708 as normative references;
- Modified environmental conditions in requirements to conditions required by GB 9706.1;
- Added requirements for scanning frame rotation speed;
- Modified the original scanning time to exposure time;
- Deleted indicating instrument (5.5.5 of 2005 edition);
- Added requirements and test methods of radiation treatment planning (RTP).

This Standard was proposed by China Food and Drug Administration.

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

Drafting organizations of this Standard: Liaoning Provincial Medical Device Testing Institute, and GE Healthcare.

Main drafters of this Standard: Wang Jianjun, Hao Suli, Mou Li, Han Qiang, and Wang Shoumin.

This Standard replaces the following previous standards:

- YY 0310-1998, YY 0310-2005.

# General specifications for X-ray equipment for computer tomography

## 1 Scope

This Standard specifies the terms and definitions, classification, composition, requirements and test methods of X-ray equipment for computed tomography (hereinafter referred to as CT scanner).

This Standard is applicable to CT scanner, including CT scanner which provides image data for radiation treatment planning.

## 2 Normative references

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

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

GB 9706.11 *Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

GB 9706.12 *Medical electrical equipment - Part 1: General requirements for safety 3.collateral STANDARD: General requirements for radiation protection in diagnostic X-ray equipment*

GB 9706.14 *Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

GB 9706.15 *Medical electrical equipment - Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems*

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

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

GB/T 10151 *Medical diagnostic X-ray equipment - Specifications for high voltage cable plugs and sockets*

GB/T 19042.5-2006 *Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests-Imaging performances of computed tomography X-ray equipment*

YY 0076-1992 *Coating classifications for metal product - Technical conditions*

YY/T 0291 *Environmental requirements and test methods for medical x-ray equipment*

YY 0505 *Medical electrical equipment Part 1-2: General requirements for safety Collateral standards: Electromagnetic compatibility Requirements and tests*

YY 0637 *Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems*

YY/T 0708 *Medical electrical equipment - Part 1-4:General requirements for safety - collateral standard: programmable electrical medical systems*

# 3 Terms and definitions

Terms and definitions defined in GB/T 10149, GB 9706.18, GB/T 19042.5-2006 and YY 0637 apply to this document.

# 4 Classification and composition

## 4.1 Classification

Security classification shall comply with the requirements on classification in GB 9706.1.

## 4.2 Composition

CT scanner shall be composed of the following parts:

a) Scanning frame;

b) X-ray generator;

c) Patient support;

d) Console;

$M_1$, $M_2$ - Marks on patient support surface;

$d_1$, $d_2$ - Distance between marking point and Z-axis.

**Figure 2 Positioning at Z-axis of patient support on level plane**

### 5.7.2 Patient support surface

Patient support surface shall be plane, or the attachment which can make it as plane shall be indicated in accompanying file and make it obtained.

Positioning aids of therapy system are allowed to use by patient support.

### 5.7.3 Diagnostic bed sag (patient support rigidity)

It shall stipulate the diagnostic bed sag within 40 cm (typical scan length plus the amount of movement of scanning plane).

### 5.7.4 Integrated positioning light used for patient positioning

If positioning light is integrated in CT scanner, accompanying file shall verify if the intended use of positioning light can be used for patient positioning in RTP.

If the intended use of positioning light can be used for patient positioning in RTP, it shall have the following accuracy:

The accuracy of axial positioning light at isocenter shall be ± 1 mm. The accuracy at ± 250 mm in X direction shall be ± 2 mm.

Sagittal and coronal positioning lights shall be extended to within scanning plane. The accuracy related to rotation axis shall be ± 1 mm.

Marking line width of positioning light at isocenter (FWHM) shall not exceed 1 mm.

### 5.7.5 Typical scanning mode that generates RTP

The accompanying file shall stipulate the typical CT operating conditions which generate images for RTP. The agreement not applicable to generate RTP image shall be indicated in the accompanying file.

For RTP's typical CT operating conditions, the accompanying file shall provide measurement results of noise, average CT value and uniformity measured by the methods in GB/T 19042.5-2006.

### 5.7.6 HU value conversion

HU value of each model measured under CT operating conditions indicated in 5.7.5, and the conversion of electronic and mass density values related to

a) CT scanner appearance shall look neat, beautiful; the surface shall be smooth and clean; the color shall be even; there must no damage spots, cracks and other defects;

b) The main electroplating pieces of CT scanner shall comply with requirements on grade 2 appearance in YY 0076-1992.

### 5.9 Environment test

It shall comply with requirements of YY/T 0291. The final test items shall at least contain 5.2.1, 5.2.2, 5.2.3, 5.2.5, 5.2.8 and 5.5.3.

### 5.10 Safety

It shall comply with requirements of GB 9706.1, GB 9706.11, GB 9706.12, GB 9706.14, GB 9706.15, GB 9706.18, YY 0505 and YY/T 0708.

## 6 Test methods

### 6.1 Test conditions

CT scanner shall be tested under the following conditions:

a) Unless otherwise specified, all performance tests shall be conducted under conditions stipulated in 5.1;

b) CT body model which complies with American Association of Physicists in Medicine (AAPM) standard is recommended;

c) Unless otherwise specified, it shall use CT conditions of typical head and body to scan.

### 6.2 Performance

#### 6.2.1 Image noise

Under typical head scanning conditions (recommended to use 10 mm slice thickness), use head CTDI body model to measure center dose.

If the equipment does not have 10 mm slice thickness, the product standard shall stipulate the conversion factor of image noise.

Place the homogeneous medium body model (20 cm water model) within scan field of view. Make body model axis coincide with the rotation axis of scanning frame. After scanning, select a region of interest of which the diameter is about 40% of image diameter. Measure the standard deviation SD of CT value in this region. Use formula (1) to calculate noise value N.

reconstruct. Adjust the window width and window level. Observe the image through monitor. Take the diameter of the distinguishable minimum hole group as reference.

### 6.2.6 Operating noise

In the fastest scan state, use sound level meter to respectively measure the operating noise at 1.5 m height from ground, 1 m from the front, back, left and right of scanning frame surface. Take the maximum.

### 6.2.7 Artifact

Place water model within scan field of view. Make body model axis coincide with the rotation axis of scanning frame. Select a group of CT operating conditions to scan. Observe water model's CT image when window level is 0, window width are respectively 50 HU, 100 HU.

### 6.2.8 Slice thickness

This Standard recommends the following method.

Place measurement slice thickness body model within scan field of view. Make body model axis coincide with the rotation axis of scanning frame. Set CT operating conditions. Respectively set different nominal slice thickness and scan. In the formed CT image, adjust window width to the narrowest position, window level to the position where the background disappears. In this case the window level shall be CT value of the background. Make the aforementioned processing to the image formed by each inclined plane, so as to determine its maximum CT value. Divide the sum of this maximum CT value and the background CT by 2 to obtain the half value of the maximum CT value. The measured width shall be layer thickness (full width half maximum). Take the average value of result as slice thickness.

For helical scanning, the test method of slice thickness shall be stipulated in the product standard.

## 6.3 Scanning frame

This Standard recommends the following method.

a) Firstly, adjust tilt angle of scanning frame to zero. Tilt the scanning frame forward and backward to any angle and the maximum angle. Use inclinometer to measure;

b) Lift the bed to the head scanning position. Place the film of which the side length is not less than 15 cm within beam range of positioning light on bed panel. Along the center line of the beam, use a needle to make

### 6.6 Software features

Practical operation and observation.

### 6.7 Requirements when CT scanner provides images for radiation treatment planning (RTP)

#### 6.7.1 Positioning of patient support surface

##### 6.7.1.1 Summary

By examining the accompanying files to verify if it complies with all positioning requirements.

##### 6.7.1.2 Positioning of patient frame on vertical plane (tilt)

By examining the accompanying files to verify if it complies with requirements.

##### 6.7.1.3 Positioning of patient frame on level plane

By examining the accompanying files to verify if it complies with requirements.

#### 6.7.2 Patient support surface

By actual examination to verify if it complies with requirements.

#### 6.7.3 Diagnosis bed sag (patient support rigidity)

Estimate the sag of patient frame surface at scanning plane according to the following test specifications:

- Starting from scanning frame side end of patient support, evenly distribute 135 kg of load on 1.9 m length (when it is less than 1.9 m, take patient support's maximum length);
- Place the scanning frame side end of patient support at scanning plane (position 1);
- Measure vertical height of patient support surface position in scanning plane (height 1);
- Move patient support surface 400 mm so as to make it enter scanning frame (position 2 = position 1 + 400 mm);
- Measure vertical height of patient support surface position in scanning plane (height 2);
- Move patient support surface 400 mm further into scanning frame

#### 6.7.7.3 Angle adjustment of CT image

Place the body model of which the mark is parallel to horizontal or vertical plane within scanning region. Scan and examine mark's direction in the image.

By measuring the deviation between the mark and horizontal or vertical plane to verify if it complies with requirements.

#### 6.7.7.4 Accuracy of helical scan z position

Use the body model of which the mark is at 0 cm, 15 cm, 30 cm, etc. The mark shall be visible in CT image (e.g. metal ball). Place the body model so as to make '0 cm' within positioning light field. Set the position where diagnostic bed is as zero position.

Use the scanning agreement which is intended to generate RTP image in the scanning range of covering three marks of body model to conduct helical scan. Use the thinnest layer slice to reconstruct overlapping image. Use the maximum contrast of mark to identify and record the layer position of each mark.

By examining the deviation between image position and its nominal z value to verify if it complies with requirements.

### 6.8 Appearance

Visual observation.

### 6.9 Environmental Test

Conduct according to the method stipulated in 5.9 and YY/T 0291.

### 6.10 Safety

Conduct according to the method stipulated in GB 9706.1, GB 9706.11, GB 9706.12, GB 9706.14, GB 9706.15, GB 9706.18, YY 0505 and YY/T 0708.

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