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**Protective Devices against Diagnostic Medical X-radiation -  
Device and Tool**

医用诊断 X 射线辐射防护器具 装置及用具

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# Protective Devices against Diagnostic Medical X-radiation - Device and Tool

## 1 Scope

This document specifies the requirements and inspection methods for the protective devices and tools against diagnostic medical X-radiation (hereinafter referred to as protective devices).

This document is applicable to protective devices provided to users to shield or attenuate medical diagnostic X-ray radiation.

This document does not apply to wearable medical diagnostic X-ray radiation protective supplies.

**NOTE 1:** the users mentioned in this document include operators (doctors, technicians and nurses), patients (subjects) and other persons around the patients during radiographic examination or interventional operations at a medical X-ray tube voltage of 150 kV and below.

**NOTE 2:** the wearable medical diagnostic X-ray radiation protective supplies include, but are not limited to: protective skirts, thyroid protective scarves, protective caps, protective gloves, protective glasses and protective masks, which are used for operator protection, as well as gonad protective skirts, scrotal protective curtains, ovary protective curtains and dental protective skirts, which are used for patient protection.

## 2 Normative References

The contents of the following documents constitute indispensable clauses of this document through normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB 9706.1-2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

GB 9706.103 Medical Electrical Equipment - Part 1-3: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment

GB 9706.243 Medical Electrical Equipment - Part 2-43: Particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Interventional Procedures

YY/T 0292.1-2020 Protective Devices against Diagnostic Medical X-radiation - Part 1: Determination of Attenuation Properties of Materials

### 3.7 protective shield

A constituent unit of the protective device that is made of hard X-ray attenuation material and provides protection to the users.

### 3.8 protective curtain

A constituent unit in protective device made of an inner layer of soft X-ray attenuation material and an outer layer of waterproof knitted fabric or other waterproof soft materials, which provides protection to the users.

### 3.9 protective baffle

A constituent unit in protective device made of a combination of X-ray attenuation material and elastic material or elastic X-ray attenuation material, which provides protection to the users.

### 3.10 mobile type

A description of the functional characteristic of a protective device capable of being moved from one place to another on its own wheels or by similar means.

### 3.11 suspended type

A description of the functional characteristic of a protective device capable of moving and remaining stationary in the expected space by relying on its own support or suspension.

### 3.12 table mounted type

A description of the functional characteristic of a protective device capable of being fixed at the bedside where a **fluoroscopy-guided interventional operation equipment** performs by its own connector.

## 4 Requirements

### 4.1 Materials and Composition

The key materials and main components constituting the protective device:

- The key materials of the protective device shall be **X-ray attenuation materials**, including **lead attenuation material**, **lead-free attenuation material** and **lead mixture attenuation material**;
- The main part constituting the protective device should be **protective shield**, **protective curtain**, **protective baffle** or combination thereof made of **X-ray attenuation materials**, and a supporting, fixed or suspended structural member;
- Or as some of the commonly used protective devices listed in Appendix A, which shall comply with the corresponding specific stipulations in Table A.1.

**NOTE:** in a few circumstances, protective shield, protective curtain and protective baffle can also independently become a protective appliance without the help of supporting, fixed or suspended structural members, for example, the medical X-ray protective cloth in Appendix A.

## 4.2 Structure and Basic Mechanical Functions

The structure and basic mechanical functions of the protective device:

- The size and shape of the **protective shield, protective curtain, protective baffle** or combination thereof in the protective device shall provide necessary protection for the users, and avoid or reduce the users' exposure to unnecessary radiation;
- Through the movement, rotation and lifting, etc. of the supporting, fixed or suspended structural members in the protective device, the **protective shield, protective curtain, protective baffle** or combination thereof can be conveniently positioned between the users and the X-ray source or scattered radiation generation area at any time;
- The protective device shall not hinder necessary operation and use;
- Or as some of the commonly used protective devices listed in Appendix A, which shall comply with the corresponding specific stipulations in Table A.2.

## 4.3 Protective Performance Indicators

### 4.3.1 Lead equivalent class

The lead equivalent of the protective device shall be no less than its **lead equivalent class**.

The **lead equivalent class** of the protective device:

- It shall be any one or a set of 0.25 mmPb, 0.35 mmPb, 0.50 mmPb, 1.0 mmPb and 2.0 mmPb;
- Or the protective device is some of the commonly used protective devices listed in Appendix A, which shall comply with the corresponding specific stipulations in Table A.3.

### 4.3.2 Effective shielding area

The **effective shielding area** of the protective device:

- It shall not be less than the value specified by the protective device;
- Or as some of the commonly used protective devices listed in Appendix A, which shall comply with the corresponding specific stipulations in Table A.3.

**NOTE:** the lead equivalent class and effective shielding area are indicators that reflect the protective capability of the protective device, but do not represent the actual protective

residual risk if it or its components become unbalanced;

- d) If a protective device with a mass of 25 kg or above may cause imbalance due to pushing, pulling, leaning and placing, etc., a permanently affixed, clear and easily legible mark shall be provided (see safety mark 5 in Table D.2 of GB 9706.1-2020), to warn of the risk of imbalance.

#### 4.6.1.2 Protection against fall hazard

If applicable, the following requirements shall be satisfied:

- a) For protective devices with supporting or suspended structural members, the safety factor of the supporting or supported components shall at least satisfy the corresponding stipulations in rows 1 to 6 of Table 21 in GB 9706.1-2020;
- b) The movable parts of the supporting or suspended components shall be connected in such a way that they will not fall under a single fault;
- c) If a **mechanical protective device** is used for the movable parts of supports or suspensions, then, the **mechanical protective device**:
  - 1) When the connecting parts fall off, the mechanical protective device shall be able to be automatically activated;
  - 2) When the **mechanical protective device** is activated, there shall be identifiable prompts and warning displays;
  - 3) The **tensile safety factor** of the **mechanical protective device** shall comply with the stipulations of Table 21 in GB 9706.1-2020.

#### 4.6.1.3 Protection against pierce or puncture hazard

In accordance with the requirements of 9.3 in GB 9706.1-2020, sharp corners and sharp edges on any accessible surface of the protective device that may cause injury or damage shall be avoided or covered.

#### 4.6.1.4 Protection against splash hazard

For **mobile** or **suspended** protective devices, if the **protective shield** or part of the **protective shield** uses lead glass with an area greater than or equal to 0.24 m<sup>2</sup>, then, the lead glass shall be pasted with anti-splash film on both sides or use laminated lead glass.

### 4.6.2 Safety requirements for active protective devices

**4.6.2.1** In addition to comply with mechanical hazard protection safety in 4.6.1, active protective devices shall also comply with other relevant requirements in GB 9706.1-2020.

**4.6.2.2** The electromagnetic compatibility performance of active protective devices shall

comply with the requirements of YY 9706.102.

## 4.7 Appearance

**4.7.1** The surface of the soft **X-ray attenuation material** in the protective device shall be free of scratches, tears, speckles and stains. If the **X-ray attenuation material** and surface adopt:

---Sewing mode, the stitches shall be even and straight, and there shall be no obvious skipped or broken stitches;

---Heat-sealing mode, the heat-sealing strips shall be flush and there shall be no cracks.

**4.7.2** The surface, such as: lead glass and lead acrylic panels, of transparent **X-ray attenuation material** in the protective device shall be smooth, without cracks, obvious impurities, bubbles and scratches.

**4.7.3** The metal structural parts in the protective device:

---If the surface is sprayed or spray-painted, then, the surface shall be completely covered by the coating, basically smooth, without obvious bubbles, spots and wrinkles, without relatively deep scratches, and consistent in color;

---If they are made of stainless steel, then, the outer surface shall be frosted, brushed or polished.

## 4.8 Specification Markings

The content and example of the specification markings of the protective devices in this document are as follows:

××<sup>a)</sup> Pb××<sup>b)</sup> /××<sup>c)</sup> ××<sup>d)</sup> YY/T 0128-2023<sup>e)</sup>

- a) Enterprise name or brand abbreviation;
- b) **Lead equivalent class** (mmPb) of the protective device;
- c) Voltage value or voltage range (kV) of the X-ray tube used for detection:
  - 1) When the protective device uses lead X-ray attenuation material, and the voltage value of the X-ray tube used for detection should be 120 kV, and marked as 120;
  - 2) When the protective device uses lead-free X-ray attenuation material or lead mixture X-ray attenuation material for **stray radiation** protection, which is mainly **scattered radiation**, the voltage values of the X-ray tube used for detection shall be 50 kV, 70 kV, 90 kV and 110 kV, and marked as 50-110;
  - 3) When lead-free X-ray attenuation material or lead mixture X-ray attenuation material is used for **radiation** protection, including X-ray **radiation beams** with X-ray tube voltage up to 150 kV, the voltage values of the X-ray tube used for

or / and on the labels:

- Recommended methods for the cleaning and disinfection of the protective device before use and / or daily;
- For protective devices used in a sterile environment, it shall be stated that physical isolation mode is recommended for the users, for example, wrapping them with disposable sterile transparent plastic films. Inform the users how to use the preset structure of the protective device or utilize relevant structural parts to tie or hang the disposable sterile transparent plastic films.

## 5 Inspection Methods

### 5.1 Materials and Composition

Conduct visual inspection of the protective device and check the bill of materials, which shall comply with the stipulations of 4.1.

### 5.2 Structure and Basic Mechanical Functions

Conduct the inspection through visual inspection and / or by means of the following gauges or methods:

- Use a meter ruler to measure the movement or lifting range;
- Use an angle ruler to measure the rotation angle range;
- Use your arms to press down on the upper **protective baffle**. After lowering the height by 5 cm, release the pressure and observe the recovery of the upper **protective baffle**.

It shall be determined that they comply with the corresponding stipulations of Table A.2 for some commonly used protective devices listed in Appendix A in 4.2.

### 5.3 Protective Performance Indicators

#### 5.3.1 Lead equivalent class

##### 5.3.1.1 Tube voltage value and other radiation mass of X-ray beams

The selection of the tube voltage value and other radiation mass of X-ray beams for detection:

- Protective devices intended to shield or reduce **stray radiation**, which is mainly **scattered radiation**, and the **X-ray attenuation material** is **lead-free attenuation material** or **lead mixture attenuation material**: the tube voltage value of the X-ray **radiation beams** used to detect lead equivalent shall be 50 kV, 70 kV, 90 kV and 110 kV;
- Protective devices intended to shield or reduce X-ray **radiation beams** with X-ray tube

voltage up to 150 kV, and the **X-ray attenuation material** is **lead-free attenuation material** and **lead mixture attenuation material**: the tube voltage value of the X-ray **radiation beams** used to detect lead equivalent shall be 60 kV, 80 kV, 100 kV, 120 kV and 150 kV;

---Protective devices using **lead attenuation material**: the tube voltage value of the X-ray **radiation beams** used to detect lead equivalent should be 120 kV;

---The **radiation mass** of the X-ray **radiation beams** used to detect lead equivalent shall also comply with other requirements specified in Table 1 of YY/T 0292.1-2020.

**NOTE:** since the lead equivalent value of lead attenuation material hardly changes with the tube voltage of the detected X-ray **radiation beams**, the X-ray tube voltage value for the **lead equivalent detection** of lead attenuation material should all be 120 kV.

### 5.3.1.2 Test method

Adopt the X-ray **radiation beams** that comply with the **radiation mass** specified in 5.3.1.1, under the configuration of **wide beam conditions** specified in 4.3 or the **reverse wide beam conditions** specified in 4.4 of YY/T 0292.1-2020, carry out the test. The **lead equivalent class** of the protective device shall comply with the stipulations of 4.3.1.

### 5.3.2 Effective shielding area

Through the detection and size measurement of lead equivalent at multiple locations or sampling at multiple locations, the **effective shielding area** of the protective device shall comply with the stipulations of 4.3.2.

## 5.4 Mobility and Stability

### 5.4.1 Mobile protective device

Place the mobile protective device on a hard and flat horizontal ground (for example, a concrete floor covered with 2 mm ~ 4 mm thick vinyl flooring material), and measure the external force required to propel the protective device at a speed of  $0.4 \text{ m/s} \pm 0.1 \text{ m/s}$ , and this external force is applied at a distance of 1 m from the ground. If the height of the mobile protective device does not exceed 1 m, the external force shall be applied at the highest point and shall comply with the stipulations of 4.4.1.

### 5.4.2 Suspended protective device

Adopt the methods specified below to respectively measure the horizontal and vertical starting forces of the **suspended** protective device:

---The starting force in the horizontal direction shall respectively be measured when the extension arm is locked with the fixed shaft and the spring arm is locked with the extension arm. Use a tension gauge to pull the handle position of the **suspended protective shield** or **protective curtain** in a horizontal and orthogonal direction, or

- c) If the movable parts of the supporting or suspended components adopt a **mechanical protective device**, then:
- 1) When the connecting parts fall off, observe whether the **mechanical protective device** is automatically activated, which shall comply with the stipulations of 1) in 4.6.1.2 c);
  - 2) Observe whether there are identifiable prompts and warning displays during startup, which shall comply with the stipulations of 2) in 4.6.1.2 c);
  - 3) By whether the tensile strength applied during the tensile strength test of the **mechanical protective device** is greater than or equal to the product of the declared **tensile safety factor** and the **total load**, determine the safety factor, which shall comply with the stipulations of 3) in 4.6.1.2 c).

**NOTE:** the total load of the protective device is equal to the sum of the gravity generated by the supporting or suspended objects and related components and the vertical downward starting force they may be subject to.

#### **5.6.1.3 Protection against pierce or puncture hazard**

Through observation and touch, determine the protection against pierce or puncture hazard, which shall comply with the stipulations of 4.6.1.3.

#### **5.6.1.4 Protection against splash hazard**

Through visual observation, inspect the lead glass or check the bill of materials of the lead glass, and determine the protection against splash hazard, which shall comply with the stipulations of 4.6.1.4.

### **5.6.2 Active protective device**

**5.6.2.1** In accordance with the method specified in the relevant stipulations of GB 9706.1-2020, conduct the determination, which shall comply with the stipulations of 4.6.2.1.

**5.6.2.2** In accordance with the method specified in the relevant stipulations of YY 9706.102, conduct the determination, which shall comply with the stipulations of 4.6.2.2.

### **5.7 Appearance**

Conduct the inspection through visual inspection, which shall comply with the stipulations of 4.7.1, 4.7.2 and 4.7.3.

### **5.8 Specification Markings**

Check the specification markings in the instructions and labels, which shall comply with the stipulations of 4.8.

## Appendix B

(informative)

### General Guidelines and Preparation Instructions

#### B.1 General Guidelines

This Appendix provides the preparation guidelines and brief preparation instructions for the main chapters and clauses of this document. The purpose is to help understand and grasp the requirements of this document and improve its effective application by explaining the relevant chapters and clauses of this document and providing additional guidance.

#### B.2 Guidelines

The preparation guidelines of this document are as follows:

- The design of the protective devices shall be based on the principles of protection and safety optimization: minimize unnecessary X-ray **radiation** to the users.
- The design of the protective devices shall match their auxiliary role and emphasize the practicability and usability.
- Based on the differences in the protection modes adopted by the protective devices and X-ray equipment: the protection mode of X-ray equipment is to reduce the absorbed dose of the users by actively controlling the amount of X-ray **radiation beam** exposure and the **incident surface**, and by actively controlling the leaked radiation and protecting against residual radiation; the protection mode of the protective devices is mainly to reduce the absorbed dose of the users by protecting against **scattered radiation**. This document emphasizes the importance of the design of protection against **scattered radiation**, especially the importance of the design of protection against **scattered radiation** in designated **effective occupied areas** during **fluoroscopy-guided interventional operations**.
- Since the requirements for the protective effect of **operators** performing **fluoroscopy-guided interventional operations** in the designated **effective occupied areas** are stipulated in WS 76-2020, in the design of **suspended** medical X-ray **protective shield**, **table mounted type** medical X-ray **protective curtain**, **mobile** medical X-ray **protective curtain** and medical X-ray protective surgical plate, this document has considered how to satisfy the requirements for the surrounding dose equivalent rate ( $\mu\text{Sv/h}$ ) on the detection plane of the fluoroscopy protective area specified in row 7 of Table B.1 in WS 76-2020 in the **lead equivalent class** and **effective shielding area size**. In addition, the **suspended** medical X-ray **protective shield** and **table mounted type** medical X-ray **protective curtain** have passed the test verification in compliance with WS 76-2020.
- In accordance with the risk management requirements for medical device products,

through risk analysis, risk assessment, and risk and benefit evaluation, this document selects some provisions applicable to passive products from GB 9706.1-2020 regarding the protection against mechanical hazard.

**NOTE:** the “fluoroscopy protective area” described in row 7 of Table B.1 in WS 76-2020 can be comprehended as the designated **effective occupied areas** mentioned in this document. For the designated effective occupied areas, see 13.4 of GB 9706.103-2020.

## **B.3 Preparation Instructions of Some Chapters and Clauses**

### **B.3.1 Scope**

Compared with the original standard, the scope of this document is no longer limited to specific medical diagnostic X-ray radiation protective devices or tools, instead, it extends to all protective devices or tools except wearable medical diagnostic X-ray radiation protective equipment.

This document makes major adjustments to the items related to protective devices and tools in the original standard. In addition to deleting products such as protective room, protective door and protective chair that no longer belong to the category of medical devices or currently have little market demand, wearable protective equipment, such as protective glasses, protective mask and thyroid protective curtain are also deleted; the “protective shield” in the original standard is modified into “mobile medical X-ray protective shield”, the “suspended protective curtain” in the original standard is modified into “suspended medical X-ray protective shield”, and the “protective curtain next to the examination bed (or photography bed, etc.)” is modified into “table mounted type medical X-ray protective curtain” or “mobile medical X-ray protective curtain”.

### **B.3.2 Terms and definitions**

In addition to citing some terms and definitions defined in GB 9706.1-2020, GB 9706.103, GB 9706.243, YY/T 0292.1 and IEC/TR 60788, this document also defines the following terms and definitions that are quite important to this document.

---**Lead equivalent class** is defined as a magnitude used in this document to express and classify the X-ray attenuation properties of protective devices. When compared to lead equivalent, **lead equivalent class**:

- 1) In addition to expressing the magnitude, it also has the concept of class; it is not an arbitrary value, but a set of specific values that represent the X-ray attenuation properties;
- 2) Specifies the conditions of lead equivalent class: including not only specific regulations on the radiation mass of the X-ray beams used for lead equivalent detection, but also regulations on the determination of inspection results (for information on the specified conditions of lead equivalent class, see 5.5.3 of YY/T 0292.1-2020).

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