



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

YY/T 0128-2023

**Protective devices against diagnostic medical X-radiation -
Devices and appliances**

医用诊断X射线辐射防护器具 装置及用具

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1 Scope

YY/T 0128 covers the shielding used against diagnostic X-rays: the aprons, thyroid collars, gonad shields, gloves, screens and mobile barriers that protect patients and staff in radiology, cardiology and theatre. It sets the requirements such devices have to meet and the test methods that verify them, covering the lead equivalence they provide, the uniformity and integrity of the shielding material, the coverage the design offers and the marking that tells the user what protection they are wearing. Protective equipment ages invisibly, since a crack inside an apron leaves no external trace, which is why the standard specifies how attenuation is verified rather than assumed. For a manufacturer or a hospital radiation safety officer in China, this is the document conformity and periodic testing refer to.

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.

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

3 Terms and Definitions

The terms and definitions defined in GB 9706.1-2020, GB 9706.103, GB 9706.243, YY/T 0292.1-2020 and IEC/TR 60788, and the following are applicable to this document.

3.1 x-ray attenuation material A uniformly distributed material mainly composed of one or more elements with an atomic number higher than 47.

3.2 lead attenuation material A uniformly distributed material mainly composed of lead element, and does not contain other elements with an atomic number higher than 47.

3.6 effective shielding area The area formed by the X-ray attenuation material with a lead equivalent value reaching a specified lead equivalent class.

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.

3.12 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.

4.2 Structure and Basic Mechanical Functions The structure and basic mechanical functions of the protective device.

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.

4.4 Mobility and Stability of Movement

4.4.1 Mobile protective device When the mobile protective device moves under the condition of normal use, the external force required to move the mobile protective device on a hard and flat horizontal surface shall not be greater than 200 N, unless the instruction manual states that multiple people are required to push it.

4.5 Visible Light Transmittance At the light wavelength of 550 nm, the transmittance of the transparent part of the protective shield required for visual observation shall not be less than 80%.

4.6.1 Protection against mechanical hazards for passive protective devices

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 m², then, the lead glass shall be pasted with anti-splash film on both sides or use laminated lead glass.

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.

5.3.1 Lead equivalent class

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.

5.4 Mobility and Stability

5.5 Visible Light Transmittance From the transparent X-ray attenuation material or product of the same batch to be measured, cut a test sample. Use a spectrophotometer and light

with a wavelength of 550 nm to conduct the measurement, which shall comply with the stipulations of 4.5.

5.6.1.2 Protection against fall hazard

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.