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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 15476-2026

Replacing GB/T 15476-2008

Multifunctional measuring instruments for kidney and thyroid

肾及甲状腺多功能测量仪

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Table of Contents

1 Scope

GB/T 15476-2026 is the Chinese national standard covering the nuclear medicine instrument that measures kidney and thyroid function by following a radiotracer with external detectors - the renogram and the thyroid uptake study. It fixes the composition of the instrument, the performance requirements on the detectors and the electronics, the safety, the test methods and the marking. It replaces GB/T 15476-2008. It was issued on 2 July 2026 and takes effect on 1 February 2027, replacing GB/T 15476-2008. The document is under the responsibility of the Standardization Administration of China. This page is published from the official record of the 2026 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the technical requirements, inspection items, markings, packaging, and transportation of the multifunctional renal and thyroid measuring instrument (hereinafter referred to as the "instrument"). The requirements for storage are described, along with the corresponding test methods. This document applies to diagnostic instruments that use NaI(Tl) crystals as detectors and employ radionuclides to examine the function of the human kidneys and thyroid gland. The instrument serves as the basis for the design, manufacture, and inspection of this type of product.

4 Technical Requirements

4.1 Instrument Composition The instrument mainly consists of a probe, support arm, column, secondary instrument, and connecting cables.

4.2 General Requirements

4.2.1 Appearance The coating on the instrument surface should be firm and smooth, and there should be no rust, cracks, peeling coating, or loose fasteners.

4.2.2 Mechanical properties The motion mechanism should be flexible, with the probe moving up and down and rotating freely on the column and arm, without any mechanical malfunctions.

4.2.3 Data Measurement and Result Output during Functional Check

4.2.3.1 The instrument should have the function of normalizing measurement data.

4.2.3.2 The instrument should have the function of numerical output and graphical display of measurement data.

4.2.3.3 The instrument should be able to display the left and right kidneys, kidney index, time for C segment to decrease by 1/2, peak time and 15-minute residual rate.

4.2.3.4 The instrument should have the function of displaying thyroid iodine uptake rate.

4.3 Radiation Characteristics

4.3.1 Energy Nonlinearity Energy nonlinearity should be better than ±5%.

4.3.2 Energy Resolution The energy resolution of the 137Cs radioactive source should not exceed 9%.

4.3.3 Background count rate The background count rate should not exceed 500 min^-1.

4.3.4 Point Source Sensitivity The point source sensitivity should be no less than

0.18 min^-1·Bq^-1.

4.3.5 Repeatability The repeatability of the instrument should not exceed 0.05.

4.3.6 Nonlinearity of activity response The nonlinearity of the activity response should be better than ±15%. 4.3.7 8h stability The instrument should be powered on continuously for 8 hours, and the additional error should be better than ±3%.

4.3.8 Multi-probe consistency The relative deviation of the activity response between each probe should be better than ±5%.

4.4 Alignment characteristics

4.4.1 Point Source Response Curve When the 131I point source moves along a plane centered on the geometric center (marker point) of the detector crystal with a radius equal to the working distance, at the collimator... Within the field of view, the count rate is greater than or equal to 90% on the axis; when moved to 1.2R (R is half the diameter of the field of view), the count rate is less than... When the count rate is moved from 50% on the axis to 1.4R, it is less than 5% on the axis. See Appendix A for details on the point source and its structural dimensions.

4.4.2 Shielding Leakage Rate The shielding leakage rate of the shielding cover should be less than 10%.

4.5 Electrical Characteristics

4.5.1 Protective grounding impedance For plug-connected (non-fixed connection) equipment, the protective connection impedance should not exceed 0.1Omega. If the equipment has a non-removable power supply... For power cords, the impedance between the power cord protective conductor plug pins and each accessible component of the protective connection should not exceed 0.2Omega.

4.5.2 Contact Current Under normal operating conditions, the leakage current between the equipment casing and the reference test ground should not exceed 1mA DC.

4.5.3 Voltage Test The test should not result in electrical gap arcing or solid insulation breakdown, and corona effects and similar phenomena (such as single instantaneous flashes) are not considered. After the test, the equipment should be inspected. The equipment and its components should be free of damage (e.g., scorch marks), and should function normally when powered on and maintain its performance. characteristic.

4.6 Environmental adaptability The instrument requires the following environmental conditions.

a) Power supply. AC220V (10-12%), 50Hz±3Hz; the relative error of the instrument should be better than ±5%.

b) Rated high temperature. 40°C, the relative error of the instrument should be better than ±20%;

c) Rated low temperature. 0°C, the relative error of the instrument should be better than ±20%;

d) Constant humidity and temperature. relative humidity 85% (30°C), the relative error of the instrument should be better than ±10%.

4.7 Electromagnetic Compatibility

4.7.1 Electrostatic Discharge Immunity The instrument should meet the requirements of Class 2 in GB/T 17626.2, and be able to withstand ±4kV air discharge and ±4kV contact discharge interference. After that, it should be able to work normally.

4.7.2 Electrical Fast Transient/Bulk Immunity The instrument should meet the requirements of Class 3 in GB/T 17626.4, and the AC power port of the instrument should be subjected to a peak voltage of ±2kV under repeated conditions. It should be able to work normally after interference at a frequency of 5kHz.

4.7.3 Surge Immunity The instrument should meet the requirements of Class 3 in GB/T 17626.5, and the AC power supply port of the instrument should have a line-to-line voltage of 1.0kV; line-to-line voltage. It should be able to work normally after being subjected to interference from an open-circuit test voltage of 2.0kV.

4.7.4 Immunity test for voltage dips, short interruptions and voltage variations on the power supply input line The instrument should meet the Class 2 usage requirements in GB/T 17626.11 and should be able to work normally.

5 Test Methods

5.1 Test Conditions The placement of the point source should conform to the point source response curve specified in this document, and a minimum distance of not less than 10cm should be ensured for the field of view diameter. The radioactive source used for testing should be calibrated. When conducting various tests, the instrument should be set within the specified energy window. The reference conditions and standard test conditions for instrument testing are shown in Table 1.

5.2 Test Equipment Devices without multichannel analysis capabilities. multichannel analyzer, computer. Equipment with multichannel analysis capabilities. computer.

5.3 Appearance The appearance of the instrument is inspected visually.

5.4 Mechanical Properties For manually controlled equipment, the support arm for moving up and down/rotating the instrument should move smoothly without jamming; tightening the fixing screws should ensure the support arm remains in a fixed position without slipping; Rotate each probe to ensure that the probe is aligned with the target position. For automatically controlled equipment, the height of the outrigger and the orientation of the probe toward the target position can be controlled by a computer.

5.5 Data Measurement and Output during Functional Check Visual inspection.

5.6 Energy Nonlinearity Detection was performed using a set of gamma-ray sources comprising at least three different energy gradients. A multichannel analyzer was used to acquire the corresponding energy spectra of the radioactive sources. By selecting fewer