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PHARMACEUTICAL INDUSTRY STANDARD
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**Medical Electrical Equipment - Radionuclide
Calibrators - Particular Methods for Describing
Performance**

医用电气设备 放射性核素校准仪 描述性能的专用方法
(IEC 61303:1994, MOD)

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Medical Electrical Equipment - Radionuclide Calibrators - Particular Methods for Describing Performance

1 Scope

This Standard is applicable to well-type radionuclide calibrators with gas-filled ionization chambers used in nuclear medicine practice.

The purpose of this Standard is to determine the most important characteristics of the radionuclide calibrator; and to specify the corresponding test methods; so that manufacturers may declare the characteristics of their equipment in a standardized way, and to facilitate the comparison between equipment.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this document.

GB/T 17857-1999 Medical Radiology – Terminology (Equipment for Radiotherapy, Nuclear Medicine and Radiation Dosimetry)

GB/T 24247-2009 Calibration and Usage of Ionization Chamber Systems for Assay of Radionuclides (IEC 61145:1992, MOD)

3 Terms and Definitions

For the purpose of this document, the terms and definitions given in GB/T 17857-1999 apply.

3.1 Radioactive standard source

A general term that is used to refer to the following standard sources.

3.2 Certified radioactive standard source

Radioactive sources that are calibrated by the laboratory recognized by the national radiological standard laboratory and have been qualified by the above-mentioned

3.12 Instrument accuracy

The ratio of the largest possible measured value to the true value.

4 Measurement of Instrument Accuracy

4.1 Overview

The instrument accuracy of the reference device is determined by the primary method. The instrument accuracy of other devices is determined by secondary methods.

a) Primary test method

For each radionuclide, the reference device is calibrated with a standard source, and the device has a specified radionuclide factor. If a radioactive standard source is not available, the manufacturer may also use the calculation method of the radionuclide factor. The calculated radionuclide factor shall be clearly given.

b) Secondary test method

The calibration of other devices is performed by the method of comparative measurement, and the selected radionuclide is compared with the reference device of the same type and structure measured by the above-mentioned primary method a). This method implies strict quality control procedures for the reference device. Alternatively, the subsets of a series of radioactive standard sources that are not compared with the reference device may also be used.

4.2 Primary test method

4.2.1 Test procedure

For devices with radionuclide factors, this test shall be repeated for each nuclide and each sample container.

The radionuclide shall be placed in a container (e.g., ampoule, vial, syringe) in a certain form (e.g., liquid); introduce to the measurement position of the device; and apply to the appropriate radionuclide factors. For each container type, the volume of the solution shall be equal to the reference volume of the container. The activity of the radioactive standard source shall be known accuracy, and its accuracy may be traced back to national standards. Suitable radionuclide factors shall be used. The activity determined by the device shall be recorded; and the effects of background, radioactive decay and radioactive contamination shall be corrected. The measurement shall be repeated until the average standard deviation S_m of the measured value is less than $2/10$ of the uncertainty S_0 of the activity of radioactive standard source.

radionuclide between 0.74MBq and 37MBq (0.02mCi and 1mCi) to a straight line and extrapolate it to the beginning of the measurement. The ratio, E_R , between the expected y-value and the measured y-value shall be calculated for each test point. A curve graph showing the relationship between E_R and the measured y-value shall be drawn and provided. Where the difference between the observed value and the expected value extrapolated from the low-value straight line is 1% and 5% of the observed value, the observed activity value shall be marked and explained.

5.2.2 Sub-packaging source method

5.2.2.1 Test procedure

A series of sources shall be prepared, which are obtained by diluting the same raw material solution of radionuclides with known activity and half-life. At this time, no decay correction is required. The maximum activity of the source shall be at least the maximum used activity specified by the equipment. The reading of the minimum activity source is less than 10 times the background reading of the device. For each source with an activity level difference of 10 times, their approximate activity ratio shall be prepared to be 10:5:2:1. The volume, geometry, and sample container of each source shall be the same and placed in the same measurement position of the device. No correction factor is required when the measurement is recorded.

5.2.2.2 Evaluation

The measurement results shall be corrected for background and radioactive impurities, and the expected activity value shall be calculated from the known activity and dilution factor of the original solution. For each measurement, the ratio, E_R , between the corrected measured activity and the expected activity shall be calculated. The observed activity value should be plotted relative to the expected activity value and E_R . From this figure, the different values as in 5.2.1.2 shall be found and expressed.

5.3 Secondary test method

5.3.1 Simplified decay source method

5.3.1.1 Test procedure

Except that only one measurement is required for every 10 times difference in the activity level, the procedure used in 5.2.1.1 shall be followed.

5.3.1.2 Evaluation

The measurement shall be calibrated by 5.2.1.2. The measurement of 10 times and 100 times of the background level shall be used; so as to determine the extrapolation to the measurement start time. For each of these two points, at least three readings shall be averaged. For each decimal place of the activity reading, the ratio, E_R , shall be determined. It shall be compared with the corresponding ratio of the reference

mode. The subset of radionuclides shall include high, medium and low energy sources. The manufacturer shall select a subset of radionuclides and product samples for test under the premise of ensuring the volume characteristics of a single device.

8.2 Test methods

The radioactive solution shall be introduced into a sample container with a known calibration value; and the volume of the solution shall be 1/10 of the maximum volume that can be contained in the container. The container shall be introduced and measured at the measuring position of the equipment. After correction for background and decay, the average standard deviation of these measurements shall be specified after correction for background and decay. The volume shall also be specified. The non-radioactive solution volume shall be added to the sample container. The volume shall be 1/10 of the maximum volume that can be contained in the container. The non-radioactive solution shall have the same chemical form and density as the radioactive solution. The measurement shall be performed at the same position as the above. This process shall be repeated until the maximum range is reached.

8.3 Evaluation

The A_V value (measured value at volume V) shall be plotted relative to V on the linear graph; with A_V as the Y-axis and V as the X-axis. From the fitted curve, the value A_{V_0} of the reference volume V_0 shall be determined; V_0 serves as the volume of the determined system accuracy (see 4.2). The sample volume characteristics are obtained by determining the ratio of A_V to A_{V_0} .

9 Measurement of Background Response

9.1 Overview

For each reference device, a test to determine the inherent background response and response to a known radiation field shall be performed. As a secondary test process, these tests shall be performed on periodic selection samples of each product drawn from a given model. Sample selection shall be done in this way: the manufacturer can guarantee the inherent background response and the response to the known field of each other device.

9.2 Inherent background response - test method

The equipment shall be placed where the radiation level is lower than $0.2\mu\text{Sv/h}$. The radionuclide factor of ^{137}Cs shall be used. The background correction shall not be set. A series of measurements shall be taken. The average value shall be recorded. The average standard deviation of the measurement shall be stated.

9.3 Background response to known radiation field - test method

12 Accompanying Document and Performance Statement

Each radionuclide calibrator shall carry a document containing the following information:

- a) The type and pressure of the gas filled in the ionization chamber;
- b) The size of the ionization chamber well;
- c) The size of the source support;
- d) Type and thickness of shielding;
- e) The maximum deviation of the test parameters between the reference device and other devices shall be determined and explained;
- f) The radionuclide factor and instrument accuracy obtained by the relevant test method (Clauses 4 or 5) for each radionuclide and each sample container with a suitable reference volume (with or without shielding is optional);
- g) Under the reference volume, corresponding to ^{99m}Tc , the maximum activity of the instrument being calibrated;
- h) The system repeatability of the full-scale activity value available in the ionization chamber;
- i) The system linearity reported in unit of activity;
- j) Air-density characteristics (only for unsealed ionization chamber);
- k) For each sample container type and the sample volume characteristics for each radionuclide;
- l) Inherent background effects (with or without shielding is optional);
- m) The background effect determined in 9.3 (with or without shielding is optional);
- n) Long-term repeatability and its reference date of the radionuclide factor of the ionization chamber test source (with or without shielding is optional);
- o) The radionuclide content of the ionization chamber test source (including pollutants and their half-lives);
- p) A certificate describing the test results obtained by a specific device.

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