Advances in Medical Physics and Applied Sciences

Review Article
DOI: https://doi.org/10.63187/ampas.28
Adv Med Phy App Sci, 2025; 1(3): 97-104

Quality Control Tests For Thyroid Uptake Device And Intraoperative Gamma Probe Device

YÜKSEL, Alptuğ Özer [1], HACIOSMANOĞLU, Tuğba [2], PARLAK, Yasemin [3]

[1] *Ankara Bilkent City Hospital Nuclear Medicine Clinic, Ankara ,Turkey*
[2] *University of Health Sciences , Gülhane Vocational School of Health Ankara,Turkey*
[3] *Manisa Celal Bayar University Nuclear Medicine Clinic,Manisa,Turkey*

Correspondence:
Alptuğ Özer YÜKSEL Ankara Bilkent City Hospital Nuclear Medicine Clinic, Ankara ,Turkey
alptug.ozer.yuksel@gmail.com

Received: *8 July 2025*
Revised: *11 August 2025*
Accepted: *23 September 2025*

ABSTRACT

In the 21st century, the healthcare system is undergoing a significant change in terms of emphasis on "quantitative quality", with evidence-based outcomes being targeted along with patient safety and satisfaction. Every medical product should be subjected to predetermined and established tests to verify its quality, performance, efficacy, safety, reliability, stability, etc. The quality system ensures that unfavorable situations are identified and necessary arrangements are made before the start of the application. From the point of view of our profession, these practices will prevent further radiation exposure of patients and employees and it will be possible to detect systems that have lost their performance compared to the time they were installed.

Keywords: *Throid Uptake Device, Intraoperative Gamma Probe Device quantitative quality,radiation exposure,safety.*

INTRODUCTION

A quality management system (QMS) was established with the idea of building quality policies and objectives on a documentation system that includes clearly defined processes, procedures and responsibilities, with the main objective of helping to coordinate activities in order to meet regulatory requirements and continuously increase effectiveness and efficiency. Nuclear medicine has been an inherently multidisciplinary approach as it involves many different professional competencies, each with its own regulations, processes and outcomes. It must therefore incorporate a comprehensive quality management system. Quality management system in nuclear medicine,

- Clinical applications, including the use of equipment and their Quality Assurance and Quality Control,
- Radiopharmaceutical preparations and their Quality Assurance and Quality Control,
- They should be capable of answering clinical questions such as radiation protection of both patients, staff and the environment.

It was brought to the agenda with the Health Transformation Program in 2003 in our country and in this context, the General Directorate of Health Services initiated quality in health studies and finally published the Health Quality Standards, Hospital (Version 6) set in 2020. In addition, the REGULATION ON QUALITY CONFORMITY AND QUALITY CONTROL TESTS, the first version of which entered into force in 2022 and received its last revision in December 2023, was published by TİTCK and the quality conformity tests to be applied for the devices covered by the regulation; the minimum equipment required for the

tests, the relevant standards / guidelines / instructions that can be taken as reference are clearly stated. In this article, we will try to explain the quality conformity and control tests related to the Thyroid Uptake Device and Intraoperative Gamma Probe Device, which are valid in the TİTCK regulation.

THYROID UPTAKE DEVICE

The Thyroid Uptake System is a device that measures the iodine uptake capacity of the thyroid gland. This device is especially used in the evaluation of thyroid function, diagnosis of thyroid diseases and planning of radioactive iodine treatment [1].

Areas of Use

A thyroid uptake device calculates the iodine uptake rate of the thyroid gland, usually using radioactive iodine (I-123 or I-131) [2]. The uptake of radioactive iodine into the thyroid gland reflects the functional activity of the thyroid. It is widely used in the diagnosis of thyroid diseases such as hyperthyroidism, hypothyroidism and nodules. It is also used to determine the optimal dose for radioactive iodine therapy (RIT) and to control iodine uptake after treatment [8].

Device Features

Detector System: Usually includes a gamma detector. This detector measures how much radioactive iodine is collected in the thyroid. Calibration The instrument must be calibrated at regular intervals. This is necessary to ensure accurate and reliable measurements of the radioactive source. Dose Calculation: The device calculates the administered dose of radioactive material and its uptake rate in the thyroid gland, which is critical in the treatment process.

Application Features

- The patient drinks a small dose of radioactive iodine (usually I-123 or I-131). This iodine is absorbed by the thyroid gland.

- Between 2 and 24 hours after ingestion of radioactive iodine, the patient is measured under a thyroid uptake device. The device detects gamma rays of radioactive iodine in the thyroid gland and calculates the iodine uptake capacity of the thyroid.

- The thyroid uptake percentage is calculated and provides information about thyroid function. A high uptake rate usually indicates hyperthyroidism, while a low uptake rate may indicate hypothyroidism or iodine deficiency. The control tests that should be performed for the Thyroid Uptake System are listed in the table.(Table 1).

Table 1. The quality control tests for the Thyroid Uptake System.

Test Name	Test Procedure	Frequency	Expected Result / Acceptable Error Margin
Physical Inspection	Visual inspection of the device's exterior, cables, buttons, screen, and components for damage or contamination.	Before each use	No physical damage, dust, or contamination should be present. No error margin in visual inspection.
Background Count Rate	The device is operated without a radioactive source for a set period (5-10 minutes) to measure background radiation levels.	Before each use	Environmental radiation effect should be within a ±2% error margin.
Energy Calibration	Using a Cs-137 source, the device's energy response is tested, and calibration adjustments are made if necessary.	Before each use	Must comply with the manufacturer's test procedure. An error margin of ±3% is acceptable.
Sensitivity	A low-activity Tc-99m source is placed at a fixed distance (e.g., 10 cm). The count rate is recorded and compared to reference values at different distances.	Before each use	Count rate should match reference data within ±2√n limits and ±3% error margin.
Counting Accuracy (Stability)	A low-activity I-131 source is measured at regular intervals (e.g., daily) to assess long-term stability and consistency.	Every 3 months	Results must fall within a 95% confidence interval based on the Chi-square test.
Energy Resolution	Measurements are performed using I-123 and I-131 sources to determine the device's ability to distinguish between different energy peaks.	Every 6 months	Energy resolution should be better than 10%; acceptable error margin is ±4%.
Linearity	Tc-99m sources with varying activities (e.g., 100 µCi, 200 µCi) are measured to check for a linear relationship between activity and count rate.	As recommended by the manufacturer / Periodically	Measured values should correlate linearly with known activities. Deviations require recalibration.
Energy Accuracy	Using a known gamma energy source (e.g., I-131 at 364 keV), the measured peak is compared to the expected energy value.	As recommended by the manufacturer / Periodically	Energy peak should match the known value. Deviations must be corrected via adjustment.

1. Physical Review

Test Preparation

- The external surface of the device, cables and connections are carefully visually inspected. Any physical damage or wear is checked.

- Buttons, display and other functional components are checked for proper functioning.
- The external surface and internal components of the device are cleaned of dust and dirt.

Frequency: It is recommended to be done before use.

Conclusion: Visual inspection has no margin of error, but may vary depending on the operating condition of each component.

2. Background Count Rate

Test Preparation

- The device is operated for a certain period of time (5-10 minutes) without a radioactive source.
- The background counts obtained are recorded.

Frequency: It is recommended to be done before use.

Conclusion: It tests whether the device minimizes the effect of environmental radiation (background). 2% margin of error is acceptable.

3. Energy Calibration

Test Preparation

- A radioactive source Cs-137 (1 μCi) with a known energy level is used.
- The device is adjusted according to the energy level of the source.
- The measurement results of the instrument are compared with the calibration source.
- Calibration settings are made if necessary.

Frequency: It is recommended to be done before use.

Conclusion: The manufacturer's procedure should be used to verify whether the device is within the range of test results that can be considered appropriate. 3% margin of error is acceptable.

4. Sensitivity

Test Preparation

- A known radioactive isotope such as Tc-99m with low activity (100 μCi) is usually used for the test.
- The source is placed at a certain distance (e.g. 10 cm) from the detector of the device.
- The counting rate (cps) measured by the device is recorded.
- Sensitivity change is monitored by measuring at different distances.
- The counts obtained are compared with known reference values.

Frequency: It is recommended to be done before use.

Conclusion: The accuracy of the welding activity should be calibrated against national standards. It should be within the limits ($\pm 2\sqrt{n}$) determined according to the value in the reference test. Values measured at different distances are expected to be regular. The source and counting conditions in the reference test must be met. 3% margin of error is acceptable.

5. Counting Accuracy (Stability)

Test Preparation

- A low activity (10 μCi) I-131 radioactive source is selected.
- The device measures the supply at regular intervals (e.g. every day).
- The data obtained is recorded to assess consistency over time.

Frequency: It is recommended to be done in 3-month periods.

Conclusion: X 2 value should be within the 95% confidence interval.

6. Energy Separation Power

Test Preparation

- Radioactive sources I-123 (50 μCi) and I-131 (50 μCi) are selected at two different energy levels.
- The device measures both sources separately.
- The energy separation power of the device is determined by comparing the measurement results.

Frequency: It is recommended to be done in 6-month periods.

Conclusion: It must be within the test result range specified by the manufacturer for which the device can be considered suitable. Energy separation power shall be better than 10%. 4% margin of error is acceptable.

7. Other tests that are expected to be within the test result range in which the device can be evaluated as appropriate together with the hardware / documents (technical document, user manual, etc.) determined by the manufacturer during the use

processes of the medical device and other tests specified by the users.

Also some other tests not included in the TİTCK guidelines;

Linearity

Test Preparation

- Tc-99m is used for different activities (e.g. 100 μCi, 200 μCi, etc.).
- For each activity, the counting rate detected by the device is recorded.
- Check for a linear relationship between the measured count rate and the known activity.

Conclusion: The difference between the known value of the activity and the measured values must be within acceptable limits. If there are deviations, the instrument must be recalibrated.

Energy Accuracy

Test Preparation

- A radioactive source with a known energy spectrum is used (for example, the gamma rays of I-131 with an energy of 364 keV).
- The energy spectrum of the device is measured and its peak and width are analyzed.
- The measured energy peak is compared with the known energy value of the source.

Conclusion: This test determines whether the instrument can accurately detect a given gamma photon energy. Energy resolution and accuracy should be within acceptable limits. If there are deviations, the energy settings must be corrected.

INTRAOPERATIVE GAMMA PROBE DEVICE

The Intraoperative Gamma Probe Device is a device used in nuclear medicine and surgery that helps surgeons identify radioactive tissues during surgery by detecting radioactive labeled substances [4]. This device is especially important in the surgical removal of cancerous tissues or sentinel lymph nodes (the first point of spread). These devices support minimally invasive surgery and help preserve healthy tissue [9].

Areas of Use

The intraoperative gamma probe device is used in cancers such as breast cancer and malignant melanoma to detect and surgically remove the sentinel lymph node, the first step in the spread of cancer. A radioactive isotope is injected near the cancerous tissue, then the gamma probe device is also used during surgery to detect radioactive lymph nodes or Parathyroid glands and identify the correct tissues to remove.

Device Features

Detector System: The intraoperative gamma probe device has a detector that can detect gamma rays emitted from radioactive isotopes. The detector is usually handheld and small in size so that surgeons can easily use it in the operating field.

Audible and Visual Warnings: The device guides the surgeon by providing audible or visual signals in areas where the radioactive source is concentrated. This feature is particularly useful for locating tumors or lymph nodes in sensitive areas.

Easy Portability: It has a compact and ergonomic design suitable for use during surgery. It is important that the device can be practically carried and used in the surgical environment.

Application Features

- Before surgery, the patient is injected with a radioactive isotope (for example, Technetium-99m or I-131). This isotope binds to the target tissue, usually the tumor or sentinel lymph node.
- During surgery, the surgeon uses the gamma probe to locate tissues where the radioactive isotope has accumulated. The gamma probe device emits audible alerts when it detects the area where the radioactive source is located.
- Radioactive tissues detected with the help of the device are surgically removed. This helps to remove the cancerous tissue or sentinel lymph nodes completely.

Quality control and calibration tests for gamma probe equipment should be performed at regular intervals to ensure that the equipment is working correctly and to obtain reliable results [3, 5]. The control tests that should be performed for the intraoperative gamma probe are listed in the table.(Table 2).

Table 2. p values for biochemical parameters between experimental groups.

Test Name	Purpose / Description	Test Frequency	Acceptance Criteria / Result
Battery Check	Checking the battery charge status.	Before each use	±5% deviation is acceptable.
Physical Inspection	Visual inspection of the device's surface, buttons, and screen.	Before each use	No defects allowed. Must be physically intact.
Background Count Rate	Checking whether the device correctly measures natural background radiation.	Before each use	±2% deviation is acceptable.
Sensitivity	Verifying the device detects a radioactive source correctly depending on the distance.	Before each use	±3% deviation is acceptable.
Short-Term Sensitivity Stability	Evaluating the measurement stability of the device over a short period.	Every 6 months	X^2 test should be within 95% confidence interval.
Energy Resolution	Checking the ability to distinguish sources with different energy levels.	Every 6 months	±4% deviation is acceptable.
Sensitivity in Scattering Environment	Measuring the device's sensitivity in a scattering environment.	Before each use	±4% deviation is acceptable.
Side Shielding Sensitivity	Testing the performance of the device when shielding material is applied on the side.	Before each use	±3% deviation is acceptable.
Scattered Radiation Sensitivity	Testing the device's measurement ability under scattered radiation conditions.	Before each use	±5% deviation is acceptable.
Spatial Resolution in Scattering Environment	Evaluating the ability to distinguish two sources in a scattering environment.	Before each use	±6% deviation is acceptable.
Volume Sensitivity for Distributed Activity	Checking measurement accuracy for sources distributed in different volumes.	Before each use	±5% deviation is acceptable.
Side and Back Shielding	Evaluating the device's performance under side and back shielding conditions.	Before each use	±5% deviation is acceptable.
Manufacturer-Specified User Tests	Other tests specified by the manufacturer for user checks and compliance with technical documentation.	Before use / As specified	Must meet manufacturer's specified limits.
Linearity	Testing if the count rate remains linear across different activity levels.	Before each use	Should be linear, calibration required if deviation.
Energy Accuracy	Checking that maximum counts are recorded at the expected energy value.	Before each use	Energy peaks must match the source.
Directionality Test	Testing the device's ability to detect the source at different angles.	Before each use	No significant deviation allowed at different angles.

1. Battery Check

It is applied to battery-powered systems and it should be verified whether the battery is sufficient for the period of use.

Test Preparation

- The gamma probe turns on.
- The battery status is displayed on the screen. If the charge level is below 20%, it is recorded that the battery needs to be charged.
- A measurement is made of how long the device runs on a full charge.

Frequency: It is recommended to be done before use.

Conclusion: 5% margin of error is acceptable.

2. Physical Review

Test Preparation

- The external surface and components of the device are visually inspected.
- Buttons, display and other functions are tested.

Frequency: It is recommended to be done before use.

Conclusion: Visual inspection has no margin of error, but may vary depending on the operating condition of each component.

3. Background Count Rate

Measures whether the gamma probe detects background radiation. It should be verified that there are no other sources in the environment during the test and the instrument should minimize the counts of background radiation.

Test Preparation

- The device is operated for a certain period of time (5-10 minutes) without a radioactive source.
- It is checked whether the device detects natural radiation (background radiation) present in the environment.
- The background count values obtained are recorded. These counts are expected to be below a certain value (e.g. 5-10 cps).

Frequency: It is recommended to be done before use.

Conclusion: If the instrument's background counts are higher than normal, ensure that the detector part of the instrument is shielded and properly isolated and check for environmental radiation sources. 2% margin of error is acceptable.

4. Sensitivity

It is tested how effectively the gamma probe detects gamma rays emitted from the radioactive source. It is required to be within the range of test results that the device specified by the manufacturer can be considered appropriate.

Test Preparation

- A known radioactive isotope such as Tc-99m with low activity (100 μCi) is usually used for the test.
- The source is fixed at a certain distance from the detector of the gamma probe (for example, at a distance of 10 cm).
- The count rate (cps - counts per second) detected by the device is recorded.
- The sensitivity of the device is tested at different distances (e.g. 5 cm, 10 cm, 15 cm) and the counts at each distance are noted.
- Measured counts are evaluated against the known activity of the source. The count rate is expected to decrease with distance and activity.

Frequency: It is recommended to be done before use.

Conclusion: If the device counts efficiently depending on the distance, its sensitivity is normal. If there are significant deviations, the instrument may require calibration. A margin of error of 3% is acceptable.

5. Short Term Sensitivity Stability

Test Preparation

- A low activity (100 μCi) Tc-99m radioactive source is selected.
- The device measures the supply at regular intervals (e.g. every day).
- The data obtained is recorded to assess consistency over time.

Frequency: It is recommended to be done in 6-month periods.

Conclusion: X 2 value should be within the 95% confidence interval.

6. Energy Separation Power

Test Preparation

- Radioactive sources I-123 (50 μCi) and I-131 (50 μCi) are selected at two different energy levels.
- The device measures both sources separately.
- The measurement results are compared to determine the energy separation power.

Frequency: It is recommended to be done in 6-month periods.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered appropriate. 4% margin of error is acceptable.

7. Sensitivity in Scattering Environment

Test Preparation

- To test the device, low activity (50 μCi) Tc-99m is placed in a scattering medium (e.g. a container of water or a tissue model).
- The device measures the source from different angles and distances.
- The measurement is repeated under the same conditions.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered appropriate. 4% margin of error is acceptable.

8. Side Armoring Sensitivity

Test Preparation

- Side armoring materials (e.g. lead) are placed around the device.
- A low activity (10 μCi) I-131 radioactive source is placed together with the shielding material.
- The device measures the source together with the armoring material.
- The measurement is repeated under the same conditions.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered appropriate. 3% margin of error is acceptable.

9. Scattered Radiation Sensitivity

Test Preparation

- A low activity (75 μCi) Tc-99m radioactive source is placed so as to generate scattered radiation (e.g. at a distance of 15 cm).
- The device measures the scattered radiation and the data is recorded.
- Measure again under the same conditions.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered appropriate. 5% margin of error is acceptable.

10. Spatial Separation Power in Scattering Media

Test Preparation

- Two separate radioactive sources Tc-99m (50 μCi) are placed at a certain distance (e.g. 5 cm).
- The device tests the ability to distinguish between two sources.
- Measurement is repeated at different distances.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered suitable. 6% margin of error is acceptable.

11. Volume Sensitivity to Scattered Activity in Scattering Media

Test Preparation

- Prepare the volume (e.g. a liquid medium) in which the radioactive material will be dispensed.
- The radioactive source I-131 (20 μCi) is dispensed.
- The device measures dispersed activity.
- Repeat measurement at different volumes.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered appropriate. 5% margin of error is acceptable.

12. Side and Rear Armoring

Test Preparation

- Side and rear armoring materials (e.g. lead) are used.
- A low activity (100 μCi) Tc-99m radioactive source is placed together with the shielding material.
- The device measures the source under shielding and the data is recorded.

Conclusion: It should be within the range of test results that the device specified by the manufacturer can be considered appropriate. 5% margin of error is acceptable.

13. Other tests that are expected to be within the test result range in which the device can be evaluated as appropriate together with the hardware / documents (technical document, user manual, etc.) determined by the manufacturer during the use processes of the medical device and other tests specified by the users. Also some other tests not included in the TİTCK guidelines;

Linearity

Test Preparation

- Tc-99m is used for different activities (e.g. 100 μCi, 200 μCi, etc.).
- For each activity, the counting rate detected by the device is recorded.
- Check for a linear relationship between the measured count rate and the known activity.

Conclusion: This test tests whether the instrument gives accurate results for radioactive sources of different activities. If the instrument gives accurate

counts for sources of different activities, its linearity is normal. If there are deviations, the instrument may require calibration.

Energy Accuracy

Test Preparation

- A radioactive source with a known energy spectrum is used. For example, the photon energy of Tc-99m is 140 keV.
- The device should detect this energy and show the highest count on the spectrum around 140 keV.
- The energy spectrum is compared to the instrument's energy settings and the peak and width are measured.

Conclusion: This test tests how accurately the Gamma probe detects gamma rays in a given energy range. If the instrument is operating in the correct energy range, the energy accuracy is good. If a wide energy range is detected, the energy resolution of the instrument may be low and may need calibration.

Directionality Test

Test Preparation

- The radioactive source is held in a fixed position.
- The device is tested by placing the source at different angles to the detector. For example, the probe is placed at 0°, 30°, 60°, 90°, etc.
- Detection capacity and counting rates at each angle are recorded.

Conclusion: This test tests the ability of the Gamma probe to detect gamma rays from different angles. The instrument should not show a decrease or increase in the count rate at certain angles. If there are deviations, there may be a problem with detector alignment.

References

1.Quality control of nuclear medicine instruments. IAEA TECDOC 602. Vienna: International Atomic Energy Agency; 1991.

2.International Electrotechnical Commission. Nuclear medicine instrumentation-Routine tests-Part 1: Radiation counting systems. 2001. IEC/TR 61948-1. http://www.iec.ch.

3.NEMA NU-3. Performance measurements and quality control guidelines for non-imaging intraoperative gamma probes. Rosslyn, VA: National Electrical Manufacturers Association; 2004.

4.Wengenmair W, Kopp J, Sciuk J. Quality criteria of gamma probes: Requirements and future developments. In: Shauer AJ, Becker W, Reiser MF, Possinger K, eds. The sentinel lymph node concept. Berlin Heidelberg New York: Springer; 2005.

5.Chiesa C, Toscano F, Mariani M, Bombardieri E. Physical performance parameters of intraoperative probes. In: Mariani G, Giuliano AE, Strauss HW, eds. Radioguided surgery: A comprehensive team approach. New York: Springer; 2008.

6.Busemann Sokole E, Płachcinska A, Britten A; EANM Physics Committee. Acceptance testing for nuclear medicine instrumentation. Eur J Nucl Med Mol Imaging 2010;37:672-681.

7.Busemann Sokole E, Płachcinska A, Britten A . EANM Working Group on Nuclear Medicine Instrumentation Quality Control. Routine quality control recommendations for nuclear medicine instrumentation. Eur J Nucl Med Mol Imaging 2010;37:662-671.

8.European Commission. Radiation Protection 162. Criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy. 2012.

9.Matheoud R, Giorgione R, Valzano S, Sacchetti G, Colombo E, Brambilla M. Minimum acceptable sensitivity of intraoperative gamma probes used for sentinel lymph node detection in melanoma patients. Phys Med 2014;30:822-826.