Guidelines on the Quality Assurance of Intraoperative Gamma Probes

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Contents

Introduction

This document is intended as a guide for the quality assurance (QA) of intraoperative gamma probe systems, at a level that should be accessible to non-radiation specialists. Publication of this document by the UK Gamma Probe Group has been prompted by the introduction of the sentinel node biopsy procedure into the management of Breast Cancer within the UK (1). A technical specification questionnaire document is also available for use in the purchase process (2).

A further document published by the Group (3) defines an evaluation protocol comprising a set of functional measurements devised to permit the performance of a probe system to be objectively characterised. For each probe system under consideration, the user is actively encouraged either to conduct the performance measurements according to this evaluation protocol within their own institution, or to access a set of data obtained by the manufacturer, the UK Gamma Probe Group or other experienced users. Having performed the baseline characterisation it is then necessary to carry out a series of regular checks on the system as part of an ongoing QA programme.

The objective of QA is to ensure the safety and diagnostic accuracy of the equipment during surgical use. The QA measurements are based on procedures described in the standards publication NU-3-2004 published by the US National Electrical Manufacturers Association (4). The measurements to be undertaken are simple to perform and only require a simple test object and a radioactive source. An example is given of a type of simple test object to hold the probe and a source, but users may devise other methods to achieve the same outcome.

Note that the manufacturer's directions for operational use and Quality Assurance procedures must be carefully read and followed, since each particular probe may have special requirements. The advice in this document is meant to add to these procedures, and to inform the user in their application of the manufacturer's recommendations. Nothing in this document over-rides the responsibility of the user and the manufacturer to correctly use and maintain the equipment.

The document has a description and explanation of each proposed QA test, a recommendation of frequency, and an indication of how long each test should take.

A pro-forma procedure is given in an appendix, as a skeleton example for editing to produce your own equipment specific procedures

The authorship of this document is outlined in Appendix 1.

QA Procedures

During routine surgical use over a period of time probe equipment may become damaged or develop faults. In cases where the damage or fault is obvious the surgeon will be aware of the malfunction and use alternative equipment, or even reschedule the procedure. In some cases however the fault may not be so obvious and the malfunction could lead to the collection of incorrect data or misleading information that could adversely affect the clinical procedure and the clinical outcome.

The following procedures should be performed regularly to ensure that the gamma probe is functioning safely and within the manufacturers' specifications. These procedures do not identify any minimum level of performance, but aim to ensure that routine measurements are made under standardised test conditions, so that ongoing measurements can demonstrate consistent operation and performance.

The quality control tests are listed under the headings given below

1. Visual Inspection
2. Power supply
3. Sensitivity
4. Energy window

Visual Inspection

A Gamma Probe system is made up of the hand-held probe and any collimators, the cable and plugs and the analyzer unit containing the electronics for the detection of signal from the probe, and the visual display of counts and sound generation. All components should be regularly checked for signs of physical damage. In particular the probe and collimators should be checked for nicks, cracks and chips that would indicate damage or deterioration of the outer surfaces. Surface cracks and chips could lead to a loss of shielding or ingress of moisture. Signs of damage to the probe tip could indicate physical shock to the probe, which may result in a

loosening of the detector crystal with loss of directional properties, shift in spectral response or change in sensitivity.

Take particular care to examine for any cracks or sharp edges which could lead to biological contamination or result in tears in the sterile sheath during surgery.

The cables and connectors should be examined for damage such as nicks, exposed wires, crushed sections and loss of insulation.

It is important to consider aspects of electrical safety and the possibility of electric shock even from battery powered units which may operate at several hundred volts to the probe. Equipment with any exposed wiring or damage to the insulation should be taken to the hospital medical equipment servicing unit or returned to the manufacturer for repair.

Frequency of check:

Visual inspections should be carried out prior to surgery on each day the probe is to be used.

Estimated time to perform:

5 minutes.

Power Supply

Mains powered systems should have their power cable checked for damage by visual inspection. A note of the correct fuse rating and occasional check is recommended.

Some surgical probe systems have internal batteries for electrical power. The battery cells are usually housed in the analyser unit. If rechargeable batteries are used they should be charged in accordance with the manufacturers instructions. It is worth noting that rechargeable cells contain a memory which will be established on the initial charge when first used. It is important to ensure that this full charge is established on first use and that the system is then properly charged prior to each surgical session. The life of rechargeable batteries may be extended by being drained at regular intervals, at a frequency and following a method recommended by the manufacturer.

If reserve batteries are installed, users should keep track of battery reserve and arrange for replacement or recharging following the manufacturers recommendations.

Frequency of check:

Before every use.

A reserve battery supply, if fitted, must be checked following the manufacturers recommendations.

Estimated time to perform:

5 minutes to check, but note that re-charging batteries will usually take several hours.

Sensitivity

Measurement of the sensitivity is the most important single parameter that will indicate change or failure, such as crystal damage, probe gain shift, energy window drift or electronic fault.

The purpose of this test is to demonstrate that the count rate detected by the system is reproducible over time given that all the equipment settings are constant. Sensitivity is expressed in counts per second per unit activity (cps/MBq).

The activity of the source must be measured accurately (±5%). This could be achieved by measurement of a Tc-99m liquid source using an accurate and stable radionuclide calibrator. However, for convenience and absolute constancy of the source activity, a long- lived solid source of radioactivity is ideal. Co-57 is the preferred radionuclide since it has a relatively long physical half-life (270 days), a gamma energy of 122keV (similar to that of Tc-99m) and will often be available in the Nuclear Medicine Department in the form of a “pencil marker” or “disk marker” for routine use in patient positioning in nuclear medicine imaging.

To carry out this test on a routine basis it is important that the source can be positioned at a constant distance away from the probe in a stable and reproducible manner.

The measurement may be carried out in air or for convenience using a simple test object made from Perspex. An example of such a test object is

given in Figure 1, allowing the tip of the Co-57 pencil source containing between 0.5 and 5 MBq to be positioned at least 30 mm from the tip of probe, which is inserted into the hole in the top of the block. Other devices may be used to position a Co-57 disk source, with different sized holes being used to accommodate the range of probes in use.

All system settings, should be set as for routine clinical use, including the energy window. Users should note that this means that the Co-57 test source is being counted with the window set to Tc-99m, that is, an “Incorrect” window. This is justified since the energy window for Tc-99m will overlap with the Co-57 photopeak for all current probes, and so a detectable count rate will be obtained. Changes in the sensitivity within the Tc-99m window will therefore still be detected with this arrangement, though it is possible that future probes will have narrower energy windows and so will not give sufficient counts – refer to the manufacturer if in doubt.

Note that the use of the standard clinical energy window setting also reduces the risk of the probe energy window being left set on Co-57 after the QA check.

A timed period of counting to measure a minimum of 5,000 counts should be set and the counts per second recorded. Note that some systems may only allow a short fixed counting time (say 10 seconds), in which case it may be necessary to repeat this count interval several times to collect a total of at least 5,000 counts. Deviation of a control reading from the mean of more than 2 standard deviations (sd) should occur less than 5 % of the time; repeat the measurements if this occurs, and if the reading is more than 2 sd from the reference mean value take investigative action.

Note that the expected value (the “reference mean value”) should be established when the QA programme is first set up. Obtain a measure of the sensitivity with exactly same set up as for routine checking, recording at least 10,000 counts in a set time. Calculate the count rate (cps) and record this as the reference value. This reference value must be corrected as the standard source decays (Co-57 has a half life of 270 days).

Faults may be indicated by either a fall in counts (less sensitive) or a rise in count rate (more sensitive), and all changes in sensitivity, both gain or loss, must be investigated.

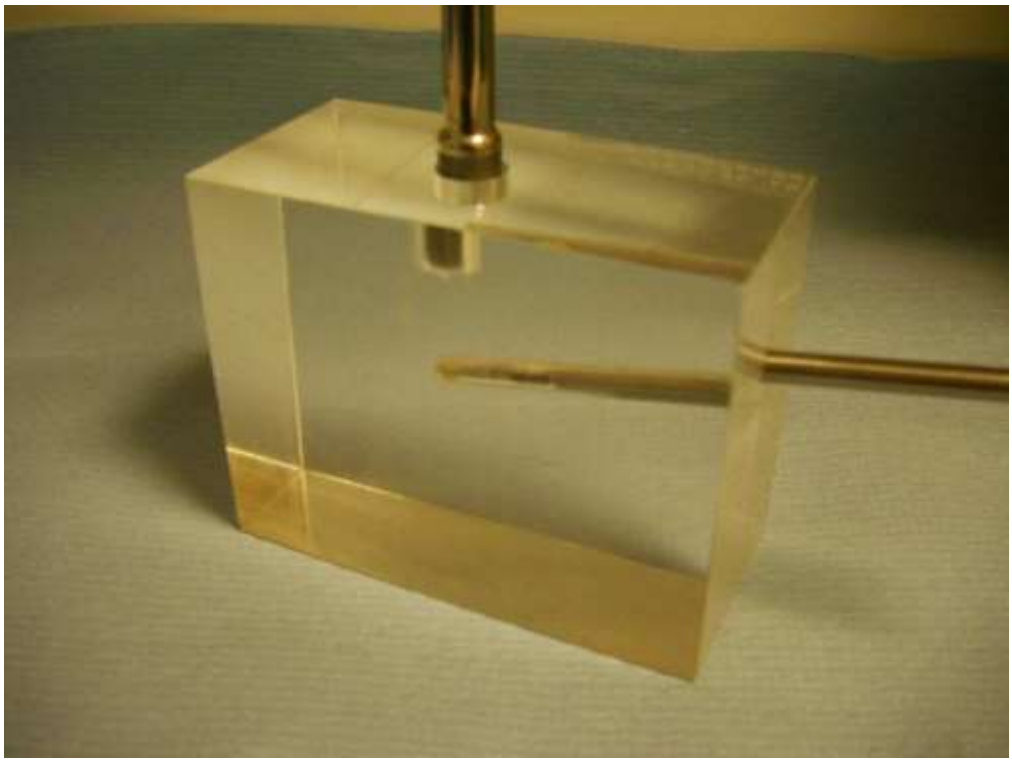
Frequency of check:

On each day of use or a minimum of once a week.

Estimated time to perform:

15 minutes

Figure 1: A Perspex test block suitable for the measurement of probe sensitivity. The probe is placed vertically in a drilled hole on the upper surface with the detector face directly above the tip of a Co-57 pencil source inserted into a second drilled hole. The distance between the probe tip and the pen tip is about 30 mm.



Energy Window

The probe system is designed to accept gamma rays of the appropriate energy. The gamma energies of the gamma emitting radionuclides most commonly used for intraoperative surgery are listed below.

Radionuclide	Energy (keV)
Tc-99m	140
I-123	159
In-111	171 and 245
Co-57	122

The standard procedure for sentinel node detection uses Tc-99m-labelled colloid, and so the Tc-99m isotope energy window must be set on the analyzer following the manufacturer's instructions.

It is crucial that the correct setting is used for all surgical procedures.
The same window must be used for all QA procedures to ensure reproducibility between QA measurements, and if a non-Tc-99m window is set for QA, say to match a Co-57 check source, then the person performing the QA must take particular care to re-set the window to Tc-99m.

Changes to the energy window will be reflected in the sensitivity checks, so there is no recommended separate test of the energy window.

Some systems may allow more detailed inspection of the energy window and/or the spectrum of detected events, and the manufacturer's procedures should be followed to apply these tests.

Frequency of check:

The selection of the energy window to that for the isotope in use should be checked on every occasion the system is used either surgically or for QA tests, following the manufacturer's instructions.

Estimated time to perform:

1 minute or less to check the correct setting of the isotope window.

Documentation

It is recommended that a work-sheet is produced to document the dates and results of regular QA procedures. Numerical data may be displayed graphically so that any gradual trend or deterioration in performance may be seen more clearly.

Such records should be kept to be available for audit of the proper management of radiation detectors.

References

1. Clinical Protocol for the Application of the Sentinel Node Technique to Breast Cancer. UK Steering Group for Sentinel Node in Breast Cancer.

2. Intraoperative Gamma Probe Procurement Document – Standard Specification Questionnaire. UK Gamma Probe Working Group. April 2004.

3. Intraoperative Gamma Probe Procurement Document – Performance Evaluation Protocol. UK Gamma Probe Working Group. 2004.

4. NEMA Standards Publication NU 3-2004. Performance Measurements and Quality Control Guidelines for Non-Imaging Intraoperative Gamma Probes. National Electrical Manufacturers Association, Rosslyn, VA 22209, USA (www.nema.org).

Appendix 1: The UK Gamma Probe Working Group.

The UK Gamma Probe Working Group is a group of Medical Physicists established in April 2004 to provide support to the application of Gamma Probe technology in Nuclear Medicine and Surgery.

The group is working with the knowledge and the approval of the British Nuclear Medicine Society (BNMS) and the Radionuclide Special Interest Group of the Institute of Physics and Engineering in Medicine (IPEM), but is not an official group of either body.

The group membership at January 2005 is:

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W.D. Evans, University Hospital of Wales, Cardiff.

P. Hinton, IPEM nominated member, Royal Surrey County Hospital, Guildford.

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W.B. Tindale, BNMS nominated member, Royal Hallamshire Hospital, Sheffield.

W.A. Waddington, University College London Hospitals, London.

Appendix 2

Pro-forma skeleton Protocol for Probe QA, to be edited for specific equipment.

This brief protocol is based upon guidelines from the UK Probe Working Group, V1 2005.

1. Check the probe for physical damage.

Pass [ ] Fail [ ] Comment:

2. Check the cables and connectors for signs of physical damage.

Pass [ ] Fail [ ] Comment:

3. Check that the battery is charged (delete if not applicable).

Pass [ ] Fail [ ] Comment:

4. Check any reserve power supply (delete if not applicable).

Pass [ ] Fail [ ] Comment:

5. Is there a removable collimator fitted?

Yes - In place – Pass [ ] Missing – Fail [ ]

6. Sensitivity check:

a. Set the energy window to the clinical setting for Tc-99m.
b. Position the Co-57 test source in the holder (check that this is the correct Co-57 check source if there is more than one in use).
c. Position the probe in the holder.
d. Set a timed count to record at least 5,000 counts (or repeat a shorter interval until the total counts is above 5,000 – record the total time interval).
e. Calculate the count rate (cps) (“control value”) and the standard deviation.
f. Correct the control count rate for radioactive decay since the time of collection of the Reference count.
g. Compare the decay corrected control count rate to the reference value, calculating the standard deviation between the reference and control readings, taking into account the radioactive decay correction. An example spreadsheet is available for this calculation.

h. Is the control reading within the acceptable range (less than 2 standard deviations from the reference value)?
    i. NO – test failed:
        1. Repeat the procedure, checking all steps, especially the probe energy window settings, the presence of any collimator, and the source identification.
        2. If the reading is still outside of the range, call your support personnel (Medical Physics, Nuclear Medicine, Manufacturer etc).
        3. Do not use until expert advice obtained.

    ii. YES – test passed: set the energy window to the clinical setting for Tc- 99m and continue to clinical use.