

QUALITY CONTROL OF NUCLEAR MEDICINE INSTRUMENTATION AND PROTOCOL STANDARDISATION

EANM TECHNOLOGISTS GUIDE

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Foreword

In the ever-evolving field of nuclear medicine (NM), technologists are at the intersection between the clinical, research and academic domains, embodying the bridge towards patients. Quality has become an unavoidable word in NM practice. In the last two decades, NM has earned an established place in various clinical areas on the basis of the advances in respect of evidence-based practice and high-level research. Naturally, nuclear medicine technologists (NMTs) have been and will be involved in the clinical, research and academic domains and therefore require the necessary tools to carry out their tasks in compliance with best practice. This is the main motivation for choosing Quality Control of Nuclear Medicine Instrumentation and Protocol Standardisation as the topic for our annual Technologist's Guide.

The Technologist's Guide is an annual publication envisioned and edited by members of the EANM Technologist Committee (EANM-TC). It is one of the many EANM educational initiatives and has the aim of completing the training of NMTs and encouraging scientific exchange within the NM community. The Technologist's Guide was and continues to be a reference for educational standards inside and outside Europe.

As the topic of this guide encompasses a very broad range of applications, we decided to divide the book into three parts. The first part focusses on the principles of quality and standardisation, an understanding of which is needed in order to completely grasp the more practically oriented parts 2 and 3, which are devoted to imaging procedures and non-imaging instrumentation, respectively.

This book is a multidisciplinary effort involving different professional groups that

work to achieve the same outcome in the domain of NM: maintenance of the best practice standards to ensure optimal implementation of patient-focussed diagnostic and therapeutic procedures. I am extremely grateful to all authors for sharing their expertise, which has been fundamental to the successful completion of this Technologist's Guide. I would like to thank the EANM Physics Committee, the SNMMI-TS (Society of Nuclear Medicine and Molecular Imaging Technologist Section) and the International Atomic Energy Agency (IAEA) for their help in ensuring the outstanding quality of this book. I am very much indebted to the EANM-TC editorial and language revision group for their dedication in reviewing and editing this guide. Finally, thanks are due to the EANM Board, the EANM Technologist Committee and all of those involved in the Technologist's Guide project.

Pedro Frago Costa
Chair, EANM Technologist Committee

Introduction

Technologists are members of the team required for implementation of diagnostic imaging in nuclear medicine (NM). In many hospitals, the technologists are responsible for the quality assurance (QA) duties. The development of hybrid imaging has increased further the need for strict implementation of quality control (QC) and also rendered QC more demanding. These new guidelines from the EANM Technologist Committee address the tasks necessary for the smooth implementation of QC in NM departments.

Quality control is required to ensure that NM equipment is functioning properly and constitutes an important part of the quality management in an NM department. The described QC tests are designed to detect problems before they affect clinical patient studies. They are intended to provide a full evaluation of equipment performance and to ensure that equipment is performing properly after service or adjustment.

Quality control is important due to the need to optimise patient exposure and image quality during NM imaging examinations. The image quality is dependent upon the data acquisition parameters, which must be adapted to the detector system and also the reconstruction algorithm, on the basis of which the acquisition time can be shortened or the administered activity of the radiopharmaceuticals can be decreased.

These guidelines cover the principles of QC and QA, including QC and improvement of imaging protocols for both imaging and non-imaging instrumentation. The first part describes separately the

QC tests for conventional NM modalities such as planar gamma camera imaging, SPECT and PET and also for hybrid methods such as SPECT/CT and PET/CT. An individual chapter is devoted to CT system QC as this constitutes an important element in the optimisation of acquisition protocols. The second part covers image optimisation protocols for SPECT/CT and PET/CT modalities and accreditation for clinical trials. The third part describes QC of non-imaging instrumentation, such as radionuclide dose calibrators, intraoperative probes, body uptake probes and well counters.

This overview of QC and protocol optimisation will be a valuable tool for technologists and all clinical staff involved in this particular field.

In the name of the EANM Technologist Committee, I would like to thank all the authors who have taken the time to prepare and write the chapters and to all the editors who have helped to create this book.

Sebastijan Rep
on behalf of the editors

QUALITY CONTROL OF NUCLEAR MEDICINE
INSTRUMENTATION AND PROTOCOL STANDARDISATION

PRINCIPLES OF QUALITY CONTROL AND QUALITY ASSURANCE

by Goran Vuleta

Quality is an important factor for any product or process in medicine. It is widely recognised that the attainment of high standards of efficiency and reliability in the practice of nuclear medicine, as in other specialties based on advanced technology, requires an appropriate quality assurance programme^[1].

In order to maintain or improve the quality of equipment and processes, careful attention must be paid to the two standard concepts of quality assurance and quality control:

» **Assurance:** the act of giving confidence.

Quality assurance (QA) is a way of preventing mistakes or failure in products. QA is a **process-focussed concept**. It is a systematic process implemented within a quality system (Table 1).

» **Control:** the act of guiding a process.

Quality control (QC) is a process involving the inspection of equipment to ensure that the quality of all aspects is sat-

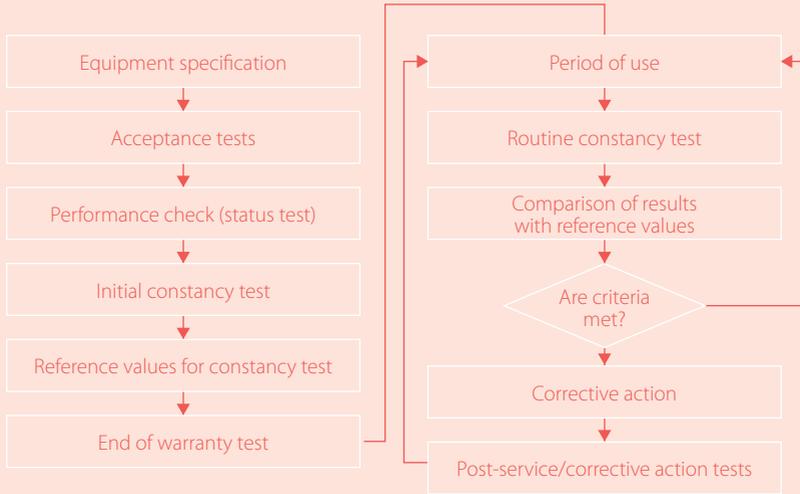
isfactory. QC is a **product-focussed concept**. It comprises a set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of performance criteria (Table 1).

Hence, QA in nuclear medicine should cover all aspects of clinical practice. Specifically, QC is necessary in the submission of requests for procedures; the preparation and dispensing of radiopharmaceuticals; the protection of patients, staff and the general public against radiation hazards and accidents caused by faulty

	Quality assurance	Quality control
Activities	Set of activities for ensuring quality in processes	Set of activities for ensuring quality in products
Aim	To prevent defects	To identify (and correct) defects
Process	Proactive	Reactive
Means of achievement	Planned and systematic activities, including documentation	Activities or techniques to achieve and maintain the product quality, process and service
Responsible persons	Everyone involved in the process	Specific team that tests the product
Tool	QA is a managerial tool	QC is a corrective tool

Table 1: Quality assurance versus quality control

Figure 1



QA and QC cycle for a medical imaging device (based on information in [3] and [4])

equipment; the scheduling of patients; the setting-up, use and maintenance of electronic instruments; the methodology of the actual procedures; the analysis and interpretation of data; the reporting of results and, finally, the keeping of records^[1].

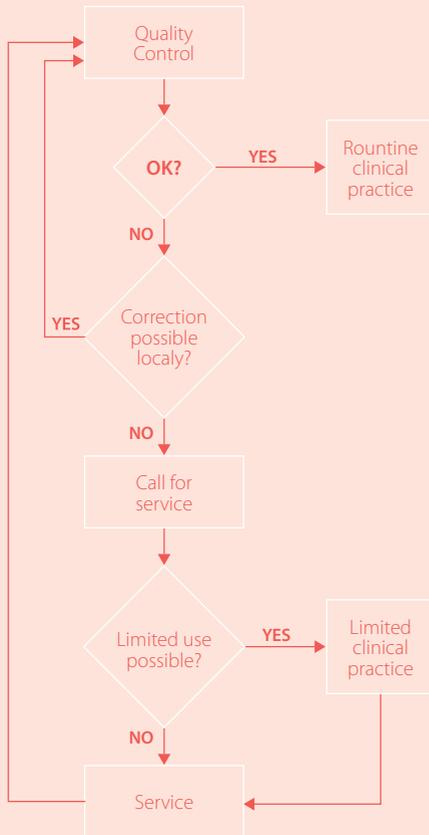
A fundamental principle in the QC of nuclear medicine instruments is that it should be undertaken as an integral part of the work of the nuclear medicine unit and by members of the unit staff themselves^[2]. All equipment used in nuclear medicine for examinations (diagnostic procedures) or treatment (therapy) must be subject to internal QC (Fig. 1).

Routine QC testing starts after installation of the instrument and continues until end use.

After installation, and before it is put to clinical use, a nuclear medicine instrument must undergo thorough and careful acceptance testing, the aim being to verify that the instrument has been installed and performs in accordance with its specifications and its clinical purpose^[5]. For each instrument, a set of basic specifications is produced by the manufacturer. These specifications should be traceable.

Acceptance testing verifies the manufacturer's specifications.

Figure 2



Example of a flowchart for a QC programme (based on information in [2])

At the same time, reference tests should be undertaken. These reflect operating conditions under clinical conditions and provide results against which to test the ongoing performance of the equipment by routine testing at weekly, monthly, quarterly or yearly intervals.

A basic level of routine QC is required to ensure that nuclear medicine equipment is functioning properly. Routine QC tests are intended to detect problems before they impact on clinical patient studies (Fig. 2). Once the instrument has been installed and accepted for clinical use on the basis of the acceptance testing results, its performance needs to be tested routinely with simple QC procedures that are sensitive to changes in performance. Tests must be performed by appropriately qualified and trained staff, and detailed local operating procedures should be written for this routine work. All test results must be recorded and monitored for variations, and appropriate actions taken when changes are observed. The QC tests are an important part of the routine work, and sufficient equipment time and staff time must be allocated for routine QC^[5]. All test results must be recorded and monitored.

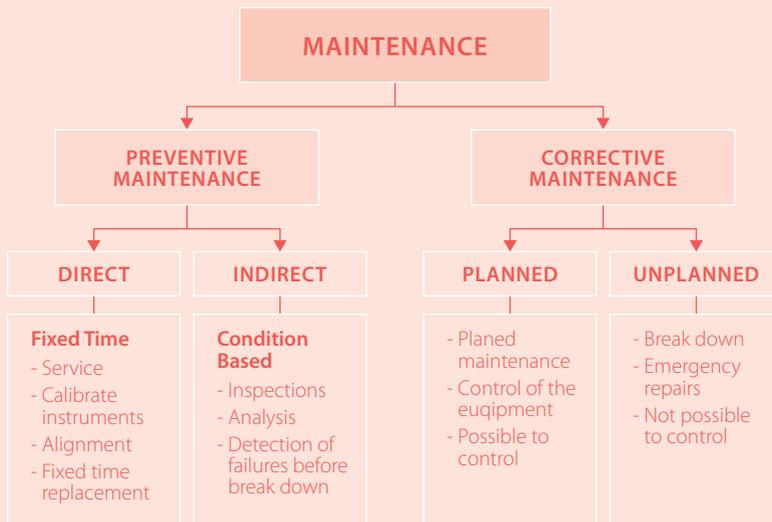
The QC of each instrument should have as its starting point the selection and procurement of the instrument itself, because instruments may differ in their characteris-

tics and performance. The recommended frequency of QC tests depends on the stability of the equipment. The routine testing can be performed on a daily, monthly, quarterly or annual basis.

The siting of an instrument in the department is largely determined by its expected use. The selection of a location for mounting the instrument can affect the performance of the instrument (e.g. crystals in scintillation detectors), and therefore the QC. Further parameters that can affect the proper functioning of the instrument are:

- » Availability of space (sufficient space for the instrument, for the clinical practice and for QC and maintenance procedures)
- » Electrical power supplies (which must follow instrument specifications regarding voltage and frequency)
- » Temperature, humidity and air pollution (stable temperature and slow temperature gradients, low humidity and clear air)
- » Background radiation levels (location of the hot cell, the storage and movement of radioactive materials, and the movement of patients)

Figure 3



Types of maintenance

All of the instruments used in nuclear medicine are complex systems built from mechanical, electrical and electronic parts. Any of these components can fail at some point in time. For this reason, the maintenance of instruments is necessary.

The goal of maintenance is to avoid the consequences of equipment failure. Maintenance of instruments is divided into two categories (Fig. 3):

- » Preventive maintenance: a fundamental, routine and planned maintenance activity to keep equipment in operating status and to avoid unplanned maintenance activity.
- » Corrective maintenance: a set of activities to detect and rectify a defect so that the equipment is returned to its normal state.

Preventive maintenance in nuclear medicine means the maintenance of equipment in a given functional state through continued overviews, QC and detection and elimination of possible failures. Corrective maintenance in nuclear medicine means the restoration of equipment to a functional status by means of repairs.

As already noted, all obtained results, from the installation of equipment through to acceptance tests and then QC procedures, need to be recorded and stored. It is necessary that, apart from the

results of QC, there is a written description of all QC procedures, acceptable levels of tolerance and corrective measures in the event that results are not within the level of tolerance.

Records must be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system^[6]. All records must remain legible, readily identifiable and retrievable. They must be permanent and non-erasable, as must changes to a record^[6]. Record keeping is a main component of an internal QC programme. Records showing frequent malfunction and degradation of equipment performance provide evidence of the need for complete instrument repair or replacement.

Record keeping may include (depending on the equipment):

- » Instrument condition (physical, mechanical and electronic)
- » All calibration records
- » QC results
- » Instrument maintenance records

The record keeping can be used to:

- » Monitor compliance with QC procedures
- » Educate employees
- » Help prevent instrument breakdowns
- » Evaluate service personnel
- » Help ensure reliable patient results

Recognition by the head of department and the management of the institution of the need for QC is essential to its satisfactory implementation and adequate funding.

It is necessary to clearly define who is responsible for each aspect of QC as well as who will supervise the entire QC plan. That person must know all the technical details and should be involved in the evaluation of the results. It is important that tests for certain instruments are carried out by people familiar with their use, and responsibility for daily and operational tests should rest with the operators who regularly use these devices.

If the results of certain tests show a deviation from the allowed tolerance and acceptability it is necessary to decide whether the instrument is fit to be used or needs to be put out of operation. This decision must be the responsibility of people with clearly defined responsibilities.

The choice of tests and the frequency of their performance must be specified for each device in nuclear medicine in order to take account of their condition and their status. Protocols should be adapted to suit individual instruments. It is essential that these protocols are strictly followed.

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INTERNAL AND EXTERNAL AUDITING OF QUALITY MANAGEMENT SYSTEMS: THE APPROACH OF THE INTERNATIONAL ATOMIC ENERGY AGENCY

*by Maurizio Dondi,
Thomas Pascual
and Diana Paez*

INTRODUCTION

The health care sector is highly regulated and relies on state-of-the-art diagnostic technologies. Additionally, health care costs are usually covered by a third party, such as an insurance company or a government programme. Third party payers request suppliers to show, and document, that their products are not only controlled, to ensure consistency, but also provided in adherence with national regulations regarding patient and worker safety, and that medical practice is based on evidence.

This requires the identification of quality policies and objectives and the production of a documentation system with clearly defined processes, procedures and responsibilities. Such a system is usually referred to as a quality management system (QMS) and its purpose is to help coordinate and direct activities in order to meet customer and regulatory requirements and to improve effectiveness and efficiency on a continuous basis. In health care, effective quality management is focussed on the needs of patients because they are the ones who judge the effectiveness of treatments and the appropriateness of the service.

Quality management in health care requires the close cooperation of people with diverse expertise and is essentially about delivering consistent quality, which, in turn, is dependent upon reliable processes. Reliability requires the existence of performance goals, risk reduction procedures, quality improvement policies,

quality measurement systems and reward mechanisms.

NUCLEAR MEDICINE AND QUALITY MANAGEMENT

Nuclear medicine services (NMS) are multidisciplinary by nature as several different professional competencies are involved, each with its own regulations, processes and outputs. However, they all contribute to the success of the discipline. For this reason, a comprehensive QMS is not limited to quality assurance/quality control (QA/QC) but has to involve all aspects of NMS, including but not limited to: clinical applications, including machinery handling and their QA/QC; radiopharmaceutical preparations and, again, their QA/QC; radiation protection of both patients and staff and of the environment; and the ability of final reports to satisfy clinical questions.

Several factors may influence the structure of a QMS in nuclear medicine, includ-

ing the size and structure of the NMS and the financial resources available. The latter in turn have an effect on the complexity of clinical practice, which may vary from limited applications to more sophisticated ones. But, whatever the situation, any NMS should implement, document and maintain a QMS. Its effectiveness should be continuously improved in accordance with the requirements of professional, regulatory and also standardisation or accrediting bodies.

A QMS should include:

- » A quality manual (QM) with a clearly defined “Policy of Quality” confirming the willingness to act appropriately to attain objectives and describing the tools to be employed in order to achieve the stated goals. The creation of a QM is the first step: here the organisation’s strategies are clearly identified, with statement of goals and description of plans to achieve those objectives. Main processes, as well as supporting processes, are defined, including roles and responsibilities. When possible, objectives should be described in quantitative or qualitative terms with measurable indicators of processes and monitoring of routine activities.
- » A departmental organisation chart with clear definition of roles and responsibilities and reporting lines.
- » Written standard operating procedures (SOPs) for both primary (diagnosis and therapy) and supporting processes and their reference documents, such as guidelines from scientific societies.
- » Records of indicators and parameters.
- » Identification of a quality manager, to be appointed by and to report to the head of the organisation. The quality manager will be in charge of the operations and application of the QMS. This role can be assumed by a person who has other duties within the organisation.
- » A documentation control procedure, to keep under control all documents concerning the QMS, including their storage, updating and distribution to staff.
- » Procedures for human resources development, concerning the recruitment of staff and their continuous professional development, where necessary.
- » The QM should also provide evidence that internal audit reviews are being periodically carried out, with the aim of verifying that the procedures are being followed, ensuring that they are congruous with the established goals and establishing whether there are possibilities to improve them.

The QMS standardises the processes to guarantee consistency in providing high-level services to patients, referring physicians and other stakeholders in a

safe environment. The NMS management ensures the availability of necessary resources and information to support the operation and for monitoring of processes. The management also ensures the effectiveness of the QMS through self-assessments, data analysis, verification of activities and management reviews.

THE QUANUM PROJECT OF THE IAEA

The IAEA (www.iaea.org) is one of the organisations of the United Nations (UN) system and has the mission of supporting peaceful applications of nuclear technologies in the UN member states, which number more than 170. Therefore, in addition to activities in many other fields, it has a long history of providing assistance in the specialty of nuclear medicine. In many of these countries, NMS are rare and often isolated and practitioners have serious difficulties in exchanging experiences with their peers and even in accessing scientific journals.

On the basis of its awareness of the very different levels of quality of practice and the need to raise them to internationally recognised standard levels, the Nuclear Medicine Section of the IAEA planned the preparation and the implementation of a project called Quality Management Audits in Nuclear Medicine (QUANUM). The aim of the project was to provide

nuclear medicine practitioners in low- to middle-income countries with a tool that would help them identify areas of weakness in their practices, raise awareness of international standards and eventually encourage the implementation of an annual systematic audit process for the nuclear medicine practice as a whole. Following various interactions among meeting participants, a manual entitled *Quality Management Audits in Nuclear Medicine Practices* (QUANUM) was published in 2008.

For the first time, a unique and holistic programme covering all the disciplines involved in the delivery of nuclear medicine was made available to practitioners worldwide, and in the subsequent years the QUANUM tool was successfully applied across the world. Lessons were learned from the first IAEA expert missions, and throughout this period the specialty of nuclear medicine continued to develop rapidly. Consequently, the IAEA recognised that there was a need to update the manual so that it would reflect current and best practices in NMS. The new edition was published in 2015 under the title "Quality Management Audits in Nuclear Medicine Practices, Second Edition. IAEA Human Health Series No. 33". It is accessible at <http://www-pub.iaea.org/books/IAEABooks/10714/Quality-Management-Audits-in-Nuclear-Medicine-Practices-Second-Edition>.

The QUANUM methodology

The QUANUM methodology aims at defining a comprehensive auditing procedure that covers all aspects of nuclear medicine and is designed to be applicable in a variety of settings (bearing in mind the global discrepancies in availability of resources and the great diversity in economic circumstances). Adopting this methodology will allow the NMS to demonstrate the level of efficiency, quality, safety and reliability in delivering clinical services. The overall quality depends on the inventory of strengths and weaknesses together with the critical appraisal of the 'variables' as observed in practice. The primary goal is to raise the standards of nuclear medicine practices by fostering the introduction of a culture of quality management into routine daily work.

To this purpose, and taking into account the multidisciplinary aspects of nuclear medicine, the QUANUM process is accomplished by completing a comprehensive quality checklist which focusses on the following key areas and is available at https://humanhealth.iaea.org/HHW/NuclearMedicine/QUANUM_2.0_Excel_Tool_and_QNUMED/index.html:

- » Strategies and policy
- » Administration and management
- » Human resources development
- » Radiation regulation and safety

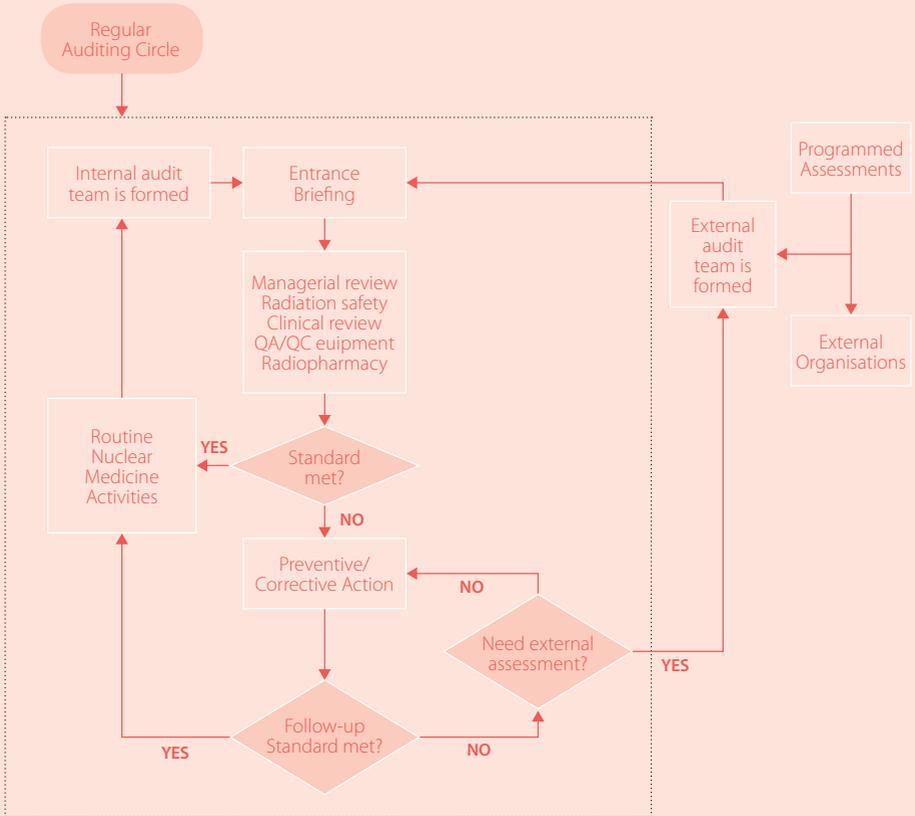
- » Radiation protection aspects relating to patients, staff, public and environment
 - » Evaluation of the quality system
 - » Quality control of equipment
 - » Computer system and data handling
 - » Clinical services (assessment of diagnostic procedures and therapy)
 - » Assessment of non-imaging procedures
- Assessment of hospital radiopharmacy (three different possible levels) and laboratories (hormones and tumour markers)

Internal and external audits and audit review procedure

A quality audit process has to be patient oriented, systematic and outcome based. It should include regular internal checking, assessment and review. It will further reinforce the system of documentation in a busy clinical setting and should be carried out on a regular basis to ensure adequate quality of practice in nuclear medicine (*internal audits*).

For the *internal audit*, the head of the NMS selects the audit team leader, usually the quality manager, who will be in charge of the audit and selects the other members. The audit team consists of staff members with extensive knowledge of the current procedures of the NMS. An audit team may include the following members: nuclear medicine physician, medical physicist, radiopharmacist, nuclear medicine technologist/radiographer, radiation safety officer, delegates of nuclear

Figure 1



The internal and external auditing cycle (adapted from: *Quality Management Audits in Nuclear Medicine Practices*, Second Edition. IAEA Human Health Series No. 33. Vienna, 2014)

medicine administrative and nursing staff and a representative from the hospital administration and QMS. It is advisable to include independent persons from other services of the institution who represent the end-user group (e.g. oncologists, cardiologists, endocrinologists, nephrologists, administrators).

Following the internal audit, an *external audit* by international experts may be carried out if necessary. The flow chart of the cycle is shown in Fig. 1.

For the *external audit*, the composition of the team is agreed among the parties: the criteria of multidisciplinary, auditing competencies and independence should be adopted as indicated above for the internal audit team.

Besides self-assessment based on QUANUM, the completion of the IAEA web-based nuclear medicine database (<http://nucmedicine.iaea.org/>) is a prerequisite for IAEA external audits.

Components of the audit and responsibilities of the audit team

As part of the procedure, standardised audit practices include:

- A. Entrance briefing:** The entrance briefing is required to introduce the audit team and to present the staff, finalise the agenda and discuss the objectives, methods and details of the audit. The
- auditors should assure the staff that confidentiality (including patient confidentiality) will be respected, and that, if required by the host, an appropriate document to this effect will be signed. Audit teams nominated by the IAEA have signed such a confidentiality document before the audit.
- B. Actual assessment,** which includes:
 - a. A complete tour of the premises
 - b. Review and evaluation of procedures and all relevant documentation, including review of treatment records
 - c. Observation of practical implementation of working procedures
 - d. Staff interviews
 - e. Meeting with the management of the institution and/or associated educational institution
 - f. Review of the previous audit (self-assessment according to QUANUM)
 - g. Filling the audit checklists
- C. Operational information:** As part of their responsibilities, the audit team collect all management and operational information, including (but not limited to):
 - a. Updated copies of licenses/accreditation documents
 - b. Organisational flow chart and function descriptions
 - c. Samples of SOPs

- d. Samples of study reports
- e. Copies of data regarding patients' waiting times
- f. Updated information on waiting lists
- g. Copies of QC data for relevant equipment and radiopharmaceuticals
- h. Radiation safety records
- i. Copies of letters of appraisal/complaints
- j. List of deviations and non-conformances
- k. Customer/stakeholder satisfaction surveys

D. Exit briefing: The preliminary feedback from the auditors is documented and presented to the staff of the NMS and any other relevant key person during an interactive exit briefing. This includes time for questions and an open discussion on all the findings of the auditors. The institution is then encouraged to give an immediate response to the assessment. The steps intended by the institution to react to the recommendations should be part of the action plan. With the aim of defining priorities, non-conformances are scored and then prioritised as:

- a. Critical:** issues impacting the safety of patients, staff, caregivers and/or environment that should be promptly addressed (within days or weeks). Discontinuation of the con-

cerned activity might need to be considered.

- b. Major:** issues impacting the capacity of the NMS to adequately perform its activities that should be addressed in a timely manner (e.g. 3–6 months).
- c. Minor:** issues that may be the object of optimisation, to be accomplished within a defined time period and re-evaluated during the next audit.

Particularly, where a critical non-conformance has been found, the action plan should be sent to the audit team for further interaction. If appropriate, the service has the responsibility to notify the regulatory authorities.

- E. Conclusion** of the audit and report: The audit report contains conclusions identifying critical, major and minor priorities with clear and practical recommendations.

Minimum requirements and conformance and non-conformance scoring

A scoring system has been designed to evaluate the level of conformance as indicated in Table 1, where the system is explained using the example of documentation of clinical procedures.

Items marked as NA will not be included in the assessment of the final scores. The

Score	Description	Example
NA	Not applicable	When a particular activity is not in place (e.g. laboratory determinations for tumour markers)
0	Absent or inappropriate	No documents available
1	Planned or approximate	Documentation is planned or exists as an informal draft
2	Partially conforming or partially implemented	A limited number of SOPs or most SOPs exist, but important parts are lacking
3	Largely conforming or largely implemented	Most SOPs are complete but some information is missing (e.g. reference to guidelines, dosimetry data) or documents are not being updated regularly
4	Fully conforming or fully implemented	All documentation is in place and SOPs are complete and subjected to review

Table 1: Use of the scoring system for evaluation of the level of conformance: the example of documentation of clinical procedures

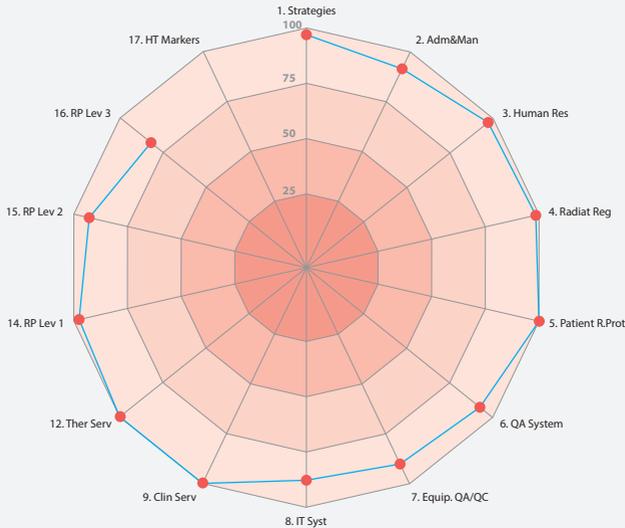
items 'Absent or inappropriate', 'Planned or approximate' and 'Partially conforming or partially implemented' fall into the category of 'Non-Conformance', whereas the elements 'Largely conforming or largely implemented' and 'Fully conforming or fully implemented' are classified as 'Conformance'. The scores are used to build a radar plot to enable visual presentation of the overall results (Fig. 2).

IMPLEMENTATION CHALLENGES TO THE QUANUM PROCESS: FROM VOLUNTARY TO COMPULSORY

As previously mentioned, QUANUM is a voluntary process and self-evaluation

or internal audit is demanded before an NMS engages in the external peer review process arranged by the IAEA through expert missions. However, an emerging trend in clinical practice is the "compulsification" of the audit process for verification of mandatory quality operations. As mentioned by Pascual (2016) "This process of compulsification of clinical audits is not entirely new and exclusive to nuclear medicine practitioners worldwide. Globalization and the neoliberal environment have slowly influenced imposing clinical audits not only in the medical imaging field but in other medical fields as well." As an example, in the European Union, the EN ISO 8402 directive has mandated that clinical audits shall be im-

Figure 2

*Example of a radar plot*

plemented and requires that countries in the European Union formally establish, as a policy, that clinical audits are performed under published and regulated national guidelines.

Following this directive, the QUANUM programme, in slightly modified form, has become the reference standard in some European countries, such as Belgium.

CONCLUSIONS

The QUANUM programme has been very well received by counterparts, who welcome the opportunity to have their daily

practices assessed and audited by colleagues from other countries. Particularly appreciated is the exchange of information and advice received during the visits.

In almost all cases, the visit from international experts for an external audit and the work done in preparing for this audit, including filling of the checklist, has triggered the implementation of a quality system; this in itself represents an excellent outcome. Indeed, the QUANUM programme was conceived exactly for this purpose.

In the majority of the externally audited practices, the audit has shown that

the quality of practice is already satisfactory. On average, almost no difference was found between the scores achieved on pre-mission self-assessments and post-mission evaluation by the external QUANUM team. The average level was 75%, which is indeed a good performance at international level.

In one case, the implementation of a QMS after the QUANUM mission enabled

a centre to achieve a remarkable improvement in its performance after 3 years. This case emphasises the importance of follow-up missions: not only do such missions help in assessing the outcome of the QUANUM programme but also the very fact that they are going to happen empowers audited centres to take corrective actions and pursue the full implementation of their quality system.

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PLANAR CAMERA AND SPECT SYSTEM QUALITY CONTROL

by Mario Medvedec

INTRODUCTION

In the twenty-first century, healthcare systems are undergoing a significant change in that the emphasis is now on 'quantitative quality' through targeting of evidence-based outcomes together with patient safety and satisfaction. In this context, every (medical) product should be subjected to certain tests in order to confirm its quality, performance, efficacy, safety, reliability, stability, etc.

Planar and SPECT scintillation cameras should also undergo different evaluation steps during their life-cycle: factory testing before shipment, acceptance and reference testing after their on-site installation and before their clinical use, and routine periodic quality control (QC) testing thereafter.

After reading this chapter, readers should be able to:

- » define acceptance testing on planar and SPECT scintillation cameras, and understand the reasons for performing such testing;
- » define, understand and explain the need for and the procedures and periodicity of recommended QC tests on planar and SPECT scintillation cameras:
 - daily*: visual and physical inspections, collimator touch pads and emergency stop buttons, energy window settings, uniformity and sensitivity;
 - weekly and monthly*: centre of rotation, bar phantom spatial resolution and linearity, high-count flood uniformity/sensitivity correction map;

quarterly, half-yearly and annually: collimator hole angulation, tilt-angle check, tomographic spatial resolution, SPECT/CT alignment;

- » describe the Jaszczak phantom and understand and explain the procedure for testing of overall SPECT system performance;
- » describe the most common artefacts and explain how to proceed in such cases.

ACCEPTANCE TESTING

Acceptance testing is a set of standard procedures intended to verify that the imaging equipment performs in accordance with the manufacturer's specifications and intended clinical use without any deficiencies or defects. The standard procedures and performance measurements usually employed in acceptance testing are those published by the National Electrical Manufacturers Association (NEMA), International Electrotechnical Commission (IEC) or other international authorities. In addition, some patient studies should be

performed as a part of the acceptance procedure. In this way, acceptance and reference testing provides baseline performance data to be referred to in future QC tests, and supports the final user's decision to accept or reject a particular piece of equipment for safe routine clinical use. The warranty period for the imaging system should begin only when the system has passed acceptance testing by achieving at least the minimum acceptable results under clinical conditions. It should be noted not only that good clinical practice for medical devices entails compliance with professionally agreed and widely accepted technical standards, but also that, at the time of writing, acceptance testing is becoming a legal requirement within the European Union: Member States are to bring into force European Council Directive 2013/59-compatible laws, regulations and administrative provisions by 6 February 2018 and ensure that acceptance testing is carried out before the first use of equipment for clinical purposes^[1–15].

QUALITY CONTROL TESTING

A basic requirement for the successful establishment of quality management systems, quality assurance programmes and QC procedures is that the leadership of healthcare institutions, including nuclear medicine departments, recognises and understands quality-related principles and

is committed to quality-related practices. For many years, QC testing was perceived to be the responsibility of the individual, to be performed at the individual's discretion. In the 1990s, however, aspects of QC testing were incorporated within the European legal framework by European Council Directives, with subsequent merging and updating in 2013. Now, as stated above, the requirement for QC is to be fully implemented in European Union Member States through the introduction, by 6 February 2018, of laws, regulations and administrative provisions necessary in order to comply with European Council Directive 2013/59. In this context, QC means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at the required levels of all characteristics of performance of equipment that can be defined, measured and controlled. Member States shall ensure that performance testing is carried out on a regular basis, and after any maintenance procedure liable to affect performance. Furthermore, Member States shall ensure that the competent authority takes steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective performance of medical radiological equipment in use, and also adopt specific criteria for the acceptability of equipment

in order to ascertain when appropriate corrective action is necessary, including taking the equipment out of service.

Decisions on the types and frequencies of QC tests should take into account overall circumstances and resources in the individual nuclear medicine department in relation to its instrumentation. QC procedures for planar and SPECT scintillation cameras usually include visual and physical inspections and tests in relation to emergency stop buttons, collimator touch pads, background, photopeak and energy window settings, intrinsic/extrinsic uniformity and sensitivity, energy and uniformity calibration, high-count flood uniformity, spatial resolution and linearity, multiple window spatial registration, whole-body scan and tomographic spatial resolution, pixel size, detector head tilt, centre of rotation calibration, overall SPECT system performance and attenuation correction. QC tests are performed on a daily, weekly, monthly, quarterly, half-yearly or yearly basis. Local regulations may require additional checks, but in every case QC testing should be associated with careful record keeping^[1–15].

DAILY QC TESTS

Daily QC tests are usually performed on the morning of each working day or, at least, the day on which the imaging equipment is planned to be used.

Start-up

As the first operational check it is recommended to initialise the planar and SPECT scintillation imaging system by performing the daily reset/start-up procedure, which should complete without any warnings or error messages. It saves time if all power switches are not turned off, so that the detector system does not need to warm up. Ideally, all clocks within the nuclear medicine department, including those of all imaging, counting and computer systems, should be synchronised and checked daily for the purpose of ensuring accurate activity administration and quantitative analysis of acquired data.

Visual and physical inspection of planar and SPECT scintillation cameras should detect external mechanical or electrical defects or damage, particularly with respect to the detector heads and collimators, which may compromise imaging quality and patient or staff safety. If any deficiencies are detected, the imaging equipment should not be used until the problems have been resolved. If the detector's collimator and yoke have a touch pad that halts all motion when contact is made, a touch pad test should be performed on a daily basis and after each change of collimators. An additional operational check should be performed on emergency stop buttons, if available, which should light

and shut down all motor-driven system movements when pressed [1–3, 6, 7, 11–13, 15].

Energy window

Daily operational checks of energy window settings should be performed to confirm that all preset pulse height analyser energy windows are properly centred around the energy photopeaks of the radionuclides to be used with the scintillation camera for clinical imaging purposes, thus suggesting correct energy calibration of the system [1–7, 11–13, 15].

Background

Operational check of the background count rates with or without collimators and within one or more energy windows should be performed daily to detect radiation caused by possible radioactive contamination of the scintillation camera, floor or walls, radiation from some neighbouring unshielded source or an excess of electronic noise. Under constant measuring conditions the background count rates should be approximately constant in all detector directions used for clinical imaging [1–4, 11, 13].

Uniformity and sensitivity

One of the basic assumptions in nuclear medicine imaging is that the response of the imaging system to a uniform irradiation is uniform within defined limits. Observed differences in activity distribution

are then due to the patient only and not the scintillation camera itself. QC testing of intrinsic or extrinsic uniformity and sensitivity of the imaging equipment should be performed daily in order to check the system's response to spatially uniform flux of ^{99m}Tc or ^{57}Co photons. Such a flood field uniformity may be tested qualitatively by visual inspection or quantitatively by calculation of the integral and differential image uniformity within the camera's central field of view and useful field of view. If a daily intrinsic low-count uniformity test is selected, then each collimator should be checked weekly or monthly by an extrinsic high-count uniformity test. Overall sensitivity of the detection system is calculated as count rate per unit activity (cps/MBq) of the imaged radioactive source [1–9, 11–13, 15].

CT checkup and quality

Daily X-ray CT QC testing of the SPECT/CT system should be performed according to the manufacturer's recommended procedures and medical physics expert advice. For instance, it may be recommended to perform daily CT checkup and CT quality procedures which automatically execute a set of CT tube warm-up acquisitions, automatic function checks, and different air and water calibration steps for all available voltage settings, in order to guarantee optimum image quality [2, 11, 12, 15].

WEEKLY QC TESTS

Centre of rotation

Centre of rotation (COR) is by definition a single point around which detectors rotate and which ideally should also be the centre of the projections recorded by detectors at all angles. In other words, the COR is the point at which the axis of rotation and the perpendicular from the centre of the detector plane intercept. The transaxial alignment of acquired projection images with the system's mechanical centre of rotation is critical for accurate generation of tomographic images reconstructed from acquired projection images. Similarly, for the multi-head SPECT system it is crucial that the electronic centre of each angular projection used in the image reconstruction process is consistently aligned with the centre of mechanical rotation. The COR offsets principally vary with collimator type, detector orbit as a function of angle and radius, detector configuration and image zoom factor. The alignments should be checked in both the x- and the y-axis and should stay within acceptable limits given in millimetres. Any error related to COR will lead to image distortion and loss of tomographic spatial resolution, or even the appearance of ring artefacts in reconstructed point source images.

The COR QC test can be performed weekly to monthly by using one, but more

usually by simultaneously using three or more point sources of similar activities of ^{99m}Tc and collecting a specified number of image counts. The sources are placed in the same plane in the air, on and off the axis of rotation and the centre of the field of view. Each detector must be positioned parallel to the axis of rotation and must acquire an image at 0° and 180° . Point sources are imaged at an even number of detector angular positions equally distributed over 360° . COR offsets are easily corrected if the equipment manufacturers provide alignment measurements and software which calculates and includes corrections for COR variations in tomographic acquisition and reconstruction processes [1–9, 11–15].

Spatial resolution and linearity

Spatial resolution is the ability of the scintillation camera to accurately resolve spatially separated radioactive sources. The quantitative measure of spatial resolution is given in millimetres as the full width at half maximum (FWHM) or full width at tenth maximum (FWTM) of the peak of the imaged point or line radioactive sources.

Spatial linearity is the ability of the scintillation camera to accurately determine the position of photons without displacement in relation to the actual position where these photons enter the detector. Spatial linearity is quantitatively expressed in millimetres related to the displacement

of the measured peak location from the best-fit peak location.

The bar phantom is a rectangular or circular sheet of plastic material in which a number of lead bars are embedded in a pattern of parallel stripes, usually arranged into four quadrants of parallel bars. Lead bars of a given thickness are supposed to stop radiation, whereas plastic stripes are supposed to be transparent to radiation. The width of the lead bars and the distance between two bars is equal within one quadrant, but different for each of the four quadrants (e.g. 2, 2.5, 3 and 3.5 mm or 3.2, 4.0, 4.8 and 6.4 mm). The increment of bar separations and widths from one to another quadrant should be small enough to provide reasonably accurate final semi-quantitative estimation of spatial resolution, for instance $\text{FWHM} \leq 8$ mm.

The bar phantom should match the spatial resolution of the scintillation camera in such a way that at least one quadrant of stripes cannot be fully resolved in the acquired bar phantom image. Bar phantoms can be used weekly, biweekly or more infrequently in routine QC testing for visual determination of extrinsic or intrinsic spatial resolution of the scintillation camera, whichever appears more convenient. The same high-count images of bar phantoms can also serve for the evaluation of the scintillation camera spatial linearity, which is normally measured by using the slit phantom. When used for deter-

mination of extrinsic spatial resolution and spatial linearity, the bar phantom is placed directly on the collimated detector. The detector is irradiated either by the flood source placed directly on top of the bar phantom or by the point source placed several metres away from the bar phantom. After collecting the required number of counts with an appropriately set-up camera for the imaged radionuclide, spatial resolution is expressed in terms of the quadrant pattern, with the narrowest stripes still resolvable on the acquired images. When used for determination of intrinsic spatial resolution and spatial linearity, the bar phantom is placed directly on the uncollimated detector and irradiated by the point source placed away from the bar phantom at a distance which is at least five times the largest dimension of the detector. After collecting the required number of counts with an appropriately set-up camera for the imaged radionuclide, the intrinsic spatial resolution can be approximated as $\text{FWHM} = 1.75 \cdot B$, where B is the width of the narrowest bars that the scintillation camera can still resolve. For the purpose of thorough evaluation of spatial resolution and linearity, the bar phantom can furthermore be rotated and inverted in such a way that the quadrant of the bar phantom with the narrowest bars is imaged in each quadrant of the detector in each direction, i.e. with the imaged stripes parallel to the x- and the y-axis of the detector. Moreover, the bar

phantom can be imaged in air at a certain distance from the detector equipped with different parallel-hole collimators or in tissue-equivalent material added between the bar phantom and the collimator.

The purpose of checking spatial resolution and linearity is to detect gradual long-term deterioration of spatial resolution, and to display imaged linear objects as exactly linear as possible, as compared with acceptance and reference measurements. Bar phantom image acquisition may or may not be required by imaging equipment manufacturers, but is done at the discretion of the user [1–9, 11–13, 15].

High-count flood and uniformity

A flood source is typically a rectangular source of uniformly distributed radioactivity, in the form of either a sealed ^{57}Co sheet source or a plastic phantom fillable with a solution of the selected radionuclide. Detector irradiation can also be considered uniform if a point radioactive source is placed away from the detector face at a distance five or more times greater than the largest linear dimension of the detector. Ideally, a uniform irradiation of a scintillation camera detector should produce an image of homogeneously distributed radioactivity. The purpose of acquiring a high-count flood image is to verify uniformity within the field of view of the scintillation camera and to provide a uniformity/sensitivity cor-

rection of its detection system after it has been properly tuned and adjusted. This correction is basically applied by multiplying each particular pixel in acquired images by a factor calculated as the ratio of the average counts in the high-count flood image to the counts in the corresponding pixel in the high-count flood image. Intrinsic uniformity correction corrects for non-uniformities in the detector only, whereas extrinsic uniformity correction corrects for both detector and collimator non-uniformities. The total number of counts to be collected in high-count flood images depends upon the particular procedure and equipment but is typically in the range of tens to one or a few hundred million. Modern scintillation cameras include on-line corrections for detection system variations in energy response, spatial linearity and spatial uniformity across the field of view of the scintillation camera, but these should be periodically verified and re-created if necessary to assure acceptable integral and differential uniformity [1–9, 11–13, 15].

QUARTERLY AND ANNUAL QC TESTS

Collimator hole angulation

Collimator hole angulation is the geometric relationship of the actual collimator holes and septa to the crystal face of the

planar or SPECT scintillation camera or to the axis of rotation of the SPECT scintillation camera. In the case of an ideally collimated and rotating scintillation camera detector, all edges of the holes and septa in a parallel hole collimator should be parallel to each other and exactly perpendicular to the crystal and the axis of rotation. Any differences in these angles are referred to as collimator angulation error. Non-orthogonality in the x-direction (perpendicular to the axis of rotation) actually represents a centre of rotation offset, whereas non-orthogonality in the y-direction (parallel to the axis of rotation) represents scintillation camera head tilt. Both non-orthogonalities can deteriorate the quality of reconstructed images.

Quality control testing of the collimator hole angulation checks the septal alignment and angulation for all parallel hole collimators used. It is performed by using a point radioactive source placed a few metres from the face of the collimator, in the centre of each parallel hole collimator and in four or more other positions approximately halfway to the edge of the field of view. Acquired images should be visually inspected and checked for any asymmetries, streaks and distortions. If the collimator holes and septa do not appear appropriately aligned and angulated, the manufacturer should provide a new collimator [1–4, 6, 11, 13, 14].

Tilt-angle check

The angle of tilt of the SPECT scintillation camera detector is the angle between the detector plane and the axis of rotation, measured along the axis of rotation. Assuming that the axis of rotation is horizontal, the parallel hole collimators should also be levelled exactly horizontally. This adjustment is usually done by careful use of a spirit level or an angle gauge. Head tilt should normally be 0° at the beginning of tomographic acquisition of the correctly set up system, and should remain 0° for all angles of rotation. The angle of tilt can be determined from summed projection images over 360° of a radioactive point source placed off the axis of rotation.

If there is no head tilt, the amplitude of the sinusoidal motion of such a radioactive point source in the y-direction will be equal to zero, showing a constant rather than a sinusoidal pattern in the y-direction of the projection images and a flat rather than ellipsoidal shape (i.e. a short ellipse axis equals zero, while a long ellipse axis equals a distance $2r$ off the axis of rotation) when all projection data in the x- and y-directions are taken together. If there is a head tilt, it can be determined from the length of the short ellipse axis and the known radius of the radioactive point source [1–6, 11, 13, 14].

Tomographic spatial resolution

Tomographic spatial resolution is the ability of the scintillation camera to accurately resolve spatially separated radioactive sources in the images acquired in tomographic mode and reconstructed from the raw data using the filter backprojection technique with a ramp filter. The main quantitative measure of tomographic spatial resolution is the FWHM of the peak of the reconstructed radioactive point or line source, which is given in millimetres for the x-, y- and z-directions. It can be measured in air or in scatter medium, usually by using three point or line sources of similar activity, well centred in the field of view and imaged over the range of 0° to 360° evenly covered by collimated scintillation camera detector(s) rotating at a radius of about 15 cm and collecting a sufficient number of counts in each step. After data acquisition and image reconstruction as outlined above, the corresponding tomographic spatial resolution quantities should be calculated according to the prescribed methods^[1–8, 11–13, 15].

SPECT/CT alignment

One of the prerequisites for accurate overall registration, attenuation correction and anatomical localisation by SPECT/CT hybrid imaging systems is determination of the three-dimensional alignment vector of the SPECT and CT fields of view in

order to allow correction of possible mechanical offset between the SPECT and CT gantry positions. Calibration of the SPECT and CT fields of view must be performed every time the SPECT gantry and CT gantry are separated, and after each major service or upgrade. Thereafter, SPECT/CT alignment should be tested periodically, with the frequency of testing depending on the stability of the particular SPECT/CT system. This QC test is done by performing a SPECT/CT scan using the manufacturer's test objects or a phantom that contains radioactivity (and sometimes contrast agent, too) and is visible on both SPECT and CT. Following SPECT/CT scanning, the image fusion software is used to complete the calibration process and ensure accurate alignment of the SPECT and CT fields of view. The same procedure should be repeated for each collimator set and detector configuration used in bimodal SPECT/CT imaging^[2, 11, 12, 15].

Jaszczak phantom and overall SPECT/CT system performance

Different phantoms are designed for different purposes. Some total performance phantoms are used to check the best performance characteristics of the SPECT imaging systems achievable by time-consuming and high-count non-clinical studies. Other phantoms are used to simulate typical clinical conditions and to show

how the imaging system performs in such situations. Cylindrical phantoms, used in QC testing of system performance, are plastic cylindrical tanks that have different shapes, dimensions, inner structures, inserts and other physical characteristics and are fillable with solutions containing different radionuclides. Image quality parameters which may be evaluated during system performance tests include tomographic uniformity, contrast, resolution, attenuation, noise, linearity and lesion detectability. Two examples of commercially available cylindrical tomographic phantoms are the Jaszczak phantom and the Carlson phantom. A Data Spectrum ECT (emission computed tomography) phantom, usually known as the Jaszczak phantom, consists of a main plastic circular or elliptical tank which contains few parts: a segment of homogeneous radioactivity, a segment of non-radioactive solid spheres of different sizes and a segment of (non-)radioactive rods of different sizes. These segments are used after image reconstruction in order to detect possible ring artefacts and distorted spheres and rods, to evaluate the contrast and spatial resolution of objects of a known size and to calculate the linear attenuation coefficient for attenuation correction if related software is available. The phantoms are typically filled with ^{99m}Tc and are imaged for tens of minutes to acquire high-count

SPECT data to be reconstructed with filtered backprojection and a ramp filter. Different total performance phantoms and studies are used in acceptance, reference or QC testing at less frequent intervals to check for possible slow degradation in the performance characteristics of different low- to ultra-high resolution SPECT systems. Total performance phantom studies are also useful to assess the performance characteristics of SPECT system hardware and software after significant preventive or corrective maintenance and upgrades, or when conducting research activities ^[1–4, 6, 11, 13, 15].

Artefacts

Artefacts in biomedical imaging are misperceptions and misrepresentations of the imaged objects caused by the imaging equipment or the employed image acquisition and processing techniques. Various sudden or gradually developing problems may become evident at any time, but taking appropriate preventive measures – planning, preparing and organising the nuclear medicine facility, conditioning the electrical power supply, performing acceptance, reference and QC testing, carrying out regular maintenance, conducting overall clinical practice competently, etc. – decreases the likelihood of artefacts.

The most common imaging artefacts are: full or partial ring and bull's eye arte-

facts; different forms of distortion; blurrings; variations in intensity; lines and stripes or other discontinuities; local spots of higher or lower intensity; artefacts due to patient movements or metallic objects; artefacts caused by energy spectrum distortions and energy resolution degradation; and artefacts due to decreases in detector sensitivity, poor spatial uniformity, poor contrast and spatial resolution, inadequate image acquisition and processing etc. All of these artefacts are extensively illustrated elsewhere.

According to the general troubleshooting flowchart (including but not limited to artefacts), the acquisition of QC results within acceptable limits is a necessary

requirement before proceeding with routine clinical practice. If full correction of detected problems is possible locally and in a timely way, this should be implemented, with subsequent successful repetition of QC procedures before continuation with daily clinical practice. If correction is not possible, limited use of the imaging system should be considered. For this purpose a call for service is usually made. Depending on the outcome of this call, limited clinical practice may be continued. If immediate service is needed, it should be followed by successful QC testing before again proceeding with full routine clinical practice [1, 3, 4, 6, 13].

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PET SYSTEM QUALITY CONTROL



by Claudiu Peştean

INTRODUCTION

Since the first prototype of a PET/CT scanner was installed in Pittsburg by Townsend in 1998, this technology has been developed in a way that even the most optimistic specialists could never have anticipated.

This trend is due not only to the contribution that PET/CT has made to medicine by virtue of its combined morphological and functional perspective, but also to its wide application in various pathologies, including above all oncologic diseases, against a background of increasing prevalence. In relation to the PET part of the PET/CT technology, it is necessary to underline the importance of quantification of radiotracer uptake in pathological tissues, commonly achieved by calculation of the standardised uptake value (SUV) for fluorine-18 fluorodeoxyglucose (FDG), which reflects the metabolic rate of the tissue and, implicitly, the aggressivity of the tumour. Importantly, PET/CT has also started to be used for radiation therapy planning. As PET/CT has developed into an indispensable imaging procedure in diagnostic and therapeutic strategies, it has become ever more important that reliability of the produced images is ensured. This is achieved by the quality control (QC) and quality assurance (QA) procedures employed to ensure correct scanner set-up and operation^[1].

To understand the concepts of QC and QA tests for PET, it is essential to under-

stand the basic principles of acquisition and reconstruction. Like all diagnostic procedures in nuclear medicine, PET technology uses the ability of scintillator detectors to record signals produced by the interaction of gamma photons with the detector crystals. PET is a technique based on the administration of a radiotracer containing positron-emitting isotopes. With respect to QA/QC, it is not of great importance and is beyond the purpose of this chapter to detail aspects relating to the radiopharmaceutical properties of the radiotracers used in PET. This information may be found in different papers, including the technologist's guide published by EANM Technologist Committee on the subject: *Principles and Practice of PET/CT. Part 2 – A technologist's guide*^[2]. The QC and QA for PET are directly related to the nuclear physics exploited in this technique and to the technology used to create PET/CT images. After administration of the radiopharmaceutical and following allowance for the uptake time, the patient is placed in the scanner and the data are acquired. First, the CT data are recorded based on measurement of the attenuation in the tissues of

the X-rays emitted by an X-ray tube. For this purpose, the patient is placed in the gantry and X-rays are emitted from different angles, traversing the patient and being recorded on the opposite side by a solid state detector. The CT image is produced on the basis of the recorded attenuation values from all the projections, and using specific reconstruction and filtration methods.

The most important aspect of the CT image in PET/CT, besides the anatomical information that it provides, is its utility in correcting the attenuation within the patient's tissues of the gamma photons used to produce the PET image. This process, termed CT attenuation correction (CTAC), is necessary to minimise introduction of bias into the PET image, which should precisely reflect the biodistribution of the radiotracer. Based on the attenuation values calculated with the CT technique, also referred to as CT numbers or Hounsfield units, the tissue densities are calculated; once the density map of the investigated tissues is known, the attenuation of gamma photons detected by PET is calculated. An attenuation map is elaborated and applied to the PET non-corrected image based on the acquired data and the CTAC PET image is produced. This attenuation correction process is performed after the PET data have been acquired. These PET

data are recorded after the CT acquisition. The table moves the patient inside the PET detector. The PET detector (consisting in a multitude of scintillation crystals organised in blocks and modules distributed on a ring with several rows) detects, very close to the point of release, the annihilation photons that are produced when the positrons released by the PET isotopes interact with electrons in the matter. The two photons produced by each annihilation travel through matter in opposite directions and interact with the detector crystals. If these photons are recorded by the detector within the same time window, they are called coincident. If two photons are recorded by two crystals, the system will assume that the annihilation process has been produced somewhere on the line between these crystals, the so-called line of response (LOR). Faster detectors may calculate the time interval between the arrivals of the two annihilation photons and can more accurately estimate the origin of the annihilation process and the presence of the radiotracer; as a consequence, this so-called time-of-flight (TOF) technique offers superior spatial resolution. LOR or TOF information is recorded on sinograms and, using specific reconstruction methods, the PET image is obtained^[3]. In order to gain a fuller understanding of the basic principles of PET and PET/CT, the reader can access the EANM website to consult

the technologist's guide produced for this purpose: *Principles and Practice of PET/CT. Part 1 – A technologist's guide*^[4].

Before any PET image is analysed, it is mandatory to guarantee that quality standards for the equipment are met. This is the aim of the QC and QA procedures which we shall describe in this chapter. We shall try to define the concepts of QC and QA, starting with acceptance testing procedures and then describing the basic QC tests that are required for PET equipment. There are various vendors on the market who provide several types of PET/CT scanner, designed according to the same principles but with slight differences in both the technologies used for detection or reconstruction and the QC and QA procedures. In modern PET scanners, the QC and QA procedures are increasingly automatic or semi-automatic, which excludes potential human errors to the greatest possible extent. Nevertheless, it is important to understand the principles of the technique and to be able to recognise the artefacts than can be produced if QC or QA fails. It is also necessary to know the measures to be taken in this circumstance in order to eliminate errors from the diagnostic information and thereby benefit patients. Here we aim to review the QC and QA procedures that are of the greatest importance in the practice of PET, identify-

ing any relevant differences in relation to the various PET scanners on the market. While we shall describe the principles of the procedures, we shall not detail the practical aspects.

ACCEPTANCE TESTING FOR PET

Since PET and PET/CT techniques were first introduced into clinical medical imaging, the need for standardisation has grown tremendously as the sensitivity and the applicability of the method have increased. In response to this trend, American and European associations and bodies, such as the Society of Nuclear Medicine, the National Electrical Manufacturers Association (NEMA) and the International Electrotechnical Commission, started to establish and develop sets of standards for positron emission tomographs. The benefit is that now all the manufacturers can specify the performance of their equipment using the same set of parameters and standards, which can be measured and verified after installation. NEMA standards have been imposed over time and now all the vendors relate the performance of their equipment to these standards. Following the elaboration of the first NEMA NU2-1994 standard, the need for further standardisation gradually grew, and several updates have since been produced:

NEMA NU2-2001, NEMA NU2-2007 and NEMA NU2-2012^[5].

After installation of the equipment, acceptance testing procedures need to be performed in order to ensure that the levels of performance specified by the manufacturer are met. The acceptance tests and the parameters verified usually refer to the NEMA standards. If the acceptance tests are failed, the system will need to be corrected. It is also important to perform a new set of acceptance tests prior to the end of the warranty.

Depending on the type of scanner, various tests will form part of the acceptance testing procedures and these are discussed below.

Sensitivity

The sensitivity is determined during the acceptance tests, at the end of the warranty and when the system suffers important changes in its performance. For this test, a 7-cm line source of 5 MBq is used, placed in a phantom with five aluminium sleeves with a wall thickness of 1.25 mm. Acquisitions are performed starting with the smallest sleeve and with the source in the centre of the field of view (FOV) (or at 10 cm offset from the centre if variations in sensitivity within the FOV are being checked); for subsequent acquisitions the attenuation is increased by adding the other sleeves one by one. Sensitivity is

analysed by calculating the count rate for each slice and for each sleeve using a decay correction formula and an attenuation correction for each sleeve^[6].

Spatial resolution

The spatial resolution should be assessed during the acceptance testing, at the end of the warranty and whenever there is suspicion that the performance of the equipment has suffered important changes. The principle of the test consists in image acquisition using three point sources (with an activity of approx. 1 MBq) that have a diameter less than 1 mm and are suspended in the air to avoid any effect of scattered radiation; these point sources are placed 1 cm vertically from the centre of the FOV, 10 cm vertically from the centre of the FOV and 10 cm horizontally from the centre of the FOV. Two acquisitions are performed: one in the centre of the axial FOV and one at a quarter of the axial FOV. The spatial resolution is derived on the basis of the full-width at half-maximum (FWHM) of the response function calculated for each source^[6].

Energy resolution

A test relevant for scanners that use only singles-based attenuation correction and calibration is performed by acquiring more than 10 kcts after placing a point source of ^{18}F with an activity of approx. 1 MBq in

the centre of the FOV. Usually, the energy resolution is analysed using the vendor's procedure for energy testing^[6].

Scatter fraction, count losses and random measurements

This test is very important since the scatter and random photons may affect image quality. The test reflects the count rate performance of the scanner, expressed as noise equivalent count rate. To test this, a polyethylene cylindrical phantom of 70 cm length and 200 mm diameter is used; the cylinder is traversed from end to end by a hole that is parallel to the axis and at a radial offset of 45 mm, to contain the line source. From the acquisition data, prompt and random sinograms are obtained and, based on Poisson statistics, the scatter fraction is calculated using the vendor's specifications and applying complex statistical calculations^[6].

Image quality and accuracy of attenuation and scatter correction and quantitation

It is very difficult to simulate the distribution of the radiopharmaceutical in the patient's body and to assess the image quality using a phantom. The image quality, the attenuation and scatter correction and even the quantitation on the PET image can be evaluated reproducing as closely as possible the particularities

of clinical imaging conditions. This can be achieved by acquiring the data using two types of phantom. The first is a body phantom with spheres, a so-called image quality phantom, which consists in three compartments: a body compartment, six hollow spheres with diameters of 1, 1.3, 1.7, 2.2, 2.8 and 3.7 cm and a cylindrical central insert filled with material that simulates lung tissue's attenuation properties. This body compartment of this phantom is filled with ¹⁸F solution. A sphere-to-background ratio of 4:1 is used for the first study for the four smallest spheres (the other two are filled with cold water) and a second study is performed using a ratio of 8:1. The second phantom is used to mimic the radioactivity present outside of the FOV in clinical situations. This is a cylindrical phantom similar to the phantom described for the determination of scatter fraction, with a concentration activity in the line source equal to the concentration of the background compartment of the image quality phantom.

One transverse slice centered on the spheres is used for image analysis. ROIs are drawn on each sphere and in addition 12 ROIs are drawn in the background compartment at a distance of 15 mm from the edge. The per cent contrast is calculated for each sphere (hot and cold) in relation to the background average counts measured on the previously drawn ROIs.

The accuracy of the attenuation and scatter correction is estimated using ROIs drawn on the lung compartment. The counts measured in the lung insert of the phantom are related to the counts measured in the ROIs placed in the background compartment as described above.

Using the option provided by the software, the concentration of the radioactivity is displayed and compared with the true radioactivity concentration, known from the time of preparation of the ^{18}F solution when filling the phantom^[6].

Coincidence timing resolution

Coincidence timing resolution is estimated by histogramming the differences in the arrival times of annihilation photons after acquiring data using a point source placed in the centre of the FOV within a scattering material^[6].

Uniformity of the reconstructed image

This test is a measure of the system response to a homogeneous radioactivity distribution. A cylindrical hollow phantom filled with ^{18}F solution or, alternatively, a cylindrical $^{68}\text{Ge}/^{68}\text{Ga}$ cylindrical phantom is used. On the reconstructed slices, the non-uniformities are assessed by determining the counts on square ROIs of 1×1 cm. The evaluation is performed on each slice and the maximum value of non-uniformity should be within

the tolerance values established by the manufacturer.

PET normalisation

Even when non-uniformities are within the tolerance level, it is important that the reconstructed image is normalised to ensure optimal uniformity. For this purpose, a rotating ^{68}Ge or a uniform ^{68}Ge cylindrical phantom may be used. Calibration data are obtained which are used to normalise the acquired data in the clinical mode.

Radioactivity concentration calibration

For this test, a cylindrical fillable ^{18}F phantom is used, performing an acquisition with consistent data statistics. It is also possible to evaluate the SUV accuracy by scanning a phantom with a known activity using a multibed protocol. If the information relating to the tracer and phantom (e.g. activity, calibration time, phantom weight, phantom volume) is recorded as part of the patient data, then the measured SUV should be 1. Practically, this calibration test evaluates the ability of the system to correctly measure the SUV.

The above represent a minimum set of tests that need to be performed in relation to the PET system during the acceptance testing for a PET/CT scanner. It is recommended that the tests are repeated before the end of the warranty to ensure that the

system will conform to the original acceptance testing and the manufacturer's performance specifications at the start of the subsequent cycle of use.

ROUTINE QC FOR PET

Even though acceptance testing remains the most important element of equipment testing, it is the responsibility of the operator (nuclear medicine technologist and/or physicist) to ensure that the equipment continues to work optimally, thereby ensuring that the first premise for acquisition of good diagnostic information is met.

In order to respect the principles of radiation protection, the routine QC procedures must be successfully completed before any radiopharmaceutical is administered to the patient^[7].

The daily QC and QA process starts with the simplest procedures like visual inspection of the scanner, synchronisation of the clocks in the department and inspection of the handling systems for patients. The main daily QC steps, however, relate to the working parameters of the detector, namely coincidence detection, singles, dead time, timing resolution and energy resolution. The procedure is automatic or semi-automatic, using a phantom, a point source or a rod source, and depends on the manufacturer's recommendations. Therefore here we shall briefly present the

daily QC procedures for the main types of PET/CT scanner.

For the PET/CT scanners produced by Philips, the daily QC test is performed using a point source placed in the centre of the FOV. The performance of the system is evaluated on the basis of the sinograms obtained^[5].

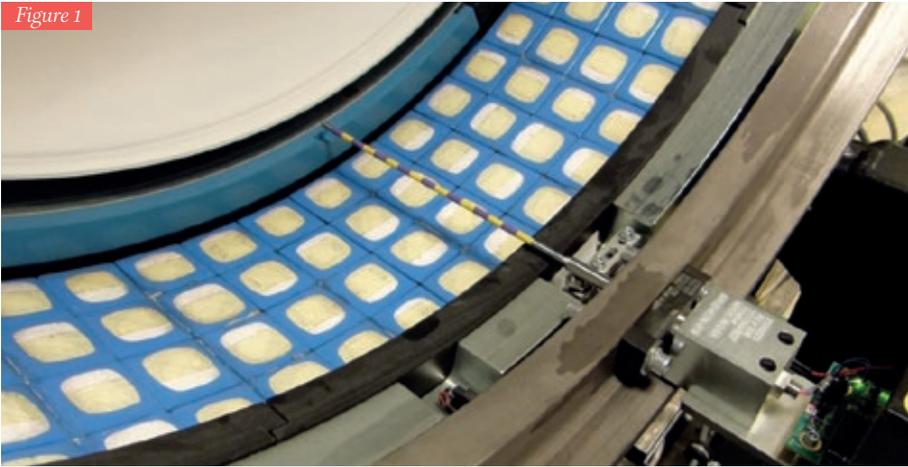
For the PET/CT scanners produced by Siemens, the daily QC is performed using a cylindrical ⁶⁸Ge phantom placed in the centre of the FOV. The obtained sinograms are evaluated to identify eventual abnormalities^[5].

General Electric designed a calibration system based on a rod source of ⁶⁸Ge placed behind the scanner, which is shielded when not in use. It is extended in the FOV and constantly rotated in front of the crystals to ensure a constant exposure of all the crystals (Fig. 1). The system evaluates the functionality of the detector but also estimates the lifetime of the calibration source^[5].

The daily QC tests evaluate the constancy of the detector's functionality and may detect malfunctions such as failure of crystals or modules. The principle of the daily QC is to correlate the data obtained from the sinograms with the levels established during the calibration of the system. If the differences are beyond the tolerance levels established by the manufacturer, recalibration or maintenance should be performed.

The frequency of QC tests should be in accordance with the manufacturer's

Figure 1



Calibration system based on a ^{68}Ge rod source placed in the FOV of a GE PET/CT scanner Discovery series, Optima 560 (courtesy of CT-Clinic Positron Emission Tomography)

recommendations and the national regulations established for nuclear medicine practice. These recommendations and regulations should be strictly respected to ensure proper functionality of the equipment; the latter is a prerequisite

for acquisition of accurate diagnostic information and also for reproducibility of scanning conditions, which in turn is necessary to allow correct comparison and evaluation of images during the diagnostic sequences.

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QUALITY CONTROL OF NUCLEAR MEDICINE
INSTRUMENTATION AND PROTOCOL STANDARDISATION

CT SYSTEM QUALITY CONTROL

INTERNATIONAL ATOM ENERGY AGENCY

by *Urban Zdešar and
Dean Pekarovič*

INTRODUCTION

CT scanners produce cross-sectional images of high radiographic contrast, which is especially important when diagnosing disease in organs or tissues in which object contrast is intrinsically low. Modern CT scanners are also very fast, which makes CT the technique of choice for a growing number of examinations.

CT scanners are used not only in diagnostic radiology but also in radiotherapy and nuclear medicine. In radiotherapy departments, they are used for treatment planning and in nuclear medicine departments mostly as a part of SPECT/CT or PET/CT systems. In spite of rapid technological development, a drawback of CT is still the relatively high patient radiation exposure. Patient doses per procedure are rarely below 1 mSv and can easily reach several tens of mSv. In some procedures (e.g. perfusion imaging), doses can even reach the threshold for deterministic effects ^[1]. An exception to this can be nuclear medicine, if CT images are used for attenuation correction only and are therefore not of diagnostic quality.

The performance of the CT scanner and its components has a significant influence on the outcome (image) and the patient exposure. CT image quality is influenced

by the dose to the patient – a higher dose usually means better image quality, but sole attention to the latter can cause doses to become inappropriately high. An effective quality assurance (QA) system should therefore be implemented to assure adequate performance and optimised use of the CT system. QA begins already with the specifications of the equipment being purchased. When equipment is installed, an acceptance test is performed; this is best done on a collaborative basis by the service engineer, medical physicist and radiographer who will be responsible for the scanner. At acceptance testing, the CT scanner and its operation are tested to establish whether the scanner functions as designed, whether it complies with regulatory requirements and whether it meets the requirements set in the purchase specification. Acceptance testing is also useful in establishing baselines for future QC testing.

Quality control (QC) is an important element of the QA system. It is intended to verify that CT scanner performance is consistent with the predetermined requirements. The QC programme should therefore include a list of tested parameters, a description of testing methods and the tolerances used to check that quality requirements are met. It should also include anticipated actions to adjust or correct performance if the tolerance limits are exceeded.

There are many books and guidelines dealing with QA and QC in CT (e.g. [2–5]). QC tests are usually divided into basic and optional or according to the recommended frequency. Some QC tests need to be performed frequently (daily, weekly or monthly), so it is recommended that these tests be performed by radiographers working on a CT scanner. More comprehensive testing is done semi-annually or annually and is usually performed by medical physicists.

The focus of this guide is technical QC, which refers to procedures designed to show that the CT equipment and its performance conform to the set cri-

teria. However, one should not forget that proper functioning of equipment is merely a necessary condition for the performance of optimised diagnostic procedures. Appropriate use (protocols) of procedures is also of vast importance and should therefore also be monitored. This can be done using different techniques, for example clinical audits and dose monitoring (tracking).

TESTS TO BE CONDUCTED BY MEDICAL PHYSICISTS

Tests described in this section are divided into three types: (a) geometry, positioning and movement tests, (b) image quality tests and (c) CT dosimetry tests. The basic equipment needed to perform these tests is an image quality phantom and a CT dosimetry set (dosimetry phantom, ionisation chamber and electrometer). As test procedures are at least partially dependent on the available equipment, the user should read the instructions provided with the equipment. We have tried to describe the test procedures listed below as generally as possible, so that the information is not specific to particular equipment.

Geometry, positioning and movement tests

Alignment of lasers with the scan plane

<i>Purpose.</i>	Alignment of the scan localisation laser and the scan plane is important because basic patient positioning is done using alignment lasers. Testing can be performed using narrow film strip (e.g. GAFCHROMIC® CT strips) or a phantom with a suitable module.
<i>Description.</i>	<p>When using radiochromic film strip:</p> <ul style="list-style-type: none"> » Position radiochromic film strip on the table or on the phantom and centre it vertically and horizontally using lasers. » Mark laser position on the film or (if the film has its own markings) centre it at a certain position (Fig. 1) » Scan using narrow collimation. » Observe/measure the difference of scan plane (blackening of film) and marked laser indicator [cf. Fig. 1, where one can observe that the beam (beam blackening) was slightly to the right of the centre for all three positions at which CT beams were centred: -30 mm, 0 mm and +30 mm]. <p>CT test phantoms usually include a module with a narrow absorber (wire) or two sets of opposing ramps, the centres of which pass through the actual axes of the module:</p> <ul style="list-style-type: none"> » Centre the test device in the external light field parallel to the tomographic plane. » Move the test device into the tomographic plane and check that the test device is aligned with the internal field light. » Scan the test object with a narrow axial scan over the range of ± 3 mm about the centre of the light field. » Observe images and evaluate alignment.
<i>Tolerances.</i>	Laser indication of scan plane should be within ± 2 mm.

Accuracy of indicated table movements

<i>Purpose.</i>	The test is performed to check that the table movements are consistent with the planned movements.
<i>Description.</i>	<p>The movement test should be performed with a weighted table (e.g. with a person sitting on it):</p> <ul style="list-style-type: none"> » Attach a tape measure to the table in such a way that the central laser crosses it at a certain number. » Set the table position to 0. » Move the table for a certain distance (e.g. 30 cm) and see whether the laser crosses the tape measure at the expected distance. » Return the table to the previous position and check it with the laser line on the tape measure.
<i>Tolerances.</i>	Movement accuracy should be within 2 mm.

Irradiated beam width

<i>Purpose.</i>	To check that the irradiated slice width is within the specifications.
<i>Description.</i>	<p>The test can be performed together with the test of alignment of lasers with the scan plane (see above). Proceed as follows:</p> <ul style="list-style-type: none"> » Position the film strip on the table or on the phantom and centre it vertically and horizontally using lasers. » Using the central laser, position the film so that the laser crosses the film at 0 mm. » Scan the film strip using the axial head protocol and a certain thickness. » Move the table for a certain distance (e.g. 30 mm) and scan with a different thickness. » Observe the image (see Fig. 1 for example). » If strip film is scanned, radiation profiles can be deduced and the slice width accurately measured (Fig. 2).
<i>Tolerances.</i>	Beam widths within manufacturer's specifications.

Geometry, positioning and movement tests

Image slice width

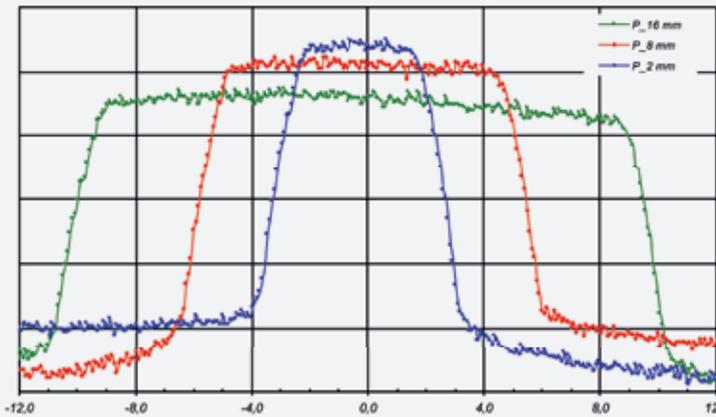
<i>Purpose.</i>	To check that the image slice width is as selected within the protocol.
<i>Equipment.</i>	Phantom with a suitable module (e.g. CATPHAN or PRO-CT phantom) – usually there is an insert with wire ramps at a certain angle (α). When wire length on the image is measured, slice width can be calculated (Fig. 3).
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the phantom with a suitable module on a stand on a CT table and set the gantry to the vertical position. » Centre it horizontally and vertically using lasers. » Use routine head protocol. » Set the scanning plane on the middle of the module and perform an axial scan. » Determine the CT number maximum (CT_{max}) for wire ramps. Restrict the window to 1 or the lowest selectable value and move the window centre to the point at which the ramp image almost disappears. This level value will be the maximum for the ramp. » Determine the background CT number (CT_b) using the average HU value near the ramps. » Calculate the CT number corresponding to half the maximum height (CT_{half}): $CT_{half} = \frac{(CT_{max} - CT_b)}{2} + CT_b$ » Set the window centre to the calculated CThalf and the window width to 1. » Measure the length of the ramp to obtain full width at half maximum (FWHM). » Calculate the image slice width T: $T = FWHM \cdot \tan(\alpha)$
<i>Tolerances.</i>	Deviation of image slice width from nominal value: + 0.5 mm for beams <2 mm; \pm 1 mm for slices >2 mm.

Figure 1



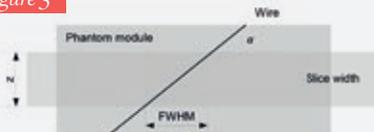
Film strip irradiated at three different positions determined by central laser (-30 mm, 0 mm and 30 mm) using three different beam widths

Figure 2



Profiles of beam widths 4x4 mm, 4x2 mm and 4x0.5 mm)

Figure 3



Calculation of image slice width (T):
 $T = FWHM \cdot \tan(\alpha)$

Image quality tests

CT number uniformity and noise

<i>Purpose.</i>	To check the uniformity of a CT image of a homogeneous object by measuring the CT numbers (Hounsfield units, HU) across the image of a homogeneous phantom [a CT dose index (CTDI) phantom can also be used].
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the phantom on the table or head support and centre it vertically and horizontally. » Choose the protocol most often used clinically (head or abdomen, depending on the phantom). » Make a scout image and scan the phantom as would be done clinically. » On reconstructed images, select regions of interest (ROIs) in the centre and in four places at the periphery (usually 12 h, 3 h, 6 h and 9 h). » Read the average CT number and standard deviation (noise). » Calculate the difference in average CT number between peripheral ROIs and the centrally placed ROI. » Compare to reference values.
<i>Tolerances.</i>	<p>Tolerances for uniformity and noise are as follows:</p> <p>Uniformity: Deviation of CT number from specified value ± 20 HU</p> <p>Noise: Deviation of noise from the specified values $< 25\%$</p>

Artefact evaluation

<i>Purpose.</i>	To evaluate the presence/absence of artefacts on images.
<i>Equipment.</i>	Image quality phantom or other homogeneous phantom.
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the phantom on the table or head support and centre it vertically and horizontally. » Choose the most clinically used head protocol on the CT scanner. » Set the scanning plane in the middle of the homogeneous module and make a scan. » Evaluate the image visually using a narrow window centred at the CT number of the phantom material.
<i>Tolerances.</i>	There should be no significant artefacts or distortions.

CT number accuracy

<i>Purpose.</i>	To check that the CT numbers of different materials are within the range of expected values.
<i>Equipment.</i>	Image quality phantom with different materials with known CT numbers (for example: CATPHAN, PRO-CT phantom, Mini CT QC Phantom, ACR CT accreditation phantom).
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the phantom on the table or head support and centre it vertically and horizontally. » Choose the most clinically used head protocol on the CT scanner. » Set the scanning plane in the middle of the phantom module containing different materials and make a scan. » Read the average values of CT numbers in the regions of interest (ROIs) placed in the centre of each material in the module. » Compare the measured CT numbers with the reference values.
<i>Tolerances.</i>	<p>Deviation of CT numbers from specified values:</p> <p>± 10 HU for water and air</p> <p>± 20 HU for other materials</p>

Spatial (high contrast) resolution

<i>Purpose.</i>	To test the high contrast resolution of the CT scanner.
<i>Equipment.</i>	Image quality phantom with high contrast resolution module.
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the phantom on the table or head support and centre it vertically and horizontally. » Choose the most clinically used head protocol. » Set the scanning plane in the middle of the phantom high contrast module. » Evaluate the number of resolved high contrast patterns. » Compare the result with the limiting values.
<i>Tolerances.</i>	Deviation of spatial resolution $\leq 10\%$ from manufacturer's specification or 0.5 lp/mm, whichever is greater.

Image quality tests

Low contrast resolution

<i>Purpose.</i>	To test the low contrast resolution of the CT scanner.
<i>Equipment.</i>	Image quality phantom with low contrast resolution module.
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the phantom on the table or head support and centre it vertically and horizontally. » Choose the most clinically used head protocol. » Set the scanning plane in the middle of the phantom low contrast module. » Evaluate the number of resolved low contrast objects. » Compare the result with the values at acceptance.

CT dosimetry tests

Accuracy of indicated dose parameters

<i>Purpose.</i>	To check the accuracy of CT dose parameters (CTDI _{vol} and/or DLP) displayed on the CT scanner control console.
<i>Equipment.</i>	Calibrated dosimeter with 100-mm pencil ionisation chamber (CTDI probe) and PMMA CTDI phantom (16 cm and 32 cm PMMA).
<i>Description.</i>	<p>Proceed as follows:</p> <ul style="list-style-type: none"> » Place the CTDI head phantom on the head support and centre it vertically and horizontally using lasers. » Place the CTDI probe in the centre hole of the phantom. » Prepare the CTDI probe for the measurements as described in the manufacturer's manual. » Place the CTDI probe in the CTDI phantom in such a way that the centre of the CTDI probe will be in the centre of the CTDI phantom. » Centre the table at this position (put the position to zero or note the actual position). » Make a scout image of the CTDI phantom. Set the start and end of the scan in such a way that the centre of the CTDI phantom (CTDI probe) is in the middle of the scanning area. » Set the table movement to 0. During this test, the table should stay in a fixed position. » Select the axial scan using exposure parameters close to the most frequently used head scan. » Make a scan (1 rotation) and record the measured dose (P_{kl}). Repeat to obtain at least three measurements. The ionisation chamber measures the product of air-kerma and length (P_{kl}), which is usually called the dose-length product (DLP). To calculate the CTDI_f use the following formula: $CTDI = \frac{P_{kl}}{N \cdot T}$ where $N \cdot T$ is the nominal beam collimation (N slices of thickness T). » The dose parameter, which is usually displayed on the CT scanner control console, is the weighted CT dose index CTDI_w, which is a combination of measurements in the centre of the phantom and at the periphery (CTDI_c and CTDI_p, respectively): $CTDI_w = \frac{1}{3} CTDI_c + \frac{2}{3} CTDI_p$ » Repeat the measurements by placing the CTDI probe in all four periphery holes (positions: 12 h, 3 h, 6 h, 9 h). All unused holes of the phantom must be filled with plugs. » Calculate the deviation of measured CTDI value to CTDI displayed on the control console.
<i>Tolerances.</i>	Deviation of measured dose from indicated dose <20%.

Notes.

- Measurements should be done for all tube voltages that are used in practice.
- The same procedure is followed using a body phantom (32 cm PMMA) and a standard body protocol.
- Measurements of P_{kl} in the centre can also be used to test some other properties of the CT scanner, such as linearity with tube load (mAs), repeatability and dependence on beam width.
- Instead of measurements within the phantom, measurements free in air can be performed. In this case, an ionisation chamber is attached to the centre of the CT scanner gantry.

RADIOGRAPHERS' TESTS

The role of the radiographer is to perform and understand more frequent CT scanner tests (daily, weekly, monthly). The American College of Radiologist (ACR) and International Atomic Energy Agency (IAEA) have recommended that radiographers should be competent to perform basic tests [2, 6]. More specifically, the ACR has recommended that the QC tests listed in Table 1 should be performed by the radiographer.

Radiographer QC	Frequency
Water CT number and standard Deviation	Daily
Artefact evaluation	Daily
Wet laser printer QC	Weekly
Visual checklist	Weekly
Dry laser printer QC	Monthly
Display monitor QC	Monthly

Table 1: CT QC tests for radiographers recommended by the ACR [6]

As a first action, a daily calibration (air calibration) should be performed before any other test. All tests must be performed using the same exposure and reconstruction parameters in order to ensure that reproducible results are obtained. All unexpected changes in the constancy of measurements should be documented,

evaluated by the QC team and reported to the service engineer if necessary.

The main objective of the CT number test is to ensure that the relative calibration of all CT numbers to water remains within acceptable limits and that quantum noise and electronic system noise do not increase. After scanning, the phantom CT number and its standard deviation in specified ROIs are recorded and compared with reference values set by the manufacturer or medical physicist. If any remarks are documented or reported to the QC radiographer regarding artefacts on images, all image series must be analysed. The QC radiographer should try to identify possible causes of artefacts on images.

In addition a visual QC checklist for radiographers has been suggested by the ACR^[6] in order to ensure that other components of the CT scanner are functioning satisfactorily and to aid in avoiding repeated scans. According to this checklist, the following items should be checked on a monthly basis:

- » Table height indicator functioning
- » Table position indicator functioning
- » Angulation indicator functioning
- » Laser localisation light functioning
- » High-voltage cable/other cables safely attached (and not frayed)
- » Acceptable smoothness of table motion
- » X-ray on indicator functioning
- » Exposure switch functioning

- » Display window width/level
- » Panel switches/lights/meters working
- » Door interlocks functioning
- » Warning labels present
- » Intercom system functioning
- » Postings present
- » Service records present

Most modern CT scanners have their own QC procedure in which the test phantom provided with the scanner is used. In CT software QC packages, tests are automated and measurement data are stored in CT software and can be accessed and analysed. Such tests are not time consuming and can therefore be performed relatively quickly. As such they can be easily incorporated into a QA programme.

CONCLUSION

Radiographers must be a part of the QC team in order to secure, maintain or improve the health and well-being of the patient. Radiographers have a specific responsibility to actively participate in QA and therefore should have the competences required to perform QC tests for CT scanners and to evaluate the results of routine QA and QC tests.

The document "Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union"^[7] is useful for the evaluation of existing ed-

ucational programmes. It provides an opportunity to expand learning outcomes for educational institutions and improve the competencies of radiographers who already perform CT procedures. In order to ensure the provision of an effective, safe and efficient service, radiographers' training should incorporate instruction on QA and QC practices, to include: legislation, regulations and guidelines, test equipment and methodologies, programme design and implementation and reporting^[7]. With effective analysis and collaboration with medical physicists and radiologists, QC tests can also become an important training tool regarding the ways in which parameters monitored during these tests affect image quality and dose. Although QC phantoms cannot fully simulate patients, they can still provide radiographers with useful knowledge on the performance of their CT scanner and can be used as a valuable tool in the optimisation process.

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OPTIMISATION OF SPECT AND SPECT/CT – ACQUISITION AND RECONSTRUCTION

*by Maximilien Vermandel
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INTRODUCTION

Single-photon emission computed tomography (SPECT) is a medical imaging technique that allows in vivo measurements of the 3D distribution of gamma photon-emitting tracers. Technetium-99m (^{99m}Tc) is the radioactive isotope most commonly and widely used with SPECT imaging. ^{99m}Tc SPECT is mostly used in association with a vector in order to study the metabolism of a given organ.

The range of medical indications for SPECT is wide and includes bone resorption, studied using a bisphosphonate labelled with ^{99m}Tc , and renal function, investigated using ^{99m}Tc -labelled mercaptoacetyltriglycine (MAG3). ^{99m}Tc is also used with sestamibi to study myocardial perfusion. In neurology, brain perfusion analysis is achieved using ^{99m}Tc coupled with a neutral and lipophilic complex whose molecular mass is sufficiently low to allow passage across the blood-brain barrier. However, some other isotopes are also used, such as iodine-123 in thyroid scintigraphy for hyperthyroidism or congenital hypothyroidism, indium-111 with a somatostatin analogue for neuroendocrine tumours, krypton-81m for lung ventilation, thallium-201 for evaluation of cardiac viability and iodine-131 for the treatment of thyroid cancer.

For some of these applications, the visual inspection of SPECT images provides sufficient information (e.g. bone fracture, arthritis, metastasis). For other applications, however, quantification on SPECT images

remains of interest. Indeed, for nephrology indications, quantification is expected to estimate renal function or cortical transit time. In cardiology, cardiac function can also be analysed using ^{99m}Tc -pertechnetate-labelled red blood cells and calculating the portion of isotope ejected during each heartbeat to determine the ejection fraction. In particular, radiotracer uptake is measured at the end of systole and diastole to estimate the ejection fraction, followed by evaluation of the kinetics in 3D. Moreover, prior to therapy, the avidity of the thyroid for iodine-123 may be assessed through measurement of the uptake rate, which serves as the basis for estimation of the iodine-131 activity to be prescribed.

Since the range of applications of SPECT imaging is wide, acquisition parameters must be chosen carefully, in accordance with the indication being investigated. Indeed, SPECT studies depend on the settings and methods used during acquisition, reconstruction and post-processing. These parameters may drastically affect

the image quality and have to be carefully considered both when performing the acquisition itself and when interpreting the images.

The first section of this chapter presents important background information on the principles of SPECT instrumentation. The following section is devoted to the factors that affect image reconstruction quality and the parameters that must be considered in order to achieve optimal acquisition. Finally, some new advancements in SPECT are discussed.

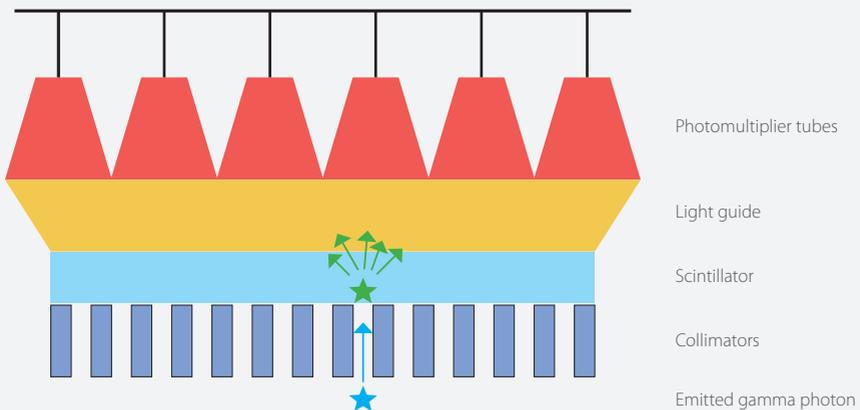
SPECT AND SPECT/CT IMAGING INSTRUMENTATION

Gamma camera basics

A gamma camera is a set of planar detectors, usually two (dual-head), mounted on a gantry that enables simultaneous detector acquisition of parts of a patient's body from different orientations. Detection of the gamma photons emitted by the decay of the radioactive isotopes relies on the scintillation principle^[1]. A basic sketch of a detector is shown in Fig. 1.

Figure 1

Transverse view of a gamma camera detector



A gamma camera acquires two-dimensional projectional images of the distribution of a radiotracer based on detection of the emitted photons. As illustrated in Fig. 1, an emitted photon (or event) passes through the collimator, which aims to select photons from certain directions. The collimator consists of an array of holes, most often parallel holes, resembling an assembly of lead straws. On Fig. 1, non-parallel photons would be stopped by the hole walls, the so-called septa. Once they have passed through the collimator, photons interact with the scintillator, which is a large-area NaI(Tl) scintillation crystal, where they are absorbed; the absorbed energy is then re-emitted, with release of photons in the visible light spectrum. Basically, the scintillator is a “wavelength converter” that converts high-energy photons to low-energy photons. The low-energy photons are then guided through the light guide to photomultiplier tubes (PMTs) that serve to convert the light signal into an electrical signal. PMTs are arranged in a 2D array in such a manner that the electrical signal collected at each PMT enables estimation of the 2D location of each event.

SPECT

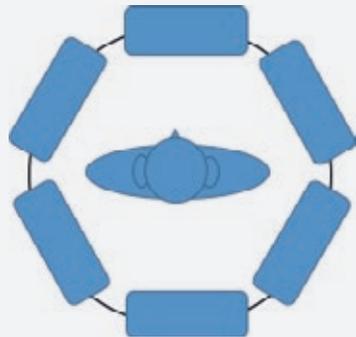
When used in static or whole-body mode, gamma camera detectors only allow for planar imaging of the radiotracer distribution. However, in SPECT imaging, acquisi-

tion of multiple projections from multiple positions enables reconstruction of the three-dimensional distribution of gamma photon-emitting tracers (Fig. 2). SPECT is usually acquired in addition to planar scintigraphy in order to refine the diagnosis.

SPECT imaging is basically achieved by rotation of the detectors around the subject. The motion of the detectors can be either step by step (SS) or continuous, the latter option being preferred for unstable patients (e.g. those with dementia). During continuous SPECT acquisition, continuous motion cycles are employed to maximise the number of events measured. In the event of unexpected patient movements, one or several cycles may be rejected before the reconstruction phase. In contrast,

Figure 2

Illustration of the acquisition of multiple projections to achieve SPECT imaging



SS acquisition requires just a single cycle, which basically entails rotation of each detector through 180° around the subject in order to cover the full 360° range (for detector configuration in 180° or “H” mode). Step duration or speed and number of cycles in continuous mode depend primarily on the intensity of the radiotracer uptake and the patient’s condition.

Finally, image reconstruction is achieved using specific algorithms to render the spatial distribution of the radiotracer into matrices of 64×64, 128×128 or 256×256 pixels according to the location and size of the organ studied.

SPECT/CT

Image reconstruction with conventional SPECT acquisitions cannot be corrected for attenuation or scatter when considering non-heterogeneous areas, an exception being the brain, for which Chang modelling gives satisfactory results. For the purpose of such correction, the SPECT gantry can be coupled to a computed tomograph (CT) so that a CT scan can be acquired in conjunction with SPECT imaging. This hybrid imaging system has two major advantages: First, the quasi-simultaneous acquisition of SPECT and CT allows for the fusion of functional and anatomical data with minimal concerns regarding registration. Second, the CT images, converted to a map of electronic densities, are used for the pur-

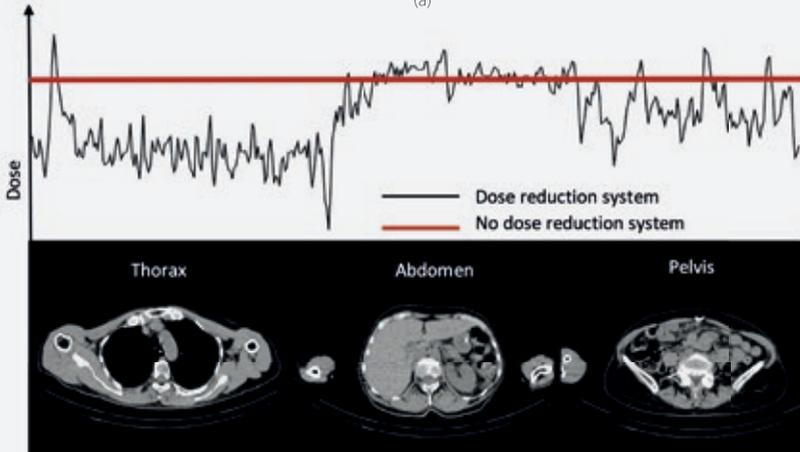
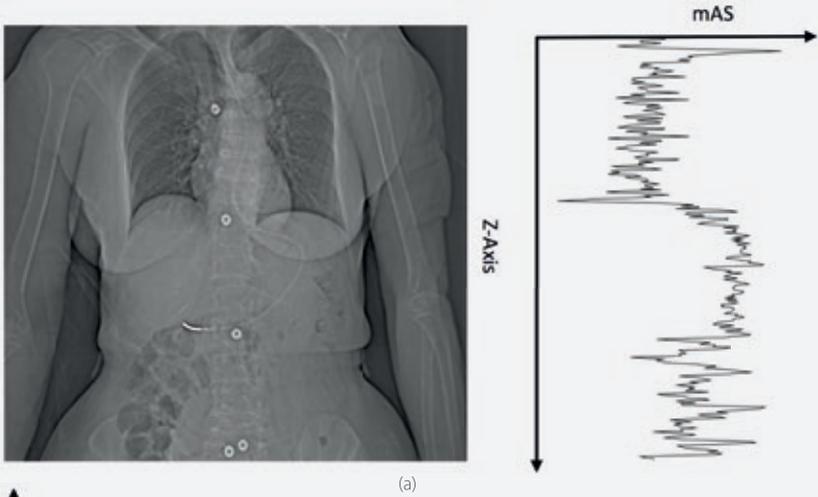
pose of attenuation and scatter correction during tomographic reconstruction.

The use of hybrid technologies may entail significantly increased radiation exposure for the patient. In order to reduce the exposure while maintaining good image quality, manufacturers have released systems that automatically modulate the tube current (mAs) according to the density of tissues being explored. Basically, the system automatically adapts, in real time, the tube current to the thickness of tissue crossed by the X-ray beam as deduced from the topogram acquisition (Fig. 3). For example, the X-ray beam is more strongly attenuated by the shoulders than by the abdomen owing to the lower density of the latter; thus decreasing the tube current for the abdominal exploration allows for a substantial dose reduction. However, in specific cases the dose reduction system may not be activated. For instance, when the CT scan is only acquired for the purpose of attenuation correction, minimal dose exposure is expected and thus high voltage and tube current are carefully balanced to achieve this goal.

Collimator

In the chain of acquisition, the collimator type is the first element to be considered for optimisation of SPECT image acquisition since it closely depends on (1) the energy of the emitted photons to be measured and

Figure 3

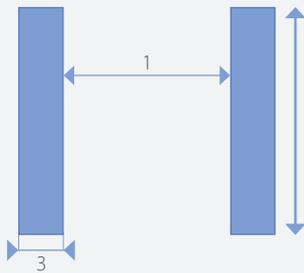
Illustration of a dose reduction system.**a)** Estimation of the mAs on the Z-axis according to the topogram.**b)** Dose level for different locations when using the dose reduction system

(b)

(2) the location being investigated. As described previously, the collimator is an array of holes or honeycomb structure. Thus, the main factors influencing the acquisition are hole length, septa width and hole diameter (Fig. 4). For instance, increasing the length of the hole improves the collimation and spatial resolution but leads to a lower sensitivity. Septa thickness is related to emitted photon energy and is thicker for higher energy photons (e.g. 0.4 mm for 140-keV photons versus 1.9 mm for >300-keV photons).

Figure 4

Main characteristics of a collimator affecting the image acquisition



1 – Hole diameter | 2 – Hole length | 3 – Septa width

Hole diameter (or hole size) influences the spatial resolution: a smaller hole diameter increases the spatial resolution but decreases the sensitivity. In general, the choice of collimator for SPECT imaging should prioritise sensitivity over spatial resolution to

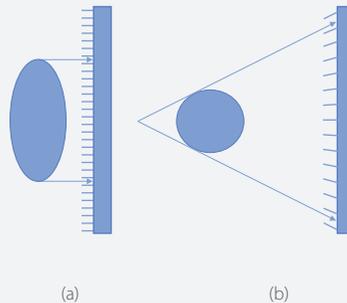
limit the study duration and thus restrict the patient's movements as far as possible.

Depending on the energy, the collimator is classified as low energy (^{99m}Tc , ^{123}I , ^{201}Tl), medium energy (^{111}In , ^{67}Ga) or high energy (^{131}I).

Collimator types also differ according to the geometry of the holes. Most collimators used in SPECT imaging are of two types: parallel-hole collimators and con-

Figure 5

Parallel-hole (a) and fanbeam (b) collimators



(a)

(b)

verging-hole (fanbeam) collimators (Fig. 5). The collimator type to be used for a given imaging application depends on the ratio between the size of the field of view (FOV), the size of the detector and the expected spatial resolution and sensitivity^[2].

The parallel-hole collimator is the historical design by Anger and this is still the standard collimator employed in clinical practice. For a parallel-hole collimator, the point source sensitivity is the same over the whole FOV. When the organ or location under investigation is smaller than the FOV, the use of fanbeam collimators results in improved performance in terms of both sensitivity and spatial resolution^[3]. This latter configuration may be preferred for brain imaging, for instance.

Finally, for cardiology imaging, specific collimators allowing for faster cardiac SPECT acquisition have recently been released^[4].

Crystal

Interaction of emitted photons with the scintillator crystal leads to the emission of fluorescence photons (light) in all directions. Only a limited fraction of light travels to the PMT. Thus, the scintillator is surrounded by a reflector material on all surfaces, except the surface in contact with the PMT, in order to maximise light collection at the PMT. Additionally, the crystal is coupled to the PMT array through a transparent medium of the same index of refraction as the crystal so that reflection is minimised at the interface between the PMT and the scintillator.

The thickness of the crystal impacts on both sensitivity and spatial resolution. As illustrated in Fig. 6, a thick crystal will

improve photon interactions and the sensitivity. Indeed, a thick crystal increases the probability of total absorption of the incident photons when the energy is high. However, the resultant gain in sensitivity comes at the cost of a reduction in spatial resolution.

The thickness of the crystal/scintillator is specific to the gamma camera and depends on the type of radiotracer used. For a low-energy tracer, a thin crystal should be preferred (3/8 inch) while a thicker crystal (5/8 inch) is to be preferred for higher energy tracers.

Finally, the choice of crystal thickness depends on the type of daily use. For instance, SPECT with ^{99m}Tc will be acquired using a thin crystal, whereas if most uses involve ¹³¹I, a thick crystal will be preferred.

Photomultiplier tubes

Light emitted inside the crystal is collected by the PMTs in order to convert the light signal into an electrical signal (Fig. 7). PMTs comprise an evacuated glass package with a photocathode, to convert light to electrons, followed by a string of electron-multiplying dynodes. The amplification gain is high (>10⁶). High voltage for the whole PMT array and gain for each PMT have to be carefully fine-tuned in order to achieve a similar response on all the FOV for both the energy of incident pho-

Figure 6

Illustration of the effect of the crystal thickness on light collection at the PMT array. In **(a)**, the crystal is thicker, improving the sensitivity but limiting the spatial resolution (the cone of light collected at the PMT array is wider). In **(b)**, not all of the photons interact with the crystal but the spatial resolution is higher (i.e. the cone of light collected at the PMT is narrower).

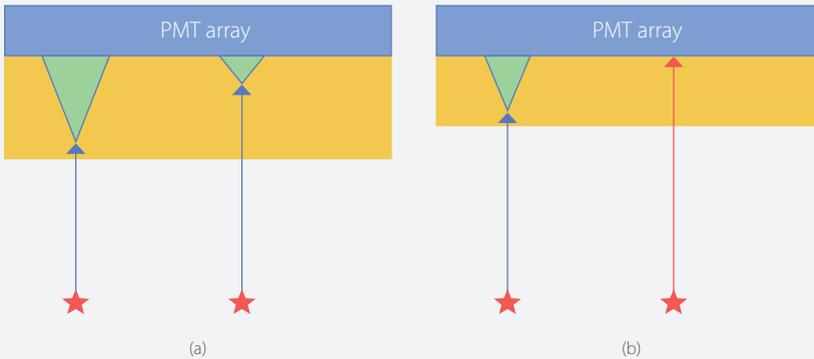
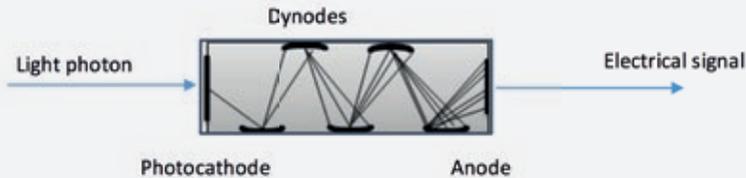


Figure 7

Illustration of a PMT converting light into an electrical signal



tons and the sensitivity. Furthermore, the response of each detector has to be homogeneous independently of the angle of

the gantry. Variation in the PMT response according to angle may have an impact on the reconstructed image.

IMAGE RECONSTRUCTION

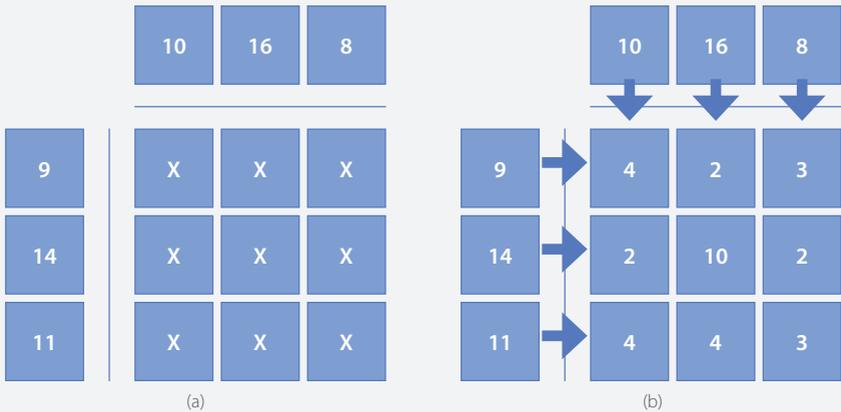
Algorithms

Reconstruction of the images from projections is a crucial stage in SPECT imaging. After the acquisition process, each pixel of the projection images at each angular position contains the number of events detected. The principle of reconstruction consists in building a slice from the different projections. Figure 8 shows an example of reconstruction from planar acquisition.

Basically, two types of reconstruction are used: analytic methods and iterative methods^[5]. Analytic methods are based on a back-projection algorithm, the most

frequently used being filtered back projection (FBP). FBP consists in filtering projection data before propagating the pixel value on the slice to be reconstructed. Because FBP is more computationally efficient (fast), it has long been preferred. However, FBP requires a huge amount of projection data to enable well-defined images to be obtained. In view of the high number of projections acquired during X-Ray Computerised Tomography (CT) examination, FBP leads to satisfactory image reconstruction. However, the low resolution of scintigraphic imaging and the low number of projections available prevent proper rendering of the three-di-

Figure 8



a) Two projections acquired at two angular positions.

b) Reconstruction of the slice from the events contained in each pixel of the projections

dimensional distribution of the radiotracer when reconstructed using FBP methods. Iterative methods address this issue and, thanks to the performance of the most recent generations of computers, they are now commonly used for SPECT image reconstruction. The general concept of iterative methods is to solve $p=A \times f$ where p is a vector of the projection data (i.e. projections acquired), f is a vector representing the three-dimensional distribution to be reconstructed (i.e. tomographic images) and A is a function of projection (i.e. geometry of acquisition). The principle of iterative algorithms is to find a solution (i.e. f) by successive estimates. Ordered subsets expectation maximisation (OSEM) is the most commonly applied algorithm and is based on the maximum likelihood expectation maximisation (MLEM). The aim of MLEM algorithms is to find a solution as the best estimate of f than can produce projections p with the highest likelihood. OSEM allows acceleration of computation by dividing the set of projections into subsets (Fig. 9). Thus, independently from the acquisition duration and the numbers of projections, the main factors influencing the image quality are the number of subsets and the numbers of iterations.

Finally, the higher the number of iterations, the higher is the spatial resolution, but with an increase in the noise level, and the higher the number of subsets,

the faster is the convergence. Accordingly, the number of subsets and the number of iterations should be carefully balanced. Indeed, if the number of subsets and iterations is too small, the algorithm does not converge and the result is a poorly contrasted and blurred image, while if the number of iterations is too large in respect to the number of subsets, the reconstructed image displays an increased noise level (Figs. 10 and 11).

Other benefits of iterative reconstruction are that the projection function may include different acquisition parameters in order to optimise image rendering. Indeed, spatial resolution (both intrinsic and extrinsic, depending on the collimator used), attenuation by the patient, Compton scatter (in the patient, collimator and/or crys-

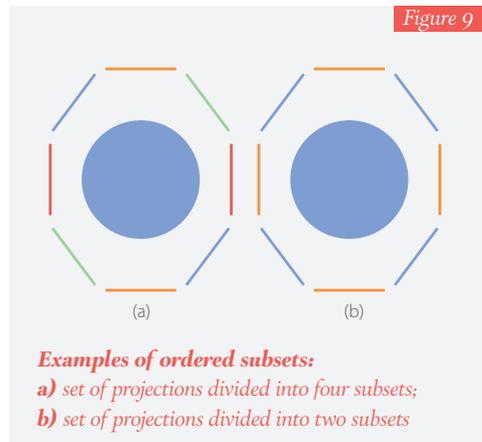
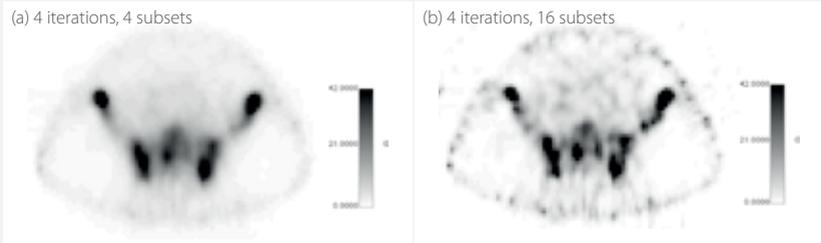
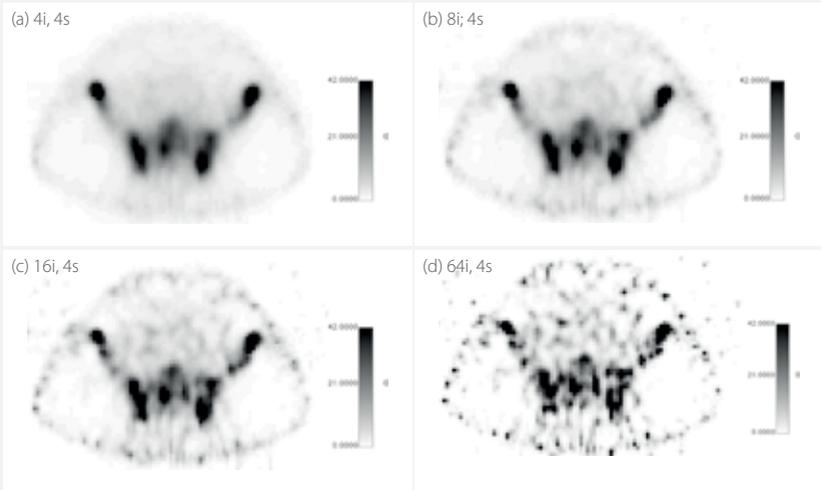


Figure 10



Example of the poor contrast and blurring that occur if the number of subsets and iterations is too small. Tomographic reconstruction of a bone study (^{99m}Tc), no attenuation reconstruction, 5-mm Gaussian post-filter, 64 angular positions (128 projections). Reconstruction was achieved with OSEM, with 4 iterations and either 4 **(a)** or 16 subsets **(b)**

Figure 11



Example of the increase in noise level that occurs with a higher number of iterations. Tomographic reconstruction of a bone study (^{99m}Tc), no attenuation reconstruction, 5-mm Gaussian post-filter, 64 angular positions (128 projections). Reconstruction was achieved with OSEM, 4 subsets and an increasing number of iterations: 4 **(a)**, 8 **(b)**, 16 **(c)**, and 64 **(d)**

tal) and collimator septal penetration can be modelled to optimise the reconstruction. These reconstruction options with the possibility of applying post-processing filters must be implemented within acquisition and/or post-processing software to facilitate the optimisation of image quality.

Attenuation correction

Emitted photons have different trajectories across the patient's body, such that those emitted from deeper locations are

subject to higher attenuation on their paths. In other words, a photon emitted from the surface of the patient is less attenuated than a photon emitted from a deep location. As a consequence, the emission of photons from deeper locations are underestimated on the projections (Fig. 12).

For some locations, attenuation correction may be achieved with the Chang algorithm. However, this algorithm is only suitable for a homogeneous location, such

Figure 12

Example of photons emitted from different depths, with more attenuation occurring for photons emitted from deeper locations

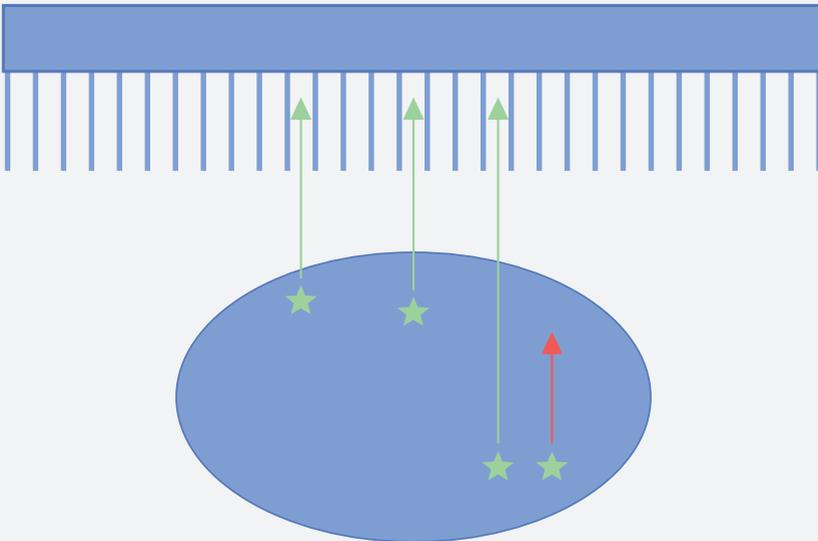
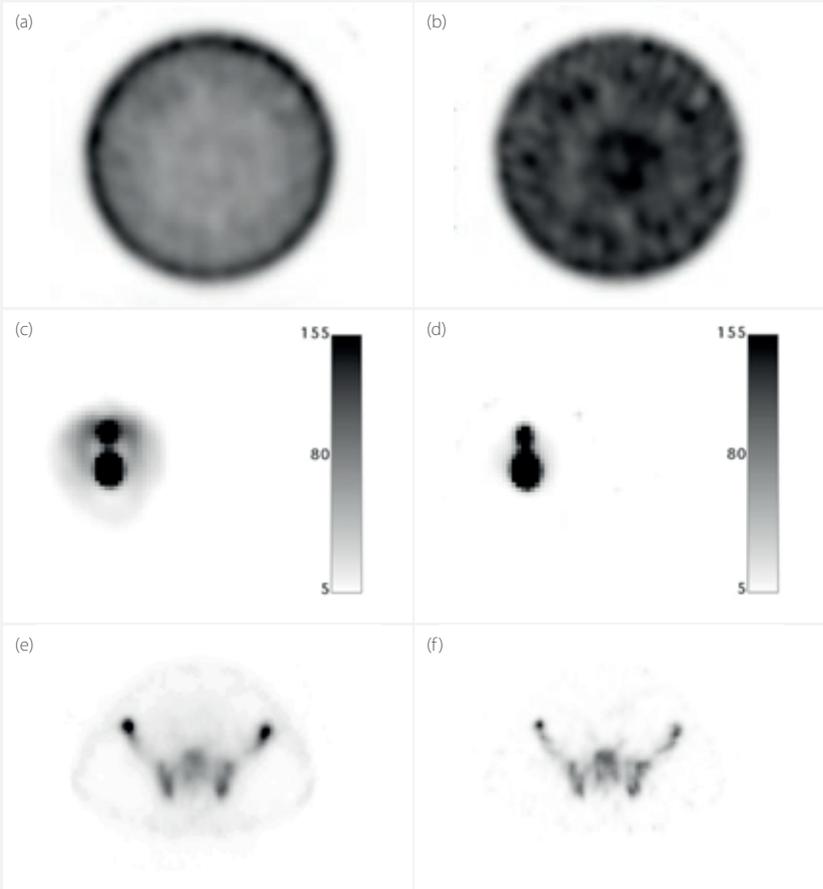


Figure 13



Examples of images reconstructed without and with the use of attenuation correction based on CT acquisition. **a,b**) A phantom filled with ^{99m}Tc solution and images reconstructed without **(a)** and with **(b)** attenuation correction. **c,d**) A plain phantom with two sources of ^{177}Lu in the centre and images reconstructed without **(c)** and with **(d)** attenuation correction. **e,f**) Patient images reconstructed from a ^{99m}Tc study without **(e)** and with **(f)** attenuation correction. The images clearly show that without attenuation correction, events at depth are underestimated.

as the brain. For heterogeneous areas, an electronic density map of tissues acquired from CT is preferred for attenuation correction. Figure 13 shows examples of reconstruction without and with the use of attenuation correction based on CT acquisition.

Matrix size and zoom

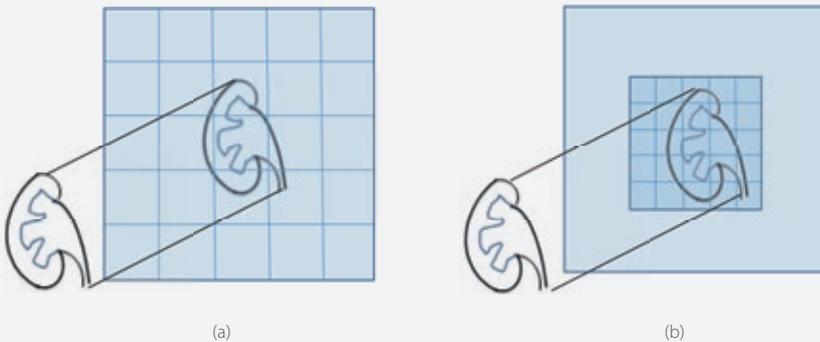
Events detected on a projection are distributed on a grid, a so-called matrix. Each picture element (pixel) of the matrix basically covers the entire FOV and contains the total number of events detected during the acquisition. A matrix is described by the number of rows (m) and columns (n) defining its size: $m \times n$. For SPECT imaging, standard matrix sizes are 128×128 or

256×256 up to 512×512. The size of the acquisition matrix will define the size of the tomographic images to be reconstructed. Thus, a higher matrix size will result in recording of finer details within the limits of the intrinsic spatial resolution. Matrix size selection directly affects the signal to noise ratio (SNR) of acquired data. Indeed, larger matrix sizes lead to events being spread over a greater number of pixels; accordingly, to maintain the same SNR with a larger matrix, the acquisition duration must be longer so as to increase the number of events. Thus, acquisition duration and matrix size must be carefully balanced.

Zoom is used for the magnification of the object (e.g. specific body location, Fig. 14) while keeping the matrix size un-

Figure 14

Illustration of a 4x4 acquisition matrix for the study of a kidney. a) The matrix covers the entire FOV. b) A zoom of 2 is applied during the acquisition to achieve higher spatial resolution.



changed. For example, an unzoomed image with a 128x128 matrix and a pixel size of 5 mm will allow a pixel size of 2.5 mm with the use of a zoom of 2. Finally, the zoom allows for acquisition of the same matrix size on a limited FOV area but the duration of frame acquisition may need to be altered in order to maintain the SNR.

NEW ADVANCEMENTS IN SPECT

Today, the newest CT scan reconstruction technologies, including iterative reconstruction, are contributing in reducing patients' radiation exposure. Additionally, new detection technologies will also help to minimise this exposure. Indeed, the new detectors based on semiconductor technology (CZT: cadmium-zinc-telluride) directly convert emitted photons into an electrical pulse without the use of a scintillator or PMT. Thus, CZT detectors increase spatial resolution, energy resolution and sensitivity. Finally, the improved sensitivity of this technology, initially developed for cardiology applications^[6], means that less radiotracer activity is required for an equivalent image quality and allows reduction of the study duration, thereby avoiding movement artefacts and reducing overall patient exposure^[7].

CONCLUSION

Optimisation of SPECT/CT acquisition relies on multiple factors. Obviously, the protocol acquisition may be optimised taking into account both the technical aspects detailed above and the ALARA principle (whereby the radiation exposure is kept "as low as reasonably achievable"). However, patient status must be taken into consideration. Indeed, the patient's age and comorbidities may influence the design of the acquisition protocol, which thus may vary depending on the context. For instance, the exploration of pelvic pain by means of bone scintigraphy in an elderly patient largely justifies a CT acquisition with SPECT because (1) risk of fracture of the pelvis is high and the bladder uptake may prevent study of the sacrum and (2) the CT dose exposure remains acceptable since SPECT alone contributes the majority of the patient's overall exposure^[8]. Furthermore, the duration of the SPECT/CT acquisition may be reduced if uptake on planar scintigraphy is high. On the other hand, in a child with gait abnormalities, acquisition of a SPECT/CT after planar study may be considered unnecessary if a complementary examination is scheduled (e.g. MRI), thereby avoiding needless dose exposure.

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OPTIMISATION OF PET/CT — ACQUISITION AND RECONSTRUCTION

1

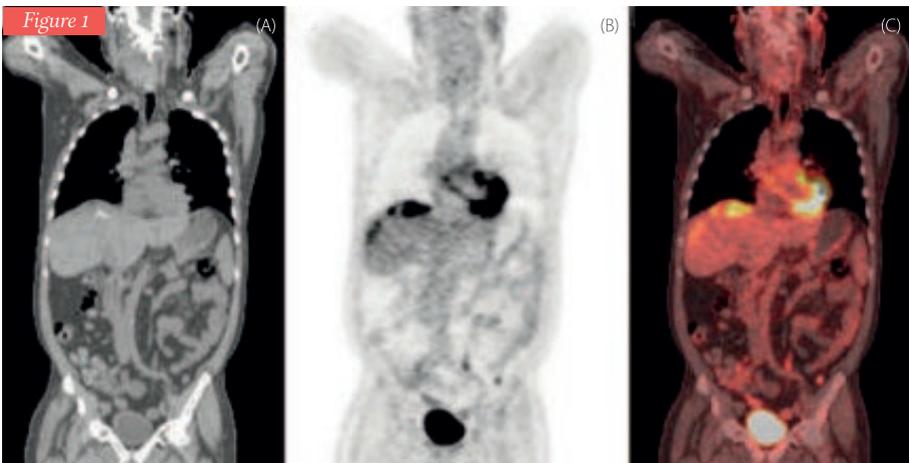
by Leesa Ross and Dusty York

INTRODUCTION

Footnote: This chapter will mainly focus on whole-body FDG imaging. For specific brain and cardiac PET/CT, please refer to the Tech Guides on Brain Imaging and Myocardial Perfusion Imaging.

Positron emission tomography (PET) is able to evaluate the metabolic activity of target tissues. The principle behind PET is that two 511-keV photons are emitted from an annihilation reaction between a positron and an electron. When the 511-keV photons are detected simultaneously by the PET scanner, the process of image formation is begun. The isotopes carbon-11 and germanium-68 are frequently used; however, the most common PET ra-

diopharmaceutical is fluorine-18 fluorodeoxyglucose (^{18}F -FDG), which can be used for total body imaging as well as for brain and cardiac imaging (Fig. 1). Acquisition and reconstruction are important steps in the scanning process. Without standards and protocols, the patient outcome may suffer. It is best to use the manufacturer's settings; however, with advances and changes in the profession, due to research, optimisation may require modifications.



A: A PET/CT image consisting of coronal whole-body CT image. **B:** PET image with CT attenuation correction. **C:** Fused PET/CT image (C). Courtesy of the Journal of Nuclear Medicine Technology (JNMT)^[1]

Patient preparation for a whole-body PET scan with ^{18}F -FDG includes no consumption of food, simple carbohydrates or liquids other than plain (unflavoured) water for 4 h prior to ^{18}F -FDG injection for the non-diabetic patient. It is also recommended that the patient should not consume food after midnight the night before the study. A low carbohydrate diet is preferred for one day prior to the study^[2].

The patient's blood glucose level should be evaluated prior to injection of ^{18}F -FDG. For clinical studies involving the whole body, the blood glucose level should be lower than 11 mmol/L (~200 mg/dL). Patients with glucose levels out of this range may be excluded from the study^[3]. The patient should be injected in a quiet area and remain in that location with the lights dimmed for 60–120 min post injection. The patient should be kept warm and requested to sit still during the waiting period. For the purposes of radiation safety and compliance with ALARA, explanation of the procedure should be completed prior to injection, thereby reducing radiation exposure to the technologist.

Before the patient is positioned on the table, he or she should be instructed to empty the bladder to enhance comfort and decrease the opportunity for artefacts. The patient is then placed in the supine position, with arms elevated and supported above the head for torso acquisition

and by the sides for head and neck imaging. Elevating the arms when imaging the torso will reduce beam-hardening artefacts, as well as artefacts caused by truncation of the measured field of view (FOV). If imaging the head and neck area, as well as the torso, it is beneficial to acquire two separate acquisitions — one with the arms elevated for torso acquisition and one with the arms by the sides for head and neck imaging. In radiation therapy treatment planning, the position of the patient should be the same as for radiotherapy treatment set-up.

Skull base to proximal thigh imaging is recommended for most tumour imaging, typically from the external auditory meatus to the mid-thigh region. For tumours with an increased potential for scalp, skull, or brain involvement or for lower extremity involvement, whole-body imaging is performed. Limited-area imaging can be performed when there is a specific area of interest.

PET acquisition and reconstruction protocols should always begin with the factory-recommended settings. Any modifications in protocol should be evaluated carefully to avoid affecting patient images in a negative manner. Over time, software upgrades and changes in professional recommendations may occur that warrant modification of the factory-recommended settings.

Many brands of scanners are available for use by the nuclear medicine community. Selection is based on patient population, department needs, costs and facility vendor preference.

Various professional organisations and societies have developed performance guidelines, including the American College of Radiology (ACR). The ACR-recommended scanner specifications are as follows:

For the CT scanner:

- a. Spiral scan time: <5 s (<2 s is preferable)
- b. Slice thickness and collimation: <5 mm (<2 mm is preferable)
- c. Limiting spatial resolution: >8 lp/cm for >32-cm display field of view (DFOV) and >10 lp/cm for <24-cm DFOV

For the PET scanner:

- a. In-plane spatial resolution: <6.5 mm
- b. Axial resolution: <6.5 mm
- c. Sensitivity (3D): >4.0 cps/kBq
- d. Sensitivity (2D): >1.0 cps/kBq
- e. Uniformity: <5%

For the combined PET/CT scanner:

- a. Maximum co-scan range (CT and PET): >160 cm
- b. Maximum patient weight: >159 kg
- c. Patient port diameter: >59 cm

EMISSION IMAGES

The acquisition time varies from 2 to 5 min or longer per bed position for body imaging. Continuous bed movement may also be utilised to image the patient, if the scanner has that capability. Acquisition time varies according to the administered activity, the patient body weight, 2D versus 3D and the count rate capability and sensitivity of the PET scanner. The average imaging time for skull to mid-thigh acquisition is 15–45 min. A variation in time per bed position can be used if the system is capable of that technique. This enables a faster scan time by permitting reduction in the time per bed position in areas outside of the torso because those areas have less attenuation. Administration of a higher activity can also reduce the image acquisition time, but compliance with ALARA principles requires a lower dose and longer acquisition. Formulas are available to calculate dose taking into account bed overlap and patient weight, and whether maximum or minimum activity is used.

When using systems with a high count rate capability, ^{18}F -FDG activity and scan duration for each bed position must be adjusted so that the product of the ^{18}F -FDG activity and scan duration $\pm 10\%$ is equal to or greater than the specifications set out below^[3]:

The figures for systems with bed overlap of <25% are:

- » Product of $\text{MBq/kg} \times \text{min/bed} > 27.5$ for 2D scans
- » Product of $\text{MBq/kg} \times \text{min/bed} > 13.8$ for 3D scans

The dosage is then calculated as follows:

- » FDG activity in MBq for 2D scans = $27.5 \times \text{weight}/(\text{min/bed})$
- » FDG activity in MBq for 3D scans = $13.8 \times \text{weight}/(\text{min/bed})$

And for systems with a bed overlap of 50%:

- » Product of $\text{MBq/kg} \times \text{min/bed} > 6.9$ (3D only)
- » FDG activity in MBq = $6.9 \times \text{weight}/(\text{min/bed})$

No matter what technique is used to determine the administered activity, the activity within the FOV should not exceed the peak count rate capability of the system.

2D VERSUS 3D ACQUISITION

PET images can be acquired in 2D or 3D mode. Earlier scanners used septa made of lead or tungsten that were positioned within the FOV. The septa provided a way to limit photons emitted or scattered outside the transverse or transaxial plane to the detector. This limited the sensitivity of

the scanner. Acquisition systems with septa are 2D scanners. Recent scanners developed in the early 2000s use 3D technology and do not use septa^[5]. Some scanners are capable of 2D and 3D acquisition^[6].

3D acquisition increases sensitivity four to ten times due to an increase in lines of response (LORs) resulting from the detection of cross-plane events^[7]. Removal of septa in 3D acquisitions provides a higher detection probability. Increased sensitivity also results in increased random and scatter contributions. To compensate, these scanners are also equipped with new and fast detectors using new scintillation crystals. Faster crystals provide better count rate performance. A short coincidence timing window can be applied, which results in a reduction of random and scatter coincidences. Due to low sensitivity at the edge of the detector ring in 3D acquisition, bed overlap from one bed position to the next may be warranted. In continuous motion acquisition there is no need for overlap, as there is uniform detector sensitivity over the patient^[6].

DYNAMIC IMAGES

Dynamic images may also be obtained when a specific area is to be imaged as a flow study. A bed position of 15–26 cm is capable of imaging smaller regions. Dynamic PET images are similar to dynamic

gamma camera images. Dynamic PET imaging acquires complete volume images within a set time frame. Typical times for evaluating arterial flow are 2 s per image followed by a longer imaging time to demonstrate further uptake of the tracer over time^[7].

LIST MODE

If the system is capable of it, images may be acquired in list mode. Events, timing markers and physiological gating markers are stored as lists in list mode; the data may be rebinned (recreated) during use of cardiac or respiratory gating. These data can then be formatted into sinograms for reconstruction. Time of flight scanners are capable of acquiring in list mode; therefore, list mode may become the standard method for acquiring data^[7].

DUAL TIME POINT

For certain disease states, dual time point imaging may be beneficial. This involves an initial scan, a waiting period and then a delayed scan. In the case of tumour imaging there will be an increase in activity over time, whereas in infections there will be a decrease over time^[6]. Thus delayed imaging can increase the specificity of whether activity is due to either tumour or inflammation.

STANDARD UPTAKE VALUE

Reported data should include the type of isotope utilised, the patient's height and body weight, FDG activity administered, assay time and time of injection. This aids in standardised uptake value (SUV) reporting. SUV is used to quantitate activity in body organs, abnormalities or the total body and supplements visual interpretation of an area. It is derived as follows^[8]:

$$SUV_{BW} = \frac{\text{(Region of interest (kBq/mL))}}{\text{Injected activity with decay-corrected residual subtracted (MBq/kg)/patient weight (kg) where BW is body weight.}}$$

ACQUISITION PARAMETERS

Further instructions on obtaining the emission image include that the online randoms correction should be based on the "delayed coincidence time window" technique or randoms correction using a model based on (block) single count rates. This has an effect on image contrast. Decay correction must be 'on', as well. Shorter image times result because of the increase in contrast that occurs from the high-quality image obtained with time of flight^[3].

TRANSMISSION IMAGE

The typical PET/CT scan involves the acquisition of a topogram followed by single or multiple helical CT scans. CT can be performed for attenuation correction, anatomical alignment or acquisition of an optimised diagnostic scan. When obtaining attenuation-corrected/anatomical alignment images, a low milliampere-seconds setting is used to reduce the radiation dose. In an optimised diagnostic CT scan, standard CT milliampere-seconds settings are used. This results in better spatial resolution of the CT scan. Modulation of the tube current may also be used to reduce radiation dose in patients without metal implants^[3]. This can be accomplished with dose reduction software developed by the manufacturer of the scanner, when available, and enables optimal low mA and kV settings to be used. It is always the case that selection of CT acquisition parameters, such as pitch, rotation time, slice thickness, increment, voltage and tube current, depends on the purpose of the CT scan. If the CT image is obtained solely for the purpose of attenuation correction, voltage and current can be reduced to near the lowest the scanner is capable of producing and still be acceptable.

Pitch is the ratio of table movement through the gantry during one 360° rotation, relative to beam collimation. The lower the pitch, the more the overlap. A pitch

of 1.0 will result in no spacing. A pitch of less than 1.0 results in overlap, while a pitch of 2.0, or higher, results in spaces between slices, equal to the thickness of the slice. Pitch is inversely proportional to patient dose. Increasing the table speed or pitch reduces the radiation dose in proportion to the increase in pitch (unless the scanner automatically increases mA with increase in pitch). However, image quality will be reduced^[9].

Slice thickness and increment define the positional relationship of image slices and the amount of separation between the slices or potential overlap. If the slice thickness is equal to the increment, there is no separation. If the slice thickness is less than the increment there is overlap. It is beneficial to have some overlap when attempting to detect smaller lesions^[9].

Regarding rotation time, at slower times a compensatory increase in mA is required to add more X-rays to the image. The slower the rotation time, the more blurred the image. A faster rotation time is beneficial when body motion is a concern. Increasing the rotation time will result in better resolution because each image is generated from more projections^[9].

Other CT acquisition parameters are voltage and tube current. Denser areas require a higher voltage. This voltage is measured in kVp. The higher the mA setting, or tube current, the higher the quality of the

image acquired; however, radiation dose will increase, as well^[9].

Attenuation correction is critical for both visual and quantitative accuracy of PET images. Attenuation will vary from patient to patient due to body make-up and size. The only way to accurately evaluate the attenuation coefficient is to pass a beam of radiation through the body and measure the attenuation. The first commercial PET/CT scanners appeared in 2001. By 2006 PET-only systems were

no longer available. Since 2006, scanners have used CT to accomplish attenuation correction^[5]. A topogram image is obtained prior to the PET scan, followed by single or multiple helical CT. When obtaining a CT scan for attenuation correction, a low milliampere-seconds setting is used to reduce radiation exposure. Some vendors offer patient-specific software which calculates the lowest acceptable dose to the patient (Tables 1 and 2).

Table 1: Example of a CT protocol based on current clinical practice^a

Topogram	35 mA 120 kVp 1024 mm
Dose modulation parameters	Patient-specific dose reduction techniques available on most systems
Slice	5 mm
Rotation time	0.5 s
Pitch	0.8 s
Reconstruction for AC	B30s, medium smooth FOV 780 mm
Reconstruction for imaging	B30f medium smooth 5x5 mm, 500 mm FOV

^a Check vendor specifications for scanner utilised. For acquisition and reconstruction protocols involving the brain and heart, please refer to the Tech Guide publications by the EANM on Brain Imaging and Myocardial Perfusion Imaging

Table 2: Example of a PET protocol based on current clinical practice^a

Scan duration	Continuous bed motion 1–2 mm/s 2–5 min/bed position
Matrix	256
Zoom	1
Reconstruction	Iterations 2, subsets 21
Filter	Gaussian
FWHM	5 mm

^a Check vendor specifications for scanner utilised. For acquisition and reconstruction protocols involving the brain and heart, please refer to the Tech Guide publications by the EANM on Brain Imaging and Myocardial Perfusion Imaging

USE OF CONTRAST

Contrast may be used when performing the CT portion of the scan to enhance demonstration of the anatomy. Contrast can be administered orally or intravenously. Oral contrast is administered when the area of interest is in the gastrointestinal tract. Intravenous (IV) contrast is administered when vascular structures need to be differentiated^[3].

The patient's creatinine level and/or glomerular filtration rate should be tested prior to administration of IV contrast in order to reduce the possibility of damage to the kidneys. Metformin, an oral hypoglycaemic agent, should be discontinued for 48 h post IV contrast injection^[6].

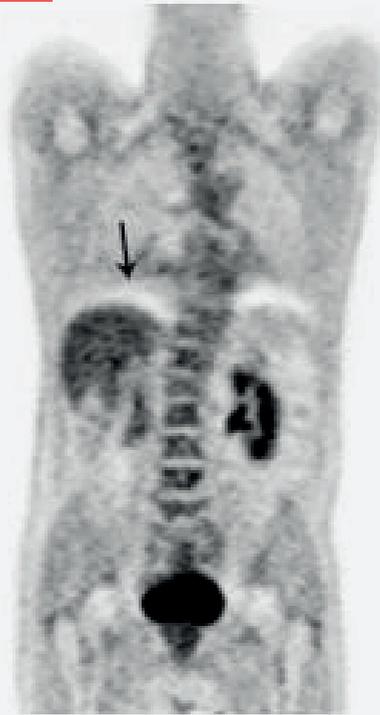
BREATHING PROTOCOL

The CT for attenuation correction should be acquired during the resting phase or shallow breathing. If the CT scanner has six or fewer detector rings, use of a breath-hold protocol in normal expiration should be considered for the duration of scanning of the thorax and upper abdomen. Deep breath-hold for chest CT acquisition can cause misregistration artefacts on the emission image (Fig. 2).

IMAGE FORMATION AND RECONSTRUCTION

The method of reconstruction of PET images can vary greatly according to the manu-

Figure 2



A curvilinear cold artefact (arrow) is commonly seen at the dome of the diaphragm/ liver or at the lung base because of a respiration mismatch on PET images with CT attenuation correction. Courtesy of the Journal of Nuclear Medicine Technology (JNMT)^[4]

facturer and age of the equipment. There is typically a proprietary file format, unique to each vendor and model, which contains the raw data. Raw data are first formatted into sinograms. The sinograms represent the activity across the detector at each projection angle. The sinograms are reconstructed into axial image slices and corrections are

applied. Other projection planes are then created from the PET and the CT, to include coronal and sagittal. The CT scan data are used to create an attenuation correction map for use in image reconstruction.

IMAGE RECONSTRUCTION METHODS

PET/CT image reconstruction is similar to SPECT. Image reconstruction is a process of calculating the 3D activity distribution from the sinograms. During reconstruction the data are normalised, with application of corrections for random coincidences, scatter radiation, attenuation, dead time and decay. Reconstruction algorithms and order of application vary between equipment manufacturers and may be proprietary.

Reconstruction algorithms are generally classified into two methods: analytical and iterative. Image reconstruction differs for 2D and 3D imaging. One sinogram is created for each 2D slice during 2D reconstruction and one sinogram is created for each projection plane during 3D mode image reconstruction^[9]. The majority of current scanners are 3D; therefore 3D image reconstruction will predominantly be discussed in this chapter.

In the past, the most commonly used analytical image reconstruction method was filtered back-projection (FBP). FBP is

the process of back-projecting data across the imaging matrix. It is a quick and simple method. However, the produced images suffer from extra noise and streaking artefacts which result in an overall reduction of contrast. FBP has consequently been replaced by iterative methods.

Iterative reconstruction is the process of creating estimates of actual radiopharmaceutical distribution in an object. Each projection estimate is compared with the measured projection data, and the difference between them is then used to create a new estimate^[10]. This process continues until the difference between the estimate and the measured values reaches a specified value. A point is reached in the number of iterations where there will be no further improvement in image quality. Once this point has been reached, further iterations can actually begin to degrade the image quality. It is important to determine the number of iterations which will yield optimal image quality. The number of iterations is preset by the user. While iterative reconstruction produces images with less noise and artefacts than FBP, it is computationally intense and takes significantly longer than FBP.

Maximum likelihood expectation maximisation (MLEM) was one of the first iterative algorithms. MLEM requires the use of all the image data. The process proved to be time consuming and oth-

er techniques were developed which are faster and more efficient. Ordered subset expectation maximisation (OSEM) is one of the most common iterative algorithms. OSEM does not require the use of all the image data; instead only a subset of the projection data is used, resulting in a drastic reduction in reconstruction time. Two approaches are used: (a) a higher number of subsets (8–24) and small number of iterations (2–8) and (b) fewer subsets (2–8) but more iterations (8–24). Both methods maintain the image quality despite the reduction in reconstruction time. In clinical practice, use of fewer iterations and increased subsets appears to be the most widely used approach. Other iterative methods have been developed by proprietary vendors as well^[7].

Use of 3D image reconstruction requires additional steps beyond the requirements of 2D image reconstruction. Reconstruction options for 3D image data are determined by the age of the scanner and software limits. The reconstruction of 3D data requires that the raw data, 3D sinograms, be either rebinned into 2D information or reconstructed completely as a full 3D volume^[10]. Significantly more data are acquired in 3D mode due to the increase in sensitivity. Reconstructing 3D data in full 3D mode is computationally intense and currently this option is only available on newer scanners. Traditional methods require 3D data to be

converted into 2D sonograms, followed by completion of the process of iterative reconstruction. Methods available to complete this conversion of data from 3D to 2D include single slice rebinning (SSRB) and Fourier rebinning (FORE). SSRB rebins 3D data into 2D projection sinograms. SSRB results in a blurring of image data and is not commonly used today since there are better approaches. FORE incorporates a more accurate process for converting data from 3D to 2D projection data and is therefore the most widely used technique. Rebinning results in reduced resolution as the distance from the axial centre of the FOV increases. Full 3D reconstruction does not require the conversion of data and is the optimal method to avoid the resolution loss associated with rebinning. Fully 3D reconstruction is only available on modern scanners but is the standard on new equipment. There is a significant increase in data in the reconstruction process due to the increase in the number of LORs contained in each sinogram, which means that additional computer components must be devoted to this step^[11]. The process of full 3D reconstruction is very complicated and is beyond the scope of this chapter.

Along with reconstruction algorithms, the data must also undergo filtering. The filter most commonly used in PET whole-body imaging, for the purpose of smoothing the image, is the Gaussian filter. This filter is not

defined by a parameter in frequency space like most filters used in nuclear medicine; rather, it is defined by its full-width half-maximum (FWHM) in pixel space, which is more commonly known as the spatial domain. The width of the filter is measured in millimetres. Increasing the FWHM on the Gaussian filter will result in a smoother image. A high-resolution image can be produced by applying a FWHM value of 5 mm.

SCATTER CORRECTION

Scatter correction is essential to achieve accurate PET data. In 3D acquisition modes, scatter coincidences are even greater than in 2D mode. Therefore, scatter correction methods are even more important. There are two scatter correction methods: energy window-based methods and calculation-based methods. Accurate scatter correction is difficult to determine. Energy window-based methods require acquisition of a second energy window below the original energy window. Calculation-based methods are preferred. Such methods are modelled rather than measured, the amount of scatter correction depending on the model applied. Single scatter simulation is a currently used calculation-based method. Scatter correction is applied during image reconstruction and should take place prior to attenuation correction.

TIME OF FLIGHT

Time of flight (ToF) PET systems are not a new concept. ToF PET coincidence imaging was used during the 1980s on experimental systems^[12]. The first PET scanners used bismuth germinate (BGO) crystals, which have a low stopping power and limited spatial resolution and cannot support ToF PET. ToF systems were limited to research until the early 2000s. Current PET systems provide scintillators with a higher density, shorter decay time and modern electronics which allow for faster computing power. Lutetium oxyorthosilicate (LSO) and lutetium-yttrium oxyorthosilicate (LYSO) both have good timing resolution and increased stopping power and energy resolution. ToF PET is common on today's scanners. ToF PET allows for more accurate determination of where an event has taken place. If an event occurs anywhere other than the midline of an LOR, the crystal closer to the annihilation event will detect its photon first. The time difference between the arrival of the two photons is used to determine where along the LOR the event took place. As a result, ToF PET increases image resolution. The greatest benefit is found in larger patients, who suffer most from poor image quality. ToF PET requires additional considerations during reconstruction. The addition of ToF data prompts a shift from sinogram to list mode reconstruction^[12].

POINT SPREAD FUNCTION CORRECTION

Point spread function (PSF) correction is a software option that corrects for the blurring arising from mispositioning of events due to variation in depth of detection within the patient. Some vendors refer to such correction as high-definition imaging. PSF corrections are applied during reconstruction as part of the reconstruction algorithm. Detections along the edges of the axial FOV can be slightly misplaced, resulting in blurring of small outer lesions. PSF corrects for the blurring and enhances visualisation of these lesions. PSF corrections are available on new scanners.

PITFALLS AND ARTEFACTS

Due to issues beyond the control of the technologist, common artefacts can be demonstrated on the PET/CT scan due

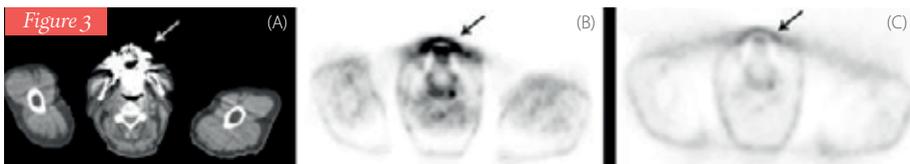
to the partial volume effect, metallic implants, respiratory motion, contrast medium and truncation.

Partial volume effect

The partial volume effect is the apparent loss of density or concentration of a small object which occurs on PET and CT when lesions are small compared with the resolution of the scanner. The size of an object or lesion needs to be approximately three times greater than the image resolution for the activity to be accurately represented^[7].

Metallic implants

Streaking artefacts are generated when metallic objects exist within the patient, such as dental fillings, hip prosthetics or chemotherapy ports. The metallic object leads to an overestimation of PET activity in the region of the object when the CT attenuation correction map is applied. This will lead to a false positive PET finding. However, not



A) Example of the way in which high-density metallic implants generate streaking artefacts and high CT numbers (arrow) on CT images. **B)** High CT numbers will then be mapped to high PET attenuation coefficients, leading to overestimation of activity concentration. **C)** PET image without attenuation correction helps rule out metal-induced artefacts. Courtesy of the Journal of Nuclear Medicine Technology (JNMT)^[8]

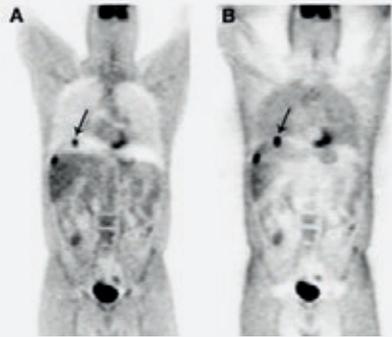
all metallic objects produce false positives. For example, in the case of hip prosthetics, the implants produce high CT numbers because of their high photon absorption. These implants will also attenuate the PET 511-keV photons. This results in no emission data and demonstration of a cold area. When CT attenuation correction is performed, the PET images show diminished uptake in that area. In these cases, the non-attenuated PET images can be useful for interpretation of the study (Fig. 3).

Respiratory motion

Due to the nature of the human body, respiratory motion is the most common artefact demonstrated on a PET/CT image. The artefact is due to the difference between the chest position on the PET image and the chest position on the CT image. The image resulting from a PET scan is an average of many breathing cycles while the CT image is obtained at a single stage of one breathing cycle. To partially compensate for this possible artefact, the CT image can be obtained at mid-expiration, at mid-inspiration or during shallow breathing. The image produced has a curvilinear cold area at the lung–diaphragm interface. The most critical impact of this artefact is on liver lesions. Because of this motion, a liver lesion may appear to be in the lung, simulating a lung nodule. This type of artefact is a misregistration of lesions. In these cases,

use of the CT image to define the location of the lesion will help in interpretation. To minimise respiratory motion artefacts, the breathing procedure should be explained to the patient thoroughly before beginning the study (Fig. 4).

Figure 4



A 58-year-old man with colon cancer.

A) Lesion at the dome of the liver is mislocalised to the right lung (arrow) because of respiratory motion. **B)** Image without attenuation correction shows that all lesions are confined to the liver. Courtesy of the *Journal of Nuclear Medicine Technology (JNMT)*^[1]

Contrast media

As previously mentioned, contrast agents can be administered in PET/CT studies. Contrast agents such as barium sulphate and iodine that are within the patient from a previous study can give rise to a false pos-

itive finding on the PET image because they mimic metallic object artefacts. The higher the concentration of the contrast, the higher the CT number, resulting in higher PET attenuation coefficients. This causes an overestimation of the PET tracer uptake, which

mon in larger patients or patients imaged with their arms down by their sides. When a patient extends beyond the CT FOV, the extended anatomy is truncated and not represented in the reconstructed CT image. This results in no attenuation correc-

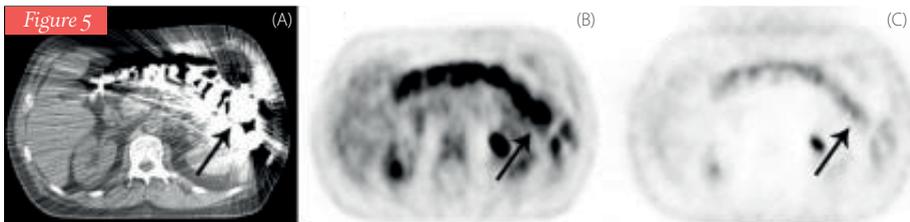


Figure 5 A 61-year-old patient with lung cancer who ingested barium for an oesophagogram one day before PET/CT scan. **A)** Concentration of contrast medium in colon (arrow) is increased because of significant water reabsorption, shown on the CT image. **B)** High CT numbers of residual barium overcorrect attenuation of PET emission data and mimic increased ^{18}F -FDG uptake on the PET image with CT attenuation correction. **C)** No increase in ^{18}F -FDG uptake is seen on the image without attenuation correction. Courtesy of the Journal of Nuclear Medicine Technology (JNMT)^[1]

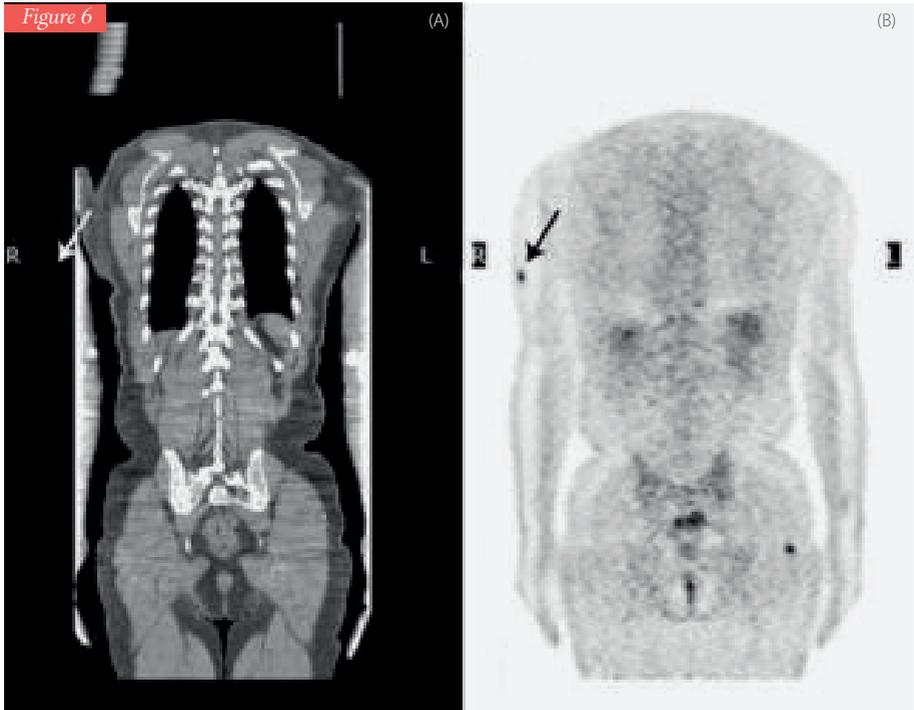
is the reason for the false positive study. A technologist should be aware of whether the patient has had a previous study involving use of contrast. In the case of prior contrast use and presence of the resulting artefact, the non-attenuated PET images can be used for interpretation (Fig. 5).

Truncation

Truncation artefacts occur because of the difference in size of the FOV between the CT and PET images. They are most com-

mon in larger patients or patients imaged with their arms down by their sides. When a patient extends beyond the CT FOV, the extended anatomy is truncated and not represented in the reconstructed CT image. This results in no attenuation correc-

tion values for the corresponding region. The consequence is a bias on the PET attenuation-corrected images, which underestimate the SUV in the region in question. Truncation also produces streaking artefacts at the edge of the CT image, resulting in an overestimation of the attenuation coefficients to be used to correct the PET data. To avoid this artefact, the patient should be positioned in the centre of the FOV and imaged with the arms above his or her head, when possible (Fig. 6).



A 54-year-old man with a history of metastatic melanoma (arrow). The CT image **(A)** appears truncated at the sides and biases the PET attenuation-corrected image **(B)**. Courtesy of the *Journal of Nuclear Medicine Technology (JNMT)*^[4]

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ACCREDITATION FOR CLINICAL TRIALS: THE EANM EARL PROJECT



by Giorgio Testanera and Michel de Groot

INTRODUCTION

Multiple research studies have shown the benefit of combined positron emission tomography (PET) and computed tomography (CT) in clinical decision making using 2-[¹⁸F]fluoro-2-deoxy-D-glucose (FDG) as the leading radiopharmaceutical for diagnosis, staging, prognosis and response monitoring. PET/CT has the ability to provide quantitative information through image analysis of the distribution of a wide variety of PET radiopharmaceuticals, including FDG, using standardised uptake values (SUVs).

Both quantification and the development of new and promising PET radiopharmaceuticals have become more important in clinical decision making and improved quality of care for the individual patient^[1,2].

The use of FDG-PET as a surrogate tool for monitoring of therapy response offers better patient care by allowing individualisation of treatment and avoidance of ineffective treatments: surgery, radiation therapy or chemotherapy. Imaging biomarkers are of paramount importance, not only for patient evaluation but also for drug development.

QUANTITATIVE PET/CT

Quantification in PET/CT can be defined as the use of a combination of methods to enhance image resolution, reduce image noise and perform data analysis, and use of the maximum standardised uptake value (SUV_{max}) can be considered as the standard quantitative method in practice. Assessment of cellular uptake is one of the

greatest tools for establishing the position of PET/CT as a state of the art modality in oncology patient care within the competitive environment of diagnostic imaging.

Owing to its widespread use in tumour response assessment studies, the SUV, defined as the activity concentration ratio in tissues, can be considered the measure to be used in order to standardise PET scans. Absolute SUV is used for definition of patient eligibility, patient stratification and lesion selection, while relative SUV (percentage changes from pre-treatment values) can also be used to evaluate response to therapy. However, SUV measurements present uncertainties that may result in resistance to their use in clinical trials of cancer therapies. Possible causes of uncertainties are as follows^[3]:

Technical factors

- » Relative calibration between the PET scanner and dose calibrator (10%)
- » Residual activity in the syringe (5%)
- » Incorrect synchronisation of clocks (10%)

- » Injection vs. calibration time (10%)
- » Quality of administration (50%)

Physics-related factors

- » Scan acquisition parameters (15%)
- » Image reconstruction parameters (30%)
- » Use of contrast agents (15%)
- » ROI (50%)

Biological factors

- » Uptake period (15%)
- » Patient motion and breathing (30%)
- » Blood glucose levels (15%)

Furthermore, the variability in methodology across centres hinders the exchange of SUV measurements. Therefore, standardisation of FDG-PET whole-body procedures is essential in multicentre trials. Accordingly, the nuclear medicine community is working to achieve standardisation of PET/CT imaging and to improve the quality of the images generated, both in clinical routine and in clinical trials^[1,2].

EARL

In 2010, the European Association of Nuclear Medicine (EANM) initiated a programme for the accreditation of PET/CT scanners using FDG in order to support compliance with requirements regarding quality control (QC) and quality assurance of PET/CT systems. The programme, run

within the scope of EANM Research Limited (EARL) activities, was originally based on *FDG-PET and PET/CT: EANM procedure guidelines for tumour PET imaging: version 1.0*, published in the European Journal of Nuclear Medicine and Molecular Imaging (EJNMMI). This widely accepted guideline, revised to version 2.0 in 2014, aims at harmonising quantification in multicentre studies and providing a minimum standard for the acquisition and interpretation of PET and PET/CT scans obtained with FDG. The guideline specifically addresses patient preparation, dosage of FDG as a function of scanner model, patient weight and scan duration, data acquisition, image reconstruction, data analysis and QC procedures^[2,4].

The FDG-PET/CT accreditation ensures harmonised quantitative performance of PET/CT systems within a multicentre setting through the standardisation of acquisition and processing of PET/CT scans. This rigorous harmonisation of imaging systems enables PET/CT sites to compare, exchange and combine FDG-PET/CT findings as data are collected and processed. SUVs can also be reliably used owing to the resultant reduction in inter- and intra-institute variability. The standardisation achieved by the accreditation programme relates to imaging procedures and methodology, including patient preparation,

scan acquisition and image processing and analysis, which is of the utmost importance for quality assurance in daily clinical practice as well as in multicentre trials^[2].

COLLABORATION WITH OTHER INSTITUTIONS

The EARL FDG-PET/CT accreditation programme is strongly supported by the European Organisation for Research and Treatment of Cancer Imaging Group (EORTC-IG), which was founded in 2009 to ensure standardisation of image acquisition and quality assurance for EORTC clinical trials with regard to CT, PET, magnetic resonance imaging (MRI) and other imaging modalities as they become available^[5]. EANM/EARL and the International Atomic Energy Agency (IAEA) are also working together with respect to quality standards in nuclear medicine. EANM/EARL is aware of the different harmonisation and standardisation efforts regarding PET/CT worldwide and is eager to contribute to a possible alignment of accreditation programmes. To this end, discussions are being held with the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Clinical Trials Network (CTN).

Furthermore, the Japanese Society of Nuclear Medicine (JSNM) has adopted the basis of the EARL accreditation pro-

gramme. The Italian Lymphoma Foundation (FIL), Lymphoma Study Association (LYSA) and GELA (Groupe d'Etude des Lymphomes de l'Adulte, i.e. Adult Lymphoma Study Group) are further groups that have taken the EANM imaging guideline as the basis for PET/CT QC within their studies. The Society of Nuclear Medicine, India (SNMI) and the Brazilian Society of Nuclear Medicine (Sociedade Brasileira de Medicina Nuclear/SBMN) have also expressed great interest in the EARL FDG-PET/CT accreditation programme.

The EANM imaging guideline is widely accepted and is also well represented within the draft of the Uniform Protocols for Imaging in Clinical Trials (UPICT), established by the Quantitative Imaging Biomarkers Alliance (QIBA).

MULTICENTRE CLINICAL TRIALS

The goal of the EARL FDG-PET/CT accreditation programme is to enhance the quality standard of PET/CT investigations for both daily use and multicentre studies. FDG-PET/CT accreditation ensures similar performance of PET/CT systems within a multicentre setting through the harmonisation of acquisition and processing of PET/CT scans. Centres can compare, exchange and combine FDG-PET/CT findings, including SUVs, since data are collected and processed in a standardised manner^[2].

In order to ensure that data can be exchanged between centres participating in a multicentre trial organised in collaboration with EARL, it is essential that all PET/CT systems used in the trial are accredited by EARL. Furthermore, all centres should be required to apply the EARL-approved parameter settings (used for processing of the QC phantom images) for the reconstruction of imaging during the course of the trial. The sites can apply additional reconstructions for other purposes, local use or diagnostic interpretations. The EANM provides recommendations for acquisition times per bed position in combination with dosage per kg patient weight for various types of PET/CT system in the EANM imaging guideline^[2].

An up-to-date list of accredited centres participating in the EARL FDG-PET/CT accreditation programme, also known as the Centres of Excellence (CoE), can be found via the EARL website.

ACCREDITATION BENEFITS

The current established and scientifically validated FDG-PET/CT accreditation programme provides independent quality control/assurance within multicentre clinical trials and specifically addresses the needs of the pharmaceutical industry regarding harmonisation and standardi-

sation. Centres seeking accreditation also benefit from:

- » EARL's knowledge, which is based on the contributions of worldwide-recognised imaging experts, with a global leading role in PET/CT research, who provide advice within the programme and monitor its development.
- » Imaging results that can be compared, exchanged and combined, since the prerequisite for evaluation of imaging results within preclinical and clinical (multicentre) trials is comparable scanner performance across multiple sites (reduction of inter- and intra-institute variability in SUV results; provision of lower/upper limits of recovery coefficients; calibration factor within $\pm 10\%$).
- » Accurate, reproducible and quantitative assessment enabled through standardisation of methodology, including patient preparation, scan acquisition, image processing and analysis.
- » Reliable and quantitative imaging biomarker results generated within multicentre clinical trials, leading to an enhanced outcome (e.g. information on biological/pathological processes and response to therapeutic intervention) and thus accelerating compound development and approval by the regulatory agencies and lowering costs in the long run^[4].
- » An exploratory further optimisation, presently being evaluated by EARL. This

procedure would allow lowering of the administered FDG activity for PET/CT systems with higher sensitivity or improved performance using new enhanced technology (e.g. better time-of-flight performance, continuous bed motion or extended axial field of view, i.e. length of bed position).

PROCESSES INVOLVED IN ACCREDITATION

Sites which are seeking EARL FDG-PET/CT accreditation for the first time need to pass through the initial procedure. This procedure includes submission of the online questionnaire and signing of the statement and signet policy. Additionally, sites are asked to perform and submit QC data within the subsequent 3 weeks. For this purpose, sites have to perform calibration QC measurements using a cylindrical calibration phantom and image quality QC measurements using a NEMA NU2-2001/2007 image quality phantom and to submit online the image data in DICOM format and the results to EARL. A detailed step-by-step procedure is published in the FDG-PET/CT accreditation manual to assist sites in adequately performing these measurements. After submission and independent review of the results by EARL, the site is granted EARL FDG-PET/CT accreditation, assuming the results meet EARL requirements^[2,6].

After initial accreditation, centres are requested at fixed quarterly intervals to meet the standard requirements, as described in the most recent versions of the EANM imaging guideline and manual, in order to retain their accreditation. Failure to adhere to the deadlines for submission may lead to EARL putting a centre's accreditation on hold. The documentation in the initial accreditation procedure needs to be submitted only once, whereas the QC measurements and documents need to be regularly performed and submitted to retain the accreditation. An update of the online questionnaire in the first quarter of each year is a prerequisite for submission of the QC documents^[2,6].

SPECIFIC QUALITY CONTROLS

Calibration QC

Calibration QC measurements should be performed for initial accreditation and have to be repeated every 3 months. The aim is to verify that the average activity concentration and/or SUV within the phantom is within 10% of the expected value. For this purpose a cylindrical calibration phantom of any dimension but with a precisely known volume is required (it is preferable to obtain the phantom via the manufacturer, ensuring that it is specific for the used PET/CT model; if this is

not possible, the phantom should be 20 cm in diameter and 20–30 cm long) (Fig. 1¹). The process of cross-calibration determines the correct and direct (cross- or relative) calibration of the PET/CT system with the institution's own dose calibrator or against another one which is used to determine patient-specific FDG activities^[4].

ly 70 MBq (65–75 MBq) FDG. The FDG activity is dispensed into the phantom when it is completely full with water, ensuring that all the activity is in the phantom by flushing the syringe a few times. The phantom must then be vigorously shaken in order to homogenise the distribution of the activity.



Figure 1

Calibration QC setup (© Giorgio Testanera and Fabio Provenzano, Humanitas Research Hospital)

All relevant information on the standard operating procedure (SOP) needs to be recorded accurately, including the exact phantom volume, the scanner hardware and software, the exact doses and the time of performance of every step.

It is first necessary to prepare a 5- to 10-ml syringe with an activity of approximate-

After positioning the phantom in the centre of the gantry, a PET/CT scan consisting of at least two PET bed positions needs to be acquired. PET/CT scan acquisition and reconstruction should be performed identically to patient studies as prescribed in the clinical protocol. However, for statistical reasons somewhat longer emission

times (e.g. 5–10 min per bed position) are recommended, with inclusion of a standard transmission scan or (low-dose) CT for the purpose of attenuation correction.

Reconstructions should be performed with corrections for attenuation, scatter, normalisation, decay and dead time, i.e. all corrections necessary for quantification [6].

- » to determine/check the correctness of a calibration and quantification using a non-cylindrical (calibration) phantom containing a set of high-contrast spherical objects
- » to measure standardised “activity concentration or SUV recovery coefficients” as a function of sphere (tumour) size

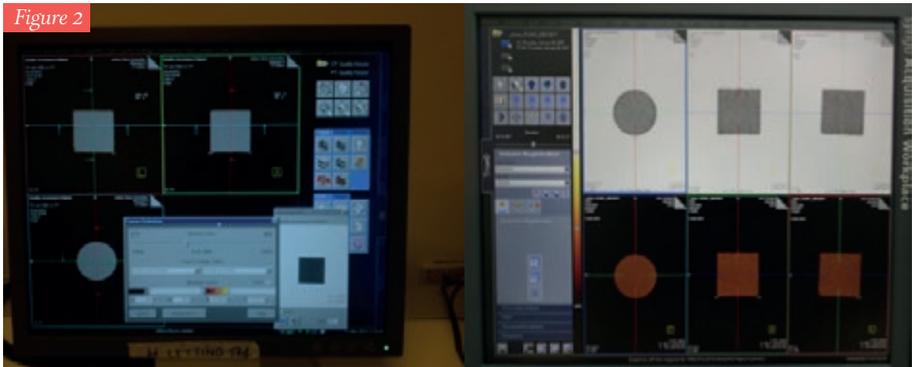


Figure 2
Typical calibration QC images

Image quality QC

Although correct cross-calibration is guaranteed using the calibration procedure described above, differences in SUV quantification may still occur between centres as a result of differences in the reconstruction and data analysis methodology. Consequently, an image quality QC procedure has been developed:

The main aim of this procedure is to guarantee comparable quantitative PET/CT system performance with respect to SUV recovery and quantification. Image quality QC measurements should be performed for initial accreditation and thereafter have to be performed and submitted every year. These measurements are based on calculation of SUV

recovery coefficients using the NEMA NU2-2007 image quality phantom (Fig. 3). The recovery coefficient is determined as a function of the sphere size, using the maximum pixel value and the A50 volume of interest (VOI). As for calibration QC, all relevant information on the SOP must be recorded accurately, including the exact volume of the phantom, the scanner hardware and software, the ex-

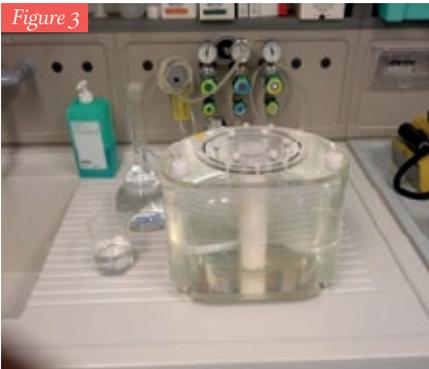


Figure 3

The NEMA NU2-2007 image quality phantom

act doses and the time of performance of every step^[4, 6].

The first step is to prepare two syringes, each containing 20 MBq of FDG at the expected phantom acquisition time. To prepare the solution for use in the spheres, a bottle should be filled with exactly 1,000 ml of water, which is then

mixed with the FDG contained in one of the syringes (20 MBq), flushing the syringe several times and homogenising the solution (Fig. 4). After this step, the different diameter spheres inside the phantom should be filled, leaving no air inside of the spheres.

The next step is to remove 30 ml water from the background compartment



Figure 4

The image quality phantom preparation procedure, step 1

of the phantom and to add 20 MBq of FDG, flushing several times to ensure that all activity has been dispensed from the syringe into the phantom. At this point, the background compartment should be filled entirely with water and the solution homogenised by shaking the phantom vigorously (Fig. 5).



Figure 5

The image quality phantom preparation procedure, step 2

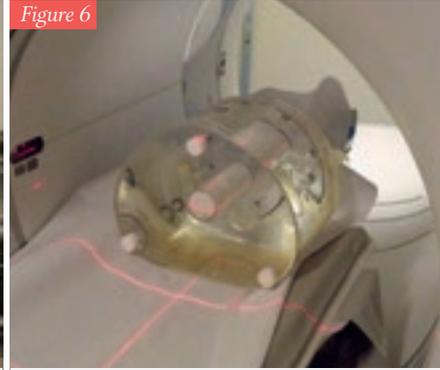


Figure 6

The image quality phantom scanning procedure

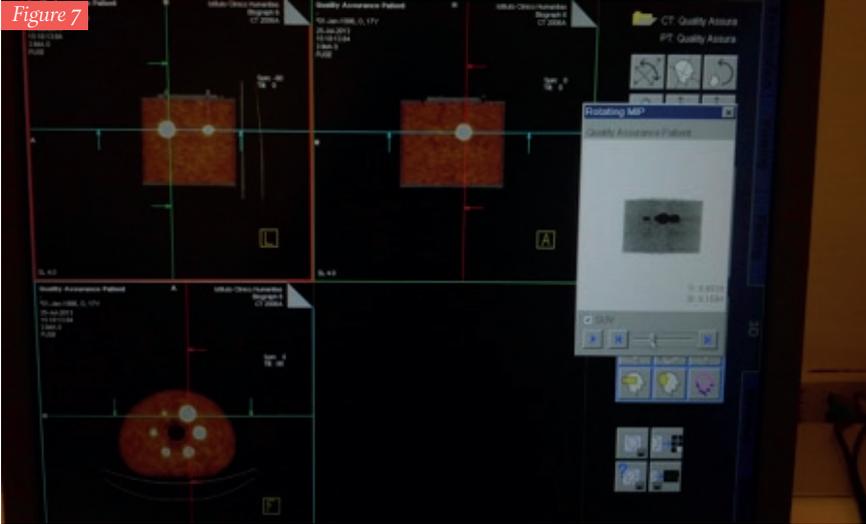
It is now possible to acquire a routine quantitative whole-body FDG-PET scan of at least two PET bed positions (at least 5 min per bed position), covering the entire phantom, with use of standard acquisition parameters as specified in the guidelines (Fig. 6). It is important to position the phantom so that the spheres are located at the centre of the axial field of view.

Reconstructions should be performed with corrections for attenuation, scatter, normalisation, decay and dead time, i.e. all corrections necessary for quantification (Fig. 7)^[4].

GENERAL SUGGESTIONS

All procedures require great accuracy, and various pitfalls are possible:

- » Equipment used in obtaining EARL accreditation (e.g. dose calibrator, PET and/or CT system, clocks) should be able to perform accurately and precisely within operational tolerances; typically this means that equipment is calibrated and periodically serviced.
- » All clocks involved in the procedure (dose calibrator, PET or PET/CT system) should be synchronised with the official local time to within 1 min in order to prevent unnecessary deviations in activities.
- » Residual activity within the syringe will result in incorrect verification of PET or PET/CT system calibration; therefore post-injection measurement of activity in the syringe is advisable.
- » Accurate quantification in PET or PET/CT can be threatened by high dead time or



Typical image quality phantom images

random fractions. To prevent this, it is important to check whether the count rates exceed the limits of the scanner acquisition system. If count rates do exceed these limits, it is suggested that a QC with a lower FDG activity should be performed, perhaps with preparation of the phantom a couple of hours in advance to allow for radioactive decay.

- » The use of FDG with high activity concentrations can result in inaccurate dosing; in these cases (a portion of) the stock solution should be diluted to clinically used activity concentrations before use.

Additionally, sites should always be aware that accreditation is granted for a

specific system (manufacturer and model) and that EARL needs to be informed if a PET/CT system has been replaced and/or upgraded (since this may have consequences for the current accreditation) or if a centre wishes to obtain accreditation for an additional PET/CT system [2, 3].

DATA ANALYSIS

The dedicated software that has been developed to ensure standardised analysis of QC documents allows the automatic import of data from the scan report forms to the analysis tool, which minimises sources of error and further standardises and facilitates work procedures. The calibration

Figure 8

ACCREDITATION FOR CLINICAL TRIALS:
THE EANM EARL PROJECT

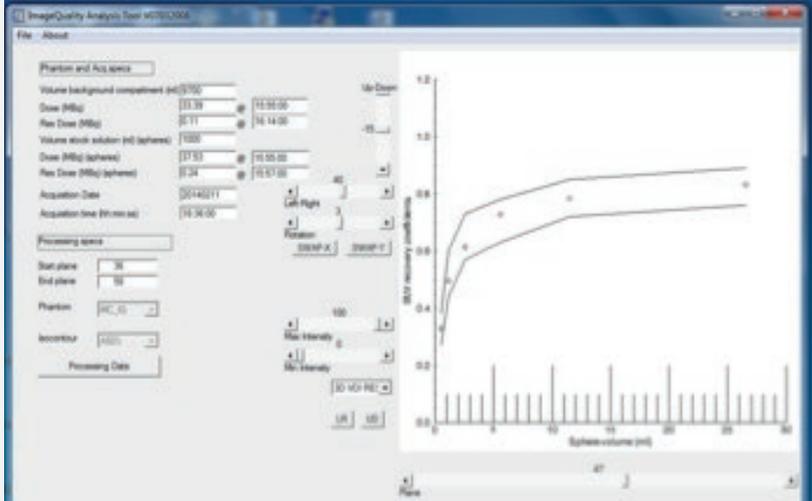
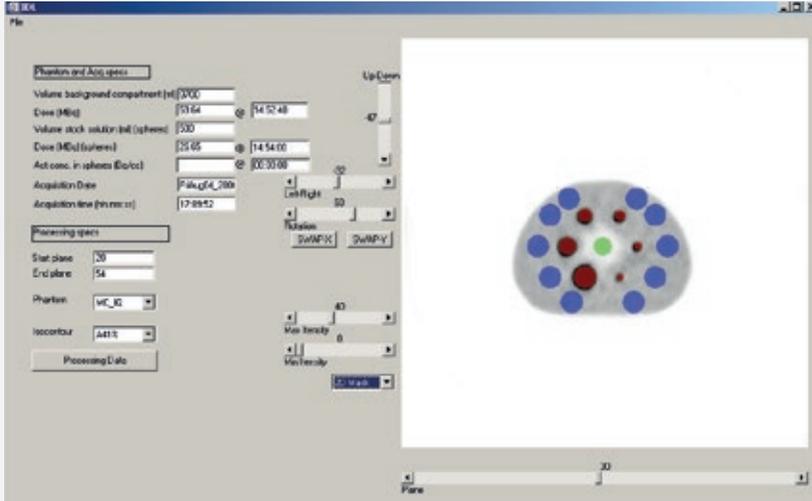


Image quality results verification with dedicated software

QC phantom measurements reveals the cross-calibration factor between the PET/CT system and the dose calibrator. This factor needs to be within $\pm 10\%$ from 1. The image quality QC phantom measurements are analysed in order to determine the background calibration factor by using several VOIs placed in the uniform background compartment. The maximum allowable calibration deviation is again $\pm 10\%$ from 1. Additionally, the SUV recovery coefficients are calculated for each sphere (Fig. 8). A cold spot recovery using a central insert to verify the accuracy of scatter correction is also performed. The software automatically compares the results of both QC phantom analyses with the EARL specifications^[2].

TECHNOLOGIST'S ROLE AND DAILY PRACTICE

In PET centres, technologists have the major role of acquiring images with PET and PET/CT scanners and ensuring that the acquired images meet the quality standards established by departmental criteria. The first step in assuring that quantitative imaging is accurate is compliance with all QC procedures stipulated for the PET scanner by national regulations, the vendor and local regulations. Working at an accredited site for clinical trials implies not only greater accuracy in standard daily practice but also a different mindset. Involvement

in the accreditation procedure may help technologists to develop this new mindset and to raise operating standards. There is a great ongoing debate in Europe regarding the basic competencies and advanced practice of nuclear medicine technologists. A consensus document^[7] has distinguished two levels, as follows:

Entry level

- » A competence and skill set that is considered necessary to ensure that nuclear medicine procedures are conducted to an appropriate level
- » This competence and skill set would be acquired during basic training/formative professional education

Advanced practice

- » A competence and skill set that is acquired after basic training
- » The competence and skill set would be at a higher cognitive and clinical level than basic training/formative professional education
- » The competence and skill set would seek to improve patient care and management
- » The competence and skill set would seek to offer clinical career progression opportunities

It is true that the technologist's role in EARL accreditation can be considered a basic

competency, since it mainly relates to QC, but meeting the high-quality standards required surely pushes technologists to improve their working skills. This improvement, often requiring a completely new skill set, can be considered at the higher cognitive level and fosters improvement of patient care and departmental efficiency. Therefore, the role of the technologist can be considered to be either basic or advanced, depending on whether he or she is taking the lead in the process, and can be a good starting point in further

developing advanced practice in nuclear medicine departments.

Useful links

<http://earl.eanm.org/cms/website.php>
(EARL website – home)

Copyright Information

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FURTHER SUGGESTED READING

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QUALITY CONTROL OF NUCLEAR MEDICINE
INSTRUMENTATION AND PROTOCOL STANDARDISATION

RADIONUCLIDE CALIBRATOR



by Aljaz Socan

INTRODUCTION

When undertaking any practices involving the human administration of a radiopharmaceutical, it is essential to use sensitive instrumentation for the detection and measurement of radioactive emissions. This allows a practical measure for dispensing the low amounts required for diagnostic uses and an accurate measure of therapeutic levels of radioactivity. This is also especially important for experimental work contributing to scientific knowledge relating radiation doses to biological effects.

When radiations from a radioactive material pass through matter, they interact with atoms and molecules and transfer energy to them. The transfer of energy has two effects: ionisation and excitation. Ionisation occurs when the energy transferred is sufficient to cause an orbital electron to be stripped away from its parent atom or molecule, thus creating an ion pair (a negatively charged electron and a positively charged atom or molecule). Excitation occurs when electrons are perturbed from their normal arrangement in an atom or molecule, thus creating an atom or molecule in an excited state. Both of these processes are involved in the detection of radiation events; however, ionisation is the primary event, and hence the term ionising radiation is frequently used when referring to the emissions from radioactive material^[1].

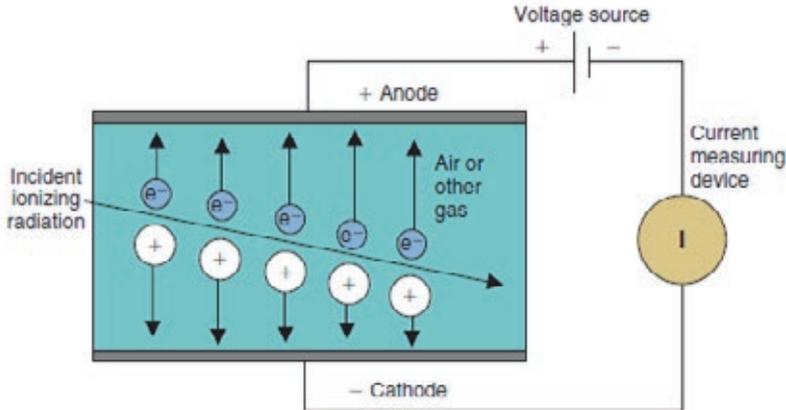
BASIC PRINCIPLES

Most gas-filled detectors belong to a class of detectors called ionisation detectors

(ionisation chambers). These detectors respond to radiation by means of ionisation-induced electrical currents.

A volume of gas is contained between two electrodes having a voltage difference (and thus an electric field) between them. The negative electrode is called the cathode, the positive electrode the anode (Fig. 1). Under normal circumstances, the gas is an insulator and no electrical current flows between the electrodes. However, radiation passing through the gas causes ionisation, both direct ionisation from the incident radiation and secondary ionisation from delta rays^[1]. Gas-filled detectors include ionisation chambers, proportional counters and Geiger-Müller (GM) counters. The use of these detectors in nuclear medicine is somewhat limited because their stopping power and detection efficiency for X-rays and gamma rays are quite low; however, they find some use for applications in which detection efficiency is not a major factor and for detection and measurement of non-penetrating, particle-type radiations^[1].

Figure 5



Basic principles of a gas-filled detector. Electrical charge liberated by ionising radiation is collected by positive (anode) and negative (cathode) electrodes. (Adopted from [1])

The electrons produced by ionisation are attracted to the positive electrode and the ionised atoms to the negative electrode, causing a momentary flow of a small amount of electrical current.

For maximum efficiency of operation, the voltage between the electrodes must be sufficient to ensure complete collection of ions and electrons produced by radiation within the chamber. If the voltage is too low, some of the ions and electrons simply recombine with one another without contributing to electrical current flow (recombination region)^[1].

As the voltage increases there is less recombination and the response (electri-

cal current) increases. When the voltage becomes sufficient to cause complete collection of all of the charges produced, the saturation region begins. The voltage at which the saturation region begins is called the saturation voltage (V_s , typically $V_s \approx 50\text{--}300\text{ V}$). Ionisation chambers are operated at voltages in the saturation region (Fig. 2). This ensures a maximum response to radiation and also that the response will be relatively insensitive to instabilities in the voltage applied to the electrodes. The amount of electrical charge current released in an ionisation chamber by a single ionising radiation event is very small^[1].

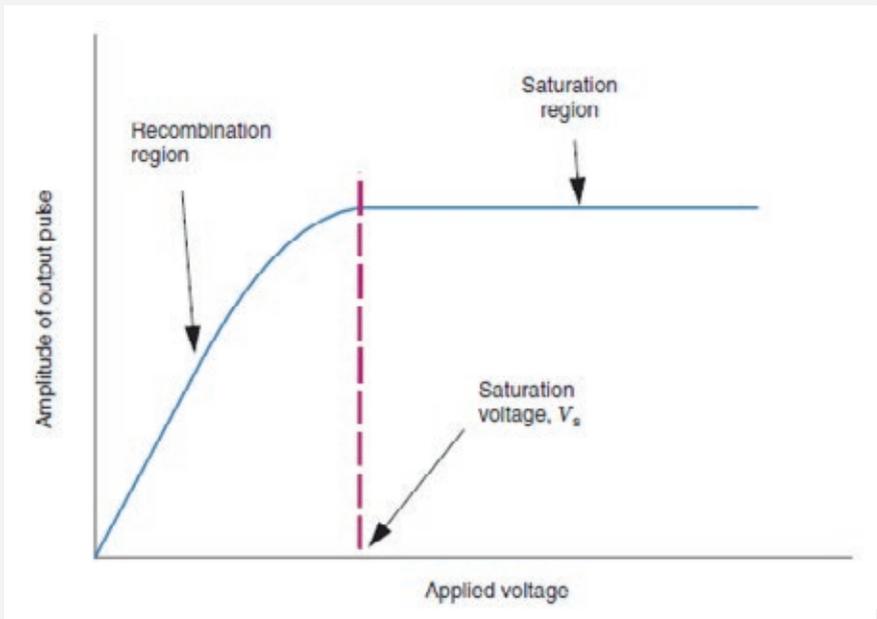
Because of the small amount of electrical charge or current involved, ionisation chambers generally are not used to record or count individual radiation events. Instead, the total amount of current passing through the chamber caused by a beam of radiation is measured. Alternatively, the electrical charge released in the chamber by the radiation beam may be collected

and measured. Small amounts of electrical current are measured using sensitive current-measuring devices called electrometers^[1].

RADIONUCLIDE CALIBRATOR

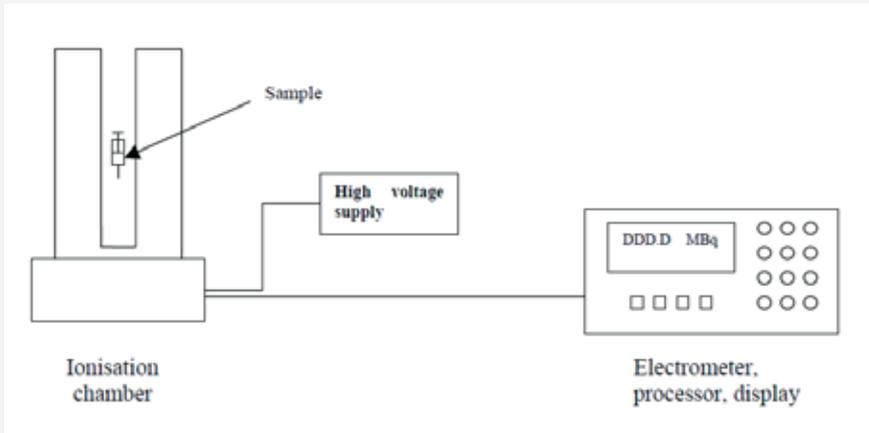
A radionuclide calibrator is a device consisting of an ionisation chamber and an

Figure 2



Voltage response curve (charge collected vs. voltage applied to the electrodes) for a typical ionisation chamber. In usual operation, applied voltage exceeds saturation voltage V_s to ensure complete collection of liberated charge. (Adopted from [1])

Figure 3



Schematic view of radionuclide calibrator. (Adopted from [6])

electrometer (Fig. 3). Unlike other types of ionisation chamber, radionuclide calibrators employ sealed and pressurised chambers filled with argon gas. This eliminates the effect of changing barometric pressure on output readings. Ionisation chamber radionuclide calibrators assay the total amount of activity present by measuring the total amount of ionisation produced by the sample. Radionuclide calibrators typically are calibrated to read directly in units of activity (Bq or Ci), with switches to set the display for different radionuclides. They are used for assaying relatively large quantities (i.e. MBq range) of gamma ray-emitting radioactivity too

large for assay with NaI(Tl) detector systems.

Because ionisation chambers have no inherent ability for energy discrimination, they cannot be used to select different gamma ray energies for measurement, as is possible with detectors having pulse-height analysis capabilities. An approach that is used to distinguish low-energy from high-energy gamma ray emitters (e.g. ^{99m}Tc vs. ^{99}Mo) is to measure the sample with and without a few millimetres of lead shielding around the source (Fig. 4). Effectively, only the activity of the high-energy emitter is recorded with the shielding

in place, whereas the total activity of both emitters is recorded with the shielding absent. This technique can be used to detect tens of kBq quantities of ^{99}Mo in the presence of tens or even hundreds of MBq of $^{99\text{m}}\text{Tc}$ [1].

Figure 4



*^{99}Mo breakthrough test lead shield
("radionuclide purity testing")*

As with the NaI(Tl) well counter, radionuclide calibrators are subject to sample volume effects (the fraction of gamma rays escaping through the hole at the end of the well depends on the position of the source in the well: it is about 7% if the source is near the bottom of the well but increases to 50% if it is near the top) and the geometric efficiency of a well

counter depends on sample positioning [1]. If a small volume of radioactive solution of constant activity in a test tube is diluted progressively by adding water to it, the counting rate recorded from the sample in a standard well detector progressively decreases, even though the total activity in the sample remains constant. In essence, the geometric efficiency for the sample decreases as portions of the activity are displaced to the top of the well. If the volume of a sample is increased by adding radioactive solution at a constant concentration, the counting rate first increases linearly with sample volume (or activity) but the proportionality is lost as the volume approaches and then exceeds the top of the well. Eventually there is little change with increasing sample volume, although the total activity is increasing. For example, an increase in sample volume in a standard test tube from 7 to 8 mL, i.e. a 14% increase in volume, increases the counting rate by only about 1% [1]. Thus the sample volume has significant effects on the counting rate with well counters. For the stated reasons, sample volumes should be the same when comparing two samples. A technique applicable when adequate sample volumes are available is to use identical test tubes for all samples and to fill them such that the volume of activity inside the well itself does not differ between samples.

Absorption of gamma rays within the sample volume or by the walls of the test tube is not a major factor except when low-energy sources, such as ^{125}I (27–35 keV), are counted. Identical test tubes and carefully prepared samples of equal volume should be used when comparing samples of these radionuclides^[1].

The discussed effects should be investigated experimentally when a new dose calibrator is acquired (acceptance testing), so that correction factors can be applied in its use, if necessary. For example, a quantity of activity can be measured in a very small volume (e.g. 0.1 mL in a 1-mL syringe). Activity can be diluted progressively afterwards to larger volumes in larger syringes and then in beakers, and so forth, to determine the amount by which the instrument reading changes with the sample volume^[1]. Another parameter worth evaluating is linearity of response versus sample activity; this may be determined conveniently by recording the reading for a $^{99\text{m}}\text{Tc}$ source of moderately high activity (e.g. 1 GBq, or whatever is the approximate maximum amount of activity that the dose calibrator will be used to assay) and then recording the readings during a 24- to 48-h period (four to eight half-lives) to determine whether they follow the expected decay curve for $^{99\text{m}}\text{Tc}$. Deviations from the expected decay curve may indicate instrument electronic

non-linearities requiring adjustment or correction of readings. In applying this technique, it is necessary to correct for ^{99}Mo contamination using the shielding technique, especially after several $^{99\text{m}}\text{Tc}$ half-lives have elapsed^[1].

QUALITY ASSURANCE OF RADIONUCLIDE CALIBRATORS

For radionuclide calibrator installation, operation and maintenance, the manufacturer's operating manual should be followed. Only authorised personnel should operate the calibrator, and up-to-date instructions on the operation and maintenance of equipment should be readily available for reference and use. The radionuclide calibrator should be placed on a solid, vibration-free base and, as recommended by the manufacturer, operated at a relatively constant temperature and humidity and away from direct sunlight and any room heater or air conditioner. The area should not be affected by high-activity sources and additional shielding may be required for background reduction and/or personnel exposure reduction^[2].

Radionuclide calibrators may be located within laminar airflow workbenches or isolators to facilitate the compounding of sterile radiopharmaceutical preparations. Since all surfaces in the aseptic processing area require frequent cleaning and disin-

fection, the radionuclide calibrator must be able to withstand frequent cleaning and disinfection with a variety of agents.

Extreme caution must be exercised to avoid damaging the radionuclide calibrator chamber and readout unit(s) when using cleaning and disinfection agents. The surfaces of chamber plastic liners and plastic dippers in the aseptic processing area must be cleaned and disinfected by appropriate means, such as wiping with a sterile 70% isopropyl alcohol-dampened cloth. Readout units may also be protected with plastic covers that can be disinfected frequently with sterile 70% isopropyl alcohol wipes^[2].

Acceptance testing

The International Commission on Radiological Protection (ICRP) defines an acceptance test as a “test carried out at the request and with the participation of the user or his representative to ascertain by determination of proper performance parameters that the instrument meets the specifications claimed by the vendor”. The ICRP recommends that an acceptance test be carried out at the time of installation and when appropriate after a major service. In addition to ascertaining that the radionuclide calibrator meets the vendor specifications, test or reference data are obtained at acceptance testing and used for comparison with future rou-

tine tests^[3]. The most thorough assessment of calibrator performance occurs at acceptance testing. Routine performance testing includes most of the same measurements. At acceptance testing or before first use, calibration settings for radionuclides in source geometries other than those provided by the calibrator manufacturers must be determined if the potential assay uncertainty is unacceptable (greater than 5%)^[2-4]. Radiopharmaceutical manufacturers and commercial nuclear pharmacies should be required to provide dosages whose assays are accurate to within $\pm 5\%$. These dosages can be used to calibrate facility calibrators for the respective source geometries. At acceptance testing or before first use, those individuals who will use the radionuclide calibrator should be instructed in calibrator operation, maintenance and quality control as appropriate. Instruction should include reading and comprehending the manufacturer's operating manual^[2].

Routine QC tests

Routine quality control (QC) tests are repeated at specific intervals to establish and document changes from the initial performance of the radionuclide calibrator established at acceptance testing. The overall objective of performance testing is to assure the continued accuracy of the dosage assays^[2].

The tests recommended by EANM Physics Committee and the EANM Working Group on Nuclear Medicine Instrumentation Quality Control^[5] are as follows and summarised in Table 1:

- » Physical inspection
- » High voltage
- » Clock accuracy
- » Zero adjustment
- » Background counts/contamination check
- » Constancy (check source, relative response)
- » Stability
- » Accuracy test
- » Linearity

Physical inspection

Check the calibrator and source holders for damage. Damaged source holders should be repaired or replaced. Check the display screen for proper operation and the console for keypad damage or damage to or malfunction of any push-buttons/switches/dials. Check to assure that the chamber liner is in place and that small items (e.g. needle caps) have not fallen into the well.

High voltage

Test the high voltage and compare the result with the manufacturer's tolerances in accordance with the instructions in the operator's manual. Constant and correct operating voltage is essential for accurate activity measurement.

Clock accuracy

For radionuclide calibrators that incorporate a clock, the accuracy of the stored time should be checked. The time should be synchronised to a standard time. The time should be accurate to within 1 min^[3]. Accurate time measurements are essential when working with radionuclides that have short half-lives and/or for quantitative or semiquantitative imaging. Clock accuracy should be checked following power outages or when investigating aberrant readings. Other facility clocks referenced during dosage administration should be synchronised with the radionuclide calibrator clock. Calibrator clock adjustments should be performed in accordance with the instructions in the operator's manual.

Zero adjustment

The zero setting should be tested and recorded on each day of use prior to first use, and compared with the manufacturer's tolerance in accordance with the instructions in the operator's manual and before any adjustments are performed.

Background response/contamination check

Background may be caused by external radiation fields, chamber/dipper/liner contamination or electronic noise. The test should be performed with the source holder/liner in place in the chamber; near-

Routine test	Purpose	Frequency	Comments
Physical inspection	To check system and any source holders and other accessories for damage	Daily	The chamber may be concealed, and not accessible for physical inspection, but the loose accessories should be checked
High voltage	To check the constancy and correct operating voltage	Daily/as recommended by manufacturer	Essential for an accurate activity measurement
Clock accuracy	To check that the calibrator clock is the same as the time of day	Daily	Essential for calibrating radioactivity to a specific time of day; clock time throughout the department must be the same (i.e. all wall clocks and internal computer clocks)
Zero adjustment	To check that the display is at zero when no radioactivity is present	Daily	Record the zero setting (before any adjustment); a drift in the "zero" reading may indicate that the instrument needs repair
Background counts	To check background response under operational conditions appropriate for a particular radionuclide; to detect contamination	Daily	Perform the test with the source holder/liner in place in the chamber; remove nearby radioactive sources that might cause an incorrect background reading
Constancy	To check the stability and reproducibility of the ionisation chamber, electrometer and calibrator nuclide settings	Daily	Measure a long half-life radionuclide, e.g. ^{137}Cs , with its own calibration factor; also, obtain relative measurements for each nuclide setting to be used that day
Stability	To check the short-term counting precision	Yearly	Counting precision is a measure of the stability of the whole system, and is measured by repeated measurements and application of the chi-square test
Accuracy	To check the accuracy of the activity reading	Yearly	This requires readings of sources of known activity; refer to the supplier and national measurement standards for guidance
Linearity	To confirm that the calibration setting for a particular radionuclide indicates the correct activity over the entire range of use	Six monthly/yearly	The change in response when the measurement range is changed should be minimal; the range of use should be chosen between the maximum activity to be measured (e.g. in the GBq range for a $^{99\text{m}}\text{Tc}$ eluate) and the lowest activity to be measured (e.g. 1 MBq) for a particular radionuclide

Table 1: Routine QC tests for a radionuclide calibrator. Equipment type: gas ionisation chamber. (Adapted from *Eur J Nucl Med Mol Imaging* 2010;37:662–671 [6])

by radioactive sources that might cause an incorrect background reading must be removed. The test should be performed on each radionuclide setting to be used that day. The magnitude of the background should be established at acceptance testing and measured on each day of use prior to first use and checked at each use. The measurement should be taken with no radioactive source in the chamber and on the most common radionuclide setting with the source holder and contamination shield in place. Any increase in the background above the normal value should be investigated. For calibrators that have a background adjust function, background should be within the allowed range of adjustment. Routine performance tests should be corrected for significant background contribution.

Constancy (check source and relative instrument response)

Routinely measuring a long half-life check source (or standard source) allows the user to demonstrate the constancy of the calibrator's response (e.g. electrometer stability or gas pressure changes) over time. The measurements are taken (following the above daily tests) with a long half-life solid check source in the source holder in the measurement position. The measurements are compared to the initial measurements performed at acceptance testing and the

results kept for the life of the chamber. The source should be measured on its own setting (e.g. ^{137}Cs on ^{137}Cs). Using the same procedure, the source is also assayed on all commonly used settings (e.g. ^{137}Cs on $^{99\text{m}}\text{Tc}$, ^{137}Cs on ^{131}I , ^{137}Cs on ^{18}F , etc.). This is referred to as a "relative response test"⁽¹³⁾ and is a measure of the constancy of the calibrator response for commonly used settings. If a standard source is used rather than a test source, the measurement obtained on the setting for the source radionuclide can also serve as an accuracy test. Measurements should be within $\pm 5\%$ of the decay-corrected initial values. For secondary standard radionuclide calibrators and reference radionuclide calibrators, measurements should be within $\pm 2\%$. The measurements should be recorded and available for regulatory review⁽²⁾.

Accuracy test

Measurements are taken with the reference source in the source holder in the measurement position following the recommended daily tests. In practice, accuracy testing involves testing with one or more traceable standards. The standards are typically in a solid plastic matrix in a vial format and include ^{57}Co , ^{133}Ba , ^{137}Cs and ^{60}Co . The geometry of these standards is typically not identical to that of the standard sources used by manufacturers to calibrate their systems. The accuracy test

is not a calibration; it is a test of system stability. Ideally, the test should use standards of radionuclides that are employed by the radionuclide calibrator manufacturer to set the system when transporting calibration settings to production models (e.g. ^{57}Co and ^{137}Cs or ^{57}Co and ^{60}Co). Ascertaining which radionuclides were used by the manufacturer should be part of the purchase process. The use of one source (e.g. ^{137}Cs) in combination with the routine “relative response tests” should be sufficient for most medical facilities. For more complex programmes, instrument stability should also be checked annually with at least two traceable reference sources and the radionuclides used should vary from year to year^[2]. Measurements of the long-lived standards and the two traceable reference sources should be within $\pm 5\%$ of the decay-corrected initial values. Secondary standard radionuclide calibrators and reference radionuclide calibrators should be within $\pm 2\%$ ^[3]. The measurements should be recorded and available for regulatory review.

System linearity

A calibrator is considered linear if the ratio of the measured response to the predicted response remains constant over the range of current inputs. The decaying source method, the shield method (Fig. 5) and the graded source method may

be used to determine linearity. The graded source method involves manipulation and accurate measurement of stock solution aliquots. The decaying source method is recommended for secondary standard radionuclide calibrators and reference radionuclide calibrators. For “field” instruments, the decaying source method should be used at acceptance testing and following repair. The shield method should be sufficient for annual testing; alternatively, the facility can employ the decaying source method. Measurements are taken following the daily tests. The decaying source measurements are taken with the source in the source holder in the measurement position. The graded shielding measurements are taken in accordance with the shield manufacturer’s instructions. At acceptance testing and following repair, measurements should be taken using the decaying source method from the highest activity (highest current) measured down to approximately 1 MBq. Annually, measurements should be taken between the maximum activity administered and 1 MBq over the range of use. Measurements should be within $\pm 5\%$ of the expected values. For secondary standard radionuclide calibrators and reference radionuclide calibrators, linearity testing should be performed quarterly using the decaying source method and the measurements should be within $\pm 2\%$ ^[3].

For the shield method, the shields should be calibrated on a radionuclide calibrator whose linearity using the decaying source method is within $\pm 5\%$. The measurements should be recorded and available for regulatory review^[3].

Figure 5



Linearity test kit (shield method): enables user to simulate decay for a range from a few hours up to 4 days. (Adopted from Capintec™)

Documentation

Sufficient records need to be maintained to demonstrate proper calibrator operation, including personnel training and competence testing, and adherence to the quality assurance programme. The details of any calibrator maintenance or repair should also be recorded^[3].

Radionuclide calibrators should be operated in accordance with the manufacturer's instructions. If the manufacturer recommends additional tests, they should be performed at the frequency recommended by the manufacturer. Additional tests are normally limited to tests of the electronic circuitry and other tests that are specific to the manufacturer's systems. As part of the purchase process, the manufacturer should be asked to document additional routine tests^[2].

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GAMMA PROBES: INTRAOPERATIVE PROBES AND ORGAN UPTAKE PROBES

by Kristof Baete

EQUIPMENT AND BASIC PRINCIPLES

A gamma probe is a radiation detector that allows for the detection and localisation of gamma ray-emitting radionuclides^[1, 2]. From this general concept, two device types have been derived for in vivo application in nuclear medicine, without the need for imaging: (a) the intraoperative probe and (b) the organ uptake probe. The clinical use of these devices is different, but the principles of operation are quite similar and require a largely equivalent quality management (QM).

The intraoperative gamma probe is a compact and hand-held device for convenient localisation of radionuclides in the body during surgical interventions^[3]. The technique, for which a probe is used, is often referred to as radio-guided surgery. The main application is the sentinel lymph node (SLN) procedure, in which a gamma probe can not only detect and localise an SLN but also reveal occult disease and allows minimisation of surgical invasiveness^[4]. For that purpose, specific probe shapes have been designed, e.g. with a bent tip or laparoscopic units. Intraoperative beta probes also exist. However, the specific quality aspects are beyond the scope of this chapter.

The organ uptake probe, on the other hand, uses a more optimised detector

and collimator, which makes it larger and heavier. Therefore, the probe is usually mounted to a fixture or a holder, and allows for the measurement of a radionuclide in vivo using a standardised source-detector setup. The most common application of this device is the determination of iodine uptake in the thyroid^[5]. However, an organ uptake probe can also be used for whole-body dosimetry in molecular radiotherapy or as a measuring instrument for isolated limb perfusion.

The gamma probe, in general, needs to be well shielded to protect the detector against unwanted radiation from its surroundings. In front of the detector, a primary collimator usually allows the radiation to enter the detector along a certain aperture angle. Manufacturers tend to offer a variety of intraoperative probe units, and additional or exchangeable collimators. Organ uptake probes, on the other hand, are typically manufactured with a dedicated wide or flat field collimator for reliable operation. The detector unit of a gamma probe is usually connected to a console or readout unit. For better agility, some intraoperative probes have detectors that are wirelessly connected to the readout unit. The settings on the console of an intraoperative probe are usually limited, and primarily allow for selection of a radionuclide, count rate indicator and sound settings. The acquisition

console of an uptake probe is generally much more extensive.

Two types of radiation detector are used for the manufacture of gamma probes: (a) scintillation detectors, or scintillators, and (b) semiconductors.

A scintillator is mostly a crystal that is able to absorb incident gamma rays. The energy of the charged particles, created by the ionisation of the incident gamma rays, is re-emitted as scintillation light. This happens such that the light output of the crystal is proportional to the energy of the incident gamma ray. Subsequently, a light detector converts the scintillation light to a measurable signal that is again proportional to the energy of the incident gamma ray. Scintillator crystals for gamma probes are usually inorganic materials, such as NaI(Tl) or CsI(Tl). For higher energy applications, BGO, LSO or GSO may be used owing to their better stopping power. Photomultiplier tubes (PMTs) or photodiodes are used for the detection of the scintillation photons.

In a semiconductor, the incident radiation is measured directly by the amount of electron-hole pairs that are created in proportion to the energy of the gamma ray. The charge carriers are collected using electrodes which then produce a measur-

able electrical signal. Semiconductor detectors are usually fabricated out of crystalline materials, such as CdTe, CdZnTe (or CZT) and HgI₂.

Both detector types enable energy discrimination of the radiation and allow for the selection of upper and lower energy level discriminators. Events that are recorded within the energy range can be accepted for further processing, while events outside of that range can be rejected or used for the purpose of scatter correction. In uptake probes, the entire energy spectrum can be recorded.

The higher density and effective atomic number of inorganic scintillators allow for a better detector efficiency at higher energies. However, scintillators in combination with a PMT are sensitive to environmental changes and therefore have a less stable energy calibration. Scintillator-based probes with a photodiode have shown an improved ruggedness compared with PMT-based systems. Nevertheless, scintillators have a poorer energy resolution than semiconductors; this means that a semiconductor has a better scatter rejection capability.

QUALITY ASSURANCE

The international Basic Safety Standards, laid down in European Council Directive

2013/59/Euratom, recommend that for all medical radiological equipment a quality assurance (QA) programme needs to be in place in order to uncover defects and to prevent procedural mistakes during the execution of tasks. For the verification of good equipment manufacturing, such a QA programme should include at least: (a) the execution of formal acceptance testing of the instrumentation and (b) the installation of a QC programme. The QA should also involve good registration and documentation of all information related to the use of the system. A good foundation for the QM is described in the IEC 61223-1 technical report [6].

The issue of protocol standardisation for the clinical use of gamma probes is a further aspect of QA. The sensitivity of an uptake probe, for example, relies particularly on the source–detector distance and it is important to know the exact data acquisition requirements for acquisition of reliable results. Therefore, standard operational procedures should be available to all end-users. Procedural mistakes or pitfalls may include the misuse of collimators, isotope or energy settings, and display or audible settings. It is important that all aspects related to the routine use of the device are clarified in written procedures that have been explained well to the end-user.

For intraoperative probes, it is very important to follow the manufacturer's recommendations regarding instrument cleaning, disinfection and sterile operation. Ignoring the advice can cause serious system damage. Manufacturers may also provide specific directions for wireless detector probe units, such as recharging of batteries and how to safely store probe units.

QA and QC recommendations for gamma probes in general are available in the literature^[7–10]. More specific guidelines for intraoperative probes exist^[11–13], as do minimum system performance requirements^[14,15].

ACCEPTANCE AND REFERENCE TESTS

Before a gamma probe can be used in clinical practice, its performance should be assessed by a thorough verification of equipment specifications. This assessment is done by a medical physics expert. The acceptance test results are the reference values for the QC tests that will be executed periodically from the moment of commissioning. Therefore, the acceptance tests should be documented well and appended to the equipment log.

Acceptance tests are usually more comprehensive than QC tests. A performance

analysis encompasses more than those aspects that need to be verified once the equipment is in routine use. Performance tests for gamma probes have been proposed in the literature^[7, 11, 13]. The most common acceptance and reference tests, in general, are:

- » Physical inspection, shielding
- » Power supply, high voltage, detector gain, battery
- » Energy peaking or calibration, energy settings
- » Background count rate
- » Energy resolution
- » Sensitivity
- » Counting precision
- » Linearity of the response

Some device-specific acceptance tests should be added, such as the source geometry influence for uptake probes and spatial resolution for intraoperative probes.

First of all, physical inspection of the probe should be carried out immediately after its reception. Any problem or deficiency observed during the warranty period should be reported and repaired at once. Physical impact to the detector, or its shielding, can lead to malfunctioning or changes in efficiency. For intraoperative probes, the signal from a nearby injection site, caused by a leak in the shielding, may conceal an SLN.

The power supply of the device is critical and should be verified. Also, the battery-supplied intraoperative probe unit should be checked. The energy response of an uptake probe depends on the stability of the high voltage and detector gain, but also on the environmental conditions, such as temperature. Therefore, it is extremely important to assess the detector energy calibration or peaking. After reception, the energy settings should be verified for all used radionuclides, and if necessary the instrument should be (re)calibrated. For an uptake probe, direct spectral analysis of the energy peak of a reference source (e.g. caesium-137) is usually obvious. However, visualisation of the energy spectrum of an intraoperative probe by the end-user is not always possible.

The background count rate of a gamma probe is an essential property. Each measurement should in fact be preceded or followed by a reading of the background count rate. This system parameter depends on the energy settings. For any of these settings, a typical background count rate should be analysed and reference values should be determined. It is important to perform a follow-up of background measurements for various detector locations and positions. In addition to the ambient conditions, the electronics and connecting cables can have an impact.

The energy resolution of a gamma probe indicates how well it is able to distinguish between closely spaced energy peaks of detected gamma rays in the energy spectrum. A good energy resolution enables the gamma probe to reject scattered radiation. Hence, measuring energy resolution can identify the potential for a good system performance. The energy resolution of the probe is quantified by the full-width at half-maximum (FWHM) of the gamma peak at a certain energy. In uptake probes, FWHM can be reported by the console as part of the energy calibration or peaking procedure.

An important parameter is the sensitivity of the gamma probe. In a standardised setup, with a reproducible source-to-detector distance and a reference source activity, the count rate response can be determined for the available energy settings. The results of these sensitivity measurements are the reference values for the subsequent QC tests. These QC measurements are therefore usually referred to as a test of the constancy or the long-term stability of the sensitivity. For a more realistic analysis, sensitivity may also be assessed taking into account the influence of scatter^[1].

The short-term stability of the sensitivity is often referred to as the count rate preci-

sion. The decay of a radioactive source is a random process that obeys Poisson statistics. A chi-square test can be used to verify that the short-term detector sensitivity is in accordance with the Poisson distribution^[1]. With a series of measurements, a chi-square value can be computed and converted to a probability. A high probability (>0.99) means that the variations in the measurements are smaller than statistically expected. This may indicate that, for example, periodic noise is being measured instead of a radioactive source. A low probability (<0.01) indicates that the measurements are too irregular to follow the Poisson nature of the source, and there may be something wrong with the device. A probability of 0.5 indicates a perfect detector behaviour according to Poisson statistics.

The linearity of the detector response, or the count rate capability, verifies the sensitivity at different levels of source activity. Radiation detectors are influenced by a number of effects at increased count rates. Some of these effects can lead to a shift of the measured energy spectrum. Even though this effect is small for most applications, it should be recognised and measured at least during acceptance testing. The most important effect, however, is dead time or the loss of counts. With a decaying source, for example, one can

compare the observed detector count rate with the true count rate of the source.

For the uptake probe, a specific acceptance test should be added. Since the instrument is used to quantify an amount of activity, it is important to know the influence of different source geometries on the response of the detector. The result of this assessment reveals the robustness of the measurement setup and source (i.e. organ) positioning.

For the intraoperative gamma probe, the directional or angular detector sensitivity is very important. A narrow measurement field, using an appropriate collimator, allows for a high signal to background ratio and SLN detectability. In addition, the lateral detector sensitivity defines the spatial resolution of the probe and the ability to separate neighbouring lesions^[12].

QUALITY CONTROL

The acceptance and reference tests are complemented by the subsequent QC programme. This part of the overall QM focusses on the fulfilment of the quality requirements or acceptability criteria by the performance of verification tests in clinical practice, at regular intervals. If the criteria are not met, corrective actions should be imposed by the medical physics expert,

such that the QC results of the device are brought back in line with the reference values. Moreover, trend analysis of the QC results is a powerful tool for observation of the performance of the instrument over time.

QC recommendations and test frequency proposals have been described in a number of publications^[8-10]. The most important routine QC tests for gamma probes, in general, are:

- » Physical inspection
- » Power supply, high voltage, gain, battery
- » Energy peak verification
- » Background count rate
- » Sensitivity or constancy
- » Counting precision

Physical inspection of the gamma probe should be performed at regular intervals, preferably before each use. The user should be aware that any observation or knowledge of imprudent use, e.g. a drop or collision of the detector unit, can result in system malfunctioning or changes in the response. Such events should be reported immediately and registered in the instrument log, and their impact analysed by a quality inspection of the shielding and detector sensitivity and verification of the energy settings. Also, the power supply should be checked before each use,

especially for those mobile units that use batteries.

Regular verification of the energy settings of a gamma detector is preferred. For intraoperative probes, the energy spectrum analysis is unfortunately not always available to the end-user. On the other hand, daily verification of the energy peak for quantitative measurements with uptake probes is easy and highly recommended. Moreover, a trend analysis of the energy settings has the power to reveal subtle performance changes or drift. The same holds true for the energy resolution. A sudden increase in the energy resolution may be a sign of crystal damage (e.g. a crack) or decoupling of the light detector (PMT, photodiode). A more gradual broadening of the energy resolution may indicate crystal yellowing due to humidity or a deterioration in the light detector.

As mentioned above, the background count rate of a probe is an important

property that should be observed prior to any use. There is the risk of contamination of the instrument, or its surroundings, or the influence of an unexpected local radioactive source. In addition, there may be a sudden change in the detector background reading due to, for example, electronic noise. The observation of an elevated background should always be investigated before proceeding.

The follow-up of detector sensitivity, as determined during acceptance testing, is known as the constancy test. This QC test verifies whether the sensitivity has changed, and it is an easy test to assess influences on the detector response, for example, due to incorrect detector energy settings or the condition of the hardware. As explained above, counting precision analysis may reveal subtle detector issues.

In conclusion, carrying out sustainable QM leads to the correct and safe use of gamma probes in clinical routine.

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WELL COUNTERS

*by Petra Kolenc Peitl
and Marko Krošelj*

PRINCIPLES OF RADIATION DETECTION

Radiation is detected through its interaction with matter. When ionising radiation interacts with matter, ions can be produced directly or indirectly. Alpha or beta particles are highly energised particles that interact directly with atoms and produce charged ion pairs. On the other hand, X-rays and gamma photons interact primarily with orbiting electrons, which are ejected and then interact with other atoms, producing charged ions^[1].

There are two basic principles of radiation detection:

- » Ionisation is caused when the radiation is passing through. The ions produced are detected and measured.
- » Electronic excitation in atoms or molecules is caused by the radiation. The excess of energy is then dissipated and detected and measured.

GAMMA AND BETA RADIATION DETECTORS

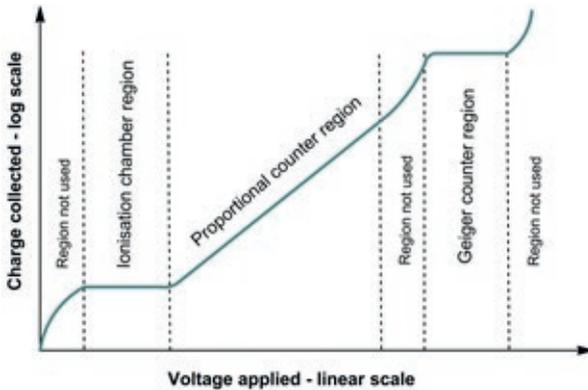
Three types of detector are used for the quantitative determination of radioactivity: gas-filled ionisation detectors, scintillation detectors and semiconductors. No detector is suitable for universal detection of all types of radiation. The factors influencing the choice of detector are sensitivity, response to different radiation types,

energy of radiation, detector volume, source geometry and detector dead time.

Gas-filled detectors

Gas-filled detectors include ionisation chambers, proportional counters and Geiger-Müller (GM) counters. The detector consists of gas contained between two electrodes with a suitable high voltage difference between them. Gas is normally an insulator and no electrical current flows between the electrodes. When ionising radiation passes through the chamber, it causes ionisation of the gas molecules, producing negatively charged electrons and positively charged gas ions. Electrons are attracted to the positively charged electrode (anode) and ionised atoms to the negative electrode (cathode), causing a small amount of electrical current which is proportional to the number of ionising photons or particles in the chamber. To achieve maximum efficiency of gas-filled detectors, the voltage between the electrodes must be optimal so as to ensure complete collection of electrons and ions (Fig. 1). If the voltage is too low, recombination of some of the ions and electrons occurs, with no contribution to electrical flow. As the voltage is increased (to 50–300 V), all of the primary charges arising from the initial ionising event are collected (ionisation chamber region). Moreover, increasing the voltage further (to approx.

Figure 1



Voltage-response curve for gas-filled detectors

300–1000 V, depending on the detector gas) will allow the moving electrons to become ionising particles themselves, and the signal is amplified (proportional counter). With a voltage of 1000–2000 V (depending on geometry) an avalanche is created and the resulting pulse becomes independent of the size of the original ionising event that triggered the signal (Geiger-Müller counter)^[1, 2].

Scintillation detectors

After the radiation causes excitation of atoms and molecules, the energy is released during the de-excitation. Most of the energy is released as thermal energy; however,

in some materials a portion of the energy is released as a weak flash of light (scintillation). When such materials (scintillators or scintillants) are used in the detection of radiation, the detectors are called scintillation detectors. Scintillators can be divided into two general types: inorganic materials (solid crystals) and organic materials dissolved in liquids. Organic liquids and plastic scintillators are usually used for the detection of beta particles and fast neutrons. The higher density and atomic number of inorganic crystals usually lead to a better detection efficiency, so these scintillators are used for the detection of X-rays and gamma rays^[3]. The most common crystal scintillators

used in nuclear medicine instrumentation are summarised in Table 1. The amount of light produced when gamma rays or beta particles interact with a scintillator is proportional to the energy deposited by the radiation in the scintillation material. These scintillations are detected by the light cell or photomultiplier (PM), which converts light energy into weak electric currents that are amplified and converted into voltage pulses. The heights of these pulses are related to the radiation energy and the number of pulses is related to the activity of the radioisotope^[1, 3].

Semiconductor detectors

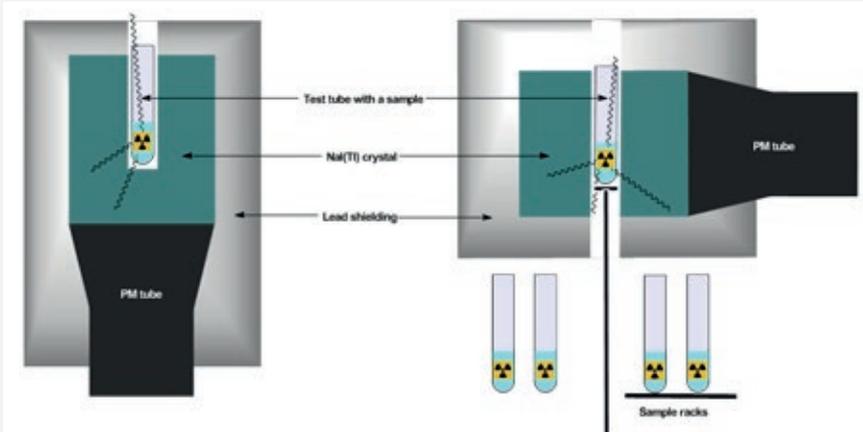
In comparison to other materials, semiconductors have unique characteristics that make them very suitable for ionising

radiation detection: linear response with deposited energy, negligible absorption of energy in the entrance window of the detector, excellent energy resolution, formation of pulses with fast rise times and small detector sizes. The signal formation in a semiconductor detector is very similar to that in an ionisation chamber. Ionisation is produced within the sensitive volume of the detector and converted to a voltage pulse that is amplified and counted^[4]. The most commonly used semiconductor materials are elemental silicon (Si) and germanium (Ge). Both Si and Ge have a limited use in the detection of X-rays and gamma rays: (a) they need ancillary cooling systems due to a significant amount of thermally induced electrical current at room temperature; (b) they have mod-

Table 1: Basic characteristics of common scintillator crystals used in nuclear medicine applications [1, 3]

Crystal	Atomic number, Z	Density (g/cm ³)	Hygroscopic	Rugged	Decay constant (ns)	Emission wavelength (nm)
NaI(Tl)	51	3.67	Yes	No	200	410
BaF₂	53	4.88	No	Yes	0.8	220 and 310
CsI(Tl)	54	4.51	Slightly	Yes	1000	565
Gd₂SiO₅(Ce) (GSO)	59	6.71	No	No (cleaves easily)	60	430
Lu₂SiO₅(Ce) (LSO)	65	7.40	No	Yes	40	420
Bi₄Ge₃O₁₂ (BGO)	75	7.13	No	Yes	300	480

Figure 2



Left panel: Schematic diagram of well counter.

Right panel: Most automated multiple sample systems use a so-called through-hole detector

est stopping powers and (c) impurities are present even in relatively pure crystal and capture electrons released in ionisation, leading to lower detection efficiency. Compound semiconductors, such as cadmium zinc telluride (CZT), can overcome these drawbacks^[2,5]. CZT detectors have been applied to various medical imaging modalities in CT, PET and SPECT^[6].

NaI(Tl) WELL COUNTERS

Well counters are an important instrument in nuclear medicine since they play a key role in preclinical and clinical practice. The most important clinical applications are

studies of glomerular filtration rate, cerebrospinal fluid leak, red cell mass, plasma volume and radioimmunoassay tests with ¹²⁵I-radiolabelled probes^[7,8]. Preclinically, well counters are used in in vitro cell studies, biodistribution studies, determination of radionuclidic impurities (e.g. determination of ⁶⁸Ge in the ⁶⁸Ge/⁶⁸Ga generator eluate) etc. Well counters usually comprise a well-type detector, which surrounds the sample and therefore provides high detection efficiency (Fig. 2). A photomultiplier tube (PMT) with associated electronics backs the detector. Very high detection efficiency of the NaI(Tl) well counters limits the amount of activity that can be count-

ed (~37 kBq). With higher levels of activity, problems regarding dead time can be encountered. Dead time is the time required to process individual detected events. The shorter the dead time, the smaller are the dead time losses. NaI(Tl) and semiconductor detector systems usually have a dead time in the range of 0.5–5 μs ^[2].

The majority of well counters employed in nuclear medicine use thallium-activated sodium iodide [NaI(Tl)] crystals as scintillators. NaI(Tl) detectors enable detection of the majority of the gamma-emitting radionuclides in nuclear medicine (e.g. ^{99m}Tc, ¹²³I, ¹¹¹In, ²⁰¹Tl). Since pure sodium iodide crystals are scintillators only at liquid nitrogen temperatures, thallium is added in small amounts as a so-called activator centre in the crystal matrix and is responsible for the scintillation effect at room temperature. There are many advantages of NaI(Tl) which make these detectors suitable for almost all routine applications in nuclear medicine:

- » Due to its relatively high density, NaI(Tl) is a good absorber with high detection efficiency for penetrating radiation (X-rays and gamma rays in the energy range from 50 to 250 keV).
 - » It is a relatively efficient scintillator, since it yields one visible light photon per 30 eV radiation energy absorbed.
 - » Little loss of scintillation light is caused by self-absorption, even with large crystal sizes.
 - » It is relatively inexpensive.
 - » The scintillation light is well matched in wavelength to the peak response of the PM photocathode.
- However, NaI(Tl) detectors also have some disadvantages: the crystal is quite fragile and easily damaged; NaI is hygroscopic, which can impair light transmission to the PM upon exposure to moisture; and at energies >250 keV a large volume of NaI(Tl) is required for adequate detection efficiency.
- The efficiency of detection depends on the following factors:
- » The energy of gamma photons: high-energy photons can pass completely through the crystal matrix without energy dissipation.
 - » Crystal size: larger crystals absorb high-energy photons more efficiently, but the size of the crystal is limited by the optical transmission of scintillation.
 - » Geometry: it is essential that samples are counted using the same volumes, in the same size tubes and always in the same position within the counter.
 - » Photomultiplier high voltage: PMTs have to be supplied with an optimal and stable source of high voltage. At too low a voltage, no electrical pulse is produced in PMTs. At increased voltage, sponta-

Figure 3



Left panel: Example of an automated multisample well type counter.

Right panel: Example of computerised routine QC tests

neous electron emission and thermal noise contribute to an increased count rate^[1,9].

The overall advantages of NaI(Tl) make these detectors the first choice for almost all routine applications in nuclear medicine involving the detection of gamma rays in the 50–250 keV energy range.

In daily practice, rather than manual well counters, automated multiple sample systems are used (Fig. 3). Most such systems use a so-called through-hole detector, where the sample hole passes throughout the NaI(Tl) crystal and the PMT is connected to the side of the scintillator (Fig. 2). Samples in such a detector can be automatically positioned at the centre of the NaI(Tl) crystal, inde-

pendently from the sample volume. Systems with an automated sample arm can save a lot of time, since the sample vials can be loaded into a rack and counted automatically. One disadvantage of automated systems is that they are not as well shielded as manual well counters, since there is no lead shielding directly on the top of the sample being counted. This can increase background counting rates, particularly from the other samples in the rack, which can be problematic, especially when low-activity samples are counted together with high-activity samples in the rack.

For very high throughput one can use multidetector systems which can contain multiple NaI(Tl) scintillation detectors. This

allows multiple samples to be counted simultaneously. The individual detectors are separated and shielded from each other to prevent crosstalk, which can give rise to substantial counting error when counting high-energy gamma rays. Background measurements in one detector while counting a sample in an adjacent one can be used to estimate the extent of the crosstalk^[2].

Because of the high-energy photons, in the case of PET applications the NaI(Tl) crystal thickness needs to be optimised and the shielding around the detector has to be sufficient to prevent crosstalk from either the samples in adjacent rack positions or the adjacent detector in the case of multidetector systems^[10,11]. Recently, a high-sensitivity well counter with a bismuth germanate (BGO) detector was developed for preclinical animal PET investigations in which quantitative measurements of small blood volumes and activities are needed^[12].

QUALITY CONTROL

Quality control (QC) is defined as an established set of ongoing measurements and analyses designed to ensure that the performance of a procedure or instrument is within a predefined acceptable range^[13]. Every nuclear medicine instrument, including well counters, must undergo

strict acceptance testing after installation to verify that the instrument meets specifications and performs according to its clinical purpose. Acceptance testing results are the reference data for future QC tests, and some of them may be repeated periodically (every 6 or 12 months) or after a major service or component change^[14]. At the time of installation of a well counter, physical inspection, energy window calibration and checking of the energy resolution, sensitivity and linearity are performed as acceptance testing^[15].

Since the electronic components and detectors of well counters can fail or deteriorate over time, a good quality assurance programme should be employed to ensure consistently accurate results. The routine QC tests for well counters include energy window calibration (energy peaking), measurement of background, energy resolution, constancy, efficiency, reproducibility (chi-square test), linearity and minimal detectable activity^[13,14]. Table 2 provides an overview of basic QC tests, their purpose and their frequency. Some of the tests are described in detail below:

» When a well counter is equipped with a multi-channel analyser, the energy spectrum should be checked to verify that the photopeak of the radionuclide coincides with the preset photopeak energy window. Usually, energy peaking is done with a 20% photopeak energy

Table 2: Summary of routine QC tests performed for well counters

QC test	Frequency ^a	Purpose
Background	Daily	To detect contamination and to determine background radiation
Constancy	Daily	Day-to-day counting of long-lived reference sources
Energy window calibration	Daily / quarterly	To verify that the photopeak of the radionuclide coincides with the preset photopeak energy window
Energy resolution	Quarterly	To evaluate the sharpness of a photopeak of reference source radionuclide
Reproducibility	Quarterly / half-yearly	To check variations in the set of measurements of reference source (chi-square test)
Efficiency	Annually	To determine the sensitivity (ϵ : efficiency) in cpm/Bq for each radionuclide

^a The type of test and the frequency depend on the manufacturer's instructions, national legislation and different guidelines.

window, equivalent to 90–110% of the gamma ray energy of the radionuclide.

- » The background counting rate should be checked daily before use for each photopeak energy window. It is of utmost importance to determine the level of background radiation, which can be relatively high and variable in nuclear medicine departments. Measuring a blank sample (empty tube) will also show any contamination of the counting well.
- » Constancy: at least one reference source traceable to a certified metrology institute should be counted daily. Day-to-day counting rates should be $\pm 10\%$. Long-lived radionuclides, such as ^{57}Co , ^{68}Ge , ^{129}I and ^{137}Cs , can be used as reference sources for well counter constancy determination.
- » Energy resolution evaluates the sharpness of a photopeak produced when a well detector is exposed to a single energy radionuclide. It is expressed as the percentage full-width at half-maximum (FWHM) and is checked with a reference source, such as ^{137}Cs . Widening of the peak indicates a malfunction of a certain system component (e.g. breakdown of the crystal to photomultiplier tube seal).
- » Calibration for each radionuclide should be performed at installation, annually and after any major repair. Efficiency in cpm/Bq can be determined using a precisely calibrated sample, prepared by appropriate dilution of a sufficiently large activity of radionuclide to allow accurate measurement in a radionuclide cali-

brator. On the other hand, a surrogate radionuclide (reference standards, e.g. ^{57}Co instead of $^{99\text{m}}\text{Tc}$ or ^{68}Ge instead of ^{18}F) can be used to routinely determine the efficiency. In this case, the factor for conversion of the efficiency of the surrogate to that of a particular radionuclide has to be determined at installation of the well counter.

- » Reproducibility of a well counter is checked with the chi-square test, which shows whether random variations in a set of measurements are consistent with the expected Poisson distribution. Any inconsistency with a Poisson distribution is indicative of a well counter malfunction.
- » Linearity of activity response is checked either with the decaying source method

or by aliquoting the initial solution with known radioactivity.

- » Minimum detectable activity (MDA) is the smallest amount of activity detectable from background which can be quantified at a given confidence level of 95%.

Whichever tests are performed in the quality assurance programme for a well counter, it is essential that the procedures are documented and the results are recorded (Fig. 3). Test methods and results have to be maintained in electronic or hard-copy form and archived in order to accurately compare all QC tests with the acceptance test results^[14–16].

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QUALITY CONTROL OF NUCLEAR MEDICINE
INSTRUMENTATION AND PROTOCOL STANDARDISATION

RADIATION PROTECTION MEASUREMENT EQUIPMENT

by Søren Holm

OVERVIEW OF PHYSICAL ENTITIES AND UNITS IN DOSIMETRY FOR RADIATION PROTECTION

The fundamental entity in radiation dosimetry is the *absorbed dose* D (and dose rate dD/dt). This is a purely physical entity, defined as the energy E (unit joule, J) absorbed in a small (tissue) volume divided by the mass m (unit kg) of that volume. The unit of D therefore is J/kg, but is given the special name gray (Gy). The biological effects of radiation depend not only on the amount of energy imparted, but also on its distribution at the microscopic level, which in turn depends on the characteristics of the radiation. Therefore the absorbed dose is averaged over an organ or a tissue (T) and weighted by a factor, the radiation weighting factor w_R , to give the *equivalent dose* H_T . The factor w_R equals one for photons (X-ray and gamma) and for electrons (beta⁻ or beta⁺), which cov-

er most applications in nuclear medicine. For alpha particles a value of 20 is applied in radiation protection. To distinguish the equivalent dose from the absorbed dose, the unit of H_T is changed to sievert (Sv). To establish a single “risk parameter”, the values of H_T are finally weighted together using tissue factors w_T that reflect individual organs’ radiation sensitivity. The resulting entity is the *effective dose* H (unit Sv), which is used when setting limits for whole-body exposure. The precise definitions and the tables of w_R and w_T can be found in ICRP 103^[1] and the IAEA Handbook on Nuclear Medicine Physics^[2]. The dosimetry concepts are summarised in Table 1.

Effective dose is not directly measurable even in a uniform external field. For practical use in radiation protection the following “operational” entities have been defined (for details, see IAEA): *Ambient dose equivalent* $H^*(10)$ (unit sievert) corre-

Table 1: Entities and units in radiation measurement and protection

Name	Activity	Absorbed dose	Radiation weighting factor	Equivalent dose	Tissue weighting factor	Effective dose
Symbol	A	D	w_R	H_T	w_T	E
Unit	becquerel, Bq	gray, Gy 1 Gy = 1 J/kg	Sv/Gy = 1 for beta and gamma = 20 for alpha	sievert, Sv 1 Sv = 1 J/kg	No unit (sum of all w_T equals 1)	sievert, Sv 1 Sv = 1 J/kg

Operational dose entities:

Ambient dose equivalent $H^*(10)$ (unit sievert)

Personal dose equivalent $H_p(d)$ (unit sievert) – with d (mm) = 0.07 (skin), 0.3 (eye lens), 10 (body)

sponding to equivalent dose at a depth of 10 mm in tissue (equivalent) material, and *personal dose equivalent* $H_p(d)$ (unit sievert) defined as the equivalent dose at a depth d in soft tissue below a specified point in the body. Relevant values of d are $d=10$ mm (used for estimating effective dose), $d=0.07$ mm (used for skin dose) and $d=0.3$ mm (for dose to the eye lens). These entities are listed here because radiation protection equipment will normally be specified (calibrated) in terms of H^* or $H_p(d)$.

RULES AND REGULATIONS IN RADIATION PROTECTION

The fundamental concepts are laid out by ICRP in their recommendations, the most recent general one being from 2007 (ICRP 103^[1]). Based on this, international (IAEA) and regional (EU) Basic Safety Standards (BSS) have been issued^[3,4]. The EU BSS-directive (Euratom 2013/59^[4]) must be implemented in the national legislations of all the EU member states by February 2018. Despite the European cooperation between authorities and attempts to harmonise, there will be some differences between countries. Further, local institutions may have their own (stronger) demands, and therefore it is recommended always to look (also) at what local rules may apply.

Two important issues of interest that were already present in previous directives, but may be interpreted differently in the new implementation, are: categorisation of (exposed) workers and classification of workplaces. Workplaces must be divided into controlled areas with more restricted access and surveillance and supervised areas with a lower risk and therefore more ready access. Workers are divided into two groups: group A, who are “liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities”, and group B, who are not. It is possible to design nuclear medicine departments and to plan the work so that it is highly unlikely that anyone (technologists, physicians or medical physicists) will exceed the dose limits listed above. However, even then it will still be necessary to monitor (most of) the staff to document this. The rest of this chapter shows the types of equipment that can be used for monitoring of persons and workplaces.

DOSIMETERS FOR PERSONAL MONITORING

Monitoring of effective dose and finger dose has been routine for decades. The recently lowered dose limit to the eye lens^[5] has created some uncertainty as to

whether special measures are necessary for documenting compliance with this limit. Currently there is no consensus on the issue, but in nuclear medicine (unlike interventional radiology) it seems likely that the measure of effective dose will be sufficient to cover also the dose to the eye lens. Radiochemistry may be an exception to this.

Two kinds of dosimeter are used: passive, integrating devices that require a

(rates) and also provide an alarm function for “active” protection. These two kinds of dosimeter form a useful supplement to each other: the passive one for legal use and the active one as a reminder in daily processes. Dosimeters for personal monitoring are normally calibrated to provide $H_p(d)$ and results are reported in mSv.

The legal, integrating dosimeters should be worn at all times in the department by all staff for whom this is relevant

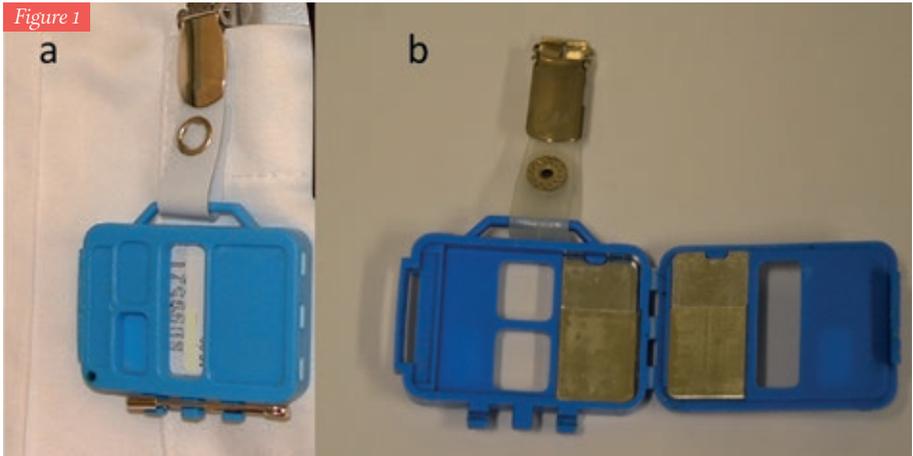


Figure 1

a) Personal film dosimeter. **b)** Open (empty) film holder showing the metal filters and openings allowing the distinction of different radiation qualities

special process to provide a reading and active instruments (battery included!) that can immediately show actual dose

(as defined by the medical physics expert or a radiation protection officer). They should normally be worn at the front of

the body and at belt height. When working in front of a shielded workplace, the dosimeter may be placed at chest level in order to avoid underestimation of the exposure here. Pregnant staff members (to the extent that they are allowed to work at all in the department) should always wear the dosimeter at or near belt level to give a better representation of the dose to the foetus.

Electronic dosimeters can be considered optional. They are most important for new staff or when introducing new procedures. They may also be given to short-term visitors for whom the monthly (or 3-monthly) dosimeters do not make sense.

The classical personal dose meter is film based (Fig. 1a); the interaction of ionising radiation with a photographic film was what in 1896 led Becquerel to the detection of radioactivity. As with other film materials, processing (developing, fixing) is required to show the exposure, and a special device is needed to read and convert the gray scale into a dose value. The placement of the film in a specially designed film holder (Fig. 1b) with different thicknesses of plastic material and metal filters (Al, Sn, In, Cd, Pb) to some extent allows determination of the radiation quality (soft/hard gamma, soft/hard beta, neutron). Further, contamination by small drops of radioactivity can easily be identified. Film has the advantage that the developed ma-

terial can be stored and will retain the information for potential later re-evaluation. Against the film material speaks the rather high uncertainty at low exposure, which over the years has become more important as the dose limits have been reduced and the price of the silver in the emulsion has increased.

An alternative that is becoming increasingly common is the use of thermoluminescence dosimetry (TLD). Many materials have the property, when irradiated, that some of the absorbed energy will get “trapped”. Electrons are excited out of their stable ground state and end up in a higher energy state that is also quite stable at normal (room) temperatures. By heating (*thermo* = *T*) the material to 180–260°C, the electrons are “lifted” out of the traps and will fall back emitting light (*luminescence* = *L*). The amount of light can be collected and will be proportional to the energy absorbed in the first place (dose = *D*). For dosimetry, the most common basis material is lithium-fluoride (LiF) with certain impurities added to determine its properties in detail. The material is “tissue equivalent” and can be formed into tablets (Fig. 2); in addition to being used for whole-body monitoring (Fig. 3), these tablets are small enough that they not only can be mounted in finger rings or wrist dosimeters (Fig. 4) but can even be attached to the fingertips (and covered by gloves).

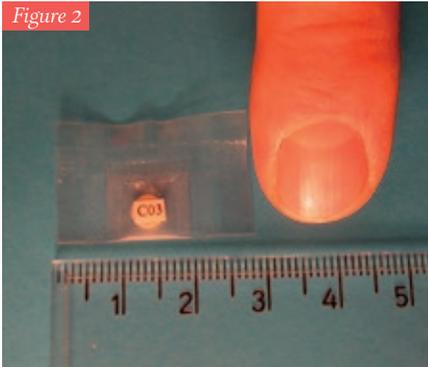
As soon as the reading (heating) has been performed, the information vanishes by “annealing” and the tablet can be reused. The minimum detection limit for TLD is lower than for film, but TLD provides little information on radiation quality, contamination is more difficult to observe and re-examination after the first reading is not possible.

Electronic dosimeters (Fig. 5) are usually based on silicon solid-state detectors,

(unexpected) higher dose levels. The setting of the alarm level requires some consideration when working with patients who may be unnecessarily scared if they observe that they are triggering the signal.

Film and TLD require no quality control from the user except for a simple check that the film holder or TLD package is not damaged. Most often the handling of film or the TLD is performed by centralised institutions that must be accredited

Figure 2



The size of a TLD tablet is only a few millimetres

Figure 3



The author's current TLD

where ionising radiation produces pairs of electrons/holes that can be collected and converted to a dose reading in $\mu\text{Sv/h}$. The advantage of such an instrument is straightforward. The user can keep an eye on the dose rate during different work processes and can even be warned against

it to perform that task and adhere to certain standards, e.g. ISO/IEC 17025, ISO 14146. Electronic dosimeters will typically loudly signify that they are running low on battery; if they do not do so, then it is the responsibility of the user to check and detect this. The function of alarm

levels can be checked (again, by the user) simply by moving the device gradually towards any (sufficiently strong) gamma source, e.g. a ^{57}Co flood source, a ^{137}Cs or ^{68}Ge calibration source or a vial containing $^{99\text{m}}\text{Tc}$ or ^{18}F (in this last case, the device must be brought just above the vial as it is shielded at the sides!). The absolute calibration should be certified at delivery, and constancy of the reading can then be checked using, for example, a long-lived

tering material in such a measurement should be minimised.

Most personal electronic dosimeters have an energy response (efficiency) that rapidly falls off towards zero for photon energies below 30–50 keV, dependent on the type. This may result in underestimation of doses, in particular if a major part of the radiation consists of scattered radiation at low energy. However, a comparison in a PET department has shown that results ob-

Figure 4



TLD tablets can be used for finger and wrist dosimetry and even attached to the fingertips

calibration source in a fixed geometry. Proving the correct absolute calibration from first principles is not easy even with a known, certified calibration source. Remember (if trying this) that the distance square law is valid only for the direct radiation and therefore the presence of scat-

Figure 5



Two examples of personal electronic dosimeters

tained using dosimeter film, a TLD and an electronic dosimeter are reasonably consistent^[6]. In such a comparison, one key issue is the handling of (natural) background radiation, which is corrected for in the integrating film or TLD systems by subtraction of the measured value from an “unex-

posed" sample, whereas for the electronic device it must typically be corrected by subtraction of the product of an assumed background dose rate and the number of hours that the device has been turned on.

INSTRUMENTS FOR DOSE RATE AND CONTAMINATION MEASUREMENTS

The ability to detect and monitor ambient dose rates and control for contaminations is mandatory in a nuclear medicine department to maintain a safe working en-



Figure 6

A portable survey meter for measurement of dose rate

vironment. The basic detection principles have been described in Chapter 11. The instruments shown in this chapter must be seen only as examples of classes of equip-

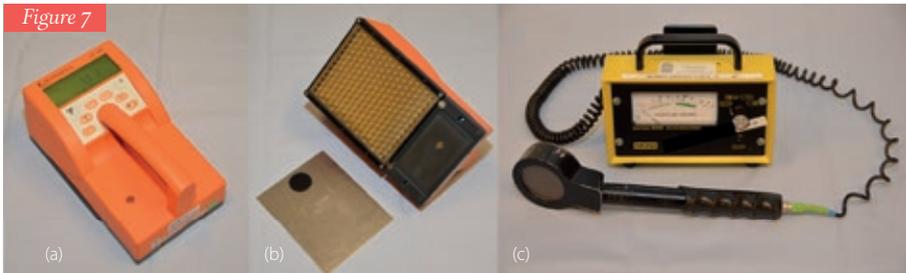
ment. There are many manufacturers and varieties, and individual specifications may vary from the ones mentioned here.

Portable devices

A portable *survey meter* like the one in Fig. 6 is useful for estimating the dose rate in the work place or the emission from a patient. The illustrated example is based on two Geiger-Müller (GM) tubes. Using special (metal) filters around the tubes yields an energy response that is reasonably independent of the photon energy. The instrument is calibrated to approximately yield the ambient dose equivalent H^* , and the display shows mSv/h. It can handle gamma radiation from a fraction of natural background ($<0.01 \mu\text{Sv/h}$) up to dose rates (10 Sv/h) infrequently encountered in a nuclear medicine department. By itself, the device is not sensitive to beta-radiation. It can be equipped with an external probe (end-window GM tube) that allows beta particles to enter and provide a signal which is normally displayed as counts per second. The quality control of such an instrument consists in battery check, check for potential contamination of the instrument (in a low background environment) and constancy control with a known (preferably long-lived) source. Deviations of up to $\pm 10\%$ from the expected values are usually considered acceptable.

Contamination monitors exist in many forms, but typically they are either large-area (100–200 cm²), rectangular detectors (Fig. 7a,b) or circular (cylindrical) detectors that detect at an “end-window” of diameter 2–6 cm (Fig. 7c). Obviously the large-area detectors in general have a higher ef-

detector for particles (alpha, beta) must have a thin entry window to facilitate their access, and a detector for photons (X-ray, gamma) must have a high density and high atomic number to provide stopping power. Figure 8 shows a gamma source (¹³⁷Cs) in the upper half and



a) Contamination monitor with a large detection area. **b)** For particle measurements, the bottom plate must be slid off. Note the mesh protecting the thin cover foil. **c)** Small circular contamination monitor

ficiency which is useful when surveying a large surface. The smaller ones, on the other hand, are easier to apply in the search for localized spills (single drops), where the large-area monitors yield a rather constant signal when moving over the spot.

Some instruments look quite similar, and yet their probes have very different properties. It is easily understandable that a detector can function only if the radiation of concern has a high probability of entering the active detector volume and a high probability of being stopped (interacting) in that volume. Therefore a

a beta source (³⁶Cl) in the lower half. The instrument to the right has an end-window GM tube which is sensitive to beta particles and will even detect some alpha particles. It has a rather low sensitivity for gamma photons because it is a gas detector. To the left is a scintillation (NaI) detector which is highly sensitive to gamma rays (and X-rays). The alumina cover of the crystal, however, does not allow beta particles (at least below 1 MeV) to enter. It can therefore be very important to choose the right instrument in a given situation. Some instruments (like the one

in Fig. 7a) use a plastic scintillator covered with a thin foil (lightproof) and allow for detection of both particles and photons with reasonable efficiency.

Quality control of contamination monitors should include battery check, background check and check for con-

stancy with a relevant source, preferably long lived, in a fixed geometry. For the end-window detectors (and cylindrical NaI detectors) a point source will be a natural choice. For large-area monitors, a foil of, for example, 100 cm² with a weak gamma or beta activity is convenient (Fig. 9).



A demonstration of the difference in detection properties between a scintillation counter (left) and a GM tube (right). In (a), with the detectors pointing to a gamma source, the scintillation counter yields 100 cps while the GM tube only shows 5–6. With the beta source, the scintillation counter (b) is down to 5 cps (mostly background) while the GM tube in (c) shows almost 50 cps



Example of calibration/ test sources for large-area detectors

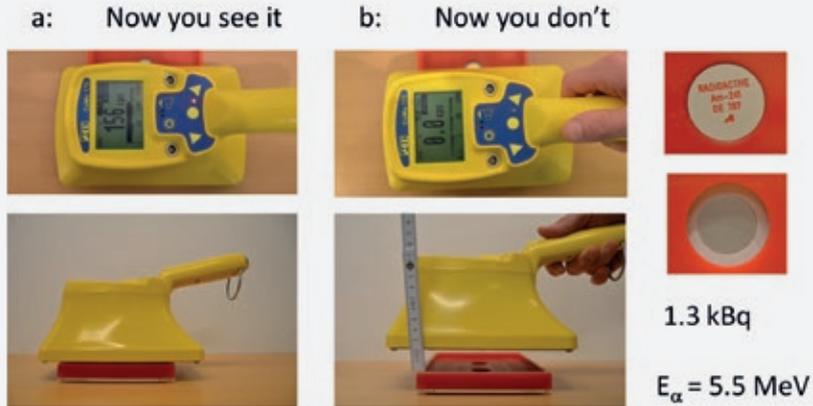
Not all contamination monitors can detect alpha particles. A particularly thin window is required for the particles to enter. When measuring alpha radiation on a surface, it is also important to remember that the range even in air is quite limited and that the energy is gradually lost along the path. For protection, it is a reasonably easy rule of thumb that the range in air is always below 10 cm. For a 5-MeV alpha particle, however, the range is really only 4.5 cm, and after passing the air gap from the source to the detector, the particle

should still have enough energy to penetrate the cover foil and trigger the detector, which may use energy discrimination to distinguish alpha from beta particles (and noise). A $\sim 3\text{-}\mu\text{m}$ cover foil may correspond to 0.5 cm of air, so to be sure of detection the distance should not exceed 2 cm (Fig. 10). Then it is obvious that there is a high probability of contaminating the foil by touching potential activity directly. It is possible to cover the instrument by a single layer of standard household plastic foil ($8\text{--}10\ \mu\text{m}$) and still have a signal. In this way a potential contamination can easily be removed by replacing the plastic foil. Alpha monitors should be checked for constancy with an appropriate source, which could be a point source of ^{241}Am , which has a half-life of 433 years.

Stationary instruments

A hand-foot monitor (Fig. 11) is a convenient piece of equipment for a fast check of personnel contamination. One of the hand detectors can be removed from its position to scan clothes. In older instruments, the panels used to be proportional counters (gas-based) but today plastic scintillator systems are common. Quality control of this kind of monitor is the same as for portable contamination monitors, i.e. checking at regular intervals for background and constancy, e.g. with a long-lived beta-active sheet (^{14}C or ^{90}Sr).

Figure 10



When measuring for alpha-particles, a close distance to the (potential) source is mandatory

Figure 11



A hand-foot monitor is useful for a fast check of personal contamination

At certain places in the department it may be relevant to install a survey instrument that can warn against (temporary) high dose rates. This could be outside a cyclotron room, next to a radiochemistry lab or in other places where a (temporary) warning is appropriate. Readings can be checked with a ^{137}Cs source in a reproducible position (assuming low or corrected background).

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