



Best Practice in Nuclear Medicine

Part 2

A Technologist's Guide

Produced with the kind Support of



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Foreword

Sylviane Prévot

“Whatever the value of equipment and methods is, high efficiency finally depends on the staff in charge of their use”... Marie Curie

In the ever-changing field of Nuclear Medicine, best practice considerations can't simply go unchallenged for months and years ahead. In this respect, Nuclear Medicine Technology is no different from medical practice. Nuclear Medicine Technologists (NMTs) need constantly to invest in additional education to offer best patient care. While it is recognised that the delivery of education and training varies widely from one European country to the other, adherence to European guidelines seems to be the only way to harmonise practices.

The impact of policy and legislation on best practice is emphasised in this booklet, the fourth in the series “Technologist's guide” that were produced with the kind support of Bristol-Myers Squibb Medical Imaging (BMS). Many thanks are due to BMS, who have contributed enormously to the education of NMTs in Europe for years, as well as to all the contributors involved.

Dealing with the complex changes that have been driven by European legislation over the last ten years remains an everyday challenge in a Nuclear Medicine department. Before being extended to the general public and to the patients, the scope of radiation safety was aimed at workers only. A careful approach fixed more and more restrictive dose constraints and limits to ensure the safe practice of Nuclear Medicine. Quality control of the performance of imaging equipment and procedures relating to medical exposures are required as part of an efficient and effective quality assurance programme to ensure patient protection. Ionising radiation must be treated with care rather than fear.

With this new brochure, the EANM Technologist Committee offers to the NMT community one more useful and comprehensive tool that may contribute to the advancement of their daily work and, by doing so, to the optimisation of national radiation safety systems throughout Europe.

Sylviane Prévot
Chair, EANM Technologist Committee

Introduction

Alberto Cuocolo, MD

Improvements in radionuclide imaging technologies and radionuclide therapy are contributing to an increase in the demand for nuclear medicine services in Europe. This rising demand has further reinforced the important role of nuclear medicine technologists; and best-practice guidelines become crucial to offer the best service to the public. It is also important that best-practice guidelines are developed and implemented at the European level to harmonise patient care across the European countries.

The Technologist Committee of the EANM has been very active and successful in promoting high standards for the daily work of nuclear medicine technologists in the different countries of Europe and has assisted in the development of high-quality national systems of education and training of nuclear medicine technologists. The Committee has also contributed to several EANM initiatives on education; and the Education Sub-Committee has published a series of "Technologist's Guides".

The present booklet "Best Practice in Nuclear Medicine - Part 2" covers important items, such as European regulatory issues, best practice in radiation protection, quality assurance of equipment and best practice in procurement.

This booklet may serve not only as a reference for improving the quality of practice but also as a resource providing a quick and efficient method to find references for additional readings.

Alberto Cuocolo, MD
President, EANM

Chapter 1 – European Regulatory Issues

1.1 Radiation Protection

Sylviane Prévot

The potential harm of ionising radiation was recognised shortly after its first use for medical applications. First recommendations on radiation protection date back to the late 1920s. An international radiation protection group “The International X Ray and Radium Protection Committee” was formed in 1928 during the 2nd International Congress of Radiology in Stockholm (SE) to respond to the dramatic increase of leukaemia in radiologists. In 1950, this committee was re-named “International Commission on Radiological Protection” (ICRP). Other international bodies were established later: United Nations Scientific Committee on the Effects of Atomic Radiations (UNSCEAR) (1955), International Agency of Energy Atomic (IAEA) (1956), European Community of Atomic Energy (ECAE / Euratom) (1957).

Key organisations

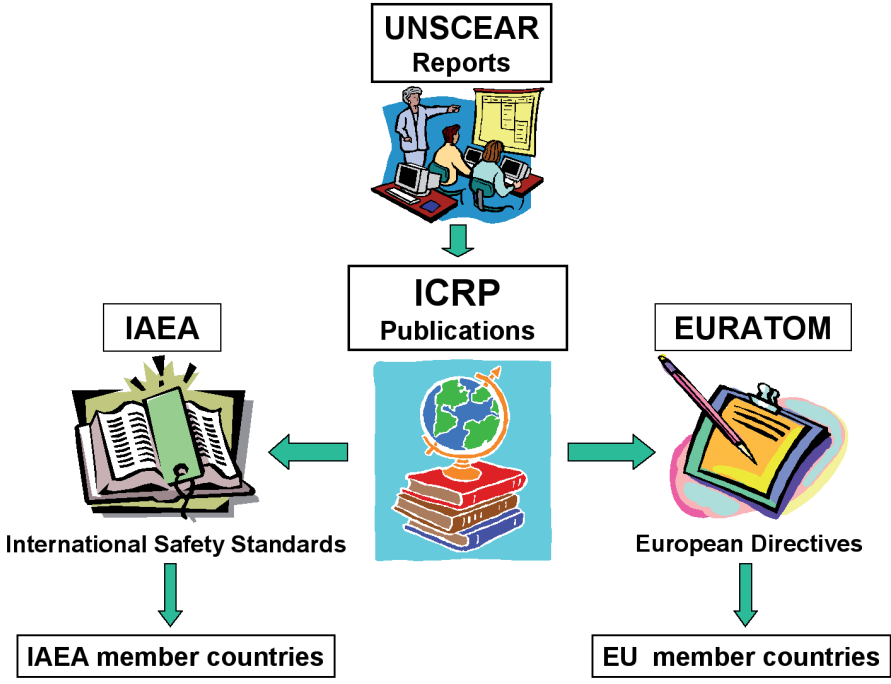
UNSCEAR consists of 21 scientists from different member states. Their role is to assess and report levels and effects of exposure to ionising radiation.

ICRP is an independent registered charity consisting of international experts whose aim is to provide an appropriate standard of human protection. Recommendations on the principles of radiation protection are based on UNSCEAR scientific data. Reports addressing all aspects of protection against ionising radiation are issued as numbered publications. ICRP 60 (1) published in 1990 forms the basis of current legislation. A new set of fundamen-

tal recommendations taking account of new biological and physical information and trends in the setting of radiation standards was approved in Essen (DE) in March 2007. They will replace ICRP 60.

In the United Nations organisation (UN), the IAEA is an independent inter-governmental, science and technology based organisation that promotes a high level of safety in applications of nuclear technologies as well as the protection of human health and the environment against ionising radiation. The IAEA develops basic safety standards based on ICRP publications. Guidelines relating to ionising radiation and safety of sources intend to harmonise radiation protection standards at international level.

EURATOM turns ICRP recommendations into Directives, aiming at the harmonisation of EU member states’ legislation. Contrary to standards issued by other organisations, Euratom Directives dictate the results to be obtained. Member countries can choose the procedures and the way they are implemented in order to achieve these results according to their own national legislative structure. The objective is to ensure the safe practice of Nuclear Medicine, protecting patients, public and workers against the risks of ionising radiation.

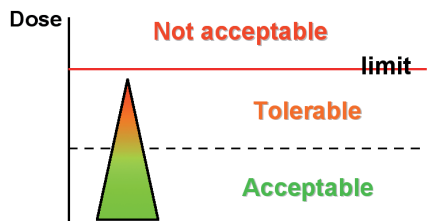


Principles underlying radiation protection regulation

As any dose is likely to have either deterministic (with threshold) or stochastic effects, a radiation protection system must be based on three principles:

- **justification of a practice:** the benefits must be believed to be above any health detriment it may cause;
- **optimisation of protection:** the benefits must be increased and detriments decreased as far as possible;
- **dose limitation:** the different groups of persons exposed (public, workers, students, apprentices) must be taken into account in order to ensure the most appropriate protection avoiding deterministic effects and reducing the frequency of stochastic effects to an acceptable level (Figure 1).

Figure 1 : Principle of limitation of doses



Three types of exposure can be considered

- **occupational:** incurred at work;
- **medical:** incurred by individuals as part of their own medical diagnosis or treatment and exposures incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis or treatment;
- **public:** encompassing all exposures to radiation except occupational and medical ones.

Since 1980 the ALARA concept – the principle of optimisation of radiation protection acronym of “As Low As Reasonably Achievable” - has been part of the European Basic Safety Standards. It was progressively introduced into national regulation. Individual and collective exposures must be kept as low as possible under the regulation limits. The ALARA principle concerns workers’ exposures as well as those of members of the public.

The ALARA principle was re-emphasised in two European Directives both having roots in ICRP 60 (1):

- Euratom Council Directive 96/29 (May 13, 1996) (2) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation
- Euratom Council Directive 97/43 (June 30, 1997) (3) on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Euratom Directive 84/466

Euratom Council Directive 96/29

General principles of the radiation protection of workers and the general public

Many requirements, including prior authorisation for practices involving a risk from ionising radiation and those relating to the transport, keeping and disposal of radioactive substances, must be taken into account by member states to ensure the best possible protection of the population. A system of inspection is required to enforce compliance with the law.

In the context of the optimisation of protection in occupational exposure, dose constraints - restrictions on the prospective doses to individuals - must be used when designing new premises. The sources to which they are linked must be specified; and dose limits are applied as part of the control of practice.



The effective dose limits for exposed workers, public and fetus are lower than in previous legislation. The new dose limit for exposure of the public does not include the patients and the accompanying persons involved with the patient in their medical exposure (under the comfort and care exception).

A qualified expert must be assigned technical responsibility for the radiation protection of workers and members of the public.

Limitation of doses

All exposures must be kept as low as reasonably achievable and the sum of the doses from all relevant practices must not exceed the doses limits. It is not normally expected that limits should be reached (Table 1).

Special protection during pregnancy & breastfeeding

Studies have shown that the unborn child is sensitive to high doses of ionising radiation, more particularly during the first three months of gestation (4). Additional controls must be implemented in order to protect pregnant staff from the hazards of ionising radiation.

As soon as a pregnant woman informs her employers of her condition, the protection to the child to be born must be comparable with that provided for members of the public. The conditions of employment of the pregnant woman must subsequently be such that the equivalent dose to the unborn child will be as low as reasonably achievable and that it will be unlikely that this dose exceeds 1 mSv during at least the remainder of the pregnancy.

Table 1: Dose limits

Limits	Exposed workers	Apprentices & students aged between 16 & 18 years	Public
	Apprentices & students aged 18 years or over		Apprentices & students aged < 16 years
Effective dose	100 mSv in 5 consecutive years max 50 mSv in 1 year	6 mSv / year	1 mSv in 1 year Average 1 mSv / 5 consecutive years Foetus 1 mSv over pregnancy
Equivalent dose Lens of eye Skin Hands, Forearms, Feet, Ankles	150 mSv / year 500 mSv / cm ² / year 500 mSv / year	50 mSv / year 150 mSv / cm ² / year 150 mSv / year	15 mSv in 1 year 50 mSv in 1 year / cm ² -

Policies governing the duties that pregnant staff are allowed to undertake can vary between member countries and sometimes in the same country from one Nuclear Medicine department to the other. It is not risky for pregnant staff to work in Nuclear Medicine provided that practical measures to avoid accidental high dose situations are implemented (4) and as long as there is reasonable assurance that the fetal dose is kept below 1 mSv during the pregnancy.

As soon as a breastfeeding mother informs the employer of her condition, she must not be employed in work involving a significant risk of bodily radioactive contamination.

Operational protection of exposed workers, apprentices and students for practices

Must be based on the following:

- Prior evaluation to identify the nature and magnitude of radiological risk to exposed workers & implementation of the optimisation of radiation protection in all working conditions

- Classification of workplaces into different categories
- Classification of workers into two categories
- Implementation of control and monitoring measures relating to the different areas and working conditions, including individual monitoring where necessary
- Medical surveillance of exposed workers

Delineation of areas and monitoring of workplaces

Controlled and supervised areas must be designated through a risk assessment of potential dose received. Signage indicating the type of area, nature of the sources and their inherent risks is required.

The aim of this classification is to ensure that anyone outside the designated areas does not need to be regarded as occupationally exposed but can be considered as member of the public (Table 2).

Table 2: Classification and delineation of areas

Annual limit	Public	Supervised area	Controlled area
Effective dose	1 mSv	6 mSv	20 mSv
Equivalent dose	1/10 one of dose limits for lens of eye, skin or extremities	3/10 one of dose limits for lens of eye, skin or extremities	dose limits for lens of eye, skin or extremities

A controlled area requires the workers to follow well-established procedures and practices specifically aimed at controlling radiation exposure. Access must be in accordance with written procedures and restricted to designated individuals who have received appropriate instructions. Wherever there is a significant risk of spread of radioactive contamination, specific arrangements must be made including access and exit of individuals and goods. Radiological surveillance of the working environment must be implemented including, where appropriate, the measurement of external dose rates, air activity concentration and surface density of contaminating radioactive substances.

A supervised area is one in which the working conditions are kept under review without requiring special procedures.

Categorisation of exposed workers

According to the risk, exposed workers must be classified into two categories:

- Category A: exposed workers who are liable to receive an effective dose greater than 6 mSv / year or an equivalent dose > 3/10 of one of the dose limits for lens of eye, skin or extremities
- Category B: exposed workers who are not classified in category A

Information and training

Exposed workers, apprentices and students must be informed on the health risks involved in their work. Woman working with ionising radiation must be informed about the need of early declaration of pregnancy and the risk of contaminating the nursing infant in case of bodily radioactive contamination.

Relevant training in the field of radiation protection must be implemented for exposed workers, apprentices and students.

Assessment of exposure

Radiological surveillance of the working environment must be organised in controlled areas including measurement of external dose rates, measurement of air activity concentration and surface density of contamination.

Individual monitoring must be systematic for category A workers. Monitoring for category B workers must be at least sufficient to demonstrate that they are correctly classified. Individual monitoring must be recorded for each exposed category A worker. Records must be retained throughout their working life and for not less than 30 years from the termination of the work involving radiation.

Medical surveillance

The medical surveillance of category A workers is the responsibility of approved medical practitioners or occupational health services. A medical examination is required prior to

employment or classification as a category A worker. The state of health of category A workers must be reviewed at least once a year. Reviews can be performed as many times as the medical practitioner considers necessary.

Euratom Council Directive 97/43

General principles of the radiation protection of individuals in relation to medical exposure

Dose limitation is not applied to therapeutic medical procedures, as their expected benefit is always higher than the risk. Diagnostic exposures are not limited except by the requirement that the examination is justified.

Justification of medical exposure ensures that unnecessary exposure is avoided either because the diagnostic benefit is too low or because alternative techniques having the same objective but involving less or no exposure to ionising radiation can be used. Medical exposures should be justified for each patient before they are performed: if an exposure can't be justified, it should be prohibited.

Clinical research is an integral part of Nuclear Medicine. Special attention must be paid to the justification of exposures with no direct health benefit for the volunteer individuals exposed.

Optimisation of medical exposure (except therapeutic procedures) ensures that doses are kept as low as reasonably achievable whilst

remaining consistent with the purpose of obtaining the required diagnostic information and taking into account economic and social factors.

The optimisation process includes:

- The selection of equipment;
- Quality assurance on procedures including quality control of equipment;
- The use of diagnostic reference levels (recommended maximum exposures and administered activities) for diagnostic examinations;
- The need to inform volunteer individuals undergoing exposure for clinical trials about the risks of this exposure and to establish a dose constraint for their exposure when no direct medical benefit is expected;
- The individual assessment and evaluation of patients' doses (administered activities);
- The need to provide patients undergoing treatment or diagnosis with radionuclides with written instructions on procedures they should follow in order to minimise the doses to the people around them;
- The need to use dose constraints for the exposure of accompanying persons;

- Written protocols for every type of standard diagnostic procedure for each piece of equipment;
- Written procedures such that patients are unambiguously identified;
- Written procedures such that potential pregnancy status is determined so that pregnant women are not exposed unknowingly;
- Special attention to quality control measures and administered activity assessment for the exposure of children;
- The requirement to have an expert medical physicist involved in standardised therapeutic and diagnostic Nuclear Medicine practice
- The need for clinical audit of all medical exposures in accordance with national procedures;
- The need to review practices in the light of new evidence relating to efficacy;
- The education and training of practitioners and technologists involved with patient exposure along with a requirement to keep it updated;

Special protection during pregnancy and breastfeeding

Fetal radiation risks throughout pregnancy are related to the stage of pregnancy and to the absorbed dose. Radiation risks are more significant during organogenesis and in the early fetal period, somewhat less in the second trimester and least in the third trimester (4).

The necessary information about possible pregnancy should be obtained from the patient herself. A missed period in a regularly menstruating woman should be considered due to pregnancy until proven otherwise (4). In the case of a female of childbearing age, the referrer and the practitioner must inquire whether she's pregnant or breastfeeding. If pregnancy cannot be excluded, special attention should be given to justification (in particular with respect to urgency) and to the optimisation of the administered activity so that it takes into account the exposure of both the expectant mother and the unborn child. This also applies to the case of breastfeeding women, in which attention is given to the type of examination and to the exposure of both the mother and the child.

Potential exposure

All reasonable steps to reduce the probability and the magnitude of accidental or unintended doses to patients should be taken. Working instructions, written protocols and quality assurance programmes are of particular relevance for this purpose.



References:

1. ICRP Publication 60. Vol. 21 n° 1-3. Pergamon Press
2. Council Directive 96/29 Euratom (OJ n° L159, 06/29/96)
3. Council Directive 97/43 Euratom (OJ n° L180, 07/09/97)
4. ICRP Publication 84 – Pregnancy and Medical Radiation. Pergamon Press

Chapter 1 – European Regulatory Issues

1.2 What are quality assurance and quality control and why do we need them

Ellinor Busemann Sokole, PhD

Background

Quality assurance and quality control have become an integral part of our language. What do they mean and how do they relate to the nuclear medicine service in which we are involved, in particular to the equipment we are using?

Quality (derived from the Latin word *qualis*) means “description, attribute, or property”. *Assure* (derived from the Latin word *ad securus*, which in turn comes from *secura*) implies “without care, without anxiety or without worry”. *Assure* invokes a feeling of certainty and hence the further meaning “to take thought for” or “to be concerned for”. Thus the words *quality assurance* mean that we characterise and describe the attributes (quality) and the level of performance that we wish to achieve, about which we are concerned and the achievement and maintenance of which we want to make certain (assure). In the nuclear medicine department, achieving, maintaining, and developing quality assurance means applying it to the entire department, including organisation, communications, facilities, staffing, radiopharmaceuticals, equipment, procedures, evaluation and follow-up of results, as well as training. Quality assurance should not be considered to be a static process but a continuing effort to improve.

Quality control (QC), also known as quality assessment, is a part of quality assurance. It means that when the attributes and level of

performance have been defined, we need to perform checks, measurements and evaluation that the required performance is actually achieved and maintained. For equipment, this applies not only to its performance, but also to its optimal clinical use.

History of quality assurance and quality control applied to equipment

Quality assurance and quality control applies to all equipment used in the nuclear medicine department for radiation protection, for preparation of radiopharmaceuticals, for imaging and archiving clinical data, and for administration. This includes radiation monitors, radionuclide dose calibrators, uptake probes and probes used for sentinel node investigations, all imaging and associated equipment such as (ECG) trigger monitors, computers and hardcopy devices, and all the other equipment used in the radiopharmacy section of the department or hot laboratory. The major development in QC over the years has been with respect to imaging equipment: for the scintillation camera used for planar, whole body, and single photon emission tomography (SPET) imaging modes, for position emission tomography (PET), and, recently, for SPET and PET in combination with computed tomography (CT).

Early quality control testing of the scintillation camera was limited to obtaining and comparing images (for example uniformity and bar pattern spatial resolution images) and making

subjective visual assessments and decisions regarding their acceptability. Test methods were not standardised. In the early 1980s, the equipment organisations NEMA (National Electrical Manufacturers' Association) and IEC (International Electrical Commission) defined a set of parameters that described the various aspects of image formation of the scintillation camera. They also developed measurement protocols to quantify these parameters. Thus, by using these standard measurement protocols, each scintillation camera manufacturer could supply a set of specifications measured according to the same criteria and method. This enabled, for the first time, a comparison to be made of the performance of cameras from different manufacturers (e.g. parameters such as the uniformity, spatial resolution, energy resolution). These protocols have developed over the years and are now available for the scintillation camera (planar, whole body, SPET), positron emission tomography (PET), and probs. Equipment manufacturers generally apply the NEMA protocols.

It is easy to see that by applying the same or comparable methods as given by NEMA (or IEC), we can obtain quantitative QC test results for different parameters that can be compared with specifications. The quantified QC test results provide objective data, which can also be compared with quantitative action thresholds for the decision making of whether or not the QC results are acceptable. The QC tests can then be used for subsequent testing

and, when carried out in a standard way, for monitoring performance over the lifetime of the equipment. Thus different stages of quality control testing have developed: acceptance testing (after installation of an instrument), periodic testing (annually or semi-annually, and after major maintenance) and routine testing (daily, weekly, or whenever the equipment is to be used).

For many years, QC testing has been performed at the discretion and responsibility of the individual nuclear medicine department. However, the 1997 European Council Directive 97/43, which was implemented by each European country in 2000, specifically states that for equipment "appropriate quality assurance programmes including quality control measures" should be ensured, and that "acceptance testing is carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis and after major maintenance procedure". QC is thus no longer a personal responsibility but is now a legal requirement.

Acceptance testing

When we obtain new equipment in the department, we need to learn how the equipment works and to test that it performs correctly before it is put into clinical use. This first crucial step in QC is called acceptance testing. This means confirming not only that the equipment performs according to the specifications of the manufacturer, but also

that it performs satisfactorily for the intended clinical applications. This latter condition usually requires extra QC tests, and would include QC tests for all the radionuclides to be used with the equipment.

Our first encounter with the equipment that has been purchased and installed is when we undertake acceptance testing. One can almost say that this is the start of a “relationship” with the equipment, as we shall be working with it for many years. Acceptance testing should therefore be given sufficient time and should not be rushed. It is important to understand the purpose of each test, and how it applies to the performance of the equipment. The acceptance test results form the baseline reference data for subsequent tests, and must therefore be carefully documented and archived. It is a good idea at this time to start a record (the log book) for each piece of equipment, either in written or in digital form, of any problems encountered and their solutions.

Testing requires radioactive sources, phantoms, standard test protocols and methods and software. Acceptance testing is never easy especially when we are confronted with equipment from another manufacturer, a new type of equipment, or a new modality. We recommend that the technologist works with an experienced nuclear medicine physicist who knows and understands the specific equipment type and manufacture, the computer

and the appropriate standard QC test protocols. Acceptance testing may be performed with the assistance of an outside agency or the vendor but an independent evaluation of results must be made. Any dubious QC test results must be repeated and questioned; and action has to be taken. Because the equipment has a guarantee period, this is the time to ensure that the components of the equipment that have been purchased perform within specifications and give the best possible quality.

Often acceptance testing for the sole purpose of verifying equipment specifications is not sufficient to cover all aspects of performance to be encountered in clinical practice. As an example, for the scintillation camera, the NEMA NU1 protocols are not sufficient to cover all aspects of the camera performance. A specific example is testing the collimator. The collimator is an important mechanical component in the image formation. Defects in the collimator will cause artifacts in clinical images. The parallel-hole collimator consists simply of holes and lead septa that must be exactly aligned perpendicular to the crystal surface over the whole surface area. This hole alignment is susceptible to errors during manufacture. Moreover the collimator structure is easily damaged in use. The collimator therefore requires careful extra testing in addition to the methods described by NEMA NU1.

Over the years many documents giving QC protocols for the different equipment of the nuclear medicine department have been published, and some countries have their own national standard QC protocols. However, these are usually general protocols. For overall departmental quality assurance, specific standard QC test protocols (giving details of methods, amounts of radioactivity to be used, analysis, action thresholds, etc.) are required for each specific piece of equipment. In this way the same methods can be applied within the department; and results can be compared with each other, regardless of who is performing and evaluating the test. This is no different from preparing radiopharmaceuticals or performing clinical patient studies. These standard departmental test protocols can be developed and documented at acceptance testing.

The International Atomic Energy Agency (IAEA) has produced technical documents for quality control of equipment. These provide a good source of detailed reference material and include rationale of tests, phantoms to be used, step by step test protocols and evaluation criteria. The crucial aspect of decision-making regarding acceptability of test results is especially difficult for QC images from imaging equipment. For the scintillation camera, the IAEA Quality Control Atlas for Scintillation Camera Systems can assist with QC test evaluation for cameras; and the image examples given in the Atlas provide a comprehensive overview of types of QC tests to be per-

formed. These images can be seen in the free downloadable version of the Atlas at http://www-pub.iaea.org/MTCD/publications/PDF/Pub1141_web.pdf

Routine testing

Once the equipment has been accepted and is put into routine use, a schedule of routine testing is required. The priority of routine tests should have the same status as clinical studies. They must be scheduled, results immediately assessed, and action taken if the results are unacceptable or dubious. The purpose of routine testing is to assure that the level of quality is maintained.

Periodic QC testing

Periodic QC tests form a part of the initial acceptance tests. They are the QC tests to check performance parameters that are not routinely performed. They are necessary to confirm satisfactory performance of specific aspects of the equipment whenever a malfunction is suspected, after component replacement, following major equipment maintenance or modification as well as when equipment has been moved to another site. They may also be repeated at annual (or semi-annual) intervals as a re-acceptance testing procedure.

Quality assurance of clinical studies

Ultimately the equipment is used for clinical studies. This means using the equipment correctly and taking care to use standard techniques and methods consistently in the clinical

setting. For imaging, this includes consistent patient positioning, data acquisition and data processing (e.g. consistency with creating and checking regions of interest for quantification) for each patient study.

Conclusion

By applying QC in order to ensure consistent and optimum equipment performance and by using the equipment in a consistent and optimum way, we have contributed our part to overall quality assurance. Each person contributes to this process. Only with overall quality assurance can the patient feel free of anxiety knowing that the best care and the best nuclear medicine procedure or treatment is available to him or her.

Further reading:

Council of the European Union Directive 1997/43/EURATOM.

IEC documents

www.iec.ch

IEC/TR 61948 series 1-4:

Nuclear medicine instrumentation - Routine tests - Part 1: Radiation counting systems (2001)

Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography imaging (2001)

Nuclear medicine instrumentation - Routine tests - Part 3: Positron emission tomographs (2005)

Nuclear medicine instrumentation - Routine tests - Part 4: Radionuclide calibrators (2006)

IEC60789 - Medical electrical equipment - Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras (2005)

IEC 61675-2 - Radionuclide imaging devices - Characteristics and test conditions - Part 2: Single photon emission computed tomographs Consolidated Edition 1.1 (2005)

IEC 61675-3 Radionuclide imaging devices - Characteristics and test conditions - Part 3: Gamma camera based whole body imaging systems, Ed1 (1998)

NEMA documents

<http://www.nema.org/stds/>

NEMA NU1 Performance measurement of scintillation cameras (1984, 2001)

NEMA NU2 Performance measurement of Positron Emission Tomographs (2001)

NEMA NU3 Performance Measurements and Quality Control Guidelines for Non-Imaging Intraoperative Gamma Probes

IAEA documents

<http://www-pub.iaea.org/MTCD/publications/publications.asp>

Quality Control Atlas for Scintillation Camera Systems, ISBN 92-0-101303-5, International Atomic Energy Agency, Vienna, 2003. Downloadable from

http://www-pub.iaea.org/MTCD/publications/PDF/Pub1141_web.pdf

Quality control of nuclear medicine instruments. Technical document 602 (TECDOC), Vienna, 1991 (includes probes, and dose calibrators)

<http://www-pub.iaea.org/MTCD/publications/tecdocs.asp>

IAEA tecdoc 606 (in revision, update to be printed 2008)

IAEA – TECDOC For PET and PET/CT (to be printed 2007)

Chapter 2 – Best Practice in Radiation Protection

Felicia Zito, PhD; Cristina Canzi, PhD & Franco Voltini, PhD

The use of unsealed radioactive sources implies a risk to the health of technologists resulting from external and internal ionising radiation exposure. International and national commissions of radiological protection recommend restrictions on individual dose from ionising radiation sources, the use of which is heavily regulated by national laws as result of these recommendations.

The hazards depend on the physical and chemical status of the radionuclides used, and on the type of operation; they are proportional to the amount of activity manipulated, the time in contact with it and the time spent in areas where permanent radioactive sources are present. When sources are administered to patients, the hazards depend also on the workload and the radiopharmaceuticals' biodistribution and biologic half-life in the patients. A good level of safety for the workers can be reached by appropriate planning of the nuclear medicine department depending upon the hazards. Publication number 57 of the International Commission of Radiological Protection (ICRP) gives criteria by which to determine the category of hazards (Table 1) in order to plan and classify areas. The criteria are based on calculations obtained by multiplying the largest activity that can be present in any time in the area with weighting factors according to the specific radionuclide and

operation in which it is used. Once the category of hazard is established, adequate facilities are required to optimise radiation protection.

Table 1. Hazard categories

Weighted activity	Category
< 50 MBq	Low hazard
50 – 50000 MBq	Medium hazard
> 50000 MBq	High hazard

External irradiation hazard

The situations leading to the highest hazard are:

- manipulation of unsealed sources for dose preparation and administration;
- irradiation from patients from performing the examination and attending to their nursing needs.

To quantify the external irradiation hazard, in the following tables 2-3, typical exposures are reported, for some unsealed radioactive sources, in contact with syringes and at 1 m from 10 ml vials and also from patients for "in vitro" and "in vivo" use. Greater hazards result from manipulation of higher amounts of activity for "diagnostic and therapeutic" doses than "in vitro" ones.

Table 2. External exposure for an activity of 1MBq at contact

Radionuclide	μSv/h at contact with 5 ml syringe	μSv/h at contact with 10 ml glass vial	Use
³ H	< 1	0	In vitro
¹⁴ C	< 1	0	In vitro
³² P	23900	5.4E-3	In vitro/Therapeutic
³⁵ S	< 1	0	In vitro
¹²⁵ I	620	1.4E-2	In vitro
¹⁸ F	2880	1.6 E-1	Diagnostic
⁶⁷ Ga	402	2.5 E-2	Diagnostic
¹¹¹ In	1220	7.2 E-2	Diagnostic
^{99m} Tc	354	2.2 E-2	Diagnostic
¹²³ I	605	3.4E-2	Diagnostic
⁸⁹ S	16400	1.8E-4	Therapeutic
⁹⁰ Y	43500	7.1 E-2	Therapeutic
¹³¹ I	1130	6.3E-2	Therapeutic
¹⁵³ Sm	241	1.5E-2	Therapeutic

Table 3. Mean dose rate 1 m from patients after radiopharmaceutical administration

Study	Radionuclide	Administered activity (MBq)	μSv/h at 1 m
Bone scan/Cardiac perfusion	^{99m} Tc-MDP/MIBI	740	5
Neuroendocrine tumors	¹¹¹ In-Octreoscan	111	2
Tumor imaging	⁶⁷ Ga-Citrate	111	4
Neuroreceptors	¹²³ I-Datscan	111	2
Tumor imaging	¹⁸ F-FDG	370	55
Thyroid cancer therapy	¹³¹ I (NaI)	7400	200
NHL-immunotherapy	⁹⁰ Y-Zevalin	900	1

Internal irradiation hazard

The risk of ingesting radioactivity when solutions are used is always present, even if they are low. Potentially the main ways nuclides may be ingested are via:

- contaminated hands;
- contamination of the skin;
- accidental wounds during manipulation;
- accidental punctures during dose preparation in syringes and dose administration;
- inhalation of radionuclides vaporised in air during manipulation;
- inhalation of radioactive gases used for patient examinations.

Except for liquid iodine substances, the majority of radiopharmaceuticals used in nuclear medicine are non-volatile; nevertheless manipulation under a shielded fume hood is recommended to lower this risk further. Radioiodine capsules have a much lower volatility than liquid solution and their use is recommended for radiotherapy purposes.

Policies for radiation protection

Radiation protection aims at preventing deterministic effects and limiting the probability of stochastic effects. The system of dose limitation imposes the requirements that all

exposures be as low as reasonable achievable (ALARA) taking into account social and economic factors and that limits provided in the regulations are observed.

External irradiation

To avoid and limit the hazard from external irradiation, the three main principles time, distance and shielding, together with optimised procedures and lay-out of nuclear medicine departments are applied.

Time: Accumulated dose from external irradiation is directly proportional to the amount of time spent working with or near the source. Typically, the highest radiation exposures encountered in nuclear medicine applications are associated with the preparation of radiopharmaceuticals and with the management of radioactive patients. For both tasks, experience is crucial: training technologists in specific procedures should prevent unnecessary radiation exposure.

Distance: one of the most effective and commonly used strategies in radiation protection is the increase of distance from the source. When the source dimensions are small compared with the distance, radiation field intensity can reasonably be assumed to decrease by the "inverse square law". With regard to radiation dose to hands, a great reduction can be obtained by using long tongs or forceps when handling unshielded sources or vials. Imaging rooms should be large, allowing

control areas to be as far as possible from the location of the radioactive patients. In this, the a-priori knowledge of potential exposure at different distances from an unshielded X/γ radioactive sources can be calculated by means of the exposure rate constant Γ. As

shown on Table 4, the constant Γ, expressed as mSv.cm²/MBq.h is specific of each radionuclide and is a function of its decay scheme. This information should be used in designing the imaging areas.

Table 4. Energy of emitted radiation (E_{max} for beta), rate constants Γ and HVLs in Pb for some radionuclides

Radionuclide	Main emissions [keV]	[mSv*cm ² /MBq*h]	HVL in Pb [mm]
¹⁸ F	E _{β+} =634 (97%), E _γ = 511(194%)	1.6E+00	4.0
⁶⁷ Ga	E _γ =93(39%),185(21%)	3.0E-01	1.4
^{99m} Tc	E _γ = 140(89%)	3.2E-01	0.3
¹¹¹ In	E _γ =171 (90%),245(94%)	1.3E+00	0.7
¹²³ I	E _γ = 27 (71%), 159(83%)	7.3E-01	0.4
¹³¹ I	E _{β-} =606 (90%), E _γ = 365(82%)	7.6E-01	3.0

Shielding: radiation exposure is commonly reduced by shielding radioactive sources with adequate materials. The choice of shielding material depends on the type and energy of radiation. External radiation fields from radionuclides used in nuclear medicine consist mainly of γ rays for which high atomic number (Z) materials such as lead are very effective for maximum attenuation. Beta (β) radiation is best shielded with low Z materials to minimise the production of Bremsstrahlung X rays, which are much more penetrating than the β particles. When large activities of high-energy β- emitters are used, e.g. for radio-therapeutic purposes, a mixed shielding of lead outside a plastic shield is preferred. For γ radiation,

shielding efficacy of a specific material is expressed by the half-value-layer (HVL) representing the thickness of the material needed to reduce the intensity of radiation from a particular source to one half. For high energy gamma radiation such as positron emitters (e.g. ¹⁸F compounds), the dose rate can be significantly reduced by combining distance and shielding, as shielding is not as effective as for lower energy γ rays.

Manipulation of radiopharmaceuticals must be done in shielded “hot cells” to avoid exposure to the body. The operator must always shield vials and syringes to minimise direct contact with the radioactive source and limit hand exposure.

In summary, the following radioprotection rules should be followed:

- Design a nuclear medicine department with dimensions, positions and shielding of working areas appropriate to the type of radiation sources, clinical procedures and workload. It must be designed so that radiation exposure similar to that of the natural background is ensured in surrounding areas;
- Plan all appropriate facilities to limit hazard (cleanable and non-permeable floors and surfaces, ventilated shielded hot cells, forced air ventilation and negative pressure within the laboratory);
- Train personnel to use the right procedures, avoiding staying close to radioactive sources or to injected patients longer than is necessary for correct performance of the examination and required patient care.
- radiopharmaceuticals retained in the body longer than those rapidly eliminated;
- radioactive substances that concentrate in or near radiosensitive tissue (e.g. bone marrow) rather than those concentrating in less radiosensitive tissues or those uniformly distributed in the body.

Equipment used

Personnel dosimetry

Personnel dosimetry assesses the individual exposures of people to ionising radiation and verifies that individual dose limits are being respected. Different devices can be used as personnel dosimeters. The factors that affect the choice of dosimeter are:

- response: independence of radiation energy, geometry of irradiation or environmental conditions;
- ability to distinguish doses from different type of particles (β, γ);
- sensitivity and ability to measure a range of levels of exposure.

Internal irradiation

Small amounts of radioactivity in the body can produce large radiation doses, depending on the physical and biologic behaviour of the radiopharmaceutical. More hazardous are:

- radionuclides emitting energetic electrons rather than those emitting photons;
- radioactive substances with a longer physical half-life than those with shorter ones;

Furthermore, the dosimeter should ideally be small, lightweight, robust, easy to use, low cost and immediately readable with a permanent memory of dose measurements. No dosimeter commercially available today satisfies all the above requirements.

Film badge: the film badge dosimeter is still the most widely used personnel dosimeter. The radiation sensitive material is a piece of X-ray film enveloped in light-tight and resistant plastic and contained in a plastic holder, having in front of the film a series of radiation metal filters. Its advantages are the ability to distinguish between photons and beta particles, the broad dose range for photons and beta particles, the capacity to evaluate photons grossly as high, medium and low energy together with the low cost, the small weight and dimensions. These outweigh its disadvantages, which are the environmental effects (e.g. heat) and the delayed reading.

Thermoluminescent dosimeter (TLD): for this type of dosimeter, the radiation sensitive material is a small piece of inorganic crystal characterised by migration of valence-band electrons to the higher-energy conduction band when excited by energy absorption from ionising radiation. Excited migrating electrons are trapped in metastable states leaving vacancies in the conduction band. The more radiation received by the TLD, the more electron traps are generated. TLD reading is not immediate and requires the crystals to be heated to 300-400 °C to allow metastable electrons to re-enter the conduction band, filling the holes, with consequent emission of energy as visible light photons. To collect these light photons, a photomultiplier tube (PMT) is positioned in the heating chamber; and the current detected is proportional to

the intensity of the light and hence to the absorbed dose. After being heated at a high temperature for 24 h, the crystals are reusable. The most common TLD material is lithium fluoride (LiF): its effective atomic number is similar to that of soft tissue and therefore is accurate for absorbed doses over a wide range of X, γ radiation energies. The main advantages of LiF are: the wide range of dose-response (0.1 – 1000Gy), the tissue equivalent Z, the very small dimensions, the light weight and the easy use. Usually single chips of LiF are used in finger rings to monitor extremity exposures. The high cost of the reader, the loss of information after reading and the susceptibility to environmental heat and humidity are its principal disadvantages.

Electronic personnel dosimeters: G-M tubes or silicon solid-state diodes are used as radiation detectors. Even if they are larger and heavier than a film badge, they have real time display of dose rate and cumulated absorbed dose as major advantages. Models currently available using solid-state diodes are quite reliable and sensitive to energies of X/ γ rays from 50 keV to 6 MeV, maintaining a good linearity from 10 μ Sv to 10 Sv. These features together with the possibility of setting visual and acoustic alarms at predetermined doses and dose-rates make this type of dosimeter particularly suitable for nuclear medicine workers. The high cost and the impermanent record of the dose measurement can be considered as their principal disadvantages.

Bioassays

Assays of excreta, usually urine, are performed to test for or estimate amounts of radioactive material in the bodies of workers. In nuclear medicine related occupations, workers particularly susceptible to internal contamination, such as technologists manipulating large amounts of radioactivity, may be checked.

Methods developed to assess effective dose from the activity measured on a bioassay require the biodistribution and kinetics of the relevant radioactive compounds and the minimum detectable activity to be known or modelled.

Radiation survey instruments and survey procedures

Radiation surveys are performed to evaluate external radiation fields and check contamination of facilities and personnel. Surveys assist in keeping the level of exposure as low as possible by showing when corrective actions need to be taken to limit exposures. Instruments commonly used to detect and measure external radiations are portable ionisation chambers and Geiger-Muller (G-M) monitors.

Portable ionisation chamber (IC): this consists of an air-filled chamber containing two electrodes, a battery or power supply and a sensitive electrometer to measure the current flowing between the electrodes generated by ionisation. For X and γ rays, the higher the current, the higher the exposure rate. To dis-

tinguish low energy X photons and γ radiation, most ion chambers have plastic/metal caps that must be placed over the thin entrance window. Advantages of ion chambers are the wide and accurate range of exposure rate measurements and the ability to correct for environmental factors. Disadvantages are slow response times and low sensitivity.

G-M monitor: this instrument consists of a thin, cylindrical metal shell with a wire mounted at the centre of the cylinder. The detector is filled with a noble gas (neon, argon) and a small amount of halogen such as chlorine for quenching. It works like the IC but with a higher potential difference between anode (central wire) and cathode (shell) to supply sufficient kinetic energy to the produced electrons so that they cause additional ionisation. This cascade effect allows a large amount of current to be collected for a single event and thus very high sensitivity albeit with a short dynamic range. The multiplication effect has, however, some negative effects, namely dead time count loss at high exposure rates and inability to distinguish the type of the incident radiation. To distinguish the β and γ ray components, a metal or plastic slide is usually used to cover a portion of the G-M tube. G-M survey meters, calibrated to indicate the dose rate, present a nonlinear response to the energy of γ rays; therefore a calibration factor determined for high energy radiation (600 keV) can overestimate low energy photons in the range 40-100 keV by a factor of five.

Among the advantages of G-M monitors are their low cost, light weight, robustness and their high sensitivity for β and γ rays making them particularly suitable for locating radioactive contamination. The dependence of the response on the γ ray energies, the dead time count loss for high count rates and insensitivity to photons with energy lower than 30keV represent the main disadvantages.

It is worth noting that calibration of portable survey instruments should be performed at least every two years. Battery tests and checks with a small radioactive source should be performed as regular quality control.

Wipe tests

When it is necessary to assess low activity on contaminated surfaces, wipe tests measurement should be performed as an indirect survey method. Furthermore, wipe tests can check if the contamination is removable. Glass fibre filter disks or similar materials are usually used to wipe surfaces and counted with calibrated counting systems (NaI gamma well-counter for γ and a beta counter for β rays contaminations). If a combination of γ and β emitting radioisotopes are used in the laboratory, then gamma followed by beta counting should be employed. For each radionuclide used, wipe tests allow surface contamination to be calculated in Bq/cm² after appropriate calibration factors are used. The calibration factor is a function of the instrument's efficiency for the specified radionuclide, the area

wiped, the counting duration and the removal factor (wipe test efficiency is only about 10%). The frequency with which the wipe tests are conducted depends on the amount of radioactive material manipulated and the types of manipulation; but it should be performed on a monthly basis as a minimum.

Air Sampling

Air sampling is used to check for and assess the potential risk of internal exposure due to inhaled radioactive air. There are basically two different methods to sample airborne particulates by means of pumps. Activity in known volumes of air is assayed either (i) inside a calibrated Marinelli geometry counter or (ii) through filters. For the former, calibration factors for each radionuclide are set, and then Bq/cm³ of sampled air are directly measured. For the latter, filters are measured with a counting instrument, and Bq/cm³ are indirectly assessed as for a wipe test after determining calibration factors.

Radiation protection issues in daily practice

All practices with radioactive sources must be performed in classified "controlled or supervised" areas; and only expert trained personnel are authorised to work with radioactive sources. The success of a good system of radiation protection depends greatly on the individual workers observing safety procedures.

The following basic rules should be observed when working with radioactive substances:

- laboratory coats, shoes and protective clothing must be worn before entering a controlled area;
- body and finger personnel dosimeters must be worn by workers;
- disposable impermeable gloves must be worn and replaced frequently during manipulations;
- hands should be washed after removing gloves;
- radioactive sources must be handled in designated areas, labelled with radioactive warning signs and enclosed in appropriate shielded boxes;
- all preparations of radiopharmaceutical solutions should be performed in shielded cells;
- no eating, drinking or smoking is allowed in classified areas;
- pipetting should never be done with mouth;
- work areas should be kept as clean as possible, absorbent paper, used to cover bench surfaces, should be changed periodically and in cases of contamination;
- syringe and vial shields should be always used to transfer radiopharmaceuticals to the patient administration room;
- gaseous radioactive administration should be performed in a room with frequent air changes and negative pressure with respect to the outside; during gas dispensing, the operator should wear a mask to protect mouth and nose, disposable protective laboratory clothes and gloves;
- the recapping of needles should be discouraged because of biological and radiological risks;
- shielded containers, differentiated for short and long half-life radionuclides, for the disposal of solid wastes must be used;
- at the end of work, hands, lab-clothes and shoes must be checked for contamination before leaving the controlled area.

References:

1. ICRP Publication 57. Vol. 20 n° 3-1989. Radiological protection of the worker in medicine and dentistry. Pergamon Press

Chapter 3 – Quality Assurance of Equipment

Eric P. Visser, PhD

Introduction

Quality Control (QC) is important to determine the integrity of nuclear medicine equipment when used in clinical routine or research studies. High standards are needed for such equipment, especially in relation to image quality, quantitative imaging and size or volume measurements in therapy and dosimetry. Although nuclear medicine departments may have service contracts with their equipment suppliers for preventive maintenance and calibration, several QC procedures should be carried out on a regular basis by the technologists or physicists working in the department.

Selection of tests

Nuclear medicine equipment suppliers generally have many protocols available to assess whether their equipment meets all its specifications. Most of these protocols are complex, time-consuming, and often need special test equipment. To guarantee the normal day-to-day functioning of the equipment, fewer and simpler tests can be used.

A QC programme can never replace the attentiveness of the “operator”. In normal use, several of the problems with the equipment that can occur are immediately obvious. In these cases, the investigation can usually be repeated and there is no risk of the patient’s diagnosis being affected. A QC programme, however, aims at detecting those changes that happen so slowly that they are normally not detected in everyday use.

When setting up a QC programme, several criteria have to be met.

- A QC programme should provide concrete test results. These results should be compared with a predefined value, usually the value obtained during equipment acceptance tests.
- An action threshold value should be defined, as well as a protocol for the actions to be taken whenever this threshold is exceeded.
- The “costs” and “benefits” of a QC programme have to be balanced. Examples of “costs” are the down time of the equipment, personnel costs, costs of phantoms, radioactive sources and the radiation burden to the personnel. The level of benefit is related to the chance that if any degradation has actually occurred, it will be detected by the test and that the consequences of the degradation (for example a faulty diagnosis) can be pre-empted.

Frequency of tests

Choosing fixed test frequencies may either result in too few tests being performed, with a greater chance that the equipment may not always be at its optimum condition, or too many tests being performed so that the equipment is not available for patient care for long periods of time. Therefore, the test frequencies should be adapted to the reli-

ability of the equipment and the conditions of use. Of course, the cost-benefit aspect of these tests should also be taken into account. However, equipment tests should always be performed after the first installation (to obtain reference values for all test parameters), after hardware or software upgrades, and after specific problems and repair. In other cases, the tests should be carried out using a frequency that is adapted over time to the reliability of the individual piece of equipment. This will generally lead to the optimal test frequency. As a rule of thumb, one should start with a relatively high frequency, which can be then halved if no deviations that exceed the action threshold occur during four consecutive tests. In case of a sudden, unexpected deviation, the test frequency should be increased again. However, a certain minimum frequency should still be used; mostly this coincides with the frequency of (preventative) maintenance of the equipment.

Action levels

Whereas test procedures and equipment specifications are generally described in a very exact way (e.g. in NEMA test procedures), this does not hold for action threshold levels. In general, it is not possible to define absolute values for action levels from “first principles”. Instead, action levels are determined by experience with the cost-benefit aspect kept in mind. With the proper choice of action levels, degradations should not yet have reached a stage where they can be detected in clinical

images but on the other hand the equipment is not put out of use for readjustments, calibrations, etc. for too long a time period.

Equipment to be tested

The type of equipment present in each nuclear medicine department will vary depending on the local situation. However, in general, the following equipment will be present in most departments

- Gamma cameras
- PET and / or PET/CT scanners
- Dose calibrators
- Flood sources and other sources for calibration and quality control
- Probes such as thyroid and surgical probes
- Radiation monitors
 - Exposure rate meters
 - Contamination monitors
 - Personal dose meters
- Semiconductor detectors
- Gamma counters

Gamma cameras

A test that should be performed with a relatively high frequency is the intrinsic (without collimator) homogeneity (uniformity) test. A frequency of once a week or fortnight is suitable. The reason is that this test provides a simple and quick indication of the overall performance of the gamma camera. Malfunctioning of one or more photomultiplier tubes is immediately seen, and when looking at the

trend of sequential results, a possible drift from the optimum value is easily detected. The intrinsic uniformity of the detector can be measured by using a point source located at a long distance from the detector to provide a uniform flux of parallel gamma photons.

The system (detector with collimator) homogeneity should be measured on a regular basis, typically once a month. System uniformity images allow checking for any damage to the collimators. Depending on the type of scans performed, collimators may have to be changed frequently, thus increasing the risk of mechanical damage to the septa that may be unnoticed from the outside. The system uniformity can be measured by placing a uniform flood source (e.g. Co-57) onto the collimator.

Other tests should be performed using an adaptive frequency. The complete list recommended is given below. It should be noticed that some tests partly overlap with others in the specific information provided. The user may therefore decide to skip one or more of these tests.

Zero measurement

By performing a zero measurement, that is, a measurement with nothing in the field of view of the detector, one checks for possible radioactive contamination on the detector or the patient bed. Since there is always a certain level of background radiation, which differs from place to place, it is not possible to give

an absolute value for the acceptable zero level measured. However, in order to check for contaminations, one should compare the measurement results with those of previous measurements. If an increase of, say, 20% is recorded, action should be taken to check for and remove its source.

Shielding

The detectors should be shielded at the front, back and sides in order to minimise background radiation and stray radiation from other patients or from parts of the patient outside the field of view. The shielding can be checked by placing a radioactive source near the detector head and recording the deviation from the zero measurement. A typical measurement configuration uses a source strength of 5 MBq at a distance of 50 cm from the detector. When the measured activity differs significantly from the zero measurement, the shielding should be checked for damage and for indications that there is a gap between the collimator and the detector head. This test should be performed during acceptance of the camera and when obvious problems are present.

Dead time, count rate performance

For very high activity levels, the gamma camera will not register all the counts due to the dead time effect. According to the NEMA specifications, the count rate should be recorded at which a loss of 20% occurs relative to the expected rate. This can be done by measuring and plotting the count rate of a strong

Tc-99m source either as it decays over several half-lives or is successively attenuated using a set of copper plates. The first test is very time consuming, taking approximately two days (NEMA), and the other one is very elaborate. A quicker alternative is provided by the “two source method”, in which two sources of a suitable activity are measured separately and together. From these three measurements the dead time can be calculated. Each measurement typically takes only 2 minutes. The recorded dead times should be compared to previous values.

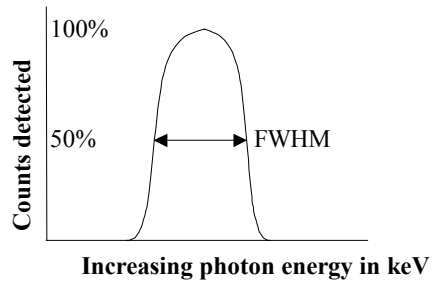
Image size / pixel size

Pixel size is important in multimodality matching for image fusion, attenuation correction, and when determining radiation fields in radiotherapy. The easiest and most straightforward way to measure pixel size is by placing 2 or more point sources at known distances apart in the detector’s FOV, and dividing these distances by the number of pixels between the sources in the image. This test should only be performed using parallel collimators, since, for pinhole collimators, the pixel size is dependent on the collimator-to-patient distance.

Energy resolution

A good energy resolution is important to distinguish between the non-scattered radiation from the patient and the radiation scattered in the patient or in the detector. Most gamma

cameras allow the complete energy spectrum to be displayed. The full width at half maximum (FWHM) of this spectrum should be measured.

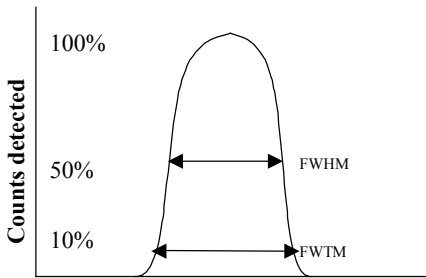


Sensitivity

The sensitivity of a gamma camera is expressed as the number of registered counts per second, divided by the activity (e.g. in cps/MBq). Sensitivity is an important parameter, since a low sensitivity results in more noisy images. Sensitivity is measured by placing a source of known activity in the camera’s FOV and by recording the resulting count rate. The source specified by NEMA is a liquid-filled 200 mm diameter cylindrical phantom. In practice, when the absolute sensitivity does not have to be known and only the constancy has to be tested, the sensitivity measurement can be combined with the system uniformity measurement.

Spatial resolution

Spatial resolution determines the sharpness of the image. It determines the details that can be discerned in an image. A quantitative expression is given by the width of the image of a line source, expressed as FWHM and FWTM.



Distance across camera face

Linearity

The linearity determines to what extent straight objects are imaged as straight objects. System spatial resolution and linearity can be measured by imaging lines sources e.g. in the form of a single capillary tube filled with radioactivity. Intrinsic spatial resolution and linearity can be measured using a lead phantom containing several slits (PLES phantom) that are illuminated by a strong point source placed at a large distance from the slit pattern.

Whole body tests

Since the motion of the bed and the translation of the bed position to the position of

pixels in the whole body image can introduce errors, several of the above parameters have to be measured in the whole body mode of operation. Also the proper opening and closing of the electronic window at the start and the end of a whole body scan, if present, has to be verified. The necessary tests are: whole body uniformity, whole body image size or pixel size, and whole body spatial resolution.

SPECT tests

Several tests related to SPECT imaging have to be performed. These test are related to the definition of the centre of rotation and non-circular orbits. In most cases, the equipment manufacturer provides software protocols and test phantoms for these tests.

PET and PET/CT scanners

Since a PET scanner provides quantitative information about the distribution of radiopharmaceuticals, that is activity concentrations for each organ or other volume of interest, attention should be paid to factors that could affect proper quantification. On the other hand, since the detectors in a PET scanner are fixed, several tests related to detector motion, such as whole body tests or centre of rotation test in SPECT, are not necessary.

Before any quality test is performed, the PET scanner should be "well tuned", which means that the following actions should have been performed:

- Hardware set-up: Optimising all electronics in the scanner, that is photomultiplier position readout, photomultiplier gain, detector time alignment, etc.;
- Normalisation: Correcting differences in detector response by software;
- Create a reference scan: This scan should be compared with daily QC results;
- Calibration: The activity concentration readings in the PET image should be calibrated against the local dose calibrator or well counter;
- For PET/CT scanners, the co-registration of PET and CT should be optimised;
- The usual CT procedures common in radiodiagnostics should be performed.

After the scanner has been properly set up, the normal quality assessment programme basically consists of the following:

Daily QC

The daily QC forms the heart of the quality assessment of a PET scanner. It involves scanning a standard phantom, usually a radioactive cylinder with uniform activity distribution. In scanners that contain built-in sources for transmission scans, these transmission sources can be used for daily QC; and the protocol can be run totally automatically. The results of the

daily QC scan are compared with the reference scan made immediately after the set-up. Most daily QC protocols perform a comparison on a detector-by-detector basis, so that detector drift leading to less uniform images is detected. Sometimes, an overall detector drift leading to improper activity concentration reading is detected, necessitating a new calibration of the scanner (see below). The daily QC results can be used to decide whether a new set-up, normalisation and/or calibration are necessary. In general, the supplier of the scanner will provide the threshold values.

Calibration and cross calibration

For quantitative measurements, that is for standard uptake values (SUV) or any pharmacokinetic modelling, the PET scanner should be calibrated to provide accurate activity concentrations (Bq/ml). One can calibrate the scanner using a fixed phantom of known activity, e.g. a Ge-68 cylinder, or cross-calibrate it to the dose calibrator in which the PET radiopharmaceuticals are measured. In the latter method, a water-filled phantom is used into which a certain amount of activity, measured in the dose calibrator, has been introduced. The first method is quicker and easier, whereas the second method allows for possible drift in the dose calibrator without affecting the quantitative PET results.

Uniformity, sensitivity and spatial resolution

Uniformity, sensitivity and spatial resolution can be measured using standard protocols

(NEMA NU 2-2001). Although these parameters have to be measured during acceptance or after any major hardware or software upgrade, they are very stable as long as the daily QC results do not exceed their threshold values. Therefore, routine measurements of these parameters, either with a fixed or adaptive frequency, are not necessary.

Dose calibrators

For nuclear medicine therapy and also for diagnostics, especially when quantitative results or comparisons with previous scans are important, accurate and reproducible doses are crucial. Therefore, strict quality standards apply to dose calibrators. The parameters of zero reading, stability, accuracy and linearity should be measured in the QC programme.

- For every dose calibrator, the zero reading and stability should be checked on a day-to-day basis. These two tests should be performed before the first radiopharmaceutical sample is measured. A proper zero reading guarantees that there is no radioactive contamination of the dose calibrator.
- The stability measurement can be performed by measuring the same radioactive source (e.g. Cs-137 which is convenient due to its long half life of 30 y) every day, giving a quick indication of any problem.
- Accuracy should be measured as needed by using calibrated sources, preferably in the low, medium and high energy ranges (e.g. Co-57 at 122 keV, Ba-133 at 356 keV, and Cs-137 at 662 keV).
- Linearity should be measured as needed and should cover the complete range of activities used, typically from several GBq for therapeutic doses down to the lowest diagnostic doses of several tens of MBq. The easiest way to do this is to start with a Tc-99m sample of high activity and to let it decay over several half-lives. A typical example is Tc-99m with a starting value of 2 GBq, decaying over 5 half lives (i.e. 30 h) down to 30 MBq. Performing 3 to 4 measurements each day, over two days, produces the measured decay curve, which can be compared with the theoretical decay curve.

Probes

Non-imaging detectors such as thyroid probes and surgical probes are also used in nuclear medicine departments. Although much more attention is generally given to imaging equipment, the less frequently used probes should be checked for zero reading, sensitivity, stability, linearity, side shielding, field of view, and energy resolution. Since these probes are hand held and used at different locations, attention has to be given to battery life, broken cables, damage to the detector head, etc. When used irregularly, basic quality tests are recommended before each use.

Radiation monitors

Every nuclear medicine department needs exposure rate meters (or dose rate meters), contamination monitors and personal dose meters.

- Exposure rate meters have to be checked typically once a year. This can most easily be done using a point source of known activity (e.g. 100 MBq) at a fixed distance (e.g. 0.5 m). The reading should be compared with the calculated exposure rate.
- Contamination monitors can be used for general contamination detection or for quantitative measurements. In the first case, periodic measurements of a point source at a fixed distance can be performed. In the second case, a more elaborate test is necessary to check that the maximum allowable contamination (4 Bq/cm²) is being properly detected. The test can be performed by uniformly “contaminating” a filtration paper of 10 x 10 cm² using droplets of a Tc-99m solution of known radioactive concentration.
- Personal dose meters have to be checked yearly. This can be done by placing a source of known activity (e.g. 500 MBq) at a fixed distance (e.g. 50 cm) and checking the reading against the theoretical value.

Semiconductor detectors

Semiconductor detectors are used to determine the radionuclidic purity of radiopharmaceuticals and calibration sources. They are also used for quantitative analyses of tracers in different kinds of samples (blood, excreta, waste water, etc.) Mostly, the detector utilises a Ge crystal and is then called a germanium detector. The important parameters to be tested (typically on a yearly basis) are the energy calibration, energy resolution and sensitivity. In the range 50 keV - 2 MeV, the relationship between the energy and the channel number is linear. Therefore, the use of two well-defined photo peaks that cover the energy range will suffice. In the range below 50 keV, the relationship is quadratic so that at least three energies are necessary. One could, for instance, use the X-ray emissions of Cs-137. The energy resolution can be measured by recording the FWHM of the photopeak of several nuclides in the energy range of the instrument, for instance Co-57, Co-60 and Cs-137. Sensitivity can be measured using a source of known strength with photons of different energies, e.g. Eu-152. This source should be placed in exactly the same geometry with the detector as the samples to be investigated.

Gamma counters

In a gamma counter, several samples placed in vials or test tubes can be measured automatically. The QC parameters of interest are the zero reading, shielding and sensitivity. The zero reading can be measured very easily by adding an empty vial or test tube to each measurement series. Shielding can be measured by using one empty vial surrounded by two highly active vials in front and two more at the back of it. The counts of the empty vial should not be higher than the zero reading. The sensitivity should be checked several times per year. It can easily be done by measuring a source of known strength in a volume equal to the normal volumes measured. The sensitivity in cps/Bq should be compared to previously measured values.

Central archiving of all data

Reliable and easily accessible electronic data archives are vital to maintain good Quality Assurance.

References:

Example images can be seen on IAEA Quality Control Atlas for Scintillation Camera Systems, ISBN 92-0-101303-5, International Atomic Energy Agency, Vienna, 2003.

Downloadable from http://www-pub.iaea.org/MTCD/publications/PDF/Pub1141_web.pdf

Chapter 4 – Best Practice in Procurement

Sarah Allen, PhD

For most of us, buying a gamma camera is the largest capital purchase we will make in our career. We get involved in the process once or twice in a decade; and when we do, we are often uncertain of the legalities with which we must comply and the steps to be taken in order to secure the best deal.

Deciding what is needed.

New equipment is purchased because of a specific need. This could be the replacement of an unreliable camera, increased demand requiring acquisition of a dual-headed system or provision of a new service to the hospital. Before purchasing, it is worth taking the time to look at the service as a whole. Could you make the workflow more efficient by changing other aspects of the department? Evaluating the service may change your priorities and lead to a different choice in gamma camera and ultimately improve your department.

You may need to write a business case for the procurement, requiring you to put your needs on paper and make clear the financial costs and benefits of what you plan to purchase. This documentation will help to secure funding for the project. By whatever route the financing of the purchase is obtained, it is advisable not to proceed further until the money needed has been secured. It is also important to consider the cost of any building works that may be required to accommodate new equipment. These costs are likely to be high if you purchase a hybrid SPECT/CT where

the CT has diagnostic capabilities as the radiation shielding requirements for this type of system are significant and will cost money to put in place.

As the procurement process is likely to take several months, it is important to have a clear timescale of when the equipment needs to be up and running and of deadlines when money needs to be spent. All steps must be managed to comply with this timescale. It is worth taking advice from an expert in procurement to help you through this complex process. Something that you are doing once or twice every ten years may be done once or twice a month by a specialist who works in your organisation. You need to find them and involve them in the process.

Choosing the best equipment for the purpose.

Within the EU, equipment purchase is governed by EU directives. This is to ensure that choices are made objectively and make the best use of public money. The key principles underpinning the public procurement regulations are “equality of treatment” and “transparency”. Public Sector Directive (2004/18/EC) brings together three previous directives on public sector procurement (supplies works and services) and governs purchases over 150K Euros. The regulations on the supply of equipment require public tenders for contracts exceeding this specified value to be advertised in the Supplement to the Of-

ficial Journal of the European Union (“OJ S”) and published on a website for visibility throughout the EU. The website <http://ted.publications.eu.int/official/> lists the current tenders, allowing all manufacturers to access the information.

The Directive gives options on the Tender process. You can choose to have an “Open” or “Restricted” Tender. The main difference is that in a Restricted Tender, you shortlist the suppliers before issuing the detailed tender documents. In an Open Tender, all expressions of interest are issued with the tender details. The best choice in the specialist market of gamma cameras is the Restricted Tender option.

You will need to write “A Summary of Need” for the OJ S: this statement sets out the basic requirements of the purchase and allows companies to express their interest. Once the advert is in place, it makes good sense to meet with the prospective suppliers. Local requirements can be discussed ensuring that all parties are fully briefed.

At this pre-tender stage you should begin assessing the range of products on the market. Companies display their newest models at commercial exhibitions during conferences. This is a good starting point when looking into what is currently available. Industry representatives are in the best position to organise visits to see their products in use in a working environment. It is advisable to go to depart-

ments that have a similar workload and system requirements to your department so that you can ascertain whether the new equipment will meet your particular needs. Before you go on a visit, make a list of the essential and desirable features. Ask all levels of staff what their priorities for system functionality are. In particular, remember what the camera is being purchased for. In single camera departments, make sure the camera can do everything you need. Can it image patients on beds, what about children, what about patients who are claustrophobic, how do you change collimators, will it fit in the available room? For equipment that comes from a company with which you have not dealt before, you will want to know how reliable the equipment is (usually quoted as “up time for the product”) and, when there is a problem, who carries out the maintenance? Therefore, allow time during your visit to ask all about the practicalities of using the camera and issues concerning reliability and service support. Take advantage of their knowledge and experience and ask them whether you can contact them in the future with extra questions; get their email address. All the information will prove to be invaluable when it comes to making a decision.

After these preliminary discussions and visits, the final tender questionnaire is issued to the companies. This gives you the opportunity to ask numerous questions about many aspects of the performance of the gamma camera. There are several advantages to us-

ing a standard tender questionnaire. It provides you with a comprehensive and detailed set of questions; it should reduce the work required by the supplier and thus speed up the whole tender reply process. In the UK, The British Nuclear Medicine Society, in association with the Institute of Physics and Engineering in Medicine, and industry have produced a standard tender questionnaire. This comprehensive document has been in use since the mid 1990s and has recently been updated to include the purchase of gamma camera PET. Although detailed and comprehensive, it does allow for extra questions to be added by each customer and has them clearly signposted in a separate section. The questionnaire is available at www.bnms.org.uk

Once the tender documents have been returned, they can be opened and analysed. The purchaser must look through the returned documents and start to make a decision as to what equipment is preferred. At this stage, you may need to get back to the manufacturer and clarify some of the details of their offer. If you need optional extras to be included in the main cost, go back and ask them if this is possible. This is your one chance to procure the best deal. You should discuss with the companies their recommendations for servicing the camera. Find out what levels of contract they offer and what each one will cost. Ask where their service engineers are based, how many they have, and what the response time is. The main depot for spare parts is likely to

be located somewhere in mainland Europe near a large airport. Get assurances from the vendors that they have an efficient and robust operational policy to get critical parts to you in a timely fashion.

No doubt a fully comprehensive service contract gives peace of mind; but it will come at a cost, so you may want to consider alternatives, for example a contract where you pay for the parts but the cost of the engineer is included in the contract. It is also worth noting how many days they expect to spend on preventative maintenance: the more complex the system, the more days required. A complicated SPECT/CT camera may require up to three consecutive days three times a year.

When you reach the decision as to what system and service level agreement best suits your needs, you should clearly document why you have chosen that particular camera and the reasons why the other systems are not as suitable. Unsuccessful companies will expect to be briefed on why they have not been awarded the contract. The final stages are to award the contract and order the system.

Installing the system.

Pre-installation work can then take place before the camera is delivered and acceptance testing commenced. Before the camera is installed, a detailed set of plans for its location and requirements should be drawn up. These will show its position in the room

and all the other services that are needed. Take time to look over the plans and discuss the details with the supplier - it is your only chance to get things as you want them. If you purchase a high end SPECT /CT, you will need to take advice from specialists in CT to ensure the shielding requirements are met. Most companies will want the specialist Radiation Protection Advisor / Expert of the hospital to approve the plans prior to the start of construction work.

Acceptance testing

Once the camera has been installed, it is good practice to follow standard NEMA protocols for acceptance testing. The latest standards are found at www.nema.org. Following internationally recognised standards ensures that you are testing the equipment under similar conditions to those in the factory. Some departments will use an outside agency to perform these tests for them, as the equipment needed can be quite complex. You can compare your results to the detailed camera specification given in the tender response; and you can judge that the camera is functioning as expected and is suitable to be released for clinical use. If the testing process brings to light technical problems with the equipment, make sure to feed issues back to the installation and service engineers immediately so that they can be looked into and rectified. A useful publication when trying to diagnose issues is the IAEA Quality Control Atlas for Scintillation Systems. Downloadable from <http://>

www-pub.iaea.org/MTCD/publications/PDF/Pub1141_web.pdf. The Atlas contains numerous examples of possible reasons behind unexpected image artifacts and problems. Once this formal acceptance testing process is completed, the camera can be signed off as meeting the specifications requested; and the payment for the equipment can be authorised.

Training

After acceptance testing and before using the camera clinically, you will need time to get staff trained on how to use the new equipment and time to set up protocols. Training may be quick and easy if the staff have used that type of gamma camera before. However training needs may be extremely complex. A system with diagnostic CT will require staff with specialist knowledge of this modality not only during the testing process but also for setting up protocols. It may be that the local team will have this knowledge, particularly if the system is being installed in a radiology department where experts from all modalities are available. For others, knowledge must be gained by attending courses and observing the practice of CT colleagues. Training is required for technologists with no previous experience, so they can setup the patient, understand the selection of CT protocol and have enough theoretical knowledge and practical experience to be competent to press the button and exposure the patient to the extra radiation from the CT. Training programmes at

degree and postgraduate levels are just starting to incorporate the knowledge required for SPECT-CT but it will take several years before these are established. However with careful planning and well thought-out training programmes, hybrid imaging incorporating high-end CT can be established within several months even in departments with no previous history of imaging at this level.

Summary

Equipment procurement is complicated but if you follow the process outlined and take expert help when needed, you will ensure that you comply with EU regulations. Consider using a standard tender questionnaire to streamline the paperwork and international standards for acceptance testing. By taking time to train staff and putting efficient and relevant protocols in place, you should find that the route to final purchase is not too arduous; and you will emerge with the right equipment to meet your specific needs.

References:

<http://ted.publications.eu.int/official/>
<http://www.bnms.org.uk>

Wells CP, Buxton-Thomas M. "Gamma Camera Purchasing" Nucl Med Commun. 1995, 3, 168-185

IAEA Quality Control Atlas for Scintillation Camera Systems. ISBN 92-0-101303-5. Can be accessed at www.iaea.org

Nuclear Medicine Resources Manual. ISBN 92-0-107504-9. Published by IAEA can be accessed at www.iaea.org.

Conclusion – Dealing with Best Practice – an everyday challenge

Julie Martin

There is always the feeling that one can do more and that a state of perfection is never reached. However on reading the contributions in this second publication on Best Practice, there is clearly so much expertise expressed either in the systems under which everyday work is performed or by tacit knowledge, experiences and strategies that are drawn upon subconsciously to achieve the final result. We can be justly proud that there is a determination by professionals within this speciality to work to a high standard across the many facets of Nuclear Medicine. The knowledge and skills required are extensive when looking at the chapter titles; European regulation, quality assurance including theoretical models, scientific justification and practice, radiation protection and its widespread applications and procurement which requires expert knowledge on policy, project management, business planning, legislation and operational proficiency to name but a few.

Despite differences between European colleagues (ranging from cultural factors to variations in the interpretation of the legislation at a national level), we are all aiming to respond to both external and internal requirements while at the same time managing our resources responsibly. The challenges are many; but by adopting the processes described in this book, Nuclear Medicine professionals can deliver immediate, measurable and sustained service improvements and thus ensure not only a high quality approach to imaging but

also an aspiration to a level of standardisation across Europe.

In analysing how we can perform daily at the highest level, it is important to consider both the external and internal environment and the factors by which they can prevent or facilitate good practice.

Firstly, analysis of the external environment can be undertaken by utilising a model called a 'PEST' analysis whereby examination of the political, economic, social and technological impacts can help identify external pressures that impact on the capability to maintain and develop best practice.

Political mandates and changes in legislation by organisations such as UNSCEAR, ICRP and the IAEA not only require that we implement change but often require adaptations to practice that affect already stretched resources. It is a continuous challenge to meet the ever increasing legislative requirements. Nuclear Medicine, however, has always been about balance; and from the early days of using qualitative and quantitative judgements to determine counts versus time, we can use this balanced proposition to implement best practice at a local level.

Technological impacts equally determine changes in practice. Fifteen years ago when undertaking SPECT gamma camera quality control, the trend was to perform centre of


rotation (COR) measurements either daily or after any collimator change. This could result in 3 or 4 COR measurements being performed on one camera every day. Now these systems are so stable that this level of testing is no longer necessary. However new standards are implemented as others fall away; and the requirement is always to review and evaluate procedures and protocols to ensure that the objectives remain within the required framework. In addition, within the web-based world, we all now work in, it is far easier to seek advice from colleagues 'virtually' thereby ensuring we benchmark continuously and seek advice from the plethora of experts in our specialty. This access to expertise is not limited to Europe but can be accessed globally. The introduction of training programmes such as Distance Assisted Teaching (DAT) also means that these practices can be shared with developing countries and is not determined by economics, thereby providing equality of access.

Social and economic pressures also determine the ability to maintain standards. Variables such as availability of an appropriately trained workforce and access to the latest equipment will always impinge on the ability to meet desired standards.

The second challenge lies within the internal environment and encompasses the specialty as a whole (including individual professional bodies) along with the employer. This is where national and European guidelines play a cru-

cial role and help determine the priorities both locally and within this multi-disciplinary profession. Validated guidelines play a crucial function in influencing the acquisition of appropriate resources which facilitate the achievement of best practice. Providing appropriate staffing numbers and employer objectives related to efficiency and productivity do not always go hand in hand. If evaluation and performance metrics can be validated and measured against prescribed standards, however, then it is likely to be resourced. An example of the guidance change from acquiring static myocardial perfusion images (MPI) to gated MPI SPECT studies helps to provide evidence supporting the acquisition of this type of equipment along with validating the continuous improvement of these imaging procedures. Although access to this type of practice may not exist in all departments, there is at least a standard for which there is evidence of improved diagnostic quality.

Clinical professionals need to share best practice (such as this book provides), ensuring that there is documentation which can be utilised to enable departments to work to a desired standard. It is important, as Europeans working under European directives, that we work together as professionals, agreeing on levels of performance for the provision of Nuclear Medicine services. Differences in practice will occur due to many variables; but standards will include criteria related to structure, process and outcome and will contribute to



achieving the operational and strategic objectives of departments.

The final and the most important challenge (which we meet on a daily basis when endeavouring to provide best practice) is that of ensuring the training and development of the most important resource within the speciality, our staff. This is not always highlighted in the guidance; but clearly it is only by developing the knowledge and skills of Nuclear Medicine professionals to perform the competencies outlined that we can ensure best practice. This is an ongoing process; and no matter where we work, it is the greatest challenge that we face. On reading this and the previous guide (Best Practice in Nuclear Medicine – Part 1), however, it appears that best practice is alive and well in Europe.

Further reading:

Nuclear Medicine Resources Manual 2006,
IAEA ISBN 92-0-107504-9

Downloadable from

<http://www-pub.iaea.org/MTCD/publications/PubDetails.asp?publd=7038>

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