IAEA HUMAN HEALTH SERIES

No. 37

Nuclear Medicine
Resources Manual

2020 Edition

IAEA
International Atomic Energy Agency

NUCLEAR MEDICINE RESOURCES MANUAL

2020 EDITION

The following States are Members of the International Atomic Energy Agency:

AFGHANISTAN
ALBANIA
ALGERIA
ANGOLA
ANTIGUA AND BARBUDA
ARGENTINA
ARMENIA
AUSTRALIA
AUSTRIA
AZERBAIJAN
BAHAMAS
BAHRAIN
BANGLADESH
BARBADOS
BELARUS
BELGIUM
BELIZE
BENIN
BOLIVIA, PLURINATIONAL
   STATE OF
BOSNIA AND HERZEGOVINA
BOTSWANA
BRAZIL
BRUNEI DARUSSALAM
BULGARIA
BURKINA FASO
BURUNDI
CAMBODIA
CAMEROON
CANADA
CENTRAL AFRICAN
   REPUBLIC
CHAD
CHILE
CHINA
COLOMBIA
COMOROS
CONGO
COSTA RICA
CÔTE D'IVOIRE
CROATIA
CUBA
CYPRUS
CZECH REPUBLIC
DEMOCRATIC REPUBLIC
   OF THE CONGO
DENMARK
DJIBOUTI
DOMINICA
DOMINICAN REPUBLIC
ECUADOR
EGYPT
EL SALVADOR
ERITREA
ESTONIA
ESWATINI
ETHIOPIA
FIJI
FINLAND
FRANCE
GABON

GEORGIA
GERMANY
GHANA
GREECE
GRENADA
GUATEMALA
GUYANA
HAITI
HOLY SEE
HONDURAS
HUNGARY
ICELAND
INDIA
INDONESIA
IRAN, ISLAMIC REPUBLIC OF
IRAQ
IRELAND
ISRAEL
ITALY
JAMAICA
JAPAN
JORDAN
KAZAKHSTAN
KENYA
KOREA, REPUBLIC OF
KUWAIT
KYRGYZSTAN
LAO PEOPLE'S DEMOCRATIC
   REPUBLIC
LATVIA
LEBANON
LESOTHO
LIBERIA
LIBYA
LIECHTENSTEIN
LITHUANIA
LUXEMBOURG
MADAGASCAR
MALAWI
MALAYSIA
MALI
MALTA
MARSHALL ISLANDS
MAURITANIA
MAURITIUS
MEXICO
MONACO
MONGOLIA
MONTENEGRO
MOROCCO
MOZAMBIQUE
MYANMAR
NAMIBIA
NEPAL
NETHERLANDS
NEW ZEALAND
NICARAGUA
NIGER
NIGERIA
NORTH MACEDONIA
NORWAY

OMAN
PAKISTAN
PALAU
PANAMA
PAPUA NEW GUINEA
PARAGUAY
PERU
PHILIPPINES
POLAND
PORTUGAL
QATAR
REPUBLIC OF MOLDOVA
ROMANIA
RUSSIAN FEDERATION
RWANDA
SAINT LUCIA
SAINT VINCENT AND
   THE GRENADINES
SAN MARINO
SAUDI ARABIA
SENEGAL
SERBIA
SEYCHELLES
SIERRA LEONE
SINGAPORE
SLOVAKIA
SLOVENIA
SOUTH AFRICA
SPAIN
SRI LANKA
SUDAN
SWEDEN
SWITZERLAND
SYRIAN ARAB REPUBLIC
TAJIKISTAN
THAILAND
TOGO
TRINIDAD AND TOBAGO
TUNISIA
TURKEY
TURKMENISTAN
UGANDA
UKRAINE
UNITED ARAB EMIRATES
UNITED KINGDOM OF
   GREAT BRITAIN AND
   NORTHERN IRELAND
UNITED REPUBLIC
   OF TANZANIA
UNITED STATES OF AMERICA
URUGUAY
UZBEKISTAN
VANUATU
VENEZUELA, BOLIVARIAN
   REPUBLIC OF
VIET NAM
YEMEN
ZAMBIA
ZIMBABWE

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

NUCLEAR MEDICINE RESOURCES MANUAL

2020 EDITION

COPYRIGHT NOTICE

FOREWORD

Nuclear medicine is an important component of medical imaging, and the IAEA continues to support its development throughout the developing world and will continue to play a leading role in setting and maintaining standards of practice. Since the preparation and publication of the first edition of the Nuclear Medicine Resources Manual in 2006, the practice of nuclear medicine has changed dramatically, mainly owing to the extraordinary increase in the use of positron emission tomography, which has demonstrated the importance of molecular imaging in clinical practice; the introduction of multimodality imaging and its wide acceptance; and the introduction of newer therapeutic radiopharmaceuticals.

Nuclear medicine requires not only specific medical competences but also support from radiopharmacists, radiochemists and medical physicists. This publication describes the requirements for the safe production, quality assurance and quality control of radiopharmaceuticals as well as protocols for general radiation safety and radiation protection in nuclear medicine facilities.

This edition addresses the most current needs in nuclear medicine and describes best practices in clinical procedures, radiation safety and patient protection, human resources development and training. The basic goal and framework envisaged in the earlier version are maintained, deleted, expanded or amended to better reflect new developments and best practice in the field. This edition also expands its scope to cover positron emission tomography–computed tomography, cyclotron and all related clinical applications. A review of the relevant equipment, fundamental for the acquisition of the diagnostic information, is also given, including the aspects of quality assurance aimed at the optimization and radiation protection of the patient.

The IAEA is grateful to all who contributed to the drafting and review of this publication. The IAEA officers responsible for this publication were D. Paez, F. Giammarile and E. Estrada of the Division of Human Health.

EDITORIAL NOTE

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

In the field of nuclear medicine, trace amounts of radiopharmaceuticals, which are pharmaceutical products containing radioactive atoms, are used for the diagnosis and treatment of many health conditions, such as certain types of cancer, neurological illnesses and cardiovascular diseases by performing: (i) molecular and functional diagnostic investigations, through the visualization, characterization and quantification of biological processes taking place at the cellular and subcellular levels in patients; and (ii) metabolic and immune targeted radiopharmaceutical treatments (see Refs [1–3]).

Establishing a nuclear medicine facility is a major undertaking that requires careful planning, contributions from multiple stakeholders, the support and approval of the relevant authorities, secure funding and a detailed implementation strategy. Detailed strategic planning is particularly important in developing countries, where nuclear medicine may currently be unavailable, and the benefits and complexities of nuclear medicine imaging and therapy may not be clearly appreciated. The accreditation of staff and their departments, with full documentation of procedures to international standards, will soon become a requirement, and this need is addressed in an IAEA publication on quality management [4].

It is essential that the project is consistent with government policies and strategies on health care. Potential stakeholders can include the ministries of health, education and science, agencies involved in the peaceful use of radiation and radioactive substances, universities, clinical specialists (e.g. oncologists, endocrinologists, cardiologists), and medical physicists and radiopharmacists.

1.2. OBJECTIVE

This publication takes a systematic approach to the needs for nuclear medicine practice with regard to assessment, premises, human resources, equipment and quality assurance and quality control, medical physics and radiopharmacy support, radiation protection and safety, and clinical applications. This publication explores the key elements and the information provided is intended to inform decision making and resource allocation.

1.3. SCOPE

This publication is intended as a general guide for health care administrators, project and site planners and all professionals involved in providing nuclear medicine services. This updated version covers all the most important, recent evolution of the specialty, including the development of positron emission tomography (PET) services, which was considered beyond the scope of the first version [5]. This 2020 update also includes content from the IAEA publications in Refs [6–15]. Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.4. STRUCTURE

Section 2 assesses the need for a nuclear medicine service in a hospital, and Section 3 describes the planning of a nuclear medicine facility. Section 4 outlines the equipment used, and Section 5 describes information technology, networking, archiving and general office equipment. Section 6 focuses on the human resources aspects, detailing roles and responsibilities and training needs. Sections 7–9 explore aspects of radiopharmacy, medical physics and general clinical applications of nuclear medicine, respectively. Section 10 concludes with radiation protection and safety, and presents the relevant paragraphs to IAEA Safety Standards Series Nos SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [6], and GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [9].

2. NEEDS ASSESSMENT

2.1. BACKGROUND

To successfully complete a nuclear medicine implementation project, an evaluation of expected health care activities, the resulting patient referral patterns and workload is critical. The design of the nuclear medicine facility in terms of buildings, hardware, personnel capabilities and inpatient facilities will depend on local health care requirements. The spectrum of services required may vary over time to complement developments in other medical specialties. Close liaison with the local medical community is essential to predict referral patterns. The

profile of existing health care provision will affect both referral streams and the capacity to make use of information provided by the nuclear medicine service. For example, it would be appropriate to develop a dedicated nuclear cardiology service together with a strong clinical and interventional cardiology presence in the local health care system, and to develop a PET–computed tomography (CT) and cyclotron centres within the scope of a comprehensive cancer programme in the country.

In nuclear medicine studies, radiopharmaceuticals can target specific organs or cellular receptors in a given patient to view physiological changes in internal structures for the early diagnosis of disease. This powerful and significant tool provides unique information on a variety of important diseases including cardiovascular disease, cancer, renal, infection and endocrine diseases. Advanced molecular images can be used for initial diagnosis, follow-up for therapy and restaging of most malignant diseases.

Since rapidly dividing cells are particularly sensitive to damage by radiation, radionuclide targeted therapy using short range radiations is highly efficient in treating benign and malignant disease with minimal side effects. The range of clinical indications for radionuclide therapy mainly includes cancer therapy, metastatic bone pain palliation and therapy for thyroid diseases. This is of particular relevance to low and middle income countries (LMICs) considering challenges from competing medical technologies in a scenario of ever shrinking health care budgets.

2.2. EPIDEMIOLOGY AND MAIN CLINICAL APPLICATIONS

In recent years, the main causes of mortality and morbidity across the world have changed. Heart disease, stroke, cancer, diabetes and other non-communicable diseases (NCDs) used to be considered public health issues only in high income countries. However, changes in lifestyle, increasing life expectancies and ageing populations are bringing the developing world closer to the developed world with regard to the nature of health problems [16]. Chronic diseases and NCDs, especially cardiovascular diseases and cancer, are now leading causes of mortality, followed by infectious diseases; and 70% of cancer deaths now occur in LMICs. Although the incidence of cardiovascular diseases has declined in developed countries following appropriate therapeutic approaches and prevention measures, it has become a major public health concern in LMICs. According to the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 [17] of the World Health Organization (WHO), NCDs are the world's biggest killers.

Individuals can reduce the chances of developing NCDs through preventive measures that address identified risk factors associated with chronic disease, such as an unhealthy diet, physical inactivity, tobacco use and harmful alcohol consumption. However, this does not prevent the development of NCDs, and it often takes time to have a clinical impact. Indeed, other factors, such as hereditary predisposition, may influence the development of disease. While prevention is important, key factors to enhance the survival rate of NCDs, especially cancer and cardiovascular diseases, are early detection, diagnosis and treatment.

Given these demographic changes and the rising impact of NCDs and infectious diseases, the role of nuclear medicine in both communicable and non-communicable disease management is becoming more salient, and its potential impact should no longer be limited to any particular region of the world [16]. Nuclear medicine can effectively monitor changes in tissue, diagnose and characterize disease, treat disease and evaluate the patient's response to treatment. Despite converging needs for nuclear medicine across the developed and developing worlds, there remain key differences between these areas because of socioeconomic disparities [16]. Making nuclear medicine centres more accessible and efficient in LMICs will lead to earlier diagnosis and better treatment.

2.2.1. Nuclear medicine resource distribution

The introduction of nuclear medicine into routine use in LMICs continues to encounter significant delays and impediments, where limited often infrastructure hampers the rising demand for nuclear medicine services — especially in the management of cancer, cardiovascular diseases and other NCDs. Although the average equipment age is over six years for all types of camera in all regions of the developing world, prolonged use of instrumentation often goes beyond the obsolescence period [16].

Medical imaging modalities have been adopted and developed under various scenarios in different countries and have also proliferated through different routes and in various settings. Moreover, both socioeconomic disparities and academic heterogeneity have resulted in unbalanced development in scientific trials. If nuclear medicine is to play a key role in the current imaging revolution in new diagnostics, it will remain a complex discipline.

2.2.2. Nuclear medicine needs

The differences in the practice of nuclear medicine across the world is because of heterogeneity in factors such as instrumentation, radiopharmaceuticals and educated human resources [16]. Nuclear medicine is a highly technical field and requires a particular infrastructure. It should be established in a hospital with

specialties such as radiology and clinical pathology, where at least some of the clinical specialties are flourishing. Not only is it advisable to have a centralized nuclear medicine facility in a hospital, it is equally desirable to have a consortium of interested clinicians associated with the unit because of the diverse range of medical disciplines that nuclear medicine serves.

The main interests and activities of the facility should first be assessed, in order to set up the needed facilities. Orders can then be placed for the instruments which would be most useful for the intended work. The total available space of the unit can be planned in an effective way. An integrated service is essential to the efficient conduct of nuclear medicine procedures. Nonetheless, the interrelations of radionuclide imaging and other imaging modalities, among them angiography, ultrasonography, CT and magnetic resonance imaging (MRI) should be appreciated, and the competing claims of the latter given due recognition. For these reasons, it may be convenient to locate radionuclide imaging facilities adjacent to other imaging facilities in the institution to share some of the necessary infrastructure, for example the patient reception area.

2.2.3. Clinical applications

In nuclear medicine imaging, gamma cameras and positron emission scanners detect and form images from the radiation emitted by the radiopharmaceuticals. There are several techniques of diagnostic nuclear medicine:

(a)   Gamma camera performs both scintigraphy, as a 2-D image.
(b)   Single photon emission computed tomography (SPECT) as a 3-D tomographic technique that uses data from many projections and can be reconstructed in different planes.
(c)   PET uses coincidence detectors to image annihilation photons derived by positron emitting radiopharmaceuticals.
(d)   Multimodality imaging exploit SPECT and PET images superimposed to CT or MRI for a detailed anatomical localization. This practice is often referred to as hybrid imaging.

In nuclear medicine therapy, radiopharmaceuticals with a very specific uptake in pathological tissue and emitting ionizing radiation with a high local energy deposition are used to maximize the damage to the disease area while minimizing side effects to healthy tissues or nearby structures.

2.2.3.1. Fields of application

The main fields of applications include the following (see Section 9 for more information):

— Neoplastic processes;
— Cardiovascular diseases;
— Central nervous disorders;
— Bone and joints diseases;
— Respiratory diseases;
— Gastrointestinal diseases;
— Urinary and genital diseases;
— Endocrine diseases;
— Haematopoetic and lymphatic diseases;
— Inflammatory and degenerative processes.

2.2.3.2. World distribution

With the aim of collecting information, the IAEA launched a nuclear medicine database (NumDAB).[1] Periodic assessments indicated that about two thirds of the practice was used to perform bone, thyroid and renal scans [16]. Bone scans accounted for 25–28% of all procedures performed over a three year period and remained the most widely used application of nuclear medicine. Thyroid scans ranked in second place. Remarkably, renal scans ranked in third place, and they remain widely applied in the developing world. Cardiovascular applications, widely applied in developed countries, ranked in fourth place. In general, data collected from voluntary contributors show a positive trend on nuclear medicine practice worldwide (see Fig. 1).

2.3. DETERMINANT OF LEVEL OF SERVICE

The profile of an individual facility will be determined by local circumstances. The following models of nuclear medicine have been proposed and provide the basis for detailed processes described later in this publication. The term 'level' refers to the complexity of procedures that a facility performs. For maximum flexibility, diagnostic and therapeutic levels have been addressed separately, so that any combination of these services can be chosen as considered appropriate.

---

[1]   See http://nucmedicine.iaea.org
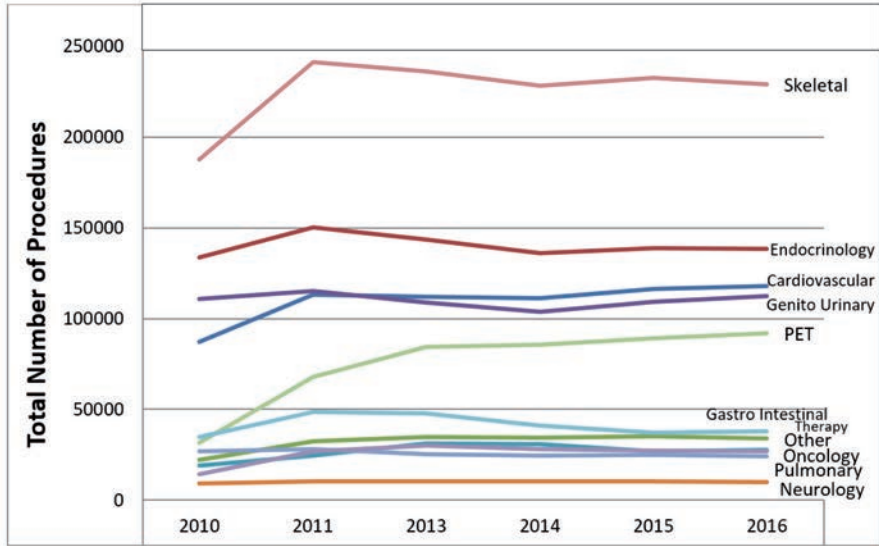
FIG. 1. Procedures by type and year (2010–2016).

2.3.1. Diagnostic nuclear medicine level l

This facility would provide a basic and general nuclear medicine service. It would be appropriate to site this level of facility as the first department in an area that has a basic primary and secondary health care infrastructure but perhaps not tertiary medical services. This level comprises relatively simple instrumentation, a modest infrastructure and the lowest staffing levels.

2.3.2. Diagnostic nuclear medicine level 2

This facility would be able to offer specialized diagnostic nuclear medicine imaging including cardiac and oncological investigations in addition to the level 1 service. At this level, more complex equipment (e.g. tomographic capability and quantification), infrastructure and human resources will be required.

2.3.3. Diagnostic nuclear medicine level 3

This facility would operate at the highest level, using complex equipment such as hybrid single photon tomographic and computed tomographic (SPECT–CT) cameras to perform specialized investigations. This is the most resource intensive level.

2.3.4. Therapeutic nuclear medicine level 1

This level provides outpatient services to administer a limited amount of radioactivity to patients. Relatively modest support with regard to patient isolation and waste management is required.

2.3.5. Therapeutic nuclear medicine level 2

This level provides for inpatient treatment. The infrastructure will include a designated isolation facility, where patients can remain for the necessary period following administration of high activity radionuclide treatment. Appropriate radiation monitoring equipment and protected waste storage areas are essential. Staff must be trained to administer high radionuclide activities safely.

2.4. MODELS OF POSITRON EMISSION TOMOGRAPHY–COMPUTED TOMOGRAPHY AND CYCLOTRON CENTRES

The different models of PET facilities reflect the distinct historical development and organizational structures of health care in different regions of the world (see Refs [14, 18] for an extensive review).

2.4.1. Inside a hospital

A PET facility located in a large hospital has the advantage of the hospital providing services locally, which is convenient for patients. PET–CT scans can be introduced into a standardized institutional diagnostic as well as treatment paradigms. All patients that meet prescribed criteria can thereby rapidly access PET–CT. Informing the referring physicians is easier, as is the communication of results. The logistic services of the hospital can act to support the operation of the PET facility, which is usually organized as a separate clinic of the hospital that is licensed to handle unsealed radioactive sources. A clear advantage is the availability of advanced life support teams capable of resuscitation in the rare event of life threatening allergic reactions to intravenously administered contrast media.

2.4.1.1. Oncology oriented hospital

A PET facility located within a hospital with a large oncologic case load can operate very efficiently owing to the ease of patient scheduling. When a late cancellation of PET–CT investigation occurs, another patient can easily replace the cancelled one without loss of scanner time or waste of short lived

radiopharmaceuticals. In an oncological hospital, the need for PET–CT investigation can easily exceed the capacity of a single PET–CT scanner, limiting access for patients from nearby health care facilities. If equity of access is to be achieved, this should be considered at the national or regional level when introducing the first PET facility.

2.4.1.2. General hospital

A hospital may not be able to fully utilize a PET–CT scanner with its own patients, but this is usually offset by greater potential equity of access to the PET–CT scanner by patients from other health care facilities.

2.4.1.3. Stand alone facility

PET facilities have also been established outside of a hospital as a stand alone centre. These PET facilities have to overcome the disadvantages of not having an intrinsic patient population. This does not, however, present an insurmountable problem, since the vast majority of patients can undergo PET–CT on an outpatient basis. The communication of such a PET centre with collaborating health care facilities needs to be facilitated as much as possible. Connection of patients and the picture archiving and communication system (PACS) for rapid access to reports and images and the possibility of teleconferencing are desirable. Access to medical emergency facilities is also important.

2.4.1.4. Mobile facility

Some PET–CT scanners can be mounted on trucks. This mobile unit can operate on a regular or irregular basis in one region to enable even small health care facilities gain access to PET–CT technology tailored to their demands (e.g. two days a week or once per three weeks). This has the advantage that patients do not have to travel to a distant PET centre. The major disadvantage is the additional cost of a mobile unit. When local personnel are employed to report the PET–CT scans, there is the disadvantage of generally lower experience compared with high throughput facilities and therefore a risk of lower accuracy of some reports. However, communication with the local referring physician is more likely to be better than when reports are generated remotely by specialists using teleradiology.

2.4.1.5. Research institution (non-clinical)

In the past, PET scanners were also installed in some non-clinical facilities where they primarily served a research role. When not being occupied by research studies, these scanners could also be utilized for clinical investigations.

2.4.1.6. Tertiary care hospital

Of all the current models of PET–CT facilities, optimal clinical utilization of PET–CT is generally best achieved in a tertiary care hospital, since an efficient use of scanner, staff, isotope and infrastructure requires a high throughput of patients.

3. PLANNING A NUCLEAR MEDICINE FACILITY

3.1. INFRASTRUCTURE

Particularly for emerging economies, a very important consideration when planning a new nuclear medicine site is the location. There are particular infrastructure needs for nuclear medicine: a regular supply of (relatively) long lived radioactive material as well as precursor materials, equipment and spare parts essential for the facility to function. In the case of local production of short lived radiopharmaceuticals, also the possibility of reliable delivery to other institutions also becomes fundamental. A reliable method of transport is necessary to ensure consistent supply and delivery capacity. Several transport companies and airlines are wary of transporting radioactive material, and it is prudent to discuss the stability and reliability of the supply line at the initial planning stage.

Another infrastructure requirement is a stable electricity supply. In this, a nuclear medicine facility is no different to any other sophisticated medical department. However, the cost of alternate means of electricity provision (i.e. generators, battery backups) can be substantial, both at the time of installation as well as during operation. When the electricity supply is unreliable, a strategy needs to be in place to ensure reliable backup supply, such as an uninterruptible power supply (UPS) or a relay of options (UPS, followed by a generator).

The power requirements for a nuclear medicine facility can be significant. While a SPECT gamma camera has power absorption of 3–4 kW·h, a SPECT–CT system can require a peak demand of 90 kW·h and a continuous level of power of about 20 kW·h. Similar figures are required for a PET–CT scanner. Information on the specific requirements for radiopharmacy laboratories and related equipment

can be found in Refs [8, 18]. Apart the equipment itself, power requirements for the infrastructure, mainly the heating, ventilation and air conditioning (HVAC) system, may be very demanding.

Once the city has been selected, the location of a nuclear medicine facility should be made taking first into account the existence and active role of the main medical specialties for which nuclear medicine support is relevant. Moreover, it may be preferable to locate the nuclear medicine facility within a hospital where resources can be shared. Given the sophistication of nuclear medicine imaging information, location within a secondary or tertiary hospital might make for a more efficient utilization of nuclear medicine information than a primary care hospital. If the facility is to be located within an existing building, the floors will need to be strong enough to bear the weight of any heavy equipment necessary. Additional structural strengthening might be needed in some places, as a modern multimodality scanner weighs 2500–3000 kg, which is mostly concentrated in the gantry, with an area of 1–1.5 m^2. If a new facility is being created, it is easier to locate the equipment appropriately.

The layout of a facility needs careful planning (see Fig. 2), taking into account the flows of patients and staff, as well as of incoming materials (e.g. radiopharmaceuticals, other supplies) and outgoing materials (e.g. radioactive waste). Local regulations on radiation safety and on compounding of radioactive drugs will have a fundamental role, not only on safety but also on the quality and effectiveness (functionality) of the design. If local regulatory authorities have not yet developed a specific approach and technical rules, one of the existing protocols can be adapted, according to a principle of similarity, as it is easier to build according to safety requirements rather than having to comply with these later.

The nature of the existing medical resources will have an impact on the type of nuclear medicine equipment and human resources. If a cardiac centre is nearby, investment will need to be made in cardiac nuclear medicine equipment and nuclear cardiology training. If there is an oncology unit nearby, PET facilities might need to be included in future plans. It is imperative that the facility does not run out of space as the services grow; it may also be difficult to predict future demand, and new techniques or facilities might emerge with their own unanticipated infrastructure and resource needs.

Nuclear medicine is unique in that it has both diagnostic and well as therapeutic dimensions. A diagnostic only facility is simpler to set up and run, and in many places a diagnostic only facility is established first. Rapid advances are being made in nuclear medicine therapy that promise to improve the therapy profile of this specialty, and most future nuclear medicine facility may have to allocate space for therapy, including inpatient facilities and probably support of vascular radiology and specialized haematology laboratories. Although each

Outpatient waiting area Entrance Inpatient waiting area

Offices for administrative staff

Reception

Filing

Administrative staff

Offices for trainers

Patient toilets

Examining rooms

Imaging rooms

Offices for administrative staff

Interpretation room

Imaging rooms

Staff toilets

Conference room

Teaching aids

Exit Exit

Radioimmuno-assay Physics lab. Storage Storage Hot lab.

In vitro studies Radiopharmacy

FIG. 2. *Floor plan of a typical nuclear medicine facility.*

nuclear medicine facility will have a unique layout, there are some general rules to follow.

3.1.1. General concept

A nuclear medicine facility is a service that operates upon referral from external physicians or other hospital departments, providing diagnostic examination or therapy procedures based on the administration of radiopharmaceuticals to patients. In order to perform the main tasks of the nuclear medicine facility, additional procedures may be provided, such as patient visits, cardiac stress testing (functional to myocardial SPECT), ancillary imaging procedures (e.g. thyroid ultrasonography) and other radiological non-imaging

tests. Ancillary functions supporting the overall operation may include radiopharmaceuticals preparation and dispensing and medical physics support activities (e.g. data analysis, dosimetry, dose optimization, quality assurance and quality control, radiation protection).

3.1.2. Patient flow in imaging procedures

Imaging procedures are typically the core activity of a nuclear medicine facility and they have a major impact on the layout and structure. When a patient is referred to nuclear medicine, the following steps occur [19]:

(a)   Upon arrival, the patient is received, his or her request/files are verified and some administrative function may be requested. The patient is then directed to an appropriate waiting area.
(b)   Depending upon the type of procedure, the patient may proceed directly to the diagnostic room, where he or she receives the radiopharmaceutical (e.g. for a dynamic renal scan).
(c)   Otherwise, prior to imaging, the patient goes to the injection area, where dose administration is performed. The administration area is generally located in strict relation with the radiopharmacy.
(d)   Depending on the examination prescribed, the patient may access a separate waiting area, designed to accommodate injected patients. This 'hot' waiting area should be different and physically separated from the 'cold' waiting area.
(e)   The patient then proceeds to the procedure area, where the examination is made.
(f)   Within the control room, studies are processed and checked for possible artefacts, to ensure the quality of images.
(g)   The attending nuclear medicine physician receives the images for any need for postprocessing and interpretation.
(h)   After completion of the scan, the patient can be dismissed.
(i)   Image records are stored electronically and retrievable for consultation, follow-up and exam comparisons. This may be accomplished either in central viewing areas or remotely.

3.1.3. Organizational concepts

The design of nuclear medicine facilities should consider the separation of non-radioactive areas from radioactive sensitive areas [19]. In particular, the circulation of patients and of staff should be separated as much as possible. Some staff functions, such as patient reception and filing, could be located both

within the service and in another appropriate location, even shared with different services, typically radiology [19]. Offices and all functions that are not directly involved with the process should be located outside of the radiation area.

The nuclear medicine facility is interested by several fluxes of incoming and outgoing materials: (i) radiopharmaceuticals and other products received from outside the facility require access to specific areas or laboratories, by cart or hand delivery; and (ii) some radiopharmaceuticals or other products (i.e. blood samples) can be shipped outside for use in other departments, as well as radioactive wastes are delivered outside for disposal. None of these fluxes should mix with patient traffic. In order to plan the distribution of space properly, it is good practice to prepare maps and drawings reporting the different fluxes (e.g. with different colours) to check adequacy and to avoid non-appropriate superimposition.

Depending on the size on the nuclear medicine facility and the complexity of machinery and activity, additional activities may require dedicated spaces. For instance, the medical physics aspects of nuclear medicine and radiopharmacy require specialized staffing to be on-site. Departments such as endocrinology and cardiology utilize nuclear techniques and may benefit from joint activities with nuclear medicine. Departments such as the radiology service may be involved in common use of image technologies.

In the design of a nuclear medicine facility, many efforts are dedicated in realizing a high technology health care environment, taking into account safety, ease of maintenance, durability and sanitation. Designers frequently consider these aspects first. However, human related factors that should be considered include the following:

(a) Stress determined from an unknown technological ambient, noise, lack of privacy and poor lighting, among other things.
(b) High tech, unfamiliar equipment and negative public perception of radiation issues can be additional causes of patient stress.
(c) Patient dignity and self-determination should be taken into account, while considering operational efficiency.
(d) An attempt to de-emphasizing the institutional image of traditional health care facilities and to surround the patient (and family members, when appropriate) with architectural finishes and furnishings that are familiar.

A proper balance between technological and human factors is necessary when approaching the design of a nuclear medicine facility.

3.1.4. Specific requirements

3.1.4.1. Reception area

With regard to the reception area:

(a) This area controls the access to the patient areas and to operational areas where radionuclides are stored or used.
(b) GSR Part 3 [9] requires that an appropriate, standardized signage be displayed prominently to identify areas where radioactive products are used.
(c) Signage and information boards for possibly pregnant or breast-feeding patients are also required.
(d) The access to the working area of the facility should be restricted.
(e) Only authorized staff and patients should be admitted.
(f) The entrance doors should be normally kept closed and opened as necessary by staff.
(g) An intercom or a video system may be adopted.

3.1.4.2. Radiopharmaceuticals administration rooms

With regard to the administration of radiopharmaceuticals:

(a) The rooms in which radiopharmaceuticals are administered to patients should be located, as much as possible, in close connection with the radiopharmacy laboratory.
(b) To minimize distances and to reduce the risk of contamination, a 'pass through' box (or hatch box) is the optimal solution.
(c) Depending on the pharmaceutical classification of the laboratory, it may be necessary that the pass through box is interlocked and ventilated.
(d) A sink should be available in the administration room for frequent hand washing as well as for rapid decontamination of the hands in case of contact with radioactive material.
(e) Emergency medical gases (oxygen, nitrous oxide, vacuum) can be requested, according to national regulations.
(f) In the administration of radioaerosols, a special ventilation system may be necessary.

3.1.4.3. Hot waiting areas

In some nuclear medicine examinations, the patient is requesting to wait for a relatively long time between the injection and imaging (e.g. bone scintigraphy, myocardial SPECT):

(a) It is helpful to provide to patients means of distraction to minimize the perceived length of waiting time.
(b) A system of remote patient control (webcam, TV chambers) may be requested to ensure proper patient's surveillance.
(c) Patient dedicated toilet facilities need to be available.
(d) There should be signage and information boards for patients who are or may be pregnant or are breast-feeding.

3.1.4.4. Diagnostic rooms

Rooms for the installation of gamma cameras and PET–CT scanners require some specific construction requisites:

(a) The floor load should be carefully considered. The weight of a modern scanner is typically more than 2500 kg, mostly concentrated in the gantry, over a surface of about 1 m^2. Floors should be accurately levelled in order to avoid problems of misalignment.
(b) It has to be noted that some equipment may require floor trenches for electrical and signal cables.
(c) Some SPECT–CT and PET–CT may require extra technical space for external components (i.e. special ventilation, chiller, reconstruction computers) and a video system for the patient's surveillance.
(d) Positioning of the scanners should take into account extra space for bed movements, collimator's carts and maintenance.
(e) Structural shielding should be planned and approved by a radiation protection officer (RPO).

Manufacturers of equipment provide preinstallation and site planning guides that provide detailed information on the requisites for each model. These guides should be taken into account when preparing for installation and to avoid any incompatibility.

3.1.4.5. Toilets and services

With regard to washroom facilities:

(a) Patients and staff must use separate services.
(b) Dedicated toilet facilities must be available for patients following an injection.
(c) In addition to normal toilets for staff, at least one decontamination area should be available, including a sink, eye washing facilities and a shower.

3.1.4.6. Radioactive waste collection room

At least a limited, but dedicated, space is necessary within the nuclear medicine facility for the collection and short term storage of radioactive waste before it is sent to depot or disposal. The storage room should have the following:

(a) A secure door;
(b) Adequate lighting;
(c) An electrical system with a high degree of protection;
(d) Containment against flooding;
(e) A fire extinguishing system.

3.1.4.7. Therapy rooms

Rooms for inpatient treatment can be contiguous to the diagnostic services, but they are most frequently located in connection to, or even within, other wards (e.g. of an oncology department) in order to share the nursing staff dedicated to patient assistance. In addition to what is requested for a 'conventional' ward, specific requirements include the following:

(a) Access to patient rooms should be controlled. A system of remote patient control can help to ensure proper patient surveillance, avoiding frequent access.
(b) According to local regulations, discharges from the toilets of these rooms might need to be collected and their emission to the sewage system delayed for a time sufficient to grant some decay of the radionuclides.
(c) In the case of volatile radionuclides (e.g. ^{131}I), a specific ventilation system may be necessary, depending on national regulations as well as the patient's workload.
(d) Structural shielding may be needed and should be planned and approved by an RPO.

(e) A room for the temporary collection of radioactive waste is necessary (see Section 3.1.4.6. for specifications).

3.1.5. Specific recommendation on finishes and systems

3.1.5.1. Floors

Floors should have welded seam sheet flooring with an integral base in all radiation areas, including:

(a) Radiopharmacy;
(b) Other laboratories;
(c) Administration rooms;
(d) Exercise and stress testing rooms (where tracer administration is performed);
(e) Hot waiting rooms;
(f) Diagnostic rooms;
(g) Radioactive waste storage.

3.1.5.2. Ceilings

With regard to ceilings:

(a) They are frequently and conveniently made by lay-in acoustic ceiling tiles.
(b) Certain areas, such as procedure rooms and treatment rooms, should have lay-in acoustic ceiling tile with a washable sprayed plastic finish.
(c) Radiopharmacy laboratories should have a pharmaceutical grade ceiling, in plastic laminate or aluminium, welded and sanitizable.

3.1.5.3. Walls and wall protection

With regard to walls:

(a) In corridors and all other non-specific areas, wall and corner guards should be used where damage from cart and stretcher traffic is possible.
(b) In areas with specific risk of contamination, like imaging and administration rooms, walls should be easily cleanable and de-contaminable. This may be obtained by painting with de-contaminable epoxy paintings.
(c) Floor tiles may be used to cover corners.
(d) In radiopharmacy laboratories, according to the classification, walls maybe covered with pharma grade walls or at least painted with de-contaminable epoxy paintings.

(e)   Corners should be rounded.

(f)   Specific materials for the pharmaceutical industry are available.

3.1.5.4. Doors

With regard to doors:

(a)   Doors leading to radiopharmacy are required to be secure.

(b)   Depending on the classification of the laboratory, the access can be through two doors interlocked or between a filter/changing room.

(c)   Other rooms, such as radioactive waste storage, may require secure doors.

(d)   Other rooms do not require special arrangements, apart from ease of cleaning and decontamination.

(e)   With scanner rooms, systems to control access interlocked to the status of the equipment (e.g. micro switches aimed to interlock access during radiation emission) are not required.

3.1.5.5. Security and access control

As previously noted, security and access control requirements apply to the nuclear medicine facility radiation area. Some specific, selected areas may require specific arrangements. In particular, access to the radiopharmacy laboratory and all other rooms in which radioactive sources are stored, and all the areas where sensitive data are stored, should be further restricted. In most cases, access will be granted only to authorize staff.

3.1.5.6. Heating, ventilation and air conditioning system

The HVAC system has a central role in the planning of a nuclear medicine facility, given the need of controlling the possibility of radioactive contamination of the staff and the environment from unsealed radioactive sources. At the same time, the latter might be pharmaceuticals, and therefore the possibility of their microbiological contamination should be prevented. For these reasons, the design of the HVAC system is even more demanding than those of shielding and should be addressed at the very initial stage of the design of the facility. In general, the flow of air should be directed from the areas with less risk of contamination towards those at higher risk. This is usually achieved by keeping the latter at a pressure lower than the first. Radiopharmacy laboratories are an exception to this principle and should be managed with special arrangements.

The air coming from the outside must be filtered to reduce the input of dust and particulates. The position of the outside air intakes needs to prevent any

possibility of recirculation of exhaust air. The exhaust air must be expelled to the outside through appropriate filters, according to the area of origin. In the rooms in which hot cells or fume hoods are installed, a dedicated exhaust system should be provided for each device. The supply air diffusers should be positioned as far away as possible from air inlets and cell doors.

When HVAC services must penetrate a shielding, coordination is required between HVAC design and the medical physicist or RPO, to check feasibility and conditions. Table 1 presents some very general indications on the main characteristics of a properly designed HVAC system. It has to be noted that these general indications should be carefully checked for conformance with existing national regulations.

3.1.5.7. Power supply and IT network requirements

Modern multimodality scanners require dedicated feed lines, with adequate power, for example a modern SPECT–CT or PET–CT scanner may require up to 95 kVA of peak power and about 20–30 kW·h of average power demand. A UPS is highly recommended, for patient safety as well as for equipment protection.

Each major imaging equipment will require several network plugs, to connect a variety of subsystems. Not only connectivity of the imaging workstations, reconstruction servers, PACS and radiology information system (RIS) systems is necessary, as well as other ancillary equipment, which is computer controlled (e.g. radionuclide activity meters, radiopharmaceuticals dispensing systems).

3.1.6. Licensing and regulatory aspects

Most States have a nuclear regulatory authority or are in the process of establishing one. To ensure safety and compliance with regulations, licences have to be obtained to establish and run a nuclear medicine service in a manner that minimizes radiation hazard to the general public, radiation workers and patients. In practice, information needed to register a nuclear medicine establishment should be carefully checked with local regulations and includes the following:

(a) Owner/director of the establishment with proof of identity, address and contact information.
(b) Purpose for which the licence is required (e.g. diagnostic and therapeutic nuclear medicine).
(c) Location of facility and address.
(d) Details of premises (e.g. owned or leased).

TABLE 1. GENERAL INDICATIONS ON MAIN CHARACTERISTICS OF A PROPERLY DESIGNED HVAC SYSTEM

	Pressure relationship to adjacent areas	Differential Pressure (Pa)	Min. air changes (vol/h)	Max. air changes (vol/h)	All air exhausted directly to outside	Air recirculated within room units	Filters (typical)*
'Hot' waiting room	Negative	15	2	10	Yes	No	EU9
Administration room	Negative	15	5	10	Yes	No	EU9
Diagnostic imaging room	Negative	15	5	10	Yes	No	EU9
Control room	Neutral or negative	0–15	5	10	Yes	No	EU9
Corridors	Neutral or negative	0–15	2	5	Yes	No	EU9
Radiopharmacy laboratory	Neutral or positive	0–15	10	>10	Yes	No	EU14 + charcoal
Radiopharmacy changing room	Negative	>30	10	>10	Yes	No	EU14 + charcoal
Radiation therapy ward	Negative	15	5	10	Yes	No	EU9 + charcoal

* Classification according to Eurovent CEN EN-779–2002 standard.

21

(e)   Drawings of the establishment:
— Patient waiting area;
— Patient injection room;
— Scanner rooms;
— Radiopharmacy laboratory;
— Wall thickness, any shielding, material used for construction;
— Ventilation system and other means to prevent contamination of the workplace and the environment;
— Rooms/area adjacent to the nuclear medicine facility and their use/occupancy.

(f)   Particulars of radioactive material:
— Name;
— Activity;
— Physical form;
— Application (diagnostic or therapeutic);
— Maximum amount of radioactive material that will be possessed at any one time.

(g)   Radiation working staff with their qualification, training and experience (authorized users):
— Nuclear medicine physician;
— Medical physicist;
— Radiopharmacist;
— Technologist;
— Nurses;
— Other.

(h)   Frequency of delivery of radiopharmaceuticals.

(i)   Equipment detail.

(j)   Radiation protection programme (procedures should be available in writing) should include:
— Occupational dose limits;
— Dose limits for members of the public;
— Limitation of access;
— Sources security;
— Minimization of contamination and spill procedures;
— Material receipt and accountability, ordering, receiving and opening packages;
— Radiation surveys and calibration of survey;
— Instruments;
— Caution signs and posting requirements;
— Labelling containers, vials and syringes;
— Determining and optimizing patient doses;

— Sealed source inventory and leak testing;
— Waste disposal and decay in storage;
— Records and reports;
— Safety instruction for workers;
— Medical surveillance of staff.

(k) Radiation monitoring equipment (e.g. survey meters), number, calibration and well counters.

(l) Personal dose monitoring instruments.

(m) Arrangements for the handling of radioactive sources.

(n) Arrangement for the transport of radioactive sources.

(o) Arrangement for the security of radioactive sources (e.g. secured store).

(p) Arrangement of receiving radioactive material (e.g. secured parking area).

(q) Waste management.

(r) Other concurrent risks (e.g. microbiological, chemical, heavy loads).

Licensing implies permission to operate and the licence is issued to a specific facility for a given period of time, starting from receipt of the first acquisition of radioactive material or radionuclide generator. Licences need to be timely renewed to ensure the continuity of service.

3.1.7. Financial resourcing and business plan

A nuclear medicine service can exist only within an overall health system, funding for a new facility would be similar to funding sources for other health facilities. A financial plan that emphasizes the high costs of running a nuclear medicine facility is necessary so that an adequate budget can be allocated for recurring expenses. A business plan organizes the various planning elements and arguments in a readily accessible manner and gives an overview of the objectives of the project as well as the steps needed to establish, sustain and continually improve services. Although unique for each project, there are some common headings under which a business plan is created (see Box 1).

When making a case for funding to the government, hospital or a financial institution the following need to be commented upon, emphasizing the unique strengths of the project:

(a) Exclusive service, how it integrates with existing medical facilities and advantages of nuclear medicine in certain situations;

(b) Define the need that the facility meets;

(c) If this is not the first facility of its kind in the area, why an additional facility is needed (need still exists despite full capacity utilization of other facilities, better quality of material and human resources);

BOX 1. BUSINESS PLAN HEADINGS

Executive Summary
Purpose
Mission [of the facility or hospital]
Vision [of the facility or hospital]
- Client Service
- Quality
- Safety

Competence
Business Plan
Strategic Plan
Operational Plan [services, charges, admission strategy,
strategic policy, employee management]
Salient Features [equipment to start with, number of
major equipment, wards, other imaging facilities]
Recruitment
Projected Expansion [provision of additional space]
Expenses [of various medical equipment and treatment]
Operating Expenditure
Revenue
Strengths, Weaknesses, Opportunities and Threats Analysis
Prospects
Market Competitors
Role and Responsibilities of Executive Director, Operations and Staff
Managerial Format
Remuneration
Plan for Staff Improvement/Training
Fiscal Model Analysis [recurring prices, initial expenses]
Fiscal Estimates
Advertising Plan
Timeline
Contingency and Support Plan
Exit Strategy [and scenarios where this might be needed]
Conclusion

(d) Advantages of the facility equipment, services and staff;

(e) If similar facilities exist, it will help in determining the costs, size and sophistication of your services;

(f) Available space, ease of transport to this place, available infrastructure, size of construction and space available for future expansion;

(g) Marketing plan, target patients and referral base, patient and physician education and sensitization to the services;

(h) Sustainability needs to be built into the project;

(i) Potential for growth and profit if this is being on commercial lines, and impact on health of the population in all cases.

3.2. CONCEPT OF OPERATION

3.2.1. General aspects

In a nuclear medicine facility, following operational flow should be planned in accordance with IAEA quality assurance in nuclear medicine (QUANUM) methodology [4]. In deciding upon the performance of a particular test, one should be aware of the contribution of the test result to patient management and be cognizant of appropriate use criteria and of possible alternatives where no radiation is involved. Relevant details include clinical history, pregnancy, breast-feeding allergies, medication and urinary continence as specified in facility protocols. Proper communication, at an early stage, concerning specific preparations for certain procedures is essential. Local guidelines about informed consent must be followed.

The radiopharmaceutical is administered (oral, inhalation, intravenous or intracavity) to the patient in a designated room. Some procedures require immediate imaging, while in other cases a distribution or incorporation phase is required prior to data acquisition. In the latter case, the patient needs to wait in a controlled area or may be sent home for later attendance.

Data acquisition may involve imaging, counting with a probe, or collection of biological samples for later analysis. Due to the nature of nuclear medicine procedures, some may be completed within minutes; others may require repeated acquisitions over several days.

Before discharging the patient, quality analysis of the study should be performed by the technologist and nuclear medicine specialist to ensure proper completion. All exams must be reported by trained specialists in a timely manner. Critical findings demanding urgent medical attention should be communicated immediately to the referring physician. The report should record the clinical indication for the procedure, the description of methodology (ideally in a template

format), a description of results with a highlighting of important positive and negative findings and then a concise conclusion that addresses the key clinical questions. The report should be signed (electronically or with a formal signature) and delivered to the referring clinician in a timely manner.

The end result of establishing a nuclear medicine service is to ultimately provide a clinical application that will benefit and impact on patient management. Specific arrangements are necessary for particular categories of patients (elder or bed ridden, paediatric). Paediatric patients are particularly relevant given the role of nuclear medicine studies in this field. Purpose built areas of the facility, including waiting areas, toilets and diagnostic rooms, specifically adapted to children needs should be considered. Specific training should be given to staff.

3.2.2. Patient scheduling

The daily work schedule should match the facility throughput capacity and consider available resources including personnel, equipment and radiopharmaceuticals. The number and type of procedures performed each day can be adapted to suit local demand. An administrative system that allows patients and referring clinicians ready access to clerical staff to ensure optimal appointment scheduling is strongly encouraged:

(a) Referring physician fills a request form for a nuclear medicine test including short clinical information (history, medical records, medication, results of relevant diagnostic investigation).
(b) Request form is received in nuclear medicine reception and assessed for completeness and any possible additional information.
(c) Nuclear medicine specialist, as per requirements in GSR Part 3 [9] and regulations (e.g. EU directives) is consulted about the justification for the procedure.
(d) If request is approved, the appointment is scheduled and instructions for patient preparation are provided.
(e) Information on the study procedure and relevant illustrated material is made available to the patient.
(f) If applicable by local regulation, the patient is asked to sign an inform consent.

3.2.3. Registration

Patient registration is essential for correct patient identification, efficient storage and retrieval of information, reporting and billing. Most countries have

statutory requirement for reports and images to be retained for determined periods of time:

(a)   The patient's entry is activated on the day of the appointment.
(b)   Any available previous patient's study is retrieved.
(c)   The patient's data are entered in the workflow for the nuclear medicine procedure (nuclear medicine information system).

3.2.4. Procedure

With regard to the procedure:

(a)   Before radiopharmaceutical administration, patients wait in general waiting areas or a quiet area for PET-fluorodeoxyglucose (FDG) studies.
(b)   Radiopharmacy receives the related patient information (body weight, age, height, procedure) and prepares the requested radiopharmaceutical in the desired activity.
(c)   Radiopharmacy transfers the patient information to the technologist (or nurse) when the product is ready.
(d)   The technologist (or nurse), under the supervision of attending physicians, deals with patient preparation (hydration, appropriate medication, intravenous line, proper patient position) in line with standard operating procedures (SOP).
(e)   Qualified staff administer the radiopharmaceutical and start procedure as for the appropriate SOP. Note that in some PET studies, an automatic injector could be used.
(f)   The technologist consults the acquisition protocol with the nuclear medicine resident or specialist, sets the imaging equipment for that specific procedure.
(g)   The technologist places the patient according to the relevant SOP.
(h)   Upon completion of the acquisition, the technologist consults with the nuclear medicine qualified physician to decide on further actions.
(i)   Before discharging the patient, the attending physician should carefully assess the quality of the images in relation to the clinical questions and the SOP.

3.2.5. Data processing and management

Data processing is a necessary part of many procedures. This is usually accomplished by a trained technologist using a standard workstation. Data archiving and storage is a legal requirement and essential for clinical follow-up,

education and research. Archiving can take the form of print or digital media (PACS if available).

3.2.6. Reporting and approval of reports

With regard to reporting:

(a) A nuclear medicine qualified physician reviews the patient information and images.
(b) Studies should be reported according to the relevant SOP.
(c) Before signing the report, the nuclear medicine specialist reviews images and findings.
(d) A final diagnosis is set for the patient and the final report is signed off to appear in hospital's intranet (if available) and to be retrieved by the patient or sent to the referring physician.

3.2.7. Additional requirements for radionuclide therapy

Therapy can be administered on an outpatient or inpatient basis depending upon procedure complexity, administered activity and statutory requirements for radiation protection, in addition to patient specific clinical considerations. Radionuclide therapy places additional, specific demands, which should be reflected in the SOP:

(a) The indication of radionuclide therapy should be the result of a multidisciplinary decision.
(b) Clinical history, histological reports, concomitant treatments, hormonal status and possible medical interactions relating directly to therapy should be available to confirm appropriate indication.
(c) Pregnancy tests are of particular importance before the radionuclide therapy.
(d) Information should be given in case of breast-feeding patients.
(e) The administered activity should be prescribed taking into account targets and critical organs' absorbed dose by the nuclear medicine physician and medical physicist.
(f) A summary of radiation protection advice provided, a record of activity administered and arrangements for medical follow-up after treatment.
(g) Documentation needs to include confirmation of patient identity, written information about the treatment provided and, in accordance with local regulation, a record of signed informed consent to the particular treatment.
(h) Arrangement for admission, staying and discharge from therapy ward should be taken.

4. EQUIPMENT

Much of the content of this section is based on Ref. [10], which should be referred to for additional information.

4.1. GAMMA CAMERA

The gamma camera, invented by H. Anger at the end of the 1950s, is a biomedical imaging device aimed at acquiring 2-D planar images of the gamma radiation emitted by a radiopharmaceutical administered to patients in order to trace in vivo a specific functional, biochemical or molecular process (see Fig. 3):

(a) One or more detection heads, each containing:
  (i) A radiation sensitive element; in most cases, a relatively wide scintillation crystal of NaI(Tl) (sodium iodide doped with thallium), typically about 40 cm × 50 cm, with a thickness of 9.5 mm.
  (ii) A matrix of photomultiplier tubes (PMTs) coupled to the crystal. PMTs convert the scintillation light into an electric signal.
  (iii) A sophisticated nuclear electronic system that manages the incoming pulses, performing a series of operations, including giving the pulses a standardized shape, amplifying them and converting to digital signals.
  (iv) A digital signal processor that organizes the signal information in spatial coordinates X, Y and energy (Z signal), applies to the pulses specific corrections and analyses their height, selecting them according to criteria defined by the user in the acquisition protocol.
(b) An imaging workstation, which allows the user to select the acquisition protocol and control the camera, and in which the digital information is stored as one or a series of digital images that can be recorded in a standardized format, displayed and processed.
(c) A gantry, supporting the heads and allowing an accurately controlled motion according to a variety of degrees of freedom (radial, tilt, rotation, translation).
(d) A patient handling system, the main component of which is the patient bed, which safely hosts the patient and whose controlled motion complements that of the gantry and heads (vertical, longitudinal and lateral translation).

The gamma camera requires several sets of collimators, aimed at selecting only the desired lines of response (LORs), defining the geometrical relationship between the emission of the photons and their detection point. A physiological
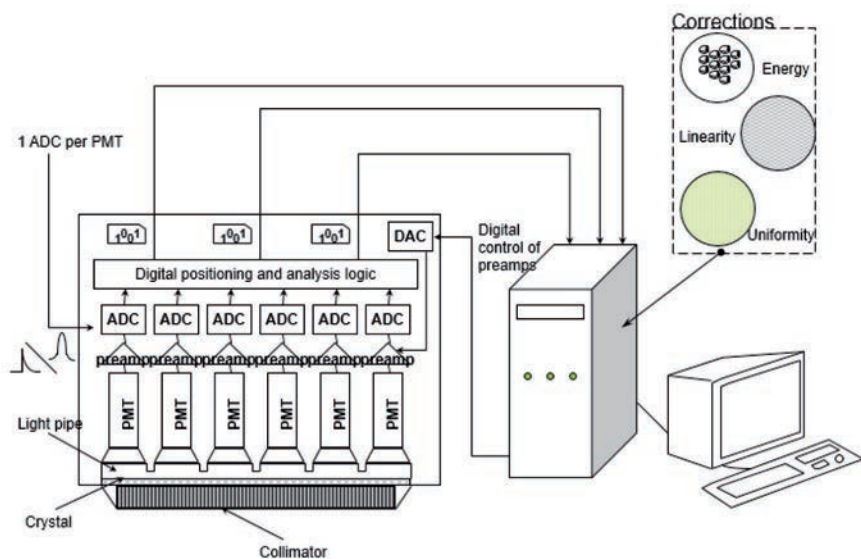
FIG. 3. Main components of a digital gamma camera.

signals trigger (e.g. an electrocardiogram device) is frequently used in order to synchronize the acquisition with the monitored physiological process.

4.1.1. Detector crystals

The scintillation crystal, typically used in most gamma camera models, converts gamma ray photons incident on the crystal into a number of visible light photons. Table 2 reports the main characteristics of NaI(Tl), the type of scintillator most largely adopted, compared to CsI(Tl) (caesium iodide doped with thallium), another useful scintillating material.

TABLE 2. SPECIFICATIONS OF SOME INORGANIC SCINTILLATORS

Scintillator	Density (g/cm^3)	Z_{eff}	μ (140 keV) (cm^{-1})	Wavelength of emitted light (nm)	Light yield (photons/MeV)	Energy resolution at 140 keV	Scintillation half-life (ns)
NaI(Tl)	3.67	51	29	410	41 000	6.5	230
CsI(Tl)	4.51	54	23	540	64 000	4.3	800, 10 000

Ideally, the crystal should be dense and of a high Z material, so that as many incoming gamma rays as possible would interact through photoelectric effect. Another desired characteristic is a high light output to provide low quantum noise for energy and position estimation. The decay time of the light output needs to be fast enough to avoid pile-up of pulses at count rates experienced in nuclear medicine imaging procedures.

In modern gamma cameras, each detector head is typically of about 40 cm × 50 cm, with a thickness of 9.5 mm. Increased crystal thickness (12.7 mm, 15.9 mm or 25.4 mm) can optionally be adopted, to obtain increased counting efficiency at medium to high energies, at the price of some loss of spatial resolution in the low energies range.

NaI(Tl) is an excellent scintillating material but is highly hygroscopic. If exposed to air humidity, it changes in colour, thus losing its normal properties of light transmission. In a gamma camera, the detector is always hermetically sealed by a metallic coating (typically aluminium), while the back of the crystal is coupled to PMTs through an optical glass; however, during the operational life of a camera, crystal hydration might happen. In this case, the crystal, or frequently the whole head, needs to be replaced.

Some commercially available gamma camera systems, based on room temperature operating semiconductors CdZnTe (cadmium zinc telluride (CZT)), have been introduced. More details on the principles of scintillating crystals, as well as on gamma cameras based on solid state photodetectors are described in Ref. [10].

4.1.2. Collimators

The collimator functions as a sort of mechanical lens defining LORs. The collimator accomplishes this by preventing photons emitted along directions that do not lie along the LOR from reaching the detector. Collimators consist of a set of holes in a dense material with a high atomic number, typically lead. The holes of a collimator geometrically define the LORs. Ideally, each point in the object would contribute to only one LOR. This requires the use of collimator holes that are relatively long and narrow. However, such holes would allow very few photons to pass through the collimator and being detected. Conversely, increasing the diameter or decreasing the length of the holes results in a much larger range of incident angles passing through the collimator, which results in degraded spatial resolution.

In an ideal collimator, the septa would block all incident radiation. However, in real collimators, some fraction of the radiation passes through the septa and is detected. These phenomena are referred to as septal penetration. Thus, there is not one single type of collimator satisfying all the conflicting requirements.

Since gamma cameras are used to image radionuclides with a wide range of energies, collimators are available for different energy ranges: low energy collimators are designed for isotopes emitting photons with energies lower than approximately 160 keV; medium energy collimators are designed for energies up to approximately 250 keV; and high energy collimators are designed for higher energies, typically up to 364 keV.

With regard to the different level of trade-off between spatial resolution and sensitivity, in current practice collimators are classified as having high sensitivity or high resolution. A collimator optimized for low energy and high resolution is typically indicated as low energy high resolution (LEHR), while a low energy and high sensitivity collimator is termed as an LEHS.

Collimators having intermediate resolution and sensitivity are indicated as 'general purpose' or 'all purpose', for example low energy general purpose (LEGP). Medium and high energy collimators are normally available as medium energy general purpose and high energy general purpose. In case a specific level of performance is necessary, vendors can normally supply on request a collimator satisfying other requisites (e.g. a medium energy high resolution collimator).

However, it has to be noticed that these definitions do not reflect an internationally accepted standard. It may be that a collimator defined as LEHR by a vendor has characteristics close to what a different vendor may classify as an LEGP. A careful consideration of the quantitative specifications in terms of spatial resolution (typically given at a distance of 10 cm from the collimator surface) and sensitivity (count rate per unit activity) is encouraged.

Another important characteristic of collimators is the hole's geometry. There are four common geometries in nuclear medicine: parallel, converging, diverging and pinhole (see Fig. 4). Parallel holes are the most commonly used collimators.

Finally, collimators are relatively heavy, and each collimator normally weighs more than 100 kg. Their handling and exchange require the aid of trolleys or semi-automatic systems, whose placement in a diagnostic room and space for proper functionality require to be carefully planned.

4.1.3. Photodetectors

An array of photodetectors is coupled to the scintillation crystal to measure the distribution of incident scintillation photons and to convert it into a set of electrical pulses, whose charge is proportional to the number of scintillation photons incident on each corresponding element in the array. In clinical gamma cameras, the photodetector array comprises a set of 30–90 PMTs arranged in a hexagonal close packed arrangement.

Since the position and energy are estimated from the set of charge signals from the elements in the photodetector array, it is highly desirable that the
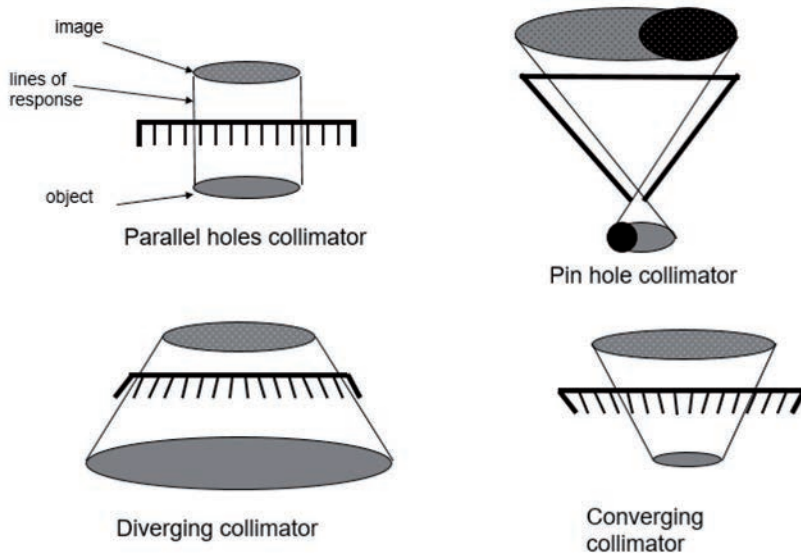
FIG. 4. Principal types of collimator geometry.

proportionality constants relating light intensity to charge be the same for all of the photodetectors. This can be ensured by choosing matching devices and by carefully controlling and matching the electronic gain. For PMTs, the gain is controlled by the bias voltage applied to the tubes. Since gain is also a function of temperature, the temperature of the photodetectors needs to be carefully controlled. The gains of PMTs are very sensitive to magnetic fields, even those as small as the Earth's magnetic field. Thus, the PMTs have to be magnetically shielded using mu-metal. Finally, since the gains of tubes can drift over time, periodic recalibration is necessary.

4.1.4. Electronic pulse processing

The charge pulse from each PMT is small and thus subject to noise. To make pulse analysis easier and more resistant to electrical noise, the pulse is amplified and shaped prior to processing and estimate of interaction position and photon energy. The preamplifier integrates the charge pulse from the PMT to form a voltage pulse with height proportional to the input charge. Preamplifiers are mounted directly to the PMT outputs. Since the output pulses from a preamplifier have a relatively long decay time, they need to be further processed by a shaping circuit, typically using a sequence of integrating and differentiating (CR-RC) stages. Alternatively, in the more recent commercial gamma cameras, the output waveform from the

preamplifier is directly digitized. This provides an automatic control of the trade-off between energy resolution and count rate depending on the requirements of the particular imaging procedure, and independently form a preselection by the user in the acquisition set-up protocol.

Once signals are digitized by analogue to digital converters, digital methods implemented in a microprocessor are used to estimate pulse heights in order to establish position and energy, as well as to apply a variety of corrections (linearity, energy, uniformity) aimed at optimizing images. In some modern systems, these are done using statistical estimation techniques such as maximum-likelihood estimation, with a significant improvement compared to historical, analogue gamma cameras.

4.1.5. Image framing

The final step in generating gamma camera images is image framing. This involves several steps and is typically done either by microprocessors in the camera or in an acquisition computer. The framing algorithm performs a number of other important functions:

(a) Rejection of photons that lie outside of a user selected energy window in order to reduce scatter. Gamma cameras typically offer the ability to simultaneously frame images corresponding to more than one energy window. This can be useful for isotopes having multiple photo peaks, for acquiring simultaneous images of two or more radionuclides or for scatter compensation based on multiple energy windows methods. Framing software typically enables the summation of photons from multiple, discontiguous energy windows into one image, as well as simultaneously framing multiple images from different energy windows into different images.

(b) Obtaining a sequence of dynamic images. This means that photons are recorded into a set of images depending on the time after the start of acquisition. For example, images could be acquired in a set of images with frame duration of 10 s. Thus, for the first 10 s, photons are recorded into the first image; for the other 10 s, they are recorded into a second image; and so on. Thus, just as multiple images are obtained in the case of a multi-energy window acquisition; multiple images are obtained corresponding to a sequential set of time intervals. Dynamic framing is used for monitoring processes such as kidney function and gastric emptying.

(c) Obtaining a sequence of gated images. A gated acquisition is similar to dynamic acquisition in that photons are recorded into a set of images depending on the time they are detected. However, in gated acquisition, the time is relative to a physiological trigger, such as an electrocardiogram signal that provides a signal at the beginning of each cardiac cycle. This is appropriate for processes

that are periodic. The photons are counted into a set of frames, each of which corresponds to a subinterval of the time between the two triggers (e.g. in cardiac imaging 8, 16 or 32 frames). The photons arriving in each of the subintervals are counted in the corresponding frame. This is useful for assessing wall motion and thickening.

(d) Saving the data in list mode. In list mode acquisition, the energies and positions of incoming photons are simply saved to a file in the order in which they appear. Additional information is recorded in the form of events in the list mode stream. These events include things such as physiological triggers, gantry or table motion, start and stop of acquisition, and timing marks which are injected at regular intervals. The advantage of list mode data is that they contain all of the information obtained during the acquisition. As a result, it can be retrospectively reframed using different pixel sizes, energy windows and frame intervals, among other things. However, the downside is that list mode files are very large (typically eight or more bytes of data are stored for each photon). List mode is often not made available for routine clinical use but can be very useful for research.

4.1.6. System configuration

Even if single head gamma cameras are still widely diffused, the standard model is nowadays a dual head system, in which two identical heads are supported by a vertical gantry that allows for their complete rotation around the longitudinal axis of the patient. This makes possible efficient SPECT acquisition, while maintaining a good accessibility to the imaging field of view and sufficient flexibility of patient positioning in planar acquisition.

The distance between each head and the patient body can be adjusted (manually or automatically when the body contouring function is available). The heads can be configured at 180° or at 90° (for cardiac SPECT). This feature being frequently termed as variable geometry, in order to optimize SPECT acquisition protocols according to the organ of interest. In some modern systems, the heads can also be placed in a contiguous configuration to allow for an extended planar static acquisition.

For whole body acquisition (e.g. for whole body bone scan), the patient bed can translate at a controlled speed within the heads in order to allow the reconstruction of a single image with the distribution of the radiopharmaceutical in the entire body or a length selected by the user. Triple head gamma cameras have been effectively used for tomographic studies; however, the flexibility of dual head, variable geometry systems has led to a limitation of the use of triple head systems. Finally, a few types of dedicated system have been proposed for

dedicated cardiac SPECT imaging, based either on multihole collimation or on multipinhole collimation and solid state CZT detectors.

4.1.7.   New trends

In recent years, CZT detectors have been introduced as an alternative to traditional NaI(Tl) crystals coupled with photomultiplier tubes, and now are available in large field of view SPECT systems as well. Due to the absence of the PMTs, CZT systems have thinner and lighter heads and allow for a very close positioning of the detector to the patient, resulting in an excellent spatial resolution. Moreover, the good energy resolution of CZT make possible an increased sensitivity and scatter rejection compared to conventional NaI(Tl) based cameras.

Despite the different solutions adopted in terms of detectors, configuration and choice between dedicated or general purpose systems, state of the art SPECT cameras have in common the potential for substantial increase in count sensitivity with no loss of spatial resolution. This results in the potential for acquiring a SPECT scan with a standard activity in a fraction of the time, or, alternatively, in taking advantage of the higher sensitivity for reducing the injected activity, while maintaining a good image quality. These features are further enhanced by iterative reconstruction algorithms that may include accurate modelling of the detector–collimator system, making possible a recovery of spatial resolution and thus improved image quality.

4.2.   POSITRON EMISSION TOMOGRAPHY SYSTEMS

Positrons are emitted from the nucleus during the radioactive decay of proton rich isotopes. A positron is the antimatter conjugates of an electron and has the same mass as an electron but positive charge. As with beta decay, positrons are emitted from the nucleus with different energies, according to continuous spectrum and a specific maximum value that is characteristic of the parent isotope. Once emitted from the nucleus, the positron propagates through the surrounding material and undergoes scattering interactions, changing its direction and losing kinetic energy (see Fig. 5). Within a short distance, the positron comes to rest and combines with an electron from the surrounding matter. This distance is dependent on the energy of the positron and is typically on the order of a millimetre. The combination of a positron and an electron results in the annihilation of both particles and the creation of two photons, each with an energy of 511 keV, equivalent to the rest masses of the two original particles.
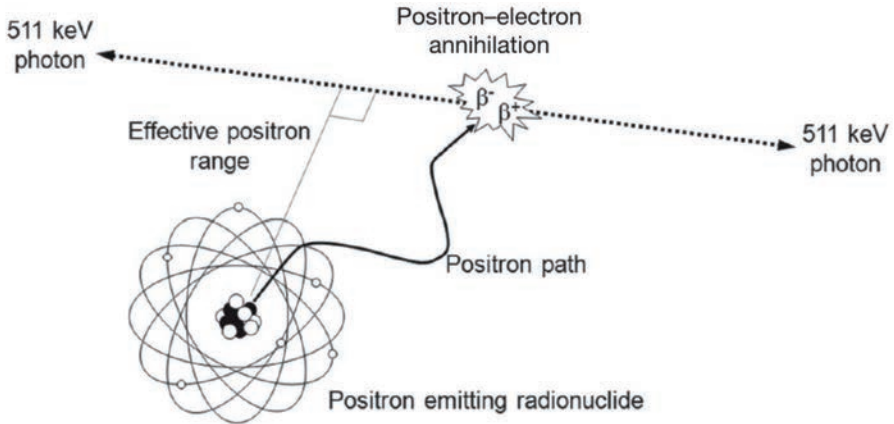
FIG. 5. *Positrons emitted from a radioactive nucleus propagate through the surrounding material before eventually coming to rest a short distance from their site of emission. At this point, the positron annihilates with an electron, creating two 511 keV photons that are emitted approximately 180° apart. The perpendicular distance from the line defined by the two photons to the site of positron emission places a limit on the spatial resolution that can be achieved with PET systems.*

Conservation of momentum, which is close to zero immediately before annihilation, ensures both photons are emitted almost exactly 180° apart. These characteristic photon emissions (known as annihilation radiation) are always 511 keV, always emitted simultaneously and almost exactly 180° apart form the basis of PET and result in distinct advantages over single photon imaging in terms of defining the LOR.

The advantages of PET over SPECT, in terms of improved spatial resolution, statistical quality and quantitative accuracy, can be attributed to the fact that PET does not require a mechanical collimator and therefore eliminates the weakest link in the SPECT image formation process. Instead of physical collimation, PET systems employ a form of detection that can be thought of as electronic collimation. If a positron source is surrounded by suitable detectors, both back to back photons from an individual positron decay can potentially be detected (see Fig. 6). As both photons are emitted simultaneously, they will be detected at approximately the same time, allowing temporal acceptance criteria to be used to associate pairs of corresponding detection events. This mode of detection is referred to as coincidence detection and allows corresponding photon pairs to be distinguished from other unrelated, potentially numerous, photon detection events.

As both photons that arise from positron decay are emitted almost exactly 180° apart, coincidence detection can be used to localize the source of the
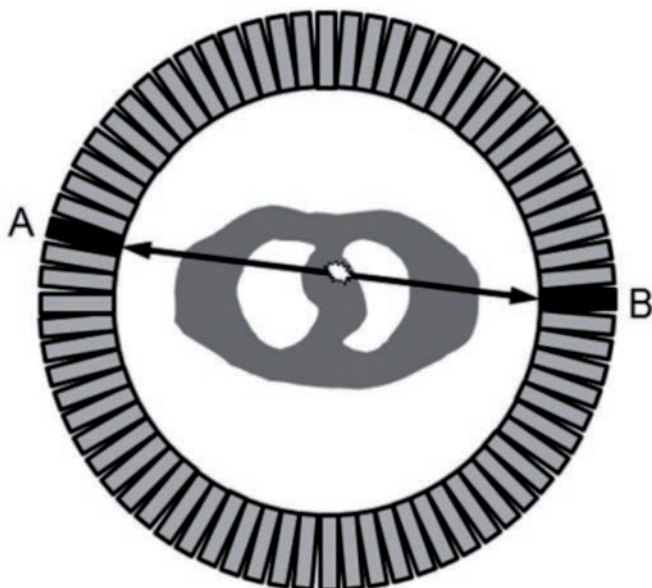
FIG. 6. The back to back photons that result from positron–electron annihilation can potentially be measured by detectors placed around the source. Coincidence detection involves the association of detection events occurring at two opposing detectors (A and B) based on the arrival times of the two photons. An LOR joining the two detectors is assumed to intersect the unknown location of the annihilation event. Coincidence detection obviates the need for a collimator and is sometimes referred to as electronic collimation.

photon emissions. In general, a line drawn between corresponding detectors can be assumed to intersect the point of photon emission, although information is usually not available about exactly where along that line the emission occurred. However, if a system of detectors is arranged at different positions around the source, multiple coincidence events can be recorded at different angular orientations. Over the course of an extended scanning period, a large number of coincidence events will be recorded, and angular projections of the activity distribution can be estimated. These projections may then be used to reconstruct 3-D images using CT methods.

4.2.1. Design considerations for PET systems

4.2.1.1. Spatial resolution

Good spatial resolution is clearly an important design objective for PET imaging systems. As such, the trend in modern scanner systems has been to

decrease the width of individual detectors and to increase the total number of detector elements surrounding the patient. The increased concentration of detector elements decreases the sampling interval and generally improves spatial resolution.

Another factor that influences spatial resolution is the distance between opposing detectors. This distance is relevant because of a small uncertainty in the relative angle of the 511 keV annihilation photons. Although the basic assumption of coincidence detection is that annihilation radiation is emitted 180° apart, this is not strictly true. Positrons frequently annihilate before they have lost all momentum, and this residual momentum translates to a small deviation of about ±0.25° from the expected back to back emissions. This effect is referred to as non-collinearity and tends to degrade spatial resolution as detector separation increases. For PET systems with opposing detectors separated by only a few centimetres, such as those optimized for specific organs such as the brain or breast, this is not a major issue. However, for whole body systems, in which opposing detectors are typically separated by about 80 cm, the effect of non-collinear photons contributes a blurring with a full width at half maximum of approximately 2 mm.

The distance travelled by a positron between its point of emission and annihilation is an additional factor that degrades the spatial resolution that can be achieved by PET systems. As previously discussed, this distance, or positron range, is dependent on the energy of the positron and also the type of material through which the positron is passing; a greater range is expected in lung as compared to other soft tissues. Software corrections have been implemented that model the effect of positron range and can potentially reduce the loss of resolution in reconstructed images.

4.2.1.2. Sensitivity

The best possible PET spatial resolution is not always achieved in clinical practice due to statistical noise (see Fig. 7). To suppress this noise, clinical protocols generally employ low-pass filters or other similar image reconstruction methods, but the consequence is invariably a loss of spatial resolution. Improving the statistical quality of the measured coincidence data not only reduces image noise but also allows to reduce image smoothing and to improve spatial resolution. The need to optimize this trade-off between statistical noise and spatial resolution influences both image reconstruction development and scanner design.

Noise in PET images is influenced by a number of factors, including the sensitivity of the detector system, the amount of radioactive tracer administered to the patient and the amount of time the patient can remain motionless for an imaging procedure. Limitations on the latter two factors mean that high
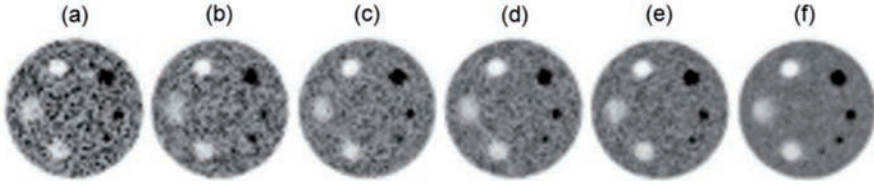
FIG. 7. *Images of the same phantom, each showing different statistical quality. The images shown in (a)–(f) were acquired for 1, 2, 3, 4, 5 and 20 min, respectively. Increasing the acquisition time increases the total number of true coincidence events and reduces statistical variability in the image.*

sensitivity is an important objective for scanner design. Sensitivity is determined by the geometry of the detector arrangement and the absorption efficiency of the detectors themselves.

4.2.1.3. Quantitative accuracy

One of the strengths of PET is its capability to quantify physiological processes in vivo. A prerequisite for this kind of quantitative analysis is that the images accurately reflect the local activity concentration in the body. To ensure this kind of quantitative accuracy, it is important to minimize effects that corrupt the data and to correct residual corruption as necessary. Quantitative error can arise from many sources but is primarily due to random coincidence events photon scatter within the body, photon attenuation within the body and detector dead time (see Fig. 8).

Software processing prior to (or during) image reconstruction can mitigate the above effects, but the accuracy of these corrections may not be reliable if the contamination overwhelms the signal from true coincidence events. PET systems are therefore designed to minimize the contribution of the various degrading factors described above.

Optimization of the coincidence timing window for a particular scanner represents a compromise between wanting to reduce the number of random coincidence events without significantly reducing the number of true coincidences. Detector systems that are able to measure photon detection times with low variability (high timing resolution) are therefore desirable from the perspective of random reduction. Timing resolution also contributes to detector dead time as a shorter coincidence timing window reduces the likelihood of more than two photon detection events occurring. Other contributions to dead time include the time required by the detector to measure an individual photon event and the time spent processing coincidence events.
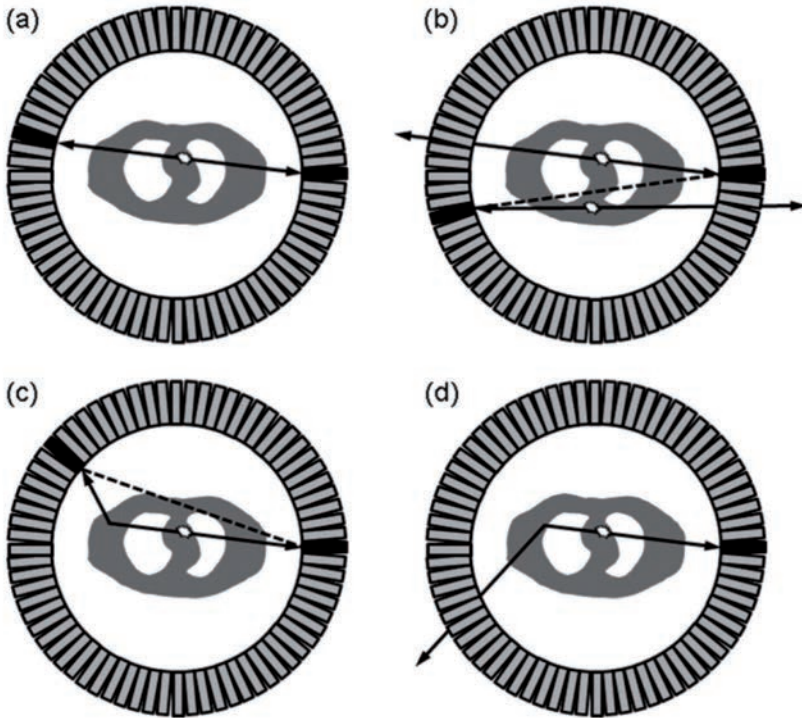
FIG. 8. (a) A true coincidence event can occur when both photons escape the body without interacting. (b) A random coincidence event occurs when two photons from unrelated annihilation events are detected at approximately the same time. (c) A scattered coincidence event can occur when either photon is scattered within the body but is still detected. (d) No coincidence event is recorded when one or both photons are attenuated, typically due to scatter out of the field.

4.2.2. Detector systems

4.2.2.1. Radiation detectors

Almost all current systems adopt an approach based on scintillation detectors, whose emitted light is converted to an electrical signal by means of a photodetector, usually a PMT, coupled to the crystal material. Various scintillator materials have been used in PET, including NaI(Tl), bismuth germanate (BGO) and cerium doped lutetium oxyorthosilicate doped with cerium (LSO).

The properties of an ideal crystal for PET would include: (i) a high stopping power for 511 keV photons (high linear attenuation coefficient); (ii) short scintillation light decay time to reduce dead time and allow short coincidence

time windows to reduce random coincidences; and (iii) high light output. High light output enables good energy resolution, which gives rise to improved scatter rejection. It also affords cost savings in the construction of a complete scanner system as the number of photodetectors required to resolve a given number of crystal elements can potentially be reduced.

Although NaI(Tl) is ideal for lower energy single photon imaging, its relatively low linear attenuation coefficient for 511 keV photons makes it less attractive for PET applications. Initially BGO and, more recently, LSO have replaced NaI(Tl) as the scintillator of choice for PET. For commercial reasons, some PET systems employ lutetium–yttrium oxyorthosilicate doped with cerium which has substantially similar properties to LSO.

4.2.2.2. Detector arrangements

Space and cost constraints mean that individual scintillation crystals are not usually coupled directly to individual photodetectors in a one to one fashion. Instead, the most common arrangement is a block detector in which a group of crystal elements share a smaller number of PMTs (see Fig. 8). The design of each block varies between manufacturers and scanner models but usually involves a matrix of crystal elements, a light guide and four PMTs.

An example configuration might be an 8 × 8 array of closely packed 4.4 mm × 4.0 mm × 30 mm crystal elements, where the longest dimension is in the radial direction to maximize detection efficiency. The (x, y) position of the detection event is calculated from the outputs of the four PMTs using a weighted centroid algorithm, similar to the Anger logic of a gamma camera. In this way, only four PMTs are needed to localize signals from a much greater number of crystal elements. The number of crystal elements divided by the number of PMTs in a PET system has been referred to as the encoding ratio. A high encoding ratio implies lower production costs and is therefore desirable.

One of the advantages of the design described above is that each block operates independently of its surrounding blocks. This leads to good count rate performance as light is not transferred between blocks and the PMTs of one block are unaffected by detection events in an adjacent block. An alternative arrangement referred to as quadrant sharing, increases the encoding ratio by locating the PMTs at the corners of adjacent blocks. This arrangement differs from the conventional block design in that each PMT can now be exposed to light from up to four different blocks. This can result in better spatial resolution and a higher encoding ratio but is also susceptible to greater dead time problems at high count rates.

Another alternative to the block design adopts an approach similar to that used in conventional gamma cameras. These Anger logic designs involve detector

modules that have a much larger surface area compared to conventional block detectors (e.g. 92 mm × 176 mm). Each module is comprised of many small crystal elements which are coupled, via a light guide, to an array of multiple PMTs and positional information is obtained using Anger logic in the same way as a gamma camera. The PMTs used in this design are typically larger than those used in block detectors, increasing the encoding ratio. The larger area detector modules encourage more uniform light collection compared to block designs, which leads to more uniform energy resolution. However, a disadvantage of this design is that the broad light spread among many PMTs can lead to dead time problems at high count rates.

4.2.2.3. Scanner configurations

In almost all state of the art scanners, the PET detector is designed as a series of rings of crystals surrounding the patient. Each ring defines a transaxial plane and the direction perpendicular to this plane is referred to as the axial direction. The multiplicity of rings allows for the simultaneous acquisition of multiple transverse slices.

Human whole body systems typically have an axial field of view of around 15–20 cm, adequate to cover most individual organs and representing a trade-off between the total sensitivity and the cost of the detector assembly. In whole body oncology studies, the mechanism for translating the patient through the scanner is determinant for an optimal acquisition. The patient bed or patient handling system has to be made of a low attenuation material, while still being able to support potentially very heavy patients. The travel range needs to be long enough to allow whole body studies in a single pass without the need for patient repositioning. Precise motion control is also critical, particularly for PET–CT systems where accurate alignment of the two separately acquired modalities is essential.

4.2.2.4. Data acquisition

The basis of coincidence detection is that pairs of related 511 keV annihilation photons can be associated together by the detector system based upon their times of measurement. Two photons detected within a short time interval are assumed to have arisen from the same positron–electron annihilation and a coincidence event is recorded. The time interval determining when events are considered to be coincident needs to be kept as short as possible and, for many typical systems, is around 12 ns, or even less for modern scanners based on fast scintillating materials (see Fig. 9).

Scanners consisting of multiple detector rings provide extended axial coverage and are advantageous for rapid acquisition of volumetric data. However,
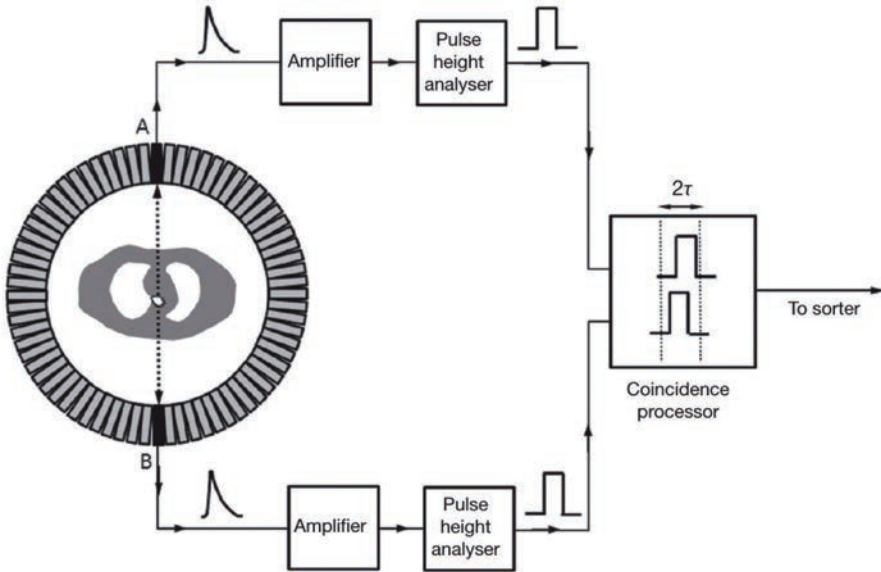
FIG. 9. Coincidence circuits allow two photon detection events to be associated with each other based upon their arrival times. Photons detected at A and B produce signals that are amplified and analysed to determine whether they meet the energy acceptance criteria. Those signals that fall within the energy acceptance window produce a logic pulse (width τ) that is passed to the coincidence processor. A coincidence event is indicated if both logic pulses fall within a specified interval (2τ).

the presence of multiple detector rings raises issues concerning the choice of the detectors combination used to measure coincidence events. In a system with only one ring of detectors, the acquisition geometry is simple as each detector measures coincidence events with other detectors on the opposite side of the same ring. When additional detector rings are added to the system, it is possible to allow coincidence events to be recorded between detectors in different rings (see Fig. 10).

Previous generation of equipment used interplane septa of an absorbing material (2-D mode), in order to reduce acceptance of coincidences arising from different rings of detectors. In this way, not only a good control of scattered radiation was achieved, but also only LORs that could be reconstructed by simple algorithms and using the relative power of available computers, could be used. Modern scanners operate in 3-D acquisition mode, without any physical collimation restricting the photons that are incident upon the detectors. Coincidence events can be recorded between detectors in different rings and potentially between all possible ring combinations.
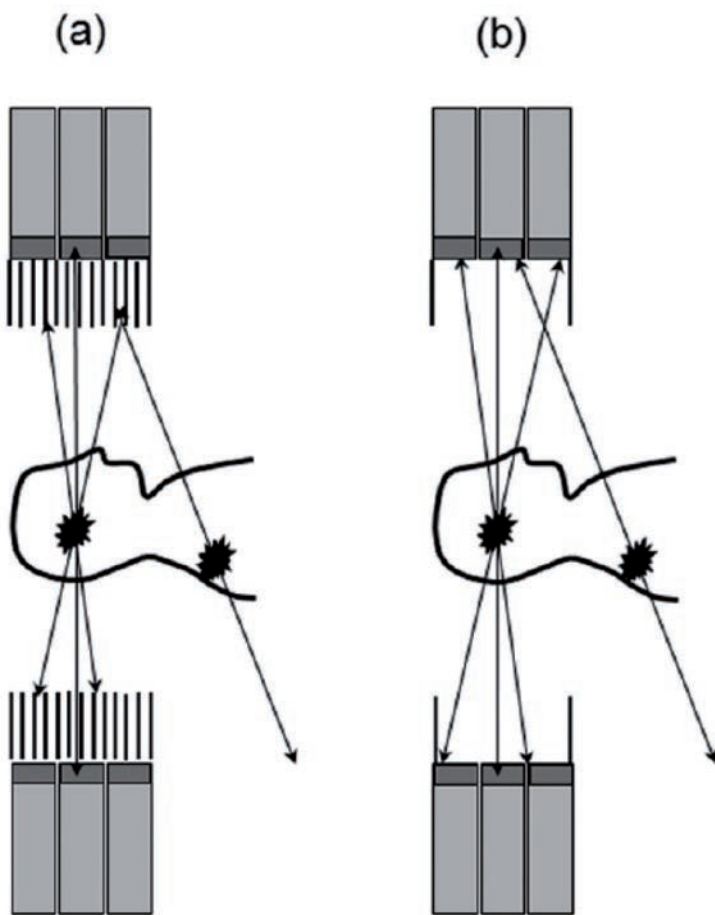
FIG. 10. (a) 2-D and (b) 3-D acquisition geometries. In 2-D mode, a series of annular septa are inserted in front of the detectors to absorb photons incident at oblique angles. In 3-D mode, these septa are removed, allowing oblique photons to reach the detectors. 3-D mode is associated with high sensitivity but also increased scatter and randoms fractions, the latter partly due to single photons from outside the coincidence field of view.

As a consequence of the substantial sensitivity increase, 3-D acquisition is associated with higher detector count rates, leading to more random and greater dead time than corresponding acquisitions in 2-D mode. Furthermore, 3-D mode cannot take advantage of the scatter rejection afforded by interplane septa and, as a result, records a greatly increased proportion of scattered coincidence events.

However, 3-D acquisition is nowadays the standard modality, thanks to its large increase in sensitivity compared to 2-D acquisition, resulting in images with improved statistical quality or, alternatively, comparable image quality with

shorter scan times or reduced administered activity. This can be obtained thanks to sophisticated reconstruction algorithms that require high power and costly computer systems in order to manage the huge number of LORs.

4.2.2.5. Time of flight

Detectors operating in coincidence mode provide spatial information relating to individual positron–electron annihilations but this information is not sufficient to determine the exact location of each event. A line joining the two detectors can be assumed to intersect the site of the annihilation but the exact position along this line cannot be determined. For this reason, PET systems measure signals from multiple events and the resulting projections are used to reconstruct images using CT. However, it has long been appreciated that the difference in the detection times of the two annihilation photons provides a mechanism for precisely localizing the site of individual positron–electron annihilations (see Fig. 11). Given that photons travel at the speed of light, essentially irrespective of the composition of the material through which they pass, the difference in the arrival times of the two photons can potentially be used to localize their original point of emission. This is clearly attractive because it means that each coincidence measurement provides significantly more information, promising substantial improvements in image statistical quality.

Incorporating information derived from differences in the photon arrival times has been referred to as time of flight (TOF) mode and a number of PET systems have been developed that exploit this approach. A prerequisite for TOF PET systems is high timing resolution (Δt). To exploit all the possibilities of TOF, a timing resolution of the order of 50–60 ps would be necessary. Nowadays, systems can instead achieve at most 500–600 ps. This involves that while useful information can be added in the reconstruction process, determining at least an improvement in the signal to noise ratio (meaning some improvement in lesion detectability), improvements in spatial resolution are only partially achieved.

4.2.2.6. Image calibration

Properly reconstructed and corrected PET images have a satisfactory level of control of artefacts and quantitative errors caused by the various physical effects that degrade PET data. As a result, the reconstructed images can reflect the activity distribution within the field of view, within the limitations imposed by the system's limited spatial resolution. These reconstructed images can then be used to quantify the in vivo activity concentration in a particular organ or tissue. Although this capability is not always fully exploited, the potential to accurately
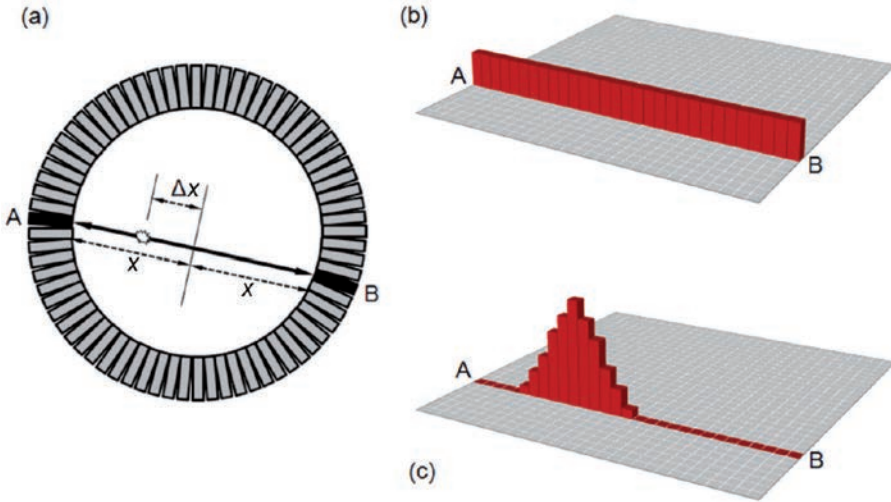
FIG. 11. (a) A coincidence event detected along an LOR between detectors A and B. The average time difference between the two detectors is given by $(x + \Delta x)/c - (x - \Delta x)/c = 2\Delta x/c$, where c is the speed of light. (b) With conventional PET, no information is available about the location of the annihilation event along the LOR. During reconstruction, the event is assigned with equal weight to all pixels between A and B. (c) With TOF PET, the time difference between the signals recorded at detectors A and B is used to estimate the position of the annihilation event along the LOR. During reconstruction, events are weighted according to the detector time difference and a function that reflects the limited time resolution of the system.

quantify images in terms of absolute activity concentration facilitates a range of potential applications.

After image reconstruction, including the application of the various physical corrections, PET images have arbitrary units, typically counts per voxel per second. Quantitative data can be extracted from the relevant parts of the image using region of interest techniques but cannot be readily compared with other related data such as measurements made with a radioactivity calibrator. To convert the PET images into units of absolute activity concentration such as becquerel per millilitre, a calibration factor is required. This calibration factor is experimentally determined, typically using a uniform cylinder phantom and provides accurate results providing that it is made using an activity calibrator that has been calibrated for the isotope of interest using a standard source that is traceable to a national metrology institute. Calibrated PET images can thus be determined by multiplying the raw image data by the calibration factor and dividing by the positron fraction for the particular isotope of interest. This quantitative feature of PET imaging is particularly relevant in repeated PET

scans, for example in follow-up studies or in monitoring response to treatment, as well as in multicentre trial studies (see Ref. [20]).

4.3. HYBRID MULTIMODALITY SYSTEMS

Functional imaging of the biodistribution of radiopharmaceuticals is, by its own nature, limited in supplying detailed anatomical information, being aimed to reproduce biochemical function of tissues rather than some anatomy related descriptor, such as tissues composition or density. Moreover, accurate anatomic localization of functional abnormalities imaged by emission scans, is hindered by the limited spatial resolution achievable in SPECT and also, even if at a different extent in PET.

For most of the molecular tracers used, some anatomic information can be inferred from non-specific uptake in muscles, brain, heart, liver, colon and other organs, or from excretion through the urinary system. Even if localization relative to such low resolution anatomic landmarks may help image interpretation, a detailed anatomic framework such as that provided by CT represents clearly a major improvement.

Hybrid multimodality imaging is one of the most rapidly growing imaging modalities. The combination of nuclear medicine imaging (SPECT or PET) with CT is considered to be an evolution in imaging technology where fusion of two established modalities offers more than the sum of the parts. Both modalities have their strength: CT scanners image anatomy with high spatial resolution; nuclear medicine imaging (SPECT or PET) provides the metabolic and functional information. Modern hybrid imaging modalities have the ability to provide, in a single imaging session, detailed anatomical and metabolic and functional information. PET–CT has revolutionized the care of cancer patients in developed countries and is increasingly being adopted in emerging economies. Similarly, the use of SPECT–CT is rapidly increasing and probably this hybrid imaging technology will become the gold standard for conventional nuclear medicine.

In addition to this substantial clinical benefit of registering anatomical and functional images, the coupling of CT with SPECT and PET systems provides additional technical benefits, by enabling CT to be used for attenuation correction, thus reducing the duration of the procedure, reducing motion artefacts, increasing quality of the corrections and, as a consequence, making possible accurate quantitative imaging.

4.3.1. The problem of attenuation correction

Self-absorption of photons emitted within the body of a patient administered with a radiopharmaceutical is a well known effect that significantly degrade both the quality of reconstructed images, and the capacity of collecting quantitative information, in terms of absolute quantification (Bq/g of tissue) or of semiquantitative indexes, such as the standardized uptake value (SUV).

Owing to differences in the principle of detection, specific issues appears in SPECT and in PET in developing strategies for attenuation correction. Despite these differences, a common approach can be identified since in both modalities to properly take into account self-absorption and correct for its effect, an accurate description of the distribution of the attenuation coefficient of radiation (strictly correlated with the distribution of densities of tissues) is necessary for the imaged volume. Techniques for attenuation correction were then developed in order to assume or to measure the distribution of the linear attenuation coefficient μ in imaged tissues.

In the first category is the Chang method, widely used in SPECT, or similar geometrical method used in PET in which, once a description of the shape of the imaged volume is defined, a uniform value for the effective μ is assigned to each voxel in the volume. While these techniques are computationally efficient, they cannot reach a good level of accuracy, since they do not take into account differences in tissues density. In particular, these techniques fail when marked variations in densities are present, like in the case of highly inhomogeneous districts (thorax) or when bone is involved (lack of proper characterization of in-homogeneity within bones, age related variations in bone density).

This has led to the first attempts to acquire patient specific information of the density distribution, that were based on simultaneous transmission acquisition during simultaneous emission studies, making use of radionuclide sources (e.g. ^{153}Gd sources emitting at 100 keV in the case of SPECT imaging and rotating ^{68}Ge/^{68}Ga sources, emitting 511 keV annihilation photons, in PET).

While these methods can allow for sufficiently accurate collection of tissues density distribution, they typically require prolonged acquisition time and increased running costs for acquiring calibrated transmission sources, their management and disposal, once their operational life is terminated due to physical decay. This complex series of problems was the initial motivation for exploring the use of multimodality systems, including a CT scanner coupled to an emission camera, with the aim of acquiring high spatial resolution and low noised images of the density distribution within the imaged volume.

4.3.2. SPECT–CT

A multimodality system, integrating a SPECT scanner with a CT system, in which the patient can be positioned in the same bed that automatically moves in the two imaging positions with a simple translation, provides a huge advance in technology. The two imaging datasets can be acquired in a close sequence, so that they can be practically considered simultaneous, and a simple rigid re-alignment allows for the registration of corresponding slices. The CT data can then be used both to correct for tissue attenuation in the SPECT scans and to display metabolic data on an accurate morphological context, allowing for efficient, simultaneous 'navigation' in function and anatomy.

To accomplish this, since the two datasets are acquired at different level of spatial resolution, resampling is necessary in order to match voxel sizes. In early systems, this was typically made by degrading the spatial resolution of SPECT images, while in more modern systems, CT images are used as the basis to be superimposed with properly interpolated and scaled SPECT data.

Early SPECT–CT designs coupled SPECT with low performance CT, based on low power X ray tubes and slow rotation speeds, where the CT component was by no means optimized for diagnostic quality imaging. The aim was focused in providing attenuation correction and a basic but satisfactory anatomical context for the SPECT, while saving the running costs of attenuation correction radionuclide sources and maintaining a relatively low cost of the CT component.

The success of these systems, the increased experience in proper clinical use of the information gathered by both modalities and the parallel experience with PET–CT, has led to the introduction of SPECT–CT systems that incorporate a high performance CT component with capabilities comparable to dedicated CT scanners. With this development, SPECT–CT now benefits from substantially improved CT image quality, faster data acquisition and a broader range of CT protocols. A full range of different multidetector CT slice configurations are now available, as well as alternative designs including those based upon flat panel detectors, reflecting the vitality of this technique and its continued relevance in clinical practice.

4.3.3. PET–CT

PET imaging is affected by several physical effects, like scattered and random coincidences, photon attenuation, detector efficiency variations, spatial resolution non-uniformity, scanner dead time and others. Of these, the most important is by far photon attenuation within the body of the patient that influences image quality as well as quantitative accuracy. The CT component of a PET–CT system allows for an accurate attenuation correction, with a marked improvement

in both image quality and quantification. This is per se an extraordinary result that could justify its use. However, the primary purpose of multimodality imaging is the precise, high spatial resolution anatomical localization of regions identified on the PET tracer uptake images.

CT and PET have been for long time used sequentially in the diagnosis and staging of disease and in monitoring the effects of therapy, with PET acquiring an increasing role, particularly when the CT scan was equivocal. For years, visual comparison of the separate anatomic and functional image sets has been the standard approach adopted to synthesize additional information, eventually using, where appropriate, software to fuse and align the two sets of images. This situation changed dramatically with the introduction of the multimodality PET–CT scanners. These devices solve the problem of image registration and fused display through hardware rather than software, providing the capability to acquire accurately aligned anatomic and functional images for a patient, within a single scanning session. Since the patient remains positioned on the same bed for both imaging modalities, temporal and spatial differences between the two sets of images can be neglected.

Initially, PET–CT systems were a PET scanner and a CT scanner combined together, either under a common gantry cover or effectively separate, with different acquisition systems and whose results were combined in one or the other workstation. Instead, modern PET–CTs are designed and engineered as an integrated system (see Fig. 12), controlled by the same common platform, including a common patient database containing both PET and CT data. They include all the technological improvements achieved in both methodologies. New PET scintillation crystals, together with innovative iterative reconstruction algorithms, make possible an increased spatial resolution and count sensitivity, as well as exploiting TOF information. The CT component uses multidetectors, making possible very fast, spiral acquisition at 4, 16, 64 and even more slices, not differently from stand alone CT scanners. The fusion and display software included in the last generations of workstations allows for an easy, intuitive navigation in the data sets and immediate measurement of SUV in the areas of interest. High quality fused images have supported the extraordinary diffusion of PET and particularly its widespread acceptance in oncology.

The possibility of acquisition of gated PET scans, standard feature of all new systems when equipped with proper physiological signals generators (e.g. respiratory gating triggers), can reduce image blurring due to physiological motion and has particular relevance in oncological studies, as a support for accurate treatment planning, and in nuclear cardiology studies.

The high end CT component makes modern PET–CT scanners indicated for all types of study, including applications in nuclear cardiology, given the extended coverage of multislices detectors. However, for the majority of
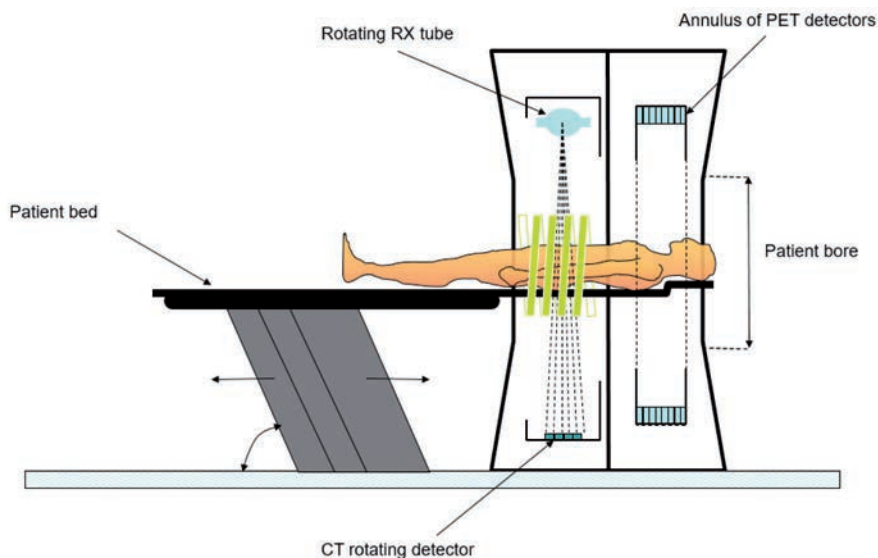
FIG. 12. PET–CT scanner (courtesy of M. Marengo).

oncological studies, a full diagnostic CT scan is not necessary: in this case, low dose protocols with limited current at the X ray tube are adopted, allowing also an extended tube life.

In any case, the fast acquisition of the CT component in a multimodality scan enables to obtain in a short time transmission data for attenuation correction with high statistics, significantly decreasing the total time for completion of a scan needed with 'classical' PET scanners using ^{68}Ge transmission sources, thus optimizing the throughput of patients and the usage of the equipment.

4.3.4. PET–MR

A multimodality imaging system combining PET and MR makes possible the in vivo assessment of biochemical processes while granting anatomical information with excellent soft tissues contrast. However, integrating PET and MRI is a complex technological task. First of all, photomultiplier tubes, typically adopted by the majority of PET detectors, cannot operate within a strong magnetic field. For this reason, the first clinical PET–MR scanners were based on separate PET–CT and MR scanner, installed at a relatively close distance and using a special 'shuttle' bed, to move the patient from one equipment to the other.

Alternative photodetectors have then been introduced, like avalanche photodiodes and, more recently, silicon photomultipliers. These can operate in the

presence of a magnetic field, in particular, fast response silicon photomultipliers have been used in TOF capable PET–MR scanners. All this made it possible to integrate the two systems to allow for simultaneous acquisition, thus preventing the small differences of time and positioning unavoidable in PET–CT. The achievements in this field have led to the development of PET detectors based of fast scintillating crystals associated with highly efficient digital photodetectors that are now adopted by the last generation of PET–CT scanners.

Compared to PET–CT, the use of MR information in the acquisition of multimodality studies presents specific differences and raises new issues. As regards attenuation correction, the basic approach in PET–MR is to segment the images from different MR sequences and classify data into a limited number of component (air, lung, fat, soft tissue, bone), each characterized by a uniform attenuation value in order to obtain an attenuation map. This approach has proven to be sufficiently accurate, even if artefact can still arise in specific cases, like very large patients or metallic prostheses.

With regard to image reconstruction of emission data, PET–MRI systems use the most advanced iterative reconstruction algorithms developed for PET–CT. These include accurate modelling of the system response, improving noise characteristics and spatial resolution of the images. However, considering quantitative aspects, this can result in SUV values overestimated compared to standard PET–CT results (see Refs [21–30]).

4.4. PROBES FOR IN VIVO GAMMA COUNTING

Current counting systems for gamma radiation measurements in vivo are essentially based on two types of detectors:

(a)   Scintillation detectors based on NaI(Tl) or CsI(Tl) crystals, mainly used for thyroid uptake studies;
(b)   Solid state cadmium telluride (CdTe) or CZT crystals, mainly used for sentinel lymph node detection.

Associated electronics provide for amplification, pulse height analysis and counting of the pulses from the detector assembly (see Fig. 13).

4.4.1.   Probes for thyroid uptake studies

In probes used for thyroid uptake studies, a cylindrical NaI(Tl) crystal is usually employed. In most of the cases, a 50.8 mm × 50.8 mm crystal is used, since these standard shaped crystals have an adequate sensitivity for proper
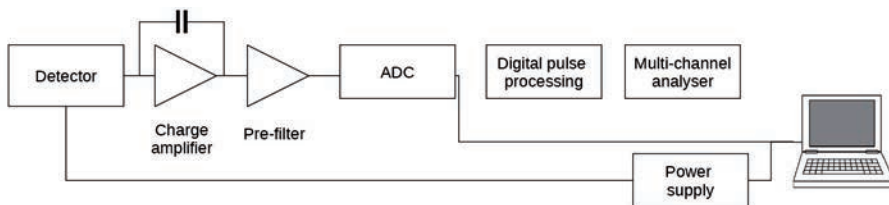
FIG. 13. A generic gamma counting system for in vivo measurements (courtesy of M. Marengo).

detection of ^{131}I, ^{123}I and ^{99m}Tc photons. Lead shielding is provided around the detector, to reduce its response to environmental radiation, as well as a lead collimator in front of the crystal to confer the necessary directional characteristics. The shielded and collimated detector (normally termed as the probe) is usually mounted in an adjustable support allowing it to be appropriately positioned in relation to the patient.

Modern systems are digitally controlled and provided with advanced software that includes protocols for in vivo counting as well as for some in vitro procedures and wipe tests. Quality assurance integrated functionalities typically include energy calibration, energy resolution, minimum detectable activity assessment and reproducibility (Chi-square test on repeated counts) that can be performed with the use of reference standards sources (^{137}Cs and other radionuclides).

4.4.2. Probes for sentinel lymph node detection

Radioguided surgery procedures can nowadays be based on a variety of hand-held intraoperative radiation detection probe systems, commercially available as certified medical devices. The most relevant characteristics of these detectors are the energy resolution, the counting efficiency or sensitivity, and the efficiency of collimation, the latter being aimed to grant a markedly unidirectional response. Scintillation detectors in use are mainly NaI(Tl) and CsI(Tl), but in the case of the detection of 511 keV annihilation photons, also BGO or LSO have been adopted. However, the type of detector most diffused is probably a solid state CdTe or CZT semiconductor.

CdTe is indeed an interesting material for the construction of solid state versions of a ionization chamber detector. It has a forbidden band (i.e. a value of energy for the production of a pair of ions) of approximately 1.6 eV (even lower than that of germanium, used in high resolution spectrometry), with eddy currents at room temperature of a few nA, such as to permit their use also in the absence of refrigeration. Obtaining efficient contact electrodes in these semiconductor detectors is complex, and cultivation techniques of CdTe crystal

are quite sophisticated. However, crystals of relatively small dimensions, which are adequate for surgical probes in the range of photon energies below about 200 keV, can be produced at reasonable costs.

Compared to scintillation detectors, CdTe and very similarly CZT detectors have the advantage of not requiring high voltage biasing and not needing a light conversion system (photomultiplier or photodiode). These characteristics involve less complication and allow probes of smaller dimension. This makes it possible to obtain probes of small sized, relatively light and manoeuvrable, in which lateral collimation is granted by lead or, more frequently tungsten, in a thin layer, sufficient to grant proper lateral shielding in the range of energies of interest. In addition to visual display of count or count rate, these systems are normally provided with an acoustic signal proportional to the count frequency, aimed to give the surgeon an immediate idea of the instrument response, without the need to divert attention from the surgical field for looking at the display.

Many commercial systems, certified as medical devices, are available on the market, including systems in which the probe is wireless connected to the control unit. The control software typically includes routines for daily quality control testing, periodical calibration, as well as functionality for recording the data acquired during the surgical procedure.

4.5. RADIOAEROSOL SYSTEMS

When aerosol is inhaled orally or through the nose, particles deposit on the airways. The major mechanisms of aerosol deposition are inertial impaction, gravitational sedimentation and diffusion. Inertial impaction occurs with larger (>3 μm) fast moving particles. Gravitational sedimentation is a function of particle mass and time, the rate of settling being proportional to particle size and mass. Diffusion occurs with particles having a diameter of the order 1 μm or less.

Larger particles (>10 μm) are filtered in the nose and the oropharynx, largely by inertial impaction. Particles of 5–10 μm generally reach the proximal generations of the lower respiratory tract, and particles of 1–5 μm reach the lung periphery. Aerosol devices that are in current clinical use typically produce polydisperse aerosol, for example a population of particles with different sizes. Conversely, monodisperse aerosols have a substantially limited range of particle sizes and are relatively difficult to produce.

Quantification of the size of particles is frequently made according to the mass median aerodynamic diameter (MMAD), that is the median of the distribution of airborne particle mass with respect to the aerodynamic diameter, or the activity median aerodynamic diameter (AMAD), that with specific reference to radioactive aerosol, is the value of aerodynamic diameter for which

50% of the airborne activity in a given aerosol is associated with particles smaller than the AMAD, and 50% of the activity is associated with particles larger than the AMAD. The higher the MMAD or the AMAD, the more particle sizes are of larger diameters.

4.5.1. Techniques of radioaerosol production

There are currently three major modalities for the production of radioaerosol in nuclear medicine, of which two are based on the nebulization of a liquid solution of a radiopharmaceutical:

(a) Jet nebulizers are based on Bernoulli's principle to convert a solution of a radiopharmaceutical into a fine mist of aerosol particles. A stream of gas is conveyed across the end of a capillary tube. The gas jet reduces the pressure at the top of the tube, causing the liquid to move to the top, where it is continuously extracted as aerosol particles that enter the mask or mouthpiece of the administration system.

(b) Ultrasonic nebulizers employ an electronic high frequency transducer that generates ultrasound waves. These break up the solution into an aerosol mist that is finally inhaled by the patient.

There are several devices commercially available based either on one or the other of these modalities, and there are advantages and disadvantages in each of them. Jet nebulizers are based on a very simple concept, requiring simply a supply of oxygen or medical compressed air; they are operating under a positive pressure, and this may be a drawback, when working with a radioactive solution. Ultrasound generators have a higher output rate, which is a significant advantage for allowing a fast administration, but typically produce particles with a larger size. In both cases, however, a selection of particle diameter can be obtained adopting appropriate aerodynamically selective components (baffles). As a result, the specification for the commercially available nebulizers typically grant an MMAD of the produced aerosol of the order of 1 μm or less.

The third, very specific approach is represented by the Technegas generator (see Fig. 14). This is a miniature high temperature furnace in which the heating element is a crucible in graphite, containing a small amount of the initial radiopharmaceutical solution of ^{99m}Tc. In this way, the heated crucible is a source of a graphite vapor which coats technetium metal crystal. The resulting aerosol (Technegas) is a dispersion of cluster nano sized (~35 nm) pure carbon platelets of hexagonal shape, encapsulating technetium metal crystals. Each particle presents a pure carbon surface to the external environment and results
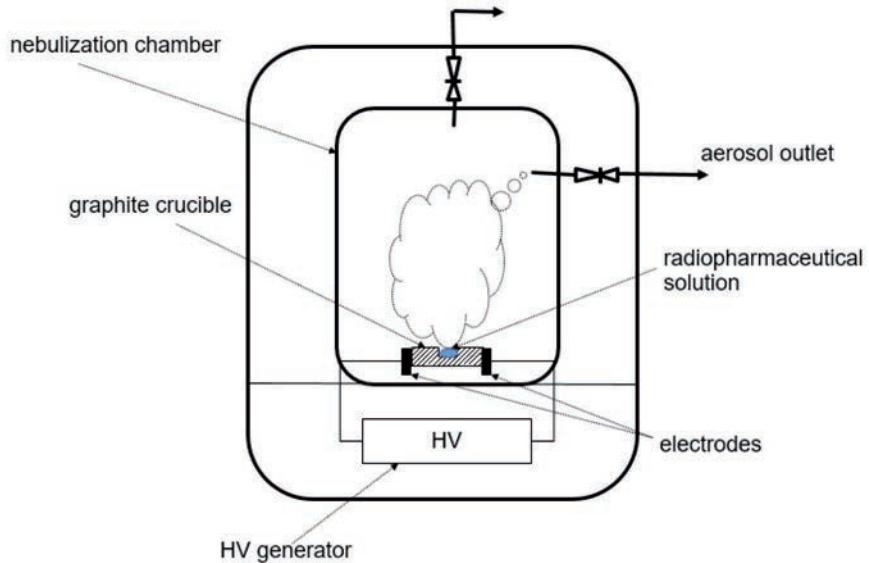
FIG. 14. Principle of operation of the Technegas generator, with a focus on the combustion chamber (courtesy of M. Marengo).

hydrophobic. This characteristic, together with the small size, give to this aerosol a gas like behaviour on inhalation into the lungs.

4.5.2. Safety aspects

All the aerosol generators specifically designed and marketed for use in nuclear medicine are approved medical devices that include safety arrangements aimed at avoiding radioactive contamination of the environment surrounding the administration area and of the staff. These include high efficiency particulate air filters in the line of exhausted gas. However, while operation of these systems is completely safe when properly connected to a laboratory testing apparatus, the connections might be suboptimal and complete tightness cannot always be ensured in reality. For example, the patient might not properly hold the mouthpiece or the mask might not perfectly fit to the face, leading to a modest loss of radioaerosol to the air.

For these reasons, aerosol generators should be used within a well ventilated area under negative pressure in order to allow for a fast extraction of the ambient air and its exhausts after proper filtration. In many cases, it is preferred to adopt a dedicated extractor, with a terminal suction swivel, which can be placed close to the patient during the administration phase of the radioaerosol.

4.6. RADIONUCLIDE ACTIVITY CALIBRATORS

A radionuclide activity calibrator is a specific type of ionization chamber in which the radiation detector has a cylindrical, well shaped geometry. Once a radioactive sample is placed into the well, the measurement geometry is approximately 4π granting a limited effect of variations in the sample shape and position; radiation emitted by the sample produces ionization in the gas filling the chamber and the resulting current is measured by an electrometer, producing a signal that is proportional to the sample's activity (see Fig. 15).

The chamber is sealed and typically contains argon under pressure. The voltage applied to the electrodes and the gas pressure determines the response of the system and is chosen to obtain optimal response, according to the use. The detector is essentially sensitive to X ray and gamma radiation, but also penetrating beta radiation can reach the sensitive volume. For activity calibrators aimed at measuring single photon emitting radionuclides the voltage is frequently
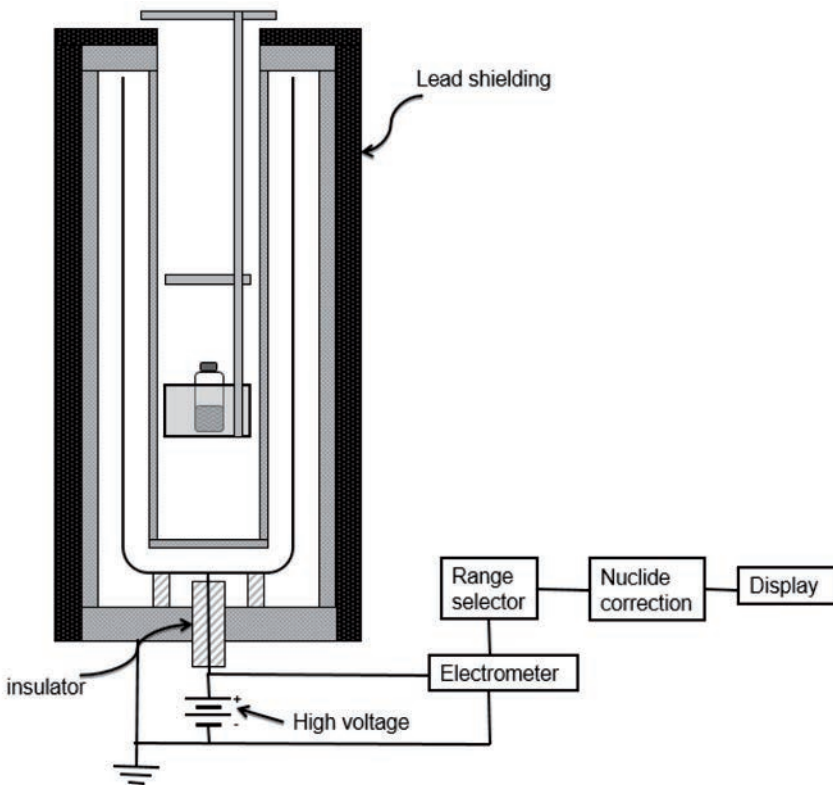
FIG. 15. Ionization chamber (courtesy of M. Marengo).

(depending on the design of the manufacturer) of about 150 V, with argon gas at a pressure of about 1 MPa. In the case of positron emitters, the voltage is typically higher, frequently about 500 V, while the pressure of the argon gas is reduced to about 0.5 MPa.

The ionization current is measured in the electrometer associated with the chamber; a microprocessor then applies radionuclide specific correction factors to convert the reading to an activity value in Bq, that is eventually further corrected to take into account factors for the shape and material of the sample container (plastic syringes of different shapes and volumes, glass vials).

By selecting the radionuclide and the type of container, the operator determines the choice of the correction factor, so that 'a priori' knowledge of the radionuclide in measurement is necessary: the radionuclide activity calibrator is not a discriminating detector, performing an analysis of the spectra of the radiation emitted by the sample, but rather an integral detector measuring all the charge produced by all radiation emitted by the sample in the sensitive volume. It is then wrong to think that the operator, by selecting the type of radionuclide, sets a 'window' peaked only on the gamma radiation emitted by a specific radionuclide, as in analogy to what happens during an acquisition with a gamma camera. By selecting the radionuclide instead, a specific calibration factor is used to proportionally convert the current produced by all radiation emitted by a radionuclide to the corresponding activity.

Radionuclide activity calibrator can be installed as a 'stand alone' instrument; that is, placed on a workbench, or included into a shielded hot cell for samples manipulation or for automatic operation of radiopharmaceutical synthesis modules or dispensing equipment (e.g. unit doses dispensers or vial filling stations). The chamber of the detector can then be shielded differently, the shielding being mainly aimed at avoiding interference from radiation coming from the surrounding environment in the measurement process, as well as at protecting the operator, limiting the radiation from the detector. The amount of shielding surrounding the detector determines a variable amount of sample's radiation backscatter into the chamber, thus influencing the final measurement.

Despite the apparently simple operation of the equipment, calibration of the radionuclide activity meters is then a delicate process, in which many factors need to be taken into proper account. In order to obtain proper traceability to the international standards of the measured quantity (activity), calibration needs to be made with certified standards of each specific radionuclide in current clinical use. The fact that an instrument's results are properly calibrated when tested with a certified source of a specific long lived radionuclide (e.g. ^{137}Cs) do not automatically means that it will correctly measure other radionuclides, such as ^{99m}Tc, ^{18}F or ^{131}I. Factory stored calibration factors cannot be assumed to be accurate if traceability to international standards is not certified (e.g. by

a secondary standard radioactivity laboratory), or certified standard sources of the specific radionuclide are used. This aspect is particularly challenging when short lived radionuclides are involved. In these cases, however, the following approaches are possible:

(a) Cross calibration with a chamber calibrated by a secondary standards laboratory within specified limits of accuracy.
(b) Use of 'mock' standards, for example a standard based on a long lived radionuclide that emits the same radiation as the clinically used short lived radionuclide, and is certified in terms of equivalence to the short lived radionuclide and traceable to international standards. As an example, standards of this type have been produced for the short lived positron emitter ^{18}F, based on ^{68}Ge/^{68}Ga.
(c) Use of an accurate Monte Carlo simulation of both the ionization chamber and the sample, to derive calibration factors; this methodology is currently under investigation. Some promising results have been published and its effective role will be clarified by further research.

When pure beta emitters are considered (e.g. ^{90}Y), the signal produced in the detector is mostly due to bremsstrahlung radiation produced in the interaction of beta particles within the sample itself and its container. In this case, geometric factors become extremely important and specific calibration procedures are necessary.

A radionuclide activity calibrator is typically supplied with several accessories, such as a syringe/vial dipper, allowing for reproducible sample positioning, and a plastic lined cover for easy decontamination of the ionization chamber well. When acquiring a new meter, it is good practice to buy spare parts of these simple but essential components. Modern calibrators are frequently computer controlled. The software allows for introducing patient's name, weight and information on the batch of the radiopharmaceutical in use. This makes possible to print patient specific labels, reporting these data and the measured activity and reference time that can be stick to individual syringes (or their container), helping traceability and limiting the risk of mis-administration.

5. INFORMATION TECHNOLOGY, NETWORKING, ARCHIVING AND GENERAL OFFICE EQUIPMENT

5.1. INFORMATION TECHNOLOGY

5.1.1. Radiology information system

Nuclear medicine facility typically use RISs as patient management databases. Standard functionality of this system should include managing a patient's personal details, procedure details and study results. Other functionality can include: the ability to schedule patient bookings; track patients; scan in procedure request forms; transfer to the acquisition modalities the worklist of patients; bill and invoice patients; and electronically distribute patient results to the referrers. Advanced functionality can include the ability to query and extract specific information for purposes such as research, performance analysis and benchmarking, and financial analysis and business reporting. A good RIS should provide a streamlined workflow for efficient study reporting, preferably integrated with a PACS to maximize productivity.

When a nuclear medicine facility is part of larger hospital networks, it is often possible to integrate the RIS with the hospital information system (HIS), as well as with other specific programmes, such as those for the management of the radiopharmacy laboratory. This will allow the RIS to directly import patient information (e.g. personal details, admissions history) from the HIS. Many different RIS programmes are available. However, regardless of the functions they offer, it is important that they are able to generate and receive compliant health level 7 (HL7) messages. HL7 is an international standard that relates to the transfer of electronic information between health service software. As long as the RIS is able to handle HL7 messaging, it should be able to transfer patient and study information between itself and PACS, HIS and any other health software system as required.

5.2. PICTURE ARCHIVING AND COMMUNICATION SYSTEM

PACS is a technology that allows for the digital storage and access of scan data acquired on diagnostic imaging systems [31]. An integrated PACS network often involves a centralized server which permanently stores the patient data and images and remote PC workstations to view the data. The size of a PACS network is scalable depending on the requirements of the nuclear medicine facility. PACS often eliminates the need to generate hard copies of images,

replacing the need for physical scan archives. Study images and results are easily viewable on any PC or workstation connected to the PACS network, improving productivity and workflow by providing a fast and convenient way to view scans from any location.

A nuclear medicine facility which is part of a hospital network or even a large diagnostic imaging practice may find most benefit from an integrated PACS network. The PACS server will be able to receive images and reports from all imaging modalities, which can be viewed throughout the hospital network, either on dedicated PACS workstations or via specialized software installed on regular PCs. Having all imaging modalities connected to the PACS network is a great benefit when reporting studies, as it allows for the easy viewing of correlative images. Smaller PACS software solutions are also available, often for free via the Internet, for facilities that may not require a large networked system but still want to utilize the convenience of PACS. Some PACS networks also allow off-site viewing of studies via secured network connections, allowing for teleradiology.

Considerations for the implementation of a PACS network include costs for PACS software, PACS network (either the installation of a new network, or the improvement of existing network infrastructure), PACS server and workstations and monitors (either the purchase of new PCs or the upgrade of existing hardware for PACS compatibility). The type of monitor required is dependent on the image modality that will be viewed on them. Commercially available monitors capable of 1080 p resolution will be sufficient for nuclear medicine images. However, if higher resolution modalities such as mammography and plain film X ray will be viewed, then specialized PACS monitors of at least 3 MP resolution will be required. Ongoing costs of a PACS network can include PACS maintenance agreements, electricity and upgrading the server size (to ensure the continual sufficient capacity for images/reports). Costs for the PACS software licences can either be upfront or ongoing, depending on the vendor. There also needs to be practices in place for frequent server backups with established plans to manage data loss and downtime in the event of a server or system failure.

It is usually advisable that the raw data from gamma cameras is archived for any future retrieval and review. All major vendors of imaging equipment usually provide an archiving solution for the storage of patient data on physical media (e.g. CD, DVD, digital audio tape). A PACS server can provide an easy data archive and retrieval option. However, many PACS programmes are unable to display raw nuclear medicine data in a useful manner. Therefore, it is often necessary to archive screen captures of suitably processed and displayed studies to PACS. If only screen captures are archived to PACS, then the raw data still needs to be archived. It is also possible to print images from a PACS network to a physical medium (e.g. laser printer, film printer), archive to CD/DVD or export to a USB. The selection of screen capture images by the physician or technologist

is critical. This image may be the only visual result available to the referring physician, sometimes during surgical procedures and hence may be an integral reflection of the facility's work performance.

PACS uses the DICOM (digital imaging and communications in medicine) standard for the transmission, archiving and printing of images and for its integration with other equipment, modalities and networks. In order to communicate with PACS, it is therefore necessary for all gamma cameras to come with DICOM conformance and compliance statements, which list the DICOM classes they support. For full integration with the RIS, the PACS must be able to communicate using HL7 messages. This integration will also ensure that all reports entered into the RIS will be available on the PACS. Some PACS vendors also provide a RIS solution, which will maximize compatibility between the two systems.

Gamma cameras can be used in worklist modality through full integration with RIS and PACS. This will enable the gamma camera to obtain all the details relating to a patient and their study electronically, eliminating the need to manually enter this information. This will then ensure there is continuity between the patient's personal details, procedures details, scan images and results between the RIS, PACS and gamma camera.

5.3. IMAGE DISTRIBUTION

Even if a PACS network is used in the nuclear medicine facility, it is often necessary to physically distribute a study either as a CD or DVD or as a hard copy from a printer capable of producing high quality, high resolution images, preferably at a minimum of 300 dpi (dots per inch). A colour laser printer is the most suitable device for this job. Laser printers are preferable to inkjet printers because they can render fine detail as well as printing documents other than nuclear medicine scans. However, it is vital that the print quality of a printer is assessed prior to purchase to ensure it is capable of producing images of a diagnostic quality.

Alternatives to conventional printers include DICOM printers and digital imagers. These are specialty products that produce high resolution hard copies for diagnostic imaging modalities. They are usually sourced via specialty vendors and can often be quite expensive, as can be their consumables (i.e. paper, film). Furthermore, not all of these devices print colour images, which might limit their suitability. However, as they have all been designed specifically for diagnostic imaging, the hard copies they produce will always be of diagnostic quality.

Scans can also be distributed via CD/DVD in DICOM formats or as images (e.g. JPEG, TIFF, BMP). Nuclear medicine imaging equipment includes PC

software to enable technologists and physicians burn disks containing DICOM images. For high volume production, dedicated burners can interface with the scanner workstations or PACS network. To view DICOM formats, specific software is required and is usually included on the disk. However, compatibility issues can still prevent the images being viewed correctly. The DICOM files can include raw and processed data, but it should be noted that not all viewing software presents data in the same way, and therefore might not display the raw or processed data in a meaningful or relevant manner. It can often be missing labels and annotations, and the intensities will often need to be readjusted. To avoid this, screen captures can also be included on the disk.

The screen capture of the processed scan can also be in an image file format (e.g. JPEG, TIFF, BMP). In order to create a disk, scan data are first saved in an image file format, and then burnt onto a disk directly from the gamma camera workstation or exported to another PC capable of burning a disk. Depending on the capabilities of the gamma camera workstation, this process can range from being very simple to very difficult. The benefit of using an image file instead of a DICOM file is that it does not require any specialized software to view. The image file is essentially a digital version of a hard copy, so it includes all the correct labels, annotations and accurate intensity levels. However, unlike a DICOM file, an image file cannot be manipulated in any way. It is also important that the image file is an appropriate file format. Some file formats do not accurately reproduce colour scales, or can introduce artefacts by overly compressing the image. Therefore, it is important that all image files are assessed prior to distribution to ensure that they are still of diagnostic quality.

5.4. DOCUMENTS SCANNERS

Many RISs and PACSs allow documents (e.g. study requests, letters, patient notes, electrocardiograms) to be saved using conventional consumer level scanners. There is no restriction to the type of scanner used as long as it is compatible with the RIS and PACS and the PC it is connected to and produces scans of a suitable quality. Document scanners with a sheet feeder can scan multiple pages, making them very fast and efficient. However, they are limited to scanning single pages. Flatbed scanners can also scan books but are bulkier than document scanners and each page needs to be scanned individually. Flatbed scanners with inbuilt document feeders are also available. The scanner choice is ultimately determined by the functionality requirements of the facility and the compatibility with the facility's existing hardware and software.

5.5. LABEL PRINTING

Most RISs print customized adhesive labels (e.g. patient labels, study labels, document labels, invoice labels) displaying specific information taken from the RIS itself. Similarly, some radionuclide activity meters (i.e. dose calibrators) are able to automatically print labels containing the indication of the radiopharmaceutical, its activity and other details (e.g. batch number, expiry date, time). Using labels generated by a RIS reduces the need for manually writing this information and, assuming the details are correct, ensures accuracy in the displayed information.

Laser printers and inkjet printers are unable to print individual labels, so a dedicated label printers are the most efficient way to print high quality individual labels. Dot-matrix printers can also be used, but the lower print quality makes them unsuitable for many situations (e.g. barcodes). Direct thermal printers use special chemically treated labels made of a heat sensitive material which blackens when exposed to the heat of the printer head. No ribbons or toners are required, making them cheaper and easier to operate, but the readability of this label can degrade over time due to excess heat, light or physical contact, making them unsuitable for long term storage. Thermal transfer printers work like conventional printers, using printer ribbons and plain paper labels. The high quality and durability from using ink and paper means this label will maintain readability for a significant time, making it suitable for long term storage.

The factors determining the type of printer chosen are the availability and cost of the printer and consumables (where applicable) and its compatibility with RIS, dose calibrators and existing PC hardware and software.

5.6. NETWORKING

5.6.1. Data transfer

A data network is an essential component for the communication and transfer of data between devices. Most commonly data are transferred between computers, workstations and external hardware via an ethernet connection (a cable connected directly to a port on the hardware), which is favoured for its speed, reliability, availability and ease of use. As most hardware only has one physical ethernet port available, to send and receive data to and from multiple sources requires all PCs and hardware to be connected to a communal data network. In some cases, wireless networks can also be configured where a physical connection is not possible or suitable.

Without a data network, each workstation and computer operates as an isolated unit, with no simple capacity to transfer data or share attached peripheral equipment (e.g. printers, scanners). This may be a suitable scenario in smaller facilities, but as a facility's size, complexity and level of integration with other modalities, work sites and hospitals increases, so does its reliance on a data network. Some worksites may already have an existing network infrastructure that can be utilized by the nuclear medicine facility. In some situations, however, it may be necessary to expand this network or create a new one in order to meet the requirements of the facility.

5.6.2. Local area networks

At its simplest level, data communication in nuclear medicine involves a single, direct connection between a gamma camera and a single workstation, with no other workstations or computers involved. However, if there is more than one workstation required, then a local area network (LAN) connecting the gamma camera and multiple workstations needs to be used. A LAN is a data network contained within a single geographical location, such as a nuclear medicine facility, a diagnostic imaging facility or a hospital. Each device, workstation or PC connects to an ethernet port and from each of these ports runs a cable connecting to a centralized location, such as a hub or switch. When data are sent from a PC or workstation through a network, it reaches this centralized location, where it is forwarded to another specific device or made available for access from all devices connected to the network.

5.6.3. Servers

If data need to be sent and stored for access from multiple PCs or workstations (i.e. for a RIS or PACS), then a server is also required. This is usually a dedicated computer or device that manages a network and stores data for access throughout that network. For example, a RIS server will store all patient and study information available, making the same data available for anyone using the RIS software. In addition to RIS and PACS servers, other types of server have a role in nuclear medicine facilities: file servers can be used to store software data (e.g. documents, spreadsheets); and print servers can manage multiple printers across a network.

Size requirements for a server are dependent on the data to be stored. A RIS server storing only text based data has a relatively small size requirement compared to a PACS server which will be storing large amounts of diagnostic image data. The types of diagnostic data being stored can also affect server size requirements. Nuclear medicine data size is traditionally very small when

compared to high quality CT or MRI data and therefore can have smaller server size requirements.

The addition of a server to a network is burdened with increased costs, not just in the initial purchase price but for ongoing maintenance and, as more data are stored on the server, storage capacity must be continually increased to meet demands. This should be negotiated with the local supplier or maintainer of the server. If possible, the server space can be partitioned to provide storage and access for other departments, who can then share the costs for the server.

5.6.4. Data backup

The data stored on a server must be backed up daily, with disaster recovery plans in place, to prevent the chance of data loss in case of a server malfunction. This is especially relevant to both RIS and PACS data where there are often legal requirements that govern the minimum time required for the long term storage of patient information.

Examples of disaster recovery plans include database mirroring and off-site backup. Data mirroring is where an up to date copy of the main server is created and maintained on a separate machine. In case of an error with the main server, the mirrored server can quickly take over. A mirrored server also ensures that data are continually accessible if maintenance is being performed on the main server. Off-site backup is where data are sent to a separate physical location for secured storage. Data can be transferred either electronically or via physical storage media. This will ensure that patient data are still recoverable even in the event of a significant disaster affecting the main server.

5.6.5. Network speed

A key goal of PACS is the efficient transfer of images for convenient viewing. The potentially large file size of images communicated across a PACS network requires a network infrastructure with the capacity to consistently transfer large amounts of data as quickly as possible. However, if a PACS network is not required, then the demands on the network are significantly reduced.

For the transfer of smaller data sizes, such as RIS data, document files or images from a gamma camera, a normal ethernet speed of 100 Mbps is suitable. Higher transfer speeds, such as those delivered by a gigabit ethernet connection (1 Gbps) are also available but are only of added benefit if there is consistent viewing via PACS of high detailed diagnostic images such as MRI or CT. When implementing a network, any connection speed can be used, the only impact is the time it takes to transfer the data.

It is also important that a network is able to maintain its speed at all times. The continual transfer of large amounts of data across a network can cause congestion which will slow network access for all users. By creating a virtual LAN for the PACS network, the transfer of image data will be isolated so that it does not negatively affect the rest of the hospital network's speed.

5.6.6. Wide area network

For data transfer between individual physical locations i.e. between hospital campuses or diagnostic imaging worksites, a wide area network (WAN) can be used. A WAN is two or more LANs that can securely transfer information across separate geographical locations via telecommunications lines. It is also possible to use a virtual private network to create a secure network between locations across the Internet.

5.7. ARCHIVING

Scan data should be archived for long term storage. All gamma camera vendors should provide an archiving solution, whether it is a disk (CD/DVD) or multiple hard drives. PACS is also a convenient option, with easy data archiving and retrieval, and a limited potential for data loss when compared to external media, which can be corrupted, damaged or lost. However, a PACS server malfunction without a sufficient backup available could result in large scale data loss. A storage area network (SAN) is also a possible option by providing a networked storage server that can only be accessed from specific workstations. When evaluating archiving options, a comparison should be considered between the costs of upgrading PACS/SAN server capacity to meet continuing storage requirements versus the ongoing cost of physical media. Another option for archiving is the use of hardcopy images (paper or film). However, this is not recommended as hardcopies can be easily damaged or lost, it can be costly and long term hardcopy storage requires significant physical space. There is also no ability for reprocessing and redisplaying scan data. Non-scan data, such as study request cards, electrocardiograms, clinical history documents, and reports can be stored digitally (either scanned or entered directly into a RIS, PACS or other software) or physically archived.

A newer archival option that is becoming available is a vendor neutral archive (VNA), which stores images and documents in a standard format that allows them to be shared across other systems and among multiple organizations. The files that can be archived on a VNA are not restricted to DICOM data. Any

file type (audio, video, image, text) can be stored and subsequently viewed using the VNA document viewer.

5.8. OFFICE EQUIPMENT

Office equipment should cover the basic clerical demands of a facility. Telecommunication equipment should include a business phone system and fax machine as well as access to a reliable email system. Equipment for document management includes a printer, a photocopier and a scanner. Multifunction devices that combine components into one machine (e.g. printer/scanner/fax/copier) are often a convenient equipment solution. All equipment is acceptable as long as it meets the quality, speed and functionality requirements of the facility.

Multiple computer configurations are available with many variables, from their hardware components such as, memory (RAM), processor type and speed, hard drive size, external media (e.g. CD, DVD, CD-R, DVD-R) to their software components (e.g. operating system, installed programmes). The most important factor when choosing a computer configuration is that it meets the system requirements of any software (e.g. RIS, HIS, PACS, billing software, word processor, email, Internet, spreadsheet software) and hardware (e.g. scanner, printer) required. If the new computers being purchased are intended to be part of a larger network (e.g. diagnostic imaging facility, hospital) specific hardware requirements may need to be met to ensure system compatibility and integration. It is also important to consider any possible future requirements for the facility when choosing a computer configuration. Technology support in the local area should be an important consideration in selecting an individual brand or provider.

6. HUMAN RESOURCES

Human resources can be defined as the total knowledge, skills, creative abilities, talents and aptitudes of the workforce in a given organization, including the values and attitudes of the individuals making up the organization. No development is possible without proper planning, and human resources planning is a prerequisite to human resources development (HRD). Human resources planning in nuclear medicine must provide for the implementation of ongoing activities, meeting the demands of changing technologies and expansion programmes, replacing a workforce dwindling as a result of retirement or separation.

Strategic thinking plays a vital role. It is imperative to define the objectives of a nuclear medicine enterprise in order to forecast future needs. A comparison of current human resources with future needs will reveal deficiencies or gaps in the competence of the workforce and provide a framework for remedial action. Proper job analysis will lead to a clear division of responsibilities and avoid unnecessary duplication and overlap. The objectives of HRD in nuclear medicine are listed in Ref. [4].

It is relatively easy to forecast human resources needs once the objectives of nuclear medicine are clear, provided a reliable database is available showing the breadth and depth of nuclear medicine practice, the range of nuclear medicine products and services, and the profile of the nuclear medicine workforce. It will be possible to extrapolate future needs from this database in terms of the size of the workforce, staff in each category (i.e. physicians, medical physicists, technologists, radiopharmacists, nurses, support staff), and qualifications and experience. It is important to note the age structure of the workforce in order to plan for replacements as a result of retirement and separation.

The ultimate aim of HRD is to place the right people at the right time in the right position so as to tap the full potential of the workforce for the benefit of the organization and its staff. There is a current shift in paradigm towards individual centred human resources management. An employee is not merely allocated work and treated simply as another resource, but the self-respect and dignity of the individual are protected and respected. HRD builds a work culture where each of its members is happy and satisfied with work and life.

At the country level, the development of human resources for nuclear medicine involves partnerships with the government (e.g. ministries of health and education at the centre and at the regional level), professional bodies (e.g. societies of nuclear medicine and their branches, and associations of medical physicists) and academic bodies (e.g. national boards and colleges of nuclear medicine). Sincerity of purpose, commitment to the cause, and close cooperation and collaboration among partners are essential for effective HRD in nuclear medicine. HRD entails the effective management and development of staff to match present and future needs. At the country level this is a complex task and requires a prodigious amount of data collection, processing, analysis, interpretation and implementation. The conventional tools of HRD include recruitment, induction, mentoring, training, development, teamwork, performance appraisal, feedback and counselling, and rewards and disincentives. Depending on local situation, some of these functions may have to be centralized while others should be decentralized. Although each of these tools is important, this section focuses on recruitment, training and performance appraisal, feedback and counselling for personal development, all of which require a great deal of thought, innovation and attention to detail.

A minimum recruitment standard should be defined for each substantive post in every category of job in nuclear medicine. These standards should be binding on all hospitals, institutions and clinics that provide nuclear medicine services for patient care. A task force comprising representatives from each party in HRD should take responsibility for preparing the minimum recruitment standards. It should be mandatory to involve a suitable member from each job family to help prepare the minimum standards, thus ensuring confidence in, and adherence to, the requirements of the recruitment process. Over and above these minimum standards, the employing authority concerned should prepare detailed job analyses for each post in nuclear medicine, including a clear and concise job description, job specification and job design. They should also define standards of performance, develop models for personal competence and link these for each job. These standards and models will serve as benchmarks for comparing actual performance of individuals, a crucial step in the implementation of performance appraisal, feedback and counselling for personal development. Collection and codification of all these data on recruitment at the national level should lead to guidelines for the recruitment of a national nuclear medicine workforce that will serve as a reference for all those engaged in the practice of nuclear medicine in a particular country. The recruitment process should reflect the values of the organization and its goals. Professional expertise and personal integrity are of crucial importance in the selection process, since without the right people for the right job there is little chance of success.

6.1. ROLES AND RESPONSIBILITIES

6.1.1. Nuclear medicine physicians

A nuclear medicine physician is a qualified medical doctor who has had specialist training in nuclear medicine, including the safe handling of nuclear materials. Nuclear medicine is a multidisciplinary practice and the training of medical doctors is critical to the performance of a nuclear medicine facility. The responsibility of the nuclear medicine physician is:

(a) To define the clinical appropriateness and justification for the request or referral, both for diagnostics and for therapy;
(b) To have the overall responsibility of all nuclear medicine procedures, including quality assurance aspects;
(c) To give instructions, based on the facility's SOP, for the appropriate tests and protocols;

(d) To tailor the protocols to the needs and condition of the patient when necessary;

(e) To assess and carry out interventions (physiological or pharmacological) when needed;

(f) To interpret the study based also on the clinical information;

(g) To interpret the results and to provide a diagnosis insofar possible;

(h) To adhere to SOP to ensure the safety of both the patient and staff;

(i) To provide training (and education) for technical and junior medical staff;

(j) To ensure proper operations of the facility in adherence with quality management rules when in managerial position.

Physicians specializing in nuclear medicine are trained through official programmes of the faculty of medicine or other programmes recognized by the competent bodies. Upon completion of the training programmes they obtain a degree from the appropriate academic institution or competent body. This qualification forms part of a process to accredit medical practitioners, as specialists in nuclear medicine.

6.1.2. Medical physicists

The use of sophisticated equipment and unsealed radiation sources calls for particular attention to radiation protection and safety and quality assurance. In this setting, the responsibility of the medical physicist for the following areas is defined in GSR Part 3 [9] (see also Ref. [32]).

6.1.2.1. Radiation safety

The main responsibility of the medical physicist is for the patient protection, while the RPO has responsibility for only staff and public protection. The RPO is often a trained medical physicist, although responsibility in a small facility may be delegated to another professional, provided advice can be sought from an available expert.

6.1.2.2. Specification, acceptance testing and quality control of instrumentation

The medical physicist is normally directly involved in equipment procurement and takes direct responsibility for acceptance testing and establishment of routine quality controls. In many cases, technologists perform routine quality control, under the supervision of a medical physicist.

6.1.2.3. Maintenance of equipment

The medical physicist is familiar with the operation of the equipment and can identify problems correctly. Medical physicists can undertake first line troubleshooting of equipment in liaison with the supplier or service personnel.

6.1.2.4. Computer system management and support

Increasingly, the medical physicist takes responsibility for overall computer system management and provides advice on computer use as well as first line support for application software. In some countries, the medical physicist is directly involved in routine computer analysis. However, this is the responsibility of technologists in most countries.

6.1.2.5. Development and validation of clinical studies

Nuclear medicine is a continually evolving field and functional information is increasingly obtained from quantitative analysis. The medical physicist usually works closely with the nuclear medicine physician to provide technical advice relevant to the execution of studies. Frequently, software needs to be developed or adapted with the subsequent validation of newly developed procedures.

6.1.2.6. Patient dosimetry and dose optimization

The medical physicist is actively involved in dose optimization, advising on the safe use of radiation and ensuring the quality of diagnostic or therapeutic procedures. The medical physicist is responsible of the determination of patient dose resulting from the administration of radionuclide activity, as well as fetal doses in cases where pregnant patients need to undergo nuclear investigations.

6.1.2.7. Supervision

The medical physicist supervises and contributes to the quality management system (QMS). The medical physicist should also supervise measurement, dispensing and sometimes administration of radiopharmaceuticals for therapeutic purposes and is also involved in radiation safety related to this procedure.

6.1.2.8. Administrative tasks

The medical physicist participates to the management and purchase of equipment and radioactive sources. Most of the above duties involve

administrative tasks such as the preparation of guidelines, record keeping and communication with other professionals and suppliers. The physicist is usually directly involved in the planning of facilities, equipment used and procedures.

6.1.2.9. Teaching and research

Most medical physicists are involved in teaching other professionals (e.g. in radiation safety and instrument principles). Many are actively engaged in development work or undertake phantom experiments as part of validation procedures (applied research) or are involved in clinical research projects (e.g. data analysis, statistical advice).

6.1.3. Radiopharmacists

Radiopharmacy is an essential and integral part of all nuclear medicine facilities. In practice, it is apparent that the preparation of radiopharmaceuticals is performed in a wide range of disciplines including technologists, physicists and nurses. Although pharmaceutical expertise and oversight is essential, the process is not always managed or performed by a pharmacist, which, although desirable, is not necessarily achievable. Standards of practice need to be consistently high, irrespective of the background of the staff performing the process.

Training should be adapted to the background and level of expertise of the trainees in order to ensure that they have the necessary grounding in those aspects of radiopharmacy relevant to their intended role [8, 33]. In most cases that are competency based in which understanding of SOP theory and practice is appropriately established and signed off by authorized person. The pharmacist or person managing the preparation of radiopharmaceuticals needs to be able to demonstrate a thorough knowledge of all areas of the specialty. The responsibilities of a radiopharmacist include the following:

(a)   The safe preparation and dispensing of radiopharmaceuticals to national regulations;
(b)   Quality control and record keeping;
(c)   Follow-up factors affecting unusual biodistributions of radiopharmaceuticals;
(d)   Oversight and governance of 'hot laboratories' and patient safety.

6.1.4. Nuclear medicine technologists

The nuclear medicine technologist plays a critical role in the routine practice of nuclear medicine, since the quality of work and care taken during diagnostic studies determines the ultimate diagnostic capability of the test being performed.

In many countries, the importance of training technologists has been poorly understood, and consequently the professional development of this group has lagged behind that of others. As a result, there are many technologists working in nuclear medicine who have had little or no formal training. The IAEA has taken this into account and developed a distance assisted training programme.[2]

The role of the nuclear medicine technologist is to perform diagnostic studies. This involves understanding the overall procedure and taking responsibility for all technical aspects of the study. The breadth of responsibility varies in different countries, with an overlap of activities between different professional groups (e.g. nurses, radiopharmacists), depending on resources. Where comprehensive training is established, and based on existing SOP, the tasks undertaken by a technologist are likely to include the following:

(a) Radiopharmaceutical preparation and quality control especially at IAEA hospital radiopharmacy operational levels 1 and 2;
(b) Activity measurement;
(c) Patient preparation;
(d) Radiopharmaceutical administration;
(e) Scanner preparation;
(f) Image acquisition;
(g) Data processing;
(h) Display of imaging or data;
(i) Routine nuclear medicine equipment quality control;
(j) Routine nuclear medicine workplace radiation monitoring;
(k) Contribute to save handling of radioactive waste.

Technologists are also likely to have responsibilities in management (personnel and data), teaching and research.

6.1.5. Nurses

The role that nurses play in patient care is just as important in nuclear medicine as in any other clinical practice. A nurse is the first interface with both in and outpatients and, following appropriate indications from the attending physician, should be able to inject patients with radiopharmaceuticals after training in radiation protection issues. The presence of nurses in the therapeutic

_____

[2] For further information, see https://humanhealth.iaea.org/HHW/index.html

nuclear medicine wards and during nuclear cardiology stress testing is essential. Nurses in nuclear medicine can be required to perform the following duties:

(a) Booking of patients;
(b) General physical and mental care of patients;
(c) Examination of vital signs;
(d) Administration of drugs and injections on the instruction of doctors;
(e) Explanation of procedures to patients and provision of support to the receptionist;
(f) Handling of radiopharmaceuticals and radioactive waste in cooperation with pharmacists and technologists;
(g) Handling and care of consumables and pharmaceuticals used in nuclear medicine;
(h) Safe collection and handling of blood sample;
(i) Taking appropriate radiation protection measures for patients and families especially those comforting children and elderly people.

In order to carry out these functions correctly, nurses need a basic knowledge of radiation, radionuclides and the biological effects of radiation and should receive training on the safe handling of radioactive materials as well as radiation protection.

6.1.6. Supporting staff

Office staff in nuclear medicine should have a basic training on the specificity of the process in nuclear medicine, in order to fully understand their responsibilities. An introductory training on patient radiation protection is also necessary, to understand the relevance of medical exposures and avoid unnecessary repetitions, as well as the necessity of proper patient preparation.

Cleaners need specialized training, since they will operate in a classified area in which radioactive contamination is possible. Clear instruction on management of all types of waste should be imparted. Cleaning products and equipment should be specifically dedicated for use in nuclear medicine. So specific training is needed in case of laboratories and imaging rooms cleaning.

6.1.7. Coordination with other clinical services

Nuclear medicine techniques require a multidisciplinary approach. Other specialists (e.g. cardiologist, endocrinologist, radiologist, oncologist, pulmonologist) may contribute to the report. Experts recommend participation in multidisciplinary meetings, such as tumour boards is highly advisable.

Multidisciplinary care is a standard feature of high quality care. In many centres, multidisciplinary meetings is an integral component of clinical practice. Health professionals from medical and allied health disciplines review diagnostic imaging and pathology, jointly discuss a patient's case, and recommend a treatment plan. This approach eventually results in evidence based practice that is individualized for the particular patient. For the nuclear physician, the value of participation is also to nurture personal clinical competences and to inform of the value of nuclear medicine studies and to learn from the general discussion.

6.2. TRAINING NEEDS

Training is fundamental to HRD since it ensures a viable and knowledgeable workforce. By measuring the actual performance of each person of the workforce with the agreed standards of performance, it will be possible to identify training needs. Training should only be conducted with the full consent of the future trainee, whose individual aptitudes and capabilities should first be considered. Training should be seen as a competence building and personal development. A training programme should lead to concrete plans of action and new directions to meet the challenges of the future. It should serve the purpose of the organization as well as the needs of the employee. In this respect, constructive trainee participation in the formulation of the training programme is necessary.

With good planning and organization, it should not be difficult to provide continual education and training to all categories of professional, using, where necessary, the services of existing training centres. What needs to be specified clearly is the standard of the end product of training. Personal competence models can be developed and linked to standards of performance upon the completion of training. This will help in the monitoring, evaluation and improvement of the training programme.

Periodic accreditation of professionals in nuclear medicine through an acceptable evaluation process should be part of continual education and training programmes for the nuclear medicine workforce. This will not only ensure that the workforce has up to date knowledge and skills to provide the best service to customers, but will also serve to boost morale and confidence.

Performance appraisal, feedback and counselling are essential ingredients of HRD. The implementation of these tools requires a high degree of sensitivity, objectivity and firmness on the part of higher management. Performance appraisal should be approached positively. It is a highly developmental mechanism and not a tool for dispensing discipline or perks.

Competence might be broken down into knowledge, skills and attitude, and incorporated into the performance appraisal mechanism. An appraisal exercise

should be carefully planned and the assessment based on mutually agreed targets. Appraisals should be carried out periodically so that the organization can track the growth and development of a person over a period of time. The appraisal should also help in the planning of further training needs. Positive feedback and counselling will reveal any deficiencies or negative attitudes. Feedback and counselling should be considered as an aid to learning and development.

Whereas HRD was originally conceived as a management tool to increase productivity and profit in business and industry, it has now become an important part of many organized endeavours. It is an integral part of a system known as enterprise resource planner that is currently the object of keen interest in the business world. Strategic planning, and the use of computers and IT, should all make HRD in nuclear medicine easier than before. Software application programmes are provided by IT experts to make the HRD process considerably less daunting than it otherwise might appear. HRD can provide a sense of direction to a nuclear medicine group, by providing definite goals and the means of achieving these goals, as well a sense of fulfilment to those involved.

7. HOSPITAL RADIOPHARMACY AND RADIOPHARMACEUTICAL PREPARATION

This section focuses on the diversity in hospital radiopharmacies and radiopharmaceutical preparation. The ultimate level of operational and quality is determined by clinical requirements and choice to 'purchase or prepare' radiopharmaceuticals at the hospital levels. These factors (operational and quality systems) need to be built in. Therefore, key IAEA guidance and references are also provided and can be applicable at different clinical practice levels to ensure safety to patient and operators involved with handling of radiopharmaceuticals.

The range of radiopharmacy facilities (commonly referred to as 'hot laboratory') required within nuclear medicine varies markedly depending on the clinical services and decision to purchase or prepare radiopharmaceuticals. Radiopharmaceuticals are medicinal products under national regulations containing radioactive isotope of short half-life (limiting shelf life) for local use. Therefore, radiopharmacy needs the appropriate staffing, facility, operating system, quality systems and equipment necessary to provide radiopharmaceuticals of the desired quality and safety for patient administration. The facilities should be adapted to suit the radioactive nature of the medicinal product (see SSG-46 [6]) and the fact that many radiopharmaceuticals are administered intravenously and thus need to be prepared aseptically and therefore sterile injections.

Any radiopharmacy will also require quality control procedures (which forms part of a QMS), as well as secure areas for the receipt and storage of radioactive materials and radioactive waste prior to its disposal. Whichever functions are being performed, it is crucial that laboratories offer safety and protection to the operator, the radiopharmaceutical and the environment. Risk assessments before starting the service and any new procedure should be performed. The operator needs to be protected from radiation emitted by the products, and facilities must minimize both external radiation hazards and internal hazards arising from unintended ingestion of radioactive materials, and/or via the inhalation of volatile radioactive substances (e.g. radioiodine) or gases (e.g. xenon). In addition, there may be chemical impurities arising from the radiopharmaceuticals (e.g. aluminium in case of technetium are residual solvents in PET radiopharmaceuticals). In situations where blood elements are radiolabelled for clinical reasons, there is a potential biological hazard (viruses or infective elements in blood). The radiopharmaceutical needs protection from unintended contamination arising during its preparation. This contamination may be chemical, radionuclide, particulate, biological or microbial [4]. The QMS programme should assess these risks and ensure suitable controls are in practice for safe preparation of radiopharmaceuticals.

The environment needs to be protected from unintentional discharges of radioactive material from the radiopharmacy, but the environment should also provide a clean and controlled space for the aseptic dispensing (techniques employed to produce a final entity that fulfils the prescribed requirement for an individual patient) of injectable. The majority of radioactivity handled will be in the form of unsealed and open sources with potential for accidental contamination or spillages. Clear decontamination procedures should be considered and staff trained to perform this in practice.

7.1. HOSPITAL RADIOPHARMACY DESIGN CRITERIA

The layout of the radiopharmacy depend on the operations performed by the facility (see Ref. [8]), and the operations should enable an orderly flow of work and avoid the unnecessary risk due to carriage or transfer of radioactive materials within the facility. Most radiopharmacies are located within existing nuclear medicine facilities to eliminate the unnecessary risk due to the transfer of radioactive materials. The access to such facilities is typically secure only granted to authorize personnel (i.e. trained individuals who have received permission to work with radioactivity and medicines). Where possible space should be shared with the main facility (e.g. administrative area, computers, lavatories).

Attention must be given to the location of the laboratory in relation to the other facilities. Since there are definite advantages situating it close to or even inside the nuclear medicine facility, use of appropriately shielded isolators or hot cells and local shielding should be duly considered. Details of the layout will need to be worked out locally (engaging architects, security, radiation protection expert, health care stakeholders, radiopharmacist, quality assurance staff if available, any medicolegal authority), depending on the accommodation available. In all cases, access to the radiopharmacy should be restricted, and for security reasons, laboratories should be lockable and away from public entrances and pathways.

All surfaces of the radiopharmacy including ceiling, walls, floors, benches, tables and seats should be smooth, impervious and non-absorbent to allow for easy cleaning and decontamination. Floor surfaces, ceiling and benches should be continuous (coved skirting, coved ceiling/wall, wall/wall junction), non-shedding, easily cleanable, and coved to the wall to prevent accumulation of dirt or contamination. Such features are necessary for radiation safety and to provide a suitable environment for the handling of sterile pharmaceutical products of intended quality and safety for administration to patients.

Floors, benches and other work surfaces must be sufficiently strong to bear the weight of shielding. It is imperative that radiation dose rates outside the laboratory, especially in areas to which the public have access, be kept below specified limits. In particular, the siting of ^{99m}Tc generators needs to be carefully considered and should be in lockable shielded containments. Although the generators contain internal shielding, additional external shielding (with lead or depleted uranium) may also be required depending on the activity of molybdenum in the generator.

The range of products to be prepared will influence the scale and complexity of facilities required [8], and need to be appropriate for their intended function. They need to be regularly monitored and maintained in a clean and orderly state. The general principles of good pharmaceutical dispensing and preparation practice need to be aspired to in all cases and national and professional requirements met.

7.2. RADIATION PROTECTION MATTERS

There is a need to provide for radiation protection support for radiopharmacy operations and necessary items include the following:

(a) Prior radiation risk assessment.
(b) Radioactive sources security.

(c)   Personnel radiation monitoring.

(d)   Provision of a storage area for decontamination kits and radiation monitors.

(e)   Maintenance of isotope and materials records.

(f)   Quality control radiation monitoring devices.

(g)   Specific area for assembly and dispensing of radionuclide therapies (fume cupboard if liquid radioiodine is in use or high dose beta (^{90}Y) and even alpha emitters (^{223}Ra)).

(h)   Provision of a storage area for test phantoms (which will at times be radioactive).

(i)   Provision of an area for assembling and filling phantoms (allocation of a non-sterile sink in the vicinity of the hot laboratory).

(j)   Radiation measuring and monitoring devices maintenance.

(k)   Radiopharmacy computer system management and software development for radiation protection records.

(l)   To deal with accidental radioactive spillage, there should be a decontamination kit containing absorbent material, decontamination solutions or sprays, gloves, coveralls, plastic sheets, tape and bags to hold contaminated items [8]. This should be regularly checked and the staff must be trained and familiar with its use.

7.3.   ADMINISTRATIVE AREA

An administrative area is commonly shared with main nuclear medicine facility. However, if separate area is required, it should be equipped with appropriate computer hardware (and software), which is networked with computers in other work areas of the radiopharmacy service. Appropriate manual and electronic record keeping facilities are required, and the fundamentals of data security, integrity and patient confidentiality need to be maintained. Personnel should have access to an intercom, telephone, Internet, hospital intranet and a fax machine. The administrative area should have secured and enough space to keep manual records, electronic data storage media and all the SOP documentation. There should be appropriate QMS documentation controls, planned backups and upgrades of all hardware and software facilities. The worksheets and daily facilities records should be kept in real time and safely stored in the administrative area for the legal duration.

7.4. DISPENSING AREA

The radiopharmacy dispensing area, for preparing individual patient doses using multidose vials, should be a separate, dedicated and secure area (unless already part of operational level 2 — see Section 7.8). In general, the dispensing room should be close to the imaging and injection areas. The operational area should be in good condition, and hygiene must be ensured. The area should meet local and national safety codes, including fire safety codes. The space should be specifically designed and maintained to handle unsealed radionuclides so as to meet the required radiation safety standards. All work surfaces should be smooth and impermeable, and should permit easy cleaning and decontamination. Pipe work and any cables should be encased and properly laid to facilitate cleaning and decontamination. The space should be sufficient to accommodate all essential equipment and accessories, and should allow enough room for at least two staff members to operate simultaneously. The work areas should maintain satisfactory lighting, temperature and humidity so as to ensure operator comfort, optimum equipment performance and expected radiopharmaceutical stability.

There should be enough space for a laminar airflow hood (LAF) or a pharmaceutical isolator. Sufficient space is needed to locate L shaped lead shields for handling radiopharmaceuticals, an activity meter with adequate lead shielding around it, and shielded sharps waste storage containers (two containers should be required one for short lived radionuclides and the other for long lived radionuclides) as well as for storage of non-radioactive waste containers. A separate shielded area is required for used generators and for radioactive waste as applicable. There should be a sufficient number of long handle forceps, tongs, syringe shields, vial shields, shielded syringe carriers for gamma or positron emitting radionuclides and suitable shielding devices for handling beta emitting radionuclides. These should be well maintained and hygienically managed.

7.5. RECEPTION AREA

In the reception area, sufficient bench space is essential to perform routine procedures, for example, to receive radioactive packages, to perform surface contamination checks and to complete administrative records. A clearly distinguishable area for storage of radioactive and non-radioactive materials on location is required. All 'out of hours' deliveries of radioisotopes need to be in a secure and lockable location overseen by good work instructions and by trained staff.

7.6. GENERAL LABORATORY AREA

The general laboratory area should have adequate bench space to properly perform quality control and to accommodate the following equipment/accessories depending on the scale of operations:

(a) Data recording personal computer.
(b) Chromatography instrumentation and for higher operational requirements high performance liquid chromatography.
(c) General laboratory instrument area (e.g. balances, pH, centrifuges).
(d) Calibrated radionuclide activity meters (dose meters) with suitable shielding.
(e) Scintillation counter with an adequate detector for spectrometry (e.g. NaI(Tl) crystal).
(f) Appropriate radiation shielding.
(g) Pharmacy grade refrigerator (2–8°C) with temperature recorder. If radioactive material is stored inside, clear signage is needed. If applicable, a −20°C freezer may be necessary.
(h) Shielded hot plate (with thermostat) or hot water bath (e.g. for preparation of methoxyisobutylisonitrile).
(i) Cleanable storage trolleys for consumable materials.
(j) Storage for inflammable products including 70% IMS (industrial methylated spirit) used for sanitization and microbial control during the aseptic dispensing process.
(k) Storage for general chemicals (chemicals cabinet).
(l) Biological reactivity binding assessment facility.
(m) Centrifuge.

Ideally a certified pharmaceutical microbiology testing laboratory should be used. If in-house microbiological and pyrogen testing is performed, the following equipment and accessories are also required together with a designated laboratory area:

— Ideally, a separate refrigerator for microbiology test media;
— Microbiological incubators controlled at 20°C and 32°C with temperature recorder;
— Limulus amebocyte lysate testing facilities (including a thermostatic heat block).

7.7. RADIOACTIVE WASTE MANAGEMENT AND STORAGE AREA

Sufficient space and facilities to store radioactive, non-radioactive, biological and radioactive biological waste separately are required. This area must be well managed (including protection against flooding, fire and theft) and adequate waste disposal records should be kept for regulatory purpose. For security and safety, each and every radioisotope must be traceable and accountable from moment of receipt in the facility to disposal.

There should be a dedicated sink for cleaning contaminated items and for defined radioactive liquid waste disposal but not in the dispensing area because of serious microbiological contamination concerns during the preparation of radiopharmaceutical injections. Any sink installed in other areas should be of suitable material and should be regularly sanitized. The sink draining heavily contaminated fluid should go directly to main drainage systems of the hospital or a shielded fluid storage tank for appropriate decay before final draining into the main outgoing drain, or in accordance with local or national regulations. The radioactive liquid disposal drain should not be fitted with a trap unless specified by local or national requirements. The sink should be identified by a suitable sign containing disposal instructions.

It is convenient to segregate technetium waste into weekly amounts, which allows ease of monitoring and waste management. In general, the generators should be returned to the manufacturer for recycling or safely disposed by trained staff. Longer lived radioisotopes such as ^{131}I, ^{111}In and ^{90}Y should be kept longer before checking radiation level before disposal in accordance to national environmental regulations.

7.8. LEVELS OF RADIOPHARMACY

The procedures performed in the field of hospital radiopharmacy can vary considerably in different parts of the world. However, hospital radiopharmacy facilities can generally be classified into operational levels 1, 2 and 3 [8]. Each category can be further subdivided to provide essential advice on staff qualifications, training, facilities, equipment, and types of procedures, record keeping, and quality assurance and quality control essential at that level.

The radiopharmacy needs to be equipped with at least one radionuclide activity meter (dosimeter) to measure all radioactivities accurately. A reference source (e.g. ^{137}Cs) will also be necessary to ensure stability of response of the radionuclide activity meter [34]. Since radiopharmacies will be handling unsealed sources of radioactivity, contamination monitors will be required to routinely

monitor different areas of the radiopharmacy and to check for any radioactivity that may have been spilt.

Storage areas will be necessary for radioactive materials as well as for non-radioactive components used in radiopharmaceutical preparation. These areas will need suitable shielding and, depending on the type of product being prepared, a refrigerator and freezer may also be required. A store for flammable products, such as sanitization fluids, solvents used in quality control procedures is also being required.

7.8.1. Operational level 1a

Operational level 1a is the dispensing of radiopharmaceuticals purchased or supplied in their final form from recognized or authorized manufacturers or centralized radiopharmacies. This includes unit doses or multiple doses of prepared radiopharmaceuticals for which no further manipulation or pharmaceutical compounding is required. Increasingly, dispensing from multidose vials is conducted in a separate room with the necessary radiation shielding for the radionuclides handled and procedures performed. The facility may also have a class A (or ISO 5) dispensing laminar flow cabinet [35, 36] or isolator for preparing final patient radiopharmaceutical injections.

Handling of volatile radiopharmaceuticals solutions, particularly those based on ^{131}I, which are intended for oral administration, should be performed within a fume cupboard with suitable filters (active carbon filter) that exhausts air away from the operator. The inflow over the working aperture should not be less than 0.5 m/s. The fume cupboard should be annually tested to provide good operator protection [37]. The exhausted air is ducted to the atmosphere, and great care has to be taken when positioning the exhaust duct to ensure it effectively disperses the discharged air. There should be adequate shielding to provide protection from ^{131}I high energy gamma irradiation and there should be a secure system for delivery and storage of ^{131}I therapy activities.

A secure waste storage area with shielded containers is necessary. There should be a sufficient number of lead lined sharps bins (at least two — one for short life radionuclides and the other for longer half-life radionuclides) with sufficiently thick walls to store radioactive waste.

7.8.2. Operational level 2a

Many of the nuclear medicine facilities prepare radiopharmaceuticals using a [99mTc] generator and approved reagent kits using 'closed aseptic procedure'. Closed aseptic procedure is one in which the prepared product is contained in a sealed vial with a rubber septum and therefore transferred material is not exposed

to external environment. The type of generator most commonly used consists of ^{99}Mo, as sodium molybdate, adsorbed onto an alumina (Al_2O_3) column. Technetium-99m is eluted from the generator by drawing sterile normal saline (0.9% w/v sodium chloride) injection through the column. This is achieved by the use of a sterile evacuated vial supplied with the generator so that the operator does not need to be in close proximity to the generator during the process.

Preparation of radiopharmaceuticals involves sodium pertechnetate (eluted from the generator) mixed to a sterile kit vial that contains all the ingredients necessary to produce the required radiopharmaceutical. The final medicine prepared is free from other contaminants from the environment and free from microbial contamination. This has to be demonstrated by regular microbiological test of the environment, operator practice and the final product (referred to as an end product test).

In order to achieve these conditions the procedures described in operational level 2a should be performed in a vertical LAF cabinet [36] placed in a room divided into 'dirty' and 'clean' zones, with a stepover benchmarking the boundary between the two zones. Traditional horizontal pharmacy LAF are not suitable for use in the radiopharmacy. Consideration needs to be given to the siting of workstations to provide suitable working conditions for aseptic transfer. This means high level of hygiene, on a grade depending on national or international regulation, defining standards for the number of particles permissible [8, 35]. All material placed in the LAF should be sanitized using a 'spray and wipe' technique with sterile biocide or 70% IMS solution. At least a two staged sanitization is required of all materials before use in an LAF. Caution is required in the use of biocides in radiopharmacies, as they are strong oxidizing agents which can alter and effect chemistry of the radiopharmaceuticals. Strict aseptic practices are essential during the dispensing process. The operators should also be well trained and demonstrate competencies is aseptic techniques. The integrity of the LAF cabinet filter should be checked at regular intervals and according to the manufacturer's guidelines.

Air filtration to the room is required and access need to be controlled. Personnel should wear protective clothing (mop cap, clean gown, beard covers, overshoes), which in addition to protecting them from radioactive contamination will also help to reduce the number of particles being shed into the environment from their skin, hair and clothing. A separate changing room or a buffer zone which has a stepover bench or other means of demarcation, is a useful way to control access to the room, and also helps to keep the air in the radiopharmaceutical preparation room less contaminated. As little material (especially paper based) as possible should be stored in the laboratory to reduce the accumulation of dirt and radioactive contamination. Materials required for the

preparation of radiopharmaceuticals can be passed into the laboratory through a transfer hatch when required.

Although it is essential to provide facilities for washing hands and the disposal of liquid radioactive waste, care must be taken in the siting of sinks, since they provide a site for accumulation of microbial contamination. The current practice is not to locate sinks in radiopharmaceutical manufacturing rooms, although ready access to sinks in the adjacent rooms is necessary. Personal should have access to comprehensive decontamination facilities. In situations where chemicals are handled, it may be desirable to have dedicated eye wash facilities available.

In the general design of a nuclear medicine facility, the entry, flow and exit of patients and staff should be separated from the entry, flow and exit of radioactive materials. A dedicated area for delivery and receipt of radiopharmaceuticals, storage room, and changing room or area, office area for records keeping and waste storage area. For radiolabelling of blood cells, a separate dedicated room with the same air quality as for dispensing is required (see Fig. 16).

7.8.3. Operational level 2b

Operational level 2b includes the radiolabelling of red bloods cells, platelets and white cells commonly used for infection or inflammation imaging.
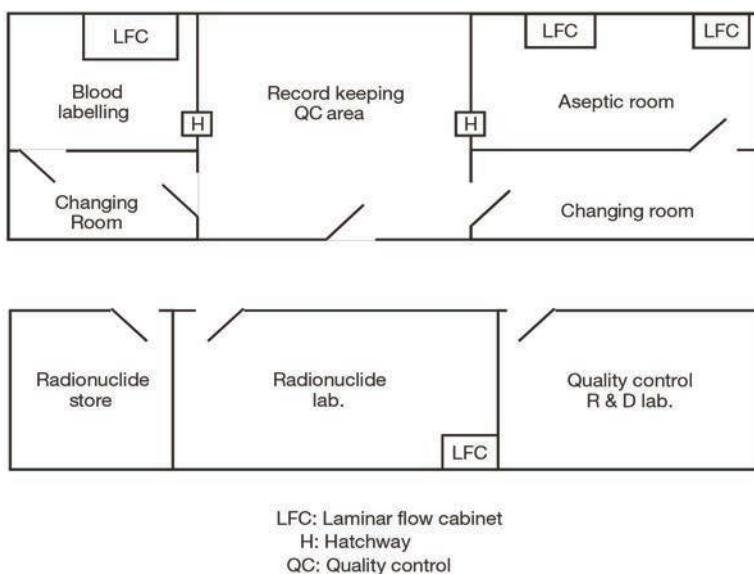
FIG. 16. Layout of an operational level 2 radiopharmacy.

It is desirable to have a separate LAF or isolator for this function, which can be readily cleaned and disinfected after each labelling procedure, thus minimizing the possibility of cross contamination of blood between patients and other environmental contaminants. Patient blood may contain viruses and other infective elements and these should not contaminate the environment, operator or other products handled with the radiopharmacy. It is equally important to ensure that blood samples are never crossed over between patients. A three point labelling of each blood sample (e.g. full name, hospital number, date of birth) is necessary. In addition, strict one product blood radiolabelling policy is required i.e. two patients' blood should never be radiolabelled at the same time (see Ref. [38] for further details). Totally enclosed workstations incorporating centrifuges are available, enabling the entire labelling process to be performed in a more dedicated and protected environment.

7.8.4. Operational level 3a

Operational level 3a includes the compounding of radiopharmaceuticals from ingredients and radionuclides for diagnostic application (including open procedure), modification to existing commercial kits (dimercaptosuccinic acid), and individualized and tailored patient diagnostics. Ideally, disposable equipment and laboratory glassware should be used for compounding any radiopharmaceutical reagent kits and radiopharmaceuticals (therefore no need to wash and prevent cross contamination).

In addition to the details stated in operational level 2a, the procedures described for operational level 3a should be performed in a class II LAF cabinet/isolator placed in aseptic environment and better air quality depending on national regulations. The quality systems also require significant advancement and regular quality audit [4].

7.8.5. Operational level 3b

The scope of operational level 3b relates specifically patient prescribed compounding of radiopharmaceuticals from basic ingredients or unlicensed intermediates and radionuclides for therapeutic application (open procedure), related research and development, and individualized and tailored patient therapies (see Refs [38, 39] for information on radiolabelled monoclonal antibodies and peptides). The compounding of these have serious complications including biological safety practices, quality assurance systems, actual methods for therapy formulation, including formulation of alpha emitting therapeutics. Again the quality systems also require significant advancement and regular quality audit [4].

7.8.6. Operational level 3c

Operational level 3c is the synthesis of PET radiopharmaceuticals, including those produced from long lived generators (e.g. ^{68}Ga).

7.9. HOSPITAL POSITRON EMISSION TOMOGRAPHY FACILITY

Locating a PET facility (i.e. PET scanner and cyclotron for PET radiopharmaceutical production) within a large hospital has the advantage of delivering health care at a single location that is convenient for patients and all patients that meet prescribed criteria can thereby rapidly access PET–CT investigations. There are also PET facilities that are established as a stand alone centre (i.e. outside a hospital). These facilities are set up as outpatient clinics as the vast majority of patients can undergo PET–CT on an outpatient basis.

Depending on the clinical services and decision to purchase or prepare PET radiopharmaceuticals is critical to overall cost. The purchase and use of PET radiopharmaceuticals would then be considered as IAEA radiopharmacy operational level 1. Caution is advice on purchased PET radiopharmaceuticals as the users need to ensure receipt of quality certificate (radiopharmaceutical certificate of conformity) from the supplier before injecting the first patient dose (see Ref. [40] for details of ^{18}F-FDG production and tests).

7.9.1. Cyclotron

The cyclotron produces radionuclides by bombarding stable isotopes with charged particles, mainly protons. There are many cyclotrons suitable for PET radionuclides with energies in the range of 7–30 MeV. The smallest cyclotrons with a proton energy of around 7 MeV and beam currents up to 70 μA; the next level of cyclotrons have an energy around 10 MeV and beam currents up to 100 μA. With this energy, all the four 'classical' PET radionuclides can be manufactured in multipatient amounts (see Table 3). These accelerators are either self-shielded or needs to be placed in a radiation shielded 'bunker'. These accelerators are good for PET centres with up to three PET–CT cameras. The highest level of PET cyclotrons are those with a proton energy of 30 MeV and beam currents above 100 μA. All the four classical PET radionuclides can be produced in multipatient doses and ^{18}F can be manufactured in such large amounts to cover a certain number of PET–CT cameras. Other long lived PET radionuclides can be produced, such as ^{64}Cu, ^{124}I, ^{86}Y and ^{89}Zr, and the SPECT radionuclides ^{123}I and ^{99m}Tc.

TABLE 3. HALF-LIVES OF
CLASSICAL PET RADIONUCLIDES

Radionuclide	Half-life (min)
^{15}O	2
^{13}N	10
^{11}C	20
^{18}F	110

Several major pieces of equipment, highly qualified and trained staff and highly developed QMS are essential in the establishment of a PET centre. Methodology of decision making and the choice of a cyclotron will depend entirely on the programme in place at a new facility. In order to choose a cyclotron, a methodology should be followed which takes into consideration the requirements of the facility and the environment in which the accelerator will be placed. A procedure that has proven to be very useful is as follows:

(a) Interview all the stakeholders and users to define the proposed programme.
(b) Generate a list of radioisotopes which will be needed from these users. Clinical need for very short half-life PET tracers (e.g. ^{11}C) will necessitate the need to have cyclotron facility on the site.
(c) Develop priorities for the programme, either clinical or research.
(d) Evaluate the space allotted to this project. Hospital space is always competitive challenge.
(e) Evaluate the potential cyclotrons with respect to this programme and space.
(f) Examine construction obstacles, staffing and chemistry requirements.
(g) Evaluate all alternatives, such as public–private partnership, 'to make or purchase' services and radiopharmaceuticals.

The most important considerations in the choice of a cyclotron are the particle beam energy and the beam current. The beam current of the cyclotron determines how much radioisotope can be produced at a given energy. The choice of the synthesis module, the radionuclide activity meter and the hot cells also needs consideration (see Ref. [41] for detailed information on the equipment needed to produce and qualify radiopharmaceuticals).

7.9.2. Hot cells

One of the key pieces of equipment in the radiopharmacy are hot cells. The hot cell provides a shielded enclosure for handling highly radioactive materials and serves as an isolator providing clean environment for the preparation of radiopharmaceuticals. Hot cells are commercially available from several manufacturers. The thickness of lead shielding is determined by the quantity of FDG being processed (75 mm of lead or equivalent is typical). For radiation safety reasons, the air pressure inside the hot cells should be maintained well below the pressure of the room where the hot cell is situated. Furthermore, the hot cells should be equipped with an appropriate air handling system (inlet and outlet air filters as a minimum). Lead glass windows or TV monitors should be provided with the hot cells. Consideration for hot cells include such as weight bearing capacity, temperature stability, and adequate power supply, as well as issues concerning radiation safety (e.g. shielding).

The choice of hot cell will depend on whether one wants two independent modules or two modules in the same hot cell. This will depend on the type of facility and the production schedule. Having the ability to carry out a second synthesis is very advantageous in a clinical programme when patients are waiting for the radiopharmaceutical. The key issue is radiation protection in case of synthesis failure. If the synthesis modules are in two separate shielded enclosures, there will be a lower radiation dose than if the hot cell must be opened in order to load the second module or to clean and prepare the same module for a second synthesis. To optimize on-site cyclotron and enable seamless production the use of several enclosures are required including a final sterile dispensing module providing grade A, ISO 5 conditions.

7.9.3. Automated radiopharmaceutical module

Synthesis of PET radiopharmaceuticals are performed in automated modules that are usually placed in lead shielded hot cells for radiation protection purposes and high level of cleanliness (hot cells are generally grade C, ISO 7). The modules use radiochemical synthesis for which the reaction parameters have been determined in detail. The final product is transferred for terminal sterilization before supply radiopharmaceutical for patient administration.

7.9.4. Final aseptic product

Terminal sterilization processes are rarely carried out on the final radiopharmaceutical prepared because of time constraints. In addition, some radiopharmaceuticals cannot withstand high temperatures, rendering them

unsuitable for autoclaving, and filtration is not applicable for particulate radiopharmaceuticals. This means that the procedure has to be carried out aseptically in order to prevent microbial contamination. The final product must be sterilized in hot cell able to achieve grade A, ISO 5 conditions. The filter must also be tested for integrity following a strict protocol to ensure the radiopharmaceutical is sterile and acceptable for human administration.

7.9.5.   Quality control equipment

As safety of drugs has become a particularly important issue in the last years, it is of great importance that the appropriate QMSs for validation and the appropriate radioanalytical equipment for radioanalytical testing are duly considered [18]. The modules applied for performing the syntheses also include high performance liquid chromatography (HPLC) systems for isolating the product out of the reaction solution. At any rate, careful analysis of each batch is necessary for ensuring radionuclide purity, the chemical (including solvents) and radiochemical purity and identity of the product. Routinely thin layer chromatography (TLC) is generally used and for developmental tracer HPLC is employed. Most pharmacopeia permit the use of TLC methods.

The purity of the radionuclides produced at a cyclotron is controlled by gamma spectroscopy. As some of the important radionuclides can only be differentiated by their half-life, a programme for automated determination of the half-lives is particularly useful. The impurity of ^{13}N in ^{18}F can only be determined in this way.

Other key equipment includes gas chromatography for determination of residual solvents in the final radiopharmaceuticals. An endotoxin test (limulus amebocyte lysate) is also essential at the time of radiopharmaceutical product release. As in any chemical laboratory, equipment includes a pH meter, osmometer, melting point apparatus, balances, microevaporator with vacuum pump, distillation unit and glassware, and for simple organic chemical work, a small infrared spectrometer and an ultrasound bath.

8. MEDICAL PHYSICS SUPPORT

Nuclear medicine is a clinical speciality that uses advanced instrumentation and applies computational techniques. The direct use of unsealed sources of radiation calls for particular attention to radiation safety. Medical physicists are members of the multidisciplinary team involved in a nuclear medicine facility

and ensure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result as prescribed in patient care. They need to be multiskilled individuals with an aptitude for general problem solving and familiarity with a wide range of the technical aspects of nuclear medicine. These skills require a strong mathematical and scientific foundation. GSR Part 3 [9] defines a medical physicist as:

"A health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics."

Medical physicists are an important component of the team of clinical professionals working in nuclear medicine. In small nuclear medicine facilities, they are not necessarily required on a full time basis, but they should at least be available for consultation (e.g. through other facilities or institutions). Medical physicists in nuclear medicine are responsible for dosimetric and quantitative aspects in all clinical procedures. In particular, they advise or assist physicians and other health care professionals in optimizing the balance between the beneficial and deleterious effects of radiation. They have responsibilities or contribute to several relevant aspects of a nuclear medicine facility, namely:

(a) In the implementation and optimization of diagnostic procedures and planning of treatments utilizing radionuclides;
(b) In defining specifications for the purchase of equipment and radioactive sources;
(c) In performing acceptance tests of diagnostic equipment;
(d) In the development and implementation of the quality assurance programmes in diagnostic and therapeutic procedures, in particular with regard to equipment;
(e) In the management and dosimetry of all of the radiation sources;
(f) In ensuring that diagnostic imaging and radiation treatment facilities comply with the national rules and regulations and follow the recommendations of competent international bodies.

Their knowledge is applied to the development and optimization of new imaging techniques and they play an important role in the adoption, implementation, development, safe use and optimization of advanced technologies. Medical physicists perform research and development of new equipment, methods, procedures and technologies for improving diagnostic and therapeutic clinical care. They also provide education and training of

applied physics and radiation safety to medical practitioners, nurses, technical staff, students and other personnel. As in the case of other nuclear medicine professionals, the role of the medical physicist varies from country to country, depending to some extent on the stage of development of nuclear medicine practice. Being a member of the multidisciplinary team involved in a nuclear medicine facility, the medical physicist works together with other health professionals in many areas.

8.1. MAIN TASKS OF THE MEDICAL PHYSICIST

8.1.1. Patient dosimetry and dose optimization

The primary role of the medical physicist in nuclear medicine is in optimization, by its own activities or by advising other health care professionals on the use of radiation to ensure the safety and quality of diagnostic or therapeutic procedures. Medical physicists establish policies, guidelines and measurement techniques for the determination of patient dose, and to collect and analyse clinical physics data for diagnosis or treatment of diseases.

GSR Part 3 [9] assigns specific responsibilities to the medical physicist for medical exposures and the patient's radiation protection, intrinsically related to diagnostic and therapeutic procedures using ionizing radiation discussed in previous sections. Medical physicists have responsibilities in investigating and analysing unintended or accidental medical exposures which could result in patients receiving an exposure significantly different from that intended. They provide consultation on the doses received by patients or personnel and on the associated risks and recommend measures to minimize the chances for accidents to happen again.

8.1.1.1. Patient dosimetry

Clinical applications of nuclear medicine include both diagnostic imaging and therapeutic treatments. Internal dosimetry in diagnostic nuclear medicine aims to measure the doses received by healthy organs and its role is to provide the basis for stochastic risk quantification, while it is used in molecular radiotherapy as a tool for establishing doses absorbed by the tumours and organs at risk.

Medical physicists are responsible for establishing procedures for the calculation and verification of the radiation dose received by different organs, as well as the total effective dose to the patient, resulting from the administration of radionuclide activity. Activity distribution data and internal dosimetry methodology can be used to estimate the dose absorbed by patients during

different clinical procedures. Measurement and calculation of specific patient doses, as well as fetal doses in cases where patients are found to be pregnant, are often necessary. The medical physicist can also give advice to the medical practitioner and the patient on any associated risks, especially those related to the induction of cancer.

In therapeutic nuclear medicine, radioactive agents are employed against various forms of cancer and other diseases. Paragraph 4.212 of SSG-46 [6] states:

"Radiopharmaceutical toxicity in therapeutic nuclear medicine depends on the absorbed dose to critical organs (e.g. to the haematopoietic system), and the efficacy of the treatment depends on the absorbed dose received by target tissues. In current clinical practice, the nuclear medicine therapeutic treatment is usually delivered on the basis of an administered activity prescription, in some cases with adjustments made for body mass or surface area. Ideally, a pre-treatment calculation of the absorbed doses received by organs at risk and target tissues would allow for an accurate prediction of toxicity and efficacy of the treatment."

Medical physicists can perform dosimetry calculations in radiopharmaceutical therapy to determine the radiation absorbed dose to critical normal organs, calculation of the safe amount of radioactivity that may be administered, and calculation of the radiation absorbed dose to the tumour. In the simplest scenario, the whole body or red marrow radiation absorbed dose can be determined typically carrying out measurements over time of the remaining activity in the whole body and activity concentration in the blood. More often, absorbed doses to healthy organs and tumours are estimated through a series of images of the patient, using whole body imaging, SPECT–CT or PET–CT. The radioactivity–time data allow the calculation of the cumulated activity (total number of disintegrations occurred over time) for each source organ targeted by the radiopharmaceutical. Cumulated activities values are used in mathematical models based upon internationally accepted reference anatomic phantoms for the final estimation of tissue absorbed doses.

8.1.1.2. Dose optimization

Nuclear medicine diagnostic procedures allow functional imaging of normal and diseased tissue, the most common applications being the localization of malignant tissue and the assessment of myocardial perfusion. The amount of radioactivity administered to the patients is typically low and the diagnostic benefit of the imaging procedure greatly outweighs the risks of cancer induction. Therefore, the amount of administered activity has to be optimized in order to

maximize the diagnostic quality of the image, while minimizing patient risk. This is particularly important for paediatric patients, because of their enhanced organ radio sensitivities and years over which any stochastic effects may become manifest.

Medical physicists have responsibilities for the optimization of the physical aspects of the imaging systems: gamma cameras, SPECT and PET systems (the latter two often combined with CT). They are responsible for the development and maintenance of a quality assurance programme for all imaging equipment, so as to produce images of optimal quality while minimizing the radiation dose delivered to patients. They are also responsible for the equipment and instrumentation needed to ensure proper quality control, optimal image quality, monitoring of patient exposure, and determination of dose to individual organs from different nuclear medicine imaging procedures, as well as for the use of the appropriate guidelines and techniques. In nuclear medicine non-imaging procedures, such as thyroid uptake or radioguided surgery, medical physicists ensure proper calibration of the equipment, as well as support data analysis and interpretation.

8.1.2. Optimization in the use of radiopharmaceuticals

The medical physicist supervises measurement, dispensing and administration of radiopharmaceuticals for both diagnostic and therapeutic purposes, granting compliance with the diagnostic reference levels, contributing to sophisticated radiometric analysis, and is also involved in radiation safety related to these procedures.

8.1.3. New equipment

Medical physicists are an essential part of the design team for new installations being responsible for shielding and installation designs of new or modified nuclear medicine facilities and ensuring that all safety requirements are complied with. They play a leading role in preparing equipment specifications according to the needs of the nuclear medicine facility and participate in the tender evaluation and purchase recommendation of the equipment. They analyse the functional requirements for clinical use, and specify the necessary conditions for integration, compatibility and connectivity to existing equipment of the equipment to be purchased. Following the installation of new equipment, medical physicists are responsible for specifying the basic standards to be applied for its acceptance and subsequent commissioning.

8.1.4. Calibration and verification of measurement instruments

Medical physicists are responsible for the calibration of the instruments they use or are responsible for following recommended standards or codes of practice and keeping appropriate calibration records. They are responsible for developing procedures to determine the stability of the instruments for clinical use.

8.1.5. Records and documentation

The duties of a medical physicist involve administrative tasks such as the preparation of guidelines and procedures, record keeping and communication with other professionals and suppliers. Medical physicists provide the documentation needed and maintain the records of their area of work, providing evidence of the compliance of equipment and procedures with the appropriate regulatory and accreditation authorities' rules and recommendations. They review the records in patient clinical histories regarding the optimization of imaging procedures and patient dosimetry. In addition, they are responsible for the documentation of quality assurance, equipment calibration, independent dosimetry audits, and any other medical physics policies and procedures.

8.1.5.1. Quality management of the physical and technical aspects of nuclear medicine

Medical physicists participate as team members in establishing a quality management programme and have responsibility for physical and technical aspects. With focus on the continuous optimization of radiation use, medical physicists develop institutional policies and procedures for imaging and treatment of patients and radiation safety (e.g. procedures relating to radiation protection, personnel monitoring, reporting of incidents and accidents, quality assurance, safe handling of radioactive sources, radioactive waste, personnel radiation dose and associated risks). They perform risk assessments and identify potential radiation emergencies and report on radiation incidents and accidents. Medical physicists participate in establishing quality assurance programmes ensuring that policies and procedures are in place, with appropriate elements of good practice for handling of radioactive material, for radiation protection of patients, and for quality control and regulatory compliance of equipment.

8.1.6. Computer system management and support

Increasingly, the medical physicist takes responsibility for overall computer system management and provides advice on computer use as well as first line

support for application software. In some countries, the medical physicist is directly involved in routine computer analysis. However, in most countries this is the responsibility of technologists.

8.1.7. Development, optimization and validation of clinical studies

Medical physicists have responsibilities in the optimization of the dose and image quality in medical imaging and the accuracy of the quantitative analysis used to obtain functional information and dose estimates [42]. The medical physicist usually works closely with medical practitioners and technologists to provide technical advice relevant to the execution of studies, as in the selection of the optimal acquisition parameters, postprocessing protocols and the optimization of digital image presentation and display. Frequently, software needs to be developed or adapted with the subsequent validation of newly developed procedures.

8.1.8. Research and development

Medical physicists evaluate new technologies and investigate the adoption of new procedures, assisting in the training of clinical staff for their implementation. They are involved in clinical research projects, giving support on the physical and technical aspects, data and statistical analysis. They carry out research and development in medical physics and instrumentation, monitor current advances in specific areas of research, and design project plans.

8.1.9. Education and training

Medical physicists play a key role in the academic education and clinical training of medical physicists and other health professionals. They lecture and develop educational material for medical practitioners, technologists and nurses, as well as for students, residents and technical maintenance staff. They supervise technologists in the implementation of new clinical procedures, being key members of the team responsible for the introduction of new imaging or therapeutic procedures in the institution.

8.2. EDUCATION AND TRAINING OF THE MEDICAL PHYSICIST

Medical physicists must have received appropriate undergraduate education in physical or engineering sciences, followed by a professional competency training that includes an additional period of one to three years of academic

education in medical physics at the postgraduate level. In order to become a clinically qualified medical physicist, the academic training at the postgraduate level needs to be followed by at least two additional years of structured practical training in a clinical environment, in one or more specialties of medical physics. Overall, the academic education and clinical training should extend over a minimum period of, typically, seven years.

The education and training of medical physicists should be recognized by a national or international accreditation body. The competence of medical physicists should be assessed by an appropriate authority, which results in a formal mechanism for their registration and/or accreditation or certification (see Refs [12, 43, 44] for the necessary academic education and clinical training for medical physicists specializing in nuclear medicine).

8.3. QUALITY ASSURANCE

Quality assurance is crucial to all aspects of nuclear medicine practice, including the measurement of radioactivity and the use of imaging and non-imaging instrumentation. It represents an integral part in establishing a comprehensive quality management programme for medical exposures as required by GSR Part 3 [9] and should be undertaken as part of the routine work of the nuclear medicine facility. Some practical aspects of quality controls can be delegated to technologists under the supervision of medical physicists, and para. 3.171(a) of GSR Part 3 [9] states:

"Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:

(i)   At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;
(ii)   Periodically thereafter;
(iii) After any major maintenance procedure that could affect protection and safety of patients;
(iv)   After any installation of new software or modification of existing software that could affect protection and safety of patients."

The medical physicist should be directly involved in equipment procurement, supporting the hospital management in defining specifications and participating in the tender evaluation and purchase recommendations of equipment. Professionals recommend that appropriate radiation sources, phantoms and other test devices needed for quality control be purchased and

available at the time of instrument acquisition, and that quality control devices in the tender document be included.

Following the installation of new equipment, the medical physicist is responsible for specifying the basic standards to be applied for its acceptance and subsequent commissioning. The medical physicist takes direct responsibility of acceptance tests, designed to establish whether its initial performance conforms to the manufacturer's specifications. The medical physicist also has, often in collaboration with computer engineers, responsibility for the verification of the computer systems. Acceptance tests should be carried out immediately after installation so that the supplier can be informed of any damage, deficiencies, or flaws before the warranty has expired. No instrument should be put into routine use unless it has been shown through acceptance testing to be performing optimally.

During the commissioning of equipment, reference tests should be carried out to provide baseline data against which its subsequent performance can be assessed. Routine tests are established under the responsibility of the medical physicist to verify that the technical parameters of imaging equipment performance remain within an acceptable range of variation with respect to the reference values. Such tests are in many cases performed by technologists, under the supervision of a medical physicist. Routine tests fall into two categories: the first includes tests that have been previously carried out as reference tests and that are repeated weekly, monthly, quarterly and yearly; and the second includes daily or operational checks that are to be carried out each day the instrument is used. Operational checks are normally simple and designed to be completed in an acceptably short time. It is advisable that the responsibility of these tests rests with the technologists being the regular users of the equipment. Careful records of the results of all these tests are typically assembled in appropriate log books and retained with the instrument and, if these reveal unsatisfactory performance, appropriate corrective action should follow.

Medical physicists collaborate with service engineers and supervise the preventive and corrective maintenance, repair and calibration of the diagnostic and measuring equipment. They are responsible for authorizing the clinical use of radiation equipment after a maintenance procedure. For this purpose, they perform quality control measurements of particular complexity after preventive or corrective maintenance, to ensure that the function of the equipment has not been affected by any alteration made during maintenance or repair. By verifying the proper function of the equipment, they aim to ensure optimal performance as well as patient and staff safety.

Quality assurance procedures are the basis for any quantitative procedure in nuclear medicine. As such they need to be regularly performed during the entire life cycle of imaging and non-imaging equipment:

— Radionuclide activity meters;
— Well counters;
— Gamma probes (thyroid probes, intraoperative probes);
— Gamma counters;
— Gamma cameras (planar, SPECT, SPECT–CT);
— PET or PET–CT scanners;
— Monitors and printers.

A basic requirement for the successful introduction of a QMS and of quality control is that the head of the nuclear medicine facility recognizes its necessity. The time required by quality control tests has to be considered in the planning and workload of a nuclear medicine facility (see Refs [13, 34, 45–47] for a description of quality control tests of the various instruments used in nuclear medicine). Tables 4–6 report a list of acceptance and routine tests for gamma cameras, PET–CT and radionuclide activity meters with an indication of possible frequencies. The decision on the tests to be performed and their frequency should be established by a medical physicist on the basis of the specific characteristics of the equipment and its use.

TABLE 4. ACCEPTANCE AND ROUTINE TESTS FOR PLANAR, WHOLE BODY, SPECT AND SPECT–CT SYSTEMS

	Test	Acceptance tests	Routine tests*
	Physical inspection	X	Y
	Detector head shielding leakage	X	N
Planar	Energy resolution	X	Y
	Intrinsic flood field uniformity	X	W/M
	Uniformity with asymmetric energy windows	X	½Y/Y
	Intrinsic spatial resolution and linearity	X	½Y/Y

TABLE 4. ACCEPTANCE AND ROUTINE TESTS FOR PLANAR, WHOLE
BODY, SPECT AND SPECT–CT SYSTEMS (cont.)

	Test	Acceptance tests	Routine tests*
	Count rate performance	X	½Y/Y
	Multiple window spatial registration	X	½Y/Y
	System flood field uniformity	X	½Y
	System spatial resolution and linearity	X	½Y/Y
	System planar sensitivity	X	½Y/Y
Whole body	Whole body system spatial resolution	X	Y
SPECT	Centre of rotation	X	W/M
	Variations of sensitivity and uniformity with rotation	X	N
	Detector to detector sensitivity	X	Y
	Tomographic uniformity	X	½Y
	Tomographic spatial resolution	X	Y
	Image quality phantom (total performance)	X	Q/½Y
	Slice thickness	X	½Y
	Pixel size	X	½Y
Checks	Energy calibration (peaking)	N	D
	Flood field uniformity	N	D
	Safety interlocks	N	D
	Background count rate	N	D

TABLE 4. ACCEPTANCE AND ROUTINE TESTS FOR PLANAR, WHOLE BODY, SPECT AND SPECT–CT SYSTEMS (cont.)

	Test	Acceptance tests	Routine tests*
SPECT–CT	SPECT–CT image quality	X	Q
	SPECT–CT spatial coregistration	X	Y
	CT number accuracy	X	M
	CT dose assessment	X	Y
	CT image quality assessment	N	D
Monitors	Computer monitors	X	Y

* D — daily; W — weekly; M — monthly; Q — quarterly; ½Y — half yearly; Y — yearly; N — none.

TABLE 5. ACCEPTANCE AND ROUTINE TESTS FOR PET–CT SYSTEMS

Test	Acceptance tests	Routine tests*
Physical inspection	X	D
Daily quality control	X	D
Computer clock	X	D
Sensitivity	X	M
Uniformity	X	Q
Spatial resolution	X	Y
Count rate performance	X	M
Image quality	X	Y
Energy resolution	X	Y

TABLE 5. ACCEPTANCE AND ROUTINE TESTS FOR PET–CT SYSTEMS (cont.)

Test	Acceptance tests	Routine tests*
Normalization	X	M
Calibration	X	M
Coincidence timing resolution for TOF PET	X	Y
X ray CT scanner acceptance	X	N
CT number accuracy	X	M
PET–CT spatial coregistration	X	Y
CT dose assessment	X	Y
Computer monitors	X	Y

* D — daily; M — monthly; Q — quarterly; Y — yearly; N — none.

TABLE 6. ACCEPTANCE AND ROUTINE TESTS FOR RADIONUCLIDE ACTIVITY METERS

Test	Acceptance tests	Routine tests*
Physical inspection	X	D
High voltage	X	D
Clock accuracy	X	D
Zero adjustment	X	D
Background	X	D
Constancy (reproducibility)	N	D
Relative responses	N	D
Stability (precision)	X	M

TABLE 6. ACCEPTANCE AND ROUTINE TESTS FOR RADIONUCLIDE
ACTIVITY METERS (cont.)

Test	Acceptance tests	Routine tests*
Accuracy	X	Y
Linearity of activity response	X	Y
Geometry	X	N

* D — daily; M — monthly; Y — yearly; N — none.

In order to perform quality control tests on nuclear medicine equipment, test phantoms, tools and radioactive sources are needed. A minimum set of necessary testing equipment for nuclear medicine is the following:

(a) Performance test phantoms and equipment:
    (i) A ^{57}Co flood source or refillable flood phantom.
    (ii) Spatial resolution and linearity phantoms (quadrant bar phantom.
    (iii) Jaszczak phantom.
    (iv) Any vendor specific centre of rotation phantom (if needed).
    (v) Disposables (petri dish, capillary tubes).
    (vi) If SPECT–CT is available, phantoms for CT calibration and SPECT–CT image coregistration.
    (vii) If PET–CT is available, phantoms for:
        — Uniformity;
        — Sensitivity;
        — Scatter fraction;
        — Image quality;
        — Any vendor specific phantom for daily quality control;
        — CT calibration;
        — PET–CT image coregistration.
    (viii) If a SPECT–CT or PET–CT is available, phantoms and equipment for CT.
(b) Radioactive testing sources:
    (i) Reference/calibration sources for well counter constancy and accuracy.
    (ii) Two reference/calibration sources for dosimeter constancy and accuracy (preferably ^{57}Co and one long lived isotope, e.g. ^{137}Cs or ^{133}Ba).
    (iii) Sufficient supply of ^{99m}Tc generators (and ^{18}F if PET–CT is available).

8.3.1. Troubleshooting and first line service

A clinically qualified medical physicist specialized in nuclear medicine is familiar with the operation of the equipment and understands the principles of measurement being used in order to diagnose problems correctly. In general, medical physicists can identify problems and, when possible, undertake first line troubleshooting of equipment. Medical physicists also have the knowledge and skills to assist in the clinical use of intranets, perform basic computer system management and perform first line system troubleshooting to eliminate common computer problems.

In many countries, the service and repair of nuclear medicine equipment is undertaken by qualified service engineers or technicians employed by the supplier. Professionals recommend maintenance contracts, particularly in the case of gamma cameras, SPECT–CT and PET–CT systems, for which maintenance and calibration are highly specialized procedures. Suppliers should provide specific training on their own equipment. Spare parts can only be guaranteed where the supplier or manufacturer, rather than simply a local agent, continues to be involved. Nowadays, direct repairs to electronic equipment usually involve board replacement rather than direct circuit troubleshooting. In most cases, centralized electronic laboratories are equipped to deal with the repair of less specialized equipment (e.g. counting equipment) that is generally robust and does not justify dedicated maintenance staff. The local atomic energy authority can often assist.

8.3.2. Occupational and public radiation protection

GSR Part 3 [9] defines the RPO as a "person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements." In many clinical environments, medical physicists have responsibilities not only for the safety of the patient, but also for the protection of the staff and the public, as well as for the safety of radioactive sources. They have adequate training in radiation protection and, as part of their assigned duties, may act as RPOs in health facilities and/or participate as members of the radiation safety committee. In small nuclear medicine facilities RPOs' responsibilities may be delegated to another professional, provided advice can be sought from an available expert.

8.3.2.1. Installation design, technical specification, acceptance and commissioning of equipment, including the establishment of criteria for acceptable performance

Medical physicists collaborate in the shielding and installation designs of new or modified nuclear medicine facilities and ensure compliance with safety requirements. They calculate and provide the thickness, material composition and placement of shielding needed to protect patients, staff and the general public, and design the system for the management of isotopes and radioactive wastes. They also verify the adequacy of the shielding after installation.

Medical physicists classify work areas into supervised and controlled areas, help to develop and define the technical specifications for the purchase of new equipment for radiation protection and safety inspections, and develop procedures for the initial and continued evaluation of such equipment. They advise on practical methods to reduce the dose to the staff and the public who work or are in areas adjacent to rooms where radiation equipment is installed, or radioactive sources used. In addition, they are responsible for designating the areas in which pregnant or breast-feeding employees may not work. They also perform calculations and surveys to verify the adequacy of the existing shielding in these rooms using their relevant dimensions, occupancy factors and workload, and establish criteria for the access to rooms that are controlled, with limited access to members of the public, supervising their implementation. Medical physicists are also responsible for supervising the installation of new radiation protection equipment and for performing acceptance testing and commissioning of such equipment, including related computer systems, their algorithms, data and results.

8.3.2.2. Radiation safety programme for the protection of staff and the general public

Medical physicists have responsibilities in the development and implementation of a clinical radiation safety programme for the hospital, including policies and procedures for the radiological protection and safety of the workers and the public. They carry out hazard assessment of the facilities and risks to which staff members may be exposed and establish the need for personal protection devices.

Medical physicists have responsibilities in establishing policies and procedures for the safe transport of radioactive material, for precautions in cases of contamination or spillage of unsealed radionuclides, for the management of radioactive waste and for the integrity and proper operation of survey meters and other measuring equipment, as required by the regulations.

Medical physicists develop a programme of physical security for radioactive sources, including procedures for receiving, storing securely, stock taking and controlling their fixed or temporary location at the hospital. They plan and supervise regular inventories of all of the radioactive sources, ensuring their safe disposal as radioactive waste when relevant, according to national and international safety regulations and recommendations. They perform risk assessments and identify possible accidents or losses of radioactive sources, develop action procedures to be followed in the event of such occurrences.

Medical physicists work with other clinical professionals, including medical practitioners, technologists and nursing staff, on special cases that may be encountered in the clinical environment and may compromise the safety of the staff and the public (e.g. an accident during the transport of radioactive materials). As required by para. 3.178 of GSR Part 3 [9], medical physicists have responsibilities with respect to discharging the patient after radionuclide therapy, to ensure that:

"(a)   The activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by the relevant authorities...; and

 (b)   The patient or the legal guardian of the patient is provided with:

(i)   Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;

(ii)   Information on the radiation risks."

8.3.2.3. Radiation dosimetry

Medical physicists organize and provide personnel dosimetry and monitoring systems at a local level, following the local legislative procedures, and evaluate the results obtained. They also have responsibilities in investigating anomalous exposures and determine whether any radiological hazard is present, particularly when hazards result from gamma rays emitted by radioactive sources or from ionizing radiation emitted by equipment used for diagnosis or treatment. They develop procedures and contingency plans to deal with unintended or accidental exposures, and make recommendations on actions required to minimize the likelihood of such unintended exposures happening again.

8.3.2.4. Quality management of the physical and technical aspects of radiation safety equipment

Medical physicists have responsibilities in developing, implementing and supervising the physical aspects of the quality management programme for the equipment used for radiation protection of the staff and the public. Quality assurance procedures should be regularly performed during the entire life cycle of radiation safety equipment (e.g. survey meters, contamination monitors, any other detector used for radiation safety purposes).

8.3.2.5. Education and training

Medical physicists provide education and continuous training to clinical staff on radiation safety and radiological protection. They ensure that training programmes are in place and deliver lectures and practical training to staff on the basic principles of radiation safety, and establish and promote a safety culture.

8.3.3. Medical physics service

In most cases the physicist will not require a specific laboratory but will operate from a standard office. However, there is a need to provide for the following (even where no physicist is employed):

(a) Radiation safety:
  (i) Provision of a storage area for decontamination kits and radiation monitors.
  (ii) Maintenance of records.
(b) Quality control:
  (i) Provision of a storage area for test phantoms (which will be radioactive).
  (ii) Provision of an area for assembling and filling phantoms (allocation of a non-sterile sink in the vicinity of the hot laboratory).
(c) Equipment maintenance:
  (i) Provision of a workbench equipped mainly for electronic testing and repair (if direct maintenance work is performed).
  (ii) Provision of an oscilloscope and avometer, and storage for electronic parts.
(d) Computer system management and software development:
  (i) Access to a workstation dedicated to these functions (or shared use, preferably on a system that is not used for routine acquisition and analysis).

(e)   General administration:
   (i)   Provision of a personal computer (preferably networked).
   (ii) Provision of filing cabinets for records.
(f)   Research and teaching:
   (i)   Provision of a laboratory area for experimental work may be required, although existing facilities may be sufficient for this purpose. The exception would be a large teaching hospital with several full time students. Computer workstations are an important feature of the training area.

The medical physics laboratory is usually a slightly expanded office and may comprise a small workbench, any necessary storage space and one or more computer terminals. The area would normally be considered 'non-active' and therefore have no specific radiation protection requirements.

9. GENERAL CLINICAL APPLICATIONS

9.1. APPROPRIATENESS

Since 2000, appropriateness has become a guiding principle to justify the introduction of new health care interventions, from the use of new drugs or new treatment modalities to the implementation of new diagnostic procedures [48]. The concept of appropriateness, with a decision aid for its assessment, provides clinicians with a tool to determine which diagnostic investigations and therapies should be implemented. In the context of diagnostic investigations, new investigations are deemed appropriate when the difference between the expected incremental information and the expected or possible adverse effects is sufficiently large that the investigation is warranted for the indication concerned. The decision tool for rating appropriateness includes a literature review and synthesis of the evidence according to designated indications. Although the concept of appropriateness has been defined in terms of clinical utility, it may also be used to assist in the allocation of limited resources in an environment of shrinking health budgets. There is, however, the danger that new interventions will be underutilized, because they are viewed by health care administrators as inappropriate. This could be due to a narrow interpretation of appropriateness that is based solely on the cost of the intervention, isolated from the potential cost savings derived from its use. In reality therefore, there might be a series of interventions, services and health services of proven effectiveness that are widely

underutilized whose necessary implementation requires, at least in the short and medium terms, an increase in costs. Paragraph 3.151(a) and (b) of GSR Part 3 [9] states clear requirements for referring medical practitioners:

"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

(a)   It is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;

(b)   The medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme".

The concept of appropriateness is often referred to as justification [9, 49].

9.2.   CLINICAL INDICATIONS

Only the major clinical utilities are recorded here. Other scans have a role, depending on institutional requirements. However, details on image acquisition, processing and interpretation are not expanded in this publication. These will vary according to the camera used, software and hardware available and patient demographics. Each institution can use this text as a guideline, but must incorporate their own, unique local standards and protocols accordingly (see Refs [14, 50, 51] for further discussion of nuclear medicine applications and indications). Current practice of nuclear medicine can be roughly divided into imaging procedures using either single photon emitters or positron emitters and radionuclide therapy.

9.2.1.   Single photon emitting radiopharmaceuticals

These procedures take advantage of the radioactive decay of isotopes emitting gamma rays (single photon). Depending on the radiopharmaceutical employed, almost all organs of the human body could be explored.

SPECT has enabled the evaluation of disease processes based on functional and metabolic information of organs and cells. Integration of X ray CT into SPECT has recently emerged as a brilliant diagnostic tool in medical imaging, where anatomical details may delineate functional and metabolic information. Clinical applications with SPECT–CT have started and expanded in developed countries.

It has been reported that moving from SPECT alone to SPECT–CT could change diagnoses in 30% of cases. Large numbers of people could therefore benefit from this shift all over the world [52]. Major clinical indications include the following:

(a) Heart:
  (i) Myocardial perfusion imaging:
    — Diagnosis of myocardial ischaemia;
    — Prognosis of documented coronary artery disease;
    — Myocardial viability.
  (ii) Gated cardiac blood pool scan (multigated acquisition):
    — Assessment of left ventricle and right ventricle function, particularly in patients unsuitable for echocardiography.
  (iii) Neuroadrenergic imaging:
    — Risk prediction in cardiac failure;
    — Adrenergic innervation evaluation.
  (iv) Cardiac involvement in systemic diseases:
    — Sarcoidosis;
    — Amyloidosis.
(b) Lung:
  (i) Pulmonary embolism (acute and chronic).
  (ii) Right/left lung function quantitation (presurgical evaluation).
(c) Kidney:
  (i) Dynamic acquisition:
    — Renal function (e.g. split function);
    — Diagnosis of renovascular hypertension;
    — Assessment of urinary obstruction;
    — Renal transplant.
  (ii) Static acquisition:
    — Identification of renal scarring.
(d) Bone and joint:
  (i) Evaluation of bone metastases (initial staging and restaging).
  (ii) Bone and joint infections.
  (iii) Possible fractures.
  (iv) Arthritis (inflammatory and localization with regard to possible therapies).
  (v) Paget's disease.
(e) Brain:
  (i) Brain perfusion:
    — Epilepsy;
    — Dementia;
    — Brain death.

(ii) Brain neurotransmission:
        — Movements disorders.
(f) Lymphatic:
    (i) Sentinel lymph node detection for cancer staging.
    (ii) Assessment of lymph flow.
(g) Thyroid:
    (i) Multinodular goitre with concomitant thyroid stimulating hormone suppression.
    (ii) Thyrotoxicosis.
    (iii) Subacute thyroiditis.
(h) Parathyroid:
    (i) Parathyroid adenoma localization.
(i) Infection and inflammation:
    (i) Acute or chronic bone infection (including rejection of prosthesis).
    (ii) Inflammatory bowel disease.
    (iii) Sarcoidosis.
(j) Oncology:
    (i) Neuroendocrine tumours.
    (ii) Lymphoma.
(k) Other studies:
    (i) Gastrointestinal:
        — Oesophageal transit and gastric emptying;
        — Assessment and localization of active gastrointestinal bleeding;
        — Hepatobiliary studies.
    (ii) Salivary scan:
        — Sjogren's syndrome;
        — Radiation induced xerostomia.
    (iii) Lacrimal study (dacrioscintigraphy):
        — Obstruction of lacrimal duct.

9.2.2. Positron emitting radiopharmaceuticals

Over the past 20 years, PET and PET–CT have revolutionized the care of cancer patients in developed countries and are increasingly being adopted in emerging economies. PET has been, and still is, one of the fastest growing fields in medical imaging. There are several reasons for the rapid development of this imaging technology. As the populations of many countries continue to age, cancer constitutes a major health problem, with increasing incidence worldwide. In developed countries, where heart disease is the primary cause of mortality, cancer is a close second and may eventually overtake it. Proper cancer

management requires highly accurate imaging to characterize stage, restage, assess response to therapy, prognosticate and detect recurrence. Such information is critical in a disease that often requires the correct initial treatment to improve the chance of successfully curing the patient. The ability to provide, in a single imaging session, detailed anatomical and metabolic and functional information, which has a powerful synergistic effect that is greater than the sum of the two individual techniques, has established PET–CT as an indispensable imaging procedure in the management of many different types of cancer. The quality and reliability of the images acquired on a PET–CT scanner depend on the quality of the imaging technique [14, 50, 51, 53–57].

9.2.3. Diagnostic studies with positron emitting radiopharmaceuticals

Major clinical indications include the following:

(a) Oncology:
    (i)   Non-small-cell lung cancer.
    (ii)   Small cell lung cancer.
    (iii)   Lymphoma.
    (iv)   Breast cancer.
    (v)   Melanoma.
    (vi)   Ovarian cancer.
    (vii)   Head and neck cancers.
    (viii) Kidney cancers.
    (ix)   Germinal tumours.
    (x)   Cancer of unknown primary.
    (xi)   Colorectal cancers.
    (xii)   Gastric carcinoma.
    (xiii) Sarcomas (soft tissue and bone).
    (xiv) Primary tumours of the central nervous system.
    (xv)   Nasopharyngeal carcinomas.
    (xvi) Gastrointestinal stromal tumours.
    (xvii) Pancreatic adenocarcinoma.
    (xviii) Cholangio- and gallbladder carcinomas.
    (xix) Oesophageal cancer.
(b) Brain:
    (i)   Brain perfusion:
        — Epilepsy;
        — Dementia.
    (ii)   Brain neurotransmission:
        — Movements disorders.

(c) Heart:
   (i) Myocardial perfusion imaging:
        — Diagnosis of myocardial ischaemia;
        — Prognosis in documented coronary artery disease;
        — Myocardial viability;
        — Quantification of coronary flow reserve.
   (ii) Neuroadrenergic imaging:
        — Risk prediction in cardiac failure;
        — Adrenergic innervation evaluation.
(d) Bone:
   (i) Evaluation of bone metastases (initial staging and restaging).
   (ii) Bone and joint infections.
   (iii) Possible fractures (non-accidental injuries).
   (iv) Paget's disease.
(e) Infection and inflammation:
   (i) Acute or chronic bone infection.
   (ii) Inflammatory diseases.
   (iii) Sarcoidosis.

9.3. RADIONUCLIDE THERAPY

Radionuclide therapy can be administered to treat benign and malignant disease. Therapy can be administered on an outpatient or inpatient basis depending upon procedure complexity, administered activity and statutory requirements for radiation protection, in addition to patient specific clinical considerations. The range of clinical indications for radionuclide therapy, approved therapeutic radiopharmaceuticals and infrastructure required to support inpatient and outpatient treatment include the following:

(a) Thyroid cancer:
   (i) Posthyroidectomy remnant ablation;
   (ii) Persistent or recurrent tumour, and metastases.
(b) Benign thyroid disease:
   (i) Graves' disease or toxic nodules;
   (ii) Large non-toxic nodular goitre (reduces thyroid volume and relieves symptoms caused by compression).
(c) Neuroendocrine tumours:
   (i) Low grade neuroendocrine tumours with positive expression of somatostatin receptors;

  (ii) Phaeochromocytoma, paraganglioma, neuroblastoma or medullary thyroid carcinoma.
(d) Painful bone metastases:
  (i) Multifocal metastatic bone metastases;
  (ii) Metastatic bone pain palliation.
(e) Non-Hodgkin's lymphoma:
  (i) Relapsed or refractory low grade, follicular non-Hodgkin's lymphoma;
  (ii) Relapsed or refractory low grade, CD20+ transformed non-Hodgkin's lymphoma.
(f) Selective internal radiation therapy of liver:
  (i) Inoperable primary hepatocellular carcinoma;
  (ii) Unresectable metastatic liver lesions.
(g) Myeloproliferative diseases:
  (i) Polycythaemia vera;
  (ii) Essential thrombocythaemia.
(h) Radiosynovectomy:
  (i) Severe joint pain arising from arthropathies.

10. RADIATION PROTECTION AND SAFETY

  The practice in nuclear medicine should be performed according to the radiation protection requirements provided in the national legislation. These requirements may vary from country to country, but compliance with the requirements of GSR Part 3 [9] is generally expected. Implementation of radiation protection in nuclear medicine facility must fit in with, and be complementary to, the system for implementing good medical practice in the facility. This section covers general requirements for safety and security of radioactive sources and for radiation protection with regard to occupational and public exposure, based on SSG-46 [6] and Refs [4, 9, 10, 58–65]. Paragraph 2.5 of SSG-46 [6] states:

  "Medical uses of ionizing radiation involve all three categories of exposure: occupational exposure for those involved in the performance of radiological procedures; medical exposure, primarily for the patients undergoing the radiological procedures, but also for carers and comforters and for volunteers subject to exposure as part of a programme of medical research; and public exposure for members of the public, such as in waiting rooms."

10.1. MANAGEMENT SYSTEM FOR RADIATION PROTECTION AND SAFETY

SSG-46 [6] states:

"2.96. ...The RPO has no direct responsibilities or roles with respect to patient radiation protection...

"2.138. ...the medical radiation facility...and its management should ensure complementarity between the requirements for radiation protection and safety and other health care delivery requirements within the medical facility...

"2.141. Depending on the size of the medical radiation facility, committees might be formed to help the implementation of the aspects of the management system pertaining to the radiation protection and safety programme. One such committee might be a radiation safety committee, with the function of advising on safe operation and compliance with radiation protection and safety regulatory requirements. The members of the committee should be at the senior level and would typically include an administrator representing the management, a radiological medical practitioner, a medical radiation technologist, a medical physicist and the RPO. The RPO should carry out day to day oversight of the radiation protection programme and should report to the radiation safety committee. The licensee should ensure that the RPO is provided with the resources required to oversee the programme, as well as the authority to communicate with the committee on a periodic basis. The RPO should be able to communicate directly with the licensee, and with the regulatory body as needed, such as in the case of breaches of compliance that may compromise safety."

Every individual involved in the nuclear medicine activities should regard the rules and regulations as necessary and should know their responsibilities for radiation protection through formal assignment of duties. The following parties have responsibilities with regard to radiation protection:

— Licensee and employer;
— Nuclear medicine specialists;
— Nuclear medicine technologists;
— Radiation protection officer;
— Medical physicists;
— Radiopharmacists;
— Nurses working with radioactive patients;

— Maintenance engineers.

Paragraph 2.44 of GSR Part 3 [9] states:

"The relevant principal parties and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures."

The management system should also provide for record keeping and access to these records. SSG-46 [6] states:

"2.146. ..Digital information systems when used appropriately can have a positive effect on the practice of radiation protection and safety in medical uses of ionizing radiation. For example, use of these systems can help to avoid the performance of unnecessary or inappropriate studies and repeat studies by making patient information available to multiple users. ...These systems can also help in monitoring doses to patients and image receptors, and monitoring image retakes; the information from such monitoring can help in the optimization of protection and safety for imaging procedures.

....

"2.148. The management system should include a review cycle. ...Clinical audits can be considered as a systematic and critical analysis of the quality of clinical care, including the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient. A clinical audit looks beyond a strict radiation protection and safety focus, and seeks to assess the quality and efficacy of the medical practice offered in the facility, ultimately the patient health outcome. This should include the radiation protection and safety aspects of medical uses of ionizing radiation and, importantly, should keep these aspects in the context of medical practice, ensuring a common goal. ...

....

"2.149. ...The radiological review involves at least the radiological medical practitioners, the medical radiation technologists and the medical physicists at the medical radiation facility.

More detailed guidance on clinical audit in nuclear medicine is given in Ref. [4].

10.2. SAFETY ASSESSMENT ANALYSIS

Paragraph 2.150 of SSG-46 [6] states that the "safety assessment can occur before a facility is operational or when a major change in operation is contemplated." It should be performed according to the requirements of the national regulatory body, should be well documented and the report should be submitted to the regulatory body if required. Furthermore [6]:

"2.151. ...For medical radiation facilities, the safety assessment should include not only considerations of occupational and public exposure but also medical exposure and the possibility of unintended or accidental medical exposures.

....

"3.284. The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and should consider their likelihood and potential consequences...

"3.285. The safety assessment should be revised when:

(a) New or modified medical radiological equipment or accessories are introduced;
(b) Operational changes occur, including changes in workload;
(c) Operational experience or information on accidents or errors indicates that the safety assessment should be reviewed.

....

"4.286. Safety assessments in nuclear medicine should include consideration of all the steps in the use of radiopharmaceuticals for diagnosis and treatment in the nuclear medicine facility. The steps include the following:

(a) Ordering, transport and receipt of radiopharmaceuticals, including unpacking and storage;
(b) Preparation and administration of radiopharmaceuticals to patients;

(c)   Examination, treatment and care of therapy patients receiving large amounts of radioactive material;

(d)   Storage and handling of radioactive waste.

....

"I.5. Factors that may influence the frequency and severity of accidental exposures include the following:

(a)   Insufficient training and expertise of radiological medical practitioners (nuclear medicine physicians), medical physicists or medical radiation technologists (nuclear medicine technologists);

(b)   No reassessment of staffing requirements after the purchase of new equipment, the hiring of new medical radiation technologists or an increase in workload;

(c)   Inadequate quality assurance and lack of defence in depth;

(d)   Lack of a programme for acceptance tests and commissioning of equipment;

(e)   Lack of a maintenance programme;

(f)   Poor, misunderstood or violated procedures;

(g)   Lack of operating documents in a language understandable to users;

(h)   Misunderstanding of displays or software messages;

(i)   Inattention of staff to the task at hand;

(j)   Inconsistent use of different quantities and units.

"I.6. In most accidental exposures, there was a combination of several contributing factors, which can be summarized as follows:

(a)   Lack of commitment of the licensee (administrators and managers of the medical facility and/or the nuclear medicine facility);

(b)   Staff insufficiently briefed or trained;

(c)   Insufficient quality assurance."

10.3. SECURITY OF SOURCES

Paragraph 4.56 of SSG-46 [6] states:

"The objective of source security is to ensure continuity in the control and accountability of each source at all times... In a nuclear medicine facility, the sources include unsealed radiopharmaceuticals as well as radionuclide

generators, radiopharmaceutical dispensing equipment and sealed sources used for calibration or quality control tests. ...Situations that are particularly critical with respect to security of sources in a nuclear medicine facility include receipt of radiopharmaceuticals, storage of sources, movement of sources within the facility and storage of radioactive waste... The licensee of the nuclear medicine facility should develop procedures to ensure the safe receipt and movement of radioactive sources within the facility and should establish controls to prevent the theft, loss and unauthorized withdrawal of radioactive materials or the entrance of unauthorized personnel to controlled areas. An inventory of sources should be maintained, and procedures should be put in place to check and confirm that the sources are in their assigned locations and are secure."

The regulatory body should promptly be informed in case of lost or stolen sources. The user is responsible for the security of sources. When a radioactive source is not in use, it should always be stored. Small sources are frequently stored in the room where preparation of radiopharmaceuticals is undertaken. Larger sources, used for quality assurance and quality control of imaging equipment, are frequently stored in a specific secure, shielded and labelled cabinet or container, in the same equipment room.

10.4. RADIATION SAFETY OF NUCLEAR MEDICINE FACILITIES AND EQUIPMENT

Paragraph 3.9 of SSG-46 [6] states:

"Provisions for the incorporation of radiation protection and safety features are best made at the facility design stage (e.g. for X ray rooms and other related rooms). The siting and layout should take into account the types of radiological procedure, workload and patient flow, both within the radiology facility and, in cases where the radiology facility is part of a larger hospital or medical centre, within other departments of the facility."

10.4.1. Design of nuclear medicine facilities

The nuclear medicine facility should be readily accessible, especially for outpatients, who comprise the majority of patients. When the facility is located in the proximity of other strong sources of ionizing radiation, such as radiotherapy sources or a cyclotron, proper safety design and shielding should be sufficient

to prevent any interference from ionizing and non-ionizing radiation, as well as from magnetic field, with the diagnostic instrumentation.

Proper design of the HVAC system is central in the planning of a nuclear medicine facility. This system should be adequate to control both the possibility of radioactive contamination of the staff and the environment, due to the unsealed radioactive sources used, and the possibility of microbiological contamination of the radiopharmaceuticals from the staff and the external environment. SSG-46 [6] states:

"4.8. ...Consideration should also be given to providing easy exit routes for patients, after the examination or treatment has been performed, that minimize movement through the facility.

"4.9. A typical nuclear medicine facility using unsealed sources...will have areas for the following: source storage and preparation (radiopharmacy, radioisotope laboratory or 'hot lab'), radiopharmaceutical administration to patients, uptake rooms, imaging (in vivo), sample measurement (in vitro), waiting areas, changing areas and toilets, radioactive waste storage and predisposal processing. Separate waiting areas for patients before and after radiopharmaceutical administration should be considered. For those nuclear medicine facilities at which therapy with radiopharmaceuticals is performed, a dedicated ward for patients undergoing such treatments should be considered. The facility will also have areas where radioactive materials are not expected to be found, such as in offices, reporting areas and staff rooms, including cloakrooms, showers and toilets for staff. ...

"4.10. For security purposes, nuclear medicine facilities should be located in areas where access by members of the public to the rooms where sources, including radionuclide generators, and radiopharmaceutical dispensing equipment are used and stored can be restricted. Furthermore, the proximity of source storage facilities to personnel that may need to respond in the event of a security breach should also be considered.

"4.11. As a general rule, the design of the nuclear medicine facility should make provision for safety systems or devices associated with the equipment and rooms. This includes electrical wiring relating to emergency off switches, as well as safety interlocks and warning signs and signals.

"4.12. A stable power supply should be available for the facility. An uninterruptible power supply or battery backup systems should be installed to capture the active information at the time of the outage and to shut down

all software in a controlled manner. Servers should be programmed to shut down automatically when the power supply is interrupted.

"4.13. The design of the facility should include an air conditioning system sufficient to maintain the temperature in the examination room within the parameters defined by the equipment manufacturers. Alternatively, in the case of PET scanners, water cooling can also be used, depending on the equipment. In addition, temperature control is necessary for uptake rooms in a PET facility to prevent artefacts (e.g. brown fat uptake) occurring if room temperatures are too low.

"4.14. Issues to be considered for the design of the nuclear medicine facility include: optimization of protection and safety against external radiation and contamination; maintaining of low radiation background levels to avoid interference with imaging equipment; meeting requirements for radiopharmaceuticals...; and ensuring safety and security of sources (locking and control of access).

"4.15. For external exposure, the three factors relevant to dose reduction (time, distance and shielding) should be combined in the design to optimize occupational radiation protection and public radiation protection. Larger rooms are preferable to allow easy access for patients on bed trolleys and to reduce exposure of staff as well as the public. Larger rooms also allow for easier patient positioning and movement during the procedures. ...

"4.16. The design of the nuclear medicine facility should include provision for secure and shielded storage for radioactive sources. ...Shielding should be appropriate to the type and energy of the emitted radiation. Storage may be provided in a room or a separate space outside the work area or in a locked cupboard, safe, refrigerator or freezer situated in the work area. Separate storage compartments for radiopharmaceuticals and an area for temporary storage of radioactive waste should be provided, with appropriate protective barriers.

....

"4.18. Signs and warning lights should be used at the entrances of controlled areas and supervised areas to prevent inadvertent entry... Signs should also be available at the entrances to areas for source preparation and storage, hybrid imaging rooms and rooms for hospitalized patients undergoing radiopharmaceutical therapy... The signs should be clear and

easily understandable. Warning lights, such as illuminated and flashing signs, should be activated when CT is being used in hybrid imaging procedures.

"4.19. Bathrooms designated for use by nuclear medicine patients should be finished in materials that can be easily decontaminated. Staff of the nuclear medicine facility should not use the patient bathrooms, as it is likely that the floors, toilet seats and tap handles of the sink will be contaminated.

....

"4.280. ...(g) ...In most situations, it is better to dilute and disperse the waste activity in a continuous sewerage system, rather than to concentrate and store excreta for decay. Some precautions may be required where sewerage systems allow rapid processing of effluent with subsequent mixing with river water or usage for irrigation of land used for growing vegetables…"

Requirements on this issue differ very much among countries and each nuclear medicine facility should comply with their country's regulations. More details on discharge options for radioactive effluents are given in Ref. [63].

10.4.2. Radiopharmacies and laboratories for handling unsealed radioactive materials

SSG-46 [6] states:

"4.21. Radiopharmacies or laboratories where unsealed radioactive materials are handled, such as the source preparation area, should have:

(a) Means to prevent access by unauthorized persons;
(b) Adequate storage space for equipment used in the given room or area to be available at all times to minimize the potential for spreading contamination to other areas;
(c) A contained workstation for easy decontamination;
(d) Shielded storage for radioactive sources;
(e) Shielded temporary storage for both solid and liquid radioactive waste, and places designated for the authorized discharge of liquid radioactive effluent;
(f) Shielding to protect workers where significant external exposure might occur;
(g) A wash-up area for contaminated articles, such as glassware;

(h)   An entry area where protective clothing can be stored, put on and taken off, and which is provided with a hand washing sink and a contamination monitor;

(i)   Taps and soap dispenser that are operable without direct hand contact and disposable towels or a hot air dryer;

(j)   An emergency eyewash, installed near the hand washing sink;

(k)   An emergency shower for decontamination of persons.

....

"4.22.   Radiopharmacies, laboratories and other work areas for manipulation of unsealed radioactive materials should be provided with equipment kept specifically for this purpose, which should include:

(a)   Tools for maximizing the distance from the source, for example tongs and forceps;

(b)   Syringe shields;

(c)   Containers for radioactive materials, with shielding as close as possible to the source;

(d)   Double walled containers (with an unbreakable outer wall) for liquid samples;

(e)   Drip trays for minimizing the spread of contamination in the case of spillage;

(f)   Disposable tip automatic pipettes (alternatively, hypodermic syringes to replace pipettes);

(g)   Lead walls or bricks for shielding;

(h)   Lead barriers with lead glass windows;

(i)   Barriers incorporating a low atomic number material (i.e. acrylic) for work with beta emitters;

(j)   Radiation and contamination monitoring equipment (surface and air);

(k)   Shielded carrying containers, wheeled if necessary, for moving radioactive materials from place to place;

(l)   Equipment to deal with spills (decontamination kits).

"4.23.   Drainpipes from sinks in a radiopharmacy or laboratory should go as directly as possible to the main building sewer and should not connect with other drains within the building, unless those other drains also carry radioactive material. This is to minimize the possibility of the drainage system 'backing up' and contaminating other, non-controlled, areas. The final plans of the drainage system, which should be supplied to maintenance personnel, should clearly identify the drains from radiopharmacies and

laboratories. Pipelines through which radioactive materials flow should be marked to ensure that monitoring precedes any maintenance.

"4.24.   Some States require that drainpipes from a nuclear medicine facility and especially from radionuclide therapy wards terminate in a delay tank. ...

"4.25.   The floors of areas with the potential for contamination should be finished in an impermeable material that is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor. The walls should be finished in a smooth and washable surface, for example painted with washable, non-porous paint. The surfaces of the room where unsealed radioactive materials are used or stored, such as benches, tables, seats, and door and drawer handles, should be smooth and non-absorbent, so that they can be cleaned and decontaminated easily. Supplies (e.g. gas, electricity and vacuum equipment) should not be mounted on bench tops, but on walls or stands.

"4.26.   The floor and benches, including worktops, should be strong enough to support the weight of any necessary shielding materials or of radionuclide generators. The need for lifting equipment for radionuclide generators should be assessed.

"4.27.   Radiopharmacies or laboratories in which radioactive aerosols or gases are produced or handled should have an appropriate ventilation system that includes a fume hood, laminar airflow cabinet or glovebox. The fume hood should be constructed of material that is smooth, impervious, washable and resistant to chemicals, and it should exhibit a negative flow rate. The work surface should have a slightly raised lip to contain any spills. The ventilation system should be designed such that the radiopharmacy or laboratory is at negative pressure relative to surrounding areas and should be adequate to the radioisotopes used [40].

"4.28.   The airflow should be from areas of minimal likelihood of airborne contamination to areas where such contamination is likely. Room air from a radiopharmacy or radiochemistry laboratory should be vented through a filtration system or other mechanism for trapping airborne radioactive materials and should not be recirculated, neither directly, in combination with incoming fresh air in a mixing system, nor indirectly, as a result of proximity of the exhaust to a fresh air intake. The possibility for competitive airflow should be considered in the design. For reasons of asepsis, some radiopharmacies may need a positive rather than a negative pressure. In this

case, the pressure gradient can be obtained by locating other workstations requiring negative pressure next to the radiopharmacy workstation."

10.4.3. Rooms for patients undergoing radionuclide therapy

SSG-46 [6] states:

"4.29. Floors and other surfaces of rooms designated for patients undergoing radiopharmaceutical therapy should be covered with smooth, continuous and non-absorbent materials that can be easily cleaned and decontaminated. Shielding should be designed using appropriate dose constraints for workers and the public. Bins for the temporary storage of linen and waste contaminated with radioactive materials should be located in secure areas. Storage areas should be clearly marked, using the basic ionizing radiation symbol recommended by ISO [66].

"4.30. Rooms designated for patients undergoing radiopharmaceutical therapy should have separate toilets and washing facilities. A sign requesting patients to flush the toilet at least twice and to wash their hands should be displayed to ensure adequate dilution of excreted radioactive materials and to minimize contamination. The facilities should include a hand washing sink as a normal hygiene measure (see para. 4.19 for guidance on bathrooms and their use).

"4.31. The design of safe and comfortable accommodation for carers and comforters (see also paras 4.235–4.239) should be considered for nuclear medicine facilities with radiopharmaceutical therapy patients."

10.4.4. Structural shielding

Paragraph 4.32 of SSG-46 [6] states:

"The shielding should be designed to meet the requirements for the optimization of protection and safety and should take into consideration the classification of the areas within the facility, the type of work to be done and the radionuclides (and their activity) intended to be used. Shielding should consider both structural and ancillary protective barriers at the design stage. It is convenient to shield the source, where possible, rather than the room or the person. The need for wall, floor and ceiling shielding should be assessed, for example in the design of therapy facilities and of PET–CT facilities, to reduce occupational and public exposure to acceptable levels.

Wall shielding may be needed in the design of rooms housing sensitive instruments (to keep a low background), such as well counters, probes and imaging equipment (gamma cameras and PET scanners). In designing such wall shielding, consideration should be given to the height of the wall to ensure that scatter radiation, such as from a CT scanner, does not pass over the wall into the area being protected."

10.4.5. Classification of workplaces

With regard to occupational exposure, GSR Part 3 [9] requires the classification of workplaces as controlled areas or as supervised areas:

"3.88. Registrants and licensees shall designate as a controlled area any area...in which specific measures for protection and safety are or could be required for:

(a) Controlling exposures or preventing the spread of contamination in normal operation;
(b) Preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

....

"3.91. Registrants and licensees shall designate as a supervised area any area not already designated as a controlled area but for which occupational exposure conditions need to be kept under review, even though specific measures for protection and safety are not normally needed."

SSG-46 [6] states:

"4.65. ...Once designated, these areas should meet the requirements...for area delineation, signage, protection and safety measures, control of access, provision of personal protective equipment, provision of individual and area monitoring, provision of equipment for monitoring for contamination, and provision of personal decontamination facilities. All other rooms and areas that are not so designated are considered as being in the public domain, and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure. Classification of areas in a nuclear medicine facility should be based on the analysis of the process as a whole, and not only on the location of the equipment and the radiation sources. ...

"4.66. In a nuclear medicine facility, rooms for preparation of radiopharmaceuticals (i.e. radiopharmacies or hot labs), for injection of radiopharmaceuticals and for storage and decay of radiopharmaceuticals meet the criteria for a controlled area and should be so designated. Imaging rooms, particularly those housing radiopharmaceutical dispensing equipment (i.e. PET radiopharmaceutical and radioactive gas and aerosol dispenser devices), as well as waiting rooms dedicated to patients who have been injected with radiopharmaceuticals (e.g. uptake rooms in a PET facility) should also be designated as controlled areas. Rooms for patients undergoing radiopharmaceutical therapy should be designated as controlled areas. Rooms housing hybrid machines that have an X ray component (PET–CT and SPECT–CT) should be designated as controlled areas. A warning light at the entry to the room should be used to indicate when the machine is on to prevent unintended entry.

"4.67. Supervised areas may include examination rooms with probes, corridors and other areas where there are patients who have been administered with radiopharmaceuticals.

"4.68. The area around the control panel of hybrid imaging equipment (e.g. PET–CT and SPECT–CT) should be classified as a supervised area, even though the radiation levels may be very low owing to the shielding design. Classification of this area as a supervised area will ensure restricted access and hence, inter alia, avoid distraction of the operator, which could lead to accidental or unintended medical exposure of patients...

"4.69. In order to avoid uncertainties about the extent of controlled areas and supervised areas, the boundaries of such areas should, when possible, be walls and doors or other physical barriers, clearly marked or identified with suitable warning signs."

10.4.6. Performance of medical radiological and ancillary equipment

SSG-46 [6] states:

"4.42. As licensees take responsibility for the radiation safety of medical radiological equipment they use, they should impose purchasing specifications that include conditions to meet relevant international standards of the IEC and ISO or equivalent national standards. In some States, there may be an agency with responsibilities for medical devices or a

similar organization that gives type approval to particular makes and models of medical radiological equipment.

....

"4.53.   The nuclear medicine facility should have equipment, instruments and test objects for measurements, dosimetry and quality control. This may include liquid scintillation counters, well counters, activity meters (dose calibrators), probes, check sources, flood sources, phantoms, and geometry and mechanical test tools. Where applicable, such instrumentation should adhere to relevant IEC standards or equivalent national standards. ...

"4.54.   The nuclear medicine facility should be equipped with properly calibrated workplace monitoring instruments, including survey meters and portable contamination monitors.

"4.55.   Radiopharmaceutical dispensing equipment should adhere to relevant IEC standards or equivalent national standards.

....

"4.57.   ...The registrant or licensee is required to ensure that adequate maintenance (preventive maintenance and corrective maintenance) is performed as necessary to ensure that medical radiological equipment used in the nuclear medicine facility retains, or improves through appropriate hardware and software upgrades, its design specifications for image quality and radiation protection and safety for its useful life. The registrant or licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer or installer before initial operation and on an ongoing basis.

"4.58.   All maintenance procedures should be included in the programme of quality assurance and should be carried out at the frequency recommended by the manufacturer of the equipment and relevant professional bodies. Servicing should include a report describing the equipment fault, the work done and the parts replaced and adjustments made, which should be filed as part of the programme of quality assurance. A record of maintenance carried out should be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

"4.59.   ...after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the nuclear medicine facility before the equipment is returned to clinical use. The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist and other appropriate professionals, should decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed, especially in the amount of administered activity.

"4.60.   The electrical safety and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work.... Electrical and mechanical maintenance should be included in the programme of quality assurance and should be performed, preferably by the manufacturer of the medical radiological equipment or an authorized agent, at a frequency recommended by the manufacturer. Servicing should include a written report describing the findings. These reports and follow-up corrective actions should be archived as part of the programme of quality assurance."

10.4.7. Quality assurance

SSG-46 [6] states:

"4.223. The complexity of the programme of quality assurance for medical exposures will depend on the type of nuclear medicine facility. A facility with only limited diagnostic procedures will have a simpler programme compared with a facility that offers a comprehensive diagnostic service, including PET–CT imaging, radiopharmaceutical therapy, and that has a radiopharmacy. ...

"4.224. Measurements on medical radiological equipment are one of the components of the programme of quality assurance. Acceptance tests are required for new or significantly refurbished or repaired equipment, or after the installation of new software or modification of existing software that could affect protection and safety. The acceptance test should be followed immediately by commissioning, and then ongoing periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological equipment performs correctly, accurately, reproducibly

and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and software that has been donated.

"4.225. Depending on the equipment purchase agreement, acceptance tests can be performed by the manufacturer in the presence of the local medical physicist and the radiological medical practitioner representing the user, or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer. The process should involve verification of all specifications and features of the equipment, in particular, protection and safety features including displayed and reported dose metrics.

"4.226. After acceptance and before clinical use on patients, commissioning should be carried out by, or under the supervision of, the medical physicist. Commissioning should include measurements of all parameters and conditions of use that are expected in clinical use. For most situations, the medical physicist should be directly involved in the measurements, calculations and interpretation of data to characterize the equipment's performance. In some simple situations, it may be sufficient for the medical physicist to provide documented advice on how the commissioning should be performed. During commissioning, the baseline for subsequent constancy tests is established.

....

"4.229. ...The programme of quality assurance for medical exposures should ensure that radiopharmaceuticals intended for administration to patients are prepared in a manner that meets clinical needs and that satisfies both radiation protection and safety and pharmaceutical quality requirements...

"4.230. Paragraph 3.171(e) of GSR Part 3 [9] specifically requires that periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the programme of quality assurance. This is to ensure that such instrumentation has a current calibration, typically conducted within the last two years (see para. 4.200), and that it is functioning correctly. The programme of quality assurance for medical exposures should establish a frequency for calibration for each instrument and a set of quality control checks on the operation of each instrument to be performed at set intervals. This applies to stand alone dosimetry equipment and to software relating to dosimetry (e.g. software used for calculating specific uptake values from which doses can be estimated).

"4.231. The results of the quality control tests should be compared with established tolerance limits. These limits may have been established to ensure compliance with a regulatory requirement... Paragraph 3.171(b) of GSR Part 3 [9] requires the implementation of corrective actions if the measured values fall outside established tolerance limits. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence a maintenance programme should be put in place at the nuclear medicine facility. In some cases, the equipment might be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained that the equipment now meets the performance requirements.

"4.232. The programme of quality assurance for medical exposures in nuclear medicine should include the use of checks to ensure that the facility's protocols and procedures for imaging and therapy, including radiation protection and safety, are being followed. The periodic review of the protocols and procedures themselves is part of the radiological review at the facility... In addition, a review of imaging procedures may have been triggered by a comparison with DRLs [diagnostic reference levels]...

"4.233. Maintaining records is a crucial aspect of the programme of quality assurance for medical exposures. This includes the procedures used in the programme, the results of the quality control tests including trend analysis, the dosimetry surveys, the DRL comparisons, the corrective actions, and the investigations of unintended and accidental medical exposures. When planning and developing an effective programme of quality assurance, the licensee should recognize that it demands strong managerial commitment and support in the form of training and allocation of time, personnel and equipment resources. ..."

10.4.8. Calibration

SSG-46 [6] states:

"4.197. ...In nuclear medicine, responsibility for calibration is assigned to the nuclear medicine facility's medical physicist. Unsealed sources for nuclear medicine procedures should be calibrated in terms of the activity of the radiopharmaceutical to be administered, with the activity being determined and recorded at the time of administration. ...

"4.198. Radionuclides should be checked for radioactive impurities when these are liable to be present. This particularly applies to examining short lived radionuclides for the presence of longer lived impurities that could deliver a significant fraction of the absorbed dose.

....

"4.200. In the nuclear medicine facility, instruments used for dosimetry of patients, such as activity meters (dose calibrators), should also be calibrated at appropriate intervals using calibrated reference sources that cover the energy range used in clinical practice. After the initial calibration, the intervals for periodic calibrations might differ, depending on the availability at the facility of radioactive sources for calibration. A period of not more than two years is recommended.

"4.201. Paragraph 3.167(d) of GSR Part 3 [9] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. ...

"4.202. Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), should be maintained...."

10.5. OCCUPATIONAL EXPOSURE

SSG-46 [6] states:

"4.61. In nuclear medicine..., occupationally exposed individuals are usually medical radiation technologists, radiological medical practitioners (including, e.g., nuclear medicine physicians), radiopharmacists and medical physicists. Other health professionals such as nurses and other support staff involved in the management of patients who have been administered with radiopharmaceuticals, particularly in nuclear medicine facilities providing therapy services, may also be considered occupationally exposed.

....

"4.63. Other nuclear medicine facility workers such as administrative personnel and other service support personnel, cleaning personnel, and workers in the wider medical facility where the nuclear medicine facility is

located, for whom radiation sources are not required by, or directly related to, their work, are required to have the same level of protection as members of the public..."

10.5.1. Local rules and procedures

SSG-46 [6] states:

"4.70.   ...as established in para. 3.94 of GSR Part 3 [9], local rules and procedures are required to be established in writing in any nuclear medicine facility. Their purpose is to ensure protection and safety for workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure both for normal work and in unusual events. The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions (see paras 4.118–4.140).

....

"4.72.   Equipment (both hardware and software) should be operated in a manner that ensures satisfactory performance at all times with respect to both the tasks to be accomplished and to radiation protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should also be considered. The final documented set of operational procedures should be subject to approval by the licensee of the nuclear medicine facility, and should be incorporated into the facility's management system (see paras 2.138–2.149).

"4.73.   Nuclear medicine staff should understand the documented procedures for their work with radiopharmaceuticals and for the operation of the equipment with which they work, including the safety features, and should be trained, with periodic refresher training, in what to do if things go wrong. Additional training should be conducted when new radiopharmaceuticals or devices are brought into nuclear medicine practice.

....

"4.75.   Work procedures should be formulated so as to minimize exposure from external radiation and contamination, to prevent spillage from occurring and, in the event of spillage, to minimize the spread of

contamination (surface and airborne). For instance, all manipulation for dispensing radioactive materials should be carried out over a drip tray..."

10.5.2. Monitoring of the workplace

SSG-46 [6] states:

"4.112. ...Workplace monitoring comprises measurements made in the working environment and the interpretation of the results. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is particularly important for staff members who are not individually monitored. In the nuclear medicine facility, workplace monitoring should address both external exposure and contamination. ...

"4.113. Laboratories and other areas in which work with unsealed sources is undertaken should be monitored, both for external radiation and for surface contamination, on a systematic basis. Contamination monitoring is required for:

(a) All work surfaces (including the interior of enclosures), tools, equipment and devices (including dosimetry systems, computers and peripherals, and stress testing units), the floor and any items removed from these areas;
(b) Workstations, ventilation systems and drains, when any of these needs to be accessed for maintenance purposes;
(c) Protective and personal clothing, and shoes, particularly when the wearer is leaving a controlled area (monitors should be available near the exit);
(d) Clothing, bedding and utensils used by radiopharmaceutical therapy patients.

"4.114. Periodic monitoring with a survey meter and contamination monitor, or by wipe tests, should be conducted for controlled areas and supervised areas. Continuous monitoring with an area monitor should be considered for areas for storage and handling of sources. If a package containing radioactive sources is damaged upon arrival, a survey of removable contamination and the external radiation field should be carried out.

"4.116. Workplace monitoring should be performed and documented as part of the nuclear medicine facility's radiation protection programme. The nuclear medicine facility's RPO or medical physicist should provide specific advice on the workplace monitoring programme, including any investigations that are triggered when investigation levels are exceeded...

"4.117. The survey meters used for external radiation monitoring should be calibrated in terms of...ambient dose equivalent... Contamination monitors should be calibrated in appropriate quantities."

10.5.3. Individual monitoring for workers

SSG-46 [6] states:

"4.118. Paragraph 3.100 of GSR Part 3 [9] establishes the requirement of individual monitoring for 'any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure'. Workers who may require individual monitoring include nuclear medicine physicians, other specialist doctors, medical radiation technologists, medical physicists, the RPO, radiopharmacists and any other persons involved in the preparing, dispensing and administering of radiopharmaceuticals to patients for diagnosis and therapy, staff dealing with radioactive waste, biomedical and clinical engineers, maintenance and servicing personnel, and any nursing or other staff who need to spend time with nuclear medicine patients or who work in controlled areas.

"4.119. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary. Individual external doses can be assessed by using individual monitoring devices, which include thermoluminescent dosimeters, optical stimulated luminescent dosimeters, radiophotoluminiscent dosimeters, film badges and electronic dosimeters. Individual monitoring devices should be calibrated and should be traceable to a standards dosimetry laboratory...

"4.120. ...each personal dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that nuclear medicine facility, and it should not be taken to other facilities where that person

may also work. ...Monitoring results can then be interpreted for the person working in a specific nuclear medicine facility, and this will allow appropriate review of the effectiveness of the optimization of protection and safety for that individual in that facility. ...

"4.121. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most States is typically in the range of one to three months. It is determined by such factors as service availability, work load and type of work. A one month monitoring period is usually used for persons performing procedures associated with higher occupational exposure. A longer monitoring period (two or three months) is more typical for personnel exposed to lower doses, as a one month cycle would usually mean that the actual occupational dose is less than the minimum detection level of the dosimeter, resulting in no detectable doses. With a longer cycle, it is more likely that a reading can be obtained. In certain circumstances (e.g. the introduction of new procedures, and work at high dose rates), shorter monitoring periods may be necessary. In these situations, the supplementary use of electronic dosimeters may be appropriate. Unnecessary delays in the return, reading and reporting of the recorded dose on dosimeters should be avoided. Dosimeters should be sent from the nuclear medicine facility to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all in a timely manner. Some regulatory bodies may specify a performance criterion for timely reporting.

....

"4.123. ...When there is a possibility of high exposure of the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters should be worn (if this is compatible with good clinical practice).

"4.124. ...in the handling of sources for preparation and administration..., ...monitoring of dose to the lens of the eye may need to be considered.

"4.125. ...Depending on the work performed by the person being individually monitored, there may be a preferred position for wearing the dosimeter, and more than one dosimeter may be used. In nuclear medicine, dosimeters are usually worn on the front of the upper torso (and under any protective clothing)...

....

"4.127. In nuclear medicine, certain workers may be at risk of both surface (skin) contamination and internal contamination by ingestion, inhalation or adsorption of radioactive material. Employers are responsible for identifying those persons and for arranging for appropriate monitoring (para. 3.102 of GSR Part 3 [9]). This requirement is typically met by monitoring the thyroid with an external detector that assesses the iodine uptake for individuals handling radioiodine and by monitoring the hands after the protective gloves have been removed. In some special cases, it may be required to measure the activity of urine samples. The committed effective dose should be calculated as part of the worker's total effective dose [67].

"4.128. When not in use, individual dosimeters should be kept in a dedicated place and should be protected from damage or from irradiation. ...

....

"4.130. Additional direct reading operational dosimeters, such as electronic dosimeters, should be considered for use in a nuclear medicine facility, for example in a new facility or with the introduction of new procedures, as these devices can give the worker an instant indication of both the cumulative dose and the current dose rate and also allow pre-setting of an alarm to alert when a given level has been reached [67]. These dosimeters are also useful for staff involved in radiopharmaceutical therapies and for pregnant workers, where a 'real time' reading of the dose is recommended."

Individual monitoring results are to be analysed and records are to be kept.

10.5.4. Health surveillance

SSG-46 [6] states:

"4.137. The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks, and requirements are given in paras 3.108 and 3.109 of GSR Part 3 [9].

"4.138. No specific health surveillance relating to exposure to ionizing radiation is necessary for staff involved in nuclear medicine. Under normal working conditions, the occupational doses incurred in nuclear medicine are low, and no specific radiation related examinations are required, as there are no diagnostic tests that yield information relevant to exposure at low doses. ...

"4.139. Only in cases of overexposed workers, at doses much higher than the dose limits (e.g. a few hundred millisieverts or higher), would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary [67]. In case of internal contamination, additional investigations to determine uptake and retention may be required. Interventions to facilitate excretion or limit uptake of the radioactive agent should be considered, as appropriate.

"4.140. Counselling should be made available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling should be made available to workers who are concerned about their radiation exposure. In nuclear medicine, the latter group may include women who are or may be pregnant. Counselling should be given by appropriately experienced and qualified practitioners. Further guidance is given in GSG-7 [67]."

10.5.5. Pregnant and breast-feeding workers

SSG-46 [6] states:

"4.146. Paragraph 3.114 of GSR Part 3 [9] establishes the requirement that:

> 'The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public.'

"The limitation of the dose to the embryo or fetus does not mean that pregnant women should avoid work with radiation, but it does mean that the employer should carefully review the exposure conditions with regard to both normal exposure and potential exposure. For example, a pregnant worker might be restricted from spending a lot of time in the radiopharmacy or working with solutions of radioiodine [68]. The main risk with radioiodine is that it crosses the placental barrier and concentrates in the fetal thyroid.

"4.147. Other possible solutions include reassignment of a pregnant worker to duties where the likelihood of an accident is lower or to a location that has a lower ambient dose equivalent. Such reassignments should be accompanied by adequate training. A further consideration is the need to avoid having pregnant workers respond to an accident such as a radioactive spill...

"4.148. ...Personal electronic dosimeters are valuable in assessing radiation doses to pregnant workers and subsequently the embryo or fetus (see also para. 4.130)."

10.6. PUBLIC EXPOSURE

Paragraph 4.263 of SSG-46 [6] states:

"Public exposure can arise from the performance of nuclear medicine for persons in and around the nuclear medicine facility and also in the wider public domain. The latter can occur as a result of the release from the nuclear medicine facility of patients with some remaining radioactivity. Radiation exposure of carers and comforters while performing that role is considered medical exposure and not public exposure and is not covered here (see paras 4.235–4.239 for guidance on carers and comforters). In addition, there is the possibility, albeit low, of public exposure from exposure pathways associated with the management of radioactive waste."

10.6.1. Non-occupationally exposed workers and visitors

SSG-46 [6] states:

"4.267. The primary means for protecting the public from external exposure is the shielding in place at the nuclear medicine facility (see paras 4.32–4.36), which should be sufficient so that public exposure resulting from being in any immediately adjacent areas, including accessible rooms above and below, is in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied...

"4.268. Patients that have been administered radiopharmaceuticals could expose members of the public in the nuclear medicine facility and upon release (see paras 4.246–4.248). In the nuclear medicine facility, the RPO should establish rules to ensure that the exposure of any member of the public will be less than the public dose limit and, preferably, lower than any applicable dose constraint. At the design stage of the nuclear medicine facility, consideration should be given to the respective flow of patients and visitors in the facility so that their contact or proximity is minimized, thereby reducing the potential for both external exposure and spread of contamination.

"4.269. ...In exceptional cases, a visitor may be permitted to enter a controlled area, but he or she should be accompanied at all times by a staff member who knows the protection and safety measures for the area. Written procedures should be drawn up specifying when such exceptions can take place and who may accompany the visitor. Particular consideration, in all cases, should be given with respect to women who are or may be pregnant or breast-feeding."

10.6.2. Members of the public in the wider public domain

SSG-46 [6] states:

"4.271. There are usually no restrictions with respect to public exposure for the release of patients that have undergone diagnostic nuclear medicine procedures. Patients should be advised on measures to enhance elimination of the residual radioactivity (such as drinking plenty of fluid and frequently emptying the bladder) and to avoid prolonged contact with sensitive members of the public (young children and pregnant women), if appropriate.

"4.272. The exposure of other persons, in the wider public domain, by patients who have received radiopharmaceutical therapy can occur through external irradiation of persons close to the patient, such as on public transport, and through internal contamination of persons as a result of excreted or exhaled radionuclides. The RPO of the nuclear medicine facility should establish rules to ensure that the exposure of any member of the public, following the release of a radiopharmaceutical therapy patient, will be less than the public dose limit and, preferably, lower than any applicable dose constraint. As stated in para. 4.248, the patient should be given written instructions that include means for avoiding external and internal exposure of the public. ...Results of the calculations should be recorded. When deciding on the appropriate discharge activity for a particular patient, the licensee and the RPO should take into account the transport and the living conditions of the patient, such as the extent to which the patient can be isolated from other family members and the safe management of the patient's excreta and body fluids (for detailed guidance on the release of radiopharmaceutical therapy patients and radiation protection of the public, see Refs [65, 69, 70].

10.6.3. Death of a patient who has undergone a nuclear medicine procedure

Paragraph 4.273 of SSG-46 [6] states:

"Precautions may be required after the death of a patient to whom radiopharmaceuticals have been administered, particularly in the case of radiopharmaceutical therapy. This applies to the immediate handling of the dead patient, both in the hospital and in the home or other place, but also with respect to autopsy, embalming, burial or cremation. The radiation protection precautions should be determined by the RPO, on the basis of a generic safety assessment of the need for monitoring personnel who carry out these procedures, the need for monitoring the premises and the need for minimizing external radiation exposure and the potential for contamination. ..."

10.6.4. Radioactive waste

SSG-46 [6] states:

"4.274. Another potential pathway for public exposure is from radioactive waste; and hence, Requirement 31 and paras 3.131–3.134 of GSR Part 3 [9] require that systems and procedures be put in place to manage radioactive waste and discharges of radioactive material. ...

"4.275. Most radioactive waste from nuclear medicine is waste containing short lived radionuclides, and it is feasible to consider such waste as non-radioactive waste, either immediately or after some time to allow for decay. A formal mechanism should be put in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of the release from regulatory control of radioactive material that is no longer are considered radioactive waste. Further guidance is given in SSG-45 [62].

"4.276. Since waiting for decay until the radioactive material meets the regulatory criteria for clearance or authorized discharge is an essential method in nuclear medicine, a room for the interim storage of radioactive waste should be made available. The room should be locked, properly marked and ventilated. Records should be kept from which the origin of the waste can be identified. The process requires the grouping (segregation) of the waste in accordance to the expected time for the decay of the radionuclides

(initial activity and physical half-life) and the physical form of the waste. Examples of different physical forms include the following:

(a)   Vials that might contain residual radioactivity;
(b)   Biological waste that will undergo decomposition;
(c)   Infectious waste requiring sterilization;
(d)   Broken glassware, syringes and needles requiring collection in separate containers to prevent personnel being injured;
(e)   Radionuclide generators, bed linen and clothing from hospital wards (therapeutic applications);
(f)   Liquid scintillation solutions.

"Containers to allow segregation of different types of radioactive waste should be provided in areas where the waste is generated. The containers should be suitable for their purpose (e.g. in terms of volume, shielding and leaktightness).

"4.277. In practice, it is mainly ^{131}I and the waste from radiopharmaceutical therapy patients that require special precautions. Appropriate storage of radioactive material to allow for decay will minimize the environmental impact of the release. The majority of diagnostic studies are performed using ^{99m}Tc, which has a physical half-life of 6 hours. Following storage of 2.5 days (10 half-lives, i.e. a decay of a factor of more than 1000), most of this waste can be treated as conventional waste. Technetium generators contain ^{99}Mo with a half-life of 2.75 days; depending on the initial activity of such generators, the time allowed for decay at the nuclear medicine facility should be 1.5–2 months.

"4.278. The most commonly used radionuclide in PET is ^{18}F. The short physical half-life of 110 minutes generally allows for discharge of the radioactive material after 24 hours.

"4.279. Management of radioactive waste containing longer lived radionuclides should take into account the initial activity and the half-life. The nuclear medicine facility's RPO should give advice in these situations."

Practical advice for common situations in nuclear medicine is given in para. 4.280 of SSG-46 [6].

Paragraph 4.282 of SSG-46 [6] states:

"The programme for monitoring public exposure arising from nuclear medicine should include dose assessment in the areas in and surrounding the nuclear medicine facility that are accessible to the public. Doses can be derived from the shielding calculations in the planning stage, combined with the results from area monitoring and contamination monitoring at the initial operation of the facility and periodically thereafter. Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In the absence of such requirements, a suggested period for keeping records is seven to ten years.

10.7. MEDICAL EXPOSURE

GSR Part 3 [9] defines medical exposure as:

"Exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to exposure as part of a programme of biomedical research."

Paragraph 3.155 of GSR Part 3 [9] states (footnote omitted):

"Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure."

Paragraph 2.8 of SSG-46 [6] states:

"Medical exposure differs from occupational and public exposure in that persons (primarily patients) are deliberately, directly and knowingly exposed to radiation for their benefit. In medical exposure, applying a dose limit is inappropriate, as it may limit the benefit for the patient; consequently, only two of the radiation protection principles apply — justification and optimization. Justification plays the role of gatekeeper, as it will determine whether or not the exposure will take place. If it is to take place, the radiological procedure should be performed in such a way that radiation protection and safety is optimized."

Nuclear medicine facilities can perform only those diagnostic examinations or therapeutic procedures that are justified. The responsibility for this generic

justification of a given radiological procedure is to the health authority in conjunction with appropriate professional bodies. At the level of the individual patient, the examination or procedure should be justified based upon a correct assessment of the indication, the actual clinical situation, the expected diagnostic and therapeutic yields, and the way in which the results are likely to influence the medical care of the patient. The responsibility for individual justification is shared between the referring medical practitioner and the nuclear medicine specialist. Three particular groups of patients identified in GSR Part 3 [9] for special considerations with respect to justification in nuclear medicine are patients who may be pregnant or breast-feeding, and paediatric patients.

The implementation of optimization of protection and safety has several components: equipment design, choice of radiopharmaceutical and activity, procedure considerations, DRLs, calibration, clinical dosimetry and quality assurance, as well as special consideration for children, pregnant and breast-feeding patients. Paragraph 4.169 of SSG-46 [6] states:

> "The use of appropriate and well designed medical radiological equipment and associated software underpins any nuclear medicine procedure. Gamma cameras, SPECT–CT and PET–CT scanners and their accessories should be designed and manufactured so as to facilitate the keeping of doses from medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information."

10.7.1. Optimization of nuclear medicine procedure

The exposure of the patient in a diagnostic nuclear medicine procedure should be the minimum necessary to achieve the clinical purpose of the procedure. Paragraph 4.170 of SSG-46 [6] states that "The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed." For therapeutic nuclear medicine procedures, the appropriate radiopharmaceutical and activity are selected and administered so that the activity is primarily localized in the organ(s) of interest, while the activity in the rest of the body is kept as low as reasonably achievable. SSG-46 [6] states:

> "4.171. The following points apply to all nuclear medicine patients, whether undergoing diagnostic or therapeutic procedures:
>
> (a) There should be an effective system for correct identification of patients, with at least two, preferably three, forms of verification, for example name, date of birth, address and medical record number.

(b)   Patient details should be correctly recorded, such as age, sex, body mass, height, pregnancy and breast-feeding status, current medications and allergies.

(c)   The clinical history of the patient should be reviewed.

"4.172. A written protocol should be drawn up for each diagnostic procedure performed in the facility, designed to maximize the clinical information to be obtained from the study, with consideration given to the appropriate DRL for the procedure... Such protocols are best developed using guidelines from national or international professional bodies, and hence will reflect current best practices... Protocols should be periodically reviewed in line with the requirements for quality assurance and radiological reviews...

"4.173. Deviations from such protocols may be necessary owing to the special needs of a particular patient or because of the local unavailability of components for a test. In such cases, the radiological medical practitioner should record a valid reason for the decision.

"4.174. Equipment should be operated within the conditions established in the technical specifications, and in accordance with any licence conditions, to ensure that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation protection and safety, so that optimal acquisition and processing of images can be achieved with the minimum patient exposure."

10.7.1.1. Diagnostic procedures

SSG-46 [6] states:

"4.175. Many factors influence the relationship between image quality and patient dose in diagnostic nuclear medicine procedures. ...Such factors include the following:

(a)   Appropriate selection of the best available radiopharmaceutical and its activity, with account taken of special requirements for children and for patients with impaired organ function.

(b)   Adherence to patient preparation requirements specific to the study to be performed. Examples include:
    — Use of methods for blocking the uptake in organs not under study and for accelerated excretion, when applicable.
    — Withdrawal of medications, food or substances that might interfere with the outcome of the procedure.

— Correct hydration.

(c)   The storage or retention of radiopharmaceuticals within specific organs can be influenced by drugs such as diuretics or gall bladder stimulants, whenever they do not adversely interfere with the procedure. This method is sometimes used to increase the specificity of the examination, but has also a positive influence on radiation protection, for example the use of a 'diuretic challenge' in renography.

(d)   For children undergoing diagnostic procedures, the amount of activity administered should be chosen by utilizing methodologies described in international or national guidelines...

(e)   Use of appropriate image acquisition parameters:

    — In nuclear medicine and with a gamma camera (planar and SPECT systems), this may include selection of the collimator, acquisition matrix, energy windows, acquisition zoom, time per frame and imaging distance.

    — For PET systems, this may include 2-D and 3-D acquisitions, matrix size, field of view, time of flight, attenuation correction, slice overlap, scatter correction and coincidence timing.

(f)   Use of appropriate reconstruction parameters (e.g. algorithm, matrix, filters, scatter correction and zoom factor), and application of appropriate image corrections (e.g. attenuation and scatter correction, and, in the case of PET systems, random correction).

(g)   Utilization of quantitative and qualitative capabilities, such as the generation of region of interest analysis, time–activity curve generation, image reformatting, or tissue uptake ratios, specific to the clinical need.

"4.176. Many radionuclides are excreted by the kidneys. Bladder doses can be minimized by drinking plenty of fluid and frequently emptying the bladder. Patients, particularly children, should be encouraged to empty the bladder frequently, especially in the immediate time following the examination.

"4.177. While most adults can maintain the required position without restraint or sedation during nuclear medicine examinations, it may be necessary to immobilize or sedate children so that the examination can be completed successfully. Increasing the administered activity to reduce the examination time is an alternative that can be used for elderly patients who are in pain.

"4.178. In some cases, if the patient is healthy and cooperative, activity can be reduced and scan times can be increased, for example for lung scans

for pregnant patients. In all cases, however, the diagnostic information produced should not be compromised by a reduction in activity.

"4.179. Care should be taken to ensure that there is no contamination on the collimator surface, patient table or elsewhere, as this might impair the quality of the images."

10.7.1.2. Radionuclide therapy

SSG-46 [6] states:

"4.181. In addition to the guidance in paras 4.170–4.180 (for both diagnostic nuclear medicine procedures and therapeutic nuclear medicine procedures), the following provisions should be put in place:

(a)   Verbal and written information and instructions should be provided to patients about their radiopharmaceutical therapy and about how to minimize exposure of family members and the public, and advice should be provided on pregnancy and contraception after therapy...
(b)   Special attention should be given to preventing the spread of contamination due to patient vomit and excreta.
(c)   A protocol should be drawn up for the release of patients after the administration of therapeutic doses of radiopharmaceuticals...

....

"4.182. ...Although algorithms for determining appropriate activities for a given patient on the basis of radiation doses to critical organs exist, there is no standardized algorithm. ...Typically, therapeutic radiopharmaceuticals are administered at standard fixed activities (GBq), standard fixed activities per unit body mass (MBq/kg) or standard fixed activities per unit body surface area (MBq/m^2), based on the results of toxicity studies and evaluation of side effects in clinical trials.

....

"4.184. Immediately prior to administration of a therapeutic radiopharmaceutical, the following information, as applicable, should be verified, preferably by two individuals:

(a)   The dose on the radiopharmaceutical label matches the prescription;

(b)   The identity of the patient by two independent means;
(c)   The identity of the radionuclide;
(d)   The identity of the radiopharmaceutical;
(e)   The total activity;
(f)   The date and time of calibration.

"4.185. The administered activity should be verified by means of an activity meter (dose calibrator) or other suitable device to ensure that the total activity does not deviate significantly from the prescribed administered activity (e.g. <5% deviation), and the measured value should be recorded. Corrections should be calculated for residual activity in the syringe, cups, tubing, inline filter or other materials used in the administration."

"4.186. Patients undergoing radiopharmaceutical therapy should be informed in advance that it will be necessary for medical personnel to minimize close or direct contact, so that this precaution will not be interpreted as a lack of concern.

"4.187. Both female and male patients should be advised about avoidance of pregnancy after therapeutic administrations. ..."

10.7.2. Pregnant patients

In nuclear medicine, possible pregnancy should be ascertained before the administration of radiopharmaceuticals. In the case of diagnostic procedures, standard requests should be made to all patients of fertile age. In the case of therapeutic procedures, accurate laboratory test should be systematically used to exclude pregnancy. SSG-46 [6] states:

"3.254. The first approach is through the posting of clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people using the radiology facility, posing the question 'Are you pregnant or possibly pregnant?' and 'If so, please tell the staff'. Such signs should be posted widely in the facility, including in waiting rooms and cubicles. ...

....

"4.189. Administration of radiopharmaceuticals for therapy to patients who are or might be pregnant should be generally avoided. There may be exceptions when the treatment is lifesaving...

"4.190. Diagnostic nuclear medicine procedures with ^{99m}Tc and radiopharmaceuticals that do not cross the placenta do not cause high fetal doses. Protection of the fetus can be optimized by using smaller administered activities and longer imaging times. This is feasible if the patient is able to remain still.

"4.191. Specific assessment of individual fetal doses is not usually necessary after diagnostic nuclear medicine studies involving ^{99m}Tc radiopharmaceuticals. In the case of other radiopharmaceuticals (such as iodine or gallium), calculation of the dose to the fetus and estimation of risk might be necessary.

"4.192. In the case of radiopharmaceuticals that are rapidly eliminated by the maternal kidneys, the bladder is the major source of fetal irradiation. After the administration of such radiopharmaceuticals, drinking plenty of fluid and frequently emptying the bladder should be encouraged. Some radiopharmaceuticals, for example radioactive iodides, including those administered for diagnostic purposes, cross the placenta freely and are taken up by fetal tissue, for example the thyroid. Failure to ascertain whether a patient is pregnant when administering ^{131}I for a scan, for example, may lead to a severe accidental exposure of the fetus.

"4.193. Of special concern is also the use of CT in PET–CT or SPECT–CT examinations. Routine diagnostic CT examinations of the pelvic region with and without contrast injection can lead to a dose of 50 mSv to the uterus, which is assumed to be equivalent to the fetal dose in early pregnancy. When PET–CT or SPECT–CT scanning is indicated for a pregnant patient, low dose CT protocols should be used and the scanning area should be reduced to a minimum...

"4.194. In the use of fluorodeoxyglucose (FDG) or other radiopharmaceuticals in PET imaging with patients who are or might be pregnant, a lower activity of FDG should be considered. ..."

10.7.3. Breast-feeding patient

SSG-46 [6] states:

"4.195. Female patients should be advised that breast-feeding is generally contraindicated after administration of some radiopharmaceuticals, due to

both the external irradiation of the suckling baby and the potential excretion of radioactivity through the breast milk...

"4.196. Depending on the radiopharmaceutical, breast-feeding may need to be interrupted for a period or even stopped following its administration. The milk expressed during the interruption period should be discarded. ..."

....

"4.244. ...it is crucial...for the nuclear medicine facility to have in place means for ensuring that the breast-feeding status of patients is known.

"4.245. The first approach is through the posting of clear signs, in languages able to be understood by the people using the nuclear medicine facility, posing the question 'Are you breast-feeding?' and 'If so, please tell the staff'. Such signs should be posted widely in the facility, including in waiting rooms and cubicles. The second approach is to directly ask patients directly whether they are breast-feeding. ...

....

"III.1.   Recommendations for cessation of breast-feeding following administration of various radiopharmaceuticals are given in Table [7]...

"III.2.   The advice on breast-feeding interruption takes into account both internal exposure from breast milk and external exposure of the infant from the mother. ...

"III.3.   For radiopharmaceuticals not included in the Table [7], the period of interruption of breast-feeding should continue until the radiopharmaceutical is no longer secreted in an amount estimated to give an effective dose greater than 1 mSv to the child [71]."

TABLE 7. RECOMMENDATIONS FOR CESSATION OF BREAST-FEEDING FOLLOWING ADMINISTRATION OF RADIOPHARMACEUTICALS *(table 3 of SSG-46 [6])*

Radiopharmaceutical	Most common clinical use	Typical administered activity (MBq)	Feeding interruption time
[11]C labelled	Tumour, brain or myocardial imaging	Any	No
[13]N labelled	Myocardial imaging	Any	No
[15]O labelled	Flow/perfusion measurements	Any	No
^{18}F-FDG	Tumour and infection imaging	400	4 h[a]
[51]Cr-EDTA	GFR	2	No
[67]Ga-citrate	Tumour and infection imaging	200	>3 weeks or complete cessation
^{68}Ga-DOTA-conjugated peptides	Tumour imaging	100–200	4 h[a]
^{99m}Tc-DMSA	Renal cortical imaging	80–200	4 h[b]
^{99m}Tc-DTPA	Renal imaging and function (GFR)	40–400	4 h[b]
^{99m}Tc-ECD	Brain perfusion	800	4 h[b]
^{99m}Tc-HMPAO	Brain perfusion	500	4 h[b]
^{99m}Tc-MDP and other phosphate agents (e.g. HDP and DPD)	Bone scan	800	4 h[b]
^{99m}Tc-MIBI	Myocardial perfusion, parathyroid scanning	250–700	4 h[b]
[99m]Tc-tetrofosmin	Myocardial perfusion	250–700	4 h[b]
^{99m}Tc-SC	Liver scan	200–400	4 h[b]

TABLE 7. RECOMMENDATIONS FOR CESSATION OF BREAST-FEEDING FOLLOWING ADMINISTRATION OF RADIOPHARMACEUTICALS *(table 3 of SSG-46 [6]) (cont.)*

Radiopharmaceutical	Most common clinical use	Typical administered activity (MBq)	Feeding interruption time
99mTc-DTPA aerosol	Lung ventilation imaging and function	50	4 h[b]
99mTc-labelled carbon (Technegas)	Lung ventilation imaging	40	4 h[b]
99mTc-MAG3	Imaging and function of kidneys and urinary tract	40–400	4 h[b]
99mTc-pertechnetate	Thyroid scan, Meckel's diverticulum	100–400	12 h[c]
99mTc-MAA	Lung perfusion imaging	40–150	12 h
99mTc-exametazime WBC	Infection imaging	180–400	12 h
99mTc labelled RBC	Radionuclide ventriculography	800	12 h
99mTc-mebrofenin/ disofenin and other IDA derivatives	Hepatobiliary imaging and function	300	4 h[b]
99mTc human albumin nanocolloidal particles	Sentinel nodesLiver scanning	5–120 120–200	4 h[b] 4 h[b]
111In-octreotide	Neuroendocrine tumours (somatostatine receptor scintigraphy)	100–200	60 h (2.5 d)
123I-MIBG	Neuroblastoma imaging	400	>3 weeks or complete cessation[d]
123I-NaI	Thyroid imaging and function	20	>3 weeks or complete cessation[d]
123I-ioflupane (FP-CIT)	Dopaminergic neurotransmission (D1) in movement disorders	150–250	>3 weeks or complete cessation[d]

TABLE 7. RECOMMENDATIONS FOR CESSATION OF BREAST-FEEDING FOLLOWING ADMINISTRATION OF RADIOPHARMACEUTICALS *(table 3 of SSG-46 [6]) (cont.)*

Radiopharmaceutical	Most common clinical use	Typical administered activity (MBq)	Feeding interruption time
[123]I-hippurate	Imaging and function of kidneys and urinary tract	20–40	12 h[e]
[131]I-NaI	Diagnostic and therapy of benign and malignant thyroid diseases	Any	Complete cessation[f]
^{131}I-MIBG	Adrenal tumour imaging and therapy	Any	>3 weeks or complete cessation
[201]Tl-chloride	Myocardial perfusion	100	96 h (4 d)

Note: DMSA — dimercaptosuccinic acid; DPD — dicarboxypropane diphosphonate; DTPA — diethylenetriaminepentaacetic acid; ECD — ethyl cysteinate dimer; EDTA — ethylene diamine tetraacetic acid; FDG — fluorodeoxyglucose; GFR — glomerular filtration rate; HDP — hydroxymethane diphosphonate; HMPAO — hexamethylpropyleneamine oxime; IDA — iminodiacetic acid; MAA — macroaggregate of albumin; MAG3 — mercaptoacetyltriglycine; MDP — methylene diphosphonate; MIBG — metaiodobenzylguanidine; MIBI — methoxyisobutylisonitrile; RBC — red blood cells; SC — sulphur colloid; WBC — white blood cells.

[a] The interruption time of 4 h during which one meal should be discharged takes into account both internal exposure from breast milk and external exposure of the infant from the mother.

[b] The interruption time of 4 h during which one meal should be discharged takes into account both internal exposure from breast milk in those unusual situations when free pertechnetate is not negligible, and external exposure of the infant from the mother.

[c] Activities of ^{99m}Tc-pertechnetate higher than 400 MBq require an interruption time of 24 h.

[d] The recommended interruption time of at least 3 weeks for all substances labelled with [123]I (except iodohippurate) is due to the risk of presence of impurities of other iodine isotopes ([124]I or ^{125}I).

[e] The interruption time of 12 h only concerns patients with normal renal function.

[f] Patients should discontinue breast-feeding 6 weeks before radioiodine administration in order to minimize the radiation dose to the breast.

10.7.4. Carers and comforters

SSG-46 [6] states:

"4.235. Some diagnostic nuclear medicine procedures, particularly of children, can be better performed with the assistance of a carer or comforter, for example a relative in the case of a paediatric patient, or a relative or friend for a disabled patient or very elderly or very ill patient. In these circumstances, the carer or comforter will be exposed. This is usually to a low dose, such as when caring for a child undergoing a renal examination, but in some cases the dose is not insignificant, for example in the case of staying with a child during a PET examination. Furthermore, in nuclear medicine there is also the additional consideration of exposure of carers and comforters after the diagnostic procedure, or in the case of radiopharmaceutical therapy with radioiodine, their exposure during the course of the treatment. This exposure is defined as medical exposure and as such is not subject to dose limits. However, paras 3.153 and 3.173 of GSR Part 3 [9] require that such carers and comforters be afforded radiation protection through the application of the requirements for the optimization of protection and safety and, in particular, the use of dose constraints in this process. These are the dose constraints established by government, as a result of consultation with the health authority, relevant professional bodies and the regulatory body..."

"4.236. Written protocols should be drawn up for implementing measures for the optimization of protection and safety for carers and comforters of patients during or after nuclear medicine procedures. The measures should utilize the basic methods for radiation protection (i.e. time, distance and shielding, and measures to minimize spread of contamination). The protocols should include the following:

(a) Criteria specifying who would be acceptable for acting as a carer or comforter;
(b) Methods for ensuring that the carer or comforter receives a dose that is as low as reasonably achievable;
(c) The values of the dose constraints to be applied..."

"4.237. The licensee should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, is unlikely to exceed the dose constraint. It is relatively straightforward to estimate effective doses to carers and comforters from measurements of the ambient dose equivalent

rates at the positions where they will be situated. These determinations should be made in advance to ensure that dose constraint is not exceeded. Therefore, individual dose monitoring is normally not necessary. For carers and comforters in a therapy ward, consideration may be given to the use of electronic dosimeters.

"4.238. Paragraph 3.153 of GSR Part 3 [9] states that:

'Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure.'

"The carer or comforter should indicate that he or she is still willing to provide support, care and comfort to the patient that is undergoing or has undergone a nuclear medicine procedure. In the case of radiopharmaceutical therapy with iodine, both for patients still in the hospital and for those that have been released (see also para. 4.248), appropriate written instructions should be provided to the carer or comforter of the patient (including for example, instructions on time spent with the patient and proximity to the patient, minimizing of physical contact and not sharing food or drinks). ..."

10.7.5. Volunteers in biomedical research

Paragraph 4.240 of SSG-46 [6] states:

"Some individuals will undergo diagnostic nuclear medicine procedures as part of their voluntary participation in an approved programme of biomedical research... Part of the approval process for the biomedical research will have been the setting of dose constraints for the nuclear medicine procedures... When the volunteer presents himself or herself at the nuclear medicine facility, he or she is to be afforded the same radiation protection as if he or she were a patient ready to undergo a nuclear medicine procedure, but with the additional restriction that his or her exposure will be subject to a dose constraint, either a nationally established dose constraint or a dose constraint specified by the ethics committee that approved the biomedical research programme..."

10.7.6. Release of patients after radionuclide therapy

SSG-46 [6] states:

"4.246. Paragraph 3.178 of GSR Part 3 [9] requires that a nuclear medicine facility have arrangements in place to manage the release of patients who have undergone radiopharmaceutical therapy. Once the patient is released, two groups of persons should be afforded appropriate radiation protection: the general public whom the patient may encounter or with whom the patient may interact, and members of the patient's family and close friends, who may be viewed simply as also being members of the public or as carers and comforters. Exposure of members of the public is subject to the public dose limits..., while exposure of carers and comforters is not subject to dose limits but is instead controlled through dose constraints (see paras 4.235–4.239). Furthermore, ...public exposure arising from a single 'source', such as a patient who has undergone radiopharmaceutical therapy, should be subject to dose constraints set at some fraction of the dose limits.

"4.247. The medical physicist or RPO at the nuclear medicine facility should establish prior to the release of a patient that the retained radioactivity in the patient is such that the doses that could be received by members of the public would not exceed public dose limits, and would be unlikely to exceed the relevant dose constraints for both members of the public and carers and comforters. An acceptable method of estimating the acceptable retained activity for patients being discharged from hospitals is to calculate the time integral of the ambient dose equivalent rate, considering the activity, energy and effective half-life of the radionuclides. When deciding on the discharge for a particular patient, the living conditions of the patient, such as the extent to which he or she can be isolated from other family members, in particular children and pregnant women, should also be considered. Safe management of the patient's contaminated excreta should be addressed. Special consideration should be given to incontinent patients. In the case of carers and comforters, the assumptions made for the calculations should be consistent with the written instructions that will be given at the time the patient is discharged from the facility. Published data suggest that systematic dose monitoring is not necessary...

"4.248. As indicated in para. 4.247, the patient or the legal guardian of the patient should be provided with written instructions on how to keep doses to members of the public and carers and comforters as low as reasonably achievable. Individuals of particular concern are children and pregnant

partners of patients (for detailed guidance, including sample information sheets, see Refs [65, 69, 70])."

10.7.7. Prevention of unintended and accidental medical exposures

SSG-46 [6] states:

"4.249. Paragraph 3.179 of GSR Part 3 [9] states that:

'Registrants and licensees…shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.'

"Paragraph 3.180 of GSR Part 3 [9] requires that the registrants and licensees promptly investigate if such exposures occur. General strategies for addressing those problems include the regular maintenance of medical radiological equipment and software, a comprehensive programme of quality assurance, continuing education and training of staff, and the promotion of a safety culture. Lessons identified from events that have occurred should be used for preventing or minimizing unintended and accidental medical exposures, as described in para. 4.251.

"4.250. Minimization of the likelihood of unintended or accidental medical exposures in nuclear medicine can be brought about by:

(a) The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks but can include actions such as double checks of the radiopharmaceutical and activity to be administered, and the correct identification of the patient.
(b) Actively encouraging a culture of always working with awareness and alertness.
(c) Providing detailed protocols and procedures for each process.
(d) Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
(e) Continuous professional development and practical training and training in applications for all staff involved in providing nuclear medicine services.

(f) Clear definitions of the roles, responsibilities and functions of staff in the nuclear medicine facility that are understood by all staff.

"4.251. Preventive measures should include reporting of incidents and near incidents, analysis and feedback, including lessons from international experience... Preventive measures should also include checking of the robustness of the safety system of the facility against reported incidents...

"4.252. In addition to the guidance in paras 4.249–4.251, the following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental medical exposures in nuclear medicine:

(a) Allocation of responsibilities to appropriately qualified health professionals only and ensuring that a management system is in place that includes radiation protection and safety;
(b) Use of the lessons from unintended and accidental medical exposures to test whether the management system, including for radiation protection and safety, is robust enough against these types of event;
(c) Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present?' in a systematic, anticipative manner for all steps in the nuclear medicine process.

10.7.8. Investigation of unintended and accidental medical exposures

SSG-46 [6] states:

"4.253. ...Unintended and accidental medical exposures can occur at any stage in the nuclear medicine process. For radiopharmaceutical therapy, unintended or accidental medical exposures can be either underexposures or overexposures. The events identified in para. 3.180 of GSR Part 3 [9] also include near misses, and these should be considered in the same way as actual events.

"4.254. ...Consensus recommendations on the level of activity difference that would be considered as substantially different appear to be lacking, but a pragmatic approach for use within the nuclear medicine facility might be the specification of deviations greater than 10% as being substantially different. A system with clear procedures should be put in place for identifying when this type of event occurs.

"4.255. Paragraph 3.181 of GSR Part 3 [9] establishes what is required during the course of the investigation. This includes calculation or estimation of patient doses, which should be performed by a medical physicist. A record of the calculation method and results should also be placed in the patient's file. When required, counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge.

"4.256. The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3 [9], has three main purposes. The first is to assess the consequences for the patients affected and to provide remedial and health care actions if necessary. The second is to establish what went wrong and how to prevent or minimize the likelihood of a recurrence in the nuclear medicine facility (i.e. the investigation is for the facility's benefit and the patients' benefit). The third purpose is to provide information to other persons or other nuclear medicine facilities. Dissemination of information about unintended and accidental medical exposures and radiation injuries has greatly contributed to improving methods for minimizing their occurrence. The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events. ...

....

"4.258. Irrespective of whether the event is also reported to the regulatory body, feedback to staff should be provided in a timely fashion and, where changes are recommended, all staff should be involved in bringing about their implementation."

GSR Part 3 [9] states:

"3.180. Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:

(a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;

(b)   Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;

(c)   Any exposure for diagnostic purposes that is substantially greater than was intended;

(d)   Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;

(e)   Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;

(f)   Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

"3.181. Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:

(a)   Calculate or estimate the doses received and the dose distribution within the patient;

(b)   Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;

(c)   Implement all the corrective actions that are under their own responsibility;

(d)   Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;

(e)   Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure."

10.8. CONCURRENT RISKS

Health care workers and patients encounter a number of health and safety hazards, the type and degree of exposure to which depend on a variety of factors. Appropriate measures require a full understanding of the hazards and risks[3]. A comprehensive overview of the occupational hazards, risk assessment and management is provided by the International Labour Organization (ILO) and WHO [72]. The two connected and essential stages in health and safety planning are the identification of potential hazards, and the assessment of the type and severity of the risk. Once the hazards have been identified and assessed, appropriate measures should be taken to manage those hazards and thus improve safety. The hierarchy of measures should be followed for each hazard: the most effective are engineering measures, followed by administrative (e.g. rules and training), and followed by personal protective equipment (PPE). International guidelines and relevant national legislation on occupational safety and health should be followed. The ILO and WHO [72] "recommended to involve an occupational health and safety specialist to provide technical guidance". The hazard assessment and required measures should be communicated to staff. The following summarizes potential hazards for nuclear medicine workers and measures to reduce the risk of exposure to the hazards.

10.8.1. Biological hazards

Biological hazards (biohazards) exist in all health care settings and include airborne and blood-borne pathogens (e.g. agents in the air that causes tuberculosis or severe acute respiratory syndrome; or those in blood which causes hepatitis or HIV) [72]. Measures to control them include [72, 73]:

(a) Engineering:
  — Proper design and maintenance of facilities;
  — Provision of sufficient basins, clean water, liquid soap and paper towels;
  — Adequate toilets and shower facilities for staff;
  — Use of needless systems and engineering needle stick prevention devices;

---

[3] Hazard is the potential for harm or adverse effect on the health of an employee or patient; anything which may cause injury or ill health to anyone at or near a workplace is a hazard. Risk is the likelihood that a hazard will cause injury or ill health to anyone at or near a workplace. The level of risk increases with the severity of the hazard and the duration and frequency of exposure. Exposure occurs when a person comes into contact with a hazard [29].

— Safe disposal of waste contaminated with body fluids or blood;
— Proper design of ventilation systems.

(b) Administrative:
— Policies and procedures, and infection prevention and control plans with clear designation of roles and responsibilities;
— Spill response procedures;
— Universal precautions and good housekeeping practices;
— High standards of hygiene;
— Chemical disinfectants to decontaminate surfaces and to clean up spills of infectious material;
— Disinfection of instruments and other contaminated equipment following the required time, temperature, methods and procedures;
— Safe management of needles or other sharp objects;
— Staff training;
— Immunization and health surveillance programme.

(c) PPE:
— Based on the risk assessment may include gloves, eye protection, masks and respirators;
— Other protective clothing.

10.8.2. Chemical hazards

Chemical hazards include chemicals used for cleaning and disinfection (e.g. alcohol hand sanitizers, chlorine compounds, glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde), chemicals used in treatment (e.g. radiopharmaceuticals), chemical wastes and other substances (e.g. latex used in gloves, lead in shielding, mercury in medical devices) [73]. Measures to control them include [72, 73]:

(a) Engineering:
— Substitute hazardous substances with less harmful product (e.g. hydrogen peroxide based cleaners rather than chlorine based cleaners, non-mercury manometers and thermometers);
— Maintain adequate general ventilation and local exhaust ventilation;
— Provide latex free and powder free gloves;
— Provide engineered needle stick prevention devices;
— Ensure that antidotes are available.

(b) Administrative:
— Safe work procedures including spill procedures;
— Monitor work environment following a spill;

— Ensure gloves and gowns are worn when workers use chemicals or administer certain drugs;
— Ensure that hazardous products are clearly labelled and stored in lockable cupboards;
— Ensure good hygiene practices;
— Ensure medical follow-up of the exposed workers and emergency response equipment;
— Ensure proper chemical waste handling and disposal.

(c) PPE:
— Eye protection and face shields when splashing is possible;
— Protective clothing and gloves;
— Respirators based on hazard assessment.

10.8.3. Physical hazards

Physical hazardous agents include radiation, electricity, fire, explosion and noise. Measures to control them include [72, 73]:

(a) Engineering:
— Workplace design;
— Equipment design and maintenance;
— Ventilation.

(b) Administrative:
— Safe work procedures that include the use of electrical cords and power lines with facility approval;
— Reduced noise levels;
— Worker training;
— Preparation for emergencies such as workplace accidents and fires or external catastrophes such as floods and earthquakes.

(c) PPE:
— Based on hazard assessment.

10.8.4. Ergonomic or work design hazards

Musculoskeletal disorders (injuries to muscles, ligaments, joints and bones) are the most common injuries suffered by health workers. Preventive measures include [72, 73]:

(a) Engineering:
  — Properly installed and secured lead brickwork;
  — Availability of adequate sizes and types of handling equipment (for heavy shields, radiopharmaceuticals containers, as well as for patients); ergonomic criteria incorporated into facility design;
  — Ergonomically designed cabinets and hot cells;
  — Ergonomically designed workstations, chairs and equipment, adjustable to operator requirements;
  — Provision of appropriate materials handling equipment such as carts, stretchers, beds and trolleys.

(b) Administrative:
  — Applying a comprehensive patient handling programme and safe work procedures;
  — Worker education and awareness sessions;
  — Early reporting of signs and symptoms of ergonomic concerns;
  — Purchasing standards and maintenance for patient handling equipment and containers.

(c) PPE:
  — Appropriate footwear with gripping soles and good support;
  — Appropriate and well fitting gloves, aprons and eye protection.

10.8.5. Stress and psychosocial hazards

The health sector is recognized as a high stress work environment. The potential psychological hazards or effects of workplace stressors include the following [72]:

— Abuse by clients or members of the public;
— Abuse by co-workers;
— Threats of violence;
— Stress related to critical incidents and medical emergencies;
— Technostress relating to the introduction of new technology;
— Depression, anxiety, sleep disorders, other mental illness as a response to excessive workplace stressors;
— Shiftwork and hours of work;
— Work–life conflict.

Actions to reduce job stress give a high priority to organizational changes that improve working conditions, control the demands of work and give more support to staff.

REFERENCES

[1]   ELL, P.J., GAMBHIR, S.S., Nuclear Medicine in Clinical Diagnosis and Treatment, 3rd edn, 2 vols, Churchill Livingstone, New York (2004).

[2]   HENKIN, R.E., et al., Nuclear medicine, J. Nucl. Med. **48** (2007) 846.

[3]   ZIESSMAN, H., O'MALLEY, J., THRALL, J. (Eds), Nuclear Medicine: The Requisites, 4th edn, Saunders (2013).

[4]   INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Management Audits in Nuclear Medicine Practices, 2nd edn, IAEA Human Health Series No. 33, IAEA, Vienna (2015).

[5]   INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Medicine Resources Manual, IAEA, Vienna (2006).

[6]   INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018).

[7]   INTERNATIONAL ATOMIC ENERGY AGENCY, Handbook of Nuclear Medicine Practice in Developing Countries, IAEA, Vienna (1992).

[8]   INTERNATIONAL ATOMIC ENERGY AGENCY, Operational Guidance on Hospital Radiopharmacy, IAEA, Vienna (2008).

[9]   EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[10]   INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Medicine Physics: A Handbook for Teachers and Students, IAEA, Vienna (2014).

[11]   INTERNATIONAL ATOMIC ENERGY AGENCY, Planning a Clinical PET Centre, IAEA Human Health Series No. 11, IAEA, Vienna (2010).

[12]   INTERNATIONAL ATOMIC ENERGY AGENCY, Roles and Responsibilities, and Education and Training Requirements for Clinically Qualified Medical Physicists, IAEA Human Health Series No. 25, IAEA, Vienna (2013).

[13]   INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Control of Nuclear Medicine Instruments 1991, IAEA-TECDOC-602, IAEA, Vienna (1991).

[14]   INTERNATIONAL ATOMIC ENERGY AGENCY, A Guide to Clinical PET in Oncology: Improving Clinical Management of Cancer Patients, IAEA-TECDOC-1605, IAEA, Vienna (2008).

[15]   INTERNATIONAL ATOMIC ENERGY AGENCY, Appropriate Use of FDG-PET for the Management of Cancer Patients, IAEA Human Health Series No. 9, IAEA, Vienna (2010).

[16] DONDI, M., et al., Trends in nuclear medicine in developing countries, J. Nucl. Med. **52** (2011) 16S–23S.

[17] WORLD HEALTH ORGANIZATION, Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020, WHO, Geneva (2013).

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Strategies for Clinical Implementation and Quality Management of PET Tracers, IAEA, Vienna (2009).

[19] UNITED STATES DEPARTMENT OF VETERANS AFFAIRS, Nuclear Medicine Design Guide, Office of Construction and Facilities Management, USDVA, Washington, DC (2008).

[20] BOELLAARD, R., et al., FDG PET/CT: EANM procedure guidelines for tumour imaging, Version 2.0, Eur. J. Nucl. Med. Mol. Imaging **42** (2015) 328–354.

[21] SHAO, Y., et al., Simultaneous PET and MR imaging, Phys. Med. Biol. **42** (1997) 1965–1970.

[22] PICHLER, B.J., et al., Performance test of an LSO–APD detector in a 7-T MRI scanner for simultaneous PET/MRI, J. Nucl. Med. **47** (2006) 639–647.

[23] DELSO, G., ZIEGLER, S., PET/MRI system design, Eur. J. Nucl. Med. Mol. Imaging **36** (2009) 86–92.

[24] PICHLER, B.J., KOLB, A., NÄGELE, T., SCHLEMMER, H.-P., PET/MRI: Paving the way for the next generation of clinical multimodality imaging applications, J. Nucl. Med. **51** (2010) 333–336.

[25] DELSO, G., et al., Performance measurements of the Siemens mMR integrated whole-body PET/MR scanner, J. Nucl. Med. **52** (2011) 1914–1922.

[26] ZAIDI, H., et al., Design and performance evaluation of a whole-body Ingenuity TF PET–MRI system, Phys. Med. Biol. **56** (2011) 3091–3106.

[27] SEONG JONG HONG, et al., SiPM–PET with a short optical fiber bundle for simultaneous PET–MR imaging, Phys. Med. Biol. **57** (2012) 3869–3883.

[28] VEIT-HAIBACH, P., KUHN, F.P., WIESINGER, F., DELSO, G., VON SCHULTHESS, G., PET–MR imaging using a tri-modality PET/CT–MR system with a dedicated shuttle in clinical routine, MAGMA **26** (2013) 25–35.

[29] BAILEY, D.L., et al., Combined PET/MR: The Real Work Has Just Started: Summary Report of the Third International Workshop on PET/MR Imaging — February 17–21, 2014, Tübingen, Germany, Mol. Imaging Biol. **17** (2015) 297–312.

[30] LEVIN, C.S., et al., Design features and mutual compatibility studies of the time-of-flight PET capable GE SIGNA PET/MR System, IEEE Trans. Med. Imaging **35** (2016) 1907–1914.

[31] HUANG, H.K., "Picture archiving and communication system components and workflow", PACS and Imaging Informatics: Basic Principles and Applications, 2nd edn, John Wiley & Sons (2010) 217–235.

[32] MEGHZIFENE, A., MCLEAN, D., VAN DER MERWE, D., THOMAS, B.J., "Clinical training in medical physics: IAEA perspective", Radiology Education: The Evaluation and Assessment of Clinical Competence (HIBBERT, K.M., CHHEM, R.K., VAN DEVEN, T., SHIH-CHANG WANG, Eds), Springer, Heidelberg (2012) 157–167.

[33] INTERNATIONAL ATOMIC ENERGY AGENCY, Competency Based Hospital Radiopharmacy Training, Training Course Series No. 39, IAEA, Vienna (2010).

[34] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for Radioactivity Measurement in Nuclear Medicine, Technical Reports Series No. 454, IAEA, Vienna (2006).

[35] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Cleanrooms and Associated Controlled Environments, Part 1: Classification of Air Cleanliness by Particle Concentration, ISO 14644-1:2015, ISO, Geneva (2015).

[36] EUROPEAN COMMITTEE FOR STANDARDIZATION, Biotechnology: Performance Criteria for Microbiological Safety Cabinets, EN 12469:2000, CEN, Brussels (2000).

[37] AMERICAN NATIONAL STANDARDS INSTITUTE, AMERICAN SOCIETY OF HEATING, REFRIGERATING AND AIR-CONDITIONING ENGINEERS, Method of Testing Performance of Laboratory Fume Hoods, ANSI/ASHRAE Standard 110-2016, ASHRAE, Atlanta, GA (2016).

[38] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiolabelled Autologous Cells: Methods and Standardization for Clinical Use, IAEA Human Health Series No. 5, IAEA, Vienna (2015).

[39] INTERNATIONAL ATOMIC ENERGY AGENCY, Clinical Translation of Radiolabelled Monoclonal Antibodies and Peptides, IAEA Human Health Series No. 8, IAEA, Vienna (2009).

[40] INTERNATIONAL ATOMIC ENERGY AGENCY, Cyclotron Produced Radionuclides: Guidance on Facility Design and Production of [^{18}F]Fluorodeoxyglucose (FDG), IAEA Radioisotopes and Radiopharmaceuticals Series No. 3, IAEA, Vienna (2012).

[41] INTERNATIONAL ATOMIC ENERGY AGENCY, Cyclotron Produced Radionuclides: Guidelines for Setting Up a Facility, Technical Reports Series No. 471, IAEA, Vienna (2009).

[42] INTERNATIONAL ATOMIC ENERGY AGENCY, Quantitative Nuclear Medicine Imaging: Concepts, Requirements and Methods, IAEA Human Health Reports No. 9, IAEA, Vienna (2014).

[43] INTERNATIONAL ATOMIC ENERGY AGENCY, Clinical Training of Medical Physicists Specializing in Nuclear Medicine, Training Course Series No. 50, IAEA, Vienna (2011).

[44] INTERNATIONAL ATOMIC ENERGY AGENCY, Postgraduate Medical Physics Academic Programmes: Endorsed by the International Organization for Medical Physics (IOMP), Training Course Series No. 56, IAEA, Vienna (2013).

[45] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for PET and PET/CT Systems, IAEA Human Health Series No. 1, IAEA, Vienna (2009).

[46] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Quality Control Atlas for Scintillation Camera Systems, IAEA, Vienna (2003).

[47] INTERNATIONAL ATOMIC ENERGY AGENCY, PET/CT Atlas on Quality Control and Image Artefacts, IAEA Human Health Series No. 27, IAEA, Vienna (2014).

[48] WALSHE, K., Pseudoinnovation: The development and spread of healthcare quality improvement methodologies, Int. J. Qual. Health Care **21** (2009) 153–159.

[49] AUSTRALIAN RADIATION PROTECTION AND NUCLEAR SAFTEY AGENCY, Radiation Protection in Nuclear Medicine, Radiation Protection Series No. 14.2, Commonwealth of Australia (2008).

[50]   INTERNATIONAL ATOMIC ENERGY AGENCY, Standard Operating Procedures for PET/CT: A Practical Approach for Use in Adult Oncology, IAEA Human Health Series No. 26, IAEA, Vienna (2013).

[51]   INTERNATIONAL ATOMIC ENERGY AGENCY, Appropriate Use of FDG-PET for the Management of Cancer Patients, IAEA Human Health Series No. 9, IAEA, Vienna (2010).

[52]   INTERNATIONAL ATOMIC ENERGY AGENCY, Clinical Applications of SPECT/CT: New Hybrid Nuclear Medicine Imaging System, IAEA-TECDOC-1597, IAEA, Vienna (2008).

[53]   SCHEIBLER, F., et al., Randomized controlled trials on PET: A systematic review of topics, design, and quality, J. Nucl. Med. **53** (2012) 1016–1025.

[54]   PAONE, S., et al., FDG-PET/CT for Cancer Staging, HTA Report, Agenzia Nazionale per i Servizi Sanitari Regionali, Rome (2012).

[55]   VLAYEN, J., STORDEUR, S., VAN DEN BRUEL, A., MAMBOURG, F., EYSSEN, M., Positron Emission Tomography (PET) in Belgium: An Update, KCE Reports 110, KCE, Brussels (2009).

[56]   OSPINA, M.B., et al., Positron Emission Tomography for Nine Cancers (Bladder, Brain, Cervical, Kidney, Ovarian, Pancreatic, Prostate, Small Cell Lung, Testicular), Agency for Healthcare Research and Quality, Rockville, MD (2008).

[57]   INTERNATIONAL ATOMIC ENERGY AGENCY, Clinical PET/CT Atlas: A Casebook of Imaging in Oncology, IAEA Human Health Series No. 32, IAEA, Vienna (2015).

[58]   CRUZ SUÁREZ, R., GUSTAFSSON, M., MRABIT, K., IAEA Occupational Radiation Protection Programme, Radiat. Prot. Dosim. **96** (2001) 17–20.

[59]   INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018).

[60]   INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).

[61]   INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in Newer Medical Imaging Techniques: PET/CT, Safety Reports Series No. 58, IAEA, Vienna (2008).

[62]   INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, IAEA Safety Standards Series No. SSG-45, IAEA, Vienna (2019).

[63]   INTERNATIONAL ATOMIC ENERGY AGENCY, Management of Discharge of Low Level Liquid Radioactive Waste Generated in Medical, Educational, Research and Industrial Facilities, IAEA-TECDOC-1714, IAEA, Vienna (2013).

[64]   INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

[65]   INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients After Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).

[66] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Basic Ionizing Radiation Symbol, ISO 361:1975, ISO, Geneva (1975).

[67] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).

[68] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Pregnancy and Medical Radiation, Publication 84, Pergamon Press, Oxford and New York (2000).

[69] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, Publication 94, Elsevier (2004).

[70] EUROPEAN COMMISSION, Radiation Protection following Iodine-131 Therapy (Exposure due to Out-patients or Discharged In-patients), Radiation Protection No. 97, Office for Official Publications of the European Communities, Luxembourg (1998).

[71] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Dose to Patients from Radiopharmaceuticals: A Third Amendment to ICRP Publication 53, Publication 106, Elsevier (2008).

[72] INTERNATIONAL LABOUR ORGANIZATION, WORLD HEALTH ORGANIZATION, HealthWISE Action Manual: Work Improvement in Health Services, ILO/WHO, Geneva (2014).

[73] GOVERNMENT OF ALBERTA, Handbook of Occupational Hazards and Controls for Personnel in Diagnostic Imaging and Nuclear Medicine (2011).

ABBREVIATIONS

BGO	bismuth germanate
CT	computed tomography
CZT	cadmium zinc telluride
DICOM	digital imaging and communications in medicine
DRL	diagnostic reference level
FDG	fluorodeoxyglucose
HIS	hospital information system
HL	health level
HRD	human resources development
HVAC	heating, ventilation and air conditioning
ILO	International Labour Organization
IMS	industrial methylated spirit
LAF	laminar airflow hood
LMIC	low and middle income country
LOR	line of response
LSO	lutetium oxyorthosilicate
MRI	magnetic resonance imaging
NCD	non-communicable disease
PACS	picture archiving and communication system
PET	positron emission tomography
PMT	photomultiplier tube
PPE	personal protective equipment
QMS	quality management system
RIS	radiology information system
RPO	radiation protection officer
SOP	standard operating procedures
SPECT	single photon emission computed tomography
SUV	standardized uptake value
TOF	time of flight
UPS	uninterruptible power supply
WHO	World Health Organization

CONTRIBUTORS TO DRAFTING AND REVIEW

Better, N.	Consultant, Australia
Bhonsle, U.	International Atomic Energy Agency
Dondi, M.	Consultant, Italy
Estrada, E.	International Atomic Energy Agency
Giammarile, F.	International Atomic Energy Agency
Hartman, N.	Consultant, United Kingdom
Jawa, Z.M.	Consultant, Nigeria
Koziorowski, J.	Consultant, Sweden
Llamas, A.	Consultant, Colombia
Marengo, M.	Consultant, Italy
Osso Junior, J.A.	International Atomic Energy Agency
Paez, D.	International Atomic Energy Agency
Pascual, T.	International Atomic Energy Agency
Poli, G.	International Atomic Energy Agency
Sabih, D.	Consultant, Pakistan
Solanki, K.	Consultant, United Kingdom
Vassileva, J.	International Atomic Energy Agency
Westcott, J.	Consultant, Australia

ORDERING LOCALLY

IAEA priced publications may be purchased from the sources listed below or from major local booksellers.

Orders for unpriced publications should be made directly to the IAEA. The contact details are given at the end of this list.

NORTH AMERICA

Bernan / Rowman & Littlefield
15250 NBN Way, Blue Ridge Summit, PA 17214, USA
Telephone: +1 800 462 6420 • Fax: +1 800 338 4550
Email: orders@rowman.com • Web site: www.rowman.com/bernan

REST OF WORLD

Please contact your preferred local supplier, or our lead distributor:

Eurospan Group
Gray's Inn House
127 Clerkenwell Road
London EC1R 5DB
United Kingdom

Trade orders and enquiries:
Telephone: +44 (0)176 760 4972 • Fax: +44 (0)176 760 1640
Email: eurospan@turpin-distribution.com

Individual orders:
www.eurospanbookstore.com/iaea

For further information:
Telephone: +44 (0)207 240 0856 • Fax: +44 (0)207 379 0609
Email: info@eurospangroup.com • Web site: www.eurospangroup.com

Orders for both priced and unpriced publications may be addressed directly to:
Marketing and Sales Unit
International Atomic Energy Agency
Vienna International Centre, PO Box 100, 1400 Vienna, Austria
Telephone: +43 1 2600 22529 or 22530 • Fax: +43 1 26007 22529
Email: sales.publications@iaea.org • Web site: www.iaea.org/publications

Establishing a nuclear medicine facility is a major undertaking that requires careful planning, contributions from multiple stakeholders, the support and approval of the relevant authorities, secure funding and a detailed implementation strategy. This publication is intended as a general guide for health care administrators, project and site planners and all professionals involved in providing nuclear medicine services. This updated version covers all the most important, recent evolution of the specialty, including the development of positron emission tomography (PET) services.

IAEA HUMAN HEALTH SERIES