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Radiological Protection in PET and PET/CT

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RADIOLOGICAL PROTECTION IN PET AND PET/CT

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Abstract–Positron Emission Tomography (PET) is a nuclear medicine imaging procedure used today almost exclusively in multimodal imaging particularly with computed tomography (CT) but also with magnetic resonance (MR), rather than alone. Its utilisation rates are growing as clinical indications expand with the addition of new PET radiopharmaceuticals. In some countries, PET/CT scans currently make up about 10% of all nuclear medicine examinations and about 20% of the patient effective dose delivered in nuclear medicine. Radiation doses depend not only on the administered activity, but also on the CT scan utilisation. Shorter half-lives of PET radionuclides and the high energies of annihilation photons emitted present particular challenges for staff radiological protection, which are compounded because patients are required to rest for an extended period between administration and imaging. Occupational doses in PET can be of few mSv per year, and skin doses to the fingers from manipulating PET radiopharmaceuticals can exceed the annual skin dose limit of 500 mSv if proper protection measures are not followed. Public exposure is not a cause for concern, and no special recommendations are needed to limit the release of the patient after the PET scan. However, patients and clinicians remain concerned and therefore, this report provides guidance on not only occupational, but also patient, and public radiological protection in PET and PET/CT. A brief section on PET/MR is also provided.

The technology involved and the way in which it is used together with the facility design has a direct impact on patient and staff dose. Consequently, the principles of operation of both the cyclotron used for production of the radionuclides and of the scanner are reviewed in this report; the report describes optimal facility design, equipment life cycle considerations, and work flow for the radiopharmaceutical agents.

The justification of the PET procedure should be established considering also the technology available, and when performed in a PET/CT scanner, the CT protocol should correspond to the objective of the CT examination. Distinct considerations are provided for the radiological protection related to the medical exposure of patients, carers/comforters, and research volunteers, including patient dose estimation, strategies to reduce the dose, and the special cases of patients who are breast feeding or pregnant, and paediatric patients.

Sources of exposure to staff working in PET facilities have been reviewed, and records show that dose depends not only on the protective methods but also on the individual practices, education, and quality assurance program. Therefore, procedures to reduce staff dose are provided together with guidance for staff monitoring. Optimisation of radiological protection for PET should be within the frame of a dose management and quality assurance program, which describes the radiological protection program and includes metrics to evaluate the

degree of achievement. In addition, the health professionals that perform the procedures must obtain proficiency in radiological protection and safety through formal, accredited education, training, and continuous professional development.

Keywords: PET; PET/CT; PET/MR; Radiological protection; Patient; Staff; Public

MAIN POINTS

- **Planning of positron emission tomography (PET) facilities is crucial for the radiological protection of the patient, staff, and public. Proper shielding and maximum automation of the radiopharmaceutical handling should be employed and the rooms within a PET department should be arranged to facilitate patient movement, while minimising the exposure of staff members and other patients.**

- **The justification of PET, PET/CT, and PET/MR should involve consideration of the characteristics of the imaging technologies, and take account both of the PET radiopharmaceutical and the choice of protocol to achieve the clinical objective of the CT examination, with special consideration given to paediatric patients. Imaging protocols should be optimised for the clinical task, and national diagnostic reference levels (DRLs) should be established for both the PET and CT components.**

- **Occupational doses in PET can be close to one-third of the dose limit, and skin doses to the fingers from manipulating PET radiopharmaceuticals can exceed the annual skin dose limit, if proper protection measures are not followed. Adoption of appropriate shielding devices is important, but the individual techniques and optimisation of working practices are crucial.**

- **Whole-body monitoring should be carried out based on monthly measurements, and $H_p(10)$ measurement from a dosimeter worn on the upper body will also provide an approximate indication of dose to the eye lens. Monitoring extremity doses with fingertip or ring dosimeters is recommended, with correction factors to estimate the maximum dose over the two hands.**

- **Appropriate standards should address radiological protection in a PET facility for patients, staff, and public. Each member of the medical imaging team has a crucial and defined role and must obtain proficiency in radiological protection through formal education, training, and continuous professional development. The team members should work together to ensure that the agreed goals and objectives of the quality assurance program are being met.**

EXECUTIVE SUMMARY

(a) Positron emission tomography (PET) is a nuclear medicine diagnostic technique providing functional, metabolic, and molecular information by means of positron emitters. The positron emitted undergoes annihilation producing two 511 keV photons that can be detected by the PET scanner. This can be used together with computed tomography (CT) in a PET/CT scanner, or with magnetic resonance imaging (MRI) in a combined PET/MR; providing better anatomical detail (hybrid fused images). The utilisation rates of PET are growing as clinical indications expand with the addition of new PET radiopharmaceuticals. In some countries, PET/CT scans currently make up about 10 % of all nuclear medicine examinations and about 20 % of the effective dose delivered in nuclear medicine. The short half-lives of PET radionuclides and the high energies of annihilation photons emitted present challenges for radiological protection of staff. This publication provides guidance on occupational, patient, and public radiological protection in PET and PET/CT.

(b) Medical diagnosis using PET hybrid imaging requires knowledge of the technology, anatomy and physiology, and disease states involved, as well as the possible alternative imaging options in order to achieve optimisation of radiological protection. Patient preparation, the performance of the PET/CT scanner and the parameters employed during the image acquisition and reconstruction, have an impact on both the image quality and dose received by the patient. New PET equipment with improved resolution, extended field of view and increased sensitivity, together with extended acquisition modalities and improved reconstruction techniques, can effectively reduce image noise without increasing administered activity to the patient. CT parameters have an impact on the image quality and patient dose. Imaging with CT or MRI are be used with PET although each has pros and cons: for example, the type of anatomical information provided is different, the contraindications for MR in some patients with implants but the benefit of avoiding ionising radiation when using MR. The short half-life of PET radionuclides requires either an on-site cyclotron or a fast distribution system. In addition, generator systems can be used for production of other PET radionuclides. All production systems require specific radiological protection for the staff.

(c) The planning and layout of the PET facility has a direct impact on radiological protection for patients, staff, and the public. Cyclotron vaults, radionuclide transfer systems and laboratory facilities should be designed to protect against irradiation and contamination, and the release of the radioactive gases. Arrangements should be in place for monitoring gaseous releases. Adequate shielding and automation when manipulating the radiopharmaceuticals during synthesis, filling vials, dispensing and administration should be considered when setting up the facility. The layout of the imaging part of the facility should be planned taking account of movement of the patient, including the resting period in a bay, between the radiopharmaceutical administration and the imaging procedure; in order to minimise the exposure of staff members and other patients. The dominant protection will be against 511 keV gamma-ray photons, although CT x-ray photons must be considered in the PET/CT scanning room. It is important to consider the life cycle of the PET equipment and facility. The stages in the planning and creation of a PET facility include justification, specification, acquisition, installation, acceptance, commissioning, and user training, before the system is put into clinical use. The disposal of the equipment and of the sealed sources used in the facility to verify and calibrate the PET scanner will need to be considered towards the end of the clinical use.

(d) The justification of radiological practices is at three levels of application. At the first level, the proper use of radiation in medicine is accepted, at the second level, a considerable amount of evidence has been accumulated on the role and potential applications of a specific technology in the management of patients in a variety of conditions and affected by different pathologies. The application of a PET procedure to each individual patient should be justified, which involves justification at the third level. Patient dosimetric considerations should be part of justification as well as optimisation, including the choice of the radiopharmaceutical and of the modalities of acquisition and image reconstruction for both the components, PET and CT, of a multimodality imaging system. The CT component of the multimodality scan may have several different objectives, i.e. attenuation/scatter correction, low dose anatomic localisation or diagnostic image interpretation which will require a higher dose level, and this leads to a broad range of radiation doses to patients. The appropriate protocol should be selected to fulfil the purpose.

(e) In a PET/CT examination, the total radiation dose is a combination of the dose from the PET radiopharmaceutical and that from the CT. The dose received by the patient is directly proportional to the activity of the radiopharmaceutical administered to the patient. National diagnostic reference levels (DRL) should be established for both the PET and CT components to aid optimisation. New PET, PET/CT, or PET/MRI hardware and software can reduce radiation dose while maintaining image quality. For paediatric patients, justification and optimisation in both PET and CT components have special considerations. Infants that are breastfed by mothers who have been submitted to a PET exam have two potential sources of radiation, the radiopharmaceutical itself which can be excreted in breast milk, and external exposure during the act of breastfeeding. Radiological protection principles should also be applied for carers and comforters of the patient.

(f) Patients undergoing diagnostic PET radiopharmaceutical studies generally do not pose a significant radiation risk to the public. No specific post imaging restrictive advice is recommended; 'holding' the patient post imaging in a separate waiting area to allow for further dose rate reduction post imaging is not necessary and is not recommended. The general advice is not to bring accompanying persons especially children, and by extension pregnant women, to the facility. Radiological protection measures such as administered activity, distance, time, shielding, facility design, and restricted access need to be considered to protect other patients, non-radiation workers, and the general public during the PET radiopharmaceutical uptake period and during PET/CT imaging.

(g) Occupational doses in PET can be of few mSv per year, and skin doses to the fingers from manipulating PET radiopharmaceuticals can exceed the annual skin dose limit of 500 mSv if proper protection measures are not followed. As shown in the document, dose depends not only on the protective methods but also on individual practices. Therefore, optimisation of the working practices is crucial. Patient preparation and co-operation are important factors in minimising contact time and in increasing the distance between patient and staff member, and so the dose directly from the patient. The optimisation of the working practice and the application of shielding for the vial and syringe are important factors in reducing the magnitude of doses to the fingers when radiopharmaceuticals are handled.

(h) Whole-body doses to the staff should be monitored based on monthly measurements, and the measurement from a dosimeter worn on the upper body will also provide an approximate indication of dose to the eye lens. The most exposed area of the hand is often the tip of the index finger of the non-dominant hand, but this does vary, so individual monitoring to establish dose patterns is important. It is recommended to monitor extremity doses with either fingertip dosimeters or ring dosimeters, with correction factors to estimate the maximum dose over the two hands.

(i) The Quality Assurance and Quality Control program in PET or PET/CT must address and ensure radiological protection and safety related to medical, occupational and public exposures. Each member of the medical imaging team has a crucial and defined role. The quality assurance program must include metrics to demonstrate that the goals and objectives of the program are being met. In addition, each facility should have a system for reporting and reviewing undesired events (accidents, misadministration, near misses).

(j) Education and training in radiological protection is a key issue. International stakeholders have detailed the responsibilities and needs for education and training in Radiological Protection for all groups of health professionals involved in a PET or PET/CT facility. The health professional performing the procedures in the facility must obtain proficiency in radiological protection and safety through formal education, training and continuous professional development. These educational programmes could be established based on educational documents and tools developed by stakeholders and some Scientific Societies and Councils.

1. INTRODUCTION

1.1. Nuclear medicine and PET

(1) Nuclear medicine is a medical speciality that involves the use of radiopharmaceuticals in the diagnosis and treatment of patients. In diagnostic procedures, short-lived radionuclides that label an appropriate pharmaceutical are used to examine organ function and thereby diagnose disease. The images obtained give functional, metabolic, and molecular information. Gamma or annihilation photons produced as a consequence of radioactive disintegration are detected with a suitable system and this information is presented in images that show the biodistribution of the radiopharmaceutical. Traditionally, the radionuclides used in diagnostic nuclear medicine have been radionuclides that emit gamma photons.

(2) Positron emission tomography (PET) is a nuclear medicine technique that produces images of the distribution within the body of radioactive tracers that emit positrons, such as ^{11}C, ^{13}N, ^{15}O, and ^{18}F. The positron emitted during disintegration undergoes annihilation with an electron, producing two photons that can be detected by the PET scanner. PET radiopharmaceuticals can be incorporated readily into biological processes and have an increasingly important role in oncology, namely in diagnosis, staging, treatment response and assessment for recurrence. They are also used in neurology and cardiology. PET is used together with computed tomography (CT) in a PET/CT scanner to provide better anatomical detail (hybrid fused images), and thus increase specificity and diagnostic accuracy. CT images are used to correct for the attenuation of the annihilation photons in the patient's body. Introduced in early 2000 (Beyer et al., 2002), PET/CT scanners have become the standard technology configuration for PET imaging. The integration of positron emission tomography and magnetic resonance imaging (MRI) in a combined PET/MR scanner provides another bimodal approach with functional-anatomical and multiparametric applications (Herzog and Van Den Hoff, 2012).

(3) A few positron emitting radionuclides are produced by generators, such as ^{68}Ge/^{68}Ga, ^{62}Zn/^{62}Cu, and ^{82}Sr/^{82}Rb. Most PET radiopharmaceuticals, however, are labelled with ^{11}C, ^{13}N, ^{15}O, or ^{18}F, which are produced in a cyclotron. Due to their short half-lives (from 2 minutes to a little under 2 hours), there are some limitations to their distribution, and some PET/CT facilities have their own cyclotron and a laboratory to label PET tracers.

(4) The directory of cyclotrons used for radionuclide production in 39 Member States of the IAEA, updated in 2006, had 262 entries for cyclotrons. This was an increase of 7% over the 246 reported in the 2002 cyclotron directory. However, it was believed to be a total of about 350 cyclotrons operating in the world, involved in some aspects of radionuclide production. The increase in number during these years was driven by several factors: advances in medical imaging, the introduction of a compact, user friendly medical cyclotron; and a decision that costs for [^{15}O]-oxygen PET studies in Japan and 2-[^{18}F]FDG PET studies in Germany and the United States of America were eligible for reimbursement by government or health insurance companies. 75 % of the cyclotrons were used to produce 2-[^{18}F]FDG, either for in-house use or for distribution to external facilities, and 36% of the centres producing 2-[^{18}F]FDG were distributing it (IAEA, 2006). The number of cyclotrons is still increasing, with more than 1300 cyclotron facilities worldwide (IAEA, 2021a), and 1484 are quoted in by another report (Goethals, 2020). Since this data depends on voluntary data collection, the number of cyclotrons could be higher and is estimated at around 2000.

(5) The use of unsealed radionuclides, which implies their production, and the use of CT in diagnostic PET examinations, involves exposure of staff, patients and public to two

different radiation sources. Exposure must be optimised, and for the patient also without compromising their diagnosis, by means of appropriate design of the facility and by means of good working and administrative procedures.

(6) This report will cover the principles and technology behind PET and PET/CT, and include a summary of the clinical applications in Section 2, provide general guidelines on facility design in Section 3, and review the imaging equipment life cycle in Section 4.

(7) Categories of medical and healthcare professionals working in PET, and therefore in PET/CT or PET/MR, considered in this report are nuclear medicine specialists, radiologists specialists, radiopharmacists, and radionuclide laboratory staff, nursing staff and other healthcare professionals assisting in radiopharmaceutical administration, nuclear medicine technologists/radiographers, medical physicists, maintenance engineers, and clinical applications specialists, with duties described in *Publication 113* on 'Education and Training in Radiological Protection for Diagnostic and Interventional Procedures' (ICRP, 2009). Where there are citations to data in the literature, the category names of the professionals in the references used have not been changed.

1.2. Radiological protection in medicine

(8) The primary aim of radiological protection is to provide an appropriate standard of protection for people and the environment without unduly limiting the beneficial practices giving rise to radiation exposure. *Publication 103* untitled The 2007 'Recommendations of the International Commission on Radiological Protection' (ICRP, 2007b) sets the three fundamental principles of radiological protection, namely justification, optimisation, and the application of dose limits.

(9) Two principles are source-related and apply in all exposure situations:

- The principle of justification: Any decision that alters the radiation exposure situation should do more good than harm
- The principle of optimisation of protection: the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.

And one principle is individual-related and applies in planned exposure situations:

- The principle of application of dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission.

These three principles apply to the radiological protection of the worker and the public.

(10) In relation to occupational exposure and practical protection methods, the principles of how to protect workers from ionising radiation, including those in the field of medicine, are discussed fully in *Publication 75* on 'General principles for the radiation protection of workers' (ICRP, 1997a); these principles apply to staff in PET/CT facilities. The control of occupational exposure is of particular importance during radiopharmaceutical preparation by staff in nuclear medicine, and careful shielding and time limits are needed (ICRP, 2007a).

(11) *Publication 105* on 'Radiation Protection in Medicine' (ICRP, 2007a) was prepared to underpin the Commission's 2007 Recommendations (ICRP, 2007b) with regard to the medical exposure of patients, including their carers and comforters, and volunteers in

biomedical research. It addresses the proper application of the fundamental principles (justification, optimisation of protection, and application of dose limits) of the Commission's 2007 Recommendations with respect to the above-mentioned groups of individuals.

(12) For patients, there are three levels of justification for use of radiation: at the first level, the proper use of radiation in medicine is accepted as doing more good than harm to society; at the second level, a procedure with a specified objective is defined and justified; and at the third level, the application of the procedure to an individual patient should be justified. The optimisation of radiological protection in medicine is usually applied at two levels: the design, appropriate selection, and construction of equipment and installations; and the day-to-day methods of working (i.e. the working procedures) (ICRP 2007a).

(13) The principle of optimisation has been a major part of radiological protection thinking for three decades (ICRP, 1991) and is key to effective use of medical imaging. Optimisation in relation to medical imaging requires provision of clinical images for individual patients that are of sufficient quality to ensure accurate and reliable diagnoses, in order to enable informed care decisions to be made. In addition, the radiation doses used in acquiring such clinical images should be adjusted so that, while being adequate to produce the images, they are minimised to the level appropriate to the applied imaging technology (ICRP, year2).

(14) The optimisation of radiological protection for patients in medicine is usually applied at two levels: (1) the design, appropriate selection, and construction of equipment and installations; and (2) the day-to-day working procedures. The basic aim of this optimisation of protection is to adjust the protection measures for a source of radiation in such a way that the net benefit is maximised. The optimisation of radiological protection is best described as management of the radiation dose to the patient to be commensurate with the medical purpose. Therefore, it is not appropriate to apply dose limits or dose constraints, because such limits may often do more harm than good (ICRP, 2007a).

(15) Optimisation is not a single action and there are many aspects that need to be in place before a PET or PET/CT facility can even embark on the road to achieving optimisation; these are not straight forward and have become quite complex in the healthcare environment. Proper initial education and ongoing training of staff on operation of equipment is crucial to starting the process (Vassileva et al., 2022). However, this needs to be coupled with arrangements for the ongoing monitoring, review, and analysis of imaging performance, that can be used to gradually improve overall effectiveness (ICRP, year1). Optimisation of medical imaging requires continuing development of knowledge, skills, competencies, and experience of all professionals involved in the imaging process (ICRP, year2).

(16) As dose limits are not used with patients, Diagnostic Reference Levels (DRLs) are applied for a particular procedure and used as an optimisation tool (ICRP 2007a). DRLs were introduced by the Commission in *Publication 73* on ' Radiological protection and safety in medicine' (ICRP, 1996), and developed further in a *Supporting Guidance* (ICRP, 2001) and in *Publication 135* on 'Diagnostic reference levels in medical imaging' (ICRP, 2017a). In diagnostic nuclear medicine, administered activity [in becquerels (Bq)], or, preferably, administered activity per body weight, is the measurable quantity used to indicate the magnitude of a patient's internal irradiation. This quantity is used to assist in managing the patient dose. For PET/CT, as a system that combines two imaging modalities, DRL values should be set for each modality independently (ICRP, 2017a).

1.3. Coverage of PET and PET/CT in previous ICRP Publications

(17) *Publication 84* entitled 'Pregnancy and medical radiation' provides clarification on risks to the embryo and fetus from medical exposure (ICRP, 2000). It also offers general

advice for diagnostic nuclear medicine procedures, focusing on gamma emitters, covering scenarios before, during, and after a diagnostic procedure as well as the breast-feeding scenario.

(18) *Publication 95* on 'Doses to infants from radionuclides ingested in mothers' milk' reported information on radiation doses to infants due to intake of radionuclides in maternal milk. (ICRP, 2004). Dose coefficients per unit intake by the mother were given for selected radionuclides of 35 elements that could be released into the environment due to various human activities. These radionuclides included the ^{99m}Tc used in nuclear medicine but not PET radionuclides.

(19) *Publication 128* on 'Radiation dose to patients from radiopharmaceuticals: a compendium of current information related to frequently used substances' (ICRP, 2015a) provided a compendium of current information relating to radiation dose to patients from radiopharmaceuticals. The information includes biokinetic models, biokinetic data, dose coefficients for organ and tissue absorbed doses, and effective dose for the major nuclear medicine diagnostic radiopharmaceuticals. The radiation dose calculations are based on the radiological protection guidance given in *Publication 60* (ICRP, 1991) and cover 19 PET radiopharmaceuticals. These data were mainly compiled from *Publications 53, 80*, and *106* (ICRP, 1987, 1998, 2008a), and related amendments and corrections. Diagnostic procedures with positron emitting radiopharmaceuticals were included in the recommendations. *Publication 106* (ICRP, 2008a) also included annexes on 'Recommendations on breast-feeding interruptions' (Annex D), and on 'Radiation exposure of hands in radiopharmacies: monitoring of doses and optimisation of protection' (Annex E). With regard to breast-feeding, if correct procedure is followed, a baby should not be breast fed until the radiopharmaceutical is no longer secreted in an amount estimated to give an effective dose of >1 mSv. With regard to hand exposure, the report was mainly focused on ^{99m}Tc as it was the most common radionuclide used in nuclear medicine, and at that time there was also limited information on hand exposure to PET radiopharmaceuticals.

(20) Training requirements and suggested content for training courses in nuclear medicine, including the radiological protection for personnel working in PET/CT, was included in the *Publication 113* on 'Education and training in radiological protection for diagnostic and interventional procedures' (ICRP, 2009) considering the categories of medical and healthcare professionals specified in section 1.1.

(21) Finally, in *Publication 139* on 'Occupational radiological protection in interventional procedures' (ICRP, 2018), PET/CT was considered when used for radiological imaging to guide interventional procedures. In this context, the principal factor determining radiation exposure to the operator was the time spent in close proximity to the patient.

1.4. Frequency of PET examinations and patient exposure

(22) The annual frequency of diagnostic nuclear medicine examinations per 1000 people in developed countries increased from 16 in 1985–1990 to 19 in 1997–2007 (UNSCEAR, 2010). In European countries only, the annual frequency was somewhat lower: 14 per 1000 in the period 2007–2010 (EC, 2014a). The increasing relevance of PET and PET/CT is demonstrated by the fact that the UNSCEAR 2008 report included these examinations per million of population for different countries (UNSCEAR, 2010), while these data were not included in the previous report (UNSCEAR, 2000).

(23) The average frequency per 1000 of population of the five most-common nuclear medicine diagnostic procedures was 13.7 for UNSCEAR health-care level 1 countries (in 1997–2007, level based on the number of physicians per population), and 9.2 for European

countries (in 2007–2010). For PET and PET/CT the frequencies were 0.9 for UNSCEAR health-care level 1 countries and 0.8 for European countries (EC, 2014a).

(24) The annual per person effective dose due to diagnostic nuclear medicine examinations in health-care level 1 countries was estimated to be 0.08 mSv for the period 1990–1996 (UNSCEAR, 2000). The estimate was 0.12 mSv for the period 1997–2007 (UNSCEAR, 2010). At the time, doses due to PET studies were estimated to be at the high end of the spectrum for diagnostic nuclear medicine procedures; and the 511 keV annihilation photons contributed to staff radiation doses. PET procedures accounted for an average of 18% of nuclear medicine procedures. The average change in frequency of nuclear medicine procedures since the UNSCEAR 2008 Report was +14% (UNSCEAR, 2022).

(25) By the year 2000, the development of new compounds for labelling with short-lived positron-emitting radionuclides was enabling a broad range of metabolic tracer imaging and physiological studies through the use of PET (UNSCEAR, 2000). Over 1000 compounds had been labelled to study specific biochemical processes and physiologic function by PET; however clinical applications in oncology, cardiology and neurology relied upon 25 different PET radiopharmaceuticals, although for their specific clinical needs, most PET centres use 2 to 5 PET radiopharmaceuticals (Lambrecht, 1998).

(26) In Europe, data from national surveys carried out between 2007 and 2010 showed that while PET and PET/CT constituted about 6 % of nuclear medicine diagnostic procedures, the median contribution of tumour imaging with PET and PET/CT to the total per caput effective dose was about 16 %. Of all nuclear medicine procedures, PET together with PET/CT was identified as having the fourth highest contribution to the total effective dose (EC, 2014a). In England, the number of PET/CT scans increased by 16.2% between 2016/17 and 2017/18 (NHS, 2018). In USA, tumour imaging with PET represented 14.6 % of the nuclear medicine studies in 2016 and was the second largest contributor to the dose from nuclear medicine studies (NCRP, 2019). Worldwide, 2-[^{18}F]FDG is the most used PET radiopharmaceutical. The utilisation of PET/CT imaging is increasing, and indications in oncology, inflammation, cardiology and neurology are expanding with the addition of new PET radiopharmaceuticals.

(27) Patient exposure from PET/CT examinations depends not only on the administered activity, but also on the nature of the CT scan. The degree of exposure is expected to depend on whether CT is used for anatomical localisation and attenuation correction or to provide the necessary image quality for diagnosis, with or without intravenous (i.v.) iodine contrast agent, resulting in a higher CT dose.

(28) PET and PET/CT justification is reviewed in Section 5, while the radiological protection related to the medical exposure of patients, carers and comforters, and research volunteers is considered in Section 6, as well as the exposure of infants breast fed from women who have had a recent PET radiopharmaceutical injection, and fetus exposure. Patient dose management and development of a quality assurance program when working with PET/CT will be covered in Section 9.

1.5. Public exposure

(29) Public radiation exposure includes exposure to members of the general public, workers who are not designated as nuclear or radiation workers, and unintended patient-to-patient exposure after PET radiopharmaceutical administration. In a well-designed facility, public exposure should not be a cause for concern. Because the half-life of most positron emitter radionuclides is short, irradiation of the public by patients is usually lower than that with other nuclear medicine examinations. Recommendations concerning minimization of public exposure will be provided in Section7.

1.6. Staff exposure

(30) The short half-lives of PET radionuclides and the high energies of annihilation photons emitted (i.e. 511 keV) present particular challenges for staff radiological protection. These challenges are compounded by the fact that patients are required to rest for an extended period between PET radiopharmaceutical administration and imaging. While the worldwide average annual effective dose for monitored workers in nuclear medicine was 0.7 mSv (2000–2002), the annual doses for PET technologists were higher than those for technologists performing general nuclear medicine studies, with values averaging about 3 mSv and 2 mSv, respectively, and occupational exposure could be higher for technologists than for physicians working in PET by a factor of 2–4 (UNSCEAR, 2010). Large variations in staff doses are reported between centres, however when the PET centre is appropriately designed and personnel are well trained, a highly productive operation centre can be achieved with whole-body doses to staff not exceeding 5 mSv per year (IAEA, 2008a). These dose differences depend on the degree of optimisation of facility shielding and design, the protection tools available, the techniques used by staff, number of patients, and the level of experience and involvement of the staff in implementing protection methods.

(31) The ORAMED project (7th EU Framework Programme, 2008–2011), which evaluated dose distribution across the hands while preparing and administering ^{18}F- and ^{99m}Tc-labelled radiopharmaceuticals, showed that the preparation of ^{18}F was the most critical of the studied diagnostic procedures (Vanhavere et al., 2012); the fraction of workers who went over the annual equivalent dose limit for the extremities of 500 mSv was estimated to be 23% and 40% for ^{18}F administration and preparation, respectively, showing the need for proper protection measures. In the study, several participating centres did not use shielded vials and syringe, and before 2010 no automatic dose dispensers were available as nowadays.

(32) Approaches to monitoring finger doses and positions for wearing dosimeters proposed in the ORAMED project differed from those recommended in *Publication 106* entitled 'Radiation dose to patients from radiopharmaceuticals. Addendum 3 to ICRP *Publication 53*' (ICRP, 2008a). The recommendations were based on practices followed in different groups of centres and it is likely that, in addition to requirements for more optimisation of protection, dosimetry methods need to be tailored to doses received, especially when they are near the limit. Recommendations on staff dose monitoring and optimisation procedures will be provided in Section 8.

1.7. Education and ongoing training

(33) Educational programs and ongoing training in radiological protection and safety for professionals working in a PET/CT facility have three aspects related to patient exposure and the ALARA principle, occupational exposure to staff, and public exposure. Section 10 will review the recommendations provided by ICRP and other international organisations, responsibilities regarding education and training, and training in radiological protection and safety for health care professionals.

1.8. Scope

(34) This publication provides guidance on radiological protection in PET and PET/CT, giving recommendations on occupational, patient, and public radiological protection.

(35) Guidance is provided for facility design, including the design of areas for PET radiopharmaceutical production (cyclotron and laboratory). For staff, advice is provided with regard to optimisation of procedures and dose monitoring. The report covers justification for PET and PET/CT diagnostic procedures, as well as radiological protection related to the medical exposure. A chapter on radiological protection of the public attends to the non-nuclear worker and patient-to-patient dose scenarios. Finally, guidance is given for dose management, for development of a quality assurance program, and for education and ongoing training in radiological protection for workers in a PET/CT and PET/MR facility.

1.9. Target audience

(36) The target audience of this publication includes nuclear medicine physicians, radiologists, referrers, medical physicists, radiopharmacists, radionuclide laboratory and cyclotron staff, nuclear medicine nurses, nuclear medicine technologists/radiographers, technical staff, radiological protection officers, patients, hospital and nuclear medicine department managers, regulatory authorities, equipment manufacturers, and the nuclear medicine industry in general.

2. PET AND PET/CT PRINCIPLES

(37) Key points in this section:

- PET uses a detection principle based on the annihilation photon radiation that follows a positron decay.
- The PET detection principle has the advantage that high resolution can be obtained without compromising sensitivity.
- Biologically important elements like carbon, nitrogen, and oxygen have positron emitting isotopes with short half-lives.
- PET is a quantitative technique when all the relevant corrections are applied.
- Originally a complex research tool with limited accessibility, PET has evolved into an important and widespread clinical modality.
- The combination of PET with CT into one system has been a driving force for the clinical applications.
- PET and PET/CT have important applications within oncology, neurology, and cardiology.
- The short half-life of PET-nuclides requires either an on-site cyclotron, a fast distribution system, and/or the use of generator systems.

2.1. PET, principles and technology

(38) Positron emission tomography as the name indicates utilises for imaging the positron decay taking place in certain radioactive nuclides with an excess number of protons. Having lost its initial kinetic energy by interacting with matter over a short distance, the positron will annihilate with its antiparticle, an electron (from another atom), and create a pair of annihilation photons, each having an energy of 511 keV corresponding to the particle masses ($E = mc^2$). Due to the law of conservation of momentum and observing that the positron-electron 'compound' (positronium) is almost at rest at the time of annihilation, these two photons travel in (almost precisely, 180 ± 0.25 degrees) opposite directions, forming for practical purposes a straight line (Fig. 2.1). Neglecting the travelling distance of the positron during slow-down, this line is assumed to contain the point of decay. In the following, some important technical aspects of relevance for radiation doses and protection are described together with a brief view on today's clinical applications. For more details the reader is referred to general textbooks (Cherry et al., 2012; Dahlbom, 2017).

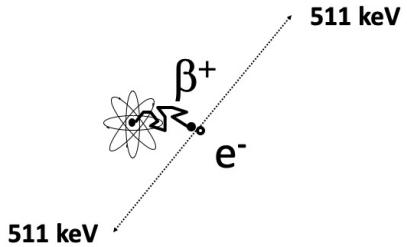

Fig. 2.1. The annihilation of the positron with its anti-particle, an electron, results in the emission of two photons of 511 keV each, almost on a straight line.

(39) The two annihilation photons are detected 'in coincidence'. Since the photons are travelling with the speed of light, approximately 30 cm ns^{-1}, the relevant time scale here for the coincidence timing window is ns and fractions hereof. Dependent on the timing properties of the detection system such a coincidence event can either just be assigned to the line [Line of Response (LOR)] or by more precisely observing the time difference between the two detectors, to a point or interval on that line. The latter is termed 'time-of-flight' (TOF) (Fig. 2.2).

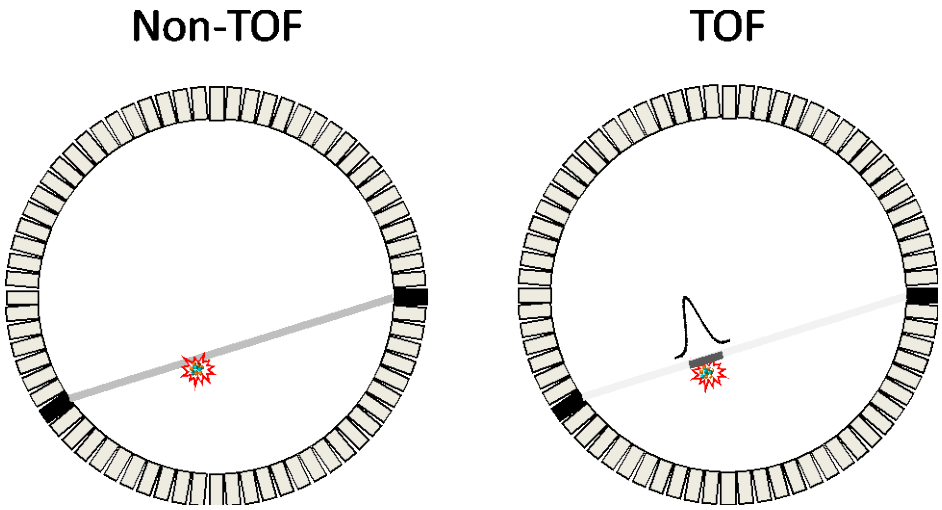

Fig. 2.2. In 'ordinary' PET (left), a coincident event is assigned to the line (LOR) between the two responding detectors with equal probability to all points. In time of flight, TOF-PET (right), the probability is assigned to a segment of the line based on the measured difference in arrival time to the detectors.

(40) One major advantage of the coincidence principle is that sampling takes place in all directions (angles) simultaneously without the need for rotating parts or collimators. This allows for a high detection efficiency (sensitivity) well suited for dynamic studies, and it also means that spatial resolution can be improved (e.g. by smaller detection elements) without compromising the sensitivity. In nuclear medicine imaging outside PET, where only 'single photons' are available, imaging requires a collimator with narrow holes to define the direction of origin, and only a very limited fraction of the emitted photons can contribute to the image. Under these circumstances, any attempt to improve resolution necessarily further reduces the number of events that can reach the detector and this trade-off represents a serious limitation for dose reductions. For typical low energy collimators the detection fraction may be around 0.01%. The similar value for PET early reached 1% and is still increasing (see below).

(41) Another fundamental advantage of PET is, that biologically important elements like carbon, nitrogen, and oxygen all have isotopes with positron decay (^{11}C, ^{13}N, ^{15}O), but no gamma-emitting isotopes suited for single photon detection. Due to practical limitations of half-life, labelling with ^{18}F ($T_{½}$ = 110 min) is however preferred, when possible.

(42) Most detected photons in PET do not form part of a coincidence pair but are just 'singles'. And not all detected coincident events truly represent a decay position either. Those which do, are determined 'True coincidences' or 'Trues', but scattered photons may be detected in coincidence, leading to the assignment of the event to a 'false' LOR (not containing the decay point), and two photons from independent decays may by chance be detected by a detector pair (random events, or just randoms). While for any given object the number of scattered events is proportional to the number of true events, the number of

random events scale with the square of the activity and in proportion to the duration of the timing window. Both scatter fraction and importance of randoms increase with object size, while the relative number of trues is reduced (Fig. 2.3).

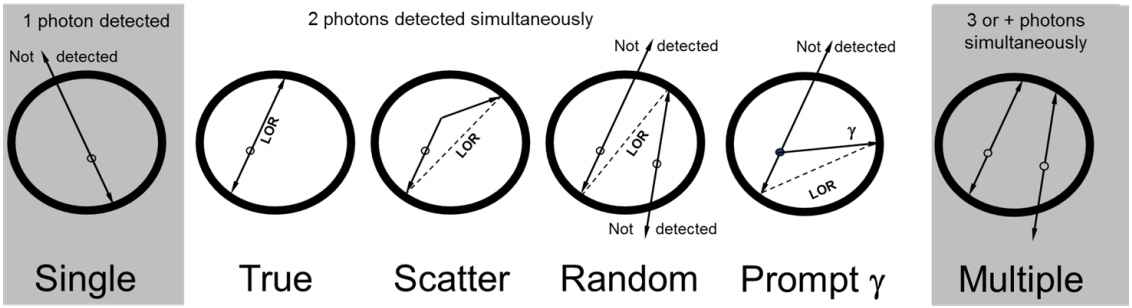

Fig. 2.3. Examples of possible events detected within a coincidence timing window (typically 4–12 ns). Singles are stored for correction purposes (e.g. deadtime) while multiple events (more than two) usually are discarded. The registration of two coincident events can either be 'true', where the LOR correctly contains the point of decay, or it can be a 'false' detection. The latter can be either a 'scatter' event or a 'random' event. When the positron decay goes to an exited state in the daughter nucleus, a 'prompt gamma' photon may result: If its energy falls within the acceptance window for 511 keV, or it is downscattered into this window, if can interfere with the annihilation detection.

(43) The above mentioned four PET-nuclides all have positron decays going to the ground state of the daughter nucleus. In some other, useful, nuclides a fraction of the decay goes to one or more excited states, and the remaining energy is released as a gamma photon. If the lifetime of the exited state is short compared to the defined coincidence window, and the energy lies around or above 511 keV, these 'prompt gammas' may interfere with the annihilation photon detection, also leading to false counts that must be taken into account in the reconstruction (Fig. 2.3). Examples are ^{68}Ga and ^{124}I. If the life-time is much longer than the timing window width (e.g. ^{89}Zr) the influence is only through additional singles and randoms. In both cases, however, calculation for the necessary shielding must include these additional (higher) energy photons.

(44) Since the necessary subtraction of false counts from scatter and in particular random events adds noise to the data, this effectively limits the useful count rate that can be obtained from a system. To describe this effect in quantitative terms, the concept of noise equivalent count rate, NECr has been defined, basically yielding the corresponding trues count rate that – in a perfect system – would provide the same relative image noise (coefficient of variation) based on pure Poisson statistics (Strother et al., 1990). After an initial almost linear increase the NECr curve rises slowly towards a maximum peak at a certain activity (concentration) and then decreases due to dead time effects (Fig. 2.4).

(45) In recent systems this limit (peak) is normally higher than what would be seen in clinical applications for other reasons (availability of radiotracer or limitation of radiation dose to patient). Knowledge of the NECr curve in principle allows for an evaluation of how efficient the activity is utilised (Watson et al., 2005). In terms of patient throughput, the optimum would be reached by scanning at or near the top of the NECr curve, with the obvious problem that the count rate is different in different body regions. It is, however, to be noted that the NECr curve is rather flat. Compared to scanning at the NECr peak, a significant reduction in activity (hence patient dose) will often only imply a rather limited reduction in noise equivalent counts, and therefore increase in image noise, which could be compensated by a minor extension of imaging time.

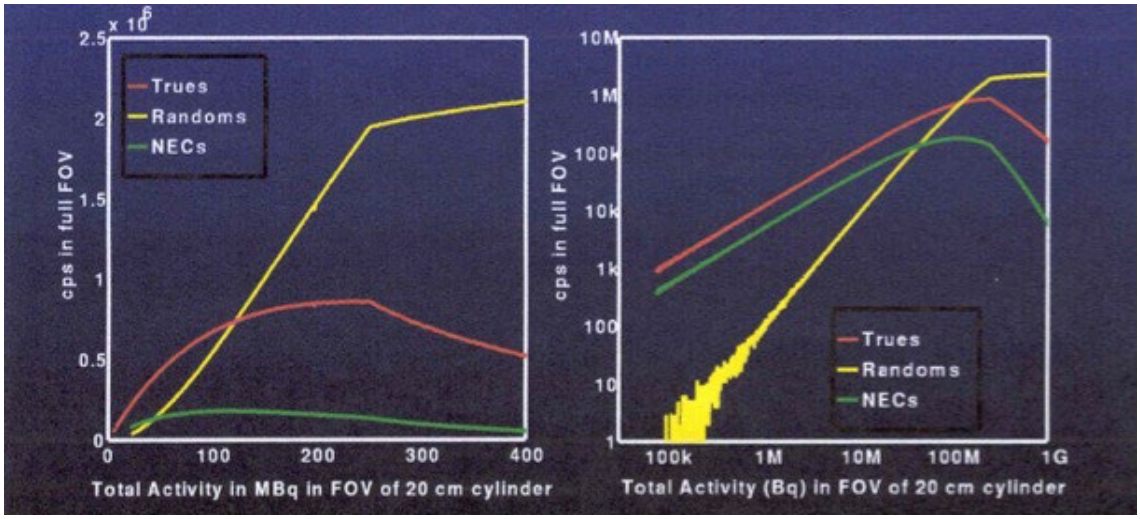

Fig. 2.4. Example of the relation between trues, randoms and noise equivalent counts (NEC) rates. The same dataset acquired from a 20 cm cylinder phantom during decay over four orders of magnitude in count rate is shown in linear scale (left) and log-log scale (right) high-lighting different aspects of the relations. On the left, the non-linearity of trues is caused by deadtime. Note that the NECr is much lower than the trues and that it peaks (with a very flat peak) at a much lower activity than the trues. The break point in all the curves is caused by a limit in the electronics on total count handling. To the right, the NECr follows the trues at low count rate, the constant ratio reduction being caused by the (almost) count rate independent scatter fraction. At low count rate, the slope of the line for random events is two, while it is one (linearity) for the true and scattered events. Image: Søren Holm, Denmark.

(46) The requirements for an ideal PET detector are that it should be able to efficiently stop the 511 keV photons and create a measurable electric pulse with precise information about the energy and the arrival time of the photon. The detection process thus consists of two steps: the stopping (and conversion) of the energetic photons, and an amplification of the (light) signal created. While the first part of stopping remains based on scintillation crystals of different kinds, the amplification part can be made either with traditional photomultiplier tubes (PMT) or recently with solid-state based materials. Due to the size and cost of PMTs, detectors have traditionally been built as an assembly of detector crystals covered with a (smaller) number of PMTs, in a so-called block structure which requires a decoding scheme similar to gamma camera Anger logic to assign events to a single crystal element (Casey and Hoffman, 1986).

(47) To stop the energetic photons a scintillation material with a high stopping power is needed, which requires a high element number (Z) and a high density. The material should also convert the energy into low energy photons (visible or UV, 2–3 eV) with high efficiency, and this process of scintillation decay from excitation must be fast as well. A fast and high signal from the crystal eases the timing detection, which basically must rely on the first few light photons that arrive to the 'amplifier'. It is also important in reducing the dead time of the system and thereby determines the count rate applicable. While sodium iodide (NaI) is still the dominant crystal material for most nuclear medicine applications, it is insufficient to stop 511 keV. For many years (1985–2000) bismuth germanate (BGO, $Bi_4Ge_3O_{12}$) became the material of choice, having very good stopping power (Z for Bi is 83) but less perfect photons/keV (9) and timing properties ($T_{½}$ = 300 ns). Most current PET systems use Lutetium (Z=77) based crystals, either lutetium oxyorthosilicate [LSO, (Lu_2SiO_5:Ce)], lutetium yttrium orthosilicate [LYSO, $(Lu,Y)_2SiO_5$:Ce], or others all having high stopping power, high density, photons/keV (35) , and short decay times (40 ns).

(48) Such systems may offer TOF (Surti et al., 2007) and the time resolution has been improved down to 0.2 ns, corresponding to a spatial uncertainty of only 3 cm (van Sluis et al., 2019).

(49) The advantage of using solid-state amplification [avalanche photo diodes (APDs), or silicon photo multipliers (SiPM) rest on their smaller size, and the insensitivity to magnetic fields that make them compatible with MR systems. In particular, SiPM also has less timing uncertainty on the signal peak ('time jitter') and a potential gain in sensitivity with better utilisation of the light output from the crystals. One vendor provides a matched crystal-SiPM system (one-to-one coupling) (Zhang et al., 2018) while others have maintained a block decoding. One disadvantage of SiPM is a high temperature dependency that requires strict control of local temperatures with distributed cooling tubes to all elements and potentially online sensitivity corrections.

(50) Signal handling includes validation of the pulse in terms of energy (511 keV), assignment to a certain detector crystal using a decoding scheme, and decision of a potential coincidence with any other (relevant) detector element. This requires a scheme for energy-windowing at the crystal level and a very precise timing calibration between detectors.

(51) Raw data in a PET acquisition are either stored in sinogram matrices where each element corresponds to one LOR (detector pair) and each sinogram contains the information of one detection plane, or are acquired in 'list mode' where the events are registered sequentially by writing the addresses of the detector pair together with a time stamp to a data stream. In this mode, also signals from cardiac and respiratory gating can be included. After the end of acquisition, the list mode data may be 'replayed' and sorted into time frames and /or gating bins without the need to define these before scanning. Random events are either subtracted online (in list mode during the sorting) or are stored separately for later processing during reconstruction.

(52) Reconstruction of raw data into transaxial image sets can be performed either by direct Fourier methods [Filtered back projection (FBP)] or by iterative reconstructions which are now the methods of choice in PET. When applying all necessary corrections, the PET images form a three-dimensional quantitative representation of the activity distribution within the depicted object. The corrections are (among others) for geometry of the LOR's, dead time of detector and coincidence electronics, random and scattered coincidences, and attenuation. The stack of transaxial slices can be resampled to provide sagittal or coronal slices or, for heart studies, the traditional long and short axis representations. For that purpose, an isotropic spatial resolution is an advantage to avoid any resampling artefacts.

(53) Attenuation correction (AC) serves to restore the signal dependency on depth caused by the higher probability of photon loss through absorption and scatter. In principle, AC in PET is simple. Due to the fact that each event is created by two photons that together have travelled through the full length of a LOR, the probability of detection depends only on the total attenuation properties along that LOR and not on the position of the event on the line. Therefore, it can be (and traditionally has been) measured using an external source of monoenergetic photons in form of a point or pin source rotating around the object, typically ^{68}Ge (annihilation photons from ^{68}Ga) or ^{137}Cs (single gamma photons) A significant drawback of the external source method was that due to practical limitations of source strength and count rates for the proximal detector, the noise-optimised acquisition time almost equalled that of the emission scan and still added significant noise to the final image in the reconstruction process (Holm et al.,1996).

(54) It was therefore a major breakthrough when PET was combined with Computed Tomography, CT, to form PET/CT (Beyer et al., 2000). CT can, in very short time, provide attenuation information that is essentially noiseless. In today's iterative reconstructions,

attenuation knowledge is normally integrated in the forward projection step of the algorithm rather than applied to raw data before reconstruction.

(55) Scatter correction is more complex and less accurate. One of the main methods today is known as the single scatter simulation technique (Ollinger, 1996).

(56) The development of PET instrumentation has improved the spatial resolution by providing smaller detector elements, and values of <4 mm are now realistic in a clinical setting. The dependency on position in the gantry (centre or edge) and direction (radial or tangential) can be corrected by including into the forward projection of the iteration knowledge about the point spread function (PSF), the image of an ideal point source (Tong et al., 2010). This can also improve the results from nuclides with high positron energy (like ^{15}O, ^{68}Ga, or ^{82}Rb) where the influence of the width of the PSF is otherwise considerable.

(57) The sensitivity has also been vastly improved. First, by extending the axial field of view (scanned length of the patient without the patient moving) from 10 cm in early systems (~1985) to 15 cm (~1993) allowing dynamic scans of the whole brain or myocardium, and next, most important, by the acceptance of inter-ring coincidences (known as 3D). Current systems are often modular in construction, providing axial field of views of 15–25 cm or more. Since the sensitivity is almost quadratic in this parameter, an extension from 15 to 25 cm nearly triples the sensitivity. Recently a system has been proposed and built that covers a full body length of 2 m (Badawi et al., 2019). Since a major part of the price of a system scales with length, systems like that most likely will remain instruments for research and special application, e.g. study of whole-body tracer kinetics, while systems spanning 0.5–1 m are more likely to gain clinical importance.

(58) The axial sensitivity profile when scanning in 3D mode forms a triangle with the top in the centre slice(s) and approaching zero at the edges. When used for whole body scanning or, actually, as soon as more than one axial field of view is required, an overlap of up to 50% between adjacent bed positions is used. Recently, systems have been delivered that move the patient bed continuously through the system with a speed that can be adjusted to the count rate and required image quality in different regions (Osborne et al., 2014). This requires a more complex correction scheme since some corrections are linked to the detector (e.g., sensitivity normalisation) while others depend on the patient (attenuation and scatter).

(59) From a radiological protection perspective, the most important technical improvements are those increasing sensitivity. While higher resolution actually will require more photons to maintain a certain noise level, and better count rate performance might allow the patient throughput to be raised by increasing patient activity, the advent of '3D' and increased axial field of view also makes it possible to decrease the injected activity (patient dose) while still maintaining image quality. TOF-PET may also reduce noise by using the added position information in reconstruction, a feature sometimes (with a slightly unfortunately term) marketed by vendors as increased 'effective sensitivity'.

(60) A number of PET systems have been designed or are under development for specific purposes, e.g. mammography (Raylman, 2018), prostate imaging (Cañizares, 2020), brain imaging (Akamatsu, 2019), and also a whole range of special animal scanners (e.g. for mice, and rats) are available, but until now the mainstream PET system remains a ring system with body sized opening (and CT attached).

2.2. CT technology

(61) Almost all CT systems today are so-called third generation systems, where data collection is made by fast continuous rotation of a balanced arrangement with an x-ray tube

exposing (with a fan beam) an oppositely mounted detector arch. CT images provide the tomographic reconstruction of recorded attenuation of the object.

(62) The attenuation of a material is determined by the atomic composition and the density of the material as well as the photon energy applied in the measurement. The possibility of an anatomical interpretation is caused by the fact that different tissues have (slightly) different atomic composition and density. For a comprehensive description of x rays and CT, see (Mahesh, 2009; Bushberg et al., 2020)

(63) While the spatial resolution of CT is inferior to ordinary planar x ray imaging, CT offers the important advantage of a high contrast resolution without irrelevant 'overlapping' tissues and can therefore distinguish even small differences in e.g. soft tissue. The reconstructed transaxial images (in CT, unlike PET, often referred to as 'raw data') are presented to the reader in the scale of 'Hounsfield units' (HU), most often without reference to photon energy. The value zero represents air, 1000 is pure water, and bone (from spongious to compact) typically will be represented in the range of 50–1500. Most often, the scale is 'clipped' at 3000 HU which may create problems for identifying and describing high attenuation materials, e.g. metal implants and, in particular, dental work.

(64) In early CT systems, the x-ray tube heat capacity and cooling rate was a limitation for scanning extended body regions. This has been solved in some modern tube designs that allow the rotating anode to be cooled by direct heat transfer, rather than through a radiative process out of the tube containment. An important correlate to this is that there is no longer a simple inherent technical limitation to the dose that might be given to a patient during a scanning session and that other guards must be in place to secure against unintended high exposure.

(65) A typical CT session will consist of: 1) a prescan 2) a CT acquisition and 3) the reconstruction of images. The CT acquisition parameters of importance for image quality and patient dose (to be set before scanning) are: high voltage (kV), tube current (mA), rotation time, slice collimation, and bed movement per rotation; the latter normally being specified by the 'pitch', the ratio of bed movement to collimation width. Of course, the selection (from the prescan) of the total scan area is also important. For PET/CT where the PET is operating in step motion, the CT scan in order to allow AC has to cover the full area of PET, which by the discrete measure could be more than actually clinically requested. One major advantage of the continuous motion mode for PET is that it allows limiting the PET scan length, and therefore the CT scan length, to what is actually needed, hence reducing the CT dose component.

(66) In a subsequent reconstruction, slice thickness and slice distance can be adjusted (upwards) and image matrix size and reconstruction filter (kernel) can be optimised. The reconstruction, of course, has no influence on patient dose, and the reconstruction parameters can be freely selected afterwards in repeated reconstructions. Traditionally, CT images have been reconstructed using FBP, but more recently iterative reconstruction methods have been applied also to CT. This allows for reduced image noise and/or a reduction in exposure (mAs), leading to reduced patient doses. One problem still controversial is concerned with the change in texture of the images that requires some adaptation for the radiologist reading the images.

(67) Modern systems have automated algorithms that can assist in dose reduction, using the information from the pre-scan and/or adjusting to data obtained during a scan (McCollough, 2006; Singh, 2011; ICRP, year2). All major vendors have proprietary programs (under different names) that can modulate the tube current, either longitudinally only (reducing, e.g. exposure over the lung region compared to abdomen) or during rotation, observing that the anterior-posterior attenuation in general is much lower than the lateral. The setting of the algorithm will require the user to enter an allowed mAs interval, an 'image

quality index' or other information to describe the wanted outcome. It must be noted that, in setting up the scan, a number of pitfalls exist. If the patient is placed off-centre, the prescan may assume the patient to be larger (or smaller) than what is actually the case and adjust the current accordingly, and if dose limiting shielding (or metal implants) are in the field, the current might be increased beyond the intended if not limited by the user.

(68) Also, the tube voltage may be selected by the system based on calculations on the pre-scan data. Unlike the tube current modulation, however, the tube voltage is normally kept fixed during a scan. Recently systems with 'dual energy' capability have been built; these can either be systems with two complete source-detector arrangements running at different keV, a single source system with fast kV switching or dual filters, or a software solution that can handle sequentially acquired data sets.

2.3. PET/CT

(69) The combination of PET and CT, developed in the late 1990s (Beyer et al., 2000) and introduced commercially in 2001, marked an important turning point for the use of PET in general. The number of installations grew rapidly, and since 2004 almost no systems have been installed as PET only (Jones, 2017). The combined PET and CT systems continue for many practical reasons (including transport into hospital buildings) to be manufactured as two separate gantries that are mounted together on site, but computer systems and programs have become more integrated over time (Fig. 2.5).

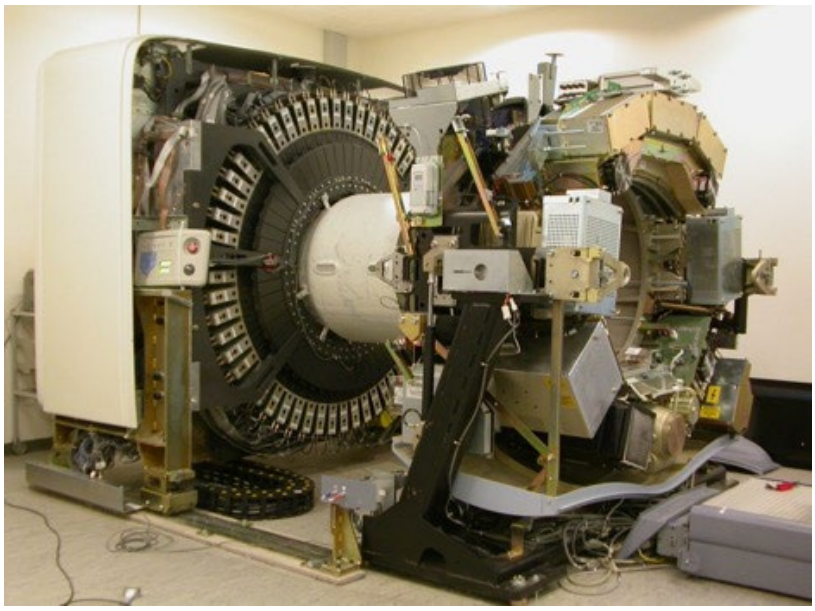

Fig. 2.5. One of the first commercial PET/CT systems (Discovery LS, General Electric, 2001) with the two gantries separated for service. The CT is in front, with the x-ray tube at the bottom and the detector arch at the top. In the back, the PET gantry is seen with its modular detector assemblies arranged in a ring around the patient bore. This two-gantry configuration is maintained in contemporary systems. Image: Søren Holm, Denmark.

(70) The added value of CT is twofold: The anatomy information provided by CT is an important complement to the physiological and molecular information provided by PET. The combination of the two modalities into PET/CT by placing the two system gantries on a common axis and with a common patient bed makes it feasible to obtain fused images with

the combined information on a single screen and to blend from one to the other by adjusting (colour) scales. In addition, the problem of AC in whole body scans is effectively solved.

(71) The CT image represents a distribution of attenuation values obtained with the actual CT energy spectrum. To use it for 511 keV requires some modelling and calculations (scaling) (Kinahan et al., 1998; Holm, 2017). In general, this works well, but artefacts may arise at the presence of materials other than air, soft tissue and bone, e.g., contrast agents, metal implants, and dental work not included in the simplified model (IAEA, 2014a).

(72) A typical PET/CT session will consist of 1) a pre-scan providing a simple x-ray projection image, 2) a CT scan, and 3) a PET scan. From a protection perspective it is important to stress the significance of the justification for the type of CT scan applied. It is possible to perform either a full diagnostic scan (potentially with intravenous and/or oral contrast agents), making a low dose CT scan, mainly for orientation (and AC), or an 'ultralow dose' CT for AC only. In general, a diagnostic CT with contrast may also be used for AC although with the potential of (recognisable) local artefacts as well as a minor deviation in the quantitative values of PET (Berthelsen et al., 2005). Therefore, if high accuracy is needed, a low dose scan for AC is performed before the PET, and the contrast enhanced CT after the PET acquisition.

(73) It should be noted here that the photon flux during a (diagnostic) CT scan can be 4–5 orders of magnitude higher than the emission rate from a patient injected with a typical activity for the PET scan, delivering the same absorbed dose to the exposed tissue in a second as the injected tracer will provide over the lifetime of the activity. The high flux ratio explains why it is not feasible to perform simultaneous measurement of PET and CT because the scatter from CT would disturb the PET detectors.

2.4. PET/MR

(74) The advent of solid-state amplifiers (APDs or SiPM) for the light output from scintillation crystals has made it possible to combine PET and MR by installing a PET detector ring system inside the MR magnet between gradient coils and receiving body coils. (Delso et al., 2011). The PET electronics is placed behind the magnet and (electrically) well shielded in a copper Faraday cage to exclude or minimise interference between the MR radiofrequency signals and the PET pulse handling electronics (Fig. 2.6).

(75) In such a system, PET and MR can be performed truly simultaneously, in contrast to PET/CT where the acquisitions must be performed sequentially. One major issue in PET/MR is that, unlike CT, the MR signal and image does not provide an immediate source for AC. Air filled structures as well as bone have no or low signal from MR and yet these two have the most different attenuation for the PET photons. For the brain, solutions have now been found that works quantitatively satisfying (Ladefoged et al., 2017) and also for whole body scans results are normally reasonably accurate (Keereman et al., 2013). For a review of recent methods, see Catana (2020).

(76) The clinical use of PET/MR is currently limited and specific clinical indications remain to be proven. One obvious advantage, from a radiological protection point of view if replacing a PET/CT examination, is that the (often high) radiation dose from CT is avoided. This is of particular interest in the examination of children. Since the radiological protection for the PET in PET/MR is not much different from other use of PET, PET/MR will not be dealt with in detail in this work. For MRI safety, see references in Sections 8, 9, and 10.

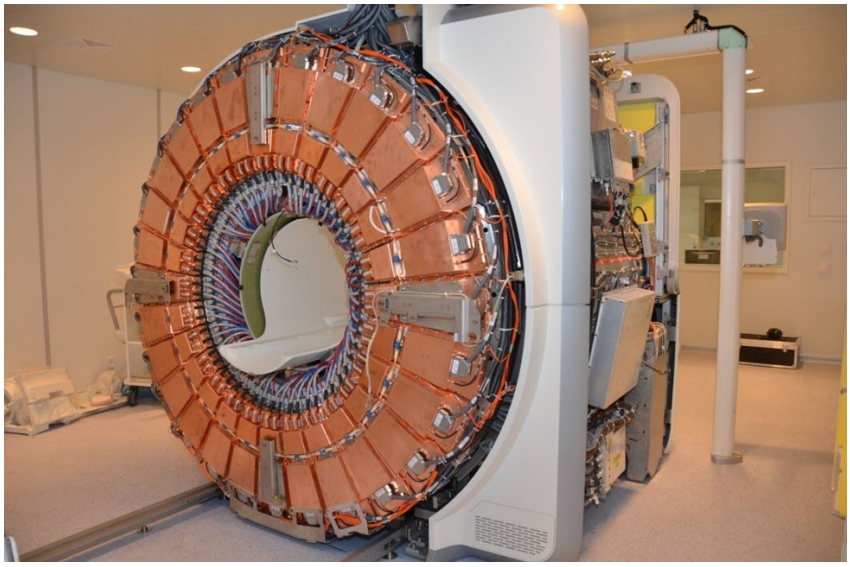

Fig. 2.6. Example of a PET/MR system with covers removed. The PET electronics is encapsulated in a Faraday cage to avoid interference with MR radiofrequency signals. The water tubes leading into the gantry provide temperature stabilisation to the PET detectors. Image: Søren Holm, Denmark.

2.5. Cyclotron

(77) The cyclotron principle was introduced by Lawrence in 1930 for accelerating protons (Lawrence and Livingston, 1932). Originally only meant to provide a proton beam for physics experiments, the possibility of creating artificial radioactivity by bombardment with high energy protons was soon detected (Curie and Joliot, 1934). Today the cyclotron is an essential device for producing the nuclides used in PET and an important integrated part of many PET centres (Braccini, 2016).

(78) The basic principle (Fig. 2.7) derives from the fact that a charged particle moving in a stationary magnetic field will describe a circular path. The radius of that circle is proportional to the speed (and energy), hence the rotation time is fixed, dependent only on the strength of the magnetic field and the ratio of charge/mass of the particle, but independent of radius. This holds as long as relativistic effects can be ignored (or internally corrected for by locally modifying the magnetic field strength) which means that proton energies up to at least 30 MeV, sufficient for most nuclear medicine relevant nuclear reactions, are feasible. The acceleration is performed by a rapidly switching constant (radio)frequency electrical field (RF, at MHz level) applied at certain gaps in the circle. Between these gaps the particles are moving in a Faraday cage (named due to their traditionally form as 'D-s'), unaffected by electrical fields following half-circular paths. The whole process requires a high-quality vacuum and therefore is contained in a tank equipped with diffusion pumps that can maintain a vacuum of 10^{-9}–10^{-10} bar. The particles (ions) to be accelerated are extracted from an ion source at the centre of the cyclotron, by forming a plasma of the relevant gas.

(79) While early cyclotrons actually accelerated protons (or deuterons), modern devices instead often use H^- -ions; a proton with 2 electrons attached is a rather stable configuration. It has the advantage that the beam exit can be controlled by placing a thin carbon foil at a radius corresponding to the required particle energy. The foil will strip off the electrons and the shift in the sign of the net charge (from minus one to plus one) will reverse the curvature of the particles' trajectory, making it possible to direct them towards the target that has been prepared for the bombardment process. The target can either be located right next to the

cyclotron tank or accessed through an external beam line that may reach into a shielded neighbouring room (Fig. 2.8).

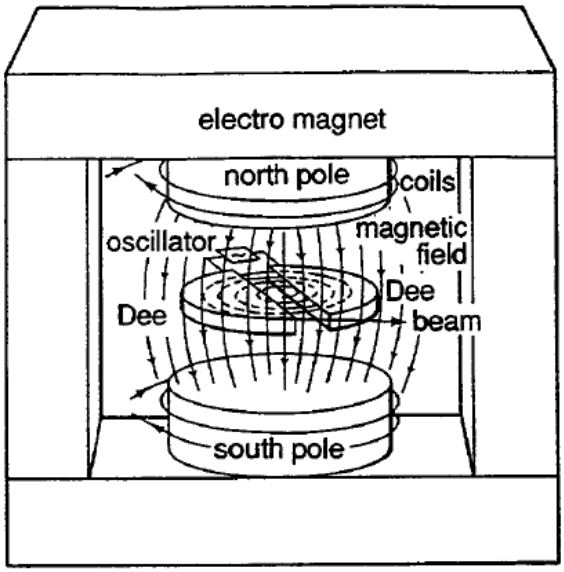

Fig. 2.7. The cyclotron principle showing a magnetic field created by an electro magnet, the (electrical) shielding 'D-s' or 'Dees', the oscillator providing acceleration in the gap between the two D-s and the resulting (proton) path (from a brochure published by the Lawrence Berkeley laboratories).

(80) Targets can be gas- or liquid based or can be solid targets. A critical part of the cyclotron is the foil separating the cyclotron tank vacuum from the target material. It has to be thin, not to take out too much energy of the beam particles, yet it should be able to withstand the pressure difference that for a pressurised gas-target may be 20–50 bar. Further, it must be well cooled to remove the excess energy deposited that otherwise easily could melt the foil. Transporting the product from gas or liquid targets into radiochemistry hot cells can be controlled remotely by blowing inert helium or argon gas through thin plastic tubes; the use of a solid target normally will require access to the cyclotron vault although some automated systems have been built.

(81) In addition to H^- -ions, some cyclotrons are capable of accelerating also deuterons or alpha particles, widening the spectrum of possible nuclear reactions. This requires slightly modified ion sources and a gas supply of deuterium or helium, respectively.

(82) Commercially available cyclotrons vary in size and performance. Models essentially dedicated to PET typically range from 10 to 20 MeV of maximum energy of the accelerated ions (protons or H^-), and may have beam currents exceeding 100 μA. Some systems with energy as low as 7 MeV and relatively low beam current have been proposed. Most of the cyclotrons employed for the commercial production of gamma-emitting radionuclides, operating at 30 MeV, can effectively produce also ^{18}F and other PET radionuclides. Such systems typically have maximum beam currents of several hundreds μA, up to more than 1 mA. A limited number of 70 MeV cyclotrons for commercial production are installed worldwide; these are very important for the massive production of a variety of clinically useful radionuclides, including some of relevance for PET, like ^{68}Ge, the parent of ^{68}Ga. However, these systems are in general not directly involved in the PET process. Some of the (smaller) PET cyclotrons can be supplied with an integral or a partial (local) self-shield. They can be installed in rooms with reduced shielding compared to the extensive shielded bunkers

otherwise needed for 'unshielded' cyclotrons. The choice among the available options depends on the desired production reactions and amounts, taking into account also any eventual collateral use for research, the needs for maintenance, the use of surrounding areas and inferred dose constraints.

(83) A typical reaction in the target is (p,n) or similar (Table 2.1), where excess energy from the compound nucleus is removed by (one or more) neutrons. This means that during bombardment, a high neutron flux will be present around the target (in the cyclotron vault). Often, the neutrons will be the determining factor for shielding requirements. Further, neutron activation of cyclotron components and building materials is an issue that must be considered carefully in the planning phase.

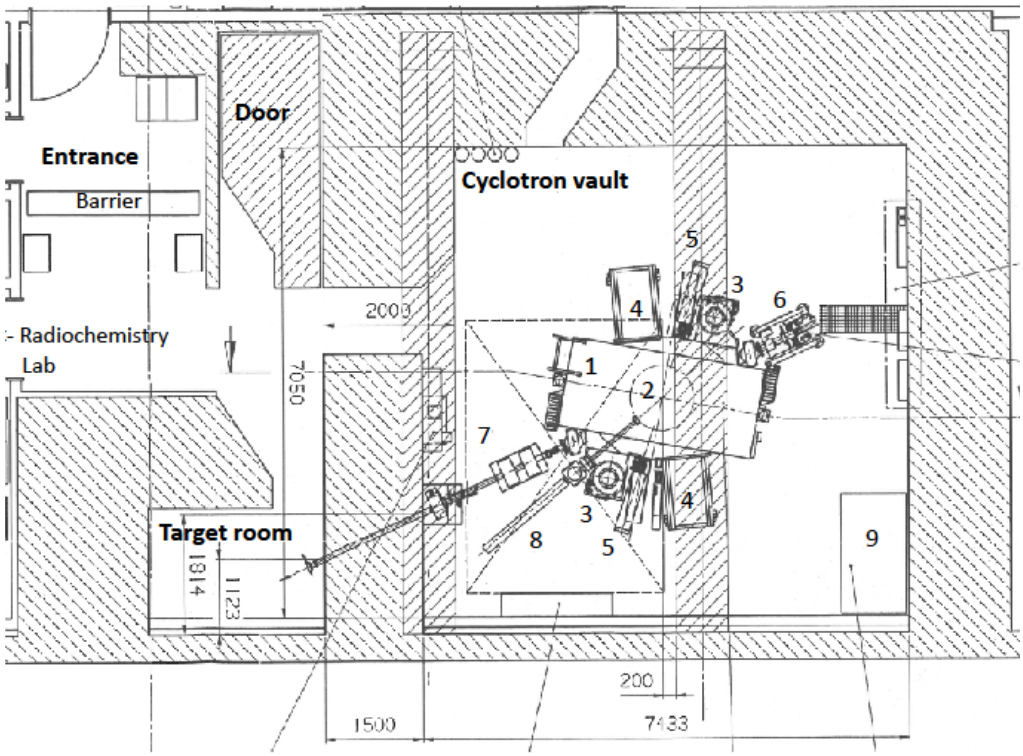

Fig. 2.8 Example of a (32 MeV) cyclotron installation comprising a common entrance (with barrier) to radiochemistry lab and cyclotron vault. A 2 m thick sliding concrete door protects the surroundings. In the vault is shown the electro magnet (1), the central accelerating circle area (2), diffusion pumps (3), radiofrequency generators (4), extraction systems (5), a target exchange station (6) at one beamline, a second beamline with focusing quadropoles (7) leading into the separate target room, a diagnostic probe (8) and the cooling water exchange systems (9).

Table 2.1. The 'classical four' cyclotron produced radionuclides for PET.

Nuclide	Half-life	Production route(s)
^{11}C	20.4 min	$^{14}N(p,\alpha)^{11}C$
^{13}N	9.97 min	$^{16}O(p, \alpha)^{13}N$
^{15}O	2.04 min	$^{15}N(p,n)^{15}O$ or $^{14}N(d,n)^{15}O$
^{18}F	109.8 min	$^{18}O(p,n)^{18}F$ (F^-) or $^{20}Ne(d,\alpha)^{18}F$ (F_2)

(84) As an alternative to local cyclotron production, some radionuclides can be obtained from generator systems based on more long-lived nuclides. The most important, and

currently only commercial, systems are the $^{82}Sr/^{82}Rb$ and $^{68}Ge/^{68}Ga$ generators. Interestingly, these generators were known and applied as early as in the 1960s.

2.6. Clinical applications and radiopharmaceuticals

2.6.1. Neurology

(85) The first applications of positron coincidence imaging were (technically) limited to the brain (Brownell, 1968) using, e.g. ^{74}As arsenite ($T_{½}$ = 17.8 day) or ^{64}Cu labelled EDTA ($T_{½}$ = 12.7 h) for tumour detection. The early studies with ring PET systems, also for brain only, used inhaled ^{77}Kr (Yamamoto et al.,1977) or $[^{15}O]CO_2$, and later ^{15}O labelled water as brain perfusion tracers. In combination with $[^{15}O]O_2$ and $[^{15}O]CO$ the cerebral oxygen consumption ($CMRO_2$) could be determined. During the 1980s and early 90s, PET was still primarily used for research in the brain, e.g. activation studies with $[^{15}O]H_2O$, a field taken over by the non-ionising method of functional Magnetic Resonance Imaging at the end of the 90s. The study of brain receptor systems e.g. dopamine and serotonin also became important research applications and remains so.

(86) 2-$[^{18}F]$FDG can be used to measure the glucose consumption of the brain, and much effort in the 90s was put into its quantitative determination, but due to the high complexity this never got a clinical impact. Compared to its use in the rest of the body (see Oncology below), 2-$[^{18}F]$FDG is less useful for tumour detection in the brain due to the high physiological uptake in normal tissue.

(87) PET and PET/CT today has important clinical roles in neurology:

- For neurodegenerative disorders particularly 2-$[^{18}F]$FDG and radiotracers for the detection of amyloid accumulation in suspected Alzheimer's disease are in clinical use.
- In Parkinson's disease a number of tracers are gradually being introduced: 6-$[^{18}F]$FDOPA, $[^{18}F]$FE-PE2I.
- In brain tumours radiolabelled amino-acids are used for glioma, ^{11}C labelled methionine, 6-$[^{18}F]$FDOPA and $[^{18}F]$FET. $[^{68}Ga]$Ga-DOTA-conjugated peptides are binding to the SSTR2 receptor in meningiomas.
- Finally $[^{15}O]H_2O$ is (still) used to estimate the cerebral hemodynamic reserve capacity in chronic cerebrovascular disease.

2.6.2. Cardiology

(88) Through the early advent of systems with an opening that allowed scan of the body (Hoffman et al., 1976), the heart became another important target for PET research. The primary topics are myocardial perfusion and metabolic uptake of different substrates. The main clinical condition is the assessment of 'viability', where regions of the heart show reduced perfusion while (glucose) metabolism is still preserved, indicating that the patient might benefit from an intervention (revascularisation) with the intension of restoring the perfusion (Schelbert, 2002).

(89) The PET tracers in common and competing use for quantitative determination of myocardial perfusion are ^{15}O labelled water $[^{15}O]H_2O$, ^{13}N labelled ammonia $[^{13}N]NH_3$ and $[^{82}Rb]RbCl_2$. While ^{15}O and ^{13}N are cyclotron products, $[^{82}Rb]RbCl_2$ is injected directly from a generator system eluted with saline, which makes it available for a more widespread clinical use. $[^{15}O]H_2O$ is often considered the reference tracer because it is the most direct measurement. It is metabolically inert, essentially freely diffusible, and has an extraction

fraction close to one up to very high perfusion values. Rubidium is taken up as a potassium analogue, and the uptake is non-linear in perfusion. [^{13}N]NH_3 is taken up and retained by various metabolic pathways and the resulting signal is influenced by several variables, including perfusion, extraction fraction and metabolic status. Due to the difference in positron energy (range) as well as half-life, image quality with rubidium and [^{15}O]H_2O is inferior to that of ammonia; for [^{15}O]H_2O often only the calculated perfusion values will be used. A major advantage of the shorter half-life, however, is that it is possible to repeat examinations (rest - stress) with a short time interval completing a full examination within half an hour. More details can be found, e.g. in European Association of Nuclear Medicine (EANM) guidelines (Sciagrà et al, 2021).

2.6.3. Oncology

(90) The majority of all PET/CT scans are performed on oncological indications, and primarily using 2-[^{18}F]FDG as the standard tracer. 2-[^{18}F]FDG whole body scans are used for diagnosis, staging, radiotherapy planning, response to therapy and assessment for recurrence. Some details for production of 2-[^{18}F]FDG and patient handling are shown in Section 3, and due to its importance, most examples in this publication refer to this tracer.

(91) Other tracers with more specific indications have been developed and come into routine use like ^{68}Ga or ^{64}Cu labelled somatostatin receptor ligands (DOTATOC/DOTATATE) for neuroendocrine tumours or ^{68}Ga labelled peptides to prostate specific membrane antigen (PSMA) imaging in prostate cancer (metastases).

3. PET/CT FACILITY DESIGN

(92) Key points in this section:

- Cyclotron vaults should be planned and constructed primarly to protect against secondary neutron radiation and concrete is the primary material normally used. Shielding requirements will depend on the incorporation of self-shielding.
- Radionuclide transfer systems within a cyclotron facility should be designed to minimise leakage and staff exposure, and pressures and airflow designed to limit spread of any airborne contamination.
- Handling of PET radiopharmaceuticals during synthesis, filling vials and dispensing in shielded syringes should be automated as much as possible.
- Patients remain in the PET facility for several hours including a rest period following 2-[^{18}F]FDG administration that may be 60 minutes. Planning movement of the patient through the department to minimise exposure of staff members is crucial.
- The provision of shielded rooms for resting patients, the location of active toilets to minimise distances of any patient movement, and the siting of patient facilities adjacent to the scanning room are all important.
- PET/CT facilities require shielding against almost continuous low dose rate exposure from 511 keV photons emissions and short higher dose rate CT x-ray exposures. Protection of walls against 511 keV photons using concrete will dominate shielding requirements, but scattered CT x rays must be considered for the scanning room doors and windows.

3.1. Types of PET/CT facility

(93) Radionuclides used in PET imaging have relatively short half-lives and are mainly produced using cyclotrons. ^{18}F is the mainstay for PET studies and it has a half-life of 110 minutes, so a PET imaging facility without a cyclotron of its own needs to be located with a production centre within a few hours transport distance (Ducharme et al., 2009). Facilities of this type carry out scans using primarily 2-[^{18}F]FDG, but may supplement this with other radiopharmaceuticals labelled with ^{18}F (such as [^{18}F]NaF, [^{18}F]Choline, [^{18}F]-PSMA, [^{18}F]FLT, [^{18}F]-DOPA) and positron emitting radionuclides produced by generators, such as ^{68}Ge/^{68}Ga, ^{82}Sr/^{82}Rb. This type of facility requires laboratory areas for labelling of radiopharmaceuticals using either a commercial kit or synthesis module (IAEA, 2010).

(94) Other PET radionuclides such as ^{11}C, ^{13}N, or ^{15}O, with half-lives of about 20, 10, and 2 minutes respectively, can only be used if there is a cyclotron on-site. Therefore, specialist PET facilities usually have a cyclotron incorporated into the same building. A facility of this type with its own cyclotron that produces ^{18}F and other common positron emitting radionuclides for use within the facility can use a variety of automated modules for synthesis of different radiopharmaceuticals that are commercially available. These are installed in laboratories located near the cyclotron, within 'hot cells' suitably shielded and equipped with the necessary ventilation and safety systems. All radiopharmacies must meet stringent requirements arising from drug legislation as regards the facility infrastructure, quality of air, finishes, flows of staff and products, etc, involving the design of the site. Furthermore, each centre should establish an extensive quality assurance system in order to guarantee the quality, safety and efficacy of the products. According to local regulations, the requisites for

facilities that produce radionuclides for distribution to other centres may be more stringent. Radiological protection of cyclotron radiopharmaceutical production facilities needs to take into account good manufacturing practice (GMP) requirements for the use of such products in humans and in accord with the specific jurisdiction (FDA, 2011; Vidal et al., 2020; EC, 2022).

(95) The majority of this document will be devoted to the design and operation of a PET scanning facility applicable to all types, but some discussion will be included at the start relating to centres with cyclotrons.

3.2. Cyclotron facilities

3.2.1. Shielding the cyclotron vault

(96) The cyclotron vault should be planned and constructed primarly to protect against secondary neutron radiation produced during irradiations, while paying attention to the prompt gamma radiation resulting from the de-excitation of nuclei following interactions with the beam (IAEA, 1988; NCRP, 2003). Absorption of neutrons will require a material with significant hydrogen content, while attenuation of gamma radiation will require high Z materials. Concrete is used predominantly, given the favourable balance between attenuation capacity, mechanical and structural strength, availability and cost. Type and thickness of the walls will depend on the make, model, and energy of the cyclotron, and whether or not there is a self-shielding component.

(97) The level of risk associated with this class of accelerators is dependent on the position and distribution of the shielding. When the cyclotron is supplied with a factory designed shielding, entirely surrounding it, this is termed as a self-shielded cyclotron (Hertel et al., 2004). If part of the shielding is placed only around the target stations, this is termed a 'local shield' (Infantino et al., 2017); in many cases however the shield is included only in the vault walls (Mendez et al., 2005). Self-shielded or locally shielded cyclotrons require a lower level of additional shielding, but nevertheless they need to be placed inside a vault to provide additional shielding (NCRP 2003; Schmor, 2011). The choice of the type of cyclotron and shielding, and the overall design of the facility will depend on the intended use (Marengo et al., 2023). Where research is to be undertaken on different radionuclides, the space required will depend on the dose constraints applied for staff and the public, and the prospective plans for future decommissioning (Braccini, 2016).

(98) In addition to the cyclotron vault, rooms for the cabinets containing the electronics, the cooling system, and the control system, and other equipment associated with the cyclotron, will be needed, as well as for storage. Gas cylinders required for the operation (including high purity H, He, N, and others) are typically located in an external area, close to the vault (IAEA 2009a).

(99) The high level of radiation produced during cyclotron irradiation, together with the magnitude of the activity levels generated, and the amount of processing involved require extensive radiation safety measures to ensure staff safety. These measures include: systems to ensure that an operator cannot become trapped inside the vault, automated equipment to minimise personnel handling of radionuclides, the extensive use of shielding and safety interlocking devices, a specific ventilation and air conditioning system, and the radiation level monitoring system to protect personnel and the environment (Mishani, 1999; Sharma, 2006; Alwani, 2016; IAEA, 2020a).

(100) PET Cyclotrons produce radionuclides through bombarding a suitable target with ^{1}H (p) or ^{2}H (d), that involve nuclear reactions such as (p,n), (p,2n), (p,α), (d,n), etc. In

cyclotrons for the production of PET radionuclides, the primary beam of charged particles will be completely absorbed by the target. Neutrons produced in nuclear reactions are the most important secondary radiation, even if protection against gamma photons is also required. The radiation field created around the cyclotron will vary with the type of target material, the beam current and the maximum energy used (Vega Carrillo, 2001). The neutron dose rate produced by a modern cyclotron - target system, which is not self-shielded, during high current irradiation, will exceed 10 Sv h^{-1} at a distance of 1 m from the target (Infantino et al., 2016), and the cyclotron manufacturer can provide information on this. Full details of the fields that occur, both during and after operation, which will aid in the design and specification of shielding can be obtained in the literature (IAEA, 1988; NCRP 2003). Concrete is largely used for shielding, granting sufficient hydrogenous content to attenuate neutrons, whilst having suitable protection characteristics against gamma photons. Materials used for the self-shield or local-shields include: concrete, water, heavy concrete, e.g. loaded with Limonite (an iron ore), and Iron; these are frequently added with some material including boron, which has a high capture cross-section for neutrons and the energy of the capture gamma photon emitted (478 keV) is lower than that from the hydrogen interactions (2.2 MeV). For these systems, the cyclotron manufacturer should provide details of the radiation fields that occur during operation, and information on the activation.

(101) New systems and methods are continually being developed, so a literature review should be undertaken to identify the most recent techniques used for operation and production processes, and appropriate waste streams. The vault will normally be at ground or basement level to facilitate shielding and minimise structural support issues. The production of neutrons in nuclear reactions at the energy levels of PET cyclotrons is essentially isotropic. The groundshine and skyshine effects should be appropriately accounted for (IAEA, 1988; NCRP, 2003).

(102) Calculations of shielding requirements for cyclotrons may use a formalism similar to those involved in radiotherapy linacs (NCRP, 2003), once the appropriate data for neutron HVLs or TVLs are selected. Monte Carlo methods have proven to be highly useful in the calculation of wall shielding, and provide more accurate results with respect to analytical methods in the calculation of the doses transmitted through mazes and conduits (Infantino et al., 2017; Facure and França, 2010). The primary purpose of the shielding is to reduce the neutron flux during cyclotron operation. A typical thickness could be 0.5–0.6 m of concrete for a 10–11 MeV self-shielded cyclotron (Pant and Senthamizhchelvan, 2007; Masumoto et al., 2014), and of the order of 2.0–2.4 m of concrete (density 2.3 g cm^{-3}) for a non-shielded 18 MeV cyclotron (Facure and França, 2010; Infantino et al., 2017). However, these values are purely indicative, being influenced by the type of target and beam current, local workload, and distance from walls. Shielding that will reduce the neutron flux to an acceptable level will provide adequate protection against the gamma flux. When designing the shielding consideration should also be given to possible future upgrades to the cyclotron, such as increased beam current (e.g. new ion sources) or new targets that would increase the ^{18}F production and therefore increase neutron flux through the reaction $^{18}O(p,n)^{18}F$. The shielding should be tested using a reaction which produces a high neutron flux to ensure that the protection is sufficient; typically the $^{18}O(p,n)^{18}F$ reaction is the preferred benchmark. Since not all activation reactions generate equal intensities of neutrons, an assessment of the radiation dose made during an irradiation of a target for the production of ^{13}N or ^{11}C would severely underestimate the flux of neutrons.

(103) Many vaults will have a shielded door (Heaton et al., 2014), although a maze is favoured in some cases (Russo et al., 2011); prospective evaluation using Monte Carlo simulations, when possible, can be helpful in making the optimal choice between the options available (Facure and França, 2010). The drive mechanism for the door should be located on

the outside of the vault to facilitate repair if stuck in the closed position (Heaton et al., 2014). The light signalling system can include a series of gradual alarms activated by the subsystems of the cyclotron that are progressively turned on. As an example: a green light indicates that all the subsystems are off or in standby mode; Magnet ON is frequently yellow, Radiofrequency ON is typically orange, BEAM ON is red. However, this light coding is not standardised. The door can be opened via a local control panel; this usually produces an additional luminous and acoustic signal to indicate 'moving door'.

(104) The cyclotron will have interlocks and incorporate fail-safe (last man out) buttons, to confirm that the vault is clear of personnel when the cyclotron is in operation. A visual control system, based on radiation-resistant cameras, is recommended, and if combined with a movement detection system it can further increase safety, avoiding the possibility of trapping an operator in the bunker (ICRP, 1997b).

(105) Other aspects that should be considered include firefighting systems, that should be based on extinguishing gases, since the use of liquid or powder extinguishing media could damage the cyclotron irreparably. Since the beam is generated from hydrogen or deuterium gas, there should be a detection system for any gas leaks, which could cause explosions. A flood detection system can be useful in order to avoid damage to the accelerator and also to avoid the possible spread of contamination. The level of illumination in the vault should be adequate for ensuring proper maintenance.

(106) Access to the bunker should be regulated. During irradiation, access to the bunker of a cyclotron that is not self-shielded, or that is only locally shielded, must be impossible. In the case of self-shielded cyclotrons, for some models operating at proton beam energies of 10–11 MeV, the levels of environmental dose rate during irradiation are of the order of several tens of $\mu Sv\ h^{-1}$; access could be allowed even in the irradiation phase. However, the actual need for such access should be carefully evaluated and strictly regulated; what has been said does not apply in any case to self-shielded cyclotrons operating with higher beam energies. Access to the bunker should require that the operator wear specific work clothes and use gloves and face masks. For the maintenance operations carried out inside the acceleration chamber of the cyclotron, these requirements can be more stringent, in particular to avoid the inhalation of contaminated or activated dust (Calandrino et al., 2010; Terranova et al., 2011; Biegała et al., 2022), as well as for the protection from beta radiation that could arise from some components.

(107) The concrete used for shielding the vault will contain some components that can be activated with half-lives ranging from a few hours, such as ^{24}Na, up to years for ^{60}Co and ^{152}Eu (Birattari et al., 1989; Calandrino et al., 2006, 2020; Martinez-Serrano and Díez de los Ríos, 2010; Vichi et al., 2019). The level of long-term activation will depend strongly on the workload of the accelerator and on the composition of the concrete and may become a liability when a facility is decommissioned. Whenever possible, a low alkali grade concrete should be used to minimise activation through neutron capture reactions and reduce doses to cyclotron workers. Iron reinforcement bars should be placed at a depth greater than 30 - 40 cm in the concrete, to reduce activation (Vichi et al., 2019). Addition of neutron absorbing components, such as colemanite or borosilicate glass powder could be considered, provided that the mechanical characteristics of the concrete are preserved (Gunduz and Usanmaz, 1986; Gencel et al., 2010; Korkut et al., 2010; Korkut et al., 2012; Okuno, 2005; Jang et al., 2017). Additional shielding around the target could be installed to avoid unnecessary activation of the concrete shielding, and will determine the level of activation of the 'local' shield.

(108) It is important to consider at the planning stage the ease with which a cyclotron facility can be decommissioned, as this can save a considerable amount of work and expense later by reducing the amount of radioactive waste generated when the facility is replaced. If

there is a service access to the vault through which the whole cyclotron can be removed, this will avoid the expense of having to cut up the main magnet. The planning of the vault in such a way as to minimise the activation will also be beneficial (Paans and de Jong, 2017; Tesse et al., 2018; Vichi et al., 2020). Use of non-metallic reinforcement will reduce the possibility of activation. The outer layers of concrete (away from the cyclotron) can often be disposed of as regular waste whereas the inner layers will probably be low level radioactive waste if they contain iron reinforcement, but could be removed and disposed of more easily during decommissioning if they do not contain metal, in the form of a strippable layer of concrete or 'sacrificial layer' (Eppinger et al., 2001; IAEA, 2016; Lee et al., 2019;). Therefore, careful planning of construction and use of layers of material on walls and floors that can readily be stripped away will significantly reduce the mass of concrete for final disposal.

(109) All surfaces within the vault should be hard, washable, and smooth, and either painted or covered with an epoxy coating, to minimise the creation of dust and allow any contamination to be removed easily. It is important that dust is kept to a minimum as this can be a means through which radioactive contamination is transported out of the vault.

3.2.2. Radionuclide production and transfer

(110) The pattern of air flow within a facility should be designed to control airborne contamination. All the active part of the ventilation system should be redundant, in order to grant proper function even in conditions differing from those originally planned. The fans for air expulsion should be placed after the filtering systems. Filters should be adequate for the types of effluent. In general, high efficiency particulate air (HEPA) filters or ultra-low particulate air (ULPA) filters are requested; in addition, activated charcoal or other supplementary filters can be necessary for specific products. The ventilation system should be designed to avoid re-circulation of air in normal working conditions. Air outlets and inlets should be positioned so that expelled air is not recirculated. In the internal laboratories, the flow of ventilation should normally be directed from the top downwards, to avoid resuspension. Air outlets should normally be placed at low levels and the airflow should be from areas where there is minimal likelihood of airborne contamination to areas where such contamination is probable. 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, or 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 (IAEA, 2020b; EudraLex, 2020).

(111) In general, the cyclotron vault should be at the lowest pressure, the hot laboratories at an intermediate pressure, and the surrounding public areas at a higher pressure. For reasons of asepsis, some radiopharmacies may need a positive rather than a negative pressure with respect to the surroundings (IAEA, 2018; Eudralex, 2020). In this case, the pressure gradient can be obtained by locating other workstations/areas at negative pressure next to the radiopharmacy workstation/area. As an example, the entrance air lock and the technical space behind the hot cells can be at a negative pressure, with respect to the clean room where radiopharmaceuticals are synthesised and dispensed under conditions that meet a specified level of air quality.

(112) The general control for the ventilation system should be placed in an external, easily accessible area, kept clear in order to facilitate intervention. Internally to the laboratories there should be regulation controls, measuring devices, alarm signals, and displays of the local relative pressure. In emergency conditions, an emergency push-button for reactivation

of the ventilation system should be provided, in order to avoid dangerous levels of contamination inside the premises.

(113) Minimising radiation exposure is paramount in the design of a facility through provision of a smooth flow in processing. One way of achieving this is by ensuring that areas where successive steps are carried out are adjacent to each other; vented pass-through boxes may help to avoid disruption of the air cleanliness required for processing pharmaceuticals.

(114) The delivery of radionuclides in liquid or gaseous form from the targets, within the cyclotron bunker, to the points of use must be done via a shielded transport system. The fluids can be transferred using an inert carrier gas (IAEA, 2009a, 2012). The passage of delivery lines through walls or in trenches under the vault floor provides an effective means of moving material from one area to another with essentially no possibility of irradiation. The radionuclide activities they carry are likely to be large, so they will need to be shielded appropriately. The level of shielding is typically the order of 0.3–0.5 m of concrete, or 5–10 cm of lead, but this will depend on the distance from areas where staff have access, the occupancy of these areas and transit times.

(115) In order to minimise the possibility of spreading contamination, the radionuclide transport lines should be tight, controlled and replaced regularly at agreed intervals of time, taking account of the deterioration caused by the radiations to which they are exposed; arrangements should allow this to be done without the need for lifting of heavy shields. Safety interlocks should be in place, in order to avoid delivery to a hot cell that is not in a safe condition (e.g. with door closed, ventilation active, and synthesis module ready to receive the radionuclide).

(116) Penetrations through the walls of the vault, either for flow lines, ventilation, electrical supplies or other services should avoid any direct line of sight through which exposure might occur. Monte Carlo modelling is useful for planning and verifying design proposals (Infantino et al., 2016). This can be achieved by running penetrations at an angle or using an S-shaped curve (IAEA, 2009a). Curved plastic pipes may be set into the concrete walls or floor at installation to act as conduits.

(117) Components of the cyclotron will be activated by proton interactions, if they are hit by the beam or in close proximity to it, or irradiated by secondary neutrons produced in the target. Components of the extraction system (the 'deflector' and the 'septa') in positive ion cyclotrons will be activated significantly.

(118) In modern cyclotrons accelerating negative ions, the design will aim to reduce activation to a great extent. The most activated components will be the targets, in particular the foils used to seal the target with respect to the vacuum chamber. The foils are crossed by the beam, so their activation is significant. The material used most frequently is Havar, an alloy of cobalt, chromium, iron, tungsten and others. A variety of radionuclides are produced in Havar foils: among many others, the most relevant are ^{51}Cr, ^{57}Co, and ^{54}Mn. The extraction system will also be activated. In negative ion cyclotrons, the principal components are graphite foils, in which only short-lived radionuclides will be produced. However, the foils are typically mounted on an aluminium or other metal frame, and the whole assembly could be hit by the tails of the beam, or by stray protons, resulting in activation. Another site where activation may occur is the collimators, used to shape the beam before it enters the target. The collimators typically absorb a current of the order of 5–10 % of the beam current, which means several μA, and depending on the material, activation can be significant. Collimators are typically made of a high melting point material. Tantalum is an excellent collimator material, since even a very limited thickness stops the beam tails completely, but it produces significant activation (^{181}Ta, ^{182}W). Graphite is much better in terms of reduction of activation, but a greater thickness is necessary. Other internal components in copper, may be

activated with ^{65}Zn (Calandrino et al., 2006, 2020; Marengo et al., 2008; Terranova et al., 2011).

(119) Dose rates at a distance of 1 m from targets after ^{18}F production can be of several mSv h^{-1}, decreasing to levels of hundreds of μSv h^{-1} several hours after production of ^{18}F, so the standard practice might be to carry out any work on targets after the weekend or holidays, in order to allow a reasonable time for decay. For maintenance inside the vacuum chamber of the cyclotron, targets should be disconnected and removed, to avoid unjustified exposure. After that, in negative ion cyclotrons, the dose rates in close contact with internal components will be limited to a range of several tens of μSv h^{-1}, particularly if collimators are made from graphite (Calandrino et al., 2010).

(120) During maintenance operations within the vacuum chamber, care is needed in minimising the possibility of contamination. Residuals and powders coming from all the components previously reported could be present, and the possibility of inhalation cannot be excluded. All maintenance operations should be carried out bearing this in mind; operators should wear proper protective clothes, gloves, and a face mask. A point that requires attention is cleaning of the ion source, when this is internal to the cyclotron. The ion source body is relatively far (30–50 cm) from the targets, so that any activation comes only from secondary neutrons. The body of the ion source, typically made of brass, needs to be scrubbed to remove residues. During these mechanical operations powders are produced, that present a potential hazard from inhalation. The deposits on the ion source body come from tantalum, the main component of the cathodes, and contain ^{182}Ta, due to the (n, γ) reactions in ^{181}Ta, induced by the secondary neutrons. The ion source can be disengaged and cleaned in a laboratory area, within a vented hood (Calandrino et al., 2010; Terranova et al., 2011).

(121) ^{40}Ar is a natural component of air. Given the high cross section for thermal neutron capture (^{40}Ar(n, γ), σ = 600 mbarn), ^{41}Ar is produced in the air of a vault and the amount depends on the total volume of air irradiated. In fully self-shielded cyclotrons, this volume will be limited. In 'naked' cyclotrons, the whole internal volume of air is significantly irradiated with thermal neutrons, and the production of ^{41}Ar will not be negligible. Nevertheless, it has been shown that the concentration of ^{41}Ar in the air exhaust is very low, and the radiological consequences for the public in the surrounding areas are not significant (Birattari et al., 1986; Infantino et al., 2015; Cicoria et al., 2017; Fischer et al., 2019).

(122) The target assembly, that is the body and device holding the target material, are essential components in a modern cyclotron, in order to produce clinically relevant amounts of the radionuclides. Concerning safety aspects, targets should be tightened, in order to prevent any release of radioactivity during irradiation. Most cyclotron control systems provide for a quick tightness test prior to each irradiation. In addition, the target tightness should regularly be fully checked by pressurising each target with inert carrier gas. Targets should be periodically dismounted, cleaned and worn components such as foils, gaskets and seals should be replaced. After disconnecting a target, a period of 'cooling down' to allow for decay of radioactivity, storing the target in a shielded container, is recommended. For this reason, a PET Cyclotron centre should always have spare target assemblies, for replacement. After appropriate 'cooling down' (e.g. 2–4 weeks), the target assembly can be disassembled. The foils will be the most activated component. They should be quickly removed, using tweezers or other tools to avoid contact with fingers, and disposed of in a shielded container, before proceeding with any further operation (O'Donnell et al., 2004; Ledesma et al., 2008).

3.3. PET radiopharmacy/radiochemistry laboratory

3.3.1. Laboratory facilities

(123) The PET Radiopharmacy should be close to the cyclotron, so that the distance for transfer of radionuclide from the target to the hot cell is as short as possible. Several different areas or laboratories will be required for production, quality control, research, preparation and packing if radiopharmaceuticals are to be sent to other facilities (IAEA, 2009a). Production operations should take place in shielded hot cells, with shielded lines used for transfers between cells, using automated systems. A facility producing radionuclides for distribution to other centres will also need an area for packaging radiopharmaceuticals for dispatch to other centres. Appropriate authorisations, licences, or permits will be required in every country relating to radiation and pharmaceutical production regulation (IAEA, 2009a; 2010; Russo et al., 2011; Heaton et al., 2014).

(124) Nowadays, most manual operations on radiopharmaceuticals can be assisted, if not replaced, by automated operation. Appropriate devices are available to perform synthesis, filling vials and dispensing in syringes, with minimal if any need for manual intervention. In particular, dispensers to automatically fill the final unit dose in a syringe are now available not only to be installed within dedicated hot cells, but also as 'stand alone' dispensers that can fit in almost any type of cell or workbench. These systems, in addition to standard radiological protection measures in radiopharmacies, make it possible to minimise staff doses. Purpose built commercial hot cells are available, with 3.5–10 cm thick lead shielding depending on the activities to be handled, and finished in stainless steel to facilitate cleanliness and sanitation. The synthesis modules for radiopharmaceutical production are placed inside the hot cells and require controlled environmental conditions and supplies of gases, such as helium, compressed air, or nitrogen. Therefore, the design and location of the hot cells should be planned, to ensure they are sufficient in both number and size to accommodate the synthesis rigs required for the range of radiopharmaceuticals to be produced.

(125) The hot cells are normally operated at a low pressure to reduce the possibility of leaks into the laboratory (Russo et al., 2011). The stainless-steel box in which synthesis modules or dispensing devices are installed should be tightened and specifically tested and certified at the factory.

(126) In the event of malfunction of a synthesis module, such as a break in a connector or a leakage in the reactor vessel, there can be a significant loss of radioactivity within the hot cell. Each hot cell should have a monitoring system aimed to control all operation conditions like temperature, pressure, air flow inside the cell, including monitoring of radiation levels inside the cell and in the exhausted air. The control system of the hot cell should include an interlock to ensure safe operation: delivery of activity should be possible only if the hot cell is in a safe condition and 'ready' to receive the activity; the door of the hot cell should not open if the level of activity contained exceeds an agreed threshold; ventilation should be variable according to the needs; in case of a leakage of radioactivity, such as a gas or vapour, there should be a feedback system based on monitoring, controlling the ventilation system (e.g. stopping the ventilation and activating a containment system). Routine releases of gases from the synthesis modules should be collected elsewhere, as explained in section 3.3.2.

(127) The production of liquid radioactive waste by a PET Radiopharmacy Laboratory should be substantially reduced so that it is a minimum. Small volumes of liquid waste can be absorbed on a specific substrate, and so converted into solid waste, the management of which is preferable.

(128) Some PET tracers such as ^{82}Rb and ^{68}Ga are obtained from elution of generators stored on site. ^{82}Rb generators are typically installed within a specific infusion system. They should always be eluted according to the procedure indicated by the manufacturer, using the appropriate eluate and testing method.

(129) ^{68}Ga generators should be installed within a hot cell; even if manual elution is feasible, the use of an automated or semi-automated system will reduce dose to the extremities of operators, while granting repeatable operation (Boschi et al., 2012, Heaton et al., 2014) eluates should be checked for breakthrough of ^{68}Ge (Cicoria et al., 2009).

(130) The final dispensing of radiopharmaceuticals in the syringe for injection to patients can be performed either in the PET Radiopharmacy laboratory, or in the clinical area, in a shielded cabinet. Independent of the location, dispensing is an activity that involves a significant exposure to the hand of staff (Kolaard et al., 2021; McCann et al., 2021; Andriulevičiūtė et al., 2022), as well as the possibility of contamination. The use of an automatic dispenser, that fills syringes already fitted with a shield reduces the exposure to a minimum. For other details on the injection procedure see Section 3.5.2.

3.3.2. Release and monitoring of radioactive gases

(131) In addition to the neutron activation of the bunker air and the production of ^{41}Ar, there are two main sources of production of gaseous radioactive effluents: the cyclotron, including its targets, and the modules for the synthesis of radiopharmaceuticals.

(132) Release of radioactive gases can occur from the cyclotron vault, in several different ways. Some of the materials that are irradiated are gases, as in the case of the production of ^{11}C and ^{15}O, but the majority are liquids, such as for ^{18}F and ^{13}N, and these are held within targets that are sealed assemblies that, in normal routine use, should not release any radioactivity. Target rupture, that is breaking of the foils in the target, generally is followed by the containment of the volume of target material inside the vacuum chamber of the cyclotron, with limited if any release to air. The latter may happen through the helium cooling system or the pumps in the vacuum system; to take account of this, the outlets of the He compressor and mechanical pumps could be connected to a containment system or to a gas waste delay line. A delay line can simply be a length of tubing, that is sufficient to create a transit time for gases, that will provide a substantial amount of decay in radioactivity.

(133) Release of radioactivity to air may occur if the target assembly, or a valve of the target filling/voiding station, or the delivery line are not as tight, as they should be. Since a rupture or defect in these components due to wear cannot be excluded, prevention is the only way to minimise risk. Checks of tightness of all components that may potentially leak radioactivity should be included in routine testing procedures.

(134) Routine release of radioactive gases during synthesis of radiopharmaceuticals may occur in different phases, and strongly depends on the type of process. It is important to consider first of all the production of 2-[^{18}F]FDG. In the delivery of the irradiated bolus of ^{18}O enriched water from the target to the synthesis module, the carrier gas (typically a flow of He or N) is generally transporting some ^{13}N produced by the cyclotron during ^{18}F production, due to the (p, α) reaction on the residual ^{16}O. The carrier gas flows in the module and can be collected at an exit point that depends on the technology of the module. Some types of modules have an output fitting for collection of exhaust gases 'pushed out' by the cyclotron; in other types of modules there is a vacuum pump that sucks the bolus, and the output stage of this pump is the release point. In any case, the emission point should be appropriately identified and connected to a collection system. Other potential phases of gaseous release during the synthesis of 2-[^{18}F]FDG are the processes happening in the reactor vessel of the module. The total volume of gases released is typically of the order of a few litres. If not collected properly, these gases may contaminate a much larger volume of air, used in ventilation of the hot cell. Appropriate solutions are the collection by means of plastic bags (Schweiger, 2001), or the connection of the exhausts to a gas delay line. The above

indications provide useful guidance for all other processes of synthesis of $^{18}F^-$ based radiopharmaceuticals.

(135) The issues may be more complex in the case of the production of ^{11}C radiopharmaceuticals. Given the variety of products and synthesis modalities, it is not possible to give simple, straightforward indications. In general, the volumes of gases are higher than in the production of ^{18}F in liquid phase. All possible release points from a synthesis module should be identified in advance and fitted with a sequence of chemical traps based on Ascarite, sodium or potassium hydroxide, molecular sieves, and finally activated charcoal.

(136) Nevertheless, it is possible for a release of gases to occur during a synthesis, e.g. due to rupture of tubing in a module. Even if the material is in liquid phase, given the high ventilation rate in the hot cells, the drops of liquid will be transported as an aerosol. This class of incidents can be dealt with by using appropriate filters in the emission duct of each hot cell. If the chemical form of the release makes the filtering approach ineffective, a compression station to collect the exhaust of the hot cell, activated if a predefined threshold of radioactivity detected in the exhaust is exceeded, can be adopted (Mishani et al., 1999).

(137) In general, the main discharge point of the cyclotron and PET laboratories should be on the roof of the building complex, which may be some distance from the facility, requiring tens of metres of ducting.

(138) The radiological impact of any possible release of radioactive gas, in routine operation or as a consequence of a malfunction in any phase of the process, must be assessed. This requires the use of software codes developed under strict Quality Assurance and properly validated, like HotSpot, released by the Lawrence Livermore National Laboratories (Homan and Aluzzi, 2020; Hotspot, 2022).

(139) The exhaust air travelling through the extraction system must be monitored before release either through online monitoring or extraction of gas samples. The monitoring system acts as an alarm system for detection of any unexpected discharges and can activate feedback reactions, such as closure or regulation of the ventilation system. Furthermore, the monitoring system will provide a record of routine gaseous releases, and can give the integrated amount of activity being released when properly calibrated (Marouli, 2007; de Sousa Lacerda et al., 2011).

3.4. Radiation components of PET/CT imaging

(140) When designing a PET/CT facility, there are two component radiations that need to be considered that have very different shielding requirements. The 511 keV photons emission resulting from positron annihilation and the x-ray emission associated with the accompanying computed tomography (CT) scans. The emission component, aimed to study the in-vivo bio-distribution of the radiopharmaceutical administered, is in general the reason for which the examination is performed. The transmission CT component of the multi-modality scan may have different goals: basically, it is necessary in order to ensure accurate attenuation corrections for the emission component of the study, as well as to improve 'navigation' in the anatomy of the patient, enabling regions of radiopharmaceutical uptake to be positioned more accurately. Furthermore, the CT component may be setup as a fully diagnostic study per se. The purpose of the CT component will influence the radiation output level (Townsend, 2008).

(141) The two radiation sources against which shielding is required will be considered separately, because there are fundamental differences both in the physical properties of the radiations and the sources of exposure. The 511 keV photons have a much higher energy than

other radiations used for imaging, so attenuation through photoelectric interaction is much less. A rough indication of the differences can be obtained from comparison of values for the tenth value thicknesses (TVLs) radionuclide emissions with the thickness required to attenuate a beam of x rays. The TVL for 511 keV photons is of the order of 16 mm of lead, whereas for the 140 keV gamma photons from ^{99m}Tc it is about 0.9 mm, but attenuation of the wide range of lower energy photons in an x-ray beam is different, so 0.4 mm of lead would reduce 120 kV CT x-ray air kerma by a factor of ten, 1.2 mm of lead would reduce it a factor of one hundred, and 2.1 mm by a factor of a thousand (Madsen et al., 2006; RPII, 2009; Smith and Stabin, 2012; Sutton et al, 2012).

(142) Exposure to 511 keV photons can occur during radiopharmaceutical preparation and injection, and wherever staff is dealing with a patient after administration has taken place. In particular, since several injected patients will be waiting for proper bio-distribution of the radiopharmaceutical before being admitted to the scanning room, waiting areas ('uptake rooms') are typically those in which dose rates are higher. Therefore, not only is the design of the laboratory facilities important, but also the planning of the entire imaging process and the progress of the patient, as the radiation source, through the department (Madsen et al., 2006; IAEA, 2008b, 2010). Exposure to 511 keV photons will be almost continuous, but at a relatively low dose rate. Instead, exposure to x rays will only occur in the scanning room during the relatively short time (normally less than 1 min per PET/CT procedure) when the CT scan is being performed, but the un-shielded dose rate levels from a CT scan are significantly higher (up to 4–5 orders of magnitude in the direct beam) than those from a patient to whom a PET radiopharmaceutical has been administered.

3.5. The journey of the PET patient through the facility

(143) This section considers primarily requirements relating to imaging with 2-[^{18}F]FDG which are likely to make up the majority of the workload in most PET facilities (with PET, PET/CT, or PET/MR scanners). The following sections could be used a guidance for a PET/MR, but specific consideration should be followed in relation to the MR component of the study and its safety aspects.

(144) In summary, the patient examination with 2-[^{18}F]FDG involves the following steps, and an extensive description can be found, e.g. in EANM guidelines (Boellaard et al., 2015):

- Written material about the procedure should be provided to the patient in due time before the examination.
- The patient must fast for (at least) 4 hours before the injection, if the procedure is performed for oncological purposes, to avoid an insulin mediated uptake in muscles that either directly or by reducing the activity available could mask the malignity in question.
- The patient is received and again (orally) informed about the examination procedure, and the patient's or caregiver's doubts and questions are answered.
- The patient is placed comfortably in a bed or an injection chair, and in a warm environment, to avoid uptake of the radiopharmaceutical from brown fat, and instructed to remain relaxed. Any muscle (or brain) activity shortly prior to tracer injection may influence local uptake. In particular for brain examinations is this important and here also visual and auditive stimulation should be avoided.
- An i.v. line is installed, to facilitate the administration of the radiopharmaceutical.

- The amount of activity to be injected is determined according to local rules. Typically, a weight based activity is used.
- After injection, the patient remains resting so that the interval between 2-[^{18}F]FDG administration and the start of the PET acquisition becomes as scheduled, typically 60 minutes for oncological imaging. The i.v. line may be kept, in particular if CT contrast is to be injected. The patient is asked to go to the toilet and empty their bladder before being imaged. The patient is placed in the PET/CT and the examination is performed.
- Dynamic PET investigations require the administration of the radiopharmaceutical directly on the scanner table, that depending on the protocol would be acquired simultaneously with the start of the acquisition. In the case of PET/MR scanners, the administration must be done taking care to use devices and shields compatible with the magnetic field.
- After the examination, the i.v. line is removed. The patient is instructed to drink sufficient fluid and to empty their bladder frequently in order to minimise dose to the bladder wall.
- The patient is released, taking into account (local) rules relating to dose constraints to members of the public.

(145) It is helpful to break down the journey of a 2-[^{18}F]FDG patient through a department into the component steps associated with different tasks. When patients are called for appointment, they will be given basic instructions, such as the need to fast for several hours, and to avoid going to the PET facility with children or a pregnant woman.

3.5.1. Checking the patient

(146) Patients will be interviewed by a nuclear medicine physician or other qualified healthcare professional. In many departments this detailed interview about the procedures will be carried out at a separate appointment, but this may not necessarily be the case. This step is a fundamental moment of exchange of information: the patient will provide information about her/his condition, recent medication, interventions of concomitant pathologies and fasting conditions. This information could help in the interpretation of the images.

(147) During the interview, or even better before the patient appointment, the correct indication for PET (or other procedures) should be determined by a nuclear medicine physician or a qualified specialist on the basis of clinical information provided by the referring physician prior to the procedure.

(148) When patients attend for scanning their identification will be checked; this is a critical point in the process as regards patient safety and radiological protection. Patient identification is not a simple step, but rather a process that allows establishing correct matching between a patient and appropriately intended interventions, as well as communicating information about the patient's identity accurately and reliably throughout the continuum of care. Identification should be confirmed using more than one independent identifier, e.g. name, ID number or social security number, date of birth, etc. At the same time, she/he will be given an explanation of what the procedure involves, and on radiation safety aspects. In some countries it could be requested for the patient to sign an informed consent form. In the case of studies with 2-[^{18}F]FDG a quick glucose testing will be performed. This should all be performed prior to administration of radiopharmaceutical and the patient should also be asked if she is pregnant or possibly pregnant, as well as if she is

breastfeeding. At this point the patient will be sent to the administration-uptake room where radiopharmaceutical will be administered and the patient will remain at rest until the imaging phase.

3.5.2. Administering the radiopharmaceutical

(149) To reduce the staff irradiation, and the movement of the patient, the administration room should be the same as the uptake room. In most cases, this is one of a series of small rooms, suitable for hosting a single patient. It is at the point the radiopharmaceutical has been injected that the patient becomes a source of external radiation, and from then onwards shielding of staff and others from the patient needs to be considered.

(150) It is essential not to inject the patient directly. Both for automatic injection systems and in case of manual injection, it is suggested to place in advance an infusion line or cannula in the patient's vein and pre-fill it with saline solution. Injection of the radiopharmaceutical can be made once the operator is sure that the line is well positioned and open, connecting the syringe to a three-way valve in the line, or injecting in a septa. This optimises the time of operation with the radioactive syringe and the distance to the patient, minimising the dose to staff. In this way, injection using a shielded syringe becomes feasible and at the same time, the possibility of extravasation is reduced.

(151) Exposure to PET radionuclides in the imaging department comes from vials or syringes containing radiopharmaceutical activities for injection, as well as patients. However, vials of the batch of radiopharmaceutical, patient syringes etc. all have their local shielding. The injection of the radiopharmaceutical is likely to be the largest component of the radiation dose received by clinical staff working in PET facilities (Heaton et al., 2014). If the radiopharmaceutical is drawn up from a multi-administration vial this can lead to significant exposure, but automated dispensing systems, syringe fill stations, and specially designed shielding are available commercially and careful consideration should be given to finding the best option to suit the situation; further details are given in Section 8.

(152) Typical shielding of transport containers for vials of radiopharmaceuticals is of about 30–35 mm lead. Syringe shields are available in a variety of shapes and thicknesses; the most frequently used are made in tungsten, with thicknesses of 2–10 mm, but also very heavy shields are commercially available (tungsten, about 15 mm thick). Vials and syringes can present a significant hazard to those manipulating them, but local shielding should ensure that they do not contribute significantly to external dose rates within the main department, and are not a major consideration in the design of shielding for the facility. The use of syringe shields for administering PET radionuclides can reduce staff finger doses by 80%–90%. Although the shields need to be thick and the additional weight (up to 0.8 kg) can make injections difficult, they should always be used.

(153) Automatic patient injectors are available, that allow for installation of a vial of the radiopharmaceutical, as received by the production laboratory, and for automatic injection to a sequence of patients, by connecting single-use injection lines. These systems allow for a reduction of the dose to the staff in the injection procedure (Lecchi et al., 2012; Schleipman and Gerbaudo, 2012; Sánchez et al., 2015; Skovorodko et al., 2020) the critical aspect is the loading of the vial containing the batch of the radiopharmaceutical (of the order of 10 GBq or even more). This operation may involve significant exposure of the operator; specific procedures should be adopted and carefully monitored. Where these devices are used it may be necessary to include structural reinforcement of work tops in order to take the weight of the necessary shielding.

(154) Local procedures and staff expertise will determine the best approach. The use of syringe-drawing devices and semi-automatic injectors can reduce finger doses by 80%–90%

and fully automatic dispensers can virtually eliminate hand exposure (Madsen et al., 2006; Mattsson and Söderberg, 2011). The provision of equipment for drawing up of injections will be discussed further in Section 8.

3.5.3. The patient rest period

(155) Once the radiopharmaceutical has been administered to the patient, the external dose rates are significant (of the order of 30–50 μSv h^{-1} at 1 m, see in the following Section 3.6.4), and so careful planning is required to maintain dose rates in the working environment at an acceptable level, especially around the uptake rooms since it is where patients spend most of their time other than on the scanner.

(156) Given the time needed to obtain optimal bio-distribution of the radiopharmaceutical (60–70 min for 2-[^{18}F]FDG) versus the time of a scan with modern scanners (less than about 20 minutes, including patient access and positioning), there are likely to be a number of patients in a PET scanning facility at any one time during the working day either resting, being cared for, or being scanned. It is recommended to have 3–4 individual shielded rooms / positions provided per PET/CT scanner. Furthermore, other patients will be waiting to be discharged, or to receive information; a dedicated waiting area, different from the one used prior to the study, should be provided.

(157) During the uptake period, patients should rest and avoid any exercise, as active muscles will take up the radiopharmaceutical, and for brain studies minimise stimulation (no reading, talking, television, mobile phones etc.). Dim lights and soothing music can aid relaxation and the temperature should be comfortable, as a cold environment has been known to cause activation of brown adipose tissue leading to accumulation of 2-[^{18}F]FDG that could obscure metastatic disease (Cohade, 2010; Kiefer, 2017).

(158) The patient uptake rooms are the most relevant source of radiation exposure to staff in a PET department. They should be positioned near the imaging room in order to facilitate the transfer of patients, taking care, with their arrangement, distance and shielding, to avoid unwanted dose levels in the control room and possible interference with the acquisition equipment (IAEA, 2010). Closed circuit television cameras can be included in the uptake rooms to allow staff to monitor patients remotely and allow audio communication without the need for direct contact.

3.5.4. The imaging period

(159) The end of the uptake phase, when the radiopharmaceutical has been distributed within the body, is the time for imaging. The patient should be requested to void their bladder in the toilet allocated specifically for active patients, and then move to the PET scanner room (IAEA, 2010).

(160) Apart from the preparation and injection phase, the main period when staff will be exposed is during the patient positioning and set-up of the scanner and assisting the patient from the scanning room when the scan has been completed. Staff should not need to be in the scanning room during the acquisition, although there is a possible exception, in the case of some (relatively rare) image guided biopsies or where blood samples are drawn for quantification or research studies. The scan time used may vary to some extent, but with the use of modern scanners, it can be reduced below 20 minutes.

3.5.5. Patient discharge

(161) When the acquisition of the PET procedure has finished, the patient should go to the changing room and recover his/her clothes and possessions. At this time, the patient may need to go to the toilet after the PET/CT study, or be required to as a protection measure, so this should be taken into account when locating the toilet.

(162) A hot waiting area will be needed for some patients before leaving the facility while their scans are checked, or for a post imaging interview with the staff. This room could also be used to wait if a second/late image is needed.

3.6. Design of a PET facility

3.6.1. Planning the facility

(163) The flow of all sources and incoming/outgoing materials should be carefully considered in the design phase. Specific drawings illustrating the movement of each type of material, of staff, and of patients, should be prepared and optimised. Movement of patients through the facility, and separating patients from staff not directly involved as much as possible, are important considerations when setting out the design for a PET/CT suit.

(164) As for any other Nuclear Medicine facility, floors should have welded continuous flooring in an impermeable material, washable and readily decontaminated, curved to the walls, with all joints sealed. Walls should be finished in a smooth and washable surface. Ceilings should be lined with acoustic tiles, washable or sprayed with a plastic washable finish. Radiopharmacy laboratories should have a pharmaceutical grade ceiling (IAEA, 2018, 2020a).

(165) Many different approaches can be taken to the design, which will depend on the local requirements such as the predicted workload and space available for the facility. The numbers of patients scanned in a day varies considerably between facilities, but the aim is usually to maximise the number imaged, so it is common for all uptake rooms to be occupied for most of the working day. The number of required resting bays will be determined mainly by the time between patients, considering the uptake period and the duration of the PET/CT acquisition. In general, not less than 3 or 4 individual uptake rooms are necessary per each scanner (IAEA, 2008b, 2010).

(166) The flow of radiopharmaceuticals and the areas required will vary according to the method of operation. There are several options and combinations regarding (1) how to receive 2-[^{18}F]FDG and other radiopharmaceuticals from an internal or external Radiopharmacy, and (2) whether to use an automatic injector instead of manually injecting the radiophamaceutical. The function, design, and capabilities of the dispensing/preparation room would be different and must be accommodated to the working scenario.

(167) The room for radiopharmaceutical dispensing will normally be adjacent to the administration-uptake rooms, and distances between these rooms, the active toilet, and the scan room should be kept as short as possible, to minimise patient movement.

(168) Distances from positions where staff and the public remain for longer times should be maximised to take advantage of the inverse square law. The positions of the patient uptake rooms should be as far as possible from the scanner control room, other offices, and any areas where staff remain for long periods, but they should be close to the scanner room, to reduce the movement of patients within the working area. Areas adjacent to the administration-uptake rooms should have low occupancy where practicable. Lines of sight, between patient administration-uptake rooms and positions where staff spend significant proportions of their time, should be avoided to reduce direct exposure from patient emissions. All criteria cannot

be fulfilled, so any design will be a compromise based on the space available and the patient workload.

(169) Administration-uptake rooms for individual patients should be of sufficient size to allow easy patient access and be able to take wheelchairs, trolleys or automatic injectors. Bench space should be provided to take equipment such as syringe carriers and shields.

(170) Since patients are requested to void their bladder just before the beginning of the examination, there should be a toilet designated solely for patients, adjacent to the uptake/resting area and wherever possible the patients should be able to use the toilet without passing into the main corridor to avoid irradiating staff.

(171) In the administration area it is necessary to have an activity meter on hand to allow checks to be made at the time of injection. A separate work surface will also be required for completion of clerical tasks. Benches, sinks, floors and other surfaces should all be easy to decontaminate. There should also be adequate storage room available for radioactive materials, and radioactive waste, as well as general clinical consumables.

(172) The scanner room should have enough space for the movement of personnel with their necessary tools, such as contrast media injector, anaesthesia trolley and others, around the patient lying on the scanner bed. Extra space may be considered for a future replacement of the scanner.

(173) Adequate space is needed for sources used for calibration and daily QC of the scanners. Some models have linear sources installed in the gantry of the equipment, within a shielded container. Other models of scanner use external cylindrical or point sources. In most cases these sources are of ^{68}Ge/^{68}Ga, but also ^{22}Na or ^{137}Cs are used. Typically, the range of activity of linear and cylindrical sources is in the range 20–80 MBq, while point sources have lower activities, but higher activities may be used for specialist applications, such as a high-resolution research PET brain scanner that has a built in ^{137}Cs source of 1.1 GBq for transmission scanning. All of the sources are supplied by the vendor with their own shielded containers. Some scanners may require additional space, a technical room, for the computers and the cooling system.

(174) Consideration will need to be given to arrangements for the release of aqueous waste to the sewer and a sink designated for this purpose, in addition to the sink for hand washing which should be adjacent to the work area and have taps that can be operated without direct hand contact. However, an additional waste water tank is not normally required. It is important to ensure that “hot” sink and toilet plumbing discharge lines do not run under the PET camera(s) and, if this is not avoidable, that sufficient shielding over the plumbing line is provided to avoid interference with patient imaging (e.g. bolus of “hot” urine post uptake period).

(175) Other hot areas of the facility are the temporary waste collection room, to allow the contaminated materials to be safely collected and decay before disposal or any further step, and the decontamination room.

(176) Depending on the organisation of the hospital, reporting rooms for PET/CT, where the images are checked when the examination is finished and where the medical report is prepared, can be located in different positions. It is recommended to have at least a small reporting room within the PET/CT facility as a workspace for nuclear medicine physicians, in order to favour control of the workflow, capacity for solving current problems, decision taking and timely communications with other staff. A wider reading/reporting room can also be placed outside of the PET facility, or in a non-supervised area of the facility.

3.6.2. Example of PET/CT facility design

(177) Fig. 3.1 shows a possible layout of a PET/CT facility. The drawing considers a hospital facility; therefore, inpatients may have access to the facility with a different entrance than outpatients. The entry of the radiopharmaceutical from an internal/external radiopharmacy has been considered through a sterile access system (SAS)/Pass-through in the dispensing room, where the total activity received can be prepared according to the form of administration of the radiopharmaceutical, either by individual shielded syringes or with an automatic injector.

(178) The waiting area is outside the supervised area of the facility. The patient enters from the left, after being accepted in the reception. The procedure can be explained to the patient in the interview room, where they can be tested for glucose. The patient would enter the controlled radiation section of the department, which makes up the centre and right-hand part of the plan. The radiopharmaceutical is to be administered in the patient administration and uptake rooms.

(179) Patients clothes and belongings can be kept in the lockers until the end of the imaging procedure. In some cases it is preferred that the patients change their clothes prior to administration of the radiopharmaceutical, to reduce the possibility of their clothes being contaminated. In other situations, to optimise the patient flow, the next patient enters the changing room adjacent to the scanner and can change his/her clothes, when the previous patient is called inside the scanning room.

(180) After the injection the patient would wait in the shielded uptake rooms near to the scanning room. The number of uptake rooms will be determined partly by the workload and the incorporation period of the radiopharmaceutical before the scan. The provision of four administration-uptake rooms could allow the scanner to be used to maximum capacity. Shielded walls in the uptake rooms may have angled tips, often called nibs or mini-mazes, to restrict any line-of-sight exposure of staff in the scanner control cubicle, in the corridor, and when assisting other patients in the other uptake rooms. Exposure of individual patients by radiation from other patients (regarded as a public exposure) is minimal, less than 50 μSv, compared to the internal dose from the radiopharmaceutical (order of 5 mSv). The active toilet is located within the administration-uptake room area, so that patients who use it do not pass along the main corridor, which would irradiate staff in the facility, and to reduce the possibility from spread of patient related contamination (Kumar et al., 2015).

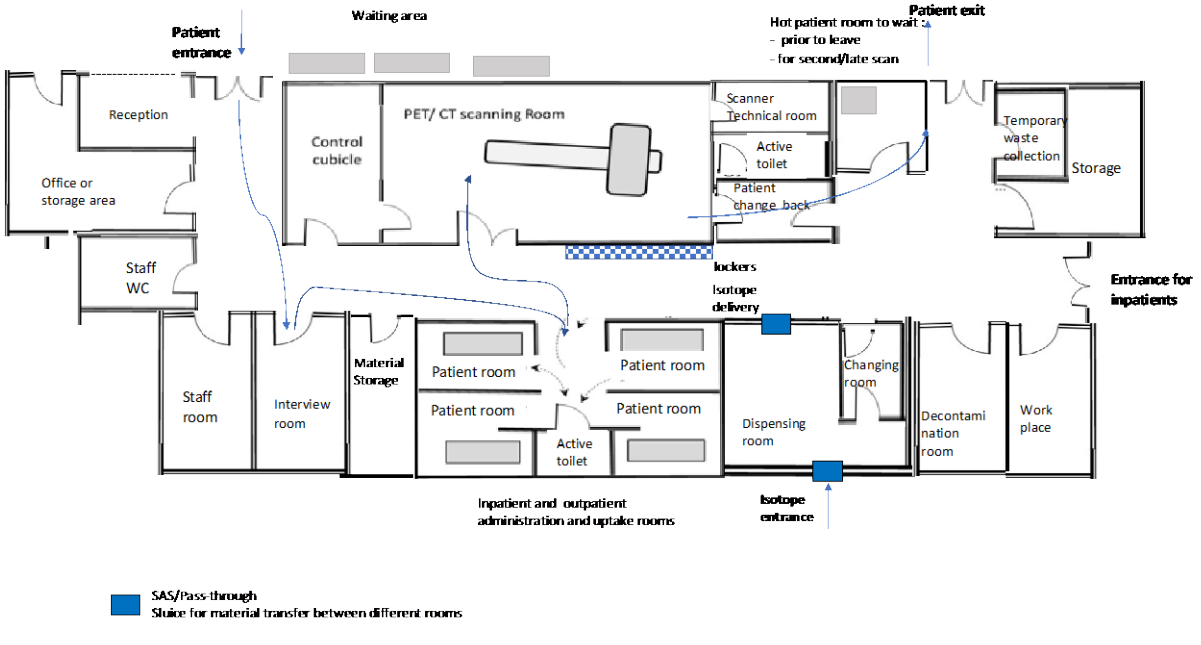

Fig. 3.1. Schematic plan of the layout of a PET/CT facility. The patient route through the facility is indicated by dotted line arrows. The diagram is not of a real facility and is not to scale.

(181) The imaging room is in front of the administration-uptake rooms to optimise the movement of the patient. When the PET procedure is completed, the patient goes into the patient changing room adjacent to the scanner, getting back his belongings. If necessary, because a second/late image is needed or for a post imaging interview with the staff, the patient can wait in a hot room before leaving the facility.

3.6.3. 511 keV photon dose rates around PET patients

(182) While patients are in the department, the activity within their bodies will decay as the half-life of ^{18}F is only 110 minutes and this can be taken into account in assessing dose levels. Decay during the rest period prior to the scan will reduce the activity administered by over 30%. The average dose rate over the rest period will be about 83% of the initial value. The patient should be asked to use the toilet at the end of the rest period before the scan, and it is estimated that this will reduce the activity by a further 15–20% (Madsen et al., 2006). The amount of 2-[^{18}F]FDG activity administered varies around the world, depending on regional practice, patient cohort, diagnostic reference levels, and availability (Ducharme et al., 2009), being typically of about 300–370 MBq in Europe (EANM, 2016; ARSAC, 2021), around 370–740 MBq in North America (SNMMI, 2018), and with median values of 220 and 257 MBq in Japan, depending on the origin (in-house-produced or delivered, respectively) (Abe et al., 2020). However, research and continuous developments in PET detectors and reconstruction algorithms, are increasing the sensitivity of scanners, and the values reported here are likely to decrease in the future. The amount of activity administered will be a factor in determining amounts of shielding required. Dose rates from unshielded sources and from patients during the different phases reported in various publications are given in Table 3.1.

3.6.4. Assessment of dose levels and protection requirements

(183) When an initial layout has been developed, the flow and residence time of each type of source can be evaluated for each area; inverse square law calculations should be used to assess potential dose rate levels from which shielding requirements can be determined. The patients should be considered as radioactive sources and the times that active patients are likely to be in the administration room, uptake rooms, and scanning rooms evaluated and combined with appropriate dose rates (Table 3.1) to derive the doses resulting from each source. The workload in terms of the numbers of patients per week or per year is a crucial factor in determining the dose levels and so the amount of protection.

(184) The patient administration area and uptake rooms will be a major source of exposure. Therefore, they will need substantial shielding, as well as consideration of any shine through paths from the patient couches that might irradiate others. Exposure from patients in toilets will need to be considered, and is best done by evaluating the total amount of time that the toilet is likely to be occupied by active patients.

(185) Scanning of patients is likely to take place throughout the working day in order to maximise throughput, so the scanning room will again require extensive shielding. This must take account of both radiation emitted by the patient and the CT component of the examination, and this is considered in more detail in Section 3.7.

(186) It is necessary at the outset to decide upon dose constraints that individuals within the facility should not exceed during a year, relating to the annual dose limits. This will vary with country and region, as well as for individual roles. For staff working in the reception,

adjacent offices, wards, or departments, a dose constraint applicable to a member of the public, e.g. 300 μSv effective dose, representing 3/10th of a 1 mSv dose limit might be appropriate for staff not working directly with radiation, whereas for radiation workers a higher constraint is likely to be required (IAEA, 2008b). The exposure of those in other areas must be taken into account. Wherever possible offices and other rooms that are likely to be occupied for a significant proportion of the time should not be sited adjacent to radiation areas, and if this cannot be avoided, it will require the installation of additional shielding to minimise staff exposures.

Table 3.1. Dose rates from various sources of ^{18}F exposure.

Source	Dose rate at 1 m (μGy h^{-1} MBq^{-1})	Dose rate at 1 m from 400 MBq (μGy h^{-1})	Reference
Unshielded ^{18}F source	0.148	59	Madsen et al., 2006
Unshielded ^{18}F source	0.16	64	Delacroix et al., 2002
Patient immediately after ^{18}F injection	0.092	37	Madsen et al., 2006
Patient immediately after ^{18}F injection	0.11	45–52	Benatar et al., 2000, Peet et al., 2012
^{18}F uptake phase (average)	0.09	37	Benatar et al., 2000*
^{18}F patient end of rest period	0.08	30	Benatar et al., 2000*
			Lo Meo et al., 2014
^{18}F scan phase	0.06	24	Sutton et al., 2012
^{18}F patient leaving department	0.04	15	Cronin et al., 1999

*Calculated from data in Benatar et al. (2000).

(187) The amount of exposure to staff working in different areas can be taken into account by using occupancy factors (NCRP, 2004; Madsen et al., 2006; Sutton et al., 2012). Consider the proportion of the time that staff will occupy in different locations within the department. Areas such as the scanner control room, receptions areas, nurses' stations and offices will be occupied 100% of the time when the department is operational. Whereas there might only be people in staff rooms, wards, and clinics for 20% to 50% of the time, and corridors, stairways, waiting rooms, and toilets might only be occupied for 5% to 15%. When considering occupancy of the corridor and the active toilet, this will apply to both staff and patients. The derivation of protection requirements will be based on a comparison of the annual dose constraint with the annual doses within different parts of the facility.

3.7. Determination of shielding requirements for a PET/CT imaging facility

3.7.1. Protection against PET annihilation photons

(188) Once an initial layout for the facility has been devised and the positions and exposure times for radiopharmaceutical and patient sources have been determined, decisions should be made about which walls require protection. Distances from all the source positions to various rooms and locations where staff and others may be present should be determined and dose levels calculated by application of the inverse square law to each source. Concrete or solid brick are suitable materials for shielding in terms of weight, although restrictions in the available space and considerations on thermo-acoustical performance may make the use of lead preferable. A combination of concrete, or bricks, and lead is in several cases a good trade off. Lead protection will be required for the scanning room doors and lead loaded glass, or standard glass with very high thickness, is necessary for direct view windows. In general, use of shielding as close as possible to the sources, as in the case of uptake rooms, is more effective. For some sources the radiation may pass through two or more protected walls, so the shielding capabilities of each can then be summed during the calculation phase. For example, in figure 3.1 radiation from patients in some of the uptake rooms will pass through the room shield and then the scanning room wall before reaching the scanner control cubicle. Methods for determination of air kerma levels from PET scanning and calculating shielding requirements are can be found in NCRP (2004), Madsen et al. (2006), IAEA (2008b), and Sutton et al. (2012).

(189) When patient uptake rooms are provided with a door, a lead thickness of 2 mm or more is required, but the trade-off between the protection and the ease of handling of the door should be considered. In other cases, depending on the total space available, the presence of a door may limit the access of patients in wheelchairs, trolleys, etc., and therefore use of concrete barriers with angled tips (nibs or mini-mazes) may be preferred. Mobile lead barriers with a thickness of 1 cm could help to improve shielding of the entrance of uptake rooms, as well as to provide additional shielding during assistance to patients with specific needs. A relatively low level of shielding from PET photons of patients is typically acceptable for entrance doors in scanning rooms, since these doors are communicating with low occupation areas, like corridors, if not with a patient changing room. A short concrete barrier adjacent to a lead shielded door could be used to protect scanning room entrances communicating with the control room. The eventual lower level of protection from PET 511 keV photons in doors makes it particularly important to minimise any lines of sight to areas where staff are present for longer periods and sketching of isodose contours onto a plan of the facility can aid in the optimisation process (Madsen et al., 2006; Peet et al., 2012).

(190) The exposure of staff and the public on floors above and below a PET facility needs to be considered and additional shielding may be required to protect against PET radiation. If the floor-to-floor distance is 4 m, then the distance to a person on the floor above can be considered as 4 m, but it will only be 3.5 m to a person standing on the floor below, as the sensitive organs are in the upper half of the body. The thickness of the floor slab is sometimes sufficient to guarantee a certain absorption of photon radiation. However, often either this thickness is made of a lighter material or pre-caste sections with a hollow core are used for structural reasons to optimise weight. Therefore, a careful investigation of the slab structure may be necessary. In the case of a new construction, the concrete of density 2.3 g cm^{-3} might be used, but the density and thickness are interdependent and can be adjusted according to the protection requirements.

(191) In determining the likely doses that individual staff members will receive for comparison with dose constraints, it is necessary to take account of doses from preparation and administration of radiopharmaceuticals, as well as dose rates from patients during different phases, including periods of direct contact with patients that cannot be avoided. This will be considered in detail in Section 8.

3.7.2. PET/CT scanning room design and protection

(192) The layout in the PET/CT scanning room should be designed to host patients in a safe environment during the examination, while streamlining workflow and patient movement in order to ensure that the amount of time that staff spends handling and attending patients is kept to a minimum. Space and distance are at a premium both to facilitate operations and enable staff to maximise their distance from the patient as radiation source. The entrance through which the patient is brought will normally be at the side or foot of the couch, placement within the shadow of the scanner gantry may provide advantages in door protection (see later). The control room would normally be to the front or side of the couch, with the scanner positioned at an acute angle to the walls to enable the nuclear medicine technologist/radiographer to view the patient within the scanner gantry, and have sufficient appreciation of the longitudinal position of the couch to enable a visual assessment to be made. The distance from the CT scanner will determine the protection required for the control cubicle window.

(193) Vendors of PET-CT scanner typically provide minimum and optimal space requirements for proper installation of the equipment, and suggest a layout. The project must be approved by the designated persons, i.e. the responsible Physician and the Medical Physicists/Radiation Protection Expert, as regards both the aspects of clinical operation and radiological protection. Shielding 511 keV photons in a broad beam geometry requires specific calculations, taking into account multiple scatter and buildup beyond the walls. Consolidated guidelines for shielding calculations are given in (Madsen et al., 2006; RPII, 2009; Sutton et al., 2012).

(194) Every facility will need to be considered on an individual basis and expert advice taken from the healthcare and radiological protection professionals involved to maximise patient, staff, and public safety, while providing an efficient workable arrangement. In larger centres, scanning rooms can be located adjacent to each other and have a shared control area that can provide advantages in communication and supervision. The control will contain viewing windows for each scanner room, so care should be exercised in siting the windows, to ensure that patients in one room are not able to view patients in the second.

(195) Given the difference in the HVL, the level of protection required for the higher energy PET 511 keV photons is generally sufficient for protection of the walls of the scanning room against the heavily filtered x-ray beams with tube potentials of 120–140 kV used for CT scans - the so called 'rule of the two sources' (NCRP, 2011). However, the dose levels in a scanning room from the CT component are significantly greater than those from a PET patient. Approximate air kerma levels from various sources within the scanning room from imaging of one patient are shown in Table 3.2.

(196) The presence of a window for direct viewing is always recommended. There can be different approaches to protecting windows and doors against both 511 keV photons and CT x rays. The x-ray dose per year in the control room can be reduced below 1 mSv with 2–3 mm of lead, but reducing the dose from 511 keV photons to this level will require thicker shields. The control room window can be reduced in size to say 30 cm×40 cm, protected with lead glass equivalent to 4–5 mm lead at 511 keV, and additional vision provided through cameras. Alternatively, the shielding requirement for the window can be based on achieving

adequate protection of the control room from CT x rays, but accepting a certain dose transmission from 511 keV photons and thus adapting the dose constraint for the limited area in correspondence of the window. Shielding of the doors into the scanning room with lead will reduce the exposure from x rays to an acceptable level and offer some protection against 511 keV photons. Decisions will depend on local approaches and requirements at each installation.

(197) For the CT scanner, the primary beam is effectively attenuated by the scanner detectors and hardware in the gantry, so the protection required is against scattered radiation which is related to the amount of radiation incident on the skin of the patient. The scatter dose distribution from a CT scanner is well defined and reproducible, because the x-ray tube follows the same path around the patient for every rotation and all current models of PET-CT scanner have the CT component in front, as the first element of the gantry. The PET detector is heavily shielded, in order to avoid interference from activity in the body of the patient, out of the field of view. This shielding typically comprises several centimetres of tungsten, and its presence introduces a substantial amount of attenuation of the scattered dose due to the CT component in the lateral and posterior directions (Fig. 3.2).

Table 3.2. Air kerma exposure during a single PET/CT scan from different component sources to which staff might be exposed within the scanning room if there is no protection in place.

Exposure scenario	Conditions			
	Distance from patient	1 m	2 m	3 m
CT body scan DLP 600 mGy cm*		217 µGy	54 µGy	24 µGy
CT head scan DLP 600 mGy cm*		84 µGy	21 µGy	10 µGy
30 min scan period of PET patient (400 MBq)†		12–25 µGy	3–6 µGy	1.3–2.6 µG
	Distance from patient		2 m	3 m
Scatter from wall into cubicle for CT body scan 600 mGy cm*		Unprotected door	1.3 µGy	0.7 µGy
	Ceiling height	3.2 m	3.6 m	4.0 m
Scatter over 2 m barrier for CT body scan 600 mGy cm*		0.6 µGy	0.5 µGy	0.4 µGy

*Scatter dose calculated using data from Sutton et al. (2012) and Martin (2015).
†Results for dose rates from PET patients are variable (Tables 3.1 and 6.3), so a range of values is given here.

(198) The air kerma exposure within the control cubicle due to CT x-ray scatter from adjacent walls, which might occur if the entrance into the scanning room is not shielded, are similar to those from direct exposure to radiation from the patient over the length of the scan (Table 3.2). Therefore, in these circumstances it may be necessary to shield the door of the PET/CT scanner control room with lead or use a mini-maze entrance, in order to protect those inside from wall scatter, even if there is sufficient space to accommodate the operators behind the main control barrier. This will also provide additional shielded space for other occupants. The likely dose level due to scatter from the ceiling slab into the control cubicle and other adjacent areas, if the space above the protective screen and scanner room walls is

not shielded, is about half that from direct exposure to the PET photons from the patient, so extension of the protection to the ceiling slab, perhaps with a lower level of shielding above 2 m, may need to be considered (Sutton et al., 2012).

(199) The level of scatter can be predicted from the CT workload in terms of the dose-length product (DLP) using scatter factors derived from measurements on a range of CT scanners (NCRP, 2004; Wallace et al., 2011; Sutton et al 2012; Martin, 2015). The gantry provides protection equivalent to about a factor of ten, so it may be possible to use less shielding for doors and penetrations lying within the arc protected by the scanner gantry. It is useful to consider the gantry position in regard to the location of large penetrations such as ducts for air conditioning. Doors of the scanning room will require to be shielded typically by about 2 mm of lead.

(200) Shielding may be required in floors and ceilings and should be assessed as for side walls (Madsen 2006). The protection of areas above and below the PET/CT scanning room against PET 511 photons emissions is likely to be sufficient to protect against CT x rays. Moreover, scattered x rays will only be incident on the floor and ceiling at an oblique angle, because of attenuation by the gantry of vertical scatter), so an obliquity factor can be applied to both the distance to the barrier and the barrier thickness in calculations (Sutton et al., 2012; Martin, 2015).

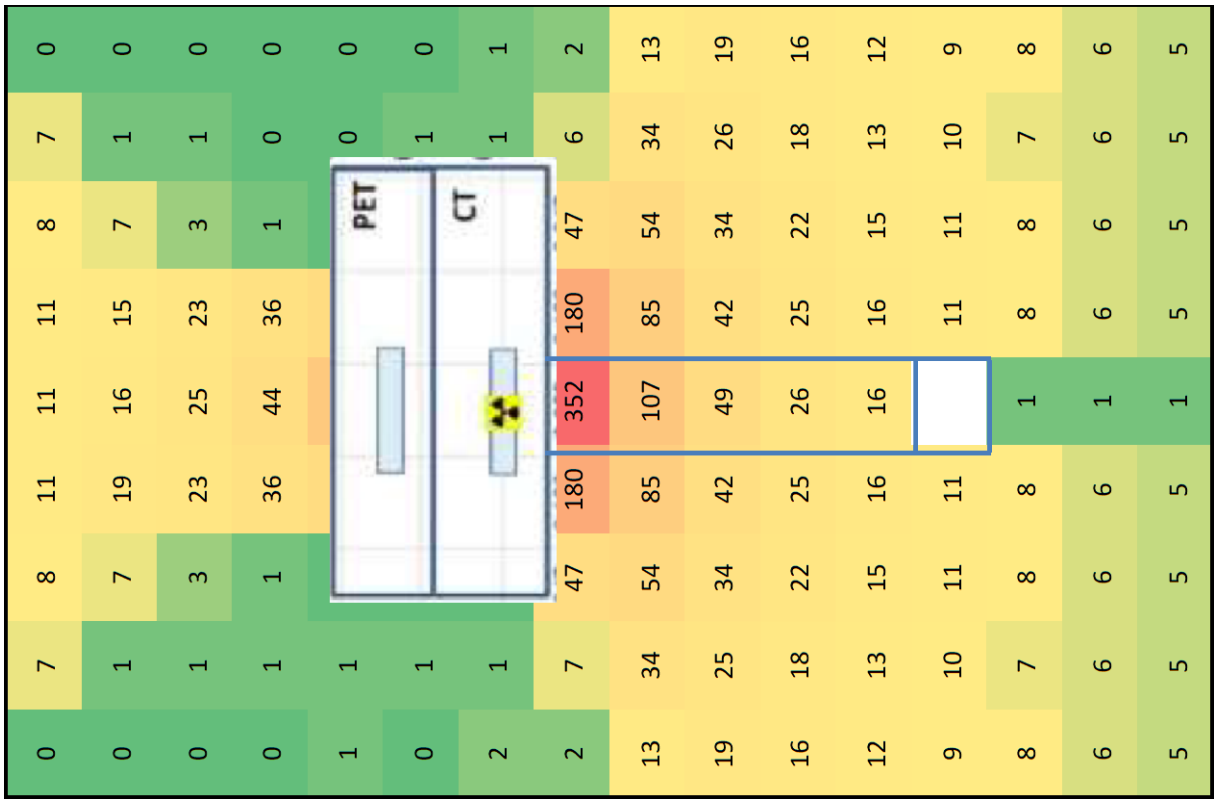

Fig. 3.2. Example of dose in μGy/(1000 mAs) around one PET/CT system. Room is 8 m × 4.5 m (each field 0.5 m × 0.5 m).

4. IMAGING EQUIPMENT LIFE CYCLE

(201) Key points in this section:

- The equipment life cycle is a well understood concept, and describes medical equipment, including imaging equipment, from 'cradle to grave'.
- The skills of each of the professionals involved should be respected in a team approach, using the methodology, expertise, and the process controls available for the optimal management of equipment throughout its life cycle.
- The stages in the planning and creation of a PET/CT facility include justification, specification, acquisition, installation, acceptance, commissioning, user training, before the system is put into clinical use.
- The QA programme should comprise equipment performance evaluation during clinical use, and include QC measurements to verify that systems and components of the PET/CT imaging system operate effectively and meets specifications. They should include appropriate maintenance arrangements in place and require a system for ongoing staff training after upgrades, periodic review of policies and procedures, and review of dose misadministrations and near miss events.

(202) The equipment life cycle is a well-known concept, and its application to imaging equipment for x-ray installations has been described previously in *Publication xxx* on 'Optimisation of radiological protection in digital radiology techniques for medical imaging' (ICRP, year1). This section reviews application of the principle for a PET/CT installation.

4.1. The life cycle of equipment

(203) PET facilities require a variety of equipment (IAEA, 2010; 2012), apart from specific radiological protection equipment, such as dose and contamination monitors. Facilities with the capacity for producing PET radionuclides will require a cyclotron and laboratory areas for labelling of radiopharmaceuticals and quality control (QC), that would include synthesis modules, radionuclide activity calibrators, and specific equipment for QC, among others (IAEA, 2009a). The imaging area includes the scanner, currently in the form of PET/CT or PET/MR, radionuclide activity calibrators, and radioactive verification sources.

(204) Setting up a new or replacing an existing PET facility requires careful planning by a team of professionals (IAEA, 2010). Depending on the scope of the facility and the variety of the equipment, this team would include staff of the facility: nuclear medicine physicians, nuclear medicine technologists/radiographer, medical physicists, radiopharmacists, and radiation safety experts.

(205) Medical imaging equipment is generally procured through a tender process wherein equipment suppliers are invited to submit a bid to supply the equipment or services. The team need to prepare a technical specification based on the clinical requirements, including education and training, maintenance and repair arrangements. Once a contract has been agreed, the equipment will be installed according to agreed standards, personnel trained in its use, and a quality assurance (QA) programme put in place to ensure that standards are maintained.

(206) The equipment life cycle applies to medical equipment from 'cradle to grave', equipment used both for production of radionuclides, their quality control and for imaging

within the PET facility. But for simplicity, this section is focused on the lifecycle of the imaging part.

(207) The initial conception of the clinical need for the equipment must first be developed into a proper robust justification. This is the embryo stage of the life-cycle shown at the top of Fig. 4.1. The skills of the different healthcare professionals, the methodology and expertise available, and the process control to ensure required tasks are performed, all play a vital role in understanding and managing equipment appropriately throughout its life and optimising performance. The different aspects of the lifecycle of imaging equipment should be incorporated into a healthcare organisation's planning and follow a systemic approach through acquisition, deployment, maintenance, QC, repair and disposal of imaging equipment.

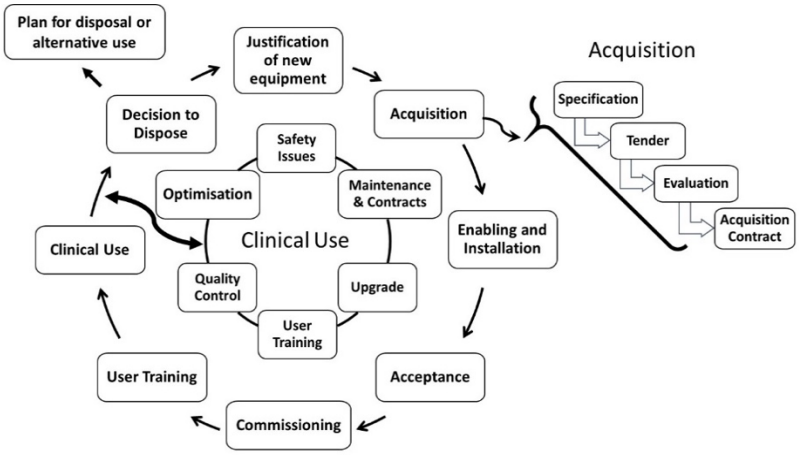

Fig. 4.1. The Life Cycle of PET imaging equipment, with a sub-cycle showing the requirements to ensure performance is maintained during clinical use (ICRP, year1).

(208) Fig. 4.1 shows the elements required through the period leading up to the equipment being put into clinical use, with a sub-cycle showing the requirements that are needed continually to ensure performance is maintained and optimisation is improved. Steps involved in acquiring the equipment, in enabling and installing of equipment, in the operational requirements in clinical use, and the end of clinical use are described in the following sections.

(209) The life cycle of the imaging equipment shown in Fig 4.1 can also be applied with some degree of simplification to other equipment in the imaging part of the PET facility, like the radiological protection elements (shielded protectors and radiation detectors) and sources used for the verification of the PET scanner and the activity calibrators.

4.2. Acquisition of equipment

4.2.1. Justification of equipment

(210) The procurement of all medical imaging equipment should be justified, both in terms of clinical need and radiation dose. Justification should be evidence driven and take into account present and future clinical applications and revisions of workflow, whilst ensuring that there is no unnecessary proliferation of equipment. Justification of new or replacement equipment requires the involvement of a multidisciplinary group (MG) composed of nuclear medicine physicians, nuclear medicine technologists/radiographers, medical physicists,

nurses or other health care professionals involved in the PET imaging procedures, and management system leadership.

4.2.2. The acquisition and procurement process

(211) Once procurement of equipment has been justified, it is essential that a full performance specification of the entire system is prepared to reduce the possibility of inappropriate devices being purchased. This should include detail of the performance and regulatory requirements that the equipment will be expected to meet, and the manner (e.g. procedures and technical documentation) in which the manufacturer/installer is expected to demonstrate that the equipment supplied meets the acceptance criteria (see Section 9.5.1). The specification in first instance should define the clinical needs and, on this basis, the performance parameters that are requested (e.g. depending on the most relevant use and other equipment available). The specification should include maintenance requirements with options for maintenance contracts and prices on essential spare parts and options, delivery timescales, requirements on acceptance testing, commissioning, and the type and amount of training required.

(212) Specification is a task that requires input from all the members of the MG. The specification document should:

- address the issue of enabling and infrastructure work required – for example, what level of connectivity is required for the equipment to function appropriately, and how the vendor will address those requirements within the organisation's ICT infrastructure.
- include the resourcing and vendor activity involving the initial optimisation of equipment to ensure that the purchase does not only include the technology and applications but also the right initial setting of the technology for the first phase of optimisation in practice. The initial optimisation would include specific PET protocols for the different applications and radiopharmaceuticals, such as 2-[^{18}F]FDG whole body oncological imaging, neurology, cardiology, paediatrics, with an indication of the optimal administered activity for the established imaging time, and CT protocols according to the scan purposes (attenuation correction, anatomical positioning and full diagnostic).

(213) A tender comprises the specification, and terms and conditions under which the equipment is to be purchased. Responses to the tender will form the basis for the evaluation process, therefore questions posed by the specification document and stipulations regarding terms and conditions should be correctly formulated. The vendor could be required to identify options for the disposal of redundant equipment, and the removal of the verification sources out of use.

(214) On receipt of tender returns the MG including procurement experts should convene to consider the responses from the vendors offering their products. Evaluation should be carried out in an objective manner against predetermined criteria to maintain not only neutrality but to ensure selection of the optimal equipment package. After evaluation, lead in times can be agreed, the contract signed, and the order placed. The contract should address all of the items included in the specification and the associated terms and conditions, including the initial optimised protocol settings.

4.3. Enabling and installation of equipment

(215) Equipment life cycle is part of the facility life cycle. The operation of a PET facility includes the scanner, and the management of radiopharmaceuticals and of sealed sources for equipment verification. According to international safety standards, the operation of a new PET facility shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing (IAEA, 2014b). Any modification should require the submission to the regulatory body a notification and, as appropriate, an application for authorization.

(216) Enabling and installation are essential components of the equipment life cycle. Planning and construction of the PET facility rooms (see Section 3), protection, electrical and other services all need to be prepared beforehand. If the installation is not completed correctly or the correct infrastructure and building work is not carried out appropriately then at best delays will be encountered, but this may also lead to ongoing issues throughout the life of the equipment. Basic connectivity issues and possible mitigation should be identified at this stage as should issues around licensing and registration (WHO, 2019).

4.3.1. Acceptance

(217) Acceptance testing is the process whereby the purchasers satisfy themselves that the equipment supplier has provided what has been ordered, that it is safe to use, and that it functions according to the manufacturer's and purchaser's specification. This will involve both medical physicists and nuclear medicine technologists/radiographers, in consultation with nuclear medicine physicians, and will include identifying the inventory and probably performing electrical and mechanical safety checks. Regulatory requirements may require demonstration of radiation safety, which should be carried out at this stage. Acceptance tests will involve quantitative measurements to demonstrate that the equipment specification in terms of imaging performance is met. These tests should meet NEMA, IEC or other relevant standards, but in some cases, they could be vendor-specific and follow the vendor's methodology. The set of QC tests should guarantee that the system parameters, modes and programmes are optimised for the intended clinical use and their deviations during the equipment life are within the acceptable limits.

(218) Acceptance tests for equipment in a PET, PET/CT, or PET/MR imaging facility are described in Section 9. Sealed sources and phantoms with certain activities are required for tests of PET scanners and radionuclide activity calibrators, and information on this should be included in the acceptance tests schedule. The presence of operator and service manuals should be verified at this stage.

4.3.2. Commissioning

(219) In the commissioning phase, the purchaser should ensure that the equipment (including PET/CT or PET/MRI, radionuclide calibrator, radiation monitoring instruments…) is ready and optimised for clinical use and establish baseline values against which the results of subsequent routine performance tests (constancy tests) can be made (see Section 9). After any major work on the equipment the relevant baseline test may have to be repeated; for example, when the electronic components of a set of PET block detectors or the CT x-ray tube are replaced.

(220) Clinical protocols, which include issues such as the amount of activity used, the time between its administration and the acquisition of the images, and reconstruction protocols, should be evaluated at the commissioning phase and checked for consistency with other

equipment operated by the healthcare organisation. This could include the use of CT in the context of PET/CT protocols, and the harmonisation of PET image quality among scanners. The accreditation of the PET/CT performance can be done by an international organisation (Aide, 2017). Commissioning should also address issues of interoperability in relation to the hospital imaging system (AAPM, 2019a).

4.3.3. User training

(221) User training on PET/CT or PET/MRI scanners, that may include nuclear medicine specialist, radiologist, nuclear medicine technologist/radiographer, nurses, and medical physicist, is critical for safe, optimised use of any imaging equipment (see Section 10). Organisations should have a policy for user training that should be part of the Quality Management Programme where it exists (see Section 9). Users need to understand the intended purpose and normal functioning of the device in order to use it effectively and safely. Initial user training should ideally be provided by the representative of the installer/manufacturer (applications specialist) following acceptance and before the equipment is put into clinical use. Since all end users of the equipment may not be able to receive this initial training, it is important that 'superusers' are identified who are given sufficient training to allow them to disseminate the knowledge to others and provide practical guidance for subsequent refinement of protocol optimisation. These superusers can be encouraged to develop their knowledge and skills further and can then provide refresher courses, training for new staff, and be involved in additional training required for updates. All training should be recorded for quality, continuing professional development (CPD), and safety purposes. User manual needs to be available in the local language for end user use after user training is completed.

4.4. Operational requirements for equipment in clinical use

(222) A part of the overall QA programme is to optimise the equipment parameters, to ensure the performance meets the specifications set during clinical use. Part of this is achieved through systematic QC, through which management facilitates measurement of the parameters used to test and verify that structures, systems, and components of the PET/CT or PET/MRI imaging system are operating effectively and correspond to predetermined requirements. The QC programme includes routine periodic (e.g. daily, weekly, monthly, quarterly, semi-annually etc.) testing to monitor technical performance (follow-up measurements). Detailed tests of the equipment are described in Section 9. Each element of the equipment life cycle contributes to successful optimisation and QC helps to ensure this is achieved through focussing attention on the many different aspects of performance that need to be maintained.

(223) All medical imaging equipment must be maintained appropriately. Often equipment comes with a limited warranty providing maintenance to manufacturers' specifications for a set time. Subsequent arrangements should be made using an evidence and risk-based approach to decision making – costs alone should not be the determining factor. Decisions about maintenance and contract management are often made by hospital stakeholders, and those involved should have an understanding of the clinical implications of any decisions made. Maintenance contracts should be specific and auditable and those personnel (in-house or external) performing service and maintenance should be adequately trained and competent to operate the equipment they work with. When equipment is returned to clinical use from either planned preventative maintenance (PPM), scheduled in the maintenance contract, or

repair, service personnel should provide an indication of what changes they have made and whether those changes could impact on image quality or patient dose for CT. If a PPM or repair has resulted in a potential change to image quality or dose, a predetermined QC test should be performed by a qualified specialist according to the QA/QC programme.

(224) Upgrades occur throughout the life cycle of imaging equipment, and these should be understood both by users and nuclear medicine management. It is important that appropriate commissioning tests are performed after an upgrade (software or hardware) and that staff groups are properly trained in the changes.

(225) An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients or other persons. The activities of radionuclides involved in PET procedures should not produce deterministic effects in patients, but staff finger doses may exceed dose limits if radiological protection measures are not well managed, especially during radiopharmaceutical administration (see Section 8).

(226) In PET/CT and PET/MR, any misadministration of a radiopharmaceutical or other overexposure due to both PET and CT of a patient or a staff member, would count as a safety issue, and above guidance levels would require to be reported to the regulator. However, it is also useful to record and learn from near misses and Local Adverse Event Reviews should be integral to the routine use of medical imaging equipment.

4.5. The end of clinical use and equipment disposal

(227) At some point during its life cycle, the equipment will become a candidate for disposal. This may be for example, because it can no longer be repaired or be brought economically back to acceptable specification by the manufacturer, it is no longer supported by the manufacturer, a lease has expired, it is obsolete, its clinical performance is no longer sufficient for the task, or repurposing is required. At that point, a decision to remove it from service might be made. However, a policy on removal from service is an essential part of device management (MHRA, 2021) and planning for replacement should be in hand before any decision is necessary. The planning cycle should include considerations on the justification for the new equipment that is to be obtained and go on to consider all of the other items in the equipment life cycle identified above. The cycle should take into account Health Technology Assessments where they exist.

(228) Because of their diversity and complexity, there are many ways that medical devices such as PET scanners or radionuclide activity calibrators can be disposed of. Options range from resale for subsequent reuse to scrappage, where appropriate consideration of environmental impact and relevant regulatory controls should be considered. When donation is an option, potential health risks must be considered, and equipment safety and performance should be verified prior to donation. Decommission procedures will need to be followed by performing contamination survey to include areas surveys and area wipes to ensure no residual radioactivity is present above background and this survey should be submitted to the Radiation Safety officer for review and signoff.

(229) According to the World Health Organisation (WHO), quality problems associated with donated medical devices have been reported in many countries. These problems often result in receiving countries incurring unwanted costs for maintenance and disposal and may also create the impression that the equipment is 'substandard' and has been 'dumped' on a receiving country (WHO, 2017). Specific advice on the donation of medical imaging equipment can be found in WHO (2011) and THET (2013).

(230) Sealed radioactive sources used for the verification and calibration of PET scanners and of the activity meters have to be replaced periodically because activity decay limits their

proper use. Adequate disposal according to the national regulations should be followed. The source should be treated as radioactive waste, and its management should follow basic standards with the cooperation of the source supplier [see requirement 31 in 'Radiation protection and safety of radiation sources: International basic safety standards' (IAEA, 2014b)]. Disposal or removal of cyclotron has to be considered carefully in order to comply with local regulations (IAEA, 2020c) (see Section 3.2.1, Para. 102).

5. JUSTIFICATION AND OPTIMISATION OF PET, PET/CT AND PET/MRI

(231) Key points in this section:

- Justification of PET, PET/CT, and PET/MRI should be established by considering the characteristics of evolving imaging technologies, and especially by taking advantage of the unique hybrid imaging features with PET/CT and PET/MRI.
- Evidence on diagnostic accuracy and clinical value of PET, PET/CT, and PET/MRI is increasingly endorsing appropriate use in clinical areas including oncology, neurology, and cardiology.
- The application of PET, PET/CT, and PET/MRI to an individual patient should be justified, which can be facilitated in clinical situations by following referral criteria or appropriateness criteria that have been proposed by professional bodies.
- Radiological exposure of the patient should be part of justification as well as optimisation for both PET pharmaceuticals and CT in PET/CT as a hybrid imaging, considering the image quality.

5.1. Characteristics of PET, PET/CT, and PET/MRI in association with justification

(232) The technologies of PET, PET/CT, and PET/MRI have been making progresses. Nowadays, PET/CT scanners have almost replaced dedicated PET scanners that are used only in special fields such as brain and breast imaging. A PET/CT scanner is a hybrid imaging modality, incorporating the benefits of PET and CT, and provides anatomical, functional and molecular information through fused images, which may give significant impacts on the management of patients (IAEA, 2008b). A PET/CT may require radiation safety standards of both techniques in terms of principles of justification and optimisation when applied to patients (IAEA, 2008b; Alenezi and Soliman, 2015). The information obtained by PET/CT is more accurate in evaluating patients with known or suspected malignancies than the information obtained from either PET or CT alone or the results obtained from PET and CT separately but interpreted side by side (Delbeke et al., 2006; Boellaard et al., 2015). Recent technological advances have made PET/MRI a reality in clinical practices, which provides advantages of good soft tissue resolution on MRI and no CT radiation over PET/CT (Mannheim et al., 2018).

(233) Among PET pharmaceuticals that have been developed and supplied, 2-[^{18}F]FDG is the most frequently used PET pharmaceutical worldwide for patients with disorders including neoplasms, cardiac diseases, brain diseases, infection and acute and chronic inflammatory conditions including vasculitis, and therefore radiological protection issues covering PET and PET/CT performed using 2-[^{18}F]FDG will involve the main part of discussions (Delbeke et al., 2006; Boellaard et al., 2015; IAEA, 2023). With growing applications of ^{68}Ga somatostatin analogues for neuroendocrine tumour (Bozkurt et al., 2017; Sanli et al., 2018) and ^{68}Ga-PSMA ligands for prostate cancer (Fendler et al., 2017; Liu et al., 2018; Schmidt-Hegemann et al., 2019) as evolving PET techniques, issues specific to PET pharmaceuticals should be incorporated in the entire radiological protection measures of PET/CT for mainly patients but also for the staff members and the public. Justification for the staff members and the public in PET/CT is based on a common platform with other areas of use of ionising radiation (ICRP, 2007a,b).

5.2. Justification of radiological practices

(234) Justification of a radiological practice in medicine generally depends on a review of the benefits and disadvantages of the possible options, both radiological and non-radiological practices. In the fundamental recommendations, three levels of justification of a radiological practice have been proposed as follows (ICRP, 2007a,b). At the first level, the proper use of radiation in medicine is accepted as doing more good than harm to society, and this general level of justification is taken for granted in the radiological protection in medicine. At the second level, a specified procedure with a specified objective is defined and justified. Justification of a specific radiological procedure is a matter for national and international professional and scientific bodies, in conjunction with national health and radiological protection authorities and international organisations. National variations are to be expected by considering national incidence of a disease and availability of effective treatments. At the third level, the application of the procedure to an individual patient must be justified. Such justification should include checking that the required information is not already available. The details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, the expected dose to the patient, and the information on previous and subsequent examination or treatment are key issues that can help make decisions. At the individual/patient level the argument to support the decision to expose the patient, should be that, according to the available scientific evidence, the radiologic procedure results would probably change the patient management. Referral criteria or appropriateness criteria often serve as a decision-aiding tool (Jadvar et al., 2017; Canadian Association of Radiologists, 2022; ACR, 2022; European Association of Nuclear Medicine, 2022; Society of Nuclear Medicine and Molecular Imaging, 2022).

5.3. Justification of PET, PET/CT, and PET/MRI procedures

(235) When justification of PET, PET/CT, and PET/MRI is discussed, justification of PET may usually be incorporated in that of PET/CT or PET/MRI because both PET and CT or MRI should be justified in procedures at the facilities by the medical specialists. Combined PET/CT devices provide both the metabolic information from PET and the anatomic information from CT in a single examination (Garcheva-Tsacheva, 2015). On the basis of this advantage, substantial amount of evidence is continuously being accumulated on the role of PET/CT in the management of patients with various disorders (Delbeke et al., 2006; Boellaard et al., 2015; IAEA, 2023). Such evidence on diagnostic accuracy and clinical value is endorsing the second level justification processes of PET/CT as one of appropriate modalities available in clinical imaging examinations. Thereafter, the application of PET/CT to a specific individual patient should be justified, which involves justification at the third level. This may be facilitated in daily routine clinical situations by following referral criteria or appropriateness criteria that have been crafted and proposed by professional bodies (Jadvar et al., 2017; Canadian Association of Radiologists, 2022; American College of Radiology, 2022; European Association of Nuclear Medicine, 2022; Society of Nuclear Medicine and Molecular Imaging, 2022), which have been defining the expanding roles of PET/CT as the newer treatments of patients come up. The referral for a PET/CT decided on tumour boards and other multidisciplinary group meetings, in which professionals from nuclear medicine and radiology are present, is a growing tendency in clinical practice, with a clear commitment to the justification process at the third level. With regard to justification for PET/MRI, it may guide clinical management comparably to PET/CT and improve disease detectability, and patients may benefit from the reduced radiation (Martin et al., 2020).

(236) In the clinical practices, the second and third levels of justification are a common part of the everyday operations of medical imaging departments. Justification in general is delegated to a member of the imaging team specifically the nuclear medicine specialist or the radiological practitioner, but it is important to understand that the entire team contributes to both the second and third levels to ensure that justification happens effectively and that good communication through a team approach will produce the best method for success. Each member of the team including referring physician, nuclear medicine specialist, radiological practitioner, technologist/radiographer in nuclear medicine, CT and/or MRI, nurse, and medical physicist, can use their resources including evidence-based guideline, appropriate use criteria, and departmental protocols to facilitate the process of justification. Such imaging teams will use appropriate criteria and guidelines that have been developed with a strong evidence base to build their protocols for each diagnosis or for specific disease processes, each of which will be the responsibility of the lead radiological practitioner. While each member has a distinctive role; the nuclear medicine specialist or radiological practitioner is providing the input to the clinical referral guidelines; the technologist/radiographer in nuclear medicine, CT and/or MRI is providing image acquisition protocols of the relevant imaging modality and the physicist is providing information on how to achieve the best image with the lowest dose achievable to obtain a high-quality image with input from the medical staff responsible for reading the image. Once this process happens, the discussion then must take place between the referring physician and the nuclear medicine specialist or radiological practitioner to resolve the matter which may result in the request being modified to a more appropriate procedure, the request being cancelled with the reasons documented in the patient's notes, or the examination continuing to be performed.

(237) Application of PET/CT and PET/MRI has been evolving from mere diagnostic imaging to image-guided external-beam radiation therapy planning (Konert et al., 2015). Beside justification issues themselves, optimisation through quality assurance processes in image acquisition constitutes a key for good practice and radiological protection in PET/CT and is inseparable from justification in clinical circumstances. Recommendations for administered activities of PET pharmaceuticals are provided by academic societies (Boellaard et al., 2015; Fendler et al., 2017) (see Section 6). Radiological exposure of the patient should be part of justification as well as optimisation for both PET pharmaceuticals and CT in PET/CT as a hybrid imaging (Salvatori et al., 2019). Radiation dose to patients of PET pharmaceuticals have been evaluated on the basis of techniques including biokinetic models and biokinetic data (ICRP, 2015a).

(238) CT protocols (parameters including voltage, tube current, rotation time, slice thickness, and pitch) for PET/CT studies should be deliberately chosen according to the objective of the CT examination, i.e. attenuation/scatter correction, low dose anatomic localisation or standard higher dose for diagnostic image interpretation (Boellaard et al., 2015), which leads to the broad range of radiation doses to patients. Justification for both PET and CT must be decided by the medical practitioners at the PET facilities. Recently, concerns have been arising on cumulative radiation doses of patients who undergo repeated radiological examinations. Implementation of justification for PET/CT examinations and utilisation of dose reduction measures (see Section 6) are key issues in coping with the cumulative doses in patients (Hosono et al., 2021). Only a few reports on the cumulative doses with PET/CT examinations are available in the literature. There are scenarios where the patient is booked for both a PET/CT scan and a diagnostic CT scan. In this case the diagnostic CT scan could be done in the PET/CT with dual purpose, for attenuation correction and the clinical CT – net reduction of CT by one on some cases.

(239) In relation to the use of intravenous contrast, Zeman and Akin point out that for individual tumours very limited comparative literature of PET with and without IV contrast

material has clearly indicated a superior approach. However, studies have identified no added clinical benefit of IV contrast material administration in some PET/CT indications (Yau et al., 2005; Chiaravalloti et al., 2014; Barai et al., 2020). Without a net clinical benefit to the patient, performing a costlier study with increased risk, ranging from increased radiation dose to possible contrast reactions, is not fully justified. As the debate continues over the use of intravenous contrast material for PET/CT, we must first and foremost keep the patient in mind and acknowledge that more is not always better (Zeman and Akin, 2022).

5.4. Optimisation of radiological practices

(240) In optimisation of protection of the patient in diagnostic procedures, the same person gets the benefit and suffers the risk, and individual restrictions on patient dose could be counterproductive to the medical purpose of the procedure. Therefore, individual dose constraints are not relevant. In PET/CT, the dose to the patient is deliberately administered, using national or local benchmarks and cannot be reduced indefinitely without impairing the intended outcome; if the dose were too low it would not provide sufficiently good image quality (ICRP 2007a).

(241) Therefore, the term 'ALARA' (as low as reasonably achievable) that is used in relation to optimisation of protection for occupational and public exposure situations is not appropriate when referring to medical uses of radiation, as it omits an important component, namely the benefit that is derived by the patient from the exposure (ICRP, year2). As stated in *Publication 120* 'the entire concept [of optimisation applied to medical exposures] implies keeping patient exposure to the minimum necessary to achieve the required medical objective (diagnostic or therapeutic)' (ICRP, 2013). In diagnostic imaging, and consequently in PET/CT, it means that the quality of images is adequate to obtain the information needed for diagnosis. "Use of the abbreviation 'ALARA' alone and out of this context may be misleading and raise unnecessary controversy" (ICRP, year2).

(242) Because it is not appropriate to apply dose limits or dose constraints, since such limits could do more harm than good, DRLs are applied for a particular procedure and used as an optimisation tool (ICRP 2007a). More information on DRLs and their application in PET and PET/CT is provided in section 6.4 below.

(243) The key to optimization is "to perform the right test with the right dose on the right patient at the right time" and recognize that "the radiation dose delivery by any radiologic procedure should not be a determining factor in the selection of the most appropriate test" (Fahey and Stabin, 2014). Once a procedure has been clinically justified, the protocol for each individual patient has to be optimized, taking into consideration all factors involved, mainly, related to the patient, the age, the body surface and the clinical condition. For the latter, the main balance to influence the protocol is between the need and risks with sedation versus diminishing the duration of the images acquisition, eventually at the expense of a slightly higher dose delivery, which might be acceptable in older and seriously ill patients, with a shorter postexposure life expectancy. Regarding age, the main challenges are in children, due to their higher radiosensitivity and longer postexposure life expectancy, and all aspects have to be optimized both for the radiopharmaceutical (activity administered) and specific paediatric CT protocols (Parisi et al, 2017). As for the body surface, increasing radiopharmaceutical activity might not be solution to have good diagnostic quality images in obese adults (Chang et al, 2011), and the optimized protocol might require longer acquisition times for the PET component and higher dose delivery from the CT component. The main responsibility of the members of an imaging team is to keep updated in order to continuously optimize the protocols to be used in each specific patient, e.g., accompanying artificial

intelligence developments into instrumentation and software's (Zaharchuk and Davidzon, 2021).

6. OPTIMISATION RELATED TO THE MEDICAL EXPOSURE OF PATIENTS, CARERS/COMFORTERS, AND RESEARCH VOLUNTEERS

(244) Key points in this section:

- The total radiation dose from a PET/CT examination is the combined dose from the PET radiopharmaceutical and from the CT.
- New PET, PET/CT, or PET/MRI hardware and software can optimise the radiological protection reducing radiation dose while maintaining image quality.
- ICRP recommends constitution of national DRLs to optimise protection in the medical exposure of patients for diagnostic and interventional procedures including PET and PET/CT. DRL values are not static.
- Infants and children have a higher risk of cancer after radiation exposure, versus adults. This patient population deserves special consideration relative to justification and optimisation in the PET and the CT components of the procedure.

6.1. Dose estimation of patients

(245) ICRP has issued a number of reports addressing the radiation dose to patients from radiopharmaceuticals for diagnostic nuclear medicine procedures. The first report contained results from calculations of organ absorbed dose and effective dose equivalent per unit activity administered for some 120 radiopharmaceuticals in regular use at the time (ICRP, 1987). It also included the short-lived positron emitting radionuclides and related PET pharmaceuticals. Over the years, ICRP has provided reports, amendments, and corrections (ICRP, 1998, 2008a, 2015a). These provide conversion factors for administered activity to absorbed dose to organs (in mGy MBq^{-1}) and effective dose (in mSv MBq^{-1}) based on known biokinetic model applied to reference phantoms of patients of different ages (1-, 5-, 10- and 15-year-olds and adult) (Table 6.1). *Publication 128* on 'Radiation dose to patients from radiopharmaceuticals: a compendium of current information related to frequently used substances' dealt with 19 PET radiopharmaceuticals labelled with positron emitters such as ^{11}C, ^{15}O, ^{18}F, ^{68}Ga, ^{82}Rb, and ^{124}I (ICRP, 2015a). However, the effective doses for radiopharmaceuticals calculated according to the ICRP *Publication 60* in Table 6.1 are under revision and will soon be updated to the ICRP formalism defined in ICRP *Publication 103*.

(246) 2-[^{18}F]FDG is the most commonly used PET radiopharmaceutical. It accumulates in organs or tissues, such as the brain, the heart and various types of tumours. It is excreted through the kidneys and the urinary bladder. The absorbed dose to organs and tissues of an adult patient as well as the effective dose are shown in Table 6.2 (Kamp et al, 2023). An administered activity of 300 MBq will result in an effective dose of 5.1 mSv.

(247) During a PET/CT examination, the patient is exposed to radiation from both the radiopharmaceutical and CT. The total radiation dose from a PET/CT examination is the combined dose from PET radiopharmaceutical and from CT.

(248) The magnitude of the radiation dose to the patient from the CT examination depends on several scan parameters such as tube voltage, tube current including modulation, rotation time, slice collimation, pitch, total scan length, and position in the body (although this is not reflected in the CTDI or DLP surrogate measure). Radiation dose in CT is typically measured by using a simple cylindrical phantom and expressed as a volume averaged CT dose index

(CTDI). Volume CTDI ($CTDI_{vol}$) is the parameter for the average absorbed dose at a point with the scan volume for a particular scan protocol for a standardised phantom (IEC, 2002). To better represent the overall energy delivered by a given scan protocol, the $CTDI_{vol}$ can be integrated over the scan length to compute the dose-length product (DLP). Dose descriptors such as $CTDI_{vol}$ and DLP are to be used for comparison against reference doses set for typical CT examinations (EC, 2000; ICRP, 2017a).

(249) CT scan of the PET/CT examination can be carried out for three different purposes. The protocol for CT scan can be selected for attenuation correction of the PET image, for anatomical localisation of the radiopharmaceutical within the patient or for diagnosis using CT itself (see Table 6.3 for examples of published protocols and doses) (Akin et al., 2017). For the purpose of attenuation correction or anatomical localisation, CT image quality is not an important issue. So, low dose CT with the use of a low tube current (30–50 mAs) for anatomical localisation results in an effective dose to the patient of 3–6 mSv. For attenuation correction alone, a much lower mAs is possible, as shown in Table 6.3, resulting in a lower effective dose. When the CT scan is performed as a full diagnostic CT, using contrast agents and several scan cycles, the effective dose to the patient varies from 11 to 20 mSv depending on the scan parameters used.

Table 6.1. Normalised effective doses for commonly used PET radiopharmaceuticals.

Effective dose per unit activity administered (mSv MBq^{-1})

Effective dose as defined in ICRP *Publication 103*

Radiopharmaceutical	Adult	15 years	10 years	5 years	1 year
2-[^{18}F]FDG*	1.7×10^{-2}	2.0×10^{-2}	2.9×10^{-2}	4.4×10^{-2}	7.6×10^{-2}
[^{18}F]choline†	1.1×10^{-2}	1.2×10^{-2}	1.8×10^{-2}	2.6×10^{-2}	4.6×10^{-1}
[^{124}I]iodide‡	9.0×10^{-1}	1.5	$1.9\times10^{+1}$	3.1	5.5

Effective dose as defined in ICRP *Publication 60* (excerpt from ICRP, 2015a)

Radiopharmaceutical	Adult	15 years	10 years	5 years	1 year
[^{18}F]FET§	1.6×10^{-2}	2.1×10^{-2}	3.1×10^{-2}	4.7×10^{-2}	8.2×10^{-2}
[^{18}F]FDOPA¶	2.5×10^{-2}	3.2×10^{-2}	4.9×10^{-2}	7.0×10^{-2}	1.0×10^{-1}
[^{18}F]fluoride	1.7×10^{-2}	2.0×10^{-2}	3.3×10^{-2}	5.6×10^{-2}	1.1×10^{-1}
[^{18}F]FLT**	1.5×10^{-2}	1.9×10^{-2}	2.9×10^{-2}	4.6×10^{-2}	8.8×10^{-2}
[^{11}C]acetate	3.5×10^{-3}	4.3×10^{-3}	6.5×10^{-3}	9.9×10^{-3}	1.8×10^{-2}
[^{11}C]methionine	8.2×10^{-3}	1.1×10^{-2}	1.6×10^{-2}	2.5×10^{-2}	4.7×10^{-2}
[^{11}C]raclopride	5.0×10^{-3}	6.4×10^{-3}	9.8×10^{-3}	1.5×10^{-2}	3.0×10^{-2}
[^{15}O]water	1.1×10^{-3}	1.4×10^{-3}	2.3×10^{-3}	3.8×10^{-3}	7.7×10^{-3}
[^{82}Rb]RbCl	1.1×10^{-3}	1.4×10^{-3}	3.0×10^{-3}	4.9×10^{-3}	8.5×10^{-3}

*2-[^{18}F]FDG model based on Kamp et al (2023).
†[^{18}F]choline based on Guissani et al (2012).
‡[^{124}I]iodide for saturated thyroid, intravenous administration is based on ICRP *Publication 137* (ICRP, 2017b).
§O-(2-[^{18}F]-fluorethyl)-L-tyrosine.
¶[^{18}F]-fluoro-L-DOPA.
**30-deoxy-[^{18}F]-30-fluorothymidine.

(250) In a study calculating doses for 429 paediatric 2-[^{18}F]FDG PET/CT patients, a mean effective dose of 6.4 (±1.8) mSv was found for the CT component of the PET/CT exam, using a scan technique for attenuation correction and localization, not for diagnostic purposes (Quinn, 2020). This value reinforces the need to develop, in paediatrics, optimisation and dose-reduction strategies.

Table 6.2. Organ absorbed doses for 2-[^{18}F]FDG (Kamp et. al., 2023).

	Absorbed dose in mGy/MBq									
	Adults		15 years		10 years		5 years		1 year	
Organs	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Adrenals	1.4×10^{-2}	1.6×10^{-2}	1.2×10^{-2}	1.3×10^{-2}	2.0×10^{-2}	2.0×10^{-2}	3.4×10^{-2}	3.4×10^{-2}	6.5×10^{-2}	6.5×10^{-2}
Brain	3.0×10^{-2}	3.3×10^{-2}	3.5×10^{-2}	3.8×10^{-2}	3.7×10^{-2}	4.1×10^{-2}	4.1×10^{-2}	4.5×10^{-2}	5.6×10^{-2}	5.6×10^{-2}
Breast	7.6×10^{-3}	9.7×10^{-3}	9.2×10^{-3}	1.0×10^{-2}	1.4×10^{-2}	1.4×10^{-2}	2.5×10^{-2}	2.4×10^{-2}	4.2×10^{-2}	4.2×10^{-2}
Colon wall	1.2×10^{-2}	1.5×10^{-2}	1.5×10^{-2}	1.4×10^{-2}	2.2×10^{-2}	2.2×10^{-2}	3.7×10^{-2}	3.5×10^{-2}	7.2×10^{-2}	7.1×10^{-2}
Endosteum (bone surface)	1.0×10^{-2}	1.2×10^{-2}	1.6×10^{-2}	1.6×10^{-2}	2.4×10^{-2}	2.4×10^{-2}	4.5×10^{-2}	4.4×10^{-2}	8.9×10^{-2}	8.9×10^{-2}
ET region	7.6×10^{-3}	8.5×10^{-3}	2.0×10^{-2}	2.0×10^{-2}	2.5×10^{-2}	2.5×10^{-2}	2.9×10^{-2}	2.9×10^{-2}	4.0×10^{-2}	4.0×10^{-2}
Gall bladder wall	1.1×10^{-2}	1.3×10^{-2}	1.1×10^{-2}	1.4×10^{-2}	1.8×10^{-2}	1.8×10^{-2}	2.9×10^{-2}	2.9×10^{-2}	4.9×10^{-2}	5.0×10^{-2}
Heart wall	6.5×10^{-2}	8.4×10^{-2}	8.3×10^{-2}	9.1×10^{-2}	1.4×10^{-1}	1.4×10^{-1}	2.2×10^{-1}	2.2×10^{-1}	3.9×10^{-1}	3.9×10^{-1}
Kidneys	2.0×10^{-2}	2.3×10^{-2}	2.2×10^{-2}	2.4×10^{-2}	3.2×10^{-2}	3.2×10^{-2}	5.3×10^{-2}	5.3×10^{-2}	8.9×10^{-2}	8.9×10^{-2}
Liver	1.5×10^{-2}	1.8×10^{-2}	1.7×10^{-2}	2.0×10^{-2}	2.8×10^{-2}	2.8×10^{-2}	4.2×10^{-2}	4.3×10^{-2}	7.4×10^{-2}	7.4×10^{-2}
Lung	1.3×10^{-2}	1.7×10^{-2}	1.3×10^{-2}	1.4×10^{-2}	2.0×10^{-2}	2.0×10^{-2}	3.0×10^{-2}	3.0×10^{-2}	5.8×10^{-2}	5.8×10^{-2}
Lymphatic nodes	1.3×10^{-2}	1.4×10^{-2}	1.2×10^{-2}	1.2×10^{-2}	1.8×10^{-2}	1.8×10^{-2}	3.0×10^{-2}	3.0×10^{-2}	5.1×10^{-2}	5.1×10^{-2}
Muscle	8.3×10^{-3}	1.0×10^{-2}	9.7×10^{-3}	1.0×10^{-2}	1.6×10^{-2}	1.6×10^{-2}	2.6×10^{-2}	2.5×10^{-2}	4.8×10^{-2}	4.8×10^{-2}
Oesophagus	1.5×10^{-2}	1.7×10^{-2}	1.6×10^{-2}	1.6×10^{-2}	2.5×10^{-2}	2.5×10^{-2}	4.0×10^{-2}	4.0×10^{-2}	6.7×10^{-2}	6.7×10^{-2}
Oral mucosa	8.8×10^{-3}	9.9×10^{-3}	2.0×10^{-2}	2.0×10^{-2}	2.7×10^{-2}	2.7×10^{-2}	3.3×10^{-2}	3.3×10^{-2}	5.0×10^{-2}	5.0×10^{-2}
Ovaries	---	2.4×10^{-2}	---	3.8×10^{-2}	---	5.0×10^{-2}	---	7.4×10^{-2}	---	1.2×10^{-1}
Pancreas	1.6×10^{-2}	1.8×10^{-2}	1.7×10^{-2}	1.9×10^{-2}	2.8×10^{-2}	2.8×10^{-2}	4.5×10^{-2}	4.5×10^{-2}	7.9×10^{-2}	7.9×10^{-2}
Prostate	2.7×10^{-2}	---	3.1×10^{-2}	---	5.3×10^{-2}	---	7.5×10^{-2}	---	1.4×10^{-1}	---
Salivary glands	7.8×10^{-3}	9.7×10^{-3}	2.1×10^{-2}	1.9×10^{-2}	2.5×10^{-2}	2.5×10^{-2}	3.3×10^{-2}	3.3×10^{-2}	5.2×10^{-2}	5.2×10^{-2}
Skin	6.3×10^{-3}	7.7×10^{-3}	8.0×10^{-3}	8.6×10^{-3}	1.3×10^{-2}	1.3×10^{-2}	2.2×10^{-2}	2.2×10^{-2}	4.2×10^{-2}	4.2×10^{-2}
Small intestine wall	1.3×10^{-2}	1.7×10^{-2}	1.3×10^{-2}	1.3×10^{-2}	1.8×10^{-2}	1.9×10^{-2}	3.3×10^{-2}	3.5×10^{-2}	6.3×10^{-2}	6.3×10^{-2}
Spleen	1.4×10^{-2}	1.7×10^{-2}	1.4×10^{-2}	1.6×10^{-2}	2.3×10^{-2}	2.3×10^{-2}	3.8×10^{-2}	3.8×10^{-2}	7.0×10^{-2}	7.1×10^{-2}
Stomach wall	1.2×10^{-2}	1.3×10^{-2}	1.1×10^{-2}	1.3×10^{-2}	1.8×10^{-2}	1.8×10^{-2}	3.1×10^{-2}	3.1×10^{-2}	5.8×10^{-2}	5.8×10^{-2}
Testes	8.6×10^{-3}	---	1.9×10^{-2}	---	2.4×10^{-2}	---	3.9×10^{-2}	---	5.5×10^{-2}	---
Thymus	9.8×10^{-3}	1.2×10^{-2}	1.4×10^{-2}	1.5×10^{-2}	2.2×10^{-2}	2.2×10^{-2}	3.6×10^{-2}	3.6×10^{-2}	7.0×10^{-2}	7.0×10^{-2}
Thyroid	9.1×10^{-3}	1.1×10^{-2}	1.3×10^{-2}	1.3×10^{-2}	1.9×10^{-2}	1.8×10^{-2}	3.2×10^{-2}	3.2×10^{-2}	5.4×10^{-2}	5.3×10^{-2}
Urinary bladder wall	7.5×10^{-2}	9.2×10^{-2}	9.1×10^{-2}	9.2×10^{-2}	1.5×10^{-1}	1.5×10^{-1}	1.9×10^{-1}	1.9×10^{-1}	2.7×10^{-1}	2.7×10^{-1}
Uterus/cervix	---	3.3×10^{-2}	---	9.0×10^{-2}	---	1.3×10^{-1}	---	8.7×10^{-2}	---	3.3×10^{-1}
Effective dose [mSv/MBq]	1.7×10^{-2}		2.0×10^{-2}		2.9×10^{-2}		4.4×10^{-2}		7.6×10^{-2}	

Table 6.3. Data from Image Wisely, regarding the CT component for a whole-body oncological PET/CT scan with 2-[^{18}F]FDG (Akin et al., 2017).

CT	mAs	$CTDI_{vol}$ (mGy)	CT Effective dose (mSv)
Attenuation correction	5–10	0.3–1.0	0.5–1.0
Localisation	30–60	2–4	3–6
Diagnostic	110–200	8–14	11–20

(251) Effective dose is a dose quantity that provides an approximate indicator of possible risk (ICRP, 2021). Since effective dose is derived from standard phantoms, it should not be used to assess risks of stochastic effects in retrospective situations for exposures in identified individuals. It should also not be used in epidemiological evaluations of human exposure (ICRP, 2007b).

(252) Use of the value for effective dose should be sufficient to give an indication of risk compared to other medical procedures or other sources of radiation. But if a full assessment of the risk for an individual is required, then this is best evaluated using appropriate risk values for the individual tissues at risk, and for the age and gender distribution of the population groups undergoing the medical procedures. For the exposure of young children, since the risk would be higher, dose optimisation is more important.

6.2. Optimisation and dose reduction strategies

(253) There are several strategies that can be used to minimise the radiation dose to the patient undergoing a PET, PET/CT, or PET/MRI scan. To ensure that the administration activity injected to the patient is correct, it must be adequately measured using an activity meter, ideally double-checked by a second person, and the activity meter should be calibrated regularly. A thorough development of referral guidelines, a team culture, standard protocols for common imaging procedures, and policies for quality assurance contributes to prevent unnecessary radiation exposures and thus also to dose reduction (Alenezi et al, 2015).

(254) For the PET component, the best way to reduce dose is by reducing the injected activity, since the dose is proportional to the administered activity. Reduction of PET tracer dose might have an impact not only for the patient but also in the exposure of the nuclear medicine staff. However, reducing the injected activity would result in a reduction in image quality. One method of reducing the injected activity while maintaining image quality is by increasing scan duration. However, this would come at the cost of decreased scanner throughput as well as increased patient motion which leads to increased image blur (Devine and Mawlawi, 2010).

(255) The patient should be encouraged to drink water and then void prior to scanning, to decrease the whole-body dose, especially the dose to the bladder. Since 2-[^{18}F]FDG is mainly excreted by the urinary system, the urinary bladder wall is the tissue that gets the highest absorbed dose, 39 mGy for 300 MBq. This dose can be markedly reduced by encouraging the patients to increase their consumption of water and frequently void their bladder (Boellaard et al., 2015).

(256) For the CT component, several acquisition parameters can be modified. Reduction in voltage and/or current time product reduce radiation dose, but image quality become degraded by increasing noise. If a diagnostic contrast-enhanced CT is needed, it is preferable to perform a diagnostic CT only for limited portions of the body. For the rest of the body, a low-dose CT is sufficient for attenuation correction and anatomic localisation. If a full diagnostic CT is needed, it could also be used for attenuation correction of the PET image

and there is no need to make an additional low-dose CT in connection with the investigation. However, for a diagnostic CT with contrast, it should be noticed that artefacts can appear if no proper software that corrects them is used (IAEA, 2014a). If the patient has recently undergone a clinically relevant CT examination there is no need to repeat it and only low-dose CT should be used. Using a low dose CT should also be considered in repeated PET scan to have a better signal to background ratio for a limited part of the body, repeated PET with another tracer (e.g. ^{11}C-methionine + 2-[^{18}F]FDG) and clinical trials with frequent PET/CT scans. In this way the CT dose component can be reduced with a factor of 2-3 (Mattsson et al., 2015). Another strategy that might be implemented in clinical activity is to use, for attenuation correction, an ultra-low dose CT. Prieto et al. (2021), through phantom experiments, demonstrated that these ultra-low dose CT do not introduce noticeable degradation in the attenuation corrected PET/CT.

(257) In PET/CT scans with different scan lengths, effective patient dose from PET is the same and related to administered radiotracer activity. However, effective dose from CT increases according to the scanned length. As demonstrated by Martí-Climent et al, the CT effective doses were 8.0, 10.4, and 11.9 mSv for head and neck, torso, and whole-body protocols, with mean scanned patient length of 761, 839, and 926 mm, respectively (Martí-Climent et al., 2017).

(258) Prieto et al. (2018) reported that significant dose reduction is feasible in 2-[^{18}F]FDG PET/CT protocols without compromising diagnostic quality. 2-[^{18}F]FDG activity was reduced from 5.18 MBq/kg to 4.44 and 3.70 and reference CT current-time-product was reduced from 120 mAs to 100 and 80. Effective dose from 2-[^{18}F]FDG was gradually reduced from 6.5 ± 1.4 to 5.7 ± 1.3 and 5.0 ± 1.0 mSv. Effective dose from CT was progressively reduced from 9.5 ± 2.8 to 8.0 ± 2.3 and 6.2 ± 1.5 mSv. Overall, a significant radiation dose reduction of 28.7% was reached. Despite a slight reduction in image quality, the new regime was successfully implemented with readers reporting unchanged clinical confidence.

(259) In some clinical scenarios and if available, it could be considered using PET/MR instead of PET/CT, thus reducing patient dose by omitting the CT exposure.

6.3. Radiological protection optimisation using both hardware and software

(260) New PET, PET/CT, or PET/MRI hardware and software provide new opportunities for radiological protection optimisation, reducing radiation dose while maintaining image quality. Optimisation of protocols can be found in publications as well as in websites of scientific educational initiatives, like Image Wisely (2023) and Image Gently Alliance (2023).

(261) Maintaining the image quality while still reducing the injected dose can be achieved by improving the scanner sensitivity. This can be achieved by scanning in 3D rather than 2D mode, by increasing the axial extent of the scanner, or, most recently, by acquiring PET data in TOF mode. According to a nation-wide questionnaire in Korea, the radiation doses from 2-[^{18}F]FDG and CT were significantly lower in case of newer scanners than older ones (6.10 to 4.60 MBq/kg; $P < 0.001$) (Kwon et al., 2016). Advanced PET technologies such as TOF acquisition and PSF recovery were also related to low radiation dose ($P < 0.001$).

(262) Regarding 2-[^{18}F]FDG, the EANM recommends using administered activities of 380 MBq for 2D and 190 MBq for 3D for a standard adult patient (75 ± 5 kg) (Boellaard et al., 2015). The EANM guideline recommends the minimum 2-[^{18}F]FDG administered activities in adults, which assume a linear or a quadratic relationship between PET acquisition time per

bed position, patient weight and recommended 2-[^{18}F]FDG activity. Compared with the linear activity prescription, the quadratic scheme results in a slightly higher administered activity for patients >75 kg. This compensates degradation of image quality due to the lower signal to noise ratio from excessive attenuation. One may decide to apply a higher activity and reduce the duration of the study. However, it is preferable to use a reduced activity and increase the study duration, keeping ALARA principles in mind. For patients weighing over 90 kg, increasing the emission acquisition time per bed position is recommended rather than increasing the administered 2-[^{18}F]FDG activity by the quadratic scheme.

(263) Newer PET, PET/CT, or PET/MRI scanners with TOF technology improve image contrast and higher sensitivity, which can help to overcome poor signal from large patients. Use of TOF technology permits a decrease in the average administered activity of ~25% (from 4.6 MBq kg^{-1} to 3.5 MBq kg^{-1}) without loss of image quality (Etard et al., 2012).

(264) Increasing axial field of view of the scanner is increasing sensitivity of PET signal from the patients in 3D mode. Recently, the total body PET system covering total body was developed. The 195 cm axial field of view of the EXPLORER PET/CT scanner is sufficient to cover the entire human adult body in a single acquisition (Cherry, et al., 2018). Injection of 8.3 MBq 2-[^{18}F]FDG is sufficient to acquire PET images in 10 min. This corresponds to an effective dose of 0.16 mSv (Badawi et al., 2019).

(265) Several CT radiation dose quality assurance tools are available. The CT radiation dose can be lowered by adjusting a combination of the following parameters: shorter scan length, lower tube current (i.e. mAs), lower tube voltage (i.e, kVp), automatic tube current modulation and properly centring the patient, collimation, increase pitch, image acquisition and processing software options such as iterative reconstruction and thicker slice thickness. (McCollough et al., 2006; Huang et al., 2009; Singh et al., 2011; Martin and Sookpeng, 2016; ICRP, year2).

(266) Using optimal reconstruction parameters helps to obtain better diagnostic image quality with less radiation dose. Image reconstruction techniques such as iterative reconstruction, while requiring more computation, have many advantages over filtered back projection (FBP). A study by Shin et al. (2013) reported that, in abdominal CT, through applying new iterative reconstruction algorithms, and an automated kV modulation, the dose was reduced by 41.3%, while maintaining the same image noise as in the standard-dose FBP images.

(267) Park et al. (2018) proposed a deep-learning-based approach for CT image super-resolution. The convolutional neural network yielded high-resolution images (thin slice) once the low-resolution image (thick slice) was given. Thus, artificial intelligence using deep learning feature may help to reduce radiation dose in CT. Recently, some manufacturers have introduced deep learning reconstruction algorithms into their scanners, which not only lowers radiation dose, but also improves image quality and speeds reconstruction, being presently considered the future of CT (McLeavy et al., 2021).

6.4. The value of DRLs for optimisation of PET and PET/CT

(268) ICRP recommends the constitution of national DRLs to optimise protection in the medical exposure of patients for diagnostic and interventional procedures (ICRP, 2017a). In Europe, this is also mandated to member states through Council Directives, the last being Council Directive 2013/59/EURATOM (Council of The European Union, 2013). DRLs are defined as dose levels in radiological diagnostic and interventional procedures or typical levels of radiopharmaceutical activity for groups of standard-sized patients or standard phantom.

(269) A DRL value is a selected level of a radiation dose quantity for broadly defined types of equipment for typical examinations for groups of patients within an agreed weight range or, in certain specific circumstances, a standard phantom. Radiation dose quantities used for DRLs should be appropriate to the imaging modality being evaluated, should assess the amount of ionising radiation applied to perform a medical imaging task, and should be easily measured or determined. When two imaging modalities are used for the same procedure such as PET/CT, it is appropriate to set and present DRLs for both modalities independently.

(270) DRLs are derived from an arbitrary threshold from a distribution of values obtained locally and collected nationally or regionally. Data for determining national DRL values are obtained from surveys. Values of appropriate dose quantities from patient examinations are collected from several different health facilities. The 75th percentile value of the distribution of median values (the 50th percentile) of a dose quantity at healthcare facilities throughout a country is used as the national DRL.

(271) Median values of distributions of dose quantities at a facility should be compared with DRL values. If a DRL value for any procedure is exceeded, an investigation should be undertaken without undue delay to determine possible reasons, and if it is shown that corrective action is required, a plan should be implemented and documented. A dose below a DRL value does not, by itself, indicate that the procedure is performed at an optimised level regarding the amount of radiation used. Image quality is always to be considered in optimisation. The median dose may be considered as a balance point of image quality and dose in the general review. Users who have values significantly lower than the median of the national or regional distribution may need to look at image quality as a priority.

(272) Where it is apparent that further optimisation is being achieved locally, or where no national DRL values exist, ‘local DRLs or typical values’ based on audits or surveys might be introduced to further assist the optimisation process.

(273) Values of DRL quantities for individual patients should not be compared with national or regional DRL values, because the DRL process is intended for optimisation of protection for groups of patients, and is based on standard patients, not individual patients. National or regional DRL values should not be used as dose limits. Dose limits do not apply to medical exposures of patients.

(274) DRL values are not static. As optimisation of examinations continues or hardware and software improve, DRLs should be updated on a regular basis. The DRL process should be applied in a continual process of quality assurance (QA), with repeat surveys following any optimisation, and then repetition of the whole process after an appropriate time interval. National and regional DRLs should be revised at regular intervals of 3–5 years, or more frequently when substantial changes in technology, new imaging protocols or improved post-processing of images become available.

(275) For nuclear medicine, DRL quantities will be established in terms of the administered activity. The ideal is for the administered activity to be adjusted for patient weight. For some procedures, activity per kg body weight of a specific radionuclide for a specific clinical task and the radiopharmaceutical used may be appropriate. Different radiopharmaceuticals may be used for PET imaging, depending on the clinical condition and the purpose of the study. Since the physical half-lives of radionuclides and biological half-times of radiopharmaceuticals are different, DRL values should be set for each radiopharmaceutical. DRL also depends on the diagnostic purpose. The administered 2-[^{18}F]FDG activity is different for whole body oncological or brain studies (Martí-Climent et al., 2017). Administration of Radioactive Substances Advisory Committee (ARSAC) published DRLs, effective doses and dose to uterus of commonly used PET procedures from UK in Notes for Guidance on the Clinical Administration of radiopharmaceuticals and Use of

Sealed Radioactive Sources (ARSAC, 2021) (Table 6.4). The effective doses given in these Notes have been calculated from the corresponding DRL using the methodology described in *Publication 128* (ICRP, 2015a), using weighting factors from *Publication 60* (ICRP, 1991). DRLs are varying among countries and regions (Table 6.5) (Song et al., 2019).

(276) For CT imaging in PET/CT, volume CT dose index ($CTDI_{vol}$) and dose-length product (DLP) are used for DRL quantities which are displayed from the CT scanners. Patient dose depends on the purpose of the CT examination. DRL values for diagnostic CT of the trunk are too high for the CT component of PET/CT if the CT is performed only for attenuation correction and localisation. Despite wide variations between PET/CT protocols (4-fold variations in $CTDI_{vol}$), CT DRL values of 8 mGy ($CTDI_{vol}$) and 750 mGy·cm (DLP) for attenuation correction and localisation have been proposed for whole-body PET/CT in France (Etard et al., 2012). Since there is a wide variation of dose depending on the purpose of CT scan, separate DRLs for attenuation correction, localisation and diagnostic scans should be proposed.

Table 6.4. DRLs, effective doses (ED) and dose to uterus of PET procedures (ARSAC, 2021).

Radionuclide Chemical form (MBq kg^{-1})	Investigation	Route of admin	DRL (MBq)	Activity by Weight (MBq Kg^{-1})	ED (mSv)	Dose to uterus (mGy)
[^{11}C]choline	hepatocellular cancer imaging	IV	370		1.6	0.7
[^{11}C]choline	prostate cancer imaging	IV	370		1.6	n/a
[^{11}C]methionine	brain tumour imaging	IV	400		3.3	2.7
	parathyroid tumour imaging	IV	740		6.1	5
[^{13}N]ammonia	myocardial imaging	IV	550		2	1.4
[^{18}F]choline	hepatocellular cancer imaging	IV	370	4	7.4	5.6
	prostate cancer imaging	IV	370	4	7.4	n/a
2-[^{18}F]FDG	brain tumour imaging	IV	250		4.8	4.5
	differential diagnosis of dementia	IV	250		4.8	4.5
	focal epilepsy	IV	250		4.8	4.5
	infection/inflammation imaging	IV	400	4.5	7.6	7.2
	myocardial imaging	IV	400		7.6	7.2
	whole body tumour imaging	IV	400	4.5	7.6	7.2
[^{18}F]florbetaben	cerebral amyloid assessment	IV	300		5.8	4.9
[^{18}F]florbetapir	cerebral amyloid assessment	IV	370		6.9	5.8
[^{18}F]fluoride	bone imaging	IV	250		4.3	3.3
[^{18}F]FET	brain tumour imaging	IV	370		5.9	6.3
6-[^{18}F]F-DOPA	neuroendocrine tumour imaging	IV	280	4	7	7.8
	suspected congenital hyperinsulinism	IV	280	4	7	7.8
[^{18}F]flutemetamol	cerebral amyloid assessment	IV	185		5.9	4.6
[^{68}Ga]Ga -DOTATATE / DOTATOC / DOTANOC	somatostatin receptor imaging	IV	250		6.4 TATE 4.2 NOC 5.8 TOC	3.7
[^{68}Ga]Ga -PSMA	Prostate cancer imaging	IV	200		4.6	n/a
[^{82}Rb]RbCl	Myocardial imaging	IV	2220		2.4	2.2

IV, Intravenous.

Table 6.5. Diagnostic reference levels of 2-[^{18}F]FDG PET procedures among different countries and regions (MBq) (Song et al., 2019).

Procedures	NCRP	EU	UK	Australia	Brazil	Japan	Korea
2-[^{18}F]FDG (tumour)	461–710	200–400	400	310	370	240	370
2-[^{18}F]FDG (brain)			250	250	350	240	370

NCRP, National Council on Radiation Protection and Measurements; EU, European Union; UK, United Kingdom.

6.5. Radiological protection and dose issues in paediatric patients

(277) Infants and children have more risk of cancer than adults after radiation exposure since not only are their organs and tissues more sensitive to radiation, but also, they have a longer post exposure life expectancy. Thus, it is prudent for those using the technology to understand the factors that affect radiation dose from both the PET and the CT components of the procedure (Fahey, 2009).

(278) Using effective dose, which averages risk in both sexes and over wide age ranges, is not ideal for estimating paediatric radiation risk. Thus, there are limitations of using effective dose for comparing the radiation risk of one age group to another group. Despite these constraints, effective dose remains most useful as a method for comparing the potential radiation effects of different medical imaging studies to children within a single age group.

(279) Calculation of organ-absorbed doses relies on biokinetic models for each organ and each radiopharmaceutical. The ICRP typically uses the same biokinetic models for all ages, as most data are from adults, with little paediatric-specific biokinetic data. In some circumstances, this may overestimate dose, as children may have more rapid clearance of radiopharmaceuticals (ICRP, 2015a).

(280) For children and adolescents, administered 2-[^{18}F]FDG activity should adhere to the most recent EANM or Society of Nuclear Medicine and Molecular Imaging (SNMMI) recommendations on paediatric radiopharmaceutical administration (Treves, 2016; EANM, 2016) or national activity limits, if national limits are lower. Fahey F.H. et al demonstrated that for commonly performed paediatric nuclear medicine studies, following either the EANM Dosage Card (version 1.5.2008) (Lassmann et al., 2008) or the 2010 North American consensus guidelines for administered activities of radiopharmaceuticals (Gelfand et al., 2011) can result in substantial differences in radiation exposure for the same procedure (Fahey et al., 2016). This discordance has identified opportunities for harmonization of the guidelines, which may lead to further reduction in nuclear medicine radiation doses in children (Table 6.6) (Lassmann and Treves, 2014, Treves and Lassmann, 2014; Grant et al., 2015). EANM Dosage Card set the minimum values determined based upon considerations concerning the limitations of PET scanners in terms of image quality. However, PET images of sufficient quality can be obtained with an activity that is considerably less than that suggested as the 'minimum' in the new dosage card, considering the overall gain in true coincidences in a small body (Holm et al., 2007). Also, the administered activity might be reduced especially when using newer PET systems, provided that these optimised protocols guarantee high-quality studies (Vali et al, 2021).

(281) Recently, IAEA conducted a survey on paediatric nuclear medicine practice, in which 133 institutes from 62 different IAEA member states participated. For 2-[^{18}F]FDG PET more than half of the facilities reported to use the EANM Paediatric Dosage Card, and the level of compliance found for this exam was high, with not more than 4% of the institutes exceeding 120% of the EANM recommended activity. Also, most of the facilities (more than

90%) stated that they were using tube current modulation in children, for their CT acquisitions (Poli et al., 2020). Another survey, aimed at evaluating the impact of the 2010 North American Consensus Guidelines, was undertaken in the United States in the Spring of 2013 and gathered information from 121 sites. Thirteen out of the 18 sites that performed paediatric studies with 2-[^{18}F]FDG, reported that they were familiar with the Guidelines and 84,6% responded that their administered activities were ±20% the recommended value of the guideline (Fahey et al., 2016).

Table 6.6. Radiation dose estimates for 2-[^{18}F]FDG PET for adults and children at four different ages using the administered activities recommended by the European Association of Nuclear Medicine Dosage Card (EANM, 2016) and the 2010 North American (NA) consensus guidelines (Grant et al., 2015).

Age	1 year	5 years	10 years	15 years	Adult
Nominal weight (kg)	9.8	19	32	55	70
2-[^{18}F]FDG PET torso					
EANM administered activity (MBq)	70	120	189	302	370
EANM effective dose (mSv)	6.7	6.7	7.0	7.2	7.0
NA administered activity (5.2 MBq kg^{-1})	51	99	166	286	364
NA effective dose (mSv)	4.8	5.5	6.2	6.9	6.9
NA critical organ dose (mGy) - Bladder	24	34	42	46	47
2-[^{18}F]FDG PET brain					
EANM administered activity (MBq)	37	65	102	163	200
EANM effective dose (mSv)	3.3	3.4	3.8	3.9	3.8
NA administered activity (3.7 MBq kg^{-1})	37	70	118	204	259
NA effective dose (mSv)	3.5	3.9	4.4	4.9	4.9
NA critical organ dose (mGy) - Bladder	17	24	30	33	34

(282) There are several strategies for decreasing radiation exposure in PET/CT. Many improvements should be pursued when performing PET/CT studies in children to reduce risks, not only from radiation exposure, but also from the need to perform exams sometimes under general anaesthesia, that should also be reduced. These strategies involve careful patient preparation and the use of appropriate immobilization techniques, working with carers /comforters and family to prepare the patient, assuring compliance to recommended paediatric activities and the use of paediatric-specific CT imaging parameters. (Parisi et al., 2017; Hansen et al., 2022).

(283) Eliminating unnecessary examinations reduces radiation exposure. Each PET/CT examination should be clinically justified. Referring physicians should order the imaging study that is standard in clinical practice. To help them, both the American College of Radiology and SNMMI have been developing a set of evidence-based, expert recommendations 'Appropriateness Criteria' (Jadvar et al., 2017). For specific pathologies, including in children, evidence-based guidelines can be found in many scientific organisations, such as the National Comprehensive Cancer Network (NCCN) or the European Society for Medical Oncology (ESMO). SNMMI also collaborated with The Image Gently Alliance, preparing some booklets dedicated to the referring paediatricians, in which radiological protection issues related to nuclear medicine procedures are dealt with, and thus can help these physicians to further justify their referrals (The Image Gently Alliance, 2022).

(284) Following the current guidelines and using paediatric appropriate radiopharmaceutical administered doses can optimise radiation dose from the PET component. Increasing imaging times per bed position facilitates further reduction in

administered radiopharmaceutical doses, but it cannot be forgotten that this might increase the need for sedation. Sedation or anaesthesia may be used for infants, young children and its related complications should be also considered. Newer PET systems with wider axial field of view, or equipped with more efficient detector systems, or certain examination protocols, allow also to reduce the administered activity (Vali, 2021) and so, if available, should be the preferred ones to perform PET/CT studies in children.

(285) It has been shown that applying the same adult CT protocols in paediatric patients can lead to a twice increase in organ and effective doses delivered to the youngest children as compared with an adult (Brenner and Hall, 2007). To keep children specific CT protocols, one needs to reduce CT imaging parameter dosages by decreasing mAs and reducing kVp. For children, it is especially important to choose the appropriate scan field of view, use dose modulation techniques, and avoid, when possible, multiphase imaging.

(286) When more than one PET/CT scanner is available within a department, paediatric patients should be assigned to the scanner on which clinically acceptable image quality can be achieved while imparting the lowest radiation dose.

6.6. Breast Feeding

(287) There are two potential sources of radiation to breast fed infants. First, the radiopharmaceutical itself may be excreted into breast milk and second, the breast-feeding woman can be a radiation source irrespective of whether the radiopharmaceutical is excreted into breast milk. For 2-[^{18}F]FDG dose to the breast feeding child appears to be primarily related to breast activity, which appears to increase with suckling, versus activity secreted into breast milk (Hicks et al., 2001).

(288) For PET radiopharmaceuticals labelled with the short lived ^{15}O,^{13}N, ^{11}C PET isotopes there are no recommended restrictions to breast feeding (ICRP, 2015a Table D1). For 2-[^{18}F]FDG breast feeding cessation recommendations range from: no interruption (ICRP, 2015a Table D1, Leide-Svegborn et al., 2016), one-hour (ARSAC, 2021), and three-hours (IAEA, 2018). These recommendations are primarily based on the dose to the baby from close proximity to the mother during breast feeding. However, when using the ALARA principle, for 2-[^{18}F]FDG PET studies these ranges should be accommodated by advising the patient to breastfeed just before PET radiopharmaceutical injection to maximise time between injection and the next feeding, or to express the milk before and let another person feed the baby via a bottle. For ^{124}I labelled PET radiopharmaceuticals, the recommendation is to cease breast feeding (NRC, 2018). For a more comprehensive discussion on breast feeding recommendations related to a variety of PET and non-PET radiopharmaceuticals readers are referred to Annex D1 of *Publication 128* (ICRP, 2015a).

(289) There is minimal data to guide recommendations for non 2-[^{18}F]FDG PET radiopharmaceuticals. For radiopharmaceuticals not listed, one option is to perform photon counting on specific samples, although the logistics, as well as the subsequent dose calculations, may be difficult. Consultation with a nuclear medicine physicist and/or other appropriate specialists is recommended if administration cannot be postponed in such cases until breast feeding has ceased.

6.7. Fetal dose

(290) Ionising radiation diagnostic imaging should be avoided in pregnant patients unless the medical justification is compelling. If imaging proceeds the study should be optimally

protocolled to reduce fetal dose as low as reasonably achievable (Segall et al., 2010; Boellaard et.al., 2015).

(291) Noting this, diagnostic ^{18}F related PET radiopharmaceuticals do not generally result in a high fetal dose. Xie et al. (2016) published fetal doses ranging from approximately 1 to 10 mSv post 2-[^{18}F]FDG injection with the stage of gestation being a contributing factor for the range (i.e. higher doses in early gestation). Table 6.7, adapted from Stabin (2017), estimates fetal doses for 2-[^{18}F]FDG and Na[^{18}F]F (^{18}F-Sodium Fluoride).

(292) These data demonstrate two points: fetal dose decreases with gestational age and the maximum estimated fetal dose for a routine 2-[^{18}F]FDG procedure (e.g. nominal dose of 400 MBq 2-[^{18}F]FDG) would be 9.2 mSv in the less than 3 month gestation period reduced to 6.8 mSv at 9 month gestation. Adult activities for Na[^{18}F]F bone scans typically fall between 185 to 370 MBq (Segall et al., 2010) which, based on Table 6.7 will result in lower fetal doses (i.e. 4.1 mSv to 8.1 mSv for the early fetal period).

Table 6.7. 2-[^{18}F]FDG and Na[^{18}F]F fetal dose by stage of pregnancy.*

Radiopharmaceutical	Early(< 3months) mGy MBq^{-1}	3 months mGy MBq^{-1}	6 months mGy MBq^{-1}	9 months mGy MBq^{-1}
2-[^{18}F]FDG †	2.3×10^{-2}	2.2×10^{-2}	1.7×10^{-2}	1.7×10^{-2}
Na[^{18}F]F	2.2×10^{-2}	1.7×10^{-2}	7.5×10^{-3}	6.8×10^{-3}

*Adapted from Stabin (2017)

†Dose contributions from mother and fetal self-absorption

6.8. Carers/Comforters

(293) For the performance of a PET/CT study, patients might be accompanied by carers and comforters, meaning individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure (Council of The European Union, 2013). This definition, in terms of a PET/CT, applies to different sorts of persons: regarding children, mainly their parents or other family members, as well as tutors and other caregivers; and for vulnerable adult patients, with autonomy or not, relatives, close friends, caregivers or simple institutional volunteers may fall into these categories of individuals. Also, considering procedures with radiopharmaceuticals, carers and comforters concern care to patients either in-hospital or at home, following a procedure with ionising radiation.

(294) In terms of radiological protection and safety, exposure incurred by carers and comforters is a medical exposure, and dose constraints are applicable and should be established by the national regulator (Council of The European Union, 2013; ICRP, 2008b). *Publications 103* and *105* recommend a dose constraint of 5 mSv per occurrence for carers and comforters (ICRP, 2007b; ICRP, 2008b).

(295) These dose constraints should be defined mainly to establish protection policies for the carers and comforters (ICRP, 2008b), but the main issue is that, as any other medical exposure, before it is undertaken, there is a need to evaluate the specific situation and show that here is a sufficient net benefit in the involvement of the comforter or carer, taking into account the direct health benefits to a patient, the possible benefits to the carer/comforter and the detriment that the exposure might cause (Gill, 2000; Council of The European Union, 2013).

(296) Not many studies are available to clarify the level of exposure that carers and comforters are submitted to when accompanying a patient performing a PET study. At the

EANM Congress in 2019, Kalogianni E. et al. presented a work to quantify the radiation exposure to carers and comforters from adult patients undergoing a 2-[^{18}F]FDG-PET/CT study. They have evaluated 23 patients [median age 62 (30–93) years] undergoing a 2-[^{18}F]FDG-PET/CT scan, randomly selected. The median injected activity was 342 (224–425) MBq. All patients had equivalent dose rate measurements recorded at 1 m and 10 patients had additional equivalent dose rate measurements recorded at 0.5 m and 0.1 m from the mid abdomen. The median cumulative dose received during a median resting period of 51 (43–61) min, measured at 1 m, 0.5 m, and 0.1 m was 20 (12–39) μSv, 76 (34–201) μSv, and 234 (167–301) μSv, respectively. The 95th percentile for these measurements were 33 μSv, 152 μSv, and 286 μSv, respectively. These authors concluded that their work confirmed that carer and comforter radiation exposure levels from 2-[^{18}F]FDG-PET/CT examinations practice are acceptably low (Kalogianni, 2019) and within dose constraints recommended by ICRP Publications (ICRP, 2007b; ICRP, 2008b).

(297) Although seemingly low the radiation exposure a carer or comforter, when accompanying the performance of a PET examination, is subject to radiological protection principles of justification and optimisation have to be applied. As such, not only a clear net benefit for both the patient and the accompanying person should be demonstrated, as well as there should always be a conjoint effort between health professionals, patient, carer and comforter, to find the best solution and practices. For example, if a child is comfortable when accompanied by an older patient such as a grandparent, instead of the younger parent, this should be decided.

(298) Finally, nuclear medicine and imaging departments should prepare and provide carers and comforters with guidance, preferably written and standardised, on how to act and reduce the exposure in the course of their caregiving activities (Council of The European Union, 2013).

6.9. Research volunteers

(299) Investigations involving radiation exposure of humans are an important part of biomedical research. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects (WMA, 2018). *Publication 62* has provided a well-designed guidance on radiological protection of patients or healthy volunteers participating in research (ICRP, 1992).

(300) Before the project is started, its aims, outline, methods, justification (benefit vs risk evaluation) and detailed plans should be evaluated by an independent body, referred to as the 'Ethics Committee'. The Ethics Committee should be formally independent of the individual investigators proposing the project. It is necessary to explain why the investigation is needed, the benefit that will result if it is successful, the extent to which that benefit is to the volunteer or to society at large, the type of benefit, e.g. potentially life-saving, reducing disease and suffering or increasing knowledge that will give rise to other benefits. On the other hand, the investigator must present an assessment of the likely harm to the volunteers from the investigation, based primarily on the best quantification of doses available, but modified to take account of any particular characteristics of the group of volunteers that might affect the risk resulting from the radiation, e.g. their age, sex, and state of health.

(301) The risks and likely benefits of the proposed research should be explained to volunteers in advance. Then a free will informed consent should be obtained from volunteers. Informed consent includes three key components: (1) that human subjects are informed in such a way that they understand the risks and benefits of participating in radiation research; (2) that the decision to participate in such research is not because of controlling influences;

and (3) that their consent is voluntary. The subject has the right to accept the risk voluntarily and has an equal right to refuse to accept. Some demographic groups are considered to be vulnerable populations, who are particularly at risk for coercion or undue influence in a research setting. These groups include children, wards of the state, prisoners, pregnant women, persons who are intellectually disabled or otherwise cognitively impaired, and economically or educationally disadvantaged persons. Voluntary accepting or refusing investigations is difficult to carry out on groups such as on children or those who are intellectually ill or defective, as they cannot give free and informed consent. In exceptional circumstances, such as when proposed investigations are likely to benefit children or persons with intellectual disabilities and the risks are sufficiently small, those responsible for such individuals might be able to agree to their participation. This might also apply for example when the proposed societal benefit of the investigation is obviously advantageous and substantially exceeds the risk.

(302) Pregnant women should not be asked to take part in research projects involving irradiation of the fetus unless the pregnancy itself is central to the research, and then only if other techniques involving less risk cannot be used. The proposed benefit of the study should be clear and substantially exceed the possible detriment. In this case the full and informed consent of the pregnant patient must be obtained and it would usually be appropriate to seek the same from the father. In some investigations it would be prudent to consider the possibility that a woman may be pregnant but not know it. If so, the protocol involved in the investigation should recognise this possibility.

(303) If the subject is in a position of obligation towards the investigators, for example as an employee, a student or even a patient, or can expect some non-health benefit such as promotion, special privileges or payment, a difficult situation arises. It is particularly important in such circumstances that consent should not be influenced unduly and should be given as freely as possible.

(304) The principal investigator (PI) or sponsor involved in human-studies research involving ionising radiation should have a working knowledge of the basic concepts of radiation exposure, absorbed dose, and effective dose (E) or should consult with a knowledgeable medical physicist or radiological or radiation therapy professional. Research including PET, PET/CT or PET/MRI scans is generally within a range of minor to low doses of radiation (E = 3–50 mSv) (NCRP, 2020). But some studies including repeated PET, PET/CT, or PET/MRI scans can be in the range of low dose (E = 50–100 mSv). Although scientists are not certain about the actual cancer risk at these doses, the amount of radiation involved in this research may slightly increase the risk of getting cancer later in life. Dose limits do not apply to medical research participants, although a dose constraint needs to be considered for 'healthy volunteers'. Optimisation requires that the dose should be kept as low as reasonably achievable. Research and development of new radiopharmaceuticals must be supplemented by animal experiments to estimated radiation dose to volunteers. Efforts should be made to avoid research subjects participating in multiple research studies (with monetary benefit in mind) to avoid excessive radiation exposures.

7. RADIOLOGICAL PROTECTION FOR THE PUBLIC

(305) Key points in this section:

- Patients undergoing diagnostic PET radiopharmaceutical studies generally do not pose a significant radiation risk to the public.
- Radiological protection measures such as administered activity, distance, time, shielding, facility design, and restricted access need to be considered to protect other patients, non-radiation workers, and the general public during the PET radiopharmaceutical uptake period and during PET/CT imaging.

7.1. Background

(306) Public radiation exposure includes exposed members of the general public, workers who are not designated as nuclear or radiation workers, and unintentional patient-to-patient exposure after PET radiopharmaceutical administration. Public radiation exposure excludes occupational, medical (i.e. to the intended patient), designated caregiver and natural background exposures. Please see Section 6 regarding radiological protection of breast-fed infants from women who have had a recent PET study as well as a discussion on PET procedures during pregnancy.

(307) Public dose limits are based on the sum of internal and external exposures from sources related to practices that are justified. The recommended annual public dose limits are: effective dose -1 mSv, lens of eye dose - 15 mSv, and skin dose - 50 mSv (ICRP, 2007b).

(308) Apart from the basic radiological protection practices, such as, maintaining distance from the patient, reducing the time spent in close contact with the patient, and using appropriate shielding whenever practicable, the radiation dose reduction to members of the public is achieved through a reduction in the patient activity which is due to physical radioactive decay, which is in the range of minutes to a few hours for the most used PET radiopharmaceuticals, and biological elimination (i.e. by renal excretion for 2-[^{18}F]FDG). Specific biokinetics for 2-[^{18}F]FDG, the most used PET radiopharmaceutical, are provided in *Publication 128* (ICRP, 2015a).

(309) Taking this into consideration practical ways to reduce external dose rates from patients injected with 2-[^{18}F]FDG include:

- Consultation with the appropriate regulatory jurisdiction on nuclear medicine relative to PET/CT facility construction and site design guidelines. These guidelines should include recommendations on how to reduce public and occupational dose via the specifications of the facility design (e.g. optimal layout for work flows, plumbing, shielding, etc.) (CNSC, 2010; IAEA, 2018) (see Section 3).
- Adequate combinations of distance from, and shielding of, injection/uptake rooms.
- Limit access to the injection/uptake areas to essential staff and patients i.e. no general public access including those accompanying patient (e.g. family, friends, non-health care worker caregivers) unless there are compelling circumstances.
- Dedicated 'hot patient' toilets with shielding from public areas (e.g. waiting room, adjacent offices etc.)
- 2-[^{18}F]FDG dosing by weight or body mass index (BMI), adequate hydration and adopting PET/CT technologies and image processing software/hardware which produce clinically adequate images with lower injected doses, which will result in a

lower patient dose and a lower external dose from the patient to others, including the general public, after the procedure (Segall et al., 2010; Boellaard et al., 2015).

7.2. General recommendation on radiation dose to the general public

(310) In general, radiation dose rates are sufficiently low post imaging in 2-[^{18}F]FDG injected patients that they do not pose a radiation risk to those around them. For example, Quinn et al. (2012) estimated a patient post injection ^{18}F dose rate constant of 0.092 μSv m^2 MBq^{-1} h^{-1} which can be scaled for decay and distances beyond a meter in distance. Taking this dose rate constant into account public dose limits will not be exceeded. No specific post imaging restrictive advice is recommended regarding taking public transit or close contact with the general public, children or pregnant women. More specifically, 'holding' the patient post imaging in a separate waiting area to allow for further dose rate reduction post 2-[^{18}F]FDG PET/CT imaging is not necessary and is not recommended.

(311) The general advice is not to bring children, especially young children, and by extension pregnant women, to the imaging centre and for family/caregivers to wait in the waiting room during patient uptake and imaging (Cronin et al., 1999; Bartlett, 2013).

(312) Use of unconventional or novel PET radiotracers, which may have longer half-lives and more complex decay schemes, may require additional external dose rate radiation safety considerations to reduce doses to the public (Williamson and Dauer, 2014). Normally this would be accommodated by lower administered activities but still needs to be considered especially in basic, applied and clinical research settings. For example, Williamson and Dauer (2014) advises that radiation safety instructions are required when patient ^{124}I activities are above 160 MBq.

7.3. Radiation dose to non-radiation workers

(313) Given the relatively short half-lives and biological elimination, radiation dose rates from 2-[^{18}F]FDG injected patients are generally low post uptake period and imaging. However, it could be appropriate to decide upon dose constraints that non-radiation workers should not exceed during a year, relating to the annual dose limits. Patients may be returned to the ward or go on to other diagnostic testing requiring close contact (e.g. ultrasound). Bartlett (2013) published expected dose rates to other health care workers post 2-[^{18}F]FDG PET imaging. The highest dose was to intimate patient contact settings such as intensive care units with the assumption of one-on-one nursing care for 8 hours for a post 2-[^{18}F]FDG injected patient. Even in this setting the estimated staff dose was only 77 µSv per patient, well below the 1 mSv threshold for non-radiation workers noting that jurisdictions may set lower dose constraints. If intensive care unit (ICU) staff routinely manage post 2-[^{18}F]FDG injected patients, a cumulative dose assessment should be performed to reduce dose and implement procedures (e.g. staff rotation) in line with ALARA.

(314) Griff et al. (2000) and Earl et al. (2018) published radiation doses from 2-[^{18}F]FDG injected patients to ultrasound sonographers, these are generally not classified as nuclear or radiation workers. Taking into consideration that it would be at least 2 hours post injection for an 2-[^{18}F]FDG injected patient to receive an ultrasound study, radiation doses to sonographers are low and well below public dose limits. Earl et al. (2018) estimated a sonographer dose of 19 µSv for a 30-minute ultrasound scan. In keeping with the ALARA principle, and when there are otherwise no compelling clinical reasons, it is recommended to

schedule ultrasound exams first and PET scans thereafter, if there are sequential PET and ultrasound exams ordered on the same day, for the same patient.

(315) Cronin et al. (1999) concluded that even for the highest exposure scenario, i.e. oncology ward nurses caring for patients undergoing 2-[^{18}F]FDG PET scans, it is unlikely that any nurse would receive more than 24 µSv day^{-1} and it is unlikely they would receive this dose every day at work. In the unlikely scenario where nurses worked daily with post 2-[^{18}F]FDG injected patients, dose estimates would be helpful to mitigate dose via strategies such as staff rotation.

7.4. Patient to patient dose

(316) The layout and shielding between PET radiopharmaceutical injection/uptake rooms needs to be considered to reduce patient to patient dose as low as reasonably achievable. This is noting that an unshielded exposure for one hour at one metre from an injected patient would result in a low dose in the range of 50 to 60 µSv (e.g. 2-[^{18}F]FDG dose of 400 MBq and a gamma ray effective dose rate 1 m, of 1.398×10^{-4} mSv h^{-1} MBq^{-1}) or lower when taking decay into account (CNSC, 2018) (see Table 3.1).

8. OPTIMISATION FOR STAFF

(317) Key points in this section:

- Radiation sources in a PET/CT or PET/MR installation include the cyclotron, the PET radionuclide generators, the radiopharmaceutical, the CT scanner, sealed sources used for calibration and quality control, patients themselves, and radioactive waste; producing the possibility of exposure to the nuclear medicine staff due to irradiation, and external and internal contamination.
- The dose to staff in a PET/CT or PET/MR facility can be optimised by applying basic radiological protection practices, such as, maintaining distance from the radiation source or patient, performing operations in the shortest possible time, and using appropriate shielding whenever practicable.
- Dosing schedules for patients which lower administered activity will reduce staff exposure.
- The optimisation of the working practice and the application of shielding for the vial and syringe are the most important factors in reducing the magnitude of doses to the fingers. Patient preparation and co-operation are important factors in minimising of contact time and in increasing the distance between patient and staff member.
- The most important factor that has decreased staff exposure is the use of automatic dispensing and infusion systems.
- Whole-body monitoring should be carried out based on monthly measurements, and an $H_p(10)$ measurement from a dosimeter worn on the upper body will also provide an approximate indication of dose to the eye lens.
- Dose distribution across the hands varies between individuals, depending on technique and the use of shields, but the most exposed area of the hand is usually the tip of the index finger of the non-dominant hand.
- Monitoring extremity doses with ring dosimeters is recommended. It is important to have an indication of the maximum dose over the two hands, and measurements on both hands, with trials using finger stall dosimeters, and subsequent application of correction factors are recommended to achieve this.
- An individual monitoring program for internal contamination should be decided based on risk assessment.

8.1. Sources

(318) In a PET/CT or PET/MR facility, apart from the patients and members of the public accompanying the patient, some staff can have a significant radiation exposure. Staff includes physicians, nuclear medicine technologists/radiographers in nuclear medicine/CT or MR, technologists in laboratory areas, nurses, chemists, and physicists, engineers, receptionists, maintenance staff, managers, cleaning staff. The activities performed are varied and include:

- Activities related to radiopharmaceutical production, including cyclotron operation and maintenance, quality control and dispensing.
- Activities in the PET/CT or PET/MR imaging area related to patient, including radiopharmaceutical preparation and administration to the patient, escorting of the

patient, positioning of the patient on the scanner bed, patient imaging, and removing the patient from the bed.

(319) Radiation sources in a PET/CT or PET/MR facility can include the cyclotron, the PET radionuclide generators (^{68}Ge/^{68}Ga, ^{82}Sr/^{82}Rb, and ^{62}Zn/^{62}Cu), the radiopharmaceutical produced, the CT, the sealed sources used for calibration and quality control, patients themselves, and radioactive waste. Because the facility infrastructure, the protocols and the groups of personnel that carry out different activities can vary widely between facilities, the impact of radiation sources on the exposure of staff is reviewed in this section according to the different activities in a PET/CT or PET/MR facility. Annual occupational doses should be considered in conjunction with similar activities in a nuclear medicine facility, like gamma camera, SPECT, and SPECT/CT diagnostic procedures.

(320) The ICRP recommended dose limits are:

- Effective dose limit of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year,
- an equivalent dose limit to the extremities (hands and feet) or the skin of 500 mSv in a year. The equivalent dose limits for the skin applies to the average dose over 1 cm^2 of the most highly irradiated area of the skin,
- an equivalent dose limit to the lens of the eye of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year.

(321) *Publication 147* on 'Use of dose quantities in radiological protection' (ICRP, 2021) presents a proposed change in operational quantities which is expected to be introduced after the next set of general ICRP recommendations. In this scheme, the personal dose equivalent $H_p(0.07)$ to the skin will be changed as the operational quantity to the personal absorbed dose in local skin D_p(local skin). This new operational quantity would be expressed in Gy, and no longer in Sv. This proposed change will help avoid confusion between doses used to control tissue reactions (in Gy) and whole-body effective doses relating to stochastic effects (in Sv). However, in this report $H_p(0.07)$ expressed in Sv is used as the current quantity used in measurements and reported in the literature.

(322) Radiation sources produce risks of exposure to nuclear medicine staff due to irradiation and contamination. Personal dose equivalents $H_p(0.07)$ and $H_p(10)$ have been reported for different scenarios, including point sources, a uniform planar source resembling a contaminated surface, and several source volumes contained in plastic or glass receptacles (Delacroix et al., 2002; Amato et al., 2018). To evaluate internal contamination, effective dose coefficients for inhalation and ingestion have been provided by ICRP (ICRP, 2015b, 2016, 2017b, 2019, 2022).

8.1.1. Risk of exposure due to contamination

8.1.1.1. External contamination

(323) The use of routine hygienic measures such as wearing gloves and protective clothing, limits skin contamination. Nevertheless, contamination can often not be completely avoided in the case of accidental spills or cross-contamination. The best way to limit cross-contamination is to frequently measure contamination during and after a manipulation by means of contamination monitors, including exit monitoring for staff, which should be available in any location where unsealed sources or contaminated components are handled.

Proper detector location should consider any background source that could interfere the measurement. It is important that contamination monitors are properly calibrated.

(324) Almost half of the incidents reported in nuclear medicine involve contamination (Martin, 2005). In 23 % of the incidents, skin or clothing of a person handling the radiopharmaceutical became contaminated and up to 26 % of the incidents resulted from spill of radioactive material.

(325) Contact exposure due to external skin contamination depends on the activity distribution. Dose rates produced by a skin contamination due to a 1 kBq 0.05 mL droplet and a uniform deposit of 1 kBq.cm^{-2} for positron emission radionuclides are presented in Table 8.1, including their main emissions.

(326) The contributions due to positron radiation and photons to $H_p(0.07)$ and $H_p(10)$ for distances of 10 cm and 1 m from an infinitely and uniformly contaminated surface are presented in Table 8.2 for ^{18}F and ^{68}Ga, that have the lowest and highest maximum energy of the positrons in table 8.1. Total absorption thicknesses for positrons are included and should be considered to reduce $H_p(0.07)$. For photons, dose rates at 10 cm and 1 m are similar because the increased distance is compensated by the increased solid angle. The $H_p(0.07)$ produced by the positrons is higher for ^{68}Ga than for ^{18}F, showing their higher penetration power (Delacroix et al., 2002).

Table 8.1. Personal dose equivalent $H_p(0.07)$ values due to contaminations for different positron emitters (Delacroix et al., 2002).

Radio-nuclide	Half life	Photon Emission		Positron emission		$H_p(0.07)$ (mSv/h)	
		Energy (keV)	Probability (%)	Energy max (keV)	Probability (%)	Uniform deposit (1 kBq/cm^2)	0.05 ml droplet (1 kBq)
^{11}C	20.4 min	511	200	960	100	1.95	1.12
^{13}N	9.97 min	511	200	1199	100	1.90	1.2
^{15}O	2.04 min	511	200	1732	100	2.00	1.4
^{18}F	1.83 h	511	194	634	97	1.95	0.788
^{68}Ga	1.13 h	511	178	822	1	1.81	1.25
		1077	3	1899	88		

Table 8.2. Exposures (mSv h^{-1}) due to an infinite surface uniformly contaminated with 1 MBq cm^{-2} and total absorption thicknesses for positrons (Delacroix et al., 2002).

Parameter	Radiation	Distance	^{18}F	^{68}Ga
$H_p(0.07)$	Positrons	10 cm	9.6×10^{-2}	1.2×10^{-1}
		1 m	5.3×10^{-4}	4.5×10^{-2}
$H_p(0.07)$	Photons	10 cm	6.8×10^{-3}	6.5×10^{-3}
		1 m	4.3×10^{-3}	4.1×10^{-3}
$H_p(10)$	Photons	10 cm	6.4×10^{-3}	6.2×10^{-3}
		1 m	4.1×10^{-3}	3.9×10^{-3}
Total absorption	Positrons	Glass (mm)	0.9	3.9
		Plastic (mm)	1.7	7.2

(327) The superficial contamination of the skin by a ^{68}Ga droplet will produce a dose rate 60% higher than a ^{18}F droplet, illustrating the contribution of the higher maximum energy of the positron. The localised skin dose rate produced by a ^{18}F droplet of 3.7 MBq is 49 mSv min^{-1}, while a uniform deposit of the same ^{18}F activity in a 5×5 cm^2 square will give 4.8 mSv

min^{-1}. If a full decontamination is carried out 10 minutes after the incident, the cumulated $H_p(0.07)$ values would be 471 mSv at the location of the droplet or 47 mSv over the 25 cm^2 area, respectively. Due to the short range of the ^{18}F positrons, laboratory gloves can provide a high reduction in the dose rate produced by a droplet.

(328) The influence of contamination area, epidermal thickness, and percutaneous absorption on skin dose rate conversion factors after contamination with radiopharmaceuticals has been reported (Covens et al., 2013). When doses approach the recommended skin dose limit, the influence of the epidermal thickness and the percutaneous absorption make it necessary to do a proper evaluation of the equivalent skin doses.

(329) During the period 2007–2013, one of the most significant events notified to the French Nuclear Safety Authority in nuclear medicine, was due to contamination with ^{18}F, which led to an equivalent dose to the extremities of 320 mSv (Rousse et al., 2014). During a 10 months survey that included 560 inspections, contamination of the skin was detected in 40 (7%) cases (thirty-three ^{99m}Tc-labelled radiopharmaceuticals, seven 2-[^{18}F]FDG) (Covens et al., 2012). The majority of the contaminations found were highly localised spots on the palm of the hand, rather than uniform deposits. They were mostly located at the tip of the index finger of the nondominant hand (67% of the cases). Skin doses to nuclear medicine technologists due to ^{18}F contamination varied from approximately 0.02 to 20 mSv. Considering the incidence rate and the calculated skin doses, skin contaminations can contribute substantially to the total extremity dose of nuclear medicine technologists (Covens et al., 2012). Furthermore, the skin dose limit of 500 mSv y^{-1} can easily be exceeded as a result of the poor efficacy of decontamination and the electron dose contribution at shallow depths (Covens et al., 2013).

(330) If the quantification of the contamination occurs shortly after the event and the first decontamination, the retrospective calculation of the initial activity is not required (Covens et al., 2012). In this case the order of magnitude of the cumulated skin dose can be estimated as:

$$H_p(0.07) = 3.42 \text{ mSv kBq}^{-1} \times A_D$$

where A_D is the remaining ^{18}F activity spread over 1 cm^2 after the first decontamination (kBq) Therefore, the skin dose limit would be exceeded if more than 146 kBq remained on the skin.

(331) An accidental ^{18}F contamination has been reported in a person during a routine cyclotron maintenance procedure (Kairemo, et al. 2016). The accident occurred during target replacement, when liquid ^{18}F was spilled. Quantitative gamma imaging of two separate spots was performed with a gamma camera, with doses around 1.7 mSv.

8.1.1.2. Internal contamination

(332) For workers, the most frequent route of internal intake is inhalation. Intakes by ingestion are not usually expected, since eating or drinking in controlled areas in workplaces is not permitted and inadvertent ingestion is limited by the use of personal protective equipment. However, when contamination levels in the workplace environment are significant, ingestion may occur as a result of contamination of the mouth or lips, or transfer to the mouth from the hands (EC, 2018).

(333) During the maintenance operations on PET cyclotrons there is a possibility of internal contamination, due to the inhalation of dust particles produced by interaction of the beam with internal components of the cyclotron and during the mechanical operations of rebuilding the ion source, adjusting or replacing the collimators, and cleaning and rebuilding the ^{18}F target (Terranova et al., 2011).

(334) During maintenance operations within the vacuum chamber, care is needed in minimising the possibility of contamination. Residues and powders coming from all the components previously reported could be present, and the possibility of inhalation cannot be excluded. All maintenance operations should be carried out bearing this in mind; operators should wear proper protective clothes, gloves, and a face mask. A point that requires attention is cleaning of the ion source, when this is internal to the cyclotron. The body of the ion source, typically made of brass, needs to be scrubbed to remove residues. During these mechanical operations powders are produced, that present a potential hazard from inhalation. The deposits on the ion source body come from tantalum, the main component of the cathodes, and contain ^{182}Ta, due to the (n, γ) reactions in ^{181}Ta, induced by the secondary neutrons. The ion source can be disengaged and cleaned in a laboratory area, within a vented hood (Calandrino et al., 2010; Terranova et al., 2011).

(335) The potential contaminants that could be of concern for operating personnel during cyclotron maintenance because they might be found in the metallic particulate are (Calandrino, et al. 2010):

- High probability of intake: ^{97}Tc, ^{56}Co, ^{57}Co, ^{58}Co, ^{60}Co, ^{49}V, ^{48}V, ^{52}Mn, ^{55}Fe
- Low–medium probability of intake:^{109}Cd, ^{65}Zn, and ^{22}Na

(336) According to the methodology proposed by IAEA (IAEA, 1999), a decision factor (D) is evaluated with the aim to identify those working conditions for which the committed dose to any operator is <1 mSv y^{-1}:

$$D = \frac{\sum_{j=1}^{P}\sum_{i=1}^{N} A_{i,j}\ e(g)_{i,inh}\ f_{fs}\ f_{hs}\ f_{ps}}{0.001}$$

where $A_{i,j}$ is the cumulative activity (Bq) handled annually by the worker, for the i-th radionuclide in the j-th operation, $e(g)_{i,\,inh}$ is the dose coefficient (Sv Bq^{-1}) for inhalation of radionuclide i, P is the number of operations performed yearly by the worker, N is the number of radionuclides managed, and f_{fs}, f_{hs}, and f_{ps} are the physical form safety factor, handling safety factor and the protection safety factor, respectively. Terranova et al. (2011) found that the decision factor both for the hospital staff, performing simple routine operational maintenance, and for field engineers of the cyclotron service was <1, meaning that for their facility an individual monitoring program was not mandated. In order to have a fast 'yes or no' screening for internal contamination, they conceived a simplified technique of whole body counting using a portable NaI(Tl) spectrometer. In a period of 17 months, five operators were checked with a total of 22 acquisitions, and no internal contamination was observed.

(337) A programme of internal contamination monitoring was established to monitor the risk for the maintenance staff due to intake of activated elements in a hospital with two cyclotrons. 30 to 40 interventions were done yearly, including both preventive and emergency interventions, and involving two to four technicians at a time. Every 6 months, three to four operators were sent to the whole-body counter. Data from 19 individual measurements showed only one case of internal contamination, due to long-lived radioisotopes, measuring a total body activity of 286 Bq of ^{65}Zn. In a few cases, a very low level of contamination was also observed, likely attributable to gaseous ^{18}F inhaled by the operators involved in the early morning preparation of 2-[^{18}F]FDG (Calandrino, et al. 2010).

(338) In a study investigating the incorporation risk during all stages of the process through which a typical PET radiopharmaceutical passes from its production to the final administration, involving 20 workers, 79 whole body measurements were performed

(Eschner, et al. 2000). 38 cases were above the detection limit (50 Bq), and estimated yearly effective doses exceeded 50 μSv in only 10 of 79 cases and they were lower than 1500 μSv; 7 cases were during ^{124}I tracer development, 2 taking care of scanner quality control and cleaning the rooms in the control area, and one was an incident during production syntheses. Eschner et al. conclude that internal exposure from routine procedures in a PET centre is rather low and that the measured whole-body activities, and conservatively estimated resulting doses, do not warrant the necessity of incorporation monitoring on a regular basis.

(339) Inhalation of airborne activity can produce internal contamination. When it was measured with a gas flow proportional counter, airborne activity did not increase significantly over background during routine radiosynthesis. However, a significant increase in ^{15}O concentration was recorded in the scanner room during the [^{15}O]CO administration and patient acquisition (Calandrino et al., 2010).

8.1.2. Staff irradiation during patient management

(340) Unshielded sources and patients are the major irradiation sources for staff working in the PET/CT or PET/MR imaging areas. The dose rate constant for ^{18}F is 0.143 (μSv m^2 h^{-1} MBq^{-1}) (Madsen et al., 2006). Dose rates from patients at various distances and times after 2-[^{18}F]FDG administration are given in Table 8.3. Doses rates range from 2.25 μSv h^{-1}MBq^{-1} at 0.1 m from the patient immediately after administration down to 0.05 μSv h^{-1} MBq^{-1} at 1 m after the PET imaging.

(341) Dependence of the dose rates at various body positions and at different distances from the patient has been studied (Chiesa et al., 1997; Benatar et al., 2000). Differences in measured dose rates at different positions around the patient could be attributed to the difference in 2-[^{18}F]FDG distribution, but measurement conditions such as patient positioning and scatter from the bed, floor and ceiling should also be considered. The dose rates measured at the head are higher than at the feet (Benatar et al., 2000), as the mean percent of injected activity to the brain is 3.9% at 33 min after 2-[^{18}F]FDG administration (Jones et al., 1982).

Table 8.3. Mean dose rates (μSv h^{-1} MBq^{-1}) at various distances from the patient at different time points.

Time after injection (min)	0.10 m	0.25 m	0.50 m	1 m	2 m	Reference
50				0.04		Chiesa et al., 1997[§]
120	0.31		0.12	0.047	0.017	Cronin et al., 1999[¶]
After injection	1.28		0.41	0.15	0.06	Benatar et al., 2000[†]
1	1.58	1.29	0.86	0.33	0.12	
62±8	1.07	0.74	0.47	0.17	0.05	Demir et al., 2011[‡]
117±11	0.62	0.39	0.25	0.09	0.03	
After injection	2.25[*]		0.33	0.11	0.05	Pant and
After imaging	0.88[*]		0.15	0.05	0.02	Senthamizhchelvan, 2006[†]

[*]at 0 m.
[†]from the anterior chest.
[‡]distance to thorax plane.
[§]from the abdomen.
[¶]from the mid thorax.

8.1.2.1. Whole-body dose

(342) The dose received by staff depends on the time spent in close contact with the radioactive sources and the patients and varies among the different facilities. Durations of the various steps reported in several studies are given in Table 8.4, and the total time for the operations is between 6 and 12 min (Guillet et al., 2005, Seierstad et al., 2007).

(343) Depending on the facility design, radiopharmaceuticals can be received in single or multiple administration packaging. Subsequently, there is a range of tasks that will be performed. These include: receipt of the containers, measurement of the total activity of the vial, drawing up the activity in a syringe, moving the syringe from the dispensing unit to the administration room, injection of the radiopharmaceutical dose, attending to the patient during the bio-distribution period before the scan, escorting the patient to the PET scanning room, positioning of the patient on the scanner bed, patient imaging, removing the patient from the bed, and escorting the patient from the department.

(344) Although procedures vary from site to site, an indication of whole-body doses received by the staff performing different tasks can be obtained from Table 8.5, which collates reports from various publications. Different distributions of dose have been reported for each phase of the examinations and are summarised in Table 8.6.

Table 8.4. Time (minutes) per different steps during the PET procedure.

	Demir et al., 2010	Guillet et al., 2005	Kumar et al., 2012
Radioactivity preparation	1.8	2.1–2.3	-
Radioactivity administration	0.8	1.8	1.0
Escorting the patients to the PET room	1.3	] 2.6	-
Positioning within the camera	1.6		-
Escorting the patient out of the department	2.0		-

Table 8.5. $H_p(10)$ received by a technologist during different tasks. Values are mean dose ±SD per examination (μSv).

	Chiesa et al., 1997	Guillet et al., 2005	Demir et al., 2010	Al-Aamria, et al. 2019
Activity (MBq)	500	345	518	298
Receipt of the containers	-	0.3±0.4	-	-
Fractioning/preparation	0.3±0.1	0.1±0.1	1.2±0.6	-
Placement of activity into a injector	-	0.8±0.9	-	0.3±0.2
Removing the IV line and interacting with patient after the scan	-	-	-	1.0±0.01
Injection	2.8±1.8	1.1±1.6	0.9±0.6	0.8 ±0.6
WB emission	1.7±1.5	0.7±1.1	-	
Escorting to the scanner	-	-	2.3±0.6	] 1.7±0.1
Positioning within the camera	-	-	1.7±1.2	
Patient leaving	0.8±0.2	-	1.5±0.4	1.4±0.7
Total	5.9±1.2	3.2±2.1	7.6±0.7	5.2

Table 8.6. Percentage contribution of the different tasks to the $H_p(10)$ dose.

Task	Seierstad et al., 2007 Mean (Median)	Peet et al., 2012 Mean
Dispensing		9%
Collecting radionuclide	34 (33)%	
Preparation for injection	5 (0)%	
Injection of the radionuclide	25 (23)%	32%
Removing the canula		9%
Setting up patient in bed / Scanning	23 (25)%	18%
Removing the patient / Discharging the patient	9 (9)%	14%
Other handling of the patient / Others	4 (0)%	12%
Escorting to the hot toilet		6%

(345) Values reported for whole-body staff doses from PET examinations are presented in Table 8.7. As the administered activity covers a wide range (250 to 500 MBq), the normalised dose per injected activity to the patient is also provided. The variation of this normalised dose (nSv MBq^{-1}) reflects the different procedures and radiological protection measures followed in each PET facility, providing valuable information on how local practice can affect the degree of staff exposure. With regard to the whole process (drawing up, injection and patient management), mean dose per study ranges between 3 and 14 μSv, with normalised doses from 5 to 39 nSv MBq^{-1}. These wide ranges reflect differences in methodologies. Note that in some cases, staff can receive relatively high doses in spite of the use of good shielding (2.5 cm lead shielded holder for transporting a syringe and 5 cm lead pig for dose injecting) and this has been attributed to prolonged periods of time near the patient (Marti-Climent and Peñuelas, 2002).

(346) Most PET/CT examinations are analysed using the standard uptake value (SUV), a semi-quantitative parameter. Quantitative PET studies generally involve dynamic image data acquisition and may also require that blood sampling is carried out. McCormik and Miklos (1993) showed that, when conducting quantitative PET studies, doses received by the technologists are higher than when conducting qualitative scans (37 and 14 μSv, respectively), because the technologist stands next to the patient's torso during arterial sampling for 5 to 10 minutes. The authors report an average dose of 14.2 μSv per patient for the blood sampling task. Typical administered activities for PET studies were 370 and 3700 MBq for 2-[^{18}F]FDG and ^{15}O-water. The authors also measured an average whole-body dose of 10 μSv while carrying out blood pressure measurement.

(347) The use of radiopharmaceuticals like [^{18}F]-fluorothymidine (FLT) and [^{18}F]fluoromethylcholine (FCH), among others, can require new techniques of imaging, with the injection inside the PET/CT room and a dynamic acquisition protocol. The impact of the introduction of these radiopharmaceuticals on whole body doses has been studied, showing a 10% increase in nurses' doses, due to the longer time they spent near the patient in the dynamic protocol, and 15–21% increase for technologists, since they come near the patient immediately after administration (Dalianis et al. 2015).

(348) Different diuretic protocols can be used to lower bladder 2-[^{18}F]FDG activity and potentially improve image quality by reducing bladder activity artefacts and avoid invasive bladder catheterisation (Nijjar et al., 2010). However, when urinary catheters are used for assessment of pelvic disease in selected oncology patients, normal saline is used to flush the bladder via a connection in the catheter tubing. Flushing the catheter periodically throughout

scanning, to ensure the remaining urine in the bladder is diluted and the bag drained, resulted in a dose to the technologist of 0.8 μSv per procedure (Roberts et al., 2005).

(349) When 2-[^{18}F]FDG PET/CT is used for radiotherapy planning, positioning of the patient on the scanner bed should correspond to the position of the patient in the accelerator bed during the therapy, using the same fixation tools and therefore a strict control, which can add a considerable dose to the staff. Since the most time-consuming part of the process is the initial preparation of the patient in the scanner, if this is carried out before the patient receives the 2-[18F]FDG injection (as "cold preparation session"), it is estimated that the radiation doses received by radiotherapy radiographers are reduced by approximately three times (14.1 mSv versus 5.1 mSv) (Carson, 2009).

(350) During PET/CT guided biopsy of ^{68}Ga avid lesions using an automated robotic arm, 2 to 3 hours after injection of 111–185 MBq of ^{68}Ga labelled radiotracer (DOTANOC, PSMA, or chemokine analogue), the mean radiation exposure from the PET tracer to the interventionist during the molecular biopsy was 1.13 μSv per procedure, with an estimated annual whole-body dose of 0.57 mSv (Kumar et al., 2020).

(351) Occupational radiation exposure from myocardial perfusion imaging (MPI) with ^{82}Rb PET, that comprises rest and stress scans performed in a single session, has been evaluated. The generator, placed on a cart next to the scanner, delivers precalibrated doses via an intravenous line. PET scan starts 60–120 seconds after. Mean $H_p(10)$ dose to all staff members for combined rest and stress administration and imaging varied from 0.4±0.4 μSv (Tout et al., 2014) to 0.9 μSv (Schleipman et al., 2006). Mean administered activity was 1110 and 1587 MBq for the separate scans, respectively. This higher dose may be attributed to the higher administered activities and to the procedure, since personnel move behind a mobile shield in the scanning room during ^{82}Rb infusion and acquisition instead of moving to the control room. The mean $H_p(10)$ for monthly ^{82}Sr/^{82}Rb generator change was 6 μSv and for daily generator QC was 1.2 μSv. In the event of a medical emergency, the patient may require extended close contact with the staff after ^{82}Rb infusion. The $H_p(10)$ readings for 7 min PET scans ranged from 2.7 to 59 μSv, depending on the position relative to the patient and to the unshielded line; a lead shield would reduce the dose. Due to the short half-life, approximately half of the dose would be received during the first minute of ^{82}Rb infusion (Tout et al., 2014).

8.1.2.2. Hand exposure

(352) The dose due to positrons is the principal component of skin irradiation, by a factor of 3–100, depending on the conditions. The use of shields for syringes and vials is necessary to avoid unjustified skin exposures, that may challenge the skin dose limit (Marengo and Rubow, 2023). Thus, the dose rate at contact of a 5 ml unshielded syringe body containing 400 MBq of ^{18}F is 20 mSv min^{-1}, and consequently the annual skin dose limit would be reached in 25 minutes (Delacroix et al., 2002; Vanhavere et al., 2012). There is a wide range in extremity doses reported in the literature (Table 8.8), and there is no consistent pattern as to whether the dominant or non-dominant hand is more exposed. Leide-Svegborn (2012) found that the fingers that got the highest doses were the thumb, the long finger or the index finger of the dominant hand. Conversely, Covens et al. (2007) found that highest skin dose was often located on the non-dominant hand, since the syringes and needles were often supported by that hand during several manipulations.

(353) When the study includes multiple dosimeters on each hand, large variations in personal dose equivalent $H_p(0.07)$ are observed (Covens et al., 2007, 2010; Carnicer et al., 2011; Sans-Merce et al., 2011; Wrzesień and Napolska, 2015). Extremity dose values for technologists working in the same centre have been found to vary by up to a few orders of

3557 Table 8.7. Whole-body doses $H_p(10)$ received by a technologist.

Injected activity (MBq)	Dose (μSv study^{-1})	Dose (nSv MBq^{-1})	Comment	Activity	Reference
	14		Qualitative study	D + I + PM	McCormik and Miklos, 1993
	37		Quantitative study	D + I + PM	
500	5.9	12		D + I + PM	Chiesa et al., 1997
320	5.5	17	Various tracers	D + I + PM	Benatar et al., 2000
414	13.3	32.1	Various tracers	I + PM	Marti-Climent and Peñuelas, 2002
370	14.3	38.6	Unshielded syringes	D + I + PM	Biran et al., 2004
	10.7	28.9	Shielded syringes	D + I + PM	
345	3.01	8.1	Semiautomated injector	I + PM	Guillet et al., 2005
370	4.1	11		I + PM	Roberts et al., 2005
370	3.34	8.76		I	Pant and Senthamizhchelvan,
	0.62	1.7		PM	2006
350	8.8	25	No shielded syringe	D + I + PM	Seierstad et al., 2007
518	9.3	20	Before shielding	D + I + PM	Demir et al., 2010
	7.6	15	After shielding	D + I + PM	
250–400		20.1		I + PM	Covens et al., 2010
370	9.5	25.7	Before optimisation	D + I + PM	Peet el al., 2012
	4.8	13.0	After optimisation	D + I + PM	
308	2.1	6.8		I	Kumar et al., 2012
	0.6	1.9		PM	
	4.2–7	17–19	Automatic dispenser	D + I + PM	Antic el al., 2014
	5–6	21–26	Semi-automated dispenser	D + I + PM	

3558 D, Drawing up; I, Injection; PM, Patient management.

Table 8.8. Extremity dose $H_p(0.07)$ normalised to activity received by technologists, all 2-[^{18}F]FDG unless otherwise specified.

Mean (μSv GBq^{-1})		Maximum (μSv GBq^{-1})	Location	Activity	Position of the dosimeter	Reference
Left hand	Right hand					
86.7*				Injection		Marti-Climent and Peñuelas, 2002
	187					Biran et al., 2004
				Dispensing from:		Guillet et al., 2005
575	594	5329		Multidose vials		
185	422			Monodose vial		
		850		Dispensing	Multiple dosimeters on each hand	Covens et al., 2007
		97		Dispensing	Index and ring finger of each hand	Tandon et al., 2007
		324		Injection		
		560		Scintigraphy		
483*				Dispensing	Multiple dosimeters on each hand	Covens et al., 2010
334*			Tip index finger	Injection		
340	450			Before shielding	Second finger of each hand	Demir et al., 2010
250	340			After shielding		
2550		3000	The thumb, long or index finger of the dominant hand		Fingertips on both hands	Leide-Svegborn, 2012
	276				Right index finger	Kristoffersen et al., 2010†
	65				Right wrist	
407–419*				Dispensing	Base of the middle finger	Kopec et al., 2011
39.8–41.9*				Administration		
2.0–27.5*				Patient operation		
1200*		4430	Tip	Preparation	Multiple dosimeters on each hand	Carnicer et al., 2011;
930*		4110	Tip	Administration		Sans-Merce et al., 2011
	170–680			Semi-automatic dispenser	Index finger base of the dominant hand	Antic et al., 2014
	200		Index finger	Automatic dispenser	All fingertips of both hands	Wrzesień and Napolska, 2015
450	340	1370	Index finger on the palm side	Preparation	Multiple dosimeters on each hand	Hudzietzova et al., 2016
1440	2880	7650		Administration		

*Hand not specified.

†Quantitative coronary perfusion PET with ^{13}N-ammonia.

magnitude, related to the level of protection used and to different working habits (Antic et al., 2014).

(354) Dose distribution across the hands depends on several factors, as shown in the ORAMED project (Sans-Merce et al., 2011). The distance between the radioactive source and the specific part of the hand is an important factor, as dosimeters that are close to the source are more exposed. Shields are considered a key factor, reducing significantly the exposure to those parts of the hands covered by the shield. This has also been shown to be the case in 99mTc manipulation (Whitby and Martin, 2005). The ORAMED multicentre study showed that, even when performing the same procedure with the same devices, workers receive doses that vary significantly from one worker to another due to each worker's individual habits. The ORAMED study concluded that overall, the most exposed area was more likely to be the tip of the index finger of the non-dominant hand, but this will vary with individual technique.

(355) The results of the ORAMED project, that also included procedures with 99mTc, showed that the preparation of 18F is the most critical of the studied diagnostic procedures (Vanhavere et al., 2012): the fraction of workers surpassing the annual skin dose limit for the extremities was estimated to be 23% and 40% for 18F administration and preparation, respectively; while the proportion exceeding 3/10th of the annual limit was estimated to be 66 % and 87% for 18F administration and preparation. Other publications have also reported cases of workers who could exceed the annual skin dose limit (Hudzietzova et al., 2016).

(356) Finger skin doses to the radiochemists during semi-automated synthesis of ^{68}Ga-DOTA-NOC and to the physician during injecting have been measured. Mean dose to the base of left (right) ring finger was 3.02 (1.96) mSv during synthesis and 1.26 (1.03) mSv during injection. Although the mean dose was higher during synthesis than injection, the difference was not significant. None of the workers used a syringe shield during handling radioactivity (Dwivedi et al., 2011).

8.1.2.3. Eye lens exposure

(357) Measurements of the equivalent dose to the eye lens have been made in a few PET/CT facilities (Table 8.9). $H_p(3)$ normalised to total activity handled ranged between 1.1 and 56 μSv GBq^{-1} depending on the staff group, but those involved in tracer administration to the patient received the highest doses.

(358) With regard to eye lens exposure in comparison with whole-body exposure, data show a great variability. While Kubo and Mauricio (2014) found that the eye lens received doses that were up to 200% higher than the thorax, Kopec et al. (2011) showed that eye lens and whole-body doses were comparable with $H_p(3)/H_p(10)$ ranging between 0.7 and 1.0, suggesting that for medical staff $H_p(3)$ could be estimated from measurements of $H_p(10)$. These results are similar to those in the publication by Kubo and Mauricio (2014), which reported a ratio of 2.92 and 0.85 for preparation and injection, showing that during preparation the eye lens is at a shorter distance to the radiation source, while during injection, the radiopharmaceutical is closer to the thorax, and the measured dose values on the thorax were larger than those on the eye lens. Furthermore, during fractionating the activity was transferred from a shielded device to a syringe that was protected with a shield after measuring the activity. A multicentric study in nuclear medicine, involving diagnostic procedures mainly performed with ^{99m}Tc and ^{18}F, showed $H_p(3)/H_p(10)$ values ranging between 0.3 and 2.3, with estimated annual doses to the eye lens from 0.6 up to 9.3 mSv. Therefore, some doses could be close to or even exceed the three-tenths of the eye dose limit (Dabin et al., 2016). The variation in $H_p(3)/H_p(10)$ between publications is related to differences in procedures and individual habits. Thus, when preparing the syringes, personnel

use different shielding that could partially cover them, which could cause heterogeneous exposure and a large variation in $H_p(3)/H_p(10)$ values.

Table 8.9. Eye lens exposure in PET procedures.

Staff	Normalised dose		$H_p(3)/H_p(10)$	Reference
	Mean	Units		
Technical (preparation)	1.2	μSv GBq^{-1}	0.9	Kopec et al., 2011
Technical (operation)	1.1 ; 6.1‡		0.7 ; 1.1‡	
Injection (nurses)	3.3		0.9	
Technologist	56	μGy GBq^{-1}		Leide-Svegborn, 2012
Radiographers			0.15–1.56	Walsh et al., 2014
Preparation Injection			2.92 0.85	Kubo and Mauricio, 2014
Operators	0.02–0.27	mSv $week^{-1}$	0.3–2.3	Dabin et al., 2016†
Preparation Injection	4.3 3.0	μSv $procedure^{-1}$		Guiu-Souto et al., 2016
Injection			0.56	Marti-Climent et al., 2018
Injection Dispensing	199* 54*	μSv day^{-1}		Wrzesień, 2018a

*Maximum.
†Nuclear medicine data including PET.
‡Data from two centres.

(359) During a [^{68}Ga]Ga-DOTA-TATE procedure, the maximum normalised personal eye dose equivalent values ($H_p(3)$/activity) reported for ^{68}Ge/^{68}Ga generator elution, the radionuclide labelling peptide procedure, the dispensing of activity for the patient, and the radiopharmaceutical injection were 80, 72, 274, and 128 μSv GBq^{-1}, respectively (Wrzesień and Albiniak, 2018). Depending on the work load, annual exposure of the eye lenses to workers preparing and injecting the radiopharmaceutical may exceed the eye dose limit for the eye of 20 mSv. In contrast, maximum annual dose (extrapolation of quarterly results) for nuclear medicine and PET technologists has been estimated at 3.68 mSv for $H_p(3)$, with a corresponding value for $H_p(10)$ of 4.72 mSv (Demeter et al., 2019).

(360) The impact of laboratory protective eyewear (made of about 2 mm polycarbonate) for the reduction of the eye lens dose while handling different radionuclides has been measured on phantoms through the transmission factor ($H_p(3)_{protected\_dosimeter}/H_p(3)_{dosimeter\_without\_protection}$). This was 0.99 and 0.65 for ^{18}F and ^{68}Ga, respectively. The high transmission factor (lack of effect) for ^{18}F is caused by the facts that 1) most positrons are already stopped within the syringe and do not have enough energy left to affect the $H_p(3)$ measurement outside the eyewear, and 2) the eyewear has almost no effect on the remaining 511 keV photons. In contrast, for ^{68}Ga with its much higher positron energy, a larger fraction of positrons reach the eyewear and are only partially stopped there. Thus, the eye lens dose (per MBq) will be higher for ^{68}Ga than for ^{18}F due to the remaining positrons (Bruchmann et al., 2016).

8.1.3. Staff irradiation during radiopharmaceutical production

(361) Activities performed by staff during radiopharmaceutical production include cyclotron operation, the synthesis of the compound, its quality control, and finally its distribution to a PET/CT or PET/MR facility. In clinical routine, the synthesis is performed using automatic synthesis modules designed for the different PET radiotracers, placed in shielded hot cells. When the product is distributed to other centres, it is automatically prepared as single or multiple administration syringes or vials and placed in shielded containers. When the compound is supplied in syringes to the same centre, the process is not always as automated as when the distribution is carried out in other centres. Before the distribution, a sample of the radiopharmaceutical should be delivered to the quality control laboratory for analysis. Quality control may be performed while the tracer is being distributed. A secure system must be in place to assure that the tracer has passed quality control tests before injection to the patient.

(362) The cyclotron, whether with self-shielding or placed in a vault, is managed from the operating console in a room designed to meet local regulatory dose limits. Therefore, personal exposure during operation of the cyclotron should not be a cause for concern. Neutron equivalent dose rate measured with a Bonner sphere system in the laboratory next to the vault of an 18 MeV Cyclotron was 0.26 μSv h^{-1} (Fernández et al., 2007). However, exposure to radiation must be considered when accessing the different activated parts of the cyclotron. This is done during scheduled preventive maintenance or during unscheduled maintenance, including repairs. Activation products in the targets and other metallic parts of the cyclotron can produce high dose rates. Some activation products can deliver high dose rates even 24 hours after cyclotron operation.

(363) Dose rates at a distance of 1 m from targets after ^{18}F production can be of several mSv h^{-1}, decreasing to levels of hundreds of μSv h^{-1} several hours after production of ^{18}F, so the standard practice might be to carry out any work on targets on Monday in order to allow a reasonable time for decay. For maintenance inside the vacuum chamber of the cyclotron, targets should be disconnected and removed, to avoid unjustified exposure. After that, in negative ion cyclotrons, the dose rates in close contact with internal components will be limited to a range of several dozens of μSv h^{-1}, particularly if collimators are made from graphite, (Calandrino et al., 2010).

(364) External dose measurements carried out over a period of 3 years showed mean yearly doses to maintenance staff ranging from 609 ± 860 to 732 ± 973 μSv (Calandrino et al., 2010). In another facility, using a radiation monitoring system, with gamma and neutrons detectors in a fixed position (cyclotron control room, cyclotron zone corridor and radiopharmaceutical production room), the estimated annual exposures of staff operating the cyclotron were 1.39 ± 0.16 mSv and 2.61 ± 0.14 mSv for photon and neutron radiation, respectively. In the case of employees in the radiopharmaceuticals' production zone, the annual exposures measured for gamma and neutron radiation were 0.15 ± 0.03 mSv and 0.11 ± 0.01 mSv (Biegała and Jakubowska, 2020). Otherwise, for the personnel of the production laboratory the largest sources of exposure were the activities with the produced isotope.

(365) In the analysis, by Kumar et al. (2017), of the experience of operation of a medical cyclotron, the most frequent problems encountered were with the ion source, radiofrequency, and target foil rupture. These problems were solved during interventions by rebuilding the ion source, changing the fuse of radiofrequency, and rebuilding the target. When there is the need to remove a target from the target port, this operation should be made quickly, since the target foils (or windows) are emitting a significant amount of radiation. The target should be brought in shielded workbench and disassembly of the target body and removal of the foils/windows should be made carefully and rapidly in order to avoid contamination and radiation exposure. After removal of the target window, the radiation exposure to the working personnel can be reduced by up to 80%.

(366) Wrzesień and Albiniak (2016) analysed the hand exposure of workers in a single 2-[^{18}F]FDG production centre. Measurements were made for operators of the cyclotron, those who produce the 2-[^{18}F]FDG, and quality control staff. The highest exposure was in the quality control of the radiopharmaceutical with a maximum dose of 0.35 mSv GBq^{-1}. Those involved in 2-[^{18}F]FDG production were less exposed: exposure of fingertips during a year was estimated not to exceed 5% of the annual skin dose limit. The operators of the cyclotron had the lowest values of $H_p(0.07)$: between 0.3 µSv and 0.12 mSv for one working day. In a similar study involving two production centres, Wrzesień (2018b) showed that automatic production of 2-[^{18}F]FDG helped optimise radiological protection of personnel, but aspects of manual activities performed as part of quality control of the radiopharmaceutical resulted in increased hand exposure.

(367) Thyroid and eye exposure were also evaluated. The maximum equivalent dose to the skin at the location of the thyroid gland for staff involved in production procedures, quality control procedures and cyclotron operation was 116, 83, and 62 µSv d^{-1}, respectively; with an estimated maximum annual thyroid gland exposure lower than 30 mSv (Wrzesień, 2018c). Mean eye lens exposure ($H_p(3)$) was 30 µSv d^{-1}, but maximum doses were 89, 236, and 70 µSv d^{-1}, for staff performing production procedures, quality control procedures and cyclotron operation, respectively. On the basis of these figures, the estimated annual eye lens exposure of workers performing quality control procedures could exceed the eye dose limit (20 mSv year^{-1}) (Wrzesień, 2018a). In contrast, in another centre, the estimated annual eye lens dose for technologists, involved in PET radiopharmaceutical synthesis, quality assurance, and syringe preparation, was below 1.2 mSv. Where the maximum technologist eye lens dose measured was 25 µSv week^{-1}, and 6 measurements were below the detection limit of 15 µSv (Marti-Climent et al., 2018). Differences in eye lens doses could be attributed to the workload, methodologies and protective devices used in PET facilities performing radiopharmaceutical production.

(368) Demeter et al. (2019) conducted a study involving technologists, that handled nuclear medicine and PET radionuclides. Radiopharmacy participants included general duty production and senior supervising personnel, while cyclotron participants included quality assurance and production personnel. Maximum annual doses (extrapolation of quarterly results) for radiopharmacy and cyclotron technicians were 0.44 mSv and 1.48 mSv for $H_p(3)$ and 1.24 and <0.1 mSv for $H_p(10)$.

(369) When 2-[^{18}F]FDG is distributed to a PET/CT facility, exposure due to the radiopharmaceutical preparation ready for distribution can also be taken into account as part of radiopharmaceutical production.

(370) In the case of one centre that started with implementation of a semiautomatic system for 2-[^{18}F]FDG distribution, exposure to technologists actually increased. However, this was predominantly due to the amount of activity distributed (Marti-Climent and Peñuelas, 2002), and the dose relative to the manipulated activity remained similar for the whole-body (2.5 µSv GBq^{-1}) and decreased for finger exposure (155 µSv GBq^{-1}).

8.2. Measures to optimise staff radiological protection

(371) Optimisation of radiological protection for PET and PET/CT of staff, and patients, involves selection and installation of equipment, design and construction of facilities, choice of optimal equipment settings, day-to-day methods of operation, quality control programmes, and ensuring that all personnel receive proper initial and career-long training. The radiation dose levels that patients receive also have implications for doses to staff.

(372) In the same way as for other radiological imaging techniques (ICRP, year1), as new imaging equipment incorporates more options to improve performance, it becomes more complex and less easily understood, so operators have to be given more extensive training. Ongoing monitoring, review, and analysis of performance is required that feeds back into the improvement and development of imaging protocols. Several different aspects relating to optimisation of protection should be considered. The first is collaboration between the staff involved in the process, each having key skills that can only contribute to the process effectively when individuals work together as a core team. The second is appropriate methodology and technology, with the knowledge and expertise required to use each effectively. The third relates to organisational processes that ensure required tasks, such as equipment performance tests, patient dose surveys, and review of protocols are carried out (ICRP, year1). Aspects related to methodology and technology, teamwork, training and skills, as well as organisation are dealt with in other sections. This section focuses on operational optimisation measures.

(373) PET procedures are recommended to be performed in dedicated facilities using appropriate protection tools. Continuing improvements in PET technology is allowing increased patient throughput. Although this may lead to a corresponding increase in exposure of technologists, improvement in protection methods may allow reductions in exposure. Rotation of these staff is important to allow for shared higher exposures across the pool of technologists, when possible.

(374) The most important factor that has decreased staff exposure is the use of an automatic dispensing and infusion system, as automation reduces $H_p(0.07)$ up 95% (Covens et al., 2010). The dose to staff in a PET/CT or PET/MR facility can also be minimised by applying basic radiological protection practices, such as, maintaining distance from the radiation source or patient, performing operations in the shortest possible time and using appropriate shielding whenever practicable. Additionally, dosing schedules for patients with lower administered activities will reduce staff exposure.

(375) Greater attention to optimisation should be observed when patients may require greater staff attention, such as paediatric patients or patients requiring assistance.

(376) Protective measures that should be considered to minimise the dose received by staff are as follows:

(377) General measures:

- Operational protocols, including the use of shielding devices, should be evaluated carefully. When such protocols are established, they should be practised through appropriate training programs. It has been noted that - even when performing the same procedure with the same device - exposure can vary significantly from one worker to another due to each worker's individual habits (Carnicer et al., 2011).
- The application of shielding for the vial and syringe is the single most important factor in reducing the magnitude of doses to the finger tips (ICRP, 2008a).
- Any tool increasing the distance (e.g. forceps, automatic injector, cradle to sit the PET syringe injection pig) between the hands/fingers and the source is effective in dose reduction (Sans-Merce et al., 2011).
- Use of an automatic dispensing and infusion system is desirable, as automation reduces exposure (Kollaard et al., 2021).

(378) To prevent the contamination risk:

- Use personal protective equipment (PPE), like gloves, lab coat, splash shielding as appropriate.

(379) Staff should be instructed and trained to maximise the distance between themselves and hot patients and to use the protection of shielding:

- Practice doing procedures with inactive materials.
- Minimise contact with the patient after radiopharmaceutical injection, reducing time and increasing distance.

(380) The wearing of personal protective aprons is not useful due to the high energy of the annihilation radiation as they will only reduce the dose by a few percent (Seierstad et al., 2007; Leide-Svegborn, 2010); however, an apron will be required if protection against CT x rays is needed (e.g. in case of problems with injecting contrast agents during a CT scan).

(381) The ORAMED project, which involved 17 PET/CT facilities and evaluated hand exposure during both preparation and administration of ^{18}F-radiopharmaceuticals, identified several good and bad practices (Carnicer et al., 2011): low doses were related to well-optimised procedures or working habits, such as, the use of appropriate shields for syringes and vials; while high doses were associated with either failure to use suitable means of radiological protection, usually a shield, or inappropriate use, for example, injecting with a shielded syringe, but placing fingers next to the needle as a guide. Analysis of the factors that affected the maximum skin dose showed that the most important factor was the shield, both for the vial and for the syringe, and that good working habits were more important than experience. The importance of an individual technologist's personal habits has been corroborated by other studies (Covens et al., 2007; Sans-Merce et al., 2011; Hudzietzova et al., 2016).

(382) Active personal dosimeters that can give faster feedback of the radiation field will always be useful in helping to reduce doses, especially for personnel involved in cyclotron maintenance or setting up a new radiosynthesis. They have also been used in a clinical setting (Peet et al., 2012).

(383) Another approach to controlling the magnitude of staff exposure in a PET/CT facility is to rotate the staff members performing particular duties associated with higher dose levels (Antic et al., 2014; Alenezi and Soliman, 2015).

8.2.1. During radiopharmaceutical production

(384) Preventive maintenance should be scheduled at times when residual activity will be at the lowest point (e.g. last run on Friday - maintenance on next Sunday or Monday). During cyclotron maintenance, prior to starting on any work, a radiological survey should be carried out around the cyclotron to assess the level of hazard. If manipulation of the target is required, the main hazard is from beta particles due to their high stopping power (short range). Therefore, finger contact with activated parts should be avoided, and suitable handling tools should be used wherever possible (Martin et al., 2018). Staff should wear gloves and single use filtered masks (class FFP3), to prevent the inhalation of activated dust particles. Use of an additional active personal dosimeter, with the alarm level set to a defined integrated dose, can be helpful at least during phases when routines are being established or modified (Calandrino et al., 2010).

(385) During radiopharmaceutical production:

- Use fully automatic synthesis modules to minimise contact with the high activity managed during the radiopharmaceutical production.

- Use dedicated hot cells for each radiopharmaceutical to provide flexibility and decrease the possibility of exposure.
- Minimise the activity handled in each step of the production process (cyclotron production and radiopharmaceutical synthesis).
- Use the remote control of the hot cells to move loaded vials and syringes.

(386) Doses received during quality control procedures can be an area of concern. Attention should be paid to the design of the site for radiopharmaceutical quality control in order to reduce eye lens dose. In particular, the size and positioning of the shielding used (lead glass) should be adjusted to the height of the quality control personnel (Wrzesień M., 2018a). Staff members performing quality control can be rotated.

8.2.2. Use of automatic units

(387) The introduction of automatic dose dispensing and infusion (D&I) units has brought about a significant reduction in finger and whole-body doses received by technologists (Table 8.10). However, the percentage dose reduction depends not only on the final doses, but also on the starting point, which might not be optimised. Therefore, an effect on whole body doses would not be found if the syringe preparation is done behind a higher lead shielding than that provided by the dispensing machine. Technicians may also spend more time per day around the bulk source in the injector. There is also the need to carefully consider the modality of loading the incoming radiopharmaceutical batch on the injector system, since this procedure may involve significant exposure (given the high activity of the batch), as well as the potential risk for incidents.

(388) Application of an automated system has been reported to reduce $H_p(10)$ by up to 50 % in terms of the dose during tracer administration, resulting in a dose reduction of 20% during the entire procedure of injection, and escorting and positioning the patient on the camera. Extremity doses were reduced by more than 95%, down to a mean level of 10 µSv per GBq. Additionally, finger doses were more evenly distributed across the hand (Convens et al., 2010).

Table 8.10. Efficacy of automatic dispensing and infusion (D&I) units in reducing staff $H_p(10)$ and $H_p(0.07)$.

$H_p(10)$		$H_p(0.07)$				
(μSv GBq^{-1})	Dose reduction	(μSv GBq^{-1})	Dose reduction	Action	System	Reference
3.6	50%	10	95%	D&I	A	Covens et al., 2010
1.4	90%	2.5*	90%	D&I	B	Schleipman and Gerbaudo, 2012
	12%			D&I	B	Antic et al., 2014
		11	87%	D&I	B	Sánchez et al., 2015
	40%			I	B	Alnaaimi et al., 2017
	31%		78%	D	C	Ferretti et al., 2019
	77%		96%	I		

A, Posijet (Lemarpax); B, Intego (Medrad); C, KARL$_{100}$ + Rad-Inject (Tema Sinergie).
*Wrist dose.

(389) In comparison with a semiautomatic system that prepares the 2-[^{18}F]FDG injections for manual administration to the patient, an automated infusion device that both prepares and delivers the 2-[^{18}F]FDG dose reduced fingertip doses by 63% for preparation of the vial and 83% for injection (Sánchez et al., 2015). When a self-dispensing system and an automatic infuser were used respectively by a technician and a physician, effective dose to the whole body and equivalent dose to the hands were reduced significantly (Ferretti et al., 2019).

8.2.3. During patient management

(390) Measures to reduce the staff dose during patient management can be grouped according to the different steps of the procedure.

(391) General measures:

- Patient preparation and co-operation are important factors in minimisation of contact time and in increasing the distance between patient and staff member. Two measures, where clinically practical, are to encourage patients to empty their bladder and get on and off beds independently. The task of going to the toilet prior to the PET scan has been reported to contribute 0.32 μSv to staff whole body dose per patient, which is 6% of the total dose (Peet et al., 2012).
- Maximise the distance to the patients while escorting them from the injection room to the bathroom, to the scanner for imaging, as well as escorting the patient to the lobby after the PET scan.
- Minimise close contact time with the patient.

(392) Measures during patient preparation prior to injection:

- The patient should be advised about the whole PET/CT or PET/MR procedure beforehand, as this will reduce the time of contact when the patient is a source of radiation.
- When the patient arrives to the PET facility, the verification process should include patient identification and exam requested, review with the patient that the preparation instructions were followed correctly to proceed with PET/CT or PET/MR procedure, and completion of all forms and questionnaires (such as those for intravenous contrast and MRI safety questionnaire). A good patient identification is important to reduce the dose by avoiding mistakes in tracer administration, preventing unintended and accidental radiation exposures (Martin et al., 2019a).
- Enquiries about the patient's pregnancy, or the possibility of pregnancy, as well as breast feeding status should be made prior to injection.
- Hospitalised patients, or those who require other forms of special accommodation, should not be scheduled in the same slots of time, at least try to have them evenly distributed according to the rotation/distribution of staff, to decrease their exposure.
- Patients should be prepared by placing in advance an intravenous cannula in their vein ready for administration of activity, which should be flushed with saline. In this way, the time for performing an injection can be minimised. This also reduces the possibility of extravasation.

(393) Measures during injection:

- The activity of the radiopharmaceutical administered should be the minimum that is compatible with the clinical purpose.
- When moving the shielded syringe from the dispensing area to the administration room, syringe holders and a transport cart should be used.
- Syringes should not be removed from shielding when injecting a radiopharmaceutical into a patient. Although the injection could be done faster without syringe shielding, the total exposure is less with shielding.
- When injecting the radiopharmaceutical:
  - an intravenous line should be used,
  - caution should be taken to ensure that the PET professional is standing on the side of the shield when injection and flushing the lines and not on the axis, which will place him/her in the direct beam from the radiopharmaceutical (Figure 8.1).
- When a cradle is used to hold the PET syringe injection pig on a flat surface, to allow easier administration of the radiopharmaceutical, the technologists can be further away from the radiation source and reduce exposure of their body and hands.

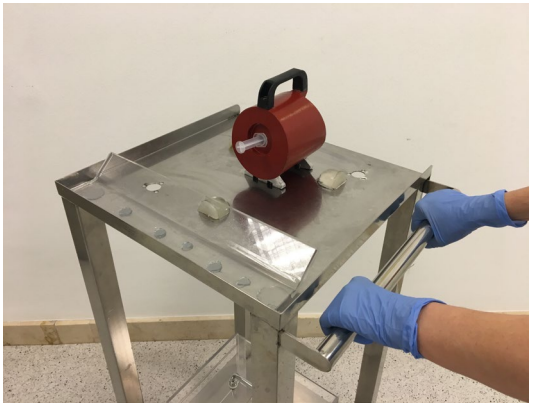

Fig. 8.1. During transportation and injection, the technologist does not stand on the axis of the syringe shield (cylinder) which would place her/him direct in the beam from the aperture. Image: Josep M Martí-Climent. Spain.

(394) Measures during the uptake phase:

- Once the patient has been injected in a shielded resting room or taken to a shielded resting room, the door (if any) of that uptake room should be closed with a sign on it indicating that the room is occupied, so that staff could not enter accidently.
- Minimise time spent near the patient after administration.
- Patients should be encouraged to drink water and void the bladder when needed during the uptake phase, although it is ideal for the patient to remain relaxed and still during the uptake period and void the bladder on the way to imaging.
- Most PET examinations include the bladder in the scanned area of the patient (for example, 2-[^{18}F]FDG oncological scans), and since radioactivity accumulates in the bladder, the patient should void to clear this radioactivity. Approximately 20% of administered activity is excreted within the first 2 h (Jones et al.,1982; Mejia et al., 1991; Madsen et al., 2006). This reduction of activity in the patient, used primary to reduce the patient dose, can be considered as a measure to reduce the dose received by the staff and also by any person accompanying the patient and by the public after the patient leaves the PET facility.

- Hence, in order to minimise staff exposure, the patient should be asked to empty their bladder before the scan and just before leaving the department.
- In order to guide patients from the uptake rooms to the toilet, include a line on the floor if the toilet is not immediately adjacent to the room. Staff should not accompany the patient to the toilet.
- Any un-necessary movement during the uptake phase should be avoided.
- Patients should be viewed remotely via a video monitor in the uptake room and in the scanning room. There should be an audio communication system to allow staff to talk with patients remotely.
- If a staff member needs to attend the patient, it should be considered that dose rates measured at the head are significantly higher than at the feet of the patient (Benatar et al., 2000).

(395) Measures during the imaging phase:

- Distance from the patient should be maximised when escorting and positioning the patient.
- Minimise close contact time with the patient.
- Staff positioning is also another measure to reduce their exposure. Thus, unless the patient needs special assistance, it has been recommended that, when setting up a scan, staff should be encouraged to stand in two identified positions: at the end of the bed or to the side of the gantry (Peet et al., 2012). Another possibility is to allow remote adjustment of the scanner bed position to be possible from the control room.
- When performing continuous bladder irrigation in evaluating pelvic pathologies (Garcia Vicente et al., 2010), the technologist fills the bladder with physiological saline and then empties the urine back into the bag rinsing the bladder to dilute the urine. To reduce occupational exposure to the technologist performing the technique, apply inverse square law and step back away from the scanning table both during the filling phase and the emptying phase. In addition, the bag should be shielded.
- When flushing a urinary catheter, placement of shielding around the catheter bag has been considered to only have a minor effect on total exposure because urinary catheterisation is only performed sporadically (Roberts et al., 2005).

(396) Measures after the imaging phase:

- When allowing the patient to get out of bed, move the scanner bed from the control room.
- The patient should be asked to empty their bladder just before leaving the department.

8.2.4. Shielding

(397) The 0.63 MeV positrons emitted by ^{18}F, which have ranges of 0.9 mm and 1.7 mm in glass and plastic (Table 8.2), respectively, will be absorbed in the fluid, in the walls of the vial and to a large extent also in a syringe wall. However, the higher energy positrons emitted by ^{11}C (0.96 MeV), ^{13}N (1.2 MeV), ^{15}O (1.7 MeV), and ^{68}Ga (1.9 MeV) have ranges in plastic of 4–7 millimetres, and to absorb these, PMMA or plastic liners may be incorporated within vial and syringe shields (ICRP, 2008a). The possibility of producing bremsstrahlung x rays from positron interactions with lead should be considered. When stopping 1 MeV

positrons in lead, 10% of their total energy is converted to bremsstrahlung with a spectral distribution up to 1 MeV. The amount (but not the max energy) can be reduced by an order of magnitude by using PMMA as a first shielding; however, 511 keV photons are the main source to be shielded from.

(398) In a facility, no syringe shields were used during the handling of 2-[^{18}F]FDG because the technologists worked faster without syringe shields, and the shield was not considered to be very effective for the 0.511 MeV photons, (Seierstad et al., 2007). However, when technologists put into practice important shielding precautions, such as, shielding for a sterile syringe and a lead container for the shielded syringe, a significant reduction of the mean whole-body dose per study was achieved (9.3 µSv before and 7.6 µSv after shielding introduction) (Demir et al., 2010). The significant dose reduction due to primary shielding (portable 511 keV-syringe shields of 12.7 mm lead equivalent) and to a secondary shield (trolley-mounted shield of 20 mm of lead) has also been demonstrated by Roberts et al. (2005). This example shows the importance of using syringe shielding, even if the procedure takes longer.

(399) Shielding recommendations coming out of the reported studies are:

- For radionuclide manipulation: lead bricks, lead glass, lead transport containers (Antic et al., 2014). For ^{18}F the minimum acceptable thickness of shielding for a syringe is 5 mm of tungsten, and for a vial it is 3 cm of lead (Sans-Merce et al., 2011).
- Containers and 30-cm long forceps; and a 4.5 cm-thick tungsten vial shield and 0.8 cm of tungsten syringe shield (Antic et al., 2014).

(400) Examples of good and bad practices during preparation and administration of the radiopharmaceutical using different shielding devices are illustrated in Fig. 8.2: Use of appropriate shields for syringes and vials (Fig 8.2. a, b, e, and f), inappropriate use of shields that allow some parts of the hand to directly touch unprotected regions such as the needle and the bottom of the syringe (Fig. 8.2 c), and no shielding is used for either the syringe or the vial (Fig. 8.2 d, g, and h).

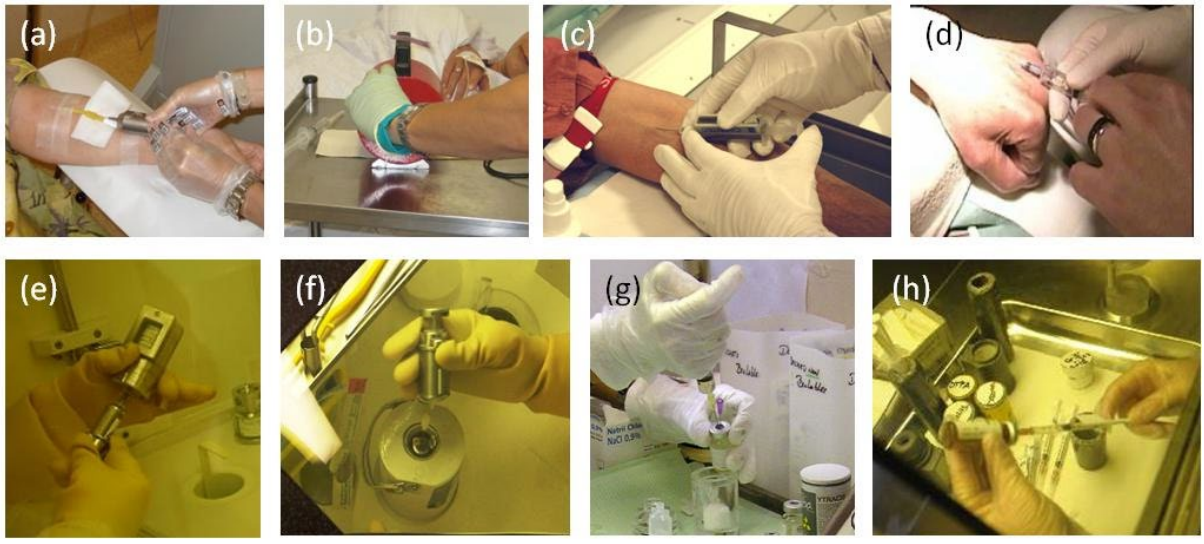

Fig. 8.2. Examples of good administration (a) (b) and preparation (e) (f) practices, and examples for bad administration (c) (d) and preparation (g) (h) practices (Vanhavere et al., 2012). The shielding is used in (a), (b), (c), and (d) with a correct position of the hands, while (c) shows an incorrect position of the left hand and the right index finger in relation to the shielding, and there is no use of shielding in (d) (g) and (h).

8.2.5. Case examples of optimisation

(401) In the literature there are various reports of dose reduction by means of optimisation of procedures:

- Optimisation on the basis of a study of the dose arising from the different phases within each patient-study resulted in a reduction of the total whole-body dose for all staff for each patient from 9.5 μSv in the first year of operation to 4.8 μSv in four years (Peet et al., 2012).
- The introduction of an automatic dispensing system and injection and optimisation of working practice resulted in dose reduction ranging from 12% in $H_p(10)$ to 96% in $H_p(0.07)$, as shown in Table 8.10.
- Training specifically for time optimisation has been shown to have an important role. Antic et al. (2014) showed that training of staff with non-radioactive material improved efficiency and led to a time reduction of up to 32% during the dispensing phase, 50% during the injection phase and nearly 40% during the removal of a butterfly needle.

8.2.6. Summary of measures for optimisation

(402) Table 8.11 summarises the measures to optimise staff radiological protection in a PET/CT and PET/MR facility.

Table 8.11. Practical measures to optimise staff radiological protection in a PET/CT and PET/MR facility.

General measures General for irradiation General for contamination	• Operational protocols should be assessed and trained • Shielding for the syringe and vial is the single most important factor in reducing the magnitude of doses to the finger tips • Use any tool to increase the distance between the hands/fingers and the source • Automatic dispensing and infusion systems are desirable • Active personal dosimeters can give faster feedback of the radiation field, and can assist in lowering doses • Rotate the staff members performing particular duties associated with higher dose levels • Personal protective aprons are not useful • Use personal protective equipment (PPE), like gloves, lab coat, splash shielding as appropriate)
Cyclotron maintenance Radiopharmaceutical production	• Schedule preventive maintenance at times when residual activity will be at the lowest point • Perform a radiological survey around the cyclotron to assess the level of hazard • Use active personal dosimeter, with alarm level set to a defined integrated dose • Wear single use filtered masks to prevent the inhalation of activity • Use fully automatic synthesis modules • Use dedicated hot cells • Minimise the activity handled • Use the remote control of the hot cells to move loaded vials and syringe • Adjust the position of the shield to the height of the quality control personnel

General for patient management	• Promote patient preparation and co-operation to minimise contact time and in increase the distance • Maximise the distance to the patients • Minimise close contact time with the patient
Preparation phase	• Patient should be advised about the whole PET/CT or PET/MR procedure • Verification process should include patient identification, pregnancy and breast-feeding status, and exam requested, review of whether the preparation instructions were followed correctly and completion of questionnaires, including MRI Safety questionnaire when appropriate • Hospitalised patients, with difficult cooperation, should be scheduled evenly distributed according to rotation/distribution of staff. • Instruct the patients to empty their bladder before and after imaging and get on and off beds independently if possible • Prepare the patient by placing an intravenous cannula in their vein ready for dose administration
Injection phase	• The activity of the radiopharmaceutical administered should be the minimum that is compatible with the clinical purpose • Use syringe holders and a transport cart, when moving the shielded syringe from the dispensing area to the administration room • Syringes should not be removed from shielding when injecting • Use an intravenous line • The technologist should not stand in the axis of the syringe shield (cylinder) which would place her/him in the direct beam when injection and flushing the lines
Uptake phase	• The door of the uptake room should be closed with a sign on it indicating that the room is occupied • Patients should be viewed remotely via a video monitor • Use audio communication system to talk remotely with patients • Minimise time spent near the patient after administration • Patients should be encouraged to drink water and void the bladder frequently • Avoid any unnecessary movement during the uptake phase • Distance from the patient should be maximised when escorting and positioning the patient • If a person is needed to assist the patient, consider the use a lead shield and that dose rates measured at the head are higher than at the feet of the patient
Imaging phase	• When setting up a scan, unless the patient needs special assistance, staff should be encouraged to stand at the end of the bed or to the side of the gantry, although it is preferable to move the scanner bed from the control room • Patients should be viewed remotely via a video monitor • Use audio communication system to talk remotely with patients • When performing continuous bladder irrigation, increase the distance to the scanning table
After imaging	• When allowing the patient to get out of bed, move the scanner bed from the control room • The patient should be asked to empty their bladder just before leaving the department

8.3. Staff dose monitoring

8.3.1. Introductory information

(403) As described in Section 8.1, staff working in the imaging facilities and the radiopharmaceutical production are exposed to ionising radiation. They can be considered as occupationally exposed workers, and thus monitoring of the staff is likely to be needed, depending on the exposure levels. Monitoring can be needed for internal exposures, whole body exposures and localised extremity exposures.

(404) Individual monitoring is required to verify compliance with dose limits. Extremity, skin, and lens of the eye monitoring should be undertaken for workers who have a reasonable probability of receiving per year an equivalent dose higher than 3/10th of one of the yearly limits (Section 8.1).

(405) For doses above the monitoring level, a monitoring period of one month is recommended. Shorter monitoring periods can be chosen (weekly monitoring or even monitoring per procedure), when setting up new procedures, when optimising working conditions or when there is a possibility of potentially high exposure.

(406) The dose to the extremities, skin and the lens of the eye need to be monitored in situations where non-homogeneous exposure conditions for which the whole-body monitoring does not provide an adequate estimate of these doses.

(407) The skin of the extremities is the limiting organ rather than the extremity itself. An estimate of the equivalent dose to the skin, H_{skin}, is normally a conservative estimate of the equivalent dose to the extremities. Therefore, an extremity dosimeter becomes a skin dosimeter and shall be designed to measure $H_p(0,07)$ and be placed as close as possible to the most exposed part of the skin surface.

8.3.2. Routine monitoring of staff

(408) Whole-body doses of staff should be measured based on continuous whole-body dose monitoring with doses reported on a monthly basis. This is required not only because exposures could reach 3/10th of the annual effective dose limit, but because high levels of radiation exposure could occur during any incidents.

(409) The exposure of the medical staff can be considered homogeneous. This means that one whole body dosimeter at the height of the chest measuring $H_p(10)$ is sufficient to monitor the worker. If this $H_p(10)$ value is below the legal limits, it can be assumed that no organ will be at risk for any stochastic effects.

(410) Radiation doses to the eyes have been found to be similar to whole-body doses, although some workers - depending on their specific procedures and habits - could exceed the limit of 20 mSv $year^{-1}$. A whole-body dosimeter worn on the chest should give a measure of probable eye dose levels. If these are high (approaching 6 mSv per year), independent measurements of eye doses should confirm the levels of the eye lens doses.

(411) Doses to the extremities and the skin, cannot be estimated from whole-body monitoring results, due to the non-homogeneous exposure conditions, so these need to be monitored. The skin of the extremities is the limiting organ, so an extremity dosimeter designed to measure $H_p(0.07)$ is required and should ideally be located so that it will measure the most exposed 1 cm^2.

8.3.3. Dosimeter positioning to monitor the extremity dose

(412) The extremity dosimeter should be placed as close as possible to the most exposed part of the skin surface. This is often difficult as the most highly exposed area is not known a priori.

(413) The dosimeter should be oriented towards the radiation source. The dosimeter shall be worn under protective clothing, especially inside gloves, if such clothing is worn. The dosimeter could also be worn outside the protective clothing, but under an appropriate thickness of material that approximates to the type and thickness of the protective clothing.

(414) Depending on the exposure situation, common extremity monitoring positions, such as the base of the fingers or the wrist, often underestimate the maximum dose. To estimate the maximum skin dose from a routine dosimeter, a correction factor, for the specific routine monitoring position, shall be established and employed.

(415) Measurements of hand exposure at multiple locations on each hand have shown differences between hands of individuals and high dose gradients across the hand (Covens et al., 2007; Carnicer et al., 2011). The magnitude of such dose gradient is determined by the proximity of the fingertip to the unshielded source (Martin et al., 2019b).

(416) Several publications have proposed a multiplicative correction factor to estimate the maximum dose from the reading of a ring dosimeter (Table 8.12). Factors ranging from 2 to 9, with the dosimeter positioned on the ring, middle or index fingers, have been proposed. The most extensive survey in this respect is the ORAMED project, with participation from PET facilities in six European countries, involving 30 workers in ^{18}F preparation and 30 in ^{18}F administration. The mean values of the ratios between the maximum dose and the dose at the base of the index finger and base of the ring finger, for the non-dominant (dominant) hand, were 4 (5) and 6 (5) for preparation and 4 (5) and 6 (5) for administration (Vanhavere et al., 2012). The study concluded that an appropriate method for routine monitoring of the extremities is to put the dosimeter at the base of the index finger of the non-dominant hand with the sensitive part of the ring dosimeter oriented towards the palm side and to use a multiplicative factor of 6 to estimate the maximum local skin dose.

(417) The use of wrist dosimeters is discouraged because of significant underestimation and low correlation with the maximum dose (Carnicer et al., 2011; Vanhavere et al., 2012).

8.3.4. Type of extremity dosimeters

(418) The dosimeters used for extremity monitoring are generally based on passive techniques. The dosimeter shall be appropriate for the radiation fields to be monitored, and shall measure the operational quantity $H_p(0,07)$.

(419) Two types of passive dosimeter design are available for fingers: rings, worn at the thumb, index, middle or ring finger, and finger-stalls, pulled on at either the index, middle or ring finger with the detector located at the fingertip. Wrist dosimeters are not recommended. The technical specifications for extremity dosimetry systems measuring the quantity $H_p(0,07)$ shall be as defined in IEC 62387 (IEC, 2020) for passive dosimeters.

8.3.5. Guidance on the use of extremity dosimeters

(420) In order to provide guidance on the appropriate monitoring for individual staff members a flowchart is given in Fig. 8.3 relating to requirements based on an initial trial of wearing a ring dosimeter. Options are given about whether monitoring is necessary based on dose levels recorded.

(421) It is recommended to set up a trial period for a minimum of three months, whereby the worker is monitored with a ring dosimeter at the base of the index finger. The sensitive element should be on the palmer side, so that it will face towards the syringe, vial or other

source held directly in the hand. If it is clear from the individual practices, which is the most exposed hand, it is sufficient to monitor only this hand. Otherwise, the trial period should monitor both hands.

Table 8.12. Multiplicative correction factor to estimate the maximum dose from the reading of a dosimeter.

Correction factor	Comment	Ring position with the TLD placed towards the palm side	Highest dose location	Reference
3		Base of the index finger	Tip of the index finger, dominant hand	Morton et al., 2006
6		Base of the ring finger		
Mean 2.5–3.5	^{18}F and ^{99m}Tc	Base of the middle finger, right hand	Tip of the ring finger of the left hand	Covens et al., 2007
Up to 9	^{18}F			
3	Recommended for preparation and administration of ^{18}F and ^{99m}Tc	Base of the middle finger		*Publication 106* (ICRP, 2008a)
6*				
Median (mean)		Base of the index finger		Sans Merce et al., 2011
3 (4) Preparation				
4 (5) Administration				
6	Recommended for preparation and administration of ^{18}F and ^{99m}Tc	Base of the index finger of the non-dominant hand,	Fingertips of the non-dominant hand	Carnicer et al., 2011 Sans-Merce et al., 2011
1.9–6.3	Preparation	base of the index finger	Index finger on the palm side of the hand	Hudzietzova el al., 2016
4.0–7.8	Administration			
6	Recommendation for PET	Base of the index finger		Martin et al., 2018

*Base of the middle finger facing the dorsal side of the hand

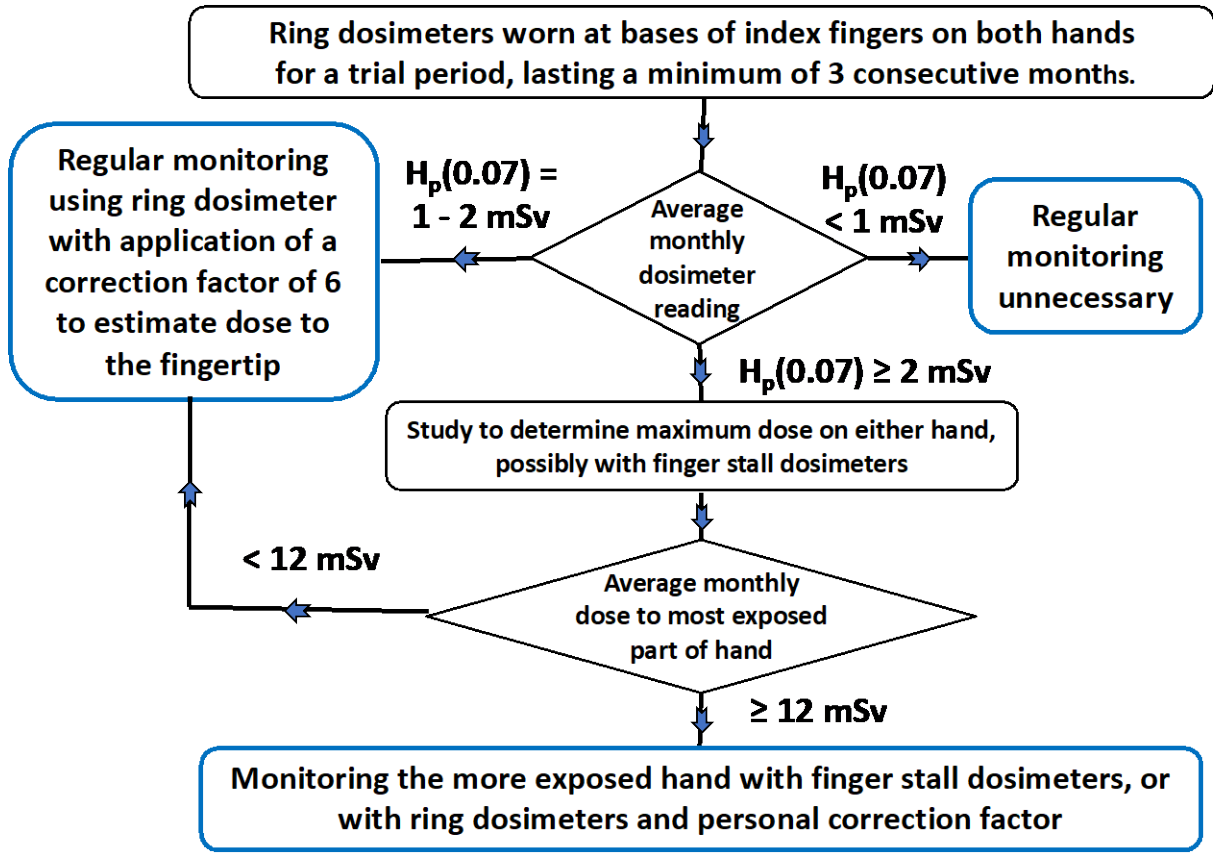

Fig. 8.3. Flowchart setting out decisions about extremity monitoring options based on a trial period with staff wearing ring dosimeters.

(422) If the average monthly dose, without correction factor is less than 1 mSv, regular monitoring is not necessary.

(423) If the average monthly dose, without correction factor is between 1 and 2 mSv, routine monthly monitoring can be done by a ring dosimeter that is worn at the base of the index finger of the more exposed hand. In order to derive the maximum skin dose, a multiplicative factor of 6 is recommended to estimate the maximum local skin dose.

(424) If the average monthly dose, without correction factor is above 2 mSv, the correction factor can no longer be considered accurate enough, and the real maximum dose across the hand (mostly the finger tip) should be determined. This can be done in a trial period by using finger stall dosimeters or other methods.

(425) If, as a result of this extra study, the average dose to the most exposed part of the hand is below 12 mSv, the correction factor of 6 can be considered conservative enough, and routine monitoring by a ring dosimeter that is worn at the base of the index finger of the more exposed hand using this factor of 6 can be done on a routine basis.

(426) If the trial shows that the average dose to the most exposed part of either hand is above 12 mSv, the correction factor of 6 cannot be considered appropriate. At this point routine monitoring by a finger stall dosimeter should be done, or an individualised multiplication factor should be derived from a more extensive monitoring trial comparing the fingertip dose to that at the routine monitoring location of the ring dosimeter, and this applied for future dose monitoring. If doses to the most exposed parts of both hands are above 12 mSv per month, regular monitoring of both hands is recommended. If a ring dosimeter is

used in this way, periodic checks of the fingertip dose should be made to confirm there has been no change in doses received because of increased workload or change in practices.

(427) If the vial and syringe containing radiopharmaceutical are both shielded effectively throughout all manipulations, and staff have undergone extensive training in techniques to avoid receiving high doses to the hand, then the ratio between the dose to the fingertip and that to a ring dosimeter worn at the base of the most exposed finger is likely to be less than six (Martin, 2016). If this is the case a lower correction factor may be applied to the ring dosimeter reading, but this must be justified based on evidence from extensive monitoring of the base and tip of the exposed finger(s) for an extended trial period.

8.3.6. Skin dose monitoring under contamination

(428) In cases of skin contamination with radioactive substances, immediate and rapid decontamination measures are of higher priority than an exact evaluation of skin activity and dose.

(429) Corrections of the measured dose with a dosimeter might need to be made if a dosimeter is contaminated or in the case of contamination on the protective clothing (ISO, 2015):

- When contamination is on the skin, there is a proportional relationship (for a given radionuclide) between instrumentation count rate and skin dose rate for contamination averaged over a small area (1 cm^2 or less). Thus, evaluations where the dose is low can be done without knowing the individual radionuclide activities, as the uncertainties will be big anyhow. For higher doses, though, it is important to determine the radionuclide activities so that a more accurate estimation of the skin dose can be made.
- When contamination is on protective clothing (e.g. gloves), it irradiates the skin and contributes to the skin dose. Its contribution to the skin dose should be quantified, taking into account attenuation through the protective clothing. After quantification, if its value is higher than the dosimeter reading, it shall be registered as the skin dose value obtained for the monitoring period. When the contamination is homogenous across the protective clothing or located directly at the dosimeter position, the dosimeter reading already takes into account the contribution.
- When an individual dosimeter is contaminated, the dosimeter reading is larger than the true dose to the respective individual. If the time the dosimeter has been contaminated, the activity and position of the contamination is known, this excessive reading of the dosimeter can be determined.

8.3.7. Internal dose monitoring

(430) An individual monitoring program for internal contamination should be decided based on risk assessment. If the decision factor is greater than 1, evaluated according to methodology proposed by IAEA (IAEA, 1999) and described in Section 8.1.1.2, a technique of whole-body counting should be implemented to quantify the internal contamination (in Bq). Once the activity (and the timing) is known, an estimate of dose can be obtained with the help of the OIR data viewer provided by ICRP on the web as supplementary material to ICRP *Publication 151* on 'Occupational Intakes of Radionuclides: Part 5' (ICRP, 2022).

9. DOSE MANAGEMENT AND QUALITY ASSURANCE PROGRAM

(431) Key points in this section:

- ICRP recommends an infrastructure exist to ensure appropriate standards of radiological protection and safety culture for staff, patients and the public.
- The infrastructure should include a legal framework, a regulatory authority, and a robust management system to address radiological protection in PET/CT settings.
- Comprehensive facility or hospital management involvement is key to a successful PET/CT or PET/MRI radiological protection quality assurance (QA) (aka quality management) and quality control (QC) program (aka quality management systems).
- A QA program is integrated into the healthcare system that describe what is expected of the PET/CT or PET/MRI radiological protection program including metrics to demonstrate the goals and objectives of the QA program are being met. Each facility should have an accident and misadministration review plan.
- Each member of the imaging team has a crucial and defined role.

9.1. Regulatory authority and legal framework

(432) *Publication 103* entitle 'The 2007 Recommendations of the International Commission on Radiological Protection' provides general recommendations for radiological protection, for three exposure situations (i.e. planned, emergency and existing) which includes PET/CT and PET/MRI mainly under the planned situation. The recommendations start with recommending ‘an infrastructure to ensure that appropriate standards of protection and safety are maintained’. The infrastructure should include: ‘…a legal framework, a regulatory authority, the operating management of any undertaking involving ionising radiation (including the design, operation, and decommissioning of equipment and installations as well as adventitious enhancement of natural radiation including aviation and space flight), and the employees at such undertakings.’ (ICRP, 2007b). Regulatory authority and legal frameworks are paramount for all aspects of radiological protection (ICRP, 2007b). This same concept is reported in the Safety Guide No. SSG-46 (IAEA, 2018).

(433) The Safety Guide No. SSG-46 asserts that comprehensive facility or hospital management involvement is key to a successful Quality Assurance and Quality Control program, to ensure radiological protection and safety related to medical, occupational and public exposures (IAEA, 2018). The IAEA has also developed a comprehensive program, Quality Management Audits in Nuclear Medicine (QUANUM) for Nuclear Medicine Practices, which would be applicable to PET/CT. *Publication 103* states that, ‘Verification procedures should include a review of quality assurance programmes and some form of inspection’ (ICRP, 2007b).

9.1.1. Management systems

(434) The IAEA revised the requirements and guidance in the area of quality assurance for safety standards on management systems for the safety of facilities and activities involving the use of ionising radiation (IAEA, 2018).

(435) *Publication 75* on 'Radiation dose to patients from radiopharmaceuticals' (ICRP, 1997a) reported: ‘management bodies of the institutions have the responsibility to maintain control and conduct the operation of the radiation exposures’ and that ‘explicit commitment

of an organisation to safety should be manifested by written policy statements from the highest level of management, by the establishment of formal management structures for dealing with radiological protection, by issuing clear operating instructions, and by clear and demonstrable support for persons with direct responsibility for radiological protection in the workplace and the environment'.

(436) The function of a management system provides confidence that specified requirements will be fulfilled (IAEA, 2014b). One of the most important functions of a management system in hospital or clinic-based PET/CT or PET/MRI operations is establishing institutional leadership that supports a 'just culture of quality and safety'. Management systems have several other responsibilities relating to radiological protection.

(437) Management systems, via organisational leadership, have a responsibility to establish a radiological protection quality management team that oversees, monitors and analyses quality indicators. Process improvements are implemented as required, based on the findings.

(438) Management systems should create policies and procedures that meet regulatory, accreditation and safety standards. Policies lay out the big picture of what needs to be achieved, whereas goals, objectives and procedures describe how the policies will be operationalised and monitored to demonstrate congruence with associated policies (IAEA, 2002).

(439) Management systems coordinate and facilitate department quality assessment and improvement plans. A best practice, quality assurance or quality management program includes an assessment of policies, protocols, and guidelines to improve radiological protection and safety including dose management and optimisation, performance improvements on operating equipment, and process improvement and plans for accidents (e.g., spills of unsealed sources) and misadministration of radiopharmaceuticals.

(440) ICRP recommends that management systems be subject to periodic review to guide continuous quality improvement, and result in written management requirements. It is best practice to include all relevant professional worker's involvement in developing management systems and methods to ensure that doses are as low as reasonably achievable (ICRP, 2007b).

(441) Management systems in a PET/CT or PET/MR department should set up a systematic process for analysing and managing reported events, safety incidents and improving safety as well as part of radiological protection and safety for patients, workers and the public. Management systems should also establish quality indicators to assess quality management issues and create an effective action plan to minimise disruption during implementation of the quality improvement that are found during the assessment phase. Management system should include review of MRI safety policy, when a change is made to the safety parameters of the MRI system (ACR, 2020).

9.1.2. Medical imaging team

(442) The American College of Radiology and the Association of Physicists in Medicine (ACR-AAPM) Technical Standards, outline the range of personnel who should be included in radiation safety protection i.e.: 'Radiologist, medical physicist, registered radiologist assistants, radiologic technologists and all supervising physicians have a responsibility for safety in the workplace' (ACR-AAPM, 2018). Please note that the term radiologist also includes a nuclear medicine physician and the term radiologic technologist includes the nuclear medicine technologist/radiographer as referenced to personnel that should be included in radiation safety protection. There is a need for the individuals to work together as a team. Each have unique skills and the individuals within the team should have a mutual respect for the contribution that each makes.

(443) This same concept holds true when working in a PET/MRI centre, in which, also, all personnel are responsible for their assigned MRI Safety. Each individual has a responsibility to work together as a team for the safety of the personnel, patient and public (ACR, 2020).

(444) These personnel contribute to radiation safety, 'by keeping radiation exposure to staff and to society as a whole 'as low as reasonably achievable' (ALARA) and to ensure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective' (ACR-AAPM, 2018).

9.1.3. Quality assurance and quality control in radiological protection

(445) Quality assurance (QA) also called 'quality management' or 'quality management system' can be defined as: all those planned and systematic actions necessary to provide confidence that a structure, system or component will perform satisfactorily in service. Quality control (QC) can be defined as: programs and processes related to the QA or quality management program to verify that structures, systems, and components correspond to predetermined requirements (adapted from IAEA, 2019).

(446) QA/QC programs are driven by senior leadership who are responsible for producing an overall quality assurance agenda. This agenda includes, continuous quality improvement goals for the overall health care system, coordination and implementation of improvements between different departments and services, and analyse relevant data and results to ensure optimal performance relative to radiological protection. Each member of the imaging team has a crucial role in PET/CT QA/QC programs as radiological protection in PET/CT is a shared responsibility of the entire imaging team.

(447) Successful QA/QC programs have assessment activities that determine the qualifications of personal working in the PET/CT department. The QA/QC program will also include activities that determine the equipment performance as well as processes that determine the effectiveness of quality control measures. A peer evaluation and technical review that assess the clinical images and exam protocols for dose optimisation and quality will also be incorporated into the program. Each facility QA/AC program should also include an accident and misadministration review plan (see section 9.2.2).

9.2. Optimisation of dose to patient

(448) Planned and systematic actions are needed to provide adequate confidence that all processes or services will satisfy given requirements for quality: for example, those specified in the facilities operational license.

(449) Optimisation of patient radiation dose is one of these planned and systematic actions to ensure ALARA principles are being followed (IAEA, 2014a). Optimising patient dose is finding the right balance between administered PET radiopharmaceutical activity and PET image quality. All member of the imaging team (e.g. Radiologist, Nuclear Medicine Physician, Physicist, Nuclear Medicine Technologist/Radiographer and Management) can have valuable input on how to achieve the optimal balance. Recommendations concerning optimisation of dose to the patient are provided in Section 6.

9.2.1. Patient dose management

(450) Optimisation should result in the lowest administered radiopharmaceutical activity possible while preserving image quality (see Section 6.3).

- It is acknowledged that administered activity and patient throughput are related, but this should be monitored keeping ALARA in mind. In the setting of high clinical demand higher administered activity may prevail to shorten imaging time to allow for higher patient throughput.
- PET/CT technologies are continually evolving relative to increased detector sensitivity, hardware and software improvements, and lower dose CT options. Such technological improvements should be exploited to achieve the optimal combined injected PET radiopharmaceutical and CT patient doses.
- The European Association of Nuclear Medicine (Boellaard et al., 2015) published the following 2-[^{18}F]FDG dosage guidelines (linear-pragmatic approach for adults):

  (i) For systems that apply a PET bed overlap of ≤30 %, the minimum recommended administered activity is calculated as follows:

  $$\text{2-[}^{18}\text{F]FDG (MBq)} = 14\ (\text{MBq}\cdot\text{min}\cdot\text{bed}^{-1}\ \text{kg}^{-1}) \times \text{patient weight (kg)} / \text{emission acquisition duration per bed position (min bed}^{-1})$$

  (ii) For systems that apply a PET bed overlap of >30 %, the minimum 2-[^{18}F]FDG administered activity is calculated as follows:

  $$\text{2-[}^{18}\text{F]FDG (MBq)} = 7\ (\text{MBq}\cdot\text{min}\cdot\text{bed}^{-1}\ \text{kg}^{-1}) \times \text{patient weight (kg)} / \text{emission acquisition duration per bed position (min}\cdot\text{bed}^{-1})$$

- For systems that allow variable imaging times per bed positions (e.g. reduced time for extremities) the time per bed position for abdomen/thorax should be used in the above calculations (Boellaard et al., 2015).
- For heavier patients, i.e. > 90 kg, increasing time per bed position is preferred over increasing injected dose especially for L(Y)SO detector systems (Masuda et al., 2009).
- Lassmann et al. (2014) have summarised European and North American paediatric 2-[^{18}F]FDG dosing guidelines.

9.2.2. Standard operating policy for accidents, radioactive spillage or misadministration of radiopharmaceuticals

(451) Medical radiation accidents, spills, and unintended radiopharmaceutical administrations may lead to accidental or unintended medical exposure of patients and exposure of staff or the public, and have been reviewed (Marengo et al., 2022). As part of the Quality Management program, leadership should establish a robust safety system which includes an accident reporting system to capture near misses, deviations, accidents, radioactive spillage or contamination incidents and misadministration (e.g., wrong dose, wrong patient, extravasations) of radiopharmaceuticals (Martin et al., 2019a). The safety program should include policies and procedures to ensure safe practice is being followed during the clean-up of an unsealed radioactive source spill or any other radioactive accident (e.g. waste accident). It should also include a dosimetric assessment when dealing with misadministration of radiopharmaceutical. The safety program needs also to include both regular ongoing training of staff and a continuous quality improvement risk management strategy related to radiation exposures (public, patient and occupational) from standard operating policies. Within this risk management strategy leaderships should include assessment of radiation protection related processes, such as periodic review and updates, which could be in a form of a review or audit. The IAEA Quality Management Audits in Nuclear Medicine (QUANUM) for Nuclear Medicine Practices, would be an example that could be used in PET/CT (IAEA, 2021b).

9.3. Optimisation of equipment parameters

(452) As technologies and protocols evolve dose management strategies should be reviewed to determine if further dose reductions are possible without adversely impacting on image quality. Section 6.3 on patient dose optimisation by hardware and software provides several strategies for optimisation.

9.3.1. PET subsystem

(453) New PET/CT technology, as reviewed in Section 2, allow 3D mode acquisition imaging with higher count statistics. Also, time of flight (TOF) imaging improves signal to noise ratio, especially for larger patients. All of these factors allow for reduction in the patient's dose of the radiopharmaceutical.

9.3.2. CT subsystem

(454) CT portion of the PET/CT may specifically be used for attenuation correction and anatomical location resulting in a lower radiation dose and a lower, but acceptable image quality. Depending on the circumstances it may also be efficient to obtain a standard clinical quality CT as part of the PET/CT study which may avert duplicate CT studies and be more convenient for patients.

(455) Several CT radiation dose quality assurance tools are available (see Section 6.2). The CT radiation dose can be lowered by adjusting a combination of the following parameters: lower tube voltage (i.e. kVp), lower tube current (i.e. mAs), automatic tube current modulation and properly centring the patient, shorter scan length, increase pitch, collimation, image acquisition, and processing software options such as iterative reconstruction and thicker slice thickness (ICRP, year2). Hara et al. found that mis centring the patient by 2.2 cm from the isocentre can increase the CT dose index by an average of 23% (Hara et al., 2013).

(456) Lowering CT dose by adjusting tube current and peak kilovoltage is a good option noting that this will have to be tailored between different vendor scanners. Hara (2013) explains, 'Vendors use different tube current modulation techniques and reconstruction algorithms to achieve high quality image with lowest dose possible i.e. GE uses noise index to determine image quality by adjusting the peak kilovoltage and minimum or maximum tube current' (Hara et al., 2013; Martin and Sookpeng, 2016). Ensuring the pre-scan image includes the entire area of interest for the scan will ensure that the ideal tube current module is used.

(457) A good rule to remember, holding kVp and mAs constant, is that the thinner slices result in noisier images. While thinner slices may be desirable, in order to maintain constant noise you will have to increase kVp or mAs or both.

(458) Denoising and Iterative reconstruction techniques can enable CT doses to be lowered through the reduction in image noise. The operator will have to actively select exposure parameters to reduce the doses. In very large practices with multiple PET/CT system from different vendors, a vendor neutral denoising can be used to reduce the CT radiation dose.

(459) The CTDI dosimetry measurement is based on phantoms of standard size and so the value displayed is independent of patient size. As a result, authors have reported that CTDIvol will underestimate patient dose in small patients and notably paediatric patients. Optimally CT dose should consider a combination of the patient size and scanner radiation output. The AAPM Task Force report 204 published, 'conversion factors that were developed

to be used with CTDIvol, to estimate the dose at the centre of the scanned region' (AAPM, 2011).

(460) The conversion factors give a size specific dose estimate (SSDE), 'which takes into account the size of the patient, using linear dimensions measured from the patient or patient image (AAPM, 2011).

9.4. QA/QC program overview in a PET imaging facility

(461) A part of the overall QA/QC program aims at ensuring the optimisation of the equipment parameters, in order to systematically guarantee that the performance meets the specification set by the overall QA/QC for the PET/CT imaging system.

(462) Each member of the imaging team has a specific role and contribution to make to the overall QA/QC program while noting they work as a team and their individual role will overlap and rely on other team members. Because of this, it is essential that all members of the team have a sound understanding of the goal and components of the entire QA/QC program.

(463) There are many organisations that have published international and national guidance to assist in establishing a best practice QA/QC program that contributes to radiological protection measures.

(464) The National Electrical Manufacturers Association (NEMA) created a set of standards for the performance characterization of PET scanners (see below). International organisations such as the International Atomic Energy Agency (IAEA) have also issued publications 'guidelines for the implementation of QA/QC Programmes concerning the combined medical diagnostic modalities of PET and CT Technologies.' (IAEA, 2009b). For example, the IAEA (2009b) has published guidelines for routine QC of PET and PET /CT scanners, including acceptance testing on measuring performance standards against the manufacturer's published specifications including best practice for timing and documentation QA.

(465) AAPM task group 126, 'has published that the most widely implemented and cited reference for testing PET/CT systems is the NEMA Standards Publication NU 2–Standard Performance Measurements of Positron Emission Tomography (PET) set forth by the Medical Imaging and Technology Alliance (MITA) division of NEMA' (AAPM, 2019b). The NEMA NU 2 (NEMA, 2018) standard is generally the best performance evaluation of the PET subsystem because the different manufacturers publish performance specification based on this standard. NEMA PET procedures require additional testing materials and special phantoms to perform the testing.

(466) The International Electrotechnical Commission (IEC) has also produced several procedure assessments that can be used as best practice which can provide uniform methods and procedures to measure performance published specifications of PET/CT scanners (IAEA, 2009b).

(467) National and international professional bodies and associations such as the EANM, the American Association of Physicists in Medicine (AAPM), SNMMI, and the American College of Radiology (ACR) have developed technical standards, recommendations, and guidance documents (e.g. Sokole, 2010a,b; Hristova, 2017; AAPM, 2019b; ACR-AAPM, 2018) that can simulate procedures that do not require proprietary equipment and software. These guidance documents, technical standards, and best practice documents can all help to establish QC tests that can be compared with the manufacturer's PET/CT published specifications and customise an appropriate QA/QC Programs that provide best practice at your facility.

(468) Existing QC technical standards, recommendations and guideline documents from national professional bodies are less common for PET /MRI but both the American College of Radiology and Intersocietal Accreditation Commission (IAC) have developed and published documents. The AAPM have also provided guidelines for QC Procedures for associated MRI units that can be used (AAPM, 2010). Recently, the EU-funded HYBRID project published a survey and an attempt to reach a consensus on the topic of PET/MR QC (Valladares et al., 2019).

(469) National professional bodies such as the AAPM and the ACR have developed technical standards, recommendations and guideline documents that provide guidelines for acceptance testing and QC procedures for Computed Tomography scanners (AAPM, 1993; ACR-AAPM, 2017).

9.4.1. QC imaging personnel

(470) Best practice QC program have processes in place that allow tracking of relatively small changes in the system performance that can contribute to decreased imaging quality which is illustrated in the results of the Quality Control testing done during the initial acceptance testing, commissioning, daily, weekly, monthly, quarterly or annual testing. These tests are performed by the Nuclear Medicine Technologist/Radiographer or Medical Physicist and analysed by the appropriate member of the Imaging team. The Department Medical Director should be involved with reviewing the results as need be.

(471) The Radiologist or Nuclear Medicine Physician oversees the clinical PET and PET/CT practice including assessing the diagnostic quality of the acquired images. They play an important role to ensure and help determine the lowest achievable PET radiopharmaceutical and CT radiation doses to the patient for specific imaging studies while preserving overall image quality. They play an indirect role by evaluating the image quality against the results in the final evaluation of QC tests of instrumentation of both the PET and CT, or PET and MRI and the radionuclide calibrator.

(472) Medical Physicists help to determine the output of radiation dose from the CT component of the PET/CT scanner and adjust imaging parameters of PET and CT (or MRI) scans to obtain the highest quality image while aiming for the lowest achievable radiation dose to the patient. They also play a vital role in helping optimise imaging protocols for both PET/CT and PET/MRI. During the commissioning of the PET/CT scanner the physicist helps to establish CT protocols which can be used for attenuation correction, localisation and diagnostic purposes.

(473) Nuclear medicine technologists/radiographers customise image acquisition and processing software, and operate the PET/CT and PET/MRI scanner, to ensure that the PET/CT or PET/MRI operate as expected and achieve expected predetermined injected radiation and CT patient doses. Vendor protocols are customised, based on site specific needs and factors, to optimise both image quality patient dose.

(474) Boellaard et al. (2015) state ‘PET is a quantitative imaging technique and therefore requires a common quality control (QC)/quality assurance (QA) procedure to maintain the accuracy and precision of quantitation. Repeatability and reproducibility are two essential requirements for any quantitative measurement and/or imaging biomarker’.

(475) The QA/QC program is generally overseen by Medical Physicists who assist in a range of activities including pre-acquisition equipment assessment, acceptance testing, routine QC procedures and trouble-shooting unexpected equipment events. They may also be involved with tailored software and hardware solutions for research protocols and this activity involves assessing such protocols to ensure they meet the ALARA principle. When

performing QC testing that will be used for radiation therapy treatment planning collaboration with a radiation therapy physicist is recommended (AAPM, 2019b).

9.4.2. QC process overview

(476) PET/CT equipment should undergo manufacturer, operator, and regulator recommended, and depending on the jurisdiction, required surveys/testing by qualified individuals at specified periodicities. This survey is to ensure that the equipment is functioning properly and producing optimal imaging at the lowest radiation doses possible to the patient.

(477) There are three components which make up an equipment QC program or quality management program: acceptance testing, periodic routine testing sometimes called performance testing, and annual testing. These three QC program components are intended to verify that the specific predetermined criteria are met at installation, the system is optimally performing properly, and that the images produced are accurate, reproducible and of high quality.

9.5. Components of QC program

9.5.1. QC acceptance testing on equipment

(478) The first component of a QC program is acceptance testing, which happens following equipment installation and should be performed on all equipment used in the PET/CT or PET/MRI department. The acceptance testing of the PET/CT or PET/MRI scanner and all other equipment needs to be completed prior to clinical imaging.

(479) The ICRP *Publication 60* defines an acceptance test as a 'test carried out at the request and with the participation of the user or his representative to ascertain by determination of proper performance parameters that the instrument meets the specifications claimed by the vendor' and recommends that an acceptance test be carried out at the time of installation and when appropriate after major service (ICRP, 1991).

(480) Acceptance testing establishes baseline performance parameters which can be used to track changes and trends in future performance (IAEA, 2009b; AAPM, 2019b). Acceptance testing outcome data also helps in determining optimal operating parameters for clinical procedures.

9.5.2. QC periodic and performance testing on equipment

(481) The second component of a QC program is routine periodic which generally includes daily, weekly, monthly testing and the quarterly performance testing to monitor the technical performance (follow-up measurements). These tests include assessing for performance trends to ensure compliance with regulatory agencies and recommending bodies, as well as to evaluate if the scanner performance has deviated from the initial assessment (AAPM, 2019b).

(482) Unscheduled performance testing should occur prior to recommencing imaging on a patient after PET/CT repairs or part replacement (e.g. a new CT tube) as well as after re-calibration or software/hardware upgrades.

(483) Performance testing is part of a QC program that periodically evaluates the performance of the PET/CT scanner. This testing generally happens after quarterly preventative maintenance and periodic scheduled calibrations. Generally, it is set up on a

timeframe that is established according to manufacturer's recommendations and according to best practice recommendations established by professional and national accreditation bodies.

(484) As with all parts of aspects of the QC program annual testing serves an important component of the overall program, with service engineers ensuring that the system is performing within the manufacturer published specification during maintenance testing, nuclear medicine technologists/radiographer and medical physicists also perform specific annual QC tests (ACR, 2017). Annual QC testing can detect possible equipment failures before they create an image quality problem (ACR, 2017). Annual QC testing also illustrates important information that can contribute to the optimisation of medical dose to the patient and the ability to continue to find ways to improve image quality with the ALARA principle.

(485) In addition, PET radiopharmaceutical dosing schedules should be periodically reviewed to ensure optimisation of the administered activity. Dose delivered for the CT or related to the CT protocols should be also verified annually.

(486) Annual Testing of the PET, CT or MRI subsystem of the scanner by a medical physicist trained in each of the specific subsystem is essential to a successful Quality assurance program.

9.6. QC Testing PET, PET/CT, or PET/MRI

9.6.1. QC Acceptance testing

(487) Acceptance testing is a legal, regulatory or policy requirement in many countries. This testing is performed to ensure that PET/CT scanners, including hardware and software, are installed and set up properly according to manufacturers and industry published specifications. Acceptance testing should always be performed by a qualified and knowledgeable medical physicist with expertise in both PET and CT (Rausch et al., 2014; ACR-AAPM, 2018).

(488) Acceptance testing guideline has been published by several organisations including AAPM, EANM and IAEA for PET/CT scanners (Table 9.1). Acceptance tests of the CT part of PET/CT scanner systems have been described in an IAEA document (2009b) (Table 9.2), and performance evaluation of the CT in reports by AAPM and ACR (ACR, 2017; AAPM, 2019c).

(489) Acceptance testing for a PET/MRI scanner should always be performed by qualified and knowledgeable medical physicists with expertise in both PET and MRI (AAPM, 2010; ACR, 2015). Acceptance testing guidelines for MRI have been established by several organisations including ACR and the AAPM, and establish a baseline performance of the equipment (AAPM, 2010; ACR, 2015). Common QC Acceptance testing on the MRI from these organisations include magnetic field homogeneity evaluation, slice-position accuracy, slice-thickness accuracy, RF coil checks, including signal-to-noise ratio and image intensity uniformity of volume coils, soft-copy monitor QC and MR safety program assessment (Valladares et al., 2019).

Table 9.1. Acceptance and periodical testing for PET.

Test	AAPM (2019b)	EANM (Sokole, 2010a,b)	IAEA (2009b)	ACR-AAPM (2018)
Physical inspection		Ac/D	Ac	
Computer clock synchronization	W	Ac	Ac	
Daily QC	D	D	D	D

Normalization	Q	S	AC/M	
Radioactivity concentration calibration	Q	S	M	Q/A
Sensitivity	Ac/A	AC/M	Ac	A
Uniformity	A	AC/*	Ac/Q	Q/A
Spatial resolution	Ac/A	AC/A	Ac	Q/A
Count rate performance		AC/†		A
1. Scatter fraction, count loses and randoms	Ac/A		Ac	
2.Accuracy: Corrections of count losses and randoms	Ac/A		Ac	
Image quality	Ac	A	Ac/A	Q/A
Energy resolution			Ac	
Time of flight resolution			Ac/D	
PET/CT co-registration accuracy/offset calibration	Q		Ac/Q	A
PET/CT scan in clinical mode			D	
Routine image quality PET/CT	Q		D	
Image display monitor evaluation	A			
Emergency button testing/Safety	A			A

Ac, Acceptance; A, Annual; Q, Quarterly; S, Variable, at least six-monthly; W, Weekly, D, Daily.
*After maintenance/new setups/normalization.
†After new setups/normalization/recalibration.

Table 9.2. Acceptance and periodical testing for the CT subsystem.

Test	IAEA (2009b)
Scattered radiation measurement and shielding verification	Ac/A/P
CT laser alignment	Ac/A/P
Table top alignment and positional accuracy and pre-scan view accuracy	Ac/A/P
Visual inspection and programme review	Ac/A
Display profile and width	Ac/A/P
High contrast modulation	Ac/A/P
kVp and half-value layer	Ac/A/P
Radiation dose and image Quality	Ac/A/P
CT number accuracy	Ac/A/P

Ac, Acceptance; A, Annual; P, Post Service of related components.

9.6.2. Daily and weekly QC

(490) The technical parameters of daily and weekly PET and CT QC testing will vary by manufacturer and should be followed to ensure optimal overall performance and consistency (IAEA, 2014a). These QC tests are usually performed by nuclear medicine technologists/radiographers at the start of the day and prior to patient imaging, to make sure the scanner is operating correctly. The tolerance is generally set by the manufacturer of the system and the outcome of this procedure is generally a visual change or a warning displayed that lets the nuclear medicine technologist/radiographer know there is a change in detector uniformity or an electronic error (IAEA, 2009b). These procedures help to ensure that the PET and CT systems are operating correctly and that the radiation output of the scanner is accurate (IAEA, 2009b; Boellaard et al., 2015).

(491) When a nuclear medicine technologist/radiographer observes a parameter outside of the tolerance range or an artefact appears on the PET sinogram it generally means there is a minor drift or a PET detector block defect and there are protocols to help determine the clinical impact of such artefacts (Elhami et al., 2011). The nuclear medicine technologist/radiographer should repeat the detector normalization test to see if it comes back in tolerance. If the PET/CT does not meet daily QC parameters the appropriate person should

be called (e.g. medical physicist, equipment vendor etc.,) depending on the malfunction of the equipment or software. Of note major changes or replacement of parts generally require recalibration of the detector and this should be performed and approved by the e.g. medical physicist before clinical use (IAEA, 2009b).

(492) The guidelines and frequency of technical parameters, including daily and weekly MRI subsystem, QC testing have not achieved a consensus between national and international bodies but there is agreement that QC testing is beneficial to detect equipment performance or image quality issues (ACR, 2015; Valladares et al., 2019).

9.6.2.1. Daily QC on PET Subsystem

(493) The daily PET detector stability test or daily system test is performed to assess the function of the detector modules (Elhami et al., 2011; Sokole, 2010b; IAEA, 2014a; Valladares et al., 2019). Coincidence timing resolution is also recommended daily on Time-of-Flight PET scanners to ensure constancy of the timing resolution (IAEA, 2014a). Some PET systems can perform these tests/measurements automatically over night.

9.6.2.2. Daily QC on CT Subsystem

(494) Daily quality control procedures include a system CT warm up procedure which warms the x-ray tube and should be performed any time the system sits idle for a certain time frame or when the CT tube temperature falls below an established temperature set by the vendor (IAEA, 2009b; IAEA, 2014a). Another daily CT system procedure verifies that the structures, systems and components are meeting corresponding predetermined requirements sometimes called an air calibration procedure. The final step in the daily QC on the CT system is to use a water filled phantom to check the CT parameters of contrast scale, noise, uniformity, linearity, high contrast spatial image resolution and low contrast detectability test (IAEA, 2014a).

9.6.2.3. Daily QC on MRI sub-component of PET/MRI

(495) The European commission HYBRID project summarised relevant guidelines and recommendations for PET/MRI system QC testing. (Valladares et al., 2019). In general MRI QC should not be overdone. Centre frequency tuning, gain adjustment and shimming are intrinsically performed on a per patient basis. If no vendor specifications are provided the image quality test should be performed according to the AAPM or ACR guidelines (AAPM, 2010; ACR, 2015).

9.6.3. Periodic QC

9.6.3.1. QC testing PET subsystem

(496) More detailed maintenance and PET/CT scanner testing are done usually quarterly, semi-annually or annually (Table 9.1). Most of the procedures should be performed using a team approach with both the nuclear medicine technologist/radiographer and the medical physicist participating in the procedure (IAEA, 2009b). For example, one such quarterly PET/CT QC test is the normalization scan on the PET subsystem which provides corrections required to obtain uniform coincidence sensitivity within a single imaging plane (Keim, 2014). According to IAEA, the PET normalization test is critical as, incorrect normalization data will compromise the image quality (IAEA, 2009b). Some recent PET systems, however, will check the normalization on a daily basis, based on an automatic overnight scan.

Following manufacturer's guidelines on this procedure is essential to ensuring image quality. A good practice is to perform a back-up of the previous calibration file in case there is a problem with the normalization or if the radioactivity concentration calibration study is outside of the tolerance parameters that have been established during the acceptance testing. Manufacturers use different terms to define dose calibrator QC procedures including: well counter calibration, radioactivity calibration factors and SUV calibration (IAEA, 2009b).

(497) Hristova describes that 'Implementation of rigorous QC procedures ensures that basic data affecting SUVs are verified prior to readouts. In the absence of QC, readouts could be merely a reflection of technical factors, and conclusions about the validity of PET as an imaging biomarker may be inappropriate' (Hristova et al., 2017). The efficiency data is used in calculation of radioactivity concentration and presented as the Standard Uptake Values (SUV) or units of activity per cm^3 of decay corrected activity. These Quality Control procedures should be performed quarterly or whenever the PET part of the system has a malfunction or a part replaced or serviced.

(498) The comprehensive performance testing should include annual QC activities that determine whether predetermined requirements are being met (IAEA, 2018). The medical physicist can add the annual evaluation to one of the quarterly PET subsystem QC performance evaluations. Accurate co-registration of the PET system and the CT system, which is essential to ensure that proper attenuation correction occurs, should also be performed at acceptance testing, quarterly as well as annually. AAPM, EANM, IAEA, and ACR-AAPM all provide international protocols for recommendation for testing of PET system and their frequency (IAEA, 2009b; Sokole, 2010b; ACR-AAPM, 2018; AAPM, 2019b).

9.6.3.2. QC testing CT subsystem

(499) Annual Testing on the CT subsystem of the scanner by the medical physicist is an essential component of a successful Quality assurance program. Laser positioning QC is especially important if PET/CT images are exported and used for RT planning. The annual CT review should also include a review of the clinical protocols to ensure optimisation of the CT component in relation to the required level of image quality. QC annual tests of the CT part of PET/CT scanner systems (Table 9.2) have been described in an IAEA document (2009b). Detailed QC evaluation of the CT systems can also be found in reports of AAPM and ACR (ACR, 2017; AAPM, 2019c;).

9.6.3.3. QC testing MRI subsystem

(500) In order to discover possible failures, a more frequent testing scheme was suggested by the HYBRID consortium increasing the image quality test frequency to at least quarterly to check for minimum acceptable MRI image quality. Due to the large discrepancy between recommendations, HYBRID suggested a monthly check of the most used coils and whenever a coil is replaced for easy implementation (Valladeres et al., 2019).

(501) In general, no significant interference between MRI and PET subsystems has been observed (Delso et al., 2011). Simultaneously testing of the PET and MRI subsystems is therefore not likely to be necessary. However, registration of MRI and PET isocentre should be tested to ensure proper image alignment. The PET and MRI alignment should be checked and calibrated after mechanical changes or repairs and after major software update revisions.

(502) In addition to the HYBRID recommendations, specific site quality assurance and testing can be necessary. The QC program and frequency should be tailored to the specific need of the MRI application and use.

(503) ACR recommends testing the image quality once a year (ACR, 2015). Annual testing of the MRI subsystem includes: setup and table position accuracy, centre frequency, transmitter gain or attenuation, geometric accuracy measurements, high-contrast spatial resolution, low contrast detectability, artefact evaluation, visual checklist, magnetic field homogeneity, slice-position accuracy, slice-thickness accuracy, radiofrequency coil checks, soft -copy quality control and MR safety program assessment. The medical physicist annual review of the MRI QC program should also include a review of the sites' safety guidelines, practices and policies (ACR, 2015).

9.7. QC testing radionuclide calibrator

(504) Radionuclide calibrators or activity meters are used to assay the radioactive material to ensure the patient receives the appropriately prescribed activity. Both AAPM and EANM provide international protocols for recommendation for acceptance and testing of radionuclide calibrators and their frequency (Sokole, 2010a,b; AAPM, 2012) (Table 9.3).

(505) Harmonised clock accuracy is important between the activity meter, injection time and imaging times. Accuracy between these functions should be within one-minute to ensure quantitative imaging accuracy (IAEA, 2009b; AAPM, 2019b). If multiple activity meters are being used, they should be cross calibrated to within an acceptable degree of variance (Chu and Simon, 1996).

Table 9.3. Recommended testing for radionuclide calibrators.

Test	Acceptance		Daily		Annually	
Physical inspection	E	A	E	A		A
System electronic		A		A		A
Clock	E	A	E	A		A
High voltage	E	A	E	A		A
Zero adjustment	E	A	E	A		A
Background	E	A	E	A		A
Check source		A		A		A
Constancy			E			
Accuracy	E	A			E	A
Stability/ Precision/Reproducibility	E	A			E	A
Linearity	E	A			E	A
Geometry	E					
Calibration for different containers and volumes	E					
Supplier equivalence		A				A

A, AAPM (AAPM, 2012); E, EANM (Sokole, 2010a,b).

9.8. QC radiation monitoring instruments and other equipment

(506) Daily radionuclide QC involves different tests (AAPM, 2012; Sokole et al. 2021b). The acceptable level of the accuracy test is within 5% of the expected value (Chu and Simon, 1996). Constancy, background and voltage testing are also done daily. Annual radionuclide QC includes most of the acceptance tests.

(507) Radiation monitoring instruments: exposure meter, contamination monitor, personnel electronic dosimeters or area monitors need routine QC tests performed. QC

procedure should be performed before each day of use including physical inspection of detector, measuring unit and cables, battery voltage check and background count. Annual QC testing includes: sensitivity to test constancy using a long half-life radioactive source, accuracy, precision and linearity of response are also recommended annually by a qualified party (e.g. medical physicist) or according to compliance with national guidelines (Sokole et al., 2010b). In some countries radiation monitoring instruments have to additionally be certified on a periodic basis by an External Body, recognised by the Regulatory body.

(508) Additionally, annual QC testing on the scale that a patient is weighed on should be checked and calibrated if outside of tolerance levels.

9.9. Summary overall QC program

(509) The acceptance and annual report are essential for a best practice in Quality Assurance and Quality Control programs and should also be kept and available for regulatory inspections, accreditation reviews and management meeting review. Written reports with finding from the performance evaluation and the corrective action implemented from the service engineer should all be kept and available to any member of the Imaging team.

10. EDUCATION AND TRAINING IN RADIOLOGICAL PROTECTION

(510) Key points in this section:

- A health professional that performs PET/CT or PET/MRI procedures must be proficient in radiological protection and safety, not only due to legal requirements, but to guarantee safety for patients, workers, and public in general.
- This proficiency is obtained through formal education at undergraduate and post-graduate levels, practical training and continuous professional development.
- Many International stakeholders, such as the IAEA, WHO, ICRP, EC, EUTERP Foundation and HERCA have extensively detailed the responsibilities and needs for education and training in Radiological Protection, for all groups of health professionals.
- It is important to use existing tools to further develop and adapt a local framework for the educational programs, that would ensure radiological protection and safety in a PET/CT or PET/MRI facility.

10.1. Foreword

(511) Although many stakeholders have for many years been developing and publishing documents that provide an educational framework for radiological protection, including specificities for the practice of PET/CT, practices and education across the world differ widely, and have many weaknesses. This was also acknowledged recently by a consensus document issued by representatives of European professional societies (Rainford et al., 2022).

(512) Therefore, taking into consideration the observed differences, a need to construct a standardised framework has led to the revision of current training plans (formal and informal, as well as continuing education), and these may be implemented in those countries that need them.

10.2. International stakeholders' recommendations

(513) The introduction and use of hybrid imaging, such as PET/CT or PET/MRI, linked with increasing clinical applications of these diagnostic methods, arose challenges early on for the professionals' core education and training. Focus on how to implement training for each of these modalities and their fusion in the same procedures, both formally (i.e. within current educational systems) and informally, became agenda items for discussion among nuclear medicine physicians, radiologists, nuclear medicine technologists/radiographers and medical physicists, either locally or in respective professional and scientific organisations.

(514) Traditionally, nuclear medicine technologists educational training programs did not include CT or MRI in their curricula. Regarding nuclear medicine physicians, their contact with these imaging modalities was mainly concerning indications and their role into diagnostic decisions flowcharts, and not the procedures in depth. This new technology then posed some equipment operational challenges and potential greater risk to the patient radiation dose, due to the less preparation of these professionals regarding the CT image acquisition protocol.

(515) There are distinct aspects of exposure that need to be included in radiological protection and safety educational programs and ongoing training for professionals practising in a PET/CT facility. First, the education and ongoing training on how to deliver medical

exposure to the patient with special focus on dose optimisation and implementation of the ALARA principle. Related to this, educational programs have to include the concept and proper use of Diagnostic Reference Levels (ICRP, 2017a). Second, education and ongoing training on how to reduce the occupational exposure to the staff performing the procedure and strategies to be considered which ensure that the occupational exposure will be as low as possible. Finally, educational and ongoing educational training to understand public exposure, for example that related to members of the public in waiting rooms, who may receive radiation from patients that have already been injected with a radiopharmaceutical (IAEA, 2018).

(516) Each member of the imaging team plays a crucial role in radiological protection, andradiation safety in PET/CT or PET/MRI. Initial qualification and initial educational training help ensure a baseline understanding of how to deliver safe and appropriate use of the medical exposure. Continuous professional development (CPD), education and training will help to ensure that the imaging team is knowledgeable on how to appropriately optimise the dose to the ALARA principles, and continuously improve it as well as understanding MRI safety. As health care professionals, each and every member of the team has different roles to play in each of these areas of radiological protection and safety.

(517) In 2012, a technical meeting was organised by the IAEA to understand 'the current status and trends of hybrid imaging using nuclear techniques, hybrid imaging role in clinical practice and associated educational needs and challenges' (Kashyap, 2013). Educational training and requirements for the use of this technology was of key concern for all stakeholders. It became apparent that education and practice needs differed depending on what part of the world you were working in.

(518) At this technical meeting, a Strengths; Weaknesses; Opportunities; Threats (SWOT) analysis was performed for PET/CT, as well as data collected concerning hybrid equipment availability in regions throughout the world, practices of nuclear medicine and radiology professional groups and educational training available for both Nuclear Medicine and CT practitioners. It was concluded that practice and education was very different all over the world and that there was a need to draw a more standardised approach, appropriate to formal and on-the-job training, to meet the technological advances in a timely manner, in order to allow for growth in knowledge and clinical benefit for patients. This Technical Meeting, in terms of education and training needs, focused more in the clinical curricula for future medical specialists dedicated to hybrid diagnostic procedures, but also approached Radiological Protection and Safety topics, as, for instance, reinforcing the need for training the process of justification of requests for diagnostic procedures with radiation exposure.

(519) Stakeholders and professional organisations are continuously trying to determine how to best meet the educational demands for medical users of radiation in a timely manner. At another meeting, hosted both by IAEA and WHO, and held around the same time as the above-mentioned Technical Meeting, a document was produced, called 'The Bonn Call for Action', which highlighted 10 actions that would strengthen Radiological Protection for patients and health care workers. Action Four, called 'the strengthening of radiological protection education and training of health Professionals', states this response will happen by integrating 'radiological protection into the curricula of medical schools, ensuring the establishment of core competency in these areas' as well as paying 'particular attention to the training of health professionals in situations of implementing new technology' (IAEA and WHO, 2012).

10.2.1. Recommendations for educational and training from ICRP

(520) *Publications 103* ('The 2007 Recommendations of the International Commission on Radiological Protection '), *105* ('Radiation Protection in Medicine'), and *113* (' Education and training in radiological protection for diagnostic and interventional procedures.') set out the framework for Radiological Protection, providing needs in terms of categorical educational training to support radiological protection, respectively. Hence, in all these documents it is possible to identify educational and training issues relevant for PET/CT and PET/MRI.

(521) *Publication 113* provides the relevant components and specific details of education, training and continuous professional development that are essential for all health care professionals that have a direct role with medical exposure including the specificities for PET/CT (ICRP, 2009). Education should start at the entry of the professional's career through formal education and continue throughout the professional's entire career in the form of CPD.

(522) *Publication 113* states that the specific training related to radiological protection should be included whenever new equipment or techniques are introduced in the professional facility (ICRP, 2009). This training and education contribute to the establishment of core competency in radiological protection. This specific training also helps the imaging team establish safe practices that will contribute to ALARA principle during the medical exposure to the patient, occupational exposure to the staff and public exposure.

(523) Formal education on radiological protection should be an established part of the curricula for physicians, nuclear medicine technologists, radiographers and medical physicists. Regarding physicians, although with different levels of complexity, this education and training in radiological protection should be applied not only to nuclear medicine specialists and radiologists, but also to physicians referring patients for nuclear medicine and radiological procedures.

(524) Training and education on radiological protection for all staff should be a standard of practice during new staff orientation and induction procedures and as part of the overall education that staff receives as employees during their employment. This training should be a part of an ongoing yearly CPD to assess a competency. Because of the highly sophisticated hybrid equipment that PET/CT or PET/MRI staff are using every day and the evolving role of technologies, CPD on new clinical indications, new PET/CT or PET/MRI technology and the development of new radiopharmaceutical is a common day practice for the nuclear medicine physician, nuclear medicine technologist/radiographer and medical physicist, and indispensable for them to stay abreast on developing technology.

10.2.2. Recommendations for education and training from other international organisations

(525) In 2014, the Directorate-General for Energy from the European Commission, in its Radiological Protection Series, published a booklet with guidelines on education and training of medical professionals in radiological protection (EC, 2014b). This document is in agreement with *Publication 113*, and in fact reinforces its orientations, also defining: 1) different categories or groups of health professionals, with corresponding levels of knowledge and expertise expected; 2) objectives and topics for the education, training and CPD; 3) orientations for credentialing entities for education in radiological protection.

(526) Both these two documents - *Publication 113* (ICRP, 2009) and Radiological Protection N. 175 (EC, 2014b) - complement each other, and provide detailed contents for education and training in radiological protection for the different categories of health professionals, including those not working directly with radiological procedures but referring to them, such as physicians from almost all medical specialities. They both also emphasise that this education should start at undergraduate level, at medical and other health

professional schools. Thus, they can both be the beacon that helps governments and responsible entities to define frameworks and curricula for training and education in radiological protection and safety. Considering that these documents also include operational topics in hybrid techniques, they can certainly help in assuring radiological protection and safety in the performance of PET/CT or PET/MRI procedures.

(527) Also, two other international organisations can help in the development and continuing implementation of educational programs in radiological protection and safety, working together with ICRP, IAEA, WHO and EC, namely, the European Training and Education in Radiological Protection (EUTERP) Foundation and the Heads of the European Radiological Protection Competent Authorities (HERCA), the first providing different helpful training materials - available at its website - and the latter defining the criteria to obtain the highest levels of qualification in radiological protection and safety (HERCA, 2017).

10.3. Main responsibilities regarding education and training

10.3.1. Regulatory responsibilities

(528) *Publication 113* discusses the importance of a sound infrastructure for radiological protection which begins with a government and the associated regulatory body setting a framework for the educational requirements for a country's national strategy (ICRP, 2009). This infrastructure will contribute to strengthening radiological protection and safety in PET/CT.

(529) One of the most accepted and adopted international radiological protection standard is the Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. General Safety Requirements (No. GSR Part 3) (BSS), which describes important standards for safety which should be implemented to ensure the safe use of medical imaging using ionising radiation. It includes standards for education applied to professionals that work delivering ionising radiation for medical uses, such as those in field of radiology or nuclear medicine, and also states the need for an educational qualification required for all personnel that are completing training (IAEA, 2014b).

(530) The BSS describes the responsibilities for these requirements starting with the government, regulatory agencies and the institution responsibilities with specified training criteria for speciality areas: 'The government is also responsible for ensuring, as necessary, that provision is made for support services, such as education and training, and technical services' (IAEA, 2014b). Each country will have its own laws and regulations relating to radiological protection including requirements for education, training, and competencies for all professionals working with radiation and medical exposure (IAEA, 2014b).

(531) Many International Authorities cooperated with IAEA for the making of this document, such as the WHO and the EC. The latter, through its Council Directive 2013/59/EURATOM and reinforcing previous Directives, continued imposing to all state members the development of a legal frame for specialised education and training in radiological protection, and with particular considerations for the medical uses of ionising radiation (Council of the European Union, 2013). Within this area, this European Regulatory Body, in accordance with ICRP, reinforces the need to 'ensure continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiological protection requirements' as well as encourages 'the introduction of a course on radiological protection in the basic curriculum of medical and dental schools' (Council of the European Union, 2013).

(532) The BSS states that 'Competence of persons is normally assessed by the member state by having a formal mechanism for registration, accreditation or certification of medical radiation technologists in the various specialities (e.g. diagnostic radiology, radiation therapy, nuclear medicine)' (IAEA, 2014b). In most countries national regulatory authorities either provide the certification process or delegate it to a professional organisation in place of them. This process happens for all these three professional categories of the medical imaging team of the PET/CT or PET/MRI facility.

(533) The BSS also describes, that 'the regulatory body is responsible for carrying out its required regulatory functions, such as the establishment of requirements and guidelines, the authorization and inspection of facilities and activities, and the enforcement of legislative and regulatory provisions' (IAEA, 2014b). Most countries have established accreditation standards relating to education and training for all medical staff. Inspections are mandated to ensure these regulatory requirements were being met.

(534) Finally, the BSS states that 'the government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of persons engaged in activities relevant to protection and safety; (b) The formal recognition of qualified experts; (c) The competence of organisations that have responsibilities relating to protection and safety' (IAEA, 2014b).

(535) These rules ensure that governments have to establish provision in place to provide the education, training and certification necessary to maintain the competency for all professionals working in health with ionising radiation, and thus in a PET/CT or PET/MRI department, ensuring that the facility or organisation takes on the responsibility to have established policies and procedures that ensure this happens, with the safeguard of protection and safety measures (IAEA, 2014b).

10.3.2. Institutional responsibility

(536) The BSS explains that not only governments, but also the facility or institution needs to ensure that all personal have responsibilities in relation to protection and safety (IAEA, 2014b). Additionally, the facility or institution needs to provide appropriate education, training and qualification. The BSS states ‘This process will ensure that all personnel will have competency to perform their role with a full understanding and can perform their duties with appropriate judgment and in accordance with procedures’ (IAEA, 2014b).

(537) In accordance with these orientations for this topic, the facility or institution has not only to guarantee, before employing someone to work in the PET/CT or PET/MRI unit, that the worker has had the necessary education and training, certified by the applicable Regulator, but also that each time a new technology or procedure is introduced, adequate training is provided, as well as the employer has had CPD activities in topics related with radiological protection and safety, specific and appropriate for the installation of PET/CT or PET/MRI.

10.3.3. Health professional responsibility

(538) Finally, each and every health professional that works with ionising radiation, namely in a PET/CT or PET/MRI facility, has the responsibility to be committed to keep themselves updated in their education and training in radiological protection and safety, as well in the specific diagnostic modalities with which they work, in order to guarantee a safe environment for patients, workers and public in general (IAEA, 2018). They also have to be available to work with their own organisations and authorities, in order to contribute to a general culture of radiation safety and constructive uses of ionising radiation.

10.4. Health care professional training in radiological protection and safety

(539) The education and training of the multidisciplinary team engaged in PET/CT or PET/MR practices will depend on each of professional's separate responsibilities. Included in the training will be aspects of the radiation dose due to medical examination, the type of technological advancement in that area of practice, the type of equipment being operated and the type of procedures being performed. Each health professional's education and training will incorporate a framework to ensure that the professional is academically prepared and clinically competent to work in their appropriate area of practice. PET/CT and PET/MR are advancing technologies with emerging software, hardware and new radiopharmaceuticals being frequently developed and introduced as standard patient imaging procedures that make radiological protection an essential part of all educational training programs, which need frequent updates. *Publication 113* provides definitions for all personnel working in PET/CT or other medical areas with ionising radiation. This document also provides appropriate formal educational categories for training as well as CPD categories for retraining for all personnel working in PET/CT (ICRP, 2009).

10.4.1. Nuclear medicine physician

(540) *Publication 113* defines different categories for physicians, according to their main speciality or clinical field. According to this publication, the physicians that will be working and reading the procedures that are produced in the PET/CT facility fall under Category 2 which defines them as 'nuclear medicine specialists: physicians who are going to take up a career in which the major component involves the use of radiopharmaceuticals in nuclear medicine for diagnosis and treatment including PET or PET/CT'. Their recommended requirements in terms of radiological protection are defined in Table 10.1. (ICRP, 2009).

10.4.2. Medical physicist

(541) *Publication 113* defines Medical Physicists as a Category 9, medical physicist 'specializing in radiological protection (RP), nuclear medicine, or diagnostic radiology' (ICRP, 2009). A medical physicist should have the highest level of training in radiological protection and, in many countries, is the one that, at institutional and facility level, will be overseeing the radiological protection program as a Radiation Safety Officer, including teaching all medical staff in matters relating to radiological protection. A medical physicist will also undertake the equipment acceptance testing, and annual or periodic QC, as well as advise on optimisation of the dose for different protocols, working together with the remainder of the imaging team. Their recommended requirements in terms of radiological protection are defined in Table 10.1 (ICRP, 2009).

10.4.3. Nuclear medicine technologist/radiographer

(542) *Publication 113* defines a nuclear medicine technologist as a Category 10, 'individual who is going to take up a career in which a major component of their work is involved with operating and/or testing x-ray units, including those carrying out some tests on a range of x-ray units in different hospitals and operating radionuclide imaging equipment'. Their recommended requirements in terms of radiological protection are defined in Table 10.1 (ICRP, 2009).

Table 10.1. Recommended radiological protection training requirements for different categories of personnel (ICRP, 2009).

	Category				
Training area	2 NM	9 MP	10 RDNM	13 NU	16 RL
Atomic structure, x-ray production, and interaction of radiation	H	H	M	L	M
Nuclear structure and radioactivity	H	H	M	-	M
Radiological quantities and units	H	H	M	L	M
Physical characteristics of x-ray machines	L	H	H	-	L
Fundamentals of radiation detection	H	H	H	L	M
Principle and process of justification	H	H	H	L	-
Fundamentals of radiobiology, biological effects of radiation	H	H	M	L	M
Risks of cancer and hereditary disease	H	H	H	L	M
Risk of deterministic effects	H	H	H	L	L
General principles of RP including optimisation	H	H	H	M	M
Operational RP	H	H	H	M	H
Particular patient RP aspects	H	H	H	M	-
Particular staff RP aspects	H	H	H	M	H
Typical doses from diagnostic procedures	H	H	H	-	-
Risks from fetal exposure	H	H	H	L	M
Quality control and quality assurance	H	H	H	-	L
National regulations and international standards	M	H	M	L	M
Suggested number of training hours	30–50	150–200	100–140	8–12	20–40

L, low level of knowledge indicating a general awareness and understanding of principles; M, medium level of knowledge indicating a basic understanding of the topic, sufficient to influence practices undertaken; H, high level of detailed knowledge and understanding, sufficient to be able to educate others.
NM, nuclear medicine specialists; MP, medical physicists specialising in RP, nuclear medicine, and diagnostic radiology; RDNM, radiographers, nuclear medicine technologists, and x-ray technologists; NU, nurses assisting in x-ray or nuclear medicine procedures; RL, radiopharmacists and radionuclide laboratory staff.

10.4.4. Nurses or other health care professionals

(543) *Publication 113*, defines a Nurse and other health care professionals as a Category 13, 'individuals assisting in diagnostic and interventional x-ray fluoroscopy procedures, radiopharmaceutical administration, or the care of nuclear medicine patients'. Their recommended requirements in terms of radiological protection are defined in Table 10.1. (ICRP, 2009). Nurses and other health care professional assist during procedures (i.e. Venepuncture, continuous Bladder irrigation or Sedation) in the PET/CT or PET/MR department.

10.4.5. Other professionals with a close relation with a PET/CT unit

(544) Among other categories of professionals defined in *Publication 113*, two have not to be forgotten in terms of radiological protection and safety, when considering activity in a PET/CT or PET/MR facility, namely: the medical referrers (Category 8) - 'physicians who request examinations and procedures involving ionising radiations, and medical students who may refer for examinations in the future'; and radiopharmacists (Category 16) – 'radiopharmacists and radionuclide laboratory staff: radiopharmacists and individuals who use radionuclides for diagnostic purposes such as radioimmunoassay' . The recommended

requirements in terms of radiological protection for this latter category are defined in Table 10.1 (ICRP, 2009).

10.5. Formal and informal educational training priorities and certification in PET/CT

(545) The imaging team, including the nuclear medicine physician, medical physicist and nuclear medicine technologist/radiographer, working in the PET/CT or PET/MRI department, should undertake formal didactic education and training in radiological protection. This includes coursework in radiation physics, radiation biology, radiation dosimetry, radiation safety and protection principles, radiochemistry, radiopharmacology, instrumentation and quality control, just to mention a few topics of the formal courses needed. Since in these Units, hybrid equipment will be used, it is mandatory that these courses also include knowledge in PET and in CT, and dose reduction in both imaging modalities. For those working with hybrid equipment such as PET/MRI, courses should include knowledge relating to MRI safety as well.

(546) Also, in all diagnostic facilities, including PET/CT or PET/MRI units, informal training has to be kept continuously, meaning unstructured training in workplaces, driven by the professional's interest in continuous improvement and under close supervision of more differentiated and experienced team members.

(547) Formal and informal, didactic and clinical education help form the foundation for the traditional core knowledge needed to build the appropriate skills required to undertake duties assigned during the work day as a nuclear medicine physician, a medical physicist or a nuclear medicine technologist/radiographer. This type of education also ensures that the foundation of knowledge is there to appropriately achieve occupational radiological protection for all members of the imaging team.

(548) Bozidar describes Certification as a 'formal process by which an authorised body evaluates and recognises the knowledge and proficiency of an individual, which must satisfy pre-determined requirements or criteria' (Bozidar, 2016). The article also describes that the person taking the certification should have performed some formal education and clinical training with the established qualification. Most countries have established a certification process for all medical personnel involved in nuclear medicine. Countries are trying to address additional training and education in hybrid techniques, including PET/CT and PET/MRI.

10.5.1. Nuclear medicine physician

(549) Nuclear medicine physicians meet stringent education training standards and, as other medical specialties, they are duly certified in Nuclear Medicine Specialty (e.g. in some countries by the Medical Boards within Medical National Associations, and in Canada and UK by Royal Colleges certifications and fellowships). This certification includes formal didactic education in radiation physics, instrumentation, radiochemistry, radiopharmacology, radiation dosimetry, radiation biology, radiation safety and protection and quality control. Additionally, they are clinical trained in PET/CT or PET/MRI including understanding technical performance and acquisition parameters, how to apply appropriate calculation of dosages, clinical justification for the procedures, evaluation of images and correlation with other diagnostic modalities and interpretations. In some countries, and with a tendency to expand, they need also to obtain recertification at definite time intervals, in order to guarantee that they are updated in their field of knowledge. This may be considered a compliance to

CPD and also a safeguard, relevant for radiological protection and safety, since it guarantees that stay abreast on developing technology.

(550) In different continents and countries, we find that the regulating entities that certify nuclear medicine physicians and radiologists trained in nuclear medicine define that, to work and have privileges to practice PET/CT or PET/MRI, the physicians have to prove knowledge in radiological protection.

(551) In USA, the American College of Radiology, in 2021, published a document entitled 'ACR–ACNM–SNMMI–SPR practice parameter for performing FDG -PET/CT in oncology' (ACR, 2021). From this document, it is understood that if a physician is not Board certified by one of the Specialties boards that require education and training in radiation topics – such as Nuclear Medicine or PET/CT – and wants to practice PET/CT, then the candidate will have to present 'evidence of CME in PET/CT and of ongoing interpretation of oncologic PET/CT' (ACR, 2021).

(552) In most of the countries within the European Union, only Nuclear Medicine certified medical specialists are allowed to practice PET/CT, and the Section of Nuclear Medicine/European Board of Nuclear Medicine of the Union Européenne des Médecins Spécialistes/European Union of Medical Specialists (UEMS/EBNM) periodically publishes syllabus to help member states, through their medical boards, to define their specialization programs. At the last update of these syllabus, it is again stated, like in the previous versions, that a future nuclear medicine specialist, besides having to be trained in correlative/multimodality imaging methods, such as CT, has also to have education and develop expertise in physics; radiation physics; data acquisition and image processing techniques, including SPECT/CT and PET/CT; radiobiology; justification and optimisation [as low as reasonably achievable (ALARA), and as low as reasonably practicable (ALARP) concepts]; limitation of doses; and radiation hazards (UEMS, 2017).

10.5.2. Nuclear medicine technologist/Radiographer

(553) Certification by the appropriate certification body in the field of practice is essential for the nuclear medicine technologist/radiographer operating the PET/CT or PET/MRI scanner. Nuclear medicine technologists/radiographer performing duties in the field of nuclear medicine and the subspecialty of PET/CT or PET/MRI require formal education and training from a post-secondary institution with academic courses to include radiology, health sciences, patient care, nuclear medicine technology and radiological protection and safety. Formal education and training from a post-secondary institution vary from country to country. The major of European countries combines initial radiographer education curriculum with either nuclear medicine or radiotherapy education curriculum. Graduates in these countries are fully qualified to work in all of the areas of their combined programme. Rare is the nuclear medicine only education curriculum in Europe. In the United States a post-secondary formal education and training is the standard with nuclear medicine being the focus and additional education being provided in CT. With the advent of hybrid imaging such as PET/CT or PET /MRI, additional education was developed to ensure the nuclear medicine technologist /radiographer can cross train to operate the CT or MRI component. Just recently MRI Safety was added to the formal education and curriculum in the United States.

(554) Once the nuclear medicine technologist/radiographer obtains a diploma from a formal education institution, most countries will mandate these professionals working in the nuclear medicine field and the subspecialty of PET/CT or PET/MRI to take a mandatory national certification exam. This national certification will demonstrate a mastery of the body of knowledge in the field of nuclear medicine and in some countries additionally a PET/CT

or PET/MRI component. Some countries have developed an additional certification for the CT component of the PET/CT or MRI component of PET/MRI.

(555) The passing of a national certification examination recognises that a nuclear medicine technologist/radiographer is educationally prepared and clinically competent to perform procedures and routine tasks within the nuclear medicine scope of practice. Additional informal training in the field of PET/CT or PET/MRI will prepare the nuclear medicine technologist/radiographer with the base knowledge to perform procedures and routine tasks within the PET/CT or PET/MRI scope of practice.

10.5.3. Medical physicist

(556) The medical physicist should be highly qualified, trained and be board-certified in an area of practice. Medical physicists attend in accredited college or university to attain their formal graduation in the field of physics, engineering, medical physics or bioengineering and, additionally, in many countries, in order to practice in healthcare organisations, this is complemented with a residency period (e.g. 3 years program, in Spain) in a hospital, to obtain a certified speciality diploma as Medical Physicist, sometimes with subspecialties (e.g. Nuclear Medicine, Radiology and Radiation Oncology). Once finished with the formal training, the medical physicist may also go on to attend a master's or doctoral degree in physics, medical physics, biophysics, radiological physics, or medical health physics to complete their formal education process.

(557) Some physicists gain a certification in a subfield of medical physics with a national certifying body, which demonstrates a mastery of that body of knowledge. The passing of the national certification exam demonstrates that the medical physicist is educationally prepared and clinically competent to work in the medical physics subspecialty area of practice and can perform routine tasks within that scope of practice which in this instance would be nuclear medicine, PET and/or CT or MRI.

(558) Some scientific organisations contribute to homogenise and define standards for this certification in Medical Physics, such as the European Federation of Organisations for Medical Physics (EFOMP), who together with EANM in 2013 published a curriculum for education and training of medical physicists in nuclear medicine (Del Guerra et al., 2013), and in 2017 published a Policy Statement concerning Medical Physics Education and Training (EFOMP, 2017).

(559) Professional certification of medical physicists is established either by a government body within a country or by a national medical physics organisation authorised by the government. The medical physicist, then follow a formal registration, which is generally operated at the national level by an official authority (e.g. Ministries of Health) or professional medical physics society/organisation authorised by the government. Also, these professionals, in some countries, to act as Radiation Protection Safety Officer within a facility, such as a PET/CT or PET/MRI unit, need to have a separate certification as Radiation Protection Experts, and with different degrees of responsibility and knowledge. For instance, in the European Community, the Council Directory 2013/59/EURATOM obliges member states to 'establish the arrangements for the recognition of radiological protection experts', as a separate recognition from the one of medical physicist, although these professionals may have double certification. (Council of the European Union, 2013).

(560) In Europe, after the publication of Council Directive 2013/59/EURATOM, EFOMP also provided some guidelines to help National Regulatory Bodies to organise the structure for medical physicist's registry. In 2016, EFOMP also published a Policy Statement with guidelines for National Registration Schemes applicable to Medical Physicists (Christofides et al., 2016).

10.5.4. Nurses working in nuclear medicine facilities

(561) Registered nurses that work in nuclear medicine, including PET/CT or PET/MRI facilities, need to have special training not only in radiological protection but also in the nuclear medicine procedures in which they cooperate, with a particular emphasis in the safe handling of radiopharmaceuticals.

(562) In most countries, worldwide, there is not a nurse's specialisation in nuclear medicine, as there is in other clinical areas, such as oncology, for example. So, most of the training in nuclear medicine for nurses is informal, in the workplace, supervised by the other dedicated staff with certification in nuclear medicine, such as physicians and technologists. Some guidelines for this training-in-service are provided by some scientific organisations in nuclear medicine (BNMS, 2010).

(563) Nevertheless, to be allowed to work in nuclear medicine, most National Regulatory Bodies define as mandatory that they receive training in radiological protection and safety by a certified organism for education, or, when this is not the case, by a medical physics expert or the Radiation Protection Officer of the facility. To define the curricula for these educational programs, guidelines are provided either in *Publication 113* (ICRP, 2009) or in Radiation Protection N. 175 (EC, 2014b).

10.5.5. Radiopharmacists and radionuclide laboratory staff

(564) In radiopharmacies or nuclear medicine laboratories, materials and radiopharmaceuticals can be prepared by nuclear medicine technologists/radiographers, but also by pharmacists or other clinical scientists, that had specialised training in radiopharmacy. In some countries, it is compulsory that radiopharmacy activity be performed under the supervision of a certified radiopharmacist.

(565) Qualification as radiopharmacist, depending on National legal requirements, can be achieved either by a residency program, similar to the one organised for physicians or medical physicists; or by a postgraduation program at university.

(566) These qualification programs include topics in radiological protection and safety, for which contents guidelines are provided in *Publication 113* (ICRP, 2009).

10.6. Continuous professional development (CPD) and self-assessment needs

(567) Most professions in the medical field mandate CPD education and continuous learning. A common definition for this is a structured approach to learning to help ensure competence to practice, taking into account knowledge, skills and practical experience. There are many educational tools that can be accessed to obtain CPD with some being formal and structured, and others more informal being self-directed based on individual needs. They should however, meet requirements of the body overseeing the award of CPD accreditation. Advancing technologies and changes to the standard of care for patients require additional knowledge and skills to sustain the expertise and knowledge needed to ensure optimal radiological protection of the medical dose and safe practice in the medical field for all professionals in the PET/CT or PET/MRI department.

10.6.1. Nuclear medicine physician continuing education

(568) Physicians continue their medical education with lifelong learning, which starts with the physician being licensed to practice in their country and get a board certification in a definite speciality like Nuclear Medicine, after which, in some countries, the medical physician will be subject to recertification, using proof of their lifelong learning records through the accredited medical education programs. Depending on the physician speciality a certain number of hours of specific medical education will be required relating specifically to their medical practice. Some credit is given relating to that of a general nature. A second part of physician's continuous education is a cognitive assessment were physician complete self-assessment modules during a predetermined time frame. Finally, physicians also have to complete a practice performance assessment and if necessary, an improvement project that meet the countries requirements.

(569) The presence and practice of a physician with a recognised specialization in nuclear medicine, which includes expertise in PET/CT or PET/MRI, is a legal requirement to keep the clinical activity in the facility. Due to the exponential growth of knowledge in this field of medical practice, it is also compulsory that these nuclear medicine physicians keep and have evidence of CPD with certified programs, in many countries indispensable to guarantee the compulsory recertification process. Nowadays, many National and International Societies, such as the SNMMI and the EANM, provide high level and certified CPD modules, in all fields, including radiological protection and safety topics in PET/CT or PET/MRI, such as clinical justification, dosimetry, dose reduction and optimisation and MRI safety.

10.6.2. Nuclear medicine technologist/radiographer continuing education

(570) As the field of Nuclear Medicine, PET/CT and PET/MRI is continually changing there is a need for professionals working together to continue to accumulate knowledge in their field of practice. CPD or continuing education courses are typical platforms, that uses educational tools for nuclear medicine technologists/radiographers to engage and demonstrate a continued accumulation of knowledge in the field of practice. It is a way to ensure that the nuclear medicine technologist/radiographer is educationally prepared and clinically competent in their area of practice.

(571) Safe operation of the equipment and safe operation of procedures requires some type of formal and informal education with an assessment tool to demonstrate competency before undertaking medical procedures on patients using the PET/CT or PET/MRI equipment. Thus, CPD is a key component in contributing to the quality of professional practice, including updated education in optimisation of radiological protection, radiation safety, the understanding of radiation effects, MRI safety, the role of quality management including quality assurance and quality control.

(572) National and International scientific and professional organisations, such as the International Society of Radiographers and Radiological Technologists (ISRRT), the SNMMI and the EANM offer a variety of educational material including CPD, online PET Review workshop and educational review programs, which are designed to help contribute to the professional knowledge in the field of practice as well as prepare nuclear medicine technologist/radiographer to take advanced certification board in PET/CT or PET/MRI.

10.6.3. Medical physicist continuous professional development

(573) Medical Physicists need to engage in CPD or continuing education in the basic physics concepts, basic medical topics, instructions for performing procedures and emerging technologies.

(574) Again, many national and international scientific and professional organisations, such as Institute of Physics and Engineering in Medicine (IPEM) and EFOMP, provide high level educational modules, that help medical physicists to keep updated in their fields of expertise, and thus relevant for PET/CT or PET/MRI instrumentation and operational radiological protection.

(575) EFMOP provides CPD-activities e.g., through an e-learning platform, summer schools, and refresher courses at the biannual congress ECMP. They also offer a European Diploma in Medical Physics, which can be considered a CPD activity, since it is not compulsory to undertake medical physics professional activity in the European Community.

10.6.4. Nurses continuous professional development

(576) Nurses working in nuclear medicine departments, including PET/CT or PET/MRI facilities, are subject to the conditions for recertification or continuous professional development applied in their own countries, related to their job descriptions and functional content of their profession as nurses.

(577) Regarding the specific activity in nuclear medicine and topics in radiological protection and safety, they also attend educational and scientific modules provided by the national and international societies in the field.

10.6.5. Radiopharmacists and radionuclide laboratory staff continuing education

(578) For these groups of professionals, the situation is the same as the nurses, i.e. they have to comply to national requirements in terms of recertification or continuous professional development, related to their specific profession; but they also have available different educational and scientific programs provided by scientific societies, such as SNMMI and EANM.

(579) EANM, in collaboration with the Swiss Technical University, provides also a Postgraduate Certificate Course in Radiopharmaceutical Chemistry/Radiopharmacy, valid for 5 years, and with compulsory modules in PET radiopharmaceuticals. This can also be considered a CDP activity, since the Certificate obtained is not compulsory to practise radiopharmacy in the European Community.

10.6.6. ICRP recommendations for continuous profession development education for all medical staff in PET/CT

(580) *Publication 113*, outlines contents for CPD education which can be used to define courses to guarantee that nuclear medicine physicians, nuclear medicine technologists/radiographers and medical physicists, stay current in all topics relevant to both Operational Radiological Protection and Optimisation of medical dose. These comprehensive lists of topics include education regarding optimisation of radiological protection for professionals that administer radiopharmaceutical to patients, operation of PET/CT equipment, performance of quality control, interpretation of images to ensure radiological protection and radiation safety including additional requirements as listed below' (ICRP, 2009):

(581) Regarding nuclear medicine physicians and technologists (Categories 2 and 10, as defined in Table 10.1), *Publication 113*, in the subheading A.1. of its ‘Annex A. Examples of suggested content for training courses’ provides detailed orientation to prepare course materials relevant for the practice of PET/CT (ICRP, 2009).

(582) Topics related to education in the CT component of the PET/CT studies, can also be found in the 'Annex B. Outline of specific educational objectives for Paediatric Radiology' of *Publication 113* (ICRP, 2009).

(583) Finally, *Publication 113* provides examples of sources of training material in its Annex C (ICRP, 2009).

10.7. Final remarks

(584) Expertise in PET/CT or PET/MRI, as any other modality of work with ionising radiation or magnetic radio waves, includes being highly knowledgeable in radiological protection, in order to guarantee a positive benefit-risk ratio and a safe environment both for patients, workers and public in general.

(585) Education and training in radiological protection and safety, has to guarantee expertise in these fields, at the level of practice of each health professional, and has to be robust, evidence-based, and accredited by authorities in the field.

(586) The present section tried to revise guidance provided by international authorities and main stakeholders in this field of knowledge, in order to help identify what cannot be missed by any healthcare professional working in PET/CT or PET/MRI, in terms of education (undergraduate and postgraduate), training and continuous progressive development in topics relevant for radiological protection and safety.

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