

CORE CURRICULUM FOR MEDICAL PHYSICS EXPERTS IN NUCLEAR MEDICINE

2nd revised edition

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Austrian Society of Medical Physics (ÖGMP)

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Swiss Society of Radiobiology and Medical Physics

Ukrainian Association of Medical Physics (UAMP)

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Acronyms (Glossary)

AI – Artificial Intelligence
ALARA – As Low As Reasonably Achievable
BED – Biologically Effective Dose
CC – Core Curriculum
CDW – Clinical Dosimetry Workflow
cGRPP – current Good RadioPharmacy Practice
CIRS – Critical Incident Report System
CNN – Convolutional Neural Networks
CPD – Continuous Professional Development
CT – Computed Tomography
CTDI – Computed Tomography Dose Index
CTDI_w – weighted Computed Tomography Dose Index
CTDI_{vol} – volumetric Computed Tomography Dose Index
DAP – Dosimetry Analysis Plan
DICOM – Digital Imaging and COmmunication in Medicine
DLP – Dose Length Product
DOM – Dosimetry Operating Manual
DRL – Diagnostic Reference Level
EANM – European Association of Nuclear Medicine
EBRT – External Beam Radiotherapy
EC – European Commission
ECTS – European Credit Transfer and accumulation System
EFOMP – European Federation of Organisations for Medical Physics
EM – Expectation Maximisation
EMS – Equipment Management System
EPR – Electronic Patient Record
EQF – European Qualifications Framework
ESR – European Society of Radiology
ESTRO – European Society for Therapeutic Radiology and Oncology
EU – European Union
EURATOM – EUROpean ATOMIC energy community
EUBED – Equivalent Uniform Biologically Effective Dose
EUD – Equivalent Uniform Dose
FDA – Food and Drug Administration
FMEA – Failure Mode and Effects Analysis
FTP – File Transfer Protocol
GAN – Generative Adversarial Networks
GDPR – General Data Protection Regulation
GMP – Good Manufacturing Procedure
GPRS – General Packet Radio Service
IAEA – International Atomic Energy Agency
ICRP – International Commission on Radiation Protection
ICRU – International Commission on Radiation Units and Measurements
ICT – Information and Communication Technology

KSC – Knowledge Skills Competencies
KPI – Key Performance Indicators
LET – Linear Energy Transfer
LNT – Linear, No Threshold (model for dose risk)
LR – Likelihood Ratio
MIRD - Medical Internal Radiation Dose committee
ML – Machine Learning
MPE – Medical Physics Expert
MDE – Medical Device Engineers
MDR- Medical Device Regulation
MRI – Magnetic Resonance Imaging
NM – Nuclear Medicine
OAR – Organ At Risk
OIS - Oncology Information System
PACS - Picture Archiving and Communication System
PDMS - Patient Data Management Systems
PBPk - Physiology Based Pharmacokinetic (analysis)
PET – Positron Emission Tomography
QA – Quality Assurance
QC – Quality Control
QMS – Quality Management System
RF – Random Forest
ROI – Region Of Interest
RNN – Recurrent Neural Network
RNT – Radionuclide Therapy
RPE – Radiation Protection Expert
RT – RadioTherapy
SOP – Standard Operating Protocol
SPECT – Single Photon Emission Computed Tomography
SUV - Standardised Uptake Value
SUV-LBM - Standardised Uptake Value – Lean Body Mass
SVM – Support Vector Machine
SSDE – Source Surface Distance Equivalent
TAC – Time Activity Curve
TDS – Test Data Sets
TGV - Total Glycolytic Volume
TLG - Total Lesion Glycolysis
US – UltraSound
XGBoost – Extreme Gradient Boosting
VOI – Volume Of Interest
WHO – World Health Organization

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I. INTRODUCTION

In this document we refer to the education and training of Medical Physicists working in the speciality of nuclear medicine (NM) to achieve ‘Medical Physics Expert’ (MPE) status in NM. A certified MPE can independently practice medical physics in health care.

It should be noted that only the term “MPE” appears in European documents [1,2] and in many European countries, only the Medical Physics Expert certification exists (as opposed to a Medical Physicist –not “expert”). Therefore, we will only refer to MPE in this document. In line with the latest European Commission (EC) guidelines and following the EC Council directive 2013/59/EURATOM, a Medical Physics Expert is defined as a Medical Physicist who has reached European Qualifications Framework (EQF) level 8 in one or more chosen specialties of clinical Medical Physics. This core curriculum addresses the learning needs of the MPE in NM.

I. 1 Aim of the document

The European Association of Nuclear Medicine (EANM) and the European Federation of Organisations for Medical Physics (EFOMP) have a longstanding commitment to improve and harmonize clinical practice, science, education, and training of medical physics professionals.

In 2013, EANM and EFOMP jointly issued guidelines covering theoretical and practical aspects of education and training for medical physicists within NM [3]. The document focused on knowledge and expertise required to safely and effectively act as a medical physicist within a NM team. These activities include all aspects related to the diagnostic and therapeutic usage of radionuclides (unsealed sources of ionising radiation) and associated radiopharmaceuticals (combination of radionuclides and pharmaceuticals targeting specific physiological and pathological processes). These guidelines represented the first common work from the two organisations describing the knowledge and corresponding skills and competences necessary for a medical physicist working in NM. These guidelines were drawn up using terminology in accordance with the EU recommendations on the EQF for lifelong learning [4] in which learning outcomes were defined in terms of knowledge, skills and competences (KSC). Since publication of the 2013 NM guidelines, requirements for KSC of medical physicists have increased due to the strongly increasing technological complexity of imaging equipment, newly introduced radionuclide treatments, and increasing requirements for quality

and risk management. This current revised CC for MPEs in NM arises from a need to update the education and training requirements to accommodate the KCS of a MPE in NM in the 2020’s. Different existing documents including the previous 2013 document [3], the CanMEDS [5], the latest EU guidelines (RP-174) [1] and EFOMP Policy Statement 12.1 [2] have been considered when putting together this revised document. They are also in accordance with the guidelines concerning the National Registration Schemes as given by EFOMP [6].

This document is intended to provide a common standard and framework for the training of a MPE in NM, to guide national regulatory bodies in their own curriculum development and serve as an orientation in the assessment of the necessary KSC. We have defined four different levels of competences that the trainee needs to develop corresponding to increasing levels of proficiency in each specific topic (see section II).

Once the training is complete, trainees should have reached the level of KSC in each topic area listed in this CC and will therefore meet the requirements to become a MPE [1,2] in NM, that is, being able to act independently without supervision in the required topics and gain formal recognition from a National Competent Authority [8,9]. After certification, the MPE is expected to master his/her own general and specific competences in a specific area and continue to develop with continuing professional development.

The structure of this document and the different levels of competencies have been based on the recent EFOMP/ European Society for Therapeutic Radiology and Oncology (ESTRO) revised joint CC guidelines for MPEs practicing in the field of radiotherapy (RT) [15]. A common curriculum and career pathway for the profession of MPE encompassing all subspecialties of medical physics is a prerequisite for the harmonisation of MPE education and training standards across Europe. This approach has become essential due to advancements in clinical practice, where different specialties are increasingly interconnected. Examples include sophisticated imaging guidance in the daily radiotherapy workflow, including multimodal imaging devices, increasing dosimetry requirements for radiopharmaceutical therapy. These techniques, as they are becoming more common in hospitals, demand an integrated approach to their various functionalities. Therefore, a unified training curriculum for Medical Physics Experts (MPEs) is needed to equip them with the knowledge, skills, and competencies across all subspecialties, enabling them to handle today’s complex hospital environments. This position is also in line with what EFOMP has reported in the Malaga Declaration

updated in 2023, which promotes an integrated and holistic management of physical agents in hospitals to pursue the quality of care and safety of patients, staff and community [18]. This approach ensures consistency in the competences required to become an MPE, thereby standardising quality and safety for the medical applications involving ionising radiation. Furthermore, this initiative streamlines the recognition of the MPE profession in those EU Member States where it has yet to be formalised. Despite the tremendous progress made in the last years, there is still much work to do in Europe to harmonise the level of education and training at European level and the recognition of MPE as health profession. EFOMP in coordination with ESTRO, EANM, and European Society of Radiology (ESR) will consider developing a “single combined Curriculum for all three MPE specialties” once the revised CCs for MPE in NM and in Radiology will be finalised. In this way, the total length of the training for MPE can be clearly defined. The homogeneous training of MPEs through Europe would support the harmonisation of training and cross-border mobility of MPEs within the different countries in Europe [18].

I. 2 The Medical Physics Expert

Medical Physics Experts in NM are members of the multidisciplinary clinical teams responsible for the diagnostic and therapeutic applications of NM in line with the EU Council Directive 2013/59/Euratom [11]. The MPE has 3 main areas of responsibilities: 1. Leading physics aspects of NM (equipment management, image analysis / quantification, dosimetry, quality assurance, radionuclide production and radiation protection), 2. Training of personnel, 3. Research and innovation.

1. Leading physical aspects of NM: development, introduction, modification and quality assurance of medical technology for delivering diagnostic and therapeutic protocols using NM techniques. Involvement in the development of quality management programmes for up-to-date standard of care in NM. The MPE is also qualified to give advice on, and to act in radiation protection matters for the patient, staff and public. The MPE is responsible for effective and correct installation and use of different devices necessary for the implementation of diagnostic NM procedures (laboratory equipment for the measurement of physical quantities relative to NM, multimodality imaging equipment, parts of radiopharmacy, software management) and the appropriate dose delivery for the treatment of individual patients in therapeutic NM procedures. The MPE actively follows new technological advancements in the field and evaluates (needs for)

possible clinical application. The MPE determines and develops, together with NM imaging medical specialties and the hospital management, the strategic and medical-physics policy related to the practice of NM.

2. **Training of personnel:** responsibility for the training of MPE trainees. The MPE also teaches non-physicists the physics aspects of NM diagnostic and therapeutic procedures and the safe and effective use of medical equipment and software.
 3. **Research and innovation:** initiating and implementing innovations to improve qualitative and quantitative radionuclide based imaging / non-imaging diagnostic and therapy procedures, equipment development as well as performing and publishing scientific research, presenting results to colleagues, and applying them to clinical practice.
- I. 3 MPE Training: minimum entrance level, education, residency, and certification**

Currently, the length, level and content of the education, as well as the required pre-education, still varies among the various European countries [12]. However, the European Commission Guidelines on Medical Physics Expert-RP 174- [1] and EFOMP policy statement 12.1 [2] give clear and detailed information on the role and education requirements for the MPE in Europe (see Figure 1 in both publications), stating as a prerequisite for MPE certification: a BSc (180-240 European Credit Transfer and Accumulation System (ECTS)) predominantly in Physics, an MSc in Physics or Medical Physics, a structured accredited clinical residency comprising a training of two years in Medical Physics and structured accredited advanced experience and, afterwards, continuing professional development (CPD, [13]) of at least 2 years.

In general agreement with the above statements and in line with developments in the field, we suggest the following, as summarized in figure 1:

The KSC described in the CC are obtained by attending courses/conferences, performing self-studies, performing clinical projects, hands-on training in the hospital, etc. The minimum time to be spent on each specific topic is given in ECTS (The European Credit Transfer and Accumulation System; 60 ECTS correspond to the workload of a full-time academic year, [14]). The total amount of ECTS is 240, as shown in Table 1. The methods to assess the competences are described in

<u>PRE-EDUCATION</u>	<u>EDUCATION AND TRAINING</u>	<u>MPE CERTIFICATION</u>	<u>CONTINUING PROFESSIONAL DEVELOPMENT (CPD)</u>
<p>BSc degree (predominantly in Physics)</p> <p>MSc degree (Physics or Medical Physics) = BSc + MSc (including in total at least 180 ECTS in Fundamental Physics and Mathematics)</p>	<ul style="list-style-type: none"> • Duration of at least 4 years to obtain the competences (CanMEDS roles) to become an independent specialist • The trainee appointed as a paid resident <p>Training in one or more sub specialties of Medical Physics</p> <ul style="list-style-type: none"> • Training conducted in a hospital/healthcare facility accredited by the competent authority • Training facility and quality of the MPE training regularly audited by the competent authority 	<p>By competent authorities as MPE in Medical Physics speciality (one or more sub specialties)</p>	<p>Following European guidelines</p>

Figure 1. Qualification Framework for the Medical Physics Expert (MPE) in Europe, as proposed in the updated CC. The proposed CC covers the second box for the NM subspeciality.

•The minimum education level to enter an MPE training program should be a **BSc degree, predominantly in physics, followed by an MSc degree in Physics or Medical Physics** (BSc + MSc including in total at least 180 ECTS focused on fundamental physics and mathematics).

It is understood that a candidate with these qualifications would also have a solid basis in computing and programming skills.

•The **MPE training should have a duration of at least 4 years** and the trainee must be appointed as a **paid resident**. MPE training can be in one or more subspecialties of Medical Physics. This period is required to obtain the competences (CanMEDS roles [4]) to become an independent specialist, in accordance with the CanMEDS based CC for Radiation Oncologists [7]. The MPE training should be conducted in a hospital / healthcare facility that is accredited by the competent authority responsible for this [9, 10]. The training facility and the quality of the MPE training should be regularly audited by the competent authority. After the training period the resident should obtain the national MPE certificate.

•Continuing professional development should be carried out following European guidelines [13] after the 4-year training.

Chapter V. The competent authorities responsible for the continuous evaluation of the trainees and the following MPE certification may be different in each country [8,12].

The following should be noted:

- From this CC for MPE in NM, Chapter II (General MPE Competences) and large parts of Chapter III (especially sections 1-2, 5-6, 9-12) are also relevant for training in the other subspecialties (Radiology and Radiation Oncology). In addition, the Science and Innovation (Research) part may be relevant also for other specialities than NM. Thus in a medical physics schema including not only NM but also Radiology and Radiation Oncology, the amount of ETCs proposed in this CC specific for NM is realistic.
- In those European countries where the MPE certificate automatically implies a full qualification as a radiation protection expert, the amount of ECTS for section III.5. "Radiation protection in medicine" in Table 1 should be increased (considering all competences mentioned in section III.5).
- 60 ECTS of the training period should be spent to deepen knowledge of topics in this CC in addition to the minimum requirements (e.g., topics that are particularly important in the country, such as extra time for radiation protection), or on Radiology or Radiotherapy subjects from the corresponding CCs [12,16,17], given the increasing overlap of

the different disciplines of Medical Physics (e.g., in those countries where the MPE is certified for several Medical Physics specialities). This freedom of ECTS implies that the MPE is not an expert in everything, and they can further specialise in those areas after certification.

The recommended qualification framework for MPE in NM is currently far from the actual situation in many European countries [12] where the median period is three years with 50% of the time fully dedicated to NM (meaning 1.5 year fully dedicated to NM).

The proposed 4-year training programme is a complete description of the knowledge, skills and competences required to be certified as an MPE, realizing that there could be some overlap with a previous MSc programme. The proposed competency profile defines competences for the MPE profession, and individual competency sets of MPEs may vary depending on the details of their clinical practice, acknowledging that not all MPEs will necessarily possess all competences to the same degree.

Following this structure, the trainees will contribute to daily clinical work, under the supervision of an MPE, performing their tasks with an increasing level of independence. Moreover, the trainees can concentrate for a certain period of the training on specific topics, resulting in benefits for the hospital.

Our proposal should represent a goal that all European countries would aim to achieve in the near future with the objective of improving the quality of education and training of MPEs towards a harmonization of the level of MPE across Europe. It should be noted that this qualification framework requires that the trainees are paid during their education and training programme, as clearly stated in Figure 1.

Partnership between public and private NM institutions, to ensure that education and training can be rolled out homogeneously across the country, should be developed. Moreover, the mobility of trainees to meet the requirements of the training in specific topics that cannot be performed in their own centre should be encouraged.

Table 1. ECTS in function of the different subjects to be covered for an MPE in NM

Specific MPE physics knowledge, skills and competences	ECTS
III.1. Fundamentals of human anatomy and physiology (including pathologies)	8
III.2. Core radiation physics	10
III.3. Equipment management	24
III.4. Radiobiology and radiobiological models	20
III.5. Radiation protection	24
III.6. Dosimetry in NM	23
III.7. Radionuclide production / radiopharmacy	6
III.8. Radiobiology and Preclinical imaging	4
III.9. Risk Management, Quality and Safety in the Medical Environment	5
III.10. Organisation, management and ethical issues in health care	3
III.11 Information and communication technology	8
III.12. Data processing, statistics, modelling and artificial intelligence	15
IV. Research and innovation	30
<i>Deepen knowledge from this CC and/or additional topics from the CC of Medical Physicists in Radiotherapy and/or in Radiology [7,13]*</i>	60
TOTAL	240

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II. General MPE competences

II. 1 Medical Physics Expert

The MPE in NM is a member of a multi-disciplinary team that includes nuclear medicine physicians / radiologists, MPEs, biomedical engineers, radiopharmacists, radiochemists, computer scientists, technologists, radiographers, nurses, administrators, hospital management and other healthcare professionals, working closely together to provide safe and effective NM services.

The Expert role reflects the level at which the knowledge of physics and medicine are applied by the medical physicist together with clinical skills and professional values in their provision of high-quality and safe patient-centred care.

The Medical Physics Expert role is central to NM. The MPE draws upon an evolving body of knowledge, scientific and practical skills, and professional values. They collect, analyse, interpret and critically evaluate information, advise on diagnostic and therapeutic NM procedures, perform treatment related tasks and are responsible for the quality assurance of equipment and physics related procedures. They do so within their scope of practice and with an understanding of the limits of their expertise. Their decision-making is informed by best practices and research evidence and considers the request of the nuclear medicine physicians as well as the availability of resources. Their work in the clinic is up-to-date, ethical and resource-efficient, and is conducted in collaboration with other health care professionals.

Effective operation in this environment requires a broad spectrum of general competences, in line with the following roles of an MPE. Six roles for medical physicists are integrated into the role of MPE:

- Communicator
- Collaborator
- Leader
- Health Advocate
- Scholar
- Professional

General Competences

- Lead and be responsible for the medical physics issues related to clinical care, education and training, innovation and scientific research. This also includes cost-effective use of available resources and decisions on investments

- Assess and optimise diagnostic imaging and radionuclide treatment approaches, including associated medical technology infrastructure. Prioritisation of tasks focusing on high quality diagnostic and therapeutic care and safe application of NM procedures, including radiation protection
- Assess required staffing levels and establish management plans
- Remain informed about changes in the practice of medical physics in NM on the national and international level to critically evaluate existing institutional practice
- Establish plans for availability of up-to-date medical equipment to support the clinical process
- Stay aware of upcoming novel legal requirements that can impact clinical practice and the roles and responsibilities.
- Actively contribute to the continuous improvement of health care quality and patient safety

II. 2 Communicator

The MPE in NM must communicate efficiently with their peers as well as with other healthcare professionals being mainly nuclear medicine specialists, radiologists, radiopharmacists, technologists, radiographers and nurses. MPEs also communicate with hospital management, National Competent Authorities etc. They also need to communicate with service engineers and IT personnel, and radiopharmacists / radiochemists. Communication with patients and their relatives and caregivers is also increasingly required.

Competences

- Understand and respect opinions of all discussion partners
- Clearly explain complex physics issues to non-physicists
- Communicate with the responsible personnel of medical equipment manufacturers and suppliers
- Show empathy and good listening skills to perceive the point of view of other health care professionals
- Produce written reports with relevant and understandable information for the receiver or target group
- Assist in helping patients and the general public to identify and make use of the information and communication technology on radiation physics topics related to their NM diagnostic / therapeutic procedures, radiation protection and health
- Prepare written material in the form of reports and scientific papers to be presented at seminars/conferences or to be submitted for publication in scientific journals
- Report harmful patient safety incidents and near-misses to the authorities

- Interact effectively with other professionals, based on specific medical physics expertise
- Discuss with patients and their relatives and caregivers, answering specific questions and concerns, providing them with concise information about diagnostic imaging and treatment procedures, including radiation protection issues.
- Use new communication channels effectively for the professional environment, e.g. social media

II. 3 Collaborator

Nuclear medicine involves team work and the NM MPE must therefore be able to effectively collaborate with other healthcare professionals in order to provide safe, high quality, patient-centred care. Other collaborators outside the clinical team include industry, academic partners, financial experts, statisticians, hospital management, National Competent Authorities, stakeholders and policy makers.

The MPE should be a member of the collaborative multidisciplinary group on issues regarding sub-optimal delivery of NM services (diagnostic and/or therapeutic) such as lack of or outdated resources for quality assessment and improvement, patient access, and shortage of skilled staff. The MPE can use their technical and physics knowledge and skills to support the group using evidence-based reports on options available and to propose patient-centred innovative solutions.

Collaborative skills are broadly applicable to MPE activities, including scientific and clinical work.

Competences

- Identify potential areas of collaboration based on one's own capabilities within the NM team
- Contribute to a constructive atmosphere with effective interactions, based on trust and mutual respect
- Negotiate shared responsibilities with physicians and other healthcare professionals exploiting possibilities for win-win solutions
- Contribute to work with other healthcare professionals in relevant multi-disciplinary teams and patient interactions.

II. 4 Leader

The MPE will naturally lead teams that collaborate on topics with high levels of physics input. The teams can be multi-disciplinary (e.g. involvement of physicists, nuclear medicine

specialists, technologists, radiographers, radiopharmacists / radiochemists, engineers or other specialists), or consist of physicists only. Timely communication, active listening, networking, flexibility, creativity and mentoring are among the different skills required to motivate staff and build teams. The MPE should be central to planning and equipping new NM departments and upgrading equipment and department infrastructures. They should promote the optimal selection of imaging equipment to deliver safe, high quality diagnostic services and protocols to ensure radionuclide treatments are in line with current and emerging advances in the NM field. The MPE should be closely involved in ensuring all mandatory radiation protection measures for patients are included in the design.

Competences

- Understand the importance of taking leadership in all physics and technical issues related to safe, effective and efficient delivery of NM diagnostic and therapeutic services
- Demonstrate leadership skills to enhance and facilitate changes in health care
- Demonstrate skills to lead a team on specific tasks
- Take initiatives for the development and implementation of patient safety approaches in diagnostic imaging and therapies as well as strengthen safety culture
- Prioritise tasks needed to be performed in order to ensure effective and safe patient specific NM procedures
- Chair meetings effectively and efficiently and take part in discussions concerning current and future challenges in health care including their impact on NM practice
- Identify where quality improvements have to be initiated in diagnostic equipment and therapeutic protocols, patient workflow and related procedures
- Contribute to discussions concerning funding arrangements for NM service delivery in their institution/region/country of practice
- Demonstrate awareness of the roles and organisational structures of relevant professional societies and how MPEs contribute to these
- Negotiate and solve problems with other team members
- Design career paths adapted to the development of each of their team members.

II. 5 Health Advocate

As part of the multidisciplinary team, the MPE has a role to be an advocate for patients undergoing NM diagnostic and/or therapeutic procedures. The principle of ensuring safe, high quality, effective and appropriate diagnostic and therapeutic

NM based procedures for all patients should be upheld by the MPE. The MPE can actively participate in patient advocacy by preparing, producing and presenting well-researched and evidenced based reports regarding advances in NM technology, radiation safety and NM techniques. These reports can be used to support decision making within a healthcare institute, which is in the patients' best interest.

Competences

- Be a good collaborator within the healthcare profession to positively influence the multidisciplinary team on behalf of the patient
- Keep up-to-date with international recommendations and guidelines on quality and quality improvements in NM, including patient safety
- Be a good communicator to present technical and scientific data to non-physicist healthcare decision makers and patient populations
- Be a good communicator about the risks of ionizing and non-ionizing radiations to the public
- Be familiar with health economics when promoting the responsible and best use of resources that prioritise the needs of the patient while still balancing cost-effectiveness with clinical efficacy
- Understand the organisation of the national healthcare system and understand the principles of clinical governance
- Understand the dynamics of healthcare policy development and participate in consultation mechanisms by providing scientific knowledge to inform and promote improvements within the scope of NM
- Understand medical ethics, ethical governance, research ethics, data protection, patient's rights to privacy, dignity and respect
- Promote new recommendations to improve NM and associated radiation protection procedures

II. 6 Scholar

MPEs have a solid scientific background in physics, mathematics, data science and engineering. Their contribution to NM lies in the acquired KSC for the application of this particular scientific background in ensuring safe and effective NM services. MPEs need to engage in life-long learning through a continuing professional plan, which identifies areas for improving their KSC-base and keeping up-to-date with technical and clinical developments related to their profession. They also need to encourage colleagues to engage in departmental quality improvement initiatives and be involved in the training and

education of medical physicists and other nuclear medicine professionals by providing teaching lectures, supervising clinically based projects and mentoring colleagues and trainees.

MPEs need to keep updated with relevant professional literature and regularly attend national and international scientific meetings. MPEs should be involved in multidisciplinary journal clubs and other meetings for the dissemination of newly published literature in the field of NM. Collaboration with peers in other NM departments is needed in order to share information and benchmark their own centre against others.

MPEs are also encouraged to cooperate in projects with universities and tertiary level institutions with BSc, MSc or PhD projects, co-supervise students, and publish in scientific journals and present at scientific conferences.

The MPE's scholarly abilities allow them to contribute to the application, dissemination, translation, and creation of knowledge and practices applicable to health and health care.

Competences

- Engage in the continuous enhancement of professional activities through ongoing learning
- Recognise levels of uncertainty in practice and knowledge gaps in clinical and other professional encounters and generate focused questions to address them.
- Critically evaluate the integrity, reliability, and applicability of health-related research and literature
- Pose questions amenable to scholarly inquiry and select appropriate methods to address them
- Understand the scientific principles of research and contribute to the creation and dissemination of scholarly inquiry and the role of research evidence in healthcare
- Teach students, residents, the public, and other health care professionals
- Perform and contribute to scientific research and innovation and dissemination of obtained results
- Apply for research calls and participate in research projects.

II. 7 Professional

As professionals, MPEs are committed to the health and well-being of patients and society through high professional standards, integrity and governmental regulation. This includes self-awareness / reflection and knowledge of limits, high standards of ethical and moral behaviour, reliability and responsibility, and respect for patient dignity and autonomy.

The professional role reflects contemporary society's expectations of an MPE, which include clinical competence, a commitment to ongoing professional development, promotion of the public good, adherence to ethical standards, and values such as integrity, honesty, altruism, humility, respect for diversity, and transparency with respect to potential conflicts of interest. It is also recognized that, to provide optimal patient care, the MPE must take responsibility for self-care concerning their own health and well-being and that of their colleagues. Professionalism is the basis of the implicit contract between society and the MPE profession.

Competences

- Demonstrate appropriate professional behaviours and relationships in all aspects of practice, including honesty, integrity, humility, commitment, compassion, respect, altruism, respect for diversity, and maintenance of confidentiality
- Provide excellence of services and ensure a patient-centric-practice
- Improve quality for patient safety
- Promote public good in healthcare to society
- Commit to the profession by complying with international, and national guidelines and regulatory authorities
- Encourage research and development to advance Medical Physics practice, showing a commitment to science
- Fulfil and adhere to the professional and ethical codes, standards of practice, and laws governing practice
- Recognise and manage conflicts of interest
- Recognise and respond to unprofessional and unethical behaviour in the health care professions
- Exhibit self-awareness and manage influences on personal well-being and professional performance.

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- EFOMP Policy Statement 12.1: Recommendations on Medical Physics Education and Training in Europe 2014, <https://www.efomp.org/index.php?r=fc&id=policy-statements>
- EFOMP policy statement no. 15: Recommended guidelines on the role of the medical physicist within the hospital governance board, <https://www.efomp.org/index.php?r=fc&id=policy-statements>
- EFOMP policy statement 16: The role and competences of medical physicists and medical physics experts under 2013/59/EURATOM, <https://www.efomp.org/index.php?r=fc&id=policy-statements>
- COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.
- Radiation Protection No 174 (European Commission)
- Core curriculum for medical physicists in radiotherapy. ESTRO-EFOMP. 2011
- EFOMP school Manual, www.efomp.org
- Recommendation of the European Parliament and of the Council of 23 April 2008 on the establishment of the European Qualifications Framework for lifelong learning. Recommendation 2008/C 111/01. Official Journal of the European Union 6.5.2008.
- Frank, J. R., Snell, L., Sherbino J (2015). CanMEDS 2015 physician competency framework. Ottawa 2015: Royal College of Physicians and Surgeons of Canada. <https://www.royalcollege.ca/content/dam/document/standards-and-accreditation/2015-canmeds-framework-reduced-e.pdf>
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III. Specific MPE knowledge, skills and competences

III. 0 Levels of specific competences

We have defined four different levels of competences the trainee needs to develop and some associated examples are given below for illustration for each competence level:

Expert competence: to undertake independently and take responsibility for

The MPE should be able to undertake these tasks independently, without supervision, and take full responsibility for all aspects of the outcome, report, etc. For example, commissioning of a new imaging equipment.

Collaborative competence: to undertake alongside an MPE with expertise on that particular topic

The MPE should be able to undertake these tasks, working alongside another MPE or healthcare professional with specific expertise on a given topic, and make a useful contribution; however, they would not be expected to take full responsibility, as they would not be considered an expert in this topic. An example could be a MPE starting to work as a radiation safety officer in a Positron Emission Tomography (PET) radiotracer production unit; the MPE would be fully trained on common diagnostic and therapeutic NM procedures but would clearly require a radiopharmacist/radiochemist as a partner in order to fully apprehend labelling/quality assurance (QA) procedures associated with radiotracer production.

Contributive competence: to undertake alongside an expert in a different discipline (e.g. radiation oncologist, oncologist, neurologist, cardiologist, endocrinologist, surgeon etc..)

The MPE should be able to undertake these tasks, alongside an expert from a different discipline and make a useful contribution from a physics perspective, however they would not be expected to take full responsibility for the final decision which would be from another discipline. An example could be to discuss tumour target volumes on PET/Computed Tomography (CT) images with radiation therapy professionals – this would be a two-way conversation with input from both sides rather than the MPE explaining.

Awareness competence: to be aware of aspects that may influence one's activity

The MPE should have a basic understanding of different aspects of artificial intelligence and how they relate to NM, but would not be expected to be an expert. For example, be

aware of how artificial intelligence may play a role in image reconstruction and image analysis and could influence overall image quality and quantitative accuracy for NM imaging procedures.

III. 1 Fundamentals of human anatomy and physiology (including pathology)

As part of a multidisciplinary team, the MPE in NM requires a background in basic medical sciences including human anatomy, biology and physiology and its translation in imaging anatomy and function. This knowledge allows the MPE to appropriately develop imaging and radionuclide therapy optimisation protocols in NM while efficiently communicating and collaborating with nuclear medicine specialists and other healthcare professionals.

Expert competences

- Understand and interpret relevant medical terminology
- Basic imaging interpretation from various modalities (X-ray, CT, magnetic resonance imaging (MRI), gamma camera, single photon emission computed tomography (SPECT) and PET) to recognise the various anatomical structures and physiology of the human body relevant to NM procedures, especially with emphasis on their representation in 2D, 3D and functional imaging

Awareness competences

- Explain relevant sections of the human biological sciences (anatomy, physiology, pathology, cellular and biomolecular science, radiological anatomy)
- Define the human anatomy and function, including major organs systems (eg. lung, brain, heart, liver, kidneys) and describe physiological mechanisms for repair, maintenance, and growth
- Explain basic knowledge of physiology and function such as metabolism, cell division, hypoxia, apoptosis, angiogenesis, carcinogenesis, circulation (blood flow and volume), lung (respiratory) function, kidney function, brain function, lymphatic and endocrine systems
- Basic explanation of pathology in cardiovascular and neurological diseases as well as in oncology and associated treatment options (for example, in the case of oncology radiotherapy, surgery, chemotherapy immunotherapy, hormone therapy, highly focalized ultrasound, radiofrequency ablation)

- Basic explanation of radiation biology including radiation effects to biological entities, tissues and cells.

Core curriculum items

- Nomenclature of human anatomy
- Anatomy of skeletal structures
- Anatomy and physiology of head and neck, brain, thorax, abdomen and pelvis
- Anatomy and physiology of the following systems: muscular, respiratory, digestive, urinary, reproductive, and circulatory
- Function of bone marrow
- Anatomy and function of brain and central nervous system
- Cell physiology and function
- Structures and organs of the human body in the images (X-ray, CT, US, MRI, PET, SPECT, etc.) used to visualize them

Time to be spent on this topic: 8 ECTS

Recommended literature

- Sherman and, Luciano's Human Physiology, McGraw-Hill, 2004.
- McKinley M, O'Loughlin V, Human Anatomy, 5th Edition. McGraw-Hill, 2016.
- Marieb EN, Hoehn KN, Human Anatomy and Physiology, 10th Edition. Pearson, 2015.
- Moore KL, Dalley AF, Agur AMR. Clinically Oriented Anatomy, Eighth, International Edition. Lippincott Williams and Wilkins, 2017.
- Widmaier E., Raff H., Strang K. Vander's Human Physiology. 15th Edition. McGraw-Hill Education, 2018.
- Jonathan D. Spratt, Lonie R Salkowski, Marios Loukas, Tom Turmezei, Jamie Weir, Peter H. Abrahams. Weir & Abrahams' Imaging Atlas of Human Anatomy, 5th Edition. Elsevier Science & Technology, 2016.
- e-Anatomy the interactive atlas of human anatomy. IMAIOS SAS (<https://www.imaios.com/en/e-Anatomy>). <https://doi.org/10.37019/e-anatomy> (2019).
- Ruddon RW, Cancer Biology, Oxford University Press, 2007 Introduction to the Cellular and Molecular Biology of Cancer, Eds. Margaret Knowles and Peter Selby, Oxford University Press, 2005.
- Raymond E Lenhard Jr, Robert T Osteen, Ted Gansler Eds. Clinical Oncology, American Cancer Society.
- D Hanahan and RA Weinberg, "The Hallmarks of Cancer", Cell 2000;100(1):57-70 and "Hallmarks of Cancer: The next generation", Cell 2011;144(5):646-74.
- F Bray, J Ferlay, I Soerjomataram, RL Siegel, LA Torre, A Jemal. CA Cancer J Clin. 2018 Nov;68(6):394-424. doi: 10.3322/caac.21492. (www.cancer.org)

- G. Knoll, Radiation Detection and Measurement, 4th Edition ISBN: 978-0-470-13148-0

III. 2 Core radiation physics

The MPE in NM should have a good knowledge of radiation physics in order to understand how ionising radiation is applied in medical diagnostics and therapy. Since X-rays, gamma rays, alpha-particles, electrons of variable energies are nowadays applied in radiopharmaceutical development, and/or medical diagnostics and/or radionuclide therapy, a broad knowledge of nuclear and atomic physics is required for the MPE in NM. Knowledge of general concepts of radiation quantities and units as well as radioactive decay and radiation interactions with materials and matter is required. As the theory of radiation physics has already been studied, to some extent, at the BSc/MSc level, this should really be a review with extension to practical NM applications.

Expert competences

- Explain the difference between the physical interactions of indirectly and directly ionising radiation
- Explain the different mechanisms of generation of ionising radiation, including radioactive decay types
- Describe the different mechanisms of energy loss and energy deposition for various types of radiation through various media
- Use radiation quantities and units correctly.

Core curriculum items

- Physical and radiation quantities and units (activity, absorbed dose, absorbed dose rate, etc)
- Types and sources of ionising radiation
- Atomic and nuclear structure and associated models
- Nuclear models
- Radioactivity (including activation of nuclides and modes of radioactive decay)
- Interaction of photons with matter (attenuation, scatter)
- Interaction of charged particles in with matter: alphas, positrons, electrons (stopping power, linear energy transfer, etc.), protons, neutrons

Time to be spent on this topic: 10 ECTS

ECTS Recommended literature

- Johns & Cunningham, The Physics of Radiology 5th ed. 2021
- Andreo et al. Fundamentals of Ionising radiation Dosimetry, Ed. Wiley 2017
- Graham DT, Cloke P. Principles and Applications of Radiological Physics. 6th Ed. Churchill Livingstone 2011

- Podgorsak EB. Radiation Physics for Medical Physicists. 3rd Ed. Biol Med Phys, Biomedical Engineering. Springer 2016
- Attix FA. Introduction to Radiological Physics and Radiation Dosimetry. John Wiley & Sons, 2008.
- Hobbie RK. Intermediate Physics for Medicine and Biology. 5th Ed. Springer Int. Publishing Switzerland, 2015
- ICRU Report 95. Operational Quantities for External Radiation Exposure, 2020, <http://www.icru.org/>

III. 3 Equipment management

The detection and measurement of radiation is a fundamental component in diagnostic and therapeutic NM applications. NM utilizes a great variety of medical imaging and non-imaging devices in order to deliver a safe and effective service to patients. Radiation detection/measuring systems are used in nuclear medicine to a) measure the radiation emitted from patient tissues b) measure the activity of radiopharmaceutical doses to be administered in patients or other radioactive samples and c) to monitor ambient dose rate and occupational exposure in Nuclear Medicine facilities. In recent years there has been a rapid advancement of medical equipment and procedures in the NM field. MPEs in NM are responsible for the safe and effective operation of all equipment. They provide technical advice and participate in the specification, selection, installation design, acceptance testing, commissioning, installation design and decommissioning of nuclear medicine devices in accordance with the latest published European or International recommendations. They also manage the specification, management and supervision of associated quality assurance / control programmes. Design of all testing protocols is to be based on current European or international recommended techniques and protocols. Proper handling of the medical equipment and associated patient safety rely on the education and training of medical physics experts. In this context MPEs must have an expertise on principles of operation of the nuclear medicine imaging equipment, radiation measurement instrumentation, their management and QA.

Expert competences

- Describe the general physics principles and explain the different components of a scintillation detector, a semiconductor detector and a gas filled radiation detector used in NM
- Understand the physics and operation principles of the different types of personal dosimeters (passive and active)

- Explain the main advantages and disadvantages of different personal dosimeter types
- Describe and explain traceability of active and passive dosimeters
- Describe and explain the different types and physics principles of ambient exposure monitoring systems, waste exposure measuring systems and contamination detectors and associated models
- Understand the physics and operation principles of the different types of activity meters and gamma counters (intraoperative gamma probes, well counter, other uptake measuring probes)
- Explain the physics and operation principles of conventional Gamma Camera, SPECT, SPECT/CT and hybrid PET (PET/CT, PET/MRI) systems
- Explain and apply optimisation strategies (patient absorbed dose/image quality) the different acquisition protocols (Planar/tomographic, Static, Dynamic, Gated, single field-of-view or axially extended) concerning the different NM equipment listed above
- Understand the factors that affect patient absorbed dose from CT exposure involved in SPECT/CT and PET/CT examinations
- Understand EU Directives, national regulations, guidelines and recommendations from national and international organizations related to medical equipment management
- Prepare and evaluate technical specifications for tender purposes regarding Nuclear Medicine equipment and devices
- Evaluate the conformity and compliance of devices used in nuclear medicine with applicable European requirements
- Prepare and implement routines and guidelines for quality assurance (QA) and quality control (QC) of medical devices related to nuclear medicine
- Create quality policy documentation and contribute to the implementation of quality management systems (QMS) in Nuclear Medicine
- Understand the procedure of certification and accreditation of medical equipment and devices
- Create and implement routines for decommissioning and disposal of medical equipment and devices

Collaborative competences

- List and explain the statutory and institutional role of Medical Physicist in radiation measurements of activity and exposure in Nuclear Medicine departments/laboratories
- List and explain the considerations for the choice of radiation measurement instruments used in Nuclear Medicine

- Define the specifications of any radiation measurement instrument to be purchased
- Explain the structure for managing medical devices including corresponding lines of accountability and responsibilities in Nuclear Medicine
- Cooperate with local/national reference metrology for well counter and activity-meters calibration
- Understand the European Medical Devices Regulation 2017/745 (MDR) and associated documentation in relation to conformance and acceptance testing
- Explain the routine to track and distribute manufacturer's update of instructions and field safety notices
- Understand EU Regulatory Requirements on CE Marking for medical devices and equipment
- Explain the procedures for acceptance testing, commissioning, QC and decommissioning of nuclear medicine equipment
- Understand the procedures and requirements for calibration and testing of medical devices and instrumentation in accordance with ISO 17025
- Explain the physics and operation principles of medical imaging systems used in NM
- Supervise and provide guidance for the development of new acquisition protocols
- Provide instructions and guidance for safe use of all medical devices and equipment in NM
- Provide guidance regarding specifications and selection of new imaging equipment
- Prepare written materials, reports and communication with authorities

Contributive competences

- Develop written standard operating procedures (SOPs) for QA and QC of medical devices and equipment
- Prepare written materials related to the image acquisition systems in the form of reports, instructions etc.
- Describe how a QMS works in a Nuclear Medical context
- Describe the safety and performance requirements under the MDR and related documentation
- Discuss the imaging equipment physics and principles of operation with nuclear medicine team

Awareness competences

- Understand the main steps of medical equipment management procedures
- Understand the main components of QMS

Core curriculum items

- Describe and explain the function of radiation detectors

used in Nuclear Medicine

- Illustrate the characteristics of a NM counting system including the effect of background counts and minimum detectable counts
- Explain the concepts of fundamental detector properties in terms of sensitivity, energy resolution, spatial resolution and temporal resolution and how they affect the performance of NM devices
- Explain how count statistics affects the performance of radiation detection in NM
- Operate radiation measurement devices/detectors and interpret the results in the context of NM
- Take responsibility for the handling, management and maintenance of radiation measurement devices
- Define the quantities (including units and interrelationships) used in measurements of activity of radioactive sources
- Explain the physics and operation principles of a) exposure rate measuring instruments, b) activity measuring instruments and c) personal dosimeters used in NM facilities
- Describe the calibration procedures of a) exposure rate measuring instruments, b) activity measuring instruments and c) personal dosimeters used in NM facilities
- Understand the practical applications of anatomical and functional imaging modalities in NM (SPECT/CT, PET/CT, PET/MR)
- Describe the usage of QC/QA Phantoms such as flood field, count rate, sensitivity, resolution, linearity and image quality for hybrid PET and SPECT imaging systems
- Propose optimization strategies (absorbed dose/ activity / image quality) in NM
- Explain the physics and principles of operation of CT and its advantages and disadvantages in hybrid imaging
- Explain the physics and principles of operation of MR and its advantages and disadvantages in hybrid imaging
- Describe and explain Systems for EMS and QMS
- Describe and explain quality management and assurance programs
- Describe and explain MDR and its associated documentation
- Describe and explain medical devices and equipment definitions, regulation and related standards
- Describe and explain audits and reviews to verify compliance and identify areas for improvement

Time to be spent on this topic: 24ECTS

Recommended literature

- Physics in nuclear medicine, Cherry SR, Sorenson JA, Phelps ME, eds. 4th ed. Philadelphia: Saunders; 2012
- Review of the characteristics of radiation detectors for dosimetry and imaging, Seco J, Clasié B, Partridge M. Phys Med Biol 2014;59: R303.
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- Iniewski K. CZT detector technology for medical imaging. J Instrum 2014;9:C11001
- IAEA, Quality Assurance for SPECT Systems, IAEA Human Health Series No. 6, IAEA, Vienna (2009)
- IAEA, Quality Assurance for PET and PET/CT Systems, IAEA Human Health Series No. 1, IAEA, Vienna (2009)
- IAEA, PET/CT Atlas on Quality Control and Image Artefacts, IAEA Human Health Series No. 27, IAEA, Vienna (2014)
- IAEA, Nuclear Medicine Physics, Non-serial Publications, IAE Nuclear Medicine Physics (Series in Medical Physics and Biomedical Engineering) by Joao Jose De Lima (Editor) 2018 A, Vienna (2015)
- Problems and solutions in medical physics: Nuclear Medicine, By Kwan-Hoong Ng, Chai Hong Yeong, Alan Perkins, 2019
- IAEA, SPECT/CT Atlas of Quality Control and Image Artefacts, IAEA Human Health Series No. 36, IAEA, Vienna (2019)
- Nuclear Medicine Physics. The Basics, 8th Edition. Ramesh Chandra and Arman Rahmim. Lippincott Williams & Wilkins, a Wolters Kluwer business. Philadelphia, 2018.
- The European Medical Devices Regulation 2017/745 (MDR)
- WHO -Quality Assurance in Nuclear Medicine
- IAEA TECDOC-602 - Quality control of nuclear medicine instruments
- National Electrical Manufacturers Association (NEMA) Performance Measurements of gamma cameras and PET cameras
- EFOMP policy statement 17: The role and competences of medical physicists and medical physics experts in the different stages of a medical device life cycle. van Asten et al, Physica Medica, 2023-04-01, Volume 108, Article 102557
- ISO 9001 - Quality Management Systems
- ISO 13485 - Medical devices Quality management systems
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO 12052 - Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management
- ISO 14155 - Clinical investigation of medical devices for human subjects - Good clinical practice

- IEC 62304 - Medical device software
- ISO 14971 - Application of risk management to medical devices
- Ljungberg M (2022) Handbook of Nuclear Medicine and Molecular Imaging for Physicists, ISBN: 9781138593350

Volume 1: Instrumentation and Image Processing, doi:10.1201/9780429489556

III. 4 Image Analysis and Quantification

Image analysis and quantification is a key component of nuclear medicine imaging. Given that NM imaging uses radiopharmaceuticals to image physiological processes, it is of huge benefit to be able to quantify the uptake of the radiopharmaceutical as a marker of a physiological process and understand target specific uptake and uptake relative to other tissues.

The role of an MPE has optimization as one of its pillars. It is therefore essential that an MPE can optimize and evaluate imaging and analysis for quantification purposes in order to meet the required clinical outcome. The MPE should also have a strong understanding of the analysis and quantification methods themselves.

Expert competences

- Explain analytical and iterative tomographic reconstruction and associated parameters (e.g. iterations, subsets, penalization) for SPECT and PET influences image quality
- Understand the benefits and compromises of acceleration such as ordered subset EM reconstruction
- Explain the need and integration of corrections (including the necessary steps) for attenuation, scatter, resolution etc. on SPECT, SPECT/CT, PET, PET/CT and PET/MR scanners
- Be able to explain correction for attenuation on planar imaging using geometric mean calculation
- Explain the use of motion management techniques to help improve image quality
- Explain how scanner malfunctions and limitations affect image appearance/quantification
- Illustrate image artefacts that can arise, and the strategies that can be taken to correct or mitigate against recurrence
- Explain the concept of list mode as method in helping image optimization
- Understand spatial, angular, and temporal image sampling and the effects of under or over sampling

- Understand noise and image quality indices
- Explain noise handling strategies, including the use of image filtering together with the compromises that come with these strategies
- Explain the different methods of region/volume definition on an image such as those based on isocontours, thresholds or more advanced techniques
- Understand the benefits and issues around voxelwise quantification
- Explain how the partial volume effect and spatial sampling affects quantitative values
- Explain the definition of Standardised Uptake Value (SUV), and its derivatives and variants such as SUV-Lean Body Mass (LBM), Total Glycolytic Volume (TGV), Total Lesion Glycolysis (TLG). Understand the assumptions behind the measurement of SUV
- Understand the benefits and challenges of ratio-based metrics in image quantification
- Understand the benefits and challenges of using normative values and databases in quantification
- Understand the applications of dynamic imaging and time activity curves (TAC) in quantitative nuclear medicine imaging
- Explain inter site and inter operator variations in image quantification and strategies that can mitigate these issues
- Know how to implement methodological approaches available for image analysis as a function of the objective to be reached (inter- and intra-image comparison, i.e. visual interpretation vs semi-quantitative vs fully-quantitative evaluation)
- Understand image registration (rigid, affine, deformable) related to NM imaging

Awareness competences

- Understand the mathematical underpinnings of tomographic reconstruction including the use of Fast Fourier Transforms
- Understand the benefits of artificial intelligence in tomographic reconstruction
- Understand the clinical implication of the use of specific algorithm/corrections in line with the disease type, its management and the final objective (detection purpose, quantitative performance, visual analysis...)
- Explain the concept of tissue compartment kinetic modelling and kinetic analysis and the process of deriving kinetic parameters
- Understand the benefits and challenges of arterial input functions and image derived input functions as data source

- for pharmacokinetic and dynamic modelling
- Explain graphical analysis of dynamic data e.g., Patlak and Logan plots
- Understand the basic principles of physiology based pharmacokinetic (PBPK) analyses
- Understand the use of artificial intelligence in the segmentation and parcellation of organs and features
- Understand the use of radiomics to characterise tissues

Core curriculum items

- Tomographic reconstruction and corrections
- Motion management
- Sampling theory
- Image filtering
- Image artefacts
- ROI/VOI definition
- Partial volume effects
- Kinetic Modelling
- Radiomics

Time to be spent on this topic: 20 ECTS Recommended literature

- International Atomic Energy Agency. (2014). Nuclear Medicine Physics: A Handbook for Teachers and Students (D. L. Bailey, J. L. Humm, A. Todd-Pokropek, & A. van Aswegen (eds.)). International Atomic Energy Agency. <https://doi.org/10.1055/s-0038-1625324>
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- Lamare F, Bousse A, et al (2022). PET respiratory motion correction: quo vadis ? Phys Med Biol Feb 1;67(3). [doi: 10.1088/1361-6560/ac43fc](https://doi.org/10.1088/1361-6560/ac43fc).
- Ljungberg M (2022) Handbook of Nuclear Medicine and Molecular Imaging for Physicists, ISBN: 9781138593350 Volume 1: Instrumentation and Image Processing, [doi:10.1201/9780429489556](https://doi.org/10.1201/9780429489556)

III. 5 Radiation Protection

Radiation protection is important in all applications of ionizing radiation, and the general principles as laid out by ICRP apply to all types of use including the medical field. The overall justification of the medical use of radiation is based on the large benefit obtained by the patients when compared to the small associated risks. Still these risks must be reduced and mitigated as much as practical possible.

Nuclear medicine differs from the other medical applications by the use of unsealed radioactive sources of ionising radiation that are given to patients. The MPE in NM must therefore not only have a solid general knowledge about radiation protection but also have profound specific competencies in the handling of such sources under normal planned situations as well as in the case of incidents/accidents.

The protection of the patient is an inherent part of the optimization of the actual diagnostic or therapeutic procedure. The fact that the patients undergoing these procedures become moving radiation sources implies a responsibility for protection of staff, comforters and carers, members of the public, and the environment that extends beyond the completion of the procedures.

The use of radioactive sources is strongly regulated at international and national levels with regulations differing between different countries and even institutions. It is essential that the MPE has knowledge of the general recommendations (International Commission on Radiological Protection (ICRP), EU) as well as the local implementations.

Expert competences

- Describe the operational quantities and units of exposure rate and activity of radioactive samples
- Explain the basic principles of radiation protection; justification, optimization and dose limitation.
- Explain dosimetry variables/concepts applied in radiation protection (absorbed dose, equivalent dose, effective dose)
- Define and survey dose constraints for all relevant situations in the department
- Lead the work for optimization of protection, i.e. the ALARA, principles of Time Distance Shielding, good radiation safety practice and the use of personal protective equipment
- Define and survey dose constraints for all relevant situations in the department
- Calculate relevant entities regarding waste (solid and liquid discharge)
- Define radiation protection emergency procedures. Take responsibility for the prevention and investigation of adverse incidents, e.g. accidental or unintended medical exposures.
- Perform risk analyses and write safety assessments
- Teach (all) other professionals in topics of radiation and radiation protection
- Explain the operational quantities for individual monitoring in external dosimetry.
- Monitor personal dosimetry of the personnel
- Describe extremity dosimetry techniques
- Supervise the use of personal protective means
- Explain the requirements for radiation shielding (lead windows, bricks, containers for storage and transportation, apron, collar and other personal equipment) and supervise their use
- Explain the physics and technical principles of direct and indirect detection mechanisms.
- Explain dose rate, activity concentration in air and surface contamination levels, and their expected fluctuations under operational conditions.
- Explain the workplace monitoring control process, waste disposal of radioactive material, and managing of waste principles (including transportation, storage, handling).
- Explain principles of legal requirements of radioactive waste management and waste release criteria.
- Account for radiation protection, workflow, air quality (hot lab, waste storage), infection control in the design of a NM department.
- Perform shielding calculations for a gamma camera, PET/CT, SPECT/CT rooms, radiopharmaceutical production (hot lab, cyclotron, etc), patient uptake areas, toilets, etc.
- Carry out workload assessment - taking into account examination technique and/or procedure type (diagnostic, therapy), patient numbers, injected activities.
- Management of documentation of all assumptions, design, and specifications for future reference, and maintenance.
- Able to supervise the construction work of the NM facilities in terms of radiation safety and correct application of shielding.
- Assess the effectiveness of shielding by measurements (upon completion of the construction).
- Take responsibility for the classification of radiation areas within a NM facility as Supervised or Controlled and specify correct warning signs.
- Implement the procedure for qualitative and quantitative assessment of radiation risk in terms of absorbed dose to the patient arising from both internal and external sources of exposure.
- Perform risk assessment for continued and limited use of

- equipment that does not meet acceptability criteria.
- Take responsibility for management of any radioactive waste arising from the work conditions.
 - Explain the main principles of environmental monitoring.
 - Explain how to perform environmental assessment using different measurements and calculations.
 - Describe and explain the design of a proper storage facility for radioactive waste with minimal environmental impact from a release.
 - Explain the requirements for radiation shielding (lead windows, bricks, containers for storage and transportation, apron, collar and other personal equipment) and supervise their use.
 - Describe the dose constraints in accordance with national and international guidelines, recommendations for the members of the public caring for patients after radionuclide treatment.
 - Explain the main principles of public safety in nuclear medicine facility including classification of areas.

Collaborative competences

- Explain principles of a NM facility design for other professional groups (engineers, architects).
- Explain the optimal choice of the shielding material for other professional groups (engineers, architects) considering radiation protection, financial, constructional aspects.

Contributive competences

- Explain how research medical exposures are managed in the context of NM, including the processes of ethical review and clinical trials administration and governance and the use of appropriate dose constraints.

Awareness competences

- Evaluate the NM conditions in all workplaces and be able to recommend the proper device for workplace monitoring.
- Discuss with engineers about systems, such as water-cooling system for PET/CT systems, air-ventilation/pressure system for hot lab, cyclotron facility related systems.
- Explain basic principles of environmental monitoring and the possible impact to general public members.

Core curriculum items

- Justification, Optimization, Dose Limits
- The linear dose-risk model (LNT) implicit in the protection system
- Nominal probability coefficients ("5% / Sv")
- Radiation and tissue weighting factors, effective dose
- Categories of exposure (occupational, public, medical)

- Dose limits (all sources in planned situations) and constraints (one source in all exposure situations)
- ALARA = optimization of protection
- Optimisation of personnel exposure
- Radiation monitoring: classification of areas, personal monitoring, documentation associated within a procedure
- Calibration of radiation monitoring devices
- Design of a new NM facility
- Shielding consideration in respect to energy and particle type and neutrons
- Shielding for types of facilities and means in respect to type of procedures: diagnostic or therapy
- Shielding calculation and assessment of a gamma camera, PET/CT, SPECT/CT, hot lab, radioactive waste storage facility
- Risk assessment - qualitative and quantitative: for routine and non-routine procedures, equipment that do not meet/only partially meets criteria, for sensitive groups of patients
- Incident analysis
- A knowledge of national and international regulations of radioactive material transport/management, and radioactive waste /management
- Categorisation of waste in nuclear medicine
- Safe management of radioactive material (transport, handling, monitoring) and associated waste (storage handling, release)
- The radiation protection precautions for deceased patients after radiopharmaceutical therapy
- Engineered controls such as ventilation, liquid waste collection systems
- Impact of released radioactive waste on the environment
- Operational limits and conditions relating to public exposure, limits for patient discharge

Time to be spent on this topic: 24 ECTS

Recommended literature

- AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, AAPM Task Group 108: PET and PET/CT Shielding Requirements, AAPM Rep. 108, New York (2006).
- EANM-EFOMP PAPER Curriculum for education and training of Medical Physicists in Nuclear Medicine* Recommendations from the EANM Physics Committee, the EANM Dosimetry Committee and EFOMP (2012)
- IAEA: Guideline on current good radiopharmacy practice (cGRPP) for the small-scale preparation of radiopharmaceuticals (2011)
- IAEA human health series no. 11: Planning a clinical PET centre (2010)
- IAEA Safety Standards Series No. GSG-7 Occupational Radi-

ation Protection

- IAEA Safety Standards Series No. GSR Part 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
- IAEA Specific Safety Guide No. SSG-46 Radiation Protection and Safety in Medical Uses of Ionizing Radiation
- IAEA technical course series no. 50: Clinical Training of Medical Physicists Specializing in Nuclear Medicine (2011)
- IAEA TRAINING COURSE SERIES No. 76, Education of Radiation Metrologists for Secondary Standards Dosimetry Laboratories, 2023
- ICRP publication 103, The 2007 Recommendations of the International Commission on Radiological Protection (2007)
- ICRP publication 135, Diagnostic Reference Levels in Medical Imaging (2017)
- NCRP publication 49, Structural shielding design and evaluation for medical use of x-rays and gamma rays of energies up to 10 MV (1976).
- NCRP publication 147, Structural Shielding Design for Medical XRay Imaging Facilities (2004).
- Radiological Institute of Ireland, The Design of Diagnostic Medical Facilities where Ionising Radiation is used (2009)
- IAEA Safety Standards Series No. GSG-7 Occupational Radiation Protection
- IAEA Specific Safety Guide No. SSG-46 Radiation Protection and Safety in Medical Uses of Ionizing Radiation
- Ljungberg M (2022) Handbook of Nuclear Medicine and Molecular Imaging for Physicists, ISBN: 9781138593350; Volume 2: Modelling, Dosimetry and Radiation Protection, doi:10.1201/9780429489549
- Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

III. 6 Dosimetry in NM

Patient NM dosimetry is developing, along with a wider availability of new radiopharmaceuticals or medical devices in a context of radionuclide therapy. Here it should be noted that NM dosimetry applies to two distinct NM applications, diagnostic and therapeutic. In a context of diagnostic applications (90% of all clinical NM procedures), patient dosimetry is intended in a context of radiation safety, to document the irradiation delivered, but does not represent a clinical challenge. Reference dosimetry is therefore implemented, before a new radiopharmaceutical is put on the market, to appraise the irradiation delivered, but radiation effects are confined in the domain of stochastic effects, and the NM dosimetry procedure

follows the recommendations of the ICRP. Absorbed doses are computed for groups of patients, healthy volunteers or extrapolated from animal data, pooled pharmacokinetics are used as input in reference models to derive effective doses.

In a context of radionuclide therapy (RNT), the principle is to concentrate radiation at the level of the clinical targets (usually a tumour), while sparing organs at risk (OARs) (i.e. maintain a radiation concentration below dose constraint). Deterministic effects on the targets are expected/intended and shall be as high as safely attainable while they shall be kept as low as possible for the OARs. Absorbed doses to targets and OARs may be high. As in external beam radiation therapy (EBRT) this requires accurate and precise absorbed dose calculations / assessment. In that context, patient-specific dosimetry is implemented, based on sequential imaging or non-image-based activity measurements, pharmacokinetic determination, and absorbed dose assessment using a variety of absorbed dose calculation algorithms. This process is eased by the growing availability of both free and commercial dosimetry software (equivalent to treatment planning systems in EBRT), the latter provided with CE marking or FDA approval that allow for performing clinical dosimetry in routine in a nuclear medicine department.

III. 6. 1 Quantities and units

The quantities and units used in Nuclear Medicine include physical, radiation, radiation protection, dosimetry and those related to medical internal radiation dose formalism.

Expert competences

- Define and explain the measured operational quantities and units of exposure rate
- Describe and explain the relationship between the various dosimetric quantities used
- Take responsibility for the measurement of dosimetric quantities for ionizing radiations and other physical agents in nuclear medicine
- Select and use instruments for dosimetric quantities for the various types of ionizing radiations and other physical agents for patients, workers and public in Nuclear Medicine
- Apply the different operational quantities used for dosimetry
- Explain the symbols used to represent quantities in the medical internal radiation dose formalism and their application in specific patient dosimetry

Core curriculum items

- General concepts of quantities and units (radiation, radioactive decay)
- Radioactivity: Decay constant, Activity, Air-kerma-Rate Constant
- Radiation interactions with materials and matter: Mass Attenuation Coefficient, Linear Energy Transfer (LET)
- Dosimetry: Kerma, Kerma Rate, Absorbed Dose and Absorbed Dose rate, Effective dose
- Operational quantities used in personal dosimetry e.g., depth dose equivalent Hp(10) and skin dose equivalent Hp(0.07)
- CT dose concepts: CTDI, CTDI_w, CTDI_{vol} DLP, SSDE
- Measure quantities relevant to Nuclear Medicine (Activity, dose rate, others)

III. 6. 2 General dosimetry for staff, public, and diagnostic patient procedure

Please note that some of the competences below are complementary to, while others may be overlapping with, some radiation protection competences covered under section III.5.

Expert competences

- Take responsibility for the radiation safety of staff, including systems for monitoring the dose of the worker and public, and practical measures to support this
- Take responsibility for dosimetric measurements necessary for dosimetric investigations
- Explain the principles of dosimetric measurement standards and traceability
- Take responsibility for statutory and institutional requirements for Medical Physics Services in NM with respect to Occupational Dose Optimization when there is an impact on medical exposure or own safety
- Take responsibility for the optimisation of procedures in terms of patient safety and for patient dose optimisation (including software aspects)
- Take responsibility for statutory and institutional requirements for Medical Physics Services in Nuclear Medicine with respect to Patient safety / Dose Optimization for diagnostic & therapeutic procedures
- Describe the main working principles of dose reporting by modalities and equipment
- Describe how diagnostic medical exposures are managed in the context of Diagnostic Reference Levels (DRLs)
- Take responsibility for setting up the local DRLs
- Understand how DRLs affect practices. Oversee the use of DRLs, review records on examination procedures and discuss

the possibilities for optimization

- Take responsibility for the planning for emergency situations with regard to patient safety in own area/s of Medical Physics practice (dose estimations)
- Take responsibility for ensuring the optimal patient radiation protection applying the ALARA principle
- Take responsibility for optimisation of acquisition protocols in both standard and non-standard situations (eg. research medical exposures)
- Take responsibility and supervise the development of appropriate dosimetry protocols (time-sampling, time-activity curves derivation and dose calculations)
- Take responsibility for optimisation of procedures in non-standard situations, for e.g. the pregnant patient, the lactating patient, and paediatric patients
- Implement appropriate systems for monitoring the absorbed dose of the worker (including pregnant and lactating workers), comforters and carers and the public; including selection, management and calibration of devices used to record absorbed doses and practical techniques for absorbed dose measurement
- Take responsibility for the prevention and investigation of adverse incidents (example: risk of a foetus in a pregnant patient)
- Explain practical techniques for dose measurement of pregnant and lactating workers, and young workers
- Take responsibility for the radiation safety of public, including systems for monitoring the dose of the public, and practical measures to support this
- Take responsibility for statutory and institutional requirements for Medical Physics Services in NM with respect to Public Dose Optimization when there is an impact on medical exposure or own safety

Collaborative competences

- Explain how doses to comforters and carers are managed including the use of appropriate dose constraints
- Communicate the risks to sensitive groups (children, pregnant patient, unborn child etc.) in the case of medical exposure to ionizing radiation

Explain how standard exposures and procedures can be modified in special cases, e.g. the pregnant patient, the lactating patient, and pediatric patients

- Identify circumstances in which it might be appropriate to exceed the recommended DRL
- Discuss the CT dosimetry exposure control in hybrid imaging

Core curriculum items

- Measurements for dosimetry specific image quantification
- Activity measurements
- Cumulated activity
- Methods for determining patient-specific organ masses
- Computer codes for dose optimisation
- Patient dose and risk assessment (external, internal sources of exposure)
- A knowledge of national and international regulations on personnel dosimetry and principles of patient dose monitoring
- Special protection during pregnancy
- Diagnostic reference levels
- Optimization of procedures, dose reduction techniques
- Modification of standard procedures in special cases
- Dosimetry reporting in diagnostic and therapeutic procedures
- Patient protection
- Passive and active personnel dosimetry
- External and internal personnel dosimetry
- Dosimetric quantities used for personnel dosimetry

III. 6.3 Patient dosimetry for radionuclide therapy (RNT)

Expert competences

- Explain the differences between diagnostic and therapeutic nuclear medicine
- Explain the nuclear medicine patient dosimetry formalism
- Explain the concept of reference model
- Explain the concepts of non-penetrating radiations and their application in radionuclide therapy
- Explain the clinical dosimetry workflow (CDW)
- Understand the differences between activity and absorbed dose rate workflows and explain the potential consequences on the CDW
- Explain the quantification of activity applied to patient NM dosimetry and required calibration steps
- Explain the various time-integration approaches, their domain of application and limitations
- Explain the different absorbed dose calculation algorithms
- Explain the pro/cons of voxel-based dosimetry
- Describe the obtained results and radiobiology indices determination
- Describe the different steps that require traceability and reproducibility in patient dosimetry
- Understand the role of Test Data Sets (TDS) in patient dosimetry QA
- Implement clinical dosimetry QA in the nuclear medicine

department

- Describe the different software types available for patient dose calculations (commercial, academic) and the regulatory implications
- Explain the different steps to consider when purchasing software
- Define and implement procurement and commissioning of clinical dosimetry software
- Explain the different components of a clinical dosimetry protocol
- List the components of a Dosimetry Operational Manual (DOM)
- List the components of a Dosimetry Analysis Plan (DAP)
- Write the different Standard Operational Procedures adapted to physicists and technologists

Contributive competences

- Pharmacokinetics, pharmacodynamics
- Compartmental analysis
- Population pharmacokinetics and possible applications in NM patient dosimetry
- Understand the different steps of clinical trials and radiopharmaceutical development
- Participate to the writing of single or multicentric clinical trial involving dosimetry
- Participate to laboratory specific regulatory aspects

Awareness competences

- Radiopharmaceutical (type, production, clinical use)
- RNT principles and clinical indications
- Systemic internal radiotherapy
- Selective internal radiotherapy (e.g. ^{90}Y and ^{166}Ho microspheres)

Core curriculum items

- MIRD formalism & ICRP formalism
- Differences between ICRP and MIRD
- Concepts of S factor,
- Time-integrated-activity and time-integrated-activity-coefficient
- Model-based vs. image-based dosimetry
- Reference vs. patient-specific dosimetry
- Models and their evolution in time
- Differences between the different versions (mathematical vs. voxel vs. hybrid)
- Non-penetrating radiations and their use in RNT
- Differences between alpha, Auger, beta and possible use in RNT
- The different steps from activity determination to irradiation

characterisation

- From the general MIRD formalism to patient image-based dosimetry
- Quantitative imaging applied to dosimetry
- Image-based vs. non image-based activity determination
- Concepts of surrogate emitter or direct determination of activity
- Time-series and consequences on acquisition procedures
- Calibrations (Sensitivity, Dead-time corrections)
- TAC fitting and integration (Mono/bi/multi exponential fits, Trapeze fit, From zero to first time point, From last time point to infinity)
- Absorbed dose calculation (Local energy deposition (with or without density correction); Convolution (with or without density correction); Monte Carlo radiation transport and energy deposition)
- Organ vs. voxel-based dosimetry (Spatial resolution vs. absorbed dose calculation algorithms)
- Dosimetry variables and related indices (Mean absorbed doses, absorbed dose volume histograms, BED, EUD, EUBED)
- Specificities and components of QA in NM dosimetry
- Software available for NM dosimetry
- Tools for software testing and commissioning
- Phantom vs. models vs. patient data
- Validation and commissioning of clinical dosimetry software
- Understand the different steps of clinical trials and radiopharmaceutical development
- The different components of a clinical dosimetry protocol (Calibration/data acquisition/processing)
- Dosimetry Operating Manual (DOM): Protocol definition, Calibration procedures, Acquisitions and reconstruction, Blood/excreta sampling and activity measurement, Absorbed dose determination, Reporting
- Dosimetry Analysis Plan (DAP): Protocol definition, CDW, Security of patient data (storage and disposal)
- Standard Operational Procedures adapted to physicists and technologists
- Clinical trials and radiopharmaceutical development (specificities of multicentric trials, centre accreditation, local vs. centralised processing)
- Dosimetry framework (alpha/beta/Auger emitting nuclides)
- Activity determination (small animal imaging, ex vivo counting, allometry)
- Absorbed dose determination (analytical approaches, numerical approaches, absorbed dose point kernels, Monte Carlo radiation transport)

Time to be spent on this topic: 23 ECTS Recommended

literature

- ICRU Report 95. Operational Quantities for External Radiation Exposure, 2020, <http://www.icru.org/>
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 - ICRP, 2021. Use of dose quantities in radiological protection. ICRP Publication 147. Ann. ICRP 50(1).
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- Activity for Selected Radionuclides and Organs," New York, NY: Society of Nuclear Medicine, 1975**
- Siegel JA, Thomas SR, Stubbs JB, et al. MIRD pamphlet no. 16. Techniques for quantitative radiopharmaceutical biodistribution data acquisition and analysis for use in human radiation dose estimates," J Nucl Med 1999, 40(suppl):37S-61S
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 - International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources. Vienna, Austria: IAEA, 1996, no.51, Safety series no. IAEA 115
 - ICRP publication 135, Diagnostic Reference Levels in Medical Imaging (2017)
 - ICRP, 2019. Radiological protection in therapy with radio-

pharmaceuticals. ICRP Publication 140. Ann. ICRP 48(1).

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III. 7 Radionuclide production Radiopharmacy

A prerequisite for NM diagnostics and therapeutics is the production of radionuclides and radiopharmaceuticals to be used in both clinical and pre-clinical environments. The principal difference between nuclear medicine and X-ray procedures is that nuclear medicine relies on image formation by photon emission from the patient, while X-ray procedures rely on transmission through the patient. Diagnostic and therapeutic procedures in nuclear medicine utilize radionuclides for this purpose.

The MPE in NM must be able to outline a new nuclear medicine facility, design radiation safety details and perform / explain the need for risk assessment for a NM facility: radiopharmaceutical production including PET-radionuclide production unit (cyclotron). As radiation protection expert (RPE), an MPE should be able to optimize radiation safety for workers and the public. In addition, an MPE should be able to organize and implement personnel orientation and continuation training in terms of radiation safety. An MPE should be aware of requirements for regulatory compliance with regards to both radiation safety and GMP production.

Expert competences

- Explain the physics and technical principles of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$, $^{68}\text{Ge}/^{68}\text{Ga}$, $^{82}\text{Sr}-^{82}\text{Rb}$, $^{81}\text{Rb}-^{81\text{m}}\text{Kr}$ generators (basic principles of e.g. column chromatography and elution)
- Explain the physics and technical principles of a cyclotron (basic principles of particle acceleration with ion source, extraction unit, targets) and the sources of interlocks within the system (internal QC)
- Explain the physics and other principles of cyclotron-produced radionuclides (general characteristics of the products e.g. in terms of line of stability, specific activity, buildup)
- Take responsibility for the radiation safety design of a PET

radiotracer production site (cyclotron unit)

- Specify, justify and rank the criteria for selecting cyclotron unit
- Supervise the construction work of the cyclotron facilities in terms of radiation safety
- Explain the need for, and use of radiation risk assessments in PET-radionuclide production unit using qualitative and quantitative risk assessment and perform the assessment of absorbed dose to workers and public arising from internal and external exposure.
- Take responsibility of education and orientation of personnel as well as preparation of instructions for safe and effective use of cyclotron unit
- Explain different patient dosing techniques including injections, automatic injectors, inhalation and capsules (therapies)

Collaborative competences

- Explain principles in radionuclide production to different professionals' groups

Contributive competences

- Explain the principles of quality control for production of radionuclides
- Discuss quality control procedures of generators including e.g. ^{99}Mo and aluminium ion breakthrough
- Discuss GMP requirements: room pressures, clean room classifications, logistics, packing and transportation
- Discuss GMP documentation principles
- Discuss the principles of radiopharmaceutical preparation and associated quality control

Awareness competences

- Discuss with engineers about systems, such as water-cooling system, vacuum, extraction units and targets, influencing the correct functioning of the cyclotron unit
- Discuss ICT connectivity standards with ICT engineers to facilitate the integration of different systems, e.g. radiation monitoring integration with system interlocks, within cyclotron unit
- Discuss other radionuclide production methods such as reactors
- Discuss essential equations for radionuclide productions such activation rates, activation cross section etc.
- Discuss with engineers about acceptance testing, commissioning and quality control of a cyclotron unit
- Discuss legal basis of the production of radiopharmaceutical and the possibilities /the restrictions for the use of self-production

Core curriculum items

- Accelerator-produced radionuclides (cyclotron)
- Reactor-produced radionuclides
- Laser produced radionuclides
- Generator produced radionuclides (99mTc, 68Ga)
- Generator yield
- Gamma spectroscopy
- QC of the generator eluate
- QC of the accelerator-produced radionuclides
- Concept of GMP
- GMP requirements/specifications
- Principles of sterile work
- Syntheses and dispensing of radiopharmaceuticals
- Quality control of radiopharmaceuticals
- Automation in radionuclide and -pharmaceutical production
- Chemical and physical forms of radiopharmaceuticals
- Routes and forms of radiopharmaceutical administration
- National and international regulations on radionuclide production
- Prospective risk assessment and management for the radionuclide production and preparation of radiopharmaceuticals

Time to be spent on this topic: 6 ECTS

Recommended literature

- IAEA technical reports series no. 465: Cyclotron produced radionuclides: principles and practice
- IAEA technical reports series no. 471: Cyclotron produced radionuclides: Guidelines for setting up a facility
- IAEA radioisotopes and radiopharmaceuticals series No. 1: Technetium-99m Radiopharmaceuticals: Status and Trends
- IAEA radioisotopes and radiopharmaceuticals series No. 3: Cyclotron Produced Radionuclides: Guidance on Facility Design and Production of Fluorodeoxyglucose (FDG)
- IAEA radioisotopes and radiopharmaceuticals series No. 4: Cyclotron Produced Radionuclides: Operation and Maintenance of Gas and Liquid Targets
- G. B. Saha: Fundamentals of Nuclear Pharmacy (Springer)
- Kowalsky and Weatherman, Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine, 4th Edition, American Pharmaceutical Association, 2019.
- Ljungberg M (2022) Handbook of Nuclear Medicine and Molecular Imaging for Physicists, ISBN: 9781138593350; Volume 3: Radiopharmaceuticals and Clinical Applications doi:10.1201/9780429489501

III. 8 Radiobiology and Preclinical imaging

Preclinical studies of both diagnostic and therapeutic new drugs are mandatory to assess the potential of such compounds in view of a possible clinical translation. The in-vivo stability, safety, tolerability, and efficacy assessments of radiolabelled drugs are typically tested first in cell cultures and then in small animal models. Preclinical studies with radiolabelled substances are not limited to the development of radiopharmaceuticals only but are also used in general for the investigation of biological mechanisms of drugs, for instance in the domain of immunotherapy. The main goal of animal studies is to characterize the biokinetic of the drug in tissues to predict the biodistribution and biokinetics (pharmacokinetic and dynamic behaviour) in humans.

Similarly to clinical, preclinical investigations benefit from information from quantitative imaging and non-imaging devices to guide the development of new drugs for both diagnostic and therapeutic applications. In this context, the MPE in NM must be able to work in a multi-disciplinary team including radio-pharmacists/chemists, biologists, veterinarians, pathologists and physicians.

The MPE in NM knows the specificities and differences of clinical and preclinical devices and has a key role in setting and optimizing the imaging and non-imaging quantitative protocols used in preclinical studies. Furthermore, the MPE in NM knows the decay characteristics of conventional and non-conventional radioisotopes used in preclinical investigations.

The MPE must be able to quantitatively calibrate activity-meters and well counters (implementing specific factors) used to measure the amount of activity applied in cell and animal experiments as well as pre-clinical micro-PET and micro-SPECT devices. Moreover, the MPE has the competence to supervise and/or perform acceptance and routine quality assurance procedures in preclinical devices.

Radiobiology is the science providing the basis for radiation protection regulations. Knowledge of this basis is important for understanding the radiation protection concepts. Furthermore, it is needed for understanding dose-effect relationships of radiopharmaceutical therapies. Preclinical studies are the test bed for safety, tolerability, and efficacy evaluations of new radiopharmaceuticals before the possible in human translation. In this frame, the MPE in NM must be able to understand and characterize the tissue biodistribution of radiolabelled compounds and compute the organ/tissue biokinetic and

dosimetry calculations in the concerned preclinical animal models. In addition, the MPE should know the methods to perform the animal-to-human dosimetry extrapolations.

Expert competences

- Evaluate specifications of commercial devices and provide advice before purchasing
- Perform calibration and quality control of gamma counters and activity-meters
- Participate in acceptance tests and constancy tests procedures in preclinical imaging devices
- Verify the quantitative accuracy of pre-clinical imaging (micro-PET, micro-SPECT, including hybrid devices with CT and MR imaging)
- Define acquisition and optimize reconstruction protocols to assure required image quality
- Handle and analyse preclinical SPECT and PET images
- Advise investigators in imaging interpretation and quantification
- Knowledge of bioethical issues

Collaborative competences

- Participate in small animal facility design and structuring specific to the use of ionising radiation imaging and treatment protocols
- Participate in the experimental design of the specific pre-clinical investigation in a multidisciplinary team
- Discuss and define requirements for quantitative imaging, biokinetics and dosimetric studies. This includes for instance the determination of number and timing of sequential acquisitions
- Participate in organ/tissue biokinetic and dosimetric analysis at the preclinical level
- Participate in predicting human dosimetry using data from the preclinical investigation and appropriate extrapolation methods

Awareness competences

- Discuss with physicians (NM or oncology) the action mechanisms of specific radionuclide therapies and their optimization and limitations
- Organ/tissue/cell biokinetic and dosimetric analysis at the preclinical level
- Human dosimetry using data from the preclinical investigation and appropriate extrapolation methods

Core curriculum items

- Knowledge of cell-survival models in radiation therapy set-ups with specific focus on low dose-rate and heterogenous irradiation conditions
- Bases of micro-dosimetry (at cellular and subcellular level)
- Direct and indirect (biochemical) damage
- Stochastic effects and deterministic effects (tissue reactions)
- Awareness of differences between treatment with external beam and internal (radionuclide) irradiation (e.g. dose rate effects)
- Basic knowledge of physiology and animal handling in pre-clinical studies
- Physics and functionality of preclinical imaging devices (PET, SPECT, CT and MR)
- Decay characteristics of conventional and non-conventional radioisotopes used in preclinical investigations, with focus on radioisotopes promising for preclinical to clinical translation
- Methods for biokinetic and dosimetry analysis of preclinical data (time activity curve fitting, time-activity integration, use of specific animal models and software)
- Models for pre-clinic to human dosimetry translation

Time to be spent on this topic: 4 ECTS

Recommended literature

- IAEA, Guidance for Preclinical Studies with Radiopharmaceuticals, IAEA Radioisotopes and Radiopharmaceuticals Series No. 8, IAEA, Vienna (2023)
- Carter LM, Zanzonico PB. MIB Guides: Preclinical radiopharmaceutical dosimetry. Res Sq [Preprint]. 2023 Aug 14:rs.3.rs-3225362. doi: 10.21203/rs.3.rs-3225362/v1. Update in: Mol Imaging Biol. 2023 Nov 14;: PMID: 37645915; PMCID: PMC10462246.
- Sattler B, Kranz M, Starke A, Wilke S, Donat CK, Deuther-Conrad W, Patt M, Schildan A, Patt J, Smits R, Hoeppling A, Schoenknecht P, Steinbach J, Brust P, Sabri O (2014) Internal dose assessment of (-)-18F-flubatine, comparing animal model datasets of mice and piglets with first-in-human results. J Nucl Med, 55[11], 1885-1892, doi:10.2967/jnumed.114.137059, PMID:25286922
- Mínguez P, Gustafsson J, Flux G, Gleisner KS. Biologically effective dose in fractionated molecular radiotherapy-application to treatment of neuroblastoma with (131)I-mIBG. Phys Med Biol. 2016 Mar 21;61(6):2532-51.
- Kranz M, Sattler B, Wüst N, Deuther-Conrad W, Patt M, Meyer PM, Fischer S, Donat CK, Wünsch B, Hesse S, Steinbach J, Brust P, Sabri O (2016) Evaluation of the Enantiomer Specific Biokinetics and Radiation Doses of (18)FFluspidine-A New Tracer in Clinical Translation for Imaging of σ_1 Recep-

- tors. *Molecules*, 21[9], doi:10.3390/molecules21091164, PMID:27598110
- Sattler B, Kranz M, Wenzel B, Jain NT, Moldovan R-P, Tous-saint M, Deuther-Conrad W, Ludwig F-A, Teodoro R, Sattler T, Sadeghzadeh M, Sabri O, Brust P (2020) Preclinical Incorporation Dosimetry of ¹⁸F-FACH-A Novel ¹⁸F-Labeled MCT1/MCT4 Lactate Transporter Inhibitor for Imaging Cancer Metabolism with PET. *Molecules*, 25[9], doi:10.3390/molecules25092024, PMID:32357571
 - Cicone, F., Gnesin, S., Denoël, T. et al. Internal radiation dosimetry of a ¹⁵²Tb-labeled antibody in tumor-bearing mice. *EJNMMI Res* 9, 53 (2019). <https://doi.org/10.1186/s13550-019-0524-7>
 - Cicone F, Viertl D, Denoël T, Stabin MG, Prior JO, Gnesin S. Comparison of absorbed dose extrapolation methods for mouse-to-human translation of radiolabelled macromolecules. *EJNMMI Res*. 2022 Apr 11;12(1):21. doi: 10.1186/s13550-022-00893-z. PMID: 35403982; PMCID: PMC9001797.
 - Konijnenberg, M.W., de Jong, M. Preclinical animal research on therapy dosimetry with dual isotopes. *Eur J Nucl Med Mol Imaging* 38 (Suppl 1), 19–27 (2011). <https://doi.org/10.1007/s00259-011-1774-4>
 - National Electrical Manufacturers Association (NEMA). NEMA NU4-2008: performance measurements of small animal positron emission tomographs. Rosslyn: National Electrical Manufacturers Association; 2008
 - EANM Radiobiology Working Group; Pouget JP, Konijnenberg M, Eberlein U, Glatting G, Gabina PM, Herrmann K, Holm S, Strigari L, van Leeuwen FWB, Lassmann M. An EANM position paper on advancing radiobiology for shaping the future of nuclear medicine. *Eur J Nucl Med Mol Imaging*. 2023 Jan;50(2):242-246.
 - Hallen P, Schug D, Schulz V (2020) Comments on the NEMA NU 4-2008 Standard on Performance Measurement of Small Animal Positron Emission Tomographs. *EJNMMI Phys*, 7[1], 12, doi:10.1186/s40658-020-0279-2, 24.02.2020, PMID:32095909
 - Bolus NE. Basic Review of Radiation Biology and Terminology. *Journal of Nuclear Medicine Technology* Dec 2017, 45 (4) 259-264.

III. 9 Risk Management, Quality and Safety in the Medical Environment

The complexity of the NM protocols continues to increase with the advent of new diagnostic imaging hybrid devices and novel radiopharmaceutical therapies, which in turn requires a high level of safety control, constant quality improvement, and

upgrading of the medical physics services. Quality management is of utmost importance in the training of the MPE, since it is one of their main responsibilities. During their professional practice, they will have to master different methodologies for efficient and effective quality management in order to be able to allocate time and resources for cost effective quality assurance at different levels. The MPE must understand and take responsibility for the quality from a broader perspective including the complete NM process: from the radionuclide production and pre-clinical imaging to delivering a quality diagnostic and therapy patient specific NM service.

Therefore, they need to be involved in quality indicator specification and monitoring, quality improvement strategies and technology evaluation. They should also be involved in prospective risk management whenever a new technique, technology or any change in the procedures is introduced in the NM department, including both diagnostic and therapeutic innovations. Finally, the MPE should have a knowledge of methods for retrospective and prospective risk analysis in order to be an integral part of the patient safety committee.

Expert competences

- Describe and apply quality management system (QMS) in NM
- Build a process chart
- Analyse and apply different methodologies for prospective and retrospective risk assessment and management
- Explain quality improvement strategies (peer review, lean, internal audits, etc.)
- Describe and plan how a comprehensive clinical quality audit is run
- Identify national regulations on quality systems in NM
- Explain an emergency plan

Contributive competences

- Define and monitor relevant quality indicators and key performance indicators (KPI) in NM

Core curriculum items

- Concepts of quality system, quality management, risk assessment and management
- National and international regulations on quality management in NM
- Building a process chart
- Prospective risk assessment and management (Failure Mode and Effects Analysis (FMEA) and risk matrices)
- Accidents in NM and critical incident report system (CIRS)
- Quality indicators definition and monitoring
- Quality improvement methods (identify a process step with

potential for quality improvement, propose a quality improvement initiative, define quality indicator, monitor)

- Quality Management Audits in NM practices (including clinical quality audits)
- Dosimetry audits
- Methods for technology assessment

Time to be spent on this topic: 5 Recommended literature

- IAEA Method for the Development of Emergency Response Preparedness for Nuclear or Radiological Accidents, IAEA-TECDOC-953 (1997)
- IEC standards publications (specifically IEC standards publications (specifically: IEC 601-2-8 (1987), IEC 60601-1-4 (1997), IEC 60601-2-11 (1997), IEC 60601-2-1 (1998), IEC 60601-2-17 (1998), IEC 60601-2-29 (1999), 62C/62083
- ISO, Quality Management and Quality Assurance Standards – Part I. Guidelines for Selection and Use, ISO 9000, ISO, Geneva (1994).
- Policy Statement No.13: Recommended guidelines on the development of safety and quality management systems for medical physics departments. Physica Medica (2009), DOI: 10.1016/j.ejmp.2008.11.002
- International Organization for Standardization, “Quality management and quality assurance Standards” Guidelines for selection and use,” ISO 9000, ISO, Geneva 1994

III. 10 Organisation, management and ethics in healthcare

The MPE in NM should understand the structure of, and be able to participate in, the management of a hospital NM department. The MPE should have basic knowledge of the organisation and management of the local healthcare system and of the relevant guidelines and recommendations from national or international organisations. In addition, they should be trained in ethics of medical practice and research, encouraging a diversity of perspectives, cross-cultural dimensions of healthcare, and inclusivity in team-building and project management.

Expert competences

- Take responsibility for the implementation of a detailed organisational (hospital) policy to support the radiation safety of staff and public in NM
- Take responsibility for the implementation of formal systems of work ('local rules') with regards to radiation safety in NM

- Take responsibility for regulatory compliance with respect to the management of radiation sources and radiation waste
- Take responsibility for regulatory compliance with regards to the transportation of radioactive substances
- Communicate with authorities for license application, audits preparation and other related regulatory duties
- Develop a policy for regulatory compliance with regards to the management and disposal of radioactive waste
- Be aware of current national and international regulations, standards and guidelines related to radiation protection aspects
- Create and maintain radiation records for a Nuclear Medicine department that conform with regulatory requirements and usual standards of practice
- Play a leading role in departmental issues on safe, effective and efficient treatment, related to equipment and physics
- Participate in departmental and physics management teams
- Compare EU Directives, national regulations and guidelines and/or recommendations from national and international organisations on the provision of equipment and staff in NM
- Apply equipment management (e.g., servicing, purchasing of new equipment, etc.)
- Understand how to make staff provisions and allocate roles and responsibilities
- Undertake procurement of new equipment
- Apply team management and projects management
- Describe and apply ethical considerations in medical practice and research
- Apply equity, diversity and inclusion criteria to all aspects of MPE activities

Collaborative competences

- Able to advise on local, regional, and national radiation protection and safety legislation

Contributive competences

- Discuss the personal related exposure risk and dosimetry parameters (effective dose, equivalent dose, extremity doses, eye lenses dose, dose limits)
- Discuss with the radiation protection officer regarding the radiation protection program for a NM department and the necessary documentation

Awareness competences

- Discuss the position of the MPE's own institution as part of the organisation of healthcare at local and national levels
- Discuss the financial structure for funding of NM at the local and national level

- Discuss the development of medical physics and NM in the MPE's country and outline the development in the Euro- pean Union

Core curriculum items

- National and local system, global view of other European systems
- National regulations and EU directives in medical applica- tion of ionizing radiation
- Guidelines and recommendations from national and inter- national organizations
- Principles of hospital / department management and proj- ect management, etc.
- Principles of personnel management
- Staff provision calculation, particularly the needs for the staff- ing level of MPEs in NM depending on the scope and extension of the service of a particular NM Department (i.e. institution of minimal, standard, maximum and/or superior care)
- Allocation of roles and responsibilities
- Ethical considerations in medical practice and research
- Equity, diversity and inclusion criteria

Time to be spent on this topic: 3 ECTS

Recommended literature

- EU Council Directive 2013/59/Euratom of 5th December. <https://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:013:0001:0073:EN:PDF>
- Shortell SM, Kaluzny AD. Essentials of Healthcare Manage- ment. Delmar Publisher
- Brown M. Healthcare Management. Strategy, Structure & Programs. Healthcare Management Review. An Aspen Pub- lication
- Duncan W. Handbook of Healthcare Management. Blackwell Science
- Ghaye T. Building the Reflective Healthcare Organisation. Willey-Blackwell
- Griffith JR, White KR. The Well-Managed Healthcare Organi- zation. 6th Ed. Health Administration Press US
- Walshe K, Smith J. Healthcare Management. Open University Press
- Moulin M. Delivering Excellence In Health And Social Care. Open University Press
- Sherriff SB, Dendy PP. The European Federation of Or- ganisa- tions for Medical Physics. Policy Statement No 11. Guidelines on Professional Conduct and Procedures to be implemented in the event of alleged misconduct. Phys Med 2003; 19(3): 227-229

- Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine, Sixth Edition (Jonsen, Clinical Ethics
- The Oxford Textbook of Clinical Research Ethics, Ezekiel J. Emanuel, Christine C. Grady, et ál. 2011
- Hospital Administration and Management: A Comprehen- sive Guide, Gupta
- Human Resource Management in Health Care: Principles and Practice, Jr. L. Fleming Fallon (Author), Charles R. McConnell (Author)
- The Power of a Positive Team: Proven Principles and Practic- es that Make Great Teams Great
- WHO, Standards and Operational Guidance for Eth- ics Review of Health-Related Research with Human Participants; <https://www.who.int/publications/i/item/9789241502948>
- https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en

III. 11 Information and Communication Technology (ICT)

The MPE must have a good understanding of ICT in the clin- ical field. Part of this is knowledge of the main systems for information sharing, storage, and retrieval in a hospital, and of the formats most common for medical data, such as Digital Imaging and COMMunications in Medicine (DICOM). The MPE should be able to advise on the purchase and use of medical equipment within the hospital IT system. The use of appli- cations like a Patient Data Management Systems (PDMS), a Picture Archiving and Communication System (PACS), an electronic patient record (EPR), or the use of a patient moni- toring system are fields an MPE typically advises on, often in close collaboration with the IT department. Knowledge on general ICT-security regulation for collection, storage and transmission and data protection legislation is necessary.

The MPE is also required to communicate effectively with IT professionals from inside and outside the hospital organisa- tion in order to work with the different healthcare processes, medical technology and the increasing availability of health- care data. Finally, the MPE is also responsible for safe (and legal) use of in-house developed software, in line with MDR.

Expert competences

- Advise the IT department and the hospital on the needs, use, and maintenance of IT as related to NM
- In-depth KSC in medical image data communication stan- dards i.e. ACR, DICOM etc.

- Advise on the use of ICT in line with General Data Protection (GDPR) / MDR
- Explain the processes manufacturers undergo to achieve licencing of software products.
- Understand the processes involved to develop, write, and bring site-written software into clinical use
- Have knowledge of DICOM structures
- Understand the concept of anonymization and use of cloud based solutions
- Be able to develop and use tools for simulation purpose (analytical/Monte Carlo)

Contributive competences

- Discuss ICT concepts of NM equipment and connections, e.g., in the hospital IT network, with other healthcare professionals, to assist with the specification, commissioning, implementation, problem solving and safe operation
- Discuss healthcare data connectivity standards with colleagues from other disciplines to facilitate the integration of general systems within NM departments
- Discuss hardware configuration, operating systems and typical software applications

Awareness competences

- Understand HL7, and how it together with DICOM helps form the IHE (Integrating the Healthcare Enterprise) framework
- Software development steps
- Open source regulatory framework
- Software as a medical device: rules and regulations
- CE-marking and FDA approval

Core curriculum items

- Data exchange formats and standards (for example: file transfer protocol (FTP)) and their implementation (DICOM)
- Relevant data and ICT security standards for collection, storage and transmission and data protection legislation
- Data safety (integrity and privacy, protected sub-nets, etc.)
- Data anonymization/ pseudo-anonymization, e.g., for clinical trials
- Operational relationships between hospital information systems and management systems used in NM
- Data warehousing for archiving and storage and relevant legislation regarding the required time
- DICOM – general understanding of DICOM and its operation
- PACS – general understanding of PACS and its operation
- GDPR and MDR, National regulations regarding the use of medical software, both developed in-house and commercially

Time to be spent on this topic: 8 ECTS Recommended literature

- W. Buchanan, Mastering networks. 2010
- ACR-AAPM-SIIM Practice Parameter for Electronic Medical Information Privacy and Security <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Elec-Info-Privacy.pdf?la=en>
- ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Elec-Practice-MedImag.pdf?la=en>
- Digital Imaging and Communications in Medicine (DICOM) <https://www.dicomstandard.org/>
- IAEA Human Health Campus: Imaging Informatics <https://humanhealth.iaea.org/HHW/MedicalPhysics/DiagnosticRadiology/TechnologyManagement/Imaginginformatics/index.html>
- Worldwide implementation of digital imaging in radiology. IAEA Human Health Series 28 <https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1647web.pdf>
- UK Imaging Informatics Group – Introduction to PACS <http://www.pacsgroup.org.uk/forum/messages/419/5961.html?0>
- ACPSEM ROSG Oncology-PACS and OIS working group recommendations for quality assurance, John Shakeshaft, Mario Perez, Lindsay Tremethick, Abdurrahman Ceylan & Michael Bailey, Australasian Physical & Engineering Sciences in Medicine volume 37, pages3–13(2014)
- Python in medical physics <https://docs.pymedphys.com/>
- Pydicom (Python for working with DICOM) <https://pydicom.github.io/>

III. 12 Data statistics, modelling and artificial intelligence

Complex quantitative data analysis is becoming increasingly important in NM with many new developments. Examples of approaches that start appearing in the clinical practice, and therefore are under the technical responsibility of MPEs, include the use of artificial intelligence (AI) in image reconstruction, tumour volume segmentation, the generation of pseudo-CT's from MRI for attenuation correction in PET/MR, and low dose NM imaging. From the clinical perspective, the MPE will, more and more, encounter advanced (statistical) data analysis approaches in e.g., predictive modelling, outcome data analysis, multi-modality imaging, radiomics, development and application of imaging biomarkers, and genetic profiling. With their high-level numerical/mathematical

background, the MPE in a NM department is a bridge between the nuclear medicine professionals and manufacturers / suppliers of systems based on complex data analysis. It is a primary task of the MPE to ensure that the tools are used safely and effectively, in line with current regulations e.g. related to the GPRS and MDE. In many cases, tools need to be validated or configured for the local situation, which is also a major responsibility of the MPE. On the other hand, an MPE may also be involved in clinical innovation and research studies, as well as development of new applications based on advanced data analysis. To fulfil these responsibilities, the MPE must have knowledge and skills in data collection and advanced data processing and analysis using deep learning tools as part of AI/Machine Learning (ML) technologies. A sound knowledge of statistics is a pre-requisite for success. Computing and programming skills are implicitly required to reach the expert competences on data processing, statistics, modelling and artificial intelligence.

Expert competences

- Analyse, interpret and report experimental results, including uncertainties
- Apply fundamental concepts of statistics relevant for data analysis in NM
- Differentiate, choose and eventually apply the most common statistical tools used in NM physics and clinical NM in common software platforms like Python, R, Matlab, SPSS, etc.
- Apply regulations on data collection, processing and application in practice
- Understand the training, implementation and validation required for a sound and robust application of AI/ML techniques, including the need for independent assessment.
- Understand the possibilities of the use of AI/ML to assist in diagnostic algorithms.
- Perform QA of AI/ML models

Collaborative competences

- Discuss the principles of (big) data collection, storage and handling of data
- Discuss the working principles and training of major statistical modelling approaches and algorithms applied in NM (including radiomics, AI/ML, etc.), needed for ensuring safe and effective clinical application
- Discuss the major pitfalls in the training, validation and use of statistical modelling approaches in NM and ability of coping with them
- Discuss and apply the basic principles of statistics for clinical trial design, cohort and case-control studies

Contributive competences

- Co-lead departmental acquisitions of NM software applications that rely on complex statistical data handling, based on the specific expertise.

Awareness competences

- Be aware of basic machine learning approaches (random forest (RF), support vector machine (SVM), logistic regression (LR), Extreme Gradient Boosting (XGBoost))
- Be aware of the different families of deep learning approaches (convolutional neural networks (CNN), generative adversarial networks (GAN), recurrent neural networks (RNN)).

Core curriculum items

- Central limit theorem
- Probability functions and applications: normal, binomial, Poisson, Student's t, chi-square, etc.
- Statistical inference testing depending on the problem at hand – assessment of statistical significance, p-values, confidence intervals, parametric and non-parametric tests, multiple testing
- Type I and type II statistical errors, statistical power, sample size calculations
- ROC analyses
- Co-variance, correlation, regression, R²
- Analysis of variance (Anova)
- Superiority and non-inferiority clinical trials, cohort studies, case-control studies
- Survival analysis – Kaplan-Meier curve, censoring, log-rank test, Cox proportional hazards regression, hazard ratio
- Regression and classification, decision boundary
- Machine learning: Supervised and unsupervised learning
- Important machine learning models: linear and logistic regression, neural networks, support vector machine, decision trees, k-means cluster analysis
- Machine learning: training, bias-variance trade-off, overfitting
- Handling co-linearity of predictors (Variance inflation factor, VIF)
- Model selection and regularization: forward and backward stepwise predictor selection, ridge regression, t LASSO
- Basics of Deep learning including convolutional neural networks, back-propagation
- AI/ML in image reconstruction, image analysis, image noise reduction (transformers, foundation models, etc)
- Model validation: external, cross-validation.
- K-fold cross-validation, Monte-Carlo cross-validation, leave-one-out cross-validation, bootstrap
- Texture analysis as applied in radiomics

Time to be spent on this topic: 15 ECTS Recommended literature

- Nickoloff E. Applications of Statistics to Medicine and Medical Physics. Medical Physics Publishing 2011
- An introduction to Statistical Learning, Eds. Gareth James et al., Springer
- The Elements of Statistical Learning; Data Mining, Inference and Prediction, Eds. Trevor Hastie et al., Springer
- Hustinx R, Pruim J, Lassmann M, Visvikis D. An EANM position paper on the application of artificial intelligence in nuclear medicine. Eur J Nucl Med Mol Imaging. 2022 Dec;50(1):61-66. doi: 10.1007/s00259-022-05947-x.
- Visvikis D, Lambin P, Beuschaus Mauridsen K, Hustinx R, Lassmann M, Rischpler C, Shi K, Pruim J. Application of artificial intelligence in nuclear medicine and molecular imaging: a review of current status and future perspectives for clinical translation. Eur J Nucl Med Mol Imaging. 2022 Nov;49(13):4452-4463. doi: 10.1007/s00259-022-05891-w.
- El Naqa. A guide to outcome modelling in radiotherapy and oncology. 2018 <https://www.routledge.com/A-Guide-to-Outcome-Modeling-In-Radiotherapy-and-Oncology-Listening-to/El-Naqa/p/book/9781498768054>
- Big data in radiation oncology, Jun Deng, Lei Xing, CRC press, Francis and Taylor 2019
- Cui S, Tseng HH, Pakela J, Ten Haken RK, El Naqa I. Introduction to machine and deep learning for medical physicists. Med Phys. 2020;47(5):e127-e147
- El Naqa I, Das S. The role of machine and deep learning in modern medical physics. Med Phys. 2020;47(5):e125-e126
- Mahadevaiah G, Rv P, Bermejo I, Jaffray D, Dekker A, Wee L. Artificial Intelligence-Based Clinical Decision Support in Modern Medical Physics: Selection, Acceptance, Commissioning, and Quality Assurance Med Phys. 2020;47(5):e228-e235
- Avanzo M, Wei L, Stancanella J, Vallières M, Rao A, Morin O, Mattonen SA, El Naqa I. Machine and deep learning methods for radiomics. Med Phys. 2020;47(5):e185-e202
- Rogers W, Thulasi Seetha S, Refaee TAG, Lieveise RIY, Granzier RWY, Ibrahim A, Keek SA, Sanduleanu S, Primakov SP, Beuque MPL, Marcus D, van der Wiel AMA, Zerka F, Oberije CJG, van Timmeren JE, Woodruff HC, Lambin P. Radiomics: from qualitative to quantitative imaging. Br J Radiol. 2020;93(1108):20190948
- Challen R, Denny J, Pitt M, Gompels L, Edwards T, Tsaneva-Atanasova K. Artificial intelligence, bias and clinical safety. BMJ Qual Saf. 2019;28(3):231-237
- Shen C, Nguyen D, Zhou Z, Jiang SB, Dong B, Jia X. An introduction to deep learning in medical physics: advantages, potential, and challenges. Phys Med Biol. 2020;65(5):05TR01
- Sahiner B, Pezeshk A, Hadjiiski LM, Wang X, Drukker K, Cha KH, Summers RM, Giger ML. Deep learning in medical imaging and radiation therapy. Med Phys. 2019;46(1):e1-e36
- Jia X, Ren L, Cai J. Clinical implementation of AI technologies will require interpretable AI models. Med Phys. 2020;47(1):1-4
- Cabitza F, Rasoini R, Gensini GF. Unintended Consequences of Machine Learning in Medicine. JAMA. 2017 Aug 8;318(6):517-518
- Welch ML, McIntosh C, Haibe-Kains B, Milosevic MF, Wee L, Dekker A, Huang SH, Purdie TG, O'Sullivan B, Aerts HJWL, Jaffray DA. Vulnerabilities of radiomic signature development: The need for safeguards. Radiother Oncol. 2019;130:2-9

IV. Research and innovation

The MPE has an important role in research and innovation in NM. The MPE is responsible for initiating technical and physics innovation to improve diagnostic and therapeutic NM applications. An MPE should be able to initiate and perform scientific research in medical technology, including clinical trials and apply the results to improve patient diagnosis/treatment and prepare reports and presentations for journal and scientific meetings respectively. The MPE translates clinical problems into scientific questions and translates scientific results into clinical innovations and practice. Moreover, the MPE should be able to correctly and critically analyse published research results.

IV. 1 Research

To prepare the MPE in NM for this responsibility, a focused research project should be undertaken during the training programme, either as a full-time activity within a well-defined period or on a part-time basis over a prolonged time period (e.g. integrated in other parts of the training). The project should be performed under the guidance of a supervisor with extensive expertise in the chosen topic. Preferentially the supervisor is an experienced researcher. The research project should be well structured and defined in order to fit within the given time frame and be relevant for NM physics and clinical practice. The project should result in a written report, preferably in the form of a manuscript suitable for submission to a peer-reviewed medical physics journal, or as an abstract to be presented at an international congress.

Expert competences

- Design a study in NM physics research, including motivation, statement of hypotheses, and metrics of evaluation
- Perform a structured literature review
- Evaluate critically the novelty and feasibility of research idea/project
- Evaluate critically the urgency of the proposed idea/project
- Select scientifically appropriate methodology for the research project
- Plan, prepare and perform the different phases of the research project
- Understand EU Directives, national regulations, guidelines and recommendations from national and international organizations related to research activities
- Acquire first-hand experience in proper scientific evaluation, of both own and published data
- Apply appropriate statistical analyses
- Prepare a scientific manuscript, preferentially for publication in a peer-reviewed journal and/or an abstract for conference presentation

Core curriculum items

- Scientific literature review and analysis
- Design study methodology
- Power analysis
- Data collection and curation (i.e. identify, select, collect, standardize data)
- Selection and application of relevant data analysis methods
- Graphical presentation of results
- Selection and application of relevant statistical tests
- Science communication, writing and presentation

IV. 2 Clinical Trials

Nuclear medicine is a highly dynamic field and new methods in imaging and therapy are continuously introduced in our field. Clinical trials are research studies that evaluate medical devices or drug interventions in people and ideally lay the ground to translate them into clinical reality. To prepare the MPE in NM to be part of clinical trials, those competences will provide guidance.

Awareness competences

- Design and planning of clinical trials
- Clinical trial set-up and ongoing quality assurance program
- Clinical implementations
- Legislation and regulation

Time to be spent on this topic: 30 Recommended literature

- Gustavii, B., How to write and illustrate a scientific paper, Cambridge University Press 2003
- Goodman, N.W. & Edwards, M.B, Medical writing – a prescription for clarity, Cambridge University Press 2006
- Nicolas Wallimam, Research methods. The Basis. Taylor & Francis group 2011
- Cr Kothari, Research Methodology, NEW AGE INTERNATIONAL (P) LIMITED, PUBLISHERS, 1990
- Measurements and their uncertainties. Oxford press
- Glantz SA. Primer of biostatistics, McGraw Hill, 2005
- Rosner B. Fundamentals of biostatistics, Thomson, 2006
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

V. Assessment methods to evaluate competences

Adapted from the “CanMEDS Assessment Tools Handbook” www.royalcollege.ca/en/standards-and-accreditation/can-meds.html

Whereas a candidate’s knowledge can be assessed by means of exams, the complete set of competences needed to act safely in a healthcare setting is substantially more complex to assess. In the following, different components of a possible assessment scheme are described. The different components must, however, be adapted according to the national education and training programme. It is recommended that the assessment of competences include more than one of the assessment modules listed below.

1. WRITTEN TESTS

- **Constructed-response format (short-answer questions) (SAQ)**

The short-answer question (SAQ) format consists of a brief, highly directed question. Answers usually consist of a few short words or phrases.

- **Constructed-response format (essays)**

These kinds of questions require learners to construct an answer based on their knowledge in a written or computer-based format. They require the synthesis and communication of content and often require critical thinking skills such as evaluation, analysis and judgment.

- **Selected-response format (multiple-choice, matching, extended matching, pick N and true–false questions)**

Selected-response assessment tools consist of a question and a list of options from which the learner must choose the correct answer.

Common tools within this category are:

Multiple Choice Questions (MCQs): Consist of an opening question or stem that asks the learner to choose the most correct answer(s) from a list that also includes two to five plausible yet incorrect distractors.

Matching: Learners are given two lists and are asked to match each item in one column to an item in the other column.

Extended Matching Questions (EMQs): Learners are given a list of 10 to 20 items and are asked to match them to a series of corresponding responses. An item may be matched to more than one response.

Pick N: An amalgam of MCQs and extended matching, pick N items consist of an opening stem and an instruction to select any given number of correct responses from an extensive list.

True–false: Learners are asked to determine if a given statement is true or false.

1. STRUCTURED ORAL EXAMINATIONS (SOES)

Oral examinations typically consist of the review of four to ten topics/cases, each lasting five to fifteen minutes. The entire examination, therefore, lasts about one hour. Each case discussion may include problem-solving, treatment planning, interpretation of results, etc. They are usually scored using a predefined, structured template.

2. DIRECT OBSERVATION (DO)

Direct observation refers to the ongoing observation, assessment and documentation of actions taken by learners in real situations during their training period. The critical factor is that the learner is observed performing authentic actions that occur naturally as part of daily work experience.

In a strictly formal arrangement, the learner could be asked to perform a specific task and would be assessed by means of a standardised rating form. In an informal arrangement, no specific planning for the observation would be involved and the assessment would not be recorded on a standardised form.

3. OBJECTIVE STRUCTURED EXAMINATIONS (OSES)

The objective structured examination (OSE) samples the performance of learners as they rotate through a series of stations representing various scenarios. At each station, learners may encounter a standardized clinical situation, a structured oral examination, visual information, or a written task. Learners are usually asked to perform a specific skill, to simulate part of a clinical situation, or to answer questions based on the presented material. OSE circuits typically consist of 8 to 15 stations grouped into a series of rooms and may include one or two rest stations.

Learners are usually given 8 to 30 minutes to complete the tasks assigned per room. Assessment can be carried out using a standardised checklist, anchored global rating scales, or the evaluation of brief narrative responses.

4. MULTI-SOURCE FEEDBACK (MSF)

Multi-source feedback (MSF) is often termed 360-degree evaluation or assessment. MSF uses specific instruments designed to gather data about particular behaviours or professional constructs (e.g., professionalism and communication skills) of the learner.

MSF usually includes feedback solicited from two or more sources, potentially including the learner. Observers may include physicists (e.g., resident peers), allied health professionals (e.g., physicians, nurses, technologists). Feedback is typically provided by completing a questionnaire-based tool consisting of 10–40 items that is designed to assess behaviours that can be observed. MSF can supplement traditional sources of assessment (e.g., examinations and preceptor observations) by providing input from people who do not normally have a hierarchical responsibility for providing feedback yet may have a different perspective on actual learner performance. Finally, MSF encourages reflection and promotes development of a self-improvement plan.

PORTFOLIOS AND LOGBOOKS

University faculties may be familiar with portfolios in the context of teaching dossiers that are used in applications for academic promotion. Portfolios are a flexible educational tool that can be adapted to multiple purposes, settings and different kinds of learners.

Portfolios are really a collection of assessment tools. Their components may include logbooks, multi-source feedback instruments, continuous quality improvement projects, learning diaries, encounter cards, essays, etc. Logbooks are defined as those tools that are used to track the incidence of educationally relevant activities, such as the number of procedures performed (e.g., a list of QC test on a specific equipment). Logbooks are structured instruments for documenting that a learning activity has taken place.

ENCOUNTER CARDS

Encounter cards are a type of in-training tool characterised by direct observations that are documented after brief en-

counters between the supervisor and the learner in a clinical setting. They are also known as:

- **daily evaluation cards (DECs)**
- **daily encounter cards (DECs)**
- **daily operative cards (DOCs)**
- **daily shift cards**
- **daily teaching evaluation cards (DTECs)**
- **teaching encounter cards (TECs)**
- **interaction cards**
- **feedback forms**

Encounter cards and their variants are a method of direct assessment that helps the assessor to capture observations of competences from brief encounters with learners. Encounter cards can also be used to facilitate the more frequent assessment of teaching

Selected Tools for Assessing the Competences

	Organization	Professionalism	Communication	Collaboration	Social actions	Knowledge & science
Written tests (SAQ)		X		X		X
Written tests (essays)				X	X	X
Written tests (SRF)						X
Oral Exams (SOEs)		X	X		X	X
Direct Observation	X	X	X	X	X	X
Objective Structured Exam (OSEs)	X		X		X	X
Multi-source feedback	X	X	X	X	X	
Portfolios and/or logbooks	X	X	X	X	X	X
Encounter Cards	X	X	X	X		X

SAQ = Short Answer Questions

SRF = Selected Response Format (multiple-choice, matching, extended matching, pick N and true-false questions)

SOEs = Structured Oral Examinations

OSEs = Objective Structured Examinations

ANNEX 1. Definitions

Medical Physics

Medical Physics is the scientific healthcare field concerned with the application of the concepts and methods of physics in medicine. Physics is applied to the knowledge of the human body, to its preservation and to the cure of its illnesses [1]. Medical Physics regards both medical devices and medical software, their construction, proper use and safety. Medical Physics has been classified internationally as a profession and its benefits have been widely recognized [2].

Medical Physics Expert

2013/59/EURATOM [3] and Radiation Protection No 174 (European Commission) [4]:

“medical physics expert means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the competent authority”; in this document, we only refer to Nuclear Medicine. The MPE corresponds to the MPE defined by EFOMP (Policy statement No 12.1) [5]:

“MPE is defined as a clinically qualified MP who has reached EQF level 8 in his/her own speciality of clinical Medical Physics”.

Article 58 -2013/59/EURATOM highlighting the role of MPE in Nuclear Medicine. Member States shall ensure that: “in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular, in standardised therapeutical nuclear medicine practices, involving high doses as referred to in point (c) of Article 61(1), a medical physics expert shall be involved; ”.

Radiation Protection Expert

Radiation protection expert means an individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognised by the competent authority [3].

Radiation Protection Officer

Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements [3].

Accreditation

Accreditation is a process by which a recognised body assesses and recognises that the education and/or training provided by an institution meets acceptable levels of quality. Therefore, there are two parties involved in this process: the institution that provides education and training and an external organisation, which performs the external assessment and awards accreditation as a result of positive evaluation [6].

Recognition

Recognition is a process by which a national authority recognises by registration the professional equivalence of foreign higher education diplomas or other evidence of formal qualification awarded upon the completion of a course at a higher education or training institution [4].

Certification

Certification (or ‘credentialing’) is the formal process by which an authorized body (governmental or non-governmental) evaluates and recognizes the knowledge and proficiency of an individual, which must satisfy pre-determined requirements or criteria [6, 7].

Re-certification

Re-certification is the process by which a certified professional is checked to have maintained their level of competences according to the prevailing demands. The maintenance of certification is achieved through continual professional development (CPD).

Learning outcomes

Learning Outcomes are defined as statements of what a learner knows, understands and is able to do on completion of a learning process, which are defined in terms of knowledge, skills and competences [8].

Knowledge

Knowledge is defined as the outcome of the assimilation of information through learning. Knowledge is the body of facts, principles, theories and practices that is related to a field of work or study. In the context of the European Qualifications Framework, knowledge is described as theoretical and/or factual [8].

Skills

Skills are defined as the ability to apply knowledge and use know-how to complete tasks and solve problems. In the context of the European Qualifications Framework, skills are described as cognitive (involving the use of logical, intuitive and creative thinking) or practical (involving manual dexterity and the use of methods, materials, tools and instruments) [8].

Competence

Competence is defined as the proven ability to use knowledge, skills and personal, social and/or methodological abilities, in work or study situations and in professional and personal development. In the context of the European Qualifications Framework, competence is described in terms of responsibility and autonomy [8].

References

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ANEX 2. Definitions

Table: example of learning phase and examination modalities for each item of the core curriculum

Quality assurance	Organization			Collaboration			
	Theoretical course with exercises	Supervised practical training	Independent study (homework)	Written test	Oral	Portfolio/logbook	report
Describe and apply Quality Systems in NM	X		X	X	X		
Build a process chart	X	X				X	X
Analyse and apply different methodologies for prospective and retrospective risk management	X	X				X	X
Explain quality improvement strategies (peer review, lean, internal audits, etc.)	X	X				X	X
Describe and plan how a comprehensive clinical quality audit is run	X		X		X		X
Identify national regulations on quality systems in NM			X		X	X	
Explain an emergency plan	X		X		X		X
Define and monitor relevant Quality Indicators in Nuclear Medicine	X		X		X		X



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