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EUROPEAN GUIDELINES ON MEDICAL PHYSICS EXPERT



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Foreword

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Council Directive 97/43/Euratom (Medical Exposures Directive, MED) defines the Medical Physics Expert (MPE) as "*an expert in radiation physics or radiation technology applied to [medical] exposure, whose training and competence to act is recognized by the competent authorities; and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiation protection*". The relevant articles of MED require Member States to ensure that MPEs have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection. In a proposal for the revised Euratom Basic Safety Standards Directive, adopted by the European Commission in May 2012, role and mobility of the MPE was strengthened. A new definition of the MPEs and their responsibilities is proposed, seeking to provide a link between their required competences and assigned responsibilities. The requirements on involvement of the MPE in medical exposure procedures have been also changed to increase their presence in radiodiagnostic and interventional radiology practices.

These measures are aimed at improving the current situation where in many Member States there is an insufficient number of adequately trained MPEs to address the needs of an increasing number of medical procedures applying ionizing radiation. A further option to address this situation and bring forward the effective implementation of EU legislation and initiatives is to support the harmonization of MPE education and training in the Member States, aiming at easier mutual recognition and improved cross-border mobility of these professionals.

The present guidance document (RP 174) was developed with this aim. It contains recommendations on harmonising MPE education, training and recognition requirements in the EU. It makes recommendations for the most appropriate education and training framework, based on the European Higher Education Area and on the European Qualifications Framework for Lifelong Learning and proposes detailed syllabuses for the MPE education and training. The guidance contains also recommendations on the MPE staffing levels necessary to ensure adequate radiation protection of patients, depending on the size and type of the radiological practice.

The status and the legal and practical arrangements in the Member States regarding the MPE were assessed through an EU-wide survey and were discussed at a European Workshop, held on 9-10 May 2011 in Seville, Spain. The results of the survey and the proceedings of the Workshop can be found on the MPE project website (<http://portal.ucm.es/web/medical-physics-expert-project>).

The publication of this document in the Commission's Radiation Protection series has been recommended by the Group of Experts established under Article 31 of the Euratom Treaty. It is our hope that it will support the harmonisation of MPE approaches among the Member States and contribute to a continuous improvement of patient radiation safety.

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List of abbreviations

AAPM	American Association of Physicists in Medicine
BSS	Basic Safety Standard
CPD	Continuing Professional Development
CR	Computed Radiography
CT	Computed Tomography
DDR	Direct Digital Radiography
DGMP	Deutsche Gesellschaft für Medizinische Physik
DR	Diagnostic Radiology
EANM	European Association of Nuclear Medicine
EC	European Commission
ECTS	European Credit Transfer System
EFOMP	European Federation of Organisations for Medical Physics
EHEA	European Higher Education Area
EQF	European Qualification Framework
ESR	European Society of Radiology
ESTRO	European Society for Therapeutic Radiology and Oncology
EU	European Union
FTE	Full Time Equivalent
HTA	Health Technology Assessment
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IMRT	Intensity-Modulated Radiation Therapy
IOMP	International Organisation for Medical Physics
IPEM	Institute of Physics and Engineering in Medicine
IR	Interventional Radiology
ISTISAN	Istituto Superiore di Sanità
KSC	Knowledge, Skills and Competences
LO	Learning Outcome
MED	Medical Exposure Directive
MP	Medical Physicist
MPE	Medical Physics Expert
MPS	Medical Physics Service
NM	Nuclear Medicine
PET	Positron Emission Tomography
QA	Quality Assurance
R&D	Research & Development
RO	Radiation Oncology
RP	Radiation Protection
RPA	Radiation Protection Adviser
RPE	Radiation Protection Expert
RT	Radiotherapy
R&D	Research and Development
SABR	Stereotactic Ablative Radiotherapy
SBRT	Stereotactic Body Radiotherapy
SEFM	Sociedad Española de Física Médica
SPECT	Single-Photon Emission Computed Tomography
UCM	University Complutense of Madrid
UK	United Kingdom
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
WHO	World Health Organisation
WTE	Whole-Time-Equivalent

1. Introduction

1.1. Background

Council Directive 97/43/Euratom (Medical Exposures Directive, MED) (European Commission, 1997) defines the Medical Physics Expert (MPE) as "an expert in radiation physics or radiation technology applied to exposure, within the scope of this Directive, whose training and competence to act is recognized by the competent authorities; and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiation protection, concerning exposure within the scope of this Directive".

Article 6.3 of MED requires that the MPE be closely involved in radiotherapeutic practices, be available in nuclear medicine practices and be involved, as appropriate, in other radiological practices, for consultation and giving advice on radiation protection issues including optimisation of protection, patient dosimetry, QA, etc.

Article 7.1 of MED requires Member States to ensure that MPEs have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection. For this purpose Member States shall ensure that appropriate curricula are established and shall recognise the corresponding diplomas, certificates or formal qualifications.

The European Commission (EC) is aware of the present situation in many Member States, where there is an insufficient number of adequately trained MPEs to address the needs of medical procedures applying ionising radiation; this situation is especially startling in today's context of constantly growing use of higher-dose medical equipment (e.g. CT, PET). One possible solution to address this situation and bring forward the effective implementation of EU legislation and initiatives is to support the harmonisation of MPE education in the Member States, aiming at easier mutual recognition and improved mobility of these professionals. For this purpose, in 2010, the European Commission launched a 2-year project on the MPE to provide for improved implementation of the MED and to facilitate the harmonisation of the MPE among the Member States aiming at their cross-border mobility. This project has been supervised by the Working Party on Medical Exposure (WP MED) established by the Group of Experts referred to in Article 31 of the Euratom Treaty.

The project included the following tasks, eventually assigned to the Consortium led by the Complutense University of Madrid¹:

1. an EU-wide study on the status and the legal and practical arrangements in the Member States regarding the training, education and recognition of the MPE (European Commission Project, 2012),
2. organisation of a European Workshop on the MPE (European Commission Workshop, 2012),

¹ <http://portal.ucm.es/web/medical-physics-expert-project>

3. development of a European Guidance document on the MPE containing appropriate recommendations on:
 - a. harmonising education, training and recognition requirements for the MPE in the European Union within the existing EU legislative network and
 - b. MPE staffing levels necessary to ensure adequate radiation protection of patients, depending on the size and type of the radiological practice.

Soon after the publication of the 2007 Recommendations of the International Commission on Radiological Protection (ICRP, 2007) the EC launched a revision of the Euratom Basic Safety Standards Directive (BSS). This also involves a simplification of the Community legislation on radiation protection by integrating five current Euratom Directives², the Medical Exposure Directive (MED) included, into a single revised Euratom BSS Directive. The Commission adopted the proposal for revised Euratom BSS in May 2012 (European Commission, 2012).

The proposal for a Council Directive defines the roles and responsibilities of services and experts who should be involved in ensuring that technical and practical aspects of radiation protection are managed with a high level of competence. It defines the role of the Radiation Protection Expert (RPE) and the Medical Physics Expert (MPE). The requirements for information, training and education are also addressed and strengthened in a specific title in order to highlight the importance of education and training in radiation protection

1.2. Purpose and scope

The purpose of this European Guidance on Medical Physics Expert (MPE) is to provide for improved implementation of the Medical Exposure Directive and revised BSS provisions related to the MPE and to facilitate the harmonisation of the education and training of medical physicists to MPE level among the Member States aiming at an improvement in cross-border mobility.

This European Guidance contains appropriate recommendations on harmonising education, training and recognition requirements for MPEs in the European Union within the existing EU legislative framework. It makes recommendations for the most appropriate education and training structure, based on the European Higher Education Area and on the European Qualifications Framework for Lifelong Learning

²

- Council Directive 96/29/Euratom of 13 May 1996, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation,
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure,
- Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency,
- Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas,
- Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

(European Parliament and Council, 2008) , to achieve the defined required professional competences. It proposes detailed syllabuses for the education and training of MPEs. The Guidance also contains recommendations on the MPE staffing levels necessary to ensure adequate radiation protection of patients and, where appropriate, staff, depending on the size and type of the radiological practice.

Comment [BR1]: Does this need some explanation? MPE has no legal role in staff safety (other than training which impacts on both patient and staff safety) although it is the case that sometimes the MPE and RPE are one person for smaller practices. But even then, surely the staff safety aspect arises from their RPE role rather than their role as an MPE?

2. The Role of the Medical Physics Expert (MPE)

2.1. Role of the MPE in the revised Basic Safety Standard (BSS)

Medical Physics Experts are defined and their roles are specified in the revised BSS. The pertinent articles are:

Article 4: Meaning of Terms

(40) *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 to act is recognised by the competent authorities;

Article 57: Procedures

(3) In medical radiological practices, a *medical physics expert* shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

- (a) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;
- (b) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, a medical physics expert shall be involved;
- (c) for other simple radiodiagnostic procedures, a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

Article 59: Equipment

(2) Member States shall ensure that:

- (d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure.

Article 85: Medical physics expert

(1) Within the health care environment, *the medical physics expert* shall, as appropriate, act or give specialist advice on matters relating to radiation physics as applied to medical exposure

(2) Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient, give advice on medical radiological equipment, and contribute in particular to the following:

- (a) optimisation of the radiation protection of patients and other individuals subjected to medical exposure, including the application and use of diagnostic reference levels;
- (b) the definition and performance of quality assurance of the medical radiological equipment;
- (c) the preparation of technical specifications for medical radiological equipment and installation design;
- (d) the surveillance of the medical radiological installations with regard to radiation protection;
- (e) the selection of equipment required to perform radiation protection measurements;
- (f) the training of practitioners and other staff in relevant aspects of radiation protection.

Where appropriate, the task of the medical physics expert may be carried out by a medical physics service.

2.2. Mission statement and key activities for MPEs

In order to make the role more understandable to decision makers and management of healthcare institutions and provide direction for role holders a mission statement was formulated by the consortium based on the above articles of the revised BSS. The mission statement is the following:

“Medical Physics Experts will contribute to maintaining and improving the quality, safety and cost-effectiveness of healthcare services through patient-oriented activities requiring expert action, involvement or advice regarding the specification, selection, acceptance testing, commissioning, quality assurance/control and optimised clinical use of medical radiological devices and regarding patient risks from associated ionising radiations including the prevention of unintended or accidental exposures³; all activities will be based on current best evidence or own scientific research when the available evidence is not sufficient. The scope includes risks to volunteers in biomedical research, carers and comforters” (Legido-Quigley H, McKee M, Nolte E, Glinos IA, 2008) (European Commission. DG Health and Consumer Protection, 2005) (European Commission, 2007) (CPME, 2005) (Caruana CJ, 2011).

2.3. Areas of medicine involving the MPE

MPEs are traditionally located in departments of diagnostic and interventional radiology (D&IR), nuclear medicine (NM) and radiation oncology/radiotherapy (RO). MPEs also provide services in other areas of medicine ranging from dentistry to cardiology and neurology.

³ This document concerns the medical use of *ionising* radiation; however, if during the process of justification or at other times, alternatives to the use of ionising radiations are proposed which involve other physical agents (e.g., radio-frequencies and field gradients in magnetic resonance imaging or tumour ablation) there must be an assessment of the relative “efficacy, benefits and risks” (Article 54 of the revised BSS). It is therefore highly recommended that an MPE is appropriately knowledgeable regarding the medical use of such other physical agents to be able to participate fully in such an assessment.

2.4. Key activities of the MPE

The mission of the MPE is expressed in many aspects of medical radiological practice. The consortium has identified and defined the key activities of MPEs. These are shown in Table 1:

Table 1: Definition and elaboration of the Key Activities of MPEs

Key Activity	Main Actions
Scientific problem solving service.	Comprehensive problem solving service involving recognition of less than optimal performance or optimised use of medical radiological devices, identification and elimination of possible causes or misuse, and confirmation that proposed solutions have restored device performance and use to acceptable status. All activities are to be based on current best scientific evidence or own research when the available evidence is not sufficient.
Dosimetry measurements.	Measurement of doses received by patients, volunteers in biomedical research, carers, comforters and persons subjected to non-medical imaging procedures using medical radiological equipment for the purpose of supporting justification and optimisation processes; selection, calibration and maintenance of dosimetry related instrumentation; independent checking of dose related quantities provided by dose reporting devices (including software devices); measurement of dose related quantities required as inputs to dose reporting or estimating devices (including software). Measurements to be based on current recommended techniques and protocols.
Patient safety / risk management (including volunteers in biomedical research, carers, comforters and persons subjected to non-medical imaging exposures).	Surveillance of medical radiological devices and evaluation of clinical protocols to ensure the ongoing protection of patients, volunteers in biomedical research, carers, comforters and persons subjected to non-medical imaging exposures from the deleterious effects of ionising radiations in accordance with the latest published evidence or own research when the available evidence is not sufficient. Includes the development of risk assessment protocols and dose audit.
Occupational and public safety / risk management (<i>when there is an impact on medical exposure or own safety</i>) ⁴ .	Surveillance of medical radiological devices and evaluation of clinical protocols with respect to protection of workers and public when impacting the exposure of patients, volunteers in biomedical research, carers, comforters and persons subjected to non-medical imaging exposures or responsibility with respect to own safety. Includes the development of risk assessment protocols as well as instructions for patients' release in conjunction with the Radiation Protection Expert.
Clinical medical device management.	Specification, selection, acceptance testing, commissioning and quality assurance/control of medical devices in accordance with the latest published European or International recommendations and the management and supervision of associated programmes. Testing to be based on current recommended techniques and protocols.
Clinical involvement.	Carrying out, participating in and supervising everyday radiation protection and quality control procedures to ensure ongoing effective and optimised use of medical

⁴ When the reduction of occupational and public risk would have an impact on medical exposure (e.g., in interventional radiology in which patient and occupational exposure are correlated, or nuclear medicine in which patient, occupational and public risk are correlated) optimisation may require input from both an MPE and a Radiation Protection Expert (or an individual recognised as both). The MPE is also required to have knowledge and skills in occupational radiation protection sufficient to take responsibility for own protection. Competences (which in the EQF framework refer to responsibility) in occupational and public safety / risk management are the responsibility of the Radiation Protection Expert.

	radiological devices and including patient specific optimisation, prevention of unintended or accidental exposures and patient follow-up.
Development of service quality and cost-effectiveness.	Leading the introduction of new medical radiological devices into clinical service, the introduction of new medical physics services and participating in the introduction/development of clinical protocols/techniques whilst giving due attention to economic issues.
Expert consultancy.	Provision of expert advice to outside clients (e.g., clinics with no in-house medical physics expertise).
Education of healthcare professionals (including medical physics trainees)	Contributing to quality healthcare professional education through knowledge transfer activities concerning the technical-scientific knowledge, skills and competences supporting the clinically-effective, safe, evidence-based and economical use of medical radiological devices. Participation in the education of medical physics students and organisation of medical physics residency programmes.
Health technology assessment (HTA)	Taking responsibility for the physics component of health technology assessments related to medical radiological devices and /or the medical uses of radioactive substances/sources.
Innovation	Developing new or modifying existing devices (including software) and protocols for the solution of hitherto unresolved clinical problems.

Comment [BR2]: Introduction of new devices is very often clinician led (see general comments)

3. Qualification and Curriculum Frameworks for the MPE in Europe

3.1. Introduction

This section presents the qualification and curricular frameworks for the MPE in Europe. Use of the frameworks will facilitate harmonisation of MPE qualifications, education and training leading to improved mobility. All qualification frameworks in Europe should be referred to the European Qualifications Framework (EQF) for lifelong learning (European Parliament and Council, 2008). In the EQF, learning outcomes are expressed as inventories of knowledge, skills and competences (KSC).

3.2. Qualification Framework

The proposed qualification framework (figure 1) is based on the results of the project survey; the various systems of qualifications used in Europe were evaluated and a framework developed based on the best features of each system taking into account the modernisation of scientific careers envisaged in the field.

Owing to the rapid expansion of medical device technology and research results, it is not possible for an MPE to be competent in more than one specialty of medical physics covered by the BSS (i.e., diagnostic and interventional radiology, nuclear medicine and radiation oncology/radiotherapy); therefore, the MPE should be independently recognised in each specialty of medical physics. The KSC for the recognition of MPE status by the competent authorities are to be gained initially through learning in an institution of higher education and *structured* clinical training in a residency within an accredited healthcare institution and subsequently developed further through *structured advanced* experience and

Comment [BR3]: The authors have gone from one extreme to another. Initially it was suggested that moving from one to another was relatively simple. Now they seem to suggest it's not possible. Neither position is well founded. Each specialty should be individually recognised but that is not to say that it is not possible to be competent in more than one (see general comments).

CPD. Explanatory notes to the qualification framework diagram plus associated rationales are shown in Table 2.

Figure 1: The Qualification Framework for the MPE in Europe

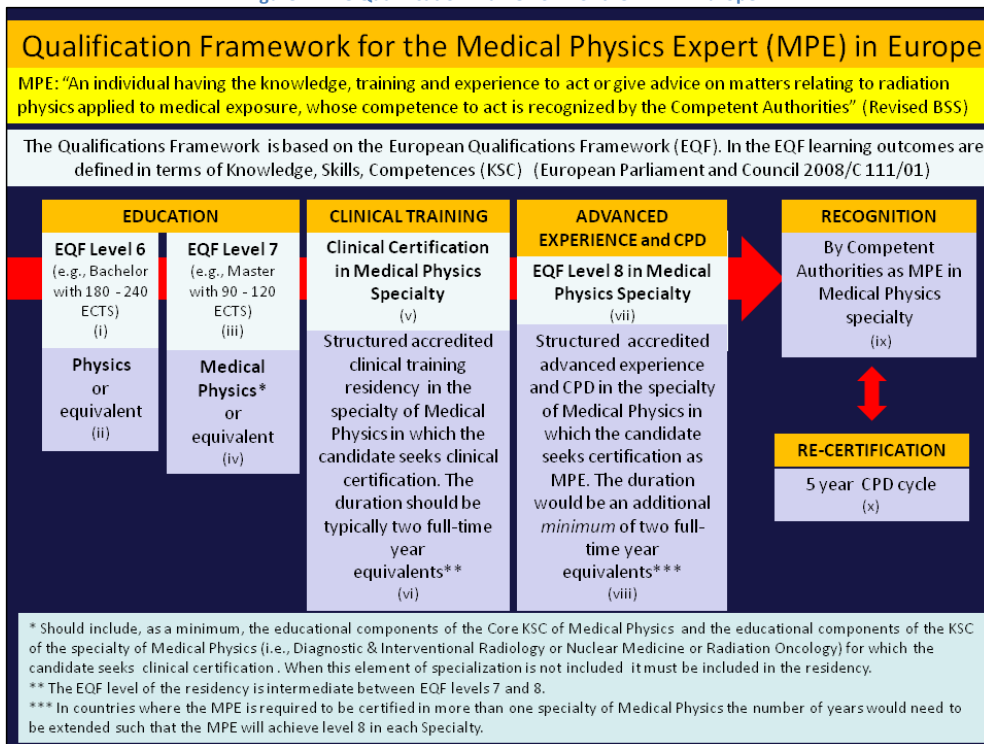


Table 2: Notes to the Qualification Framework diagram

	Note	Rationale
(i)	The fundamental educational level for medical physics professionals is a level 6 in physics and associated mathematics (Eudaldo T, Olsen K, 2010).	Medical physics professionals need to have good foundations in physics and mathematics as Medical Physics is a physical, numeric and exact science.
(ii)	'Equivalent' here meaning EQF level 6 with a high level of physics and mathematics content.	This will make it possible for graduates from other Level 6 programmes which include a high level of physics and mathematics (e.g., engineering, biophysics) to enter the field.
(iii)	The educational entry level for the medical physics professional has been set at EQF level 7. (Eudaldo T, Olsen K, 2010).	At entry level the medical physics professional needs to have highly specialised knowledge, critical awareness of knowledge issues in the field, specialised problem-solving skills, ability to manage work contexts that are complex and ability to review the performance of teams. (European Parliament and Council, 2008) Medical physics professionals require highly specialised knowledge in radiation protection and the medical devices covered by the BSS and specialised problem-solving and

		troubleshooting skills. The medical physics professional is involved in clinical contexts that may be very complex and reviews the performance of radiation protection and quality control teams in own specialty of medical physics.
(iv)	‘Equivalent’ here meaning EQF level 7 with a high level of physics and mathematics content <i>plus</i> the educational component of the core KSC of medical physics and the educational component of the KSC specific to the specialty of medical physics for which the candidate would be seeking clinical certification (as specified in this document). This additional education can be concurrent with the training.	This will make it possible for candidates with Masters in physics, biophysics, engineering etc. to enter the field; however, such candidates need to undertake an <i>additional</i> educational programme which includes the educational component of the core KSC of medical physics and the educational component of the KSC specific to the specialty of medical physics for which the candidate would be seeking clinical certification.
(v)	The medical physics professional at entry level is a professional with clinical certification in medical physics i.e., having a level of education in medical physics at a level intermediate between EQF levels 7 and 8, having typically 2 years full-time equivalent accredited clinical training and recognized as competent to act independently through enrollment in a national register for Medical Physics professionals.	The education and training to clinical certification in medical physics is a necessary foundation for further development to MPE EQF Level 8.
(vi)	Structured accredited residency based training for clinically based development of the core KSC of medical physics and the KSC specific to the specialty of medical physics for which the candidate would be seeking clinical certification. The duration of this structured training is typically <i>two</i> full-time year equivalents.	The IAEA recommends that clinical certification would need a training period of <i>two</i> full-time year equivalents for any one specialty of medical physics (IAEA, 2009) (IAEA, 2010) (IAEA, 2011).
(vii)	The MPE in a given specialty of medical physics is a professional with clinical certification in a specialty of medical physics who has achieved the highest level of expertise in that particular specialty. The medical physics professional through <i>structured advanced</i> experience, ongoing extensive CPD and commitment places the KSC at the highest possible level i.e., EQF level 8.	The qualification level for the MPE has been set at EQF Level 8 because the MPE requires knowledge at the most advanced frontier of a field of work and at the interface between fields, the most advanced and specialised skills and techniques, including synthesis and evaluation, required to solve critical problems in research / innovation and to extend / redefine existing professional practice, demonstrate substantial authority, innovation, autonomy, professional integrity and sustained commitment to the development of new ideas or processes at the forefront of work contexts including research (European Parliament and Council, 2008). To carry out activities requiring expert action, involvement or advice with authority and autonomy and which are based on current best evidence (or own scientific research when the available evidence is not

		sufficient), the MPE requires frontier knowledge in own specialty of medical physics and at the interface between physics and medicine. The MPE requires specialised skills and techniques in radiation protection and comprehensive experience regarding the effective and safe use of the medical devices in own specialty, and the synthesis and evaluation skills required to solve critical problems in service development, research, innovation and the extension and redefinition of existing professional practice.
(viii)	This will mean that to reach MPE status (Level 8) in the specialty area requires a <i>minimum</i> total of <i>four</i> years equivalent clinical training (2 years equivalent of foundation training in the specialty area to clinical certification and a <i>further</i> two years equivalent of <i>advanced, structured</i> experience and CPD in the specialty).	It should be emphasised that the <i>further</i> 2 years to reach MPE status must consist of <i>advanced, structured</i> experience and CPD and not simply CPD designed to maintain competence. The two years <u>minimum</u> of advanced experience must be measured from the time <i>when the advanced experience commences</i> . The advanced experience and CPD might not follow immediately the 2 years of basic training if the candidate is not deemed to be sufficiently prepared.
(ix)	A person who is currently recognised as an MPE and is in possession of the core KSC of medical physics and the KSC specific to the specialty for which recognition is sought should be deemed to satisfy the requirements for recognition as an MPE if they are currently on active duty as an MPE and are deemed to have reached level 8.	This is a grand parenting clause.
(x)	This is the requirement for an MPE to maintain recognition.	A five year cycle for re-certification (i.e, recognition by the Competent Authorities as having maintained a level 8 in the particular specialty of Medical Physics) is recommended.

Comment [BR4]: When we discussed this with the Contactors we envisaged that the 2 years minimum might suffice for simpler practices e.g. dental or general radiography but that 2 years would really not be adequate for an MPE that was responsible for the full range of diagnostic and interventional x-ray (see also general comments).

3.3. Curriculum Framework for MPE programmes in Europe

The curriculum framework (figure 2) consists of a structured inventory of KSC underpinning the role, mission and key activities of the MPE. The proposed curriculum framework is intended to be comprehensive yet concise. It is designed to make the commonalities between the various specialties of medical physics apparent and emphasise common terminology - hence facilitating collaboration between MPEs from the different specialties (e.g., in hybrid imaging, radiotherapy planning).

The KSC are classified in two categories: generic skills and subject specific KSC (EC Tuning Project, 2008). Generic skills consist of transferable skills which are expected of all professionals at a particular level of the EQF. In this case the relevant levels are level 7 (EC Tuning Project, 2008) and level 8 (Tuning Physics Subject Area Group, 2007). Subject specific KSC are specific to a profession. These are further classified

into sub-categories as determined by the particular profession. The following classification is based on proposals by EFOMP (Christofides S. et al., 2009), and Caruana (Caruana CJ, 2011):

- (a) *Medical physics core KSC*: these KSC are expected of all MPEs irrespective of their specialty:
- i. KSC for the MPE as *physical scientist*: these are fundamental physics KSC expected of all physical scientists
 - ii. KSC for the MPE as *healthcare professional*: these are KSC expected of all healthcare professionals
 - iii. KSC for the MPE as expert on the clinical use of medical radiological devices and protection from associated ionising radiations (and other physical agents as appropriate): these represent medical device and safety KSC common to all specialties of medical physics.
- (b) *Medical physics specialties KSC*: these KSC are highly specific to each specialty of medical physics (i.e., diagnostic and interventional radiology or nuclear medicine or radiation oncology/radiotherapy) and therefore cannot be included in the core.

It is important to note that an MPE from one specialty of medical physics who is required to assume *specific* responsibilities from another specialty may be certified to carry out those specific responsibilities following the acquisition of the corresponding KSC. Such cases may arise for example in a small nuclear medicine facility who requires its nuclear medicine MPE to take responsibility for the management of quality control testing of the CT component of a PET/CT system or at a small radiation oncology/radiotherapy facility which requires its radiation oncology/radiotherapy MPE to take responsibility for protocol optimization of a given imaging modality.

*The core KSC inventory and three specialty KSC inventories are given in **Annex 1**. A candidate seeking recognition by the competent authorities as an MPE in a given specialty of medical physics should reach level 8 in the core KSC and the KSC specific to that particular specialty.*

Education and training programmes should be based on the most updated textbooks and reports in the literature such as:

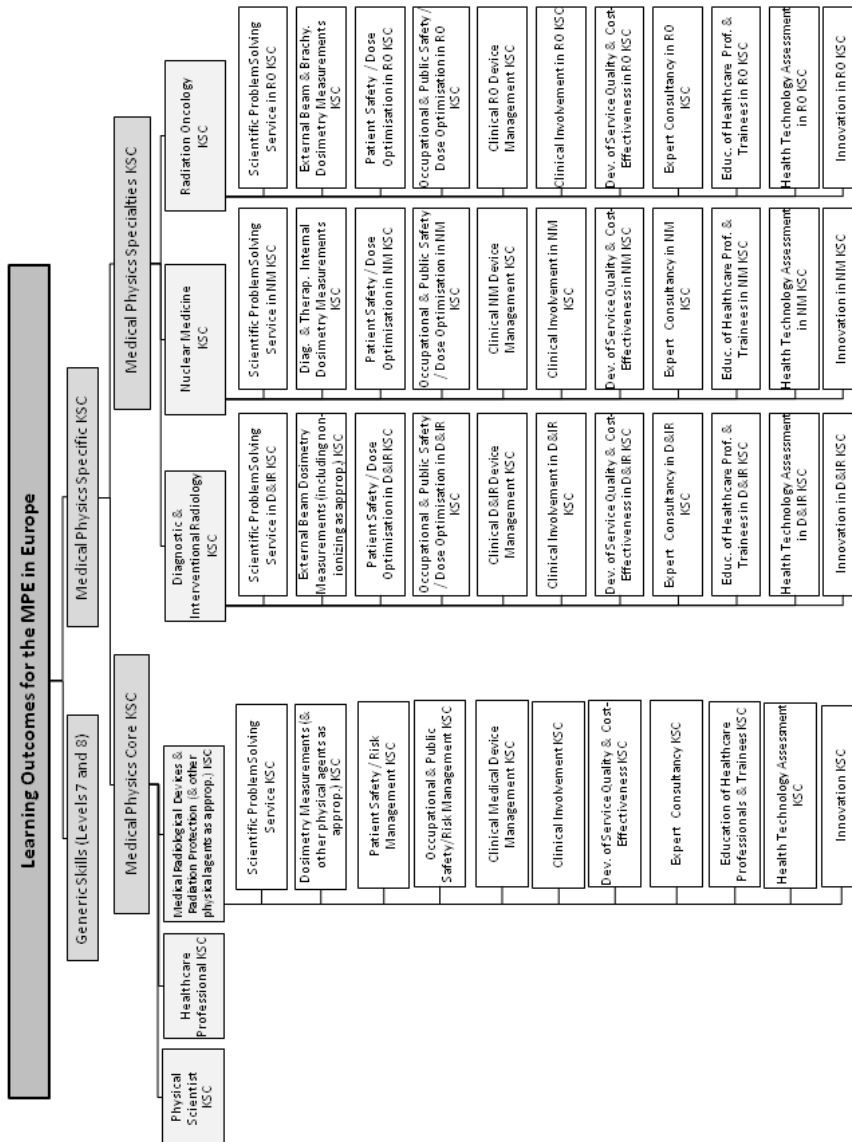
- a. Medical physics textbooks such as the handbooks and training manuals produced by the IAEA for physics in radiation oncology, nuclear medicine and diagnostic radiology,
- b. International, European and national legislation including all EU Directives relevant to radiation protection, medical devices, physical agents and personal protective equipment,
- c. Relevant EC reports, recommendations and protocols (e.g., Radiation Protection series http://ec.europa.eu/energy/nuclear/radiation_protection/medical/publications_en.htm),
- d. Reports, recommendations and protocols from relevant International organisations (e.g., IAEA, IEC, ICRP, ICRU, WHO, UNSCEAR),
- e. Reports, recommendations and protocols from International, European and national medical physics professional bodies (e.g., IOMP, EFOMP, AAPM, IPEM),
- f. Reports, recommendations and protocols from European professional and scientific bodies associated with the specific areas of medical physics practice (e.g., ESTRO, ECR, EANM),

Comment [BR5]: It is suggested to also include UK Institute of Physicists and Engineers in Medicine (IPEM)

- g. Reports, recommendations and protocols from relevant national authorities (e.g., HPA (UK), STUK (FI))
- h. Primary research reports and review articles from the research literature.

Educational and training methods should take into account modern developments in education and be based on approaches specific to adult learning (e.g., case-based learning).

Figure 2: Curriculum Framework for MPE programmes in Europe



4. Recognition of the MPE

4.1. Introduction and Background

In the definition of the MPE as given both by Directive 97/43/Euratom (European Commission, 1997) and proposal for the revised Euratom BSS (European Commission, 2012), it states that the “training and competence to act is recognised by the competent authorities”. Both these documents specify in various articles the roles and responsibilities of the Competent Authorities. The Directive 97/43/Euratom also defines Competent Authorities as “any authority designated by a Member State”.

This definition clearly allows Member States to designate different authorities to deal with specific aspects of Directive 97/43/Euratom, which has led to variation in said designation for the recognition of the MPE in the Member States.

Within the work carried out by this project, the Medical Physics Expert survey (European Commission Workshop, 2012) results identified differing interpretations of the MPE role and of the level of training and competence required for the designation of the MPE across the European Union. This may have arisen because the definition of MPE does not define the word ‘expert’.

The survey results also showed that recognition of the MPE is achieved mainly through registration, and that the existing registers recognise the competence of medical physicists but only a few explicitly recognise the competence of the MPE. The survey and professional interviews carried out during the project also showed that there was confusion in many Member States about how professional registration operates, but it was clear that a system in which MPEs need to have some formal accreditation or registration was seen as positive.

The results of the survey and interviews also indicated that there is no harmonisation between Member States in the recognition of the MPE. An additional factor contributing to this and the above discrepancies is that the level of expertise that an MPE should have is mainly dictated by the level and sophistication of the technology available in each Member State. This hinders harmonisation of competence and hence the mobility of the MPE between Member States.

4.2. Recommendations

In order to reach harmonisation in the recognition of the MPE and to allow free mobility of the MPE between the Member States it is recommended that a formal mechanism for recognising an individual’s status as an MPE should be put in place in each Member State:

1. Each Member State should consider designating, through a legal instrument, a Competent Authority specifically for the recognition of the MPE.
2. Recognition should be achieved by registration. It is highly recommended that a professional register should be kept by an official authority (e.g. Ministry of Health or Radiation Protection Authority). This task could also be delegated to a professional body such as professional medical physics societies if an official mandate is given.

3. The Competent Authority designated for the recognition of the MPE, should use the Qualifications Framework and KSC of the MPE specified in the present document, for the recognition of the MPE to Level 8 of the EQF.
4. The educational establishments of each Member State involved in medical physics education and training should use the KSCs of the present guidelines.
5. To allow the mobility of the MPE between Member States, it is recommended that the education and training of each MPE be recorded in a document that can be used as proof of the recognised competence.
6. MPE education and training requires formal steps that should be implemented by the competent authorities as recommended in the Qualification and Curriculum Frameworks to be found in this document.
7. It is highly recommended that MPE recognition should be overseen by a joint board of experts from the various stakeholders (i.e. Ministry of Education, Ministry of Health, Radiation Protection Authorities and Professional Societies, as appropriate).

The implementation of the above recommendations will ensure that the recognition of the MPE is harmonised throughout the Member States and will facilitate the mobility of MPEs from one Member State to the other.

5. Medical Physics Expert Staffing Levels in Europe

5.1. Introduction

To ensure adequate protection of the patient it is essential to have the appropriate number of MPEs and supporting staff. Annex 2 provides suggested factors that allow the numbers of MPEs required for radiotherapy, radiology (diagnostic and interventional) and nuclear medicine to be calculated. The numbers will relate to the need to assure that the key activities of the MPE derived from Article 57 of the revised BSS be achieved identifying the scope of the MPE from Article 85 of the revised BSS and as identified by this project. The factors should be used by relevant stakeholders such as healthcare decision makers and hospital administrators to identify the number of MPEs required. It is not practicable to provide guidelines for all types and complexity of clinical services (e.g. very specialised procedures, advanced clinical research etc.) and services involved in such activities will therefore have additional MPE requirements.

In deriving the factors given in Annex 2 use was made of comprehensive literature reviews and data collected from surveys to inform the group of experts associated with this project. In deriving the factors it was noted that the number of standard working hours per year varies between different Member States. For instance, the working hours per year in Ireland are around 1710 compared with around 1650 hours in the UK. However, due to the uncertainties in the factors, it is recommended that no adjustments to the factors be attempted unless staff are specifically employed to work long hours or overtime.

The MPE staffing factors required in radiotherapy, nuclear medicine and radiology are dealt with separately. To obtain the required staffing levels, the factors have to be multiplied by the number of elements associated with each factor and the results summed together to calculate the total WTE (Whole Time Equivalent) of MPEs and staff in the medical physics service (MPS).

Comment [BR6]: The concept of medical physics service and how that relates to the MPE has been adequately explained before now. Some information should be added.

Comparisons using these factors to calculate staffing levels with other data available in the literature were found to be difficult, particularly for nuclear medicine and radiology, due to the differing ways in which staffing numbers can be derived. Only the total medical physics staffing levels in an MPS could be compared since there was no data in the literature found relating specifically to the staffing levels associated with the MPE.

For radiotherapy, the MPE factors were based on the report by IPEM (IPEM 2002). The calculated MPS staffing levels required for a typical radiotherapy department was shown to be in reasonably good agreement with the total staffing levels associated with a range of other literature (ISTISAN, 2002), (Klein EE, 2010), (SEFM, 2002), (IAEA, 2010).

For nuclear medicine and radiology, the MPE factors were based on the survey results and analysis by the relevant Special Interest Groups in IPEM and from expert opinion by the core working group associated with the Guidelines on Medical Physics Expert Project (European Commission Project, 2012).

The MPS staffing levels associated with a range of diagnostic equipment found in typical nuclear medicine and radiology departments appeared to be in reasonably good agreement with the total staffing levels suggested by the AAPM (AAPM, 1991). However, they resulted in greater levels compared to those suggested by some other literature (EFOMP, 1997), (IAEA, 2010), (SSRMP, 2009), (DGMP, 2010). Reasonable agreement with these reports did exist, however, if the factors associated only with just routine work were used.

The factors associated specifically with patient activity for high dose radiology procedures have not normally been assessed separately in other reports. These have been specifically included in the present work because of the increased attention placed on the hazards associated with CT and interventional radiology studies.

A person recognised to act as an MPE may also separately be recognised to act as a Radiation Protection Expert (RPE). The staffing requirements associated with environmental monitoring, and staff and public protection and assurance with regulatory compliance are included in the MPE staffing levels. However, if the MPE is not also an RPE then these tasks may also need to involve a suitable RPE. Additional staffing requirements may also be associated with room design for new installations (especially in radiotherapy). These installations may involve both the MPE and RPE. It is recognised there will be some overlap between the work of the MPE and RPE but the staffing requirements associated with the work of an RPE are outside the scope of this project.

Comment [BR7]: This is not appropriate. The RPE role was outside the scope of this project so what is the basis for the factors used to estimate RPE requirements and on what basis is their role included here with the MPE?

Comment [BR8]: This is fine but the reader is confused by the apparent contradiction between this statement and the one marked above.

Additional factors associated with the MPE for service delivery are: ongoing service development, clinical governance, audits, research and development including clinical trials, education and training within service and management of scientific service.

5.2. Recommendations

Recommended staffing factors, given in Annex 2, have been set for estimating the number of MPEs required for a given medical physics service involving the use of ionising radiations for radiotherapy, nuclear medicine and radiology services. The factors are both equipment and task/patient based.

They provide methods that can be used by departmental managers and administrators to obtain the number of MPEs that should be employed to provide a high quality, safe, efficient and productive service with the innovation necessary for the introduction of new equipment and techniques. Additional elements for research and development have been identified separately but the amount of staff employed within pure research will be mainly a function of additional external funding and is not within the scope of this report.

For radiotherapy, the nature of the involvement of medical physics will require the presence of MPEs, recognised in the relevant specialties, to be on site for at least part of the standard working day and available for consultation during extended working days and weekends. It is expected that at least two MPEs will be required to provide this assurance. Outside normal working hours and for satellite sites, an MPE must be available for consultations at all times the service is operating, and if circumstances require, can be on-site quickly to take adequate measures to assure the radiation protection of the patient should any unforeseen or emergency situation arise.

For nuclear medicine and radiology, the nature of this involvement will require the presence of MPEs, recognised in the relevant specialties, to carry out measures related to radiation protection of the patient and quality assurance of the equipment, to optimise practices, to respond appropriately to individual patient-specific issues, to assist in matters of organisation and to be available for consultations at all other times the service is operating.

The number of MPEs required will depend upon the number of equipment and their complexity together with the amount of patient activity.

All MPEs should have time allocated for CPD some of which may take the form of in-house training, and service development projects to meet the needs of the department.

When the WTE is not a whole number, an MPE may be employed to carry out other duties commensurate with their experience. Alternatively, an MPE may be employed part time or form partnerships with other services.

In an MPS there should be one or more MPEs within each specialty who assumes responsibility for the service provision in that specialty. The MPS should employ other medical physics staff to support the work of the MPE. The skill-mix for the support staff should be decided in consultation between the

employer and the MPE. Without the appropriate level of experience and supervision of staff within an MPS there is an increased risk of failure in patient safety standards. Inadequate staff resources may directly impact on the quantity and quality of the service provided to patients. Where there is a shortfall of staff compared to these guidelines there is a potential for under usage of expensive equipment, non-optimal exposures, patients not receiving state of the art care and an increase in patient overexposures. For all MPSs some form of management and administration will be required. The amount required will depend upon the size and complexity of the service and may contribute a further one WTE per service.

For staff working at multiple locations, an additional WTE component may need to be factored into the calculated staffing levels to account for the time it takes staff to travel to the different locations.

Healthcare decision makers and hospital administrators should audit the staffing levels at intervals of no more than two years and ensure reasonable compliance with this guidance is achieved.

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