



EFOMP Malaga Declaration 2023: An updated vision on Medical Physics in Europe

Brenda Byrne^{a,*}, Loredana Marcu^b, Lorenzo Nicola Mazzoni^c, Carmel J Caruana^d,
Amanda Barry^e, Guadalupe Martín Martín^f, Michele Stasi^g, Samuel Ruiz^h,
Antonio Lopez Medinaⁱ, Kalliopi Platoni^j, Ad J.J. Maas^k, Sam Agius^l, Efi Koutsouveli^m,
Paddy Gilliganⁿ

^a Chair EFOMP Professional Matters Committee, Mater Misericordiae University Hospital, Dublin, Ireland

^b Chair EFOMP European and International Matters Committee, Faculty of Informatics and Science, University of Oradea, Oradea, Romania

^c USL Toscana Centro, Pistoia, Italy

^d Faculty of Health Sciences, University of Malta, Msida, Malta

^e Dept. Applied Science & Dept. Health and Sports Science, South Eastern Technological University, Waterford, Ireland

^f Hospital Universitario de Fuenlabrada, Madrid, Spain

^g Ospedale Ordine Mauriziano di Torino, Umberto, Italy

^h Marqués de Valdecilla University Hospital, Santander, Spain

ⁱ Servizo Galego de Saúde, Vigo, Spain

^j National and Kapodistrian University of Athens, Greece

^k Retired Medical Physics Expert, MREC Brabant for Medical Devices, Netherlands

^l Ministry for Health, Malta

^m Secretary General EFOMP, Hygeia Hospital, Athens, Greece

ⁿ President EFOMP, Mater Misericordiae University Hospital, Dublin, Ireland

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ABSTRACT

In 2006, the European Federation of Organisations for Medical Physics (EFOMP) adopted the “Malaga Declaration”. The declaration asserted the fundamental role of Medical Physics professionals in the radiation protection of patients, workers, general public, carers and comforters and research participants in hospitals. However, since that time the Medical Physics profession has evolved in Europe and new regulations and documentation have been issued, such as directive 2013/59/Euratom and the “European Guidelines on Medical Physics Expert” (RP174). EFOMP has published updated core-curricula and strived towards the recognition of the profession at the European level. In view of this, an update of the original Malaga Declaration was deemed necessary, to define the future vision that will guide the actions of the Federation in the years to come. This Declaration, which has been approved by the national member organizations of EFOMP in April 2023, is much broader than the original Malaga version. This is expected considering the rapid evolution of medical device technology over the last 17 years. The Radiation Protection Expert in hospital settings should be an MPE, since the latter has the highest level of radiation protection knowledge and training. Given the passion and energy that animated the debate, which led to the updating of the Malaga Declaration, we are confident that it represents a solid basis for the development of our profession in Europe which is in consonance with the aspirations of us all.

1. Current position of Medical Physics as a healthcare profession in Europe

Medical Physics is the application of physics to healthcare, using physics for patient assessment, imaging, and treatment. Medical

physicists are graduate scientists, holding post-graduate qualifications, who work in many different areas of healthcare managing and delivering services and carrying out clinically oriented research and development.

Medical Physicists have key responsibilities for the calibration,

* Corresponding author at: Chair EFOMP Professional Matters Committee, Mater Misericordiae University Hospital, Dublin, Ireland.

E-mail address: bbyrne@mater.ie (B. Byrne).

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quality assurance and control, optimized use and safety of medical devices, particularly devices involving ionising and non-ionising radiation. They also have responsibility for the commissioning, data acquisition, adaptation and the optimisation of the use of new devices and their insertion into clinical use. Furthermore, Medical Physicists carry out dosimetric measurements and treatment planning, which are essential components of external beam radiotherapy, brachytherapy and nuclear medicine (molecular) therapy of cancer patients. At present, most large hospitals in Europe have Medical Physics Departments. Their services face ever increasing demands due to the multidisciplinary nature of medical physics and the rapid increase in the number and complexity of medical devices including software components.

In addition to clinical activity, Medical Physicists play a key role in clinically oriented research and the development of new methodologies and instrumentation for clinical use. They also have the responsibility for organising educational and training courses in medical physics for medical doctors and other healthcare professionals.

The 2013/59/EURATOM Directive of December 5th 2013, establishing basic safety standards for protection against the dangers arising from exposure to ionising radiation has defined the Medical Physics Expert (MPE) as 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 recognized by the competent authority”. The role of the MPE has been strengthened in the 2013/59/EURATOM Directive as compared to the 1997/43/EURATOM Directive with a stronger emphasis on the involvement of the MPE. Article 57 of the 2013/59/EURATOM Directive states that “Member States shall ensure that ... in medical radiological practices, a medical physics expert is appropriately involved”. [1,2] MPEs liaise with medical doctors and other healthcare professionals to ensure safe and effective use of radiation on patients.

Medical Physicists require specialist education and training to perform the above activities effectively and safely. There is broad consensus in Europe as to these requirements: Medical Physicists should have at least a Bachelor’s degree in physics (EQF level 6), followed by a Master’s degree (EQF level 7) and several years of specialised clinical training (residency) in a hospital. Further training is required before a Medical Physicist can obtain the Medical Physics Expert (MPE) qualification (EQF level 8) [3]. The ideal level of training required to become an MPE is detailed in the European Commission Report No 174- European Guidelines on Medical Physics Expert. EFOMP recommends this format of training within a remunerated residency program [4]. EFOMP’s Core Curriculum also recommends that the qualification for access to training as an MPE should be at least a Bachelor and Master’s degrees in Physics/ Medical Physics [5,6].

The Medical Physicist and the Medical Physics Expert are healthcare professions and listed accordingly in ESCO (Classification of European Skills, Competences, Qualifications and Occupations) [7]. Approximately one third of European countries regulate Medical Physicists as healthcare professionals. In most European countries Medical Physicists have set up National Societies of Medical Physics [3]. These Societies have joined the European Federation of Organisations for Medical Physics (EFOMP) as National Member Organisations (NMOs) of which there are currently 35. The main objective of EFOMP is to harmonise and promote the education, training and practice of Medical Physics in Europe and it is actively working on the preparation of the core curricula for each specific Medical Physics sub-specialization. The importance of the activities carried out by over 9000 Medical Physicists in Europe in the service of patient health is a sufficient reason for this profession to be recognised as a regulated profession by the EU.

2. European legislation to recognise professional qualifications of Medical Physics Experts

One of the key objectives of EFOMP is the recognition by the European Commission of the Medical Physics profession as a regulated

profession under [8]/36/CE, as amended by EU Directive 2013/55/EU for Mutual Recognition of Professional Qualifications [8]. This directive provides for automatic recognition for a limited number of professions based on harmonised minimum education and training requirements, a general system for the acknowledgement of evidence of training and automatic recognition of professional experience, all within the EU.

Representative professional organisations at Union level, as well as national professional organisations or competent authorities from at least one third of the Member States, may submit to the Commission suggestions for common training frameworks which meet the conditions laid down in [8]/36/CE. The key role of the MPE in safe and effective use of ionising radiation in medicine is widely recognised in European reference documents such as EU Council Directive 2013/59/EURATOM, and the European Commission Radiation Protection Report No. 174, European Guidelines on Medical Physics Expert. The Report No. 174 gives the profession a common education and training framework for Medical Physicists up to expert level (Medical Physics Experts). In this context, EFOMP has been working over many years with the relevant clinical societies (ESTRO, EANM and ESR) to produce core curricula for MPEs in key areas where the Medical Physics profession is regulated by EU directives. The latest core curriculum for MPEs in Radiotherapy (3rd edition published in 2022) has been endorsed by the majority of EFOMP NMOs which highlights the strong belief in a harmonised education and training framework across Europe. Following the publication of the 2013/59/EURATOM directive, many of the competent authorities for radiation safety of patients in Europe have already established National Registration Schemes (NRS) for the qualification of Medical Physics Experts.

The first step to ensure harmonization is the approval by EFOMP of the NRS for MPEs of each NMO [3]. In view of the above, EFOMP introduced a new evaluation procedure in 2018 based on a number of criteria including knowledge, skills and competences (KSCs) required for an MPE as detailed in Report No 174. EFOMP plans to submit an application to the European Commission requesting the profession of Medical Physics Expert to become a regulated profession based on this common education and training framework. This can only benefit our profession and patients by allowing MPEs to transfer their qualifications and skills between NMOs and prevent unqualified personnel from using the title of MPE.

3. Medical Physicists role in radiation protection

To ensure a comprehensive, safe and high quality approach to radiation protection, in 2006, EFOMP adopted the following position (referred to as the ‘Malaga declaration’) regarding the responsibility of the MPE in the field of Radiation Protection in hospitals: “The Medical Physics Expert as defined in the directive 43/97 must be the professional to supervise and assume the responsibilities of the Radiation Protection activities in hospitals, including patients, working staff, members of the public and visitors to the hospitals” [9].

Since 2006, progress has been made in regulating radiation protection in the hospital environment. Importantly, the 2013/59/EURATOM directive highlighted the need for a liaison between MPE and Radiation Protection Expert (RPE) in the hospital setting, implicitly recognizing that lack of cooperation can limit the effectiveness of radiation protection.

MPEs have the highest level of expertise in the area of radiation protection (EQF = 8) and are healthcare professionals recognised by the International Labour Office with full responsibility for the physical aspects of the patients’ radiation protection. Moreover, MPE’s core knowledge, skills and competences include those of the RPE [10,11].

As asserted in the Malaga Declaration, actions that ensure the radiation protection of workers and members of the public are often strongly interconnected with those dedicated to the radiation protection of patients. For example, the radiation exposure of workers in nuclear medicine and interventional radiology is strongly related to the patient’s

absorbed dose. In this scenario, the responsibilities of the RPE to protect staff and the public from the harmful effects of ionising radiation may not be aligned with those of the responsibilities of the MPE to protect the patient; thus, the effectiveness of radiation protection depends on robust communication and liaison between RPE and MPE. In practice, MPEs in many European countries act also as the RPE, taking full responsibility for the physical aspects of radiation protection in hospitals. Therefore, where the RPE is a MPE, radiation protection management that, includes all the actions necessary to ensure radiation protection for all, is simplified and more effective.

Accordingly, the 2006 Malaga declaration is updated as follows:

EFOMP adopts the following position regarding the responsibility of Medical Physicists in the field of Radiation Protection in hospitals: “The Medical Physics Expert (MPE) as defined in the directive 2013/59/EURATOM should be the healthcare professional to supervise and assume the responsibilities for radiation protection activities in hospital settings, including patients, working staff, members of the public and visitors. The Radiation Protection Expert (RPE) in hospital settings should be an MPE, since medical physicists have the highest level of radiation physics knowledge and training”.

EFOMP recommends dividing national RPE registers into two groups:

- i. RPEs responsible for radiation protection in medical practices,
- ii. RPEs responsible for all other practices that involve the use of ionising radiation.

“The minimum requirement for RPEs entering a national register for radiation protection in medical practices should be recognition as an MPE by the national authority.” EFOMP outlines the importance of a rapid application of this statement where necessary, to ensure safe and efficient radiation protection for all.

4. Current scenario and future perspectives for the Medical Physics Expert

As medical device technology and the use of physical agents in medicine advance and expand, so must the role of the MPE. The range of medical devices and physical agents used in hospitals today goes far beyond the use of ionising and non-ionising radiation based imaging and therapeutic devices, and the MPE faces requests for assistance in other areas such as advanced physiological measurements, artificial intelligence and medical nanodevices.

A MPE has the core knowledge, skills and competences commensurate with that of the Magnetic Resonance Safety Expert, Laser Safety Expert and MR Scientist and is required to deal with the risk assessments described in EU Directive 2013/35 [12,13,14]. MPEs in most European countries are already in charge of these positions.

Any future-oriented vision for the MPE will therefore be based on the following mission statement “Medical Physicists and 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 optimized clinical use of medical devices and regarding patient risks from associated physical agents including protection from such physical agents, installation design and surveillance, and the prevention of unintended or accidental exposures to physical agents; 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” [15].

5. Final remarks

To meet the growing demands of clinical specialties involving Medical Physicists, and to ensure a comprehensive, safe and high-quality approach in all areas reported above, the number of MPEs is increasing in most European countries. Therefore, staffing levels should be updated accordingly.

Directive 2013/59/EURATOM defines the MPE as “...an individual or, if provided for in national legislation, a group of individuals, having the knowledge...”; EFOMP recommends that medical physics units and departments, composed of the appropriate number of MPEs and other professionals, carry out all the MPE’s duties in hospital settings [6].

Implementation of such actions at a European level would help ensure effective, safe and efficient patient care for all European citizens.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- [1] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.
- [2] 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.
- [3] Maas AJJ, Lammertsma AA, Agius S, Bert C, Byrne B, Caruana CJ, et al. Education, training and registration of Medical Physics Experts across Europe. *Eur J Med Phys* 2021;85:129–36.
- [4] Radiation Protection No. 174, European Guidelines on Medical Physics Expert (2014).
- [5] Garibaldi C, Essers M, Heijmen B, Bertholet J, Koutsouveli E, Maas A, et al. Towards an updated ESTRO-EFOMP core curriculum for education and training of medical physics experts in radiotherapy—A survey of current education and training practice in Europe. *Europ J Med Phys* 2021;84:65–71.
- [6] Garibaldi C, Essers M, Heijmen B, Bertholet J, Koutsouveli E, Schwarz M, et al. The 3rd ESTRO-EFOMP core curriculum for medical physics experts in radiotherapy. *Radiother Oncol* 2022;170:89–94.
- [7] International Standard Classification of Occupations 2008 (ISCO-08) (ILO-ISCO08 2012).
- [8] Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications.
- [9] The Malaga Declaration – EFOMP’s position on medical physics in Europe (2006) - <http://www.efomp.org/>.
- [10] ENETRAP III project, March 2016.
- [11] IRPA Guidance on Certification of a Radiation Protection Expert, 2016.
- [12] J. Hand a, H. Bosmans b, C. Caruana c, S. Keevil a, D.G. Norris, R. Padovani g, O. Speck (2012). European Federation of Organisations for Medical Physics (EFOMP) policy statement 14: The role of the Medical Physicist in the management of safety within the magnetic resonance imaging environment: EFOMP recommendations, *Europ J Med Phys*, 29(2), pp. 122-125.
- [13] Busoni S, Bock M, Chmelik M, Colgan N, De Bondt T, Hanson LG, et al. ADDENDUM to EFOMP Policy statement No.14 “The role of the Medical Physicist in the management of safety within the magnetic resonance imaging environment: EFOMP recommendations. *Europ J Med Phys* 2021;89:303–5.
- [14] Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).
- [15] Caruana CJ, Christofides S, Hartmann GH. European Federation of Organisations for Medical Physics (EFOMP) policy statement 12.1: Recommendations on medical physics education and training in Europe 2014. *Europ J Med Phys* 2014;30(6): 598–603.