

# ADDENDUM to EFOMP PS No.14

## Introduction

In 2012 EFOMP published Policy Statement No.14 entitled “The Role of the Medical Physicist in the management of safety within the magnetic resonance imaging environment: EFOMP recommendations” [1]. The present document is an addendum to the statement, which remains valid.

This addendum is necessary after:

- the publication of EU Directive 2013/35/EU which regulates “... *the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)*” [2], whose contents were not considered in EFOMP Policy Statement No.14 that was published in 2012;
- the appearance and development of new MRI settings (PET/MRI, LINAC/MRI, interventional MRI, SPECT/MRI, parallel transmit RF systems) and the clearance for the clinical application of very high field MRI systems (7 T), with related new areas of safety concern for both patients and workers;
- the publication of EC RP 174 “European Guidelines on Medical Physics Expert” in 2014 where the European Commission recommended that “... *as the linking of non-ionizing radiation devices to ionizing radiation devices is on the increase (e.g., PET/MRI, SPECT/MRI), it is highly recommended that a Medical Physics Expert (MPE) is appropriately knowledgeable regarding the medical use of such other physical agents.*” [3]. This including implementation of new methods for MR-supported radiation therapy planning and quality control evaluation (e.g. MR-based 3D dosimetry);
- a significant expansion, during the last years, of highly specialized MRI techniques has been observed, such as spectroscopy, diffusion and perfusion weighted imaging, functional imaging (fMRI), susceptibility weighted imaging (SWI), morphometry, CEST contrast, Arterial Spin Labeling (ASL), synthetic MRI, etc., the combined use of many of these techniques in pre-surgical planning, radiotherapy and multimodal imaging, and the growing use of Artificial Intelligence (AI) in diagnostic radiology, as well as the use of quantitative imaging biomarkers based on MRI data [4].

Many of the techniques listed above enable the numerical estimation of health status parameters by means of post-processing procedures and appropriate biophysical models. These parameters, sometimes displayed in the form of maps, are an important part of the information that medical doctors would use to arrive at medical decisions and prepare their medical reports.

The appropriate use of such techniques over the years has led to a progressive, natural and ever-growing involvement of specialists with strong scientific background, commonly named “MR scientists”, especially in clinical research, acting in support to the specific role of the physician responsible for the exam/reporting or for the treatment.

Among these scientists, those with a strong background in medical physics, in the following named as “Medical Physics MR Scientist”, are increasingly involved in the following activities:

- development of physics-based methodologies for the optimization and appropriate implementation of MRI protocols and quality assurance procedures specific for each medical application, body region and pathology whilst considering the entire workflow, from acquisition to post-processing and possible statistical analysis;
- the critical evaluation of the quality of MR images
- analysis of quantitative data, including the use of AI and imaging biomarkers;
- assessment of the relative uncertainty and statistical analysis;

- contribution in coordinating clinical MR research activities;
- sequence development and pulse sequence programming;
- implementation of regular Quality Control (QC) standards at MR-sites on hardware and software features; analysis of technical failures, artefacts and measurement problems, advisory on repair measures to manufacturers;
- providing advice on the purchase, installation, acceptance testing and commissioning of new magnetic resonance imaging systems/facilities;
- teaching medical doctors, MRI radiographers, and other personnel directly or non-directly connected with MRI procedures (Intensive Care Unit personnel, nurses, firefighters, etc.) entering the MRI environment, about MRI physics principles, safety and devices;
- implementing procedures regarding SAR mapping, determination of the conditionality status of devices, to report MR related adverse events and safety incidents, and for continuous quality improvement efforts.

This activity list is not an exhaustive one as technological progress and translational research in medical imaging are continuously promoting new topics requiring the involvement of Medical Physics MR Scientists.

Furthermore, the clinical use of highly complex hybrid machines, such as LINAC/MRI and PET/MRI has been steadily increasing in recent years so that the involvement of MPEs in the clinical application of MR equipment has become a matter of fact. These circumstances necessitate initiatives for continuous professional development activities.

With respect to safety considerations, additional elements must be considered like zoning systems [5], cryogenics and acoustic noise, especially for personnel directly involved in MRI diagnostic procedures.

## **Recommendations**

Given this background and considering that:

- MPs working within the hospital do routinely work in collaboration with imaging departments, including nuclear medicine and radiotherapy;
- MPs with the skills, knowledge and competences outlined in [1] are perfectly suited candidates to act as Magnetic Resonance Safety Experts (MRSE);
- MPs who have undergone appropriate specialised education and training on MR medical physics have the necessary expertise to allow them to deal also with all the activities listed in the introduction to this Policy Statement, acting as Medical Physics MR Scientists.

EFOMP makes the following recommendations/statements:

1. MPs on duty as MRSEs must deal with all the risk assessments described in EU directives, in particular referring to art. 10 “Derogations” (a) of EU directive 35/2013 [2].
2. MPs qualified and acting as MRSEs should be involved to optimally plan the MRI scan to minimize patients’ risks when ICDs, pacemaker, or other implants are present. In particular, MPs should define the limits for MR off-label examinations of patients with non-conditional implants.
3. MPs, as defined by the International Standard Classification of Occupation (ISCO-08) under group 2111, considering their knowledge of physics, their skills and competence in applying physics methods and techniques to medicine, are qualified and ideally suited to be the professionals acting as Medical Physics MR Scientists in the activities described in the

introduction to this Policy Statement, provided they have undergone an appropriate MR-specific education and training.

4. MPs on duty as Medical Physics MR Scientists will act in close co-operation with other healthcare personnel as well as with scientists from other scientific areas (biophysics, chemistry, engineering, psychology, biology, etc.) [6].
5. National Member Organizations (NMOs) are invited, if necessary, to promote initiatives for the continuous education and training of MPs acting or willing to act as Medical Physics MR Scientists. The increased number of activities potentially involving MPs in MR shall be mirrored in an increased amount of MR-content in corresponding education (e.g. in postgraduate studies for MP, especially practicals related to MR-safety)
6. Since the list of activities included in the introduction to this policy statement evolves with the scientific MR evolution and technological progress, MPs on duty as Medical Physics MR Scientists must keep up to date their skills and competences in MR medical physics. Their skills and competences should be maintained at a level corresponding to the state-of-the-art of MRI devices and techniques and, where appropriate, to those needed for certification.
7. In the case of hybrid machines, such as LINAC/MRI, PET/MRI and SPECT/MRI, and related hybrid applications, MPs, already acting as MPEs and MRSEs, should also act as Medical Physics MR Scientists to ensure on-going effective and optimized use of medical devices, as well as workers and patients' safety [3].

## Remarks

These recommendations are fully compliant with the mission of MPs in the clinical environment as stated by EFOMP in 1984 Policy Statement No.2 "The Roles, Responsibilities and Status of the Clinical Medical Physicist" [7]:

"In the future, physics will be of even more importance both in clinical medicine and in medical science. Medicine can be expected to become more scientific and quantitative. Scientific data will be of more significance in the diagnosis and treatment of diseases. Medical physics will play an increasingly important part in this development. High standards in medical physics services must be maintained and sufficient resources directed towards this."

"...Thus, the clinical medical physicist must be responsible within this area of competence for the standardization and calibration of medical physical equipment and for the accuracy and safety of physical methods used in routine clinical applications in close co-operation with other health care professionals and medical specialists. The MP has also a responsibility in research and in the development of new techniques and physical methods and equipment. Furthermore, the MP has a responsibility for providing education and training in applied physics for all healthcare professionals, student physicists and technical staff." [7].

## References

- [1] EFOMP Policy Statement No. 14: The Role of the Medical Physicist in the Management of Safety Within the Magnetic Resonance Imaging Environment: EFOMP Recommendations (2012).
- [2] Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC.
- [3] Guidelines on medical physics expert. (Radiation protection 174), European Commission (2014).

[4] Sullivan DC, et al., Metrology Standards for Quantitative Imaging Biomarkers. Radiology, 277(3):813-825(2015).

[5] ACR Manual on MR Safety v 1.0. American Congress of Radiology Committee on MR Safety (2020).

[6] EFOMP Policy Statement No.7.1: The Roles, Responsibilities and Status of the Medical Physicist Including the Criteria for the Staffing Levels in a Medical Physics Department (2016).

[7] EFOMP Policy Statement No.2: The Roles, Responsibilities and Status of the Clinical Medical Physicist (1984).