EC Project `GUIDELINES ON MPE´: proposed qualification and curriculum frameworks and the MPE in nuclear medicine

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Abstract. The objectives of EC project `Guidelines on Medical Physics Expert´ are to provide for improved implementation of the provisions relating to the Medical Physics Expert within Council Directive 97/43/EURATOM and the proposed recast Basic Safety Standards directive. This includes harmonisation of the mission statement for Medical Physics Services as well as the education and training of the MPE. It also includes detailed knowledge-skills-competence inventories for the Medical Physics Expert in each of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy. This paper presents the proposed Qualification and Curriculum Frameworks and their application to the Medical Physics Expert in Nuclear Medicine.

1. Introduction
The objective of the European Commission project 'Guidelines on Medical Physics Expert' (TREN/09/NUCL/SI2.549828) is to provide for improved implementation of the provisions relating to the Medical Physics Expert (MPE) of Council Directive 97/43/EURATOM (Medical Exposures Directive, MED) and the recently proposed recast Basic Safety Standards (BSS) Directive. This includes harmonisation of the mission statement and the education and training of the MPE. In this way, the project will support the European Commission in its actions relating to the optimisation of radiation doses to individuals submitted to medical exposures. This paper presents the proposals of the project consortium on the qualification framework for attainment of MPE status and also for the curricular framework for Education and Training of MPE.

2. Principles guiding the development of the curriculum frameworks
The principles guiding the development of the qualification and curriculum frameworks were the following:

- The proposed qualification framework should be based on the levels defined by the European Qualifications Framework (EQF) for lifelong learning [1] which is the most recent document
proposed by the EC for qualification frameworks. For the purpose of this project the appropriate Levels are EQF Level 6 (e.g., Bachelor) and EQF Level 7 (e.g., Masters) [1-2].

- The qualification framework would facilitate the mobility of the MPE in Europe through an agreed set of minimum criteria for achievement of MPE status (whilst keeping in mind the safety of the patient).
- The qualification framework would make it possible for more individuals to achieve MPE status through its flexibility, cost-effectiveness and lifelong learning approach.
- The determination of curriculum content will be guided by a mission statement for Medical Physics Services derived from the MED and recast BSS. The consortium has developed the following mission statement: “Medical Physics Services will contribute to maintaining and improving the quality [3], safety [4-5] and cost-effectiveness [6] of healthcare services through patient-oriented activities requiring expert action, involvement or advice regarding the selection, acceptance, commissioning, quality assurance and optimised clinical use of medical devices used in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology and regarding risks from associated physical agents (particularly though not exclusively ionising radiation); all activities will be based on current best evidence or own scientific research when the available evidence is not sufficient”. The term ‘physical agents’ has been used to include both ionising and non-ionising radiation. The use of non-ionising radiation imaging modalities as alternatives to ionising radiation is mandated by Article 3 of 97/43/Euratom and Article 80 of the new BSS. The term ‘physical agents’ refers to not only ionising radiation but also to static magnetic fields, radiofrequency radiation, ultrasound and any other physical agent associated with these imaging modalities. This mission includes the following key activities: General Physics Service, Physical Agents Dosimetry Service, Patient Safety / Risk Management, Occupational and Public Safety / Risk Management (when associated with patient safety), Clinical Medical Device Management, Clinical Involvement, Development of Service Quality and Cost-Effectiveness, Expert Consultancy, Education of Healthcare Professionals and Trainees, Health Technology Assessment (HTA) and Innovation.

- Learning outcomes (LO) for MPE programmes will be expressed in terms of Knowledge, Skills and Competences (KSC) as stipulated and defined in the EQF document as:
  - Knowledge (facts, principles, theories, practices),
  - Skills as the ability to use knowledge and know-how to complete tasks and solve problems (both cognitive skills involving the use of logical, intuitive and creative thinking and practical skills involving manual dexterity and the use of methods, materials, tools and instruments),
  - Competence (in the EQF meaning responsibility and autonomy) [1].
- The curriculum framework must be such as to make it possible for MPE to move easily from one area of medical physics practice (i.e., Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology) to another, according to national and professional needs and with a minimum amount of additional education and training.

3. Qualification framework for the MPE in Europe
The proposal of the consortium regarding the qualification framework is shown in figure 1.

4. Curriculum framework for MPE programmes in Europe
The curricular framework consists of a structured inventory of LO derived from the key activities of the MPE (listed above) and is shown in figure 2. LO are classified into two categories: Generic and Subject Specific [7].

  - Generic LO consist of skills which are transferable across professions. They are further classified into the following three sub-categories [7]:
    - Instrumental skills - cognitive, methodological, technological, linguistic,
    - Interpersonal skills - individual abilities involving social and co-operative aspects,
• Systemic skills - involving combinations of understanding, sensibility and knowledge and usually involving prior acquisition of instrumental and interpersonal skills.

Figure 1. Proposed qualification framework for the MPE in Europe.

Subject Specific LO are those which are specific to a profession. These would be further classified into sub-categories as determined by the particular profession. The following classification is based on proposals by the EFOMP Board and Caruana [8-9]:

• Medical Physics Core KSC. These KSC are expected from all MPE in any area of medical physics practice as follows:
  o KSC appropriate for the MPE as physical scientist (fundamental physics and measurement KSC expected of all physical scientists),
  o KSC for the MPE as healthcare professional (KSC expected of all healthcare professionals),
  o KSC for the MPE as clinical medical devices / physical agents (including ionizing and non-ionizing radiation) expert, representing KSC common to all areas of medical physics practice and reflect the fact that medical physics services are targeted towards the optimised clinical use of medical devices and towards safety from physical agents in the various areas of medicine.

• Medical Physics Areas KSC. These sets of KSC are each highly specific to particular area/s of medical physics practice (i.e., Diagnostic and Interventional Radiology or Nuclear Medicine or Radiation Oncology) and therefore cannot be considered as core.

5. Learning outcomes for Nuclear Medicine
An inventory of LO for the MPE in nuclear medicine was developed by an international group chaired by Prof. A. del Guerra (University of Pisa, Italy). The group reflected on each of the key activities of
Medical Physics Services (listed above) as applied to Nuclear Medicine and derived corresponding LO. Nuclear Medicine LO, which were considered as common to the two other areas of MPE practice, were classified under the core ‘Medical Physics Core KSC’ grouping. Nuclear Medicine LO, which were highly specific to Nuclear Medicine, were classified under a separate Nuclear Medicine section in the ‘Medical Physics Areas KSC’ group. The resulting LO inventory is the most comprehensive yet developed. For illustration, table 1 shows the Core KSC for the key activity ‘Clinical Involvement’, common to the three areas of MPE practice, and table 2, the KSC for the key activity ‘Clinical Involvement’, which were highly specific to Nuclear Medicine.

6. Outcomes
The Qualification and Curriculum Frameworks have been made available for stakeholder comment on the project website. The website for the project is http://portal.ucm.es/web/medical-physics-expert-project.

Figure 2. Curriculum framework for MPE programmes in Europe.
Table 1. Core Knowledge-Skills-Competences (KSC) for the key activity ‘Clinical Involvement’ applicable to all areas of medical physics including nuclear medicine.

| Knowledge                                                                 | Skills                                                                 | Competences                                                                 |
|---------------------------------------------------------------------------|------------------------------------------------------------------------|----------------------------------------------------------------------------|
| K1. List and explain statutory and institutional requirements for Medical  | S1. Ability to participate in clinical discussions within multidisciplinary | C1. Take responsibility for statutory and institutional requirements for Medical |
| Physics Services in own area/s of medical physics practice with respect to Clinical Involvement. | teams in own area/s of medical physics practice. | Physics Services in own area/s of medical physics practice with respect to Clinical Involvement. |
| K2. Describe and explain the principles of anatomy, physiology, biology (including radiobiology), pathology as related to the main clinical applications in own area/s of medical physics practice. | S2. Design patient plans in own area/s of medical physics practice. | C2. Advise on the physics aspects impacting the clinical effectiveness and safety of new medical devices or techniques prior to their introduction into clinical practice. |
| K3. Describe trauma / development of diseases, diagnosis, treatment and follow-up relevant to own area/s of medical physics practice, including primary healthcare and screening programmes. | S3. Adhere to procedures regarding hygiene. | C3. Advise on and take responsibility for the evaluation and optimization of clinical procedures and protocols and risk elimination / reduction in own area/s of medical physics practice. |
| K4. Explain the International Classification of Diseases (ICD). | S4. Participate in patient preparation and positioning prior to data acquisition. | C4. Exercise the role of the medical physics expert in clinical involvement within own area/s of medical physics practice. |
| K5. Explain how medical devices/physical agents are used for the solution of clinical problems in own area/s of medical physics practice. | S5. Analyze critically protocol proposals in terms of feasibility, effectiveness and safety. | C5. Advise physician in imaging interpretation and quantification. |
| K6. Describe the clinical applications and target clinical outcomes of medical devices/physical agents in own area/s of medical physics practice. | S6. Define the limits of acceptability of clinical procedures. | C6. Take responsibility for deriving semi-quantitative and quantitative data for clinical application. |
| K7. Describe and explain clinical guidelines in own area/s of medical physics practice. | S7. Assess patient and operator risks for a given experimental procedure. | C7. Advise on different patient diagnosis / treatment schedule options. |
| K8. Describe the patient's perspective in clinical processes in own area/s of medical physics practice. | S8. Handle and analyze medical images including the extraction of parametric data / images. | C8. Advise on the most appropriate procedure with respect to risk/benefit ratio. |
| K9. Describe and explain protocol optimization principles in own area/s of medical physics practice. | S9. Set up devices, experiments and protocols for the measurement of physical variables relevant to clinical practice. | C9. Take responsibility for optimization of acquisition protocols in both standard and non-standard situations. |
| K10. Describe and explain the risk/benefit justification of procedures in own area/s of medical physics practice. | S10. Operate medical devices in own area/s of medical physics practice effectively and safely. | C10. Supervise procedures for paediatric investigations in relation to dose optimisation. |
| K11. Describe and explain the design principles, the relevant legislation issues and approval procedures for clinical trials. | S11. Recognize basic anatomical / pathological structures of the human body in projection / | C11. Advise other healthcare |
| K12. Explain the principles and implementation of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) in own area/s of medical physics practice. | | |
| K13. Describe general indications and contra-indications for the use of devices in own area/s of medical physics practice. | | |
| K14. Understand the nature of anatomical/ pathological medical images as the visualization of the 3D distribution of physical variables. | | |
K15. List the main sources of evidence from within the general physics, medical physics and general healthcare (e.g., the Cochrane Collaboration) literature essential for the carrying out of a systematic survey in own area/s of medical physics practice.

K16. Explain basic concepts in health informatics such as unique patient identifier, medical record and disease coding (e.g., ICD10).

K17. Explain safety and risk related issues associated with the use of ICT in own area/s of medical physics practice.

tomographic and 3D medical images relevant to own area/s of medical physics practice.

S12. Recognize basic physiological processes in nuclear / molecular images.

C12. Live up to demands imposed by duty of confidentiality, professional secrecy, ethical standards.

C13. Represent medical physics in clinical conferences.

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**Table 2. KSC for the key activity ‘Clinical Involvement’ specific to Nuclear Medicine.**

| Knowledge                                                                                           | Skills                                                                                           | Competences                                                                                      |
|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| K1. List statutory and institutional requirements for Medical Physics Services in Nuclear Medicine with respect to Clinical Involvement. | S1. Develop optimized imaging and therapeutic protocols.                                       | C1. Take responsibility for statutory and institutional requirements for Medical Physics Services in Nuclear Medicine with respect to Clinical Involvement. |
| K2. Describe the principles of anatomy, physiology, biology, radiobiology and pathology as related to the main clinical application of Nuclear Medicine diagnostic and therapeutic techniques. | S2. Design a treatment plan.                                                                 | C2. Advise Nuclear Medicine physicians in imaging interpretation and quantification.            |
| K3. Describe the general role of Nuclear Medicine procedures in diagnosis, therapy and treatment response evaluation. | S3. Show how Nuclear Medicine data are used in radiotherapy planning.                           | C3. Take responsibility for deriving semi-quantitative and quantitative data for clinical application. |
| K4. Explain how Nuclear Medicine devices are used for the solution of a clinical problem.         | S4. Analyze how molecular radiotherapy could impact on other treatment modalities.              | C4. Advise on different treatment schedule options.                                              |
| K5. Describe the principle of radiopharmaceutical preparation and associated quality control.     | S5. Analyze critically protocol proposal (i.e. feasibility, safety…).                           | C5. Advise on the most appropriate procedure with respect to risk/benefit ratio.                  |
| K6. Describe the principles of radiopharmaceutical biodistribution in normal organ and target tissues. | S6. Analyze the limits of acceptability of clinical Nuclear Medicine procedures.                | C6. Advise on and take responsibility for optimization of clinical acquisition protocols in both standard and non-standard situations. |
| K7. Describe the fundamentals of molecular radiotherapy.                                            | S7. Calculate patients and operators doses                                                        | C7. Supervise procedures for paediatric investigations.                                           |
| K8. Explain the fundamentals of the use of Nuclear Medicine procedures in EBRT planning.           |                                                                                                  | C8. Evaluate clinical trial protocols.                                                           |
| K9. Describe general indications and contra-indications for Nuclear Medicine procedures.           |                                                                                                  | C9. Share responsibility for conducting clinical trials.                                         |
| K10. Describe diagnostic and clinical procedure guidelines.                                       |                                                                                                  | C10. Advise on relevant aspects of ethical review of a clinical trial.                           |
| K11. Describe protocol optimization principles.                                                    |                                                                                                  | C11. Assume responsibility for data handling / recording.                                        |
| K12. Describe the risk/benefit justification of Nuclear Medicine diagnostic and therapeutic procedures as related to radiation exposure risk. |                                                                                                  |                                                                                                  |
| K13. Explain the interactions/synergism between chemotherapy, EBRT and molecular radiotherapy.    |                                                                                                  |                                                                                                  |
K14. Illustrate methodologies for the measurement of the lesions response to therapy.

K15. List laboratory and imaging procedures to evaluate organ toxicity.

K16. Illustrate dose limiting toxicity classification and quantification.

K17. Describe and explain the design principles, the relevant legislation issues and approval procedures for clinical trials in Nuclear Medicine.

C12. Advise on and take responsibility for the optimization of clinical protocols for Nuclear Medicine equipment including software.

C13. Support Nuclear Medicine staff with physical-technical guidelines.

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