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REVIEW PAPER

A review of international and developed practices of medical physics from a legislative and regulatory point of view and its applicability and comparison with Pakistan

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Abstract

The importance of the medical physics profession and medical physicists is widely recognized by the international bodies like ILO, IAEA, EC, etc. The description of a medical physicist's qualification framework, their role and responsibilities have been addressed in the legislative and regulatory frameworks of developed countries like the USA (in 10CFR) and the EC (EC RP 174) and less comprehensively in developing counties like Pakistan. AFOMP has contributed positively in various regulatory and policy matters regarding the medical physics practices in Asian countries. Furthermore, the recommendations of IAEA's regional meeting on "Medical Physics in Europe—Current Status and Future Perspective" in Vienna, 2015, address the need and mechanism of a harmonized framework for medical physicists' qualifications. The lack of a comprehensive professional recognition framework becomes more challenging when we see that hi-tech diagnostic (e.g. PET CT) and therapeutic (e.g. cyberknife, VMAT, tomotherapy, etc.) modalities are now available in many parts of the world, including Pakistan which still have a basic level of medical physics qualification and practices. Therefore, international efforts like the above-mentioned IAEA-EC meeting in 2015; and by AFOMP activities related to training, qualification and recognition of medical physicists can provide a pathway to further improve medical physics practices in the developing world. The objective of this review is to (i) summarize the international practices for the legislation and regulation of medical physics, (ii) provide a brief overview of the medical physics practices in Pakistan and (iii) discuss the applicability of the IAEA-EC meeting's recommendations to the case of Pakistan. The review highlights the areas which are addressed in IAEA-EC meeting and could be beneficial to other nations as well, particularly, for low and middle income countries. The review also presents few suggestions how to progress with the medical physics profession in developing countries in general, and in Pakistan in particular. These suggestions also include further possible pathway the IAEA could consider, like IAEA project or meetings, to further strengthen the medical physics profession globally.

Keywords Legislative and regulatory framework · Qualification and certification of medical physicists · IAEA recommendations

Introduction

Medical physics is the application of laws of physics in medicine and health related areas. Medical physicists are the professionals who apply the laws of physics in the domain of hospitals, allied health facilities, Research and Development (R&D) institutes, academic institutions, equipment design and manufacturing, consultation and advice, etc. Predominantly, the term of "medical physicist" is used for the physicist working in various disciplines of medicine such as radiology, nuclear medicine and radiotherapy where the protection of patients, workers and the environment is of particular concern. Since medical physics is a combination of

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pure and applied physics, medical and engineering aspects, this profession has been under focus of many international organizations like the International Atomic Energy Agency (IAEA) and the regulatory bodies of its member states. As a result of this, the international and national bodies have addressed the standards, progress and further need of improvement of medical physics profession more comprehensively in their high level documents like standards, regulations or guides. It is worth mentioning that such deliberations on a particular profession are not a common practice.

This paper briefly gathers and discusses the activities conducted by the international and regional bodies, the possible implementation of such activities like IAEA-European Commission meeting (IAEA-EC 2015) on Pakistan and possible suggestions for further improvement. The contents would be beneficial for readers who would like to study medical physics profession in the light of international, regional and national practices.

International recognition and standards regarding medical physics

The International Labour Organization (ILO) has set the definition of Medical Physics in the International Standard Classification of Occupations (ISCO-08) under the subgroup of "Physicists and Astronomers" [1]. The definition can be summarized as follows:

Medical physicists conduct R&D, develop theories, and apply knowledge and methodology of science of physics to all aspects of medicine. Their specialized tasks of medical physics include the following:

1. Ensuring safe and effective used of radiation for patients in diagnostic and therapeutic regimen;
2. Ensuring accurate measurement and characterization of physical quantities used in medical applications;
3. Testing, commissioning and evaluating equipment used in imaging, treatment and dosimetry in medicine;
4. Consultation with medical and other allied health professionals.

Another international standard, the International Atomic Energy Agency (IAEA) General Safety Requirements (GSR); Part-3 defines a medical physicist as "a health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the subfields (specialties) of medical physics" [2]. The subfields have been further elaborated as radiology, radiotherapy and nuclear medicine. Another specialty, radiation protection, is also considered to be included in the list of subfields or specialties. The IAEA Human Health Series (IHHS) Number 25 "Roles and responsibilities, and education and training requirements for clinically qualified medical physicists" was published in 2013 to present the findings of IAEA technical cooperation project "Strengthening Medical Physics in Radiation Medicine" for the cycle 2009–2013 [3]. Other international professional organizations such as the International Organization of Medical Physicists (IOMP), the American Association of Physicists in Medicine (AAPM) and the Asia–Oceania Federation of Organizations for Medical Physics (AFOMP) have collaborated in the IAEA project to enhance its usefulness, practicality and acceptance throughout the world. The IHHS 25 has been endorsed by the AAPM and IOMP. The IHHS 25 outlines the qualification framework of medical physicists, roles and responsibilities, staffing and ethics of medical physics practice [3].

The IAEA held the "International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade" in Bonn, Germany, in December 2012 in collaboration with the World Health Organization (WHO). The IAEA-WHO issued a joint position statement which outlines the priorities of radiation protection in medicine for the forthcoming decade. Action (8f) of the joint statement describes the strengthening of safety culture through recognition of medical physics as an independent profession in healthcare, with radiation protection responsibilities [4, 5].

The description of the medical physicist in the above mentioned international standards demonstrates the importance and significance of the profession, and its continuous growth will continue to increase in future. The importance of medical physicists originates from the fact that they have to ensure that no errors should arise in the imaging and radiation treatment of patients due to malfunctions or errors in the equipment, software or systems. As the technology becomes more sophisticated and complex, the profession of medical physics will face new challenges. As a result of this realization, the developed countries of the world like the USA and the European Union countries have regulated and ensured the competence of medical physicists. This includes setting up the basic academic qualification, training, residency, assessment, certification, recognition systems. The regulatory bodies and professional bodies of these countries have ensured that medical physicists must possess a high level of competence before working independently in medical facilities.

Regional practices in medical physics

In the USA, the Nuclear Regulatory Commission (NRC) has set the requirements of qualification of medical physicist in 10 CFR 35.51 [6], which includes a basic qualification, a residency program, specialty board certification, attestation, etc. Other professional bodies such as the AAPM, the

American Board of Medical Physicists (ABMP) and the American Board of Radiology (ABR) ensure that medical physicists in the USA maintain a high level of competence and are aware of ongoing technological advances [7–9].

In Europe, the "Council Directive 2013/59/Euratom" addresses; inter alia, the need for recognition of the profession and the roles and responsibilities of the medical physics expert (MPE) [10]. Furthermore, the European Guideline for MPE, EC-RP 174 discusses the roles and responsibilities, qualification and curriculum framework, recognition in Europe as well as the staffing levels [11]. Similar to the USA, Europe has a proven and demonstrated uniform structure for medical physics qualifications which is mainly composed of an academic degree, residency and recognition through certification or licensing [12].

Recognizing the need of such a study in Asia and Asia-Pacific Region, the IAEA initiated a project namely "Strengthening Medical Physics through Education and Training (RAS/6/038)" in 2003 under the Regional Cooperative Agreement (RCA) program of the IAEA [13]. Another IAEA-RCA project namely "Strengthening the Effectiveness and Extent of Medical Physics Education and Training, RAS6077" was initiated in 2014 [14]. The aim of this project was to enhance the capacity and capability of the medical physicists of the region by providing recommendations of education, training, certification and technical matters and IAEA conducted a number of activities like workshops, missions, reports, etc. [13, 14].

The recommendations of the project mainly addressed the aspects of certification, accreditation of medical physicists and medical physics education and trainings. The IAEA noted that medical physics needs are not always met in the region and further sustainable improvement was desired, possibly through better regional coordination. The IAEA also presented the results of a survey, conducted in 2014–2016, which contains information of radiotherapy facilities in the region. The data of some of the countries is presented in Table 1 for example [14].

The Table 1 shows population in million, existing number of therapy units, required number of therapy units, units per million population, existing number of medical physicists, required number of medical physicists and number of medical physicists per million population. It can be seen that any particular trend is hard to extract from the data. For example, in Australia, Japan and Korea, there are currently (i.e. during 2014–2016) 7.26, 7.98 and 4.6 therapy units for each million population, respectively. In contrast, countries like Bangladesh and Pakistan have identified that there are currently (i.e. during 2014–2016) 0.25 and 0.35 therapy units for each million population, respectively. Same goes true for the number of existing and required number of medical physicists. Hence, it is clear that the countries have used their own methodologies and policies for such estimations according to their need. However, we consider that there is a need to establish some detailed standards and guidelines in order to put in some uniformity in collecting and analyzing such data.

The difference of methodology is not restricted to data collection and analysis, but the qualification criteria available at regional and country level also differs appreciably. The qualification criteria of medical physicists in Pakistan, USA, Australia and Europe are given in Table 2 to illustrate this fact.

Due to prevailing differences between the medical physics profession in EC and Asian countries, the IAEA recommendations are grossly different for these two regions. For example, the IAEA-EC meeting considered a broader picture of medical physics profession like inclusion in the board of governance of hospitals, etc. Whereas, in case of Asian countries, the IAEA has recommended to put efforts on training, qualification, etc. of medical physicists.

However, we still consider that many of IAEA-EC meeting's recommendations like staffing level, further improvement in training, qualification, accreditation, involvement in governing board of hospital, etc. may also be applied on many Asian countries. The IAEA-Asian Countries collaboration can make it possible and highly effective.

Due to better economic and educational conditions, there is increased recognition of medical physics profession within Europe. This is evident from IAEA-EC

Table 1 Data of few countries mentioned in RAS6077 survey

Country	Population in million (2013)	Existing RT units	Required RT units	RT machines per million population	Existing number of MP	REq. number of MP	Number of MP per million population
Australia	23	167	153	7.26	248	345	10.78
Bangladesh	157	39	153	0.25	29	79	0.18
China	1357	2362	3832	1.74	2000	5392	1.47
India	1252	865	1269	0.69	1200	1757	0.96
Japan	127	1014	880	7.98	813	2381	6.4
Pakistan	182	63	185	0.35	80	123	0.44
South Korea	50	230	274	4.6	132	502	2.64

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Table 2 Comparison of Medical Physicists Qualification Criteria

Pakistan	USA [6]	Australia [15]	Europe [12]
Existing (The criterion is undergoing changes) MSc Physics plus 24 weeks on the job training or MS Medical Physics	10CFR 35.51(a) 1. Masters or doctoral degree in physics, medical physics, engineering, etc 2. 2 years full time experience 3. Qualify by examination by the specialty board which is also recognized by NRC. The board is American Board of Radiology (ABR) which performs assessment and registration of medical physicists OR 10CFR 35.51(b) 1. Masters or doctoral degree in physics, medical physics, engineering, etc 2. 1 year of full time training and 1 year of full time experience 3. Attestation from an authorized medical physicist State level licensure [16] A few states such as Florida and Texas award licenses to medical physicists.	1. Bachelor's degree in Physics, electronics, electrical, mechanical or biomedical engineering 2. Postgraduate degree in Medical Physics or equivalent 3. Should be on Register of Radiation Oncology Medical Physicists held by the Australasian College of Physical Scientists and Engineers in Medicine. OR have an equivalent level of training, skills, knowledge and expertise to a person listed on the ACPSEM Register of Radiation Oncology Medical Physicists as determined by the relevant regulatory authority [17]	1. Most of the countries accept a masters degree 2. On-the-job/training experience varies from 2 to 5 years 3. Recognition in the form of "diploma" or "License" is generally practiced

"Regional Meeting on Medical Physics in Europe: Current Status and Future Perspective" at Vienna in 2015. This meeting presented seven recommendations is the area of the independence of medical physics profession, competency framework, staffing level, allowing the medical physicists in Board of Governance, legal and regulatory framework, etc. [18, 19]. A greater detail of these recommendations is furnished in coming sessions.

Due to geopolitical considerations, such harmony and a unified system was less cumbersome for the USA and the EC to develop and adopt. Although large organizations like Asia-Oceania Federation of Organizations for Medical Physics (AFOMP) have provided a platform to the Asian countries for the improvement of medical physicist in the region, the situation is far different from the USA and the EC and most of the countries in Asia have developed their own qualification criteria for medical physicists [20]. Furthermore, unlike the EC, the Asian countries do not have any legal umbrella under which these countries establish their own framework. The professional bodies like AFOMP are able to provide suggestions for improvement.

The AFOMP is playing very effective role to provide mutual collaboration of scientific activities and platform for professional recognitions and standard practices in member countries in order to reduce the identified gaps. AFOMP has already developed the policy regarding license and certification, education & training, and continuous professional development of medical physicists in AFOMP countries [21, 22]. The recommendations provided by AFOMP are also compatible with guidelines provided by other international bodies like International Organization of Medical Physicists (IOMP) and International Medical Physics Certification Board (IMPCB) [23]. In addition to this, the IAEA-EC meeting (2015) also provides a comprehensive and systematic approach for the overall improvement of the medical physics profession [19].

Like many countries in Asia, Pakistan falls in lower-middle income countries of the world [24]. In the context of the USA and the EC, Pakistan is very interesting in view of the spectrum of radiotherapy facilities available for a country with such limited resources. Pakistan has a broad range of radiotherapy technologies, including dedicated stereotactic radiotherapy systems (the Gamma Knife and CyberKnife treatment systems), and conventional linear accelerators. The availability of these techniques makes Pakistan on par with the USA and Europe in terms of the availability (although scarce) of hi-tech radiotherapy modalities but other aspects such as expertise, qualification, R&D, etc., have not developed at the same pace. Warsi et al. [25] elaborated this sort of problem in Pakistan and this paper described the challenges being faced by Pakistan in occupational radiation protection aspects of high-tech radiotherapy modalities and

the paper was shortlisted in the rapporteur report due to its importance [26].

Medical physics practice in Pakistan

One of the objectives of this paper is to analyze the case of Pakistan in the light of international practices, particularly against the IAEA-EC Regional meeting held in Vienna in 2015. Furthermore, this paper will only discuss the radiotherapy facilities (particularly hi-tech modalities) and other facilities like nuclear medicine, cyclotron (PET/CT), radiology, academic sector, etc. would not be discussed. Brief country profile of Pakistan is given below:

1. As of December 2018, there were 87 medical centres having radiotherapy or nuclear medicine facilities with over 2600 radiation workers at these facilities [27];
2. There is one "CyberKnife", one "Gamma Knife" and several "conventional linear accelerators" based facilities respectively;
3. Pakistan Institute of Engineering and Applied Sciences (PIEAS) is the only university which offers MS program in Medical Physics in Pakistan which started in 2001. An average of 12–14 graduates passes out from PIEAS on annual basis;
4. PIEAS uses IAEA guidelines for the development of curriculum and the curriculum covers all major areas of medical physics: radiotherapy, nuclear medicine, radiology and radiation protection. This is a two year graduate program which is composed of class session, lab experiments, thesis and clinical attachments at a medical centre having facilities of radiotherapy and nuclear medicine [28].
5. There is no specific journal of medical physics in the country. The research on medical physics or radiation medicine related topics is either published abroad or in local journals, including Pakistan Journal of Radiology, Pakistan Journal of Nuclear Medicine and the Nucleus.
6. A number of training courses have been conducted in Pakistan under the umbrella of Pakistan Nuclear Regulatory Authority (PNRA), the Pakistan Atomic Energy Commission, the Pakistan Organization of Medical Physicists (POMP) and various hospitals like Aga Khan Hospital and Shoukat Khanum Memorial Cancer Hospital. The study conducted by Nosheen et al. shows that improvement can be observed due to such training courses [29].
7. The National Institute of Safety and Security (NISAS) works under the PNRA to facilitate training in specialized areas like QA in imaging and therapy, radiation protection, emergency preparedness, waste management in nuclear medicine, etc. [27]
8. Almost all of the PIEAS graduates of Medical Physics join radiotherapy centres of Pakistan Atomic Energy Commission (PAEC) which is a public sector organization and bears major load, i.e. about 80% of the country's radiotherapy load [30].
9. A private hospital, namely the Aga Khan University Hospital (AKU), Karachi have radiotherapy, radiology and nuclear medicine facility. The AKU is a Joint Commission of International Accreditation (JCIA) accredited centre and it provides 2 year structured training and education to newly recruited junior medical physicists. Many of these medical physicists join other medical centres and provide useful services [31]

The PNRA has established qualification criteria for medical physicists in Pakistan which was earlier mentioned (see Table 2). Even with a cursory review, one can immediately identify the differences between the local and international standards in medical physics criteria for qualification and training. One would also appreciate that, in the absence of a systematic approach, the qualification criteria will have only a limited contribution in operation and radiation protection.

Being a member state of the IAEA and member of AFOMP, Pakistan is also on its pathway to establish the medical physics certification system.

Applicability of IAEA-EC recommendations in case of Pakistan

As mentioned in the Table 1 and IAEA RCA recommendations, Pakistan needs capacity building of medical physics profession, yet it has already acquired some hi-tech modalities and their number is likely to increase in future. Therefore, merely qualification and training will not serve the purpose of overall improvement in the profession. Therefore, IAEA-EC recommendations like certification, accreditation, involvement in governing board of hospital, etc. can provide a pathway and practical framework to further improve the medical physics profession in Pakistan or any other country.

These criteria and the current medical physics practice in Pakistan are compared in the light of IAEA-EC meeting recommendations as per the following:

Recognising medical physics as an independent profession

In Pakistan, the medical physicists are recognized as specialist professionals. As far as the legal basis is concerned, the PNRA has set the qualification criteria for medical physicists in Pakistan as mentioned in Table 1. The Regulations on Radiation Protection (PAK/904) requires that for therapeutic

uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of these regulations are conducted by or under the supervision of a qualified expert in radiotherapy physics. The Annexure of these regulations indicates that an MSc Medical Physics is the required academic qualification for radiation protection officers in radiotherapy facilities. So, there is a regulatory requirement in Pakistan to have a medical physicist in a facility for operational and radiation protection purposes [32].

Ensure that medical physics related activities are performed by qualified medical physicists

The existing regulations briefly describe the job assignment of medical physicists but there is no formal document available in Pakistan with defines such roles and responsibilities in detail as per international practice mentioned in IHHS 25 and the European Guidelines EC RP 174 [3, 11]. It is important to note that the sub-specialties of medical physics i.e. radiotherapy, nuclear medicine, radiology and radiation protection are not practiced separately in Pakistan. Due to less number of medical physicist a medical physicist in Pakistan is generally assumed to perform all tasks in a medical facility. So, there is a fundamental difference between international practice and Pakistan.

In the absence of sub-specialized fields it has been observed that a single medical physicist in Pakistan may have radiation oncology, nuclear medicine and radiation protection responsibilities. In many cases these medical physicists have obtained regular physics degree, instead of a specialized medical physics degree and they learn routine operation during their jobs. Therefore, there is not only a need of enhancing the qualification standard but also introduce sub-specialization at some stage.

Establish an appropriate qualification framework for medical physicists

Although the qualification (academic and residency) of medical physicists is established in Pakistan, there have been fundamental differences as mentioned below:

- The criteria set by USNRC and EC are far more detailed and comprehensive which is commensurate with the technical needs of medical physicists;
- A formal and structured residency program is mandatory in USA and Europe. The residency is addressed very briefly in case of Pakistan;
- Accreditation in terms of board certification or licensure is practiced in the USA and Europe but not in Pakistan;
- In addition to this, the IAEA GSR Part 3 states under the definition of medical physicist that "Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g. diagnostic radiology, radiation therapy, and nuclear medicine). States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical physicist and to decide, on the basis of either international accreditation standards or standards of a State where such an accreditation system exists, whether such an individual could undertake the functions of a medical physicist, within the required specialty". It is evident that the medical physics profession in Pakistan needs major improvement in the light of international practices.

Follow and fulfil the international recommendations regarding staffing levels in medical physics

IHHS 25 and EC 174C have addressed the issue of staffing levels in medical physics. Evans et al. [33] have presented quantitative assessment of staffing level of medical physicists in radiotherapy facility in European countries. Currently, no such staffing scheme for medical physicists exists in Pakistan. It has also been mentioned earlier that a medical physicist in Pakistan has to work, generally, in all areas like nuclear medicine, radiology, radiotherapy, radiation protection and even cyclotron operation. Therefore, such a staffing scheme is not only complex to develop and also challenging to implement.

Establish a mechanism for independent medical physics departments

In Pakistan, medical physicists enjoy the freedom to exercise their expertise and experience. Large institutes have proper head of the medical physics group and roles and responsibilities are generally well defined. A formal mechanism guaranteeing independence, however, is not addressed in any regulatory document.

Promote the involvement of MPEs in hospital governance boards

The IAEA-EC recommends having medical physicists in the board of governance in hospitals to make them on par with the management, physicians, etc. A medical physicist plays a pivotal role in deciding the selection of equipment related to radiation protection of workers, public and patients. In Pakistan, the clinical medical physicists are consulted before purchasing equipment although they are not the usually part of any board of governance. Incidentally, in Pakistan medical physicists are far less experienced in hi-tech modalities such

as cyberknife and gamma knife than the available physicians. The only degree program in medical physics was started in PIEAS in 2001 so its graduates are fairly young. This situation and the overall dominance of physicians in the hospital environment discourages the medical physicists, in general, from being part of the high-level decision making board.

Establish and enforce the legislative and regulative requirements

IAEA GSR Part 3 repeatedly addresses the need of medical physicists in radiation medicine practice. Pakistan is in the process of revising the previous safety standards as per new IAEA GSR Part 3. If the GSR Part 3 effectively becomes the part of national regulatory framework, it will serve the medical physics profession in Pakistan as well. Currently, the medical physics profession in Pakistan is in developing phase.

Conclusion

Pakistan has high-tech radiotherapy modalities but on the other hand, the medical physics profession in Pakistan is still in developing phase. There is a qualification criterion in place but a system of formal certification or licensing of medical physicists in Pakistan is not established. Tables 1 and 2 presented the overall picture of medical physics profession and availability of facilities in various developed and developing countries. This situation may result in challenges in effective operational and safety related aspects. Just as Warsi et al. [22] describes occupation protection in hi-tech modalities, this paper deals with the qualification framework and recognition of medical physics professionals in Pakistan. It is clear that countries having suboptimal systems for qualification and training will face additional challenges if they acquire high-tech modalities. Although, customized and specialized training can fill the gap in the short term, the need for a systematic approach is essential for a sustainable radiation protection system.

We also consider that an IAEA-Asian Countries project regarding the improvement of medical physics profession in Asia and Asia Pacific Region is the need of the day. Such project may address and include that rationalization of number of medical physicists and radiotherapy units against the population and number of cancer incidents. This "rationalization" may include the recommended number of medical physicists, their qualification, treatment units, etc. on some criteria (for example population or cancer incidents). Considering the importance and depth of this issue, IAEA may consider to include these findings and recommendations in the standard documents (i.e. Guides) so that regulatory bodies of member states may use these recommendations in their regulatory documents. A regulatory document would be a much powerful instrument in this regard.

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Compliance with ethical standards

Conflict of interest Mishkat Ali Jafri, Salman Farrukh, Nasir Ilyas, Sajjad Memon declares that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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