# **Global Program for Certification of Local Clinical Engineers: Back to the Future**

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Abstract—For some, Clinical Engineering (CE) profession is relatively a new profession but, according to the recent data, it is part of the fastest growing community of expanding professions that make up healthcare workforce in current decade. The Clinical Engineering Division of the International Federation for Medical and Biological Engineering (CED/ IFMBE) has initiated a project that included a global survey of CE certification programs. The purpose of this project was to gather, analyze and synthesize available information to determine the need and the model for establishing an international program for certification in CE. In simple words, certification is issuing the document of completion or qualification, accreditation is like certification of the certification body, registration is recording or registering the certificates, and licensing is issuing a permission to do something that otherwise is forbidden.

In that context, an e-letter on behalf of the CED/ IFMBE was sent to (1) affiliated National Societies of the IFMBE, (2) members of the Yahoo! Group - CED Global, Clinical Engineering Division, and (3) all CED/ IFMBE Board members. It has been estimated that survey requests were sent to approximately 200 e-mail addresses in about 50 countries.

Only a few e-mails were reported by e-mail server software as undeliverable. So far, information has been received from 18 countries, resulting in a survey's response rate of more than one-third. The certification in CE appears to exist in 6 out of those 18 countries. In 2 countries there is an explicit legal framework i.e. acts on biomedical/clinical engineering, including the scheme for mandatory professional certification. In additional 4 countries the certification in CE exists on a voluntary basis.

Global CE community in the 21st century needs and deserves an international CE certification programme to come finally into life.

*Keywords*—certification, clinical engineering, health worker, legislation, occupation.

### I. INTRODUCTION

Clinical biomedical engineering profession i.e. clinical engineer (CE) is for many people still relatively new profession, but it is projected as one of the fastest growing occupations in the current decade [1]. According to the latest International Standard Classification of Occupations of the International Labour Organization, a number of such 'upcoming' professions are clearly considered to be a part of the health work force. Apart from 'usual' health professionals (medical doctors, nursing and midwifery professionals, traditional and complementary medicine professionals, paramedical practitioners, veterinarians, etc.), such occupations include but are not restricted to biomedical engineers and medical physicists as well [2]. Similar considerations of clinical qualified professionals for physical and technical jobs have been or are supposed to be explicitly promoted through publications of the World Health Organization, International Atomic Energy Agency, European Union and other international authorities [3-5]. Thus, it stands to reason that formal career paths of clinical engineers or medical physicists should be demanding similar, if not the same, as career paths of other health professionals with commensurate duration or level of basic (university) education, as for example of medical doctors, medical biochemists, pharmacists, etc. Despite this recent encouraging news, it appears that there is a slow embracement by national healthcare systems in many countries to fully recognize, regulate and integrate clinical engineers. Although the world of sophisticated healthcare technologies substantially depends on the application of engineering within the clinical environment, in many ILO-, WHO-, IAEA- and EU-member states there is actually no legal framework for clinical engineering profession. So, clinical engineers and medical physicists, like brothers in arms in everyday practice and during the joint world congresses of medical physics and biomedical engineering, continue struggling for better perception, recognition, regulation and integration of their professions [6-14]. Well-defined specific qualifications and experience in clinical practice are necessary requirements for those interested to actively participate in the field of clinical engineering. Such qualifications and experience should be subject to certification, otherwise anybody could claim to be a CE or a clinical engineering practitioner and take part in responsibility for the healthcare technology and patients in a hospital without the need for certification, i.e. without a proof of the necessary qualifications and skills. Therefore, one of the professional milestones is certainly the establishment of certification program(s), because the purpose of certification is to promote healthcare delivery improvement nation- and world-wide through the certification and continuing assessment of competency of professionals who support and advance patient care by applying engineering and management skills to healthcare technology.

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The Clinical Engineering Division of the International Federation for Medical and Biological Engineering (CED/IFMBE) is dedicated, among other goals, to the advancement of international guidelines for professional education, professional development and certification in CE, and to the advancement of the CE role in the institutional frameworks of healthcare policy, strategy, planning, and worldwide. Therefore, in management 2010 the CED/IFMBE has initiated a project to examine global status of CE professional recognition that included a global survey of CE certification programs. The main purpose of this effort was to gather, analyze and synthesize all available information in order to determine the need and the model for establishing an international program for certification in CE. The main goal of the project is to provide recognition for meeting benchmarks, a certificate - as a formal document issued by a global awarding body, which records the achievements of candidate following an assessment and validation against a predefined standard.

The objective of this paper is to present current status of the CED/IFMBE activities towards international program for clinical engineering certification (CEC).

### **II. MATERIALS AND METHODS**

Since people may confuse the terms like accreditation, certification, licensing or registration in the professional context, it may be worth knowing that there are differences and what those differences are. For example, a certification is a 'third-party attestation related to ... persons', as defined by ISO/IEC (International Organization for Standardization/International Electrotechnical Commission). Thus, certification is the process of issuing a certificate, diploma or title formally attesting that a knowledge, know-how, skills and/or competences acquired by an individual have been assessed and validated by a competent body against a predefined standard. Accreditation is a 'third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks' as defined by ISO/IEC. Accreditation is a process of quality assurance through which accredited status is granted, showing it has been approved by the relevant legislative or professional authorities by having met predetermined standards. In simple words, certification is issuing the document of completion, qualifications or experience, accreditation is like certification of the certification body, registration is recording or registering certificates, and licensing is issuing a permission to do something that otherwise is forbidden.

In that context, an e-letter on behalf of the CED/IFMBE was sent to Affiliated National Societies of the IFMBE (using contact data at http://ifmbe.org/members/ members\_directory/ and at http://who.ceb.unicamp.br/), to the

members of the Yahoo! Group CEDGlobal - CED Global, Clinical Engineering Division (http:// health.groups. yahoo.com/group/CEDGlobal/), and to all CED/IFMBE Board Members in June/October 2010. The e-letter was kindly asking recipients to try to provide as much as possible information (criteria, procedures, titles, legislation, documents, links...) on any attempted or established national or international program for certification in clinical engineering. Further information on certification in other clinical sciences or for other professionals within healthcare system was also asked for and expected to be very useful. The final reminders were sent again in November 2010. It has appeared that a survey request was sent to approximately 200 e-mail addresses in about 50 countries.

### III. RESULTS

Only a few e-mails were reported by e-mail server software as undeliverable. So far, the information has been received from 18 countries (Argentina, Australia, Austria, Brazil, Canada, Chinese Taipei/Taiwan, Croatia, Czech Republic, Greece, Italy, Japan, Netherlands, Nigeria, Singapore, South Africa, Sweden, Ukraine and United States), resulting in a survey's response rate of 36%. The certification in clinical engineering appears to exists in 6 (Canada, Chinese Taipei/Taiwan Czech Republic, Japan, Sweden, USA) out of 18 countries. In 2 countries (Czech Republic, Japan) there is an explicit legal framework i.e. acts on biomedical/clinical engineering, including the scheme for mandatory professional certification. In other 4 countries (Canada, Chinese Taipei/Taiwan, Sweden, USA) the certification in clinical engineering exists on a voluntary basis.

## IV. DISCUSSION

Currently, CED/IFMBE is still exploring and discussing all aspects of the whole process of CEC: eligibility requirements (education, practice, job content), administration, application procedure (resume, references, transcripts, fees), grandfathering (national/regional Board of Examiners), preparation (study materials. literature availability/accessibility), examination (written, oral, language), levels of certification (clinical engineer, clinical engineering expert), certificate attainment, renewal and revocation, etc. International programs for CEC are likely to be administered regionally by a regional Board of Examiners and certainly have to be adjusted to acknowledge and respect cultural and professional differences in the distribution of the information in the clinical engineering body of knowledge required by regional groups of clinical engineers to function in their day to day job. So far, the certification in clinical engineering by the Healthcare Technology Certification Commission Program sponsored by the Healthcare

Technology Foundation and with the examination conducted by the US Board of Examiners for Clinical Engineering Certification appears to be probably the most advanced and elaborated program having already an international capacity [15].

Within the excellent European BIOMEDEA project, protocols for the Europe-wide harmonized accreditation of biomedical and clinical engineering programs, training of clinical engineers, continuing education, and the certification of clinical engineers have been developed. Also, a management structure for the European Clinical Engineering Certification Protocols has been worked out which is also applicable to the global development of clinical engineering as a regulated healthcare profession. In a next step the various BIOMEDEA protocols have been expected to be presented to the European national IFMBE member societies for adoption. However, practical real-life outcomes and impact on CE regulation Europe-wide are still unclear [6,16].

Finally, it is noteworthy to take a look more than thirty years back and to remind on the document entitled 'Agreement on Mutual Recognition of Qualifications for Clinical Engineers', where 22 affiliated National Societies of the IFMBE (Austria, Australia, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, German Democratic Republic, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Norway, Spain, South Africa, Sweden, United Kingdom, USA, Yugoslavia) mutually agreed in 1981 to recognize any holder of the IFMBE's certificate of registration as a clinical engineer. Formally, the agreement seems to be still in place, but since certification and registration have never been made mandatory by national legislations in most of the countries, the agreement has been neglected [17].

## V. CONCLUSIONS

We all need to make every effort to demonstrate more clearly and timely to policy makers and the public, but in particular to national governments, all the benefits derived from well trained health professionals who achieved and sustain mastering of the defined body of knowledge. A formal career path and opportunities in clinical engineering should be similar to those of other university-degree health professionals. Clinical engineers around the globe desperately need and deserve international professional certification program to come into life as soon as possible, in order to help to tread the path towards full perception, recognition, regulation and integration of clinical engineering professionals in healthcare systems of many countries. Primarily for the benefit of patients, WHO, IAEA, IFMBE, IOMP, IUPESM and other international organizations and authorities should work more intensively on developing the most efficient mechanisms of urging, pleading and reminding all national governments of the member-states to adopt systems of clinical quality assurance, control and safety and to make certifications within the whole health workforce mandatory.

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### REFERENCES

- 1. US Department of Labor, Bureau of Labor Statistics at http://www.bls.gov/ooh/About/Projections-Overview.htm
- International Standard Classification of Occupations ISCO-08 Volume I (2012) at http://www.ilo.org/wcmsp5/groups/public/--dgreports/---dcomm/--publ/documents/publication/wcms\_172572.pdf
- International Atomic Energy Agency (2011). Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards: General Safety Requirements - Interim Edition. IAEA, Vienna at http://www-pub.iaea.org/MTCD/Publications/PDF/p1531interim \_web . pdf.
- 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. Official Journal of the European Communities; 1996; 39: No L-159, p1.
- Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Official Journal of the European Communities; 1997; 22: No L-180, p.5
- Nagel JH (2010) The regulation of the clinical engineering profession as an important contribution to quality assurance in health care. IFMBE Proc. vol. 25, World Congress on Med. Phys. & Biomed. Eng., Munich, Germany, 2009, pp 376-378
- Lhotská L, Cmíral J (2010). Accreditation and certification in biomedical engineering in the Czech Republic. IFMBE Proc. vol. 25, World Congress on Med. Phys. & Biomed. Eng., Munich, Germany, 2009, pp 372-375
- Ask P, Pettersson NE, Andersson K (2010). Certification of clinical engineers in Sweden. IFMBE Proc. vol. 25, World Congress on Med. Phys. & Biomed. Eng., Munich, Germany, 2009, pp 430-431
- Khambete ND (2010) Biomedical engineering education and training in India - a need for new approach. IFMBE Proc. vol. 25, World Congress on Med. Phys. & Biomed. Eng., Munich, Germany, 2009, pp3 68–371
- Medvedee M (2012). Current legal framework for biomedical engineering profession in Croatia. IFMBE Proc. vol. 37, 5th European IFMBE Conference, Budapest, Hungary, 2011, pp 1404-1407

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- Geoghegan DS, Stefanoyiannis AP, Christofides S et al. (2013) The international context of education, training and certification for medical physicists in Europe, North America and Australasia. IFMBE Proc. vol. 39, World Congress on Med. Phys. & Biomed. Eng., Beijing, China, 2012, pp 2260–2263
- Oliver LD (2013) International medical physics certification: but what else is needed for international acceptance?. IFMBE Proc. vol. 39, World Congress on Med. Phys. & Biomed. Eng., Beijing, China, 2012, pp 1679–1682
- Ravindran PB (2013) Medical Physics Certification in India. IFMBE Proc. vol. 39, World Congress on Med. Phys. & Biomed. Eng., Beijing, China, 2012, pp 1676–1678
- Wu RK (2010) Creating an independent international medical physics board. IFMBE Proc. vol. 25, World Congress on Med. Phys. & Biomed. Eng., Munich, Germany, 2009, pp 68–70

- 15. Healthcare Technology Foundation HTC at http://www.thehtf.org/certification.asp
- 16. BIOMEDEA at http://www.biomedea.org
- International Federation for Medical and Biological Engineering (1981) The IFMBE international register of clinical engineers -Agreement on mutual recognition of qualifications for clinical engineers at http://www.biomedea.org/Documents/IFMBE%20Int%20Reg %20Stuttgart.pdf
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