

# IFMBE/Clinical Engineering Division projects for the advancement of the profession of Clinical Engineering

E. Iadanza

Department of Information Engineering, University of Florence, Florence, Italy  
Chairman, Clinical Engineering Division of IFMBE

**Abstract**— The IFMBE/CED has been conducting, in the past years, a project aimed to know and understand the current programs for registration and certification of clinical engineers in the whole world. A similar project has been designed and budgeted in the CED action plan for the triennium 2016-2018. One of the key issues for arriving to a worldwide guideline is having a common glossary of definitions. As a result of the first Global Clinical Engineering summit, a document has been outlined to define what are the main activities describing Biomedical Engineers and Clinical Engineers. The main purpose of this document is inserting the Biomedical Engineering and Clinical Engineering professions in the forthcoming ILO International Standard Classification of Occupations (ISCO-2018). This will be a milestone for every current and future programs of professional certification, since it will give a clear worldwide reference. One other important project is the International Forum of Clinical Engineering Societies, aimed to discuss regional but also common problems among the participants, identifying the possibility of exchange of experiences not only among the societies but also among experts worldwide. The other project that is closely connected to those above-mentioned is the definition of both a Body of Knowledge (BoK) and a Body of Practice (BoP) for Clinical Engineering. The results of this ongoing project, which at the moment involves taking online questionnaires to hundreds of clinical engineers worldwide, will form the basis for the definition of the forthcoming IFMBE/CED white paper for the assessment and design of certification and registration programs.

**Keywords**— Clinical Engineering, Registration, Certification, IFMBE, CED

## I. INTRODUCTION

The International Federation for Medical and Biological Engineering (IFMBE) is the only international professional federation that has a Clinical Engineering Division (IFMBE/CED) focusing specifically on the life cycle management of healthcare technology and embracing all those who professionally practice in the clinical engineering field, whether in academic institutions, health care facilities, industry, business, voluntary sector, or government. [1]

Some of the goals of IFMBE are very much related to the recognition of the Clinical Engineering profession worldwide:

- to promote the development of the medical and biological engineering profession, and the recognition and awareness of the profession by the public
- to advance collaboration between national and transnational societies, industry, government and non-governmental organizations engaged in health care and in biomedical research and its applications.
- to recommend policies and provide guidelines in appropriate professional, educational and ethical areas.
- to enable IFMBE to achieve its goals effectively, optimize the organizational structure and communication and enhance its finances.

## II. THE CERTIFICATION/REGISTRATION PROJECT

The IFMBE/CED has been conducting, in the past years, a project aimed to know and understand the current programs for registration and certification of clinical engineers in the whole world. A similar project has been designed and budgeted in the CED action plan for the triennium 2016-2018. The project is focused on pursuing the following CED mission statements [2]:

- to define and promote an international body of knowledge, skills and competencies on which the profession of CE can be practiced in various clinical settings
- to promote global communication, networking, and understanding of challenges related to HTM
- to advance & disseminate worldwide safety tools and effective decision-making processes within HTM system

- to define and promote quality standards in CE practices worldwide
- to stimulate innovation and efficient use of technology-related resources in healthcare worldwide
- to internationally represent and advocate the interests of the profession of CEs and their global exchange

The aims of such a complex project are various:

- developing guidelines for certification/registration programs based on IFMBE previous guidelines and existing programs. These guidelines could mainly be used for assessment and guidance
- A better knowledge of existing clinical engineering certification/registration programs by posting the programs on the CED website with contact information and where possible engineers certified
- Providing information and aid for the development of new clinical engineering certification/registration programs.
- Exploring the potential for clinical engineers to become certified that live in countries/regions with no existing certification program.

This project, in continuity with the previous one lead by Mario Medvedec and James Wear (CED board members 2012-15), involves today CED many board elected and co-opted members. The project leaders today are James Wear and Zhou Dan. Other project team members are (in alphabetical order): Saide Calil, Ernesto Iadanza, Mario Medvedec, Herbert Voigt and Ewa Zalewska.

### III. THE METHOD

One of the key issues for arriving to a worldwide guideline is having a common glossary of definitions. A first exchange of ideas has shown that in different countries the words “registration” and “certification” are used with different meanings (not to mention “qualification”, “accreditation” and others). This is partly due - aside from the linguistic differences - to different regulatory and legislative frameworks. In some countries the certifications to professionals can be only given by universities or state agencies and have a legal value, while in some others the certification bodies can be for example private associations of professionals.

To complicate more the situation, there is still a confusion between the terms “Biomedical Engineer” and “Clinical Engineer”. In some countries the first term is often used also for professionals who perform health technology management,

while in others there is a clear distinction between the two terms.



Fig. 1 Global Clinical Engineering Summit (Hangzhou, China, Oct 23 2015)

At the first Global Clinical Engineering Summit (Hangzhou, China, Oct 23 2015, event chaired by Dr. Yadin David, CED coopted member and past-chairman) 36 representatives from national and international societies convened to discuss also the above-mentioned topics (see Fig. 1). The purpose of the summit was to review various country approaches for:

- Clinical Engineering (CE), Biomedical Engineer (BME), & Health Technology Management (HTM) Definitions & Job Roles / Body of Practice (BoP)
- Value proposition and CE Recognition, including International Labor Organization (ILO) recognition of BME in 2018.
- CE Education (levels and content) Body of Knowledge (BoK)
- CE Certification (local and global)
- CE Licensing and Registration
- CE Education Accreditation
- CE Regulation [3]

As a result of that summit, a document has been outlined to define what are the main activities describing Biomedical Engineers and Clinical Engineers. This document, reviewed together with Adriana Velasquez Berumen from (World Health Organization - Medical Devices Policy Access and Use), has been presented in December 2015 to the International Labor Organization (ILO) and will be discussed in May 2017 during a workshop at the WHO Third Global Forum on Medical Devices.

The main purpose of this document is inserting the Biomedical Engineering and Clinical Engineering professions in the forthcoming ILO International Standard Classification of Occupations (ISCO-2018). This will be a milestone for every current and future programs of professional certification, since it will give a clear worldwide reference.

Health care technologies include: health, wellness and rehabilitation products and systems, artificial biological structures, organs, and prostheses, instrumentation, software and multi-technology systems.

## Subtopics of BME

<ul style="list-style-type: none"> <li>• <b>Research and development</b> <ul style="list-style-type: none"> <li>– Biomechanics</li> <li>– Biomaterials</li> <li>– Bioinformatics</li> <li>– Systems biology</li> <li>– Synthetic biology</li> <li>– Bionics</li> <li>– Biological engineering</li> <li>– Nanotechnology</li> <li>– Genomics</li> <li>– Population health / data analytics</li> <li>– Epidemiology (computational)</li> <li>– Intellectual property/innovation</li> <li>– Theranostics</li> <li>– Biosignals</li> </ul> </li>   <li>• <b>Rehabilitation</b> <ul style="list-style-type: none"> <li>– Artificial organs</li> <li>– Neural engineering</li> <li>– Tissue engineering /regenerative</li> <li>– Mechatronics</li> <li>– Assistive devices and software</li> <li>– Prosthetics</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>c) <b>Application and operation: Clinical Engineering</b> <ul style="list-style-type: none"> <li>○ Technology management</li> <li>○ Quality and regulatory assurance</li> <li>○ Education and training</li> <li>○ Ethics committee, clinical trials</li> <li>○ Disaster preparedness</li> <li>○ e-health ( telemedicine, m- health)</li> <li>○ Wearable sensors/products</li> <li>○ Health economics</li> <li>○ Health Systems engineering</li> <li>○ Health technology assessment/evaluation</li> <li>○ Health informatics</li> <li>○ Service Delivery Management</li> <li>○ Field Service support</li> <li>○ Security / privacy / cybersecurity</li> <li>○ Forensic engineering/investigation</li> <li>○ Manufacturing QMS, GMP</li> <li>○ Medical imaging</li> <li>○ Project Management</li> <li>○ Robotics</li> <li>○ Virtual environments</li> <li>○ Risk management</li> <li>○ EMI/EMC compliance</li> <li>○ Technology Innovation strategies</li> <li>○ Population- and community-based needs assessment</li> <li>○ Engineering Asset Management</li> <li>○ Environmental health</li> <li>○ Systems science</li> </ul> </li> </ul>
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Fig. 2 Subtopics of Biomedical Engineering

An extract of this document, highlighting the subtopics of biomedical engineering, is reported in Figure 2.

In October 21, 2016, the IFMBE/CED contributed to host the first Global Clinical Engineering Day, a worldwide event that included online events and webinars from twelve different countries from every continent. Hundreds of Clinical Engineers from the four corners of the planet had the opportunity to discuss about different topics, including issues about

registration and certification programs in their countries. Recordings of all the meetings are accessible at <http://global.icehtmc.com/> [4]

#### IV. CONCLUSIONS

The above described IFMBE/CED project on CE registration and certification is deeply linked to a few other projects of the CE Division. In particular, two other projects, both lead

by Prof. Saide Calil, CED board member and past chairman, are worth being cited here. The first one is the International Forum of Clinical Engineering Societies, aimed to discuss regional but also common problems among the participants, identifying the possibility of exchange of experiences not only among the societies but also among experts worldwide. The first forum has been held in Toronto, Canada, during the last IUPESM Word Conference (WC2015, May 2015), the next will probably take place in San Paolo, Brazil, next September 2017, in occasion of the Second International Conference on Clinical Engineering and Health Technology Management (ICHTM2017) [5].

The other project that is closely connected to those above-mentioned is the definition of both a Body of Knowledge (BoK) and a Body of Practice (BoP) for Clinical Engineering. The results of this ongoing project, which at the moment involves taking online questionnaires to hundreds of clinical engineers worldwide, will form the basis for the definition of the forthcoming IFMBE/CED white paper for the assessment and design of certification and registration programs.

## CONFLICT OF INTEREST

The author declares that he has no conflict of interest.

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4. Global Clinical Engineering website at <http://global.icehtmc.com/>
5. International Clinical Engineering and Health Technology Management Congress – ICEHTMC at <http://www.icehtmc.com/>

Corresponding author:

Author: Ernesto Iadanza  
Institute: Department of Information Engineering, University of Florence – IFMBE/Clinical Engineering Division Chairman  
Street: via di Santa Marta, 3  
City: Firenze  
Country: Italy  
Email: [ernesto.iadanza@unifi.it](mailto:ernesto.iadanza@unifi.it)