Clinical Engineering Certification and Education in Italy

Ernesto Iadanza

Department of Information Engineering, University of Florence, Italy

Abstract— **The purpose of certification is to promote health and patient safety through the certification and continuous assessment of the skills of professional engineers who work in health care by applying engineering expertise to the care and management of patients. In Italy it is currently in progress a process of defining common rules for recognizing the figures of biomedical and clinical engineer and for the certification of the skills of engineers. This process is the result of collaboration between the committees of biomedical engineering of the territorial Associations of Professional Engineers, a national group of coordination of such committees, and the National Council of Engineers.**

Keywords— **Clinical Engineering, Certification, Education.**

I. INTRODUCTION

The purpose of certification is to promote health and patient safety through the certification and continuous assessment of the skills of professional engineers who work in health care by applying engineering expertise to the care and management of patients.

The certification process of a clinical engineer generally includes:

- Establishing and measuring the level of knowledge required for certification as a clinical engineer
- Providing the standard knowledge requirements for the certification
- Assisting managers of health facilities in the assessment of clinical engineers
- Providing the criteria for eligibility
- Examining clinical engineers
- Requiring continuing education and professional growth in professional practice to maintain certification. [1]

In Italy the Associations of Professional Engineers have the crucial task of protecting the citizens, about the professional services that, being intellectual, are not always evaluated according to strict regulatory standards. They also have the task of ensuring the quality of services provided and the reasonableness of the applied fees. At European level the professions are governed by the Directive 2005/36/EC. [2]

In all the countries where they exist, the Associations of Professional Engineers are designed to ensure the protection of safety, welfare, public health and public interests.

In Italy it is currently in progress a process of defining common rules for recognizing the figures of biomedical and clinical engineer and for the certification of the skills of engineers. This process is the result of collaboration between the committees of biomedical engineering of the territorial Associations of Professional Engineers, a national group of coordination of such committees, and the National Council of Engineers.

II. COMPETENCES

A. Biomedical Engineering

The Biomedical Engineer works in different fields of engineering, such as design, development and marketing of medical devices and biomedical technologies, as well as playing roles of organization and management in health care.

According to Bronzino [3], "Bioengineering is usually defined as a basic research-oriented activity closely related to biotechnology and genetic engineering, that is, the modification of animal or plant cells, or parts of cells, to improve plants or animals or to develop new microorganisms for beneficial ends".

Objects and limits of the profession of Biomedical Engineer can be identified in the following activities: planning, design, development, construction management, estimating, activity for installing, testing, management, control, maintenance, investigation and assessment of appropriateness for technological projects-products-processes, training and assistance in the use of devices and in vitro diagnostic medical devices, materials, processes, machines and systems for health. Engineers may work both as freelancers as well as in manufacturing or in public administrations services, or private organizations and research institutes. [4]

Quoting again Bronzino [3]: "Like medical practice itself, it is unlikely that any single person can acquire expertise that encompasses the entire field. Yet, because of the interdisciplinary nature of this activity, there is considerable interplay and overlapping of interest and effort between them. […] The possibilities are endless."

B. Clinical Engineering

Clinical Engineering is a branch of Biomedical Engineering that sees the professional directly involved in the application of its skills to health technologies. Let us recall the

I. Lacković and D. Vasić (eds.), *6th European Conference of the International Federation for Medical and Biological Engineering*, IFMBE Proceedings 45, DOI: 10.1007/978-3-319-11128-5_237

well known 1992 American College of Clinical Engineering definition: “A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology". [5]

The certification of skills for this professional is taking, globally in the world, an ever increasing importance and urgency. This is justified by the increasing attention of the medical world to the concepts of security, risk management, safe use, appropriateness, effectiveness and efficiency. The legal and legislative framework in the field of medical devices, including software, is now very large and complex to master for a professional.

This leads to the need for an effective system for certification of competences of the clinical engineer, useful to both health managers - in the assessment and acquisition of a professional – and to the engineer himself, who has the need to demonstrate his skills in comparison with those of other engineers.

The Italian law has begun in the past few years to explicitly mention clinical engineers and clinical engineering services, making it even more urgent the need for a certification procedure.

For example, the 2013 Stability Law, at the article 134 states: "In order to promote initiatives in favor of the safety of care and implement the practices for monitoring and control of disputes concerning professional liability, the regions and the autonomous provinces of Trento and Bolzano may provide healthcare structures [...] with functions of risk management including, where present, competencies for forensic medicine, work medicine, *clinical engineering* and pharmacy, as also suggested by Recommendation no. 9 of 2009 of the Ministry of Health regarding "Recommendation for the prevention of adverse events resulting from the malfunction of medical devices and electro medical equipment." [5]

The Lombardy Region, in a recent 2012 resolution [7] contemplates a Clinical Engineering Service as a hospital function, described as follows:

1. Structure that operates in staff with the Health Management ;
2. Directed by an engineer, normally biomedical or clinical or with biomedical curriculum [...]
3. Should deal with management and strategy for biomedical technologies [...], with the primary goal of ensuring the safe, appropriate and advantageous use of all technologies in terms of economics and security
4. Will have to play a supporting role to the Top Management, in management and strategic issues about technologies, through the following activities: purchase planning and evaluation, direct maintenance or control of the maintenance of the company’s equipment, "Hospital-based Technology Assessment " for the introduction of new technologies, information technology in health care, research.

C. CE Certification

Today in Italy there is still no standardized procedure for the certification of competences Clinical Engineer. However, there are references to the following legislation:

- Legislative Decree 9 November 2007 n. 206, art. 5, letter ‘c’
- Legislative Decree 16 January 2013 n.13, art. 2, letters ‘g’,‘e’;
- Regulation for Skills Upgrading published in the Bulletin of the National Ministry of Justice July 17, 2013 132.

The above laws state that the Territorial Associations of Professional Engineers are responsible for defining a set of rules for competences certification. The document, still being drafted by the local biomedical engineering committees, suggests to identify a metric of evaluation that is as objective as possible based on the following issues:

- verification of the contents of the documents submitted for the recognition of skills;
- interview with the candidate;
- evidence for continuity of professional activity.

The qualifying activities for a Clinical Engineer, are identified as follows:

- Planning, purchases and replacements evaluation, Health Technology Assessment (HTA)
- Perform installation, testing and control of safety and quality
- Management of maintenance activities
- Management activities relating to safety for medical devices and biomedical technologies in healthcare
- Performing maintenance activities
- Training and consultancy
- Standards and standardization
- Prevention and Risk Management for medical devices and biomedical technologies in a hospital setting
- Integration of medical devices, including the Medical Software, within medical Information Technology networks
- Participation in ethics committees

The candidate must provide the following documentation:

- Title for Degree in Biomedical Engineering or other Engineering Degrees with biomedical orientation. In this case, the registration will be on the activities of Section A (the section reserved to professionals having a five years "Laurea")
- Title for Bachelor's degree in Biomedical Engineering. In this case, the approval will be on the activities of the Section B –(the section reserved to professionals having a three years "Laurea")
- Successful the State Exam
- Active Enrolment in the Territorial Association of Professional Engineers
- Curriculum Vitae with documented activity inherent in the specific area of specialization for Biomedical Engineer and, if any, postgraduate Master's degree in any inherent discipline (e.g., Clinical Engineering, Risk Management, Technology Assessment)

III. EDUCATION

A. Continuous Education

As from January 1st 2014, all Italian engineers enrolled in Territorial Associations of Professional Engineers are obliged to take care of their continuing education, attested by a system of professional education credits (CFP).

Below is an extract of the Regulation for the Update of the Professional Competence, published by the National Council of Engineers in the Official Bulletin of the Ministry of Justice of 07.15.2013: [8]

In implementation of what defined by Article 7 of Presidential Decree 137 of 07/08/2012, are tasks of territorial Associations:

a) *the organization of training activities in accordance with the guidelines valid throughout the national territory prepared by the National Council of Engineers (CNI), addressed to the members [...];*

b) the recognition, within the general guidelines common to the whole country, prepared by the CNI, of the didactics organized by the associations of members or other persons authorized by the CNI, and the simultaneous allocation of the number of recognizable credits (CFP);

c) the control and monitoring of the educational offer addressed to the members in the area of competence;

d) the management of the database of members' credits;

e) the communication to the CNI of the necessary information to the database available online for all learning activities [...]

2. The Territorial Associations of Professional Engineers have the right to set up voluntary certification of skills for their members.

B. Postgraduate Education

As for university education in the field of Clinical Engineering, exist in Italy for years some postgraduate master courses, in major universities distributed over the national territory. Some of these courses also offer distance-learning methodologies. All of them contemplate a final internship of few months in hospital or Clinical Engineering companies.

Below are the main points of the educational offer of the Second Level Master in Clinical Engineering, University of Florence, open to five-year graduates, co-managed by the author of this paper: [9]

· Fundamentals of Biomedical Engineering
· Fundamentals of Clinical Engineering
· General aspects and organizational models
· Verification and management of technology
· Evaluation of technologies and systems
· Medical devices, software and systems
· Electro-medical Systems
· Biomedical technologies
· Biomedical Instrumentation
· Medical imaging
· Innovative Applications

The Florence master course is now starting its eight edition and has trained about a hundred Italian and foreign Clinical Engineers. Most of them today work as CEs in public or private hospitals as well as in private services companies.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

REFERENCES

1. ACCE at http://www.accenet.org/downloads/reference/a_guide_to_clinical_engineering.pdf
2. DIRECTIVE 2005/36/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 September 2005 at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:0142:en:PDF
3. Bronzino J. D. (2006) The Biomedical Engineering Handbook, Third Edition – 3, CRC Press
4. Iadanza E, Dori F, Biffi Gentili G (2007) The role of bioengineer in hospital upkeep and development, IFMBE Proc. vol. 14, World Congress on Med. Phys. & Biomed. Eng., Seoul, Korea, 2006, pp 3641–3644
5. ACCE at http://www.accenet.org/default.asp?page=about&section=definition
6. Italian Law: Legge 24.12.2012 n° 228 , G.U. 29.12.2012 at http://www.altalex.com/index.php?idnot=19440
7. Lombardy Region Resolution: Deliberazione N° IX / 3822 Seduta del 25/07/2012 at http://www.aslbrescia.it/media/documenti/deliberazioni/linee%20guida%20poa/3822.pdf
8. Regulation for the Update of the Professional Competence, published by the National Council of Engineers in the Official Bulletin of the Ministry of Justice of 07.15.2013 at https://www.ording.roma.it/archivio/12601-estrattoingegnerimod-bp-13-071-133_1742_1.pdf
9. Master in Clinical Engineering, University of Florence, Italy, at http://www.masteringegneriaclinica.it

Author: Ernesto Iadanza
Institute: Department of Information Engineering
Street: v. di S. Marta, 3
City: Firenze
Country: ITALY
Email: ernesto.iadanza@unifi.it