# Tendencies and Initiatives in the Regulation of Clinical Engineers in the European Region

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## Abstract

There is a clear tendency of the Clinical Engineering (CE) profession to provide service to the healthcare institutions in a high cost-effective way, but at the same time with exceptional standard of quality assurance. Several CE issues in the European region are considered; particularly on the present employment opportunities and tendencies for the Clinical Engineer, current international situation on the occupational classification, for which a derivation of the ISCO-08 four-digit code for the CE profession is presented. The BIOMEDEA proposal for CE training protocol in Europe is highlighted and the recommended core component areas in CE training are depicted. The current situation on the normalisation of the CE profession and the issue on the required framework to implement its certification is also highlighted. In conclusion, the CE profession needs to be systematically promoted together with its required accreditation, certification and regulation infrastructure by all governments within the UN and WHO system, and it is recommended that CE educational programmes are jointly coordinated and implemented by both engineering and medical institutions.

## 1. Introduction

In few asserted words from Meabh Smith,[1] of the Irish Association of Biomedical and Clinical Engineering, the term "Clinical Engineering" is used when specifically referring to Biomedical Engineers working in the patient environment, either in hospitals or in rehabilitation. Clinical Engineering (CE) has become a discipline on its own right. Regardless of the level of practice, from the apprentice to the advanced and highly experienced specialist in biomedical equipment, and from supervisors to executives, the CE professionals do plan, install, provide maintenance and manage complex and critical medical technology for human life. Because these technologies enable surgical interventions and medical procedures, they have a direct impact on the results of patients care and on the safety and value of surgical operations.

There is at present great diversity of higher education systems in the European scenario, and most of these are controlled by the governments. To approach this problem, the International Federation of Medical and Biological Engineers (IFMBE) and a number of universities endorsed by the EAMBES alliance, have taken the initiative with the BIOMEDEA European Project, to work towards the implementation of the required European Area of Higher Education (EAHE) for the Biomedical Engineering and also for the Clinical Engineering professions. In this paper we will look at the initiatives towards the harmonisation of the clinical engineering programmes within the European region, and the core component areas for clinical engineering training recommended by the working group of the BIOMEDEA Project.[2] Another important issue to be considered here is on the international effort to identify the occupational classification of the CE profession within the ISCO-08 system, as recommended by the International Standard Classification of Occupations (ISCO), agreed by the EU (in Nov/2009). To complement the latter effort, the International Labour Organisation (ILO) has committed itself to implement the ISCO-08 classification for the CE occupation.[3]

## 2. Clinical Engineering Issues in the European Region

### 2.1 Present employment opportunities and tendencies for the Clinical Engineer

Although work responsibilities of the Clinical Engineer are continuously changing and increasing, we may identify three main employment categories: a) In the CE Department of a hospital or healthcare institution; this one has constituted the originating cause for the CE profession and continues being the main category that absorbs most of the graduates. b) In the medical equipment manufacturing industry; mainly serving as field engineers, therefore requiring to be constantly updated on healthcare cutting edge technology, skills and knowledge. c) In independent enterprises that offer their services to a healthcare institution (usually to small hospitals).[4]

Currently there is a strong tendency in the profession to serve the healthcare institutions in a way that maximises cost-affectivity, but at the same time, with an exceptional quality standard.[5] Clinical Engineers are in the transition of performing a simple medical equipment repair and maintenance task, into performing technology management tasks in the healthcare industry, including the assessment of new healthcare technologies, with regard to its economic and clinical effectiveness. An emerging opportunity for clinical engineers is on the ever growing home healthcare market. These foreseen changes in the profession, must be taken into consideration in the academic programmes that will shape future clinical engineers as highly qualified professionals, capable to respond to the job required by their fast developing industry.

### 2.2 Current International Situation on the Occupational Classification (ISCO-08)

In the official bulletin of the European Union (10.11.2009) it is publish the recommendation about using the ISCO-08 system of the ISCO (International Standard Classification of Occupations). This recommendation was based on the fact that the ISCO-08 classification is more detailed and effective than the ISCO-88 European version (ISCO-88 (COM)), thus ensuring comparability between occupational census data from State members of the European Union and the rest of the world. The next European census round is to be completed this year (2011).

A major advantage of the ISCO-08 classification is that it gives more emphasis to occupations related to Information and Communication Technologies (ICT). It should be mentioned here that the ISCO has committed itself to publish the tables of correspondence between national classification codes and ISCO-08. Also, in the meeting of the Department of Economy and Social Affairs of the United Nations, on 16/April/2007, the International Labour Organisation (ILO) did commit itself to implement the new classification according to ISCO-08. More recently, ILO has agreed that Clinical Engineering professionals can be listed not only in the category of engineers, but also as an integral part of the health professions list of classification of professionals. Therefore, as illustrated in Figure 1, the 4-digit occupational ISCO-08 code for Clinical Engineers can be assigned either as 2149 (Engineering Professionals not classified elsewhere) or as 2269 (Healthcare Professionals not classified elsewhere).

### 2.3 The BIOMEDEA Proposal for Clinical Engineering Training Protocol in Europe

As a first step towards the harmonisation of Clinical Engineering programmes in the European region, the BIOMEDEA working group proposed the training protocol presented in the following table (Table 1): [2]

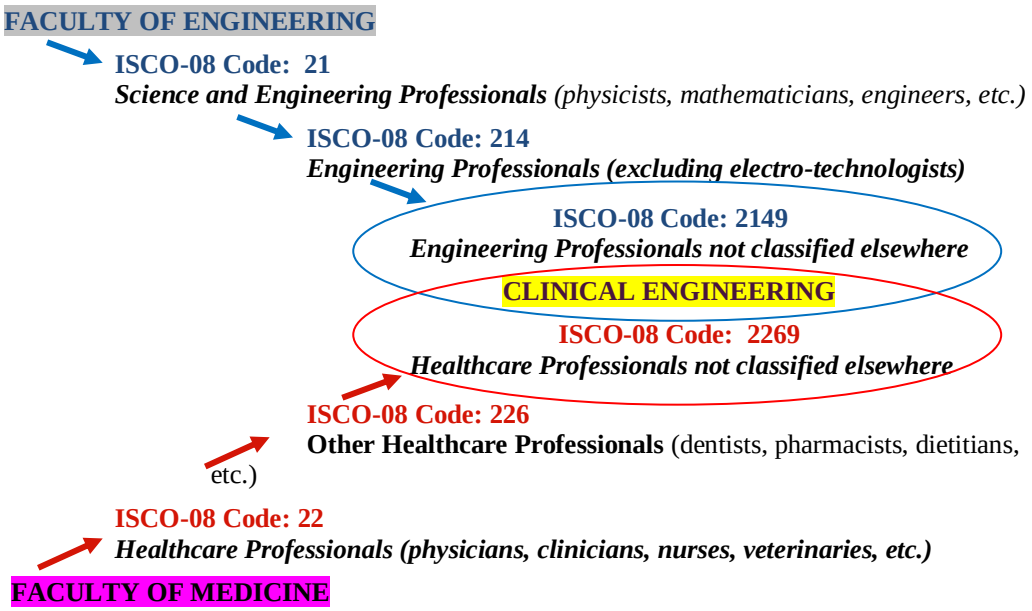


**Figure 1.** Genealogy of the ISCO-08 four-digit coding for the Clinical Engineering profession.

**Table 1.** Recommended core component areas in clinical engineering training.

| | Clinical Engineering Component Area | % Component |
|---|---|---|
| 1 | Management | 32 |
| 2 | Technology Assessment | 15 |
| 3 | Regulatory/QA Issues | 11 |
| 4 | Repair/Systems Thinking | 6 |
| 5 | Risk Management/Safety Issues | 9 |
| 6 | Education | 8 |
| 7 | Product Development | 8 |
| 8 | Miscellaneous Topics | 11 |

The following list of specialisation areas has been proposed in the BIOMEDEA report:[1]

1) Medical Electronics and equipment management.
2) Information and Technology management.
3) Rehabilitation engineering.
4) Radiotherapy technology.
5) Diagnostic imaging technology.
6) Expert systems / decision support systems.
7) Biomaterials.
8) Biomechanics.

These areas were chosen in such a way that a combination of any two of them can cover a reasonable area of Biomedical Engineering, for example, (4) and (5): radiotherapy – diagnostic imaging technology, (3) and (8), or (7) and (8): to cover the implants range.

In a training programme structure for CE, education and training are interlinked, but normally the education precedes the training scheme. Nevertheless, they both may be implemented in parallel or partially in parallel with the training scheme. Usually the training centre organises training scheme and normally the trainee is employed by the training centre. The recommended training period is 3 years, including supervision and practical experience in central areas of Clinical Engineering, and equally, in two of the speciality areas. An appointed Training Coordinator prepares the training plan.

In the training plan, two phases may be identified: the two first years of the training period are denominated as the Basic Training stage, and during this phase the trainee is always supervised; and in the third year, denominated as the Advanced Training period, some clearly identified tasks are carried out without supervision. The evaluation procedure includes an interview with the trainee at the end of each training period, to certify that a reasonable standard of competence has been attained.

### 2.4 Normalisation of the CE Profession: the current situation

In most countries there are no established norms that regulate the CE profession. In these countries any person can claim to be a Clinical Engineer and take responsibilities on the health technologies of a hospital without needing to present a certification, that is, without a credible proof of the qualifications and skills required for such a role. Therefore, there are several reasons for which the CE profession should be normalised. One of these reasons is to improve the standard of the health service by establishing a common basis for the CE professional practice. Among other reasons worth mentioning, are to facilitate the professional exchange between and within European countries, and to enable the possibility of providing commonly accepted references, which could be used by national government agencies and international organisations in generating directives for providing CE services and competent personnel. Also, to provide incentives for the collaboration between European countries and a continuous dialog on all issues concerning the profession, and to increase the understanding of the educational and training systems for CE in different countries, hence promoting its development.

### 2.5 The Certification Issue

Certification is necessary in order to promote an improvement in healthcare delivery, by means of continuous evaluation of the competence of CE professionals. A certification process, basically must provide a knowledge and skill frame needed to assist the evaluators that give the certification, and it must provide a way to formally acknowledge the individuals that comply with the qualification criteria. Also, the certification process would need to include an assessment of the continuous personal and professional development in the practice of CE, in order to keep the certification.

The main benefits of the certification of Clinical Engineers would be to define the normalised practice, to create the foundation for common practices, to allow the articulation of regional variations and to increase the recognition of the profession and the individuals by way of standardisation.

The main requisites to establish the certification system at an international level would be the following ones:

1) The development of an international Clinical Engineering Knowledge Body. For this, the central competence profile that a Clinical Engineer needs to possess in order to properly function on the role must be clearly defined. These central competences would be the basis for the certification exam. Also, an international point of reference for CE practice needs to be defined; to be used for curricula definition and validation, for the development of a training scheme and for a continuous education scheme.

2) The creation of a certification commission.

3) To identify examination agencies; which would support the development and exams administration, as well as their quality control, security and logistics.

4) To create regional Examination Councils for the administration of local programmes.

## 3. Conclusions and Recommendations

Because of the inherent direct impact that the Clinical Engineering profession has on the economic efficiency of public health policies, this engineering profession is of paramount importance in any national, regional and international development strategy, hence the obvious need to be systematically promoted together with its required accreditation, certification and regulation infrastructure by all governments within the UN and WHO system. To facilitate this process, the BIOMEDEA European Project advocates the regulation of Clinical Engineering as a health profession and has produced valuable documentation to promote the required harmonization to implement the proper EAHE for this profession, required by 2010, as agreed in the Bologna Declaration (June 1999).

The IFMBE, in cooperation with the WHO and BIOMEDEA,[1] advocates the normalisation and regulation of the CE profession. The IFMBE is soliciting to all national governments to adopt their proposed quality assurance system and make the certification compulsory.

Because CE embraces a wide multidisciplinary area, involving many sub-specialities, it is difficult for a single university to have the comprehensive knowledge that would cover all these sub-specialities required for an adequate education for its CE students. The assigned provision to the EAHE would facilitate the possibility to form consortiums or university networks at national or European levels, aimed to provide a better a more complete formation to clinical engineers.

We recommend considering the possibility of not limiting to only an engineering institution the educational programme for the formation of Clinical Engineers, but to equally involve the higher education institutions in the medical field, for an evenly and balanced participation in this process. We also recommend that on CE course promotion activities, consider to prevent the possible confusion made by the authorities and the hospital medical staff about the difference between the professional disciplines of Hospital Engineering and Clinical Engineering.

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