

# Accreditation and Certification in Biomedical Engineering in the Czech Republic

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**Abstract—** The aim of the paper is to inform about the system of undergraduate, postgraduate, and lifelong education in the fields of Biomedical Technology and Biomedical Engineering in the connection with the Act No.96/2004 Coll. on non-medical health service occupations with its amendments and related regulations. The Act and related regulations define position of technical personnel in the health service system. This legal regulation distinguishes the following categories of technical personnel: another professional, health service professional with technical competence (biomedical technician, biomedical engineer), and health service professional with specialized competence (clinical technician, clinical engineer). There exists a system of accredited medical institutions that can perform defined types of postgraduate and lifelong education. As part of lifelong education, credit system was introduced that specifies activities for which credit points can be awarded. The professionals can obtain specialized technical competence after passing the specialized education and examination. Then they can apply for registration in the Registry of Health Care Professionals.

**Keywords—** accreditation, certification, biomedical engineering, education.

## I. INTRODUCTION

As technology is becoming more and more inseparable part of most processes in medicine and health care the professions of biomedical engineer and biomedical technician are gaining greater importance. In connection with this development it has become obvious that it is necessary to set these professions (and also other non-medical healthcare professions) into standard legal framework that existed for many decades in medical professions (medical doctors, dentists, pharmacists).

During the preparation of the law, the basic philosophical principle was followed, namely that the qualification of health service professional and specialist will be required for technical professions if the technical professional or specialist comes into contact with a patient or can through his/her activity directly influence patient's health state.

We will focus in this paper on the legal regulations that define non-medical health care professions and the procedures that describe the undergraduate, postgraduate, and lifelong education, accreditation, and other important aspects of them. The paper is organized as follows. In Section

II the legal framework of education in biomedical engineering is described. Section III presents content of the undergraduate education (bachelor and master study). In Section IV the activities that can be performed by health care professionals are specified. Section V describes the specialized education of professionals in biomedical engineering. Lifelong education is briefly presented in Section VI. Conclusions are stated in Section VII.

## II. LEGAL FRAMEWORK

Since it is assumed that the graduates will find jobs mostly in the health care domain, the education, qualification, accreditation, and occupations are regulated by special legal provisions. During 2004 and 2005 new law and related regulations became effective. The Act No. 96/2004 Coll. on non-medical health service occupations and its amendments (No. 125/2005, 111/2007, 124/2008 and 189/2008 Coll.) set the basic framework for all the health care professions with the exception of the medical professions (medical doctor, dentist, pharmacist). Afterwards several related regulations were issued. In particular, the following regulations are important:

- No. 394/2004 Coll. regulates details about holding the attestation examination, examination for issuing the certificate, final examinations of accredited qualification courses, approbation examinations and examination rules for these examinations;
- No. 423/2004 Coll. and its amendment No. 321/2008 Coll. defines credit system for issuing certificate to performing health service occupations without expert supervision, further it defines educational activities for that credit points can be awarded and number of credit points;
- No. 424/2004 Coll. specifies activities of health service professionals and other employees they can perform in their jobs; it distinguishes work under specialized supervision and work without supervision;
- government decree No. 463/2004 Coll. defines fields of specialized education and specification of the expertise of health service professionals;

- No. 470/2004 Coll. concerns health capability for performing the occupations of health service professional and another specialist;
- decree No. 39/2005 specifies minimum requirements for educational programs leading to qualification to act as health service professional.

The Act and related regulations define completely new position of technical personnel in the health service system. The Act No. 96/2004 Coll. on non-medical health service occupations distinguishes the following categories of technical personnel (in the area of biomedical engineering):

- another professional;
- health service professional with technical competence:
  - biomedical technician (B.Sc.);
  - biomedical engineer (Eng., M.Sc.);
- health service specialist with specialized technical competence:
  - clinical technician (B.Sc.);
  - clinical engineer (Eng., M.Sc.).

The qualification of the health service professional and health service specialist is required for technical personnel, where technical professional or technical specialist comes into the contact with a patient or when he/she can through his/her activities directly influence patient's health state.

The Act No. 96/2004 Coll. specifies the following types of educations:

- undergraduate education, i.e. bachelor and master study (minimum requirements are given by the official regulations No. 39/2005 Coll.);
- accredited qualification course;
- specialized education;
- lifelong education (this education is obligatory for all health service professionals and also for those working in the category another professional in health service).

### III. UNDERGRADUATE EDUCATION

Basic rules and requirements concerning undergraduate (Bc. and M.Sc.) and postgraduate (Ph.D.) study in general are defined by the Higher Education Act No. 111/98 Coll. In this context, it is necessary to stress that in addition to standard accreditation of a study programme or field of undergraduate education performed by the Accreditation Board of the Ministry of Education, Youth and Sports of the Czech Republic, the biomedical study programmes or fields must get the accreditation of the Ministry of Health Care of the Czech Republic in the sense of the Act No. 96/2004 Coll. and related regulations. The graduates of these accred-

ited fields get the certificate of qualification to perform health service occupations according to the Act No. 96/2004.

The Biomedical Engineer (Biomedical Technician) qualification can be obtained by graduation in the Biomedical Engineering field of study (Biomedical Engineer) or the Biomedical Technology field of study (Biomedical Technician).

The accreditation conditions for the study programme or for the field of study defined by the Ministry of Health Care are the following:

- the structure of the study programme must correspond with the official regulations No. 39/2005 Coll. where the minimum requirements for the contents of bachelor and master study programme are determined;
- the profile of graduates must correspond with the official regulations No. 424/2004 Coll. where permitted activities for technical professionals and technical specialists are determined.

Graduates of another bachelor or master study programme in electrical engineering can obtain the qualification for health service professionals with technical competence if they pass the accredited course in Biomedical Engineering (for M.Sc./Eng.) or Biomedical Technology (for B.Sc.) The accreditation for these courses is delivered by the Ministry of Health Care of the Czech Republic. The conditions for this accreditation are defined in the official regulation No. 424/2004 Coll.

The minimum requirements on study programs to acquisition of technical competence for non-physician health care professions (including biomedical engineering) are defined by legal regulations (decree No. 39/2005). It was prepared by the Ministry of Health Care of the Czech Republic in agreement with the Ministry of Education, Youth and Sports of the Czech Republic. This decree incorporates corresponding regulations of European Community and modifies minimum requirements on study programs leading to acquisition of technical competence for non-physician health care professions. These minimum requirements are list of theoretical and practical areas necessary for practising regulated profession. It is necessary to stress that the Ministry of Health Care accredits only those study programmes satisfying the requirements. Then the graduates are allowed to certain defined positions in the hospitals and health care institutions. Graduates of other study programmes must attend specialized postgraduate courses in biomedical engineering. In addition to necessary theoretical and practical technical (engineering) knowledge and skills, the decree specifies which additional knowledge and skills the students have to acquire.

Requirements on medical and technical knowledge are specified in detail for both the bachelor study in biomedical

technology and master study in biomedical engineering. In general, the courses can be divided into theoretical courses providing knowledge of medical fundamentals (anatomy, physiology, pathology, pathophysiology), technical area (mathematics, physics, medical devices, signal theory, medical imaging, databases, etc.). Inseparable part of the education is practical training, including practice in health care facilities. Master study in biomedical engineering assumes preceding education in electrical engineering, thus knowledge of mathematics, physics, theoretical electrical engineering, electronics, electric measurements, theory of electromagnetic field, and programming.

In addition, there have been issued methodological guidelines of the Ministry of Health Care that quantify minimum load in hours for each area listed in the decree No. 39/2005 Coll.

#### IV. SPECIFICATION OF ACTIVITIES OF HEALTH CARE PROFESSIONALS IN BIOMEDICAL ENGINEERING

The regulation No. 424/2004 Coll. specifies activities of health service professionals. The biomedical technician can perform activities in the frame of diagnostic and therapeutic care in the field of biomedical technology in cooperation with a biomedical engineer or a physician.

Health care professionals that need to acquire specialized qualification have to work before under specialized supervision of a health care professional that has the adequate qualification for work without supervision in the given area.

Biomedical technician can work without supervision and indication with medical devices if he/she cannot influence directly the patient health state with his/her activity. Based on the indication of the physician and in correspondence with diagnosis determined by the physician assuming that he/she can directly influence patient health state by his/her activity, a biomedical technician can work with medical devices under specialized supervision of a clinical engineer or clinical technician with specialized qualification in the area.

The activities the biomedical engineer can perform are divided into activities he/she performs without indication and activities he/she performs based on indication. Biomedical engineer can perform the same activities as biomedical technician without supervision and indication. Under specialized supervision of a clinical engineer and without indication of the physician, he/she works with medical devices in correspondence with diagnosis determined by the physician, if he/she cannot directly influence the patient health state by his/her activity. Based on indication of the physician and in correspondence with the diagnosis determined by the physician, biomedical engineer

works with medical devices under supervision of a clinical engineer with specialized qualification in the field in cases where he/she can directly influence the patient health state by his/her activity.

Before the biomedical engineer acquires specialized competence, he/she works in a health care facility under technical supervision of a professional qualified to job without technical supervision, out of which first six months represent work under direct control. The practice of a profession of biomedical engineer is an activity in the frame of diagnostic and therapeutic care in cooperation with a physician.

It is necessary to stress that for the job of biomedical technician it is supposed that the undergraduate preparation is such that the technician can perform some activities directly after graduation without supervision. Biomedical engineer profession assumes education significantly more theoretically focused. That means that the biomedical engineer can perform independent activity only after specialized preparation (similar to physicians).

#### V. SPECIALIZED EDUCATION

The specialized technical competence for clinical technicians and clinical engineers can be obtained by passing the specialized education and training finished by official examination. The examination board is appointed by the Ministry of Health Care. The board members are appointed by the Minister of Health Care based on the proposal of professional societies and associations and accredited institutions. This specialized education and training can be provided only by those institutions that have the accreditation from the Ministry of Health Care. The Clinical Engineering is the specialized education and training for Biomedical Engineers and the Clinical Technology for the Biomedical Technicians. This type of education is organized by the Institute for Postgraduate Education in Health Care that is directly controlled by the Ministry of Health Care. The lecturers are university teachers (both from technical universities and medical schools), clinical engineers from accredited hospitals, and other invited professionals in particular areas.

In the official regulations No. 463/2004 Coll. there are defined the following fields for Clinical Technology/Clinical Engineering education and training:

- signal acquisition and signal processing (Clinical Technicians/Engineers for signal processing and signal processing);
- diagnostic devices (Clinical Technicians/Engineers for diagnostic devices);

- laboratory devices (Clinical Technicians/Engineers for laboratory devices);
- therapeutic devices (Clinical Technicians/Engineers for therapeutic devices);
- diagnostic imaging devices (Clinical Technicians/Engineers for diagnostic imaging devices);
- perfusiology (Clinical Technicians/Engineers for perfusiology).

Biomedical Technicians and Biomedical Engineers can also pass the specialized education in the Health Service Organisation and Control. After the official examination they are ranked as Professionals in Health Service Organisation and Control.

For Health Service professionals (Biomedical Technicians and Biomedical Engineers) and specialists (Clinical Technicians and Clinical Engineers) the Ministry of Health Care issues the official certificate.

Then the professionals can apply for registration in the Registry of Health Care Professionals which is part of the National Health Care Information System. They receive a certificate that is valid for 6 years and then they have to renew the registration. The basic conditions are: health care practice during last 6 years (minimum one year 0.5-part-time job or 2 years 0.2-part-time job); acquisition of minimum 40 credit point during last 6 years. The credit points can be acquired through participation in different activities defined in the regulations No. 423/2004 and its amendment No. 321/2008.

## VI. LIFELONG EDUCATION

The duty of lifelong education in the health care professions is defined by the Act No. 96/2004 Coll. The regulations No. 423/2004 Coll. and No. 321/2008 Coll. describe in detail the forms of lifelong education and also the credit system. According to this system it is possible to acquire credit points for participation in the following activities: innovation course; seminar; workshop; placement at specialized institution; congress; conference (international activities are awarded by higher number of credit points). Active participation is awarded by more credit points – these activities include: paper or poster presentation at a congress, conference, seminar or workshop; writing a journal article, educational activity (lecturing), research, development of a methodology.

Each activity must be recorded in the personal certificate of specialization. This information serves as a basis for application of registration or registration renewal.

## VII. CONCLUSIONS

The Act No. 96/2004 Coll. and all related legal regulations and provisions have a number of consequences both for undergraduate study and for postgraduate study and lifelong learning. Biomedical technicians and engineers who are working in the Health Care sector are involved in a system of education and lifelong learning for acquiring specialized competence that is similar to the system of education and training of medical doctors.

When developing curricula in undergraduate study it is necessary to respect both requirements of the Ministry of Education, Youth and Sports of the Czech Republic and requirements resulting from the Act No. 96/2004 Coll. and especially regulations No. 39/2005 Coll. that defines minimum requirements on educational programmes leading to qualification to act as health service professionals. The courses in postgraduate education and lifelong learning are managed by the Act No. 96/2004 Coll. and corresponding regulations of the Ministry of Health Care of the Czech Republic. The Act also specifies conditions for recognition of education, training and practice acquired in other countries.

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