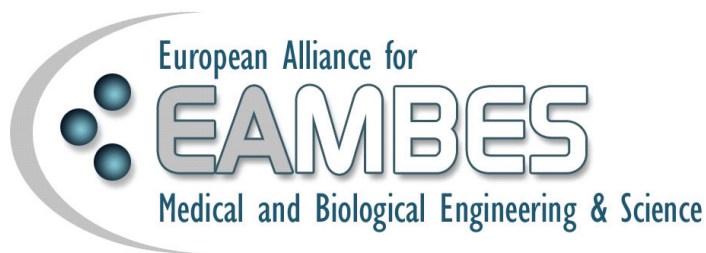


INTERNATIONAL FEDERATION FOR

**MEDICAL AND
BIOLOGICAL
ENGINEERING**



**CRITERIA FOR THE
ACCREDITATION OF
BIOMEDICAL ENGINEERING
PROGRAMS IN EUROPE**

BIOMEDEA

Copyright © 2005 BIOMEDEA PROJECT

BIOMEDEA Project Coordinator:

Prof. Dr. Joachim H. Nagel
Institute of Biomedical Engineering
University of Stuttgart
Seidenstrasse 36
70174 Stuttgart
Germany
biomedea@t-online.de
<http://www.bmt.uni.stuttgart.de/biomedea>

Preface 1

The IFMBE Ad-Hoc Committee on European Activities has accepted the challenge to establish criteria for pure and interdisciplinary BME programs within the new European framework of harmonized one and two cycle educational programs. To be internationally acknowledged, accreditation relies on ambitious, but broadly accepted criteria.

With these recommendations IFMBE is providing its European national member societies, the European universities and other institutions of higher education which offer BME programs a uniform guide to comply with the necessary international harmonization of higher education, to secure and to further improve the high quality of European BME education, to allow comparability of European BME qualifications and degrees, and thus to contribute to mobility for education, training and employment.

The intention of these recommendations is to contribute to the harmonization of biomedical engineering education in Europe, and to make the diversity of programs comparable. It is directing the attention of institutions of higher education and of governmental educational authorities to the essential contents of biomedical engineering education and thus promotes European competitiveness in this dynamic discipline.

*Joachim H. Nagel
Editor, IFMBE White Paper on the
Accreditation of Biomedical Engineering Programs in Europe
June 06, 2001*

Preface 2

In the past few decades, medicine and health care have evolved into a highly specialized technological branch, offering tremendous possibilities for the prevention, diagnosis and treatment of disease. This evolution was made possible thanks to breakthroughs in genetics and molecular biology, supported by advanced engineering realizations of 3-dimensional high resolution (medical) imaging, new (bio)materials and biomechanics, robot assisted minimally invasive surgery, artificial organs, automation of laboratory research, bio-informatics, information and communication technology, and many other biomedical engineering innovations. Modern health care is no longer the domain of clinicians alone. It depends on versatile, multidisciplinary teams, where biomedical engineers play an important role, not just as problem-solvers.

Medical and Biological Engineering and Sciences (MBES) are also a major source of industrial diversification with a huge potential for being a catalyst, enhancing a generation of new industries and creating many new start-up companies which in general Europe is relatively slow to develop.

Given the continuous development of the technological aspects of medical practice, hospitals need more specialized personnel, namely clinical engineers, for the selection of large equipment (e.g. medical imaging), for the training of clinical personnel confronted with informatics systems (e.g. intensive care units, medical file classification) and other high-technology equipment, for the operation of complex systems and maintenance.

As a result of the developments in industry and the health care systems, there is a rapidly increasing need for the educational systems to provide the necessary human resources, and to make sure that the quality of education and training satisfies the needs of the employers, also implying the need for patient safety in health care delivery. As three important aspects of quality assurance, accreditation of MBES programs, certification of biomedical/clinical engineers and continuing education (life-long learning) need to be established. While there are strict regulations in place for Medical Physicists working in radiology departments, in most countries anybody claiming to be a clinical engineer can work in the same safety sensitive environment without any need to prove any specific qualifications.

European harmonization of higher education programs, a prerequisite for student and teacher mobility, is an important political goal of the EU, and a desirable development for most academic disciplines. For MBES, this young discipline that is expanding so fast that today no single European University is able to cover all areas of MBES, it is more, it is an important prerequisite for students to be able to select the MBES specialty of their choice, no matter where they come from.

In contrast to the traditional academic disciplines where consensus about the necessary content of higher educational programs and the required qualifications of professionals could be established over many decades, MBES as a briskly growing discipline did not yet have this opportunity. Today, more than 200 universities, universities of applied science, polytechnic schools, academies and other institutions in Europe offer educational programs in MBES at all academic levels, but with only little international coordination of contents and required outcome qualifications. Until recently, not even comprehensive knowledge has been available as to which institutions are involved and which programs they are offering. Therefore, it does not surprise that the Bologna movement has triggered activities within the MBES community to promote their European Higher Education Area by looking into harmonization of the educational programs, specifying required minimum qualifications and establishing criteria for an efficient quality control.

Starting in 1999, the International Federation for Medical and Biological Engineering (IFMBE), its European member societies and numerous European Universities with an interest in MBES, joined by the European Alliance for Medical and Biological Engineering and Sciences (EAMBES), an alliance of European national and trans-national societies which was founded in 2003 on the initiative of IFMBE, have been engaged in projects aiming at creating a comprehensive survey of the status of MBES education and research in Europe, charting the MBES community, developing recommendations on harmonized MBES education and training, and establishing criteria for the accreditation of MBES programs in Europe.

BIOMEDEA, with the support of all experts, societies and institutions that have been driving these previous activities, aims at bundling those preparatory efforts, using the available synergies to bring the different initiatives to a successful outcome, thus preparing the creation of the European Higher Education Area in the field of Medical and Biological Engineering and Sciences for the benefit of the universities, the students and last but not least the whole society.

The objective of the project is to prepare and, as far as it will be possible through the means of the involved partners, establish the European Higher Education Area with improved quality assurance, i.e. accreditation of the educational programs and certification of clinical engineers, thus ensuring trans-national mobility for education, training and employment. Quality assurance of MBES education and training is also directly related to the issues of health care quality and patient safety. It offers the additional advantages of providing confidence for the employer that the employee has the necessary education, training and responsible experience, and confidence for the user of the service, meaning the patients, that those providing the service are effective and competent.

BIOMEDEA aims at establishing Europe-wide consensus on guidelines for the harmonization of high quality MBES programs, their accreditation and for the certification or even registration and continuing education of professionals working in the health care systems through the organization of three seminars where such guidelines will be developed and approved after careful preparation relying on the input of all relevant partners. Adherence to these guidelines will insure mobility in education and employment, improved competitiveness of the European biomedical industries, as well as the necessary safety for patients, and thus contribute to the health and well-being of the European people. Targets for the dissemination of results will be the European universities, political decision makers, ENQA, accreditation agencies, students and the health care providers.

The current version of the Criteria for Accreditation of Biomedical Engineering Programs in Europe is the result of intensive discussions at the BIOMEDEA workshops in Eindhoven and Warsaw.

*Joachim H. Nagel
BIOMEDEA Project Coordinator
March, 2005*

LIST OF CONTENTS

1. Introduction	2
2. Guidelines for the accreditation of BME Programs in Europe: why do we need them and what should they specify?	3
3. Goals and Concepts of the Recommendations	3
4. Addressees of the Recommendation	4
5. Programs and Degrees	5
5.1. <i>Applicability</i>	5
5.2. <i>Degrees</i>	6
6. Educational Objectives and Minimum Requirements	6
6.1. <i>Educational Objectives</i>	6
6.2. <i>Basic Structures and Categories</i>	7
6.3. <i>Program modules</i>	8
6.4. <i>Contents</i>	8
6.5. <i>Curriculum for a 3+2 year consecutive Bachelor/Master program</i>	13
6.6. <i>Curriculum for a 2 year non-consecutive Master program</i>	15
7. Organizational Requirements	15
7.1. <i>Structure of Programs</i>	15
7.2. <i>Organization of Programs</i>	16
7.3. <i>Integration of Students</i>	16
7.4. <i>Examinations</i>	17
7.5. <i>Transfer into the Master Program or the Second Cycle</i>	17
8. Quality of Teaching	17
9. Resources and Facilities	17
9.1. <i>Personnel</i>	17
9.2. <i>Facilities and Financial Resources</i>	18
10. Accreditation	19
10.1. <i>Accreditation Committees</i>	19
10.2. <i>Accreditation Commission</i>	19
10.3. <i>Audit-Teams</i>	20
10.4. <i>Accreditation Procedures</i>	20
11. References	21
Addendum 1: Typical distribution of modules in terms of ECTS credits and percentages	22

1. Introduction

Today, more than 200 universities, universities of applied science, polytechnic schools, academies and other institutions in Europe offer educational programs in Biomedical Engineering at all academic levels, but without any international coordination of contents and required qualifications. Transnational mobility for education, training and employment is an essential objective of the European Union. Such mobility is difficult to achieve because of different national practices in education, training and employment and in recognition of outcomes and accreditation. Accreditation plays an important role in ensuring transnational mobility and employability, and offers the additional advantages of confidence for the employer that the employee has the necessary education, training and responsible experience, and confidence for the user of the service, e.g. patients, that those providing the service are effective and competent.

In order to enhance the advantages of accreditation to biomedical engineers, it is essential that structures are set up enabling the comparability, compatibility and mutual recognition of BME degrees. National quality assessment and accreditation schemes have to be established where they do not yet exist, and they have to be harmonized, i.e. they need to satisfy those criteria which the European BME community will have to establish on a transnational basis and mutually agree upon.

Though accreditation in BME is extremely important and directly related to the issues of health care quality, defining internationally accepted criteria, minimum requirements and competencies is a rather challenging task. Difficulties result from the vast diversity of partially incompatible educational systems, but also from the exceptionality of the young, highly dynamic discipline of Biomedical Engineering which offers a whole range of different qualifications and directions, related to various engineering specialty matters and which, as a part of the so-called life sciences, is reaching far into neighboring sciences such as medicine, biology and biochemistry. Adding to the problem are the many established academic programs within the classical engineering disciplines offering specialization in BME up to different levels of qualification or competency.

Harmonized European accreditation will permit a diversity of biomedical engineering programs, and assure the quality and transparency of education, while still warranting mutual acceptance of competencies and degrees throughout Europe. Accreditation based on commonly accepted criteria ensures adherence to the established minimum requirements by all programs regardless of the educational system and the organization of the institution for higher education. Accreditation will promote the development and continuing improvement of education in biomedical engineering.

The goal of harmonized European accreditation is to guarantee educational standards which ensure equivalence of teaching and learning while at the same time maintaining the special profiles of individual institutions. Therefore, the accreditation criteria have to be sufficiently specific to guarantee minimum competency requirements but they must provide the necessary flexibility to allow the distinctive character of individual programs.

2. Guidelines for the accreditation of BME Programs in Europe: why do we need them and what should they specify?

There is general agreement that existing criteria and guidelines for the accreditation of engineering programs in Europe, such as the EUR-ACE documents, do not cover the special needs of BME programs and that therefore specific guidelines should be agreed upon. Such guidelines should be based on the commonly accepted, general guidelines for engineering programs, and should add the necessary core competencies as well as specializations in Medical and Biological Engineering and Science. They should also outline the basic competencies in engineering/science, biology and medicine and general competencies (soft skills) which are felt to be necessary requirements for a BME degree. The guidelines should satisfy the two purposes of specifying the criteria for accreditation and providing advice to those who want to start a new BME program, and thus should contain guidelines for curricula, too. Two different basic types of programs should be defined in the guidelines: research oriented and professionally oriented programs. In general, universities offer research oriented programs, whereas universities of applied science and polytechnic schools regularly offer professionally oriented programs.

The document should recognize the diversity of BME programs and not prescribe fixed rules. They should leave the flexibility to individual programs to maintain their specific character and acknowledge that national laws, conventions, regulations and resources may make it impossible to strictly adhere to the guidelines. Such circumstances should not exclude programs in those countries from the goal to provide European mobility for students, teachers and employees, unless such deviations would mean a substantial negative impact on the quality of the BME programs and the qualifications of their graduates. The goal is to harmonize BME programs throughout Europe, not to standardize them.

3. Goals and Concepts of the Recommendations

These recommendations specify the criteria for accreditation including qualifying programs, degrees, minimum requirements in terms of competencies, organizational requirements, faculty and quality of teaching, administration, resources and facilities, and the consequences of these criteria for the accreditation process, particularly the involved evaluation procedures. The recommendations have been developed by the European Project BIOMEDEA, based on earlier drafts of the IFMBE Ad-Hoc Committee on European Activities, in cooperation with the International Federation for Medical and Biological Engineering (IFMBE), the European Alliance for Medical and Biological Engineering and Science (EAMBES), BME Societies of nearly all Bologna signatory countries, European Universities, Universities of Applied Sciences and Polytechnic Schools, as well as representatives of the biomedical industry and health care providers.

The principles for the evaluation of biomedical engineering programs contain the specific requirement, that the members of the audit teams are appointed after consultation with the biomedical engineering societies to make sure that the persons in charge of accreditation are familiar with the criteria and principles, are convinced of

the rationale, and are able to appropriately take into account all specific aspects of biomedical engineering education.

The criteria apply to pure biomedical engineering programs and to all interdisciplinary programs in which the biomedical engineering component of the curriculum is larger than or at least as large as the component of other disciplines involved. BIOMEDEA recommends that the biomedical engineering nucleus of all those programs should be modeled in accordance with these criteria.

The presented criteria relate directly to the one and two-cycle studies called for in the Bologna declaration, mainly Bachelor and Master Programs, but they also apply to most Diploma Programs.

The criteria should be closely defined to establish the foundation of a uniform accreditation throughout Europe. On the other hand, specific profiles of programs at the individual universities should be maintained. Therefore, the recommended criteria contain mandatory and optional competencies. A specified amount of optional competencies is mandatory. With adequate justification, selected competencies can be replaced by equivalent qualification elements.

These recommendations are essentially limited to those questions specifically related to biomedical engineering. General issues, which are equally relevant for all programs in science, engineering and technology, are included only as far as they are of special importance for biomedical engineering.

4. Addressees of the Recommendation

The BIOMEDEA Project addresses with its recommendations:

- all governmental authorities responsible for higher education and accreditation, on the European as well as the national level,
- the Accreditation Councils of all European countries,
- the European Network for Quality Assurance (ENQA),
- The project Accreditation of European Engineering Programmes and Graduates (EUR-ACE),
- the Association of European Universities,
- the Confederation of European Rectors' Conferences,
- all European IFMBE member societies and its Divisions,
- all professional and scientific societies with an interest in the area of Biomedical Engineering and Clinical Engineering, and the European Federation of National Engineering Associations (FEANI),
- industry, hospitals, and the health care systems that are responsible for the employment of Biomedical/Clinical Engineers.

The participants of the BIOMEDEA Project, IFMBE and EAMBES are asking all European accreditation councils involved in the accreditation of biomedical engineering programs to consider these recommendations.

The participants of the BIOMEDEA Project, IFMBE and EAMBES encourage all accreditation agencies to have their accreditation commissions or sector committees and audit teams follow these standards and criteria for the accreditation of biomedical engineering programs.

5. Programs and Degrees

5.1. Applicability

There are different types of BME programs and programs including BME modules.

- Type 1: Biomedical Engineering Programs with a general BME module of at least 50% and an integrated, minor, application specific BME module such as medical electronics, health technology assessment, clinical engineering, medical informatics or medical physics.
- Type 2: Biomedical Engineering Programs with a general BME component of at least 50% and a major, application specific module or with a strong orientation towards one of the BME application modules.
- Type 3: Interdisciplinary Programs with a BME module that is balanced with a non-BME specialization such as electrical or mechanical engineering.
- Type 4: BME is a minor module in an engineering program.
- Type 5: Biomedical/clinical engineering training.
- Type 6: Biomedical/clinical engineering continuing education (life-long learning).

The guidelines and criteria in this document apply to program types 1, 2 and 3. Type 4 programs do not qualify for BME accreditation, but should be done in cooperation with BME and type 5 and 6 programs are covered in a separate document.

The responsibility for the accreditation of type 1-3 programs lies with:

- Type 1: Exclusive responsibility of BME.
- Type 2: Exclusive responsibility of BME.
- Type 3: Responsibility of BME in cooperation with the implicated non-BME discipline.

Whether an interdisciplinary program is a type 3 BME program or whether it belongs to some other discipline depends, in addition to the criteria above, on the intention of the program and is determined by the educational institution offering the program and requesting accreditation. The accreditation agency determines whether the requirements according to this guideline are met.

5.2. *Degrees*

The following degrees are recommended for the graduation in biomedical engineering Bachelor and Master Programs (type 1 and type 2 programs):

Bachelor of Science	in/of biomedical engineering, clinical engineering, medical informatics, or medical physics.
Master of Science	in/of biomedical engineering, clinical engineering, medical informatics, or medical physics.
Bachelor of Engineering	in/of biomedical engineering, clinical engineering, medical informatics, or medical physics.
Master of Engineering	in/of biomedical engineering, clinical engineering, medical informatics, or medical physics.
Bachelor of	biomedical engineering, clinical engineering, medical informatics or medical physics.
Master of	biomedical engineering, clinical engineering, medical informatics or medical physics.

For programs of type 3, different specifications, depending on the discipline involved, can be used.

At present, governmental authorities decide on the name of the degree since there have been no specific recommendations that are understood and recognized throughout Europe and that are based on the particulars of biomedical engineering and that take into account the particularities of different types of educational institutions and educational programs.

The specific nomenclature of degrees shall be clarified by a supplemental declaration analogous to the Diploma-Supplement. The similarity or sameness of degree names does not mean automatic equivalence or recognition of competencies, unless the programs are accredited according to the same criteria.

The use of Bachelor or Master degrees without specification is discouraged since they are not commonly used in other parts of the world.

6. Educational Objectives and Minimum Requirements

6.1. *Educational Objectives*

There are two different basic types of programs with different educational objectives: research oriented and professionally oriented programs.

The general goal of biomedical engineering education in one and two cycle professionally oriented programs is a scientifically based, application oriented study, that on the basis of broad knowledge of biomedical engineering and extensive competency of engineering methodology teaches and promotes the analytical, creative and design competencies for the development of concepts for solving engineering prob-

lems of a medical/clinical relevance, and for the development and improvement of biomedical systems.

For research oriented programs, the general goal is a scientifically based, fundamentals oriented study, that on the basis of broad biomedical engineering competencies, which must be profound in selected topics, teaches and develops the ability for basic and application oriented research in biomedical engineering and promotes analytical, creative and constructive skills for the development and improvement of complex biomedical systems and methods.

Both research and professionally oriented programs should add as learning outcomes the necessary skills for communication with the medical and biological community and the knowledge of biomedical engineering ethics. Since a generally accepted code of biomedical engineering ethics is only slowly developing, medical ethics included in professional ethics is considered to be adequate.

Additionally,

- general competencies (creative thinking, abilities for interdisciplinary work, technology management, business administration and economics, quality control) and
- social competencies (ability for teamwork, professional ethics, cultural, social, economic and political effects of technology)

are mandatory competencies for professionally oriented programs and optional competencies for research oriented programs.

The Bachelor program must teach a broad spectrum of expert knowledge, and the basics necessary for a professional occupation. The graduates must be able to use scientific results and problem solving concepts in practical applications. Education in a Bachelor program should enable the graduates to successfully continue the study nationally or internationally in a Master program.

The Master program must, based on a first professional degree, lead to deeper professional expertise. Goal of the education must be to enable the graduates to apply scientific methods and results to solve difficult and complex biomedical engineering problems both in practical applications and in research.

6.2. Basic Structures and Categories

The following categorization of courses is based on consecutively organized Bachelor and Master programs of types 1, 2 and 3 as well as for non-consecutive Master programs, type 1 and 2. The categorization establishes structure and grid that allow, upon accreditation, to verify the balance of the curriculum.

The attention to detail in the descriptions of the individual topics does not always correspond to their size. Some of the non-BME modules are deliberately presented in great detail in order to emphasize their importance for a professionally qualifying education and to accentuate the important issues.

For every single degree, the categories and their weights should be established within justifiable tolerances by specific examination requirements. The ratio between theoretical and practical skills is determined by the goals of the program. Certain topics and courses can be made mandatory.

The following paragraphs specify the examination requirements in the different categories for the different types of programs. In tables 1.1 and 1.2 (Addendum 2), the percentages for the different categories are listed.

There are no predetermined curricula, nor specific requirements or percentages for individual courses in the different categories. With regard to accreditation, the outcome, i.e. the aptitude or the acquired skills of the graduates, is more important than the curriculum that may very well contain some specific local profile.

More important than adherence to the listed percentages is a reasonable concept for the curriculum. Therefore, the application for accreditation must contain a detailed description for the objectives of the program, its quality and compatibility as well as the professional qualification of its graduates. It should be explained how students can acquire the general professional competencies.

Research oriented and professionally oriented Programs differ in their objectives. Therefore, different categories and criteria are used. Accordingly, topics listed in addendum 1 are also different.

Typical distributions of courses in terms of credits are given in addendum 3.

6.3. Program modules

The biomedical engineering topics and other modules are broken down into the following modules or categories:

1. Biomedical Engineering foundations (core topics)
2. Biomedical Engineering in-depth topics
3. Mathematics
4. Natural Sciences
5. Engineering
6. Medical and biological foundations
7. General and social competencies (soft skills)

6.4. Contents

In the following the contents of the modules are specified for the individual program categories by keywords.

Within these categories, research oriented programs should emphasize teaching of scientifically based foundations, foster analytical and creative competencies, teach

the ability to develop and improve complex biomedical systems and methods, and teach the students to work in basic or application oriented research. The programs should also educate and train the students to become our future scientists.

Courses offered by professionally oriented programs should provide a scientifically based, application oriented study, that on the basis of broad knowledge of biomedical engineering and extensive competency of engineering methodology teaches and promotes the analytical, creative and design competencies for the development of concepts for solving biomedical engineering problems and for the development and improvement of biomedical systems.

The biomedical engineering contents in terms of categories are the same for all three types of programs. Weight, depth and outline of subjects within categories, however, vary according to the differences of objectives.

Biomedical Engineering foundations (core topics)

- Biomedical instrumentation and technology
- Physiological measurements
- Biosignals, signal processing and interpretation
- Medical imaging systems and image processing
- Biomechanics
- Biomaterials and biocompatibility
- Clinical engineering
- Healthcare telematics
- Modeling and simulation
- Rehabilitation engineering
- Design and project management
- Medical informatics
- Cellular and tissue engineering
- Laboratory and analytic techniques in medicine
- Radiation therapy, therapy planning and dosimetry

For clinical engineering programs, additional core topics are:

- Safety and quality assurance
- Medical device directives
- Legal aspects of design, manufacturing and application of medical equipment
- Health technology assessment
- Hygiene and sterilization
- Radiation protection
- Equipment management
- Hospital technology management

The exact wording for the core topics can differ from the terminology used in this document, important is only the content.

Selection and depth of these topics strongly depend on the specific program objectives. Dependent on the type of program, one or several of the core topics are mandatory. The detailed contents of the topics depend on the specific nature or options of the program. As an example, the contents of Biomedical Instrumentation could be [1]:

Contents:

- Transducers and biosensors
(electrodes, electrochemical sensors, strain gauges, piezoelectric and photo-electric sensors)
- Circuitry for signal acquisition and processing
(amplifiers, filters, biotelemetry equipment)
- Diagnostic instrumentation
(in vitro diagnostics, measurement of bioelectric signals (ECG, EEG, EMG, etc.), measurement of non-electric parameters)
- Therapeutic and life support instrumentation
(radiation technology, ICU/patient monitoring, pacemakers and defibrillators, artificial kidney)

Aims:

- to provide a basic insight in how different types of sensors can be used for the acquisition of information on relevant biophysical parameters, and
- to provide an overview of the most common instruments used for diagnosis, monitoring or therapy in a clinical environment.

Objectives:

At the completion of the course the student should

- have a fundamental insight into the working principles of medical instrumentation in relation to the main classes of observed or controlled biophysical quantities, and be
- able to describe the main specifications of biomedical equipment.

Prerequisites:

Completion of fundamentals of electronics or alternative knowledge of electronics (e.g. BSc in electronics/electrical engineering)

In order to specify the normal width and depth of the core and in-depth modules as a guideline, not as a rule, it would be desirable for the BME community to develop a list of topics with a detailed list of contents, aims and objectives. Similar lists of topics have been developed by the European TEMPERE Project [1] and the German BME Society [4].

Biomedical Engineering in-depth topics

The in-depth topics can be selected from a broad range of BME topics and depend on the specific orientation of a program. They are also subject to change with the fast development of the discipline. The following catalog is not a complete list of all possible in-depth topics but thought to exemplify the term. All core topics can be expanded to in-depth topics.

- | | |
|--------------------------------------|--|
| - Artificial organs | - Lasers in medicine |
| - Anesthesia and Respiration Therapy | - Radiation therapy and radiation therapy planning |
| - Computers in Medicine | - BME in nuclear medicine |
| - Rehabilitation Engineering | - Dosimetry and radiation protection |
| - Information Management | - Biosignal processing and interpretation |
| - Information Systems | |
| - Active and passive implants | |

- Image Processing
- E-health
- Telemedicine
- Endoscopy
- Minimally invasive surgery
- Computer aided surgery
- Medical robots and manipulators
- Biocompatible materials and surfaces
- Prosthetics
- Micro- and nanotechnology
- Modeling and simulation

Mathematics

- Algebra, Calculus
- Analysis (differential equations)
- Statistics and stochastics
- Numerical mathematics
- Optimization
- Integral transformations (Fourier, Laplace, z-transformations)
- Modeling
- Operations research

Natural Sciences

- General natural sciences basics and methodologies
- Physics including mechanics, oscillations and waves, heat transfer, electricity, electrical and magnetic fields, optics, lasers, atom physics (including quantum physics and x-rays), solid state physics (including semiconductors), nuclear physics (including radioactivity)
- Chemistry including biochemistry
- Biology including cell biology and genetics

Engineering

There should be a distinction between three different profiles: electrical engineering/information technology, mechanical and chemical engineering.

- Engineering basics and methodologies
- Electrical engineering basics including electronic devices, circuits, complex alternating currents, instrumentation and signal processing, control systems, complex systems, digital electronics, micro-computer technology, basic informatics, software technology
- Mechanical engineering basics
- Chemical engineering basics, including biotechnology
- Computer science, programming and basics of informatics
- Computational tools, e.g. Matlab environment

Medical and Biological Foundations

- Physiology and anatomy:
cell physiology including nerve and muscle cells, brain and nervous system, heart and circulation, blood and haematopoiesis, vessels and circulatory regulation, immune defense, kidney and uro-genital system, liver, endocrine system, respiration, skeleton and joints, sense organs, skin

- Medical terminology
- Health and disease, introduction to diagnostic and therapeutic problems

General and Social Competencies (soft skills)

- Professional/Biomedical engineering ethics
- Foreign languages, supported by courses offered in these languages
- Communication techniques, didactics, lecture and presentation techniques, supported by seminars
- Project management
- Work and leadership psychology
- Teamwork
- Economical and legal basics
- Business administration and economics
- Ability to do interdisciplinary work
- Technology management
- Quality control
- Cultural, social, economic and political effects of technology

In professionally oriented programs the general and social competencies should have higher weight than in research oriented programs. Topics such as industrial management, business administration and quality control should be mandatory.

Application Specific BME Option – Only Type 1 Programs

The integrated application specific option, a minor subject, should introduce to an application of biomedical engineering. The courses within this subject should be the basis for the understanding of such an application. Lab courses are desirable.

Major Application Specific BME Option – Only Type 2 Programs

Programs with a significantly larger section of an application subject than those in type 1 programs should teach subjects that go well beyond basic knowledge in order to enable the graduates to successfully participate in an application oriented research project. Thus, the program has a strong orientation towards a specific BME option, which is often called a specialty subject. The option can also be used to name the program (e.g. clinical engineering). The specialty subject may also be based upon a non-BME discipline (e.g. biology), as long as the application is a BME application.

Modules from non BME Disciplines – Only Type 3 Programs

These interdisciplinary programs are characterized by a balance between courses in BME and another discipline which is the basis for specific BME applications. The student accentuates one of the two branches of learning by the choice of a thesis in the desired focal area of study. This choice determines the title of the degree.

Graduates should have good and broad basic knowledge in both subjects and in-depth knowledge in the major subject area. They should be capable of integrated problem solving for both subject matters. Contents of courses should reflect this objective. Due to the multitude of reasonable combinations of subjects, specific course contents are not specified in this document.

6.5. Curriculum for a 3+2 year consecutive Bachelor/Master program

Based on the regular workloads of 180 ECTS credits for the first cycle (Bachelor) and 120 ECTS credits for the second cycle (Master), the following tables show the recommendations for the weights of the individual program modules for type 1 programs. The lists specify the normal minimum ECTS credits for the modules. A so-called “flexible budget” allows for an individual, specific profile of the program. For consecutive programs that do not adhere to the 3+2 year model, such as 3.5+1.5 year programs, credits should be shifted from the second cycle to the first cycle such that the overall percentages for Bachelor plus Master are not changing.

Bachelor Program

Category		ECTS credits	Percent-ages
1	Mathematics	20	11.11%
2	Natural Sciences	20	11.11%
3	Engineering foundation	30	16.67%
4	Medical foundation	10	5.56%
5	General and social competencies	10	5.56%
6	BME core topics	25	13.89%
7	BME in-depth topics	15	8.33%
8	Flexible BME budget	20	11.11%
9	BME thesis with project (independent work)	15	8.33%
10	BME Internship	15	8.33%
	Total BME	90	50.00%
	Total	180	100.00%

Consecutive Master Program

Category		ECTS credits	Percent-ages
1	Advanced mathematics	5	4.17%
2	Advanced engineering	10	8.33%
3	General and social competencies	10	8.33%
4	BME in-depth topics	30	25.00%
5	Flexible BME budget	35	29.17%
6	BME thesis with project (independent work)	30	25.00%
	Total BME	95	79.17%
	Total	120	100%

6.6. Curriculum for a 2 year non-consecutive Master program

Based on the regular workloads of 120 ECTS credits for the Master program, the following tables show the recommendations for the weights of the individual program modules for type 1 programs.

Non-consecutive Master Program

	Category	ECTS credits	Percentages
1	Advanced mathematics	5	4.17%
2	Advanced engineering	10	8.33%
3	General and social competencies	5	4.17%
4	Medical foundation	10	8.33%
5	BME core-topics	25	20.83%
7	BME in-depth topics	25	20.83%
8	Flexible BME budget	10	8.33%
9	BME thesis with project (independent work)	30	25.00%
	Total BME	90	75.00%
	Total	120	100%

Examples for other types of programs are given in the addendum.

7. Organizational Requirements

The organizational requirements listed in this document apply to both consecutive and non-consecutive programs.

7.1. Structure of Programs

1. The regular duration of a Bachelor (first cycle) program is three years or 180 ECTS credits with an upper limit of 210 credits.
2. The regular duration of a Master (second cycle) program is two years or 120 ECTS credits. In consecutive two-cycle programs, the number of credits may be as low as 90 ECTS credits.
3. The regular duration of a two-cycle consecutive program is five years or 300 ECTS credits.
4. Periods for training, i.e. professional experience, and practical projects must be integrated into Bachelor programs. The total period should not be less than 10 ECTS credits. Regulations for these periods are to be established and adequate guidance has to be provided by the educational institutions.

5. A Bachelor program normally integrates a thesis with a workload of 15 ECTS credits.
6. A Master program normally integrates a thesis with a workload of 30 ECTS credits.

7.2. Organization of Programs

As general guidelines, the following principles should be adhered to:

1. In addition to lectures, practice, lab courses and projects must be offered. Professionally oriented Programs should normally offer at least 30% of courses as practice or lab courses. In research oriented programs, all mandatory courses should be complemented by practice.
2. The curriculum of Bachelor programs should contain at least one project.
3. Groups should have the following sizes:
 - a. Practice: no more than 15 students
 - b. Lab courses: 1 or 2 students per workplace
 - c. Projects: 5 to 12 students, depending on conception and goals.
4. All mandatory courses must be offered on an annual basis, or each semester if new students are admitted each semester.
5. The workload caused by mandatory and optional courses must be limited such that the students have the opportunity for additional, self-determined studies.
6. The percentage of necessary optional courses being offered must be sufficient, and they should be distributed equally on summer and winter semesters. There should be a sufficient number to allow a genuine selection, i.e. about twice the amount of necessary courses.
7. There should be a selection of courses being offered in the English language.
8. The course offering should normally be such that the program can be completed as a part time study.
9. Intensive counseling must be available.

7.3. Integration of Students

Prerequisite for a high-quality program achieving commendable outcome is a high motivation of its students. This can only be accomplished if students fully identify themselves with the objectives of the program. Therefore, the concept of the program must clearly reveal:

1. how applicants learn which prerequisites or initial competencies are required to enter the program,
2. which courses are offered to close potential gaps between prerequisites and actual knowledge and lead to an adequate entrance qualification,
3. the aims and objectives of the program and of the individual courses
4. how students can actively integrate themselves into the program, and
5. how the instructors present the program to the students and how they communicate.

7.4. Examinations

Examinations and supervision of performance should, in addition to learned knowledge, test competency in biomedical engineering procedures and methodology and the underlying perceptions, conceptions and methods.

General rules are:

1. The procedures must provide grades and credits.
2. The credits are acquired throughout the program.
3. Credits and grades can refer to blocks of linked courses.

Credits comply with the European Credit Transfer System (ECTS).

7.5. Transfer into the Master Program or the Second Cycle

Curricula for Master programs should offer additional options for those students whose first professionally qualifying degree does not correspond to the type of program that usually precedes that Master program. These options can originate from the curriculum of the Bachelor program and/or represent a distinct transition program. They should be structured such that they do not add more than two semesters to the Master program.

8. Quality of Teaching

As established for all other engineering programs.

9. Resources and Facilities

9.1. Personnel

The minimum number of instructors depends on the general structure of the program. It must be sufficient to guarantee an adequately broad spectrum of courses and to maintain administrative operations. The required number of instructors is calculated as the ratio of the minimum number of credits per semester to be offered in the program and the mandatory number of credits per instructor. The total teaching load must be taken into account, including such courses that are offered within other programs. Determination of the acceptable number of students entering the program is based on the general rules established for engineering programs.

There should be a core of qualified, permanent staff in any program. At institutions offering research oriented biomedical engineering programs of types 1 or 2, the number of full-time professors in the BME program should normally be no less than 4. At institutions offering exclusively type 3 programs, the minimum number of full-time professors in the BME program can be reduced according to the percentage of the BME modules offered in the program, but should be no less than 2. Additional adjunct professors from industry etc. are desirable.

The number of other teaching staff is determined according to the general rules valid for academic programs at the institution seeking accreditation. Above these regulations there is a minimum lower limit that results from the amount of homework, class projects and the number of lab courses to be offered, which also require a sufficient number of graduate assistants.

In institutions offering research oriented biomedical engineering programs, mandatory courses in the area of biomedical engineering must be offered by full-time professors. In institutions offering professionally oriented biomedical engineering programs, a percentage of not more than 20% of mandatory BME courses can be offered by adjunct instructors.

The scientific qualification of the teaching staff has to be proven according to the applicable university laws and regulations. These must include pertinent teaching experience. Additional obligatory qualifications are:

- At institutions offering research oriented biomedical engineering programs, scientific qualification must be proven by a sufficient number of publications demonstrating adequate performance in research. Vocational experience is desirable as additional proof of qualification.
- At institutions offering professionally oriented biomedical engineering programs, qualification for biomedical engineering applications must be proven by pertinent, broad and long-term vocational experience.

9.2. Facilities and Financial Resources

Facilities must be available and adequate to permit high-quality teaching and (applied) research & development. Study-centers and work-places, supervised by competent staff, should be offered to the students. The number of rooms available must be sufficient for all classes and lab courses. For lab courses, classes should be divided into small groups.

In institutions offering research oriented biomedical engineering programs:

- sufficient resources must be available for research projects,
- spatial separation of different BME divisions and of cooperating disciplines should be avoided.

In institutions offering professionally oriented biomedical engineering programs:

- sufficient resources must be available for applied science and development.
- biomedical instrumentation, and work-stations, system and application software should be available as they are used in the biomedical industry.
- financial resources and provisions for reductions of the teaching load for professors should be in place – in the form of additional professors – to allow continuing research and development.

10. Accreditation

The national accreditation councils, sustained by the individual European countries, coordinate the process of accrediting educational programs at universities, universities of applied science and polytechnic schools.

Regarding the actual accreditation, the national accreditation councils rely as much as possible on national or international accreditation agencies. These accreditation agencies themselves are accredited for a limited time only by the accreditation council and can grant the certificate of the accreditation council.

10.1. Accreditation Committees

The accreditation committees, as a part of the accreditation agencies, have the following assignments:

1. Determination of procedures and criteria for accreditation and the appointment and training of the auditors.
2. Auditing, i.e. evaluation whether the program requesting accreditation satisfies the criteria.
3. Decision about accreditation based on the results of the auditing (audit reports and suggestions of the audit teams).

The committee responsible for task 2 is consistently referred to as the audit team. The committees responsible for tasks 1 and 3 have varying names in the different agencies. In the following, the committee responsible for task 1 will be called the accreditation commission.

10.2. Accreditation Commission

The accreditation commission determines, for each individual discipline, the procedures and criteria. For this purpose, the accreditation commission can request proposals from expert committees (so-called sector-committees (*Fachausschüsse*)). The commission appoints the members of the audit teams and takes care of their training. When appointing the auditors for biomedical engineering programs, the commission should adequately consider the nominations by the professional and scientific BME societies).

The number of members in the accreditation commission depends on the number of different programs to be accredited. The members of the accreditation commission should be one third each representatives of the universities, the universities of applied science or polytechnic schools and industry.

For the appointment of the university representatives, the biomedical engineering community should not be excluded from being allowed to present nominations.* The nominated university representatives should be active in teaching, should have broad and profound knowledge in biomedical engineering, and should have experience in the development of biomedical engineering programs.

Should there be no BME representative among the members of the commission, the commission should admit guest BME representatives without vote whenever important questions regarding biomedical engineering are discussed or decided.

**In Germany the Fachbereichstage and Fakultätentage are supposed to have the exclusive right for nominations. However, there is no Fachbereichstag or Fakultätentag for BME.*

10.3. Audit-Teams

The audit-teams prepare a proposal regarding accreditation which is based on the established procedures and criteria, the submitted documentation and the results of the site-visit of the institution asking for accreditation of its BME program.

In each audit-team, those members who represent biomedical engineering education in universities should have a decisive majority. These members should have broad and profound knowledge in biomedical engineering, and should have experience in the development of biomedical engineering programs.

For the accreditation of interdisciplinary programs (type 3), there should be representation of the involved disciplines according to the percentages of modules from each discipline contained in the program.

10.4. Accreditation Procedures

The procedure for accreditation is accomplished in two steps. In the first step, it is examined whether the program to be accredited satisfies the established criteria including the requirements for personnel and other resources. If all criteria are met, the program is accredited. Accreditation is granted without stipulations if above and beyond the minimum requirements a sufficiently large amount of desirable requirements is satisfied, otherwise there will be conditions attached to the accreditation.

In the second step, the successful realization of the program which had been presented in the first step is examined. This examination can only be done after the first students have successfully graduated from the program. At this time all conditions imposed in the first step must be met.

Accreditation is valid for a maximum of six years and needs to be repeated according to the second step. The interval between accreditations can be reduced by the accreditation commission if special circumstances require such procedure.

Accreditation should be denied whenever any of the mandatory criteria or minimum requirements are not satisfied or when only an insufficient number of desirable criteria are met and the audit-team comes to the conclusion that these deficiencies have not been justified in such convincing manner that a regular education according to these guidelines can still be guaranteed.

11. References

- [1] Zoi Kolitsi (Ed), "Towards a European Framework for Education and Training in Medical Physics and Biomedical Engineering", IOS Press, Amsterdam, 2001.
- [2] J.H. Nagel, "Biomedical Engineering in a European Higher Education and Research Area", Lecture Notes of the ICB Seminars, International Centre of Biocybernetics of the Polish Academy of Sciences, Warsaw, pp. 11-35, 2002.
- [3] J.H. Nagel, "The Implementation of the European Higher Education Area in Medical and Biological Engineering and Science", IFMBE Proceedings, Vol. 6, BME 438, 2004.
- [4] DGMBT Gegenstandskatalog Medizintechnik, Biomedizinische Technik und Klinikingenieurswesen, VDE, 2001.
- [5] Biomedical Engineering Education in Europe: Status Reports, BIOMEDEA Project, 2005, <http://www.bmt.uni-stuttgart.de/biomedea/Status%20Reports%20on%20BME%20in%20Europe.pdf>
- [6] EUR-ACE Overview: Accreditation Procedures and Criteria for Engineering Programmes in Europe: http://www.feani.org/EUR_ACE/OverviewAccredProced180505.pdf
- [7] Standards and Guidelines for Quality Assurance in the European Higher Education Area (ENQA): <http://www.enqa.net/files/ENQA%20Bergen%20Report.pdf>

Addendum 1: Typical distribution of modules in terms of ECTS credits and percentages

Table 1: Typical ECTS credits and percentages for the individual categories in consecutive two-cycle biomedical engineering programs																			
Category	Program Type 1 Biomedical Engineering						Program Type 2 Biomedical Engineering with special application option						Program Type 3² Interdisciplinary Biomedical Engineering program						
	Bachelor		Master		B. + M.		Bachelor		Master		B. + M.		Bachelor		Master¹		B. + M.		
	Cr.	%	Cr.	%	Cr.	%	Cr.	%	Cr.	%	Cr.	%	Cr.	%	Cr.	%	Cr.	%	
Mathematics	20	11.11	5	4.17	25	8.33	20	11.11	5	4.17	25	8.33	20	11.11	5	4.17	25	8.33	
Natural sciences	20	11.11	-	-	20	6.67	20	11.11	-	-	20	6.67	20	11.11	-	-	20	6.67	
Engineering foundation	30	16.67	10	8.33	40	13.33	30	16.67	10	8.33	40	13.33	30	16.67	10	8.33	40	13.33	
Medical foundation	10	5.56	-	-	10	3.33	10	5.56	-	-	10	3.33	10	5.56	-	-	10	3.33	
General and social competencies	10	5.56	10	8.33	20	6.67	10	5.56	10	8.33	20	6.67	10	5.56	10	8.33	20	6.67	
BME core topics	25	13.89	-	-	25	8.33	25	13.89	-	-	25	8.33	25	13.89	-	-	25	8.33	
BME in-depth topics	15	8.33	30	25.00	45	15.00	15	8.33	30	25.00	45	15.00	5	2.78	30	25.00	35	11.67	
Flexible BME budget with minor application specific module	20	11.11	35	29.17	55	18.33	-	-	-	-	-	-	-	-	5	4.17	5	1.67	
Flexible BME budget for major application specific module	-	-	-	-	-	-	20	11.11	35	29.17	55	18.33	-	-	-	-	-	-	
BME thesis with project	15	8.33	30	25.00	45	15.00	15	8.33	30	25.00	45	15.00	15	8.33	30	25.00	45	15.00	
BME Internship	15	8.33	-	-	15	5.00	15	8.33	-	-	15	5.00	15	8.33	-	-	15	5.00	
Modules from disciplines other than BME													30	16.67	30	25.00	60	20.00	
Total BME	90	50.00	95	79.17	185	61.67	90	50.00	95	79.17	185	61.67	60	33.33	65	54.17	125	41.67	
Total	180	100	120	100	300	100	180	100	120	100	300	100	180	100	120	100	300	100	

² The BME section of the program without thesis and internship must be at least the size of the other disciplines.