

INTERNATIONAL FEDERATION FOR

**MEDICAL AND
BIOLOGICAL
ENGINEERING**



THE IFMBE

**INTERNATIONAL REGISTER OF
CLINICAL ENGINEERS**

**Agreement on mutual recognition of
qualifications for clinical engineers**

BIOMEDEA

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The IFMBE International Register of Clinical Engineers

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INTERNATIONAL FEDERATION OF MEDICAL & BIOLOGICAL ENGINEERING

A G R E E M E N T

on

**Mutual Recognition of Qualifications
for Clinical Engineers**

(Original Agreement: October 1981)

INTERNATIONAL REGISTRATION OF CLINICAL ENGINEERS

1. Historical Background

1.1 At the International Conference on Medical and Biological Engineering which was held in Jerusalem in 1979, the IFMBE under its Charter for Working Groups established a working group on Clinical Engineering. This working group has met on a number of occasions and formulated several goals. The first of these goals, which has been approved by the Administrative Council of IFMBE, is the establishment of criteria for the mutual recognition of qualifications in the field of clinical engineering.

1.2 The growth of the number of people throughout the world in the field of clinical engineering suggests that it is now appropriate to define clearly, preferably through peer review, the type of qualifications that should be required by those intending to practice in the field. The peer review process is taken to mean one in which assessment of an individual is carried out by colleagues of (usually) the highest professional attainment, and is already well recognised as an essential ingredient in the quality of professional registration throughout the world, and is the basis of the present proposals. It is the belief of the IFMBE that qualifications (or experience) beyond those normally agreed for registration as a professional engineer are a necessary requirement for those wishing to practice in the field of clinical engineering. We believe, furthermore, that such additional qualifications should be subject to certification through a similar review process.

The IFMBE sees the establishment of criteria for the mutual recognition of qualifications for those practicing in the field of clinical engineering as being necessary for the following reasons:

- (i) it will improve the standards of healthcare delivery throughout the world both in developed and developing countries by establishing common professional standards of practice for clinical engineers and technicians;
- (ii) it will facilitate a ready exchange of personnel between and within member countries of the IFMBE (subject only to such national registration that may impose additional limitations in individual cases – see Appendix 1);
- (iii) it will provide an agreed reference which governmental and international agencies may use to provide guidelines for the provision of clinical engineering education, services and staffing;
- (iv) it will improve collaboration between the member societies of the IFMBE by stimulating, through the Working Group on Clinical Engineering, a continuing dialogue on all matters relating to the field of clinical engineering;
- (v) it will increase the understanding of education and training systems for clinical engineering in different countries and thereby foster their development.

1.3 The IFMBE recognises that in the field of clinical engineering there are several levels of competence and ability. It is the intention of the IFMBE to provide guidance on the various levels which it recognises, and to provide the seal of approval on those who reach various levels. The Federation recognises that some levels may be inappropriate for certain countries and the responsibility of this document rests with the National Societies as and when they see fit.

1.4 As a first step towards the unification of clinical engineering throughout the world the working group is proposing that a scheme of mutual recognition between member societies, of the highest level of competence, should be established as soon as possible. It should be noted that mutual recognition does not necessarily imply reciprocity, though this is clearly the long term aim of the IFMBE. (Reciprocity may be affected by existing national legislation).

1.5 In establishing this first level, the IFMBE recognises that there will be others which are appropriate to countries both within and outside the Federation: these will be the subject of further discussion and will be circulated both within and outside the IFNBE in due course.

2. Clinical Engineering: a definition

2.1 Clinical engineering is taken to mean the application of medical and biological engineering within the clinical environment, for the enhancement of health care.

2.2 Such application is undertaken by, or under the Supervision of, clinical engineers who bring to health care facilities a level of education, experience and accomplishments which enable them to responsibly, effectively and safely manage and interface with medical devices, instruments and systems, and the use thereof, during patient care; and who can, because of this level of competence, responsibly and directly serve the patient in collaboration with other health care professions.

3. Role of the Clinical Engineer

3.1 The clinical engineer is involved at many levels in the safe, appropriate and economical use of technology in the health care system. Supported by clinical engineering technicians, the professional engineer is responsible for areas extending from design and maintenance of hardware to quality control and, where appropriate, the interpretation of signals from medical instrumentation. Some of the principal areas of responsibility can be outlined as follows. No priority is implied.

3.2 An Advisory Service on Available Technology.

The range of technological devices and systems available to improve health care is vast, extending from the simplest aid intended for use by a disabled patient in a domiciliary setting, through the variety of medical equipment standard in many hospitals, to the most complex electronic diagnostic and therapeutic equipment available as yet to few. With every passing year, technological advances in areas such as instrumentation, materials science, Computer manufacture and nuclear engineering have significant impact on what it is feasible to implement for the benefit of the patient. The clinical engineer has a responsibility to advise on the applicability of such technology in the clinic, either in direct response to the presentation of a clinical problem, or by taking the initiative to introduce new products and methods as appropriate.

3.3 Evaluation and Purchase.

Clinical Engineers should be consulted in the evaluating, purchase and installation of equipment as follows:

- evaluation of equipment, taking into account cost-effectiveness, running and manning costs and subsidiary expenses

- suitability of equipment to perform the desired task in the proposed environment
- safety of the equipment in the proposed environment
- purchase of the equipment, with respect to the required service and back-up from the manufacturer
- incoming inspection of new equipment, Installation of the equipment in a safe and functioning condition.

3.4 Maintenance.

Planned maintenance of equipment is vital to ensure safety and efficiency, and planned obsolescence and replacement of older equipment ensures continuity of service. These are important areas for the clinical engineering staff to arrange and supervise.

3.5 Hazard prevention.

Clinical engineers are responsible for obviating hazardous situations. This includes taking appropriate action on the receipt of Hazard Notices pertaining to potentially defective equipment or techniques as received from International, National, Government or commercial agencies. The clinical engineer should also inform such agencies as appropriate of hazards or hazardous situations.

3.6 Clinical measurement.

Increased objectivity and scientific investigation in health care has led to a proliferation of clinical measurement techniques. Many of the measurement devices require controlled operation by engineering staff, and many require the service of a clinical engineer to interpret the raw data into a relevant summary for clinical use.

3.7 General technical support and facilities.

The clinical engineer can contribute to a higher quality of care by providing engineering competence in many day-to-day problems; supervision of workshops providing special purpose equipment, modification of existing facilities to meet new demands or upgrade performance, computer programming and extension of computer facilities, are examples of such a contribution.

3.8 Education and training.

The clinical engineering personnel have a responsibility to educate not only the next generation of their own kind, but also their medical colleagues and the consumers of health care to some extent. More specifically, these tasks can be described as follows:

- provision of in-job training for engineering personnel who have completed adequate formal education, by the careful development of training schemes with a range of clinical experience and responsibilities;
- instructional lectures/courses/workshops aimed at providing medical staff, from student to qualified practitioner, with the clearest view of what technology can offer the patient;
- where appropriate, advice to consumer representative groups on availability of hardware, effective use of resources and new developments.

3.9 Research and Development.

The involvement of a clinical engineer with a proposed technological solution to a health care problem should begin at the point of problem definition. In the clinic, problem formulation may require extensive measurements and analysis followed by a survey of similar cases before the design stage can properly be started. After design, adequately controlled trials of the resultant system will be necessary and introduction of the new system into common use is vital for effective carry-over of research into practice.

4. Qualifications and requirements for international registration

4.1 Education and experience

In order to obtain international registration as a Clinical Engineer a candidate must:

- Have successfully completed a basic education in engineering or applied sciences to a level comparable with the examples given in Appendix 1,
and
have had not less than 3 years of pertinent clinical engineering experience,

or

- have, in addition to achieving the basic education described in (1) above have undergone a period of higher education and/or training in biomedical engineering, examples of which are given in Appendix 1, and
have had not less than 2 years' experience pertinent to clinical engineering.

4.2 Additional Requirements.

National Examining Authorities (NEA's) may, at their discretion, but with the approval of the IRB, impose such other conditions as may be dictated by local national practices.

4.3 Professional conduct.

Every Clinical Engineer who is registered with the International Registration Board shall at all times so order his/her conduct as to uphold the dignity and reputation of his/her profession and to safeguard the public interest in matters of safety and health and otherwise. He/she shall exercise his/her professional skill and judgment to the best of his/her ability and discharge his/her professional responsibilities with integrity.

In discharging these professional responsibilities, the interests of the patient are paramount and the over-riding consideration must always be that no harm or distress will ensue for the individual or his or her family and that the doctor/patient relationship will be in no way impaired.

4.4 Honorary registration.

The IRB may, at their absolute discretion, confer Honorary Registration on persons who do not satisfy conditions specified in 4.1 above, but who in the opinion of the IRB have made or are making valuable contributions to the subject of clinical engineering.

5. Mechanisms of registration

5.1 Registration of Clinical Engineers is the responsibility of the International Registration Board (IRB). Each Affiliated National Society (ANS) will act as the stimulus for the establishment of the NEA in each country, and each will act as the channel of communication with the IRB. This does not necessarily imply that each Society will be the examining body.

5.2 The NEA in each country will recommend individual candidates to the IRB for registration as a clinical engineer. Registration will be conferred by the IRB.

5.3 The IRB will consist of the Chairman of the NEA from each of the National Societies party to this present agreement, plus representatives of independent international bodies and others as appropriate. The Working Group on Clinical Engineering, together with independent authorities, will comprise the Provisional Board. The prime task of the Provisional Board will be

to establish the Constitution and Bye-Laws of the IRB. Such Bye-Laws and Constitution shall be submitted to the IFMBE's Administrative Council for approval.

5.4 A fee for certification, which is non-refundable, will be recommended from time to time and is to cover the cost of processing applications. The fee will be payable to the NEA and half will be forwarded to the IRB to defray their expenses.

5.5 Each ANS will be responsible for establishing a National Examining Authority. Each NEA will be responsible for setting up and conducting examinations for candidates and recommending action to the IRB. The exact form of the examination procedure will be left to the individual NEA's, and may consist of a written examination, an oral examination and the view of independent referees. This examination process may comprise any or all of these elements, but in all instances must satisfy the requirements of the IRB. The NEA must comprise professionals with a broad background in the practice of clinical engineering and those who are professionally capable of understanding the requirements of such a practice. The examination and the candidate review criteria must be meaningful so that successful candidates will perform well within the specialty without preventing well qualified individuals from attaining certification.

5.6 Each NEA shall publish operational guidelines for the approval of the IRB. Guidance on these may be obtained from the IFMBE's Working Group on Clinical Engineering.

5.7 Funding of the activities of each NEA will be its own responsibility though each may seek the support of its affiliated National Society.

5.8 The Constitution and Bye-Laws of each NEA will be submitted to the IRB for its approval. Once approved the Chairman of the NEA will become a member of the IRB.

5.9 Each NEA will also need to establish a secretariat to which applications for registration can be directed, and which will subsequently be responsible for applying to the IRB for conferment of Registration. (This secretariat may be the Society's own existing secretary or secretariat.)

6. Code of Confidentiality

The IFMBE hopes that each member country will develop its own code of confidentiality relating to patient information and access to patient records.

7. Reference

A Charter for Working Groups of the Federation. International Federation for Medical and Biological Engineering (1979).

8. Declaration of Intent

We, as Affiliated National Societies of the International Federation for Medical and Biological Engineering mutually agree to recognise any holder of the IFMBE's certificate of Registration as a Clinical Engineer, subject only to such additional criteria as may be specified by each National Society in addition to this document.

Signed:

Austria	Italy
Australia	Japan
Belgium	Mexico
Canada	Netherlands
Denmark	Norway
Finland	Spain
F.R.Germany.....	South Africa
France	Sweden
G.D.R.	United Kingdom
Hungary	U.S.A.
Israel	Yugoslavia

APPENDIX 1

Examples of National education systems and national variations of requirements for professional qualifications.

United Kingdom (Biological Engineering Society)

		Age
Pre-schooling (non-obligatory)	1 yr.	4 (entry)
Primary schooling (obligatory)	6 yrs.	5 (entry)
Secondary schooling (obligatory)	4-8 yrs.	11 (entry)
'O' levels or Certificate of Secondary education (some leave education at this point)		16
'A' levels		
University or Polytechnic education		18-19 (entry)
	3 yrs. B.Sc.	21-22
	1 - 2 yrs. M.Sc.	22-24
	3 - 4 yrs. Ph.D.	24-26
Postgraduate training		
	4 yrs.	27-29
Responsible experience		
	2 yrs. Chartered Engineer	29-31

IFMBE Registration requirements.

B.Sc. + 3 years experience
or M.Sc. or Ph.D. (in bioengineering) + 2 years experience

Note: The IFMBE's registration requirements will only partly satisfy the U.K. registration requirements.

For U.K. registration as a Chartered Engineer additional training in a recognised U.K. Training Centre for 2 years will be required, plus 2 years of responsible experience. Where experience is offered in lieu of training, 2 years of relevant experience will count as 1 year of training (i.e. B.Sc. + 8 years experience as a minimum).