Protocol for the Training of Clinical Engineers in Europe

Table of Contents

1. Introduction .....................................................................................................................................................2
2. Clinical engineering: a definition ...................................................................................................................3
3. The role of the clinical engineer .....................................................................................................................3
4. Clinical Engineering training .........................................................................................................................5
   4.1. Introduction ........................................................................................................................................5
   4.2. Training ..............................................................................................................................................6
   4.3. Management of the training scheme .......................................................................................................6
   4.4. The core clinical engineering competences ..........................................................................................9
   4.5. The specialisation subjects ....................................................................................................................10
   4.6. Clinical engineering grades and admission requirements for training .................................................11
   4.7. Basic Training ......................................................................................................................................11
   4.8. Advanced Training .................................................................................................................................12
   4.9. Assessment of Training ..........................................................................................................................12
5. International Perspective for Clinical Engineering and Biomedical Engineering with respect to
   Continual Professional Developments: US, UK, Canada, Australia ............................................................13
   5.1. United States of America .......................................................................................................................13
      5.1.1. Clinical Engineering Education and Training with Internship Programme ..................................13
6. Clinical Engineering courses and Training Programmes in Europe ........................................................15
7. Addendum I, CE grades and responsibilities ...............................................................................................16
8. Addendum II, Core CE areas .........................................................................................................................17
1. Introduction

The International Federation for Medical and Biological Engineering as well as the American College of Clinical Engineering (ACCE) define clinical engineering as: “A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology”. Clinical engineers generally have backgrounds in engineering applied to healthcare and the healthcare industry. They have completed a period of defined education in engineering or related disciplines in addition to defined experience as practicing clinical engineers leading to mastery of a defined core of knowledge. It is the belief of the IFMBE and EAMBES that qualifications and 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. There is the legitimate concern of the consumers, i.e. the patients to be guided and protected so that they can be confident that the professional providing the service is properly qualified and competent.

Biomedical Engineers design, develop, use and manage instrumentation for patient monitoring, diagnosis, treatment or research. Clinical Engineers are Biomedical Engineers based in the Clinical environment, usually a hospital or rehabilitation unit. They may be responsible for the design, management and quality assurance of patient-connected equipment in hospitals. They provide operational and technical support to users of clinical equipment. In rehabilitation, they provide biomechanical assessment, monitoring of patient recovery and the custom manufacture of aids for individual patients. Clinical Engineers may be employed on a graduate or technologist scale.

Clinical Engineering education is based in biomedical engineering or classical engineering supplemented with a combination of courses in physiology, human factors, systems analysis, medical terminology, measurement, and instrumentation. It is often capped with a practicum or internship in a university hospital setting, giving the student a firm grounding in hospital operations, protocols, and ethics.

This background prepares the clinical engineer to fill a variety of roles in research, design, academia, and most often, in the clinical environment. Today, healthcare technology extends into information and communications systems and traditional medical equipment is more complex than ever. Assessing, managing, and solving problems in this hyper-tech world is the work of the clinical engineer.

Clinical Engineers are often confused with another professional group in the hospital, the Biomedical Equipment Technicians (BMETs). In reality, these two groups perform different but equally valuable functions. The BMET is the person responsible for direct support, service, and repair of the medical equipment in the hospital. BMET education and training is usually of a more directly technical nature, and is supplemented with specific schooling in service to the equipment. BMETs answer the call when medical equipment fails to function properly and must work closely with nurses and other hospital staff, as well as the equipment vendor, as they service and maintain the equipment. The job of the clinical engineer, however, is somewhat different.

In recognition of the need for a formal structure for the full range of Clinical Engineers working in Europe, guidelines for the professional formation and development of the Clinical Engineer need to be developed. The guidelines need to contain a Protocol for Professional Formation and Development of Clinical Engineers, guidelines for educational providers on curriculum details relating to the different stages of career development and the associated training programmes. Also, information shall be provided on current opportunities for Clinical Engineering training in Europe.
A European protocol for the training of clinical engineers is important for the mutual recognition of qualifications for those practicing in the field of clinical engineering as being necessary since they:

- improve the standards of health care delivery by establishing common professional standards of practice for clinical engineers and technicians,
- facilitate exchange of personnel between and within European countries,
- provide a commonly accepted reference which governmental and international agencies may use to provide guidelines for the provision of clinical engineering services and staffing,
- improve collaboration between European countries by stimulating a continuing dialogue on all matters relating to the professions,
- increase the understanding of education and training systems for clinical engineering in different countries and thereby foster their development.

IFMBE and EAMBES recognise that in the field of clinical engineering there are several levels of competence and ability. It is their intention to provide guidance on the various levels which it recognises, and to provide the seal of approval on those who reach various levels. IFMBE and EAMBES recognise 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.

As a first step towards the harmonization of clinical engineering throughout Europe the BIOMEDEA working group is proposing that a European training scheme for Clinical Engineers with approval by all European members of IFMBE and EAMBES should be established as soon as possible. It should be noted that approval does not necessarily imply exact implementation, though this is clearly the long term aim of the Protocol. Exact implementation may be affected by existing national legislation.

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. A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

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. The role of the clinical engineer

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. The clinical engineering profession has changed its focus over time from equipment safety and control to healthcare technology management. Some of the principal areas of responsibility can be outlined as follows. No priority is implied (see Addendum I for a more detailed, alternate list).
3.1 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 domestic setting, through the variety of medical equipment that are standard in many hospitals, to the most complex diagnostic and therapeutic equipment available as yet to few. Technological advances in areas such as instrumentation, materials science and cell/tissue engineering, information technology and nuclear engineering have significant impact on what can be implemented 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.

3.2 Evaluation and Purchase

Clinical Engineers should be consulted in the evaluation, purchase and installation of equipment. The CEs should have the necessary skills for:

- the evaluation of equipment,
  - taking into account cost-effectiveness, operating and personnel costs as well as subsidiary expenses,
  - the suitability of equipment to perform the desired task in the proposed environment,
  - the safety of the equipment in the proposed environment,
- the procurement of the equipment with regard to the required service and back-up from the manufacturer, and
- the incoming inspection of new equipment, installation of the equipment in a safe and functioning condition.

3.3 Maintenance

Planned maintenance of equipment is vital to ensure safety and efficiency and that the equipment is working within specifications. Planned obsolescence and replacement of older equipment ensures continuity of service. Bearing the final management responsibility, these are important areas for the clinical engineering staff to arrange and supervise. Good practice rules should be in effect.

3.4 Hazard prevention

Clinical engineers are responsible for the avoidance of hazardous situations. This includes equipment and technology related safety, and 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.

3.5 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.

3.6 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.

3.7 Education and training

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

- provision of on-the-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, and
- where appropriate, advice to consumer representative groups on availability of hardware, effective use of resources and new developments.

These responsibilities require that the clinical engineer keeps up the own level of competency through continuing education.

3.8 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 hospital, 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. Clinical Engineering training

4.1 Introduction

Clinical engineers generally have backgrounds in engineering applied to healthcare and the healthcare industry. Normally they are biomedical engineers which have completed a period of defined education in addition to defined experience as practicing clinical engineers leading to mastery of a defined core of knowledge. It is the belief of the IFMBE and EAMBES that qualifications and 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.

The Biomedical Engineer is an individual competent to practice independently within one or more of the sub-specialities of Biomedical Engineering. Five broad sub-specialities of Biomedical Engineering that are related to clinical engineering are:

1. Clinical Engineering - Hospital
2. Clinical Engineering - Rehabilitation
4. Biomedical Engineering - Biomechanics/Biomaterials Specialists
5. Biomedical Engineering in the Medical Device Industry

Biomedical Engineers working in the clinical environment are the Clinical Engineers. The sub-specialities are described and the core responsibilities and activities identified in the “Proposal for a Protocol for Professional Formation and Development of Clinical Engineers in Ireland”, Biomedical Engineering Division, IEI, February, 2003.
Since future requirement for the certification and registration of clinical engineers will affect primarily those working in the hospital and rehabilitation environment, this proposal describes different levels of training to various clinical engineering career grades in the hospital and rehabilitation environment.

The protocol identifies the need for a review of career grades to ensure that:
- entrance requirements take into account the changing profile of those applying for training posts as well as the likely changes in education provision based on the Bologna Declaration;
- there is a formalised career path across the grades;
- that the Clinical Engineering professional is acknowledged in his or her own right, by title at all levels.

This Section outlines the structure of a Training Programme specifically designed for Clinical Engineers. It is based on the experience of those currently working in the field, international developments regarding Clinical Engineering, current and proposed professional structures and benchmarking across the international approaches to the professional formation and development of Clinical Engineers.

### 4.2. Training

Education and Training are linked together, training normally follows education, but it can also be done in parallel or partially in parallel with education. Training requirements for the industry are mostly specific to the products and the technologies concerned, thus it is common practice that the medical device manufacturers provide their own training programmes to their employees. Therefore, the European Protocol for the Training of Clinical Engineers has primarily been developed for Biomedical or Clinical Engineers working in a clinical environment.

The training will normally be organized in a Training Centre, and the trainee will normally be employed in the Training Centre. He or she will undergo a three year training period including supervision and experiential training in the core areas of clinical engineering as well as two of the Specialisation Subjects. During the training period which has a total duration of three years, the trainee will follow a plan of supervised experiential training for achievement of the competencies as set out below. The training plan will be developed by the Training Co-ordinator. The first two years of training are referred to as Basic Training and during this time the trainee will always be supervised. During the following year, the Advanced Training period, some limited, clearly identified unsupervised work may be performed. A log-book will be maintained throughout training and practical skills will be tested, the Trainee will be interviewed at the end of each of the periods of Training to ensure that a reasonable standard of competency has been achieved.

Equivalent protocols are acceptable.

### 4.3. Management of the training scheme

Overall responsibility for the recognition of national training schemes and their organization will lie with the European Clinical Engineering Professional Development Panel (ECEPDP) which will be appointed by a European subcommittee of the Board of the Clinical Engineering Division of the IFMBE which already has significant experience in this area, in cooperation with the European national professional associations/societies.

The Panel will advise those associations who wish to set up a national training scheme.
Representatives to the Panel should come from:
- the CE Division of the IFMBE and from EAMBES
- the Board of Examiners of the IFMBE
- the National BME/CE societies
- the European BME/CE Educational Institutions
- the Employers
- the Biomedical Industry and Medical Equipment Suppliers
- the Clinical Engineering Professionals.

The term of office for members of the Clinical Engineering Accreditation Panel will be four years, however for the purposes of continuity, in the first instance up to half the members would step down after two years.

The role of the European Clinical Engineering Professional Development Panel will be:
- to accredit national educational/training schemes
- to appoint a European Training Coordinator
- to accredit national Training Coordinators
- to ensure that a high standard of training and practical education is maintained
- to liaise with trainees via the European Training Coordinator.

Appointment to the Clinical Engineering Professional Development Panel will be by nomination from the representative bodies. Each member will have a nominee who will take their place should they need to retire from the panel. The panel will convene once each year.

The European Training Coordinator
The role of the European Training Coordinator is to coordinate and monitor the performance of the national training schemes and to liaise with the national training coordinators and the National Clinical Engineering Professional Development Panels. Additional duties are to interface with European hospital organizations and health authorities in the implementation of the program.

The Training Coordinator will:
- ideally, hold an academic appointment and
- have a minimum of 5 years experience in Engineering as it relates to Medical Technology
- have a minimum of 3 years experience as a national training co-ordinator.
- be a Certified Clinical Engineer

Initially, it is expected that this role would be met through a commitment of one day per week.

The National Training Coordinator
The role of the national training coordinator is to manage and supervise the national training scheme. Additional duties will include:
- liaison with academic institutions in all areas of the training scheme;
- interfacing with hospitals and health authorities in the implementation of the program;
- ensuring that optimum benefit is realised from the practical training scheme;
- ensuring that consistently high standards are maintained in all aspects of the scheme;

The national training coordinator will:
- have a minimum of 5 years experience in Clinical Engineering
- be at least employed at Senior Clinical Engineer Grade
- be a certified Clinical Engineer.
Participation Criteria for Training Centres

A Training Centre may be:

- a single specialised centre (e.g. radiotherapy hospital, maternity hospital or rehabilitation centre);
- a large acute hospital;
- a group of hospitals within the same geographical region offering a range of specialisations;
- a medical equipment service supplier in conjunction with a single hospital or a group of hospitals;
- a medical device manufacturer or supplier in conjunction with a single hospital or a group of hospitals.

Institutions providing basic clinical engineering training must be accredited with the national or European CEPDP and must provide

- appropriate facilities for the training,
- experienced staff, competent to provide the training, and
- paid positions for training, the number of positions not to exceed the capacities with regard to facilities and resources.

The training does not need to be undertaken in a single institution. Institutions can also build consortia for the purpose of providing training. Such consortia should be accredited as a whole.

Institutions providing advanced training for the specialization in one or more areas do not need to be accredited with the ECEPDP. If the institution is not accredited, the training must be taken under the supervision of a professional who has successfully completed the advanced training or its equivalent. The institutions have to demonstrate that they have appropriate facilities and resources for the training.
4.4. **The core clinical engineering competences**

In agreement with the American College of Clinical Engineering (ACCE), the core areas of clinical engineering training are:

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

The percentages should be understood as guidelines that allow some tolerance.

The contents of the core areas are:

1. Management
   - A. Overall Clinical Engineering Program Management
   - B. Technical Supervision
   - C. Financial Management
   - D. Service Contract Management
   - E. Computer Management Systems
   - F. Help Desk/Call Tracking

2. Technology Assessment
   - A. Technology Assessment
   - B. Product/Vendor Selection
   - C. Capital Planning
   - D. Clinical Trials Management
   - E. Building Plan Review
   - F. Building Design

3. Regulatory/QA Issues
   - A. Regulatory Compliance
   - B. Quality Assurance
   - C. Healthcare Performance
   - D. Product/Systems Quality Management

4. Repair/Systems Thinking
   - A. Equipment Repair
   - B. Equipment Installation
   - C. Other Facility Tasks

5. Risk Management/Safety Issues
   - A. Incident Investigation
   - B. Hospital Safety
   - C. Risk Management/Legal Issues
   - D. Radiation Safety
6. Education
   A. Technician Education
   B. Engineering Education
   C. Other Education
   D. User/Nurse Training

7. Product Development
   A. Product Research and Development
   B. Documentation Development
   C. Medical Device Design
   D. Other Product Development
   E. Product Sales and Support

8. Miscellaneous Topics
   A. Consulting in Healthcare
   B. Information Technology applied to Healthcare
   C. EMI/EMC Consulting
   D. Expert Witness
   E. Forensic Medical Technology Related Investigation
   F. Legal Consulting
   G. International Healthcare
   H. Chief Technology Officer
   I. Healthcare Administration
   J. Telecommunications in Healthcare

(see Addendum II: alternate list of core areas from the “Proposal for a Protocol for Professional Formation and Development of Clinical Engineers in Ireland”, Biomedical Engineering Division, IEI, February, 2003)

4.5. The specialisation subjects

The specialty areas are:

1. Medical Electronics and Equipment Management
2. Information Management and Technology
3. Rehabilitation Engineering
4. Radiotherapy Technology
5. Diagnostic Imaging Technology
7. Biomaterials
8. Biomechanics

The specialty areas have been sorted such that combining two of them allows the trainee to cover a reasonable area of biomedical engineering. Recommendable pairs are for example radiotherapy technology and diagnostic imaging technology, or rehabilitation engineering and biomechanics, or biomechanics and biomaterials to cover the range of implants.

No structured training is currently required for progress through grades to leading positions for Clinical Engineers.
4.6. Clinical engineering grades and admission requirements for training

There are five different grades for biomedical engineers working at different levels of competency and responsibility: trainee, basic, senior, a principal or a chief. This document does not include training and careers of (non-academic) Biomedical Technicians.

The different admission requirements for these grades are:

1. **Trainee CE**: Bachelor in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent,

2. **Basic grade CE**: Bachelor in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent, plus + 2 years training or Master degree in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent,

3. **Senior grade CE**: Bachelor degree + 3 years training + Core Clinical Engineering Certificate or MSc in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + Core Clinical Engineering Certificate + 2 years training,

4. **Principal CE**: MSc in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + Core Clinical Engineering Certificate + 3 years training

5. **Chief CE**: MSc in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + Core Clinical Engineering Certificate + 3 years training + additional 3 years relevant experience.

There are different pathways to each level:

1. normal academic BME education + training
2. specialized education + integrated training.

Alternative, but equivalent qualifications are acceptable.

Clinical engineers are progressively integrated in medical teams. Their role includes more research/development, collaboration with physicians, involvement in ethics committees, but less management. These professionals should be called **Medical Engineers**. Admission requirements are:

MSc in Biomedical Engineering plus 1.5 years training in a hospital.

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4.7. Basic Training

Basic Training will introduce the trainee to a broad range of Medical Technology. By the end of the basic training he or she will select two of the Specialisation Subjects which are to be completed by the end of the Advanced Training Period.

The trainee will maintain a log-book and training portfolio recording and verifying learning tasks performed. The trainee’s exposure to medical technology will be controlled by a Supervisor to ensure that he or she does not work at a level beyond their experience. The Training Coordinator will review the log-book on an annual basis, and at the end of the Basic Training period the Training Coordinator will interview the Trainee to ensure that an appropriate standard of competency has been achieved. Some practical skills may be tested.
4.8. Advanced Training

Advanced Training represents the interim time between Basic Training and self-regulated training via CPD. At the end of the Advanced Training Period the trainee will have completed all required Training modules relating to the selected Specialisation Subjects.

The trainee will maintain a log-book and training portfolio recording and verifying learning tasks performed. The trainee’s exposure to medical technology will be controlled by a Supervisor to ensure that he or she does not work at a level beyond their experience. The Training Coordinator will review the log-book on an annual basis and at the end of the advanced training period, the Training Coordinator will interview the Trainee to ensure that an appropriate standard of competency has been achieved. Some practical skills may be tested. A report will be submitted to the National Clinical Engineering Professional Development Panel. All appeals will also be addressed to the National Clinical Engineering Professional Development Panel.

Following completion of Basic and Advanced Training it is expected that the Trainee will maintain their professional standing through Continuing Professional Development.

4.9. Assessment of Training

At the end of each year of the Basic and Advanced Training periods the Trainee will be assessed by the Training Coordinator. The assessment will include an evaluation of the Training Supervisor’s reports and an inspection of the Trainee’s log-book and training portfolio. At the end of the Basic and Advanced Training Periods a further assessment will be carried out and, in addition, a selected range of the Trainee’s practical skills will be assessed by the Training Coordinator.

When assessing competencies, it is important to test the qualities of a professional Clinical Engineer. These will include the ability to:

- define a problem and formulate strategies for solving it;
- interpret standard data;
- make value judgements in unfamiliar situations;
- communicate scientific information clearly and accurately to others;
- recognise fault situations and take suitable corrective action.

The reports of the Training Supervisor will be based around competency-based assessment.
5. **International Perspective for Clinical Engineering and Biomedical Engineering with respect to Continual Professional Developments: US, UK, Canada, Australia**


5.1. **United States of America**

5.1.1. **Clinical Engineering Education and Training with Internship Programme**

Clinical engineering education and training is also available in the US at certain colleges. One Clinical Engineering Internship Programme was established in Hartford, Connecticut, in 1974. Initiated by the co-operative efforts of Trinity College, The Hartford Graduate Center and Hartford Hospital, this hospital-based two-year programme has evolved to include the University of Connecticut Medical Center in Farmington, the Baystate Medical Center in Springfield, Massachusetts, and NOVAMED, a shared clinical engineering service serving Bridgeport Hospital.

**Academic plan of graduate study**

A typical plan of study for the graduate students enrolled in the Clinical Engineering Internship Programme follows that of a normal master’s degree Programme in biomedical engineering, and includes two core courses of bio-instrumentation and clinical engineering fundamentals. At least four electives from the following set of biomedical engineering graduate courses are selected:

- electrophysiology of the central nervous system
- biomaterials
- biological control systems
- skeletal biomechanics
- expert systems in medicine
- medical imaging

At least two graduate courses in the individual student’s engineering discipline (e.g. electrical or mechanical engineering) must also be studied. A minimum requirement of 30 credit hours is then completed with a six-credit hour thesis/project, usually undertaken during the second year of the associated internship programme.

One of the core courses, clinical engineering fundamentals, requires some additional discussion. As this course provides the students with an in-depth understanding of operating a centralised clinical engineering department, it includes work on establishing budgets, preventive maintenance programmes, quality assurance, standards, pre-purchase evaluation procedures and project management. This course exposes the student to those factors important in managing medical technology within a hospital setting and serves the important function of stressing the administrative responsibilities of clinical engineers.

**Internship programme**

In addition to the usual ‘engineering-type’ courses of study required to provide an individual with the necessary fundamentals in specific biomedical engineering topics, it is necessary that students interested in clinical engineering are exposed to and carry out work in the hospital environment. Such an experience permits these pre-professionals to observe not only the operation of specific medical instruments, but also the environment in which they are used and the people who use them.
One way to obtain this experience is through an internship established as part of the individual’s overall educational programme. In the Connecticut programme described here, budding clinical engineers are treated as interns and assume the role of their medical counterparts to learn the intricacies of their profession in a personal manner. Furthermore, clinical organisational and management skills required by clinical engineers and not traditionally included in a formal curriculum can be obtained by such an internship experience. Programmes that provide such an educational opportunity offer the participating students excellent exposure to the ‘real world’ in which the clinical engineer must function.

The Greater Hartford Clinical Engineering Internship Programme offers a regional approach to provide an in-depth, rigorous, clinical experience that matches the engineering expertise gained in the classroom. The primary objectives of this intense internship programme are as follows:

1. provide exposure to hospital organisation and administrative functions.
2. allow hospital experience of clinical engineering, i.e. provide an opportunity to apply engineering techniques to patient care and hospital-based research.
3. provide substantial experience working with hospital personnel, including administrators, nurses, technicians and medical staff.

As previously mentioned, these objectives are not traditional classroom experiences, rather they emphasise the practical side of healthcare technology. They are achieved not only by observing, but by actually working on projects in the clinical environment. All of these experiences are obtained during two phases of the internship: (a) a rotation through the majority of hospital departments during the first year; and (b) an in-depth involvement with a significant, clinically oriented project during the second year of the programme.

As the programme requires that the entire two academic years are spent working 25-30 hours per week at the hospital, with the remaining time concentrated in classroom activities, there is ample time for the student to be thoroughly familiarised with hospital routines and procedures. While being immersed in the clinical environment, the student usually takes two graduate courses each semester for four semesters. In addition, two graduate course credits are awarded for the student’s research activity. The research is accomplished during the second year of the programme and constitutes a master’s thesis project. Therefore, the entire graduate programme consists of ten courses, each worth three credits, for a total of 30 credit hours. As these courses are provided during their hospital work, students can select those courses most helpful to them as they profit from their experience in the clinical environment.

This programme is specifically designed to be tuned to the needs of the individual intern, and consequently constitutes an apprentice-type training experience. For this to occur, a high degree of inter-institutional co-operation between the academic and medical components in the programme is required and has been achieved. Several interesting aspects of this arrangement should be noted. For this type of programme to be effective, it must be mutually beneficial to all concerned; the student, the university and the hospital. In this programme, the students obtain valuable education. They tend to be highly motivated, enjoy the clinical exposure and readily work overtime to gain additional experience. The academic institutions are able to provide healthcare-oriented projects for students within the healthcare system. The hospital, in return, has the opportunity to engage engineering professionals in projects of significant magnitude at minimal cost.

For the past twenty years, graduates from this programme have been successful in entering

• clinical engineering departments of moderate-large hospitals; several graduates have even been hired immediately to serve as directors of these departments.
• medical instrumentation companies.
• medical schools.
They have all been well prepared to engage in the profession of clinical engineering.

**Justification of the Internship Approach**

When reviewing any educational programme with an internship component, two questions usually arise. The first is why use the internship format? It is expensive in both time and money to tutor an intern in a hospital setting, where the primary activity and concern have nothing to do with formal educational approaches. The second question is why should a hospital pay for the education of clinical engineers? Few clinical engineer sources exist from which the hospital may recruit. Hospitals want to know what their return will be if they invest in such a programme. The economics of the internship programme depend on its organisation. The fact that the clinical engineering intern begins as a graduate engineer and provides useful work is justification for the hospital administrator. The full extent of the benefits depends on the success and value of the second-year project, which directly serves the needs of the hospital. According to hospital administrators, the key advantage of the programme is that it provides the hospital with engineering services it would otherwise have to do without.

The primary objective of any internship programme, however, is to provide a high-quality educational programme for a small number of students. The internship approach is not appropriate for large numbers of students, nor is it desirable for large numbers of clinical engineers to be trained when the market for this type of professional is still relatively small. The market may increase as the value of these professionals is realised by the industrial community’s medical instrumentation companies, and by the insurance companies who underwrite hospital and malpractice insurance policies.

**6. Clinical Engineering courses and Training Programmes in Europe**
7. Addendum I, CE grades and responsibilities

According to the Biomedical Engineering Division of The Institution of Engineers of Ireland, Clinical Engineers are employed at various grades within the Health Care System. In various circumstances depending on personnel levels and patient load, there is no strict demarcation between the specific roles carried out by the different grades, however the activities at the top of the chart below are weighted towards the "graduate" or Chartered Engineer while those at the bottom are weighted towards the "technician" or Associate Engineer.

Chartered Engineer

1. Specifically assist hospital personnel in defining their problems and needs in connection with biomedical instrumentation and its management
2. Provide and actively part-take in strategic planning with regard to a hospital's complement of medical equipment
3. Fulfill a risk management role with regard to medical equipment
4. Design and supervise the construction and testing of special-purpose electronic equipment when requirements cannot be met by commercially available apparatus
5. Conduct continuing study and research in contemporary developments, design, and construction methods as applied to medical and health care
6. Develop methods for calibrating and performance-checking biomedical instrumentation, maintaining a set of fundamental electrical standards and instruments adequate for this work
7. Supply background in physics, chemistry, mechanical engineering, control theory, and mathematics provide informal instruction in theory and practice to instrumentation section specialists for improved understanding of current developments
8. Supply background knowledge in national and international standards and guidelines pertaining to the application of medical devices and instruments
9. Provide fiscal analysis of technical issues relating to medical equipment
10. Act as a consultant and adviser to research and clinical specialists in negotiating development projects and recommending solutions to instrumentation and electrical-safety problems
11. Represent the hospital at conferences on biomedical instrumentation and electrical safety and in dealing with engineers from manufacturers and other organizations
12. Design of independent living centers which allow physically or neurologically disabled individuals to live independently through the use of assistive services
13. Creation and implementation of augmentative communication systems which give the ability to communicate to disabled individuals
14. Design materials which help improve the quality of life and health of a client
15. Modification of a motor vehicle such that a disabled client can independently operate it
16. Represent the hospital in dealings with outside organizations involving professional engineering responsibilities
17. Develop and conduct instructional courses in the application of instruments and devices
18. Implementation of a hospital's electrical safety program for medical instrumentation
19. Implementation of a maintenance program for medical instrumentation

Associate Engineer
8. **Addendum II, Core CE areas**

The core areas of Clinical Engineering according to the Biomedical Engineering Division of The Institution of Engineers of Ireland are:

1. Qualified appraisal of equipment support and safety requirements. This ensures that each asset is adequately supported, in an optimally cost effective manner and eliminates the potential of under / over supporting. Previously this consideration was a function of the vested enthusiasm of the respective equipment supplier;
2. Project Management at electromedical equipment level;
3. The management of service contracts and the supervision and control of external equipment service suppliers, where it is not feasible for this same support to be directly provided by the Clinical Engineering Department;
4. Financial management and accountability for all medical equipment assets supported by Clinical Engineering Department regarding costs and service;
5. Provision of technical advice and equipment training for clinical users;
6. Technical investigation of injury / death incidents where medical equipment is implicated;
7. Documenting and filing of all records pertaining to the support of this equipment, with integration to the hospital asset register. This facilitates the extraction of statistical data and preserves full service records relating to each item of equipment;
8. Provide and implement an extensive preventative maintenance program for clinical, pathology, radiology and radiotherapy assets;
9. Implementation of Risk Management and Health and Safety policies for medical equipment assets which address the health service obligations and reduces the potential for patient injury;
10. Provision of financial projections and reports concerning the support of the various categories of medical equipment;
11. Provision of advice to hospital administration regarding the purchase, application, commissioning, support and eventual decommissioning of all Clinical Engineering equipment;
12. Preparation of equipment technical specifications for tender purposes and the subsequent evaluation of prospective equipment as part of the standard purchasing tender procedure;
13. Continuous development of service / support initiatives within the department that pertain to medical equipment management and will enhance the facilities provided by the hospital in the context of user / patient satisfaction and financial efficiency;
14. Liasing with medical staff, service suppliers and device manufacturers to develop or enhance medical devices or establish new protocols for the optimum use of technology from a clinical perspective;
15. To contribute to Research & Education programmes in the hospital environment;
16. To be a source of advice on Standards and Legislation impacting on medical technology;
17. Contribution to Industry and Commerce through co-ordination of for example, Beta test sites.