

Version 4.0

**Protocol for  
Voluntary Professional Registration for Clinical Engineers**

**Version 4.0**

**September, 2008**

### ***Change Management Process***

*This document has been continually revised since the foundation of the Clinical Engineering Voluntary Registration Board. Versions 1.x was developed in accordance with the Department of Health and Children document, "Statutory Registration for Health and Social Professionals", 2000. Versions 2.x and 3.x were developed in accordance with "The Health and Social Care Professionals Bill, 2004" and complies with I.S. EN 17024:2003 "Conformity Assessment – General Requirements for Bodies Operating Certification of Persons".*

## **1. Introduction**

Professional Registration is a system whereby each individual member of a profession is recognised by a specified body as competent to practice within that profession under a formal mechanism.

The purpose of this document is to outline the structure of the professional registration scheme for Clinical Engineers. This is a voluntary scheme. The scheme was initially developed by members of the profession and handed over to the first Registration Board on 18<sup>th</sup> February, 2002.

## **2. Rationale for the Clinical Engineering Voluntary Registration Scheme**

This Voluntary Registration Scheme has been developed to meet the needs of the Clinical Engineering Profession. This is a relatively new profession with the first professional body set up to support it, the Biomedical and Clinical Engineering Association of Ireland ([www.BEAI.org](http://www.BEAI.org)) in 1991. A brief history of the emergence of the profession is included in Appendix 1.

Clinical Engineers have provided educational, research, technical, clinical and managerial services and support to clinicians, nurses, and healthcare managers in a variety of ways over the last forty years in Ireland. Statutory Registration provides the opportunity to identify the range of services offered by Clinical Engineers, to standardize the education and training requirements and to certify persons as fit and suitable to practice in the profession through structures which are already written into the legislation (Charter Amendment Act, 1969, Engineers Ireland).

The remainder of this section relates the development of the Clinical Engineering profession to the requirements of Health Care professions as set out in "The Health and Social Care Professionals Bill, 2004" to be regulated by that legislation.

### **2.1 The extent to which the profession has a defined scope of practice and applies a distinct body of knowledge:**

## **Outline Scope of Practice for Clinical Engineers**

### ***Core Roles and Responsibilities***

Different types of hospitals have differing Clinical Engineering needs and each hospital offers a unique profile of clinical specialisation. There is not a strict demarcation between the actual roles performed between various grades of Clinical Engineering personnel. However the Clinical Engineer's education, training and continuing professional development must prepare him for involvement in the core areas of activity of the Clinical Engineer as listed below.

Some of the core roles of the Clinical Engineer are identified below, in many cases, the Clinical Engineer makes his contribution to the Healthcare System as a member of a multidisciplinary team:

**1. Service Management with respect to Medical Technology**

- A. Technical Supervision
- B. Financial Management
- C. Service Contract Management
- D. Computer Management Systems
- E. Help Desk/Call Tracking

**2. Technology Assessment with respect to Medical Technology**

- 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 with respect to Medical Technology**

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

**4. Repair/Systems Thinking with respect to Medical Technology**

- A. Equipment Maintenance
- B. Equipment Installation
- C. Equipment Acquisition
- D. Equipment Decommissioning
- E. Equipment Libraries

**5. Risk Management/Safety Issues with respect to Medical Technology**

- A. Incident Investigation
- B. Hospital Safety
- C. Risk Management/Legal Issues
- D. Radiation Safety
- E. Medical Gas Testing
- F. Emergency Preparedness

**6. Education with respect to Medical Technology**

- A. Technician Education
- B. Engineering Education
- C. User/Nurse Training

**7. Product Development with respect to Medical Technology**

- A. Product Research and Development

- B. Documentation Development
- C. Medical Device Design
- D. Product Sales and Support

## 8. Miscellaneous

- 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

## Specialisations

Within Clinical Engineering Departments, professionals specialise in one, or possibly two of the speciality areas listed below:

- Medical Electronics, electrophysiological acquisition and monitoring technology
- Equipment Management
- Information Management and Technology
- Rehabilitation Engineering
- Radiotherapy Technology
- Diagnostic Imaging Technology
- *Expert Systems/Decision Support Systems*
- Biomaterials
- Biomechanics

Clinical Engineers operate at an international, national, regional and local level.

For the purposes of clarification, examples of generic tasks carried out by Clinical Engineers across the range of areas list above are given below:

## Management

- Project Management for patient-connected medical equipment is now a normal part of the Clinical Engineer professional role, examples are in the areas of hospital planning, capital expenditure planning projects; major capital equipment procurement, installation and commissioning.
- The management of service contracts and the supervision and control of external equipment service suppliers;
- Financial management and accountability for all medical equipment assets supported by Clinical Engineering Department regarding costs and service;

- 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;
- Provision of financial projections and reports concerning the support of the various categories of medical equipment;
- Provision of advice to hospital administration regarding the purchase, application, commissioning, support and eventual decommissioning of all Clinical Engineering equipment;
- 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;
- Analysis of records to identify problems and shortcomings in supplied equipment and define areas where new products techniques or materials Research and Development are indicated;
- Maintain data to enable evaluation of cost benefit and patient benefit of different devices and technological approaches;
- Define appropriate quality standards to apply and interpret their meaning;
- Be aware when legal implications may derive from equipment failure and alert the appropriate staff member;
- Survey current equipment in the department and use this to organise and / or monitor its use with respect to effective and safe practices.

### **Equipment Management**

- 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.
- Provide and implement an extensive preventative maintenance program for clinical, pathology, radiology and radiotherapy assets;
- Preparation of equipment technical specifications for tender purposes and the subsequent evaluation of prospective equipment as part of the standard purchasing tender procedure;
- To be a source of advice on Standards and Legislation impacting on medical technology;
- Evaluate equipment which is in use, for its effectiveness, safety and suitability;
- Commission and evaluate new equipment ensuring appropriate performance and safety tests are carried out;
- Set up equipment to meet the specified user requirements; , whilst ensuring manufacturer's recommendations are met.
- Investigate the cause of equipment failure;
- Initiate informed action following failure of equipment, and negotiate with suppliers/ producers and legislative bodies etc. regarding technical aspects of its failure.

### **Risk Management/Safety Issues**

- Technical investigation of injury / death incidents where medical equipment is implicated;
- 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;
- To be a source of advice on Standards and Legislation impacting on medical technology.

### **Education**

- Provision of technical advice and equipment training for clinical users;
- To develop, drive and contribute to Education programmes in the hospital environment.

### **Research**

- To contribute to Research programmes in the hospital environment.
- To develop, drive and contribute to Research programmes in the hospital environment.

### **Product Development**

- Liaison 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;
- To be a source of advice on Standards and Legislation impacting on medical technology;
- Development and management of Beta Testing;
- Innovate, develop, design for non-standard equipment, and oversee its manufacture testing, and commissioning;
- Manufacture of custom devices?
- Produce technical specifications for equipment which is not commercially available. Design devices and produce technical drawings and/or circuit diagrams to meet the technical specification above, demonstrating application of appropriate safety standards and produce appropriate documentation for such equipment; Evaluate technical drawings for manufacture of custom devices, and evaluate technical specifications of commercial equipment to be obtained;
- Monitor the manufacturing process and authorise modifications to meet local manufacturing capability.

### **Miscellaneous Topics**

- Contribute at a professional level to clinical teams;
- Contribution to Industry and Commerce through co-ordination of for example, Beta test sites.
- Interpret and explain current technical Standards and Legislation affecting the engineering performance of medical devices;
- Prepare Ethical approval submissions.

## **2.2 The extent to which the profession has established itself, including whether there is at least one professional body representing a significant proportion of the profession's practitioners:**

There are approximately 120 Clinical Engineers employed as Clinical Engineering Technicians or employed as Physicists but working as Clinical Engineers (there is no graduate Clinical Engineering grade currently recognized by the Department of Health and children, however, this is currently the subject of negotiation between the trade union, Impact and the Department of Health and Children) but whose work is in Clinical Engineering, practicing in Irish hospitals.

At least one hundred of these are members of the Biomedical and Clinical Engineering Association of Ireland (BEAI) or the Biomedical Engineering Division of the Institution of Engineering of Ireland (IEI).

*Members in private industry?*

**2.3 The existence of defined routes of entry into the profession:**

This is dealt with in Section 7.2(a) below.

**2.4 Commitment to continuous professional development:**

This is dealt with in Section 7.2(b) below.

**2.5 The degree of risk to the health, safety or welfare of the public from incompetent, unethical or impaired practice of the profession:**

The risks to the health, safety, or welfare of the public from incompetent, unethical or impaired practice of Clinical Engineering may arise during patient diagnosis or therapy using electrically powered patient-connected medical equipment. The Medical Devices section of the Irish Medicines Board and the UK Medicines and Healthcare Regulatory Authority (an executive agency of the Department of Health, UK), maintain reports of medical device adverse incidents in Ireland and the UK respectively. The data bases ([www.imb.ie](http://www.imb.ie) and [www.devices.mhra.gov.uk/mda](http://www.devices.mhra.gov.uk/mda)) include a large volume of recorded and reported adverse medical incidents arising from malfunction of electrically connected medical equipment.

Misdiagnosis may occur due to inappropriate calibration of devices such as physiological measurement technology or imaging devices. The patient may receive ineffective therapeutic doses or overdoses of medication due to malfunction of medical devices. The result of such incidences can cause morbidity and mortality.

Clinical Engineers play a significant role in ensuring that equipment performs according to its specification and ensuring that appropriate technology is used in the most appropriate and effective manner. In order to do this an appropriate level of technical education, practical training, Continuing Professional Development, networking and on-going academic liaison are essential. This is clearly laid out in the Scope of Practice for Clinical Engineers, Section 2.1.

**2.6 The fitness of the members to practice their profession is not regulated by or under another Act of the Oireachtas:**

While the technical component of a Clinical Engineer's proficiency is governed by the Charter Amendment Act, 1969, this is insufficient to meet the need for regulation of the Clinical component of a Clinical Engineers work. Given the scope of practice of a Clinical Engineers work and the associated risk to the public of that work not being performed in a regulated manner, it is appropriate that Clinical Engineering should be regulated by "The Health and Social Care Professionals Bill, 2004".

**2.7 The Minister has given interested persons, organisations and other bodies an opportunity to make representations to him or her concerning the proposed designation:**

The issue of professional registration for Clinical Engineers has been the subject of on-going correspondence between the Chairman (2002-2005) of the Clinical Engineering Voluntary Registration Board (CEVRB) and Department of Health and Children staff dealing with this legislation since the establishment of the Voluntary Registration Board. A meeting between a representative group from the CEVRB and William Beausang and Maeve O'Brien took place in Hawkins House in July 2004. More recent communications indicate that following passing of the "The Health and Social Care

Professionals Bill, 2004" into law the CEVRB will be invited to meet with the DOH&C officials with a view to implementation of Statutory Registration for Clinical Engineers.

**2.8 A health or social care profession is any profession in which a person exercises skill or judgment relating to any of the following health or social care activities:**

- The extent to which the profession has a defined scope of practice and applies a distinct body of knowledge;
- the extent to which the profession has established itself, including whether there is at least one professional body representing a significant proportion of the profession's practitioners;
- the existence of defined routes of entry into the profession and independently assessed entry qualifications;
- the profession's commitment to continuous professional development;
- the degree of risk to the health, safety or welfare of the public from incompetent, unethical or impaired practice of the profession.

As can be seen from the outline scope of practice for Clinical Engineers as set out in Section 2.1, Clinical Engineers are involved in the preservation or improvement of the health or well-being of others in particular by their operational and technical support of the technology and used in the diagnosis, treatment or care of those who are injured, sick, disabled or infirm;

### **3. Scope of the Clinical Engineering Voluntary Registration Board**

*“A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology”, American College of Clinical Engineering Definition, 1992.*

For the purposes of this registration scheme, Clinical Engineering describes the profession of those working at technician and graduate engineer level in the public and private sector in the provision of design input, modification, interface, research and development, management, user support and maintenance of healthcare technology and systems for and in the clinical environment. Clinical Engineers work at the application interface between technology or systems and end-users providing operational and technical support. In rehabilitation, they provide biomechanical assessment, monitoring of patient recovery and the custom manufacture of aids for individual patients. Engineers working in academia to provide tools to support Clinical Engineering work or in research and development in the Clinical field may also apply for voluntary registration under this scheme. This registration scheme is also designed to accommodate those working in Clinical Engineering education.

### **4. Voluntary Registration Board**

It is the function of the Voluntary Registration Board to ensure that an appropriate mechanism is put in place to oversee the setting and achievement of appropriate professional standards for Clinical Engineers.

The Voluntary Registration Board will fulfill this function by implementation of the following elements of the Registration Scheme:

- Set up a process of election of members to the Registration Board;
- development of a process for dealing with applications for registration in a register or for restoration to a register;
- identification of qualifications attesting to the standard of proficiency required for registration, education, training and continuing professional development of registrants;
- adoption and revision of a code of professional conduct and ethics;
- establishment and maintenance of a register of members of the Clinical Engineering profession;
- issuance of certificates of registration;
- the provision of guidance to registrants concerning ethical conduct and the provision of guidance and support to them concerning the practice of the designated profession;
- a process for monitoring the continuing suitability of programmes approved by the board for the education and training of applicants for registration.

### **5. Membership of the Voluntary Registration Board**

The composition of the Voluntary Registration Board is based on the categories of members as set out in the Department of Health Guidelines on Statutory Registration (2000). As places on the Registration Board become vacant they will be filled to ensure that membership reflects the membership requirements as set out in Section 28 of *“The Health and Social Care Professionals Bill, 2004”*. The current and historical Registration Board membership is included at the end of this document (Appendix 3).

**Term of Office**

The term of office for members of the Registration Board is four years, however for the purposes of continuity some members of the first Registration Board stepped down after two or three years.

**Chairman**

Initially, to be elected with a maximum serving time of three consecutive years. Rotation date: February 2005, February 2008, February 2011

**Vice-Chairman**

To be elected one year prior to end of term of sitting Chairman. After one year the Vice-Chairman will take over the role of Chairman. Rotation Date: February, 2004, February 2007.

**Registrar**

To be elected with a maximum serving time of 3 consecutive years. Rotation date: September, 2003, September 2007. September 2010.

**Note-taker / secretary**

To be agreed at each meeting.

**Election of new Members of the Registration Board**

At each meeting of the Registration Board, new membership will be dealt with as an agenda item. Any member stepping down at the following the meeting will propose a candidate to replace them on the Board. If the member stepping down has not identified an appropriate candidate, the Chairman will take nominations from the Board members. Proposals will be discussed and a brief career overview of (a) candidate(s) will be requested. In proposing a candidate, the proposer must take cognisance of Section 28 of "*The Health and Social Care Professionals Bill, 2004*". The candidate's suitability will be discussed at the Registration Board meeting. Following agreement from the Registration Board and a simple vote if necessary, the candidate will be contacted and invited to become a member of the Registration Board. His or her first attendance will be at the first meeting subsequent to his or her proposer stepping down.

**Quorum**

Seven members of the Board will be required for a quorum.

**Meeting Schedule**

Meetings are held every six months, usually in September and February.

**6. Applications for Registration in the Register or for Restoration to a Register**

The application form for registration as a Registered Clinical Engineer is set out in Appendix 4 of this document.

Protocols for removal from the register or restoration to the register are as yet undefined but will be dealt with as the need arises in accordance with the legislation until such a protocol has been fully developed and approved by the Registration Board.

**7. Qualifications attesting to the standard of proficiency required for registration, education, training and continuing professional development of registrants**

**7.1 Criteria for Registration**

Criteria for Voluntary Registration as a Clinical Engineer are:

- a) the applicant must be directly involved in the delivery of a Clinical Engineering service based on the written support of 2 registered Clinical Engineers;
- b) the applicant must attain appropriate professional standing, that is should hold a registered title of the Engineers Ireland, formerly the Institution of Engineers of Ireland (IEI), that is, Engineering Technician; Associate Engineer; Chartered Engineer\*;
- c) the applicant must undertake a relevant CPD programme, ideally, that set out in Section X below;
- d) the applicant must perform their professional activity within the parameters of the IEI Code of Ethics.

*\* There are well developed procedures for achieving these titles where the candidate does not have a standard educational background but has experience such that he or she can compensate. Further information may be found through contacting the Institution Of Engineers of Ireland about Alternative Routes to membership ([www.engineersireland.ie](http://www.engineersireland.ie)). The Institution of Engineers of Ireland is a signatory of the Washington Accord and Dublin Accord which allows for the mutual recognition of professional engineering qualifications between most countries with well developed professional engineering organizations.*

**7.2 Summary of Qualifications Attesting to the Standard of Proficiency Required for Registration**

**(a) Educational and Training Requirements**

As explained in Appendix C, the current educational requirements for various Clinical Engineering grades are set out below. It is acknowledged that educational and training requirements must be updated. The Clinical Engineering Voluntary Registration Board acknowledges that educational and training requirements must be updated. This is recognized by the profession and a proposed updated structure is published in the “Proposal for Professional Formation of the Clinical Engineer”, IEI, 2003. The relevant extract is included in Appendix 5.

Grade	Educational Entry	Notes

There is currently no formal training requirement for Clinical Engineers. However the IEI document “A Proposal for the Professional Formation and Development of Clinical Engineers”, 2003 is the proposed Training Scheme for Clinical Engineers. This proposal is endorsed by the Clinical Engineering Voluntary Registration Board.

(b) Continuing Professional Development Requirements

A detailed CPD protocol is set out in Appendix 6. All registrants will submit their CPD logs for annual review by a CPD working group appointed by the Clinical Engineering Voluntary Registration Board.

**8. Code of Conduct and Ethics**

The Code of Conduct of the Institution of Engineers of Ireland is adopted, subject to review of its specific application to the profession of Clinical Engineering.

By virtue of meeting the requirements for a registered title of the Institution of Engineers of Ireland (IEI), the applicant will already have undertaken to abide by the Code of Ethics of the IEI, which have been adopted by the Board for Voluntary Professional Registration for Clinical Engineers.

**9. Maintain a Register of all Persons Deemed Eligible to Practice**

Details of applications to register are held by the Registrar and the Chairman of the Registration Board and will be prepared for review at the meetings of the Registration Board. Following agreement by the Registration Board that candidates meet the criteria for Registration, their registration will be confirmed in writing and a Certificate of Registration will be issued.

Registration will be valid for 3 years. At that time registrants will request that their Registration will be renewed. *Further protocol development required.*

An Excel spreadsheet of full application details is held in paper and soft copy by the Registrar and Chairperson. A "short form" version is submitted to the voluntary registration board at each meeting. The full application details are also available in case of the need for clarification.

At each meeting of the Registration Board the applications will be reviewed and ratified or other recommendation made. Where an applicant meets the criteria for registration, they will be recommended for registration. Otherwise applicants will be written to and advised regarding which criteria for registration they do not meet and if possible a mentor will be proposed to support the candidate in attempting to attain the criteria for registration.

**10. Guidance and Support to Registrants Concerning the Ethical Conduct and Practice of the designated profession**

*This section is subject to development by the profession.*

**11. Divisions of the Clinical Engineering Register**

The legislation allows for Divisions of the register to be established. It is proposed to develop a “Clinical Engineering – Academic” division of the register. It is also proposed to develop a “Clinical Engineer – Commercial Service Provider” division of the register.

The former is directed at academics who have a particular interest in Clinical Engineering, through research and student supervision. The latter relates to those providing a Clinical Engineering service to hospitals but who are employed by a commercial company. Specific application forms for these divisions of the register are to be developed.

## **Appendix 1: The Emergence of the Clinical Engineering Profession in Ireland**

Early Clinical Engineering (hospital-based Biomedical Engineering) in Ireland, in common with many countries around the world was primarily a "technician"-based profession, where the engineer was primarily responsible for maintenance of equipment. The presence of Medical Physicists in the hospital environment arose with developments in radiation-based diagnostic procedures where their input was and is vital to the safe and appropriate use of imaging technology. The Medical Physics profession was and is primarily a "graduate"-based profession.

With the evolution of technology, technicians working in the hospital environment became increasingly specialised and no longer belonged in a "maintenance department" where the skills required, for example, to manage and maintain a building's heating system are inadequate for the application, management and maintenance of specific items of medical equipment which are used directly in patient treatment or diagnosis. There was a need for a professional home for Clinical Engineering.

To accommodate the increasing number of graduate and technician engineers, a 'marriage' of Medical Physics and Clinical Engineering occurred in some Irish hospitals. Where it did not happen, Clinical Engineers working at technician level often still belong to maintenance departments or in recent years have evolved into departments in their own right.

The rate of change of technology in terms of both application and design has required all professions to evolve. Equipment has become more reliable; electronic repairs are module-based rather than component-based and increased complexity of equipment has raised the need for user support on a day-to-day basis. The Clinical Engineering field has evolved to meet the changing needs as may be observed from the expanding role they play in the healthcare environment.

## **Appendix 2: Clinical Engineering Voluntary Professional Registration Board – Membership (current and historical)**

The composition of the Voluntary Registration Board is based on the categories of members as set out in the Department of Health Guidelines on Statutory Registration. The Registration Board is composed of the following:

- Mr. Pat Cooney, Deputy Head of Department, Department of Medical Physics, St Luke's Hospital, Dublin
- Mr Karl Goulding, Oxygen Care Teo - Irish Medical Surgical Trade Association
- Ms. Andrea Hanson, Irish Medicines Board/Enable Ireland – Irish Medicines Board
- Mr. Gerard Hurl, Head of IT, Mater Hospital, Dublin - Health Informatics Society of Ireland incorporating the Health Informatics Section of the Royal Academy of Medicine in Ireland
- Mr. Pat Lyons, Chief Executive, Bons Secours Hospital Group - Private Hospital
- Mr. John Mahady, Chief Clinical Engineering Technologist, Adelaide Meath and National Children's Hospital, Dublin - Clinical Engineering Professional Vocational Group
- Mr. John McGivney, Chief Clinical Engineering Technologist, St Luke's Hospital, Dublin - Biomedical/Clinical Engineering Association of Ireland
- Dr Richard Reilly, School of Electrical, Electronic and Mechanical Engineering, University College Dublin - Education Representative
- Ms. Meabh Smith, Senior Physicist (Clinical Engineer), Beaumont Hospital - BEAI
- Prof. Kit Vaughan, Dept. of Electronic and Electrical Engineering, University College Dublin; Dept. of Human Biology, University of Capetown, South Africa - International Representative – corresponding member
- Mr. John Vickery, Registrar, Institute of Technology, Tallaght - Education Representative
- Dr David FitzPatrick, School of Electrical, Electronic and Mechanical Engineering, University College Dublin– Bioengineering Section, Royal Academy of Medicine in Ireland Representative
- Mr Bill Grimson, Dublin Institute of Technology, Kevin St, Dublin 8 – Education Representative
- Mr Denis McGrath, Registrar, Engineers Ireland - Engineers Ireland Representative
- Dr Rebecca Beck, Biomedical Engineering Division, Engineers Ireland - Engineers Ireland Representative
- Mr John Tiernan, Principal Clinical Engineer, Enable Ireland - 2008
- Mr Wilf Higin, HSE - 2008
- Dr Ciaran Simms, TCD – 2008

The following are former members of the CEVRB:

- *Mr. Neil Ryan, Principal Clinical Engineering Technologist, Coombe Women's Hospital, Dublin - Clinical Engineering Professional Vocational Group - STEPPED DOWN, Feb, 2004*
- *Dr Brendan McCormack, Acting Head of Engineering, Sligo Institute of Technology - Bioengineering Section, Royal Academy of Medicine in Ireland – STEPPED DOWN, Feb, 2004*
- *Professor Jane Grimson, Vice-Provost, Trinity College Dublin – IEI*
- *Mr Gerry Hanley, Technical Services Manager, HSE - Public Sector Healthcare Representative, stepped down Feb 2008*

- *Mr. Patrick Pentony, Clinical Engineering Department, Adelaide Meath and National Children's Hospital, Dublin 24 – Clinical Engineering Professional Vocational Group – stepped down Feb 2008*
- *Dr Tim McGloughlin, Director of Biomedical Engineering, University of Limerick - Education Representative*

Remaining Committee Members to be appointed: Consumer

### Summary of Board Membership

Name	Constituency	Commencement Date	Stepping Down Date	Note
Mr. Pat Cooney	Clin Eng Hospitals	Feb, 2002		Vice Chairman 2004, Chairman 2005
Mr. Karl Goulding	Industry (service/sales)	Feb, 2004		
Prof Jane Grimson	IEI	Feb, 2002	February 2005	
Mr. Gerry Hanley	HSE	Feb, 2002		
Ms. Andrea Hanson	IMB	Feb, 2002		
Mr. Gerard Hurl	HISI/ Health Informatics, RAMI	Feb, 2002		
Mr. Pat Lyons	Private Hospitals	Feb, 2002		
Mr. John Mahady	Clin Eng Prof Voc Group	Feb, 2002		Registrar 2003
Dr Brendan McCormack	Bioengineering, RAMI	Feb, 2002	February, 2004	
Mr. John McGivney	BEAI	Feb, 2002		
Dr Tim McGloughlin	Education	Feb, 2002	September 2007	
Dr Richard Reilly	Education	Feb, 2002		
Mr. Neil Ryan	Clin Eng Prof Voc Group	Feb, 2002	February, 2004	
Ms. Meabh Smith	IEI BEAI	Feb, 2002 Feb, 2006		Chairperson 2002 - 2004
Prof Kit Vaughan	International	Feb, 2003	corresponding	
Mr. John Vickery	Education	Feb, 2002		
Dr. David FitzPatrick	RAMI	Sept, 2004		
Mr. Patrick Pentony	Clin Eng Prof Voc Group	Sept, 2004	February 2008	
Mr Bill Grimson	Education	Feb. 2006		
Denis McGrath	Registrar, EI	Feb, 2006		
Dr Rebecca Beck	Biomedical Eng Div, EI	Sept, 2006		
Mr John Tiernan	Rehabilitation	Feb 2008		
Mr Wilf Higgins	HSE	Sep 2008		
Dr Ciaran Simms	Education	Sep 2008		

## **Appendix 3: Application form for Registration as a Clinical Engineer**

# Clinical Engineering Voluntary Registration Board

## Application to Register

### Personal Details

Title:..... Family Name: ..... First Name(s): .....

Address for Correspondence: .....

.....

Work address (if different from above): .....

.....

### Academic Record:

3<sup>rd</sup> Level Qualifications, Main Subject, Institution and Year of Graduation:

.....

.....

.....

**Membership of Professional Bodies with Grades and Dates (for IEI membership, please give membership number):**

.....

.....

.....

### Professional Record:

Present Position: ..... Grade: .....

Name and Address of Employer: .....

.....

.....

Date appointed: .....

Address: .....

.....  
.....

**Previous positions in Chronological Order (use separate sheet if necessary):**

**Post/Employer:** ..... **Grade:** .....

**From:** ..... **To:** .....

<p><b>Sponsor for this Application:</b> I hereby confirm that the applicant is active in the field of Clinical Engineering</p> <p>Name:</p> <p>Signature:</p> <p>Voluntary Registration Number</p>
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<p><b>Sponsor for this Application:</b> I hereby confirm that the applicant is active in the field of Clinical Engineering</p> <p>Name:</p> <p>Signature:</p> <p>Voluntary Registration Number</p>
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***I wish to apply for registration as a Clinical Engineering Professional:***

**Signed:** .....

**Name (in capitals):** .....

**Date:** .....

Please send completed form to:

John Mahady  
 Chief Clinical Engineering Technician  
 Registrar, Clinical Engineering Voluntary Registration Board  
 AMNC Hospital  
 Tallaght  
 Dublin 24

## **Appendix 4: Career Paths in Clinical Engineering in Ireland**

### **Current Career Paths for Hospital Based Clinical Engineers**

Within Irish hospitals there is currently one grade of Clinical Engineer: Technician. Technicians may be employed at basic, senior, principal or chief grade. However there are a number of “graduates” employed to undertake a Clinical Engineering function. These are employed as “Medical Physicists”. The following issues have acted as catalysts for this proposal for the Professional Formation and Development of the Clinical Engineer:

The Clinical Engineering Technician has an entry requirement at Diploma level, no structured training is currently required to progress through the employment grades. The employment grades are: Basic Grade, Senior Grade, Principal and Chief. Criteria for progress is based on post availability and years of experience. It should be noted that many personnel employed at Clinical Engineering Technician level hold Bachelor or Masters degrees.

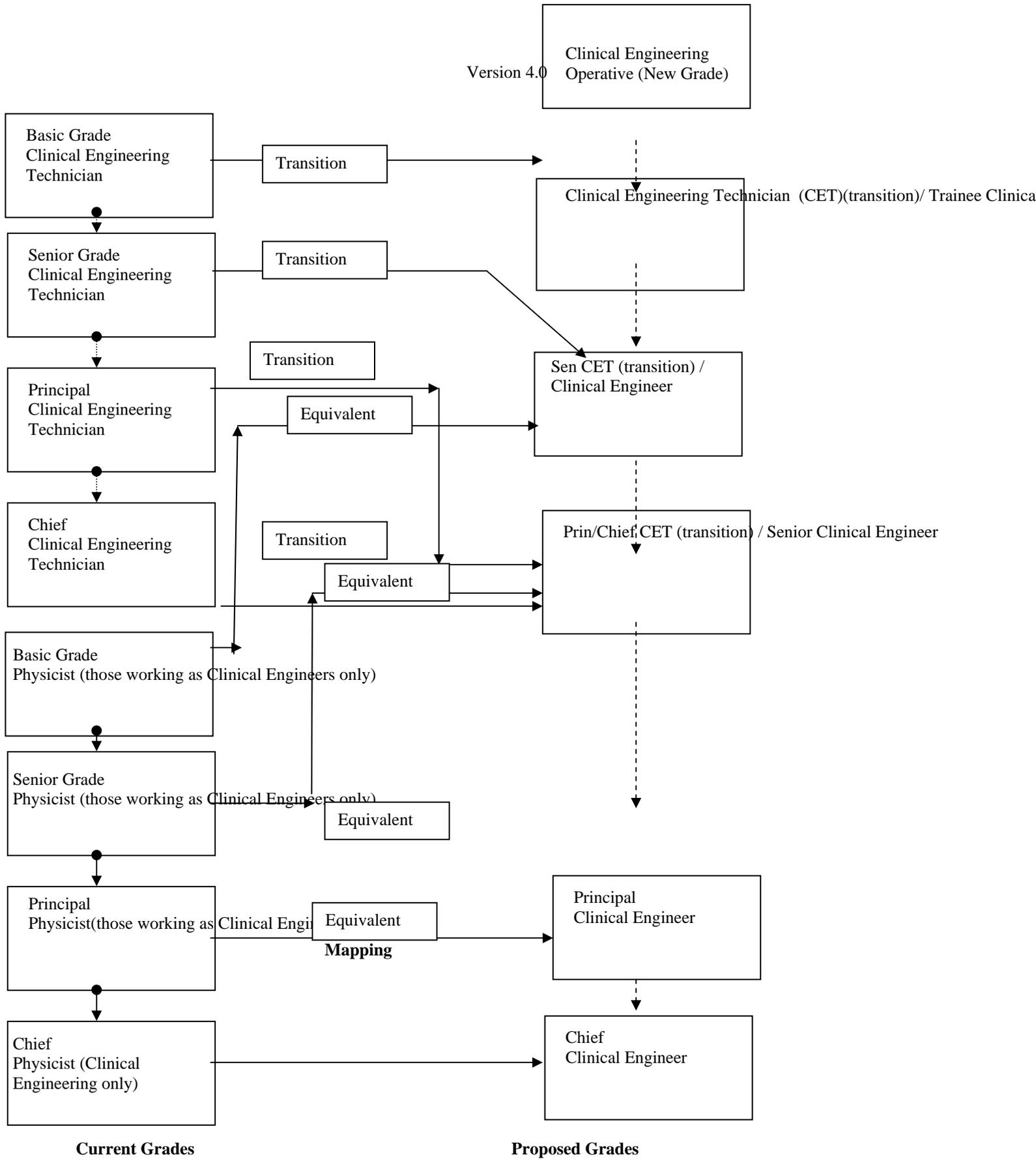
The Clinical Engineer has an entry requirement at primary level (or equivalent), no structured training is currently required to progress through the employment grades. The employment grades are: Basic Grade, Senior Grade, Principal and Chief (these are Medical Physicist Grades). Criteria for progress is based on post availability and years of experience.

There is no formal route for movement from Technician to Graduate grades, despite the profile of continuing education and professional development that is evident in the Technician group.

In the hospital environment, external service contractors are used to complement hospital Clinical Engineering services. These contractors are employed in situations when it is not viable or cost effective to use in-house clinical engineering expertise. It is a reasonable expectation that such personnel should be trained to the same level as in-house personnel.

### **Clinical Engineers employed by Medical Equipment Supply Companies**

A maintenance and technical support service is offered by many medical equipment supply companies. The service is primarily a repair and training one, most of those employed in this sector are technicians. There is currently no regulation of this function, however it should be emphasised that the majority of companies in this sector act responsibly in ensuring manufacturer's technical standards are met with respect to the maintenance of equipment.



**Figure 1:**  
**Mapping of Current Clinical Engineering Grades to Proposed Clinical Engineering Career Grades**

Figure 2 provides an outline of training and education requirements for career progression through proposed career grades.

<b>Career Grade Title</b>	<b>Entrance Qualification</b>
Clinical Engineering Operative	Certificate
Clinical Engineering Technician/Trainee Clinical Engineer	3 year diploma in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent
Senior Clinical Engineering Technician	3 year diploma in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + 2 years training with associated education
Clinical Engineer	4/5 year degree in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent
Principal Clinical Engineering Technician	3 year diploma + 4 year's training + Core Clinical Engineering Certificate + Associate Engineer, IEI
Chief Clinical Engineering Technician	4/5 year degree in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + 4 years training with associated education + Core Clinical Engineering Certificate
Senior Clinical Engineer	MSc in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + Core Clinical Engineering Certificate + 2 years training + MIEI
Principal Clinical Engineer	MSc in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + Core Clinical Engineering Certificate + 4 years training and Chartered Engineer Status
Chief Clinical Engineer	MSc in Biomedical, Computer, Electrical, Electronic or Mechanical Engineering or equivalent + Core Clinical Engineering Certificate + 4 years and Chartered Engineer Status

**Figure 2: Outline of training and education requirements for career progression through proposed career grades.**

## **Appendix 5: CPD Protocol for Clinical Engineers**

### **Introduction**

A direct consequence of Professional Registration is Continuing Professional Development (CPD).

Continuing Professional development can be defined as:

*The systematic maintenance, enhancement and development of knowledge and skill, and the development of personal qualities necessary for the execution of professional and technical duties throughout the practising engineering professionals career.*

or

*The Planned acquisition of knowledge, experience and skills required for professional practice throughout ones working life.*

CPD encompasses a large range of processes aimed at ensuring that professionals maintain and update their skills and experience in their chosen field and that they keep fully abreast of developments. CPD can comprise formal training, part-time 'off-site' training and other structured methods of maintaining and updating skills. It may or may not be formally examined. CPD is normally recorded officially, whether by a professional body or the professional him/herself, or both. It can be accredited by the professional body and can include a point system whereby professionals aim to accumulate a specified number of points per period of time.

### **CPD and Statutory Registration**

CPD is now of critical importance in the context of Statutory Registration because of a growing concern about the need continually to retain competence within a profession rather than merely to attain competence at the beginning of one's professional life. CPD has become to be seen as essential to any successful registration scheme. There is a danger that without CPD there would be no formal requirement on the practitioner to keep abreast of developments in the profession and to upgrade and maintain their skills. Registration will provide a legislative framework for the appraisal and approval of education and training courses, examinations, qualifications and institutions, thus ensuring the proper development of education and training across the professions. Registration will also provide a more widely informed and participative forum for the administration and implementation of the EU directive on the Mutual Recognition of Third level Qualifications in EU member states. The role of CPD in relation to statutory registration is therefore an important one.

The Department of Health and Children in the "Statutory Registration for Health and Social Professionals - Proposal for the Way Forward" has indicated to the professional bodies that it is prepared in principle to support financially an agreed system of CPD for health and social care professions in the specific context of introducing a system of statutory registration.

### **The Framework**

Following an in-depth review of the models of Continuing Professional Development that are in operation internationally by Engineering Organisations and Health Care Services it is proposed to develop a CPD framework that could be approved and supported by the International Association for continuing Education and Training (IACET) an internationally recognised organisation for standards and certification for continuing education and training. IACET accreditation may be sought in the

future, however the following is proposed as a voluntary CPD scheme. This scheme may be transposed into IACET CEUs at a later date.

### **Record Keeping Process**

Each individual will register with the Clinical Engineering Voluntary Professional Registration Board. He / she will start a Log Book to record the CPD activities which they carry out.

The Log Book will be made available to the Registration Board for review. Such a record will verify the CPD activities achieved by an individual over a period of time.

CPD recommendations made by the Registration Board following a review of the Log Book should be facilitated by the employer.

### **CPD Target**

Continuing Professional Development Units will be used to measure CPD Activity. One Unit is equivalent to one contact hour of participation in an organised continuing education experience. Each individual should have a minimum of 150 units of CPD over *three* years to ensure on-going professional development and to maintain Professional Registration.

This target should be comprise of a spread of a minimum of 15 units of CPD (over three years) in each of at least four of the categories specified below:

- Educational Activities
- Approved Scientific Meetings
- Individual Structured Study
- Scientific Publication
- Local Professional Development Activities
- Professional Activities

### **CPD Activities**

CPD activities may be organised by recognised professional organisations where the content or the focus of the activity contributes to the Clinical Engineering knowledge base. Such organisations include The Biomedical Engineering Association of Ireland, Health Informatics Society of Ireland, Association of Physical Scientists in Medicine, Institution of Engineers of Ireland etc. It must be emphasised that participation in the activity may be justified as earning CPD units for the individual, even if the event as a whole does not qualify. For example, a CPD registrant attending an elementary course in a field outside their current speciality, with a view to broadening knowledge or skills for new responsibilities in the immediate to medium-term future can, justifiably, earn CPD units. Teaching at such a course may also attract CPD units.

***The allocation of CPD units for specific activities is to be verified by the professional registration board. Guidance is set out below:***

**CPD Activity****Educational Activities**

Participation as a learner:	non-examined course:	1 unit per educational hour
	examined course:	2 units per educational hour
Participation as a teacher:	first delivery:	2 units per teaching hour
	subsequent deliveries:	1 unit per teaching hour
Registration for MPhil or PhD:		2 units per month
Registration for Post-grad Diploma:		2 units per month
External examiner:		
	PhD thesis:	5 units per thesis
	MSc thesis:	2 units per thesis
	MSc course:	5 units per year
	Other approved courses:	5 units per year

**Approved Scientific Meetings**

Attendance:		1 unit per educational hour
Invited or keynote speaker:		
	first delivery:	10 unit per hour
	subsequent deliveries:	2 units per hour
Proffered paper or poster:		4 units
Organiser or member of scientific or organising committee of a nationally advertised meeting:		5 units per event

**Individual Structured Study**

Structured Study:		1 unit per educational hour
Unforeseen learning opportunities:		1 unit per educational hour

For structured individual study, the learning strategy must be agreed with a Mentor, specifying the knowledge and skills to be acquired or strengthened, together with the actions to be taken. Learning experiences undertaken must be recorded and the knowledge and skills gained should be described in a synopsis of about 500 words.

Journal reading, undertaken on a specified regular schedule in a range of journals

agreed with a mentor, qualifies for CPD credit.

### **Scientific Publication**

Article published in a refereed journal	
Each principal author:	8 units
Others:	4 units
Accepted provisional patent:	5 units for each author
Review article, commissioned chapter:	15 units divided by the number of authors
Commissioned paper for government department or national advisory body:	8 units divided by the number of authors
Non-refereed invited article/book review in a professional scientific publication:	2 units
Editor of a multi-author work	10 - 20 units (in year of publication only)
Sole or joint author of a book	20 - 50 units (in year of publication only)
Invited referee of a paper or grant application	2 units
Invited referee of a book	2 units per chapter, maximum 10 units per book
Editor of a peer-reviewed journal	10 units per year
Member of an editorial board	5 units per year
Membership of the Electronic Publications Committee:	5 units per year
Editor of journal with national circulation	10 units per year
<b>Local Professional Development Activities</b>	
Participation as a learner:	1 unit per educational hour
Participation as a teacher:	
first delivery	2 units per teaching hour
subsequent deliveries	1 unit per teaching hour
Proffered paper or poster:	4 units

“Local” means not nationally advertised.

The following can be approved under this category.

- Giving lectures for nurses, physiotherapists, etc., by invitation, even if this is away from the registrant's place of employment, if the event is not advertised nationally.
- Teaching at or attending lectures or meetings organised by other professional organisations, if not advertised nationally.
- Teaching at training days of any description.
- Attending or teaching on in-house (departmental) seminar programmes.
- Study day on management topic(s), e.g. "Selection and Interviewing of Staff"
- First Aid lecture or course

### **Professional Activities**

Membership of:

BEAI Committees  
HISI Committees  
RAMI Committee  
APSM Committees  
IEI Committees  
IEE Committees  
Clinical Engineering Voluntary Registration Board  
Other health service, governmental,  
standards or international bodies

5 units per year

Holders of senior office in the above

President  
Vice President  
Honorary Secretary  
Honorary Treasurer  
Chairman

5 additional units per year

### **Activities NOT attracting CPD Credits**

1. Setting exam questions.
2. Lecturing and other teaching of clinical engineering or related courses if employed as an academic.
3. Routine departmental management meetings.

## Clinical Engineering Continuing Professional Development Summary

Please complete and submit to registration committee at end of each calendar year:

	Education	Scientific Meetings	Ind. Structured Study	Scientific Pub.	Local Develop	Prof. Activities	Total Claimed
Total Credits claimed for this year							
CPD Credits for previous year							
CPD Credits for previous 2 years							

### Note: CPD Target

One Unit is equivalent to one contact hour of participation in an organised continuing education experience. Each individual should have a minimum of 150 units of CPD over *three* years to ensure on-going professional development and to maintain Professional Registration.

This target should be comprise of a spread of a minimum of 15 units of CPD (over three years) in each of at least four of the categories specified below:

- Educational Activities
- Approved Scientific Meetings
- Individual Structured Study
- Scientific Publication
- Local Professional Development Activities
- Professional Activities

Please complete as CPD activities are completed (CPD verification may be signed by another Registered Clinical Engineer):

CPD Activity	Detail	Dates for Activity	CPD Units Claimed	CPD Verification and Date
			Educational: _____ Scientific Meetings: _____ Ind. Structured Study: _____ Scientific Publication: _____ Local Development: _____ Professional Activities: _____	
			Educational: _____ Scientific Meetings: _____ Ind. Structured Study: _____ Scientific Publication: _____ Local Development: _____ Professional Activities: _____	
			Educational: _____ Scientific Meetings: _____ Ind. Structured Study: _____ Scientific Publication: _____ Local Development: _____ Professional Activities: _____	
			Educational: _____ Scientific Meetings: _____ Ind. Structured Study: _____ Scientific Publication: _____ Local Development: _____ Professional Activities: _____	