

Report on the professional registration of engineers maintaining and servicing medical equipment within the healthcare and retails sector

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This report has been written in response to the Institute of Engineering and Technology (IET) call for members to contribute to the UK government's consultation regarding healthcare professional regulation (see Appendix 1). The report specifically addresses the professional staff that manages, maintain, repair and service medical equipment with the healthcare sector. This report recognises these services are provided in the UK by medical devices manufacturers and suppliers, third party organisations in the commercial sector and engineers working within the healthcare sector including NHS Trusts. The report examines the current situation, including controversial efforts to register medical engineers in the UK with a generic healthcare worker group called 'clinical technologists'. The report also examines the current focus on engineers working in NHS Trusts rather than those in the wider healthcare and commercial sector. The implications of the current proposals are discussed along with alternative approaches including the existing system of engineering registration run by the UK's Engineering Council (EC).

Background

Over the past few years there has been an emphasis on ensuring that all professional working within the NHS and wider healthcare system are registered^{1,2}. With the NHS healthcare sector encompassing a wide and diverse group of workers that support the organisation, few people understand the role of medical engineers involved in the management and maintenance and servicing of medical devices.

In this document the term ‘medical engineer’ is used to describe a worker who has a role in the management, maintenance, servicing, repair, design and development of medical devices and equipment. A brief discussion of names of staff and departments providing these services is given in Appendix 2. As medical devices form the backbone of modern healthcare any changes in practice will affect not only the NHS but also the wider healthcare sector and the industry that supports the design, development manufacture, servicing, maintenance and management of these devices.

Medical engineers are currently being considered for registration under the title of ‘Clinical Technologists’^{3,4}. An application has been put forward to the Health Professions Council (HPC) include this group by a body called the voluntary register of Clinical Technologists³ (VRCT) that appears to have been initiated by the Institute of Physics and Engineering in Medicine (IPEM). I have formerly raised many questions with both the HPC and the Chief Scientific Officer (CSO) of the NHS regarding the inclusion of medical engineers within these proposals and the process by which this registration is being advanced⁴.

To date few answers have been presented to these questions^{5,6}, which range from questions regarding fair representation for the staff involved to questions regarding the ability of the VRCT to understand and represent the billion pound industrial sector that support medical devices in the NHS.

The fundamental issues that I feel need addressing include the following questions:

- Who should be responsible for medical engineering workers within the commercial sector and the NHS and whose role is it to represent them?
- What will be the impact on the commercial sector that predominantly provide medical engineering services to the NHS and the wider healthcare sector?
- What will be the financial impact any changes will have on the NHS and the wider healthcare sector?
- What will be the impact of any changes on the quality of service provided to the NHS by both the commercial sector and in-house equipment management services?

- How does any planned registration fit into the European and international perspective regarding free competition and sale of good and services?
- How will any changes affect devices that are on sale directly to the company through high street retailers?

Considering the scale of the current proposals for registration of medical engineers as 'Clinical Technologists', of concern is that there has been no major impact study to address these and many other issues that surround this matter⁵.

Importantly, there also appears to have been little wider discussion within the commercial sector regarding the wider issues, for example, using the existing Engineering Councils (EC)^{7,8} engineering registration scheme and the impact of any changes on the commercial sector.

National and international issues

Registration of medical engineers working in the NHS can not be seen in isolation from the wider healthcare sector and the commercial sector or the international market. Medical devices are manufactured and supplied by the international market. The prime organisation for management, maintenance and servicing of these devices are the companies that manufacture and supply them. These companies provide servicing and support for the devices they sell to the healthcare sector. Any new proposals to register workers who are involved in providing these medical equipment services to the healthcare sector, including the NHS, have to take into account the nature of how medical devices are supplied to this sector and how they are currently supported. Major changes could have both a financial and practical impact on the commercial sector that underpins the supply of medical devices to the healthcare sector in the UK. Any proposals that impact upon medical engineers from both the commercial sector and the healthcare sector in the United Kingdom need to be implemented carefully so they do not have a negative impact on this vital international industry.

Medical Devices – what are they and where are they used

A medical device includes any device that is used for patient healthcare and includes both the highly complex equipment used through healthcare to the simplest device. Currently these devices are regulated in the UK by the Medicines and Healthcare Products Regulatory Agency (MHRA)⁹. Medical devices and equipment are not only used within the NHS, they are also available and used widely by wider healthcare sector and directly by the public. They are also available from high street shops through to private healthcare organisations and companies. There are no current laws regarding prescription and ownership of these devices in the UK. Many of the devices in question can simply be purchased over the counter from a high street retailer.

To have any satisfactory and successful system of registering professionals who provide medical engineering services there needs to be a clear understanding of what medical devices i.e. equipment that any registration of those professionals may affect.

The focus of the current proposal appears to have been to register in-house medical engineers as 'Clinical Technologists' i.e. a focus on tertiary NHS Hospitals that have in house medical maintenance organisations. However, NHS Trusts only present a part of the British healthcare system which also includes.

- Primary and secondary care
- Residential and elderly homes
- Military hospitals
- Private hospitals
- Private clinics
- Home care and equipment
- Primary care NHS Trusts

Any final system of registration for engineers has to also consider those staff managing, maintaining equipment and services outside NHS hospital Trusts.

Responsibility and roles - When is an engineer a healthcare worker?

This is a serious and often overlooked question. Should we consider medical engineers as healthcare workers? Although responsible for medical equipment it is rarely the case that medical engineers have direct contact with patients. Consider the Civil Aviation Industry. Those responsible for the management, maintenance and servicing aeroplanes are rarely, if ever, the pilots. This I feel is a useful comparison. Engineers who come into the healthcare environment to management, maintain and service medical equipment are unlikely to be users. Although they may demonstrate the equipment and explain functionality they do not actually use it on the patient. It would not be reasonable for an engineer to actually use a surgical tool on a patient or use an anaesthetic machine in theatre etc. The role of the engineer is more often to explain to manage, to maintain and service.

Where engineers do treat patients they are likely to be supervised by a clinician who has responsible for the patients safety and where not they should probably be expected to be treated as healthcare workers and have an appropriate clinical registration in the respective field. However, I feel there would be a very small number of such people require such registration.

Any proposed registration scheme for medical engineers clearly needs to identify the roles very precisely and clearly differentiate between roles where the person has a direct responsibility role in diagnosis and treatment of the patient. It is unclear that the roles of staff in Medical Engineering Departments have been defined in terms of patient responsibility. It is usually clinicians that have the direct responsibility for diagnosis and treatment of the patient.

Diversity of service provision

It is important to understand that there is no single model of service provision of maintenance, management and servicing of medical equipment within the healthcare sector⁹. Many tertiary NHS Trusts have a mixed model of service provision with some maintenance being carried out by in-house maintenance organisations while much is maintained externally via maintenance agreements. The ratio between in house-to external provision can vary from all equipment maintained by external companies to only a few specialised items maintained by commercial sector (manufacturer, supplier or third party). It is this diversity that has to be accommodated by any proposed registration scheme for medical engineering staff.

In addition equipment can be returned to the manufacturer for maintenance. It does not seem reasonable to have a registration scheme that meant that the location of the workers was a factor in who was registered. If professionals are doing similar jobs that have the same potential impact on a patient, location is immaterial i.e. an engineer maintaining an item of medical equipment in a factory should have the same registration as an engineer maintaining the equipment on a healthcare site.

The role of industry

The role of the commercial sector in the management, maintenance, servicing and development of medical devices can not be overstated. The commercial sector is ultimately responsible for the large part of medical devices used within the wider healthcare sector including the NHS. I am concerned that I have been unable to find any evidence of consultation by the HPC, DoH or VRCT regarding current proposals with the commercial sector to register medical engineering staff. At one of the meetings held by the CSO there appeared to be only one representative from a small medical company (Vitalgraph ltd)⁶. I feel that for any registration scheme to be successful it must take into account that the majority of equipment and servicing etc is carried out by the commercial sector and that they need to be involved in any future plans.

Cost to the NHS and healthcare Sector

Medical devices represent a multibillion fundamental cost to the NHS, the private healthcare and the retail sector. Any new registration scheme that requires medical engineers to be registered could have a dramatic affect on the cost and education

requirement for these workers. I have yet to see any evidence that any consideration has been made on potential cost to this sector.

Education and training

The medical engineering sector like all engineering sectors has a very diverse need for people trained at different levels. There is no one size fits all. Engineering qualifications range from vocational through to postgraduate qualifications^{7,8}. For each part of the engineering process an appropriate level of qualification is usually locally evaluated and select by the organisation concerned.

Often the education and training required is device specific. A complex device may need a highly trained engineer with postgraduate qualifications to manage service and repair the device, while a simple device may be repaired by someone with only minimum qualifications or even simple vocational training. Economically and practically it would not be reasonable for all medical engineers to meet the highest level of education. A mix in education is the fundamental nature of engineering. Organisations generally select the staff based on the requirements of the devices and service provided.

One concern is that the current model being proposed by the VRCT suggests that a specific level of education that should be achieved by all people working as medical engineers⁶. This may be impractical as suggested above the skill level and education required is often device specific. More worrying is the level of prescription of the education required. In practice we must ask what a medical engineer is and what function are they registered for? To date I am unclear if the commercial sector, who play the major role in developing managing, maintaining and servicing medical equipment, have been involved in developing the current education and training qualifications and proposals.

It is of note that the IPPEM, VRCT and HPC model of membership and registration clearly defines two levels for people working in medical engineering i.e. where as the Engineering Council has a more progressive route for registration of engineers.

Engineering Council model of medical engineering registration

- Technician Engineer – Vocational qualifications ONCOND HNC/HND
- Incorporated Engineer – Degree Level
- Chartered Engineer – Postgraduate Degree

HPC Model of medical engineer registration

- Clinical Technologist –Degree level
- Clinical Scientist – Postgraduate Degree

In addition the IPPEM/VRCT/HPC model is very closely related to the NHS pay framework¹⁰ (Knowledge and Skill Framework and Agenda for Change) where as the Engineering Council has no relationship between the pay models used in the NHS or industry.

Practically the approach taken by the HPC and VRCT appears to be dependent on education route taken rather than the job being carried out⁶. With higher levels of education routinely expected for those medical engineers registered as 'Clinical Scientists'. However, this differentiation appears largely arbitrary and confusing when people can be doing the same job but registered under different names. There appears to be an emphasis that those registered as 'clinical technologists' are more likely to be hands on carrying out maintenance, servicing and repair. In addition the HPC model appears to be no clear mechanism for career development between medical engineers registered as 'Clinical Technologists' and the more senior/academic registered as 'Clinical Scientists'. Again this is all very NHS Trust orientated and fails to take into account that most maintenance is provided by external manufacturers and suppliers.

Current system of regulating engineers

In any future proposals for registration of medical engineers it is vital to understand that a registration scheme already exists for engineers and that many medical engineers are already registered through this scheme^{7,8}. Importantly the scheme for registering engineers is not NHS or health sector specific it designed and focuses on the commercial sector. I feel that any proposed scheme must take into account the Engineering Councils scheme for registering Engineers

Representation, authority & consultation

Despite the VRCT putting forward medical engineers to be considered as 'Clinical Technologists' I am extremely concerned that this unelected body has no authority to represent the workers concerned. The VRCT was apparently initiated by IPPEM, a very small NHS orientated organisation whose previous focus has been 'Medical Physics'⁵. I feel that much wider representation is required by the stakeholders concerned. This should probably include the Unions, representatives from the commercial sector and the IET. The IET is one of the largest engineering institutions in the UK who may be in a more appropriate position to represent a wider group of staff, including the commercial sector, and not just NHS staff. I have raised this issue many times with the CSO and HPC⁶. However, the political will to proceed has been made clear at the most recent meeting addressing this issue and a decision appears to have been made to proceed without the criteria¹ being met that are required by the HPC to consider a group for registration⁶.

The role of quality systems

In industry quality systems play an important part in ensuring quality of service and manufacturing. In the UK many NHS based and commercial medical engineering departments have held quality registration for over a decade. The professional engineering based managers of these departments have understood the priority an importance of quality systems. These externally audited quality systems based on international standards can be used to ensure that engineers are qualified and competent to carry out the work allocated. In industry this route is generally taken with its emphasis

on external audit rather than enforced regulation of staff. Although many NHS Medical Engineering departments have volunteered and are now registered, meeting this standard has not been made obligatory for all organisations maintaining medical equipment. It is my view that this route has proven to be highly successful. One way of ensuring quality of medical engineering services would be to make this standard obligatory for any organisation maintaining medical equipment. This would require far less costs to industry as most companies are already registered to this widely recognised standard.

Impact studies

It has been surprising that the HPC has accepted to take medical engineers as a subgroup of 'Clinical Technologists' for registration despite no impact studies or comprehensive reports have been made which outline and discuss in detail the issues with registering medical engineers⁶.

A lesson from the Civil Aviation Authority

The current focus is placed on registration or certification of the individual rather than specific accreditation or certification for work practices. Having discussed these issues widely with a range of colleagues I am unconvinced that the approach of a general registration rather than device specific certification can ensure that staff servicing, maintaining and repairing medical equipment have the right training.

How is competency achieved for maintaining devices?

This is an important question. It is my feeling that competency on many devices can only be achieved by device specific training. Often, this training is only available from the supplier and manufacturer. Even with this training many manufacturers and suppliers will not usually issue a certificate of competency and only give a certificate of attendance.

The Civil Aviation Authority, responsible for standards of critical airplane maintenance, demands that all work is signed off by an engineer who is certified for specific products¹¹. Work can be carried out by an uncertified engineer but it must be signed off by a product certified engineer. I feel this would be the optimum approach for medical devices. For each medical devices produced, as part of its development and CE marking it could be assigned to class that defines the level of training required.

I am sure that a generalised training or certification/registration can not ensure product competency and that a clear well defined system of product certification is required. This may initially seem like a major hurdle to be overcome. However, I feel the development of such a system may be the most practical approach to ensure that all maintenance and servicing of medical equipment is carried out by people with the right level of competency.

European issues

There are a considerable number of major issues regarding Europe that need to be taken into account regarding the supply and transfer of labour and services and the open market. The scale of these issues is such that they are not considered in this document other than to highlight they need to be carefully considered and addressed. In addition there has been several conferences examining the issue of registration and training of hospital based Medical Engineers¹².

What competencies are required and for who?

When considering any proposed registration scheme it is vital that competencies are being assessed. The Engineering Council has made substantial effort at defining the competencies required by engineers in the UKSPEC^{7,8}. How should we go about defining the competencies required for medical engineers, are the UKSPEC not suitable? What efforts have gone into defining the appropriate competencies defined by the current VRCT? What are these competencies and what consultation with the stakeholders has gone into defining these competencies?

The case for registration

Is there a case for mandatory registration of medical engineers? To date I am unclear that a practical case has been presented to show that existing controls and systems have been insufficient. There appears to be no statistics or reports from the MHRA (Medicines and Healthcare Products Regulatory Agency) regarding problems and failure of the current systems of standards and mechanisms to ensure the medical devices are maintained adequately⁹. Stakeholders have their own systems of regulation and controls and responsibility to ensure these are managed to national and European law. This may be a vital point. Any new system may have an immense and unknown impact on substantive part of the British economy and have a wider impact on the European and international medical device industry. The effect of ensuring that all engineers maintaining and servicing medical devices are registered is a major task. The idea that only engineers employed in hospitals are registered when substantive maintenance in hospitals is provided by external agencies may not be practical. It would appear that the VRCT and HPC have in mind a concept of 'hospital based engineers/technicians'. However, this seems impractical as all engineering functions can be made by visiting service engineers from commercial and third part service providers. Questions abound. These questions range from the problem of defining what equipment is to be considered under such a scheme to the affect on international cross border service provision i.e. where an engineer is needed to be called in from a neighbouring country etc.

Summary

The registration of medical engineers is a complex issue. It is vital to understand that medical equipment is substantially managed and maintained and used by the private sector and although maintenance of medical devices is carried out within the NHS this is only a small part of the overall picture. Any new system must be capable addressing both the NHS and all other stakeholders such as the wider medical device sector.

This report highlight the recent work done to register staff working in the NHS who maintain, manage and service medical devices as 'Clinical Technologists' by the HPC (Health Professions Council). The process appears to have been initiated by the IPEM (Institute of Physics and Engineering in Medicine), a small society whose few thousand members are primarily NHS staff and not Medical Engineers. An unelected panel called the VRCT (Voluntary Register of Clinical Technologists) appears to have been set up, although it is not clear by who and what authority this panel has. There appears to have been little involvement of the private sector i.e. the companies that manufacture, develop and maintain medical devices. There also appears to have been little involvement of many of the other important stakeholders including the Unions or major engineering institutions such as the IET (Institute of Engineering and Technology) who have a much larger and wider membership including members from the wider private and industrial sector.

This report highlights that much of this work is done in the commercial sector and that this sector has not been consulted or been involved in the development of current proposals. The current proposals fails to recognise the existing scheme of registration for engineering staff developed by the EC (Engineering Council). This report also highlights that any new changes could have a significant effect on the provision maintenance and services for medical devices in the UK and European market.

Many questions have been previously raised regarding the current process. However there appear to have been little evidence of responses from DoH or the HPC. The document report highlights that there appears to have been no impact studies or research on the possible affect of any registration on either the healthcare and health sector medical device market and UK economy. The report emphasises that considerable caution should be taken when introducing any new registration scheme. The report also suggests that any proposals that may affect, the private healthcare sector or billion pound medical device industry should be well researched and defined to avoid a negative impact to the British economy and wider healthcare.

The existing registration scheme for engineers, including medical engineers, has been highlighted and suggested as an alternative. This registration scheme is run by the Engineering Council and is widely accepted by industry. The report encourages the use of quality systems as these are already widely and successfully used in industry. Additionally, a possible alternative device specific certification scheme modelled on the Civil Aviation Authority and the maintenance of critical aircraft and aircraft systems is proposed.

Appendix 1: IET Call for Consultation

(S)762 - Healthcare professional regulation: Public consultation on proposals for change 

IEE Members have 32 days to submit an opinion 

Description The Department of Health has invited comments on it's consultation regarding proposed changes to healthcare professional regulations.

Abstract Following the publication of The Shipman Inquiry which was highly critical of the General Medical Council and the broader arrangements for medical regulation, Lord Warner commissioned a review of medical regulation. Shortly thereafter, the Department of Health elected to conduct a parallel review of the arrangements in place for the regulation of the other clinical professions in order to provide consistency of approach and in recognition of the blurring of traditional job roles in healthcare. The review of medical regulation was conducted by Sir Liam Donaldson, Chief Medical Officer for England. His report, Good doctors, safer patients, along with the parallel departmental review of non-medical regulation, focuses upon the protection of the interests and safety of patients. This consultation paper seeks views on the proposals put forward by the Chief Medical Officer in Good doctors, safer patients, and upon the options outlined in the parallel review of non-medical regulation.

The consultation document can be found at

http://www.dh.gov.uk/Consultations/LiveConsultations/LiveConsultationsArticle/fs/en?CONTENT_ID=4137231&chk=/Ee/%2Bi

The IET Trustees propose responding to this consultation and invite comment from Members who have expertise in this area. Please base your comments on the specific questions raised on pages 4 – 5 of the consultation document. Members contributing are asked to preface their remarks with a brief note of their relevant experience. All inputs will be treated confidentially in the production of a corporate view and individual contributors will not be named.

In the above “Member” should be interpreted as IET Technician Members, Members and Fellows.

Provide comments or opinion If you are a member of the Institution and wish to provide input to the Institution's response please send your comments to [Graham Paterson](#) no later than 01-Nov-2006

[View more detail of this submission in progress](#) 

Keywords and Search Terms No keywords/search terms defined

Appendix 2: A note on names

A significant and confusing issues regarding the staff that manage maintain service and develop medical equipment is the variety of names used. In this document the term Medical Engineer is used to identify these staff.

The following names have all been used to describe such staff: Medical Technical Officer; Electronics Engineer; Electronics Technician Biomedical Engineer; Service Engineer; Medical Electronics Technician; Clinical Engineer; Biomedical Electronics Engineer; Instrument Technician; Medical Physics Technician; Medical Engineer, Field Service Engineer etc.

It is of note that any registration scheme it is the name that is being registered and not the jobs function. If a name is to have value it must be understood by the public. My own view is that many of the names proposed including the term Clinical Engineer are often very confusing to the public and even healthcare staff.

Hospital based service departments that carry out these functions also have a wide variety of names: Medical Engineering; Biomedical Engineering; Clinical Engineering; Medical Electronics; Medical Equipment Maintenance Organisation; Medical Equipment Services and many more! In Europe these services are often referred to using the Acronym BME (Biomedical Engineering).

Personal background

I am a medical engineer employed in the Grade of Principal Clinical Scientist within the NHS. I have worked in the NHS for over twenty years and am involved in both the management of a large Medical Engineering Department and Research for further details see: www.medeng.net. I am a registered Chartered Engineer with the EC and for also a registered Clinical Scientist with the HPC.

My interests include the current proposal to regulate Medical Engineers as 'Clinical Technologists'. This has involved raising the issues concerned in a positive way, attending national meetings and writing reports to the former IEE, DoH, HPC. I have many concerns regarding the inappropriate registration of engineers as healthcare workers and the impact this may have on industry, the wider healthcare sector and the NHS including my own department and Trust.

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14) Institute of Engineering Technology - <http://www.theiet.org/>

15) Institute of Physics and Engineering in Medicine
- http://www.ipem.ac.uk/ipem_public/