



THE INSTITUTE OF PHYSICS AND
ENGINEERING IN MEDICINE

Policy Statement

Rehabilitation

Engineering

Services

IPEM policy on Rehabilitation Engineering Services

Produced by a working group of the Rehabilitation Engineering and Biomechanics Special Interest Group:

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INTRODUCTION

Rehabilitation Engineering is the clinical application of engineering principles and technology in the provision of services, research, and development to meet the needs of individuals with disabilities. It involves the reduction of environmental barriers, and/or the restoration or improvement of the physical, mental and social function of a person with a disability.

Rehabilitation Engineering is an important element of a comprehensive rehabilitation service, and includes the following services and subjects of research, design, development, production and marketing:

- Wheeled mobility: chairs and special vehicles;
- Augmentative and Alternative Communication systems;
- Assistive devices, for all activities of daily living in domestic, educational, vocational, recreational, social and institutional environments;
- Electronic assistive technology, including technology access, customised or modified controls, environmental controls, and integrated systems;
- Functional Electrical Stimulation;
- Biomechanical analysis in rehabilitation;
- Specialised orthoses (including seating) and prostheses;
- Gait analysis.

A rehabilitation engineering service generally provides a selection of these activities. This document sets out policies designed to promote client-awareness, clinical effectiveness, and the efficient use of resources in these services.

This document contains various lists that are distillations of best practice and as such subject to continual review.

STAFFING STRUCTURE

Rehabilitation engineering services are provided in the NHS through a number of establishments, with a variety of functions and organisational relationships. The activities are pursued in departments with various titles including, most commonly, Clinical Engineering, Bioengineering, Rehabilitation Engineering, Medical Engineering, Medical Physics, and Disablement Services.

The education, training and qualifications of engineering practitioners are reflected in their employment grades which, in the NHS, includes Medical Technical Officers (MTOs) and Clinical Scientists/Engineers¹.

¹ The term "rehabilitation engineer" or "RE" is often used colloquially to describe a member of engineering staff in a rehabilitation service. This usage is unfortunate because it does not differentiate between three distinct levels of training and competence. In earlier documents, IPEM has referred to engineering staff operating in a clinical rehabilitation context as Rehabilitation Engineering Technician (RET), Rehabilitation

MTOs (or Rehabilitation Technologists) are primarily concerned with the operational aspects of service delivery such as routine fitting and repair, device manufacture, and basic design specification. MTO career progression depends on continuity, quality, and the scope of a service. Clinical Scientists/Engineers lead the organisational aspects of the service and may conduct independent assessment of clients. They direct complex issues such as the provision of innovative solutions for individual clients, research and development, and the development of new methods and scope of service provision.

A rehabilitation engineering service employs a team of an appropriate size and balance to meet the needs of the specialist service areas it addresses (listed above). The numbers of staff and their supporting resources will be determined by the total activity required. The team would normally comprise a mix of Rehabilitation Technologists (RT) and Clinical Scientists/Engineers (CE).

Each rehabilitation engineering service should have an identified head of department responsible for its proper functioning, for setting its priorities and for the quality of the service provided. This will normally be a consultant (C-Grade) or principal grade (B17 and above) Clinical Scientist/Engineer. Where the head of the service is not a Consultant Grade appointment, the unit should be linked formally with a larger department/unit headed by a consultant grade Clinical Scientist/Engineer with experience in rehabilitation or medical engineering. The purpose of the link is to provide professional support for assuring service standards and career development.

LEGISLATION AND POLICY

Rehabilitation engineering service structure and organisation should provide appropriate access to relevant documentation. Service policy and procedures should ensure compliance with relevant legislation and NHS policies and regulations. Information listed below is not exhaustive but merely a guide to some of the most important legislation policies and regulations.

European Directives

The following European Directives are directly relevant to rehabilitation equipment. Each European Directive has been implemented in the UK by the Regulations listed below:

European Directive	UK Regulation
The Medical Devices Directive - 93/42/EEC	The Medical Devices Regulations 1994
The Low Voltage Directive - 73/23/EEC	The Electrical Equipment (Safety) Regulations 1994
The Electromagnetic Compatibility Directive - 89/336/EEC (& 92/31/EEC, 91/263/EEC)	The Electromagnetic Compatibility Regulations 1992

Engineer (RE), and Clinical Engineer (CE). These corresponded to the Engineering Council definitions for Engineering Technician (Eng. Tech.), Incorporated Engineer (I. Eng.), and Chartered Engineer (C.Eng.) respectively. This usage has not been strictly adhered to in the Health Service and so, to avoid confusion, this document refers only to three employment grades: Technologist (usually an Incorporated Engineer or Engineering Technician, depending on duties), Clinical Scientist/Engineer (usually a Chartered Engineer) and Consultant grade Clinical Scientist/Engineer (heading a small department or major section in a large department).

Regulations and Acts

Rehabilitation Engineering Departments are obliged to operate in a manner consistent with the following Regulations and Acts of the UK parliament (in date order):

- The Data Protection Act 1998
- Provision and Use of Work Equipment Regulations 1996
- The Disability Discrimination Act 1995
- The Active Implantable Devices Regulations 1995
- The Control of Substances Hazardous to Health (CoSHH) Regulations 1994
- The General Product Safety Regulations (1994)
- The Education Act 1993
- The Personal Protective Equipment at Work Regulations 1992
- The Health and Safety (Display Screen Equipment) Regulations 1992
- The Manual Handling Operation Regulations 1992
- The Health and Safety at Work Act 1992
- The Workplace (Health, Safety and Welfare) Regulations 1992
- Access to Health Records Act 1990
- The NHS and The Community Care Act 1990
- The Children Act 1989
- The Electricity at Work Regulations 1989
- The Furniture and Furnishings (Fire) (Safety) Regulations 1988
- The Consumer Protection Act 1987
- The Health and Safety at Work Act 1974
- The Chronically Sick and Disabled Persons Act 1970

Many of these Regulations and Acts implement European Directives. Interpretation of legislation through the courts provides case law that will be applied to similar cases in the future. Thus, case law is constantly being modified and updated. There should be mechanisms in place in every Department responsible for rehabilitation services to track case law interpretations.

NHS Policy, Procedures and Guidelines

MDA, the Medical Devices Agency, is a Government Agency. It is responsible for taking all reasonable steps to protect the public health and safeguard the interests of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance. It is also responsible for ensuring that such devices and equipment comply with the relevant directives of the EU. It includes in its function:

- The introduction and enforcement of regulations.
- The investigation of adverse incidents and the publication of Hazard Notices and Safety Notices (SN99/01 details the Adverse Incident Reporting System). Device Bulletins provide guidance and information for an extended area such as MDA DB 98/01 — Medical Device and Equipment Management For Hospital and Community-Based Organisations.
- Acting as the UK competent authority to ensure that the requirements of the Medical Devices Regulations are carried out.
- Commissioning and publishing Disability Equipment Assessment Reports.

The NHS Executive issues letters detailing NHS provider actions regarding specific issues. EL(98)5 details Medical Devices Directive guidelines for NHS in-house manufacturing.

The NHS Executive issues Health Service Circulars (HSCs) detailing advice or action regarding specific issues in the NHS. These may be aimed at Health Providers and Rehabilitation Engineering Services should have access to relevant HSCs.

Local procedures should be in place to ensure that Rehabilitation Engineering Services are aware of and can operate to standards such as the Patients' Charter.

Technology Standards

Conformity with European Directives and UK regulations involves compliance with appropriate standards. Some of the key standards are listed below; the list is not exhaustive.

- BS EN 29999 – Technical Aids For Disabled Persons – Classification
- BS EN ISO 9000 – Quality Assurance
- BS EN 46000 – Application Of ISO 9000 to Medical Manufacture
- BS EN ISO 7250 – Basic Human Body Measurements for Technological Design
- BS 7313 ISO 8549 – Prosthetics and Orthotics
- BS EN 55011 – Test Limits And Methods For EMC Measurement
- BS EN 60529 – Degrees Of Protection Provided By Enclosures
- BS EN 1441 – Medical Devices, Risk Analysis
- BS EN ISO 7176 – Wheelchairs
- BS EN 60601 – Medical Electrical Equipment
- BS 2574 – Lower Limb Orthoses
- BS 308 – Engineering Drawing Practice

Service Standards

Service standards are the subject of constant re-assessment. Documents that have been useful in setting standards in rehabilitation engineering services are listed in the following bibliography, which is not exhaustive.

- RESMaG and IPEM *Rehabilitation Engineering Services: Functions, Competencies, and Resources*. Centre of Rehabilitation Engineering, King's College London, May 1996.
- King's Fund *Manual on Organisational Audit - Medical Physics and Biomedical Engineering Service*. (Rehabilitation Engineering).
- DoH Health Notice HN(90)18 *Scientific and Technical Services*.
- ISO 9000 (Quality Management) documents.
- DoH *Technician Training Programme First-Stage Technician in Rehabilitation Engineering*. DoH, 1991.
- DoH *Technician Training Programme Rehabilitation Engineering (Advanced)*. DoH, 1992.
- The Engineering Council *Code and Rules of Conduct* and their *series Code of Professional Practice*.
- The Engineering Council *Standards and Routes to Registration, (SARTOR), 3rd Edition 1998*.
- IPEM Articles of Association – *Professional Conduct*.
- IPEM *Training Scheme for Physical Scientists in Health Care – Rehabilitation Engineering*.

FUNCTIONS

The role of a rehabilitation engineering department is to provide professional engineering support to clients, both in hospitals and in the community. It should act as part of a multidisciplinary healthcare team, providing specialist engineering knowledge and skills to clinical staff and clients, as increasingly complex technology for assessment and assistance becomes available to them. A department should be flexible and responsive to changing local demands but it should employ a mix of professional engineers and technologists able to perform the following basic functions.

- 1) Assessment of client needs, either independently as a Clinical Scientist or within a multi-disciplinary team, in order to meet agreed goals.
- 2) Assessment of client function, either independently as a Clinical Scientist or within a multi-disciplinary team; use of instrumentation to provide quantitative assessment; and interpretation of data acquired.
- 3) Identification of commercial solutions. Design and development of novel, cost-effective solutions where commercial options are not available.
- 4) Customisation, integration and installation of commercially available equipment to meet specific client needs.
- 5) Analysis of risks associated with the use, provision, or development of technology.
- 6) Engineering support to purchasing decisions through creation of detailed specifications prior to contract, monitoring contract progress, and acceptance testing at delivery.
- 7) Maintenance and/or refurbishment of equipment in institutions and the community, either directly or through contractors.
- 8) Organised retention of records and data.
- 9) Training or teaching of clinical staff in engineering matters, such as basic engineering principles, use of equipment, new legislation, and developments in technology.
- 10) Contribution to the wider development of rehabilitation engineering through active participation on professional bodies, research, and the dissemination of information by published materials and scientific meetings.

A department should carry out its functions in line with the latest best practice and in compliance with current legislation and relevant national and international standards (see *Legislation and Policy*). Staff should be trained to appropriate professional levels and training should be continuous to keep pace with technological developments.

COMPETENCE

The following describes the training process for specialist staff in rehabilitation engineering services and key elements for their career progression. They are current at the time of publication and subject to regular review. Readers should contact IPEM for the latest information (www.ipem.org).

Clinical Scientists/Engineers

Grade A Training Scheme

IPEM has introduced and developed a basic training scheme for new entrants into the profession. Following graduation from a first degree course approved by the Engineering Council or the Institute of Physics, trainees follow a two year structured training programme

comprising an MSc accredited by IPEM and competence based training in three major subject areas, at a training centre accredited by the IPEM. At the end of the programme trainees submit a portfolio of their work and are assessed against a published list of competencies in each subject. Successful completion results in the award of the Postgraduate Diploma of IPEM.

Subject areas relevant to Rehabilitation Engineering include Rehabilitation Engineering (Mobility and Posture), Rehabilitation Engineering (Sensory and Communication), Medical Engineering (Design and Development), Medical Electronics, Physiological Measurement and Information Management and Technology. Competencies in Biomechanical Engineering, including gait analysis, are also being developed.

Grade B

This is the main career grade for clinical engineers and clinical scientists entry being gained through the Grade A training scheme (although not exclusively). During the first four years on the grade, the trainee follows a Programme of Advanced Training and Responsibility (PATR), usually in one of the major subject areas, leading to C.Eng. and MIPEM. This programme must be submitted for approval by IPEM following which an external assessor is appointed to monitor and assess the breadth and depth of training. After two years, having reached the appropriate standard, the trainee can apply for entry onto the Register of Clinical Scientists. This is a statutory requirement. Only those names on the statutory register will be able to practice with the title Clinical Scientist/Engineer.

Entry onto the Register removes the requirement for direct supervision and allows the clinical engineer to take increasing responsibility for their work.

Following a minimum period of two years' responsible experience the Clinical Engineer can apply for registration as a Chartered Engineer and Corporate Membership of IPEM. Simultaneous assessment is by interview following submission of a portfolio summarising the experience gained and the level of responsibility taken.

Higher Grade B and Grade C

CEng and MIPEM confer independent practitioner status and will be a requirement for appointment to senior posts such as Heads of Departments.

Continuing Professional Development

CPD will be a statutory requirement to maintain the level of competence demanded for state registration. However, all staff will be expected to demonstrate a level of CPD appropriate to their grade that will be central to their career progression.

Training of Technologists

The training of Clinical Technologists in Rehabilitation Engineering is currently less well defined but the policy of IPEM is to develop a Programme of Structured Training and Responsibility along similar lines to those for Clinical Engineers. Entry into the lower MTO grades will be via an HNC or vocational degree in a relevant subject followed by a period of in-service training to ensure competence in the particular main subject area before entry onto a statutory register. The latter will be achieved through new legislation. Following at least two years experience, the "registered" Clinical Technologist may apply for IEng status and Incorporated Membership of IPEM. These will become increasingly important for appointment to higher grade posts.

The objects for which the Institute is established are to promote for the public benefit the advancement of physics and engineering applied to medicine and biology and to advance public education in the field.

Further copies of this statement may be obtained from the Head Office of the IPEM at the following address:

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Other policy statements concerning services carried out by Clinical Scientists employed in Health Care are available from the above address.