MODERNISING SCIENTIFIC CAREERS

Scientist Training Programme
Work Based Training

Learning Guide

CLINICAL ENGINEERING

2012/13
STP WORK BASED PROGRAMME IN CLINICAL ENGINEERING

Contents

SECTION 1: GENERAL INTRODUCTION ................................................................................. 4
READERSHIP .................................................................................................................... 5
1.1 Scientist Training Programme (STP) Overview .......................................................... 6
1.2 Outcomes of the work based STP ............................................................................ 9
1.3 Key Components of Work Based Training in STP ............................................. 11
1.4 Host Training Departments .............................................................................. 12
1.5 National School of Healthcare Science (NSHCS) and the STP ............................ 16
1.6 The Structure of the Learning Frameworks ......................................................... 17
1.7 Assessment during Work Based Training ......................................................... 18
1.8 Quality Assurance and Quality Management ...................................................... 21

SECTION 2: PROGRAMME OVERVIEW ................................................................ 23

SECTION 3: ROTATIONAL LEARNING FRAMEWORKS .......................................... 30
Clinical Measurement and ICT (CMICT) ..................................................................... 32
Design and Development (DD) .................................................................................. 38
Device Risk Management and Governance (DRM) .................................................. 43
Rehabilitation Engineering (RE) ................................................................................. 54

SECTION 4: PROFESSIONAL PRACTICE LEARNING FRAMEWORK.................. 60
Professional Practice (PP1) ...................................................................................... 63

SECTION 5: ELECTIVE LEARNING FRAMEWORK..................................................... 74
Elective (EL) ............................................................................................................. 76

SECTION 6: SPECIALIST LEARNING FRAMEWORK CLINICAL MEASUREMENT AND DEVELOPMENT .......................................................... 78
The Project Life Cycle (DD1) .................................................................................... 81
Advanced Information and Communication Technology Skills (DD2) .................. 86
Clinical Measurement (DD3) ..................................................................................... 90

SECTION 7: SPECIALIST LEARNING FRAMEWORK DEVICE RISK MANAGEMENT AND GOVERNANCE .......................................................... 94
Medical Device Management Strategy (DRM1) .................................................... 97
Optimisation of Medical Device Effectiveness and Efficiency (DRM2) ................ 101
Equipment Acquisition, Acceptance Testing and Installation (DRM3) ................. 105
Planned Maintenance and Repairs to Devices (DRM4) ....................................... 110
Patient Safety (DRM5) .......................................................................................... 115
Medical Device Information System (DRM6) .......................................................... 118
Expertise in Medical Device Risk Management (DRM7) ....................................... 122
Professional Advisory Services (DRM8) ............................................................... 125
SECTION 1: GENERAL INTRODUCTION
READERSHIP

This Scientist Training Programme (STP) Learning Guide describes the STP work based training programmes in the UK:

- Trainees, host departments and managers of services that employ healthcare science staff;
- Work based trainers, which includes all those involved in supervising, coordinating, assessing and delivering education and training;
- Academic and administrative staff within Higher Education Institutions (HEIs);
- Strategic Health Authorities (SHAs), and their successor health and education commissioning bodies;
- Those involved in Modernising Scientific Careers (MSC) accreditation events and reviews.

A glossary of terms used is provided in Appendix 1.
Introduction

1.1 Scientist Training Programme (STP) Overview

1. Healthcare science (HCS) involves the application of science, technology, engineering and mathematics to health. Good Scientific Practice (GSP) [Appendix 2] sets out the principles and values on which education and training for healthcare science are founded. It makes explicit the professional standards of behaviour and practice that must be achieved and maintained in the delivery of work activities and clinical care for all those who work in healthcare science, the public and healthcare providers.

2. GSP and the Education and Training Standards of the Health and Care Professions Council (HCPC) are the basis for all MSC training curricula which contextualise the Standards of Proficiency set down by the HCPC in a way that is accessible to the profession and the public.

3. The healthcare science workforce and services have traditionally been grouped into three broad areas called Divisions, namely: Life Sciences/Clinical Laboratory Sciences, Physical Sciences/Medical Physics and Biomedical Engineering and Physiological Sciences/Clinical Physiology Sciences. Within each Division there are a number of healthcare science specialisms. With advances in scientific technology, changes to the delivery of healthcare scientific services and the development of MSC, the boundaries between these Divisions have been shifting. MSC recognises this important change and to date has identified nine themes within healthcare science for the STP, which enables training across a total of 24 healthcare science specialisms, with curricula for additional specialisms still under development.

4. The STP is designed to provide healthcare scientist trainees with strong science-based, patient-centred clinical training in a specialist area of healthcare science. Initial rotational training provides a broad base of knowledge, skills and experience across a group of related cognate specialisms reflective of the evolving clinical and scientific changes and requirements followed by specialisation in a single HCS specialism.

5. During the STP programme the scientist trainee is supernumerary but may contribute to the clinical work of the department in which they are training to gain the required clinical experience and competence.

6. The STP is an integrated training programme combining academic study leading to the award of a specifically commissioned MSc in Clinical Science and a work based training programme. Completion of both will lead to the award of a Certificate of Completion of the Scientist Training Programme (CCSTP) by the National School of Healthcare Science (NSHCS). Graduates are then eligible to apply to the Academy for Healthcare Science for a Certificate of Attainment and will then be eligible to apply to HCPC for registration as a Clinical Scientist.

7. The MSc Clinical Science Learning Outcomes and Indicative Content, and the associated work based learning outcomes, can be found by following the link www.networks.nhs.uk/nhs-networks/msc-framework-curricula. Further details of the
MSc in Clinical Science can be found in the student handbook from the university with which each trainee is registered.

8. This Introduction to Work Based Learning provides an overview of the work-based training programme and the guidance provided by the NSHCS for users of the Online Assessment Tool (OLAT) and e-learning Portfolio. All trainees and trainers will have access to the OLAT throughout their training. In addition, The Reference Guide for Healthcare Science Training and Education in England will be published in autumn 2012. This will contextualise the STP within the wider MSC programme.

9. All STP trainees will be registered with the NSHCS for the duration of their training and will be allocated a National Science Training Number (NSTN). The NSHCS working through its Themed Boards provides oversight and coordination of the STP, communicates with trainees and trainers with respect to national policy and events, liaises with the work based trainers, host employers and the academic providers, reviews progress on assessments and trainee performance including OLAT/Structured Final Assessment (SFA) and quality assurance of the work place training environment. The School overall has a responsibility to provide confidential reports in accordance with agreed governance and oversight arrangements.

10. The work based training programme has four components each underpinned by the professional practice curriculum:
   - Induction;
   - Rotational Training;
   - Elective Training;
   - Specialist Training.

11. It is anticipated that trainees will have a brief induction period in their host employing organisation prior to commencing the introduction to their MSc in Clinical Science. As the induction period may be up to 6 weeks in some departments the time should be used to begin rotational training as well as the induction period. The subsequent initial academic period is specifically designed to give an overview of the basic science and an introduction to aspects of professional practice relevant to HCS and the STP rotational training. The duration of this first university session will vary, depending on the MSc degree which is undertaken.

12. Details of the work based assessment programme can be found in Section III of this guide and also by logging onto the online assessment tool. Details of the assessment programme for the MSc in Clinical Science will usually be published in the student handbook provided by each university.

A broad overview of the STP is shown in the diagram overleaf:
Modernising Scientific Careers: Scientist Training Programme (STP):
Diagrammatic representation of employment-based, pre-registration 3 year
NHS commissioned education and training programme

Work Based Rotational and Specialist Training Programme

Single Specialism Work Based Programme
to include a 4 – 6 week period of Elective Training

Year 3
Specialist including Research Project

Year 2
Specialist including Research Project

Research Methods
Year 1
Theme

Generic Healthcare Science

Integrated Professional Practice

Work Based Themed Rotational Programme
4 x 12 weeks

Specialism One
Specialism Two
Specialism Three
Specialism Four

Induction

Generic Education and Training
Themed Education and Training
Specialist Education and Training
1.2 Outcomes of the work based STP

On successful completion of the work based STP trainees will have clinical and specialist expertise in a specific healthcare science specialism, underpinned by broader knowledge and experience within a healthcare science division or theme. They will undertake complex scientific and clinical roles, defining and choosing investigative and clinical options, and making key judgements about complex facts and clinical situations. Many will work directly with patients and all will have an impact on patient care and outcomes. They will be involved, often in lead roles, in innovation and improvement, research and development and education and training. Some will pursue explicit academic career pathways, which combine clinical practice and academic activity in research, innovation and education.

On successful completion of the work-based training programme which forms part of the MSC STP, trainees will possess the essential knowledge, skills, experience and attributes required for their role and should demonstrate:

- A systematic understanding of clinical and scientific knowledge, and a critical awareness of current problems, future developments, research and innovation in health and healthcare science practice, much of which is at, or informed by, the forefront of their professional practice in a healthcare environment;
- Clinical and scientific practice that applies knowledge, skills and experience in a healthcare setting, places the patient and the public at the centre of care prioritising patient safety and dignity and reflecting NHS/health service values and the NHS Constitution;
- Clinical, scientific and professional practice that meets the professional standards defined by GSP and the regulator (HCPC);
- Personal qualities that encompass self-management, self-awareness, acting with integrity and the ability to take responsibility for self-directed learning, reflection and action planning;
- The ability to analyse and solve problems, define and choose investigative and scientific and/or clinical options, and make key judgements about complex facts in a range of situations;
- The ability to deal with complex issues both systematically and creatively, make sound judgements in the absence of complete data, and to communicate their conclusions clearly to specialist and non-specialist audiences including patients and the public;
- The ability to be independent self-directed learners demonstrating originality in tackling and solving problems and acting autonomously in planning and implementing tasks at a professional level;
- A comprehensive understanding of the strengths, weaknesses and opportunities for further development of healthcare and healthcare science as applicable to their own clinical practice, research, innovation and service development which either directly or indirectly leads to improvements in clinical outcomes and scientific practice; alternative;
- Conceptual understanding and advanced scholarship in their specialism that enables the graduate to critically evaluate current research and innovation methodologies and develop critiques of them and, where appropriate, propose new research questions and hypotheses;
• Scientific and clinical leadership based on the continual advancement of their knowledge, skills and understanding through the independent learning required for continuing professional development.

14. Once registered as a Clinical Scientist, a range of career development options will be available including competitive entry into Higher Specialist Scientist Training (HSST). Alternatively, others may choose to undertake further career development in post through a structured programme of Continuing Professional Development (CPD), provided by Accredited Expert Scientific Practice or pursue a clinical academic career. Clinical Scientists who successfully complete HSST, or who can demonstrate equivalence to its outcomes, will be eligible to compete for available Consultant Clinical Scientist posts.
1.3 Key Components of Work Based Training in STP

The Trainee

15. The trainee is at the centre of the STP, supported on the one hand by the national oversight role taken by the NSHCS, working closely with local quality monitoring and performance processes currently undertaken by SHAs and on the other by the day-to-day delivery of training in the workplace, facilitated by the underpinning and integrated MSC in Clinical Science programme. This Guide contains important information which will help the trainee understand how the work based programme operates and its key elements.

16. At the core of successful work based training is appropriate educational supervision, facilitation and feedback. Each trainee will be allocated to a clinical training supervisor or training officer\(^1\) from within the employing host department. Trainees should ensure that a planned schedule of meetings with their training officer is agreed early in training, commencing with a meeting during the first week. Conversations between trainees and trainers are confidential, unless patient safety is at risk. When the trainee is following a rotational module a trainer from the host department will act as their main contact whilst they are away from their host department.

17. The local training departments, supported by the NSHCS working with others, are responsible for ensuring that trainees have access to training opportunities to enable the achievement of the learning outcomes of the STP. In return trainees are expected to take responsibility for:

- ensuring that they fulfill their obligations to their employer and to patients (especially with regard to patient safety and confidentiality) as healthcare professionals;
- engaging as active adult learners by initiating work based assessments; contributing to learning activities; taking into account feedback received from their trainers and assessors and; giving considered and constructive feedback on their experience of their training;
- meeting the requirements of the academic MSc Clinical Science programme.

18. Critical reflection on progress and performance is an integral part of both the STP and of being a professional. Trainees should therefore regularly critically reflect on their progress and performance, enabling them to develop skills in self-evaluation and action planning.

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\(^1\) For the purposes of this document Training Officer has been used however the title may vary between departments and may be subject to a title change in England as part of developments for the whole of the professional healthcare workforce. In essence this is the person in the host department who is responsible for the training of each trainee for the duration of the 3 years.
1.4 Host Training Departments

19. The third key component for successful training in the STP is the employing host department and other service units facilitating work based training. The success of the training and the trainee experience requires the commitment and enthusiasm of those in the work base who provide the training.

20. Host departments should therefore ensure that they are fully familiar with the four components of the work based training programme, namely: induction, rotational, elective and specialist; the underpinning professional practice curriculum and be aware of how the academic MSc in Clinical Science degree integrates with work based training.

21. All trainees must have a designated training officer who will have responsibility for:

- provision of support, guidance and mentoring for the duration of the programme, in the host department and related training environments;
- provision of a timetable which enables an appropriate balance of work and learning for the trainee;
- ensuring adequate support during periods of training outside the host department;
- ensuring that the programme of work based assessment is understood and that its outcomes for individual trainees is documented through the use of OLAT;
- ensuring that the e-learning Portfolio is discussed with the trainee and that there is clarity and agreement about its use;
- ensuring that clinical practice is well supervised for the safety of patients and the trainee, so that the acquisition of clinical competence is facilitated;
- ensuring that other contributors to the assessment process are fully aware of the requirements and the use of the OLAT.

Organisation of the Training Programme

22. The host department is responsible for organising the training programme for each of its trainees. This may involve liaising with other departments to facilitate necessary work based learning and other contributors to the associated assessment requirements. Whilst the NSHCS will provide support, host departments need to be satisfied that they are providing a training environment of appropriate quality including appropriately trained staff and facilities. Furthermore, host departments are required to engage in the quality assessment management process established by the NSHCS and provide information as necessary to enable the NSHCS to fulfil this critical function. Details of the NSHCS quality assessment management policy for work based training provider departments can be found at: www.nshcs.org.uk.
23. Induction

At the start of the STP training programme and of each new placement, trainees should be provided with an induction programme explaining trust and departmental arrangements. Initial work based induction in the host department should include an overview of the:

- hospital/healthcare setting and local policies including health and safety, confidentiality, data protection etc relevant to the placement;
- range of services provided by the department;
- range of people who use the services provided by the department;
- function, operation and routine and corrective maintenance requirements of equipment appropriate to the section(s) of the department in which the trainee will be working.

Moreover, the host department should ensure that the trainee has access to:

- Host Trust IT systems including the library and knowledge service as necessary;
- On-line Assessment and Personal Management System.

Induction should include an early discussion (within the first week) between the trainee and his/her training officer so that the curriculum, assessment and placement arrangements can be discussed. In addition, trainers should provide trainees with copies of:

- Good Scientific Practice;
- The STP work based Learning Guide;
- The OLAT learning guide;
- Links to the NSHCS (see section III for details of the role of the NSHCS in relation to STP training).

24. Rotational Training

During rotational training each trainee will undertake four rotations which will include a rotation in the area in which they will subsequently specialise. Trainees must successfully achieve all of the learning outcomes. Each rotational placement should be of approximately 12 weeks duration. It is the responsibility of the host department to organise this rotational programme and to liaise with the trainers in the rotational placement departments on the requirements of work based training and supervision and the use of the online assessment tool. The NSHCS and the SHA MSC leads (and successors) will help to facilitate rotational placements for small specialisms or where there are local issues in respect of access to particular training elements.

The host department is responsible for setting the timetable for each of the 4 rotations, which will depend on local availability and may require some time to be spent out with your locality to ensure that the learning outcomes in totality can be achieved. In agreeing the rotational training the host department will need to consider the periods of time the trainee will be required to attend the University or undertake academic activities for the MSc within the work place.
The host department must be familiar with the content, delivery and assessment programme of the MSc in Clinical Science which the trainee is undertaking at university and ensure that the departments where the trainee is placed for rotational placements are also familiar with the expected outcomes of each period of training and are trained in the assessment methods. The training officer in the host department should maintain contact with the trainee and should liaise with the person taking overall responsibility for the trainee whilst they are undertaking the rotation. Supervision meetings between the training officer and the trainee should continue whilst they are on their rotational placements.

25. Elective Training

Each trainee must undertake elective training and successfully achieve all of the learning outcomes. The host department should agree the timing and content of the elective training period with the trainee and should then inform the NSHCS of the plans for the elective by completing the appropriate form and submitting it to the School. The aim of the elective is to facilitate a wider experience of health care and/or the practice of healthcare science in a cultural and/or clinical setting that is different from the usual training environment. This may involve health care or healthcare science in a different area of the health service and may involve study abroad or pursuit of a particular clinical or research interest. The elective period can be taken any time during the specialist training, and may comprise a single period of 4–6 weeks or a series of shorter periods of elective training. It is important that the trainee is able to express their preferences for the elective period which is designed to provide a broader experience and for these to be fully taken into consideration.

26. Specialist Training

The host department will plan the timetable for specialist training. This will usually be in a single health care science specialism (except for Gastrointestinal Physiological and Urodynamic Science who share modules in the specialist training period, and Immunogenetics and Histocompatibility who share some specialist modules with Clinical Immunology). Each trainee must successfully achieve all of the learning outcomes in the specialist training modules including, by the end of the training programme, all of the professional practice learning outcomes. If the host department itself is unable to provide the necessary work based training to enable the trainee to complete all of the required learning outcomes, it will need to arrange training in other training departments and environments.

27. Supervision

STP clinical and educational supervision should promote learning, reflective practice and support the trainee to produce action plans to address identified learning needs. It will need to ensure that the trainee learns specific skills and competencies, helping them to develop self-sufficiency and self-awareness in the ongoing acquisition of skills and knowledge. At every stage, patient safety must be paramount. Supervision will require the provision of pastoral care for some trainees. Supervision may, at times during the programme, be provided by other healthcare professionals outside of healthcare science who will be appropriately trained e.g. medical colleagues.
The first supervision meeting should be set up during the first week of the training programme. At this meeting the training officer should ensure that the trainee is undertaking an induction programme that includes the hospital and department. It is recommended that following areas should be explored and agreement reached at the first meeting with respect to the:

- expectations of the training officer and trainee;
- responsibilities of the training officer and trainee;
- boundaries between the training officer and trainee;
- confidentiality;
- frequency and duration of planned supervision meetings;
- methods of communication and responsibility for arranging meetings;
- level of support and arrangements for communications between meetings;
- models of reflection and action planning;
- record keeping;
- content of the work based training programme;
- the approach to assessment and the use of the assessment tools and the online system;
- sources of help and support.
1.5 National School of Healthcare Science (NSHCS) and the STP

The NSHCS provides a national coordinating and oversight function to support trainees and host departments in the delivery of training. It is responsible for:

- national recruitment into STP, enabling a transparent and robust selection of the very best science graduates;
- providing national oversight of STP trainees throughout their training by managing and monitoring their progress through the OLAT, supporting trainees in difficulty as well as co-ordinating national structured assessments both during and at the end of STP training;
- evaluation of ongoing work based assessment outcomes through the OLAT, enabling the School to benchmark training programme delivery for early identification of programme issues which may need to be addressed and resolved and reporting these as part of agreed MSC governance arrangements;
- liaising with each HEI's MSc Clinical Science programme director to ensure the integration and coordination needed to deliver the academic and work based programmes that form the STP; liaising with MSC SHA leads (and education and quality leads in the future arrangements) on local issues and problems and their resolution;
- working closely with workplace training departments and providing support as appropriate;
- organising national ‘Train the Trainer’ programmes to ensure common standards of delivery and content and recommending on-going training activities to support the continuing professional development of work based trainers.

Professional Leads in each of the scientific divisions within the NSHCS will provide help and support with respect to organising rotations and/or specialist training that might require national coordination. In order to optimise the educational benefit and value of OLAT and the e-learning Portfolio, Professional Leads will also work with and support training departments in its use.

The School can be contacted on the following email nshcs@Westmidlands.nhs.uk and at www.nshcs.org.uk.
1.6 The Structure of the Learning Frameworks

29. The work-based programme is divided into modules, with each module following a standard format. The aim and scope of the module are described followed by:

- Learning outcomes – high level descriptors of required achievements for module;
- Clinical Experiential Learning – the learning activities that will facilitate learning and achievement of stated outcomes;
- Competences – further, outcome based statements for each Learning Outcome;
- Knowledge and Understanding as APPLIED to appropriate competences.

All of the above are focused on service need, patient care/pathway and continuous service improvement.
1.7 Assessment during Work Based Training

Trainee Assessment

30. The work-based assessment is designed to promote learning, skill development and competence within the specialist healthcare context. Trainees will be able to identify areas for development and improvement.

The assessment programme is designed to enable both trainee and trainer to obtain regular feedback on progress and achievement. It aims to nurture the trainee by providing professional educational support and encouraging critical reflection and generating regular feedback about progression. The programme embeds assessment tools to enable trainees to learn and develop but also to generate evidence so that judgments about progression can be made and areas identified for trainee improvement based on supportable evidence.

The work-based education and training programme should offer a constructive environment where a trainee understands that he/she is still developing and the assessment tools are intended for use in this context. As part of each assessment, the work-base assessor will facilitate a discussion in which the trainee is encouraged to reflect on his/her performance and identify his/her strengths and areas that could be improved, setting an action plan to achieve that improvement.

31. The structure of the work-based assessment programme.

There are distinct elements of the work-based assessment programme for all trainees:
- Assessment Tools, see Table 1 overleaf;
- Competency Log;
- Online Assessment and Personal Learning Management System (OLAT);
- Exit assessment – Objective Structured Final Assessment (OSFA).

Assessment Tools

32. The assessment programme utilises a range of work-based assessment tools, designed to promote continuous assessment and generate feedback throughout training. The assessment promotes student centred feedback to enable the trainee to gain skills in self-assessment. There is a requirement for each trainee to engage with the assessment process and to complete a defined number and range of assessments to successfully complete each module. These are set out in OLAT.
Table 1 Summary of the STP Work Based Assessment Tools

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>Direct observation of practical skills (DOPS)</th>
<th>Observed clinical event (OCE)</th>
<th>Case based discussion (CbD)</th>
<th>Multi source feedback (MSF)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>To assess a practical skill or procedure which may include interaction with a patient. Feedback is generated, learning needs identified and an action plan generated.</td>
<td>To assess a clinical encounter.</td>
<td>To assess the trainee’s ability to apply their knowledge and understanding of an aspect of an activity for example the underpinning science, aspects of professional practice.</td>
<td>To provide a sample of attitudes and opinions of colleagues on the performance and professional behaviour of the trainee. It helps to provide data for reflection on performance and gives useful feedback for self-evaluation.</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>The assessor observes a practical activity and facilitates student centred feedback either during or immediately following the observation. The trainee then generates an action plan.</td>
<td>The assessor observes a clinical activity and facilitates student centred feedback either during or immediately following the observation. The trainee then generates an action plan.</td>
<td>The assessor facilitates a discussion with the trainee about a clinical case with which the trainee has been involved. This may include a report, record, result or an aspect of professional practice arising from the case. Following the discussion the trainee generates an action plan.</td>
<td>Using an on-line system the trainee gains feedback from a range of people (8–10) who work with them and the trainee also rates themselves. On completion the report generated is reviewed in a discussion between the trainee and trainer and using critical reflection an action plan generated by the trainee.</td>
</tr>
</tbody>
</table>
33. Competences

All trainees are required to provide evidence to demonstrate that they have completed each competence which should then, at the request of the trainee, be signed off by a trainer. Trainees will gain competence at their own pace, but in line with the overall delivery of the relevant modules. Each competence may link directly to a specific learning outcome and some competences may be linked to more than one learning outcome, therefore successful completion cannot be achieved until demonstrated for all learning outcomes. All of the competences are contained within a competency log within the OLAT.

Completion of the competency log is essential for progression within the programme and in order to exit from the programme. The expectation is that as the trainee progresses the competency log will demonstrate an evidence base of achievement.

34. Online Assessment and Personal Management Tool (OLAT)

The achievement of competences and all work based assessments are recorded on OLAT. OLAT is customised for each specialism and contains all the above assessment tools as well as the full list of competences for each programme and a reflective log.

NSHCS will provide trainees with the information to allow them to register on OLAT at the start of their programme. As part of their registration they must nominate their training officer, even though others may contribute during the total period of work base training to the assessment process.

Short film clips which explain the principles of the assessment process and how to use each of the assessment tools are available on OLAT.

35. Objective Structured Final Assessment

At the end of training trainees will be assessed using an Objective Structured Final Assessment (OSFAs). This is a performance based assessment used to measure trainees across a number of different stations encompassing scientific, clinical and professional practice. The NSHCS, in partnership with the professional bodies and supported by the NSHCS Themed Boards, will design and deliver the OSFA and the Academy for Healthcare Science will provide external Quality Assurance.

All trainees will have the opportunity to undertake an OSFA mid-programme to provide formative experience of this assessment.
1.8 Quality Assurance and Quality Management

Quality Assurance of work based training

36. All host and training departments are responsible for the delivery of the work based training quality standards detailed in the Learning and Development Agreement (LDA) agreed with and issued by with the local Strategic Health Authority (SHA) and their successor bodies. All host and training departments providing training for trainees on the STP must also be MSC approved and accredited.

37. MSC work-based accreditation is carried out by the NSHCS on behalf of MSC.

38. The NSHCS provides oversight of the quality management and quality control of the STP work based training environments as agreed by the appropriate MSC governance arrangements and to be maintained into the future.

39. The NSHCS works in partnership with the professional bodies through its Themed Boards and the SHAs/LETBs to deliver a robust Quality Assessment Management (QAM) programme for the work based education and training programme. This QAM programme is UK wide and independent from the direct delivery of education and training. The purposes of the QAM programme are to:

- all STP training environments are accredited to deliver work based training;
- ensure that all training settings are working to the agreed standards;
- create an open and transparent culture where issues and concerns can be raised, investigated and resolved;
- ensure that trainees receive a high quality educational experience wherever their training takes place;
- Identify and share examples of good practice;
- provide evidence of the quality of work based education and training environments to those who regulate and register the profession;
- provide evidence of the high standard of work based education and training and assurance that these standards are robustly managed.

40. Details of the quality management approach is available from the NSHCS (Ref NSHCS Policy 03), in summary, the quality framework includes:

- Receipt, analysis, review and response with respect to:
  - annual self assessment progress reports from each work base;
  - trainee feedback questionnaires;
  - assessment progress reports;
  - ad hoc reporting of exceptions or changes to programmes;
  - individual work based education and training timetables for each trainee;
• A mechanism for receiving and reviewing reports with respect to the STP programme from trainees, trainers, patients or other stakeholders;
• Visit Programme including:
  o a five year rolling visit programme to each work base;
  o adhoc visits to departments as required.

41. The NSHCS monitors the progress of each trainee and provides support for trainees in difficulty (Trainees in Difficulty Ref NSHCS Policy 04). Staff in the NSHCS also regularly review the STP programmes using information from the OLAT and other sources through the Themed Boards (See NSHCS Policy 01).

42. The QAM processes, established jointly by the MSC governance arrangements involving all current SHAs and the NSHCS, do not absolve the training provider from responsibility for continuously managing and maintaining the quality of its own provision. Local training departments are responsible for ongoing quality control and local education providers should therefore ensure that a high quality education and training environment is maintained.

The following sections of this Learning Guide include an overview of the STP work based programme for the specialisms within this theme. This is followed by the Learning Frameworks for the Rotational, Elective, Specialist and Professional Practice components of the programme.

Further information can be found in Appendix 3.
SECTION 2: PROGRAMME OVERVIEW

CLINICAL ENGINEERING
**STP WORK BASED TRAINING PROGRAMME IN CLINICAL MEASUREMENT AND DEVELOPMENT**

The diagram below provides an overview of the programme each trainee in Clinical Measurement and Development will follow.

**Modernising Scientific Careers: Scientist Training Programme (STP):**
Diagrammatic representation of employment based, 3-year NHS commissioned, pre-registration Education and Training programme

<table>
<thead>
<tr>
<th>Work Based Rotational and Specialist Training Programme</th>
<th>P/T MSc Clinical Science</th>
</tr>
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<tbody>
<tr>
<td><strong>Single Specialism Work Based Programme</strong> to include a 4 – 6 week period of Elective Training</td>
<td>Blended learning (final problem based learning)</td>
</tr>
<tr>
<td><strong>CLINICAL ENGINEERING: Specialisms</strong></td>
<td></td>
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<tr>
<td>Rehabilitation Engineering</td>
<td></td>
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<tr>
<td>Clinical Measurement &amp; Development</td>
<td></td>
</tr>
<tr>
<td>Device Risk Management &amp; Governance</td>
<td></td>
</tr>
<tr>
<td><strong>Work Based Themed Rotational Programme</strong> 4 x 12 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Induction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Generic Education and Training</strong></td>
<td><strong>Themed Education and Training</strong></td>
</tr>
</tbody>
</table>

**PROFESSIONAL PRACTICE**

This module spans the whole of the 3-year training programme, underpinning both work based training and the MSc in Clinical Science.

**INDUCTION COMPONENT**

At the start of the training programme and of each new placement all trainees will complete an induction programme.
ROTATIONAL COMPONENT

Trainees must then successfully complete the following rotations:

<table>
<thead>
<tr>
<th>Rotation 1 (CMICT)</th>
<th>Clinical Measurement and ICT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotation 2 (DD)</td>
<td>Design and Development</td>
</tr>
<tr>
<td>Rotation 3 (RE)</td>
<td>Rehabilitation Engineering</td>
</tr>
<tr>
<td>Rotation 4 (DRM)</td>
<td>Device Risk Management and Governance</td>
</tr>
</tbody>
</table>

**Duration:** Each rotation should be of approximately 12 weeks duration.

**Order:** It is expected that the first two rotations completed will be Clinical Measurement and ICT and Design and Development in either order.

ELECTIVE COMPONENT

The elective period can be taken any time during the specialist training. It may comprise a single 4- to 6-week elective or a series of shorter periods of elective training.

SPECIALIST COMPONENT

<table>
<thead>
<tr>
<th>Module 1 (DD1)</th>
<th>The Project Life Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 2 (DD2)</td>
<td>Advanced Information and Communication Technology Skills</td>
</tr>
<tr>
<td>Module 3 (DD3)</td>
<td>Clinical Measurement</td>
</tr>
</tbody>
</table>

**Duration:** The work based component of the three specialist modules should be completed during the specialist training period. The work based component of the modules can run in parallel in order to use the time and clinical contacts to best advantage.

The following sections of the learning guide contain the learning frameworks for the rotational, elective, specialist and professional practice modules.
STP WORK BASED TRAINING PROGRAMME IN DEVICE RISK MANAGEMENT AND GOVERNANCE

The diagram below provides an overview of the programme each trainee in Device Risk Management and Governance will follow:

Modernising Scientific Careers: Scientist Training Programme (STP):
Diagrammatic representation of employment based, 3-year NHS commissioned, pre-registration Education and Training programme

PROFESSIONAL PRACTICE

This module spans the whole of the 3-year training programme, underpinning both work based training and the MSc in Clinical Science.

INDUCTION COMPONENT

At the start of the training programme and of each new placement all trainees will complete an induction programme.
ROTATIONAL COMPONENT

Trainees must then successfully complete the following rotations:

<table>
<thead>
<tr>
<th>Rotation 1 (DRM)</th>
<th>Device Risk Management and Governance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotation 2 (RE)</td>
<td>Rehabilitation Engineering</td>
</tr>
<tr>
<td>Rotation 3 (CMICT)</td>
<td>Clinical Measurement and ICT</td>
</tr>
<tr>
<td>Rotation 4 (DD)</td>
<td>Design and Development</td>
</tr>
</tbody>
</table>

**Duration:** Each rotation should be of approximately 12 weeks duration.

**Order:** It is expected that the first rotation completed will be Device Risk Management and Governance.

ELECTIVE COMPONENT

The elective period can be taken any time during the specialist training. It may comprise a single 4- to 6-week elective or a series of shorter periods of elective training.

SPECIALIST COMPONENT

<table>
<thead>
<tr>
<th>Module 1 (DRM1)</th>
<th>Medical Device Management Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 2 (DRM2)</td>
<td>Optimisation of Medical Device Effectiveness and Efficiency</td>
</tr>
<tr>
<td>Module 3 (DRM3)</td>
<td>Equipment Acquisition, Acceptance Testing and Installation</td>
</tr>
<tr>
<td>Module 4 (DRM4)</td>
<td>Planned Maintenance and Repairs to Devices</td>
</tr>
<tr>
<td>Module 5 (DRM5)</td>
<td>Patient Safety</td>
</tr>
<tr>
<td>Module 6 (DRM6)</td>
<td>Medical Device Information System</td>
</tr>
<tr>
<td>Module 7 (DRM7)</td>
<td>Expertise in Medical Device Risk Management</td>
</tr>
<tr>
<td>Module 8 (DRM8)</td>
<td>Professional Advisory Services</td>
</tr>
</tbody>
</table>

**Duration:** The work based component of the eight specialist modules should be completed during the specialist training period. The work based component of the modules can run in parallel in order to use the time and clinical contacts to best advantage.

The following sections of the learning guide contain the learning frameworks for the rotational, elective, specialist and professional practice modules.
STP WORK BASED TRAINING PROGRAMME IN REHABILITATION ENGINEERING

The diagram below provides an overview of the programme each trainee in Rehabilitation Engineering will follow:

Modernising Scientific Careers: Scientist Training Programme (STP):
Diagrammatic representation of employment based, 3-year NHS commissioned, pre-registration Education and Training programme

PROFESSIONAL PRACTICE

This module spans the whole of the 3-year training programme, underpinning both work based training and the MSc in Clinical Science.

INDUCTION COMPONENT

At the start of the training programme and of each new placement all trainees will complete an induction programme.
ROTATIONAL COMPONENT

Trainees must then successfully complete the following rotations:

<table>
<thead>
<tr>
<th>Rotation 1 (RE)</th>
<th>Rehabilitation Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotation 2 (DRM)</td>
<td>Device Risk Management and Governance</td>
</tr>
<tr>
<td>Rotation 3 (CMICT)</td>
<td>Clinical Measurement and ICT</td>
</tr>
<tr>
<td>Rotation 4 (DD)</td>
<td>Design and Development</td>
</tr>
</tbody>
</table>

Duration: Each rotation should be of approximately 12 weeks duration.

Order: It is expected that the first rotation completed will be Rehabilitation Engineering.

ELECTIVE COMPONENT

The elective period can be taken any time during the specialist training. It may comprise a single 4- to 6-week elective or a series of shorter periods of elective training.

SPECIALIST COMPONENT

<table>
<thead>
<tr>
<th>Module 1 (RE1)</th>
<th>Assistive Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 2 (RE2)</td>
<td>Clinical Gait Analysis</td>
</tr>
<tr>
<td>Module 3 (RE3)</td>
<td>Medical Engineering Design</td>
</tr>
</tbody>
</table>

Duration: The work based component of the three specialist modules should be completed during the specialist training period. The work based component of the modules can run in parallel in order to use the time and clinical contacts to best advantage.

The following sections of the learning guide contain the learning frameworks for the rotational, elective, specialist and professional practice modules.
Clinical Engineering

SECTION 3: ROTATIONAL LEARNING FRAMEWORKS
STP Learning Framework

This section describes the Learning Framework for the **Rotational Component** of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

### Rotational Module

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>Clinical Measurement and Development</td>
</tr>
<tr>
<td>ROTATION</td>
<td>Clinical Measurement and Information Communication Technologies (ICT)</td>
</tr>
<tr>
<td>MODULE TITLE</td>
<td>Clinical Measurement and ICT (CMICT)</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>AIM</td>
<td>To ensure that the trainee can apply analytical and judgement skills to novel or complex clinical measurements, implement new clinical measurement solutions, and understand and configure novel ICT hardware and software solutions safely within the clinical environment.</td>
</tr>
<tr>
<td>SCOPE</td>
<td>On completion of this module the trainee will understand the role of ICT hardware, software and network components within the context of Medical Physics and Clinical Engineering. They will gain experience of the principles underpinning a range of basic clinical measurement and be able to acquire clinical measurement data. Trainees will be expected to develop and build their professional practice.</td>
</tr>
</tbody>
</table>

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Participate in clinical measurement procedures effectively and safely with due regard to the patient, health and safety, data security and governance in ICT within the context of Medical Physics and Clinical Engineering.
2. Apply statistical techniques to clinical measurement data and interpret the outcome of the statistical tests.
3. Manipulate data using a spreadsheet environment and an appropriate programming language.
4. Use of configuration control in relation to PC software installations and local area networks, including the installation of systems and applications.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Observe the work of the department and discuss the role of ICT hardware, software and network components within the context of Medical Physics and Clinical Engineering with your training officer.
- Observe and participate in a range of clinical measurements (which may cover electrophysiology, pressure and/or flow) and reflect on how each contributes to the care pathway of the patient, attending multidisciplinary team meetings where practicable.
- Observe the administration of a local area network (user specification, initial set-up, shared resources, security issues) and reflect on the impact and risks of local area networks within the department and wider NHS with your training officer.
- Observe and assist in programming, using an appropriate language (e.g. MS VB, MS VBA-Excel, Matlab, Java) to analyse and report clinical measurement or other results.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1                     | Set up equipment for taking clinical measurements. | • Physics underpinning the measurement of physiological signals from patients.  
  • Technical, scientific and clinical basis of clinical measurements.  
  • Common artefacts in equipment calibration and performance.  
  • Sources of artefacts.  
  • Effects of signal noise.  
  • Recognition of deteriorating equipment performance. |
| 1                     | Control infection risks in accordance with departmental protocols. | • Protocols and requirements for hygiene and infection control related to the clinical measurements, including preparation, conduct and completion of investigation.  
  • Protocol for hand washing and how effective hand washing contributes to control of infection. |
| 1                     | Obtain a suitably completed request form, the greet patient, and check patient identity and recent clinical history. | • Referral routes for the clinical measurements.  
  • Requirements for correct completion of request forms and how to validate.  
  • How to communicate with patients in a way that respects their dignity, rights, privacy and confidentiality.  
  • The importance of checking patient identity.  
  • The importance of explaining the procedure to the patient and gaining consent. |
| 1                     | Explain the procedure for the clinical measurement, address any procedure-related questions and gain informed consent. | • The importance of explaining the procedure to the patient.  
  • Common questions and concerns of patients about procedures.  
  • Risks and benefits of undertaking the investigation.  
  • The information needs of patients following investigation.  
  • The authority level for provision of information to patients.  
  • Process of notifying patients of the results.  
  • The importance of explaining the procedure for each investigation to the patient and gaining informed consent.  
  • The relevant procedures and requirements for patient conformance. |
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Clinical indications for and contraindications to each investigation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Principles, guidance and law with respect to informed consent.</td>
</tr>
<tr>
<td>1</td>
<td>Undertake clinical measurements in the patient environment.</td>
<td>• Standard operating procedures.</td>
</tr>
<tr>
<td>1,2</td>
<td>Analyse data and report on the use of specific measurements (particularly in terms of accuracy, reproducibility, bias, specificity and sensitivity).</td>
<td>• Sources of appropriate literature relating to the technical, scientific and clinical basis of clinical measurements.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Statistical tests applied to clinical measuring data to measure accuracy, precision, resolution and bias.</td>
</tr>
<tr>
<td>1</td>
<td>Recognise technical artefacts and deterioration in equipment performance.</td>
<td>• Range of statistical tests and the appropriate choice for each situation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Use of commonly available databases, spreadsheets and statistics packages.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Framework for undertaking a literature review.</td>
</tr>
<tr>
<td>1</td>
<td>Critically appraise reports from a novel or complex clinical measurement.</td>
<td>• IT systems/databases for literature reviews.</td>
</tr>
<tr>
<td>1</td>
<td>Undertake a literature review of the scientific and clinical evidence base that underpins one of the clinical measurement procedures.</td>
<td>• Critical analysis of published papers.</td>
</tr>
<tr>
<td>2,3</td>
<td>Analyse, summarise and present complex data using computer software, such as word processing, spreadsheets, databases and online references sources for clinical and scientific applications.</td>
<td>• Use of computing in the context of Medical Physics and Clinical Engineering.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Configuration control and administration of local area networks.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The security and data governance processes in ICT within the context of Medical Physics and Clinical Engineering.</td>
</tr>
<tr>
<td>4</td>
<td>Participate in the implementation of ICT components in a controlled fashion, taking into account the impact on existing facilities and clinical service.</td>
<td></td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------</td>
<td>----------------------------</td>
</tr>
</tbody>
</table>
| 4                     | Participate in the maintenance of protective measures for ICT systems, including disaster measures, anti-virus protection, maintenance, updating, firewalls and virtual servers/networks. | • Security, protective measures and routine housekeeping tasks for server-based applications.  
• IT security and data integrity.  
• Governance issues relating to patient data.  
• Operation of major ICT hardware, software and networking components.  
• Concept of a system in the context of electrical safety.  
• Software development methodology (e.g. SSADM).  
• Appropriate programming languages (e.g. C++, MS VB, MS VBA-Excel, Matlab, Java).  
• Web development tools.  
• System and applications software for void personal computers. |
| 4                     | Specify, design, develop and test a small database, web application or image processing solution. | |
STP Learning Framework

This section describes the Learning Framework for the Rotational Component of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

Rotational Modules

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>Clinical Measurement and Development</td>
</tr>
<tr>
<td>ROTATION</td>
<td>Design and Development</td>
</tr>
<tr>
<td>MODULE TITLE</td>
<td>Design and Development (DD)</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>AIM</td>
<td>To introduce the trainee to the development life cycle, from user specification through to validation and verification. The trainee will apply the methodology to a small project or component of a larger project in clinical measurement, information and communication technology (ICT) or medical device design and development.</td>
</tr>
<tr>
<td>SCOPE</td>
<td>On completion of this module the trainee will be able to discuss the potential for a design solution to a clinical problem with a user, translate the concept into a full design, and undertake verification and validation tests with critical appraisal of methodology. Trainees will also have the opportunity to develop their communication skills and gain an appreciation of the impact of the specialism on patient care.</td>
</tr>
</tbody>
</table>

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Produce a user specification from a user concept.
2. Undertake a literature review to inform the design process.
3. Translate the user specification into a design using CAD software.
4. Design and undertake verification and validation tests on a design.
5. Critically evaluate their proposed methodology.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Review an ongoing or completed project within the organisation and discuss the clinical and scientific background to the project and the intended positive impact on patient care.
- For a novel medical device, novel software application or novel clinical measurement, undertake key steps in the project life cycle, including working with users to develop a user specification.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1                     | Competently use a CAD software package to produce design drawings. | • The process of project life cycle.  
  • Nomenclature in project documentation.  
  • Design methodologies.  
  • Methods of risk analysis.  
  • Safety test requirements and methods. |
| 1                     | Specify manufacturing and machining for production tasks. | • How to specify, design and construct equipment to meet appropriate safety standards.  
  • Small-scale engineering manufacturing techniques and good manufacturing practice.  
  • Materials properties and fabrication methods. |
| 1                     | Communicate technical information effectively with non-technical users. | • Effective verbal communication skills, e.g. language, signposting, listening, language, non-verbal behaviour. |
| 2                     | Perform a literature search and extract, collate and present information in a structured way. | • Identification of sources of appropriate literature relating to the technical, scientific and clinical basis of clinical measurements.  
  • Sources of other guidance on design and good manufacturing practice.  
  • Governance and approval policies and procedures within the organisation. |
| 3                     | Translate informal description of a problem into a set of detailed user requirements. | • Essential requirements of the Medical Devices Directive.  
  • Risk Classification Rules of the Medical Devices Directive.  
  • Technical standards underpinning the Medical Devices Directive.  
  • Experimental design. |
| 2,3                   | Identify performance and functional requirements for a design or an application. | • The requirements for equipment in the clinical environment, including clinical and research governance issues related to medical devices.  
  • The importance of the human/machine interface in the clinical environment. |
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Materials properties and fabrication methods.</td>
</tr>
</tbody>
</table>
| 2,3                   | Identify different options for a design and assess merits of each separately. | • Impact analysis as applied to new ideas.  
|                       |             | • The framework for intellectual property protection and exploitation.  
|                       |             | • Applications of technology in other fields. |
| 3,4                   | Plan, set up and conduct bench experiments to validate concepts, components and systems. | • Safety test requirements and methods.  
|                       |             | • Applicable qualitative and quantitative methods.  
|                       |             | • Means of assessing clinical outcomes. |
| 4                     | Plan and perform a design review. | • Scientific and engineering principles applicable and appropriate in a particular situation.  
|                       |             | • Scientific method. |
| 4                     | Plan and perform a validation study. | • Design of a validation plan and how this plan validates the project.  
|                       |             | • Design of a verification plan and the difference between verification and validation. |
| 4                     | Apply statistical analyses to data and to draw conclusions. Present the results and their discussion in a structured manner and written format. | • Appropriate statistical methods.  
|                       |             | • Effective written communication, including presenting technical information for both technical and non-technical users. |
| 5                     | Critically evaluate their proposed methodology. | • Limitations of different methods.  
|                       |             | • Evidence base underpinning the chosen method.  
|                       |             | • Report writing.  
|                       |             | • Referencing. |
This section describes the Learning Framework for the **Rotational Component** of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

### Rotational Module

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>DEVICE RISK MANAGEMENT AND GOVERNANCE</td>
</tr>
<tr>
<td>ROTATION</td>
<td>Device Risk Management and Governance</td>
</tr>
</tbody>
</table>
### AIM
The aims of the rotation are to allow the trainee to gain experience of operating a wide range of medical devices and appreciation of their application in the clinical setting, and an insight into and practical experience of all elements of the medical device management life cycle, including device selection, commissioning, device maintenance, patient safety, training and condemnation. The trainee will also be introduced to the requirements for and use of a medical device information system and patient safety and device risk management. The trainee will gain an overview of the roles and responsibilities of a device risk management service and the local arrangements for service delivery and will be able to work effectively in the clinical setting assist them in choosing their future area of specialisation.

### SCOPE
To introduce the trainee to the history, principles and practice of a medical device management service within the healthcare environment. The module will outline key service elements and associated safety standards in the context of the healthcare environment the trainee is working in.

### LEARNING OUTCOMES

On successful completion of this module the trainee will:

1. Operate a wide range of medical devices used in the clinical environment, understanding their clinical applicability, associated risks and limitations.
2. Operate standard workshop test equipment, specialist medical device test instrumentation, including electromedical safety testers. Using appropriate equipment to test a range of Class 1 and Class 2 equipment of types B, BF and CF, including some with applied parts.
3. Carry out the following device life cycle technical tasks:
   a. identify the key elements involved in a medical device procurement exercise
   b. acceptance test and commission a new medical device
   c. design of training material to support the use of a medical device in the clinical setting
   d. perform planned maintenance on a range of medical devices
   e. describe and observe the device repair process
   f. condemn a medical device.
4. Identify sources of patient safety information and describe the key elements of processes to manage safety alerts and investigate patient incidents involving medical devices.

5. Identify and navigate the standards that underpin the organisation's strategy for medical device management and service delivery arrangements for life cycle management including:
   a. prevailing national standards for healthcare
   b. legal/statutory requirements
   c. Electro-medical safety standards
   d. quality management standards
   e. risk management standards
   f. best practice standards
   g. organisational policies, and procedures, together with medical device workshop-specific procedures.

6. Use the organisation's medical device information system for device risk management activities, including the recording of key information relating to life-cycle service elements as well as the ability to retrieve essential asset-related information and reports.

7. Perform a risk assessment on a piece of equipment or a service-related issue, showing an appreciation of local institutional risk management policies and procedures.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Operate a wide range of medical devices available in the Healthcare Institution, gaining an insight into their clinical utilisation in a variety of clinical settings.
- Participate in the following medical device life cycle elements:
  - discuss and evaluate the stages of managing a procurement project for medical devices. This may include device specification, standing financial instructions (SFI), technical, clinical and financial evaluations
  - acceptance testing and commissioning
  - design of user training material for medical devices
  - planned maintenance of equipment in a clinical setting
  - repair of medical device
  - use of electromedical safety testers, specialist and general workshop test equipment
  - medical device condemnation.
- Critically appraise the use of a particular type of medical device in clinical practice. This may include an evaluation of service records, incidents, training issues and standardisation.
- Follow the process associated with receipt, action and monitoring of national safety alerts to gain an insight into the role of Clinical Engineering in supporting patient safety.
- Interact with clinical users of the medical device management service, understanding the need to provide information relating to medical device management in an accessible format to clinical staff.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
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<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1,2                   | Operate a wide range of commonly encountered medical devices used in the organisation, ensuring coverage of diagnostic, monitoring and therapeutic equipment types. | • Practical application of the principles of transducers and clinical measurement in diagnostic and therapeutic medical devices.  
• The operation of a range of clinical devices and development of a generic approach to safe device operation, which can be applied to new or novel devices encountered later in the training scheme.  
• The anatomy, physiology and disease processes or deficits in the relevant area of clinical medicine.  
• The device role in disease assessment and monitoring, with an understanding of normal results versus patients with pathological changes.  
• Risks associated with device usage.  
• Sources of interference that may affect measurements and limitation of devices.  
• The use of devices in the clinical setting.  
• Selection of appropriate test equipment, including the need for calibrated versus indicating devices.  
• The use of electromedical safety testers and the practical testing of medical devices and their constituent parts.  
• An awareness of the requirements of safety testing electromedical systems and the recognition of anomalous results in medical device safety testing. |
| 1,2                   | Electrically safety test a range of Class1 and Class 2 devices, of types B, BF and CF, including the testing of applied parts. |  |
| 1,2                   | Access information sources to aid with the operation of devices, including manufacturer’s instructions for use, medical device workshop manuals, organisations medical device training resources. |  |
| 3                     | Participate in the development and execution of a medical device procurement exercise. | • Processes for device procurement including:  
• identification of clinical need, user requirements and device application  
• development of a device or system specification  
• evaluation criteria  
• life cycle costing, including device, accessories and maintenance |
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>device evaluation by clinical users and technical staff</td>
</tr>
<tr>
<td></td>
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<td>identification of future maintenance requirements</td>
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<td>review of pre-purchase questionnaire responses</td>
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<td></td>
<td></td>
<td>disposal arrangements, including the Waste Electrical &amp; Electronic Equipment directive</td>
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<td></td>
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<td>tender evaluation and final selection</td>
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<tr>
<td></td>
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<td>device procurement.</td>
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<td>Awareness of:</td>
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<tr>
<td></td>
<td></td>
<td>the legislative and regulatory framework covering the supply, installation and maintenance of medical equipment</td>
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<tr>
<td></td>
<td></td>
<td>product liability and health and safety legislation.</td>
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<tr>
<td></td>
<td></td>
<td>Access to Medicines and Healthcare Products Regulatory Agency (MHRA) and other published sources of evaluation and assessment information.</td>
</tr>
<tr>
<td>3</td>
<td>Carry out acceptance tests, including commissioning devices into clinical use.</td>
<td>Arrangements for acceptance testing and commissioning of devices.</td>
</tr>
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<td></td>
<td>Practical use of workshop equipment and specialist medical device test instrumentation, including electromedical safety testers.</td>
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<td></td>
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<td>Key steps in the acceptance process:</td>
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<tr>
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<td></td>
<td>taking receipt of a device and checking against order requirements – no damage, all items and accessories received</td>
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<td></td>
<td>checking of device function and safety testing as appropriate</td>
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<td></td>
<td>labelling of device and gathering of information to enable device entry onto medical device information system</td>
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<td></td>
<td></td>
<td>capturing of baseline performance/maintenance data</td>
</tr>
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<td></td>
<td></td>
<td>consideration of device maintenance requirements for future planned maintenance and repair activities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Key steps in the commissioning process:</td>
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<tr>
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<td></td>
<td>user training in device usage prior to clinical use</td>
</tr>
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<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
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</tbody>
</table>
| 3                     | Medical device training:  
  i. Complete a competency-based training programme for a medical device.  
  ii. Shadow company representatives delivering equipment training to clinical users.  
  iii. Contribute to the delivery of training to support the use of a medical device in the clinical setting in conjunction with training officers in the organisation. | • Handover checks  
• Monitoring and resolution of problems as device enters service  
• Withdrawal of redundant devices.  
• How organisations develop training material for medical devices and where material is drawn from.  
• Practical approaches to delivery of training to clinical users of medical equipment, including the requirements for and approaches to record keeping.  
• The competency-based approach to training schemes.  
• The key elements required in device training to enable a generic approach to be developed to aid the trainee in writing training materials later in the training programme. |
| 3 | Undertake planned maintenance on a range of medical devices, e.g. Type 1, Type 2, Type 3, and complete service records comprehensively and legibly. | • Standards and plans for ensuring that medical devices are appropriately maintained and the level of maintenance undertaken in relation to the complexity of the device and associated risks.  
• Technical components that comprise planned maintenance which will incorporate the following elements:  
  • Device identification  
  • Visual inspection  
  • Functional check  
  • Performance verification  
  • Calibration  
  • Preventive maintenance  
  • Safety testing. |
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<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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</thead>
</table>
| 3                     | Observe the process for device repair and observe medical devices being repaired. | • The process for repair of medical devices, including:  
  • logging calls for faulty devices  
  • cleaning/decontamination processes prior to maintenance activity  
  • common faults encountered with medical devices  
  • traceability of product in the maintenance process.  
  • Health and safety risks in the workshop and clinical environments while maintenance activities are undertaken.  
  • The requirement of processes, work instructions and standard operating procedures.  
  • The requirement of the relevant quality management system.  
  • The requirement for monitoring customer satisfaction. |
| 3                     | Clean and decontaminate a medical device. | • Record keeping of maintenance activities.  
  • Choice and use of test equipment, including the use of electromedical safety testers.  
  • Non-technical benefits of planned maintenance, e.g. asset verification. |
| 3                     | Participate in the removal of a medical device from service. | • The Waste Electrical & Electronic Equipment Directive and other prevailing organisational requirements relating to disposal of devices and waste management.  
  • How to safely disable devices prior to disposal, including the need for segregation of waste for recycling purposes.  
  • Requirements for record keeping and updating of inventory records following device disposal. |
| 4                     | Participate in the actions on a safety alert from receipt into the organisation, through determination of actions, execution of work, monitoring of progress and closure. | • National and local processes for the distribution, receipt and action on national safety alerts.  
  • How to receive and disseminate an alert within the organisation.  
  • How to determine necessary actions by interpretation of the alert and analysis of whether the alert applies to the organisation.  
  • How to carry out actions in relation to an alert and record the |
<table>
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<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>relevant information.</td>
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<td></td>
<td></td>
<td>• How to communicate with key stakeholders and the mechanisms by which alerts are closed.</td>
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<td></td>
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<td>• Gain an appreciation of how alerts are escalated within the organisation if actions are not completed in a timely fashion.</td>
</tr>
<tr>
<td>4</td>
<td>Participate in the investigation of a medical device incident within the organisation.</td>
<td>• Organisational requirements for incident reporting.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How to report an incident to the MHRA and other organisations as necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The forensic approach to incident investigation and the key elements of an investigation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Information to capture in relation to a medical device incident.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Gain an appreciation of root cause analysis.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Typical incidents that have occurred with medical devices via study of MHRA reports.</td>
</tr>
<tr>
<td>5</td>
<td>Investigate and describe the organisational approach to medical device management and the management of the life cycle of medical devices.</td>
<td>• Organisational policies and procedures and reporting arrangements.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Arrangements for medical device service provision within the organisation, including roles and responsibilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Scope of medical device risk management and governance service within the organisation.</td>
</tr>
<tr>
<td>5</td>
<td>Identify and navigate the standards that underpin or are used within the organisation’s medical device management strategy and associated service delivery.</td>
<td>• Existence of and ability to navigate key prevailing standards, including:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• legal requirements, health and safety at work legislation</td>
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<tr>
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<td></td>
<td>• medical device elements of prevailing NHS standards, e.g. Care Quality Commission and NHS Litigation Authority</td>
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<td>• electromedical safety standards, IEC60601, part one, collaterals and family of particular part 2 standards</td>
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<td>• ISO 9001 quality management standards</td>
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<td>• risk management standards</td>
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<td>KEY LEARNING OUTCOMES</td>
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<td>KNOWLEDGE AND UNDERSTANDING</td>
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<tr>
<td></td>
<td></td>
<td>best practice standards.</td>
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<td></td>
<td></td>
<td>The philosophy, hierarchy of IEC 6061 and key differences from other standards, i.e. single fault condition. Understand how these standards are used by the practising clinical engineer.</td>
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<tr>
<td></td>
<td></td>
<td>The clinical governance framework and corporate objectives of the organisation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Local healthcare environment and range of services offered by the institution and the existence of relevant policies and procedures.</td>
</tr>
<tr>
<td>6</td>
<td>Use the organisation’s medical device information system to:</td>
<td>Essential requirements of a medical device information system, together with typical asset details to be recorded to ensure an effective inventory is established.</td>
</tr>
<tr>
<td></td>
<td>• recall inventory item details</td>
<td>Classification of medical devices to enable effective maintenance planning and inventory reporting.</td>
</tr>
<tr>
<td></td>
<td>• log an equipment fault or service request</td>
<td>Typical key performance indicators that can be extracted from a medical device information system.</td>
</tr>
<tr>
<td></td>
<td>• generate asset/maintenance reports, for an individual device or group of devices</td>
<td>Format of a range of simple asset-based reports, to show replacement date requirements and last maintenance dates by location or asset type.</td>
</tr>
<tr>
<td></td>
<td>• generate key performance data.</td>
<td></td>
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<tr>
<td>7</td>
<td>Undertake a risk assessment on a piece of equipment or a service-related issue in accordance with ISO 14971 and local trust risk management policies and procedures.</td>
<td>How to assess the value of existing and new techniques.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Formal and informal techniques for the assessment of risk.</td>
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<tr>
<td></td>
<td></td>
<td>Formal and informal techniques for the assessment of benefit.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The principles of the technology used in the equipment under consideration.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The clinical implications and use of the equipment under consideration.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The measurement principles and limitations of test equipment used.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Legislative and regulatory framework for equipment under consideration.</td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
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<tr>
<td></td>
<td>• Range and type of evaluation methods and how to match these to type and complexity of equipment under consideration.</td>
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<td></td>
<td>• How to establish evaluation criteria relevant to equipment functionality, performance, intended use and clinical context.</td>
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<td></td>
<td>• How and where to obtain expert advice.</td>
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<td></td>
<td>• How to assess training implications of new and emerging techniques.</td>
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<tr>
<td></td>
<td>• The type, range and level of detail of data required to enable a decision on safety and effectiveness of equipment.</td>
<td></td>
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<tr>
<td></td>
<td>• Peripheral issues affecting use and cost of equipment under consideration, including location, environment, consumables, risks and training requirements.</td>
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<tr>
<td></td>
<td>• The healthcare context of the relevant area of clinical medicine.</td>
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<tr>
<td></td>
<td>• Clinical risks associated with the use of equipment.</td>
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<tr>
<td></td>
<td>• To an appropriate level, the anatomy, physiology and disease processes or deficits in the relevant area of clinical medicine.</td>
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<td></td>
<td>• Individual level of authority and competence.</td>
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<tr>
<td></td>
<td>• The role, capabilities and limitations of medical equipment in the clinical environment and the contexts in which it is used.</td>
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<tr>
<td></td>
<td>• Common causes of equipment failure and misuse.</td>
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<tr>
<td></td>
<td>• Technical, safety and regulatory guidance and obligations with respect to medical facilities (electrical installations, emergency power requirements, piped gas and suction supplies, decontamination requirements, ancillary services, etc.).</td>
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</tr>
</tbody>
</table>
STP Learning Framework

This section describes the Learning Framework for the Rotational Component of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

Rotational Modules

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
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<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
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<tr>
<td>SPECIALISM</td>
<td>Rehabilitation Engineering</td>
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<tr>
<td>ROTATION</td>
<td>Rehabilitation Engineering</td>
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</tbody>
</table>
LEARNING OUTCOMES

On successful completion of this module the trainee will achieve the following work-based learning outcomes:

In several of the following fields:

- aids for daily living
- clinical gait analysis (CGA)
- electronic assistive technology (EAT)
- functional electrical stimulation (FES)
- postural management
- prosthetics and orthotics
- wheelchairs

1. Participate in a patient assessment relevant to the clinical placement being undertaken.
2. Assess, under supervision, biomechanics and function as part of the provision of a clinical service, including the utilisation of a range of measurement techniques.
3. Develop preliminary recommendations for intervention and rationale for each.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Participate in the process to provide a patient with a wheelchair and any associated equipment and, with permission, discuss with the patient how the provision of a wheelchair has affected their daily life.
- Participate in a clinical assessment for and the provision of an EAT system, a FES system, an orthosis and prosthesis, and discuss the potential benefits of each to the patient with your training officer.
- Attend an occupational therapy clinical assessment of patient needs for an aid for daily living and reflect on the how occupational therapy can positively influence quality of life of patients.

Note: Due to the restricted length of the rotation, it is anticipated that involvement with assessment and provision of equipment may relate to different episodes of care.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1                     | Control infection risks in accordance with departmental protocols. | • Protocols and requirements for hygiene and infection control related to the clinical measurements, including preparation, conduct and completion of investigation.  
• Protocol for hand washing and how effective hand washing contributes to control of infection. |
| 1                     | Obtain a suitably completed request form, greet the patient and check patient identity and recent clinical history. | • Referral routes for the clinical measurements.  
• Requirements for correct completion of request forms and how to validate.  
• How to communicate with patients in a way that respects their dignity, rights, privacy and confidentiality.  
• The importance of checking patient identity.  
• The importance of explaining the procedure to the patient and gain consent. |
| 1                     | Explain the procedure for the clinical measurement, address any procedure related questions and gain informed consent. | • The importance of explaining the procedure to the patient.  
• Common questions and concerns of patients about procedures.  
• Risks and benefits of undertaking the investigation.  
• The information needs of patients following investigation.  
• The authority level for provision of information to patients.  
• Process of notifying patients of the results.  
• The importance of explaining the procedure for each investigation to the patient and gaining informed consent.  
• The relevant procedures and requirements for patient conformance.  
• Clinical indications for and contraindications to each investigation.  
• Principles, guidance and law with respect to informed consent. |
<p>| 1,2                   | Participate in a patient assessment relative to the clinical placement being | • Normal and impaired human musculoskeletal and neurological system, including child development relevant to the clinical |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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</thead>
</table>
| undertaken; identify and define individual requirements for intervention; discuss with the patient and clinic team the realistic expectations of the intervention and the expected levels of enhancement. | placement.  
- Range of conditions and their functional implications relevant to the clinical placement.  
- The pathology and mechanisms of disease and of the disabling conditions that give rise to motor/control deficits for a range of musculoskeletal and neurological conditions relevant to the clinical placement.  
- The range of investigations to be undertaken.  
- Basic principles of biomechanics.  
- Disabling conditions that may result in referral and their common causes and prognoses.  
- Factors affecting the suitability and effectiveness of possible interventions.  
- The nature, type and extent of measurements and other forms of data required.  
- Requirements for attendance at the assessment by other members of multidisciplinary teams.  
- How to check that equipment used for measurement is correctly calibrated and fully operational within expected parameters.  
- Capabilities and limitations of measurement instrumentation.  
- Environmental factors that influence function, capacity and social interaction of users.  
- Functional implications of the main disabling conditions relevant to the clinical placement.  
- Range of communication strategies relevant to the patient population.  
- Where, how and when to seek advice and information from colleagues and relevant agencies. |
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<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>• The type and extent of records required for individual assessment and how to complete them.</td>
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<td>• Requirements and format for assessment reports.</td>
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<tr>
<td>1,2</td>
<td>Use a variety of clinical methods to assess biomechanics and function (e.g. forces, active and passive joint movement, motor assessment, muscle activity, interface pressure, shape and energy expenditure) taking into account the complete clinical picture.</td>
<td>• Anthropomorphic and physiological cost/effort measurements.</td>
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<td></td>
<td></td>
<td>• Measurements of tissue interface, range and accuracy of movement, type, stability, strength, spasticity, posture and function.</td>
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<td>• Review of current status, regarding perceptual, physical, sensory and cognitive abilities, and current treatment plan.</td>
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<td>• Environmental factors (user environment), existing equipment and devices.</td>
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<td></td>
<td>• Solutions considered may include rehabilitative/assistive technology, biomechanical technology or other intervention provided through multidisciplinary teams.</td>
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<tr>
<td>2,3</td>
<td>Develop objectives, recommendations and rationale for intervention.</td>
<td>• Options for action where the original referral proves to be appropriate or where additional issues have been identified.</td>
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<td></td>
<td></td>
<td>• Goal setting and measurement methods.</td>
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<td></td>
<td></td>
<td>• How to apply principles of biomechanics.</td>
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<td></td>
<td></td>
<td>• Personal level of competence, responsibility and authority for assessment and management of disabilities.</td>
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<td></td>
<td>• Normal and pathological principles of functional anatomy, physiology and their application in determining investigations for individual.</td>
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<td></td>
<td></td>
<td>• Fundamental engineering principles and practice.</td>
</tr>
<tr>
<td>2,3</td>
<td>Make appropriate adjustments to equipment or its application to enhance function, comfort and safety.</td>
<td>• The product range relevant to the clinical condition and status of the patient.</td>
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<tr>
<td></td>
<td></td>
<td>• Principles and applications of assistive technology devices.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Engineering systems relevant to assistive technology, e.g. wheelchair control systems, communication aids, environmental...</td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
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<td></td>
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<td>control systems and aids to daily living.</td>
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<td></td>
<td>• Principles and application of the interventions being considered.</td>
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<td>• Sources of information on the required product range and how to access these.</td>
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<td>• How to interpret data from patient assessments and the significance of interacting factors.</td>
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</table>
Clinical Engineering

SECTION 4: PROFESSIONAL PRACTICE LEARNING FRAMEWORK
### STP Learning Framework

This section describes the Learning Framework for the **Professional Practice Component** of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence, and Applied Knowledge and Understanding. This module spans the Rotational and Specialist period of training. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

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<tr>
<th>PROFESSIONAL PRACTICE</th>
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<tbody>
<tr>
<td><strong>DIVISION</strong></td>
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<tr>
<td>Life Sciences, Physiological Sciences, Physical Sciences and Biomedical Engineering</td>
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<tr>
<td><strong>THEME</strong></td>
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<tr>
<td><strong>SPECIALISM</strong></td>
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</table>
Introduction

Good Scientific Practice (GSP) sets out the principles and values on which good practice undertaken by the Healthcare Science workforce is founded. GSP sets out for the profession and the public the standards of behaviour and practice that must be achieved and maintained in the delivery of work activities and the provision of care. GSP uses as a benchmark the Health Professions Council (HPC) Standards of Proficiency and Standards of Conduct, Performance and Ethics, but expresses these in the context of the modalities within Healthcare Science.

Good Scientific Practice represents standards and values that apply throughout an individual's career in Healthcare Science at any level of practice. Therefore the standards have been contextualised for the role of healthcare scientist. There will, however, always be a requirement for an individual to work within the limits of their scope of practice and competence.

Professional Practice in the STP Training Programme

This generic professional practice module, which all STP trainees have to complete, defines the knowledge, skills and experience that each trainee is expected to gain and apply during the STP programme and develop in subsequent employment. The degree to which each specialism applies the knowledge, skills and experience will vary, but this module sets the baseline for all trainees. Each rotational and specialist learning framework then develops areas as appropriate, for example clinical history taking in patient-facing specialisms.

While it is expected that trainees will be able to achieve the majority of the learning outcomes and competences within their specialism, some specialisms may have to make special arrangements to ensure all trainees achieve the learning outcomes and competences defined in this learning framework. For example, to work with a local clinical skills laboratory to help trainees develop basic skills in history taking.

The Learning Framework that defines the learning outcomes, clinical experiential learning, competences, and knowledge and understanding are contained on the following pages.
Professional Practice (PP1)

AIM
Professional Practice is part of the generic curriculum (applicable to all trainees) on the Scientist Training Programme. The overall aim of the module is to ensure that each trainee has the underpinning knowledge and applies this and the accompanying skills and attitudes to work as a healthcare scientist in accordance with Good Scientific Practice (GSP).

SCOPE
GSP sets out the principles and values on which the practice of Healthcare Science is undertaken. It sets out for the profession and the public the standards of behaviour and practice that must be achieved and maintained in the delivery of work activities and the provision of care. This module encompasses the knowledge, skills, experience and attitudes across four of the five domains of Good Scientific Practice, namely Professional Practice, Scientific Practice, Clinical Practice, Research and Development, and Clinical Leadership, but all other modules within this programme will contribute to embedding professional practice at the centre of the work of each trainee.

LEARNING OUTCOMES

On successful completion of this module the trainee will:

Professional Practice
1. Place the patient at the centre of care in daily practice, ensuring the needs of patients are respected.
2. Communicate with patients, relatives, service users, other healthcare professionals, colleagues and the public with respect, empathy and sensitivity, including listening, speaking, giving and receiving information, giving and receiving feedback.
4. Demonstrate a commitment to the continuing professional development of themselves and others, and attend professional meetings.

Clinical Practice
5. Make appropriate and effective use of information and communication technology.
6. Under supervision, obtain a patient history from a normal volunteer or typical patient referred to your service and present the findings to a colleague or peer in order to understand the clinical decision-making process in clinical practice.
7. Promote the importance of patient safety and general health, safety and security in the workplace, including infection control and information governance.

**Research, Development and Innovation**

8. Apply knowledge, skills and experience of research, development and innovation appropriate to the role in order to identify effectively actions that will improve service provision.

9. Engage in evidence-based practice, participate in audit procedures and critically search for, appraise and identify innovative approaches to practice and delivery.

**Clinical Leadership**

10. Demonstrate a range of leaderships skills required of an emerging leader within Healthcare Science.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Attend clinics, ward rounds, treatment and/or rehabilitation sessions, etc., in primary or secondary care, or in the charity or voluntary sector where patients attend, and observe how patient–professional relationships are developed and maintained, and reflect on how the following impact on the patient–professional relationship:
  - response to illness
  - patient and carer perspective
  - health belief models
  - diversity of the patient experience
  - disability, including learning disabilities
  - potential health inequalities
  - self-care
  - impact of life-threatening and critical conditions
  - patient involvement in decisions regarding their healthcare.
- Observe a current screening programme in the workplace and discuss the principles and practice of screening programmes in healthcare as a means of reducing disease burden with your training officer.
- Observe and participate in internally and externally accredited quality management systems and critically appraise both in your area of practice.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional Practice</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 1 | Treat each patient as an individual, respecting their dignity and confidentiality and upholding the rights, values and autonomy of every service user. | • NHS Constitution.  
• Patient-centred care and the patient carer perspective with respect to:  
  • response to illness  
  • patient and carer perspective  
  • health belief models  
  • diversity of the patient experience  
  • disability, including learning disabilities  
  • potential health inequalities  
  • self-care  
  • impact of life-threatening and critical conditions  
  • patient involvement in decisions regarding their healthcare.  
• Local guidelines for responding to unacceptable behaviour by patients, carers, relatives, peers and colleagues, including harassment, bullying and violent behaviour. | |
| 1 | Discuss personal values, principles and assumptions, emotions and prejudices, and how these may influence personal judgement and behaviour, and identify how you will practise in accordance with Good Scientific Practice. | • Good Scientific Practice.  
• The importance of maintaining own health. | |
| 2 | Communicate effectively with the public, services users and other healthcare | • The principles of effective communication including:  
  • written and electronic, verbal and non-verbal and feedback  
  • the way effective communication can assist in identifying problems accurately, | |
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>professionals, adapting communication style and language to meet the needs of listeners.</td>
<td>increase patient satisfaction, enhance treatment adherence, and reduce patient distress and anxiety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• the importance of some key ideas, for example signposting, listening, language, non-verbal behaviour, ideas, beliefs, concerns, expectations and summarising in communication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• the range of question types that can be used in a communication.</td>
</tr>
<tr>
<td>2</td>
<td>Give and receive feedback sensitively to or from a peer or colleague.</td>
<td>• The range of feedback models for giving and receiving feedback.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The evidence base underpinning the importance of effective feedback/feedback models.</td>
</tr>
<tr>
<td>2</td>
<td>Obtain, analyse and act on feedback from a variety of sources and use it to consider personal impact and change behaviour.</td>
<td>• How to analyse feedback and frameworks for action planning.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Behavioural change models.</td>
</tr>
<tr>
<td>2</td>
<td>Present complex ideas in understandable terms in both oral and written formats.</td>
<td>• The importance of public engagement in science and its role in health and society.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The factors that enable scientists to communicate to specialist and non-specialist audiences.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Barriers to effective communication.</td>
</tr>
<tr>
<td>2</td>
<td>Use effective negotiation skills, including influencing colleagues.</td>
<td>Communication channels with/in your host department; patients and the public; your employing institution; your profession and professional body; the wider Healthcare Science community.</td>
</tr>
<tr>
<td>2</td>
<td>Work constructively and effectively as a member of a multidisciplinary team.</td>
<td>• The underpinning principles of effective teamwork and working within and across professional boundaries.</td>
</tr>
<tr>
<td>3</td>
<td>Comply with relevant guidance and laws, to include those relating to:</td>
<td>• Principles, guidance and law with respect to:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• medical ethics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• confidentiality</td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
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<tr>
<td>-----------------------</td>
<td>-------------</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>
| • your scope of practice  
• research ethics and governance  
• patient confidentiality  
• data protection  
• equality and diversity  
• use of chaperones  
• informed consent. | • information governance  
• informed consent  
• equality and diversity  
• child protection  
• elder abuse  
• use of chaperones  
• probity  
• fitness to practise.  
• The importance of maintaining your own health. | |
| 4 Contribute to the education and training of colleagues. | • The key principles and evidence base underpinning clinical education, encompassing curriculum design, planning, delivery and assessment. | |
| 4 Take responsibility for your learning and demonstrate a commitment to continuing professional development. | • How continuous personal development can improve personal performance. | |
| 4 Meet commitments and goals in your professional practice, using a range of organisational and planning tools. | • Different methods of planning, prioritising and organising, and how they can enhance personal effectiveness. | |
| 4 Reflect on your practice and generate a reflective diary that demonstrates how you utilise the skills required of an independent learner and your commitment to your continuing professional development. | • Core theories of learning, particularly adult learning and reflective practice, and demonstrate how these are relevant to your practice as a healthcare scientist.  
• Personal values, principles and assumptions, emotions and prejudices, understanding how these may influence personal judgement and behaviour.  
• The role of critical reflection and reflective practice and the methods of reflection that can be used to maintain or improve knowledge, skills and attitudes. | |
<p>| 4 Take responsibility for | • How to horizon scan, identify and evaluate the potential role for new and | |</p>
<table>
<thead>
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</tr>
</thead>
</table>
| 4                     | Develop an action plan based on your experiential learning and reflection on completion of the Scientist Training Programme. | • Action planning.  
|                       |                                                                              | • Models and frameworks for critical reflection.                                             |
|                       |                                                                              | innovative technologies and scientific advances.                                            |

### Clinical Practice

| 5                     | Use a range of information and communication technologies within the workplace for service delivery, research, audit and innovation, including data filing and archiving:  
|                       | • word processing  
|                       | • databases  
|                       | • statistics packages  
|                       | • PowerPoint  
|                       | • internet  
|                       | • email. | • The range and application of clinical information systems used in the work base.  
|                       |                                                                              | • The systems in use in the work base to file and archive information and the processes for retrieval.  
|                       |                                                                              | • The principles underpinning identification, storage and retrieval of scientific literature for example end note/end note web.  
|                       |                                                                              | • The purpose of a range of NHS information systems, including the regulations in place to ensure data security and confidentiality. This may include hospital information system, linked information systems (e.g. laboratory information management system) and middleware linking equipment to information systems. |
| 6                     | Under supervision, demonstrate that you can obtain and present a patient history from a normal volunteer or | • The importance of patient-centred care and how it ensures that the wishes, beliefs, concerns, expectations and needs of patients are respected.  
|                       |                                                                              | • Patient and carer perspective with respect to illness, disability, health inequalities and diversity of the patient experience.  
<p>|                       |                                                                              | • Structured models for presenting a patient history. |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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</thead>
</table>
|                       | consenting patient in order to better understand the clinical decision-making process in your clinical practice. | • Process of patient-centred interviewing and the features of a good consultation, including Initiating the session, gathering information, building the relationship, explaining and planning, and closing the session.  
• Link between the patient history and examination and development of clinical investigation and management plans. |
| 7                     | Apply current regulations with respect to patient safety and safe systems within the workplace. To include, as appropriate to scope of practice:  
• risk management  
• biological specimen handling  
• COSHH  
• RIDDOR  
• radioactivity  
• fire safety  
• electrical safety  
• moving and handling  
• display screen equipment  
• incident reporting  
• infection control. | • The importance of health and safety within the workplace, wider healthcare environment and NHS.  
• Principles, process and governance of risk management.  
• Factors influencing health, safety and security.  
• Current legislation, codes of practice, guidance notes and related documents.  
• Principles and practice of health and safety in the workplace.  
• The requirements of relevant local health and safety guidelines, manuals and other documents, including the underpinning legislation.  
• The cause of errors related to patient safety, including patient and/or sample identification. |
| 7                     | Use clinical coding and medical terminology in accordance with stated guidance, as appropriate to | • The importance of the correct use of clinical coding and medical terminology in contributing to good healthcare science practice.  
• Information governance principles and process. |
<table>
<thead>
<tr>
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<th>KNOWLEDGE AND UNDERSTANDING</th>
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</thead>
</table>
| 7                     | Keep accurate records in accordance with current guidelines and the legal framework for data security. | • Best practice recommendations for record keeping and data security.  
• The Data Protection Act and current key guidelines, and the legal framework for data security. |
| 7                     | Use, in your practice:  
• standard operating procedures  
• protocols  
• clinical guidelines. | • Standard operating procedure, protocol and guideline, and understand the purpose of and difference between each document.  
• Evidence base that underpins the use of procedures employed by the service. |
| 7                     | Continuously improve your practice through good practice in:  
• identifying common sources of error  
• identification of risk  
• reporting critical incidents. | • The desirability of monitoring performance, internal and external quality control, learning from mistakes and adopting a no-blame culture in order to ensure high standards of care and optimise patient safety.  
• The importance of honesty and effective apology in responding to errors of practice.  
• The principles and practice of risk management and the effective investigation of incidents, resulting in the identification of root causes. |

**Research and Innovation**

| 8,9                   | Participate in innovation, research, service development and audit activities complying with compliance with guidance and laws relating to research ethics. | • The importance of innovation across healthcare science.  
• The role of innovation in improving quality and patient care.  
• Processes to disseminate innovation, research and audit findings.  
• The role of the healthcare scientist and the potential impact of scientific research in your area of practice.  
• The role of the healthcare scientist in service developments in your area of practice.  
• Current and developing clinical practice.  
• The effectiveness of investigations, therapies, interventions and treatments and |
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>the mechanisms by which they contribute to patient care.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How to horizon scan, identify and evaluate the potential role for new and innovative technologies and scientific advances.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The role of the healthcare scientist and the potential impact of scientific developments, for example health prevention, genomic medicine, diagnostics and rehabilitation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The importance of public engagement in science and its role in health and society.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The legal framework relevant to informed consent and the application to clinical care, research, audit and teaching.</td>
</tr>
<tr>
<td>8,9</td>
<td>Contribute to service and quality improvement and productivity in the work base and embed evidence-based developments within routine practice.</td>
<td>• How planning can actively contribute to the achievement of service goals.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How to measure and monitor performance against agreed targets.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The current structure, management, legal framework and quality improvement structures and processes within the NHS.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The current quality improvement structures and processes within the NHS and give examples of the implications for Healthcare Science.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Importance of self-care and shared care as part of NHS function and the impact of life-threatening and critical conditions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Principles and application of evidence-based practice.</td>
</tr>
<tr>
<td>8,9</td>
<td>Undertake a literature review and prepare and present to peers a critical analysis of a publication from the scientific literature.</td>
<td>• How to critically analyse scientific literature.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How to structure and present a critical analysis.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Systems of referencing.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reference manager software.</td>
</tr>
<tr>
<td>8,9</td>
<td>Prepare and deliver an oral scientific communication to peers at a local, national or</td>
<td>• How to prepare an oral scientific communication.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How to give an effective and timely oral presentation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How to respond to questioning.</td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
</tr>
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<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>10</td>
<td><strong>Clinical Leadership</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lead in your clinical role through appropriate</td>
<td>• How self-awareness, self-management and self-development and acting with</td>
</tr>
<tr>
<td></td>
<td>application of;</td>
<td>integrity at all times contribute to leadership.</td>
</tr>
<tr>
<td></td>
<td>• self-management</td>
<td>• The use of evidence, both positive and negative to identify options in addressing</td>
</tr>
<tr>
<td></td>
<td>• self-development</td>
<td>challenges.</td>
</tr>
<tr>
<td></td>
<td>• integrity</td>
<td>• Methods of prioritising and organising academic and work based tasks to</td>
</tr>
<tr>
<td></td>
<td>• self-direction</td>
<td>optimise own performance.</td>
</tr>
<tr>
<td></td>
<td>• problem solving</td>
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</tr>
<tr>
<td></td>
<td>• dealing with complex issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• making sound judgements in the absence of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>complete data</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Identify potential areas for change and accept</td>
<td>• Structure of the NHS.</td>
</tr>
<tr>
<td></td>
<td>change identified by others, working across</td>
<td>• The need for change, working across different provider landscapes as required.</td>
</tr>
<tr>
<td></td>
<td>different provider landscapes as required.</td>
<td>• Change management methodologies.</td>
</tr>
</tbody>
</table>

international meeting.
Clinical Engineering

SECTION 5: ELECTIVE LEARNING FRAMEWORK
**STP Learning Framework**

This section describes the Learning Framework for the **Elective** component of **Specialist** work based learning, covering the Learning Outcomes, Clinical Experiential Learning, Competence, and Applied Knowledge and Understanding. This module spans the Rotational and Specialist period of training. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

### ELECTIVE

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Life Sciences, Physiological Sciences, Physical Sciences and Biomedical Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEME</td>
<td>ALL</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>ALL</td>
</tr>
</tbody>
</table>

The elective period can be taken any time during the specialist training. It may comprise a single 4- to 6-week elective or a series of shorter periods of elective training.
**AIM**
The aim of the elective period is to facilitate wider experience of healthcare and/or the practice of Healthcare Science in a cultural and/or clinical setting that is different from the usual training environment. This may involve healthcare or Healthcare Science in a different area of the health service, or in pursuit of a particular clinical or research interest.

**SCOPE**
The elective provides opportunities for you to:
- explore in depth areas of particular interest beyond the scope of the scientist training programme
- increase awareness of important health issues and develop an understanding of the effect of disease on communities and individuals in different cultural contexts
- explore unfamiliar scientific, social, economic or cultural areas
- become more proficient at communication with individuals from different social, cultural and ethnic backgrounds
- gain hands-on experience that might not otherwise be possible in a scientist training programme
- design and undertake a significant assignment with appropriate guidance and supervision, thereby developing personal and organisational skills
- undertake a small audit or research project in a different clinical setting
- relate your experiences to your own area of practice.

**LEARNING OUTCOMES**
Learning outcomes are specific to each student: with guidance, you are expected to identify your own educational objectives and organise an elective to achieve them.

1. Agree, organise and complete a period of education and training that provides a wider experience of healthcare and/or the practice of healthcare science, and aligns with Good Scientific Practice.
2. Critically reflect on your experience in your elective and develop an action plan as part of your continuing personal and professional development.
3. Prepare a presentation and present your elective experiences to colleagues, including trainee healthcare scientists.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Produce learning outcomes for the elective training period and link these to Good Scientific Practice.</td>
<td>• Good Scientific Practice.</td>
</tr>
</tbody>
</table>
| 2                     | Write a report of your elective training that includes your learning outcomes (mapped to Good Scientific Practice), a critical reflection on your experience and an action plan. | • Report writing.  
• Critical reflection.  
• Action planning. |
| 3                     | Plan, prepare and deliver an oral presentation that describes and reflects on the learning from your elective and shows how your experience will shape your future practice. | • How to prepare an oral communication.  
• How to give an effective and timely oral presentation.  
• Use of visual aids.  
• How to respond to questioning. |
Clinical Engineering

SECTION 6: SPECIALIST LEARNING FRAMEWORK CLINICAL MEASUREMENT AND DEVELOPMENT
STP Learning Framework

This section describes the Learning Framework for the Specialist Component of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

Specialist Modules

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>Clinical Measurement and Development</td>
</tr>
</tbody>
</table>
### CLINICAL MEASUREMENT AND DEVELOPMENT – SPECIALIST MODULES

<table>
<thead>
<tr>
<th>Module 1 (DD1)</th>
<th>The Project Life Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 2 (DD2)</td>
<td>Advanced Information and Communication Technology Skills</td>
</tr>
<tr>
<td>Module 3 (DD3)</td>
<td>Clinical Measurement</td>
</tr>
<tr>
<td>MODULE 1</td>
<td>The Project Life Cycle (DD1)</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>AIM</td>
<td>This module will enable the trainee to apply the project life cycle process to a range or specific example of Clinical Measurement.</td>
</tr>
<tr>
<td>SCOPE</td>
<td>During this module, the trainee will take part in a project life cycle process from the concept stage right through to design and development and validation.</td>
</tr>
</tbody>
</table>

**LEARNING OUTCOMES**

**On successful completion of this module the trainee will:**

1. Manage an innovation and development project within the context of a formal project management methodology.
2. Agree the clinical need with other scientists and/or clinicians.
3. Evaluate the current state of the art and limitations of existing solutions.
4. Develop a specification of requirements.
5. Develop, critically evaluate and deliver novel solutions to clinical measurement, information and communication technology (ICT) and/or medical device requirements through the full project life cycle.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Review a number of completed projects within their organisation, understand the clinical and scientific background, discuss with colleagues the development life cycle and suggest alternatives and/or improvements.
- Review ongoing projects within their organisation, understand the clinical and scientific background, be able to identify the stage in the development life cycle the projects are at and suggest ways of taking them forward.
- Undertake a new project or projects, applying the life cycle process from the concept stage right through to design, development, validation and verification relating to a novel medical device, novel software or a novel clinical measurement.
- Programming using an appropriate language (e.g. C++, MS VBA-Excel, Matlab, Java) to reduce and report clinical measurement or other laboratory data.
- Development of prototype web-based applications for clinical applications.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1                     | Devise a plan using an appropriate project management methodology to successfully deliver an innovation and development project controlling the quality, timing and costs of activities. | • The process of the project life cycle.  
• Appropriate formal project methodologies and their application.  
• Factors influencing control of quality, timing and costs.  
• An understanding of how these limiting factors are derived and quantified.  
• The requirements for project plans, dependencies and the critical path.  
• Nomenclature in project documentation. |
| 2,4                   | Work with users to develop a detailed specification of requirements for an innovation and development project. | • The technical, scientific and clinical basis of the clinical measurement or problem being addressed.  
• The requirements for project specifications, including different ways of presenting them.  
• Derivation of hazard log and risk analysis.  
• Production of a safety case statement.  
• An appreciation and understanding of the range of users for whom this solution is designed. |
| 3,4                   | Design a solution to meet the previous point by formulating various options and critically appraising them, taking into account the requirements specification, appropriateness of development tools and sustainability in the proposed operational environment. | • Sound knowledge of engineering principles and ICT skills and their applications in clinical measurement and clinical problem solving.  
• The design tools and packages available.  
• Relevant knowledge of mathematical modelling, statistical modelling, signal conditioning or modelling and analysis techniques.  
• Demonstrate critical evaluation and appraisal of options and solutions.  
• The use of development tools (computer programming, CAD, |
<table>
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<tr>
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<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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<tbody>
<tr>
<td>including signal processing, decision support, mathematical modelling and choice of development platform.</td>
<td>modelling systems, etc.) and their selection and application.</td>
<td></td>
</tr>
<tr>
<td>5 Develop and undertake a validation plan.</td>
<td>The process of the project life cycle.</td>
<td></td>
</tr>
<tr>
<td>5 Develop and undertake a verification plan.</td>
<td>The requirements for a validation plan and an understanding of how this plan validates the project.</td>
<td></td>
</tr>
<tr>
<td>5 Develop user documentation and training.</td>
<td>The requirements for a verification plan and an understanding of the difference between verification and validation.</td>
<td></td>
</tr>
<tr>
<td>5 Develop technical documentation.</td>
<td>Effective written communication, including presenting technical information for both technical and non-technical users.</td>
<td></td>
</tr>
<tr>
<td>5 Follow the requirements of an appropriate development standard (e.g. EN13485, SSADM).</td>
<td>The relevant range of development standards and their application (DSCN 14, MDD, 60601, 80001, IEC 62304:2006 and EN14971, etc.).</td>
<td></td>
</tr>
<tr>
<td>1,5 Manage a project within the framework of a formal project management methodology.</td>
<td>The practical relevance and implementation of safety standards (see above list).</td>
<td></td>
</tr>
<tr>
<td>5 Manage security, safety and business risk throughout the development, including the use of ALARP principles.</td>
<td>Risk analysis methods and techniques, including hazard workshops.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The ability to implement risk management standards.</td>
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<td></td>
<td>The practical implications of clinical governance issues</td>
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<td>KEY LEARNING OUTCOMES</td>
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</tbody>
</table>
| 5                    | Apply risk analysis iteratively to improve and redefine a design. | related to medical devices.  
• The practical implications of research governance issues related to medical devices.  
• Factors affecting security, safety and business risk, and how they influence the final design.  
• When registration of the solution is required and by whom. |
| 5                    | Perform end-stage review. | • How to critically appraise the project following completion.  
• Compile a ‘lessons learned’ report to inform future work. |
MODULE 2 | Advanced Information and Communication Technology Skills (DD2) | COMPONENT | Specialist

**AIM**

To ensure that the trainee can apply novel Information and Communication Technology (ICT) hardware and software solutions safely within a clinical environment.

**SCOPE**

On completion of this module, the trainee will be able to implement a range of novel and safe ICT solutions in the clinical environment.

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Configure ICT hardware, software and network components, applying relevant safety standards and configuration control.
2. Implement server-based applications, ensuring appropriate security, protective measures and routine housekeeping tasks.
3. Implement a novel application in the clinical environment in a controlled fashion.
4. Develop a software solution to a described problem using an appropriate high-level language.
5. Understand ICT standards applied to healthcare.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

Within the context of the projects undertaken in Module 1:

• Analyse, summarise and present complex data using computer software.
• Installation of system and applications software on a PC.
• The administration of a local area network (user specification; initial set-up; shared resources; security issues).

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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</tr>
</thead>
</table>
| 1                     | Discuss and agree the operation of major ICT hardware, software and networking components. | • Local area networks.  
• The requirements of a medical IT network as defined in 800001-1  
• Requirements for implementation and factors influencing decisions.  
• Key factors affecting security management.  
• The range of routine housekeeping tasks associated with standard server-based operating systems.  
• An appreciation of the difference between server- and client-side applications and when each is appropriate to deploy.  
• The difference between standard software components.  
• The appropriate selection of software tools, e.g. do not use a spreadsheet as a database or a database as a word processor. |
| 1,2                   | Undertake implementation of at least one standard server-based operating system, including security management and routine housekeeping tasks. |  |
| 1                     | Apply relevant safety standards and guidance for the use of computers in clinical practice, including electrical safety. | • IT security and data integrity.  
• The range of relevant safety standards and guidance and its application.  
• Factors influencing data integrity and their implications.  
• Awareness of governance issues relating to patient data: data loss prevention.  
• Awareness of the concept of a system in the context of electrical safety.  
• The governance issues relating to patient data, including appropriate legislation.  
• Protective measures for ICT systems and their appropriate application.  
• Critical appraisal of relevant ICT standards.  
• An understanding of the limitations imposed on safety and integrity by the US Food and Drug Administration (FDA) and Medical Devices Directive and an appreciation of the techniques used to mitigate the risk this introduces. |
<p>| 2                     | Develop and maintain protective measures for ICT systems, including disaster measures, antivirus protection, maintenance, updating, firewalls and virtual servers/networks. |  |
| 5                     | Critically appraise the ICT standards adopted by the NHS, including Digital Imaging and Communications in Medicine (DICOM) and Health Level 7 international Level (HL7). |  |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Plan and carry out the implementation of ICT components in a controlled fashion, taking into account the impact on existing facilities and clinical service.</td>
<td>• Use of computing in the context of Medical Physics and Clinical Engineering.</td>
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<tr>
<td></td>
<td></td>
<td>• The use of commonly available databases, spreadsheets and statistics packages.</td>
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<td></td>
<td></td>
<td>• Appropriate programming languages (e.g. C++, MS VB, MS VBA-Excel, Matlab, Java).</td>
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<tr>
<td></td>
<td></td>
<td>• The use and application of web development tools and the use and application of client-side scripting such as JavaScript.</td>
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<tr>
<td></td>
<td></td>
<td>• The potential influences/advantages/disadvantages of implementation on data management taking into account appropriate legislation, local policy and the Medical Devices Directive.</td>
</tr>
</tbody>
</table>
MODULE 3: Clinical Measurement (DD3)

AIM: To ensure that the trainee can apply analytical and judgement skill to novel or complex clinical measurements and implement new clinical measurement solutions.

SCOPE: At the end of this module the trainee will be able to develop new and innovative solutions to carry out and interpret clinical investigations safely and efficiently.

LEARNING OUTCOMES

On successful completion of this module the trainee will:

1. Innovate and develop new clinical measurement solutions.
2. Provide scientific support to a novel or complex clinical investigation.
3. Provide reports on a novel or complex clinical measurement.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

Within the context of the projects undertaken in Module 1:

• Record complex electrophysiology data such as for a novel clinical measurement and present numerically and graphically the main findings.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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</tr>
</thead>
</table>
| 1,2                   | Obtain specific clinical measurements from patients under supervision. | • The anatomy and physiology, and relating to the physiological signals recorded.  
• The range of appropriate equipment and its use in clinical measurement.  
• The physics underpinning the measurement of electrical signals from patients.  
• The technical, scientific and clinical basis of clinical measurements.  
• The importance and implications of accuracy, reproducibility, bias, specificity and sensitivity in measurements.  
• Identification of sources of appropriate literature relating to the technical, scientific and clinical basis of clinical measurements.  
• The confident application of appropriate statistical tests to clinical measuring data, with an appreciation of accuracy, precision, resolution and bias.  
• Critical appraisal of procedures, applications and strategies.  
• Requirements for reports on clinical measurement outcomes for a range of users. |
| 3                     | Interpret data and advise on the use of specific measurements (particularly in terms of accuracy, reproducibility, bias, specificity and sensitivity). | • The correct operation of a wide range of medical devices.  
• How the medical device may operate to facilitate physiological function in the patient with pathology and have an understanding of the physiological function in a healthy subject.  
• Problem-solving techniques.  
• The range of appropriate corrective actions and their application. |
| 1                     | Critically appraise procedures, applications and strategies and advise on their modification in the light of developing knowledge. | • Professional accountability and the principles of management and leadership.  
• Personal level of responsibility and authority in problem solving. |
<p>| 3                     | Write a report on the outcome of the clinical measurement. | • The sources of advice and information, both official governmental and other sources. |
| 1,2                   | Implement effective corrective actions when performance deteriorates. | |
| 2                     | Identify problems, determine their nature and devise a strategy for solving them. | |
| 2                     | Solve a problem through application of specialist knowledge and experience. | |
| 2                     | Discuss and agree with co-workers, and the patient where appropriate, | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>2</td>
<td>the steps being taken to resolve a problem.</td>
<td>• Product liability and health and safety legislation and its impact on service provision.</td>
</tr>
<tr>
<td></td>
<td>Advise on health and safety issues relevant to the investigation.</td>
<td>• How to access Medicines and Healthcare Products Regulatory Agency (MHRA) and other published sources of evaluation and assessment information.</td>
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<tr>
<td></td>
<td>Take appropriate action in the case of incidents and accidents.</td>
<td>• Interpretation of safety alerts.</td>
</tr>
<tr>
<td></td>
<td>Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues.</td>
<td>• Local policy for incident reporting and accidents.</td>
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<tr>
<td></td>
<td></td>
<td>• National policy for incident reporting to the MHRA.</td>
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<tr>
<td></td>
<td></td>
<td>• Presenting and publishing scientific material in peer-reviewed journals, books, national and international conferences and local meetings.</td>
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</tbody>
</table>
Clinical Engineering

SECTION 7: SPECIALIST LEARNING FRAMEWORK DEVICE RISK MANAGEMENT AND GOVERNANCE
STP Learning Framework

This section describes the Learning Framework for the **Specialist Component** of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

### Specialist Modules

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
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</thead>
<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>Device Risk Management and Governance</td>
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</tbody>
</table>
# MEDICAL DEVICE RISK MANAGEMENT AND GOVERNANCE – SPECIALIST MODULES

<table>
<thead>
<tr>
<th>Module</th>
<th>Module Description</th>
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<tbody>
<tr>
<td>DRM1</td>
<td>Medical Device Management Strategy</td>
</tr>
<tr>
<td>DRM2</td>
<td>Optimisation of Medical Device Effectiveness and Efficiency</td>
</tr>
<tr>
<td>DRM3</td>
<td>Equipment Acquisition, Acceptance Testing and Installation</td>
</tr>
<tr>
<td>DRM4</td>
<td>Planned Maintenance and Repairs to Devices</td>
</tr>
<tr>
<td>DRM5</td>
<td>Patient Safety</td>
</tr>
<tr>
<td>DRM6</td>
<td>Medical Device Information System</td>
</tr>
<tr>
<td>DRM7</td>
<td>Expertise in Medical Device Risk Management</td>
</tr>
<tr>
<td>DRM8</td>
<td>Professional Advisory Services</td>
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</tbody>
</table>
 MODULE 1 | Medical Device Management Strategy (DRM1) | COMPONENT | Specialist

**AIM**
To re-orientate the trainee with the history, principles and practice of a medical device management service within the healthcare environment. The module will then concentrate on a comprehensive review of prevailing guidance, regulation and policy from which medical device management strategies are developed. The trainee will revisit electromedical and risk management standards with emphasis on how standards are developed and revised.

**SCOPE**
To ensure the trainee is aware of prevailing essential guidance that the practising healthcare scientist will use as the basis of future service design and delivery, aimed at ensuring the risks associated with the acquisition and use of medical devices are minimised. The module will also provide an opportunity for the trainee to look at the practice of the local institution by studying policies and procedures developed to achieve compliance with best practice.

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Review an Institution’s medical device management policy against the prevailing national standards and professional best practice.
2. Interpret and recommend application of relevant national standards relating to medical device management and assessment of risks.
3. Apply policies associated with decontamination of medical devices to daily work practice.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Review of the institution’s medical device management policy and service delivery, illustrating services provided and responsibilities of different professional groups within the organisation, and demonstrating how policies are interlinked. Reflect on the outcomes of this review in terms of the impact of policy on service delivery, on patient care and experience and on your own future practice.
- Identify and analyse prevailing national recommendations and best practice relating to medical device management within the UK. Consider their application to your own future practice and the impact on patient care.
- Identify the local policies relating to decontamination of reusable medical devices and review their application in respect of at least two items of reusable medical devices.
- Become familiar with policies for the handling of loan devices introduced into the institution and gain an understanding of the prevailing national arrangements for indemnity insurance.
- Start to develop a detailed understanding of the IEC60601 electromedical safety standard family. To learn to navigate 60601-1 and associated collateral standards, particularly part 2 standards, and be aware of part 3 performance standards.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE
Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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<tbody>
<tr>
<td><strong>1</strong></td>
<td>Undertake a comprehensive review of the institution’s medical device management policy against the prevailing national standards and professional best practice.</td>
<td>• The prevailing national standards used to underpin medical device risk management and governance service. &lt;br&gt;• The institution’s key policies related to risk management, device management and decontamination. &lt;br&gt;• The range of services delivered within the institution to achieve the effective management of medical devices, ensuring risks associated with the acquisition and use of medical devices are minimised.</td>
</tr>
<tr>
<td><strong>1</strong></td>
<td>Outline the key elements of a medical device management strategy and the associated service delivery.</td>
<td>• The arrangements put in place at an organisational level for strategic management of medical devices, to include policies and organisational arrangements relating to medical device management.</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Navigate and interpret the IEC 60601 electromedical family of standards, including collateral, particular and performance standards.</td>
<td>• Content and structure of IEC 60601 family of standards: &lt;br&gt;  • Part 1 General standard &lt;br&gt;  • Part 1 Collateral standards &lt;br&gt;  • Part 2 Particular standard &lt;br&gt;  • Part 3 Performance standard. &lt;br&gt;• The horizontal nature of part 1 and collaterals, contrasted with the specific nature of particular standards. &lt;br&gt;• An appreciation of the typical engineering content. &lt;br&gt;• The standards development process and crucial role of the healthcare scientist in acting as the patient’s ambassador in developing standards. &lt;br&gt;• How the standards are used by different parties, e.g. the manufacturer, the regulators and the healthcare scientist. &lt;br&gt;• The existence of alternative publications where a standard is not appropriate, e.g. a rapidly changing technology leading to a technical report or publically available specification.</td>
</tr>
<tr>
<td><strong>1,2</strong></td>
<td>Navigate and interpret the...</td>
<td>• National healthcare risk management standards and arrangements</td>
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<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
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</table>
|                       | healthcare-related risk management standards, including consideration of at least the following specific examples of medical device risks encountered. | put in place within the NHS.  
• The local institution’s arrangements for risk management and the range and type of medical device risks in the organisation and actions undertaken to mitigate them.  
• How to conduct a medical device-related risk assessment. |
<table>
<thead>
<tr>
<th>MODULE 2</th>
<th>Optimisation of Medical Device Effectiveness and Efficiency (DRM2)</th>
<th>COMPONENT</th>
<th>Specialist</th>
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<tbody>
<tr>
<td>AIM</td>
<td>The trainee will build on knowledge gained in the rotational element into the operation of a wide range of medical devices commonly used in the clinical environment. The trainee will comprehensively understand the use and limitations of specialist equipment in a variety of clinical settings and will begin to understand certification and accreditation standards that apply to clinical services, e.g. ISO 9001 quality management system.</td>
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<tr>
<td>SCOPE</td>
<td>The focus of this will be to gain specialist knowledge of specific equipment types and specialist test equipment in order to support clinical staff in optimising the effectiveness and reliability of their equipment. This will be achieved by a variety of means, including research activities, maintenance optimisation, training of staff and root cause analysis of incidents. The trainee will become a specialist source of knowledge for specific equipment types and act as an adviser to the clinical team. The trainee will develop expertise in the use of specialist medical device test equipment and its associated verification or calibration, traceable, where necessary, to national standards.</td>
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**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Develop training material to aid technical and clinical colleagues.
2. Implement, develop and validate quality assurance regimens for a range of medical devices.
3. Advise on the minimisation of risks associated with device usage.
4. Critical appraisal of the information technology (IT) and interconnectivity issues associated with medical device installations.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- The trainee will gain expertise in operating a diverse range of medical devices, ensuring the clinical application is understood, together with the engineering principles that underpin device operation. This will require the trainee to understand and explain to others how to effectively and safely configure and use the device. This will include gaining a detailed understanding of associated risks, device limitations, alarm capabilities, etc.
- Similarly, the trainee will learn to select and utilise specialist test equipment, specifically including electromedical safety testers, understanding the need for calibrated devices.
- Develop training material contextualised for the audience, which may include patients, professional users and practitioners involved in device maintenance.
- Undertake a number risk assessments related to the utilisation of medical devices in complex clinical environments (e.g. theatres, intensive care), enabling the trainee to begin to offer professional advice on the use of devices in particular clinical settings.
- Gain an awareness of local quality management systems and begin to contribute to internal audit programmes.
- Gain experience of a practical medical device prescribing issues and the development of specific guidance.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Produce material that demonstrates specialist expertise in a range of medical equipment types and aids: • clinicians • technical colleagues to maximise the effectiveness and safe operation of devices, covering <strong>all</strong> the following areas: • training guides • addressing hazards • improved maintenance • quality assurance/performance checks • risk reduction.</td>
<td>• Underlying engineering principles of operation of key medical devices and associated risks. • The application of scientific and engineering principles and practice to the safe and effective clinical utilisation of equipment. • Indicators for and contraindicators to the use of equipment and/or assessment/measurement techniques. • Evolving knowledge of the clinical settings in which medical devices are utilised. • Role and influence the Healthcare Scientist can have in identifying new technologies and facilitating adoption for organisational efficiency and patient benefit. • Sources of information that will aid development of indicators/contraindicators; this will include manufacturer’s technical documentation, national safety documents, etc. • Range of medical devices, including factors that can interfere with or confound measurements or readings and actions to mitigate. • Electromagnetic interference issues in the healthcare environment. • Apply knowledge and understanding gained in specific medical devices to learn to develop: • operational guidelines to assist operators use equipment optimally • procedures to assist in device maintenance/quality assurance • technical reports to identify and explain safety and performance issues encountered with devices • risk assessments • a working knowledge of national clinical service standards. • prevailing national clinical service standards to ensure device management services evolve to effectively support clinical department.</td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
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</table>
| 2,3                   | Identify limitations of clinical devices and suggest alternative solutions. | • How to collate information from a variety of sources to enable an engineering assessment of device appropriateness and continuing suitability.  
                           |                                                                            | • Sources of information will include manufacturer device obsolescence, national patient safety recommendations, Medicines and Healthcare Products Regulatory Agency (MHRA) device alerts, Royal College recommendations, scientific journals, local audit, new technologies and patient feedback.  
                           |                                                                            | • The design and execution to audits and measurements/data collection to establish device efficacy to inform/confirm device suitability.                                                                                   |
| 2,3                   | Design processes to ensure prescribed patient medical devices are effectively introduced and managed. | • The role of the healthcare scientist in medical device prescribing.  
                           |                                                                            | • Suitability of the particular product for the environment it is to be used in (e.g. home care requirements may require alternative alarm settings).  
                           |                                                                            | • User training requirements and development of abridged guidance.  
                           |                                                                            | • Arrangements for handling routine maintenance and reporting faults, if the device is to leave the organisations premises.  
                           |                                                                            | • Arrangements to handle queries and incidents.  
                           |                                                                            | • Plans for ongoing provision of consumables.  
                           |                                                                            | • Device return or replacement.                                                                                                                                  |
| 4                     | Critically appraise the technical and information governance issues arising from a complex medical installation in a networking environment. | • Information governance standards and policies.  
                           |                                                                            | • Networking and inter-operability standards.  
                           |                                                                            | • Network architecture.  
                           |                                                                            | • IEC80001.  
                           |                                                                            | • Risks and issues relating to wireless networking, Bluetooth, etc.                                                                                           |
## MODULE 3  
**Equipment Acquisition, Acceptance Testing and Installation (DRM3)**

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>Specialist</th>
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<tbody>
<tr>
<td><strong>AIM</strong></td>
<td>The trainee will focus on medical device selection, procurement, acceptance testing and installation processes. The trainee will learn how to manage a medical device acquisition project. The trainee will understand the maintenance implications and clinical risks associated with the acquired devices to ensure patient safety.</td>
</tr>
<tr>
<td><strong>SCOPE</strong></td>
<td>On completion of this module, the trainee will have covered all elements from development of a clinical specification to identifying and evaluating products, contributing to the development of a business case to secure the acquisition of devices and finally installation. The trainee will learn to ensure that statutory regulations and national guidelines are adhered to and that selection is undertaken with a robust project management methodology, including the life cycle management of the devices.</td>
</tr>
</tbody>
</table>

### LEARNING OUTCOMES

On successful completion of this module the trainee will:

1. Work with interdisciplinary clinical teams and to understand and articulate both clinical and technical need.
2. Design and implement device evaluation material.
3. Project manages a project to evaluate and select a new medical device.
4. Manage complex medical device installations.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Interdisciplinary working with clinical colleagues to develop a device specification, covering clinical and technical elements relating to the replacement of medical devices/systems in the healthcare environment.
- Work as part of the team established to select the medical devices, gaining an insight into the organisation’s business planning, procurement and financial processes. This will involve project management skills to establish a project plan and timeline, and communication with all stakeholders throughout the project.
- Contribute to the device acquisition process by designing and implementing the means to assess and evaluate devices against the specification produced. This may well encompass a workshop evaluation of devices as well as evaluation in the clinical setting, and summarising of results into a technical report to inform the selection process. Increasingly the life cycle costing, including clinical consumable usage, will be required.
- Evaluate a pre-purchase questionnaire from a supplier to inform the selection process.
- Gain experience of arranging a trial of a medical device in a clinical setting, ensuring appropriate tests are undertaken prior to using devices on patients and that necessary indemnity insurance is in place.
- Undertake acceptance testing of the selected equipment, liaising with training staff and equipment users about device introduction into service, including necessary risk management and housekeeping requirements.
- Assess the planned maintenance requirements of a newly acquired device, including necessary technical training needs, test equipment requirements and routine maintenance procedures.
- Contribute to a complex installation of a medical device system, possibly involving IT elements to understand safety testing issues and the need for clarification of management responsibilities between IT services and medical engineering.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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</tr>
</thead>
</table>
| 2                     | Apply engineering principles and practice to the evaluation and selection of medical devices. | • The specific electrical safety implications if medical devices are aggregated to form an electromedical system.  
• How evolving standards where IT systems are connected to or embedded in a medical device require sharing of responsibilities between IT and medical engineering services.  
• The establishment of risks and known hazard of devices under consideration. |
| 1,3                   | Write a clinical specification as part of an equipment acquisition process, incorporating any technical standards and regulatory compliance. | • The development of a comprehensive clinical and technical specification incorporating clinical views to aid the device selection process.  
• Necessary standards to inform the specification.  
• The institution’s business planning and management processes around device selection. |
| 2                     | Develop evaluation criteria against which to test candidate devices. | • How user requirement and developed specification is used to produce weighted evaluation criteria based on institutional guidance and stakeholder discussion. |
| 3                     | Develop and assess responses to pre-tender questionnaires. | • How to interpret manufacturer’s pre-purchase questionnaires.  
• The identification of further information that needs to be gathered e.g. costs of user-replaceable parts, technical spares, specialist test equipment, and maintenance regimens. |
| 3,4                   | Arrange equipment trials to ensure devices meet clinical need and evaluate against established criteria. | • Criteria for undertaking equipment trials. |
| 3,4                   | Evaluate commercially available equipment against clinical requirements. | • The indemnity insurance arrangements and loan equipment policy of the organisation.  
• The clinical environment in which the equipment is to be evaluated to ensure risks are identified and mitigated.  
• Why the healthcare scientist needs to manage and co-ordinate trials ensuring user feedback is robustly obtained, with due consideration |
<table>
<thead>
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</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>of whether patient feedback can also be canvassed.</td>
</tr>
<tr>
<td>2,3</td>
<td>Contribute to business case development and write a case for medical device acquisition encompassing key requirements.</td>
<td>• The institution’s process in relation to procurement. • The detail required for specific cases, usually in proportion to the magnitude of the investment. • How to take device business cases through the Institution’s procurement processes. • The institution’s structures and committee relating to medical device acquisition.</td>
</tr>
<tr>
<td>3</td>
<td>Apply project planning methodologies to assist in the procurement and installation process.</td>
<td>• Appropriate methodologies and gaining experience of their practical application.</td>
</tr>
<tr>
<td>3,4</td>
<td>Execute the installation process, including specifying all necessary acceptance tests and commissioning processes.</td>
<td>• The key personnel to involve and at what stage. • Determination of the necessary acceptance tests that are required, and the training needs and consumable requirements necessary for the successful introduction of the device into service. • The management of a complex installation, which may involve high technology devices or large numbers of devices that require a phased deployment. • The need to ensure arrangements are made to withdraw devices from service if they have been replaced.</td>
</tr>
<tr>
<td>3,4</td>
<td>Determine the ongoing maintenance arrangements for the device and associated life cycle issues.</td>
<td>• Device-specific maintenance requirements to inform ongoing routine maintenance and to support device servicing. • Key information to capture to populate the asset information on the medical device information system, including identification of the product’s projected life.</td>
</tr>
<tr>
<td>3,4</td>
<td>Handle rejected items that fail acceptance testing.</td>
<td>• The departmental quality management system or equivalent arrangements for identifying devices that have failed acceptance testing.</td>
</tr>
<tr>
<td>KEY LEARNING OUTCOMES</td>
<td>COMPETENCES</td>
<td>KNOWLEDGE AND UNDERSTANDING</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The key actions to take to rectify the situation.</td>
</tr>
</tbody>
</table>
**MODULE 4**

**Planned Maintenance and Repairs to Devices (DRM4)**

**COMPONENT** Specialist

**AIM**
The trainee will learn how to develop, organise and monitor planned maintenance programmes, including the use of risk-based methodologies. Additionally the trainee will learn to manage and oversee the equipment repair processes within the medical engineering workshop and clinical settings.

**SCOPE**
The module will give the trainee experience in establishing new maintenance programmes and an insight into the setting up and management of maintenance contracts. The management of workshop test equipment, including its calibration, will be studied and the trainee will specify and evaluate test equipment required for effective maintenance. The trainee will begin to develop workshop policy and procedures and ensure compliance with quality management systems. The trainee will begin to develop the skills to monitor the efficacy of maintenance process performance.

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Manage the key components of the planned maintenance and repair process.
2. Develop policies and procedures, e.g. device cleaning and decontamination.
3. Apply quality management systems, such as ISO 9001 to the workshop environment.
4. Interpret electromedical safety tests and resolve safety test anomalies.
5. Identify and resolve health and safety issues while working on medical devices.
6. Advise on calibration requirements.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

• Illustrate the maintenance arrangements for all devices on the medical device information system, e.g. in-house maintained, on external service contract, loan devices, etc. Select one or two devices to follow this process through and undertake a limited range of planned maintenance and repair activities.
• Take responsibility for overseeing the delivery of a series of planned maintenance visits to a range of clinical areas, liaising with colleagues and reviewing work done following visits, and determining further actions if devices were unavailable or problems were encountered. Reflect on your experience in terms of implications for service delivery and patient care.
• Take responsibility for overseeing a range of equipment repairs as they progress through the workshop environment, giving the trainee experience of work allocation and job progress monitoring.
• Develop a range of policies and procedures relating to device maintenance, e.g. device decontamination.
• Shadow the quality manager to learn how to handle non-conforming product, document changes, internal audits and workmanship issues.
• Take responsibility for overseeing the calibration/verification of a range of workshop test equipment, as well as executing some device validation personally.
• Develop examples of risk-based planned maintenance supported by an appropriate engineering evidence base.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1,2                   | Apply engineering principles to the management of risk in designing and delivering maintenance programmes. | • Risk management standards to inform any maintenance regimens modified by risk analysis.  
• Data sources available to access engineering information and evidence to support medical device maintenance activities.  
• The role of quality management systems in the device maintenance process.  
• Calibration standards and test equipment requirements to support medical engineering workshop activities.  
• The need, from both a legal and contractual perspective to ensure all maintenance activity is effectively captured on the organisation’s medical device information system. |
| 1                     | Plan and manage preventive maintenance regimens for individual devices and the larger groupings of medical devices. | • The medical engineering services approach to planned maintenance.  
• The processes for planning, delivery, recording and reporting of planned maintenance activities within the organisation. |
| 1                     | Plan and participate in training and deploying the technical workforce to ensure coverage of all equipment types. | • The training requirements of technical staff to ensure competency prior to working on medical devices.  
• Workshop processes and practice. |
| 1                     | Specify, arrange and manage external service contract providers. | • Why the maintenance of some devices is outsourced and the requirements necessary to specify level of cover and monitor contract performance.  
• Local institutional arrangements for contractors when on site in terms of health and safety, permits to work and recording of work done. |
<p>| 1,5                   | Act as an expert on the use and interpretation of medical device safety tests as part of the maintenance process, including the | • Specific medical device types. |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>resolution of anomalies.</td>
<td><strong>1</strong> Design planned maintenance regimens for a range of medical devices.</td>
<td>• The clinical utilisation and manufacturer’s service requirements for a range of devices to enable the development of planned maintenance regimens.</td>
</tr>
<tr>
<td>1</td>
<td>Oversee workmanship standards on a range of medical devices.</td>
<td>• The necessary workmanship standards and specialist test equipment requirements.</td>
</tr>
<tr>
<td>3</td>
<td>Specify the calibration requirements for specific test equipment required to assist in the maintenance process.</td>
<td>• How to monitor the efficacy of workmanship in implementing the regimens.</td>
</tr>
<tr>
<td>1,3</td>
<td>Specify the records necessary to support the maintenance process, including determination of records to comply with all of the following: • statutory requirements • prevailing national healthcare standards/NHS requirements • customer requirements • best professional practice • local needs.</td>
<td>• Test equipment.</td>
</tr>
<tr>
<td>6</td>
<td>Provide expert advice on the cleaning and decontamination of medical devices as related to the maintenance process.</td>
<td>• Calibration and traceability of standards.</td>
</tr>
<tr>
<td>4</td>
<td>Specify test equipment required for the workshop.</td>
<td>• Equipment records and databases.</td>
</tr>
<tr>
<td>3,5</td>
<td>Monitor the service records of</td>
<td>• Protocols for cleaning and decontamination of medical devices.</td>
</tr>
</tbody>
</table>

<p>| • How to specify training requirements, and access to and |</p>
<table>
<thead>
<tr>
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<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>technical staff to ensure they are comprehensive and legible.</td>
<td>interpretation of the data.</td>
<td></td>
</tr>
</tbody>
</table>
| 1,3 | Oversee the correct use of hand tools within the workshop. | • Workshop practice to determine appropriate tools.  
• When risk assessments are necessary and enact accordingly. | |
| 1,3 | Ensure traceability of product in the maintenance process. | • Quality management systems and customer requirements.  
• Systems and methods to ensure mechanisms developed and monitored. | |
| 5 | Identify and minimise health and safety risks in the workshop and clinical environments while maintenance activities are undertaken. | • The execution of a health and safety inspection and to capture, assess and mitigate risks. | |
| 1,3 | Ensure device modifications are undertaken appropriately. | • Compliance standards that ensure modifications are effectively controlled, including an assessment as to whether this has implications for the device CE marking.  
• Monitoring/track modification undertaken by manufacturers, e.g. resulting from safety alerts. | |
| 1 | Advise on the appropriateness of in-house modifications and the necessity for risk assessment and the establishment of a design project. | • Risk assessment  
• Procedures and processes underpinning in-house modifications. |
**MODULE 5**  
**Patient Safety (DRM5)**

**COMPONENT**  
Specialist

**AIM**  
The aim of this module is for the trainee to understand how safety alerts are received into the organisation, distributed, acted on and monitored to ensure all necessary safety-related actions have been taken.

**SCOPE**  
The trainee will learn how to investigate and report incidents, both locally and to the appropriate national agencies, applying root cause analysis techniques. Act as a technical adviser on issues that could impact on patient safety via compromising equipment performance, e.g. RF interference. The trainee will reaffirm an understanding of patient safety publications and their sources.

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. How to manage and deal with safety alert standards within the organisation.
2. Act on notices and identify corrective actions to take.
3. Investigate incidents using root cause analysis or equivalent methodologies.
4. Advise on policy development to assist clinical governance and patient safety within the organisation.
5. Assess technical matters that could impair device efficacy.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Investigate and describe the institutions approach to the handling of safety alerts, identifying who the issuing agencies are and the local responsible personnel.
- Review current safety alerts on the prevailing national distribution systems.
- Shadow personnel receiving and determining actions in relation to a number of safety alerts. Reflect and report on your experience in terms of the important considerations for staff and patient care.
- Review medical device incidents that have occurred in the institution over the past year and categorise them by cause, effect on service delivery, effect on patient care and implications for your future practice.
- Contribute to an incident investigation, gaining insight into national reporting requirements and root cause analysis.
- Contribute to the institution's patient safety programme by reviewing medical devices incidents that have reoccurred with a view to establishing actions to prevent the incident in future.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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<tr>
<th>KEY LEARNING OUTCOMES</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Act as Department of Health Central Alerting System responsible officer, including ability to use the national database.</td>
<td>• The role and responsibilities of DoH Central Alerting System.</td>
</tr>
<tr>
<td>1</td>
<td>Act as the Medicines and Healthcare products Regulatory Agency (MHRA) liaison officer.</td>
<td>• Requirements for reporting incidents in appropriate detail.</td>
</tr>
<tr>
<td>1</td>
<td>Receive and determine actions associated with a national safety notice.</td>
<td>• Specific device applied to resolution of alert in question.</td>
</tr>
<tr>
<td>2</td>
<td>Investigate an incident.</td>
<td>• Key information necessary to enable effective incident investigation.</td>
</tr>
<tr>
<td>2,3</td>
<td>Interpret safety alerts and extract key information, such as actions, deadlines and stakeholders.</td>
<td>• The institution’s incident reporting mechanism.</td>
</tr>
<tr>
<td>4</td>
<td>Execute root cause analysis on a range of medical device-related incidents.</td>
<td>• Methods of root cause analysis.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Institutional policies relating to incident reporting and medical engineering response to ensure device quarantined and evidence preserved.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Information systems to extract safety alert and incident data to enable critical review and organisational learning.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specialist knowledge to recommend patient safety improvements.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The organisational risk management processes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Requirements and optimal methods for sharing results of analysis.</td>
</tr>
</tbody>
</table>
**MODULE 6  Medical Device Information System (DRM6)**

**AIM**
This module will enable the trainee to become an expert user of the institution’s medical device information system. In addition to using the system the trainee should be able to specify the features of a replacement system and ensure the existing system is robustly managed and updated.

**SCOPE**
Database and systems administration on the institution’s medical device information system, production of reports and key performance indicators.

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Act as expert user of the medical device system and advise the institute on the taxonomy of medical devices.
2. The trainee will demonstrate the ability to use a medical device information system to do complex equipment management tasks.
3. Use of a medical device information system to produce key performance indicators.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Utilise, extract, analyse and interpret data from the medical device information system in support of all equipment management activities.
- Critically appraise the organisation’s categorisation of medical devices.
- Produce reports on:
  - equipment holding, categorised by type and value
  - replacement date reports
  - maintenance achieved and items overdue maintenance
  - additionally, key performance indicator reports can be developed showing activity levels, maintenance achieved/not achieved, turn-around times, staff performance, financial information, etc.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
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<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1                    | Apply engineering principles to classify and structure the institution’s approach to medical device categorisation. | • Key performance indicators appropriate to a medical engineering environment.  
• How to use engineering principles to identify key information to capture regarding medical devices.  
• How to specify, procure and implement a medical device information system.  
• Information needs.  
• Organisation requirements for medical device-related information to support strategic decision making and operational efficacy.  
• Medical device information system and the underlying database relationships.  
• Specific equipment type categorisations and groupings to enable effective analysis and reporting.  
• Equipment classification.  
• Equipment holding in the organisation and an understanding of how it is made up, e.g. revenue versus capital split.  
• Requirements for performance indicators commonly used to monitor equipment management services.  
• How to extract information related to maintenance activities, enabling monitoring of work progress.  
• Capability to produce a range of complex bespoke reports, such as:  
  • replacement date reports  
  • activity reports  
  • reports for wards and departments.  
• Application of statistical models and analysis to identify equipment related trends, such as device reliability and cost of ownership. |
<p>| 1                    | Apply engineering principles to the specification, implementation and ongoing use of the medical device information system. |                                                                                                                                                                                                                             |
| 2                    | Analyse and interpret data from the system.                                  |                                                                                                                                                                                                                             |
| 2                    | Be an expert user of the institution’s medical device information system to display or extract all asset-related information. |                                                                                                                                                                                                                             |
| 1,2                  | Access specific equipment types for information from the medical device information system, demonstrating an understanding of equipment classification. |                                                                                                                                                                                                                             |
| 2                    | Establish the institution’s equipment holding by value and volume.           |                                                                                                                                                                                                                             |
| 3                    | Design, produce and utilise key performance indicators for use in performance management of the medical device risk management and governance service |                                                                                                                                                                                                                             |
| 1                    | Maintain data integrity and security on the Institution’s Medical Device Information System. |                                                                                                                                                                                                                             |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Use the Institution’s Medical Device Information System to monitor progress on all service requests received.</td>
<td></td>
</tr>
<tr>
<td>2,3</td>
<td>Produce a range of complex, bespoke asset based reports.</td>
<td></td>
</tr>
<tr>
<td>2,3</td>
<td>Undertake statistical analysis of device data to establish reliability of devices and cost effectiveness of devices through their life.</td>
<td></td>
</tr>
<tr>
<td>MODULE 7</td>
<td>Expertise in Medical Device Risk Management (DRM7)</td>
<td>COMPONENT</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>AIM</td>
<td>The module will develop the trainee’s ability to proactively identify, quantify and reduce risk associated with medical device usage.</td>
<td></td>
</tr>
<tr>
<td>SCOPE</td>
<td>The trainee will undertake a range of medical device-related risk assessments and learn how to articulate risk to both a technical and clinical audience. The trainee will learn how to develop a risk management technical file to support medical device modification by the institution. The trainee will reaffirm their understanding of national standards of clinical governance and risk as applied to medical device management and will have practical experience of evaluating risk and carrying out risk assessments.</td>
<td></td>
</tr>
</tbody>
</table>

**LEARNING OUTCOMES**

**On successful completion of this module the trainee will:**

1. Develop risk management strategies within the institution.
2. Articulate risk issues, their severity and the steps to mitigate them.
3. Minimise the risks associated with modifying medical devices.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Describe the organisational approach to risk management and clinical governance.
- Execute a range of medical device-related risk assessments.
- Complete a project involving analysis of risk and proposal of solutions to mitigate, involving a clinical department.
- Identify the process necessary to follow if a device is to be modified.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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</tr>
</thead>
</table>
| 1,2,3                 | Apply medical device risk management knowledge and engineering principles to identify prevailing medical device-related risks within the institution. | • How to access and update organisational risk registers and capability to critically review risks.  
• Engineering knowledge of risk management approaches used in other healthcare industries. |
| 1                    | Develop medical device risk management strategies for the institution. | • Medical device policies.  
• Standards and guidance for medical devices.  
• Standards and guidance on risk management. |
| 1                    | Develop a policy for the organisation to help manage risk. | • Requirements to include in policies and procedures, including drafting documents in organisational style. |
| 2                    | Execute a number of complex medical device- or service-related risk assessments. | • How to conduct risk assessments involving a medical device component.  
• Key clinical risks. |
| 3                    | Advise on practical risk management actions in medical device risk management and governance. | • Working groups in the organisation involved in risk management. |
| 3                    | Authorise modifications to medical devices having analysed the associated risks. | • Medical device regulatory requirements for medical devices.  
• Steps to go through when reviewing a proposed modification to a medical device and the subsequent approval/testing required. |
### MODULE 8: Professional Advisory Services (DRM8)

#### AIM
The module will develop the trainee’s ability to advise the institution on professional and technical issues relating to medical device management and governance and will be aware of medical device research and emerging technologies to ensure the institution is able to adopt innovative devices in a timely manner.

#### SCOPE
- Committees and interdisciplinary forums relating to medical devices.
- Audit of medical device issues.
- Horizon scanning for new and emerging devices and implementation within the host organisation.

### LEARNING OUTCOMES

On successful completion of this module the trainee will:

1. Establish and run interdisciplinary forums to promote the safe and effective use of technology, e.g. medical device advisory groups.
2. Serve as a contributing member of appropriate committees as required, e.g. equipment committees, governance or audit forums.
3. Audit medical device issues as requested.
4. Provide strategic business advice to the institution, e.g. medical device equipment replacement forecasts.
5. Assess the impact of emerging regulation or standardisation.
6. Advise on ad-hoc technical issues.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Attend a variety of groups relating to clinical management of medical devices and contribute to discussions relating to medical devices.
- Shadow group chairs to gain experience of meeting organisation.
- Contribute to clinical audit undertaking audits that involve devices.
- Provide advice and comments to the organisation on new technologies, articulating the potential benefits.
- Contribute to medical device-related research projects.
- Remain abreast of professional best practice.
- Provide strategic advice to the organisation, e.g. develop a five-year equipment replacement programme.
- Provide technical reports on medical device issues as required.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1,2                   | Implement interdisciplinary medical device risk management forums within the institution. | • Analysis of organisational structures to ensure all risks associated with medical devices are being captured via existing forums.  
• Key terms of reference and remit of medical device-related forums.  
• Prevailing medical device legislation, national guidance and professional best practice.  
• The objective use of engineering principles to determine the best engineering solutions to effectively manage medical devices. |
| 3                     | Undertake medical device audits. | • The organisation’s audit programme and systems, including how to influence change throughout the institution.  
• Areas that require audit based on information gathered in a professional role. |
| 6                     | Provide advice on the requirements for a clinical trial involving a novel medical device. | • The institution’s R&D approval process and the requirements of MRHA.  
• How to design, execute and report a medical device-related research project.  
• Differences between research and evaluation, the latter relating to trialling products that have already been proven to be clinically effective. |
| 4,5                   | Keep up to date with new technologies and developments within the field of medical device management. | • Where to gain up-to-date engineering data, and how to access scientific and product data to keep the trainee abreast of new and emerging techniques.  
• The importance of horizon scanning.  
• How to ensure regular engagement with clinicians in order to understand evolving clinical practice and to support the introduction of new technologies and improved techniques.  
• How to keep up to date with new European legislation, international standards and professional body best practice. |
<p>| 4,5                   | Advise the institution on equipment | • How to critically appraise models of equipment acquisition and |</p>
<table>
<thead>
<tr>
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<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>replacement requirements.</td>
<td>ownership in the light of changing business/organisational structures.</td>
</tr>
<tr>
<td>4</td>
<td>Participate in the clinical engineering response to a major business plan involving a significant medical equipment installation.</td>
<td>• How to challenge and support new business developments going through the institution.</td>
</tr>
</tbody>
</table>
Clinical Engineering

SECTION 8: SPECIALIST LEARNING FRAMEWORK
REHABILITATION ENGINEERING
STP Learning Framework

This section describes the Learning Framework for the **Specialist Component** of work based learning covering the Learning Outcomes, Clinical Experiential Learning, Competence and Applied Knowledge and Understanding. Each trainee is also expected to build on and apply the knowledge, skills and experience gained from the MSc in Clinical Science.

**Specialist Modules**

<table>
<thead>
<tr>
<th>DIVISION</th>
<th>Physical Sciences and Biomedical Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEME</td>
<td>Clinical Engineering</td>
</tr>
<tr>
<td>SPECIALISM</td>
<td>Rehabilitation Engineering</td>
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<tr>
<td>Module</td>
<td>Subject</td>
</tr>
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<tr>
<td>Module 1 (RE1)</td>
<td>Assistive Technology</td>
</tr>
<tr>
<td>Module 2 (RE2)</td>
<td>Clinical Gait Analysis</td>
</tr>
<tr>
<td>Module 3 (RE3)</td>
<td>Medical Engineering Design</td>
</tr>
</tbody>
</table>
### MODULE 1  
**Assistive Technology (RE1)**  
**COMPONENT**  
**Specialist**

| **AIM** | To allow the trainee to develop specialist skills in a subset of the wider range of clinical services and subject areas within Assistive Technology (AT) (aids for daily living, electronic AT [EAT], functional electrical stimulation [FES], posture management, prosthetics and orthotics [P&O], wheelchairs), while at the same time broadening their skills in the remaining areas. |
| **SCOPE** | On completion of this module the trainee will have gained a deeper level of competence in a range of work activities associated with AT. They will have developed their ability to apply an in-depth knowledge of both normal and impaired human musculoskeletal and neurological systems to AT solutions. They will have applied a variety of ATs to patients. They will also have experienced the provision of a range of clinical services and be able to develop detailed recommendations for interventions suitable for application within the clinical setting. |

### LEARNING OUTCOMES

On successful completion of this module the trainee will:

In relation to the following fields:
- aids for daily living
- electronic assistive technology (EAT)
- functional electrical stimulation (FES)
- postural management
- prosthetics and orthotics (P&O)
- wheelchairs

1. Undertake physical and functional patient assessment appropriate for an AT prescription. It is expected that the trainee will have exposure to the majority of the modalities listed above but focus specifically on between one and three.
2. Define and develop the interface between the patient and (a) the test/measurement equipment and/or (b) the prescribed AT equipment, discussing the possible adverse consequences in terms of safety, performance, comfort and aesthetic appearance.
3. Prescribe appropriate AT interventions in close collaboration with patients, carers and clinical colleagues and to measure and assess their outcome.
4. Design and modify devices appropriately to suit patients’ needs.
5. Train patients and carers in the safe and effective use of equipment provided.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Carry out assessment, provision, reporting, documenting and measuring outcome in a range of ATs, in people with a range of pathologies, ages and presentations. The following list describes examples and is not exhaustive:
  - clinical assessment for and the provision of an aid for daily living
  - clinical assessment for and the provision of an EAT system, to include two or more components (e.g. environmental control unit and complex wheelchair controls)
  - clinical assessment for and the provision of a FES system
  - a posture management assessment and the writing of a clinical report, including recommendations and rationale. This might include wheelchair seating, static seating and/or bed positioning, as applicable
  - provision of a piece of posture management equipment
  - a wheelchair assessment and clinical report, including recommendations and rationale. This might include manual and/or powered wheelchairs, as applicable
  - provision of a wheelchair and any associated equipment.
- In each of the above cases, follow the progress of the patient from the initial consultation, through investigations and/or assessments and/or manufacturing processes, to follow-up appointments. Reflect on your learning from this process.
- Taking two patients as case studies, critically reflect on the effect of the intervention on the lifestyle of the patient and the role of the healthcare scientist in the process.
- Observe a series of patients in an outpatient clinic, seen both as new referrals and as follow-ups. Critically appraise the process of referral, diagnosis, treatment and/or provision of equipment, including an analysis of how the interprofessional team work together.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
</table>
| 1,2,3                 | Under supervision, lead a patient assessment in **at least two** of the modalities listed above, to identify and define individual requirements for intervention. | • Local assessment procedures.  
• Take past medical history and recognise influencing details.  
• Local procedures, such as risk assessment, manual handling, etc.  
• Relevant anatomy and physiology, especially the musculoskeletal system, nervous system, digestive system, urinary system.  
• Major groupings of medicines.  
• Pathological groupings and prognoses.  
• Learning disabilities.  
• Pressure ulcer aetiology, development and treatment.  
• Ability to communicate effectively with a wide range of people. |
| 1,2                   | Apply a variety of clinical methods to assess biomechanics and function (e.g. forces, active and passive joint movement, motor assessment, muscle activity, interface pressure, shape and energy expenditure) taking into account the complete clinical picture. | • Normal joint range of motion.  
• Spinal symmetry and asymmetry.  
• Spasticity and its effect on joint range and posture.  
• Influence of pain and discomfort on posture, function and daily living.  
• Functional assessment.  
• Muscle strength.  
• Balance – seated and standing.  
• Equipment – calibration and preparation required for assessment.  
• Correct recording of data.  
• Use appropriate data processing tools.  
• Relate measured data to more general data, such as from unimpaired persons or a typical patient group.  
• Local reporting templates/pro formas. |
| 2                     | Analyse and interpret the data obtained from these measurements. |  |
| 2,3                   | Produce a formal report outlining a diagnostic/therapeutic opinion. | • Know the limitations of the equipment, techniques and sources of errors in making the measurement.  
• Impact from these errors on measured data and its interpretation.  
• Methods to minimise errors.  
• Recognise the need to retake measurement where considered |
<p>| 2                     | Recognise, quantify and discuss the errors in the measurements obtained and discuss their limitations. |  |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>appropriate.</td>
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</tbody>
</table>
| 2,3,4                 | Present to the patient and clinic team the realistic expectations of the intervention and the expected levels of enhancement. | • Relate to goals set by the patient and the clinical team.  
• The general outcomes for each type of AT, relating this to the individual patient and their own requirements. |
| 3,4                   | Develop objectives, recommendations and rationale for intervention. | • Prioritisation of the functional requirements for the individual.  
• The limitations of each AT. |
| 3,4                   | Perform a risk assessment; propose a risk management strategy. | • Local, national and international risk assessment procedures – assessing, scoring, evaluating and reviewing. |
| 1,2,3,4               | Identify indicators for and contra-indicators to the use of equipment and/or assessment/measurement techniques. | • Available equipment/assessment/measurement techniques and how to determine limits of what can be achieved.  
• The need to discuss the patient assessment, prioritising requirements and AT prescription.  
• Scientific literature of these types of AT. |
| 3,4                   | Evaluate commercially available equipment against clinical requirements. | • The importance of keeping informed of specialist equipment and state of the art techniques.  
• Evaluation of equipment against a functional specification. |
<p>| 3,4                   | Identify indicators for non-standard bioengineering requirements, e.g. for patient with profound disability. | • When it is appropriate to create a bespoke solution, balancing clinical need with the requirements of the Medical Devices Directive. |
| 3                     | Using case study examples, evaluate the impact of the intervention on the wider clinical situation. | • Awareness of the broader clinical setting for these patients. |
| 3                     | Utilise appropriate outcome | • Outcome measurements as applicable to the modality, their validity |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
<th>KNOWLEDGE AND UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>measures for <strong>at least two</strong> of the modalities; evaluate the results.</td>
<td>and reliability, potential for application and limitations of use.</td>
</tr>
<tr>
<td>2,3,4</td>
<td>Interface appropriate AT to enhance the use of equipment.</td>
<td>• Identification of when an AT needs modifying to accommodate a specific requirement. To include alternative triggering system for an FES device, different switch mechanisms or mountings for EAT, and integrating several components of a postural management solution, such as head rest and foot plates.</td>
</tr>
<tr>
<td>3,4</td>
<td>Make appropriate adjustments to any equipment or its application to enhance function, comfort and safety.</td>
<td>• How to make adjustments and assess their impact, including risk management.</td>
</tr>
<tr>
<td>5</td>
<td>Train and familiarise the patient and/or carer in the use of the equipment, and develop user instructions.</td>
<td>• The correct documentation and its use – including patient records and instruction leaflets.</td>
</tr>
</tbody>
</table>
**MODULE 2**  
Clinical Gait Analysis (RE2)  

**COMPONENT**  
Specialist

**AIM**  
To allow the trainee to develop specialist skills in this modality sufficient to allow them to carry out supervised clinical gait analysis (CGA).

**SCOPE**  
On completion of this module the trainee will have gained a deeper level of competence in this modality. They will have developed their ability to apply an in-depth knowledge of both normal and impaired human musculoskeletal and neurological systems to CGA. They will also be able to make provisional recommendations for interventions suitable for application within the clinical setting.

**LEARNING OUTCOMES**

On successful completion of this module the trainee will:

1. Undertake clinical interviews with patients as part of CGA.
2. Conduct physical/clinical examinations of patients.
3. Collect and process clinical gait data for a range of clinical presentations.
4. Interpret and report on the results from 1–3, above, demonstrating an understanding of the limitations of the techniques used.
5. Undertake system preparation, including calibration and quality assurance checks, as appropriate for use.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Under supervision, lead three CGA assessments:
  - take a past medical history by reviewing the patient’s medical notes, liaising with the referring clinician(s), and from a patient interview at a clinic appointment
  - using this history, confirm what clinical question(s) need answering and select the most appropriate gait assessment tools
  - perform a physical/clinical examination
  - Prepare the laboratory for the appointment, including all system and quality assurance checks
  - collect data in the laboratory
  - process the data obtained
  - complete for the reporting clinical scientist a real or shadow report, including options of kinematic, kinetic and/or visual assessment
  - suggest recommendations for treatment
  - participate and contribute to multidisciplinary discussions.
- In each of the above cases, follow the progress of the patient from the initial consultation, through measurement of gait, multidisciplinary interpretation of results and into the determined outcomes, be these therapeutic, surgical or pharmacological. Reflect on your learning from this process.
- Taking two patients as case studies, critically reflect on the effect of the intervention on the lifestyle of the patient and the role of the healthcare scientist in the process.
- Observe a series of patients attending the laboratory, seen both as new referrals and as follow-ups or re-referrals. Critically appraise the process of referral, diagnosis and treatment, including an analysis of how the inter-professional team work together.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
<table>
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<th>KEY LEARNING OUTCOMES</th>
<th>COMPETENCES</th>
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</tr>
</thead>
</table>
| 1                     | Under supervision and according to local protocols, conduct a clinical interview with a patient and/or their guardians/carers. | • Basis/limitations of local protocols and national guidelines.  
|                       |             | • Use of formal processes for effective data collection. |
| 2                     | Under supervision, perform a physical/clinical assessment and compare your data with local or published reference ranges. | • Relevant anatomy and physiology, especially the musculoskeletal system.  
|                       |             | • Measurement of joint angles/ranges.  
|                       |             | • Assessment of spasticity, strength, selective control.  
|                       |             | • Local protocol for patient appointment and clinical examination.  
|                       |             | • Experience clinical examinations in other laboratories and also in rehabilitation centres or departments that do not have access to a gait lab (e.g. physiotherapy department).  
|                       |             | • Need for and basis/limitations of local protocols and national guidelines.  
|                       |             | • Selection of appropriate assessment measures.  
|                       |             | • Relevance of local and published data sets to patient data. |
| 2                     | Interpret and report the results of the clinical assessment. | • Link between clinical assessment and pathology.  
|                       |             | • Normal ranges for clinical examination test data.  
|                       |             | • Impact of patient state and co-operation on data collected.  
|                       |             | • The importance of accuracy and limitations of clinical assessment.  
|                       |             | • Typical errors/difficulties in assessment, e.g. measurement and physical positioning of limbs. |
| 3                     | Place markers on patients in the correct positions according to local protocols/national guidelines. | • Surface anatomy and palpation.  
|                       |             | • How inter- and intravariability affect results.  
<p>|                       |             | • Biomechanical model used in the assessment locally and elsewhere. |
| 3                     | Conduct Electromyography (EMG) | |</p>
<table>
<thead>
<tr>
<th>KEY LEARNING OUTCOMES</th>
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</thead>
</table>
| 3 | Collect kinematic, kinetic and other data from patients with movement disorders. Use complementary clinical methods to further detail the mechanical impairments and functional deficits of these patients. | • Selection of test appropriate to the referral.  
• Prioritisation of data collection by assessing patient ability and determining relative importance of data.  
• Application of local protocols and national guidelines.  
• Use and relevance of functional scales, e.g. Functional Movement Screen (FMS) and Gross Motor Function Measurement Score (GMFCS), in qualifying/quantifying deficit. |
| 3 | Process kinematic, kinetic and other data, identifying and appropriately managing/removing artefacts. | • Identification and application of appropriate processing techniques to biomechanical assessment data.  
• How to relate data to visual and video assessment of patient.  
• Local protocols and national guidelines.  
• Selection of appropriate ‘normal’ data set for comparison. |
| 4 | Prepare and present a report for the clinical team, summarising findings and interpretation of the data, using alternative presentations of the data to emphasise particular findings. | • Appropriate combination of data from different sources.  
• How to relate data to pathology.  
• Need for and basis/limitations of local protocols and national guidelines.  
• Use/limitations of the data sets (e.g. clinical examination, kinematic and kinetic) collected in defining the factors impacting on the patient’s gait/mobility.  
• Alternative data presentations e.g. gait profile score and angle/angle plots. |
<table>
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</table>
| 5 | Perform system checks and calibration tests on a number of pieces of equipment in the laboratory. | • Importance of team approach in data interpretation. | • The importance of calibration of equipment.  
• The effect of equipment error and results in data.  
• Need for regular system checks and equipment calibration.  
• Rationale used locally in setting acceptable limits of operation of equipment.  
• Limitations of system check and calibration techniques.  
• Awareness of national standards. |
| 5 | Perform task-specific risk assessments. | • Identification of potential risk.  
• Identification of potential ways to minimise risk.  
• How to contribute to the process of risk assessment review.  
• The importance of taking responsibility, under supervision, for an aspect of the risk review.  
• Application of local and national risk assessment guidelines/procedures.  
• Appreciation of the limitations of local procedures. |
| 5 | Compare the standard biomechanical model used locally to alternative models by considering and evaluating the strengths and weaknesses of each. | • How to undertake a critical literature review of alternative models in relation to range of patients analysed locally.  
• Principles of biomechanical modelling.  
• Process of developing a biomechanical model.  
• Process of testing/validating a new biomechanical model.  
• Euler angles and other methods for representing motion.  
• Specification of a marker set and the development of technical and anatomical reference frames. |
MODULE 3  Medical Engineering Design (RE3)  COMPONENT  Specialist

AIM  To allow the trainee to develop specialist skills in a subset of the wider range of clinical services and subject areas within AT, CGA or a closely related work area.

SCOPE  On completion of this module the trainee will have gained a deeper level of competence in the area of medical engineering design as applied to mechanical engineering, electrical/electronic engineering and/or instrumentation. They will have developed their ability to apply an in-depth knowledge of both normal and impaired human musculoskeletal and neurological systems to the design process. They will also have experienced the provision of a range of clinical services and be able to develop detailed recommendations for interventions suitable for application within the clinical setting.

LEARNING OUTCOMES

On successful completion of this module the trainee will:

1. Bring new items of equipment, systems, facilities and protocols into service safely and effectively.
2. Specify, design, build and bring into service pieces of equipment, using formal design processes, to be used either (a) in a biomechanical or functional assessment, including validation against current clinical methods, or (b) to meet a specific clinical need for a particular clinical problem, including measurement of performance.
3. According to established standards, develop and keep up to date the associated documentation, including those relating to technical construction and risk management.
CLINICAL EXPERIENTIAL LEARNING

The clinical experiential learning for this module is:

- Identify requirements for at least two pieces of equipment; these may be for specific patient use or for measurement/diagnosis:
  - develop each requirement into a design brief and subsequently into a set of design specifications, suitable to allow the development of design concepts
  - evaluate these concepts using an appropriate scientific method
  - produce CAD drawings and/or circuit schematics, sufficiently detailed to allow the development of costing estimates and manufacture by an external organisation
  - take the designs through manufacture and validate a prototype
  - develop the required documentation as stipulated by the relevant legislation
  - critically evaluate all stages of the project.
- In the context of an outpatient clinic:
  - identify the need for equipment modification
  - determine the details of the required modifications in discussion with the referring clinician and the end user
  - carry out the required modifications, demonstrating an adherence to the relevant legislation
  - evaluate the effectiveness of the modification, in terms of functionality and cost effectiveness.
- Using at least two pieces of equipment that have been developed, critically reflect on the impact of the equipment on the patient/clinical environment as appropriate and the role of the healthcare scientist in the process.

All of these experiences should be recorded in your e-portfolio.

The following section details the competence and knowledge and understanding each trainee must gain. Each competence is linked to the relevant learning outcomes and trainees must demonstrate achievement of each competence for each linked learning outcome.

PROFESSIONAL PRACTICE

Trainees should ensure they refer to the professional practice learning framework and continue to achieve the professional practice competences alongside the competences defined in this module.
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</table>
| 1,2                   | Develop a detailed functional specification through discussion with the client/users, e.g. clinician and/or patient and their carer. | • Relevant aspects of medical background or clinical setting.  
• How to elicit the clinical requirements from the client/user in a process of contract review.  
• Awareness of standards and models, such as British and international standards.  
• Awareness of importance of involving the end user in development of the specification and subsequent design stages. |
| 1,2                   | Perform and document a design feasibility study from a functional specification. | • Formal design processes, such as from national or international standards or a recognised model.  
• Relevance of literature/commercial product reviews.  
• Use and application of design evaluation methods, e.g. weighted matrices. |
| 1,2,3                 | Apply the requirements of the Medical Devices Directive and appropriate standards and legislation to the design and manufacturing process. | • Relevance of Medical Devices Directive (MDD) Essential Requirements to medical devices, including custom made devices. |
| 2,3                   | Perform a risk assessment; propose a risk management strategy. | • Local, national and international risk assessment procedures – assessing, scoring, evaluating and reviewing. |
| 2,3                   | Develop technical documentation for development of a medical device. | • Requirements of the MDD and local guidelines. |
| 2                     | Source components and materials in the preparation of an estimate or quotation. | • Local procurement guidelines.  
• Departmental costing mechanisms, e.g. workshop time. |
| 2                     | Design and develop a medical device. | • Familiarity with limits, fits and tolerances in manufacture, and justification of selection of dimensional specifications.  
• Appropriate manufacturing, fabrication and assembly techniques.  
• Relevant design and manufacturing quality/safety |
<table>
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<tr>
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<tr>
<td></td>
<td></td>
<td>standards/guidelines and their application.</td>
</tr>
</tbody>
</table>
| 2                     | Carry out validation and verification of a medical device realisation. | • Familiarity of methods of validation and verification in the design process.  
• Relevant standards/guidelines and their application. |
| 1,2,3                 | Commission a medical device; produce protocols for its safe and effective introduction into service. | • Medical device life cycle.  
• The importance of training the end user.  
• Documentation, including technical files and user instructions.  
• Measurement of outcomes.  
• Risk assessment methods/techniques and their application.  
• Relevant local guidelines on equipment procurement, commissioning and maintenance. |
| 1,3                   | Train and familiarise the client/user in the use of the equipment, including the development of user instructions. | • Approaches in use locally for client/user training and the inherent limitations of these.  
• Mechanisms to establish and use feedback from clients/users. |
| 1                     | Review the use of a medical device to enhance function, comfort and safety. | • Appropriate justification and control of technical files when changes are made to designs and associated documentation, e.g. user instructions.  
• Mechanisms to establish and use feedback from clients/users. |
SECTION 9: CONTRIBUTORS
Contributor List

Members of the STP Work Based Learning Guide Development Group for Physical Sciences and Biomedical Engineering: Clinical Engineering

Production of the STP work based learning guides for Clinical Engineering has been coordinated by the Modernising Scientific Careers team and the National School of Healthcare Science working with NHS colleagues. The professionals who have contributed to the development of this Learning Guide include:

- Richard Axell Cambridge University Hospitals NHS Foundation Trust
- Emma Bowers Freeman Hospital, Newcastle
- David Ewins Douglas Bader Rehabilitation Centre, Roehampton
- Anthony Fisher Royal Liverpool University Hospital, Liverpool
- Paul Ganney University College London Hospital
- Mike Hillman Wolfson Centre, Bath
- David Long Oxford University Hospitals NHS Trust, Oxford
- Hamid Rassoulian Nottingham University Hospitals Trust, Nottingham
- Richard Scott Sherwood Forest Hospitals NHS Foundation Trust
- Adam Shortland Guys and St Thomas’ Hospital, London
- Julie Stebbins Oxford University Hospitals NHS Trust, Oxford
- Azzam Taktak Royal Liverpool University Hospital, Liverpool
- Duncan Wood Salisbury District Hospital, Sailsbury

Professional bodies and societies were invited to review the Learning Guides for Medical Physics and Clinical Engineering and their feedback has shaped the final publication:

- IPEM Institute of physics and Engineering in Medicine
- BMUS British Medical Ultrasound Society
- BNMS British Nuclear Medicine Society
- IHEE Institute of Healthcare Engineering & Estate Management
- RESMG Rehabilitation Engineering Services Management Group

Modernising Scientific Careers Professional Advisor
Dr Derek Pearson

National School of Healthcare Science Professional Lead
Dr Chris Gibson

September 2012
Clinical Engineering

SECTION 10: APPENDICES
## APPENDIX 1: GLOSSARY

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Clinical Experiential Learning</td>
<td>The cyclical process linking concrete experience with abstract conceptualisation through reflection and planning.</td>
</tr>
<tr>
<td>Clinical Experiential Learning Outcomes</td>
<td>The activities that the trainee will undertake to enable and facilitate their learning in the workplace.</td>
</tr>
<tr>
<td>Competence</td>
<td>The ability of an individual to perform a role consistently to required standards combining knowledge, understanding, skills and behaviour.</td>
</tr>
<tr>
<td>Competence statements</td>
<td>Active and outcome-based statements that provide a further breakdown of the Learning Outcomes—reflecting what the trainee will be able to do in the workplace at the end of the programme. Each competence should linked back to the numbered Learning Outcomes.</td>
</tr>
<tr>
<td>Component</td>
<td>An indication of the type of module within a learning guide ie; rotational, specialist or elective</td>
</tr>
<tr>
<td>Curricula</td>
<td>An outline of the expected educational outcomes across a subject area The learning that is expected to take place during the Scientist Training Programme described in terms of knowledge, skills and attitudes,</td>
</tr>
<tr>
<td>Division</td>
<td>A high level description of an area of practice within healthcare science. There are three divisions: Life Sciences, Physical Sciences and Biomedical Engineering and Physiological Sciences.</td>
</tr>
<tr>
<td>Domains of Learning</td>
<td>Cognitive (knowledge and intellectual skills), affective (feelings and attitudes), interpersonal (behaviour and relationships with others) and psychomotor (physical skills)</td>
</tr>
<tr>
<td>Feedback</td>
<td>Specific information about the comparison between a trainee’s observed performance and a standard, given with the intent to improve the trainee’s performance (van de Ridder JMM, Stokking KM, McGaghie WCand ten Cate OT. What is feedback in clinical education? Medical Education 2008: 42: 189–19)7</td>
</tr>
<tr>
<td>Good Scientific Practice</td>
<td>Non-statutory guidance on the minimum requirements for good practice for the healthcare science workforce.</td>
</tr>
<tr>
<td>Host Department</td>
<td>The department which is responsible for the 3-year training programme and which the training officer is based.</td>
</tr>
<tr>
<td>Job</td>
<td>A specific definition of the work activities, requirements, skills required to undertake work activities within a local context. This differs from a role – see below.</td>
</tr>
<tr>
<td>Key Learning Outcome</td>
<td>A defined learning outcome linked to relevant competence(s) within the workplace Learning Guide</td>
</tr>
<tr>
<td>Knowledge and Understanding</td>
<td>The knowledge and understanding that must be applied in the work place to achieve the stated competence.</td>
</tr>
<tr>
<td>Learning Framework</td>
<td>The specification for work based learning contained within the Learning Guide</td>
</tr>
<tr>
<td>Learning Module</td>
<td>A distinct set of learning outcomes and competences that form part of a programme. Modules may be rotational, specialist,</td>
</tr>
<tr>
<td><strong>Learning Outcome</strong></td>
<td>A high level, outcome based statement that describes what a trainee will be able to do at the end of the module</td>
</tr>
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</tr>
<tr>
<td><strong>Mentoring</strong></td>
<td>Mentoring is a process in which a trainer (mentor) is responsible for overseeing the career and development of the trainee. The emphasis is therefore on the relationship (rather than the activity).</td>
</tr>
<tr>
<td><strong>Module Aim</strong></td>
<td>The overall objective of a work based learning module – defining the intended learning achievements of the trainee. The Aim works together with the ‘Scope’ statement to define the overall objectives and scope of the module</td>
</tr>
<tr>
<td><strong>Module Scope</strong></td>
<td>A statement within work based learning modules that defines the range/limits/ of the learning undertaken by the trainee in a module – patients/investigations/equipment/modalities etc</td>
</tr>
<tr>
<td><strong>National Occupational Standards</strong></td>
<td>Nationally recognised standards of expected workplace performance and level of competence for a role. The standards are outcome-based, defining what the role holder should to be able to do, as well as what they must know and understand to demonstrate competent work performance. National Occupational Standards are supported by nationally agreed frameworks of expected attitudes, behaviour and skills.</td>
</tr>
<tr>
<td><strong>Practical Skill</strong></td>
<td>A cognitive, psychomotor, physical or communicative ability that supports performance of required role.</td>
</tr>
<tr>
<td><strong>Programme</strong></td>
<td>The package of learning, teaching assessment and quality assurance leading to an award.</td>
</tr>
<tr>
<td><strong>Provider</strong></td>
<td>An organisation that delivers required training and learning activities, to specified quality assurance requirements</td>
</tr>
<tr>
<td><strong>Role</strong></td>
<td>A collection of functions undertaken in the workplace that represent the main broad areas of work for all similar workers at national level. A role differs from a job, the latter being defined specifically for a local context.</td>
</tr>
<tr>
<td><strong>Specialism</strong></td>
<td>A focused area of practice within a theme of healthcare science.</td>
</tr>
<tr>
<td><strong>Trainer</strong></td>
<td>A qualified individual who provides learning and development support for trainees</td>
</tr>
<tr>
<td><strong>Theme</strong></td>
<td>A cluster of related specialisms within a division of healthcare science.</td>
</tr>
<tr>
<td><strong>Work based learning</strong></td>
<td>Learning that takes place in a real work setting and involves the application of academic learning to real work activities</td>
</tr>
<tr>
<td><strong>Work Performance</strong></td>
<td>The requirements of satisfactory and consistent demonstration of competence in specified functions for a work role.</td>
</tr>
<tr>
<td><strong>Work place</strong></td>
<td>A real work setting in which the trainee can apply learning.</td>
</tr>
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</table>
APPENDIX 2: GOOD SCIENTIFIC PRACTICE

Good Scientific Practice

Section 1: The purpose of this document

There are three key components to the Healthcare Science workforce in the UK:

1. Healthcare Science Associates and Assistants who perform a diverse range of task based roles with appropriate levels of supervision.

2. Healthcare Science Practitioners have a defined role in delivering and reporting quality assured investigations and interventions for patients, on samples or on equipment in a healthcare science specialty, for example Cardiac Physiology, Blood Sciences or Nuclear Medicine. They also provide direct patient care and more senior Healthcare Science Practitioners develop roles in specialist practice and management.

3. Healthcare Scientists are staff that have clinical and specialist expertise in a specific clinical discipline, underpinned by broader knowledge and experience within a healthcare science theme. Healthcare scientists undertake complex scientific and clinical roles, defining and choosing investigative and clinical options, and making key judgements about complex facts and clinical situations. Many work directly with patients. They are involved, often in lead roles, in innovation and improvement, research and development and education and training. Some pursue explicit joint academic career pathways, which combined clinical practice and academic activity in research, innovation and education.

This document sets out the principles and values on which good practice undertaken by the Healthcare Science workforce is founded.

Good Scientific Practice sets out for the profession and the public the standards of behaviour and practice that must be achieved and maintained in the delivery of work activities, the provision of care and personal conduct.

Good Scientific Practice uses as a benchmark the Health Professions Council (HPC) Standards of Proficiency and Standards of Conduct, Performance and Ethics, but expresses these within the context of the specialities within Healthcare Science, recognising that three groups of the workforce, Biomedical Scientists, Clinical Scientists and Hearing Aid Dispensers are regulated by the HPC. The aim is that the standards are accessible to the profession and understandable by the public.
Good Scientific Practice represents standards and values that apply throughout an individual’s career in healthcare science at any level of practice. The standards will be contextualised by the role within Healthcare Science that an individual undertakes. This means that the standards must be interpreted based on the role that an individual performs. For example, in supervised roles where individuals work within defined procedures, rather than autonomously, some standards will need to be interpreted appropriately for the context of the specific role. There will, however, always be a requirement for an individual to work within the limits of their scope of practice and competence.

Students and trainees will be expected to be working towards meeting the expectations set out in this document. However, if an individual is undertaking further training and development following qualification from a professional training programme, he or she will be expected to be able to meet the standards in this document within their scope of practice.

The standards have been used to support curriculum development and will be used to underpin the process of judging individual equivalence, particularly for emerging specialisms.

The standards have been divided into five domains. The domains of Good Scientific Practice detailed in section 2 are:

1. Professional Practice
2. Scientific Practice
3. Clinical Practice
4. Research and development
5. Clinical Leadership

Section 2: The domains of Good Scientific Practice

Domain 1: Professional Practice

All patients and service users are entitled to good standards of professional practice and probity from the Healthcare Science workforce including the observance of professional codes of conduct and ethics. In maintaining your fitness to practice as a part of the Healthcare Science workforce, you must:

1.1 Professional Practice

1.1.1 Make the patient your first concern
1.1.2 Exercise your professional duty of care
1.1.3 Work within the agreed scope of practice for lawful, safe and effective healthcare science
1.1.4 Keep your professional, scientific, technical knowledge and skills up to date
1.1.5 Engage fully in evidence based practice
1.1.6 Draw on appropriate skills and knowledge in order to make professional judgements
1.1.7 Work within the limits of your personal competence
1.1.8 Act without delay on concerns raised by patients or carers or if you have good reason to believe that you or a colleague may be putting people at risk
1.1.9 Never discriminate unfairly against patients, carers or colleagues
1.1.10 Treat each patient as an individual, respect their dignity and confidentiality and uphold the rights, values and autonomy of every service user, including their role in the diagnostic and therapeutic process and in maintaining health and well-being.
1.1.11 Respond constructively to the outcome of audit, appraisals and performance reviews, undertaking further training where necessary

1.2 Probity

1.2.1 Make sure that your conduct at all times justifies the trust of patients, carers and colleagues and maintains the public’s trust in the scientific profession
1.2.2 Inform the appropriate regulatory body without delay if, at any time, you have accepted a caution, been charged with or found guilty of a criminal offence, or if any finding has been made against you as a result of fitness to practice procedures, or if you are suspended from a scientific post, or if you have any restrictions placed on your scientific, clinical or technical practice
1.2.3 Be open, honest and act with integrity at all times, including but not limited to: writing reports, signing documents, providing information about your qualifications, experience, and position in the scientific community, and providing written and verbal information to any formal enquiry or litigation, including that relating to the limits of your scientific knowledge and experience
1.2.4 Take all reasonable steps to verify information in reports and documents, including research
1.2.5 Work within the Standards of Conduct, Performance and Ethics set by your profession

1.3 Working with colleagues

1.3.1 Work with other professionals, support staff, service users, carers and relatives in the ways that best serve patients’ interests
1.3.2 Work effectively as a member of a multi-disciplinary team
1.3.3 Consult and take advice from colleagues where appropriate
1.3.4 Be readily accessible when you are on duty
1.3.5 Respect the skills and contributions of your colleagues
1.3.6 Participate in regular reviews of team performance.

1.4 Training and developing others

1.4.1 Contribute to the education and training of colleagues
1.4.2 If you have responsibilities for teaching, develop the skills, attitudes and practices of a competent teacher
1.4.3 Ensure that junior colleagues and students are properly supervised
1.4.4 Support colleagues who have difficulties with performance, conduct or health
1.4.5 Share information with colleagues to protect patient safety
1.4.6 Provide work-based development for colleagues to enhance/improve skills and knowledge

Domain 2: Scientific Practice

As a part of the Healthcare Science workforce, you will keep your scientific and technical knowledge and skills up to date to effectively:

2.1 Scientific Practice

2.1.1 Develop investigative strategies/procedures/processes that take account of relevant clinical and other sources of information
2.1.2 Provide scientific advice to ensure the safe and effective delivery of services
2.1.3 Undertake scientific investigations using qualitative and quantitative methods to aid the screening, diagnosis, prognosis, monitoring and/or treatment of health and disorders appropriate to the discipline
2.1.4 Investigate and monitor disease processes and normal states
2.1.5 Provide clear reports using appropriate methods of analysing, summarising and displaying information
2.1.6 Critically evaluate data, draw conclusions from it, formulate actions and recommend further investigations where appropriate

2.2 Technical Practice

2.2.1 Provide technical advice to ensure the safe and effective delivery of services
2.2.2 Plan, take part in and act on the outcome of regular and systematic audit
2.2.3 Work within the principles and practice of instruments, equipment and methodology used in the relevant scope of practice
2.2.4 Demonstrate practical skills in the essentials of measurement, data generation and analysis
2.2.5 Assess and evaluate new technologies prior to their routine use
2.2.6 Identify and manage sources of risk in the workplace, including specimens, raw materials, clinical and special waste, equipment, radiation and electricity.
2.2.7 Apply principles of good practice in health and safety to all aspects of the workplace
2.2.8 Apply correct methods of disinfection, sterilisation and decontamination and deal with waste and spillages correctly.
2.2.9 Demonstrate appropriate level of skill in the use of information and communications technology

2.3 Quality

2.3.1 Set, maintain and apply quality standards, control and assurance techniques for interventions across all clinical, scientific and technological activities
2.3.2 Make judgements on the effectiveness of processes and procedures
2.3.3 Participate in quality assurance programmes
2.3.4 Maintain an effective audit trail and work towards continuous improvement

Domain 3: Clinical Practice

As a part of the Healthcare Science workforce, you will keep your clinical skills up to date and undertake the clinical duties appropriate to your role in order to effectively:

3.1 Clinical Practice

3.1.1 Ensure that you and the staff you supervise understand the need for and obtain relevant consent before undertaking any investigation, examination, provision of treatment, or involvement of patients and carers in teaching or research
3.1.2 Ensure that you and the staff you supervise maintain confidentiality of patient information and records in line with published guidance
3.1.3 Ensure that you and your staff understand the wider clinical consequences of decisions made on your actions or advice
3.1.4 Demonstrate expertise in the wider clinical situation that applies to patients who present in your discipline
3.1.5 Maintain up to date knowledge of the clinical evidence base that underpins the services that you provide and/or supervise and ensure that these services are in line with the best clinical evidence
3.1.6 Plan and determine the range of clinical/scientific investigations or products required to meet diagnostic, therapeutic, rehabilitative or treatment needs of patients, taking account of the complete clinical picture
3.1.7 Plan and agree investigative strategies and clinical protocols for the optimal diagnosis, monitoring and therapy of patients with a range of disorders
3.1.8 Ensure that detailed clinical assessments are undertaken and recorded using appropriate techniques and equipment and that the outcomes of these investigations are reviewed regularly with users of the service
3.1.9 Ensure the provision of expert interpretation of complex and or specialist data across your discipline in the context of clinical questions posed
3.1.10 Undertake and record a detailed clinical assessment using appropriate techniques and equipment
3.1.11 Provide specialised clinical investigation and/or analysis appropriate to your discipline
3.1.12 Provide interpretation of complex and/or specialist data in the context of the clinical question posed
3.1.13 Provide clinical advice based on results obtained, including a diagnostic or therapeutic opinion for further action to be taken by the individual directly responsible for the care of the patient
3.1.14 Provide expert clinical advice to stakeholders in order to optimise the efficiency and effectiveness of clinical investigation of individuals and groups of patients
3.1.15 Prioritise the delivery of investigations, services or treatment based on clinical need of patients
3.1.16 Represent your discipline in multidisciplinary clinical meetings to discuss patient outcomes and the appropriateness of services provided

3.1.17 Ensure that regular and systematic clinical audit is undertaken and be responsible for modifying services based on audit findings.

3.2 Investigation and reporting

3.2.1 Plan and conduct scientific, technical, diagnostic, monitoring, treatment and therapeutic procedures with professional skill and ensuring the safety of patients, the public and staff

3.2.2 Perform investigations and procedures/design products to assist with the management, diagnosis, treatment, rehabilitation or planning in relation to the range of patient conditions/equipment within a specialist scope of practice

3.2.3 Monitor and report on progress of patient conditions/use of technology and the need for further interventions.

3.2.4 Interpret and report on a range of investigations or procedures associated with the management of patient conditions/equipment

Domain 4: Research, Development and Innovation

As part of the Healthcare Science workforce, research, development and innovation are key to your role. It is essential in helping the NHS address the challenges of the ageing population, chronic disease, health inequalities and rising public expectations of the NHS. In your role, you will undertake the research, development and innovation appropriate to your role in order to effectively:

4.1 Research, Development and Innovation

4.1.1 Search and critically appraise scientific literature and other sources of information

4.1.2 Engage in evidence-based practice, participate in audit procedures and critically search for, appraise and identify innovative approaches to practice and delivery of healthcare

4.1.3 Apply a range of research methodologies and initiate and participate in collaborative research

4.1.4 Manage research and development within a governance framework

4.1.5 Develop, evaluate, validate and verify new scientific, technical, diagnostic, monitoring, treatment and therapeutic procedures and, where indicated by the evidence, adapt and embed them in routine practice

4.1.6 Evaluate research and other available evidence to inform own practice in order to ensure that it remains at the leading edge of innovation.

4.1.7 Interpret data in the prevailing clinical context

4.1.8 Perform experimental work, produce and present results

4.1.9 Present data, research findings and innovative approaches to practice to peers in appropriate forms

4.1.10 Support the wider healthcare team in the spread and adoption of innovative technologies and practice
Domain 5: Clinical Leadership

All patients and service users have a right to expect that Healthcare Science services efficiently and effectively managed to meet service needs. As a leader in Healthcare Science, you will seek to effectively:

5.1 Leadership

5.1.1 Maintain responsibility when delegating healthcare activities and provide support as needed
5.1.2 Respect the skills and contributions of your colleagues
5.1.3 Protect patients from risk or harm presented by another person’s conduct, performance or health
5.1.4 Treat your colleagues fairly and with respect
5.1.5 Make suitable arrangements to ensure that roles and responsibilities are covered when you are absent, including handover at sufficient level of detail to competent colleagues
5.1.6 Ensure that patients, carers and colleagues understand the role and responsibilities of each member of the team
5.1.7 Ensure that systems are in place through which colleagues can raise concerns and take steps to act on those concerns if justified
5.1.8 Ensure regular reviews of team performance and take steps to develop and strengthen the team
5.1.9 Take steps to remedy any deficiencies in team performance
5.1.10 Refer patients to appropriate health professionals
5.1.11 Identify and take appropriate action to meet the development needs of those for whom you have management, supervision or training responsibilities
5.1.12 Act as an ambassador for the Healthcare Science community

Good Scientific Practice AHCS V.2 Final
APPENDIX 3: FURTHER INFORMATION

NHS Networks

An open network to share curricula produced for the Modernising Scientific Careers programme. Join this network to get updates whenever there is new content.

Details of the Scientist Training Programme including MSc Clinical Science Curricula, Work Based Learning Guides.

Chief Scientific Officer (CSO), Department of Health

Source of information and news including the CSO Bulletin, latest press releases, publications and consultations.
http://www.dh.gov.uk/health/category/chief-scientific-officer/

National School of Healthcare Science (NSHCS)

The National School of Healthcare Science is an important part of the new system for healthcare science training established through Modernising Scientific Careers. This new system was set up to ensure that patients benefit from the scientific and technical advances by ensuring that healthcare science staff have the knowledge and skills to put these advances into practice.
www.nshcs.org.uk

Academy for Healthcare Science (AHCS)

The Academy for Healthcare Science (AHCS) is a UK wide organisation bringing together a diverse and specialised scientific community working within the National Health Service (NHS) and other associated organisations (e.g. the Health Protection Agency, NHS Blood and Transplant), Health and Social Care Northern Ireland (HSCNI) and the academic and independent healthcare sector.
http://www.academyforhealthcarescience.co.uk/

Health and Care Professions Council (HCPC)

The HPC are a regulator set up to protect the public. They keep a register of health professionals who meet the HPC standards for their training, professional skills, behaviour and health.
http://www.hpc-uk.org/

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