1. Background to BS 70000

UKAS has been tasked by NHSE, with support from IPEM, to implement an accreditation scheme (MPACE) covering Medical Physics and Clinical Engineering. It has already undertaken a number of pilot activities in Radiotherapy Physics and Clinical Engineering (Management of Medical Devices). UKAS is now looking to engage with the Rehabilitation Engineering community to scope out activities which could be covered by BS 70000.

BS 70000 was published in 2017 and is entitled “Medical physics, clinical engineering and associated scientific services in healthcare – Requirements for quality, safety and competence”. Through the title, scope and examples in the standard it indicates that the BS 70000 is relevant to Rehabilitation Engineering activities. For example:

Scope (1)

- Optimisation and delivery of diagnostic and therapeutic procedures
- Provision of expert professional advice
- Process of scientific support in life cycle management of devices
- Design and manufacture of devices and patient aids
- The maintenance, testing and Quality assurance of equipment within healthcare

Annex A

- Assess needs and prescribe and provide solutions to address those needs.
- Design, develop, manufacture, adapt, test, evaluate and distribute technological solutions to problems confronted by individual with disabilities
- To meet clinical, functional and social needs of individuals with long term conditions.
- Functional areas of Rehabilitation Engineering cover:
  - Posture
  - Mobility
  - Communications
  - Independent living

The requirements in BS 70000 could also ensure that a large part of the patient pathway is covered for Rehabilitation Engineering:

- Service delivery (4.5, 5.10.1 & 5.10.3)
- Patient focus (5.10.2)
- Appropriate facilities for equipment and patient (5.3, 5.10.4 & 5.10.5)
- Suitability of equipment with traceable measurements (5.5)
- Medical Device Management (5.5.1)
- Methods for design and production are fit for purpose and valid (5.4)
- Handling of productions (5.8)
- Therapeutic reporting of results (5.13)
From the scope, requirements and examples it can be seen that accreditation, against BS 70000, could potentially provide assurance on the competence and reliability from the referral to delivery of medical devices (products) for a patient along with supporting activities. It is recognised that some of the activities required to deliver the service maybe undertaken by multi-disciplinary teams where staff may not be under the direct control of the Rehabilitation Engineering department. BS 70000 is designed to accredit activities in a Service irrespective of the structure, however staff performing the tasks, employed by the organisation, will need to be integrated into the same management system which supports the activities.

2. UKAS Development Pilot in Rehabilitation Engineering

The main aim of the MPACE project in Phase 2 is to develop an accreditation scheme which provides external assurance on quality and competence of Rehabilitation Engineering services and to drive improvement in standards within this area. UKAS will provide confidence to all service users, including patients and commissioners, and promote delivery of better quality services that leads to better quality outcomes.

In order to demonstrate the applicability and value of accreditation in Rehabilitation Engineering, the aim is to find a minimum of two Services who will participate in a pilot programme to help establish a proportionate assessment approach.

The benefits of accreditation within the Rehabilitation Engineering area are:

- Ensure that the activities undertaken by multi-disciplinary teams are supported by accreditation
- Confirmation that services are technically valid by peers
- External assurance and confirmation that services are implementing national and international recommended methods and quality controls.
- Identification of service improvements
- Support NHSE and Welsh Government objectives to implement accreditation across diagnostic and scientific healthcare services
- Recognised source of information for CQC inspection programmes
- Enable Trusts to gain outstanding classification by CQC
- Work with MHRA to recognise MPACE accreditation as a trusted source and a mechanism to support exemptions under the Medical Device Regulation.
- Meet contractual requirements (e.g. genomics contracts require accreditation throughout supply chain, and Any Qualified Provider tenders)
- Output recognised nationally and internationally
- An enabler for Services to develop a collaborative approach to quality management whilst improving consistency and transparency to senior management whilst removing potential duplication in running multiple systems.
- Provide a consistent measure across healthcare science area and provide the same level of assurance already expected by Trusts for Medical Laboratory activities.
3. Potential Scopes for Accreditation in Rehabilitation Engineering under BS 70000

The following options are provided to enable a discussion with the Rehabilitation Engineering community through RESMaG over the most appropriate scopes to offer accreditation in for a PILOT EXERCISE and potentially in the future:

Option 1 – Production of posture and mobility devices (covers the manufacture/modification/adaption of medical devices to meet a prescription. It would also cover the verification that, post-production, the devices meet the patient’s needs. The sub-activities covered by this will involve reviewing the prescription needs, selection of correct design process, production or commissioning of production, quality assurance checks of production, equipment management, verification product meets patient’s needs which could include measurements)

Pro’s – scope is relatively small and manageable to get implemented. It is envisaged all of the activities are undertaken by staff under the same management within a Rehabilitation Engineering team in the Service.

Con’s – Limiting the scope to this activity will not cover some of the key steps in administrative screening of referrals, assessment of patients including measurements, production of prescription.

Option 2 – Assessment, prescription and production of medical devices within Posture/Mobility Services (as with Option 1 but also include the assessment of patients in order to produce a prescription for the production. This will involve administrative checks of the referral as well as assessment of the patient which may include testing measurements)

Pro’s – this will cover the full pathway from referral through to delivery of equipment to patient.

Complexities – There will be some aspects of the assessment activity undertaken by non-Healthcare Scientists within a multidisciplinary team approach but not under the line management of Rehabilitation Engineering. These staff will need to be integrated into the management system being utilised by Rehabilitation Engineering.

Option 3 – Assessment, prescription and production of medical devices for full remit of Rehabilitation Engineering area (As per Option 2 but also covering other areas in addition to posture and mobility, for example, Electronic Assistive Technology, aids to daily living etc.)

Pro’s – ensure that all activities within a Rehabilitation Engineering Department are covered by the initial scope of accreditation.

Con’s – Significant amount of work to bring all areas up to speed at once as it is envisaged that some areas within Rehabilitation Engineering are more compliant. In addition, it does not allow for lessons learnt to be filtered through to other areas of business therefore meaning duplication of non-compliant activities may be implemented.
Complexities – There will be challenges in integrating all the individual teams and multi-disciplinary team members under one management system. The involvement at an early stage is important irrespective of whether they fall under the initial scope.

4. UKAS preferred option

For UKAS to undertake a pilot programme to confirm the suitability of BS 70000 and confirm the assessment approach it will need to identify a potential scope to be covered. Services interested in participating could have the options to include different Rehabilitation Engineering areas and complexity in their application. However, with larger variation in applications there will be less opportunity to standardise assessment approach, look for and deal with any inconsistency for a specific discipline and provide directed feedback to the community after the pilot assessments. UKAS is therefore proposing to establish a pilot covering Option 2 for full pathway in the area of posture and mobility devices manufacture/ modification/adaptation for patients with disabilities.

4. UKAS Development Pilot

In order for UKAS to confirm the requirements of BS 70000 are applicable to Rehabilitation Engineering and also establish a proportionate and robust assessment approach for a given scope of accreditation a development pilot programme is required. The pilot programme will take the normal UKAS development approach and consist of the following steps:

1) Verification and Confirmation of the technical scope with the UKAS MPACE Technical Advisory Group and RESMaG.

2) Publish an “Expression of Interest Announcement” on the UKAS website to identify any Services who may be interested in gaining accreditation in this area.

3) Production of a Pilot Terms of Reference. The terms of reference will give details of the scope, timescales and financial commitment a Service will need to agree to. There may also be some perquisites or desirables for applicants (e.g. Services already having a quality management system in place, support from relevant professional groups if activities cover multiple departments of line management)

4) Meeting of Interest Parties. UKAS will hold a meeting with the interested parties to provide background information on UKAS and accreditation. It will also cover the Pilot Terms or Reference and also summarise the requirements of BS 70000.

5) Identification and Recruitment of Technical/Peer Assessors. UKAS will need to generate a Technical Competence Criteria to select potential assessors against. A request for Technical Assessors will be advertised on the UKAS website and through IPEM. Potential assessors will be assessed for suitability and approximately 4-5 will be selected for the initial pilot. Contracts will be agreed with the assessors or their employees, who will be paid a daily rate of £300 for assessment activities. Assessor will receive training via a 3 days course and other single day activities (only expenses covered). In addition, this may also be an opportunity for Service to contribute to the pilot if they are not in a position to participate themselves.
6) Apply for Accreditation and Sign Up to the Pilot Terms of Reference – This is the first deadline for commitment to the pilot by a Service. Depending on numbers, UKAS may need to undertake a selection process based on the readiness of Services and also the Scope and type of Service.

7) UKAS confirms participants for the pilot

8) Workshop for Pilot Participants - Services will be asked to complete a gap analysis and then attend a workshop of all participants to discuss any potential gaps or ways of meeting the requirement of BS 70000. The costs of this workshop will be funded by UKAS/NHSE.

9) Pre-assessment (Potential) - A pre-assessment of one of the pilot participants could be arranged whereby the others can observe. This will be dependent on the compliance of the participants after the gap analysis stage earlier.

10) Initial Assessment - the pilot participants will have to submit all documentation for review 1 month prior to a site visit. A UKAS team will attend site for 2-3 days (dependant on scope) to carry out its assessment.

11) Close out of Actions raised on Initial Assessment. Depending on the level of compliance witnessed during the initial assessment UKAS will need to review corrective actions remotely or potentially by another site visit. UKAS will consider capping all costs for a given time periods so that the Service is protected from additional costs.

12) Grant of Accreditation. After completing the pilot assessments UKAS will confirm the assessment approach and then grant accreditation to BS 70000 for all Services who have meet the requirements on a given date. Participants who have not completed all corrective actions or wish to progress at a slow rate after identifying issues themselves may progress their application outside the timeframe of the pilot and gain accreditation at a subsequent date.

13) Ongoing Accreditation. Once the pilot is complete UKAS will open up application for other Services to apply. In addition, the existing accredited Service will move into an accreditation cycle whereby they have an annual assessment. The pilot exercise will determine the degree of assessment required and costs (will be less than Initial Assessments).