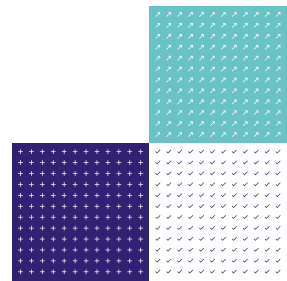


## Medical Physics & Clinical Engineering accreditation: FAQs

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### **What is MPACE Accreditation?**

MPACE is an accreditation scheme developed to provide external third-party assurance on the competence and reliability of specialism mainly undertaken within Medical Physics and Clinical Engineering departments.

NHS England asked UKAS in 2017 to manage and deliver an accreditation scheme which cover the Medical Physics and Clinical Engineering specialisms. This request was part of a wider NHSE policy to support and commission systems focused on the prioritisation of accredited healthcare services across all scientific and diagnostic services.

UKAS, the Institute for Physics and Engineering in Medicine (IPEM) and NHS England have been working together to build on the previous work undertaken in the 'iCEPSS' project and are developing appropriate accreditation scheme in a number of MPACE specialisms, for example:

- Biomedical engineering
- Clinical measurement and development
- Diagnostic radiology and MR physics
- Equipment management and clinical engineering
- Medical electronics and instrumentation
- Medical engineering design
- Nuclear medicine
- Radiopharmacy
- Radiation safety
- Radiotherapy physics
- Reconstructive Science
- Rehabilitation engineering

### **What is BS 70000?**

BS 70000:2017 is a standard owned by BSi and entitled "Medical physics, clinical engineering and associated scientific services in healthcare – Requirements for quality, safety and competence". BS 70000 is the standard MPACE departments are assessed against as part of the UKAS accreditation process.

BS 70000 was developed as a result of a demand from UK professional leads in the Medical Physics and Clinical Engineering community requiring an applicable standard which they could be assessed against. The standard was developed in consideration of ISO 15189 (Medical Labs), ISO 17025 (Testing and Calibration) and iCEPPS (early concept managed by ACHS) by group of experts. The standard has been written in a way to cover a wider range of clinical engineering activities, from equipment design, management and safe usage to diagnostic and rehabilitation medicine and therapy as well as those mentioned in the FAQ regarding what is MPACE accreditation.

The standard does not detail the technical specification required to carry out the activity. However, it does require the healthcare service to demonstrate competency and validity of the methods used along with a number of other key requirements relating to competency, traceability, uncertainty, evidence and the use of appropriate equipment & facilities amongst others.



### Where do I get a copy of BS 70000 from?

BS 70000:2017 is owned by BSi. A copy of the standard can be purchased from their [website](#).

### Who are UKAS?

The United Kingdom Accreditation Service (UKAS) is the UK's National Accreditation Body who have been appointed to manage and deliver the accreditation of MPACE services. UKAS is the only body recognised by Government, to assess and declare the competence of organisations against (inter)nationally recognised standards.

UKAS accreditation gives formal third-party recognition that a service has demonstrated the organisational competence to deliver a high-quality service. Accreditation provides reassurance and delivers confidence to users of the service, such as patients, commissioners and staff, of consistent high-quality care delivered by competent staff working in a safe environment whilst producing a continuous reliable output.

UKAS accreditation provides assurance in many health and social care specialisms, including MPACE:

- Medical Laboratories
- Point of care testing
- Physiological diagnostics
- Dental Service Certification
- Quality Standards for Imaging (formerly Imaging Services Accreditation Scheme)
- Care Home Inspection Bodies
- Conformity assessment to support Medical Devices and IVD Directives
- Clinical EQA Schemes
- Telehealth Services

### What is Accreditation?

Accreditation is the formal recognition that an organisation is competent to perform specific processes, activities, or tasks (which are detailed in a scope of accreditation) in a reliable credible and accurate manner. The provision of accreditation must:

- be undertaken impartially;
- be objective, transparent and effective;
- use highly professional competent assessors and technical (peer) experts in all relevant fields;
- use assessors (and subcontractors) that are reliable, ethical and competent in both accreditation processes and the relevant technical fields (e.g. MPACE specialisms).

Accreditation delivers confidence in reports, certificates and conformity statements. It underpins the quality of results/work by ensuring their traceability, comparability, validity and commutability.

The following [link](#) shows the impact that accreditation has on our everyday lives.



### What is the difference between Accreditation and Certification?

Within the International Organisation for Standards (ISO) framework there are some clear definitions of accreditation and certification. The terms accreditation and certification are often used interchangeably and occasionally together if communities are outside of ISO.

- **Accreditation:** “Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.”
- **Certification:** “third party assertion (declaration) related to product, processes of systems.”

Certification represents a written assurance by a third party of the conformity of a product, process or service to specified requirements. Accreditation, on the other hand, is the formal recognition by an authoritative body of the competence to work to specified standards. All accreditation standards include the principles of quality management systems, such as those found in the well-recognised ISO 9001 QMS standard. It is the ability to demonstrate technical competence that puts accredited certification on a level above non-accredited certification.

Another crucial difference between accreditation and certification relates to the activities it covers. Organisations receive accreditation for specific activities whereas certification relates to the company as a whole. For example, if you are looking to calibrate a thermometer or another piece of test equipment it would be best to choose an organisation that has been accredited against the testing and calibration standard ISO 17025 rather than one that has a general quality certification of ISO 9001. Further, the ISO 17025 testing/calibration activities themselves are tightly defined, so it is advisable to check the organisation’s schedule of accreditation closely; one that holds ISO 17025 accreditation for sound-proof testing would not necessarily hold ISO 17025 accreditation for air leakage. The same is true for MPACE specialisms as BS 70000 will provide assurance of the competency and reliability of the service delivered whereby certification will provide assurance that they have processes in place which meet generic requirements.

### Why gain accreditation to BS 70000?

Accreditation is increasingly being recognised as a valuable tool across a wide range of Government policy areas including better regulation, good governance, fair markets and public confidence. It is already being used by NHS England and the devolved Governments as an effective tool to improve the quality of care for patients, whilst delivering efficiency and productivity. Accreditation is also a pre-requisite for some NHSE contracts and also a consideration by CQC when awarding a Well-Led status for a Service.

Usually the reason for getting something independently evaluated is to confirm it meets specific requirements in order to reduce risks. Obvious examples are product failure, health risks, company reputation or to meet legal or customer requirements. MPACE department and senior management of Services are also looking to gain third party assurance on the competence and reliability of their services instead of relying on self-declaration. Accreditation is therefore used as part of the risk governance process and also benchmarking exercise within the community. Accreditation also provide opportunity for service improvements to be identified as well provide third party assurance to patients on the safety of the service.

The following reasons have been cited by services that have been accredited and are currently going through the accreditation process, for seeking accreditation:

- “To provide independent assurance in the quality of patient care and safety”
- “Had ISO 9001 certification for many years, but felt this process was not providing the right level of assurance”
- “To help facility standardisation of processes and procedures”



- “CQC to use accreditation as part of their inspections under ‘well led”

### **What are the benefits of Accreditation?**

Accreditation is a means of assessing, in the public interest, the technical competence and integrity of organisations offering evaluation services. Accreditation, with its many potential benefits for the quality in the provision of services, underpins practical applications of an increasingly wide range of activities across all sectors of the economy including healthcare science. Independent research has confirmed that accreditation has a positive economic value of nearly £1bn on the UK economy each year.

Some of the recognised benefit of accreditation are:

- Confirmation that services are technically valid by peers
- Identification of service improvements
- Support NHSE and other developed government requirements to implement accreditation
- Meet contractual requirements (e.g. genomics contract require accreditation throughout supply chain, and Any Qualified Provider tenders)
- Recognised source of trusted information for CQC, MHRA and other bodies which may result in reduced inspection activities.
- Output recognised nationally and internationally

Services involved in the MPACE accreditation process have sighted the following benefits from implementing the accreditation requirements:

- “Confirmed that we are providing a good safe service however, there are areas which could be improved”
- “Detail review of procedure/documentation helped us identify errors and departures from OEMs”
- “Improved quality controls on third party services”
- “Mechanism to identify poor performing work practices”
- “Assisted in identifying more efficient ways of implementing services”
- “Improved recognition of the value of our services by the Trust”
- “Improved escalation processes within Trust”
- “Positive feedback from Director level management”
- “Assisted in gaining additional training for staff”
- “Improvement in staff competence”

### **Which MPACE specialism and Services are accredited to BS 7000?**

UKAS announced the MPACE pilot assessment programme in July 2017. The pilot used BS 70000 as the criteria for assessment and focussed on two service areas; Radiotherapy Physics and Clinical Engineering (Medical Equipment Management).

In October 2019, UKAS awarded the first grants of accreditation in both of the pilot service areas and it was concluded that BS 70000 is an appropriate standard for accreditation and that the UKAS assessment process was robust, appropriate and undertaken in a proportionate manner.



Applications are now open to any Service that wishes to gain accreditation in these two areas. UKAS is now moving into the second phase of the project and is working with the relevant communities to identify further pilot participants in other MPACE service areas to widen the scope of MPACE accreditation. For more information about the ongoing MPACE development project and potential pilot programmes, please visit the UKAS [website](#).

### **Will UKAS accreditation against BS 70000 for Medical Physics and Clinical Engineering be mandatory now or in the future?**

UKAS is the National Accreditation Body in the UK and undertakes assessments at the request of the service it accredits. It is UKAS' understanding that there are currently no mandatory requirements for accreditation of MPACE services. However, as accreditation provides assurance to stakeholders (e.g. NHS England, CQC, Patients) of a robust and reliable service, it may be relied upon to support commissioning and regulatory requirements. For example, the CQC has indicated that they will consider approved accreditation schemes in their inspection visits with a view to reducing the burden of inspection.

### **Do I need to maintain ISO 9001 / ISO 13485 certification if I gain BS 70000 accreditation?**

ISO 9001 certification provides assurance that an organisations management system is focused on consistently meeting customer requirements. Accreditation to a standard such as BS 70000 will provide assurance that the management system is focused on the customer requirements as well as the organisations competence to produce valid results/output. It is up to an individual organisation to determine the most appropriate accreditation and/or certification it requires to satisfy the needs of its stakeholders. NHS England has made a statement indicating that Healthcare services should be underpinned by accreditation where possible.

One of the aims of the MPACE project is to demonstrate the equivalence of BS 70000 and ISO 15189 so that they can be jointly accredited. ISO 15189 is an internationally recognised standard which contains the core quality management system requirements. There is an ILAC/IAF joint statement that can be used by ISO 15189 accredited organisations to assure customers that they are operating a quality management system which meets the principles of ISO 9001.

As BS 70000 and ISO 15189 both include requirements for a quality management system, an organisation holding ISO 9001 certification can build the additional requirements into its current system. Once accredited an organisation can decide if it wishes to maintain any certification it holds based on its needs.

UKAS is currently in discussion with MHRA over the suitability of BS 70000 in meeting the Medical Device Regulations, Health Institutions Exemption (Article 5(5)). As part of the exemption, Health Institutions must ensure that the manufacture and use of 'in-house' medical devices occur under appropriate quality management systems. MHRA are looking at ISO 15189 and BS 70000 as a suitable system as well as the already recognised ISO 13485 route.

### **Will UKAS accreditation be recognised in the UK and in Europe?**

UKAS is appointed by the UK government as the National Accreditation Body by Accreditation Regulations 2009 (SI No 3155/2009) and the EU Regulation (EC) 765/2008. UKAS operates under a Memorandum of Understanding with the Government, through the Secretary of State for Department for Business, Energy & Industrial Strategy (BEIS). The EU regulation contains a specific definition for the term 'accreditation' which differentiates the accreditation awarded by the National Accreditation Body from that delivered by any other organisation. Furthermore, there

are some restrictions placed on the use of the term 'accreditation' by bodies that deliver assurance/conformity assessment services. Further information about accreditation and conformity assessment can be found here: <https://www.gov.uk/government/publications/accreditation-and-conformity-assessment-guidance-for-business-and-government-departments>

UKAS accreditation to ISO 15189, the standard on which BS 70000 is based, is recognised internationally. UKAS is a signatory of mutual recognition arrangements at a European and global level which ensures that UKAS accreditation is recognised overseas.

### **What are the overlaps with different Accreditation Standards such as ISO 15189, IQIPS and QSI?**

As part of the project UKAS is establishing a robust assessment processes to demonstrate equivalence between standards that are already being used in the healthcare area (e.g. ISO 15189) therefore enabling stakeholders to consider the need for multiple standards. UKAS is establishing a mechanism to join up the assessment of different scientific and diagnostic services to reduce duplication and facilitate shared practices across the disciplines.

### **Do we need to gain accreditation for all MPACE services at once?**

During the development project interested services will only be able to apply for accreditation in the technical areas of the pilot (e.g. Radiotherapy Physics, Medical Equipment Management, Nuclear Medicine, Clinical Movement Analysis, Rehabilitation Engineering).

It is for the Service to determine which service areas to apply for and potentially what technical activities within that area it wants to be covered by accreditation. There will be no requirement to apply for all areas at the same time.

From experience in other sectors and accreditation processes it is recommended to start with a small scope of accreditation and then extending the scope over time. By starting small the Service can focus on implementing the key management and technical requirements and take learning points to other areas. UKAS will work with all Services in developing an accreditation road map.

### **What are the costs of accreditation?**

Costs of accreditation will vary between Services as UKAS costs are based on time and effort. Therefore, depending on the scope of accreditation and the size of the applicant these will vary. Please contact UKAS for a quote.

For new areas to the MPACE accreditation process and involved in pilot schemes or early adaptor schemes UKAS may cap the costs of initial accreditation in these instances.

### **What is the Accreditation Period?**

UKAS grants accreditation for a 4 year period. It undertakes surveillance activities every year to assess continued compliance and competence of the service. Accreditation is renewed in the 4<sup>th</sup> year whereby a more in-depth assessment is undertaken, similar to the initial assessment.



### **What is involved in the accreditation process?**

To find out more about the accreditation process please visit the UKAS [website](#). When listening to the video clip BS 70000 is the standard which is relevant to MPACE applications. UKAS can provide a Gap Analysis form to assist Services in identifying gaps in their system. Services will need to use AC8 form when applying for accreditation.

The assessment process will involve a review of documentation prior to the onsite assessment. During the onsite assessment, the lead assessor will generally sit with the quality manager or lead to go through the management system requirements (section 4) of BS 70000 and the technical (peer) assessor will observe staff undertaking the technical activities, review records and have technical discussion to confirm competence and compliance (section 5) of the service.

### **How long does it take to become accredited?**

The timescales for gaining accreditation are varied and will be dependent on the readiness of the applicant. UKAS will provide a timeline at application stage and update this during the application process (e.g. after pre-assessment or review of documentation). For established technical areas, accreditation often takes 9-18 months from application. With regards to MPACE application it has taken Services involved in the pilot approximately 18-24 months.

### **What happens if I fail the process?**

There are a number of outcomes from the initial assessment process. These are:

- Accreditation is recommended and can be granted as the Service had demonstrated competence and compliance to all the requirements of BS 70000.
- Most common outcome - A positive recommendation is made to award accreditation to BS 70000 but there are a number of non-conformities identified which need actions completed and verified by UKAS before accreditation can be granted. The close out of actions can be done remotely by submission of documented evidence or can be undertaken on-site by review of documents and/or confirmation of effective implementation of required processes.
- No recommendation can be made to offer accreditation. There are significant gaps in the system which need to be addressed before another assessment is undertaken. If significant gaps are identified through the visit, UKAS will discuss these with the management team as and when they arise. A plan will be developed so the Service is aware of what it needs to do to become compliant. Another assessment visit will need to be undertaken with associated costs.

### **What happens if I lose my accreditation?**

After gaining accreditation, Services will be required to maintain the system to meet the requirements of BS 70000. Ongoing maintenance will involve demonstrating compliance through a range of activities such as internal audits, management reviews, internal quality assurance checks, calibrations.

UKAS will assess the Service annually to gain assurance that the systems are being maintained. If any significant issues are identified UKAS has the right to impose a sanction until the Service demonstrates compliance to the necessary requirements. The sanction may involve additional assessment visits, partial or full suspension of accreditation and termination of accreditation. If accreditation is suspended the Service will be provided with details of what it needs to do to regain its accreditation. For partial suspension the specific activities will be removed from the



schedule of accreditation. In the instance of full suspension, the accreditation status will be updated on the UKAS website.

If accreditation is suspended or terminated the Service will need to stop referring to its service as being accredited. It will be expected to notify all its key stakeholders including Regulators depending the nature of the suspension. It may need to recall all effected work.

### **What happens if UKAS identifies a patient safety issue?**

In order to ensure that individual assessors and UKAS are able to deal effectively when they come across situations where they believe patient safety or appropriate care is compromised, a clear line of communication will be established between (i) UKAS and its assessors and (ii) UKAS and the services concerned, and a series of escalation steps will be established which will include the following :

- UKAS will discuss the issues immediately with the service itself. The service will be required to propose and implement the necessary actions to remedy the concerns.
- The service itself shall be considered responsible for rapid notification and resolution internally, including disclosing the relevant information to the senior management within the NHS Trust/Board/Hospital/Service. UKAS will expect that the Service will provide evidence that the findings have been reported to the necessary level of management and/or to the relevant regulator in accordance with its obligations.
- UKAS will consider the need for it to undertake external escalation if the service concerned fails (i) to propose and/or (ii) to implement a satisfactory remedial plan within an agreed timeframe. The decision to escalate will be communicated to the service concerned
- As part of the escalation, UKAS may consider it necessary to approach the highest levels of the governance structure responsible for the service and/or give notice that the appropriate regulator and/or government department will be informed of the patient safety concerns. In all cases the service will be provided advance warning that this information will be divulged to any third party and supplied with the appropriate justification.

### **Will staff be expected to hold specific qualifications or be registered to specific professional bodies?**

BS 70000 requires a service to determine its training and competency requirements for its staff. UKAS does not envisage there being a requirement to hold specific qualifications or registrations rather that the service can demonstrate that it has effectively evaluated the competence of its staff. It is recognised that attainment of academic and professional qualifications and CPD form a component of overall competence. UKAS will assess the suitability of the required criteria and review objective evidence of the training and initial and on-going competency assessment of staff.

### **Who is part of the Assessment Team?**

The assessment team is generally comprised of a Lead Assessor who is a permanent employee of UKAS and will generally be the point of contact between UKAS and the Service. The lead assessor will manage the team during the assessment and assess the compliance of the management system element. A technical (peer) assessor will also be part of the team. Technical Assessors are generally contracted in by UKAS to support the assessment process. The technical assessors are competent peers from the community and have first-hand experience in undertaking the activities which are being accredited.

UKAS will inform the Service of the UKAS team before any assessment is undertaken to ensure there is no conflict of interest.

### **Are Technical Assessors (Peer Reviewers) paid?**

UKAS currently contracts in Technical Assessors via individual contracts or through their employer. The individual or the employer will be paid for the office and on-site time along with any expenses occurred as part of the assessment process. For more information on becoming a UKAS assessor please refer to the UKAS [website](#).

### **What were the general outcomes of the original MPACE pilot?**

UKAS presented the outcomes of Phase 1 of the development pilot at the September 2019 MPEC conference in Bristol. The general outcomes from the pilot confirmed that BS 70000 was an applicable standard and there were no major issues which required immediate updates by BSI. The pilot also confirmed that the UKAS assessment approach was robust and proportionate. The approach will evolve further once more Services go through the accreditation process.

In relation to Services ability to demonstrate compliance to the requirements of BS 70000 the comments were applicable:

- Quality Management Systems were seen to be in place and consisted of dedicated BS 70000 system, integration to existing Certification system and a combination of both. Services are recommended to carry out a detailed gap analysis against BS 70000 as there are specific MPACE specifics which many require the Service to extend its quality/technical policy and procedures.
- Risk Registers were in place however specific department/method risks need to be documented if not covered in wider Service risk register (e.g. Radiotherapy Service or Medical Device Policy)
- External Providers were being evaluated by procurement sections however objective evidence is required to confirm competence and suitability of providers (e.g. traceability of reference materials, competence to undertake Servicing)
- Work Instructions are in place and generally fit for purpose. However, further details are required on exceptions and evidence of compliance with good practice guides or manufacturers guidance.
- Records/Notes supporting the accredited activities require sufficient details to ensure critical information are recorded (e.g. specific values measured, specific aspects checked on treatment plans). In addition, a mechanism for identifying changes in electronic records as well as who had made changes needs to be considered.
- A formal mechanism is required along with records on how Services are keeping abreast of latest technology.
- Training procedures for new staff were general good, in some areas more detail is required to the minimum training requirements and exposure to specific activities.
- Technical competence was demonstrated and a level of evidence supporting initial sign off. Competence assessment procedure needs to have sufficient detail to ensure consistency of training/competence assessment throughout the Service.
- Ongoing competence assessment and evidence is an area which Services need to consider and implement for new and existing members of staff. Evidence is required for all staff irrespective of grade/role who undertake the accredited and supporting QA activities.
- Validity/verification of methods was mixed between the disciplines. For Medical Equipment Management verification that the Service can undertake the PPM to the manufacturer recommendation is required or demonstrating the validity of any deviations (e.g. different test equipment, omission or additional testing steps, change of acceptance criteria)

- Uncertainty of Measurement needs to be considered and as a minimum the source of uncertainty and mitigation to minimize variation needs documenting.
- Further work on ongoing assurance of quality of work is required for some of the areas in particular Medical Equipment management.
- Records of calibration and maintenance of equipment need to be in place. For example, traceability of calibration/reference materials, competence/quality of service providers.

### **Do I need to establish dedicated quality manual or management system for BS 70000?**

BS 70000 requires a number of key policies and procedures to be documented and controlled. The most effective way of implementing, maintaining and controlling these policies and documents is through a management system. A Quality Manual provides the mechanism to sign post staff to the relevant documentation.

There are no requirements for a dedicated management system or BS 70000 quality manual. If a Service does not have a system, then it can base its quality manual around the requirements and structure of BS 70000 which makes it easier to identify gaps and confirm compliance.

If a Service has a management system and quality manual already in place then this can be updated, if required, to include ensure the requirements of BS 70000. For Services who already have a ISO 9001 system (or equivalent) in place then it is important that a gap analysis is completed to ensure specific BS 70000 requirements are in place with respect to the quality management system (i.e. Section 4). The management system and quality manual will also need to be reviewed to ensure the technical policies and procedure requirements (Section 5) are incorporated into the system.

For Services that have multiple certification or accreditation across departments Services are encouraged to align their quality management teams and experience to help deliver the accreditation schemes in the most effective and efficient way. By harmonising the system this will centralise and ensure greater visibility to senior management. It will also remove duplication and effort in running similar processes and prompt standards practices across the Service.

### **How do I demonstrate on-going competency of staff?**

BS 70000 requires staff to be subject to regular performance review and competence reassessment. Ongoing competence assessments are important to provide assurance that staff are still performing to the same level of competence demonstrated when they were initially authorised to work unsupervised.

The Service will need to have a procedure which details how ongoing competence is assessed and also includes the competence criteria. The procedure should also detail what lapse competence looks like and the process for a member of staff to regain competence and be authorised to work unsupervised.

There are many ways of demonstrating ongoing competence which may vary between MPACE specialisms and Services. It is important that staff are active in the areas they are authorised to work in (this might be one of the criteria). However, just completing tasks does not provide assurance that staff are still competent in the activities. To demonstrate competence it might be possible to record comments on the quality of treatment plans which have been independently checked. These comments can be reviewed periodically to confirm compliance or identify trends in performance. This mechanism may work well for specialisms which have in-built checks for all work. However, in high volume areas of work such as PPM on medical devices a different

approach may be required in the form of witnessing/auditing staff periodically. Other mechanisms to capture evidence of on-going competence are:

- Witnessing / Auditing staff undertaking the activities
- Review of feedback on completed work by checkers
- Completing a competence tests
- Involvement in round robin exercises within department
- Participation in Inter-laboratory / PT / Interdepartmental exercises
- Completions of validation / commission work which has been peer reviewed
- Publication of scientific material / papers

It is important that all staff who undertake the accredited activities have evidence of ongoing competence. This includes technical leads who might have set up the system. The review of competence needs to be undertaken by an authorised and competent person in that activity. The standard does not require this person to be superior to the member of staff they are assessing.

### **What quality assurance activities do I need to undertake to demonstrate the continued validity of my methods?**

Before a new method, process or piece of equipment is placed into service the Service needs to demonstrate its validity. This is often achieved through the following processes:

- Validation within Service as there is no external supporting validation material
- Verification to confirm that the Service can perform an existing validated method
- Commissioning of equipment to confirm its performance
- Determination of the Uncertainties and sources of Error within the method.

After the method/equipment has been shown to be fit for purpose there is a requirement for its performance to be continually monitored. For different specialisms there are some inherent quality assurance processes in place which provide this assurance. However, in some specialisms a Service may need to implement some sampling exercise to confirm continued reliability of the service. Potential mechanisms for demonstrating on-going quality of the service are:

- Equipment QC and trend analysis
- Method witness audits to confirm Staff and Process are still fit for purpose
- Checking of critical parts of the process, especially where humans are involved (e.g. independent check of calculations, treatment plans, medical device confirmation settings)
- Checks on final reports or work being delivered
- Internal (blind) trials which demonstrate repeatability within team. They might also demonstrate reliability of method if baseline information is known.
- Participation in PT / Interlaboratory Exercise / Interdepartmental audit

### **What things should I consider when implementing BS 70000?**

When looking to implement BS 70000 it is important that a Service first purchases a copy of BS 70000 from BSI and carries out a gap analysis of its current systems and procedures. UKAS can provide a template for carrying out the gap analysis

In addition to the gap analysis there are a number of factors which need to be considered at an early stage which will enable a Service to implement BS 70000 in a more effective, efficient and timely manner. There are:

- To obtain Top Management support and gain their commitment to the accreditation process. Implementing BS 70000 may require some additional resource at the beginning to coordinate staff in developing the policies and procedures as well as gather objective evidence of the reliability and competence of the service.
- Build a business case for Top Management. Supporting evidence is provided in the Benefits of Accreditation FAQ. UKAS is looking to produce some proforma business cases to assist Services.
- Where possible Services should look to utilise and harmonise the quality management teams, systems and experience to help implement BS 70000 in the most effective and efficient way. It will save duplication of effort for a Service and provide greater visibility to Top Management. It is possible to build in BS 70000 requirements into an ISO 9001 system.
- Determine what technical areas to be covered by BS70000 first. It is recommended to apply for a small scope first so that the Service gain experience of BS 70000 and UKAS expectation. Once the Service is accredited for a small scope then it can be extended to cover all required activities. It is advisable to have discussion with UKAS at an early stage to assist with the scoping of an application.
- Carry out a gap analysis
- Identify Quality Manager and Technical Managers for different disciplines
- Develop technical procedures/instructions detailing how activities are undertaken
- Start to audit against draft procedures to confirm applicability
- Develop mechanism for capturing records of compliance (e.g. initial / ongoing competency of staff, validation of methods, contemporaneous notes associated to activity)