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IMA 1

Edition 1 July 2024

Accreditation to BS 70000:2017 *Medical physics, clinical engineering and associated scientific services in healthcare - Requirements for quality, safety and competence* for imaging services

Contents

Changes since last edition

This is the first edition of this publication.

1. Introduction

1.1 This publication has been produced by the United Kingdom Accreditation Service (UKAS) in conjunction with the UKAS Technical Advisory Committees for MPACE and imaging services. It provides guidance to those requirements in BS 70000:2017 that would benefit from clarification when applied to imaging services. It does not cover all the requirements of BS 70000: 2017 and services are reminded of the need to comply with all the requirements in the standard applicable to their service. Cross-reference is made to relevant clauses of BS 70000:2017.

In cases of difference of interpretation of the requirements, BS 70000:2017, as applied by UKAS, is the authoritative publication and UKAS, through a nominated member of staff will, in the first instance, adjudicate on unresolved matters. Other UKAS publications are referred to where relevant.

1.2 Accreditation against the requirements of BS 70000:2017 and the use of this supplementary document is intended to give confidence in the services provided by imaging services who perform any aspect of the radiological patient pathway from referral to issue of report. For the purposes of this publication the term ‘service’ shall be taken to mean an accredited imaging service.

2. Scope - imaging services covered by accreditation against BS 70000:2017

2.1 Services provided by an imaging service may include (but are not limited to):

a) NHS radiology or imaging departments with responsibility for the entire patient pathway from receipt of request through to issue of report;

b) Independent sector healthcare providers with responsibility for all or part of the patient pathway;

c) Teleradiology companies providing reporting services only;

d) NHS medical physics departments with responsibility for imaging services along the patient pathway.

2.2 It should be noted that medical physics and clinical engineering activities can also be assessed and accredited against BS 70000 and, should the activities for imaging and medical physics/clinical engineering fall under the same management system, they can all be assessed together as one accredited service.

3. Managerial requirements

3.1 Legal entity (clause 4.1.2)

The legal entity for services may be an NHS Trust or an independent company. This will need to be verified, with evidence provided to UKAS of continued registration at each assessment.

a) NHS Trusts can refer to their entry on
- https://www.england.nhs.uk/publication/nhs-provider-directory/
- NHS Wales health boards and trusts | GOV.WALES
- Organisations – Scotland's Health on the Web
- About Us - DOH/HSCNI Strategic Planning and Performance Group (SPPG)

b) Independent businesses can refer to their entry on Find and update company information - GOV.UK (company-information.service.gov.uk)

3.2 Management of change (clause 4.6)

All changes across the organisation should be considered - for example clinical practice, staff terms and conditions, new and emerging practice including AI.

3.3 Outsourcing (clause 4.7)

Please refer to Terms and Definitions 3.13.

For the purposes of accreditation for an imaging service, outsourcing is defined as any aspect of the available patient pathway in which the delivery of services is transferred by the service to an external provider.

The accredited service must have the competence to deliver the outsourced work in-house but can choose to outsource a portion of it to another provider (for example, to ease a backlog of work on a temporary basis or to increase capacity on a longer-term basis). They must be able to determine the appropriateness of the chosen external provider and to review the outputs of any outsourced work.

Note the difference between "outsourcing" and "supplier".

3.4 Management of suppliers (clause 4.8)

The management and approval of the procurement of all external suppliers to the imaging department or company is considered in this clause. Suppliers could include (but not be limited to):

a) The procurement of all supplies (e.g. equipment, medicines and consumables)
b) Contracted work by external services or agencies for regulatory compliance (e.g. radiation protection or MR safety services)
c) Any external company or NHS Trust that supplies patient pathway aspects that the service does not have the competence to deliver (e.g. paediatric or specialist neurological examinations)

Note the difference between "outsourcing" and "supplier".

Accredited services shall define appropriate selection criteria for suppliers, and periodically check that approved suppliers continue to meet the criteria and perform in accordance with any agreed key performance indicators.

3.5 Control of nonconforming work (clause 4.10)

A "nonconformity" is defined as "non-fulfilment of a requirement" (definition taken from ISO IEC 17021-1, used as the standard definition across all ISO and BS standards). A nonconformity would occur when a service does not meet a requirement of BS 70000:2017 and/or when a service does not follow its own policies or procedures.

In imaging services sources of nonconformities may include incident management, quality assurance records and action levels, complaints, external audits, and benchmarking discrepancies. Information may already be documented in individual procedures and not require a single policy or process, although a guidance document could be useful to describe the nonconformity workflows. Robust and timely investigation, corrective action, root cause and effectiveness checks are to be included in the procedures documented, and compliance with the documented procedures will be assessed.

3.6 Control of information assets (clause 4.17)

Accredited services are required to develop and implement policies and procedures for management of information, whether this is electronic or hard copy information. This clause also covers the storage and security of such records.

- General – This could include organisational level documentation for the management of IT systems
- Technical records – This could include organisational or local documentation of IT systems used for patient data (PACS/RIS/EPR) or equipment data (QA/Dose records)

3.7 Assuring quality in education and training activities (clause 4.21)

Services should ensure they are conformant to the standard in relevant requirements of this clause. Not all services, however, will need to be conformant to all requirements; this will be dependent on the training they offer. For the purposes of accreditation, the following applies:

a) "Students" or "Learners" refer to those in education establishments completing placements with the service

b) "Trainees" refer to those employed by the service and undertaking work-based training

4. Technical requirements

4.1 Operation methods/procedures and validation (clause 5.4)

For imaging services, "Operation methods/procedures" refers to clinical imaging protocols and standard operating procedures/work instructions

4.2 Validation of methods and procedures (clause 5.4.5)

"Validation" refers to confirmation that the activities being selected by an accredited service are fit for purpose and clinically appropriate.

If the techniques used are based on nationally accepted techniques or professional guidance, local validation by each accredited service is not required. These techniques or guidance may include, but not be limited, to

a) Professional body guidance

b) Published and peer reviewed books, journals and articles

c) Equipment manufacturer guidelines

If an accredited service develops an in-house protocol/activity, or modifies one based on nationally accepted techniques or professional guidance, local validation will be necessary, to demonstrate that the protocol/activity is fit for purpose and clinically appropriate. This may take place at modality specific or governance meetings. There is some guidance about validation methods/techniques in the notes against clause 5.4.5.3.

4.3 Estimation of uncertainty of measurement (clauses 5.4.6 and 5.4.7)

It is recognised that diagnostic imaging services do not have published quantifiable measurement uncertainties. Although there are measurement steps in diagnostic imaging services, the patient is the biggest contributor to measurement uncertainty. Patients are different shapes and sizes, have variable abilities to remain still while being scanned, tolerate contrast media differently, *etc.*, all of which can have an impact on the quality of the image produced.

It is expected that the service has considered and documented the sources of uncertainty, and any mitigating actions they have put in place to minimise uncertainty where possible. Mitigating actions could include staff training (including regular refresher training), review of cases by 2 personnel before reaching a diagnostic conclusion, or appropriate use of muscle relaxants to support production of a better-quality scan. A table similar to that in the *Diagnostic uncertainties in medical imaging article* (reference 2) may be helpful for initial identification of uncertainties.

Although uncertainty is inevitable in a diagnostic imaging service, accredited services must provide evidence that the impact of those uncertainties has been considered and minimised, which, in turn, minimises the risk of an incorrect result being released.

4.4 Verification of production or intervention procedures (clause 5.4.10)

"Verification" refers to confirmation that the activities being performed by an accredited service are fit for purpose, clinically appropriate, and in line with validated methods (see clause 5.4.5).

Verification applies to both equipment and new protocols or techniques. These should be verified through audit, medical physics acceptance tests, or completion of a new practice pathway.

4.5 Measurement traceability (clause 5.6)

This clause details the requirements for any traceable calibration for equipment used in imaging services, and for traceability of reference standards used.

Accredited services must identify any equipment which could have a significant effect on the accuracy or validity of diagnostic results; these pieces of equipment might need traceable calibration, to give assurance of the accuracy and consistency of results. Examples might include dose calibrators in nuclear medicine, or calliper measurements in foetal ultrasound.

Where equipment is calibrated by an external company, relevant certification held by the company shall be provided as evidence.

4.6 Handling of production, investigations, therapy, repair, test and metrological confirmation items (clause 5.8)

The term "item" is defined in the notes for clause 5.8, but for imaging service accreditation it is considered to be anything used as part of the imaging examination. For example, this clause may include the management of (but not limited to):

a) Contrast media
b) Medicines
c) Moving and handling aids
d) Immobilisation equipment
e) Infection control and nursing equipment (angiography/biopsies catheters, venepuncture etc.)

4.7 Controlling the quality of healthcare scientific service outputs (clause 5.9)

This clause requires that there are systems in place for quality control across the service. This may be monitored as part of the management system review or as part of the audit programme. A number of processes may be applicable to imaging which may include the following (but not limited to)

a) Quality assurance records
b) Observational audits
c) Scheme audit participation (e.g. DQASS)
d) Peer review of reporting
e) Feedback from patients, referrers and public

4.8 Information for patients and service users (clause 5.10)

This clause relates to the patient pathway for the purposes of imaging accreditation.

Wherever "data" or "sample" is referred to, imaging services should consider this to refer to the patient, their carers and where appropriate medical or non-medical referrers.

4.9 Surveillance (clause 5.12) and production of certificates (clause 5.13.4)

It is not expected that these clauses will be relevant for any imaging service.

5. References

5.1 TPS 71 Accreditation of healthcare diagnostic pathways delivered between multiple UKAS customers

5.2 Diagnostic uncertainties in medical imaging; Hofmann and Lysdahl

5.3 Philosophy of Advanced Medical Imaging; Lalumera, E., Fanti, S.

5.4 Protocol for Establishing and Maintaining the Calibration of Medical Radionuclide Calibrators and their Quality Control; A National Measurement Good Practice Guide