

UKAS Accreditation delivering confidence in Medical Physics and Clinical Engineering Service (MPACE)

19th June 2019 – Health Care Science Event - Glasgow

David Compton – UKAS

Aims:

- Understanding of UKAS and Accreditation
- Awareness of different UKAS Accreditation Schemes
- Background to MPACE project
- Understanding of key requirements of MPACE accreditation (BS 70000)
- Feedback from pilot activities to date
- Questions

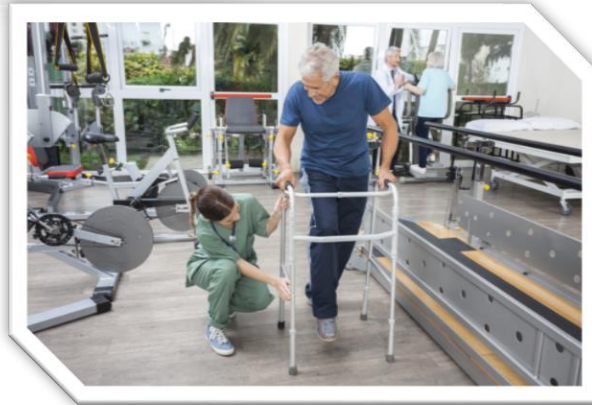


Quality in Healthcare



- Stakeholders require assurance of quality of services
- Range of mechanisms to provide assurance
 - Self declaration against defined expectations
 - Third party assurance against defined expectations
- External assessments within MPCE services
 - ISO 9001 certification (Radiotherapy, Clinical Engineering, Radiation protection)
 - ISO 13485 medical devices
 - GMP
 - Other 'accreditation' and quality assurance schemes

Quality in Healthcare



- NHS England / NHS Improvement have strongly endorsed the use of accreditation where possible to provide assurance that:
 - The service performs to **the required standard**;
 - Clinical and administrative practices are **delivered competently**
 - The resources, facilities and workforce are **appropriate**;
 - Service delivery is **patient-focused**;
 - The performance of the service **can be sustained**.
- Care Quality Commission recognized accreditation as approved information source.

What is accreditation?



“Procedure by which an authoritative body gives formal recognition that a body or person is **competent** to carry out specific tasks”

- Independent & impartial assessment by competent authoritative third party – an accreditation body
 - Demonstration of technical competence & impartiality
 - Gives confidence to all users – reduces risk
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- Benefits of Accreditation
 - Confirmation that services are technically valid by peers
 - Identification of service improvements
 - Support NHSE requirements to implement accreditation
 - Recognised source of information for CQC inspection programmes
 - Meet contractual requirements (e.g. genomics contract require accreditation throughout supply chain, and Any Qualified Provider tenders)
 - Output recognised nationally and internationally

What is accreditation



<https://youtu.be/BNsTuFKW3iM>

Why UKAS?



- UKAS established in 1995 as a non-profit distributing private company limited by guarantee
- Originated in 1966; 53 years of accreditation experience
- The UK's national accreditation body; EU Regulation gives legal framework for accreditation
- Performance is monitored by government and peer-assessed internationally

UKAS Accreditation activities in Healthcare



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



ISO 15189

BS EN ISO 15189:2012
Incorporating corrigendum October 2014



**Medical laboratories —
Requirements for quality and
competence (ISO 15189:2012)**

Clinical Biochemistry - Toxicology - Endocrinology
Haematology - Blood Transfusion
Microbiology - Virology - Parasitology - Serology - Mycology
Histopathology - Cytology - Mortuaries
Immunology

- ISO 15189 for Medical Laboratory Activities

“ a medical laboratory’s fulfilment of the requirements of this International Standard means the laboratory meets both the **technical competence** requirements and the management system requirements that are necessary for it to **consistently deliver technically valid results**”

Genetics
Andrology
Histocompatibility & Immunogenetics
Point of Care Testing

Improving Quality in Physiological Services IQIPS



IQIPS Standards and Criteria

Audiology
Cardiac Physiology
Gastro-Intestinal Physiology
Ophthalmic & Vision Science
Respiratory & Sleep
Physiology
Neurophysiology
Urodynamics
Vascular Science

- IQIPS for Physiological Services

“The accredited provider organisation must demonstrate that it have systems in place (procedures, protocols, policies, equipment, facilities, resources and workforce which are routinely implemented and regularly audited) to provide **competent, safe and effective services to all users** whether at its static, mobile and or domiciliary, including residential or nursing homes, settings.”

- IQIPS is under revision, with the aim to align and harmonise to ISO 15189.

Imaging Service Accreditation Scheme (ISAS)



The Imaging Services Accreditation Scheme
Standard: statements, rationales and criteria

ISAS Standard v3.0, 2017

General X-ray
Fluoroscopy
Interventional radiology
Ultrasound
Magnetic resonance
imaging
Computerised tomography

Bone mineral densitometry
Mammography
(symptomatic only)
Radionuclide imaging
Reporting

- ISAS for Imaging Services

“UKAS accreditation of imaging services is a patient-focused assessment that is designed to help diagnostic imaging services ensure that their patients consistently **receive high quality services**, delivered by **competent staff working in safe environments**”

- ISAS re-branded “**Quality Standard for Imaging**” on 11th June 2019.



Historical Background – BS 70000

- In conjunction with the British Standards Institution, MPCE community & UKAS a British Standard for the potential accreditation of Clinical Engineering and Physical Science Services in healthcare developed (2015/16)
- Standard sought to align with ISO 15189:2012 and ISO/IEC 17025, conveying equivalence with ISO 9001
- Standard developed with representation from European Federation of Organisations for Medical Physics (EFOMP) to support development of European Standard.
- Standard published Jan 2017

BS 70000:2017



Medical physics, clinical engineering and associated scientific services in healthcare – Requirements for quality, safety and competence

BS 70000 Standard (MPACE)

BS 70000:2017



Medical physics, clinical engineering and associated scientific services in healthcare – Requirements for quality, safety and competence

Medical Physics including:
Radiation Safety
Radiotherapy Physics
Imaging with Ionizing Radiation
Imaging with Non-Ionizing Radiation

Physiological Sciences under MPCE
Clinical Engineering including:
Rehabilitation Engineering
Biomedical Engineering
Movement Analysis
Reconstructive Sciences

Common Accreditation Requirements



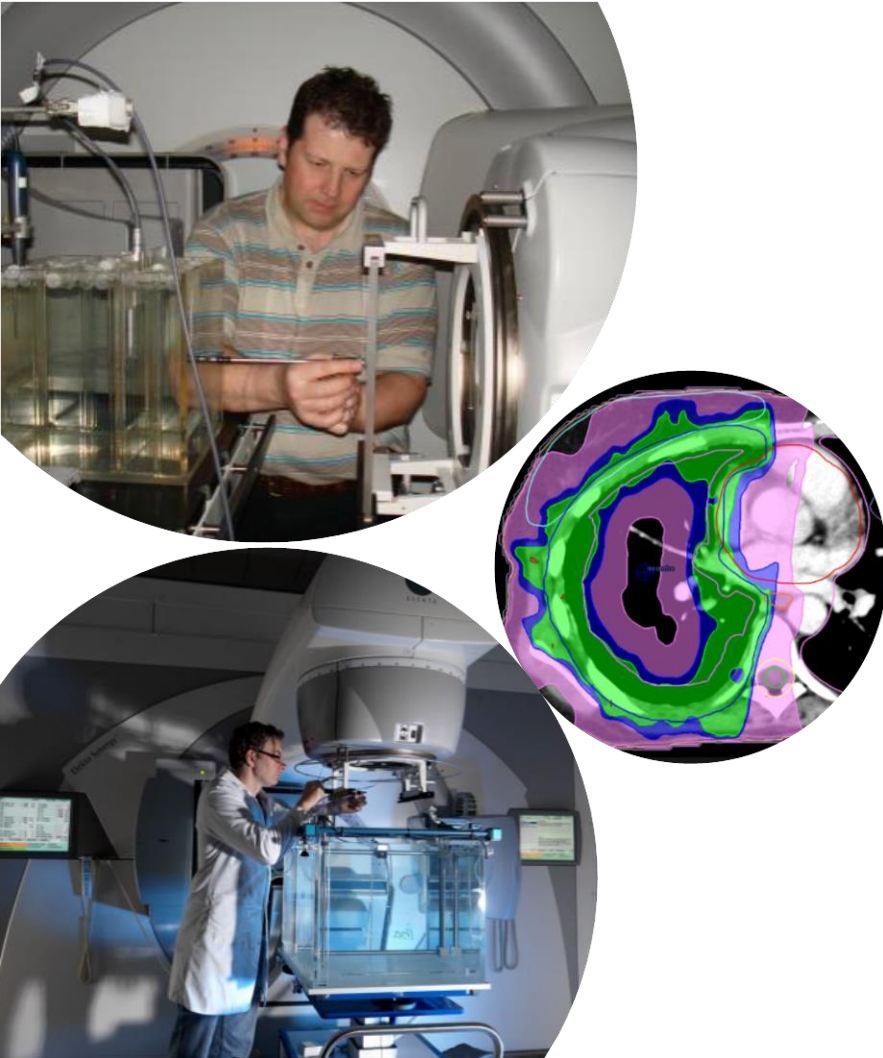
- Management Requirements
 - Management and organisation control and structure, service delivery, objectives, document and record control, non-conforming work, audits, management review, suppliers/sub-contracting, improvements, research and training policy.
- Technical Requirements
 - Personal (Training and Competency), Methods (Procedures and Validation), Quality Assurance, Equipment, Measurement and equipment traceability, Accommodation, Handling of Items/Information, Reporting
- Safety
 - Patient and staff health and safety
- Patient Experience
 - Patient service forces, Interactions, communications, available information, accommodation/transport needs.

UKAS Development Project Aims



- To confirm that BS 70000 is an appropriate standard for accreditation
- To develop and confirm that the assessment approach and criteria is appropriate and fit for purpose for a restricted number of activities (pilot)
- To ensure consistent outcomes
- To deal with any issues that arise
- To open up accreditation to wider MPCE activities
- Determine if accreditation can be awarded to ISO 15189 in conjunction with BS 70000 to assist in objective of harmonisation of standards and assessment visits

MPACE Pilot Phase 1



- Radiotherapy Physics - Scope (Technical Activities)
 - Design of the Treatment Plan
 - Performance characterisation of radiotherapy equipment
 - Linacs
 - Orthovoltage units
- Inherent activities covered by BS 70000
 - purchasing,
 - (de)commissioning,
 - quality assurance,
 - Radiotherapy IT support
 - Software and equipment management
- Not covered at this stage
 - Brachytherapy (being reconsidered)
 - Production of Masks

MPACE Pilot Phase 1



- Management of Medical Devices Scope (Technical Activities)
 - Infusion devices (Syringe and infusion pumps)
 - Anaesthetic equipment and ventilation (Anaesthetic machines, anaesthetic monitoring, ventilators, BiPAP, CPAP)
 - Medical Device Library (optional)
- Inherent activities covered by BS 70000
 - Purchasing
 - (de)commissioning
 - Maintenance / Repair
 - Quality Assurance processes
 - external supplier management
 - Research and consultancy on devices for commissioning

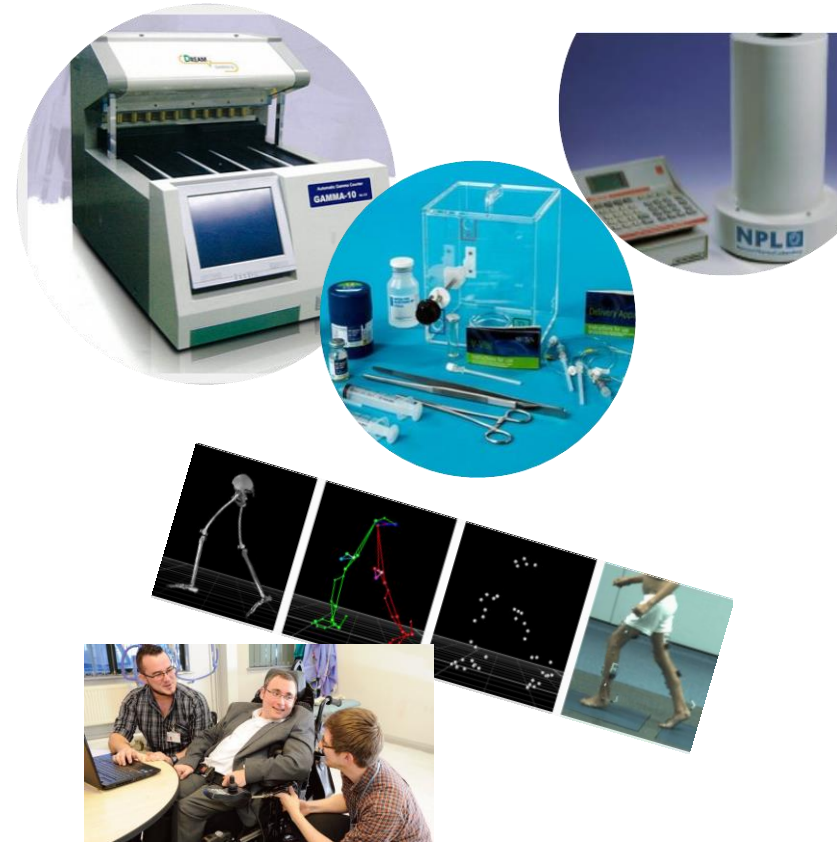
MPACE Pilot Phase 1 - Current Status



- Six Trusts signed up to Pilot Terms of Reference
- Four Assessment Visits undertaken – 2 further visits planned
- Trusts progressing corrective actions
- 1st Grant anticipated by Summer
- Compliance to BS 70000
 - Quality Management Systems in place (gap analysis against BS 70000 specifics, extended to technical policy and procedures)
 - Work Instructions (detail on exceptions, compliance with good practice guides or manufacturers guidance)
 - Technical competence demonstrated (consistency of training/competence assessment, ongoing competence assessment, MPE evidence)
 - Further work on ongoing assurance of quality of work (Determine mechanism to demonstrate ongoing quality of work)
 - Validity of methods mixed levels between disciplines
 - Records of calibration and maintenance of equipment (traceability of calibration/reference materials, competence/quality of service providers)

MPACE Pilot Phase 2 - Plan

- Nuclear Medicine
 - Supported by BNMS
 - Expression of Interest announcement
 - Determining scope of pilot and timeframes
- Rehabilitation Engineering and Gait Services
 - Visits to a number of departments
 - Potential scoping for pilot being developed
 - Planned interaction with RESMAG and CMAS
- Peer Assessors
 - Another route to support accreditation



For more information on accreditation in healthcare

- See UKAS Website
- <https://www.ukas.com/sectors/healthcare/>
- UKAS runs preparation for accreditation workshops for ISAS/IQIPS
- Standard awareness course for ISO 15189
- Supporting process being developed for BS 70000 (MPACE)



- Thank you for listening
- Questions

<https://www.ukas.com/sectors/healthcare/>

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