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

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Contents

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Foreword

Publishing information

This British Standard is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 31 January 2017. It was prepared by Technical Committee CH/100, *Healthcare and Medical Equipment*. A list of organizations represented on this committee can be obtained on request to its secretary.

Relationship with other publications

This accreditation standard references a range of certification standards where these are considered essential elements in the delivery of particular healthcare science services and products. It is expected that conformity to these standards can be demonstrated for such services and associated products as appropriate. Fundamental to accreditation to BS 70000 is the implementation of a formal quality management system equivalent to BS EN ISO 9001.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

In particular attention is drawn to the following specific directives and regulations:

- European Directive 90/385/EEC on active implantable medical devices (AIMDD) (1990) [1];
- European Directive 93/42/EEC on medical devices (MDD) (1993) [2];
- European Directive 98/79/EC on in vitro diagnostic medical devices (IVDMD) (1998) [3];
- The Medical Devices Regulations 2002 [4].

0 Introduction

The application of science and technology in healthcare is fundamental to the delivery of high-quality care and improved patient outcomes in many clinical areas. Services based on science and technology can be described as healthcare science services and are often sub-divided into laboratory and non laboratory-based services. Laboratory-based services are principally involved with the analysis and interpretation of measurements from samples, such as tissue and blood taken from the patient. Non laboratory activities provide services, including associated products aimed at delivering or supporting the direct or indirect diagnosis and treatment of disease, including equipment management, design and manufacture of medical devices and patient aids, and might or might not involve direct patient contact.

Such activities are not without risk to the patient due to technical and human factors. The need for independent and peer review of these services is widely recognized in order to minimize risk and maximize quality and safety. BS EN ISO 15189 is an international accreditation standard applied to laboratory-based services. Whilst it can be applied to non laboratory-based services it requires significant interpretation. BS 70000 provides an interpretation of BS EN ISO 15189, giving a consistent framework for the accreditation of non laboratory-based services and products irrespective of service configuration and scope. Conformity to BS 70000 satisfies the requirements of BS EN ISO 15189.

BS 70000 specifies requirements for quality, safety and competence for medical physics, clinical engineering and associated science services in healthcare. Its language and requirements are generic and widely applicable, focusing on the scientific aspects of service delivery as well as technical, managerial, leadership and patient experience.

This accreditation standard references a range of certification standards where these are considered essential elements in the delivery of particular healthcare science services and products. It is expected that services and products would demonstrate conformity to the requirements of these standards as appropriate. Fundamental to accreditation to BS 70000 is the implementation of a formal quality management system equivalent to BS EN ISO 9001.

BS 70000 has been informed by professional standards and is not intended to replace such standards, but to evolve to reflect best practice as these develop.

A service conforming to this accreditation standard satisfies both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results and advice. The management system requirements in Clause **4** meet the principles of BS EN ISO 9001 and are aligned with its pertinent requirements.

1 Scope

This British Standard specifies requirements for quality, safety and competence in medical physics, clinical engineering and associated science services, including the development and manufacture of associated products, in healthcare, which include:

a) the optimization and delivery of diagnostic and therapeutic procedures;

b) provision of expert professional advice;

c) project management;

d) provision of scientific and technical support for the procurement, governance and life cycle management of medical devices;

e) the repair, maintenance, testing, metrological confirmation and quality assurance of equipment and facilities within a healthcare environment;

f) design and manufacture of devices and patient aids;

NOTE See "Further reading" in the Bibliography for standards covering the design and manufacture of devices.

g) radiopharmaceutical production;

h) healthcare science education and training; and

i) innovation, research and development.

It specifies a framework for good practice in service delivery, training and innovation research and development, including the roles, responsibilities, activities, facilities and equipment that are required for the delivery of such healthcare science services and associated products for the benefit of patients.

This British Standard can be used:

1) by service providers in developing their quality management systems and assessing the performance of their service and the competence of their staff; and

2) for confirming or recognizing the competence of these professional services by service users (including patients), regulating authorities and accreditation bodies.

Services for the maintenance of buildings and environmental conditions of healthcare facilities are not covered by this British Standard, although its main principles can be used to improve the provision of such services.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN ISO 9000, *Quality Management Systems – Fundamentals and vocabulary* [1)]

BS EN ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*

BS EN ISO 15189, *Medical laboratories – Requirements for quality and competence* [2)]

BS EN ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*

BS EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 99, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

1) This standard also gives informative references to BS EN ISO 9000:2015.
2) This standard also gives informative references to BS EN ISO 15189:2012.

3 Terms and definitions

For the purposes of this British Standard, the terms and definitions given in BS EN ISO 9000, BS EN ISO/IEC 17000, BS EN ISO 15189 and ISO/IEC Guide 99 apply, together with the following.

3.1 clinical action threshold
level of examination result that indicates an immediate risk to the patient of injury or death and which requires immediate service intervention

NOTE 1 A threshold may incorporate a range of results.

NOTE 2 The service determines the appropriate list of alerts for its patients and users.

[SOURCE: BS EN ISO 15189:2012, **3.2**]

3.2 consensus standard
technical standard that is developed or adopted by voluntary consensus standard bodies

3.3 governance
system by which the organization is directed, controlled and held accountable to achieve its core purpose over the long term

NOTE 1 The term "corporate governance" is typically used for the governance of private and publicly-listed companies or to denote governance of the whole organization.

NOTE 2 Governance is distinguished from management.

NOTE 3 The system by which the organization is held accountable includes the accountability of the executive to the governing body, as well as the accountability of the governing body and the executive to the organization's stakeholders.

[SOURCE: BS 13500:2013, **2.7**, modified]

3.4 healthcare science service
healthcare service delivered by specialist scientists, engineers and technologists alongside other health professionals

NOTE The services referred to in this British Standard are medical physics, clinical engineering and associated science.

3.5 information asset
identifiable and definable information-based organizational component which is valuable to the business of the organization and without which critical business processes would potentially fail

3.6 key performance indicator
set of quantifiable measures used to gauge or compare performance in terms of meeting strategic and operational goals

3.7 management system
set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives

NOTE 1 A management system can address a single discipline or several disciplines.

NOTE 2 The system elements include the organization's structure, roles and responsibilities, planning, operation, etc.

NOTE 3 The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

[SOURCE: ISO/IEC Annex SL:2012, **3.04**]

3.8 medical device
instrument, apparatus, appliance, software, material, or other article – whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application – intended to be used for human beings for the purpose of:

a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

b) diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; or

c) investigation, replacement or modification of the anatomy or of a physiological process

NOTE Medical devices are defined by the EU Medical Devices Directives/ Regulations [1, 2, 3, 4].

3.9 metrological confirmation
set of operations required to ensure that equipment/materials conform to the requirements for their intended use

NOTE Confirmation generally includes metrological confirmation and verification, any necessary adjustment or repair, and subsequent metrological reconfirmation, comparison with the metrological requirements for the intended use of the equipment/material, as well as any required sealing and labelling.

[SOURCE: BS EN ISO 10012:2003, **3.5**, modified]

3.10 normal range/reference interval
set of defined values relevant to specific service activity that reflect the expected results from such actions

3.11 occupational health and safety
conditions and factors that affect, or could affect, the health and safety of employees or other workers (including temporary workers and contractor personnel), visitors or any other person in the workplace

NOTE Organizations can be subject to legal requirements for the health and safety of persons beyond the immediate workplace, or who are exposed to the workplace activities.

[SOURCE: BS OHSAS 18001:2007, **3.12**]

3.12 organization
legal entity under which the service is provided

3.13 outsourcing
practice by which the delivery of products or services is transferred by a service to an external provider

3.14 personal identifiable data (PID)
data that can be used to identify an individual patient, staff member or other member of the public

3.15 primary data
data observed or collected directly from first-hand experience

3.16 quality lead
individual with overall responsibility for the quality policy and its implementation.

NOTE This may encompass the quality manager role as defined in BS EN ISO 15189.

3.17 reference equipment
equipment used for the sole purpose of comparing the performance of other identical equipment used in their field of application

3.18 reference standard/reference material
material traceable to a primary standard, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

3.19 sampling
process of selecting a representative part of a population for the purpose of determining parameters or characteristics of the whole population

3.20 service commissioner
person or organization that specifies and/or contracts a service

3.21 stakeholder
person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity

[SOURCE: ISO/IEC Annex SL:2012, **3.02**]

3.22 standard method
document specifying detailed instructions for carrying out one or more procedures for measurement, testing, sampling, evaluating or specifying performance

3.23 top management
person or group of people who directs and controls an organization at the highest level

NOTE 1 Top management has the power to delegate authority and provide resources within the organization.

NOTE 2 If the scope of the management system covers only part of an organization then top management refers to those who direct and control that part of the organization.

[SOURCE: ISO/IEC Annex SL:2012, **3.05**]

3.24 unexpected findings
observations made during an investigation, repair or measurement that are unrelated to the original service request, but might be considered clinically significant and require further evaluation

3.25 validation
confirmation, by examination and through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term "validated" is used to designate the corresponding status.

*NOTE 2 Adapted from BS EN ISO 9000:2015, **3.8.13**.*

3.26 verification
confirmation, through provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

- *performing alternative calculations;*
- *comparing a new design specification with a similar proven design specification;*
- *undertaking tests and demonstrations; and*
- *reviewing documents prior to issue.*

*NOTE 3 Adapted from BS EN ISO 9000:2015, **3.8.12**.*

4 Management requirements

4.1 Organization

4.1.1 The service provider shall implement a policy that requires the service to:

a) operate under appropriate professional leadership;

b) ensure the services are patient/user-focused, committed to the highest levels of quality and safety and to a process of continual improvement; and

c) establish a vision and a strategy for the delivery of its services which are aligned to the needs of patients/users, ensuring appropriate financial and resource planning,

and where the service provider is part of a wider organization to:

1) ensure there is a documented agreement in regard to the scope of services to be provided, resource allocation, contingency planning, associated standards and methods for delivery evaluation;

2) ensure that services are planned in an integrated manner, including staff and resources;

3) ensure that operational policies follow the requirements of the wider organization; and

4) ensure its quality policy and processes are consistent with the wider organization governance requirements.

4.1.2 The service provider, or the organization of which it is a part, shall be an entity that can be held legally responsible for the activities of the service provider. The service shall maintain and review at suitable periods its indemnity insurance to ensure adequate cover for all activities undertaken by the service at all times.

4.1.3 The service provider shall undertake its activities in such a way as to identify, regularly review and meet:

a) relevant service user needs;

b) regulatory requirements; and

c) other accepted guidance and accreditation standards.

4.1.4 Where the service provider is part of a larger organization, top management shall demonstrate evidence of its commitment to the development and implementation of this British Standard and ensure that wider organizational requirements and pressures do not affect the service provider's ability to conform.

4.1.5 The service provider shall have processes to define, record and manage potential conflicts of interest.

4.1.6 The service provider shall:

a) ensure that personnel with service management and leadership responsibilities are identified, have the authority and resources required to discharge those responsibilities, and are free from undue pressures that might impair their clinical scientific judgement;

b) ensure that the service is led by a person or people with the professional qualifications and experience necessary to maintain the clinical scientific integrity of the service;

c) regularly assess the effectiveness of its leadership;

NOTE 1 Effectiveness may be assessed by review or benchmarking or any other suitable mechanism. The service may utilize the expertise of external professional assessors.

d) have systems for ensuring compliance with identified codes of practice, including the identification of all such relevant codes;

e) have documented structures for its management and operations that include:

1) relationships within the service;

2) relationships between the service and the wider organization and external organizations/stakeholders, where appropriate; and

3) relationships with supporting services that can impinge on operational effectiveness;

f) define the roles and responsibilities of all personnel who undertake activities within the scope of the service, including responsibility for the work of other personnel and for all aspects of the service identified in this British Standard;

NOTE 2 This may be achieved via job descriptions or contracts. Job descriptions can be defined in many ways. As a minimum, the following should be defined:

- *arrangements for management oversight;*
- *the responsibilities required of the post;*
- *expertise and experience required;*
- *qualifications, current registration status and training programmes, including continuing professional development (CPD) programmes; and*
- *managerial duties.*

g) have systems to ensure that personnel are:

1) appropriately appointed to ensure their suitability;

2) appropriately inducted in all aspects of their responsibilities and understand the importance of their role to delivering the service's objectives, including the needs to act with discretion and respect towards patients, service users, carers and others, and to maintain patients' privacy, dignity and security;

3) competent and updated in all aspects of their work to ensure continuing competence;

4) subject to and compliant with appropriate codes of professional practice;

NOTE 3 Examples include the HCPC standards of proficiency [3] and the AHCS Good Scientific Practice [4].

5) where necessary, appropriately registered and that such registration remains valid and up-to-date;

6) engaged in effective continuing personal and professional development; and

h) ensure that all key roles and processes are identified and that, for each of these roles and processes, arrangements are in place to ensure service continuity and appropriate response to emergencies, e.g. appointing deputies, establishing rotas and out of hours cover, or preparing and rehearsing contingency plans.

4.1.7 The service shall have:

a) defined roles and responsibilities for:

1) interpreting and reporting test and other results and outcomes;

2) governance, including reviewing current practice and the development of new healthcare scientific practices;

b) a designated quality lead;

c) established systems to regularly plan, define and review quality objectives and implement quality improvements;

d) contingency plans to ensure that agreed essential services are available during emergency situations;

e) systems in place to ensure contracts of employment and job descriptions/job plans are agreed, and that staff appraisals and personal development plan reviews are regularly conducted for all staff; and

f) systems in place to maintain competencies needed to provide the service (including where appropriate provision for children and those with particular needs).

4.1.8 The service shall define, implement and monitor standards of performance and quality improvement of services.

4.1.9 The service shall have systems to describe how communications are undertaken from management to staff and from staff to management at all levels of the service. These systems shall enable mechanisms for staff feedback (confidential or otherwise) on any issues of service performance and delivery, communications regarding the effectiveness of the management system, and any actions being planned.

4.2 Quality management system

4.2.1 The service shall implement and maintain an appropriate quality management system that includes documentation of policies, processes, procedures and instructions, which is made readily accessible to staff and supported by training, for the purpose of assuring the delivery of high-quality, safe and effective healthcare scientific services.

NOTE The documentation can be in any form or type of medium, providing it is readily accessible and protected fromunauthorized changes and undue deterioration.

[3] Available at: http://www.hpc-uk.org/aboutregistration/standards/standardsof proficiency/ (last accessed 23 January 2017).

[4] Available at: https://www.ahcs.ac.uk/ (last accessed 23 January 2017).

4.2.2 The quality management system shall include:

a) a quality policy, with associated responsibilities (see BS EN ISO 9001);

b) quality objectives and the mechanism for their review;

c) written commitments to defined best professional, scientific, research and development, and clinical practice;

d) methods for disseminating the quality policy to all personnel;

e) mechanisms for system review and performance measurement, including audit; and

f) the standards to which the service are to adhere and how work procedures and services are reviewed to ensure they meet these standards.

4.3 Governance and risk management

4.3.1 The service shall implement governance policies that define:

a) the requirements for the management of service risk; and

b) the arrangements to manage unexpected events in relation to service delivery, outcomes, communications, continuity and recovery.

4.3.2 The service shall demonstrate its commitment to high-quality, safe and effective healthcare scientific services by:

a) identifying its vision and strategic outcomes, and risk limits on their fulfilment, to allow managers to ensure that risks are managed effectively across the organization;

b) implementing a risk-based approach to its activities including as necessary;

   1) infection, including decontamination procedures;

   2) patients, service users and staff with contagious and communicable disease and/or suppressed immune systems, including the care of any individual exposed to contagious and communicable diseases;

   3) violence and aggression, including support for patients/service users, staff and others who have been involved in an incident;

   4) lone working;

   5) emergencies and contingency planning;

   6) health and safety risks;

   7) medical device management;

   8) product development and manufacture;

   NOTE For medical devices development this should be consistent with BS EN ISO 13485 and BS EN ISO 14971. For IT networks incorporating medical devices this should be consistent with BS EN 80001-1.

c) implementing actions to address identified risks and opportunities, taking into account how these risks and opportunities can change with time;

d) ensuring that the approach used for managing risk is aligned with the wider organization's approach for managing risk;

e) implementing, planning, controlling (e.g. policies and processes) and monitoring activities to exploit opportunities for service improvement, development and innovation, while maintaining risks at an acceptable level; and

f) evaluating the effectiveness of the processes for managing risks and opportunities.

4.3.3 The service shall ensure that external risks are considered, including those involving the service's relationships with third-party suppliers, and that, where risks are identified, these are coordinated and agreed with the relevant stakeholders to ensure that these risks are understood and managed.

4.3.4 The service shall evaluate the impact of equipment and work processes and potential failures on the safety of patients and service users, staff and the public and the quality of service. The service shall take action to reduce risks to as low a level as practicable and document decisions and actions taken.

NOTE Such people may include locum and temporary agency staff who are not permanent staff.

4.4 Planning to achieve management objectives

4.4.1 When planning the quality management system (see BS EN ISO 15189:2012, **4.2.1**), the service shall determine the risks and opportunities that need to be addressed to:

a) give assurance that the management system can achieve its intended outcome(s);

b) prevent or reduce undesired effects; and

c) achieve continual improvement.

4.4.2 The service shall determine and achieve its management objectives through local and system-wide integrated planning activities, including financial, human resources and other support functions.

4.4.3 The service shall ensure that the management objectives take into account relevant requirements coming from outside the service.

4.5 Service delivery

4.5.1 The service shall liaise with service users or their representatives to clarify service users' requests and monitor the service's performance in relation to the work performed, provided that the service ensures confidentiality to other service users.

NOTE Service users value good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the service user should be maintained and the service user informed of any delays or major deviations in the delivery of services.

4.5.2 The service shall, in partnership with service users and commissioners, provide a service specification which identifies legislation, standards or guidance applicable to the service and relevant performance measures.

4.5.3 Systems shall be in place to ensure that healthcare scientific services are scheduled and delivered in a way that meets patient/service user needs and are coordinated with delivery of other healthcare services where possible.

4.5.4 The service shall develop appropriate key performance indicators (KPIs) for service configuration and delivery, and regularly review delivery against these indicators. Where appropriate, the service shall consult existing and potential service users and stakeholders, updating its processes as necessary. The service shall communicate the services provided, and survey patients/service users to ensure services meet needs.

NOTE Examples of the types of feedback include service user satisfaction surveys and review of service outputs and reports with service users.

4.5.5 Systems, including defined roles and responsibilities, shall be put in place to:

a) obtain and manage verbal and written feedback, both positive and negative, from patients/service users and, where relevant, from carers and relatives in a variety of formats and in confidence;

b) provide relevant training and resources for feedback management roles, and subject these roles to regular appraisal and review to ensure continuing effectiveness;

c) develop, agree and maintain materials to support patient/service user feedback, involving input from lay people where relevant;

d) ensure that complaints or concerns are reported, investigated, recorded and analysed within specified time frames, with findings acted upon and disseminated to relevant parties and the effectiveness of actions taken monitored;

e) ensure that staff are able to provide timely feedback in confidence on the service and that such feedback is recorded and contributes to service planning and development;

f) give feedback to staff on suggestions in a timely manner; and

g) ensure previous patient/service user feedback is considered when reviewing or redesigning processes.

4.6 Management of change

4.6.1 The organization shall control planned changes and take action to mitigate any adverse effects and unintended consequences, as necessary.

4.6.2 Risks associated with any planned change, permanent or temporary, that can have an impact on achieving the management objectives shall be documented and assessed before the change is implemented. The organization shall ensure that such risks are managed.

4.6.3 Changes shall be reviewed to determine whether they achieve their planned outcomes.

4.7 Outsourcing

4.7.1 Where a service outsources work, due to unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent outsourcing, agency or franchising arrangements), this work shall be placed with a competent outsourcing contractor.

NOTE A competent outsourcing contractor is one that, for example, meets this British Standard for the work in question.

4.7.2 When the organization outsources any activities that can have an impact on the achievement of its management objectives, it shall document and assess the associated risks.

4.7.3 The organization shall ensure that outsourced services are provided under a formal contract specifying services required and all applicable standards.

4.7.4 The organization shall ensure product/service providers are appropriately certified or accredited. When no certification or accreditation is held, assurances shall be obtained through other means, i.e. inspections and audit.

4.7.5 When appropriate, the service shall advise the service user/commissioner of the arrangement and gain their approval, preferably in writing.

NOTE The service is responsible to the service user for the outsourcing contractor's work, except where the service user or a regulatory authority specifies which subcontractor is to be used.

4.7.6 The service shall maintain a register of all outsourcing contractors that it uses to deliver its services and a record of the evidence of compliance with the applicable standards for the work in question.

4.7.7 When the service outsources work, the service shall maintain in-house expertise to specify, monitor, audit and manage outsourced contracts.

4.8 Management of suppliers

4.8.1 The service shall have a policy and procedure(s) for the selection and purchase of supplies it uses that affect the quality of the healthcare scientific services. Procedures shall be in place for the purchase, reception and storage of equipment, reagents and service consumable materials relevant for the healthcare scientific services.

4.8.2 The service shall:

a) select and monitor suppliers of critical equipment, consumables and supplies which affect the quality of the healthcare scientific services, based on performance measures;

b) maintain records of actions taken to check compliance and list those approved; and

c) ensure that purchased equipment, supplies, reagents and consumable materials that affect the quality of healthcare scientific services are not used until they have been inspected or otherwise verified as conforming to standard specifications or requirements defined in the methods for the production, intervention, repair, tests or metrological confirmations concerned.

4.8.3 Purchasing documents for items affecting the quality of service output shall contain data describing the supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required, and the management system standard under which they were made.

4.9 Document control

4.9.1 General

4.9.1.1 The service shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, and production, intervention, repair, test and metrological confirmation methods, as well as drawings, software, specifications, instructions and manuals.

NOTE 1 In this context "documents" could be policy statements, procedures, instructions for use, flow charts, specifications, forms, metrological confirmation tables, biological reference intervals and their origins, charts, textbooks from which examination procedures are taken, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards, etc. These may be on various media, hard copy or electronic, and may be digital, analogue, photographic or written.

*NOTE 2 The control of data related to production, interventions, validation, testing and metrological confirmation is covered in **5.4.9**. Records contain information from a particular point in time, stating results achieved or providing evidence of activities performed, and requirements for their maintenance are specified in **4.17**.*

4.9.1.2 In addition to document control identifiers, documentation shall include, when applicable to the intervention procedure, the following:

a) purpose of the design, production or intervention;

b) principle and method of the procedure used for design, production or intervention;

c) performance characteristics;

d) type of product, equipment, supply or sample;

e) patient preparation;

f) type of sample container and additives;

g) required equipment and reagents;

h) environmental and safety controls;

i) metrological confirmation procedures (metrological traceability);

j) procedural steps;

k) quality control procedures;

l) interferences and cross reactions;

m) principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values;

n) reference intervals or clinical action thresholds;

o) reportable interval of product or intervention results;

p) instructions for determining quantitative results when a result is not within the measurement interval;

q) alert/clinical action threshold values, where appropriate;

r) service clinical interpretation;

s) potential sources of variation; and

t) references.

4.9.1.3 Specific documentation requirements shall be implemented for design and production when applied to medical devices in order to satisfy BS EN ISO 13485, good manufacturing practice and, where appropriate, the Medical Device Directive [2]/Medical Devices Regulations 2002 [4].

4.9.1.4 The service shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented.

4.9.2 Document approval and issue

The service shall have a documented procedure to ensure that the following conditions are met.

a) All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.

b) All documents are identified by including:

1) a title;

2) a unique identifier on each page;

3) revision number;

4) the date of the current revision;

5) page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”); and

6) authority for issue.

c) A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system is established and is readily available to preclude the use of invalid and/or obsolete documents.

d) Where the service’s document control system allows for the amendment of documents by hand, pending the reissue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is issued within a specified time period.

e) Changes to documents are identified.

f) Documents remain legible.

g) Obsolete controlled documents are dated and marked as obsolete.

h) Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.

i) At least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.

j) Authorized editions of appropriate documents are accessible at all locations where operations essential to the effective functioning of the service are performed.

k) Documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

4.9.3 Document changes

4.9.3.1 Changes to documents shall be reviewed and approved as for the original review, unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.9.3.2 Procedures shall be established which describe how changes in documents maintained in computerized systems are made and controlled.

4.10 Control of nonconforming work

4.10.1 The service provider shall have a documented policy and procedure to identify and manage nonconformities in any aspect of the healthcare scientific service.

4.10.2 The policy and procedure shall ensure that:

a) the responsibilities and authorities for handling nonconformities are designated;

b) the immediate actions to be taken are identified;

c) the extent and severity of any nonconformity are determined;

d) service activities are put on hold as necessary;

e) the clinical significance of any nonconforming service activities is considered and, where appropriate, the service user, requesting clinician and authorized individual responsible for the outcome of the service activity are informed;

f) the outcomes of any nonconforming or potentially nonconforming service activities already completed are remedied or appropriately identified, as necessary;

g) the responsibility for authorization of the resumption of service activities is defined;

h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action; and

i) feedback and learning from nonconformities are communicated to all relevant staff and service users.

4.10.3 When it is determined that nonconformities in service processes could recur or that there is doubt about the service's compliance with its own procedures, the service shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented.

NOTE Nonconforming activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument metrological confirmations, checking of consumable materials, inter-service comparisons, staff comments, reporting and certificate checking, service management reviews, and internal and external audits.

4.11 Control of unexpected findings

4.11.1 The service shall have a documented policy and procedure to identify and manage unexpected findings in any aspect of the healthcare scientific service that might require urgent action.

4.11.2 The policy and procedure shall ensure that:

a) actions to be taken in the event of unexpected findings are defined; and

b) roles and responsibilities for escalation through management structures are defined.

4.12 Service improvement

4.12.1 The service shall continually improve the effectiveness of its service delivery through the use of management reviews. These reviews shall compare the service's actual performance in its evaluation activities, corrective actions and preventive actions with its intended performance, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action plans for improvement shall be developed, documented and implemented, as appropriate. The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned.

4.12.2 Management shall ensure that the service participates in continual improvement activities that encompass relevant areas and outcomes of patient care. When the continual improvement programme identifies opportunities for improvement, management shall address them regardless of how they occur. Management shall communicate to staff service improvement plans and related goals.

4.13 Quality indicators

4.13.1 The service shall establish, in conjunction with staff and stakeholders, quality indicators to monitor and evaluate performance throughout all aspects of its activities

4.13.2 The process of monitoring quality indicators shall be planned, establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring.

4.13.3 The indicators shall be periodically reviewed to ensure their continued appropriateness.

4.13.4 The service shall, in consultation with service users, establish delivery times for each of its service activities that reflect clinical needs. The service shall periodically evaluate whether it is meeting the established performance criteria.

NOTE 1 Quality indicators to monitor non-clinical procedures, such as safety and environment, completeness of equipment and personnel records, and effectiveness of the document control system could provide valuable management insights.

*NOTE 2 The service should establish quality indicators for systematically monitoring and evaluating the service's contribution to patient care (see **5.9.1**).*

4.14 Staff engagement

Management shall encourage and support staff to make suggestions for the improvement of any aspect of the service. Suggestions shall be evaluated, implemented as appropriate, and feedback provided to the staff. Records of suggestions and action taken by management shall be maintained. Staff feedback should also be used as a part of service planning and development

4.15 Corrective action

4.15.1 The service shall take corrective action to eliminate or, where elimination is not possible, reduce the cause(s) of incidents and nonconformities in its services. Corrective actions shall be appropriate to the effects of the incidents and nonconformities encountered.

4.15.2 The service shall have a documented procedure for:

a) recording and reviewing incidents and nonconformities;

b) undertaking immediate action to mitigate effects of incidents and nonconformities;

c) evaluating the need for corrective action to ensure that incidents and nonconformities do not recur;

d) prioritizing corrective actions to ensure continuity of service;

e) determining and implementing corrective action needed;

f) recording the results of corrective action taken;

g) determining the root causes of incidents and nonconformities;

h) reviewing the impact of incidents and nonconformities on previously delivered patient services;

i) reporting incidents and nonconformities in line with local, national or legislative requirements;

j) reporting to national authorities to facilitate learning on a supra-organization basis, e.g. incidents involving medical devices and pharmaceuticals; and

k) reviewing the effectiveness of the corrective action taken.

NOTE Action taken at the time of the incident or nonconformity to mitigate its immediate effects is considered "immediate" action. Only action taken to remove the root cause of the problem that caused the incident or nonconformity is considered "corrective" action.

4.16 Preventive action

4.16.1 The service shall develop a risk management policy and procedures to support the delivery of safe, high-quality healthcare services. The service shall determine actions to prevent the causes of poor quality and unsafe healthcare services and their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

4.16.2 The service shall have a documented procedure for:

a) proactively managing risks and errors, including incident reporting and learning;

b) recording, reviewing and responding to external advice and guidance provided through professional and regulatory bodies, e.g. where risks have been identified by regulatory bodies these might require formal acknowledgement of receipt and appropriate action or removal of equipment or medicines from service;

c) reviewing service data and information to determine where potential nonconformities might arise;

d) determining the root cause(s) of potential nonconformities;

e) evaluating the need for preventive action to prevent the occurrence of nonconformities;

f) determining and implementing preventive action needed;

g) recording the results of preventive action taken; and

h) reviewing the effectiveness of the preventive action taken.

NOTE Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment (proficiency testing).

4.17 Control of information assets

4.17.1 General

4.17.1.1 The service shall have written systems for identifying and managing information assets, their integrity and associated risks, incorporating arrangements for the registration, processing, sharing, transfer and safe and secure storage of personal identifiable information conforming to guidance and legislative requirements.

NOTE These are governed by the Data Protection Act 1998 [5] as well as the National Health Service Act 2006 [6], Section 251.

4.17.1.2 The service shall:

a) establish a policy that assigns roles and responsibilities for managing information assets and defined accountabilities for each area of information management;

b) maintain procedures for the control and management of information assets

that it owns, creates or amends, such as clinical, personnel, financial, business-related information and IT systems;

c) maintain procedures for the transfer of personal identifiable data between organizations;

d) define requirements for staff training in information governance;.

e) define requirements for the security and confidentiality of information;

f) define requirements for access control to information;

g) establish periods for review of information held and the need for retention or disposal;

h) audit requirements to ensure continued conformity to the written systems; and

i) define how personal identifiable data may be shared across organizational boundaries.

NOTE Record retention times might be defined by regulations, as well as through national and local guidance.

4.17.1.3 The service shall establish a policy and maintain procedures for security, identification, collection, indexing, accessing, filing, storage, maintenance, transmission, transportation and disposal of records. Quality records shall include reports from internal audits and management reviews, as well as records of corrective and preventive actions.

4.17.1.4 All records shall be legible and shall be stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss, and retained in such a way that they are readily retrievable.

NOTE Records may be in any media, such as hard copy or electronic media.

4.17.1.5 The service shall establish and maintain systems to:

a) ensure control and audit of access to information assets;

b) ensure the safe, correct and legal (confidential) handling of information assets; and

c) provide and regularly test a service continuity/recovery plan for information assets.

4.17.1.6 The service shall have procedures to protect and back up information assets stored electronically and to prevent unauthorized access to or amendment of these assets.

4.17.2 Technical records

4.17.2.1 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.17.2.2 The service shall:

a) identify which records are to be retained;

b) establish relevant retention times; and

c) audit compliance.

4.17.2.3 Technical records shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty (see **5.4.5.4**) and to enable the measurement to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for

the measurement and checking of results. Where information is the result of computer processing details of the software and its revision shall be recorded.

NOTE 1 In certain fields it might not be possible or practical to retain records of all original observations.

NOTE 2 Technical records are accumulations of data and information which result from carrying out design, production, investigation, therapy, repair, quality assurance, tests or metrological confirmations and which indicate whether specified quality or process parameters are achieved. They can include forms, contracts, work sheets, workbooks, check sheets, work notes, control graphs, external and internal test reports, and metrological confirmation certificates, customers' notes, papers and feedback.

4.17.2.4 When mistakes occur in handwritten records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data ensuring an audit trail for changes and relevant authorizations.

4.18 Internal audits

4.18.1 The service shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to conform to current healthcare scientific practice, the requirements of the management system and this British Standard.

4.18.2 The internal audit programme shall address all elements of the service, the management system and its associated quality policies, and their impact on clinical outcomes.

4.18.3 The quality manager shall plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Input from services users, patients and the public shall be sought as appropriate.

NOTE The cycle for internal auditing should adopt a risk stratified approach, but should normally be completed in one year. It is not necessary that every area is covered to the same depth in each cycle; specific areas might require more in-depth audit in response to identified risks.

4.18.4 Audits and associated action plans and requirements shall be reported in accordance with any wider organizational governance structures.

4.18.5 The service shall audit:

a) new healthcare scientific practices for effectiveness and conformity to specification;

b) all aspects of service provision, including protocols, patient and service user information and infection control measures, to ensure they are appropriate and up to date, and that these are accessible and communicated to all relevant staff and implemented with appropriate staff training;

c) all complaints or concerns, and ensure that findings are acted upon and disseminated to relevant parties and the effectiveness of actions taken are monitored;

d) the effectiveness of the systems in place to manage biohazard risks;

e) its performance against agreed targets for the specific requirements of individual patients/service users;

f) access to its services against the database of users and potential users of the service;

g) the effectiveness of the process of receiving staff feedback;

h) the application of and compliance with the established consent policy;

i) compliance with legislative requirements; and

j) patient and public involvement.

4.18.6 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the service's design, production, investigation, therapy, repair, test or metrological confirmation activities, the service shall take timely corrective action and notify service users in writing if investigations show that the service outputs might have been affected.

4.18.7 The area of activity audited, the audit findings and the corrective actions that arise from them shall be recorded.

4.18.8 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

4.19 Management reviews

4.19.1 The service's top management shall review the service's quality management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The management review shall examine changes in the profile of risks and opportunities, and review the service's quality management system and activities to ensure their continuing suitability and effectiveness and the introduction of necessary changes or improvements.

4.19.2 The review shall take account of:

a) documentation detailing the organizational and management structure that supports the service;

b) the suitability of the management structure, ensuring there are defined roles and responsibilities for professional leadership and management;

c) the need for services to be directed by a person or people with the required competence and with delegated authority for the services provided;

d) the clarity of the arrangements for governance within the service which link to the organization's governance structure;

e) the suitability of policies and procedures;

f) the suitability of key performance indicators;

g) risk assessments and associated action plans;

h) reports from managerial and supervisory personnel;

i) mechanisms demonstrating regulatory compliance;

j) systems for managing conflicts of interest;

k) the outcome of recent internal audits;

l) corrective and preventive actions;

m) assessments and audits by external bodies;

n) the results of inter-service comparisons or proficiency tests;

o) outputs from national bodies and healthcare reporting systems;

p) new or emerging technologies;

q) changes to current or anticipated reference standards;

r) changes in the volume and the type of work;

s) service user feedback;

t) complaints;

u) recommendations for improvement; and

v) other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every twelve months.

NOTE 2 Results should feed into the service planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.19.3 Findings from the service's top management reviews and the actions that arise from them shall be recorded. The service management shall ensure that those actions are carried out within an appropriate and agreed timescale.

4.20 Assuring quality in research and development activities

4.20.1 Implementation of innovative practice

The service shall implement and monitor systems to review current and emerging clinical and scientific practice, and to implement new and innovative healthcare scientific practice, including as appropriate:

a) defined roles and responsibilities for reviewing current services and the development of new services;

b) regular audit of current healthcare science services, including review and dissemination of findings and associated action plans;

c) review of emerging healthcare science practices with implementation as appropriate; and

d) governance arrangements to support the introduction and audit of new healthcare science services.

4.20.2 Engagement in, and organization and governance of, research and development.

4.20.2.1 A service undertaking research and development shall have a system, budget and resources in place to support engagement in research and development activities.

4.20.2.2 Research and development activities shall be regularly reviewed and re-prioritized.

4.20.2.3 The service shall have in place documentation detailing the organizational and management structure that supports research and development and how it links to wider organizational governance. The service shall be directed by a person or people with competence and delegated authority for research and development activities.

4.20.2.4 The roles, responsibilities and training requirements of other members of staff with regard to research and development activities shall be defined and documented, and reviewed regularly.

NOTE The frequency of the review depends on the nature and duration of the research.

4.20.2.5 Records of staff roles and associated training for participation in research and development projects shall be maintained.

4.20.2.6 The service shall implement and monitor systems to ensure that research and development projects satisfy ethical practices, legislation, and local and national governance requirements.

4.20.2.7 The service shall maintain and regularly audit a directory of research and development activities and associated documentation, demonstrating ethical and regulatory compliance.

4.21 Assuring quality in education and training activities

*COMMENTARY ON **4.21***

In this subclause "students/learners" refers to those in education undertaking workplace experience as part of their learning, and "trainees" refers to those in employment undergoing work-based training.

4.21.1 Organization and governance of education and training activities

4.21.1.1 The service shall ensure that education and training activities are transparently governed and managed with adequate resources.

4.21.1.2 The service shall have a strategy and a plan for the delivery of education and training activities that link to national and local policy and are consistent with any relevant curricula or guidance.

4.21.1.3 There shall be a defined process for regular review of the strategy and for planning and development of education and training activities in conjunction with service top management and relevant stakeholders.

4.21.1.4 The service shall contribute to the compilation of evidence for the organization's external reporting requirements as regards education and training activities.

4.21.1.5 The service shall implement and document defined roles and responsibilities for the management and governance of work-based education and training, including regular training and appraisal.

4.21.1.6 The service shall implement and monitor systems to ensure that informed consent is obtained where trainees undertake investigations on/with patients.

4.21.1.7 The service shall implement and regularly review education and training policies to ensure consistency with health, safety and welfare and equal opportunities legislation.

4.21.1.8 The service shall implement and monitor systems for the management of risk to students/learners and trainees in the practice environment.

4.21.2 Access to education and training

4.21.2.1 The service shall implement and monitor systems to promote diversity, inclusion and equality of opportunity.

4.21.2.2 The service shall implement defined admissions criteria for entry to educational and training programmes, including evidence of reading, writing and spoken language skills.

4.21.2.3 The service shall ensure that all necessary recruitment checks are completed before trainees are admitted to the workplace.

4.21.2.4 The service shall have in place appropriate local induction programmes for trainees who are new to the workplace.

4.21.3 Quality standards for education and training activities

4.21.3.1 The service shall have in place and shall regularly review documented standards for:

a) trainees, including details of mandatory attendance requirements and professional conduct; and

b) the physical, technical and IT resources needed to support students/learners.

4.21.3.2 The service shall implement and monitor systems to ensure:

a) high-quality education and training of the current and future workforce;

b) that curricula and learning materials are student/learner-centred, patient-focused and meet the needs of employers, service commissioners, regulatory bodies and academic organizations; and

c) that all staff involved in training and education contribute to maintaining the quality of education and training, including curriculum development and delivery.

4.21.4 Supervision and progression of trainees

4.21.4.1 The service shall implement and regularly audit systems to:

a) ensure that trainees are adequately supervised while training, including provision for trainee feedback;

b) ensure that trainees and trainers have a comprehensive understanding of training programmes; and

c) manage concerns from or about trainees.

4.21.4.2 The service shall ensure that staff are adequately trained to provide supervision, assessment, feedback and training.

4.21.4.3 The service shall have systems in place to ensure that the progress of trainees is regularly and effectively reviewed.

4.21.5 Partnership in education and training

4.21.5.1 The service shall maintain a close working relationship with higher education institutions (HEIs) delivering academic components of education and training programmes.

4.21.5.2 The service shall implement and monitor systems to promote partnership and inter-professional teams working to enhance educational experience.

4.21.6 Training and workforce planning

4.21.6.1 The service shall implement and regularly review a workforce plan to determine the number of trainees required, ensure that there are sufficient numbers of appropriately qualified trainers to support trainees, including pastoral care, and examine succession planning.

4.21.6.2 The service shall put in place systems to facilitate the training and development of future trainers and assessors.

5 Technical requirements

*COMMENTARY ON CLAUSE **5***

Many factors determine the correctness and reliability of healthcare scientific activity, whether manufacture, resource management, investigation, therapy, repair, tests or metrological confirmations. The extent to which the factors contribute to the total uncertainty of the output differs considerably between (types of) tests, between healthcare scientific activities, and (types of) metrological confirmations.

5.1 General

5.1.1 The healthcare scientific service shall take account of such factors as the following in developing its operational methods and method validation, in the training and qualification of personnel, and in the selection, management and metrological confirmation of the equipment it uses:

a) staff knowledge and skills;

b) human errors;

c) facilities and environmental conditions;

d) operational methods and method validation;

e) equipment and its management;

f) measurement traceability;

g) sampling; and

h) the handling of investigation, therapy, repair, test and metrological confirmation items essential to the technical delivery of its services.

5.1.2 The service shall ensure the provision of appropriate staff training in health and safety, identification of roles and responsibilities, effectiveness reviews and access to relevant supporting services such as occupational health.

5.2 Personnel

5.2.1 The service shall ensure that people doing work under its control are supervised and competent, and work in accordance with the service's management system.

5.2.2 The service management shall ensure the competence and effectiveness of all staff. For staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

NOTE 1 In some scientific or technical areas it might be a requirement that the personnel performing certain tasks hold recognized professional qualifications or registration, supported by evidence of continuing professional development (CPD certification). The healthcare scientific service is responsible for ensuring that specified certification requirements are met. The requirements for certification might be regulatory or locally mandated, included in the standards for the specific technical field or clinical activity.

NOTE 2 The personnel responsible for the opinions and interpretation included in reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the procedure carried out, also have:

a) relevant knowledge of the technology used for the healthcare scientific service provision;

b) relevant knowledge of the selection of materials, products, etc., tested, or the way they are used or intended to be used, and of the defects or degradations which can occur during or in service;

c) knowledge of the general requirements expressed in professional guidance (see, for example, the Academy for Healthcare Science's Good Scientific Practice *at http://www.ahcs.ac.uk/2012/12/good-scientific-practice/* [5]*), legislation and standards;*

d) an understanding of the significance of deviations found with regard to the specified tests or examinations; and

e) an understanding of the significance of deviations in the normal use of the items, materials, products, etc., concerned.

5.2.3 Staff shall be subject to regular performance review and competence reassessment.

5.2.4 The management of the healthcare scientific service shall formulate the goals for the education, training and skills of the healthcare scientific service's personnel. The healthcare scientific service shall have a policy and procedures for identifying training needs and ensuring training of personnel. The training programme shall be relevant to the present and anticipated tasks of the healthcare scientific service. The effectiveness of the training actions taken shall be evaluated and recorded.

5.2.5 The management shall authorize specific personnel to perform particular types of production, investigation, therapy, repair, sampling, testing and metrological confirmation, to issue reports and metrological confirmation certificates, to give opinions and interpretations and to operate particular types of equipment. The healthcare scientific service shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills, experience and revalidation records for staff performing production, investigation, therapy, repair, testing and metrological confirmation and reporting processes, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence has been confirmed and by whom.

5.3 Facilities and environmental conditions

5.3.1 Facilities, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate efficient, safe and correct performance of healthcare scientific activities. Facilities shall be subject to a regular maintenance and audit programme.

5.3.2 Facilities shall meet the specific requirements of patients, service users, staff and public, taking note of local and national guidance and regulations, and include but not be limited to:

a) disabled access and resources;

b) support for those with limited hearing; and

c) support for those with limited sight.

5.3.3 The service shall seek regular feedback from staff, patients and service users in regard to the appropriateness of facilities and environmental conditions.

NOTE Particular attention should be given to patient and service user needs, including comfort, privacy, dignity and confidentiality.

5.3.4 The healthcare scientific service shall ensure through its governance arrangements that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement or service output including the service users' dignity or privacy. Particular care shall be taken when

[5] Last accessed 23 January 2017.

operational activities are undertaken at sites other than a permanent healthcare scientific service facility. The technical requirements for facilities and environmental conditions that can affect operational activities shall be documented.

5.3.5 The healthcare scientific service shall monitor, control and record environmental conditions, specifications, methods and procedures where they influence the quality of the service outputs or the safety of the public, staff and service users. Due attention shall be paid, for example, to biological sterility, infection risks, dust, electromagnetic disturbances, radiation, gas concentrations, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the services concerned.

5.3.6 Following documented risk assessment, services shall be stopped when the environmental conditions jeopardize public, staff or patient safety and well-being, or could affect the integrity of operational activities.

5.3.7 There shall be effective separation between neighbouring areas where there is potential for service degradation due to conflicting operational requirements. Measures shall be taken to prevent cross-contamination.

5.3.8 Systems shall be put in place to ensure appropriate hazard warnings and signage, including:

a) adequate training and resourcing of staff in the requirements for health and safety signage and personal protective equipment (PPE);

b) adequate health and safety signage; and

c) a regular health and safety signage audit.

5.3.9 Access to and use of areas affecting the quality of operational activities shall be controlled. The service provider shall determine the extent of control based on its particular circumstances, including public, staff and patient welfare. The effectiveness of access control measures shall be subject to audit.

5.4 Operation methods/procedures and validation

5.4.1 General

5.4.1.1 The service shall use appropriate methods and procedures for all operational activities and method validations within its scope.

NOTE These include infection control, sampling, handling, transport, storage and preparation of items for productions, investigations and therapies or to be tested or calibrated, and, where appropriate, an estimation of the measurement uncertainty, as well as statistical techniques for analysis of diagnostic, therapeutic interventions, test or metrological confirmation data.

5.4.1.2 The service shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for production, investigations and therapies, repairs, testing or metrological confirmation, where the absence of such instructions could jeopardize the results of the outputs. All instructions, standards, manuals and reference data relevant to the work of the service shall be kept up to date and shall be made readily available to personnel. Deviation from design, production, investigation, therapeutic intervention, test and metrological confirmation methods and procedures shall be permitted only if the deviation is documented, technically justified, authorized and accepted by the service user where appropriate.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the productions, investigations, therapies, tests or metrological confirmations do not need to be supplemented or rewritten as internal procedures if these standards are written such that they can be used as published by the staff in a service. It might be necessary to provide additional documentation for optional steps in the method or additional details.

5.4.2 Selection of methods and procedures

5.4.2.1 The service shall select methods and procedures which have been validated for their intended use. The identity of people performing activities in production or intervention processes shall be recorded.

NOTE Preferred procedures are those specified in the instructions for use of medical devices or those that have been published by the equipment manufacturer in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations.

5.4.2.2 The service shall deliver healthcare scientific services using methods which:

a) have been agreed and developed in conjunction with the service commissioner; and

b) meet the needs of the service user and are appropriate for the services it undertakes.

NOTE Methods published in international, regional or national standards should preferably be used. The service should ensure that it uses the latest valid edition of a standard, guidance document or code of practice, unless it is not appropriate or possible to do so. When necessary, the standard, guidance document or code of practice should be supplemented with additional details to ensure consistent application.

5.4.2.3 When the service user/commissioner does not specify the method or procedure to be used, the service shall select appropriate methods and procedures that have been published either in international, regional or national standards, or by reputable technical and professional organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.

NOTE Service-developed methods and procedures or those adopted by the service can also be used if they are appropriate for the intended use and if they are validated.

5.4.2.4 The service shall confirm that it can properly operate standard methods and procedures before introducing a production, investigation, therapeutic intervention, repair, test or metrological confirmation. If the standard method or procedure changes, the confirmation shall be repeated. The service shall inform the service commissioner when a method or procedure proposed by the service commissioner is considered to be inappropriate or out of date.

5.4.2.5 The service shall proactively review, evaluate and implement emerging new methods. New methods shall be evidence-based and subject to validation against specification and planned outcomes.

5.4.3 Service-implemented methods and procedures

5.4.3.1 The introduction of new operational activities and validation methods shall be planned and shall be assigned to qualified personnel equipped with adequate resources.

5.4.3.2 Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

5.4.4 Non-standard methods and procedures

When it is necessary to use non-standard methods and procedures, these shall be discussed and agreed with the service user prior to implementation. These methods and procedures shall be validated appropriately before use. The procedures shall contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the process or procedure;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including:

   1) affixing of identification marks, handling, transporting, storing and preparation of items;

   2) checks to be made before the work is started;

   3) checks that the equipment is working properly and, where required, metrological confirmation and adjustment of the equipment is made before each use;

   4) the method of recording the observations and results; and

   5) any safety measures to be observed;

i) criteria and/or requirements for approval/rejection;

j) data to be recorded and method of analysis and presentation; and

k) the uncertainty or the procedure for estimating uncertainty.

5.4.5 Validation of methods and procedures

5.4.5.1 Validation of a method or procedure shall include an evaluation of clinical impact and efficacy.

5.4.5.2 The service shall validate non-standard methods and procedures, service-designed/developed methods and procedures, standard methods and procedures used outside their intended scope, and amplifications and modifications of standard methods and procedures to confirm that these are fit for their intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The service shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

5.4.5.3 The service shall document the procedure used for the validation and record the results obtained. Staff with the necessary authority shall review the validation results and record the review.

NOTE 1 Validation may include procedures for infection control, radiation safety, sampling, handling and transportation, as well as clinical measurements and interventions.

NOTE 2 The techniques used for the determination of the performance of a method should be one, or a combination, of the following:

a) metrological confirmation using reference standards or reference materials;

b) comparison of results achieved with other methods;

c) inter-service comparisons;

d) radiation risk assessment;

e) systematic assessment of the factors influencing the result;

f) audit of clinical outcomes; and

g) assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When changes are made in the validated non-standard methods and procedures, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

NOTE 4 Patient, public and staff risk mitigation methods should be regularly reviewed.

5.4.5.4 The range and accuracy of the values obtainable from validated methods and procedures (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the sample/test object), as assessed for the intended use, shall be relevant to the service commissioner's and clinical need.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that service commissioners' and clinical needs are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 The service shall have, and shall apply, procedures for estimating uncertainty of measurement for metrological confirmations, clinical measurements and results. Where the nature of a test method precludes rigorous, metrologically and statistically valid calculation of uncertainty of measurement, the service shall:

a) at least attempt to identify all the components of uncertainty and make a reasonable estimation, based on knowledge of the performance of the method and on the measurement scope, and making use of, for example, previous experience and validation data; and

b) ensure that the form of reporting of the result does not give a wrong impression of the uncertainty.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on such factors as:

1) the requirements of the method;

2) the requirements of the clinical service and service commissioner; and

3) the existence of narrow limits on which decisions on conformity to a specification are based.

NOTE 2 In those cases where a well-recognized method specifies limits to the values of the major sources of uncertainty of measurement and the form of presentation of calculated results, the service is considered to have satisfied this clause by following the method and reporting instructions.

NOTE 3 Information on estimating uncertainty is given in UKAS publication, M3003, The Expression of Uncertainty and Confidence in Measurement*, available at: https://www.ukas.com/download/publications/publications-relating-to-laboratory-accreditation/M3003_Ed3_final.pdf* [6]*.*

5.4.6.2 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account, using appropriate methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used; the methods and equipment used; environmental conditions, properties and condition of the item being investigated, tested or calibrated; and the operator and reporter.

NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see BS ISO 5725 and ISO/IEC Guide 98-3.

5.4.7 Measurement uncertainty of measured quantity values

5.4.7.1 The service shall determine measurement uncertainty for each measurement procedure used to derive measured quantity values on equipment, supplies, patients or samples. The service shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.

NOTE 1 The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the equipment, supplies, patient or sample to the measurement procedure and ending with the output of the measured value.

NOTE 2 Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent and calibrator batches, different operators, scheduled instrument maintenance. See also UKAS publication, M3003, The Expression of Uncertainty and Confidence in Measurement*, available at: https://www.ukas.com/download/publications/publications-relating-to-laboratory-accreditation/M3003_Ed3_final.pdf* [6]*.*

NOTE 3 Examples of the practical utility of measurement uncertainty estimates might include confirmation that output values meet quality goals set by the service, and meaningful comparison of a value with a previous value of the same type or with a clinical action threshold or normal range.

5.4.7.2 The service shall consider measurement uncertainty when interpreting measured quantity values. Upon request, the service shall make its estimates of measurement uncertainty available to service users.

5.4.7.3 Where products, interventions or repairs include a measurement step but do not report a measured quantity value, the service should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the product or intervention or has influence on the product or reported output.

[6] Last accessed 23 January 2017.

5.4.8 Reference intervals and clinical action thresholds

5.4.8.1 Where relevant, the service shall define the reference intervals or clinical action thresholds relevant to each service activity, document the basis for the reference intervals or action threshold, and communicate this information to users.

5.4.8.2 When a particular reference interval or action threshold is no longer relevant, appropriate changes shall be made and communicated to the service users.

5.4.8.3 When the service changes a procedure or activity, the service shall review associated reference intervals and clinical action thresholds, as applicable.

5.4.9 Control of data

5.4.9.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.9.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of production, investigations, therapies, repairs, test or metrological confirmation data, the service shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use and, where the software falls within the definition of a medical device as detailed in the Medical Devices Regulations 2002 [4], meets the appropriate requirements;

b) where commercial software is used in conjunction with clinical systems the interoperability of software is documented and validated;

c) procedures are established and implemented for protecting the data, including but not limited to the integrity and confidentiality of data entry or collection, data storage, data transportation, data destruction, data transmission and data processing, business continuity and data recovery;

d) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of production, investigation, therapy, repair, test and metrological confirmation data; and

e) there is a named system administrator to maintain system integrity, add new users, delete old users and deal appropriately with requests for data.

NOTE 1 Commercial off-the-shelf software (e.g. word processing, database and statistical programmes) in general use within its designed application range may be considered to be sufficiently validated.

*NOTE 2 See **4.17** for requirements for the management of information assets and personal identifiable information.*

5.4.10 Verification of production or intervention procedures

5.4.10.1 Product verification methods or intervention procedures used without modification shall be subject to independent verification by the service before being introduced into routine use.

5.4.10.2 Any decision to adopt a process validation or end product verification shall be clearly justified and documented. A process validation plan shall include:

a) the rationale for process validation;

b) protocol development;

c) installation qualification;

d) operational qualification;

e) performance qualification;

f) protocol results; and

g) a final report.

5.4.10.3 The service shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the product or intervention.

5.4.10.4 The independent verification by the service shall confirm, through obtaining objective evidence (in the form of performance characteristics), that the performance claims for the product or intervention have been met.

5.4.10.5 The performance claims for the product or intervention procedure confirmed during the verification process shall be those relevant to the intended use of the product or intervention.

5.5 Equipment

*COMMENTARY ON **5.5***

Healthcare science services use a wide range of equipment that is material to the delivery of its services. This subclause outlines the requirements for equipment management where its operational and functional integrity might have an impact on the patient and clinical outcomes relevant to the healthcare science service.

Within healthcare an item of equipment, its integrated control software or stand-alone analysis software might or might not be designated as a "medical device". This designation is usually defined by regulation. The designation of a medical device is dependent on the use of the device or software and may be subject to enhanced management and maintenance requirements.

In the UK/EU this is regulated through the Medical Device Directive [2]. Further guidance can be found in Managing Medical Devices *(2015) published by the MHRA [7]. (See also WHO definitions.)*

5.5.1 Medical device management

5.5.1.1 The service shall ensure that equipment used for diagnostic and therapeutic purposes meets regulatory requirements (see Medical Devices Regulations 2002 [4]).

5.5.1.2 The service shall ensure that systems containing medical devices are installed, commissioned and operated in accordance with applicable standards, such as BS EN 80001-1.

NOTE The development of systems and IT networks that contain medical devices are deemed to have become a medical device.

5.5.1.3 The service shall retain control of all items of production, investigation, treatment, sampling, measurement and test equipment required for the correct performance of the production, therapies, investigations, tests, repairs and metrological confirmations (including sampling, preparation of test and metrological confirmation items, processing and analysis of product, investigation, test and metrological confirmation data). In those cases where the service needs to use equipment outside its permanent control, it shall ensure that the requirements of this British Standard are met.

5.5.1.4 The service shall ensure that equipment is appropriate for patients and service users, especially those with particular needs.

5.5.1.5 Procedures shall be established to ensure that equipment upgrading and replacement is planned in accordance with the strategic and commercial needs of the organization, and national and international guidelines

5.5.1.6 Systems shall be put in place to ensure that health and safety and personal protective equipment are available, and are maintained and used appropriately, with:

a) regular reviews of the adequacy of the service's health and safety arrangements linked to incidents and best practice;

b) regular audits of compliance with the health and safety policy and processes;

c) a health and safety and personal protective equipment training plan; and

d) documented policy/processes for the management of health and safety and personal protective equipment.

5.5.1.7 The service shall ensure that equipment and its environment are appropriately decontaminated to minimize risks of infection and harm to public and staff.

5.5.1.8 Equipment and software shall be capable of achieving the accuracy required and shall conform to specifications relevant to the production, treatment, investigations, tests and/or metrological confirmations concerned.

5.5.1.9 Metrological confirmation programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the outputs. Before being placed into service, equipment (including that used for production, investigations, treatment and sampling) shall be calibrated or checked to establish that it meets the service specification requirements and conforms to the relevant standard specifications (see **5.6**).

5.5.1.10 Each item of equipment and software used for production, investigation, therapy, repair, testing and metrological confirmation and significant to the result shall be identifiable and traceable.

5.5.1.11 Records shall be maintained of each item of equipment and its software significant to the production, investigation, therapy, repairs, tests and/or metrological confirmations performed. The records shall include at least the following:

a) the identity of the item of equipment and its software;

b) the manufacturer's name, type identification and serial number or other unique identification;

c) checks that equipment conforms to the specification;

d) the current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all quality assurance, quality control, preventive maintenance, metrological confirmations, adjustments, acceptance criteria, and the due date of next metrological confirmation and/or preventive maintenance;

g) the maintenance plan, where appropriate, and maintenance carried out to date;

h) any damage, malfunction, modification or repair to the equipment; and

i) details of any manufacturer-initiated safety warnings and corrective action undertaken.

5.5.1.12 The service shall have procedures for safe handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration.

NOTE Additional procedures might be necessary when measuring equipment is used outside the permanent service for tests, metrological confirmations or sampling.

5.5.1.13 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall:

a) be taken out of service; and

b) be isolated to prevent its use, or clearly labelled or marked as being out of service until it has been inspected and, if necessary, repaired and shown by metrological confirmation or test to perform correctly.

5.5.1.14 The service shall examine the effect of the defect or departure from specified limits on previous tests and/or metrological confirmations, and shall institute the procedure specified in **4.10**.

5.5.1.15 Whenever practicable, all equipment under the control of the service and requiring metrological confirmation or routine maintenance shall be labelled, coded or otherwise identified to indicate the status of metrological confirmation or routine maintenance, including the date when last calibrated and the date or expiration criteria when further metrological confirmation or maintenance is due.

5.5.1.16 When, for whatever reason, equipment goes outside the direct control of the service, the service shall have clear handover and return procedures, and shall ensure that the function and metrological confirmation status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.1.17 When intermediate checks are needed to maintain confidence in the metrological confirmation status of the equipment, these checks shall be carried out according to a defined procedure.

5.5.1.18 Where metrological confirmations give rise to a set of correction factors, the service shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.

5.5.1.19 Production, investigation, therapy, repair, test and metrological confirmation equipment, including both hardware and software, shall be safeguarded from modifications which would invalidate the test and/or metrological confirmation results.

5.6 Measurement traceability

5.6.1 General

All equipment, including software used to provide the service, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the results, shall be calibrated and verified before being put into service. The service shall have an established programme and procedure for the acceptance testing and metrological confirmation of its equipment, including software.

NOTE Such a programme should include a system for selecting, using, validating, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring, investigation and test equipment used to perform investigations, treatments, tests and metrological confirmations.

5.6.2 Metrological confirmation

5.6.2.1 A programme for metrological confirmation of equipment shall be designed and operated so as to ensure that metrological confirmations and measurements made by the service are traceable to the International System of Units (SI) (Système international d'unités).

NOTE 1 A service establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of metrological confirmations or comparisons linking them to relevant primary standards of the SI units of measurement.

NOTE 2 The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

5.6.2.2 When using external metrological confirmation services, traceability of measurement shall be assured by the use of metrological confirmation services from laboratories that can demonstrate competence, measurement capability and traceability. The metrological confirmation certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

NOTE 1 Metrological confirmation laboratories fulfilling the requirements of this British Standard are considered to be competent. A metrological confirmation certificate bearing an accreditation body logo from a service accredited to this British Standard for the metrological confirmation concerned is sufficient evidence of traceability of the metrological confirmation data reported.

NOTE 2 Traceability to SI units of measurement can either be achieved by reference to an appropriate primary standard or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) [7] *and the International Committee for Weights and Measures (CIPM)* [8]*.*

NOTE 3 Metrological confirmation laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term "identified metrological specification" means that it needs to be clear from the metrological confirmation certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the service is located.

NOTE 7 If a metrological confirmation service wishes or needs to obtain traceability from a national metrology institute other than in its own country, this service should select a national metrology institute that actively participates in the activities of BIPM (Bureau International des Poids et Mesures) either directly or through regional groups.

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[7] http://www.bipm.org/en/worldwide-metrology/cgpm/ (last accessed 23 January 2017).
[8] http://www.bipm.org/en/committees/cipm/ (last accessed 23 January 2017).

NOTE 8 The unbroken chain of metrological confirmations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

5.6.2.3 Where production and treatment specifications, measurements and metrological confirmations currently cannot be made strictly in SI units, the service shall provide confidence in outputs by establishing compliance to appropriate standards such as:

a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned, such as professional codes of practice; and

c) participation in a suitable programme of inter-service comparisons.

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

5.6.3.1.1 The service shall have a programme and procedure for the metrological confirmation of its standards traceable to primary standards.

5.6.3.1.2 Reference standards of measurement held by the service shall be used for metrological confirmation only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

*NOTE Reference standards should be calibrated before and after any adjustment by a body that can provide traceability as described in **5.6.2**.*

5.6.3.2 Reference equipment and materials

Reference equipment and materials shall, where possible, be traceable to SI units of measurement, or to certified reference equipment or materials. Internal reference equipment or materials shall be checked as far as is technically and economically practicable.

5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the metrological confirmation status of reference, transfer or working standards and reference equipment and materials shall be carried out according to defined procedures and schedules.

5.6.3.4 Transport and storage

The service shall have procedures for safe handling, transport, storage and use of reference standards and reference equipment and materials in order to prevent contamination or deterioration and in order to protect their integrity.

NOTE Additional procedures might be necessary when reference standards and reference equipment and materials are used outside the permanent service base for investigations, tests, metrological confirmations or sampling.

5.7 Sampling

5.7.1 Where the service carries out sampling of substances, materials or products, investigation reports and therapeutic procedures for subsequent testing, metrological confirmation or validation, it shall have a sampling plan and procedures for this. The sampling plan and the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test, metrological confirmation and validation results.

NOTE 1 Sampling may also be required by the appropriate specification for which the substance, material, product or output is to be tested, calibrated or validated. In certain cases, the sample might not be representative but is determined by availability. Guidance on the selection of a sampling system, scheme or plan is given in BS 6000-1.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material, product, reports and clinical outcomes to yield the required information.

5.7.2 Where the service requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test, metrological confirmation and/or validation results, and shall be communicated to the appropriate personnel.

5.7.3 The service shall have procedures for recording relevant data and operations relating to sampling that forms part of the production, investigation, therapy, testing, metrological confirmation or validation that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.8 Handling of production, investigation, therapy, repair, test and metrological confirmation items

*COMMENTARY ON **5.8***

The term "item" is used in this subclause to refer to any instrument, device, chemical or related object that is vital to the provision of a particular service or activity.

5.8.1 The service shall have procedures in place to define, assess and manage risks associated with the transportation, receipt, handling, protection, storage, retention and/or disposal of production, investigation, therapy, repair, test and metrological confirmation items, including the provisions necessary to protect the integrity of the production, investigation, therapy, repair, test or metrological confirmation item, and to protect the interests of the service and the service user.

5.8.2 The service shall have a system for identifying production, investigation, therapy, repair, test and metrological confirmation items. The identification shall be retained throughout the life of the item in the service. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the service.

5.8.3 The service shall have documented procedures for the proper collection/measurement and handling of equipment, supplies or primary data or clinical samples.

5.8.4 The documented procedures shall be available to those responsible for equipment, supplies or primary data or clinical sample collection/measurement, whether or not the collectors are service personnel.

5.8.5 Where the user requires deviations and exclusions from, or additions to, the documented collection/measurement procedure, these shall be recorded and included in all documents containing service outputs or intervention results and communicated to the appropriate personnel.

NOTE 1 All procedures carried out on a patient need the informed consent of the patient. Procedures might be subject to local, national and legislative requirements.

NOTE 2 Adequate privacy during reception and clinical intervention should be available and appropriate to the type of information being requested and the clinical intervention, including manipulation of equipment within clinical areas.

5.8.6 Upon receipt of the production, investigation, therapy, repair, test or metrological confirmation item, abnormalities or departures from normal or specified conditions, as described in the production, investigation, therapy, repair, test or metrological confirmation method, shall be recorded. When there is doubt as to the suitability of an item for production, investigation, therapy, repair, test or metrological confirmation, or when an item does not conform to the description provided, or the test or metrological confirmation required is not specified in sufficient detail, the service shall consult the service user for further instructions before proceeding and shall record the discussion.

5.8.7 The service shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the production, investigation, therapy, repair, test or metrological confirmation item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a production, investigation, therapy, repair, test or metrological confirmation item or a portion of an item is to be held secure, the service shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

NOTE 1 Where production, investigation, therapy, repair, test or metrological confirmation items are to be returned into service after testing, special care is required to ensure that they are not damaged during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on the storage and transport of samples, including information on sampling factors influencing the production, investigation, therapy, repair, test or metrological confirmation result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Keeping a production, investigation, therapy, repair, test or metrological confirmation item secure can be for reasons of record, safety or value, or to enable complementary tests and/or metrological confirmations to be performed later.

5.9 Controlling the quality of healthcare scientific service outputs

5.9.1 The service shall have quality control procedures for monitoring the validity of designs, products, diagnostic and therapeutic interventions, repairs, tests and metrological confirmations undertaken, and for evaluating the impact of each aspect of the healthcare scientific service on clinical outcomes through audit and evaluation. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed, and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in inter-service comparison or proficiency-testing programmes, including peer review;

c) replicate tests or metrological confirmations using the same or different methods;

d) retesting or further metrological confirmation of retained items;

e) correlation of results for different characteristics of an item; and

f) feedback from service users, patients and the public.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

5.9.2 Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent services being undertaken or incorrect products and repairs from release and results from interventions being reported.

5.10 Service processes

5.10.1 General

5.10.1.1 The service shall have documented procedures and information for its activities to ensure the validity of its services.

5.10.1.2 Systems shall be put in place to manage adverse healthcare events, under which the service:

a) documents all healthcare incidents and near misses;

b) effectively investigates and reports adverse healthcare events; and

c) benchmarks its performance against other similar services implementing a learning strategy.

5.10.2 Information for patients and service users

5.10.2.1 The service shall have information available for patients and service users. The information shall include as appropriate:

a) the location of the service;

b) the types of services offered, including those referred to other providers;

c) the opening hours of the service;

d) the interventions offered by the service, including as appropriate information concerning patient and equipment preparation;

e) required special precautions, turnaround time (which may also be provided in general categories or for groups of interventions), normal ranges, and clinical action thresholds and information;

f) an explanation to service users of the implications of any decision to change an existing procedure such that outputs or their interpretations could be significantly different after validating the procedure;

NOTE This requirement can be satisfied in different ways, depending on local circumstances. Some methods include directed mailings, service newsletters or part of the examination report itself.

g) instructions for:

1) completion of a service request form, whether written or electronic;

2) collection of equipment, products, samples and data, including:

i) identifying the service user from whom equipment or product is collected or to whom it is delivered, or the patient from whom a primary sample/data is collected;

ii) recording the identity of the person collecting equipment, product or primary data or sample and the collection date, and, when needed, the collection time;

iii) special timing of clinical interventions, where needed;

iv) type and amount of any primary sample to be collected, with descriptions of the primary sample containers and any necessary additives; and

v) instructions for proper storage conditions before or after equipment, product, data or collected samples are delivered to or received from the service;

vi) safe disposal of materials used in the packaging of equipment, product or samples

3) requirements for the patient to meet pre-intervention requirements, e.g. fasting status, medication status (time of last dose, cessation), including special timing of clinical interventions where needed;

4) instructions for labelling equipment, product, data or samples in a manner that provides an unequivocal link with the supplier or patients from whom they are collected

5) transportation of clinical samples and equipment, including any special handling needs;

6) patient preparation requirements prior to attendance; and

7) the safe and effective use of equipment provided by the service to patients or service users;

h) any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);

i) the service's criteria for accepting and rejecting service requests;

j) a list of factors known to significantly affect the performance of the design, product, diagnostic or therapeutic procedure, test or metrological confirmation, or the interpretation of the results;

k) availability of clinical scientific advice on ordering of services and on interpretation of service results outputs;

l) the service's policy on protection of personal information; and

m) the service's feedback process.

5.10.2.2 The service shall have sufficient information available for patients and service users explaining any clinical procedure to be performed to enable informed consent to be obtained.

5.10.3 Service request form information

5.10.3.1 The service provider shall have a documented procedure for verbal requests for services that includes providing confirmation by request form or electronic equivalent within a given time.

5.10.3.2 The service request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:

a) where relevant, patient identification, including name, gender, date of birth, address/location/contact details, and a unique identifier;

NOTE 1 Unique identification includes an alpha and/or numerical identifier, such as a hospital number, or personal health number or service-provided reference number.

b) where relevant, equipment unique identifier, location/contact details, patient details where equipment fails in use;

c) name or other unique identifier of clinician, healthcare provider or other

person legally authorized to request examinations and services or use medical information, together with the destination for the service output and contact details;

d) relevant clinical information necessary to justify service request; and

e) details of equipment, product, diagnostic or therapeutic intervention, repair, test or metrological confirmation requested.

NOTE 2 The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the service should be determined in discussion with the service users.

NOTE 3 The request form might be subject to local, national and legislative requirements.

5.10.3.3 The service shall cooperate as necessary with service users or their representatives in clarifying users' requests.

5.10.4 Transportation

5.10.4.1 The service's instructions for transportation activities shall include packaging of equipment, supplies, product samples or hazardous materials for transportation.

5.10.4.2 The service shall have a documented procedure for monitoring the transportation of equipment, supplies, product samples or hazardous materials to ensure they are transported:

a) within a time frame appropriate to the nature of the requested services and the service discipline concerned;

b) within a temperature interval specified for the equipment, supplies or sample collection and handling, and with the designated preservatives to ensure the integrity of equipment, supplies or samples; and

c) in a manner that ensures the integrity of the equipment, supplies or sample and the safety of the carrier, the general public and the receiving service entity, in compliance with established requirements.

*NOTE 1 A service which is not involved in primary sample collection and transportation is considered to have satisfied **5.10.4**c) when, upon receipt of equipment, supplies, a sample or hazardous materials whose integrity was compromised or which could have jeopardized the safety of the carrier or the general public, the sender is contacted immediately and informed about measures to be taken to eliminate recurrence.*

NOTE 2 Hazardous substances are subject to regulation through national legislation. The service requires specific arrangements to ensure compliance with legislation.

5.10.5 Equipment, product, patient, sample and data reception

The service's procedure for equipment, products, supplies, patients, sample and data reception shall ensure that the following conditions are met.

a) Equipment, products, samples or data are unequivocally traceable, by request and labelling, to an identified supplier, service user, patient or site.

b) Service-developed and documented criteria for acceptance or rejection of equipment, products, patients, samples and data are applied.

c) Where there are problems with equipment, product, service user, sample or data identification, product instability due to delay in transport or inappropriate container(s), or insufficient sample volume, and the service

chooses to proceed with the service, the final report indicates the nature of the problem and, where applicable, what caution is required when interpreting the result.

d) All equipment, product, samples or data received are recorded. The date and time of receipt and/or registration of equipment, product, samples or data are recorded. Whenever possible, the identity of the person receiving equipment, product, sample or data is also recorded.

e) Authorized personnel evaluate received equipment, product, patients, samples or data to ensure that they meet the acceptance criteria relevant for the requested service(s).

f) Where relevant, there are instructions for the receipt, labelling, processing and reporting of equipment, product, samples and data specifically marked as urgent, which include details of any special labelling of the request form and equipment, product, sample or data; the mechanism of transfer of the equipment, product, sample or data to the identified area of the service; any rapid processing mode to be used; and any special reporting criteria to be followed.

5.11 Service output management

5.11.1 Review of results

5.11.1.1 The service shall have procedures to ensure that authorized personnel review the results of productions, clinical interventions, repairs and test or metrological confirmations required for the service provision before releasing them, and evaluate them in accordance with available technical or clinical information and previous results.

5.11.1.2 Review criteria shall be established, approved and documented for reviewing designs, products, interventions, and test and metrological confirmation results.

NOTE 1 The overall purpose of all review activities is to ensure that the outputs of service activities are correct and presented accurately and clearly, and that they reach the service user in a timely and secure manner.

NOTE 2 The service has an additional responsibility to ensure that, as far as possible, the service outputs are correctly used, interpreted and applied in patients' best interests.

5.11.2 Control of unexpected findings

When products or intervention results meet established clinical action thresholds:

a) a relevant authorized health professional shall be notified immediately (this includes results received on products, equipment or samples sent to referral laboratories for examination); and

b) records shall be maintained of actions taken that document the date, time, responsible service staff member, person notified and information results conveyed, and any difficulties encountered in notifications.

5.11.3 Storage, retention and disposal of equipment, chemicals, hazardous materials, clinical waste and samples

5.11.3.1 The service shall have a documented procedure for the identification, collection, retention, indexing, access, storage, maintenance and safe disposal of equipment, chemicals, hazardous materials, clinical waste and samples.

5.11.3.2 The service shall define the length of time equipment, chemicals, hazardous materials, clinical waste and samples are to be retained. Retention time shall be defined by the nature of the equipment, chemicals, hazardous materials, clinical waste and sample, the intervention and any applicable requirements.

NOTE Legal liability concerns regarding certain types of procedures might require the retention of certain equipment, chemicals, hazardous materials, clinical waste and samples for much longer periods.

5.11.3.3 Equipment, chemicals, hazardous materials, clinical waste and samples shall be disposed of safely in accordance with local recommendations for waste management. The service shall determine whether the disposal of equipment, chemicals, hazardous materials, clinical waste and samples is covered by local or statutory regulations.

NOTE For example, the implementation and monitoring of a management system for the disposal of radioactive substances or waste electrical goods.

5.12 Surveillance

Where relevant, the service shall have documented procedures for the post-release surveillance of manufactured products and equipment.

NOTE The requirements for medical devices are defined within the Medical Device Directive [2] and for medicinal products meeting good manufacturing practice (GMP) requirements.

5.13 Reporting the results

5.13.1 General

5.13.1.1 The results of each diagnostic or therapeutic intervention, repair, test, metrological confirmation, or series of tests or metrological confirmations, carried out by the service shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the diagnostic or therapeutic intervention, repair, test or metrological confirmation methods.

5.13.1.2 The results shall be reported, usually in an intervention report or a metrological confirmation certificate, and shall include all the information requested by the service user and necessary for the interpretation of the diagnostic or therapeutic intervention, repair, test or metrological confirmation results and all information required by the method used.

NOTE 1 Test reports and metrological confirmation certificates are sometimes called "test certificates" and "metrological confirmation reports", respectively.

NOTE 2 The test reports or metrological confirmation certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this British Standard are met.

NOTE 3 In the case of diagnostic or therapeutic intervention, repair, tests or metrological confirmations performed for internal service users, or in the case of a written agreement with the service users, the results may be reported in a simplified way.

5.13.1.3 Any relevant available information which is not reported to the service users shall be readily available in the service which carried out the diagnostic or therapeutic intervention, repair, tests or metrological confirmations.

5.13.2 Diagnostic or therapeutic intervention, repair, test reports and metrological confirmation certificates

5.13.2.1 Each diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate shall include at least the following information, unless the service has valid reasons for not doing so:

a) a title (e.g. "Test Report" or "Metrological Confirmation Certificate");

b) the name and address of the service, and the location where the diagnostic or therapeutic intervention, repair, tests or metrological confirmations were carried out, if different from the address of the service;

c) unique identification of the diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate (such as the serial number), and on each page an identification to ensure that the page is recognized as a part of the diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate, and a clear identification of the end of the diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate;

d) the name and address of the service requester;

e) identification of the method used, where applicable;

f) a description of the condition of, and unambiguous identification of, item(s) repaired, tested or calibrated;

g) the date(s) of performance of the intervention, repair, test or metrological confirmation;

h) the diagnostic or therapeutic intervention, repair, test or metrological confirmation results with, where appropriate, the units of measurement;

i) the name(s), function(s) and signature(s) or equivalent identification of the person(s) authorizing the diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate; and

j) where relevant, a statement to the effect that the results relate only to the diagnostic or therapeutic intervention, repair, and items tested or calibrated.

NOTE 1 Hard copies of diagnostic or therapeutic intervention, repair, test reports and metrological confirmation certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that the service includes a statement specifying that the diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate is not to be reproduced, except in full, without written approval of the service.

5.13.2.2 Where metrological confirmations are performed by external parties, those parties shall be required to demonstrate their competence in accordance with BS EN ISO/IEC 17025.

5.13.3 Diagnostic or therapeutic intervention, repair and test reports

In addition to the requirements of **5.13.2**, diagnostic or therapeutic intervention, repair or test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to or exclusions from the diagnostic or therapeutic intervention, repair or test method, and information on specific diagnostic or therapeutic intervention, repair or test conditions, such as environmental conditions;

b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

c) where applicable, a statement on the estimated uncertainty of measurement;

NOTE Information on uncertainty is needed in diagnostic or therapeutic intervention, repair or test reports when it is relevant to the validity or application of the results, when a service user so requires, or when the uncertainty affects compliance with a specification limit.

d) where appropriate and needed, opinions and interpretations (see **5.13.5**);

e) any additional information required by specific methods, service users or groups of service users; and

f) recommendations of additional investigations.

5.13.4 Production and metrological confirmation certificates

5.13.4.1 In addition to the requirements of **5.13.2**, production and metrological confirmation certificates shall include the following, where necessary for the interpretation of metrological confirmation results:

a) the conditions (e.g. environmental) under which the products or metrological confirmations were made that have an influence on the measurement results;

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof; and

c) evidence that the measurements are traceable.

NOTE Traceability to SI units of measurement can either be achieved by reference to an appropriate primary standard or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

5.13.4.2 The production or metrological confirmation certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

5.13.4.3 When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the service shall record those results and maintain them for possible future reference.

5.13.4.4 When statements of compliance are made, the uncertainty of measurement shall be taken into account.

5.13.4.5 When an instrument for metrological confirmation has been adjusted or repaired, the metrological confirmation results before and after adjustment or repair, if available, shall be reported.

5.13.4.6 A production or metrological confirmation certificate (or metrological confirmation label) shall not contain any recommendation on the metrological confirmation interval except where this has been agreed with the service user.

5.13.5 Professional advice, opinions and interpretations

When professional advice, opinions and interpretations are included in a report, the service shall document the basis upon which the advice, opinions and interpretations have been made. Advice, opinions and interpretations shall be clearly marked as such in a test report.

NOTE 1 Advice, opinions and interpretations included in a report may comprise, but not be limited to, the following:

- *an opinion on the statement of compliance/noncompliance of the results with requirements;*
- *fulfilment of contractual requirements;*
- *recommendations on how to use the results; and*
- *guidance to be used for improvements.*

NOTE 2 Where it is appropriate to communicate the advice, opinions and interpretations by direct dialogue with the service user, this dialogue should be written down.

5.13.6 Testing and metrological confirmation results obtained from outsourcing contractors

5.13.6.1 When the test report contains results of tests performed by outsourcing contractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.

5.13.6.2 When a metrological confirmation has been outsourced, the contractor performing the work shall issue the metrological confirmation certificate to the service.

5.13.7 Electronic transmission of results

In the case of transmission of test or metrological confirmation results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of **5.4.9** shall be met.

5.13.8 Format of reports and certificates

The format of a report or certificate shall be designed to accommodate each type of production, diagnostic or therapeutic intervention, repair, test or metrological confirmation carried out, and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the layout of the production, diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate, especially with regard to the presentation of the test or metrological confirmation data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

5.13.9 Amendments to a production, diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate

5.13.9.1 Material amendments to a production, diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate after issue shall be made only in the form of a further document, or data transfer, which includes the following statement or an equivalent form of wording:

"Supplement to production, diagnostic or therapeutic intervention, repair, test report [or metrological confirmation certificate], serial number ... [or as otherwise identified]."

5.13.9.2 When it is necessary to issue a complete new production, diagnostic or therapeutic intervention, repair, test report or metrological confirmation certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Annex A (informative) Medical physics, clinical engineering and associated science services in healthcare

A.1 Introduction

Healthcare science services implement the concepts, theories and methods of science engineering and technology to support and deliver the diagnosis and treatment of patients. This falls within a number of broad themes that include, but are not limited to: measurement of physiological function; radiation therapies and diagnostics; scientific, computing and informatics; clinical measurement; imaging science; equipment management; rehabilitation engineering; regulatory compliance; image and dose optimization; education and training; and research and innovation. They are organized into a number of disciplines and sub-disciplines that deliver aspects of these general functional themes. These disciplines and sub-disciplines have organizational, departmental or service names that are described in **A.2** to **A.20** (the list is not exhaustive), based on the infrastructure and needs of the area they serve.

Disciplines and sub-disciplines evolve with time and new ones are developed following innovation and technological evolution, as well as the introduction of new medical techniques.

A.2 Radiotherapy

Healthcare scientists work as part of a multidisciplinary oncology team that implements and personalizes a patient's treatment plans. They ensure that the treatment plans are safe and effective, based on their knowledge of physics and human biology. They oversee the safe application of radiation by confirming that machinery is calibrated correctly and delivering the correct dosage of radiation, and analyse the dose response effect to improve tumour control.

A.3 Diagnostic and Interventional radiology

These services deal with the testing, optimization, and quality assurance of diagnostic radiology such as radiographic X-rays, fluoroscopy, mammography, angiography and computed tomography, as well as non-ionizing radiation modalities such as ultrasound, and MRI. They are also engaged with radiation protection issues such as radiation exposure monitoring and dosimetry.

A.4 Nuclear medicine

Healthcare scientists work in a multidisciplinary team, overseeing the safe application of radioisotopes for diagnostic and therapeutic techniques. This can include the dispensing of radiopharmaceuticals and the correct operation of equipment for in vivo and in vitro tests. They also have expertise in interpreting images and in analysing data produced, as well as ensuring that any radiation dose is minimized to the lowest practicable level. They are also engaged with radiation protection issues, such as radiation exposure monitoring and dosimetry, to ensure regulatory compliance.

A.5 Radiation protection

These services are responsible for evaluating radiation safety procedures for ionizing and non-ionizing radiation, monitoring possible radiation exposure, and ensuring compliance with government regulations on radiation safety. Staff understand how radiation can affect the human body and the environment, and can determine the risk that a radiation dose brings.

A.6 Clinical scientific computing

Healthcare scientists undertake a broad range of scientific computing activities, ranging from general management and analysis of data, including the development of clinical information systems, to more mathematically-based analysis activities such as image processing and simulation. They liaise with clinical colleagues to advance the utility of data and are key to the implementation of "big data" strategies and interconnectivity.

A.7 Rehabilitation engineering

Acting independently or as part of a multidisciplinary team, these services assess needs and prescribe and provide solutions to address those needs. These may include the design, development, manufacture, adaptation, testing, evaluation, application and distribution of technological solutions to problems confronted by individuals with disabilities, and to meet the clinical, functional and social needs of individuals with long term conditions. Functional areas addressed through rehabilitation engineering may include posture, mobility, communications, hearing, vision, cognition, and activities associated with employment, independent living, education and integration into the community.

A.8 Equipment management

These services manage the life cycle of medical equipment. They ensure that equipment and systems used in patient care are effective, operational, safe, and properly configured and maintained throughout the equipment life cycle.

A.9 Clinical instrumentation

These services lead in the design and development of new instruments and techniques, as well as contribute to their clinical use and routine preventive and corrective maintenance.

A.10 Audiology

These services measure and evaluate people's hearing and balance, fitting and adjusting aids, and offering therapeutic techniques to improve the quality of people's lives. Scientists in this field work with children or adults, as well as special needs groups, and are involved in the delivery of long-term treatment, management and care.

A.11 Cardiac sciences

These services measure and analyse the mechanical and electrical function of the heart, using ultrasound techniques and exercise stress testing. Other services include the implantation, programming, monitoring and long-term follow-up of devices such as pacemakers.

A.12 Clinical perfusion science

These services are part of the open-heart surgery team/service. They control and manage heart-lung machines and other equipment used to support patients during major operations. Their skills can also be used in critical care units, for example during heart or respiratory failure.

A.13 Critical care science

These services ensure complex equipment used for life support, diagnosis and monitoring of critically ill patients is set up and used correctly. Staff work alongside doctors and nurses as part of a multidisciplinary team to support the management and care of critically ill patients.

A.14 Gastrointestinal physiology

These services contribute to the diagnosis of abnormal function and disease of the gastrointestinal tract. This can include swallowing disorders and gastro-oesophageal reflux, as well as disorders of the gut. Services can provide therapeutic techniques which help patients improve muscle tone in the digestive system.

A.15 Neurophysiology

These services diagnose and monitor conditions of the central and peripheral nervous system in a wide range of patients, including those in critical care and during surgery. Investigations include EEG (electroencephalography) for measuring brain activity, EMG (electromyolography) and NCS (nerve conduction studies) for the study of nerves and muscles and evoked potentials to measure the response of the brain to specific stimuli.

A.16 Ophthalmic and vision science

These services study disorders of vision and diseases of the eye and visual pathway. They measure the field of vision, looking at pressure in the eye and the small electrical signals by which visual information is transmitted, and taking images of the eye. They can engage in specifying lenses for cataract surgery, as well as electrophysiological investigation of the eye and visual pathway. These support the treatment of conditions such as glaucoma, cataracts and diabetic retinopathy.

A.17 Respiratory physiology

These services work with patients who have lung, airway or blood oxygenation problems to understand causes and the response to treatment. Tests can take place at rest or during exercise, using a variety or technologies and skills. Staff can also be involved in the delivery of long-term treatment and care.

A.18 Sleep physiology

These services monitor patients who have problems with poor sleep quality. They help identify problems which require treatment and long-term management, such as sleep apnoea. These services use many of the techniques used by respiratory physiologists.

A.19 Urodynamics

These services use equipment to record pressures, urine flows and muscle activity to diagnose abnormal function and help plan and monitor treatments.

A.20 Vascular science

These services use ultrasound and other non-invasive forms of blood-flow analysis to identify and measure disease and guide treatment. The services are widely employed in such disease entities as transient ischaemic attack, stroke, aneurysm, deep vein thrombosis and varicose veins.

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