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BSI Standards Publication

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

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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 proficiency³⁾ and the AHCS Good Scientific Practice⁴⁾.

- 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 from unauthorized changes and undue deterioration.

³⁾ Available at: <http://www.hpc-uk.org/aboutregistration/standards/standardsofproficiency/> (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;