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Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence

Reference number
ISO 15189:2012(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15189 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This third edition cancels and replaces the second edition (ISO 15189:2007), which has been technically revised.

A correlation between the second and third editions of this International Standard is provided as Annex B. The third edition continues the alignment established in ISO/IEC 17025:2005.

This corrected version of ISO 15189:2012 includes various editorial corrections.

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Introduction

This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies requirements for competence and quality that are particular to medical laboratories[1]. It is acknowledged that a country could have its own specific regulations or requirements applicable to some or all its professional personnel and their activities and responsibilities in this domain.

Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Whenever allowed by national, regional or local regulations and requirements, it is desirable that medical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each laboratory should also provide suitable educational and scientific opportunities for professional staff working with it.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it useful and appropriate. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. If a laboratory seeks accreditation, it should select an accrediting body which operates in accordance with ISO/IEC 17011 and which takes into account the particular requirements of medical laboratories.

This International Standard is not intended to be used for the purposes of certification, however a medical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results. The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008, *Quality management systems — Requirements*, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009).

The correlation between the clauses and subclauses of this third edition of ISO 15189 and those of ISO 9001:2008 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard.

Environmental issues associated with medical laboratory activity are generally addressed throughout this International Standard, with specific references in 5.2.2, 5.2.6, 5.3, 5.4, 5.5.1.4 and 5.7.

1) In other languages, these laboratories can be designated by the equivalent of the English term "clinical laboratories."

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Medical laboratories — Requirements for quality and competence

1 Scope

This International Standard specifies requirements for quality and competence in medical laboratories.

This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

NOTE International, national or regional regulations or requirements may also apply to specific topics covered in this International Standard.

2 Normative references

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

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 and the following apply.

3.1
accreditation
procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks

3.2
alert interval
critical interval
interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death

Note 1 to entry: The interval may be open ended, where only a threshold is defined.

Note 2 to entry: The laboratory determines the appropriate list of alert tests for its patients and users.

3.3
automated selection and reporting of results
process by which patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention

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3.4
biological reference interval
reference interval
specified interval of the distribution of values taken from a biological reference population

EXAMPLE The central 95 % biological reference interval for sodium ion concentration values in serum from a population of presumed healthy male and female adults is 135 mmol/l to 145 mmol/l.

Note 1 to entry: A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

Note 2 to entry: A reference interval can depend upon the type of primary samples and the examination procedure used.

Note 3 to entry: In some cases, only one biological reference limit is important, for example, an upper limit, *x*, so that the corresponding biological reference interval would be less than or equal to *x*.

Note 4 to entry: Terms such as 'normal range', 'normal values', and 'clinical range' are ambiguous and therefore discouraged.

3.5
competence
demonstrated ability to apply knowledge and skills

Note 1 to entry: The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.

[SOURCE: ISO 9000:2005, definition 3.1.6]

3.6
documented procedure
specified way to carry out an activity or a process that is documented, implemented and maintained

Note 1 to entry: The requirement for a documented procedure may be addressed in a single document or by more than one document.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.4.5.

3.7
examination
set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements.

Note 2 to entry: Laboratory examinations that determine a value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

Note 3 to entry: Laboratory examinations are also often called assays or tests.

3.8
interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, definition 3.4]

3.9
laboratory director
person(s) with responsibility for, and authority over, a laboratory

Note 1 to entry: For the purposes of this International Standard, the person or persons referred to are designated collectively as *laboratory director*.

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Note 2 to entry: National, regional and local regulations may apply with regard to qualifications and training.

3.10
laboratory management
person(s) who direct and manage the activities of a laboratory

Note 1 to entry: The term 'laboratory management' is synonymous with the term 'top management' in ISO 9000:2005.

3.11
medical laboratory
clinical laboratory
laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

Note 1 to entry: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

3.12
nonconformity
nonfulfillment of a requirement

Note 1 to entry: Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence.

[ISO 9000:2005, definition 3.6.2].

3.13
point-of-care testing
POCT
near-patient testing
testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

[SOURCE: ISO 22870:2006, definition 3.1]

3.14
post-examination processes
postanalytical phase
processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results

3.15
pre-examination processes
preanalytical phase
processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins

3.16
primary sample
specimen
discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

Note 1 to entry: The Global Harmonisation Task Force (GHTF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

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Note 2 to entry: In some ISO and CEN documents, a specimen is defined as “a biological sample derived from the human body”.

Note 3 to entry: In some countries, the term “specimen” is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

3.17
process
set of interrelated or interacting activities which transform inputs into outputs

Note 1 to entry: Inputs to a process are generally outputs of other processes.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.4.1.

3.18
quality
degree to which a set of inherent characteristics fulfils requirements

Note 1 to entry: The term “quality” can be used with adjectives such as poor, good or excellent.

Note 2 to entry: “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

[SOURCE: ISO 9000:2005, definition 3.1.1]

3.19
quality indicator
measure of the degree to which a set of inherent characteristics fulfils requirements

Note 1 to entry: Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.

Note 2 to entry: Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.

EXAMPLE If the *requirement* is to receive all urine samples in the laboratory uncontaminated, the number of contaminated urine samples received as a % of all urine samples received (*the inherent characteristic of the process*) is a measure of the quality of the process.

3.20
quality management system
management system to direct and control an organization with regard to quality

Note 1 to entry: The term “quality management system” referred to in this definition relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.2.3.

3.21
quality policy
overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management

Note 1 to entry: Generally the quality policy is consistent with the overall policy of an organization and provides a framework for setting quality objectives.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.2.4

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3.22
quality objective
something sought, or aimed for, related to quality

Note 1 to entry: Quality objectives are generally based on the laboratory's quality policy.

Note 2 to entry: Quality objectives are generally specified for relevant functions and levels in the organization.

Note 3 to entry: Adapted from ISO 9000:2005, definition 3.2.5.

3.23
referral laboratory
external laboratory to which a sample is submitted for examination

Note 1 to entry: A referral laboratory is one to which laboratory management chooses to submit a sample or sub-sample for examination or when routine examinations cannot be carried out. This differs from a laboratory that may include public health, forensics, tumour registry, or a central (parent) facility to which submission of samples is required by structure or regulation.

3.24
sample
one or more parts taken from a primary sample

EXAMPLE A volume of serum taken from a larger volume of serum.

3.25
turnaround time
elapsed time between two specified points through pre-examination, examination and post-examination processes

3.26
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The term "validated" is used to designate the corresponding status.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.8.5.

3.27
verification
confirmation, through provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The term "verified" is used to designate the corresponding status.

Note 2 to entry: 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.

[SOURCE: ISO 9000:2005, definition 3.8.4]

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4 Management requirements

4.1 Organization and management responsibility

4.1.1 Organization

4.1.1.1 General

The medical laboratory (hereinafter referred to as 'the laboratory') shall meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities.

4.1.1.2 Legal entity

The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.

4.1.1.3 Ethical conduct

Laboratory management shall have arrangements in place to ensure the following:

a) there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;

b) management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;

c) where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;

d) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;

e) confidentiality of information is maintained.

4.1.1.4 Laboratory director

The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided.

The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.

The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.

The duties and responsibilities of the laboratory director shall be documented.

The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard.

The laboratory director (or designate/s) shall:

a) provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;

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b) relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;

c) ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;

d) ensure the implementation of the quality policy;

e) implement a safe laboratory environment in compliance with good practice and applicable requirements;

f) serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;

g) ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

h) select and monitor laboratory suppliers;

i) select referral laboratories and monitor the quality of their service (see also 4.5);

j) provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;

k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

NOTE This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.

l) monitor all work performed in the laboratory to determine that clinically relevant information is being generated;

m) address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);

n) design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;

NOTE Contingency plans should be periodically tested.

o) plan and direct research and development, where appropriate.

4.1.2 Management responsibility

4.1.2.1 Management commitment

Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a) communicating to laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements;

b) establishing the quality policy (see 4.1.2.3);

c) ensuring that quality objectives and planning are established (see 4.1.2.4);

d) defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5);

e) establishing communication processes (see 4.1.2.6);

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f) appointing a quality manager, however named (see 4.1.2.7);

g) conducting management reviews (see 4.15);

h) ensuring that all personnel are competent to perform their assigned activities (see 5.1.6);

i) ensuring availability of adequate resources (see 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5,5, and 5.7).

4.1.2.2 Needs of users

Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. (see also 4.4 and 4.14.3).

4.1.2.3 Quality policy

Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy:

a) is appropriate to the purpose of the organization;

b) includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services;

c) provides a framework for establishing and reviewing quality objectives;

d) is communicated and understood within the organization;

e) is reviewed for continuing suitability.

4.1.2.4 Quality objectives and planning

Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives.

Laboratory management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

4.1.2.5 Responsibility, authority and interrelationships

Laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization. This shall include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel.

NOTE It is recognized that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.

4.1.2.6 Communication

Laboratory management shall have an effective means for communicating with staff (see also 4.14.4). Records shall be kept of items discussed in communications and meetings.

Laboratory management shall ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the

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effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.

4.1.2.7 Quality manager

Laboratory management shall appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented, and maintained;

b) reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.

4.2 Quality management system

4.2.1 General requirements

The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The quality management system shall provide for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.

The laboratory shall:

a) determine the processes needed for the quality management system and ensure their application throughout the laboratory;

b) determine the sequence and interaction of these processes;

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

e) monitor and evaluate these processes;

f) implement actions necessary to achieve planned results and continual improvement of these processes.

4.2.2 Documentation requirements

4.2.2.1 General

The quality management system documentation shall include:

a) statements of a quality policy (see 4.1.2.3) and quality objectives (see 4.1.2.4);

b) a quality manual (see 4.2.2.2);

c) procedures and records required by this International Standard;

d) documents, and records (see 4.13), determined by the laboratory to ensure the effective planning, operation and control of its processes;

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e) copies of applicable regulations, standards and other normative documents.

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.

4.2.2.2 Quality manual

The laboratory shall establish and maintain a quality manual that includes:

a) the quality policy (4.1.2.3) or makes reference to it;

b) a description of the scope of the quality management system;

c) a presentation of the organization and management structure of the laboratory and its place in any parent organization;

d) a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard;

e) a description of the structure and relationships of the documentation used in the quality management system;

f) the documented policies established for the quality management system and reference to the managerial and technical activities that support them.

All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.

4.3 Document control

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

NOTE 1 Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken.

NOTE 2 Records contain information from a particular point in time stating results achieved or providing evidence of activities performed and are maintained according to the requirements given in 4.13, Control of records.

The laboratory 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 to include:

— a title;

— a unique identifier on each page;

— the date of the current edition and/or edition number;

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

— authority for issue.

NOTE ‘Edition’ is used to mean one of a number of printings issued at separate times that incorporates alterations and amendments. ‘Edition’ can be regarded as synonymous with ‘revision or version’.

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c) Current authorized editions and their distribution are identified by means of a list (e.g. document register, log or master index).

d) Only current, authorized editions of applicable documents are available at points of use.

e) Where a laboratory's document control system allows for the amendment of documents by hand, pending the re-issue 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.

f) Changes to documents are identified.

g) Documents remain legible.

h) Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.

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

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

4.4 Service agreements

4.4.1 Establishment of service agreements

The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services.

Each request accepted by the laboratory for examination(s) shall be considered an agreement.

Agreements to provide medical laboratory services shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.

The following conditions shall be met when the laboratory enters into an agreement to provide medical laboratory services.

a) The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood (see 5.4.2 and 5.5).

b) The laboratory shall have the capability and resources to meet the requirements.

c) Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.

d) Examination procedures selected shall be appropriate and able to meet the customers' needs (see 5.5.1).

e) Customers and users shall be informed of deviations from the agreement that impact upon the examination results.

f) Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.

NOTE 1 Customers and users may include clinicians, health care organizations, third party payment organizations or agencies, pharmaceutical companies, and patients.

NOTE 2 Where patients are customers (e.g. when patients have the ability to directly request examinations), changes in service should be reflected in explanatory information and laboratory reports.

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NOTE 3 Laboratories should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of examinations or patients or interfere with the practitioner's independent assessment of what is best for the patient.

4.4.2 Review of service agreements

Reviews of agreements to provide medical laboratory services shall include all aspects of the agreement. Records of these reviews shall include any changes to the agreement and any pertinent discussions.

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.

4.5 Examination by referral laboratories

4.5.1 Selecting and evaluating referral laboratories and consultants

The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline.

The procedure shall ensure that the following conditions are met.

a) The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.

b) Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met.

c) Records of such periodic reviews are maintained.

d) A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.

e) Requests and results of all samples referred are kept for a pre-defined period.

4.5.2 Provision of examination results

Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.

When the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report shall indicate which examinations were performed by a referral laboratory or consultant.

The author of any additional remarks shall be clearly identified.

Laboratories shall adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, this process shall not be hindered by commercial or financial considerations.

4.6 External services and supplies

The laboratory shall have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service (see also 5.3).

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The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement. Criteria for selection shall be established.

A list of selected and approved suppliers of equipment, reagents and consumables shall be maintained.

Purchasing information shall describe the requirements for the product or service to be purchased.

The laboratory shall monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria.

4.7 Advisory services

The laboratory shall establish arrangements for communicating with users on the following:

a) advising on choice of examinations and use of the services, including required type of sample (see also 5.4), clinical indications and limitations of examination procedures and the frequency of requesting the examination;

b) advising on individual clinical cases;

c) professional judgments on the interpretation of the results of examinations (see 5.1.2 and 5.1.6);

d) promoting the effective utilization of laboratory services;

e) consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.

4.8 Resolution of complaints

The laboratory shall have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken (see also 4.14.3).

4.9 Identification and control of nonconformities

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes.

The procedure shall ensure that:

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

b) the immediate actions to be taken are defined;

c) the extent of the nonconformity is determined;

d) examinations are halted and reports withheld as necessary;

e) the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed;

f) the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary;

g) the responsibility for authorization of the resumption of examinations 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.

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NOTE Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, interlaboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented (see 4.10).

4.10 Corrective action

The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The laboratory shall have a documented procedure for:

a) reviewing nonconformities;

b) determining the root causes of nonconformities;

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

d) determining and implementing corrective action needed;

e) recording the results of corrective action taken (see 4.13);

f) reviewing the effectiveness of the corrective action taken (see 4.14.5).

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

4.11 Preventive action

The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

The laboratory shall have a documented procedure for:

a) reviewing laboratory data and information to determine where potential nonconformities exist;

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

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

d) determining and implementing preventive action needed;

e) recording the results of preventive action taken (see 4.13);

f) 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).

4.12 Continual improvement

The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions

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and preventive actions with its intentions, 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 (see also 4.14.5).

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

4.13 Control of records

The laboratory shall have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records.

Records shall be created concurrently with performance of each activity that affects the quality of the examination.

NOTE 1 Records can be in any form or type of medium providing they are readily accessible and protected from unauthorized alterations.

The date and, where relevant, the time of amendments to records shall be captured along with the identity of personnel making the amendments (see 5.9.3).

The laboratory shall define the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are to be retained. The length of time that records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation.

NOTE 2 Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain records for much longer periods than for other records.

Facilities shall provide a suitable environment for storage of records to prevent damage, deterioration, loss or unauthorized access (see 5.2.6).

NOTE 3 For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location (see 5.10.3).

Records shall include, at least, the following:

a) supplier selection and performance, and changes to the approved supplier list;

b) staff qualifications, training and competency records;

c) request for examination;

d) records of receipt of samples in the laboratory;

e) information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts);

f) laboratory work books or work sheets;

g) instrument printouts and retained data and information;

h) examination results and reports;

i) instrument maintenance records, including internal and external calibration records;

j) calibration functions and conversion factors;

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k) quality control records;

l) incident records and action taken;

m) accident records and action taken;

n) risk management records;

o) nonconformities identified and immediate or corrective action taken;

p) preventive action taken;

q) complaints and action taken;

r) records of internal and external audits;

s) interlaboratory comparisons of examination results;

t) records of quality improvement activities;

u) minutes of meetings that record decisions made about the laboratory's quality management activities;

v) records of management reviews.

All of these quality and technical records shall be available for laboratory management review (see 4.15).

4.14 Evaluation and audits

4.14.1 General

The laboratory shall plan and implement the evaluation and internal audit processes needed to:

a) demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;

b) ensure conformity to the quality management system;

c) continually improve the effectiveness of the quality management system.

The results of evaluation and improvement activities shall be included in the input to the management review (see 4.15).

NOTE For improvement activities, see 4.10, 4.11, and 4.12.

4.14.2 Periodic review of requests, and suitability of procedures and sample requirements

Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

The laboratory shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.

4.14.3 Assessment of user feedback

The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information shall include cooperation with users or their representatives in monitoring the laboratory's performance, provided

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that the laboratory ensures confidentiality to other users. Records shall be kept of information collected and actions taken.

4.14.4 Staff suggestions

Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.

4.14.5 Internal audit

The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:

a) conform to the requirements of this International Standard and to requirements established by the laboratory, and

b) are implemented, effective, and maintained.

NOTE 1 The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The laboratory may decide to focus on a particular activity without completely neglecting the others.

Audits shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit programme shall take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined and documented.

Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall, wherever resources permit, be independent of the activity to be audited.

NOTE 2 See ISO 19011 for guidance.

The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.13).

Personnel responsible for the area being audited shall ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action shall be taken without undue delay to eliminate the causes of the detected nonconformities (see 4.10).

4.14.6 Risk management

The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

4.14.7 Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

EXAMPLE Number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports.

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

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

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

NOTE 2 The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care (see 4.12).

The laboratory, in consultation with the users, shall establish turnaround times for each of its examinations that reflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the established turnaround times.

4.14.8 Reviews by external organizations

When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken.

NOTE Examples of reviews by external accreditation organizations include: accreditation assessments, regulatory agencies' inspections, and health and safety inspections.

4.15 Management review

4.15.1 General

Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

4.15.2 Review input

The input to management review shall include information from the results of evaluations of at least the following:

a) the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);

b) assessment of user feedback (see 4.14.3);

c) staff suggestions (see 4.14.4);

d) internal audits (see 4.14.5);

e) risk management (see 4.14.6)

f) use of quality indicators (see 4.14.7);

g) reviews by external organizations (see 4.14.8);

h) results of participation in interlaboratory comparison programmes (PT/EQA) (see 5.6.3);

i) monitoring and resolution of complaints (see 4.8);

j) performance of suppliers (see 4.6);

k) identification and control of nonconformities (see 4.9);

l) results of continual improvement (see 4.12) including current status of corrective actions (see 4.10) and preventive actions (see 4.11);

m) follow-up actions from previous management reviews;

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n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

o) recommendations for improvement, including technical requirements.

4.15.3 Review activities

The review shall analyse the input information for causes of nonconformities, trends and patterns that indicate process problems.

This review shall include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, also be objectively evaluated.

4.15.4 Review output

The output from the management review shall be incorporated into a record that documents any decisions made and actions taken during management review related to:

a) improvement of the effectiveness of the quality management system and its processes;

b) improvement of services to users;

c) resource needs.

NOTE The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established.

Findings and actions arising from management reviews shall be recorded and reported to laboratory staff.

Laboratory management shall ensure that actions arising from management review are completed within a defined timeframe.

5 Technical requirements

5.1 Personnel

5.1.1 General

The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements.

5.1.2 Personnel qualifications

Laboratory management shall document personnel qualifications for each position. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed.

The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.

NOTE Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values, and should be in accordance with national, regional and local regulations and professional guidelines.

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5.1.3 Job descriptions

The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.

5.1.4 Personnel introduction to the organizational environment

The laboratory shall have a programme to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services.

5.1.5 Training

The laboratory shall provide training for all personnel which includes the following areas:

a) the quality management system;

b) assigned work processes and procedures;

c) the applicable laboratory information system;

d) health and safety, including the prevention or containment of the effects of adverse incidents;

e) ethics;

f) confidentiality of patient information.

Personnel that are undergoing training shall be supervised at all times.

The effectiveness of the training programme shall be periodically reviewed.

5.1.6 Competence assessment

Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria.

Reassessment shall take place at regular intervals. Retraining shall occur when necessary.

NOTE 1 Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:

a) direct observation of routine work processes and procedures, including all applicable safety practices;

b) direct observation of equipment maintenance and function checks;

c) monitoring the recording and reporting of examination results;

d) review of work records;

e) assessment of problem solving skills;

f) examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples.

NOTE 2 Competency assessment for professional judgment should be designed as specific and fit for purpose.

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5.1.7 Reviews of staff performance

In addition to the assessment of technical competence, the laboratory shall ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.

NOTE Staff performing reviews should receive appropriate training.

5.1.8 Continuing education and professional development

A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.

Personnel shall take part in regular professional development or other professional liaison activities.

5.1.9 Personnel records

Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel shall be maintained.

These records shall be readily available to relevant personnel and shall include but not be limited to:

a) educational and professional qualifications;

b) copy of certification or license, when applicable;

c) previous work experience;

d) job descriptions;

e) introduction of new staff to the laboratory environment;

f) training in current job tasks;

g) competency assessments;

h) records of continuing education and achievements;

i) reviews of staff performance;

j) reports of accidents and exposure to occupational hazards;

k) immunisation status, when relevant to assigned duties.

NOTE The records listed above are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as needed.

5.2 Accommodation and environmental conditions

5.2.1 General

The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.

Where applicable, similar provisions shall be made for primary sample collection and examinations at sites other than the main laboratory premises, for example point-of-care testing (POCT) under the management of the laboratory.

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5.2.2 Laboratory and office facilities

The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met.

a) Access to areas affecting the quality of examinations is controlled.

NOTE Access control should take into consideration safety, confidentiality, quality and prevailing practices.

b) Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.

c) Facilities for examination allow for correct performance of examinations. These include, for example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.

d) Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.

e) Safety facilities and devices are provided and their functioning regularly verified.

EXAMPLE Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc.

5.2.3 Storage facilities

Storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.

Clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination.

Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements.

5.2.4 Staff facilities

There shall be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.

NOTE When possible, the laboratory should provide space for staff activities such as meetings and quiet study and a rest area.

5.2.5 Patient sample collection facilities

Patient sample collection facilities shall have separate reception/waiting and collection areas. Consideration shall be given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection.

Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination.

Sample collection facilities shall have and maintain appropriate first aid materials for both patient and staff needs.

NOTE Some facilities may need equipment appropriate for resuscitation; local regulations may apply.

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5.2.6 Facility maintenance and environmental conditions

Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.

The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff. Attention shall be paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination.

There shall be effective separation between laboratory sections in which there are incompatible activities. Procedures shall be in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.

The laboratory shall provide a quiet and uninterrupted work environment where it is needed.

NOTE Examples of a quiet and uninterrupted work area include cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutations results.

5.3 Laboratory equipment, reagents, and consumables

NOTE 1 For the purposes of this International Standard, laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems.

NOTE 2 Reagents include reference materials, calibrators and quality control materials; consumables include culture media, pipette tips, glass slides, etc.

NOTE 3 See 4.6 for information concerning the selection and purchasing of external services, equipment, reagents and consumables.

5.3.1 Equipment

5.3.1.1 General

The laboratory shall have a documented procedure for the selection, purchasing and management of equipment.

The laboratory shall be furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the requirements of this International Standard are met.

The laboratory shall replace equipment as needed to ensure the quality of examination results.

5.3.1.2 Equipment acceptance testing

The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned (see also 5.5.1)

NOTE This requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.

Each item of equipment shall be uniquely labelled, marked or otherwise identified.

5.3.1.3 Equipment instructions for use

Equipment shall be operated at all times by trained and authorized personnel.

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Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, shall be readily available.

The laboratory shall have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

5.3.1.4 Equipment calibration and metrological traceability

The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:

a) taking into account conditions of use and the manufacturer's instructions;

b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;

c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;

d) recording the calibration status and date of recalibration;

e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;

f) safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.

NOTE Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.

Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

— use of certified reference materials;

— examination or calibration by another procedure;

— mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

5.3.1.5 Equipment maintenance and repair

The laboratory shall have a documented programme of preventive maintenance which, at a minimum, follows the manufacturer's instructions.

Equipment shall be maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.

Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled. The laboratory shall ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The laboratory shall examine the effect of any defects on previous examinations and institute immediate action or corrective action (see 4.10).

The laboratory shall take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.

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When equipment is removed from the direct control of the laboratory, the laboratory shall ensure that its performance is verified before being returned to laboratory use.

5.3.1.6 Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to the manufacturer and appropriate authorities, as required.

5.3.1.7 Equipment records

Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following:

a) identity of the equipment;

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

c) contact information for the supplier or the manufacturer;

d) date of receiving and date of entering into service;

e) location;

f) condition when received (e.g. new, used or reconditioned);

g) manufacturer's instructions;

h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;

i) maintenance carried out and the schedule for preventive maintenance;

j) equipment performance records that confirm the equipment's ongoing acceptability for use;

k) damage to, or malfunction, modification, or repair of the equipment.

The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement.

These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure (see 4.13).

5.3.2 Reagents and consumables

5.3.2.1 General

The laboratory shall have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables.

5.3.2.2 Reagents and consumables — Reception and storage

Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.

The laboratory shall store received reagents and consumables according to manufacturer's specifications.

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5.3.2.3 Reagents and consumables — Acceptance testing

Each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before use in examinations.

Consumables that can affect the quality of examinations shall be verified for performance before use in examinations.

5.3.2.4 Reagents and consumables — Inventory management

The laboratory shall establish an inventory control system for reagents and consumables.

The system for inventory control shall segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use.

5.3.2.5 Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available.

5.3.2.6 Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to the manufacturer and appropriate authorities, as required.

5.3.2.7 Reagents and consumables — Records

Records shall be maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include but not be limited to the following:

a) identity of the reagent or consumable;

b) manufacturer's name and batch code or lot number;

c) contact information for the supplier or the manufacturer;

d) date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service;

e) condition when received (e.g. acceptable or damaged);

f) manufacturer's instructions;

g) records that confirmed the reagent's or consumable's initial acceptance for use;

h) performance records that confirm the reagent's or consumable's ongoing acceptance for use.

Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

5.4 Pre-examination processes

5.4.1 General

The laboratory shall have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

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5.4.2 Information for patients and users

The laboratory shall have information available for patients and users of the laboratory services. The information shall include as appropriate:

a) the location of the laboratory;

b) types of clinical services offered by the laboratory including examinations referred to other laboratories;

c) opening hours of the laboratory;

d) the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values;

e) instructions for completion of the request form;

f) instruction for preparation of the patient;

g) instructions for patient-collected samples;

h) instructions for transportation of samples, including any special handling needs;

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

j) the laboratory's criteria for accepting and rejecting samples;

k) a list of factors known to significantly affect the performance of the examination or the interpretation of the results;

l) availability of clinical advice on ordering of examinations and on interpretation of examination results;

m) the laboratory's policy on protection of personal information;

n) the laboratory's complaint procedure.

The laboratory shall have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), shall be explained to the patient and user.

5.4.3 Request form information

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

a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;

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

b) name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;

c) type of primary sample and, where relevant, the anatomic site of origin;

d) examinations requested;

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e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;

NOTE Information needed for examination performance and results interpretation may include the patient's ancestry, family history, travel and exposure history, communicable diseases and other clinically relevant information. Financial information for billing purposes, financial audit, resource management and utilization reviews may also be collected. The patient should be aware of the information collected and the purpose for which it is collected.

f) date and, where relevant, time of primary sample collection;

g) date and time of sample receipt.

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

The laboratory shall have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.

The laboratory shall be willing to cooperate with users or their representatives in clarifying the user's request.

5.4.4 Primary sample collection and handling

5.4.4.1 General

The laboratory shall have documented procedures for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.

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

NOTE 1 All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents himself or herself at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, venipuncture. Patients in a hospital bed should normally be given the opportunity to refuse.

Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.

In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

NOTE 2 Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.

5.4.4.2 Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities shall include the following:

a) completion of request form or electronic request;

b) preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);

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

d) special timing of collection, where needed;

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e) clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

5.4.4.3 Instructions for collection activities

The laboratory's instructions for collection activities shall include the following:

a) determination of the identity of the patient from whom a primary sample is collected;

b) verification that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.];

c) instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;

d) in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff;

e) instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;

f) recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;

g) instructions for proper storage conditions before collected samples are delivered to the laboratory;

h) safe disposal of materials used in the collection.

5.4.5 Sample transportation

The laboratory's instructions for post-collection activities shall include packaging of samples for transportation.

The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported:

a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;

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

c) in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

NOTE A laboratory which is not involved in primary sample collection and transportation is considered to have satisfied clause 5.4.5 c) above when, upon receipt of a sample 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.

5.4.6 Sample reception

The laboratory's procedure for sample reception shall ensure that the following conditions are met.

a) Samples are unequivocally traceable, by request and labelling, to an identified patient or site.

b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.

c) Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically

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critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.

d) All samples received are recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.

e) Authorized personnel shall evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).

f) Where relevant, there shall be instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed.

All portions of the primary sample shall be unequivocally traceable to the original primary sample.

5.4.7 Pre-examination handling, preparation and storage

The laboratory shall have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

Laboratory procedures shall include time limits for requesting additional examinations or further examinations on the same primary sample.

5.5 Examination processes

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General

The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded.

The specified requirements (performance specifications) for each examination procedure shall relate to the intended use of that examination.

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

5.5.1.2 Verification of examination procedures

Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.

The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure.

The independent verification by the laboratory shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results.

The laboratory shall document the procedure used for the verification and record the results obtained. Staff with the appropriate authority shall review the verification results and record the review.

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5.5.1.3 Validation of examination procedures

The laboratory shall validate examination procedures derived from the following sources:

a) non-standard methods;

b) laboratory designed or developed methods;

c) standard methods used outside their intended scope;

d) validated methods subsequently modified.

The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

NOTE Performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity.

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

When changes are made to a validated examination procedure, the influence of such changes shall be documented and, when appropriate, a new validation shall be carried out.

5.5.1.4 Measurement uncertainty of measured quantity values

The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory 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 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.

NOTE 3 Examples of the practical utility of measurement uncertainty estimates might include confirmation that patients' values meet quality goals set by the laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value.

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

Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.

5.5.2 Biological reference intervals or clinical decision values

The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.

When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes shall be made and communicated to the users.

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When the laboratory changes an examination procedure or pre-examination procedure, the laboratory shall review associated reference intervals and clinical decision values, as applicable.

5.5.3 Documentation of examination procedures

Examination procedures shall be documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.

Any condensed document format (e.g. card files or similarly used systems) shall correspond to the documented procedure.

NOTE 1 Working instructions, card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a full documented procedure is available for reference.

NOTE 2 Information from product instructions for use may be incorporated into examination procedures by reference.

All documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, shall be subject to document control.

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

a) purpose of the examination;

b) principle and method of the procedure used for examinations;

c) performance characteristics (see 5.5.1.2 and 5.5.1.3);

d) type of sample (e.g. plasma, serum, urine);

e) patient preparation;

f) type of container and additives;

g) required equipment and reagents;

h) environmental and safety controls;

i) calibration procedures (metrological traceability);

j) procedural steps;

k) quality control procedures;

l) interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions;

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

n) biological reference intervals or clinical decision values;

o) reportable interval of examination results;

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

q) alert/critical values, where appropriate;

r) laboratory clinical interpretation;

s) potential sources of variation;

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t) references.

If the laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure.

NOTE 3 This requirement can be accomplished in different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the examination report itself.

5.6 Ensuring quality of examination results

5.6.1 General

The laboratory shall ensure the quality of examinations by performing them under defined conditions.

Appropriate pre and post-examination processes shall be implemented (see 4.14.7, 5.4, 5.7 and 5.8).

The laboratory shall not fabricate any results.

5.6.2 Quality control

5.6.2.1 General

The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.

NOTE In several countries, quality control, as referred to in this subclause, is also named "internal quality control."

5.6.2.2 Quality control materials

The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples.

Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

NOTE 1 The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made.

NOTE 2 Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

5.6.2.3 Quality control data

The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.

When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall also evaluate the results from patient samples that were examined after the last successful quality control event.

Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions shall be taken and recorded.

NOTE Statistical and non-statistical techniques for process control should be used wherever possible to continuously monitor examination system performance.

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5.6.3 Interlaboratory comparisons

5.6.3.1 Participation

The laboratory shall participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

NOTE The laboratory should participate in interlaboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043.

The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme.

Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

5.6.3.2 Alternative approaches

Whenever an interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.

Whenever possible, this mechanism shall utilize appropriate materials.

NOTE Examples of such materials may include:

— certified reference materials;

— samples previously examined;

— material from cell or tissue repositories;

— exchange of samples with other laboratories;

— control materials that are tested daily in interlaboratory comparison programmes.

5.6.3.3 Analysis of interlaboratory comparison samples

The laboratory shall integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.

Interlaboratory comparison samples shall be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.

The laboratory shall not communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data.

The laboratory shall not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

5.6.3.4 Evaluation of laboratory performance

The performance in interlaboratory comparisons shall be reviewed and discussed with relevant staff.

When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff shall participate in the implementation and recording of corrective action. The effectiveness of corrective

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action shall be monitored. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.

5.6.4 Comparability of examination results

There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.

NOTE In the particular case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable.

The laboratory shall notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.

The laboratory shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted upon and records of actions retained.

5.7 Post-examination processes

5.7.1 Review of results

The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.

When the procedure for reviewing results involves automatic selection and reporting, review criteria shall be established, approved and documented (see 5.9.2).

5.7.2 Storage, retention and disposal of clinical samples

The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.

The laboratory shall define the length of time clinical samples are to be retained. Retention time shall be defined by the nature of the sample, the examination and any applicable requirements.

NOTE Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) may require the retention of certain samples for much longer periods than for other samples.

Safe disposal of samples shall be carried out in accordance with local regulations or recommendations for waste management.

5.8 Reporting of results

5.8.1 General

The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

The laboratory shall define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory.

The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results.

Reports shall include the information necessary for the interpretation of the examination results.

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The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.

5.8.2 Report attributes

The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) comments on sample quality that might compromise examination results;

b) comments regarding sample suitability with respect to acceptance/rejection criteria;

c) critical results, where applicable;

d) interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.2) in the final report.

5.8.3 Report content

The report shall include, but not be limited to, the following:

a) a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;

b) the identification of the laboratory that issued the report;

c) identification of all examinations that have been performed by a referral laboratory;

d) patient identification and patient location on each page;

e) name or other unique identifier of the requester and the requester's contact details;

f) date of primary sample collection (and time, when available and relevant to patient care);

g) type of primary sample;

h) measurement procedure, where appropriate;

i) examination results reported in SI units, units traceable to SI units, or other applicable units;

j) biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable;

NOTE Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.

k) interpretation of results, where appropriate;

NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.

l) other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);

m) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;

n) identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);

o) date of the report, and time of release (if not contained in the report, readily available when needed);

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

5.9 Release of results

5.9.1 General

The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.

a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.

b) When examination results fall within established “alert” or “critical” intervals:

— a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)];

— records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.

c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.

d) When results are transmitted as an interim report, the final report is always forwarded to the requester.

e) There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally shall be followed by a written report. There shall be a record of all oral results provided.

NOTE 1 For the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

See also 4.9.

5.9.2 Automated selection and reporting of results

If the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that:

a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff;

NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values.

b) the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning;

c) there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination;

d) there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;

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e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection;

f) there is a process for rapid suspension of automated selection and reporting.

5.9.3 Revised reports

When an original report is revised there shall be written instructions regarding the revision so that:

a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;

b) the user is made aware of the revision;

c) the revised record shows the time and date of the change and the name of the person responsible for the change;

d) the original report entries remain in the record when revisions are made.

Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised.

When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.

5.10 Laboratory information management

5.10.1 General

The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.

The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

NOTE In this International Standard, "information systems" includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and stand alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.

5.10.2 Authorities and responsibilities

The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:

a) access patient data and information;

b) enter patient data and examination results;

c) change patient data or examination results;

d) authorize the release of examination results and reports.

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5.10.3 Information system management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;

NOTE Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation, hospital patient administration systems and systems in primary care.

b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;

c) protected from unauthorized access;

d) safeguarded against tampering or loss;

e) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;

g) in compliance with national or international requirements regarding data protection.

The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.

When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.

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Annex A
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Correlation with ISO 9001:2008 and ISO/IEC 17025:2005

The ISO 9000 quality system series is the parent document for a quality management system standard. Table A.1 illustrates the conceptual relationship between this International Standard and ISO 9001:2008.

The format of this edition more closely resembles that of ISO/IEC 17025:2005, used by ISO/TC 212 as the model for the structure of this International Standard with specific adjustment for medical (clinical) laboratories. Table A.2 shows the correlation between these two documents.

Table A.1 — Correlation between ISO 9001:2008 and this International Standard

ISO 9001:2008	ISO 15189:2012
1 Scope	1 Scope
1.1 General	
1.2 Application	
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Quality management system	4.2 Quality management system
4.1 General requirements	4.2.1 General requirements
4.2 Documentation requirements	4.2.2 Documentation requirements 5.5.3 Documentation of examination procedures
4.2.1 General	4.2.2.1 General
4.2.2 Quality manual	4.2.2.2 Quality manual
4.2.3 Control of documents	4.3 Document control
4.2.4 Control of records	4.13 Control of records 5.1.9 Personnel records 5.3.1.7 Equipment records 5.3.2.7 Reagents and consumables — records 5.8.3 Report content
5 Management responsibility	4 Management requirements 4.1 Organization and management responsibility 4.1.1 Organization 4.1.2 Management responsibility
5.1 Management commitment	4.1.2.1 Management commitment
5.2 Customer focus	4.1.2.2 Needs of users
5.3 Quality policy	4.1.2.3 Quality Policy
5.4 Planning	4.1.2.4 Quality objectives and planning
5.4.1 Quality objectives	4.1.2.4 Quality objectives and planning
5.4.2 Quality management system planning	4.1.2.4 Quality objectives and planning
5.5 Responsibility, authority and communication	4.1.2.5 Responsibility, authority, and interrelationships
5.5.1 Responsibility and authority	4.1.2.5 Responsibility, authority and interrelationships

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Table A.1 *(continued)*

ISO 9001:2008	ISO 15189:2012
5.5.2 Management representative	4.1.2.7 Quality manager
5.5.3 Internal communication	4.1.2.6 Communication
5.6 Management review	4.15 Management review 4.15.1 General
5.6.2 Review input	4.15.2 Review input 4.15.3 Review activities
5.6.3 Review output	4.15.4 Review output
6 Resource management	5 Technical requirements 5.3 Laboratory equipment, reagents and consumables
6.1 Provision of resources	
6.2 Human resources	5.1 Personnel
6.2.1 General	5.1.1 General 5.1.2 Personnel qualifications 5.1.3 Job descriptions 5.1.4 Personnel introduction to the organizational environment
6.2.2 Competence, training and awareness	5.1.5 Training 5.1.6 Competence assessment 5.1.7 Reviews of staff performance 5.1.8 Continuing education and professional development
6.3 Infrastructure	5.2 Accommodation and environmental conditions 5.2.1 General 5.2.2 Laboratory and office facilities 5.2.3 Storage facilities 5.2.4 Staff facilities 5.2.5 Patient sample collection facilities
6.4 Work environment	5.2.6 Facility maintenance and environmental conditions
7 Product realization	
7.1 Planning of product realization	4.4 Service agreements 4.7 Advisory services
7.2 Customer-related processes	
7.2.1 Determination of requirements related to the product	4.4.1 Establishment of service agreements
7.2.2 Review of requirements related to the product	4.4.2 Review of service agreements
7.2.3 Customer communication	
7.3 Design and development	
7.3.1 Design and development planning	
7.3.2 Design and development inputs	
7.3.3 Design and development outputs	
7.3.4 Design and development review	

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Table A.1 *(continued)*

ISO 9001:2008	ISO 15189:2012
7.3.5 Design and development verification	
7.3.6 Design and development validation	
7.3.7 Control of design and development changes	
7.4 Purchasing	4.6 External services and supplies
7.4.1 Purchasing process	4.5 Examination by referral laboratories 4.5.1 Selecting and evaluating referral laboratories and consultants 4.5.2 Provision of examination results
7.4.2 Purchasing information	5.3 Laboratory equipment, reagents, and consumables 5.3.1 Equipment 5.3.1.1 General 5.3.2 Reagents and Consumables 5.3.2.1 General 5.3.2.2 Reagents and consumables – reception and storage
7.4.3 Verification of purchased products	5.3.1.2 Equipment acceptance testing 5.3.2.3 Reagents and consumables — acceptance testing
7.5 Production and service provision	5.4 Pre-examination processes 5.5 Examination processes 5.7 Post-examination processes 5.8 Reporting of results 5.9 Release of results
7.5.1 Control of product and service provision	
7.5.2 Validation of processes for production and service provision	5.5.1 Selection, verification, and validation of examination procedures 5.5.1.2 Verification of examination procedures 5.5.1.3 Validation of examination procedures 5.5.1.4 Measurement uncertainty of measured quantity values
7.5.3 Identification and traceability	5.4.6 Sample reception
7.5.4 Customer property	5.7.2 Storage, retention and disposal of clinical samples
7.5.5 Preservation of product	5.10 Laboratory information management
7.6 Control of monitoring and measuring equipment	5.3.1.3 Equipment instructions for use 5.3.1.4 Equipment calibration and metrological traceability 5.3.1.5 Equipment maintenance and repair 5.3.1.6 Equipment adverse incident reporting 5.3.2.5 Reagents and consumables — instructions for use 5.3.2.6 Reagents and consumables — adverse incident reporting

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Table A.1 *(continued)*

ISO 9001:2008	ISO 15189:2012
8 Measurement, analysis and improvement	4.14 Evaluation and audits
8.1 General	4.14.1 General
8.2 Monitoring and measurement	
8.2.1 Customer satisfaction	4.8 Resolution of complaints 4.14.3 Assessment of user feedback 4.14.4 Staff suggestions
8.2.2 Internal audit	4.14.5 Internal audit
8.2.3 Monitoring and measurement of processes	4.14.2 Periodic review of requests, and suitability of procedures and sample requirements 4.14.6 Risk management 4.14.7 Quality indicators 4.14.8 Reviews by external organizations 5.6 Ensuring quality of examination results
8.2.4 Monitoring and measurement of product	
8.3 Control of nonconforming product	4.9 Identification and control of nonconformities 5.9.3 Revised reports
8.4 Analysis of data	
8.5 Improvement	
8.5.1 Continual improvement	4.12 Continual improvement
8.5.2 Corrective action	4.10 Corrective action
8.5.3 Preventive action	4.11 Preventive action

Table A.2 — Correlation between ISO/IEC 17025:2005 and this International Standard

ISO/IEC 17025:2005	ISO 15189:2012
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Management requirements	4 Management requirements
4.1 Organization	4.1 Organization and management responsibility
4.2 Management system	4.2 Quality management system
4.3 Document control	4.3 Document control
4.4 Review of requests, tenders and contracts	4.4 Service agreements
4.5 Sub-contracting of tests and calibrations	4.5 Examination by referral laboratories
4.6 Purchasing services and supplies	4.6 External services and supplies
4.7 Service to the customer	4.7 Advisory services
4.8 Complaints	4.8 Resolution of complaints
4.9 Control of nonconforming testing and/or calibration work	4.9 Identification and control of nonconformities
4.10 Improvement	4.12 Continual improvement
4.11 Corrective action	4.10 Corrective action
4.12 Preventive action	4.11 Preventive action

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Table A.2 *(continued)*

ISO/IEC 17025:2005	ISO 15189:2012
4.13 Control of records	4.13 Control of records
4.14 Internal audits	4.14 Evaluation and audits
4.15 Management reviews	4.15 Management review
5 Technical requirements	5 Technical requirements
5.1 General	
5.2 Personnel	5.1 Personnel
5.3 Accommodation and environmental conditions	5.2 Accommodation and environmental conditions
5.4 Test and calibration methods and method validation	5.5 Examination processes
5.5 Equipment	5.3 Laboratory equipment, reagents and consumables
5.6 Measurement traceability	5.3.1.4 Equipment calibration and metrological traceability
5.7 Sampling	5.4 Pre-examination processes
5.8 Handling of test and calibration items	
5.9 Assuring the quality of test and calibration results	5.6 Ensuring the quality of examination results
5.10 Reporting the results	5.7 Post-examination processes 5.8 Reporting of results 5.9 Release of results
	5.10 Laboratory information management

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Annex B
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Comparison of ISO 15189:2007 to ISO 15189:2012

Table B.1 — Comparison of ISO 15189:2007 to ISO 15189:2012

ISO 15189:2007		ISO 15189:2012	
Foreword		Foreword	
Introduction		Introduction	
1	Scope	1	Scope
2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions
4	Management requirements	4	Management requirements
4.1	Organization and management	4.1	Organization and management responsibility
		4.1.1	Organization
		4.1.2	Management responsibility
4.2	Quality management system	4.2	Quality management system
		4.2.1	General requirements
		4.2.2	Documentation requirements
4.3	Document control	4.3	Document control
4.4	Review of contracts	4.4	Service agreements
		4.4.1	Establishment of service agreements
		4.4.2	Review of service agreements
4.5	Examination by referral laboratories	4.5	Examination by referral laboratories
		4.5.1	Selecting and evaluating referral laboratories and consultants
		4.5.2	Provision of examination results
4.6	External services and supplies	4.6	External services and supplies
4.7	Advisory services	4.7	Advisory services
4.8	Resolution of complaints	4.8	Resolution of complaints
4.9	Identification and control of nonconformities	4.9	Identification and control of nonconformities
4.10	Corrective action	4.10	Corrective action
4.11	Preventive action	4.11	Preventive action
4.12	Continual improvement	4.12	Continual improvement
4.13	Quality and technical records	4.13	Control of records

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Table B.1 *(continued)*

ISO 15189:2007		ISO 15189:2012	
4.14	Internal audits	4.14	Evaluation and audits
		4.14.1	General
		4.14.2	Periodic review of requests, and suitability of procedures, and sample requirements
		4.14.3	Assessment of user feedback
		4.14.4	Staff suggestions
		4.14.5	Internal audit
		4.14.6	Risk management
		4.14.7	Quality indicators
		4.14.8	Reviews by external organizations
4.15	Management review	4.15	Management review
		4.15.1	General
		4.15.2	Review input
		4.15.3	Review activities
		4.15.4	Review output
5	Technical requirements	5	Technical requirements
5.1	Personnel	5.1	Personnel
		5.1.1	General
		5.1.2	Personnel qualifications
		5.1.3	Job descriptions
		5.1.4	Personnel introduction to the organizational environment
		5.1.5	Training
		5.1.6	Competence assessment
		5.1.7	Reviews of staff performance
		5.1.8	Continuing education and professional development
		5.1.9	Personnel records
5.2	Accommodation and environmental conditions	5.2	Accommodation and environmental conditions
		5.2.1	General
		5.2.2	Laboratory and office facilities
		5.2.3	Storage facilities
		5.2.4	Staff facilities
		5.2.5	Patient sample collection facilities
		5.2.6	Facility maintenance and environmental conditions

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Table B.1 *(continued)*

ISO 15189:2007		ISO 15189:2012	
5.3	Laboratory equipment	5.3	Laboratory equipment, reagents, and consumables
		5.3.1	Equipment
		5.3.1.1	General
		5.3.1.2	Equipment acceptance testing
		5.3.1.3	Equipment instructions for use
		5.3.1.4	Equipment calibration and metrological traceability
		5.3.1.5	Equipment maintenance and repair
		5.3.1.6	Equipment adverse incident reporting
		5.3.1.7	Equipment records
		5.3.2	Reagents and consumables
		5.3.2.1	General
		5.3.2.2	Reagents and consumables – reception and storage
		5.3.2.3	Reagents and consumables – acceptance testing
		5.3.2.4	Reagents and consumables – inventory management
		5.3.2.5	Reagents and consumables – instructions for use
		5.3.2.6	Reagents and consumables – adverse incident reporting
		5.3.2.7	Reagents and consumables – records
5.4	Pre-examination procedures	5.4	Pre-examination processes
		5.4.1	General
		5.4.2	Information for patients and users
		5.4.3	Requests form information
		5.4.4	Primary sample collection and handling
		5.4.4.1	General
		5.4.4.2	Instructions for pre-collection activities
		5.4.4.3	Instructions for collection activities
		5.4.5	Sample transportation
		5.4.6	Sample reception
		5.4.7	Pre-examination handling, preparation, and storage

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Table B.1 *(continued)*

ISO 15189:2007		ISO 15189:2012	
5.5	Examination procedures	5.5	Examination processes
		5.5.1	Selection, verification, and validation of examination procedures
		5.5.1.1	General
		5.5.1.2	Verification of examination procedures
		5.5.1.3	Validation of examination procedures
		5.5.1.4	Measurement uncertainty of measured quantity values
		5.5.2	Biological reference intervals or clinical decision values
		5.5.3	Documentation of examination procedures
5.6	Assuring quality of examination procedures	5.6	Ensuring quality of examination results
		5.6.1	General
		5.6.2	Quality control
		5.6.2.1	General
		5.6.2.2	Quality control materials
		5.6.2.3	Quality control data
		5.6.3	Interlaboratory comparisons
		5.6.3.1	Participation
		5.6.3.2	Alternative approaches
		5.6.3.3	Analysis of interlaboratory comparison samples
		5.6.3.4	Evaluation of laboratory performance
		5.6.4	Comparability of examination results
5.7	Post-examination procedures	5.7	Post-examination processes
		5.7.1	Review of results
		5.7.2	Storage, retention and disposal of clinical samples
5.8	Reporting of results	5.8	Reporting of results
		5.8.1	General
		5.8.2	Report attributes
		5.8.3	Report content
		5.9	Release of results
		5.9.1	General
		5.9.2	Automated selection and reporting of results
		5.9.3	Revised reports
(former Annex B)		5.10	Laboratory information management
		5.10.1	General
		5.10.2	Authorities and responsibilities
		5.10.3	Information system management
Annex A	Correlation with ISO 9001:2000 and ISO/IEC 17025:1999	Annex A	Correlation with ISO 9001:2008 and ISO/IEC 17025:2005

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Table B.1 *(continued)*

ISO 15189:2007		ISO 15189:2012	
Annex B	Recommendations for laboratory information systems (LIS)	Annex B	Comparison of ISO 15189:2007 to ISO 15189:2012
Annex C	Ethics in laboratory medicine		
Bibliography		Bibliography	

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