Please see the administrative notes on page iii

ISO/CEN PARALLEL PROCESSING

The CEN Secretary-General has advised the ISO Secretary-General that this final draft International Standard covers a subject of interest to European standardization. Consultation on the ISO/DIS had the same effect for CEN members as a CEN enquiry on a draft European Standard. In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, this final draft, established on the basis of comments received, is hereby submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

In accordance with the provisions of Council Resolution 15/1993, this document is **circulated in the English language only**.

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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*.

Introduction

This International Standard, based upon ISO/IEC 17025 and ISO 9001, provides 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 requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Whenever allowed by national regulations, 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 service ought also to 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 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. For it is surely preferable that a laboratory seeking accreditation select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories.

During the preparation of this International Standard, ISO 9001 and ISO/IEC 17025 were under revision, and it was therefore impossible to present this International Standard in a format and style which corresponded precisely to those of either of the aforementioned documents. The correlation that nevertheless does exist between the clauses and subclauses of this first edition of ISO 15189 and those of ISO 9001:2000 and of ISO/IEC 17025:1999 is detailed in Annex A of this International Standard.

A second edition of this International Standard, aimed at more closely aligning it with a second edition of ISO/IEC 17025 and with ISO 9001:2000, is anticipated. Moreover, terminology has changed within the disciplines concerned and this has created differences of expression such that certain terms (e.g. “sensitivity”) now have entirely different meanings between disciplines. Furthermore, it is planned to replace yet another document related to this International Standard, ISO/IEC Guide 58, by ISO/IEC 17011. The second edition of ISO 15189 is to take all this into account.

1) In the French language, these laboratories are termed “laboratoires d’analyses de biologie médicale”, while in other languages they might be referred to using a term equivalent to the English “clinical laboratories”.

Medical laboratories — Particular requirements for quality and competence

1 Scope

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

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 31 (all parts), *Standardisation and related activities — General vocabulary*

ISO Guide 31, *Quantities and units*

ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2000, *Quality management systems — Requirements*

ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, ISO/IEC 17025, VIM, and the following apply.

3.1
accuracy of measurement
closeness of the agreement between the result of a measurement and a true value of the measurand

[VIM: 1993, definition 3.5]

3.2
biological reference interval
reference interval
central 95 % interval of the distribution of reference values

NOTE 1 This supersedes such incorrectly used terms as “normal range”.

NOTE 2 It is an arbitrary but common convention to define the reference interval as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases. See [12].

3.3
examination
set of operations having the object of determining the value or characteristics of a property

NOTE In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements.

3.4
laboratory capability
physical, environmental and information resources, personnel, skills and expertise necessary for the examinations in question

NOTE A review of laboratory capability could include results of earlier participation in interlaboratory comparisons or external quality assessment schemes or the running of trial examination programmes, or all these, in order to demonstrate uncertainties of measurement, limits of detection, etc.

3.5
laboratory director
competent person(s) with responsibility for, and authority over, a laboratory

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

3.6
laboratory management
person(s) who manage the activities of a laboratory headed by a laboratory director

3.7
measurement
set of operations having the object of determining a value of a quantity

[VIM:1993, definition 2.6]

3.8
medical laboratory
clinical laboratory
laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, 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 These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or micro-organisms. Facilities which only collect or prepare specimens, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratories, although they may be part of a larger laboratory network or system.

3.9
post-examination procedures
postanalytical phase
processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the examinations

3.10
pre-examination procedures
preanalytical phase
steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins

3.11
primary sample
specimen
collection of one or more parts initially taken from a system

[IUPAC:1990, definition 2.5.2]

NOTE 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.

3.12
quantity
attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively

[VIM:1993, definition 1.1]

3.13
referral laboratory
external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report

3.14
sample
one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production

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

3.15
traceability
property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

[VIM:1993, definition 6.10]

3.16
trueness of measurement
closeness of agreement between the average value obtained from a large series of results of measurements and a true value

NOTE Adapted from ISO 3534-1:1993, definition 3.12

3.17
uncertainty of measurement
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

[VIM:1993, definition 3.9]

4 Management requirements

4.1 Organization and management

4.1.1 The medical laboratory or the organization of which the laboratory is a part shall be legally identifiable.

4.1.2 Medical laboratory services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.

4.1.3 The medical laboratory (hereafter referred to as “the laboratory” shall meet the relevant requirements of this International Standard when carrying out work in its permanent facilities, or at sites other than the permanent facilities for which it is responsible.

4.1.4 The responsibilities of personnel in the laboratory with an involvement or influence on the examination of primary samples shall be defined in order to identify conflicts of interest. Financial or political considerations (e.g. inducements) should not influence testing.

4.1.5 Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system. This shall include the following:

a) management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties;

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

c) policies and procedures for ensuring the protection of confidential information (see Annex C);

d) policies and procedures for avoiding involvement in any activities that would diminish confidence in its competence, impartiality, judgement, or operational integrity;

e) the organizational and management structure of the laboratory and its relationship to any other organization with which it may be associated;

f) specified responsibilities, authority, and interrelationships of all personnel;

g) adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures and assessment of results of the relevant examination procedures;

h) technical management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory procedures;

i) appointment of a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality management system, who shall report directly to the level of laboratory management at which decisions are made on laboratory policy and resources;

j) appointment of deputies for all key functions, while recognizing that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.

4.2 Quality management system

4.2.1 Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.

4.2.2 The quality management system shall include, but not be limited to, internal quality control and participation in organized interlaboratory comparisons such as external quality assessment schemes.

4.2.3 Policies and objectives of the quality management system shall be defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual. This policy shall be readily available to appropriate personnel, shall be concise and shall include the following:

a) the scope of service the laboratory intends to provide;

b) the laboratory management's statement of the laboratory's standard of service;

c) the objectives of the quality management system;

d) a requirement that all personnel concerned with examination activities familiarize themselves with the quality documentation and implement the policies and procedures at all times;

e) the laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system;

f) the laboratory management's commitment to compliance with this International Standard.

4.2.4 A quality manual shall describe the quality management system and the structure of the documentation used in the quality management system. The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation in the quality management system. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.

All personnel shall be instructed on the use and application of the quality manual and all referenced documents, and of the requirements for their implementation. The quality manual shall be kept up to date under the authority and responsibility of [see 4.1.5 i)] an individual appointed to be responsible for quality by the laboratory management.

The table of contents of a quality manual for a medical laboratory might be as follows.

a) Introduction.

b) Description of the medical laboratory, its legal identity, resources, and main duties.

c) Quality policy.

d) Staff education and training.

e) Quality assurance.

f) Document control.

g) Records, maintenance and archiving.

h) Accommodation and environment.

i) Instruments, reagents and/or relevant consumables management.

j) Validation of examination procedures.

k) Safety.

l) Environmental aspects [e.g. transportation, consumables and waste disposal, in addition to, and different from, h) and i)].

m) Research and development (if appropriate).

n) List of examination procedures.

o) Request protocols, primary sample, collection and handling of laboratory samples.

p) Validation of results.

q) Quality control (including interlaboratory comparisons).

r) Laboratory information system (see Annex B).

s) Reporting of results.

t) Remedial actions and handling of complaints.

u) Communications and other interactions with patients, health professionals, referral laboratories and suppliers.

v) Internal audits.

w) Ethics (see Annex C).

4.2.5 Laboratory management shall establish and implement a programme which regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded programme of preventive maintenance and calibration (see 5.3.2), which, at a minimum, follows manufacturer's recommendations.

4.3 Document control

4.3.1 The laboratory shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define the retention period. These controlled documents may be maintained on any appropriate medium — including, or not, paper. Local, regional and national regulations concerning document retention could apply.

NOTE In this context, "document" is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or examination procedures.

4.3.2 Procedures shall be adopted to ensure that

a) all documents issued to laboratory personnel as part of the quality management system are reviewed and approved by authorized personnel prior to issue,

b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained,

c) only currently authorized versions of appropriate documents are available for active use at relevant locations,

d) documents are periodically reviewed, revised when necessary, and approved by authorized personnel,

e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use,

f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use,

g) if the laboratory's documentation 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,

while amendments are clearly marked, initialled and dated, and a revised document is formally re-issued as soon as practicable, and

h) procedures are established to describe how changes to documents maintained in computerized systems are to be made and controlled.

4.3.3 All documents relevant to the quality management system shall be uniquely identified, to include

a) title,

b) edition or current revision date, or revision number, or all these,

c) number of pages (where applicable),

d) authority for issue, and

e) database identification.

4.4 Review of contracts

4.4.1 Where a laboratory enters into a contract to provide medical laboratory services, it shall establish and maintain procedures for review of contracts. The policies and procedures for these reviews leading to a change in the arrangements for examinations or contracts shall ensure that

a) requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5);

b) the laboratory has the capability and resources to meet the requirements, and

c) appropriate procedures are selected able to meet the contract requirements and clinical needs (see 5.5).

In reference to b), the review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary, for the performance of the examinations in question. The review may also encompass results of earlier participation in external quality assurance schemes using samples of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

4.4.2 Records of reviews, including any significant changes and pertinent discussions, shall be maintained (see 4.13.3).

4.4.3 The review shall also cover any work referred by the laboratory (see 4.5).

4.4.4 Clients (e.g. clinicians, health care bodies, health insurance companies, pharmaceutical companies) shall be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected parties.

4.5 Examination by referral laboratories

4.5.1 The laboratory shall have an effective documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology and related disciplines. Laboratory management, with the advice of users of laboratory services where appropriate, shall be responsible for selecting and monitoring the quality of referral laboratories and consultants and shall ensure that the referral laboratory or referral consultant is competent to perform the requested examinations.

4.5.2 Arrangements with referral laboratories shall be reviewed periodically to ensure that

a) requirements, including the pre-examination and post-examination procedures, are adequately defined, documented, and understood,

b) the referral laboratory is able to meet the requirements and that there are no conflicts of interest,

c) selection of examination procedures is appropriate for the intended use, and

d) respective responsibilities for the interpretation of examination results are clearly defined.

Records of such reviews shall be maintained in accordance with national, regional or local requirements.

4.5.3 The laboratory shall maintain a register of all referral laboratories that it uses. A register shall be kept of all samples that have been referred to another laboratory. The name and address of the laboratory responsible for the examination result shall be provided to the user of laboratory services. A duplicate of the laboratory report shall be retained in both the patient record and in the permanent file of the laboratory.

4.5.4 The referring laboratory and not the referral laboratory shall be responsible for ensuring that referral laboratory examination results and findings are provided to the person making the request. If the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretation.

However, this does not require that the referring laboratory report include every word and have the exact format of the referral laboratory report, unless national/local laws or regulations require it. The referring laboratory director may elect to provide additional interpretative remarks to those, if any, of the referral laboratory, in the context of the patient and the local medical environment. The author of such added remarks should be clearly identified.

4.6 External services and supplies

4.6.1 Laboratory management shall define and document its policies and procedures for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of its service. Purchased items shall consistently meet the laboratory's quality requirements. Records of actions taken shall be maintained in accordance with national, regional or local requirements. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.

4.6.2 Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable. Documentation of the supplier's conformance with its quality management system may also be used for verification.

4.6.3 There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased products shall be established and maintained for a period of time, as defined in the quality management system. This system should include the recording of lot numbers of all relevant reagents, control materials and calibrators, the date of receipt in the laboratory and the date the material is placed in service. All of these quality records shall be available for laboratory management review.

4.6.4 The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examinations and shall maintain records of these evaluations and list those approved.

4.7 Advisory services

Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services, including repeat frequency and required type of sample. Where appropriate, interpretation of the results of examinations shall be provided.

There should be regular documented meetings of professional staff with the clinical staff regarding the use of the laboratory services and for the purpose of consultation on scientific matters. The professional staff should participate in clinical rounds, enabling advice on effectiveness in general as well as in individual cases.

4.8 Resolution of complaints

The laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties. Records of complaints and of investigations and corrective actions taken by the laboratory shall be maintained, as required (see 4.13.3).

NOTE Laboratories are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way (e.g. surveys).

4.9 Identification and control of nonconformities

4.9.1 Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinician. These shall ensure that

a) personnel responsible for problem resolution are designated,

b) the actions to be taken are defined,

c) the medical significance of the nonconforming examinations is considered and where appropriate, the requesting clinician informed,

d) examinations are halted and reports withheld as necessary,

e) corrective action is taken immediately,

f) the results of nonconforming examinations already released are recalled or appropriately identified, if necessary,

g) the responsibility for authorization of the resumption of examinations is defined, and

h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action.

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

4.9.2 If it is determined that nonconforming examinations could recur or that there is doubt about the laboratory's compliance with its own policies or procedures as given in the quality manual, procedures to identify, document and eliminate the root cause(s) shall be promptly implemented (see 4.11).

4.9.3 The laboratory shall define and implement procedures for the release of results in the case of nonconformities, including the review of such results. These events shall be recorded.

4.10 Corrective action

4.10.1 Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem. These shall, where appropriate, lead to preventive actions. Corrective action shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.

4.10.2 Laboratory management shall document and implement any changes required to its operational procedures resulting from corrective action investigations.

4.10.3 Laboratory management shall monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems.

4.10.4 When the identification of non-conformance or the corrective action investigation casts doubt on compliance with policies and procedures or the quality management system, laboratory management shall ensure that appropriate areas of activity are audited in accordance with 4.14. The results of corrective action shall be submitted for laboratory management review.

4.11 Preventive action

4.11.1 Needed improvements and potential sources of nonconformities, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.11.2 Procedures for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective. Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance.

NOTE Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

4.12 Continual improvement

4.12.1 All operational procedures shall be systematically reviewed by laboratory management at regular intervals, as defined in the quality management system, in order to identify any potential sources of nonconformance or other opportunities for improvement in the quality management system or technical practices. Action plans for improvement shall be developed, documented and implemented, as appropriate.

4.12.2 After action has been taken resulting from the review, laboratory management shall evaluate the effectiveness of the action through a focused review or audit of the area concerned.

4.12.3 The results of action following the review shall be submitted to laboratory management for review and implementation of any needed changes to the quality management system.

4.12.4 Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. When this programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care. Laboratory management shall provide access to suitable educational and training opportunities for all laboratory personnel and relevant users of laboratory services.

4.13 Quality and technical records

4.13.1 The laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records.

4.13.2 All records shall be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional or local legal requirements (see Note, 4.3.1). Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.

4.13.3 The laboratory shall have a policy that defines the length of time various records pertaining to the quality management system and examination results are to be retained. Retention time shall be defined by the nature of the examination or specifically for each record or, in some instances, in accordance with statutory authority.

These records may include but are not limited to the following.

a) Request forms (including the patient chart or medical record only if used as the request form).

b) Examination results and reports.

c) Instrument printouts.

d) Examination procedures.

e) Laboratory work-books or sheets.

f) Accession records.

g) Calibration functions and conversion factors.

h) Quality control records.

i) Complaints and action taken.

j) Records of internal and external audits.

k) External quality assessment records/interlaboratory comparisons.

l) Quality improvement records.

m) Instrument maintenance records, including internal and external calibration records.

n) Lot documentation, certificates of supplies, package inserts.

o) Incident/accident records and action taken.

p) Staff training and competency records.

4.14 Internal audits

4.14.1 In order to verify that operations continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical, shall be conducted at intervals defined by the system itself. The internal audit shall progressively address these elements and emphasize areas critically important to patient care.

4.14.2 Audits shall be formally planned, organized and carried out by the quality manager or designated qualified personnel. Personnel shall not audit their own activities. The procedures for internal audits shall be defined and documented and include the types of audit, frequencies, methodologies and required documentation. When deficiencies or opportunities for improvement are noted, the laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed-upon time.

The main elements of the quality system should normally be subject to internal audit once every twelve months.

4.14.3 The results of internal audits shall be submitted to laboratory management for review.

4.15 Management review

4.15.1 Laboratory management shall review the laboratory's quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements. The results of the review shall be incorporated into a plan that includes goals, objectives and action plans. A typical period for conducting a management review is once every twelve months.

4.15.2 Management review shall take account of, but not be limited to

a) follow-up of previous management reviews,

b) status of corrective actions taken and required preventive action,

c) reports from managerial and supervisory personnel,

d) the outcome of recent internal audits,

e) assessment by external bodies,

f) the outcome of external quality assessment and other forms of interlaboratory comparison,

g) any changes in the volume and type of work undertaken,

h) feedback, including complaints and other relevant factors, from clinicians, patients and other parties,

i) quality indicators for monitoring the laboratory's contribution to patient care,

j) nonconformities,

k) monitoring of turnaround time,

l) results of continuous improvement processes, and

m) evaluation of suppliers.

Shorter intervals between reviews should be adopted when a quality management system is being established. This will allow early action to be taken in response to those areas identified as requiring amendment of the quality management system or other practices.

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

NOTE Data available will differ according to laboratory type or location (e.g. hospital, clinic or referral laboratory).

4.15.4 Findings and the actions that arise from management reviews shall be recorded, and laboratory staff shall be informed of these findings and the decisions made as a result of the review. Laboratory management shall ensure that these actions are discharged within an appropriate and agreed-upon time.

5 Technical requirements

5.1 Personnel

5.1.1 Laboratory management shall have an organizational plan, personnel policies and job descriptions that define qualifications and duties for all personnel.

5.1.2 Laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. This information shall be readily available to relevant personnel, and may include

a) certification or license, if required,

b) references from previous employment,

c) job descriptions,

d) records of continuing education and achievements,

e) competency evaluations, and

f) provision for untoward incident or accident reports.

Other records available to authorized persons relating to personnel health may include records of exposure to occupational hazards and records of immunization status.

5.1.3 The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided.

NOTE *Competence* is here understood as the product of basic academic, postgraduate and continuing education, as well as training and experience of several years in a medical laboratory.

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

The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the following responsibilities:

a) provide advice to those requesting information about the choice of tests, the use of the laboratory service and the interpretation of laboratory data;

b) serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate;

c) relate and function effectively (including contractual arrangements, if necessary), with

   1) applicable accrediting and regulatory agencies,

   2) appropriate administrative officials,

   3) the healthcare community, and

   4) the patient population served;

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

e) implement the quality management system (the laboratory director and professional laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable);

f) monitor all work performed in the laboratory to determine that medically reliable data are being generated;

g) ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory;

h) plan, set goals, develop and allocate resources appropriate to the medical environment;

i) provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;

j) provide educational programs for the medical and laboratory staff and participate in educational programs of the institution;

k) plan and direct research and development appropriate to the facility;

l) select and monitor all referral laboratories for quality of service;

m) implement a safe laboratory environment in compliance with good practice and applicable regulations;

n) address any complaint, request or suggestion from users of laboratory services;

o) ensure good staff morale.

The laboratory director need not perform all responsibilities personally. However, it is the laboratory director who remains responsible for the overall operation and administration of the laboratory, for ensuring that quality services are provided for patients.

5.1.5 There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system.

5.1.6 Personnel shall have training specific to quality assurance and quality management for services offered.

5.1.7 Laboratory management shall authorize personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment, including use of computers in the laboratory information system (see Annex B).

5.1.8 Policies shall be established which define who may use the computer system, who may access patient data only and who is authorized to enter and change patient results, correct billing or modify computer programs (see Annexes B and C).

5.1.9 There shall be a continuing education program available to staff at all levels.

5.1.10 Employees shall be trained to prevent or contain the effects of adverse incidents.

5.1.11 The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

5.1.12 The personnel making professional judgements with reference to examinations shall have the applicable theoretical and practical background as well as recent experience. 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.

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

5.1.13 Confidentiality of information regarding patients shall be maintained by all personnel.

5.2 Accommodation and environmental conditions

5.2.1 The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safety of personnel or patient care services. The laboratory director shall determine the adequacy of this space. The resources shall be of a degree necessary to support the activities of the laboratory. Laboratory resources shall be maintained in a functional and reliable condition. Similar provisions should be made for primary sample collection and examinations at sites other than the permanent laboratory facility.

5.2.2 The laboratory shall be designed for the efficiency of its operation, to optimize the comfort of its occupants and to minimize the risk of injury and occupational illness. Patients, employees and visitors shall be protected from recognized hazards.

5.2.3 When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions.

5.2.4 The laboratory design and environment shall be suitable for the tasks carried out therein. The environment in which the primary sample collection or examinations or both are undertaken shall not invalidate the results, or adversely affect the required quality, of any measurement.

Laboratory facilities for examination should facilitate correct performance of examinations. These include, but are not limited to, energy sources, lighting, ventilation, water, waste and refuse disposal, and environmental conditions. The laboratory should have procedures for checking that the environment does not adversely affect the performance of specimen collection and equipment.

5.2.5 The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. Attention should be paid to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature and sound and vibration levels, as appropriate to the technical activities concerned.

5.2.6 There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

EXAMPLE Where examination procedures pose a hazard (mycobacteriology, radionuclides etc.); work could be affected or influenced by not being separated, such as nucleic acid amplifications; an environment conducive to quiet and uninterrupted work is required, such as for cytopathology screening; or where work requires a controlled environment, such as for large computer systems.

5.2.7 Access to, and use of, areas affecting the quality of the examinations shall be controlled. Appropriate measures shall be taken to safeguard samples and resources from unauthorized access.

5.2.8 Communication systems within the laboratory shall be those appropriate to the size and complexity of the facility and the efficient transfer of messages.

5.2.9 Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results.

5.2.10 Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations.

Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures and training for personnel could be necessary to that end.

5.3 Laboratory equipment

NOTE For the purpose of this International Standard, instruments, reference materials, consumables, reagents and analytical systems are included as laboratory equipment, as applicable.

5.3.1 The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and 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.

When selecting equipment, account should be taken of the use of energy and future disposal (care of the environment).

5.3.2 Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.

Laboratory management shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded programme of preventive maintenance (see 4.2.5), which, at a minimum, follows the manufacturer's recommendations.

When manufacturer's instructions, operator's manuals or other documentation are available, they may be used to establish requirements, for compliance with relevant standards or to specify requirements for periodic calibration interval, as appropriate, to fulfil part or all of this requirement.

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

5.3.4 Records shall be maintained for each item of equipment contributing to the performance of examinations. These records shall include at least the following:

a) identity of the equipment;

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

c) manufacturer's contact person and telephone number, as appropriate;

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

e) current location, where appropriate;

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

g) manufacturer's instructions, if available, or reference to their retention;

h) equipment performance records that confirm the equipment's suitability for use;

i) maintenance carried out and that planned for the future;

j) damage to, or malfunction, modification or repair, of the equipment;

k) predicted replacement date, if possible.

The performance records referred to in h) should include copies of reports/certificates of all calibrations and/or verifications including dates, time and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration, as appropriate, to fulfil part or all of this requirement. Manufacturer's instructions may be used to establish acceptance criteria, procedures and frequency of verification for maintenance or calibration or both, as appropriate, to fulfil part or all of this requirement.

These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law or regulation.

5.3.5 Equipment shall be operated by authorized personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) shall be readily available to laboratory personnel.

5.3.6 Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. Manufacturer's specifications or instructions or both shall be used, as appropriate.

5.3.7 Whenever equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. The laboratory shall examine the effect of this defect on previous examinations and institute the procedure given in 4.9. The laboratory shall take reasonable measures to decontaminate equipment prior to service, repair or decommissioning.

5.3.8 A list of the measures taken to reduce contamination shall be provided to the person working on the equipment. The laboratory shall provide suitable space for repairs and appropriate personal protective equipment.

5.3.9 Whenever practicable, equipment under the control of the laboratory which requires calibration or verification shall be labelled or otherwise coded to indicate the status of calibration or verification and the date when recalibration or reverification is due.

5.3.10 When equipment is removed from the direct control of the laboratory or is repaired or serviced, the laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.

5.3.11 When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory shall ensure that

a) computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility,

b) procedures are established and implemented for protecting the integrity of data at all times,

c) computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and

d) computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons.

See also Annex B.

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

5.3.13 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures for ensuring that copies of prior correction factors are correctly updated.

5.3.14 Equipment, including hardware, software, reference materials, consumables, reagents and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results.

5.4 Pre-examination procedures

5.4.1 The request form shall contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data. National, regional or local requirements shall apply.

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

a) unique identification of the patient;

b) name or other unique identifier of physician or other person legally authorized to request examinations or use medical information together with the destination for the report (if the requesting clinician’s address is different from that of the receiving laboratory, that address should be provided as part of the request form information);

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

d) examinations requested;

e) clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes;

f) date and time of primary sample collection;

g) date and time of receipt of samples by the laboratory.

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.

5.4.2 Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management (see 4.2.4) and made available to others responsible for primary sample collection. These instructions shall be contained in a primary sample collection manual.

5.4.3 The primary sample collection manual shall include the following:

a) copies of or references to

   1) lists of available laboratory examinations offered,

   2) consent forms, when applicable,

   3) information and instructions provided to patients in relation to their own preparation before primary sample collection, and

   4) information for users of laboratory services on medical indications and appropriate selection of available procedures;

b) procedures for

   1) preparation of the patient (e.g. instructions to caregivers and phlebotomists),

   2) identification of primary sample, and

   3) primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives;

c) instructions for

   1) completion of request form or electronic request,

   2) type and amount of the primary sample to be collected,

   3) special timing of collection, if required,

   4) any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery, etc.),

   5) labelling of primary samples,

   6) clinical information (e.g. history of administration of drugs),

   7) positive identification, in detail, of the patient from whom a primary sample is collected,

   8) recording the identity of the person collecting the primary sample, and

   9) safe disposal of materials used in the collection;

d) instructions for

   1) storage of examined samples,

   2) time limits for requesting additional examinations,

   3) additional examinations, and

   4) repeat examination due to analytical failure or further examinations of same primary sample.

5.4.4 The primary sample collection manual shall be part of the document control system (see 4.3.1).

5.4.5 Primary samples shall be traceable, normally by request form, to an identified individual. Primary samples lacking proper identification shall not be accepted or processed by the laboratory.

Where there is uncertainty in the identification of the primary sample or instability of the analytes in the primary sample (cerebrospinal fluid, biopsy, blood gas, etc.), and the primary sample is irreplaceable or critical, the laboratory may choose initially to process the sample but not release the results until the requesting physician or person responsible for the primary sample collection takes responsibility for identifying and accepting the sample, or for providing proper information, or all these. In such an instance, the signature of that person taking responsibility for the primary sample identification should be recorded on, or traceable to, the request form. If this requirement is not met for any reason, the person responsible should be identified in the report if the examination is carried out. Samples to be set aside for future examination (e.g. viral antibodies, metabolites relevant to the clinical syndrome) should also be identifiable.

5.4.6 The laboratory shall monitor the transportation of samples to the laboratory such that 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 range specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples, and

c) in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with national, regional or local regulatory requirements.

5.4.7 All primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded.

5.4.8 Criteria shall be developed and documented for acceptance or rejection of primary samples. If compromised primary samples are accepted, the final report shall indicate the nature of the problem and, if applicable, that caution is required when interpreting the result.

5.4.9 The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.

5.4.10 Authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.

5.4.11 The laboratory shall, if relevant, have a documented procedure for the receipt, labelling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labelling of the request form and primary sample, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed.

5.4.12 Sample portions shall also be traceable to the original primary sample.

5.4.13 The laboratory shall have a written policy concerning verbal requests for patient examinations.

5.4.14 Samples shall be stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations.

5.5 Examination procedures

NOTE Some of the following might not be applicable to all disciplines in the scope of laboratory practice.

5.5.1 The laboratory shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international, national or regional guidelines. If in-house procedures are used, they shall be appropriately validated for their intended use and fully documented.

5.5.2 The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The validations shall be as extensive as are necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained and the procedure used for the validation.

The methods and procedures selected for use shall be evaluated and found to give satisfactory results before being used for medical examinations. A review of procedures by the laboratory director or designated person shall be undertaken initially and at defined intervals. Such a review is normally carried out annually. These reviews shall be documented.

5.5.3 All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory.

Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.

Instructions for use (e.g. package inserts) provided by manufacturers and in accordance with 5.5.1 and 5.5.2 shall be used as part of a procedure, provided the instructions describe the procedure as it is performed in the laboratory and are written in a language commonly understood by the staff in the laboratory. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Each new version of examination kits with major changes in reagents or procedure shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorized as for other procedures.

In addition to document control identifiers, documentation should include, when applicable, the following:

a) purpose of the examination;

b) principle of the procedure used for examinations;

c) performance specifications (e.g. linearity, precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness expressed as systematic error, analytical sensitivity and analytical specificity);

d) primary sample type (including container and additives);

e) required equipment and reagents or examination system;

f) calibration procedures;

g) procedural steps;

h) quality control procedures;

i) interferences (e.g. lipemia, hemolysis, bilirubin) and cross reactions;

j) principle of procedure for calculating results;

k) biological reference intervals;

l) reportable interval of patient test results;

m) alert/critical values, where appropriate;

n) laboratory interpretation;

o) safety precautions;

p) potential sources of variability.

Electronic manuals are acceptable provided that the above-specified information is included. The same requirements for document control should also apply to electronic manuals.

The laboratory director shall be responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed.

5.5.4 Performance specifications for each procedure used in an examination shall relate to the intended use of that procedure.

5.5.5 Biological reference intervals shall be periodically reviewed. If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action. A review of biological reference intervals shall also take place when the laboratory changes an examination procedure or pre-examination procedure, if appropriate.

5.5.6 The laboratory shall make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, available to users of laboratory services upon request.

5.5.7 If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing, prior to the introduction of the change.

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

5.6 Assuring quality of examination procedures

5.6.1 The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.

5.6.2 The laboratory shall determine the uncertainty of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample and changes of operator.

5.6.3 A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference. Where none of these are possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

a) participation in a suitable programme of interlaboratory comparisons;

b) use of suitable reference materials, certified to indicate the characterisation of the material;

c) examination or calibration by another procedure;

d) ratio or reciprocity-type measurements;

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

f) documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.

5.6.4 The laboratory shall participate in interlaboratory comparisons such as those organized by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled. Interlaboratory comparison programs shall be in substantial agreement with ISO/IEC Guide 43-1.

External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

5.6.5 Whenever a formal interlaboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilize externally derived challenge materials such as exchange of samples with other laboratories. Laboratory management shall monitor the results of this mechanism of interlaboratory comparison and participate in the implementation and recording of corrective actions.

5.6.6 For those examinations performed using different procedures or equipment or at different sites, or all these, there shall be a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals. Such verification shall be performed at defined periods of time appropriate to the characteristics of the procedure or instrument.

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

5.7 Post-examination procedures

5.7.1 Authorized personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorize the release of the results.

5.7.2 Storage of the primary sample and other laboratory samples shall be in accordance with approved policy.

5.7.3 Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.

5.8 Reporting of results

5.8.1 Laboratory management shall be responsible for formatting reports. The format of the report form (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory should be determined in discussion with the users of laboratory services.

5.8.2 Laboratory management shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval.

5.8.3 Results shall be legible, without mistakes in transcription and reported to persons authorized to receive and use medical information. The report shall also include, but not be limited to the following:

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

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

c) unique identification and location of the patient, where possible, and destination of the report;

d) name or other unique identifier of the requester and the requester's address;

e) date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory;

f) date and time of release of report, which, if not on the report, shall be readily accessible when needed;

g) source and system (or primary sample type);

h) results of the examination reported in SI units or units traceable to SI units (see ISO Guide 31), where applicable;

i) biological reference intervals, where applicable;

j) interpretation of results, where appropriate;

k) other comments (e.g. quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure); the report should identify examinations undertaken as part of a development programme and for which no specific claims on measurement performance are made, and, where applicable, information on detection limit and uncertainty of measurement should be provided upon request;

l) identification of the person authorizing the release of the report;

m) if relevant, original and corrected results;

n) signature or authorization of the person checking or releasing the report, where possible.

NOTE In reference to i), 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.

5.8.4 As appropriate, the description of examinations performed and their results should follow the vocabulary and syntax recommended by one or more of the following organizations:

— International Council for Standardization in Haematology (ICSH);

— International Society of Haematology (ISH);

— International Federation of Clinical Chemistry and Laboratory Medicine (IFCC);

— International Union of Pure and Applied Chemistry (IUPAC);

— International Society of Thrombosis and Haemostasis (ISTH);

— European Committee for Standardisation (CEN).

As appropriate, the description and results should follow the nomenclature recommended by one or more of the following organizations:

— International Union of Biochemistry and Molecular Biology (IUBMB);

— International Union of Microbiological Societies (IUMS);

— International Union of Immunological Societies (IUIS);

— SNOMED International (College of American Pathologists);

— world health organization (WHO).

5.8.5 The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the result.

5.8.6 Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by national, regional or local requirements.

5.8.7 The laboratory shall have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alert” or “critical” intervals. This includes results received on samples sent to referral laboratories for examination.

5.8.8 In order that local clinical needs can be served, the laboratory shall determine the critical properties and their “alert/critical” intervals, in agreement with the clinicians using the laboratory. This applies to all examinations, including nominal and ordinal properties.

5.8.9 For results transmitted as an interim report, the final report shall always be forwarded to the requester.

5.8.10 Records of actions taken in response to results in the critical intervals shall be maintained. These shall include date, time, responsible laboratory staff member, person notified and examination results. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.

5.8.11 Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.

There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to it shall be monitored, recorded and reviewed by laboratory management. Where necessary, corrective action shall be taken to address any problems so identified.

This does not mean that the clinical personnel are to be notified of all delays in examination, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and laboratory personnel.

5.8.12 When examination results from a referral laboratory need to be transcribed by the referring laboratory, procedures for verifying the correctness of all transcriptions shall be in place.

5.8.13 The laboratory shall have clearly documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall also include guidelines for the release of results directly to patients.

5.8.14 The laboratory shall establish policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorized receivers. Results provided verbally shall be followed by a properly recorded report.

5.8.15 The laboratory shall have written policies and procedures regarding the alteration of reports.

When altered, the record must show the time, date and name of the person responsible for the change.

Original entries shall remain legible when alterations are made.

Original electronic records shall be retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.

5.8.16 Results that have been available for clinical decision making shall be retained in subsequent cumulative reports and be clearly identified as having been revised. If the reporting system cannot capture amendments, changes or alterations, an audit log shall be used.

Annex A
(normative)

Correlation with ISO 9001:2000 and ISO/IEC 17025:1999

During the preparation of this International Standard, the related ISO documents ISO 9001 and ISO/IEC 17025 were under revision and it was not possible to format this edition of ISO 15189 in parallel with either of those other documents.

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 9001:2000. While many of the quality management system concepts, including management responsibility, customer focus, control of documents and management review have been incorporated into the current edition of this International Standard, greater correspondence with the parent quality management series is to be incorporated at the next revision.

The format of this edition more closely resembles that of ISO/IEC 17025:1999, used by ISO/TC 212/WG1 as the model for the structure of this International Standard with specific adjustment for medical (clinical) laboratories. Table A.2 shows the correlation between the two documents.

Table A.1 — Correlation between ISO 9001:2000 and this International Standard

ISO 9001:2000	ISO 15189:2002
1 Scope	1 Scope
1.1 General	
1.2 Applications	
2 Normative reference	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Quality management system	
4.1 General requirements	4.1.5; 4.2, Quality management system
4.2 Documentation requirements	4.3 Document control; 5.1.2; and 5.4, Pre-examination procedures
4.2.1 General	4.2.3
4.2.2 Quality manual	4.2.4
4.2.3 Control of documents	4.3, Document control; 4.13, Quality and technical records; and 5.3, Laboratory equipment
4.2.4 Control of records	4.13, Quality and technical records; and 5.8 Reporting of results
5 Management responsibility	
5.1 Management commitment	4.1.2, 4.1.5 items a) and h), 4.2.1 and 4.2.3
5.2 Customer focus	4.1.2, 5.2.3 and 5.4.2
5.3 Quality policy	4.1.5 and 4.2.3
5.4 Planning	
5.4.1 Quality objectives	4.2.3

Table A.1 (*continued*)

ISO 9001:2000	ISO 15189:2002
5.4.2 Quality management system planning	4.1.5
5.5 Responsibility, authority and communication	
5.5.1 Responsibility and authority	4.1.5 f), 5.1.3 and 5.1.4
5.5.2 Management representative	4.1.5 i)
5.5.3 Internal communication	4.2.1, 4.2.4 and 5.2.8
5.6 Management review	
5.6.1 General	4.15, Management review
5.6.2 Review input	4.15.2
5.6.3 Review output	4.15.3, 4.15.4 and 5.7.1
6 Resource management	
6.1 Provision of resources	4.1.5 a)
6.2 Human resources	
6.2.1 General	4.1.5 g) and 5.1, Personnel
6.2.2 Competency, awareness and training	5.1.2, 5.1.6, 5.1.10 and 5.1.12
6.3 Infrastructure	4.6, External services and supplies; 5.2, Accommodation and environmental conditions; and 5.3, Laboratory equipment
6.4 Work environment	5.2, Accommodation and environmental conditions; and 5.3, Laboratory equipment
7 Product realization	
7.1 Planning of product realization	4.10.1; 5.2, Accommodation and environmental conditions; 5.3, Laboratory equipment; and 5.8, Reporting of results
7.2 Customer-related processes	
7.2.1 Determination of requirements related to the product	4.4.Review of contracts
7.2.2 Review of requirements related to the product	4.4.Review of contracts
7.2.3 Customer communication	4.7, Advisory services; 4.8, Resolution of complaints; 5.5.6; 5.5.7; and 5.8, Reporting of results
7.3 Design and development	
7.3.1 Design and development planning	5.2, Accommodation and environmental conditions; and 5.3, Laboratory equipment
7.3.2 Design and development inputs	
7.3.3 Design and development outputs	
7.3.4 Design and development review	
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	
7.4.1 Purchasing process	4.5.1; 4.6, External services and supplies

Table A.1 (*continued*)

ISO 9001:2000	ISO 15189:2002
7.4.2 Purchasing information	
7.4.3 Verification of purchased products	4.6.2 and 5.5.3
7.5 Production and service provision	
7.5.1 Control of product and service provision	4.2.5; 5.2, Accommodation and environmental conditions; 5.3, Laboratory equipment; 5.4, Pre-examination procedures; 5.5, Examination procedures; and 5.7, Post-examination procedures
7.5.2 Validation of processes for production and service provision	5.3, Laboratory equipment, 5.5.1 and 5.5.2
7.5.3 Identification and traceability	5.4.5; 5.6, Assuring the quality of examination procedures
7.5.4 Customer property	
7.5.5 Preservation of product	5.5, Examination procedures
7.6 Control of monitoring and measuring devices	4.2.5; 5.3, Laboratory equipment; and 5.6, Assuring the quality of examination procedures
8 Measurement, analysis and improvement	
8.1 General	4.9, Identification and control of nonconformities
8.2 Monitoring and measurement	5.6, Assuring the quality of examination procedures
8.2.1 Customer satisfaction	4.8, Resolution of complaints
8.2.2 Internal audit	4.14, Internal audits
8.2.3 Monitoring and measurement of processes	4.2.5
8.2.4 Monitoring and measurement of product	5.5, Examination procedures; 5.6, Assuring the quality of examination procedures; and 5.7, Post-examination procedures
8.3 Control of nonconforming product	4.9.1; 4.9.2; and 4.10, Corrective action
8.4 Analysis of data	4.9.1; 4.12.1; and 4.12.2
8.5 Improvement	
8.5.1 Continual improvement	4.12, Continual improvement
8.5.2 Corrective action	4.12.2, 4.12.3 and 4.10, Corrective action
8.5.3 Preventive action	4.11, Preventive action

Table A.2 — Correlation between ISO/IEC 17025:1999 and this International Standard

ISO/IEC 17025:1999	ISO 15189:2002
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
4.2 Quality system	4.2 Quality management system
4.3 Document control	4.3 Document control
4.4 Review of requests, tenders and contracts	4.4 Review of contracts
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 client	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 Corrective action	4.10 Corrective action
4.11 Preventive action	4.11 Preventive action
	4.12 Continual improvement
4.12 Control of records	4.13 Quality and technical records
4.13 Internal audits	4.14 Internal audits
4.14 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 method validation	5.5 Examination procedures
5.5 Equipment	5.3 Laboratory equipment
5.6 Measurement traceability	5.6 Assuring the quality of examination procedures
5.7 Sampling	5.4 Pre-examination procedures
5.8 Handling of test and calibration items	
5.9 Assuring the quality of test and calibration results	5.6 Assuring the quality of examination procedures
5.10 Reporting the results	5.8 Reporting of results

Annex B
(informative)

Recommendations for protection of laboratory information systems (LIS)

B.1 General

B.1.1 Results and information are the products of the medical laboratory. Because computer systems can be damaged or subverted in a variety of ways, it is important to establish policies that protect patients from harm caused by loss or change of data.

The recommendations given in this annex ought to result in a high level of data/information integrity for laboratory information systems (LIS).

NOTE They are not applicable to

— desktop calculators,

— small programmable technical computers,

— purchased services and outsourcing,

— computers used solely for word processing, spreadsheets or similar, single-user functions, or

— dedicated microprocessors that are an integral part of an examination instrument.

B.2 Environment

B.2.1 The computer facilities and equipment should be clean, well maintained and in a location and environment that complies with vendor specifications.

B.2.2 Computer components and storage areas should be readily accessible to appropriate fire-fighting equipment.

B.2.3 Wires or computer cables should be protected if located in traffic areas.

B.2.4 There should be provision for an uninterruptible power supply (UPS).

B.2.5 The information facilities should be protected from unauthorized access.

B.3 Procedure manual

B.3.1 A complete computer procedure manual, which may be electronic, should be readily available to all authorized computer users.

B.3.2 The laboratory computer procedure manual should be reviewed and approved at defined intervals by the laboratory director or a person designated for this task.

B.3.3 There should be written procedures for actions necessary to protect the data or computer equipment or both in case of fire or hardware/software failure.

B.4 System security

B.4.1 Computer programs should be adequately protected to prevent alteration or destruction by casual or unauthorized users.

B.4.2 Strict policies should be established for authorizing use the computer system. Policies should define those authorized to access patient data and those authorized to enter patient results, change results, change billing or alter computer programmes.

B.4.3 If data in other computer systems can be accessed through the LIS (e.g. pharmacy or medical records), there should be appropriate computer security measures to prevent unauthorized access to these data through the LIS. The LIS should not be allowed to jeopardise the data security of other systems.

B.5 Data entry and reports

B.5.1 Patient data on reports and video displays should be compared with original input in order to ensure the integrity of data transfer at defined intervals by detecting errors in data transmission, storage or processing.

B.5.2 Whenever multiple copies of tables are maintained within a system (e.g. biological reference interval tables in both the laboratory information system and the hospital information system), they should be periodically compared in order to ensure consistency among all copies in use. Appropriate replication or comparison procedures should be in place.

B.5.3 Documentation should exist stating that calculations performed on patient data by the computer are periodically reviewed.

B.5.4 The LIS output to the medical record constitutes direct patient-care data. Accordingly, the laboratory director should approve and review the content and format of the laboratory reports in order to ensure that they effectively communicate laboratory results and meet the needs of the medical staff.

B.5.5 Data entered into the computer system either manually or by automated methods should be reviewed in order to verify the correctness of the input data before final acceptance and reporting by the computer.

B.5.6 All result entries should be checked against a predefined range of values for a particular examination in order to detect absurd or impossible results before final acceptance and reporting by the computer.

B.5.7 The reporting system should provide for comments on sample quality that might compromise the accuracy of examination results (e.g. lipaemic, haemolyzed samples) and for comments on interpretation of results.

B.5.8 There should be an audit mechanism allowing the laboratory to identify all individuals who have entered or modified patient data, control files or computer programs.

B.6 Data retrieval and storage

B.6.1 Stored patient result data and archival information should be easily and readily retrievable within a time frame consistent with patient-care needs.

B.6.2 The computer should be able to completely reproduce archived examination results, including the biological reference interval originally given for an examination and any flags, footnotes or interpretative comments attached to the result, as well as the uncertainty of measurement at the time the measurement was made.

B.6.3 Patient and laboratory data should be retrievable, “on-line”, for a designated period of time, depending on the needs of the individual organization.

B.6.4 Data-storage media, such as tapes and disks, should be properly labelled, stored and protected from damage or unauthorized use.

B.6.5 Efficient back-up should be in place to prevent loss of patient result data in case of hardware or software failure.

B.6.6 Computer alarm systems (usually the main computer console that monitors hardware and software performance) should be monitored and tested regularly to ensure their proper functioning.

B.7 Hardware and software

B.7.1 A written procedure and a complete record of all preventive maintenance for all computer hardware should be readily available.

B.7.2 The system should be checked after each back-up or restoration of data files in order to ensure that no inadvertent alterations have occurred.

B.7.3 Mistakes detected during system backup should be documented, along with corrective action taken, and reported to the responsible person in the laboratory.

B.7.4 Any alterations to the system hardware or software should be verified, validated and completely documented in order to confirm that changes are acceptable and appropriate.

B.7.5 The laboratory director or person designated for the task is responsible for the accurate and effective delivery of examination results to the requesting clinician and should approve all changes in the computer system that may affect patient care.

B.7.6 Programs should be checked for proper performance when first installed and after changes or modifications have been made.

B.7.7 The purpose of a program, the manner of its functioning and its interaction with other programs should be clearly stated. The degree of detail should be adequate to support any troubleshooting, system modification or programming — as applicable — done by the computer operators.

B.7.8 Those interacting with the computer system should be taught how to use a new system or modifications of the old system.

B.7.9 The laboratory should have designated a responsible person to whom all significant computer malfunctions are to be promptly reported.

B.8 System maintenance

B.8.1 “Downtime” for maintenance should be scheduled to minimize interruption of patient-care service.

B.8.2 There should be documented procedures for handling the shutdown and restarting of all or part of the system in order to ensure integrity of the data, uninterrupted delivery of laboratory services and proper functioning of the system after restarting.

B.8.3 There should be written procedures for handling downtime on other systems such as the hospital information system, to ensure the integrity of patient data. Procedures for verifying recovery of the other system and the replacement or updating of data files should be available.

B.8.4 All unscheduled computer downtime, periods of system degradation (response time) and other computer problems should be documented, including the reasons for failure and the corrective action taken.

B.8.5 Written contingency plans should be developed to handle services in the event of a computer system failure such that patient results are reported in a prompt and useful fashion.

B.8.6 Records should be maintained that document regular maintenance and allow operators to trace any work done on the computer system.

Annex C
(informative)

Ethics in laboratory medicine

C.1 General

The professional personnel of a medical laboratory are bound by the ethical codes of their respective profession. Different countries can have particular rules or requirements for some or all professional personnel which have to be observed. For an example, see [18].

Personnel responsible for the management of medical laboratories should accept that, as with other health professionals, they could have responsibilities over and above the minimum required by law.

Acceptable practice will vary somewhat from country to country. A laboratory will need to determine what is appropriate for their own situation and incorporate the details in their quality manual.

Laboratories shall not engage in practices restricted by law and should uphold the reputation of their profession.

C.2 General principles

C.2.1 The general principle of healthcare ethics is that the patient's welfare is paramount. However, the relationship between the laboratory and the patient is complicated by the fact that there could also be a contractual relationship between the requester and the laboratory. Although this relationship (which is often commercial) can frequently be seen as the more important, the laboratory's obligation should be to ensure that the patient's welfare and interest are always the first consideration and take precedence.

C.2.2 The laboratory should treat all patients fairly and without discrimination.

C.3 Collection of information

C.3.1 Laboratories should collect adequate information for the proper identification of the patient, which enables the requested examinations and other laboratory procedures to be carried out, but should not collect unnecessary personal information.

The patient should be aware of the information collected and the purpose for which it is collected.

C.3.2 Safety of staff and other patients are legitimate concerns when communicable diseases are possible and information may be collected for these purposes. Billing purposes, financial audit, resource management and utilization reviews are also legitimate management concerns for which information may be collected.

C.4 Collection of primary samples

C.4.1 All procedures carried out on a patient require the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents him- or her-self 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 the more invasive procedures, will require a more detailed explanation and, in some cases, written consent. This is desirable when there is a likelihood of complications following the procedure.

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

C.4.2 Some examinations (e.g. certain genetic or serologic examinations) may require special counselling. This would normally be carried out by the clinical staff or requesting physician, but the laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

C.4.3 Adequate privacy during reception and sampling should be available and appropriate to the type of primary sample being collected and information being requested.

C.4.4 If a primary sample arrives at the laboratory in a condition that is unsuitable for the requested examination, it should normally be discarded and the referring physician notified.

C.5 Performance of examination

All laboratory examinations should be carried out according to appropriate standards and with the level of skill and competence expected of the profession.

Any fabrication of results is completely unacceptable.

In situations where the pathologist or the laboratory can determine the amount of work involved with a requested examination (e.g. the number of blocks that may be cut from a histology specimen), the selection should be reasonable for the particular situation.

C.6 Reporting of results

C.6.1 Results of laboratory examinations that can be attributed to a specific patient are confidential unless disclosure is authorized. Results will normally be reported to the requesting physician and may be reported to other parties with the patient's consent or as required by law. 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.

C.6.2 Decisions concerning implied consent for the reporting of results to other parties (e.g. consultant practitioners to whom the patient has been referred) should be made cautiously, taking local customs into account. Laboratories should have written procedures detailing how various requests are handled and this information should be made available to patients on request.

C.6.3 In addition to the accurate reporting of laboratory results, the laboratory has an additional responsibility to ensure that, as far as possible, the examinations are correctly interpreted and applied in the patient's best interest. Specialist advice with regard to the selection and interpretation of examinations is part of the laboratory service.

C.7 Storage and retention of medical records

C.7.1 The laboratory should ensure that the information is stored such that there are reasonable safeguards against loss, unauthorized access or tampering and other misuse.

C.7.2 The retention of medical records can be defined by various statutory and legislative requirements in different countries and these requirements will need to be considered together with any guideline issues by relevant professional bodies.

Local customs, particularly the reliance of clinicians on laboratory records as opposed to their own records, also need to be taken into account.

C.7.3 Concerns regarding legal liability for certain types of procedures (e.g. histology examinations) may require the retention of certain records or materials for much longer periods than for other records or samples.

C.7.4 Laboratories should develop their own protocols for the retention of records, indicating the time various examination results are to be retained. The system should provide ready access, when required, by authorized individuals.

C.8 Access to medical laboratory records

C.8.1 Access to medical laboratory records varies somewhat according to different customs in different parts of the world. Patient access will normally be through the requesting physician. In many countries access will normally be available to

a) the person requesting the examination,

b) laboratory staff, if required for the performance of their duties, and

c) other authorized individuals.

The rights of children and mentally impaired individuals also varies from country to country. Health information can sometimes be withheld from individuals who would normally be expected to be authorized to receive it. This could be for reasons of maintenance of law or individual safety and when access would involve unwarranted disclosure of the affairs of another individual.

C.8.2 The laboratory should develop protocols adressing the handling of different requests in accordance with local laws and customs.

C.9 Use of samples for examination purposes other than those requested

The use of samples for purposes other than those requested without prior consent should occur only if the residual samples are rendered anonymous or have been pooled. Laboratories/institutions should have documented policies for handling unrequested information (e.g. follow-up examinations to clarify previous results) from identifiable samples, taking into account the legal implications. Relevant national, regional and local regulatory and ethical committee requirements should be observed. See [18].

C.10 Financial arrangements

C.10.1 Medical 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 physician's independent assessment of what is best for the patient.

C.10.2 Where possible, rooms used for primary sample collection should be completely independent and separate from referring practitioners' rooms, but where this is not possible, financial arrangements are to follow normal commercial practice.

C.10.3 Laboratories should try to avoid situations that give rise to a conflict of interest. Where this is not possible, the interests should be declared and steps taken to minimize the impact.

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