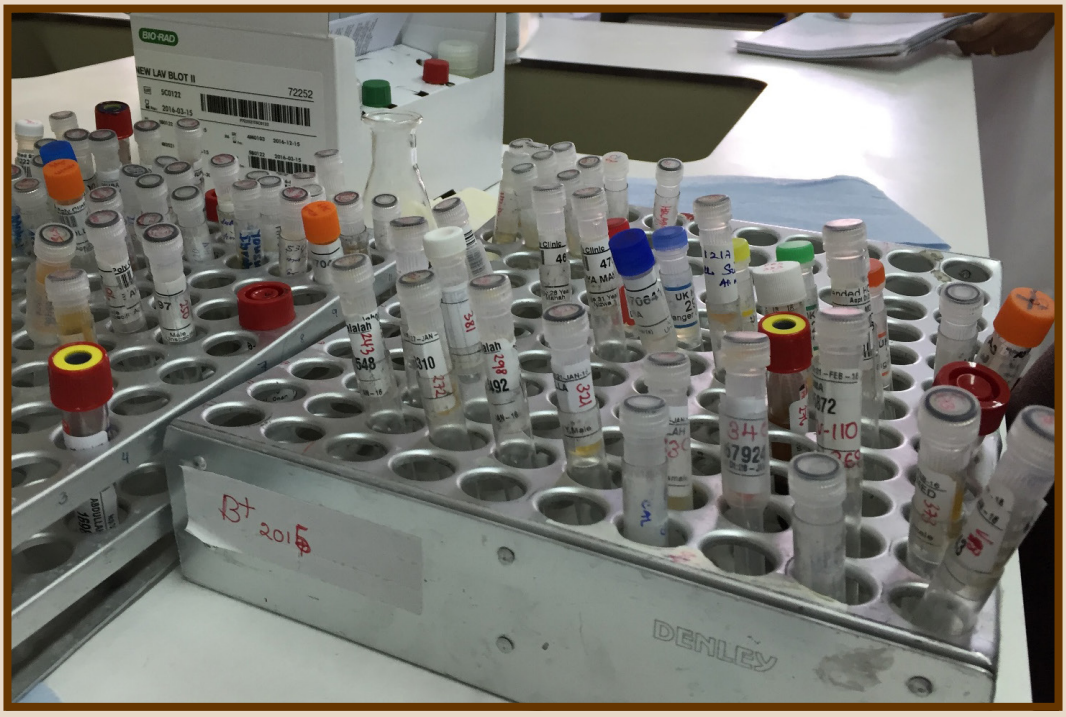
WHO Regional Publications, Eastern Mediterranean Series 39

Stepwise implementation of a quality management system for a health laboratory



World Health Organization
Regional Office for the Eastern Mediterranean

WHO Regional Publications, Eastern Mediterranean Series 39

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WHO Library Cataloguing in Publication Data

World Health Organization. Regional Office for the Eastern Mediterranean
Stepwise implementation of a quality management system for a health laboratory / World Health Organization. Regional Office for the Eastern Mediterranean
p. .- (WHO Regional Publications, Eastern Mediterranean Series; 39)
ISBN: 978-92-9022-142-5
ISBN: 978-92-9022-143-2 (online)
ISSN: 1020-041X
1. Laboratories - standards 2. Quality Control 3. Clinical Laboratory Services - standards 4. Public Health Practice I. Title II. Regional Office for the Eastern Mediterranean III. Series
(NLM Classification: WA 23)

Design, layout and printing by WHO Regional Office for the Eastern Mediterranean, Cairo, Egypt

Cover photo shows triage and preparation of patient specimens for processing and examination.
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1. Introduction

Health laboratory services are essential for human health care because decisions on diagnosis, treatment and prognosis are often based on the results and interpretations of medical laboratory tests. To assure and improve the level of patient care while simultaneously limiting the related costs, the implementation of quality systems in medical laboratories has expanded worldwide in recent years.

International standard ISO 15189 "Medical laboratories – requirements for quality and competence" was developed for medical laboratories by the International Organization for Standardization (ISO). That standard imposes stringent requirements on laboratories that many are unable to fulfil, especially in resource-limited countries.

As an outcome of the Joint World Health Organization (WHO)/Centers for Disease Control and Prevention (CDC) Conference on Health Laboratory Systems, Lyon, France, 9–11 April 2008, the following statement was issued.

> International efforts are under way to develop health laboratory standards that help to ensure quality. These efforts should be supported as follows. (i) Each country should establish its own set of standards according to country-specific needs based on internationally agreed standards. (ii) National laboratory standards need to take into account local factors, including any pertinent regulations, organization of the country's laboratory system(s), and resource constraints. (iii) It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189.

For Member States of the WHO Eastern Mediterranean Region, a WHO workshop on strengthening laboratory quality systems and promoting national laboratory planning was held in October 2010 in Oman. The workshop concluded with several recommendations that emphasized, in particular, that Member States should promote national laboratory quality systems through the adoption of national standards, which should be based on the internationally recognized standards, and that implementation of those standards by Member States should follow a step-wise approach, with the

eventual goal of meeting international standards. WHO was recommended to take the lead in developing harmonized national and regional guidance to support Member States in development and implementation of their national laboratory quality standards, and that can be practically implemented by all types of health laboratories, and adapted by other types of public health facilities, such as food- or water-testing laboratories. Such guidance should lead stepwise to compliance with international quality standards, such as ISO 15189, and include a system for internal quality control and use of reliable external quality assessment schemes operated by qualified providers in the Region.

This document was developed in response to the above recommendations and to satisfy a significant need for practical procedures and guidance on quality assurance and quality management in health laboratory diagnostics in the Region.

2. Purpose of the document

2.1 Scope and objectives

This document aims to support health laboratories to implement essential elements of quality assurance and quality management according to national health laboratory policies and systems. It presents a minimum set of standards that can be readily adapted by countries in the Eastern Mediterranean Region and applied to laboratories at every level of the health care system. It can also be used to develop a practical strategy for the preparation and implementation of national guidelines for quality assurance and quality management in health laboratories, on the basis of the quality elements provided by this guidance and after adaptation to meet local and national requirements. The guidance will also support national policy-makers and regulators in developing national quality standards.

Health laboratories are the primary focus of this document. Here, a health laboratory is defined as the basic unit, comprising single or multiple rooms (technical rooms, reception, offices, storage and wash rooms), which apply analytical methods to provide results for a defined health-related purpose, such as medical research, medical diagnostics, disease surveillance, and food testing. Most of the health laboratories are medical or clinical laboratories for biological, microbiological, immunological, chemical, immuno-haematological, haematological, biophysical, cytological, pathological, genetic or other examination of human specimens, to provide information for diagnosis, management, prevention and treatment of disease, or assessment of health. The laboratories may provide a consultant advisory service covering all aspects of laboratory investigation, including interpretation of results and advice on further appropriate investigation. Although this guidance focuses on medical laboratories, the principles laid down are also applicable to other types of health laboratory, such as food or water testing.

Countries with existing national laboratory quality standards are encouraged to review them regularly, guided by this document. The review process or establishment of standards should be carried out through a national laboratory coordinating committee under the auspices of the Ministry of Health.

This document is based on the internationally recognized standards and good practices governing laboratory services but is not intended to replace existing international or national standards. Instead, it supports the stepwise and continual improvement towards full implementation of a comprehensive quality management system, in compliance with relevant national and/or international regulations.

2.2 Target audience

The intended audience of the document is any stakeholder involved in medical and health laboratory examinations, such as ministries of health, laboratory managers, quality officers and technical laboratory staff, national public health laboratories and/or focal points, national regulatory health authorities, providers of external quality assessment schemes (EQAS), professional societies and manufacturers of in vitro diagnostic medical devices.

2.3 How to use the document

The document and its recommendations related to the implementation strategy (Section 4) can be readily used as they stand, or after adaptation to meet national/local requirements. The guidance should be read as recommendations for development and implementation of national quality standards that can be implemented by all types of medical and health laboratories. It emphasizes implementation of a quality system covering essential or minimal criteria that can lead stepwise to compliance with international quality standards, such as ISO 15189.

Together with other tools provided by WHO, such as the Laboratory assessment tool, Laboratory quality stepwise implementation tool and Laboratory quality management system training toolkit (see Bibiliography), this guidance might also be used to support situational and gap analysis and implementation of quality management systems in the laboratories of the national health laboratory system.

A correlation table is provided at the end of the guidance to help users understand the links between this document and ISO 15189.

3. Essential elements of national quality standards

3.1 Structure and organization

3.1.1 Legal identity

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

3.1.2 Laboratory director

The laboratory should be directed by a person or persons with the authority and competence to be responsible for the services provided. The responsibilities of the laboratory director should include professional, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.

Although the laboratory director may delegate selected duties to qualified personnel, the director should maintain responsibility for the overall operation and administration of the laboratory.

The laboratory director (or those designated for delegated duties) should have the necessary competence, authority and resources in order to:

- provide effective leadership of the medical laboratory service;
- ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;
- ensure and monitor the systematic implementation and sustainability of the quality management system;
- implement a safe laboratory environment in compliance with good practice and applicable requirements;
- ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

- select referral laboratories and monitor the quality of their service (see also Section 3.7.4);
- monitor all work performed in the laboratory to determine that clinically relevant information is being generated;
- address any complaint, request or suggestion from staff and/or users of laboratory services (see also Section 3.6.5);
- design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; and
- if applicable (e.g. for laboratories with public health functions), ensure that the laboratory fulfils its public health functions (e.g. networking activities, supervision, and surveillance).

Note. Contingency plans should be periodically tested.

3.1.3 Responsibility, authority and inter-relationships

The laboratory director should ensure that responsibilities, authorities and inter-relationships are defined, documented and communicated within the laboratory organization. This should include the appointment of person(s) responsible for each laboratory function and appointment of deputies for all key functions.

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

Laboratory management should ensure that appropriate communication processes are established within the laboratory, and that communication takes place regarding the effectiveness of the pre-examination, examination and post-examination processes and quality management system. In particular, effective communication should be ensured for specific laboratory clients and stakeholders, such as ministries of health, disease control programmes and funding agencies.

3.1.4 Quality manager

The laboratory director should appoint a quality manager who should have, irrespective of other responsibilities, delegated responsibility and authority that include:

- ensuring that processes needed for the quality management system are established, implemented and maintained;
- reporting to the laboratory director on laboratory policy, objectives and resources, on the performance of the quality management system and any need for improvement; and
- ensuring the promotion of awareness throughout the laboratory organization of the requirements of the quality management system and the needs and requirements of users.

3.2 Facilities and environmental conditions

3.2.1 General

The laboratory should have space allocated for the performance of its work that is designed to ensure the quality and safety of the service provided to the users, and the health and safety of laboratory personnel, patients, visitors and the environment.

3.2.2 Laboratory and office facilities

The laboratory and associated office facilities should have adequate space and provide an environment suitable for the tasks to be undertaken, to ensure that:

- access to areas affecting the quality of examinations is controlled;
  Note. Access control should take into consideration safety, confidentiality, quality and prevailing practices.
- signs for restricted areas and access controls to laboratories are provided;
- medical information, patient samples and laboratory resources are safeguarded from unauthorized access;
- facilities for examination allow correct performance of examinations, including energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions; and
- safety facilities and devices are provided and their functioning regularly verified, for example, eye washes, showers and fire extinguishers.

3.2.3 Storage facilities

Storage space and conditions should be provided that ensure the continuing integrity of samples, slides, histology blocks, retained microorganisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results.

Clinical samples should be stored under appropriate conditions, separate from reagents and materials used in examination processes, to prevent cross contamination.

Specific biosafety and biosecurity measures should be taken to ensure safe storage of highly dangerous pathogens.

3.2.4 Staff facilities

There should be adequate access to:

- hand-wash basins, including hand sanitization
- washrooms and toilets
- a supply of drinking water and facilities for food storage
- facilities for storage of personal protective equipment and clothing.

Note. When possible, the laboratory should provide space for staff activities and a rest area.

3.2.5 Patient sample collection facilities

Patient sample collection facilities should have separate reception/waiting and collection areas. Consideration should be given to the accommodation of patient privacy, comfort, and needs and accommodation of appropriate accompanying person during collection.

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

3.2.6 Facility maintenance and environmental conditions

Laboratory premises should be maintained in a functional and reliable condition. Work areas should be clean and well maintained. Measures should be taken to ensure good housekeeping and waste management. There should be policies in place for infection control, maintenance, cleaning (facility, housekeeping and laboratory waste), evacuation and hazardous events.

Attention should be paid to environmental factors such as light, sterility, dust, radiation, humidity, electrical supply, temperature, directional airflow, and noise and vibration levels, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination. Essential laboratory equipment should be supplied with a continuous uninterrupted power supply.

There should be effective separation between laboratory sections in which there are incompatible activities.

3.3 Human resources

3.3.1 General

The laboratory should have a documented procedure for personnel hiring, training and management, and maintain records for all personnel that indicate compliance with the requirements of this guidance.

3.3.2 Job descriptions

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

The laboratory should have job descriptions that describe responsibilities and tasks for all personnel. Job descriptions should contain at least the following information:

- job title
- required minimum qualifications
- key tasks
- general tasks
- accountability
- department in which the person will work
- interfaces with other departments
- staff responsibilities.

3.3.3 Training and continuing education

The laboratory management should provide a continuous training programme for all personnel that includes the following:

- the quality management system
- assigned work processes and procedures
- health and safety, including the prevention or containment of the effects of adverse incidents
- ethics and confidentiality of patient information.

Personnel at all levels should take part in appropriate continuing training and education.

3.3.4 Personnel records

Records of the relevant educational and professional qualifications, training and experience of all personnel should be maintained and readily available to relevant personnel.

Note. Examples of personnel records are copies of certification and/or license, previous work experience, job descriptions, training in current job tasks, records of continuing education and achievements, and immunization status, if relevant to assigned duties.

3.4 Laboratory equipment, reagents and consumables

3.4.1 Laboratory equipment

The laboratory should be furnished with all equipment needed for the provision of services.

Note. Laboratory equipment includes instrument hardware and software, measurement systems, and laboratory information systems. Laboratories should not be storage places for inoperable or decommissioned equipment and their supplies.

The laboratory should verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned.

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

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

Each item of equipment should be uniquely labelled or otherwise identified.

Records should be maintained for each item of equipment that contributes to the performance of examinations. These equipment records should include at least the following:

- identity of the equipment;
- manufacturer's name, type identification, and serial number or other unique identification;
- contact information for the supplier or the manufacturer and on-call service;
- date of receiving and date of entering into service;
- location;
- condition when received (e.g. new, used or reconditioned);
- manufacturer's instructions;
- records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;
- maintenance carried out and the schedule for preventive maintenance;
- equipment performance records that confirm the equipment's ongoing acceptability for use (such as periodic calibration, verification, and quality control records); and
- damage to, or malfunction, modification or repair of the equipment.

3.4.2 Reagents and consumables

The laboratory should have appropriate documented procedures for receiving, storing and managing reagents and consumables.

Note. Reagents include reference materials, calibrators and quality control materials; consumables include culture plates, pipette tips and glass slides.

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

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

3.5 Examination processes and quality assurance of examination results

3.5.1 Examination processes

The laboratory should select examination procedures that meet the needs of users and are appropriate for the examination being undertaken.

The laboratory should only use examination procedures that have been validated for their intended use.

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

Examination procedures from method developers that are used without modification should be subject to verification before being introduced into routine use. When examination procedures have been validated by the manufacturer, the laboratory should obtain information from the provider to confirm their performance characteristics.

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

The documentation should include, when applicable to the examination procedure, the following:

- purpose of the examination;
- principle and method of the procedure used for examination;
- performancecharacteristics;
- type of sample (e.g. plasma, serum, urine);
- patient preparation;
- type of container and additives;
- sample rejection criteria;
- required equipment and reagents;

- environmental and safety controls;
- calibration procedures (metrological traceability);
- procedural steps;
- quality control procedures, including verification and interpretation of control results;
- interferences (e.g. lipaemia, haemolysis, bilirubinaemia, drugs) and cross-reactions;
- principle of procedure for calculating results, including uncertainty of examination results;
- biological reference intervals;
- reportable interval of examination results, including instructions for determining quantitative results when a result is not within the measuring interval;
- alert/critical values, where appropriate;
- laboratory clinical interpretation;
- potential sources of variation;
- limitations of the test;
- references.

3.5.2 Internal quality control

Quality control materials should be examined at appropriate intervals along with patient samples, with a frequency that is based on the stability of the procedure.

Note 1. The laboratory should choose concentrations of control materials, especially at or near clinical decision values that ensure the validity of decisions made.

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

The basic concept of the control sample system is that quality control materials are processed in the same way as samples from patients. The results obtained from the quality control materials should not exceed tolerance limits (permissible deviations of measurements). The laboratory management is responsible for specifying the tolerance limits. These limits and the rationale for how they have been established should be documented.

When the quality control rules are violated, examination results should normally be rejected, and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified.

The laboratory should also evaluate the results from patient samples that were examined after the last successful quality control event.

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

Note. Established statistical techniques such as Levey-Jennings charts and process control rules should be used wherever possible to continuously monitor examination system performance.

Qualitative examinations also require specific internal quality control procedures. Qualitative examinations are those that measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. The results are not expressed in numerical terms, but in descriptive or qualitative terms such as positive, negative, reactive, nonreactive, normal or abnormal (e.g., microscopic examinations for cell morphology or presence of parasitic organisms, serological procedures for presence or absence of antigens and antibodies, some microbiological procedures, and some molecular techniques).

Conducting quality control for many of these tests is not as easily accomplished as with quantitative tests. Therefore, it is essential to conduct carefully other processes within the quality system, in addition to traditional quality control methods. The following are some important overarching concepts for quality that apply to qualitative and semi-quantitative tests.

- Sample management is important in all laboratory testing.
- Examinations that are dependent on a viable organism in the sample may need close monitoring and good communication with non-laboratory personnel/ departments.
- Incubators, refrigerators, microscopes, autoclaves and other equipment must be maintained and carefully monitored.
- Positive and negative controls must be used to monitor the effectiveness of test procedures that use special stains or reagents, and tests with endpoints such as agglutination, colour change or other non-numerical results.

- Reagents should be stored according to manufacturer's instructions, labelled with the date they are opened and put into use, and discarded at the expiration date.

Qualitative examinations require a variety of control materials. These may be built-in (onboard or procedural) controls, traditional controls that mimic patient samples, or consist of stock cultures for use with microbiological examinations.

3.5.3 External quality assessment schemes

The laboratory should participate in external quality assessment (EQA) programmes (or proficiency testing programmes) appropriate to the examinations and interpretations provided.

The laboratory should establish a documented procedure to define the responsibilities and instructions for participation in external quality assessment schemes. The basic concept of the control sample system is that quality control materials are processed in the same way as samples from patients.

External quality assessment schemes should be run on main analysers as well as backup analysers, if present.

The laboratory director should monitor the results of the external quality assessment schemes and participate in the implementation of corrective actions when control criteria are not fulfilled.

Laboratories should formalize which actions are taken and who has to take notice of the results by signing them (e.g., responsible technicians, quality manager, and laboratory or unit head). Laboratories should share the outcome of external quality assessment reports with all concerned staff to inform them about gaps and corrective actions taken.

Note. It is good laboratory practice to measure samples obtained by external quality assessment scheme providers at two different levels for each parameter, and if appropriate, at least four times per year. Laboratories that do not check bias in each cycle within their internal controls should participate six times per year in external quality assessment schemes.

3.6 Quality management system

The laboratory should establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with

the requirements of this guidance and other appropriate standards or guidelines that comply with national and international recommendations.

3.6.1 Quality policy

The laboratory should define the intent of its quality management system in a documented quality policy. The laboratory management should ensure that the quality policy:

- is appropriate to the purpose of the organization;
- includes a commitment to good professional practice, quality examinations, compliance with the requirements of this guidance and other applicable national or regional standards related to employees (training, competence and appraisal), resource management, safety management systems, and continual improvement of the quality management system;
- is communicated and understood within the organization; and
- is reviewed for continuing suitability.

The senior management of the organization should commit officially to the quality policy of the laboratory.

3.6.2 Documentation requirements

The quality management system documentation should include:

- statement of a quality policy;
- a quality manual;
- procedures and records required for the relevant processes;
- documents and records, determined by the laboratory to ensure effective planning, operation and control of its processes; and
- copies of applicable local and international regulations, standards and other normative documents.

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

Note. A document is any information, reference or instructions, including policy statements, flow charts, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters,

notices, memoranda, software, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken.

The laboratory should ensure that:

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

b) all documents are identified to include:

   i) a title

   ii) a unique identifier

   iii) the date of the current edition and/or edition number

   Note. Edition means one of several issues produced at different times, each of which incorporates alterations and amendments. Edition is synonymous with revision or version.

   iv) the number of pages among the total number of pages (e.g. page 1 of 5)

   v) author identification

   vi) authority for issue.

c) only current, authorized editions of applicable documents are available at points of use;

d) changes to documents are identified;

e) documents remain legible;

f) documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose; any change to the document requires that it be reauthorized;

   Note. The review interval for documents should be defined by the laboratory according to its needs,

g) archived documents are re retained for a time period specified in the laboratory retention policy and in accordance with confidentiality requirements.

h) obsolete documents are dated and marked as obsolete;

i) history and traceability of documents are kept; and

j) authorization for access to documentation is clearly defined and documented.

Documentation should be written in a language commonly understood by the staff and be available in appropriate locations.

3.6.3 Control of records

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

Note. Records are evidence of results achieved or activities performed and are maintained according to the requirements given below. Examples of records are staff qualifications, training and competency records, test request receipts, examination results and reports, quality control records, non-conformities identified and immediate or corrective action taken, external quality assessment records, and minutes of meetings that record decisions made about the quality management activities of the laboratory.

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

If there is a need to amend a record, then the date and, where relevant, the time of amendments should be captured along with the identity of personnel making the amendments.

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

Facilities should provide a suitable environment for storage of records to prevent damage, deterioration, loss or unauthorized access.

3.6.4 Quality manual

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

- the quality policy;
- a description of the scope of the quality management system;
- a description of the laboratory activities, functions and components;
- an introduction to the organization and description of the management structure of the laboratory and its place in any parent organization;
- a description of the roles and responsibilities of the laboratory director and quality manager;

- a description of the structure and relationships of the documentation used in the quality management system; and
- the documented policies established for the quality management system and reference to the managerial and technical processes and procedures that support them.

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

Note 1. Referenced documents are those documents that are maintained as part of the quality management system documentation. They are separate from the quality manual but are cited or referred to within the quality manual.

Note 2. It is suggested that the formal structure of the quality manual follows the structure of the standards followed by the laboratory.

3.6.5 Management of complaints, incidents and non-conformities

The laboratory should have a documented procedure for the detection, handling and resolution of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records should be maintained of all complaints, investigation of complaints, and the action taken.

The procedure for corrective actions should include: designation of responsibilities; time required for any actions to be taken; verification of the effectiveness of corrective actions; and a final response to the initial claimant.

When non-conformities are identified in any aspect of the quality management system, including pre-examination, examination or post-examination processes, the laboratory should ensure that:

- the responsibilities and authorities for handling non-conformities are designated;
- the immediate actions to be taken are defined;
- the medical significance of any nonconforming examinations is considered, and the requesting clinician or authorized individual responsible for using the results is informed;
- the results of any nonconforming examinations already released are recalled or appropriately identified, as necessary; and
- each episode of non-conformity is documented and recorded.

The laboratory should take corrective action to eliminate the root causes of non-conformities. The laboratory should determine preventive actions to eliminate the causes of potential non-conformities to prevent their occurrence.

Adverse incidents and accidents should be investigated, recorded and reported to the relevant organizations, for example, manufacturers and authorities. Appropriate corrective actions should be taken.

3.6.6 Internal audits

The laboratory should conduct internal audits at planned intervals to determine whether the quality management system is effectively implemented and maintained. The main elements of the quality management system should be subject to internal audit at least once a year.

Audits should be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. Personnel responsible for the area being audited should ensure that appropriate action is promptly undertaken when non-conformities are identified. Corrective action should be taken without undue delay to eliminate the causes of the detected non-conformities. Records of internal audits should be maintained.

Note. Examples and instructions for the implementation of effective internal audit procedures can be found at extranet.who.int/lqsi/, Laboratory quality stepwise implementation tool, under the section Phase 3 > Quality system essentials > Assessment.

3.7 Procurement and supply management

3.7.1 Selection and purchasing

The laboratory should select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the quality requirements of the laboratory. These requirements should be specified by the laboratory users of procurement and supplies and should be in accordance with national requirements and/or international recommendations.

Note 1. Key criteria for selection and approval of suppliers may be classified into logistic, purchasing, quality and technological criteria.

Note 2. Criteria, methods and instructions for selection and approval of suppliers can be found in the WHO document Laboratory quality management system (LQMS) training toolkit > Purchasing and inventory, available at www.who.int/ihr/training/laboratory_quality/purchasing.

3.7.2 Verifying purchased equipment and consumable supplies

Purchased equipment and consumable supplies should not be used until it has been verified that they comply with the requirements defined for the pre-examination, examination or post-examination processes. The verification should include appropriate technical criteria related to quality, safety and performance of equipment and consumable supplies. Related records should be maintained.

3.7.3 Inventory management and records

The laboratory should establish an inventory control system for supplies. The inventory control system should include:

a) identity of the reagent or consumable

b) manufacturer's name, contact information for the supplier or the manufacturer

c) batch code or lot number

d) date of receiving, the expiry date, and date of entering into service

The laboratory should maintain the level of stock according to its defined needs.

3.7.4 Subcontracting

The laboratory should enter into documented arrangements with referral laboratories and consultants who can provide second opinions as well as interpretation of complex testing. Criteria for selection of subcontracted laboratories should be in place. Basic responsibilities of the referring and referral laboratories should be defined.

3.8 Management and examination of laboratory specimens

3.8.1 Pre-examination phase

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

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

a) the location of the laboratory;

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

c) working hours of the laboratory;

d) the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, biological reference intervals and clinical decision values;

e) instruction for preparation of the patient;

f) instructions for patient-collected samples;

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

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

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

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

k) the laboratory's complaint procedure.

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

Proper request forms should be used and contain information to identify correctly the source of the sample (e.g. patient) and the authorized person requesting the test.

The request form should contain the following:

- patient identification, including gender, date of birth, location/source of specimen, and a unique identifier;

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

- name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information;
- type of primary sample;
- examinations/tests requested;

- clinical details (e.g., patient's family history, travel and exposure history, any drugs being taken) that may be relevant for examination performance and interpretation of results;
- date and, where relevant, time of primary sample collection; and
- date and time of sample receipt in the laboratory.

Proper management of samples during collection, transport and storage should be ensured according to standard operating procedures, which should address:

- instructions to patients including their fasting state and collection of timed samples;
- type of sample container to be used for various laboratory tests;
- volume of sample required;
- any special/necessary additives, including anticoagulants;
- continuous training for staff involved in sample collection;
- primary sample collection technique;
- storage conditions, transportation and time frame of collection, and receipt, according to national regulations;
- correct labelling;
- special transport arrangements between the site of primary sampling and the laboratory;
- trained transport/courier; and
- safe disposal of materials used to collect primary samples.

Standard operating procedures should contain any pre-examination handling and preparation, including methods to deal with shared specimens such as aliquoting..

Standard operating procedures should contain the instructions to be followed when sample quality is suboptimal or unsatisfactory (e.g., recording of unusual physical characteristics such as lipaemia, haemolysis and icterus).

All primary samples should be given a unique identifying (accession) number recorded with the date and time of receipt. Taking aliquots of samples and subsampling should be done using appropriate laboratory safety precautions.

Note. Detailed instructions for packing and shipping specimens in compliance with international transportation requirements can be found in the WHO document *Guidance on regulations for the transport of infectious*

substances. The document is updated every who years. The latest version is available at http://www.who.int/ihr/publications/who_hse_ihr_2015.2/en/.

There should be a written policy to deal with incorrectly collected and/or identified samples received by the laboratory. Criteria should be developed and adopted for acceptance and rejection of specimens.

3.8.2 Examination phase

Careful selection of the examination procedure is important and depends on the facilities, equipment, staff availability and the number of samples for examination.

- The methods should be evaluated by the laboratory to ensure that they are suitable for the examinations requested.
- Standard operating procedures should be available for all analytical methods and proper functioning of the equipment.
- The procedures should contain the information outlined in Section 3.5.1, and authorized work instructions may be made available at workstations.

3.8.3 Post-examination phase

Designated staff should review and authorize release of the test results within defined time limits. There should be a policy for laboratory confirmation testing. Sharing user names and passwords should be restricted.

Laboratory results should be legible, without transcription mistakes, and preferably reported in SI units.

Laboratory reports should include:

- identification of the laboratory issuing the report;
- identification of the requester;
- type of sample;
- date and time of primary sample collection;
- date and time of sample receipt in the laboratory;
- date and time of reporting;
- comments on the primary sample that may have a bearing on interpretation of the results, e.g. haemolysis, icterus and lipaemia;

- comments on the quality of the primary sample that might invalidate the results, for example, clotted samples for measurement of haematology parameters;
- method of testing used;
- results and units of measurement;
- each gender-specific range, where appropriate
- normal reference interval (normal range) biological reference intervals, clinical decision values or recommended cut off/target value; and
- identification of the person releasing the report.

The laboratory should establish procedures for notifying the requester or clinician responsible for the patient's care when results of critical analyses fall outside specified limits. These specified limits should be agreed upon with clinicians and other users of the service.

There should be a documented procedure for reporting urgent results by telephone.

Procedures should be in place for storage of samples post-examination to enable re-examination if required, for a specified time and for their eventual safe disposal. The storage time for all primary samples and sub-samples, stained microscope slides, histology specimens and blocks, isolates and other biological material should be adhered to.

3.9 Safety

3.9.1 General

All clinical specimens to be analysed in the medical laboratory should be treated as potentially hazardous. A biosafety manual, including proper standard operating procedures, should be available in the laboratory and easily accessible to all personnel.

The laboratory director has the responsibility for the safety of all employees and visitors and should provide the facilities, training and required safety measures, including personal protective equipment. Awareness training should be provided to at-risk personnel (e.g. pregnant women).

All personnel (laboratory, maintenance and housekeeping) should have documented evidence of training related to potential risks associated with working in medical

laboratory facilities. Proper procedures should be adhered to when dealing with sharps.

All personnel should have documented immunization to prevent infection with organisms to which they are likely to be exposed. For example, all personnel working with or handling human blood, serum, other body fluids or human tissue should be offered hepatitis B vaccination. Immunization should be provided according to national regulations.

All staff handling patient samples and other biological materials should wear appropriate personal protective equipment. This should be removed before leaving the laboratory or undertaking clerical work. Hands should be washed immediately after removing the protective equipment and before leaving the laboratory. An appropriate antiseptic should be used.

First-aid materials and facilities should be readily available to deal with accidents. All accidents or potential accidents that might have occurred ("near misses") should be recorded and reported according to national regulations. A policy for post-exposure prophylaxis should be available.

3.9.2 Laboratory safety officer

An appropriately qualified and experienced laboratory safety officer should be designated to assist the laboratory management and staff with safety issues. This person should develop, maintain and monitor the laboratory safety programme.

An effective laboratory safety programme should include education, orientation and continuous training, audit and evaluation, and procedures to promote safe laboratory practice.

The laboratory safety officer should be authorized to stop activities that are unsafe. If there is a safety committee, the laboratory safety officer should be a member of this committee, if not its chairperson.

3.9.3 Procedures and biosafety manual

The standard operating procedures for the laboratory should include detailed instructions concerning any hazards involved and how to carry out the procedure with minimum risk.

Standard operating procedures should be available in the event of spillage/leakage of biological, chemical or radiochemical materials or patient samples (e.g. when containers are broken in a centrifuge).

A biosafety manual should include protocols for hazard communication. The manual should include the following:

- arrangements for visitors and contractors;
- staff health surveillance;
- procedures for monitoring inventories for identification of chemical and other hazardous materials, including appropriate labelling requirements, and safe storage and disposal;
- procedures for safe practices in handling hazardous materials;
- procedures to prevent theft or unintended release of high-risk or contaminated materials;
- procedures for safe decontamination and maintenance of equipment;
- emergency procedures including spillage protocols;
- incident recording, reporting and investigation; and
- disposal of clinical and laboratory waste.

3.10 Laboratory information management

The laboratory should ensure that the authorities and responsibilities for management of the information system are defined, including maintenance and modification of the information system, which may affect patient care and security, and data integrity and confidentiality.

The laboratory should define the key elements of the system and its implementation, including, at least, patient identification, essential request data, logs, work sheets and reports.

Note. Information system includes management of data and information contained in computer and noncomputerized systems. Some of the requirements may be more applicable to the former than latter systems.

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

- access patient data and information
- enter patient data and examination results
- change patient data and examination results
- authorize the release of examination results and reports.

The laboratory should have documented contingency plans to maintain services in the event of failures or down time of information systems that affect its ability to provide a service.

The laboratory should develop clear procedures for sharing information and communication with its clients: patients, physicians, and other health information systems (for disease surveillance, planning or other purposes such as medical research).

The laboratory should have a data backup and archive plan to ensure that lost data can be retrieved.

3.11 Ethical conduct

The laboratory should treat all patients fairly and without discrimination.

There should be appropriate procedures to ensure that all staff treat human specimens, samples, tissues or remains with due respect and in compliance with relevant legal requirements. Patients should be informed of the information collected and the purpose for which it is collected.

Confidential information should be protected and secured.

Laboratory management should have arrangements in place to ensure the following.

- There is no involvement in any activity that would decrease confidence in the competence, impartiality, judgement, or operational integrity of the laboratory.
- Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.

Any fabrication of results is completely unacceptable.

4. Stepwise implementation strategy

4.1 General introduction

The government's values, vision and strategies for quality improvement should be comprehensive, consistent and based on evidence and consultation with stakeholders. They should be explicitly stated and disseminated to the public. The policy should be comprehensive, accessible and consistent with other national policies and legislation. Key roles and incentives for quality improvement should be identified.

The process of implementing laboratory quality standards should follow a stepwise approach according to an agreed implementation plan drawn up by a national laboratory quality committee. The document should explain and define the process to achieve key milestones at each step.

Some countries may wish to develop national laboratory quality standards appropriate for each level of the health-care system, based on the regional standards addressed in this guidance.

Each country faces its own challenges, but there are many lessons that can be exchanged between countries for the definition, measurement and improvement of quality and performance in health care, and especially in laboratory services.

Improving quality depends less on having more staff, equipment or money than on reorganizing the use of existing resources and changing work practices.

Openness, confidence, motivation and commitment should be the foundations of a national quality culture.

Several analyses of national health policy on quality development have recognized a need for a collaborative balance between voluntary, independent peer review by health professionals (such as by clinical audit, governance and accreditation) and statutory, governmental control (such as by licensing, registration and inspection). The general conclusions are that statutory and voluntary quality systems should be coordinated by national or local government to ensure valid standards, reliable assessments, transparency and public accountability.

The following steps are a guide to implementing the laboratory quality standards provided within this document.

4.2 National level

Step 1: Set up a national laboratory quality committee

The national health authority should set up a committee for national health laboratory quality. This committee is a core group where different stakeholders of the system are represented. It is the key group for the initial and continuous situational analysis, capacity building, standards elaboration, monitoring, and continual improvement programme of the country.

Step 2: Set up the national laboratory quality policy

The national laboratory quality committee should establish and communicate the national laboratory quality policy to be endorsed and implemented by the national health authority. The policy should be a public, professional and political agenda for quality, for example, by national institutionalization of quality, by identification of needs for legislation. The policy should comprise a national vision and mission statement, policy objectives and guiding principles. It should include a commitment to transparency and accountability. It should include incentives for quality and performance improvement in the health laboratory system.

Step 3: Develop national quality standards

The national laboratory quality committee should establish a set of essential quality criteria that:

- considers appropriate internationally recognized standards (e.g. ISO 15189);
- suits local needs, considering the characteristics of the country's and region's laboratory profile; and
- allows achievement of standards in a practical and feasible time frame for all laboratories in the country, following a stepwise approach.

Step 4: Develop recommendations and guidelines for stepwise implementation of the quality management system

The national laboratory quality committee should design a cascade approach for stepwise implementation of the national standards, with consideration of the following principles and activities:

- promotion of a quality culture;
- integration with stakeholders such as medical laboratories, health authorities, professional societies, providers of external quality assessment schemes, and industry;
- communication with other agencies;
- capacity-building;
- pilot testing;
- provision of adequate tools for the assessment of pilot testing; and
- nationwide implementation.

Step 5: Design an assessment programme for evaluating and monitoring the implementation process

The national laboratory quality committee should take the lead regarding evaluation and monitoring of an effective quality assessment system. Several options are possible.

- Assessment is performed through a peer evaluation system based upon adequately trained management system and technical assessors taken from the professional field and/or governmental institutions such as the Ministry of Health, laboratory units within the ministry, and other laboratories, for example, university laboratories.
- Assessment is performed by subcontracting to external, nongovernmental audit organizations (including certification or accreditation bodies).
- Assessment is performed by a combination of the two above-mentioned options, with mandatory and/or voluntary mechanisms.

Step 6: Advocate for a national regulatory system for quality assurance of in vitro diagnostic medical devices

An important function of the national laboratory quality committee is to build advocacy among senior management and administrators of the Ministry of Health on the importance of national regulation of in vitro diagnostic medical devices (IVDs). The regulation specifies the requirements for the safety, quality and performance of IVDs, thus ensuring that they do not cause harm to the health and safety of patients, laboratory staff or other parties and achieve the performance specified by the manufacturer.

4.3 Laboratory level

A similar, stepwise process will be required by individual laboratories starting to implement the national standards. The laboratory management will need to take a leadership role and involve all staff in the process. Some changes will be easy to implement and cost little, such as reorganization; other changes will require moderate inputs and funding; and yet other changes will be more expensive or more difficult to implement.

Laboratories should start by making simple and easy-to-implement changes For example, they may begin by introducing operating procedures for particular activities one by one. These procedures could be for sample collection, including phlebotomy, or examination of particular analytes.

Laboratories should make arrangements to conduct regular meetings with users of the laboratory service. This will have the benefit of keeping users informed of the efforts being made to improve the quality of the laboratory service.

Note. International recommendations describe a three-stage to four-stage process for stepwise implementation of laboratory quality management systems. See Bibliography.

Glossary

Definitions and terms used in this guidance are based on international standards and recommendations. However, definitions and explanations used in this glossary are not necessarily identical with the original wording in the respective standards referred to in the Bibliography section of this guidance

Accreditation	Procedure by which an authoritative body gives formal recognition that an organization or person is competent to carry out specific tasks
Competence	Demonstrated ability to apply knowledge and skills
Corrective action	Action to eliminate the cause of a detected non-conformity or other undesirable situation
Form	Document used to record data required by the quality management system
Internal audits	Audits that are conducted by, or on behalf of, an organization for internal purposes, and may form the basis for an organization's declaration of conformity with certain standards. In many cases, particularly in smaller organizations, independence in internal audits can be demonstrated by the freedom from responsibility for the activity being audited.
Laboratory director	Competent person with responsibility for, and authority over, a laboratory
Laboratory management	Competent people who manage the activities of a laboratory headed by a laboratory director
Non-conformity	Non-fulfilment of a requirement

Post-examination processes	Processes following the examination, including review, formatting and interpretation, authorization for release, reporting and retention of examination results, and storage of samples used in the examinations
Pre-examination processes	Processes that start with the clinician's request and include the examination requisition; preparation of the patient; collection of the primary sample, and transportation to and within the laboratory; ending when the analytical examination procedure begins
Preventive action	Action to eliminate the cause of potential non-conformity or other undesirable potential situations
Procedure	Specified way to carry out an activity or process
Quality management system	Coordinated activities to direct and control an organization with regard to quality
Quality manual	Document specifying the quality management system of an organization
Quality policy	Overall intentions and direction of an organization related to quality as formally expressed by senior management
Senior management	Person or group of people who directs and controls an organization at the highest level
Work instructions	Detailed descriptions of how to perform and record tasks

Correlation table

This table provides a comparison of this guidance to ISO 15189:2012

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Health laboratory services provide vital support for disease prevention, diagnosis, treatment management, screening and surveillance. It is therefore an imperative that laboratory operations adhere to best practices and quality standards to ensure generation of accurate, reliable and timely results. ISO 15189:2012 "Medical Laboratories – Requirements for quality and competence" was developed by the International Organization for Standardization to assist health laboratories in developing their quality management systems and assessing their competence. This document is an adaptation of the ISO 15189 standard to the context and realities of resource-limited countries, where the requirements of the ISO standard may be too stringent to implement. It provides a minimum set of requirements that can be readily adjusted by countries and applied to laboratories at every level of their health care system and is intended as a resource for those seeking to improve quality of laboratory results and implement quality management systems in their facilities and operations. It can also be used as a basis for the development and implementation of national guidelines for quality assurance and quality management in health laboratories, in developing national quality standards for the health laboratories.

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