

# Laboratory Quality Standards and their Implementation



**World Health  
Organization**

South-East Asia Region    Western Pacific Region

# Laboratory Quality Standards and their Implementation

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# Abbreviations

CPD	continuing professional development
CQI	continuous quality improvement
EQAS	external quality assessment scheme
FIFO	first in–first out
HBV	hepatitis B virus
HIV	human immunodeficiency virus
IEQAS	international EQAS
IHR	International Health Regulations (2005)
ISO	International Standards Organization
IQC	internal quality control
MoH	Ministry of Health
NEQAS	national EQAS
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PPE	personal protective equipment
QA	quality assurance
QC	quality control
QM	quality manager
QMS	quality management system
REQAS	regional EQAS



SI	Systeme Internationale (of units)
SOP	standard operating procedure
TAT	turnaround time
UPS	uninterrupted power supply
WHO	World Health Organization

## Scope and objectives

The objective of this document on Laboratory Quality Standards is for it to be used as a guideline for evaluation, development and implementation of quality systems and standards for health laboratory services. The internationally accepted standards of the International Standards Organization (ISO) 15189 and ISO 17025 have stringent requirements and can usually be met only by laboratories either at the national level or by specialized reference laboratories. They are often very resource-intensive and many countries find it difficult to implement them. Since laboratories in developing Member States are at different levels with respect to quality, the standards outlined in this document, while based on the ISO standards, have been simplified to encourage Member States to follow them. A flexible step-wise approach is encouraged so that these guidelines become a stepping-stone to achieving the ISO standards.

Establishing and maintaining laboratory quality standards are essential. This document presents a minimum set of standards that can be readily adapted by countries and applied to laboratories at every level of the health-care system. Suggestions are also provided on ways to implement them. They are important for several reasons, including ensuring the quality and traceability of patients' results; supporting clinical and public health decision-making; procuring equipment; use of standard techniques and reagents; for sharing documentation; training programmes; quality assurance; meeting requirements for reimbursement for national insurance schemes; and compliance with national or international accreditation and licensing systems.

This document will be of help to national policy-makers as well as regulators in developing national laboratory quality standards. It provides a simple approach to meet the minimum requirements set, and it is hoped that eventually laboratories can improve their systems and aspire to meet ISO 15189 in a logical and step-by-step manner.



A user-friendly checklist of national laboratory quality standards has also been developed as a supplement, which can be useful for self-evaluation and for assessment by external agencies. Different laboratories are at different levels of quality development and hence a flexible step-wise approach has been followed. Laboratories can use this model according to their facilities, resources, time-frame and state of readiness. Achieving international standards such as ISO 15189 could follow on an optional and voluntary basis.

Countries with existing national laboratory quality standards are encouraged to regularly review them, guided by this document. The process of review or establishment of standards should be carried out through the National Laboratory Coordinating Committee coordinated by the national laboratory focal point in the Ministry of Health (MoH).

Once laboratory quality standards have been developed, they are required to be approved by the appropriate national authority. An implementation plan then needs to be drawn up with short-, medium- and long-term objectives and activities, implementing partners identified, and the necessary budgetary support provided.

It is sincerely hoped that this publication will be adopted by all Member States and achieve its intended objective of getting them to establish and implement National Laboratory Quality Standards as a step towards implementing International Laboratory Quality Standards.

# Introduction

Laboratory services are an essential component of quality health-care delivery. They can be utilized effectively at every level of the health-care system, including primary health care and point-of-care testing. Quality laboratory results are required to support clinical diagnosis, rationalize and monitor treatment, for epidemiological purposes, for the surveillance and control of diseases of public health importance, and to provide early warning of disease outbreaks. This improves the accuracy of health information and promotes effective national health planning.

The purpose of establishing laboratory quality standards is to ensure the accuracy of test results, increase the confidence of patients, clinicians and communities in the value of laboratory testing, and to inform patient management.

All laboratory activities may be subject to errors, and studies have shown that errors in the laboratory can occur in all the phases of diagnostic procedures. Examples of errors that can occur in each phase are given below:

## *Pre-analytical phase*

- Incorrect test request or test selection
- Incomplete laboratory request forms
- Incorrect specimen collection, labelling and transportation



### **Analytical phase**

- Use of faulty equipment, improper use of equipment
- Use of substandard or expired reagents
- Incorrect reagent preparation and storage
- Incorrect technical procedures; non-adherence to standard operating procedures (SOPs) or internal quality control (IQC)

### **Post- analytical phase**

- Inaccurate reporting and recording
- Inaccurate calculations, computation or transcription
- Return of results to the clinician too late to influence patient management
- Incorrect interpretation of results

### **International laboratory quality standards**

There are several internationally accepted standards applicable to laboratories (Table 1) and many of these have been developed by ISO. Standards ensure desirable characteristics of products and services such as quality, safety, reliability, efficiency and reproducibility. ISO standards provide a technical base for health, safety and conformity assessment. They are accepted everywhere in the world, are voluntary and ISO has no legal authority to enforce the implementation of its standards. For the health services, there is the ISO 9000 series, which relates to administrative procedures and, in 2004, ISO 15189 was officially launched. It includes both management as well as technical requirements for medical laboratories. Table 1 shows the different international standards applicable to laboratories.

Even as each country decides which standards fit their situation, all should aspire to adopt existing international standards. A national laboratory plan should specify quality standards for laboratories at each level and define the bodies responsible for establishing, implementing and monitoring those standards.

Quality standards should be developed in consultation with stakeholders comprising key individuals in the MOH and other relevant government

Table 1: International standards applicable to laboratories

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO 15189	Medical laboratories – particular requirements for quality and competence
ISO/IEC 17043	Conformity assessment – general requirements for proficiency testing
ISO 13528	Statistical methods for use in proficiency testing by interlaboratory comparison
OECD GLP	OECD principles on good laboratory practice
ISO Guide 34	General requirement for the competence of reference material producers
ISO 8402	Quality management and quality assurance – vocabulary
ISO 19011	Guidelines for quality and/or environmental management system auditing
ISO 9001	Quality management systems – requirements

departments, the national laboratory focal point, national regulatory authorities and key stakeholders that include donors and partner agencies such as WHO, clinical and public health physicians, disease programme managers, representatives of relevant professional societies, research and training institutions, legal advisers, health administrators and representatives from the laboratory network, including nongovernmental and private laboratories.





## Development and implementation of the quality system

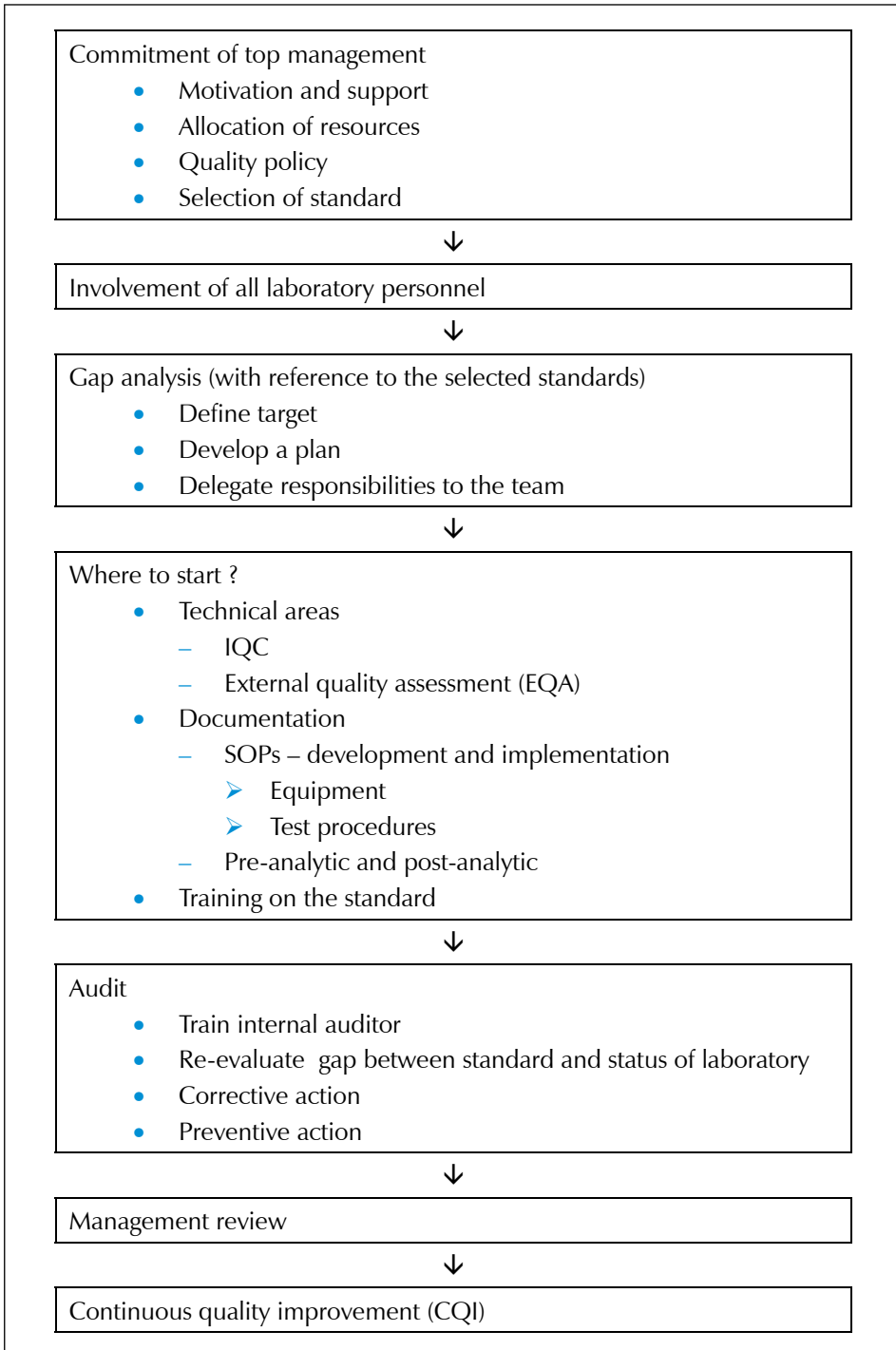
Quality standards are an integral part of the quality system. They are designed to help laboratories meet regulatory requirements, including local health regulations, and monitor laboratory functions, thereby ensuring laboratory safety and consistency of performance.

A quality system can be developed in a step-wise manner as shown in Table 2 and implemented as shown in Table 3.

Table 2: Development of a quality system

<i>Quality policy</i>	→	<i>Mission statement</i>
<i>Quality plan</i>	→	<i>Implementation of policy</i>
<i>Quality manual</i>	→	<i>Policy, plan and application of standards</i>
<i>Procedures</i>	→	<i>Development and application of SOPs</i>
<i>Work instructions</i>	→	<i>Methodology to carry out specific tasks</i>
<i>Training of staff</i>	→	<i>Implementation of quality system and use of SOPs</i>
<i>Monitoring and evaluation</i>	→	<i>Assessment of quality and correction process</i>

Table 3: Key steps in implementing a quality system



## Developing laboratory quality standards

While developing these Laboratory Quality Standards, an effort has been made to retain the essential components of the ISO 15189 laboratory standards.

These are divided into eleven sections:

- (1) Organization and management
- (2) Quality management system
- (3) Human resources (personnel)
- (4) Accommodation and environmental conditions
- (5) Laboratory safety
- (6) Laboratory equipment
- (7) Procurement and supplies management
- (8) Information management
- (9) Managing laboratory specimens
- (10) Customer service and resolution of complaints
- (11) Outbreak alert and laboratory network

### 3.1 Organization and management

The health laboratory provides a service that requires consultation with clinicians and other users of the laboratory.



A written document or booklet should be available, which describes, for instance, the range and scope of the services available; working hours; emergency services available; types of samples and containers to be used for each test; and turnaround time (TAT) for results. This information must be distributed to all users of the service, and be available in hospital wards, offices, and emergency and outpatient departments. The information must be reviewed and updated on a regular basis or as required.

Each laboratory must have an organizational chart (organogram) that describes the management and supervisory arrangements in the laboratory. This chart must be understood by all laboratory staff. Each laboratory must have a head (Laboratory Manager or Director) who is overall responsible for laboratory operations including the following:

- Ensuring that the laboratory meets all national legal and regulatory requirements;
- Ensuring that there are adequate numbers of appropriately qualified and competent technical staff;
- Appointing a member of staff (Quality Manager – QM) with responsibility for quality management who reports directly to the laboratory head on a regular basis (at least twice each month and more often if necessary); (see Annex 1)
- Appointing a member of staff to act as Safety Officer; (see Section 5 and Annex 2)
- Providing a safe and adequate laboratory environment and facilities/reports;
- Providing essential equipment and ensuring its functionality;
- Ensuring an adequate supply of laboratory chemicals, reagents, test kits and supplies;
- Establishing an effective system for documentation and record-keeping, and ensuring the confidentiality of patient information;
- Establishing an effective quality management system (QMS) covering all aspects of laboratory operations;
- Ensuring adequate communication with laboratory users, including patients and clients.

## 3.2 Quality management system (QMS)

Each administrative and technical procedure in the laboratory must be subject to a quality monitoring process developed with the help of relevant laboratory staff. Each process must be documented using a step-by-step approach. Heads of laboratories are responsible for ensuring that each document is understood and all processes are fully implemented by laboratory staff. Every document must be signed, dated and reviewed annually or when any change of procedure is required or done.

- (1) A quality manual must be kept within the laboratory. This contains all documents, policies and procedures in current use, and should include an index and an amendment page. The amendment page requires updating every time a change is made. The manual should be divided into the following major sections:
  - Main functions and responsibilities of the laboratory, including organizational structure;
  - Personnel issues, including employment policies, job descriptions, staff education and continuing professional development (CPD);
  - Accommodation and environment;
  - Inventory of instruments and records of repair and preventive maintenance;
  - Written procedures that ensure proper calibration and functioning of all instruments, reagents and analytical systems;
  - Written safety policies and instructions;
  - All sampling and transport procedures;
  - Management of samples and biological material;
  - Quality assurance (QA) systems including IQC and external quality assessment schemes (EQAS)
  - Written policies and procedures on document management;
  - Written policies and procedures on customer service and improvement processes.

- (2) **Internal quality control (IQC):** The laboratory must perform IQC checks for all relevant tests and procedures. This includes commercial controls (positive and negative samples; quantitative samples in high-, low- and normal ranges; sterility controls) and repeat testing of patients' samples with known results (called "drift controls").
- (3) **External quality assessment (EQA):** Laboratories should participate in interlaboratory comparisons and national, regional or international EQA schemes (NEQAS, REQAS or IEQAS). All results must be critically evaluated and used to take corrective action when there is non-conformity or non-compliance.
- (4) If an EQAS programme is not available for a specific test, laboratories should exchange samples and materials with another laboratory or group of laboratories on a regular basis and compare results.
- (5) All written procedures issued to laboratory staff must be reviewed and approved by the laboratory head or delegated person prior to issue. Only currently authorized documents should be available for active use at relevant locations, including work benches and stations. Only the head of the laboratory or person with delegated authority can approve any amendments. Obsolete documents must be removed from circulation and archived. Staff must be oriented to the intricacies of document control.
- (6) **Internal audit:** This is the process of critical review of laboratory activities by the laboratory head or delegated person. Once a QMS has been developed and implemented, a laboratory can verify its performance through regular internal audits. Members of staff can be trained and appointed to carry out internal audits on a regular basis using standard checklists.
- (7) **External audit:** The facility may request an external person, usually a laboratory technologist or laboratory scientist, to review the laboratory QMS. The laboratory should initiate corrective actions for all non-compliance identified during the audit.
- (8) **Management review:** At least once a year, the head of the laboratory and the QM must review the services provided by the laboratory and the established QMS. The results of the review should be documented and discussed with staff, and changes or

improvements introduced into a plan that includes goals, objectives and action required for the following year. The review should take account of, but not be limited to:

- Reports from supervisors and senior laboratory staff;
  - Results of EQA or interlaboratory comparisons;
  - Changes in the volume and type of work;
  - Feedback from users of the service;
  - Monitoring TAT (time between collection or receipt of the sample and sending out the report);
  - Results of the continuous improvement process.
- (9) **Continuous quality improvement (CQI):** All operational procedures must be systematically and continuously reviewed by the head of the laboratory to identify potential sources of non-compliance and areas that require improvement. A formal review of laboratory procedures must take place at least once a year.

### 3.3 Human resources (personnel)

Staff are the most important resource for any laboratory, and the effective management of staff is one of the most important responsibilities of the laboratory head.

- (1) The laboratory head should be a person with the training and competence to take responsibility for managing the laboratory.
- (2) There must be sufficient numbers of staff with appropriate qualifications and training to ensure that laboratory operations are effective, and all staff are adequately supervised.
- (3) Each laboratory discipline should be led by a person who has had the appropriate training, which may include graduate or postgraduate education (if required), and regular participation in a programme of CPD in the discipline for which he/she has responsibility.
- (4) All staff must be properly trained for the work they are expected to perform, and provided with the authority and resources to carry out their responsibilities.

- (5) All staff must be properly briefed as to their duties and responsibilities within the laboratory, which should be contained within a written document (job description). All job descriptions must be reviewed annually by the laboratory head, after consultation with the appropriate section head (if required) and the staff member. Job descriptions may be modified after mutual agreement and reissued. In small laboratories, individual staff may be assigned more than one responsibility.
- (6) A performance appraisal must be conducted for each staff member at least annually. A performance appraisal is intended to provide regular feedback to individual staff on work performance and to guide career development.
- (7) Laboratory heads must identify the training needs of individual personnel and ensure that staff has access to appropriate CPD programmes.
- (8) Should a staff member develop physical disability in-service, the laboratory head should consider reassigning the staff to an area where he/she can be productive and contribute to the objectives of the laboratory.
- (9) There should be regular meetings (at least monthly) between the laboratory head and all staff to disseminate information and discuss problems. Records of the discussion and decisions reached must be maintained and provided to all staff.

### 3.4 Accommodation and environmental conditions

- (1) The laboratory must have adequate space that is properly organized so that the quality of work and the safety of staff, patients, customers and visitors is not compromised. Measures must be taken to ensure good housekeeping (general tidiness, cleanliness, hygiene, freedom from rodents and insects), and maintain all work areas well. Laboratory section leaders should arrange equipment and work stations to ensure efficient and convenient workflow.
- (2) The laboratory must have an appropriate biosafety environment and facilities to safely handle microorganisms belonging to different biorisk levels as per the mandate of the laboratory.

- (3) Laboratories must be provided with appropriate utilities including clean running water, lighting (natural and artificial), ventilation, electric outlets, back-up power (if required), drainage systems that comply with environmental regulations, and sanitation facilities for patients and staff.
- (4) Where primary sample collection is carried out, consideration must be given to patient access (including patients with disabilities), comfort and privacy. Separate rooms should be available for sample collection and blood donor activities.
- (5) Potentially hazardous activities must be carried out in a separate area to prevent cross-contamination and reduce potential safety risks to all staff and visitors. Examples include: TB bacteriology, handling and examination of high-risk samples, nucleic acid amplifications, and controlled environments for large computer systems and some high-capacity analysers.
- (6) Adequate storage space with the right conditions, including refrigerators and freezers, must be available and protection from light, damp, dust, insects and vermin ensured to maintain the integrity of samples, slides, histology blocks, histology samples, retained microorganisms, documents, manuals, equipment, reagents and other supplies, records and results. Storage areas must be adequately secured to prevent unauthorized access.
- (7) Disposal of all infectious waste including sharps must be managed safely and effectively according to waste management regulations. The laboratory must use separate waste disposal systems for infectious and non-infectious waste. Special containers must be used for sharps disposal, solvents and radiological wastes.

### 3.5. Laboratory safety

Health laboratories are potentially dangerous places to work in due to chemical, electrical, physical, mechanical, biological or radiation hazards. Those at risk include laboratory staff, customers and visitors entering the laboratory environment; so it is important for all laboratory staff to recognize the potential dangers and reduce risk to a minimum.

The level of risk depends on the activities within the laboratory, and the types and sources of material entering the laboratory. Occupational injuries and

illnesses may result from bad practices, ignorance, inexperience and failure to follow established procedures. When developing safety rules, the following documents may be consulted:

1. *Laboratory biosafety manual*. Third edition, World Health Organization, 2004.
  2. *Safety in health-care laboratories*. World Health Organization, 1997.
- (1) Safety rules must be established to reduce risks to staff, customers and visitors. Staff must comply with these rules (see Annex 3) and ensure that customers and visitors are sufficiently briefed to ensure safety.
  - (2) SOPs must be prepared to ensure safe handling of laboratory equipment.
  - (3) SOPs must be developed to ensure the safe handling of all samples and procedures such as phlebotomy, sample transport, sub-sampling, analytical procedures, storage and disposal of samples. They should be available at all work stations and provided to appropriate staff.
  - (4) SOPs for safe handling of all referred samples must be available and provided to appropriate staff. A list of diseases of national and international concern that require emergency action must be available in the laboratory.
  - (5) All staff handling patient samples and other biological materials must wear appropriate personal protective equipment (PPE). These must be removed before leaving the laboratory or undertaking clerical work. Hands must be washed immediately after removing the protection and before leaving the laboratory.
  - (6) SOPs must be available in the event of a spillage/leakage of biological, chemical or radiochemical materials or patient samples, including when containers are broken in a centrifuge.
  - (7) First-aid materials and facilities must be readily available to deal with accidents. All accidents, however small, or accidents that might have occurred (“near misses”), must be recorded and reported as per national regulations.

- (8) The employing authority, through the laboratory head, is responsible for ensuring adequate protection of laboratory personnel to avoid occupational hazards. This includes the following:
- Use of vaccines, for example, against hepatitis B virus (HBV) infection;
  - Use of post-exposure prophylaxis (PEP) procedures against HIV infection in case of needle-stick injury;
  - Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work;
  - Provision of personal protective equipment (PPE).

### 3.6 Laboratory equipment

The standards in this section apply to all equipment, whether equipment it is purchased, on loan, new, reconditioned or donated.

- (1) Every laboratory must be provided with the necessary equipment that is appropriately placed for efficient performance.
- (2) The equipment selected must be of known reliability and meet the requirements of laboratories at each level. It should also be procurable at an acceptable cost. Account should be taken of energy sources needed to run the equipment, requirement for an uninterrupted power supply (UPS), environmental control such as operating temperature, and future disposal (decommissioning).
- (3) Equipment should be procured from suppliers who can assure appropriate maintenance and emergency servicing, including availability of spare parts, during the expected life of the equipment. Service contracts must be obtained for major equipment.
- (4) Donated equipment must comply with the WHO Guidelines for health care equipment donations (see Annex 5 and reference 10).
- (5) Suppliers must provide adequate training for staff in equipment use, care and maintenance; including hospital biomedical engineers who may be required to carry out maintenance procedures. Equipment must be maintained in a safe working condition, according to the manufacturers' instructions.

- (6) The ability of suppliers to meet these requirements should be carefully documented and be part of the signed contract or purchase agreement.
- (7) On installation (commissioning), the laboratory staff must check that the equipment achieves the agreed and specified performance (validation). A record of the commissioning process as well as validation must be kept and subsequent performance must be continuously monitored by the laboratory staff. Validation should be conducted regularly and at least on an annual basis, and as and when maintenance or repairs have been done.
- (8) Each item of equipment must be uniquely labelled or identified. Documents and records must be kept for each in a safe, specified place and accessible to laboratory staff. Equipment records should include the following:
  - An inventory of all equipment including unique identifying number, manufacturer's name, instrument type and serial number;
  - Whether new, used or reconditioned; date received and date put into service;
  - Manufacturers' or suppliers' contact address, telephone number and/or e-mail address;
  - User and service manuals provided by the manufacturer in a language that is understood by the users;
  - SOPs on how to use the equipment. These must be appropriately placed and routinely updated. Where equipment calibration involves correction or calculation factors, these procedures must be included in the SOPs.
  - Ongoing records of equipment performance criteria (quality control records);
  - Written instructions outlining the steps for cleaning and maintenance, and what to do in case of damage, malfunction, modification or repair;
  - Records of all maintenance and repair procedures;

- Availability of spare parts with instructions for future ordering;
- Disposal of redundant/unusable equipment.

### 3.7 Procurement and supplies management

A national selection and standardization process for laboratory supplies and reagents for laboratories at every health-care level is beneficial because it promotes efficiency in inventory control, storage and distribution; there is better record-keeping and procurement costs are lowered because items are bought in bulk. This involves the following:

- (1) There should be documents that define policies and procedures for selection, procurement of reagents and other laboratory supplies, including supplier qualification and monitoring; competitive bidding; ordering based on a reliable estimate of need; and quality checking of supplies received.
- (2) A process for validation of supplies, especially diagnostic reagents, should be established.
- (3) An inventory of all supplies to avoid stocks-outs of vital supplies should be established. Information including quantities, batch numbers, expiry dates and sources of supply must be recorded.
- (4) Lead times between the date of order and receipt should be known to avoid holding excessive quantities of materials that may deteriorate or become out of date during storage, and running out of supplies due to ordering or delivery delays. Orders must be based on an estimation of supply needs and a reasonable buffer stock kept in case of unexpected increase in demand.
- (5) Guidelines must be in place to ensure safe and appropriate storage of all laboratory supplies.
- (6) Systems must be in place to record dates and batch numbers of individual reagents that are brought into use. Reagents should not be used beyond their expiry date.

- (7) Systems must be in place to ensure that the stock is used on a “first in–first out” (FIFO) basis.
- (8) A policy must be in place to address donations of laboratory reagents and supplies.

## 3.8 Information management

- (1) Laboratory records include but are not limited to the following:
  - Request forms
  - Results and copies of reports
  - Instrument print-outs
  - Laboratory workbooks and worksheets
  - Laboratory registers (logbooks)
  - Calibration records and calculation factors
  - QC records: quality manual, IQC register, results of interlaboratory exchanges of material, EQAS records
  - Incident book, corrective action reports
  - Stock cards and supply records
  - Personnel records: staff training, competency records and health records
  - Complaints and their resolution
  - Notes and minutes of all formal meetings
  - Inventory (or assets)
  - Safety manual
  - Budgets
  - SOPs
  - Workload and surveillance reports.

- (2) Records may be stored as hard copies or electronically. Transfer of data to electronic form can be done using customized data entry screens or by scanning written forms. This will depend on the resources available, such as computers, and the necessary expertise.
- (3) Documents and records must be:
  - Legible, concise and clear
  - Retrievable
  - Stored safely.
- (4) A policy that states the length of time that various records and all samples should be kept or stored must be defined. An updated list must be kept of all materials held in stores, where they may be found and date of disposal.
- (5) The TAT expected for each test result should be agreed upon with users of the service. The laboratory must adhere to the TAT or advise the user of any delays.
- (6) There should be a documented list of critical result levels for critical tests and instructions on how requesters would be notified when results fall within these levels.
- (7) Access to records must be limited and data protected from access by unauthorized individuals. Confidentiality is important as medical and laboratory personnel are not authorized to disclose information to others without the consent of the patient.

## 3.9 Managing laboratory specimens

### Pre-analytical phase

The quality of the final result is profoundly affected by the quality of the sample material and the clinical indications. Failure to take steps to assure quality at this stage will result in poor-quality results from the laboratory, despite good-quality analytical processes.

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

treatment is required to help satisfactory interpretation of the results. Request forms must contain the following:

- Patient identification, gender and date of birth;
  - Patient location/source of specimens;
  - Identity of the requesting person;
  - Type of sample;
  - Examinations (tests) required;
  - Clinical details, e.g. any drugs/antibiotics being given that may have relevance to the interpretation of results;
  - Time and date sample taken.
- (2) Proper management of samples during collection, transport and storage must be ensured according to SOPs, which must 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;
  - Primary sample collection technique;
  - Correct labelling;
  - Special transport arrangements between the site of primary sampling and the laboratory;
  - Safe disposal of materials used to collect primary samples;
  - Procedures to be followed if the sample quality is suboptimal or unsatisfactory;
  - Recording unusual physical characteristics including lipaemia, haemolysis, icterus, etc.
- (3) All primary samples must be given a unique identifying (accession) number recorded with the date and time of receipt. Taking aliquots of samples and sub-sampling should be done using appropriate laboratory safety precautions.

- (4) The laboratory must provide instructions and monitor transportation of samples to the laboratory within the correct time frame, at the correct temperature, and in the designated preservatives for the requested analysis to be performed.
- (5) Transport must be safe for the carrier, the general public and the receiving laboratory, and adhere to national or accepted regulatory requirements. Liquid specimens, including blood specimen bottles and tubes, should be transported upright and secured in a screw-cap container or in a rack in a transport box. Containers with liquid specimens should be wrapped in absorbent paper to soak up the liquid in case of spillage.
- (6) Triple packing should be used when shipping toxic or infectious substances or dangerous goods, according to current International Air Transport Association (IATA) regulations (Infectious Substances Shipping Guidelines, 2006). All persons involved in the shipping process should be trained in the correct procedures for packaging and transportation.
- (7) Samples air dried on filter paper are exempt from shipping regulations and do not have to be sent to a laboratory via a specialist courier. These samples can be sent by airmail. To avoid damage, they should be sent in hermetically sealed triple packages after they have been properly dried.
- (8) Detailed instructions for packing specimens for shipment can be found in the WHO document *Guidance on regulations for the transport of infectious substances*. Such specimens are those in category A (infectious substances included in an indicative list of specified pathogens that are capable of causing permanent disability, life-threatening or fatal disease) and category B (all other infectious substances that are not included in category A).
- (9) There must be a written policy to deal with incorrectly identified samples received by the laboratory. Criteria must be developed and adopted for acceptance and rejection of specimens.
- (10) Taking aliquots or sub-sampling should be done before the specimen is frozen, as repeated freezing and thawing of specimens can damage the sample (reduction of virus content or denaturing antibody). Note that certain types of freezers are designated



“frost free”; these should not be used for specimen storage as the temperature cycling involved in keeping them free of ice accumulation can damage specimens.

- (11) Great care must be taken not to contaminate or cross-contaminate specimens. This is especially important when samples are intended for analysis by polymerase chain reaction (PCR), which is especially vulnerable to cross-contamination after amplification and uncapping of the tube.

### Analytical phase

- (1) Careful selection of the examination procedure is important and depends on the facilities, equipment and staff available, and the number of samples for examination.
- (2) SOPs must be available for all analytical methods. The methods must be evaluated by the laboratory to ensure that they are suitable for the examinations requested. SOPs must be available in the appropriate language. The SOPs should contain the information as outlined in Annex 5 and authorized work instructions may be made available at work stations.
- (3) The laboratory must have an IQC system to verify that the intended quality of results is achieved for every batch of examinations. Action must be taken if there is non-compliance. This may mean that the results of a batch of tests are rejected if the QC results are outside the pre-set tolerance ranges. In these circumstances, the samples will need to be re-examined once the required corrective action has been taken.

### Post-analytical phase

- (1) Designated staff must review and authorize release of the test results.
- (2) Laboratory results must be legible, without transcription mistakes, and preferably reported in Systeme Internationale (SI) units. Laboratory reports should include:
  - Identification of the laboratory issuing the report;
  - Requester’s identification;
  - Type of sample;

- Date and time of primary sample collection,
  - Date and time of receipt by the laboratory;
  - Date and time of reporting;
  - Comments on the primary sample which might have a bearing on the interpretation of the result, e.g. haemolysis, icterus, lipaemia, etc.;
  - Comments on the quality of the primary sample which might invalidate the result, e.g. clotted sample for haematology parameters;
  - Method of testing used;
  - The results and units of measurement where appropriate;
  - Where possible, the normal reference interval (normal range);
  - Identity and signature of the person releasing the report.
- (3) The laboratory must 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.
- (4) There must be a documented procedure for reporting urgent results by telephone.
- (5) Procedures must 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, and isolates and other biological material must be adhered to.

### Occurrence management

- The laboratory must have a mechanism for staff to document and report problems in laboratory operations which may interfere with patient care services.
- Appropriate correction action must be planned and implemented for the problems identified, reported and reviewed.

### 3.10 Customer service and resolution of complaints

- (1) The laboratory head and authorized staff must be prepared to offer advice to clinical staff and other customers on the use of the service, including operating hours and emergency samples, the types of samples required and interpretation of the results.
- (2) There should be regular meetings between the laboratory head and the users of the service to discuss ways of improving the working of the laboratory.
- (3) A mechanism should be established to document notification to customers when the laboratory experiences delays or interruptions in testing (due to equipment failure, stock-outs, fall in staff levels, etc.) or finds it necessary to change examination procedures.
- (4) Procedures including documents must be developed for receiving, recording and processing all complaints. Records of complaints, their resolution and minutes of meetings with the users of the service must be recorded and evaluated.

### 3.11 Outbreak alert and laboratory network

- (1) A list of laboratories that are part of the national system for surveillance and response must be available. Samples of unknown pathology or for which advice is urgently requested can be sent to the designated reference laboratories.
- (2) Clear identification and points of contact for referral laboratories must be made available for confirmation of diseases of national priority. For analysis that is not available in-country, referral laboratories must be identified at the international level and mechanisms for specimen transfer established.
- (3) A standardized reporting system for laboratory surveillance of priority diseases must be in place, including a standardized reporting form and/or software for laboratory data.
- (4) A separate data reporting system must be established in case of disease outbreaks, in a timely manner, as defined by the International Health Regulations (IHR), 2005.
- (5) The national laboratory network must establish the capacity to address disease outbreaks. Appropriate laboratory reagents and/or

rapid tests must be positioned in advance at national, intermediate and peripheral levels.

- (6) Sampling in the field should be undertaken with appropriate levels of safety. The level of PPE to be employed will be determined by the type of exposure risk.
- (7) For each type of sampling in the field, ideally two specimens should be taken in separate specimen tubes. However, if only one specimen is received in the laboratory, it may be divided into two parts and then one can be used for immediate analysis and the other retained for reference purposes or retesting.
- (8) Each patient or animal sampled or each environmental sample taken should be given a unique identifier number and accompanied by a field datasheet. The field datasheet must have space for the following:
  - Specimen identification;
  - Location of sampling;
  - Identification of the person who collected the sample;
  - Identification of the requesting service or person (for return of the report);
  - Type of primary sample;
  - Examinations (tests) required;
  - Field details;
  - Time and date of primary sample;
  - Time and date of receipt by the laboratory.
- (9) Each specimen taken from a single source should be marked with a unique identifier. This identifier should be used for all documentation concerning the specimen from that source. Specimen tubes should also be marked with information to identify the specimen and date and time of collection.





## Implementing laboratory quality standards

The process of implementing laboratory quality standards should follow a step-wise approach according to an agreed implementation plan drawn up by the national laboratory focal point, in consultation with the National Laboratory Coordinating Committee.

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 the previous chapter.

The following steps are a guide to implementing laboratory quality standards:

### A. National level

- (1) Obtain national consensus for agreed standards by peer review.
- (2) Obtain approval for agreed standards by the appropriate national authorities.
- (3) Draw up an implementation plan with short-term, medium-term and long-term objectives, activities and timelines, and indicative annual budgets.
- (4) Identify appropriate implementing agencies (the government, nongovernmental agencies, and other partners including the private sector), and sensitize them to the plan and their possible contributions.
- (5) Sensitize participating institutions and health facilities.

- (6) Use or amend existing guidelines, checklists, SOPs, record forms and recording formats, appraisal forms, audit checklists, etc.; or develop country-specific documents.
- (7) Establish national procedures for laboratory networking and referral of samples.
- (8) Draw up detailed annual operational plans with budgets.

## **B. Laboratory level**

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

Start by making simple and easy-to-implement changes, for example:

- Introduce SOPs for particular procedures or activities one by one. This could be sample collection, including phlebotomy, or an SOP for the examination of a particular analyte. The standard layout for an SOP is given in Annex 5.
- Make arrangements to conduct regular meetings with users of the service. This will have the benefit of keeping users informed of the efforts being made to improve the quality of the laboratory service.

A checklist (Annex 6) may be used to establish a baseline of implementation of laboratory quality standards as well as monitoring the progress made.

## Further reading

- (1) International Air Transport Association (IATA). *IATA Dangerous goods regulations*. 48th Edition. Geneva, International Air Transport Association, 2006.
- (2) International Standards Organization (ISO). *ISO 15189: 2007. Medical laboratories – particular requirements for quality and competence*. Second edition 2007-04-15 [http://www.rudaslab.com/od/rd\\_assets/upload/image/content/17\\_d001\\_en\\_iso\\_15189\\_2007\\_pdf.pdf](http://www.rudaslab.com/od/rd_assets/upload/image/content/17_d001_en_iso_15189_2007_pdf.pdf) (accessed 16 April 2011).
- (3) International Standards Organization (ISO). *ISO/IEC 17025:2005. General requirements for the competence of testing and calibration laboratories*. [http://www.iso.org/iso/iso\\_catalogue/catalogue\\_ics/catalogue\\_detail\\_ics.htm?csnumber=39883](http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=39883)
- (4) International Standards Organization (ISO). *ISO/DIS 9000:2000 (E). Quality management systems, fundamentals and vocabulary*. <http://www.iso.org/iso/watermarksample.pdf> (accessed on 16 April 2011).
- (5) International Standards Organization (ISO). *ISO/DIS 9001:2000 (E). Quality management systems – requirements*. [http://www.iso.org/iso/catalogue\\_detail?csnumber=21823](http://www.iso.org/iso/catalogue_detail?csnumber=21823) (accessed on 16 April 2011).
- (6) International Standards Organization (ISO). *ISO/DIS 9004:2000 (E) Quality management systems – guidelines for performance improvement*. [http://www.iso.org/iso/catalogue\\_detail?csnumber=28692](http://www.iso.org/iso/catalogue_detail?csnumber=28692) (accessed 16 April 2011).
- (7) WHO. *Safety in health-care laboratories* Geneva, WHO, 1997 [WHO/LAB/97.1]. <http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=93&codcch=105> (accessed 16 April 2011).
- (8) WHO. *Laboratory biosafety manual*. Third edition. Geneva, World Health Organization, 2004. <http://whqlibdoc.who.int/publications/2004/9241546506.pdf> (accessed on 16 April 2011).

- (9) WHO. *Requirements and guidance for external quality assessment schemes for health laboratories*. Geneva, World Health Organization, 1999 [WHO/DIL/LAB/99.2]. [http://whqlibdoc.who.int/hq/1999/WHO\\_DIL\\_LAB\\_99.2.pdf](http://whqlibdoc.who.int/hq/1999/WHO_DIL_LAB_99.2.pdf) (accessed on 16 April 2011).
- (10) WHO. *Guidelines for health care equipment donations*. Geneva, World Health Organization, 2000 [WHO/ARA/97.3]. [http://www.who.int/medical\\_devices/publications/en/Donation\\_Guidelines.pdf](http://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf) (accessed 16 April 2011).
- (11) WHO. *Guidance on regulations for the transport of infectious substances*. Geneva, World Health Organization, 2005. [http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_CSR\\_LYO\\_2005\\_22r%20.pdf](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22r%20.pdf) (accessed 16 April 2011).
- (12) WHO. *Maintenance manual for laboratory equipment*. Second edition. Geneva, World Health Organization, 2005. [http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_CSR\\_LYO\\_2005\\_22r%20.pdf](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22r%20.pdf) (accessed 16 April 2011).

## Quality Manager

In large laboratories, a member of staff will be appointed in a full-time capacity to perform this task. In smaller laboratories, the Quality Manager (QM) may also have other responsibilities.

- (1) The person appointed is responsible to the laboratory head.
- (2) The tasks include taking responsibility for:
  - monitoring the laboratory QMS and ensuring that policies are implemented on a continuous basis;
  - daily monitoring of all IQC procedures;
  - ensuring that the laboratory participates in appropriate EQA schemes and that corrective action is taken on the results, as appropriate;
  - investigating failures to conform to quality standards (non-compliance) and ensuring that appropriate corrective action is taken;
  - training all other staff in the use of the quality systems;
  - writing and implementing quality policies.

The results of the quality monitoring process should be used for educational purposes.



## Safety Officer

In large laboratories, a member of staff will be appointed in a full-time capacity to perform this task. In smaller laboratories, the Safety Officer may also have other responsibilities.

- (1) The person appointed is responsible to the laboratory head.
- (2) The tasks include taking responsibility for:
  - Giving safety advice;
  - Establishing the safety policy, in consultation with the laboratory head;
  - Administering the safety policy;
  - Assisting in the design and maintenance of the safety programme;
  - Orientating and training all staff in the elements of the safety programme;
  - Organizing membership of the hospital or institution safety committee, as appropriate;
  - Submitting regular reports on the safety status to the laboratory head;
  - Maintaining accident records;
  - Investigating all laboratory accidents;
  - Documenting regular safety inspections;



- Establishing a waste management programme addressing the disposal of all waste, including sharps such as lancets and needles;
- Ensuring that all staff comply with policies, rules and procedures.

## Suggested model safety rules for health laboratories

- (1) Eating, drinking, smoking and applying cosmetics are prohibited in the laboratory.
- (2) Pipetting by mouth is prohibited.
- (3) Appropriate protective clothing must be worn at all times in the laboratory, and gloves should be worn when required.
- (4) The laboratory must be kept clean and tidy, and should contain only those items necessary for the work carried out.
- (5) All work surfaces must be appropriately decontaminated at the end of each working day and immediately after any spillage.
- (6) All staff must wash their hands when leaving the laboratory.
- (7) Care must be taken to avoid the formation of aerosols or splashing of materials.
- (8) All contaminated waste or reusable materials must be appropriately decontaminated before disposal or reuse.
- (9) Access to the laboratory must be restricted to authorized personnel only.
- (10) All incidents or accidents must be reported immediately and appropriate action taken to prevent further occurrences.
- (11) All staff working in the laboratory must be adequately trained, both in the duties they perform and in all safety aspects of work.
- (12) All waste must be appropriately marked before disposal.
- (13) The disinfectant used must be appropriate and its efficacy must be ensured.

**Safety rules are mandatory for all staff.**



## Donated equipment

This is a summary of a WHO publication: *Guidelines for health care equipment donations*. [http://www.who.int/medical\\_devices/publications/en/Donation\\_Guidelines.pdf](http://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf)

### Guidelines for donations of health-care equipment

Many developing countries receive donor assistance to meet the equipment needs of their health-care systems. However, because not all important parameters are taken into consideration, donations sometimes do not achieve their intended objectives, and could even constitute an added burden to the recipient health-care system. There is therefore a need to improve the process of equipment donation to the mutual benefit of both donors and recipients.

The four underlying principles which form the core of good donation practices are as follows:

- (1) Health-care equipment donations should benefit the recipient to the maximum extent possible.
- (2) Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with government policies and administrative arrangements of the recipient country.
- (3) There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.
- (4) There should be effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties.

## Recipient policy and donor coordination

Health-care equipment donations should not be made in a policy vacuum. Potential recipients should use these guidelines to formulate their own national or organizational guidelines, and complement them with administrative procedures, where possible, linked to existing health-care equipment procurement systems. In seeking donations, prospective recipients should specify the need, state the quantities required and prioritize them. Other donations in the pipeline, or those anticipated, should be indicated.

- The most important prerequisite for a successful donation is that the potential recipient truly needs the requested equipment, and has the expertise and the means to operate and maintain it. The donor should use this criterion to identify potential recipients.
- The donated equipment should meet general criteria covering the quality of the equipment, safety, compliance with specifications and standards, non-obsolescence, and appropriateness of the technology for the user environment.
- Donation plans must include detailed installation and commissioning procedures.
- Special requirements for the equipment should be communicated to the recipient. These could include the need for air or water cooling, electrical power, radiation or acoustic shielding, specialized software required to install, operate or maintain the equipment and any other requirements that may be required for installation and use of equipment.
- Installation should be carried out by technically competent staff, according to instructions received from the donor, and the equipment commissioned in accordance with good health-care technical services practice. Periodic inspection, maintenance and calibration should be carried out.
- The donor and recipient should assess the level of operational success or failure of the donated equipment. The success of future donations will be enhanced as a result of such assessments.

## Example of a standard operating procedure (SOP)

### Standard operating procedure

(Name of the laboratory)

Number	Effective date	Pages	Author	Authorized by
SP033	DD-MM-YYYY	5	XXX	XXX
Version	Review period	No. of copies	Approved by	Date
1	1 year	4	XXX	DD-MM-YYYY

Location	Subject
Quality assurance laboratory	Equipment maintenance
Function	Distribution
Calibration	Quality assurance manager Master file

### 1. Scope and application

This procedure covers those measures taken to ensure the integrity, accuracy and reliability of measurement data for equipment and instruments used in the laboratory. The procedure is applicable to all equipment used to control or evaluate suitability of starting materials, in-process products and finished products.

## 2. Responsibility

It is the responsibility of the supervisor of the section to which the equipment belongs:

- (i) To plan, schedule, organize and maintain records of the calibration programmes for various equipment under their control;
- (ii) To ensure that equipment and instruments are continuously calibrated or removed from use;
- (iii) To train staff for performing calibration/performance checks.

## 3. References

*Maintenance manual for laboratory equipment.*, Second edition. Geneva, World Health Organization, 2008.

## 4. Definitions

### **Calibration:**

A set of operations which, under special conditions, establishes the relationship between the values indicated by measuring instruments and standards.

### **Performance checks:**

The routine checking of the performance of an instrument to verify that it has remained within the specified range of accuracy and precision.

### **Accuracy:**

The closeness of agreement between the result of a measure and the true value of measurement. Calibration is used to determine the accuracy of an instrument.

### **Precision (repeatability):**

The closeness of agreement between the results of successive measurements of a defined procedure under prescribed conditions.

### ***Measurement standard:***

A measuring instrument or material that physically defines a unit of measurement or value of a quantity. Measurement standards used for calibration should be traceable to the SI units of standard measurements.

## **5. Procedures**

### ***5.1 Calibration schedules***

- Purchase each new piece of equipment or instrument according to specifications.
- Enter new equipment in an asset register prior to use.
- Ask the supplier prior to delivery or after installation to calibrate new equipment and provide a certificate of calibration.
- Maintain calibration/maintenance schedules for all equipment.

The schedules of calibration or performance checks should be based on:

- Manufacturers' recommendations
- Reference standards
- Recalibration of the measuring devices based on recommended time intervals.

### ***5.2 Reference standards, traceability and calibration limits***

#### *Reference standards and traceability*

All measurement standards used to calibrate measuring devices should be traceable to a national standard of measurement. This can be done:

- (a) Directly, through purchase of pre-calibrated certified standards. These shall be supported by calibration documents or certificate from the supplier stating the date, accuracy (assigned value and units of measure), traceability and conditions under which the results were obtained. These standards shall be re-calibrated at pre-determined intervals.

- (b) Indirectly, by preparation of an internal working standard calibrated against a certified standard. Such standards shall be supported by internal test reports and any other supporting documentation.
- (c) Where no recognized external standard exists, an internal standard may be prepared and calibrated, provided a written procedure is prepared and a rationale for assigning values, accuracy and units is established. These standards shall be supported by suitable records of calibration as above.

### *Calibration limits*

Calibration is concerned with the measurement of values and their comparison with acceptable limits of standards, resulting in adjustment or correction, if necessary.

Compare calibration results with established limits of accuracy for the measuring device. If the device being calibrated does not fall within the limits, then readjust and recalibrate it until it falls within pre-established limits. If not, remove from use.

The establishment of limits should be based on a combination of:

- those specified at the time of purchase
- recommendations from the manufacturer
- limits established in reference standards.

The acceptable limits required for satisfactory calibration of each instrument should be identified or referenced in the relevant procedure.

### **5.3 Calibration and performance check procedures**

Prepare documented procedures based on the instrument manufacturer's written instructions, and use these for calibration and performance checks of all measuring instruments.

*Calibration procedure should include the following:*

- A list of equipment to which the procedure is applicable
- Calibration points, environmental requirements and special conditions

- Limits of accuracy
- List and identity of traceable standards
- Sequence of steps for calibration
- Instructions for recording data with reference to the relevant standard form.

Performance check procedures should follow a similar format.

#### 5.4 Labelling

All calibrated equipment should be labelled with the following information:

- Date of last calibration
- Signature of the person who performed the calibration
- Date when the next calibration is due.

Identify and label equipment that has passed its due date of calibration until it is recalibrated.

## 6. Documentation

Maintain complete records for the calibration and performance checks of all equipment and instruments.

Calibration and performance check test records should include (where appropriate):

- Asset register number
- Instrument serial number
- Limits for calibration (refer section 5.2.2).
- Date of calibration/performance check
- Due date of next calibration
- Any details of adjustment\* or repair
- Results of the calibration\*/performance check

- Statement of compliance or details of non-compliance and action taken
- Signature/initials of the person performing the calibration/performance check.

*\* It is important to record the results of calibration before and after any adjustment.*

Maintain calibration and performance check records for five years.

## 7. Corrective action

Conduct a review if any measuring device is found to be out of calibration and requires adjustment. Take corrective action where appropriate.

If the item can be adjusted back into calibration, it may continue to be used. If the item cannot be adjusted back into calibration, it must not be used until the problem is corrected. Under these circumstances, attach an identifying label stating that the item is under repair and is not to be used.

The supervisor must assess the likely impact of the inaccuracy of the affected measurement on the quality of the current product and that produced since the last satisfactory calibration. Factors influencing the degree of risk include the following:

- Critical nature of the measurement
- Sensitivity of quality control testing
- History of product records and performance checks.

Additional quality control testing may be instituted to determine whether quality has been compromised. Where it is likely that quality has been compromised, this shall be communicated to senior management and documented in a report

## 8. Relocation of instruments

Recalibrate equipment (especially those that are non-portable) that have been relocated. The manufacturer's recommendations on the need for recalibration shall be sought when relocating non-portable instruments.

## 9. External calibration contractors

Make an agreement with the contractors to supply written reports of calibrations, which should include the following:

- Use of standards and references traceable to national standards
- Certification/licensing by the equipment manufacturer, if available
- Checking of all certificates or reports supplied by approved external laboratories on receipt. Certificates and reports should contain the same information as required in section 6 above.

## 10. End of document





## Checklist for laboratory quality standards

Name of Hospital/Laboratory: .....

Name of Auditor: .....

Position/Title: .....

Date of audit: ..... Revision date: .....

Evaluation key:

**Instructions:** For each item, please circle either Y=Yes, P=Partial or N=No. **All** elements of the question must be satisfactorily present to indicate “yes”. Provide explanations or other comments under the “Remarks” section for each “partial” or “no” response.

Quality system		Y	P	N	Remarks
<b>(1) General information</b>					
1.	Is there a laboratory organizational chart that describes the internal management and supervisory arrangements in the laboratory?				
2.	Is there an adequate number of staff with appropriate qualifications to operate the laboratory?				
3.	a. Is a member of the laboratory staff appointed as the Quality Manager? b. Does he/she meet regularly with the Laboratory Head to discuss quality issues?				

Quality system		Y	P	N	Remarks
4.	a. Is a member of the laboratory staff appointed as Safety Officer? b. Does he/she meet regularly with the Laboratory Head to discuss safety issues?				
5.	Does the management provide a safe and adequate working environment and facility?				
6.	Does the management provide essential equipment and ensure its functionality?				
7.	Does the management provide adequate supplies to ensure continuity of service?				
8.	Is there an effective system in place for documentation and record-keeping?				
9.	Is there an effective quality management system in place?				
10.	Is there adequate communication between the laboratory and all its users?				
<b>(2) Quality management system (QMS)</b>					
11.	Does the Quality Manager have delegated responsibility to oversee compliance with the quality management system?				
12.	Does the laboratory have a Quality Manual which documents all policies and procedures currently in use in the laboratory?				
13.	a. Does the laboratory have a document control system in place? b. Are obsolete documents removed and marked "obsolete"?				
14.	Are all documents reviewed at least annually?				
15.	Is there an internal quality control (IQC) system in place that controls every batch of examinations ?				
16.	Is the IQC performed, documented and reviewed prior to release of results?				

Quality system		Y	P	N	Remarks
17.	Are the results of these IQC samples recorded and acted on if found to be outside the acceptable range?				
18.	Are QC results monitored statistically?				
19.	Are deviations followed by timely troubleshooting and corrective action?				
20.	Does the laboratory participate in an external quality assessment scheme (EQAS) ?				
21.	Are the results of the EQAS recorded and discussed with staff to resolve any possible discrepancies?				
22.	Are all operational procedures in the Quality Manual reviewed continuously to identify issues of potential non-compliance?				
23.	Is there an annual review of the QMS which is properly documented?				
24.	Are regular audits carried out in each section of the laboratory at the intervals prescribed in the Quality Manual?				
25.	Are the recommendations and/or corrective actions from these audits documented, discussed with staff and an action plan developed with clear timelines and documented follow up?				
<b>(3) Human resources (personnel)</b>					
26.	Is the Laboratory Head a person with appropriate qualifications and training for the position as per the job description?				
27.	Are there sufficient numbers of staff who are appropriately trained to carry out all the tasks in the laboratory?				
28.	Is each section of the laboratory led by a person who is adequately qualified, trained and competent in that discipline?				



Quality system		Y	P	N	Remarks
29.	Are lines of authority and responsibility clearly defined for all laboratory staff, including the designation of a supervisor and deputies for all key functions?				
30.	Do all staff have written job descriptions?				
31.	Are appropriate and regular continuing professional development (CPD) programmes available to all staff?				
32.	Is there a performance appraisal system in place for every staff member, which includes an annual competency assessment?				
33.	Are there regular (at least monthly) staff meetings between the Laboratory Head and all staff to disseminate information and discuss problems?				
<b>(4) Accommodation and environmental conditions</b>					
34.	Does the laboratory have biosafety facilities corresponding to the biorisk hazard of the pathogens it is mandated to handle?				
35.	Are the patient and testing areas of the laboratory, and incompatible testing activities, effectively separated from one another?				
36.	Is the work area kept clean and tidy for efficient operation, including cleaning and disinfecting of workbench areas on a daily basis?				
37.	Are adequate utilities provided (water, ventilation, electricity [including back-up power sources such as UPS]) for the laboratory to operate effectively?				
38.	Are there separate rooms designated for sample collection and blood donor activities?				
39.	Is there effective separation of areas where high-risk samples are collected (e.g. TB microbiology), to prevent cross-contamination and reduce potential risk to staff and patients?				

Quality system		Y	P	N	Remarks
40.	Is there adequate storage space available, with the correct conditions, to ensure the integrity of all archived samples and supplies?				
41.	Are sufficient waste disposal facilities available and is waste separated into infectious and non-infectious waste, with infectious waste autoclaved, incinerated or buried?				
<b>(5) Laboratory safety</b>					
42.	Are all staff aware of the WHO <i>Laboratory biosafety manual</i> and have they received training in its procedures?				
43.	Is the laboratory properly secured from unauthorized access with appropriate signage?				
44.	Are standard operating procedures (SOPs) available at all workstations for safe handling of all samples?				
45.	Are the work and storage areas of the laboratory free of staff food items?				
46.	Are all samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?				
47.	Are “sharps” handled and disposed of properly in “sharps” containers?				
48.	Are all staff provided with appropriate personal protective equipment (PPE) ?				
49.	Are there adequate handwashing facilities available in the laboratory, including soap and towels?				
50.	Is there an SOP to address spillage or leakage of chemicals, specimens, etc. including breakages in centrifuges?				
51.	Are adequate first aid materials and facilities available?				



Quality system		Y	P	N	Remarks
52.	Are all accidents and incidents recorded and reported as per national regulations?				
53.	Are laboratory staff offered appropriate vaccination/s such as for hepatitis B?				
<b>(6) Laboratory equipment</b>					
54.	Does the equipment provided meet the minimum standards for the level of health care?				
55.	Is there a written policy that details the process of procuring equipment to ensure that it is appropriate and meets the requirements?				
56.	Does the laboratory have a list of manufacturers and the contact persons for all equipment?				
57.	Is the equipment purchased from reputable suppliers who can provide appropriate maintenance, servicing and spare parts for the equipment?				
58.	Can the supplier assure continuity of supply of reagents and other commodities for the life of the equipment?				
59.	Has training on each piece of equipment been provided to a sufficient number of staff, including engineers, to ensure that it can be operated correctly at all times?				
60.	Is relevant equipment maintenance and service information readily available in the laboratory? a. Service contract information b. Contact details of service provider c. Performance and maintenance records d. Last date of service e. Next date of service				

Quality system		Y	P	N	Remarks
61.	Is the maintenance schedule adhered to with records kept of all maintenance carried out?				
62.	Is all equipment uniquely identified?				
63.	Is there a mechanism for validation of equipment prior to use and after repair/maintenance?				
64.	Are current equipment inventory data available on all equipment in the laboratory? a. Name of the equipment b. Manufacturer c. Condition received (new, used, reconditioned, donated) d. Serial number e. Date of purchase/acquisition f. Date of entry into service				
65.	Is there a documented procedure for the decommissioning of redundant or non-functional equipment?				
<b>(7) Procurement and supplies management</b>					
66.	Is there a policy that defines and documents the procedures for selection and purchase of consumables, reagents and other supplies?				
67.	Is there an effective inventory management system in place which ensures avoidance of "stock-outs" and details maximum and minimum stock levels of all items?				
68.	Are supply and reagent specifications periodically reviewed and approved suppliers identified?				
69.	Does the policy detail the procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials?				

Quality system		Y	P	N	Remarks
70.	Does the policy ensure that supplies are used on a “first-in first-out” basis?				
71.	Is there adequate storage available to ensure that all supplies are held at the correct environmental conditions? a. Is the storage area well organized and free of clutter? b. Are set places labelled for all inventory items? c. Are hazardous chemicals stored appropriately? d. Is adequate cold storage available? e. Is temperature monitoring conducted according to material safety data sheet (MSDS) instructions? f. Is storage in direct sunlight avoided? g. Is the storage area adequately ventilated? h. Is the storage area clean and free of dust and pests?				
72.	Is there a documented policy to ensure that when reagents are put into use, the batch number and date are recorded and they are never used beyond their expiry date?				
73.	Is there a mechanism for validation of supplies, especially diagnostic reagents?				
74.	Are expired products disposed of properly?				
<b>(8) Testing</b>					
75.	Does the laboratory have a written policy giving all the information and details required on the report form to ensure that the person who requested the tests is supplied with all relevant information regarding the result, including the normal reference range for the procedure?				

Quality system		Y	P	N	Remarks
76.	Is there a documented turnaround time for each test which has been agreed upon between the laboratory and those requesting the test?				
77.	Is there a documented list of critical/panic result levels for critical tests and details of how requesters should be notified when results fall within these levels?				
78.	Is there a written procedure for reporting results by telephone to ensure that results reach the requester?				
79.	Is there a documented policy that details what, how, where and for how long records should be retained?				
80.	Is there a documented policy that details how long samples and subsamples should be stored?				
81.	Is there a documented policy that ensures the confidentiality of all records?				
<b>(9) Managing laboratory specimens</b>					
<b>(9.1) Pre-analytical phase</b>					
82.	Does the laboratory have a request form that provides all the details required to properly identify the source of the sample (e.g. patient), the requester, the test(s) required, and the date and time the sample was taken?				
83.	Are guidelines for source sample identification (e.g. patient), specimen collection (including patient and health-care staff safety), labelling and transport readily available to persons responsible for primary sample collection?				
84.	Are SOPs available on the correct collection procedures for all types of specimens sent to the laboratory?				



Quality system		Y	P	N	Remarks
85.	Do these instructions include recommendations on safe and timely transport of specimens to the laboratory?				
86.	Is there a written policy to deal with incorrectly identified or incorrect specimens received in the laboratory?				
87.	Is each primary sample given a unique accession number along with the date and time of receipt?				
88.	Is there a written procedure for preparing aliquots of samples, which ensures the accurate transfer of patient information?				
89.	Is there a procedure to ensure that samples once registered, and if necessary made into aliquots, are delivered to the testing laboratory in a timely manner?				
90.	Are there written SOPs which are in accordance with current International Air Transport Association (IATA) regulations for the packing and shipping of samples to external laboratories?				
91.	Are specimens packaged appropriately using a triple packaging system and transported to referral laboratories within acceptable time frames?				
92.	Are there adequate supplies of the correct shipping containers?				
93.	Do some of the staff responsible for shipping have current IATA shippers' certificates?				
94.	Are referred specimens tracked properly, using a logbook or tracking form to ensure that there is no loss of specimens?				
95.	Are procedures in place to ensure the receipt of results from referral laboratories?				

Quality system		Y	P	N	Remarks
<b>(9.2) Analytical phase</b>					
96.	Are there SOPs for all analytical methods and are they available at the workbench?				
97.	Do these SOPs follow the protocol laid out in the documentation control policy of the Quality Manual?				
98.	Are there work instructions at the workbench and do these follow documentation control requirements?				
99.	Is there an IQC process in place to verify the accuracy of results on each batch that is analysed?				
100.	Is there a reagent logbook for the lot number and dates of opening, which reflects the verification of new lots?				
101.	Is action taken and documented, including rejection of patient test results, if there is non-compliance with IQC results?				
<b>(9.3) Post-analytical phase</b>					
102.	Are all test requests cross-checked with test results to ensure that all tests have been completed?				
103.	Is there a procedure whereby all results are reviewed and signed out by an authorized person?				



Quality system		Y	P	N	Remarks
104.	<p>Is the laboratory report(s) in a standard format including the following (answer each item):</p> <p>a. Is the testing laboratory clearly identified in the report?</p> <p>b. Does the report contain the patient's name, hospital number, address and the hospital/destination of the report?</p> <p>c. Is the name of the person requesting the test indicated on the report?</p> <p>d. Is the type of sample received and the test requested included in the report?</p> <p>e. Are the date and time of specimen collection, receipt of specimen and release of report indicated?</p> <p>f. Does the report indicate reference ranges for each test where applicable?</p> <p>g. Is there space for interpretation of results, where applicable?</p> <p>h. Does the result contain the name of the person authorizing release of the report?</p>				
105.	Is there a policy for communicating to the requester about specimens unsuitable for processing, specimens where testing is delayed, corrected reports and critical results?				

# Annex 7

## Contributors

Dr Susan Best  
Director  
National Serology Reference Laboratory  
(NRL)  
4th Floor, Healy Building  
41 Victoria Parade  
Fitzroy, Victoria 3065, **Australia**

Dr Sau Sokunna  
Deputy Director in  
Hospital Services Department  
Head, Bureau of Medical  
Laboratory Services  
Ministry of Health  
#151-153 Avenue Kampuchea Krom  
Phnom Penh, **Cambodia**

Mr Douglas Ngaekura-Tou  
Laboratory Manager  
Ministry of Health  
P.O. Box 109  
Rarotonga, **Cook Islands**

Ms Lisa Barrow  
National Laboratory Coordinator  
FSM Department of Health & Social Affairs  
P.O. Box PS-70  
Palikir, Pohnpei  
**Federated States of Micronesia**

Dr Litia Tudravu  
Consultant Pathologist  
Lautoka Hospital  
P.O. Box 65  
Lautoka, **Fiji**

Dr Abha Gupta  
Chief Medical Officer in Pathology  
Labasa Hospital  
P.O. Box 577  
Labasa, **Fiji**

Mr Uraia Rabuatoka  
Senior Laboratory Technician  
Fiji Centre for Communicable  
Disease Control (FCCDC)  
Mataika House, Tamavua, **Fiji**

Dr James Kalougivaki  
Pathology Department  
CWM Hospital  
Ministry of Health, **Fiji**

Dr Eka Buadromo  
Chief Pathologist  
Pathology Department  
CWM Hospital  
Ministry of Health  
Suva, **Fiji**

Ms Salanieta Elbourne Duituturaga  
Laboratory Specialist  
Public Health Surveillance &  
Communicable Disease Control  
Level 2, Lotus Building, Ratu Mara Rd, Nabua  
Secretary of the Pacific Community  
Private Mail Bag, Suva, **Fiji**

Dr Wilina Lim  
Consultant Microbiologist  
Virus Unit  
Department of Health  
Public Health Laboratory Centre  
9/F, 382 Nam Cheong Street  
Shek Kip Mei  
Kowloon, **Hong Kong**

Dr Pretty Multihartina, PhD  
Coordinator, Laboratory for Infectious  
Diseases  
National Institute of Health Research and  
Development  
Ministry of Health  
Jl.Percetakan Negara 29  
Jakarta, **Indonesia**

Ms Tiero Tetabea  
Deputy Director  
Laboratory Services  
Ministry of Health & Medical Services  
P.O. Box 268, Nowerewere  
Tarawa, **Kiribati**

Dr Jane Carter  
Technical Director, Clinical and Diagnostics  
African Medical and Research Foundation  
P O Box 30125, 00100 GPO, Nairobi  
**Kenya**

Dr Phengta Vongphrachanh  
Director-General  
National Centre for Laboratory  
and Epidemiology  
Ministry of Health  
Km 3, Thadeua Road  
Vientiane Capital,  
**Lao People's Democratic Republic**

Dr Chanphomma Vongsamphanh  
Deputy Director General  
Health Care Department  
Ministry of Health  
Simuang Road  
Sisatanak District  
Vientiane Capital,  
**Lao People's Democratic Republic**

Mr Paul Lalita  
Majuro Hospital Laboratory  
P.O. Box 16  
Majuro 96960, **Marshall Islands**

Dr Shahnaz Murad  
Director  
Institute for Medical Research  
Ministry of Health Malaysia  
Jalan Pahang  
50588 Kuala Lumpur, **Malaysia**

Professor Lai-Meng Looi  
Department of Pathology  
Faculty of Medicine  
University of Malaya  
50603 Kuala Lumpur, **Malaysia**

Ms Amarjargal Yadam  
Deputy Director  
Medical Care Policy  
Coordination and Implementation  
Ministry of Health  
Government Bldg-VIII  
Olympic St-2  
Ulaanbaatar-210648, **Mongolia**

Professor Namid Munkhtuvshin  
Director  
Central Scientific Research Laboratory  
Research Institute of Medicine  
P.O. Box 48/47,  
Ulaanbaatar-210648, **Mongolia**

Professor Dr Ne Win  
Director (Laboratory and Blood Service)  
National Health Laboratory (NHL)  
Ministry of Health Union of Myanmar  
No. 35, Maw Kun Taik ST.,  
Dagon Tsp,  
Yangon, **Myanmar**

Dr Alani Tangitau  
Director of Medical Services  
RON Hospital  
Denig District, **Nauru**

Dr Geeta Shakya  
Director  
National Public Health Laboratory (NPHL)  
Teku,  
Kathmandu, **Nepal**

Mr Philip Wakem  
Pacific Paramedical Training Centre (PPTC)  
P.O. Box 7013  
Wellington 6242, **New Zealand**

Ms Christine Briasco  
Health Advisor  
New Zealand Aid Programme (NZAID)  
Ministry of Foreign Affairs and Trade  
**New Zealand**

Mr John Elliot  
Director  
Pacific Paramedical Training Centre  
P.O. Box 7013  
Wellington, **New Zealand**

Ms Lily Ulitech  
Laboratory Supervisor  
Ministry of Health  
P.O. Box 6027  
Koror 96940, **Palau**

Dr Evelyn Lavu  
Director  
Central Public Health Laboratory  
Port Moresby General Hospital  
Boroko NCD, **Papua New Guinea**

Dr Jianwei Wang  
Deputy Director and Professor  
Institute of Pathogen Biology  
Chinese Academy of Medical Sciences  
9# Dong Dan San Tiao  
Dongcheng District  
Beijing 100730, **People's Republic of China**

Dr Dengfeng Liu  
Deputy Director General  
Department of Science,  
Technology and Education  
Ministry of Health  
1# Xizhimenwai Nanlu  
Xicheng District  
Beijing 100044, **People's Republic of China**

Ms Myrna T. Reyes  
Bacteriologist IV  
National Centre for Health Facility  
Development  
Department of Health  
Sta. Cruz  
Manila, **Philippines**

Mr Vaomalo Michael Kini  
Manager, Laboratory Services  
Laboratory Division  
National Health Services  
Private Mail Bag, Apia, **Samoa**

Dr Nguyen Khac Tien  
Medical Officer  
Department of Medical Service  
Administration  
Ministry of Health  
38, Giang Vo Street  
Ba Dinh District  
Ha Noi, **Socialist Republic of Viet Nam**

Dr Vu Sinh Nam,  
Deputy Director General & Prof.  
General Department of Preventive Medicine  
Ministry of Health  
Lane 135 Nutruc  
Ba Dinh District  
Ha Noi, **Socialist Republic of Viet Nam**

Mr Alfred Dofai  
Head of Medical Laboratory  
Medical Laboratory Department  
Ministry of Health  
P.O. Box 349, Honiara, **Solomon Islands**

Dr Ajith Mendis  
Director General Health Services  
Ministry of Health  
Government of the Democratic Socialist  
Republic of Sri Lanka  
Suwasiripaya P.O. Box 513  
Colombo 10, **Sri Lanka**

Ms Surang Dejsirilert  
WHO CC for Antimicrobial Resistance &  
Training  
National Institute of Health  
Dept. of Medical Sciences  
Ministry of Public Health  
Nonthaburi 11000, **Thailand**

Mrs Suwanna Charunut  
Director  
WHO CC on Lab Quality  
(Bureau of Laboratory Quality Standards)  
Department of Medical Sciences  
Ministry of Public Health  
88/7 Tivanon Road, Muang  
Nonthaburi 11000, **Thailand**

Mrs Latu'uta Soakai  
Senior Medical Scientist  
Central Public Health Laboratory  
Vaiola Hospital  
Ministry of Health  
Nuku'alofa, **Tonga**

Ms Silvia Rosova  
Medical Laboratory Technologist  
Ministry of Health  
Vaiauku, Funafuti , **Tuvalu**

Ms Carol Fridlund  
Centers for Disease Control (CDC)  
12 Executive Park Drive, NE  
Mailstop G-25  
Atlanta, Georgia  
**United States of America**

Ms Vasiti Uluiviti  
Regional Laboratory Coordinator  
Pacific Islands Health Officers Association  
(PIHOA)  
c/o Guam Public Health Laboratory  
Mangilao, Guam 96923,  
**United States of America**

Mr George Junior Pakoa  
National Laboratory Manager (PLO)  
Senior Medical Laboratory Technologist  
National Laboratory  
Vila Central Hospital  
PMB 9013, Port Vila, **Vanuatu**

Dr Zamberi Sekawi  
Technical Officer  
Health Technology and Laboratory  
Office of the WHO Representative in the  
South Pacific  
P.O. Box 113  
Suva, **Fiji**

Dr Sébastien Cognat  
Laboratory Quality and Management  
Strengthening  
International Health Regulations  
Coordination  
Health Security and Environment  
WHO Lyon Office  
58 Avenue Debourg  
69007 Lyon, **France**

Dr Rajesh Bhatia  
Regional Adviser  
Blood Safety and Laboratory Technology  
WHO House  
Indraprastha Estate  
Ring Road  
New Delhi 110002, **India**

Dr Gayatri Ghadiok  
Technical Officer  
Essential Health Technologies Adviser  
World Health Organization  
Regional Office for the Western Pacific  
P.O. Box 2932  
1000 Manila, **Philippines**

Establishing and maintaining laboratory quality standards are essential to generate reliable results to support clinical and public health actions. The Laboratory Quality Standards present a minimum set of standards that can be readily adapted by countries and applied to laboratories at every level of the health-care system. This document also outlines mechanism to implement them. This document will be of help to national policy-makers as well as regulators in developing national laboratory quality standards. It provides a simple approach to meet the minimum requirements set with the ultimate objective to comply with ISO 15189 in a logical and step-by-step manner.

