National Standards for **Clinical Laboratories**

Ministry of Health

World Health Organization
Maldives

National Standards for Medical Laboratories 2022

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FOREWORD

Laboratory services are an essential component of quality healthcare delivery system. It is one of the main pillars of an evidence-based healthcare delivery system and can be utilized effectively at every level of the health care system including primary health care and point of care testing. Quality diagnostics and 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.

In midst of numerous challenges, we learned quickly that clinical laboratories have a critical role to play in response to the current COVID-19 pandemic and other health emergencies. In addition to ensuring the testing requirements of the population in the present hour, laboratories have an unprecedented responsibility to prepare for the aftermath of the pandemic. And ensuring standardized processes are in place ensures optimal functioning of the laboratory which improves the accuracy of health information and promotes effective national health planning.

WHO has prioritized strengthening laboratory and diagnostic capacities in the Maldives by supporting the development of the National Laboratory Policy, but also a strategic action plan for implementation of this document. And now, I am pleased to have supported the review and updating of Maldives National Clinical Laboratory Standards and publishing the updated version of the standards in line with the global guidelines.

I acknowledge the support of all who have been involved and contributed towards this work from the first National standards released in 2013, to the current version. I congratulate the partners and stakeholders for their valuable input and dedication, and mostly the Ministry of Health for their commitment.

WHO will continue to be a trusted partner in enhancing the Maldives' laboratory capacities and quality management system, to build back a better and more resilient health system in the Maldives.

Dr. Nazneen Anwar
WHO
Representative

ACKNOWLEDGEMENT

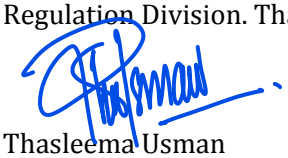
The importance of quality in the functioning of health care laboratories is well recognized globally and more significantly in developing countries. The poor quality of laboratory results can lead to inappropriate interventions and adversely affect the credibility of the laboratories. Hence, it is essential to develop and implement a minimum standard for clinical laboratories. These standards are considered an acceptable framework to increase test quality and reduce frequency of laboratory errors. Quality systems are developed by different international bodies and the International Organization for Standardization (ISO)'s standards are considered as gold standard especially for laboratory services. Majority of laboratories rely on ISO/IEC/17025 for all types of testing and calibrating laboratories and more specifically ISO 15189 for medical laboratories. However, these standards are often very resource-intensive and only a few of the leading laboratories conform to these standards, while a majority get discouraged to even attempt meeting the standards considering the exhaustive list of requirements.

The efforts in developing national standards is considered a stepping stone for all laboratories to work towards ISO certification, since national standards is the way forward in laying down the foundation of quality systems. Hence, the development of minimum national quality standards for clinical laboratory. The development of national standard on clinical laboratory embraced ISO and other relevant international standards that is locally adaptable and which can be enhanced to achieved international accreditation at a later stage. The Ministry of Health will be using this standard for regulating our health laboratory for compliance to registering and licensing facilities.

I sincerely hope that this publication will achieve its intended objective of motivating Laboratories setting up National Quality Standards as a step to achieve International Standards, and further achieve quality laboratory testing to enhance quality of clinical care.

I would like to express my gratitude to WHO country office for their continuous support and guidance in assisting the development of standards for improving health care quality. My sincere appreciation to WHO consultant Ms. Mariyam Reema for her works in reviewing the standard with involvement of stakeholders and adapt as per country context. Moreover, I am especially thankful to all stakeholders who were involved in compiling and finalizing the standard which has been locally adapted.

I am constantly impressed by the performance of the dedicated team at Quality Assurance and Regulation Division. Thank you for all your hard work.



Thasleema Usman
Commissioner of Quality Assurance

CONTENTS

1 Scope

This National standard contains a minimum set of requirements for medical laboratories that can be readily applied and adapted by laboratories, both public and private at every level of the health-care system in the country.

1.1 Description of laboratories

Category 1

Laboratories providing confirmatory tests in addition to screening or initial tests of biochemistry, microbiology, hematology, and pathology and of biosafety level 2 and/or 3.

Category 2

Laboratories providing screening or initial tests of biochemistry, haematology and pathology without confirmatory test and of minimum biosafety level

Category 3

Medical clinic or facility providing point of care tests that does not require laboratory setup.

2 Terms and Definitions

For the purpose of this standard the following apply which are based on ISO terms and definitions.

accreditation- process by which an authoritative organization gives formal recognition that a laboratory is competent to carry out specific tasks.

assessment – systematic process to collect and analyze data to determine the c the current, historical, or projected status of an organization, person, or project

audit- systematic, independent, and documented process to obtain objective evidence and evaluate it objectively to determine the extent to which the audit criteria are fulfilled.

biological reference interval -reference interval

calibration - comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of known accuracy to detect any variation from the required performance specification.

competence - demonstrated ability to apply knowledge and skills

compliance - successful fulfillment of a rule such as a specification, standard, policy, regulation, or law

document (*n*) – information and the medium on which it is contained

NOTE: Documents may be paper based or electronic.

establish - define, document (in writing or electronically), and implement.

examination – set of operations having the objects of determining the value of characteristics of a property.

information – date shaped into a form that is meaningful and useful to support decision – making, coordination, and control in an organization.

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

laboratory management - Persons who manage the laboratory headed by the manager

management – coordinated activities to direct and control an organization

medical laboratory- Laboratory for the microbiological, immunological, hematological, biochemistry, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for diagnosis, prevention and treatment of diseases in or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

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

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

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

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

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

quality - degree to which a set of inherent characteristics fulfils requirements.

quality control - the set of procedures designed to monitor the test method and the results to ensure appropriate test system performance.

quality management system – management system to direct and control an organization with regard to quality.

quantity - Quantity is the attribute of a phenomenon, body or for a substance that may be distinguished qualitatively and determined quantitatively.

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

sample – one or more parts taken from a primary sample

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

traceability - ability to trace the history, application, or location of that which is under consideration

training- process to provide instruction for performing or improving a job function

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

3 Management requirements

3.1 Organization and management

1. The medical laboratory (hereafter referred to as 'the laboratory') shall meet the requirements of this National Standard when carrying out work at its permanent facilities, or in associated or mobile facilities.
2. The laboratory or the organization of which laboratory is a part shall be registered and licensed by the Ministry of Health.
3. The laboratory shall have adequate number of appropriately qualified and competent technical staff registered under the Maldives Allied Health Council.
4. The laboratory management shall have arrangements in place to ensure that there is no involvement in any activity that would diminish the confidence in the laboratory's competence, impartiality, judgement, or operational integrity.
5. All personnel in the laboratory shall share responsibility to ensure that ethical and good professional practices are followed.
6. The laboratory management and personnel shall be free from any undue internal or external commercial, financial, or other pressures and influences that could adversely affect the quality if their work.
7. The laboratory shall have an organizational chart (organogram) that describes the management and supervisory arrangements in the laboratory. This chart must be understood by all laboratory staff.
8. The laboratory shall be directed by a person or persons with competence and delegate responsibility for the services provided. The duties and responsibilities of the laboratory director shall be documented. The laboratory organization and management shall:

    a) ensure that there are adequate numbers of appropriately qualified staff and competent technical staff.
    b) provide laboratory staff with appropriate authority and resources to carry out their duties;
    c) define responsibilities, authorities, and interrelationship of all personnel;
    d) appoint a member of staff (Quality Manger-QM) with responsibility for quality management who reports directly to laboratory head on a regular basis;
    e) appoint a member of staff to act as Safety Officer;
    f) provide a safe laboratory environment in compliance with good practice and applicable requirements;
    g) 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;
    h) establish communication processes with laboratory users, including patients and clients;
    i) provide essential equipment and ensure it functionality;
    j) ensure there are adequate supply of laboratory chemical, reagents, test kits and supplies;
    k) establish an effective system for documentation and record keeping and ensure confidentiality of patient information;

l) establish an effective quality management system (QMS) covering all aspects of laboratory operations.

9. The laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services.

3.2 Quality management system

1. The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this National Standard.
2. The laboratory shall have a quality manual that contains all documents, policies and procedures and directives. The quality manual shall be kept up to date by the management or designated person. The quality manual shall consist of the following major sections:

    a) main functions and responsibilities of the laboratory, including organizational structure;
    b) personnel issues, including employment policies, job descriptions, staff education and continuing professional development (CPD);
    c) accommodation and environment;
    d) inventory of instruments and records of repair and preventive maintenance;
    e) written procedures that ensure proper calibration and functioning of all instruments, reagents and analytical systems;
    f) written safety policies and procedures;
    g) all sampling and transport procedures;
    h) management of samples and biological material;
    i) quality assurance (QA) systems including internal quality control (IQC) and external quality assessment schemes (EQAS)
    j) written policies and procedures on customer service and improvement processes.

3. The laboratory shall have a process to review and revise the quality manual at scheduled intervals.
4. The quality system should include but not limited to:

    a) Internal quality control for all levels of laboratory and point of care testing.
    b) Internal quality control and participate in organized inter laboratory comparisons and/or external quality control scheme for level 3, specialized laboratories, and Referral laboratories.
    c) Participation in a regular National or International External Quality Assurance Scheme (NEQAS/IEQAS) and ensuring quality is a requirement of all levels of laboratories.

3.3 Document control

1. The laboratory shall have a document control system that ensure:

    a) All documents, including those maintained in a computerized system are reviewed and approved by authorized personnel before issue.
    b) Only current authorized documents are available at point of use.
    c) Procedures and authorities for amendment of documents by hand, pending and the re-issue of documents are defined.
    d) Amendments are clearly marked, initialled, and dated, and a revised document is issued within a specified time period.
    e) Obsolete controlled documents are dated and marked obsolete.

3.4 Examination by referral laboratories

1. The laboratory shall have a documented procedure for selecting and evaluating referral laboratories.
2. The laboratory management shall be responsible for selecting and monitoring the quality of performance and ensure that the referral laboratories or referral consultants are competent to perform the requested examinations
3. Records of referral samples and laboratories shall be maintained by the referee.
4. The referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.
5. When the referring laboratory prepares a report, it shall include all the essential elements of the results reported by the referral laboratory. Alterations that can affect the clinical interpretation shall not be done and the report shall indicate which examinations were performed by a referral laboratory or consultant.

3.5 Resolution complaints

1. The laboratory shall have a documented procedure to identify and manage complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigations and action taken.

3.6 Identification and control of non-conformance

1. The laboratory shall have a documented procedure to identify and manage nonconformities.

    a) Personnel responsible for investigation of non-compliance and problem resolution shall be designated.
    b) Medical significance of non conformance is identified and requesting clinician is informed if relevant
    c) Examinations are temporarily stopped, reports withheld if appropriate.
    d) If results have been released, the reports recalled or identified.

e) Corrective action(s) implemented immediately, and resumption of services authorized.
f) The root cause of non conformance shall be determined and action taken to eliminate and/or minimize recurrence.
g) These events shall be documented and recorded, with these records being reviewed at regular specified intervals.

3.7 Corrective action

a) Corrective action shall include an investigation process to determine the cause of problem, correct it and generally lead to preventive action.
b) Laboratory management shall monitor the results of corrective action to ensure the identified problem has been effectively solved.

3.8 Preventive action

The laboratory shall have a documented procedure for:

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

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

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

d) determining and implementing preventive action needed;

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

f) reviewing the effectiveness of the preventive action taken.

3.9 Continual improvement

a) All operational procedures shall be reviewed regularly by laboratory management at specified intervals to identify potential sources of non conformance and opportunities for improvement.
b) Action for improvement based on the review findings shall be implemented.
c) Quality indicators for monitoring laboratory performance should be developed and monitored.

These could include but is not limited to:

i. Sample collection and identification.
ii. Transport and processing.
iii. Analyzing and reporting.
iv. Turn around times.

3.10 Control of records

1. The laboratory shall have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records.
2. All the records shall be legible and stored in such a way that they are easily retrievable.
3. Laboratories shall have suitable storage to prevent damage loss and unauthorized access.
4. The records shall include but is not limited to:

    a) staff qualifications, training and competency records;
    b) request forms;
    c) information on reagents and materials used for examinations (e.g. lot documentation, package inserts);
    d) laboratory workbooks or work sheets;
    e) examination results and reports;
    f) instrument maintenance records, including internal and external calibration records;
    g) quality control records;
    h) incident and accident records and action taken;
    i) nonconformities identified and immediate or corrective and preventive action taken;
    j) records of internal and external audits;
    k) inter laboratory comparisons of examination results;
    l) records of quality improvement activities;
    m) minutes of meetings that record decisions made about laboratory's quality management activities.

3.11 Evaluation and audits

a) The laboratory shall plan and implement the evaluation and internal audit process to improve the effectiveness of the quality management system.
b) Audits shall be conducted by a trained person at predetermined intervals. Audit of all elements of the system, both managerial and technical shall be conducted.
c) The procedure for internal audit must be defined and documented.
d) Personnel responsible for the area being audited shall ensure that appropriate action is promptly undertaken when non-conformities are identified, and corrective action shall be taken without delay.
e) The laboratory shall request for an external person, to review the QMS. The laboratory shall initiate corrective actions for all non-compliance identified during the external audit.

3.12 Management review

1. The laboratory management shall review the quality management system and all of its services at least once a year, to ensure effectiveness and introduce any necessary

changes for improvement.

2. The results of the review shall 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:

    a) periodic review of requests and sample requirements;
    b) staff suggestions;
    c) results of EQA or inter laboratory work;
    d) internal audits;
    e) changes in the volume and type of work;
    f) monitoring and resolution of complaints;
    g) monitoring turn around time;
    h) performance of suppliers;
    i) results of the continuous improvement process.

4 Technical Requirements

4.1 Personnel

1. The laboratory in charge or head shall be a person with the training and competence to take responsibility for managing the laboratory.
2. The laboratory shall have sufficient number of staff with appropriate qualifications, training and experience to ensure that the laboratory operations are effective. All staff undergoing training shall be supervised at all times.
3. Each laboratory discipline shall be led by a person who has had the appropriate training, which may include graduate or postgraduate education (if required).
4. The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel. The laboratory head shall review all job descriptions annually, after consultation with the appropriate section head and the staff member.
5. The laboratory shall have a program to introduce new personnel to the organization, the department or area in which they will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services.
6. The laboratory head shall identify the training needs of individual personnel and ensure that all staff has access to appropriate CPD programs. All personnel need to be trained in:

    a) quality management system;
    b) health and safety, including the prevention or containment of the effects of adverse incidents;
    c) computer systems;
    d) assigned work processes and procedures;
    e) ethics;
    f) confidentiality of patient information.

7. A performance appraisal shall 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.
8. The laboratory shall maintain records of personnel.
9. These records shall be readily available to relevant personnel and shall include but not be limited to:

    a) education and professional qualifications;
    b) copy of registration and license;
    c) previous trainings;
    d) previous experience;
    e) job descriptions;
    f) continuing education
    g) performance appraisals

10. The laboratory shall establish end of employment processes that are consistent with applicable requirements. (e.g., return organization material, access to computer systems

and buildings, information about issues that contributed to individual's departure and positive practices)

4.2 Accommodation and environment conditions

1. The laboratory shall have adequate space that is properly organized so that the quality of work and safety of staff, patients, customers and visitors is not compromised.
2. Where applicable, similar provisions shall be made for primary sample collection and other examinations at sites other than the main laboratory premises, for example point-of care testing (POCT) under the management of the laboratory.
3. The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met.

    a) Access to areas affecting the quality of examinations is controlled.
    b) Medical information, patient samples, and laboratory resources are safeguarded from unauthorised access.
    c) Communication systems within the laboratory are appropriate to the size and complexity of the facility to ensure the efficient transfer of information.
    d) Safety facilities and devices are provided, and their functioning regularly verified.

4. The laboratory shall have adequate lighting (natural or artificial), clean running water, ventilation, electric outlets, back-up power, drainage systems that comply with environmental regulations, and sanitization facilities for patients and staff.
5. The laboratory shall have adequate storage space with the right conditions to ensure the integrity of samples, slides, histology blocks, histology samples, retained microorganisms, document, manuals, equipment, reagents and other supplies, records, and results.
6. Disposal of all infectious waste including sharps must be managed safely and effectively according to national waste management regulations.
7. The laboratory shall have adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.
8. Where primary sample collection is carried out, consideration must be given to patient access (including patients with disabilities), comfort and privacy. Separate rooms shall be made available for sample collection and blood donor activities.
9. Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination
10. The laboratory shall be well maintained and kept clean. Measures shall be taken to ensure good housekeeping (general tidiness, cleanliness, hygiene, freedom from rodents and insects) and maintain all work areas well.
11. The laboratory shall have an appropriate biosafety environment and facilities to safety handle microorganisms belonging to different bio risk levels as per the mandate of the laboratory.
12. The laboratory shall carry out potentially hazardous activities in a separate area to prevent cross contamination and reduce potential safety risks to all staff and visitors. e.g. TB bacteriology, handling and examination of high-risk samples, nucleic acid

amplifications, and controlled environments for large computer systems and some high capacity-analysers.

4.3 Laboratory Safety.

1. The laboratory shall establish safety rules to reduce risk to staff, customers and visitors. Staff shall comply with these rules (see Annex 1) and ensure customers and visitors are sufficiently briefed to ensure safety.
2. The laboratory shall have procedures prepared to ensure safe handling of laboratory equipment.
3. The laboratory shall have documented procedures to ensure the safe handling of all samples and procedure such as phlebotomy, sample transport, sub sampling, analytical procedures, storage and disposal of samples.
4. The laboratory shall have documented procedures for safe handling of all referred samples. A list of diseased of national and international concern that require emergency action must be available in the laboratory.
5. All staff handling the patient samples and other biological materials must wear appropriate personnel protective equipment (PPE). These shall be removed before leaving the laboratory or undertaking clerical work. Hands shall be washed immediately after removing the protection and before leaving the laboratory.
6. The laboratory shall have a documented procedure for handling spillage/leakage of biological samples, chemical or radiochemical materials or patient samples, including when containers are broken in centrifuge.
7. The laboratory shall provide first-aid materials and the facility must be readily available to deal with accidents. All accidents however small, must be recorded and reported as per national regulations.
8. The employing authority, through the laboratory head, shall be responsible for ensuring adequate protection of laboratory personnel to avoid occupational hazards. These include:

    a) Use of vaccine, for example, against hepatitis B virus (HBV infection);
    b) Use of post-exposure prophylaxis (PEP) procedures against HIV infection in case of needle stick-injury;
    c) Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work;
    d) Provision of personal protective equipment (PPE)

4.4 Laboratory equipment, reagents and consumables

1. The laboratory shall have a documented procedure for the selection, purchasing and management of equipment.
2. The laboratory shall be provided with the necessary equipment that is appropriately placed for efficient performance.
3. All equipment shall be procured from suppliers who can assure appropriate maintenance and emergency servicing, including spare parts. Service contracts shall be obtained for major equipment

4. Suppliers shall provide adequate training for staff in equipment use, care and maintenance; including biomedical engineers who maybe required to carry out maintenance procedures.
5. All equipment shall be maintained in a safe working condition, according to manufactures instructions.
6. When equipment is found to be defective, its services should be stopped, repaired and the laboratory shall ensure its performance is verified before use.
7. Equipment shall be reasonably decontaminated before service, repair or decommissioning and laboratory shall provide appropriate personal protective equipment.
8. Donated equipment shall comply with the WHO Guidelines for health care equipment donations (see Annex 2)
9. The equipment selected shall be of known reliability and meet the requirements of laboratories at each level. Consideration shall be given to the following:

    a) load-bearing capacity of the surface on which the equipment will rest;
    b) space requirements specified by the manufacturer;
    c) electrical requirements.
    d) ventilation and air quality;
    e) humidity;
    f) temperature;
    g) water type and quality;
    h) potential hazards;

10. All equipment shall be operated at all times by trained and authorized personnel and instructions on the use, safety and maintenance of equipment shall be readily available.
11. The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects the examination results.
12. The laboratory shall have a documented procedure for decommission and final disposition of equipment.
13. Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to:

    a) identity of equipment;
    b) manufacturer's name, model and serial number or other unique identification;
    c) manufacturer's or supplier's contact address, telephone number, and /or e-mail address;
    d) date of receiving and date of entering into service;
    e) location;
    f) condition when received (e.g. new, used, reconditioned);
    g) manufacturer's instructions, SOPs on how to use equipment.
    h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;
    i) maintenance carried out and the schedule for preventive maintenance;
    j) equipment performance records that confirm the equipment's ongoing

acceptability for use;
k) damage to, or malfunction, modification, or repair of the equipment;
l) disposal of redundant/unusable equipment.

4.5 Reagents and consumables

1. The laboratory shall have a documented policy and procedure for selection, procurement of reagents and other supplies that include:

    a) supplier qualification and monitoring;
    b) competitive bidding;
    c) ordering based on a reliable estimate need;
    d) quality checking of supplies received.

2. The laboratory shall establish a process for validation of supplies, especially diagnostic reagents.
3. The laboratory shall establish an inventory of all reagents and consumables. Information including the quantities, batch numbers, expiry dates and sources of supply shall be recorded.
4. The laboratory shall have guidelines in place to ensure safe and appropriate storage of all laboratory supplies.

4.6 Pre-examination process

1. The laboratory shall have documented procedure and information for pre-examination activities to ensure the validity of the results of examinations.
2. The laboratory shall use proper request forms that contain information to correctly identify the source of sample (e.g. patient) and the authorized person requesting the test and relevant clinical details
3. Request form shall contain the following:

    a) patient identification, gender and fate of birth;
    b) patient location/source of specimen;
    c) identity of the requesting person;
    d) type of sample;
    e) examination (test) required;
    f) clinical details, e.g. any drug/antibiotics being given that may have relevance to the interpretation of results;
    g) time and date of sample taken;
    h) date and time of sample receipt.

4. The laboratory shall have documented procedures for collection and handling of primary samples. The documented procedure shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.
5. Primary sample collection and handling should documents shall address the following:

a) Instructions for pre-collection

i. completion of request form or electronic request;
ii. preparation of patient (instructions to caregivers, phlebotomists, sample collectors and patients);
iii. type and amount of the primary sample to be collected with descriptions of primary sample containers and any necessary additives;
iv. special timing of collection, where needed;
v. clinical information relevant to or affecting sample collection, examination performance or result interpretation.

b) Instructions for collection

i. determination of the identity of the patient from whom the primary sample is collected;
ii. verification that the patient meets pre-examination requirements (e.g. fasting status, medications status);
iii. instructions for labelling of primary samples;
iv. recording of the identity of the person collecting the primary sample and the collection date and time;
v. instructions for proper storage conditions before collected samples are delivered to the laboratory;
vi. safe disposal of materials used in collection.

6. The laboratory shall 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 request analysis to be performed.
7. Samples transported to other referral laboratories shall be packed and transported according to current International Air Transport Association (IATA) regulations.
8. All persons involved in the shipping process shall be trained in the correct procedure for packaging and transportation.
9. The laboratory shall have a documented procedure for specimen acceptance and rejection.
10. All specimens received in the laboratory shall be recorded in an accession book or computer or other suitable means and the date and time or receipt and identity of the receiving person shall be recorded.
11. If primary sample acceptance criteria have been compromised, final report shall indicate the nature of the problem and the caution in interpretation if applicable.
12. Samples shall be stored for a specified time, under suitable conditions to ensure stability to enable examination if required.

4.7 Examination processes

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

2. The laboratory shall have all examination procedures documented. They shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations. The documentation shall include, when applicable to the examination procedure, the following:

    a) purpose of examination;
    b) principle and method of the procedure used for examination;
    c) performance characteristics;
    d) type of sample (e.g. plasma, serum, urine);
    e) patient preparation;
    f) type of container and additives;
    g) required equipment and reagents;
    h) environmental and safety controls;
    i) calibration procedures;
    j) procedural steps;
    k) quality control procedures;
    l) interferences (e.g. lipaemia, heamolysis, bilirubinemia, drugs)
    m) procedure for calculating results
    n) biological reference values;
    o) reportable interval of examination results;
    p) alert/critical values where applicable;
    q) laboratory clinical interpretation;
    r) potential sources of variation
    s) references.

4.8 Ensuring quality of results

1. The laboratory shall design quality control procedures that verify the attainments of the intended quality of results.
2. The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to the patient samples.
3. The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.
4. Laboratory shall participate in an EQAS program. Laboratory management shall monitor the results of the EQAS, and corrective action implemented when specified criteria are not met. This is a requirement for specialized and referral laboratories.
5. If EQAS program is not available, the laboratory shall develop a mechanism to determining the quality of the procedures. Laboratories shall use external control material and/or exchange of samples between laboratories. Laboratory management shall monitor the results and implement corrective actions if applicable.

4.9 Post examination process

1. The laboratory shall have procedures to ensure that authorized personnel review the test results before release.
2. The laboratory shall establish and follow a review criterion when the results involve

automatic selection and reporting.

3. The laboratory shall have procedures in place for storage of samples post-examination to enable re-examination if required. The storage time for all primary samples and sub-samples, stained microscope slides, histology specimens and blocks, and isolates and other biological shall be adhered to.
4. Samples shall be safely disposed and carried out in accordance with national regulations and recommendations for waste management.

4.10 Reporting results

1. The laboratory report shall be reported accurately, without transcription mistakes,
2. The laboratory report shall include the following but is not limited to:

    a) clear identification of the examination, where appropriate, the examination procedure;
    b) the identification of the laboratory that issued the report;
    c) identification of all examinations that have been performed by a referral laboratory;
    d) patient identification and patient location on each page;
    e) name or other unique identifier of the requester and the requester's contact details;
    f) date and time of primary sample collection
    g) type of primary sample;
    h) measurement procedure, where appropriate;
    i) examination results reported in SI units, units traceable to SI units, or other applicable units;
    j) biological reference intervals, clinical decision values;
    k) interpretation of results, where appropriate;
    l) identification of person(s) reviewing the results and authorizing the release of the report) if not contained in the report, readily available when needed);
    m) date of the report, and time of the release (if not contained in the report, readily available when needed);

4.11 Release of results

1. The laboratory shall have an established procedure for the release of test results, including the details of who may release results and to whom.
2. The laboratory shall establish procedures for notifying the requester of clinician when results of critical analyses fall outside specific limits.
3. The laboratory shall have a documented procedure for reporting of urgent results by telephone.
4. The laboratory shall determine (preferably in consultation with the clinicians) the turnaround time for examinations. The laboratory must adhere to that TAT or advise the user of any delays.
5. The laboratory shall have a policy that defines the length and time of the various records and all samples should be kept or stored.

6. The laboratory shall have a procedure to issue reports after an original report is revised. If revised the record must show the time, date, and name of person responsible for the change. Original entries shall remain legible when revisions are made.
7. Results that have been revised after issue, especially if the reports have been made available for clinical decision making should be marked as revised and the clinical should be informed.

4.12 Laboratory Information management

1. The laboratory shall have an effective information management system in place to achieve confidentiality of patient information and accessibility, accuracy, timeliness and security.
2. The laboratory shall store information as hard copies or electronically depending on the resources available, such as computers, and the necessary expertise.
3. All documents and records must be:

    a) Legible, concise and clear
    b) Retrievable
    c) Stored safely.

4. The laboratory shall have a policy that states the length of time that various records and samples should be kept or stored,
5. The laboratory access to records shall be limited and data protected from access by unauthorised individuals.
6. The laboratory shall have documented contingency plans to maintain services in the event of failure of downtime in information systems that affect the laboratory's ability to provide service.

4.13 Outbreak alert and laboratory network

1. All laboratories shall have a list of laboratories that are part of the national system for surveillance and response. Samples of unknown pathology or for which advice is urgently requested shall be sent to the designated reference laboratory.
2. There shall be clear identification and points of contact for referral laboratories for confirmation of diseases of national priority. For analysis that is not available in-country, referral laboratories shall be identified at the international level and mechanisms for specimen transfer established.
3. There shall be a standardized reporting system in place for laboratory diagnosis/surveillance of priority diseases, including a standardized reporting form and/or software for laboratory data.
4. There shall be a separate data reporting system established in case of disease outbreaks, in a timely manner, as defined by the International Health Regulations (IHR), 2005.
5. A national laboratory network shall establish the capacity to address disease outbreaks. Appropriate laboratory reagents and/or rapid tests shall be positioned in advance at national, intermediate, and peripheral levels.
6. All samplings shall be undertaken with appropriate levels of safety. The level of PPE to

be employed will be determined by the type of exposure risk.

7. Each patient shall be given a unique identifier number and accompanied by a datasheet. The sheet shall have the following:

    a) Specimen identification;
    b) Location of sampling;
    c) Identification of the person who collected the sample;
    d) Identification of the requesting service or person (for return of the report);
    e) Type of primary sample;
    f) Examinations (tests) required;
    g) Time and date of primary sample;
    h) Time and date of receipt by the laboratory.

5 References

CLSI (2019) A Quality Management System Model for Laboratory Services, 5th ed. CLSI guideline QMS01, Wayne, PA: Clinical and Laboratory Institute.

Singapore Standard (2017), Medical laboratories — Requirements for quality and competence, SS ISO 15189 : 2017, Enterprise Singapore.

World Health Organization. (2000). Guidelines for health care equipment donations. World Health Organization. Available: https://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf

World Health Organization. (2011). Laboratory quality management system: handbook, Version 1.1. World Health Organization. https://apps.who.int/iris/handle/10665/44665

World Health Organization. (2016). WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites. World Health Organization. https://apps.who.int/iris/handle/10665/250117

World Health Organization. (2020). Laboratory biosafety manual, 4th ed. World Health Organization. https://apps.who.int/iris/handle/10665/337956

World Health Organization. Health Laboratory Technology Unit. (1997). Safety in health-care laboratories. World Health Organization. https://apps.who.int/iris/handle/10665/63993

World Health Organization. Regional Office for Africa. (2014). Guidance for Establishing a National Health Laboratory System. World Health Organization. Regional Office for Africa. https://apps.who.int/iris/handle/10665/148351

World Health Organization. Regional Office for Africa. (2014). Guidance for Establishing a National Health Laboratory System. World Health Organization. Regional Office for Africa. https://apps.who.int/iris/handle/10665/148351

World Health Organization. Regional Office for Africa. (2015). Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015 for Clinical and Public Health Laboratories. World Health Organization. Regional Office for Africa. https://apps.who.int/iris/handle/10665/204423

World Health Organization. Regional Office for South-East Asia. (2009). Guidelines for implementation of quality standards for health laboratories. WHO Regional Office for South-East Asia. https://apps.who.int/iris/handle/10665/205163

World Health Organization. Regional Office for the Eastern Mediterranean. (2016). Stepwise implementation of a quality management system for a health laboratory. World Health Organization. Regional Office for the Eastern Mediterranean. https://apps.who.int/iris/handle/10665/249570

World Health Organization. Regional Office for the Western Pacific. (2011). Laboratory quality standards and their implementation. Manila : WHO Regional Office for the Western Pacific. https://apps.who.int/iris/handle/10665/206927

Annex 1

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.

Annex 2

Donated equipment

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.

1. 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.

2. 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.

3. Donation plans must include detailed installation and commissioning procedures.

4. 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.

5. 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.

6. 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.

National Standards for Clinical Laboratories