National Standards for Clinical laboratories

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Foreword

The Ministry of Health (MOH) places great emphasis on ensuring that the health care services provided to Maldivians are safe and of high quality. This can be achieved through well developed standards of care including necessary protocols, practice guideline and relevant training staff.

I'm pleased that we are publishing the first national standards for clinical laboratories in the Maldives. I would like to convey my sincere gratitude to Ms. Shareefa Adam Manik for taking the initiative to develop the National standards for Clinical laboratory and gearing the whole process of consultation, compilation, draft evaluation and completion. I would also like to congratulate the stakeholders for their valuable input and the dedication in developing the standard. I highly appreciate the dedicated efforts of MOH senior management and the relevant staffs of QAS in facilitating the compilation of this publication.

I hope the health care professionals and administrators of both public and private health care facilities will use this standard in laboratories in order to improve the quality and efficiency of their services

Dr Sheeza Ali
Director General of Health Services
14th February 2013

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Shareefa Adam Manik
Director General
14th February 2013

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1. Scope

These standards are specific to the following areas of clinical laboratory services and investigations carried out by the laboratory and also to all facilities for primary collection sites other than the main laboratories.

a) Clinical microbiology, molecular biology and Immunology

b) Clinical biochemistry

c) Clinical hematology

d) Clinical pathology

e) Histopathology and Cytopathology

1.1 Description of laboratories

This standard is applicable to all medical laboratories both public and private which shall include laboratories at the central level, regional hospitals and atoll hospitals

These classifications are in alignment with categories of allopathic health services, independent laboratories and are based on types of tests conducted and level of biosafety.

(See Annex 1 for details on biosafety levels)

Category 1

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

Category 2

Laboratories providing screening or initial tests of biochemistry, hematology 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. Definitions

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

2.1 Accuracy of measurements:

Closeness of agreement between the result of measurement and true value measured.

2.2 Biological reference interval

Reference interval

2.3 Examination

Set of operations having the objective of characterization of property

2.4 Laboratory capability

Physical infrastructure information, resources, trained personnel, skills and expertise available for the offered services.

2.5 Laboratory director / laboratory in charge:

Competent persons with responsibility for, and authority over, a laboratory

2.6 Laboratory management:

Persons who manage the laboratory headed by the manager

2.7 Measurement:

Set of operations having the object of determining a value of quantity

2.8 Medical laboratory

Clinical 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.

2.9 Pre examination procedures

Pre analytical phase

Steps starting, in chronological order, from the clinicians request and including the examination requisition, preparation of patient, collection of primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins.

2.10 Post examination procedures

Post analytical phase

Process following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of results, and storage of samples of the examinations.

2.11 Primary sample

Specimen

Set of one or more parts initially taken from system

2.12 Quality

Quality is sum total of all the characteristics of a product (or a service) that has bearing upon the utilization of the product (or services) to the entire satisfaction of the consumer.

2.13 Quantity

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

2.14 Referral laboratory

External laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report.

2.15 Sample / aliquot

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

2.16Traceability

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

2.17 Trueness of measurement

Closeness of agreement between the average values obtained from a large series of results of measurements and a true value.

2.18 Uncertainty of measurement

Parameter, associated with the result of measurement that characterizes the dispersion of the values that could reasonably be attributed to the measured quantity.

3.0 Management requirements

3.1 Organization and Management

3.1.1 The clinical laboratory (hereafter referred to as “the laboratory”) or the organization of which the laboratory is a part shall be registered and licensed by the Ministry of Health and Family.

3.1.2 The laboratory shall be design its services to meet the needs of the patients and the clinical personnel responsible for the patient care.

3.1.3 The laboratories shall meet the relevant requirements of the standard or internal standard when carrying out work both in its permanent facilities and other sites for which it is responsible.

3.1.4 The responsibilities of personnel in the laboratory, involved in or have influence on the examination of the primary samples shall be clearly defined in order to identify conflicts of interest. Financial, political and other interests should not influence testing.

3.1.5 Laboratories and the organization's management shall have responsibility to formulate, implement, maintain and improve the quality system.

This shall include:-

- **a)** Provide all laboratory staff with appropriate authority and resources to carry out their duties.
- **b)** Ensure that management and personnel are free from any internal or external commercial, financial or other pressures that may adversely affect the quality of the tests.
- **c)** Policies and procedures to ensure the protection of confidential information.
- **d)** Policies and procedures to maintain confidence, complement and operational integrity.
- **e)** Organizational and management structure of the laboratory and it's relationship to other relevant organizations.
- **f)** Specific responsibility, structural and interrelationships of all personnel.
- **g)** Adequate training and appropriate supervision by competent personnel.
- **h)** Appointment of appropriate personnel for technical operations, management and quality control.
- **i)** Appointment of deputies for all key functions. When appointed, more than one function may be allocated to one person in smaller laboratories.

3.2 Quality Management Systems

3.2.1 All policies, processes and procedures shall be documented and communicated to all relevant personnel. Management shall ensure they are understood and implemented.

3.2.2 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.

3.2.3 Each laboratory shall have a quality manual which describes all its systems and make references to all relevant procedures such as technical procedures.

3.2.4 The Quality manual should be kept up to date by the management or designated person.

All personnel shall use and apply the procedures in the quality manual. The Quality Manual consists of:-

- **a)** Introduction
- **b)** Quality policy stating its commitment to follow good professional and laboratory practices and standards
- **c)** Scope of services
- **d)** Staff education, training and their scope of practice.
- **e)** Quality control and Quality assurance
- **f)** Records and maintenance and archiving
- **g)** Accommodation and environment conditions and aspects
- **h)** Instrument, reagents and/ or relevant consumables management.
- **i)** Safety
- **j)** List of examination procedures
- **k)** Request protocols, primary sample collection and handling of laboratory samples.
- **l)** Testing and technical procedures
- **m)** Validation of results
- **n)** Reporting of results
- **o)** Corrective/Preventive actions and handling of complaints
- **p)** Internal monitoring system and/or internal and external auditaudit.

3.2.5 Laboratory management shall establish and implement a programme to calibrate and ensure proper functioning of all equipment. These shall be monitored and documented to prove proper functioning.

3.2.6 Laboratory management shall establish procedures and criteria for inspection, acceptance, rejection and storage of materials to ensure quality of reagents supplies and services.

3.2.7 An inventory control system for supplies shall be in place.

This system should include but is not limited to recording of the lot numbers of all relevant reagents, controls and calibrators, date of receipt, date of the material placed in service.

3.2.8 Specialized and Referral Laboratories or its designee shall evaluate supplies of critical reagents, supplies and services that affect the quality of examinations and document it and have an approved list.

3.3 Document control:

Laboratory shall have a document control system to ensure

a) All the documents issued to laboratory personnel are current, valid and authorized.

b) The documents are reviewed periodically at a minimum of once in 2 years.

c) Retained and obsolete documents are archived and appropriately identified to prevent improper and/or accidental use.

d) All the relevant documents must be uniquely identified and authorized prior to use.

3.4 Examination by referral laboratories

3.4.1. The laboratory shall have an effective documented system to select referral laboratories. Laboratory management shall be responsible for selecting and monitoring quality of the referral laboratories and consultants and ensure that the referral laboratories or referral consultant's relevance and competency.

3.4.2. Records of all referral samples and laboratories shall be maintained by the referee.

3.4.3. The referring laboratories and not the referral laboratory are responsible to provide the results to the requesting clinician and/or patient.

3.4.4. The report of the referral laboratory should not be copied or reproduced by the referring laboratory. However additional comments may be given. In such a case the author of such added comments or remarks must be clearly identified.

3.4.5. Laboratories shall participate successfully in an International External Quality Assurance Scheme or national External Quality Assurance Programme to qualify as a referral laboratory.

3.5 Resolution of complaints.

3.5.1 The laboratory shall have a documented procedure for resolving complaints and get feedback from clinicians, patients and other parties.

3.5.2 Complaints must be systematically investigated and corrective actions taken and documented.

Records shall be maintained for 1 year. Vertical audit may be used to investigate complaints.

3.5.3 No one should audit their own work.

3.6 Identification and control of non conformance.

3.6.1 Laboratories shall have a policy and procedure to handle non conformance.

These shall ensure that

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 recorded and records maintained for minimum 3 years

3.6.2 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.

3.6.3 Preventive action

a) Improvements needed and potential sources of non conformance both technical and other issues shall be identified.

b) If required preventive action should be implemented with appropriate monitoring to minimize recurrence of non conformances.

c) Procedures for prevention shall include but not limited to:

i. Review of the operational procedures
ii. Analysis of data including risk and trend analysis
iii. Application of controls to ensure effectiveness
iv. External quality assurance.

d) Preventive action should be a pro-active process for identifying opportunities for improvement rather than a reaction to complaints.

3.6.4 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 should 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

3.7 Quality and technical records.

a) All the records shall be legible and stored in such a way that they are easily retrievable. Patient information and results should be kept for a minimum of 5years.

b) Laboratories shall have suitable storage to prevent damage loss and unauthorized access.

These records shall include but is not limited to;

i. Request forms – minimum retention time: 1 year
ii. Examination results or reports - minimum retention time: 5 years
iii. Examination procedures – Permanent records
iv. Laboratory work books or sheets - minimum retention time: 1 year
v. Quality control records - minimum retention time: 1 year
vi. Complain and action taken - minimum retention time: 3 year
vii. Records of internal and external audits – 5years
viii. External quality assessment and inter laboratory comparisons records.- minimum retention time: 5 years
ix. Quality improvement records - minimum retention time: 5 years
x. Instrument maintenance records, including internal and external calibration records. – Permanent record
xi. Lot documentation, certificates of supplies, package inserts - minimum retention time: 1 year
xii. Incident/ accident records and action taken- minimum retention time: 5 years
xiii. Staff training and competency records. – Permanent record.

3.8 Internal audits

a) Audits should be conducted regularly by a trained person, at predetermined intervals which shall be at least twice a year.

b) Audit of all elements of the system both managerial and technical shall be conducted with emphasis on areas that are critically important to patient care.

c) The procedure for internal audit must be defined and documented.

d) When deficiencies are identified, appropriate corrective and preventive actions shall be taken, within an agreed upon time.

e) Results of the audit must be reviewed by the management. Audit is not complete until corrective and/ or preventive action to rectify the nonconformance is implemented.

3.9 Management review

Laboratory management shall review the quality system and all of its services at least once a year, to ensure effectiveness and introduce any necessary changes for improvement.

4.0 Technical requirements

4.1 Personnel

4.1.1 The laboratory in charge or designee (authorized signatory) shall demonstrate knowledge and competency in the concerned specialty.

4.1.2 Qualification norms for technical staff

i. B. Sc or higher qualification in Medical Laboratory Technology or equivalent.
ii. Diploma in MLT with the course of at least two years duration.
iii. Graduate in science with 2 year Medical Lab technology
iv. Laboratory Technologists and Laboratory specialists may perform phlebotomy only if they are trained in phlebotomy.
v. All levels of laboratory technologists to be registered in relevant boards and councils of Ministry of health
vi. Staff designated to collect blood shall be trained sufficiently.

An internal or external phlebotomist training programme could be followed.

The programme should include but is not limited to:

- Laboratory Registration Procedure and information of all investigations done in the laboratory.
- Patient preparation, instructions for patient and phlebotomist
- Procedures for informed consent if applicable.
- Sample labeling and collection system.
- Sample collection containers, types of anticoagulants and it's effects
- Primary samples required and quantity required.
- Sample acceptance/rejection criteria.
- Handling, storage and transport of specimens including precautions and special handling for relevant examinations.
- Quality control and pre analytical errors.
- Phlebotomy procedure.
- Management of adverse reactions
- Aseptic technique, infection control practices and universal precautions.
- Personal Protective Equipment and its proper use.
- Waste disposal policy and techniques

- Sufficient practice to ensure competency
- Knowledge and competency must be assessed and documented by a competent supervisory staff before designating as a phlebotomist.

4.1.3 The laboratory shall have a system for technical persons to receive adequate training and practice to acquire and maintain sufficient skills to perform the designated work.

4.1.4 Technical staff must be adequately trained in the operation of new analytical equipment and performance of new tests before designating to such work.

4.1.3 Laboratory assistants must be adequately trained before designating work. They should work under supervision of trained laboratory personnel. Number of laboratory assistants should not exceed the number of technical staff.

4.1.4 Relevant documentation of all Laboratory personnel should be maintained.
They shall include but is not limited to:-

a) Personal Identification.
b) Educational Qualifications and Work experience.
c) Registration and practicing license if applicable.
d) Certificates and registration in home country – expatriates.
e) Job descriptions.
f) Records of continuing education
g) Competency evaluation.
h) Untoward and accident reports

4.1.5 Registration body shall be notified of all technical persons leaving the job with reasons.

4.1.6 Registration body shall be informed in writing, of any Professional misconduct and/or failure to follow the code of conduct by any of their registrants.

4.2 Accommodation and environmental conditions

4.2.1 The laboratory space should be sufficient to handle the work load performed without compromising quality of work, quality control procedures, safety of personnel and patient care services.

4.2.2 Laboratories operating outside a health facility or providing outpatient services must have adequate waiting and sample collection area and patient services.

4.2.3 When primary sample collection facilities are provided, patient privacy and comfort should be addressed for optimization of collection conditions.

4.2.4 The laboratory shall have adequate lighting, power points and uninterrupted power supply.

4.2.5 The laboratory shall control and monitor environmental condition as required or when the quality of results may be affected.

4.2.6 There shall be proper separation of laboratory sections when there are incompatible activities.

4.2.7 Laboratory shall be well maintained and kept clean. Staff must be trained to ensure good housekeeping.

4.2.8 Access to laboratory areas must be controlled especially if quality of results can be affected.

4.2.9 The laboratory shall have procedures in place to ensure the integrity of refrigerated and or frozen stored samples, reagents etc. in the event of power failure.
(See Annex 2 for further details)

4.3 Laboratory equipment

(Laboratory equipment in this standard means all laboratory instruments, reference materials, consumables, reagents and analytical system)

4.3.1 The laboratory shall have all equipment required to provide specified services.

4.3.2 The equipment shall be shown to be able to perform as required and shall comply with the specifications relevant to the examinations required.

4.3.3 All equipment shall be properly calibrated, monitored and functioning well and all relevant documentation shall be maintained.

(See Annex 3 for calibration requirement)

4.3.4 Laboratory shall have a proper preventive maintenance program which at a minimum shall meet the manufacture's recommendation and records maintained.

4.3.5 Each equipment shall be uniquely identified and labeled and records maintained.

The records shall include but not limited to the following:-

a) Identity of equipment.

b) Manufacturer's name, type and serial no.

c) Date of receipt and putting in service

d) Condition when received (new /used, etc)

e) Damage / malfunction and repairs.

f) Maintenance and future plans.

4.3.6 Equipment shall be operated by authorized personnel and instructions for use shall be readily available to staff.

4.3.7 When equipment is found to be defective its services should be stopped, repaired and proper functioning verified before use.

4.3.8 Equipment shall be reasonably disinfected prior to servicing and/or repair.

4.3.9 The engineers shall be informed about disinfection measures and appropriate Personal Protective Equipment shall be provided.

4.3.10 All the consumables, reagents, stain kits and antimicrobials shall be stored as recommended by the manufacturer and used within the expiry dates.

The labels should bear the following information.

a) Content and quality
b) Concentration or titre.
c) Date of opening
d) Storage requirement
e) Expiry date when applicable.

4.3.11 The laboratory shall use adequate controls for laboratory equipment to check performance. The laboratory instruments should be calibrated and maintenance done according to manufacturer's instructions or whenever needed.
(See Annex 4 for further details)

4.4 Pre Examination Procedures.

4.4.1 The Request form shall contain sufficient information to identify the patient, authorized requester and provide relevant clinical details of the patient.

4.4.2 The request form shall include but is not limited to the following:

a) Unique identification of the patient.
b) Identification and contact details of the physician or authorized requester.
c) Examinations requested.
d) Relevant clinical information.
e) Date and time of primary sample collection.
f) Date and time of sample receipt in the laboratory if applicable.

4.4.3 Instructions for sample collection and handling of primary samples must be documented as a primary sample collection manual, and shall be readily available to all relevant personnel.

4.4.4 The primary sample collection manual shall contain the following:

a) Copies or reference to:
1. All laboratory investigations offered
2. Consent forms if applicable
3. Patient preparation information for patients before primary sample collection.

b) Procedures for:

1. Preparation of patient. (Instruction to patient and phlebotomists)
2. Identification of primary sample
3. Primary sample collection – Phlebotomy, with descriptions of the primary sample containers and additives.

c) Instructions for:

1. Request form completion details.
2. Type and amount and labeling of primary sample to be collected for specific investigations.
3. Special handling from time of collection to time of receipt in the laboratory. (Transport requirements, refrigeration, immediate delivery, etc)
4. Recording the identity of the person collecting the sample
5. Safe disposal of material used in the collection process

d) Instructions for:

1. Storage of examined samples
2. Time limits for requesting additional tests.
3. Repeat examinations due to analytical failure or repeat examination of the same primary sample.

4.4.5 Primary samples lacking proper identification shall not be processed.

4.4.6 Where there is doubt or instability of analytes, and if the sample is irreplaceable or difficult, the person collecting the primary sample shall take the responsibility for sample identification and accepting the sample. Signature of that person shall be recorded on the request form.

4.4.7 The Laboratory shall monitor the sample transportation including time interval, preservative and safety of carrier.

4.4.8 Samples transported to other referral laboratories shall be packed and transported as per current IATA guidelines for diagnostic and infectious samples and other local applicable rules.

4.4.9 All samples received in the laboratory shall be recorded in an accession book or computer or other suitable means and the identity of the receiving person shall be recorded.

4.4.10 Criteria for specimen acceptance and rejection shall be developed and documented.

4.4.11 If primary sample acceptance criteria have been compromised, final report shall indicate the nature of the problem and caution in interpretation if applicable.

4.4.12 Samples shall be stored for a specified time, under suitable conditions to ensure stability to enable repeat examinations if required.

4.5 Examination Procedures.

4.5.1 The laboratory shall use standard examination procedures that are validated and published in established books and journals.

4.5.2 All procedures shall be documented and be available to relevant staff and must be understood by staff.

4.5.3 Package inserts of test kits may be used provided they are exactly same as the procedure done in the laboratory and is written in a language commonly understood by staff.

If package inserts are used, any deviations must be documented. Additional information if required for the purpose of testing must be documented.

Documentation should include when applicable

a) Purpose of examination
b) Principle and the actual procedure used for the examination
c) Performance specifications (Linearity, precision, accuracy, detection limit, sensitivity and specificity.)
d) Primary sample type required.
e) Type of container and or additive.
f) Equipment and reagents required
g) Calibration procedures
h) Procedural steps
i) Quality control procedures
j) Interferences (eg: lipaemia, haemolysis etc)
k) Procedure for calculating results

l) Biological reference values (Normal values)

m) Reportable interval of patient examination results

n) Alert/critical values where applicable.

o) Safety precautions

p) Potential sources of variability.

Electronic manuals are acceptable provided the above information are included and access controlled. The laboratory management shall be responsible to ensure that the examination procedures are current.

4.6. Assuring quality

4.6.1 The laboratory shall have a good internal quality control system that ensures the results generated are of expected quality.

4.6.2 The system shall provide simple and clear instructions and information so that proper technical and medical decisions are made.

4.6.3 The system shall pay special attention to avoid errors in the process of specimen handling examinations and reporting.

4.6.4 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.

4.6.5 If EQAS program is not available the laboratory could develop a mechanism to determining the quality of the procedures. Laboratories could use external control material and/or exchange of samples between laboratories. Laboratory management shall monitor the results and implement corrective actions if applicable.

4.7 Post examination procedures.

4.7.1 An authorized person or designee shall check the results of examination and authorize the release of the results.

4.7.2 Primary samples and other laboratory samples shall be stored in accordance with the policy of the laboratory.

4.7.3 Safe disposal of samples that are not required for examination shall be carried out in accordance with the waste disposal procedures.

4.8 Reporting results

4.8.1 The laboratory management shall be responsible for the formatting of reports.

4.8.2 Laboratory management shall have a mechanism to ensure that the reports are received by the appropriate individuals within the agreed time.

4.8.3 Results shall be legible and reported to appropriate person(s). Confidentiality issues must be considered.

4.8.4 The report shall include the following but is not limited to:

a) Clear identification of the examination where appropriate.
b) The identification of the laboratory that issued the report.
c) Unique identification and location of the patient and if applicable destination of the report
d) Name of the requester if applicable address.
e) Date and time of the report issue
f) Source and system or primary sample type.
g) Results of the examination reported in SI units or units traceable to SI units
h) Biological reference intervals where applicable.
i) Interpretation of results where appropriate.
j) Other comments: quality and adequacy of sample if applicable.
k) Identification and or signature of the person authorizing the release of the report

4.8.5 Copies of reports or reported results shall be retained in the laboratory in a way to ensure easy retrieval. They should be stored as long as medically relevant or minimum of 5 years whichever is more.

4.8.6 The laboratory shall immediately notify the physician or other clinical personnel responsible for patient care when examination results fall into alert or critical range.

4.8.7 Laboratory shall determine (preferably in consultation with the clinicians) turnaround time for the examinations.

4.8.8 Laboratory shall have a policy and procedures to ensure results given by telephone or electronic means reach only authorized receivers. Confidentiality issues must be considered.

4.8.9 The laboratory shall have a procedure to issue reports after alteration has been made. If altered the record must show the time, date and name of person responsible for the change. Original entries shall remain legible when alterations are made.

4.8.10 Results that have been altered after issue, especially if the reports have been made available for clinical decision making should be marked as revised and the clinician should be informed.

5. Waste Management

5.1. The clinical laboratory is responsible for proper management of the waste that it generates.

5.2. It is the responsibility of the laboratory manager to understand and comply with all relevant regulations.

5.3. The laboratory shall reduce the amount of wastes to be incinerated by proper segregation, collection, treatment and disposal.

5.4. Clinical waste should be segregated from municipal solid waste or other waste streams at the point of arising. A sufficient number of appropriate containers for holding clinical

waste should be placed adjacent to the locations where clinical waste is generated so as to facilitate the segregation.

Laboratory waste should be segregated as the following categories:

i. Non-contaminated (non-infectious) waste that can be reused or recycled or disposed of as general, "household" waste.
ii. Contaminated (infectious) "sharps" – hypodermic needles, scalpels, knives and broken glass; these should always be collected in puncture-proof containers fitted with covers and treated as infectious.
iii. Contaminated material for decontamination by autoclaving and thereafter washing and reuse or recycling.
iv. Contaminated material for autoclaving and disposal.
v. Contaminated material for direct incineration.

5.5. Clinical waste should be put into appropriate containers as quickly as possible so as to avoid contaminating other materials and to minimize potential human exposure. Containers for holding clinical waste should be covered by secure lids. Every container of infectious waste must bear a biohazard label as specified in *Annex 5*.

5.6. Infectious waste shall not be disposed of at the waste management site until they have been **EFFECTIVELY TREATED**, that is rendered, biologically harmless in accordance with acceptable treatment practices as described in the current standards, and methods.

5.7. For the easy identification of appropriate discard bins, the bins should be color coded according to the pattern in *Annex 6*. The bins should be painted with appropriate colors, if colored bins are not available. All bins should be labeled by its category in English. Preferably the labels should be painted.

5.8. Appropriate trolleys and carts should be used for the transfer of clinical waste on the premises.

5.9. The management should ensure that all staff involved in handling clinical waste are provided with adequate safety information, protective equipment and training.

5.10. Procedures should be established for handling emergencies involving spillage or leakage of clinical waste and make available the procedures to their staff for reference.

5.11. All materials arising from the clean-up of spilled or leaked clinical waste should be disposed of as clinical waste and should be properly packaged and labeled before disposal.

5.12. All spillage or leakage incidents should be recorded and reported to the responsible person according to the established procedures. Follow-up investigations of the incidents should be conducted so that improvement measures can be taken to avoid recurrence of similar incidents in future.

5.13. Medical wastes generated as a result of providing home care for old age and people with special needs should not be discarded into the household garbage. These wastes should be sealed in leak proof plastic containers and transported to the medical waste treatment service to be effectively treated.

5.14. The management should compile a Clinical Waste Management Plan for reference by their staff.

6. Biosafety

A biosafety programme shall be established and implemented, with regular monitoring and review, to ensure a safe work environment and safe work practices in the laboratory, which should include but not be limited to:

6.1. Training of laboratory staff.

a) All staff shall be trained to encourage correct attitudes and understand safe working practices which include personal hygiene, appropriate use of personal protective equipment (PPE) with good microbiological techniques, safe use of equipment, recognition of hazards, risks and consequences before commencement of practical laboratory work.

b) Continuing education and training should be conducted to maintain staff awareness of the safety implication of changing technology and improvements in safety.

c) Staff's experience and competence of working safely shall be formally assessed and documented.

6.2. Promotion of appropriate biosafety measures which include but is not limited to appropriate facility design, availability and appropriate use of PPE and safety equipment and safe work practices.

6.3. A biosafety manual should be developed, adopted and regularly reviewed. It should identify known and potential hazards and specify practices and appropriate procedures to eliminate or minimize such hazards. The manual shall document the following aspects:

a) Organization of safety management
b) Laboratory access and working areas
c) Safety precautions in microbiological work
d) Decontamination/ disinfection procedures
e) Laboratory waste disposal procedures
f) Management of accidents and incidents
g) Monitoring of staff health including immunization and medical surveillance
h) Transport of biological materials

Regular safety monitoring and review with reference to the safety manual shall be conducted, with documentation of findings and any necessary improvement actions.

6.4. Monitoring of safety systems

The overall safety status of the laboratory should be reviewed regularly to ensure compliance with safety requirements and safety inspections shall be conducted regularly to ensure laboratory safety is maintained.

6.5. Safety records should be maintained which includes training, inventory and maintenance of safety equipment , updated inventory of specimens and isolates in storage , accidents and incidents , staff health including immunization and sickness , safety inspections and improvement actions

Annex

Annex: 1 biosafety levels

Laboratory facilities are designated as basic – Biosafety Level 1, basic – Biosafety Level 2, containment – Biosafety Level 3, and maximum containment – Biosafety Level 4.

Biosafety level designations are based in consideration of the following: the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various **risk groups**.

The **risk groups** for laboratory work are classified based on the hazards posed by the infective microorganisms. The risk groups and biosafety levels are based on the classification as described in the World Health Organization (WHO) Laboratory Biosafety Manual:

Risk Group 1 (no or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.
Risk Group 2 (moderate individual risk, low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3 (high individual risk, low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available
Risk Group 4 (high individual and community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available

Table 1. Classification of infective microorganisms by risk group

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

Table 2. Relation of risk groups to biosafety levels, practices and equipment

Note:

- Table 2 relates but **does not "equate"** risk groups to the biosafety level of laboratories designed to work with organisms in each risk group.

- Diagnostic and health-care laboratories (public health, clinical or hospital-based) must all be designed for Biosafety Level 2 or above.

Annex 2: Clinical Laboratory 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 are 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. 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.

3. 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.

4. 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.

5. 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.

6. 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.

Annex 3 Calibration Requirement

Item	Maximum period between checks and calibration	Procedures
Autoclaves	One year	Check effectiveness of sterilization with each cycle and with spores at least once a year
Balances and scales	One year	Balances within built calibration check facilities must also have six monthly checks. Electronic balances with more than one range must have six monthly checks carried out of ranges. Checks include repeated checks and one point check using a calibrated weights, close to balance capacity
Biological Safety cabinet	One year	Colony count at least once in a week
Centrifuge	Every six months (where operating speed is specified)	Tachometer (mechanical stroboscope or light cell type) calibration of the timing device and where appropriate. The temperature measurement device will be required. In addition performance testing is recommended for specific applications.
Piston – operated volumetric apparatus pipettes and dispensers	Initial and every six months	Gravimetric checks, volumetric delivery and weighing under specified conditions must be repeated at least ten times. For adjustable devices check volume delivered at several settings. Delivery of volumes less than 100 microlitres may be verified by spectrometry using a dye solution.
Thermometers	One year	Check against a calibrated reference Initial check at sufficient points to cover the expected working range followed by six monthly checks at icepoint within the working range.

Annex 4: Controls, calibration and maintenance of laboratory equipment

a) Reagents.

i. Each lot of reagents shall be checked against earlier in use reagents, lots or with suitable references materials before being placed in service and documentation maintained.

b) ABST Discs.

i. Each batch of ABST discs shall be checked for activity and/or potency, before being put in service and at least weekly thereafter with reference strains

c) Anaerobic jars and autoclaves.

i. Anaerobic jars, autoclaves and hot air ovens shall be checked by chemical and or biological controls.

d) Automated Analytical Systems

i. Automated analyzers: the frequency of calibration at a minimum shall be done as per manufacturer's guidelines

ii. Cell counters, biochemistry analyzers, automated coagulometers, Elisa readers etc. shall be calibrated at least once a year.

iii. Automated hematology analyzers shall be calibrated using calibrator provided by manufacturer or a suitable calibrator. Controls shall not be used for calibration.

e) pH meter

i. Calibrate with at least two standard buffer solutions appropriate to the expected pH of the sample being tested. Record of the calibration must be kept.

f) Spectrophotometer and colorimeters

i. Calibration checks shall be performed at least once in every six months.

ii. This calibration shall include checks on absorbance, linearity, matching of cells and shall be carried out following manufacturer's instructions and/or using appropriate standard reference material or calibrators. Minimum calibration check requires a blank and at least two points on the calibration curve.

iii. Records shall be maintained and the calibrations shall be compared over time to detect any system deterioration.

g) Microscopes

i. Regular cleaning and maintenance of the microscope shall be done following manufacturer's instructions.

ii. Competent persons shall do Servicing and maintenance at regular intervals.

h) Temperature controlled equipment (water baths, incubators, ovens and refrigerators)

i. Performance of temperature-controlled equipment shall be monitored regularly to ensure compliance with the temperature requirements of the test methods.

ii. Daily recorded checks of the temperature within the load space of the equipment shall be maintained.

iii. Use of temperature control monitors are recommended when temperature control is critical. (E.g. Blood bank refrigerators)

iv. The thermometers used to check temperature of the temperature controlled equipment shall be of sufficient accuracy.

v. Temperature recording devices shall be checked against a reference thermometer at least once a year.

i) Stains

i. Stains and reagents must be labeled, dated and stored properly

ii. Shall not be used beyond the expiry date if they show signs of deterioration such as abnormal turbidity and discolouration.

iii. Control smears shall be done at regular intervals and when ever new stain is being used.

Appropriate controls should be used for all stains as per the following table:

Stain	Control organism / material	Expected result
Zeihl-Neelson	Mycobacterium sp. Escherichia coli	Pink red bacilli Blue bacilli
Modified Zeihl-Neelson	Cryptosporidia in stool	Pink -red
Acridine Orange	Escherichia coli Staphylococcus aureus	Fluorescent bacilli/ cocci
Romanowsky stain	Thin film blood smear	Distinct staining of WBCs and RBCs

Stain	Control organism/ material	Expected result
Gram	Escherichia coli Staphylococcus aureus	Gram negative bacilli Gram positive cocci
Iodine solution	Formalin treated stool specimen with cyst	Visible cyst nuclei
India ink preparation	Cryptococcus neoformans Candida albicans	Encapsulated Non-encapsulated
Haematoxylin and Eosin	Nuclei Acidophilic cytoplasm Basophilic cytoplasm Erythrocytes Collagen Muscle	Blue Red Purple Cherry red Pale pink Deep pink
Papanicolaou	Nuclei Keratin Glycogen Superficial cells Iintermediate and parabasal cells Metaplastic cells	Crisp blue to black Yellow Yellow Orange to pink Turquoise green to blue Green and pink

j) Media

i. Laboratory shall ensure that all media prepared in house are sterile, able to support growth and are appropriately reactive biochemically. Commercial media: growth/sterility record need to be maintained of batches examined results and performance for traceability or erratic results.

ii. Appropriate reference organisms shall be used to test the media's ability to support growth. QC results must be documented**.**

Annex 5: Labeling of Clinical Waste Containers

Each container must bear on the outside of the container a biohazard label.

DIMENSIONS OF LABEL	
Type of container	**Dimensions of label**
Sharps container of a capacity of less than 2 Litres	not less than 40 mm x 40 mm
Sharps container of a capacity of 2 Litres or more	not less than 75 mm x 75 mm
Container other than sharps container	not less than 150 mm x 150 mm

Annex 6: Color coding of clinical waste

CATEGORY	COLOUR CODE	LINER COLOR
GENERAL WASTE	BLACK BIN	BLACK
PLASTIC WASTE	BLUE BIN	BLUE
INFECTIOUS WASTE	RED BIN	ORANGE OR YELLOW
SHARPS	YELLOW DRUM	

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