ETHIOPIAN STANDARD

ES 3609:2012

First edition

Advanced Medical Laboratory - Requirements

ICS:

Descriptors:

Price based on pages

Reference number:

DES:

Tables of Contents

ACKNOWLEDGEMENT

Ethiopian Standard Agency, ESA would like to extend its special thanks to members of the technical working group organized by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority of Ethiopia, EFMHACA in developing the draft health facility standards.The members of the TWG were Dr. Getahun Mengistu, Dr.Kidane Melles, Ato Yohannes Jorge, Dr Adefris Debalke, Dr. Wondwossen Fantaye, Dr Faris Hussein, Dr Petros Mitiku, Dr David A.conteh, Dr Ruth Lawson, Dr Birna Abdosh, Ato Liyusew Solomon, Ato Edmealem Ejigu, Dr Solomon Tessema, Dr Endale Tefera, Ato Yihalem Tamiru, Dr Abyou Kiflie, Ato K/mariam G/Michael, Sr Yeshialem Bekele, Ato Wondie Alemu, W/t Raey Yohannes, Ato Ayalew Adinew, Dr Zegeye Hailemariam, Dr. Tassew Tadesse, Dr Alem Michael, Dr. Aynalem Abraha, Dr. Mehrtu W/yes, Ato Zelalem mesele, Ato Salehunae, Dr Daniel Admassie and Dr Tekle-ab Zaid.

In addition, the Agency would also thank all the workshop participants from the Ministry of Health, Health Professional Associations, Universities, public and private hospitals, private clinics, non-governmental organizations and other governmental organizations for their commitment to enrich the draft document.

We are grateful to the USAID/PHSP-Ethiopia, MSH/SPS, Clinton Foundation and Tulane University without whose support it would have been difficult to achieve the desired result.

The Agency would also like to express its appreciation to FMHACA for the commitment, effective coordination and overall leadership shown in the development of this standard.

FOREWORD

This Ethiopia Standard has been prepared under the direction of the Technical Committee for Medical Care Practices (TC90) and published by the Ethiopian Standards Agency (ESA).

The draft document (Working Draft, WD) has been submitted to the Secretariat by the Ethiopian Food, Medicine & Healthcare Administration and Control Authority (FMHACA).

Advanced medical laboratory shall provide services in accordance with this standard and shall comply with the requirements. The standard shall enter into force starting from the day of approval as Ethiopian Standard. This standard is approved by the convention of …….. made on…..Application of this standard is MANDATORY with the intention to ensure the quality and public safety of health services through standardized licensure and inspection procedures, to promote access to quality health services and encourage health investment.

The Ethiopian Standard Agency recommends fulfilling all the requirements stipulated under this document. It has to be noted that the fruition of fulfilling these requirements will ensure the quality and safety of public health services through availing appropriate infrastructure, deployment and retention of qualified and competent health professionals that deliver best practices and by generating innovative ideas and methodologies to solve healthcare problems.

Finally, acknowledgement is made to the EFMHACA, Technical Working Group, participants of national workshop and EFMHACA collaborators for their commitment and unreserved contribution to the effort of developing Ethiopian Standards for Health Facilities.

Ato……W/O……Director General, Ethiopian Standard Agency

SECTION ONE: GENERAL

1. Scope

1.1. This Ethiopian standard shall be applicable for all advanced medical laboratory new and existing, governmental and non-governmental.

1.2. The standard covers the minimum requirements with respect to practices, premises, professionals and products or materials put into use for advanced medical laboratorys.

1.3. Requirements of a advanced medical laboratory are stipulated under section two to nine of this standard.

2. Normative References

The latest editions of the following laws, regulations, directives and guidelines shall be taken as part and parcel of this Ethiopian Standard.

2.1. Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No. 661/2009

2.2. Ethiopian Food, Medicine and Healthcare Administration and Control Regulation No. 189/2010

2.3. Health Policy of Ethiopia

2.4. Drug Policy of Ethiopia

2.5. Commercial Code of Ethiopia

2.6. Criminal Code of Ethiopia

2.7. Medicines Waste Management and Disposal Directive No 2/2011

2.8. Ethiopian National Guideline for Health Waste Management, 2008

2.9. Ethiopian Building Proclamation, No. 624/2009

3. Terminologies and Definitions

3.1
Appropriate Organ

Shall mean a state government organ authorized to implement food, medicine and healthcare administration and control activities at a state level;

3.2

Authority

Shall mean the Ethiopian Food, Medicine and Healthcare Administration and Control Authority.

3.3

Proclamation

Shall mean the Ethiopian Food, Medicine and Healthcare Administration and Control proclamation No 661/2009.

3.4

Appropriate Law

Shall mean a law issued by a state to implement regulatory activities regarding food, medicine and healthcare.

3.5

Person

Shall mean any physical or juridical person

3.6

Authorized Person

Shall mean any advanced medical laboratory staff who is responsible for a given service

3.7

Advanced Medical Laboratory

Shall mean a medical laboratory facility which provides all rang of comprehensive, specialized, and high caliber medical Laboratory diagnosic services.

.

SECTION TWO: LICENSURE

2.1. General

2.1.1 This standard provides minimum requirements for the establishment and maintenance of advanced medical laboratory in order to protect the public interest by promoting the health, welfare, and safety of individuals**.**

2.1.2 No advanced medical laboratory shall be built or be functional by any person without prior permission of the appropriate organ.

2.1.3 The requirements set by this standard may not be waived unless otherwise for public interest and there is a substantial need for waiver. There shall be an assurance that the waiver will not create a hazard to the health and well- being of patients or others than the public interest.

2.1.4 All health professionals shall respect & abide with the code of professional practice of their respective profession.

2.1.5 Any information or complaint regarding this standard may be presented to the Authority or any appropriate organ.

2.1.6 In the absence of the licensee or his /her equivalent the laboratory shall not deliver those services stated by the license.

2.2. Application for Licensure

2.2.1. No person shall operate a Advanced medical laboratory in Ethiopia, whether governmental, nongovernmental or private, without being licensed as required by appropriate law and thsi standard.

2.2.2. Any person desiring to operate a medical laboratory shall:

(a) Apply to the authority or appropriate organ for a new license on forms prescribed by the authority or appropriate organ as per article 2.2.6;

(b) Pay the prescribed license fee; and

(c) Provide additional information or document upon written request by the appropriate organ.

2.2.3. A person desiring to operate a medical laboratory shall consult the authority or appropriate organ on the plant design conformity with thsi standard before starting construction or renovation work.

2.2.4. An application for the initial licensure of medical laboratory shall be submitted to the authority or appropriate organ no later than ninety (90) days prior to the stated date of operation. The license fee shall accompany the application.

2.2.5. The first pre-licensing inspection shall be conducted by the authority or appropriate organ upon application without service fee. In case of failure to comply with thsi standard during the first pre-licensing inspection, the applicant has the right to reapply not more than two times upon paying service fee. If the applicant fails to comply with thsi standard for the third time, its application for licensure shall be suspended for three months.

2.2.6. The application for a medical laboratory license shall state each service for which the applicant undertakes to furnish medical laboratory services and other information as may be required by the authority or appropriate organ including.

(a) Location and address of the Medicla laboratory,

(b) Name and address of the applicant (if the applicant is an authorized delegate, written delegation letter shall be submitted)

(c) Previous owner, license number for existing medical laboratory;

(d) Name, qualification and address of the licensee;

(e) Type and level of Medical Laboratory

(f) Number, types, work experience and original releases of all technical staff;

(g) Number of administrative staff

(h) Physical plant/ medical laboratory design and its description;

(i) Surrounding environment;

(j) Proposed use of idle space;

(k) Manager/ CEO of the medical laboratory;

(l) Chain organization (organization structure);

(m) Owner of the building;

(n) Professional license and registration certificate of the licensee and all other health professionals responsible for each service in the laboratory;

(o) Any other requirements set by the authority or appropriate organ.

2.2.7. An application for a license or change in service shall be denied if the applicant cannot demonstrate that the premises, products, personnel and medical laboratory services are fit and adequate in accordance with thsi standard.

2.2.8. The authority or appropriate organ shall consider an applicant's prior history in operating a medical laboeratory facility either in Ethiopia or in other countries in making licensure decision. Any evidence of licensure violations representing serious risk of harm to clients or environment shall be considered by the authority or appropriate organ, as well as any record of criminal convictions representing a risk of harm to the safety or welfare of patients or environment.

2.3. Initial / New Licensure

2.3.1. Every Advanced medical laboratory shall have a separate license. The authority or appropriate organ shall issue each license in the name of the owner and licensee only for the premises and person named as applicant in the application and the license shall not be valid for use by any other person or at any place other than the designated in the license.

2.3.2. The medical laboratory license shall specify the following:

(a) Name and address of the medical laboratory;

(b) The name and professional license and registration number of the licensee;

(c) Ownership of the medical laboratory;

(d) Name of the owner;

(e) License number, issuance and expiration dates of the license;

(f) Signature and official seal of the authority or the appropriate organ and

(g) Footnotes of Notices or reminders prepared by the appropriate organ.

2.3.3. Prior to initial licensure of the medical laboratory, the authority or appropriate organ shall conduct an on-site inspection to determine compliance with the applicable laws and standards governing the medical laboratory.

2.3.4. The authority or appropriate organ shall send a written report of the findings to the medical laboratory after the conclusion of the inspection.

2.3.5. A medical laboratory with deficiencies shall correct them and submit written proof of correction of deficiencies.

2.3.6. The authority appropriate organ shall conduct a follow-up inspection to determine correction of deficiencies cited within ten (10) days following the one hundred and eighty (180) day correction period or upon notification from the medical laboratory that the deficiencies have been corrected.

2.3.7. The authority or appropriate organ shall deny the application for licensure to a Advanced medical laboratory that has not corrected deficiencies. The applicant shall reapply for licensure when deficiencies are corrected.

2.3.8. The authority or appropriate organ shall conduct on-site inspection of the medical laboratory to assess it's continued compliance with the laws and standards governing the medical laboratory.

2.3.9. The authority or appropriate organ shall issue a replacement license where the originally issued license has been lost or destroyed upon an application supported by affidavit.

2.3.10. The original license shall be posted in a conspicuous place at reception at all times.

2.4. License Renewal Requirements

2.4.1. A license, unless suspended or revoked or under consideration in pending case, shall be renewable annually and the medical laboratory shall submit an application for license renewal to the authority or appropriate organ no later than sixty (60) days before the expiration date of the current license.

2.4.2. Without prejudice to article 2.4.1;

(a) Subsequent to submitting renewal application, the owner shall pay the prescribed license fee

(b) License renewal shall be made during the first quarter of each fiscal year (Hamle 1 to Nehassie 30) based on routine inspection findings over the year

(c) In case of failure to renew license within the prescribed period, license may be renewed upon paying penalty (50% of renewal fee) within one month

(d) In case of failure to renew license as per article 2.4.2 (c), license shall be considered as cancelled

2.4.3. Every applicant who needs to renew a license shall:

(a) Apply to the authority or appropriate organ in the prescribed form;

(b) Pay the prescribed license renewal fee; and

(c) Provide additional information or document upon written request by the appropriate organ.

2.4.4. The authority or appropriate organ may conduct background checks on the applicant or licensee to determine its suitability or capability to operate or to continue operating a health care facility. Background checks shall consist of, but not be limited to, the following:

(a) Verification of licensure status;

(b) Verification of educational credentials;

(c) Verification of residency status;

(d) Verification of solvency; and

(e) Contacts with federal and states officials to determine outstanding warrants, complaints, criminal convictions, and records of malpractice actions.

2.4.5. The authority or appropriate organ shall renew a license for a medical laboratory in substantial compliance with the applicable laws and thsi standard.

2.5. Removal Permits, Change of Operation and Forfeiture of License

2.5.1. No Advanced medical laboratory or part thereof shall move from the premises for which a license has been issued to any other premises without first having obtained from the authority or appropriate organ a permit to move to the premises not covered by the license issued to the medical laboratory.

2.5.2. Without the prejudice to article 2.5.1, permit in change of address shall indicate the special conditions governing the moving of the medical laboratory or part of it as the authority or appropriate organ may find to be in the interest of the public health.

2.5.3. Without prior permission of the appropriate organ, change of owner and/or licensee shall not be made.

2.5.4. The Advanced medical laboratory licensee shall inform the authority or appropriate organ any change in operation or professional. Change of operation means any alteration of services that is different from that reported on the medical laboratory's most recent license application.

2.5.5. The license shall not be assignable or transferable to any other person or place without the prior approval of the authority or appropriate organ and shall be immediately void if the Advanced medical laboratory ceases to operate, if its ownership changes, or if it is relocated to a different site.

2.5.6. When change of ownership of a medical laboratory is contemplated, the laboratory shall notify the authority or appropriate organ in writing and give the name and address of the proposed new owner.

2.6. Suspension and Revocation of a License

2.6.1. The authority or appropriate organ may suspend or revoke a license or order closure of a service/ unit within the Advanced medical laboratory where it finds that there has been a substantial failure to comply with thsi standard.

2.6.2. Without prejudice to grounds of suspension provided under relevant laws, the authority or appropriate organ shall suspend the license for 3 to 12 months in any of the following grounds:

(a) Where the advanced medical laboratory is legally suspended;

(b) Where the advanced medical laboratory fails to practice medical ethics;

(c) Where the advanced medical laboratory engages in rendering services which are outside the competence of the laboratory for which the license is obtained;

(d) Where the Advanced medical laboratory fails to allow inspection pursuant to the law and thsi standard;

(e) When the advanced medical laboratory allows a practitioner, who has been suspended by authority or appropriate organ from practicing his profession;

(f) Members of the Governing Board or the Chief Executive Officer or other key staff member are convicted of a serious offence involving the management or operation of an advanced medical laboratory, or which is directly related to the integrity of the facility or the public health or safety;

(g) When the advanced medical laboratory fails to implement or fulfill comments and corrections given by the appropriate organ;

(h) When the Advanced medical laboratory shown any act which constitutes a threat to the public health or safety;

(i) When the advanced medical laboratory fails to observe laws relating to health services and thsi standard;

(j) When the advanced medical laboratory fails to submit relevant information required under thsi standard.

2.6.3. Without prejudice to grounds of revocation provided under relevant laws, the authority or appropriate organ shall revoke the advanced medical laboratory license from one to two years on any of the following grounds Where the license is proved to have been obtained by submitting false information;

(a) Where the license is proved to have been obtained by submitting false information;

(b) Allows a practitioner who is not licensed pursuant to the appropriate law or who has been revoked by authority or appropriate organ from practicing his profession;

(c) Where any of its permanent health personnel is found registered/ employed as a permanent staff in any other facility;

(d) Where the faults referred to in Article 2.6.2 have been committed for the second time;

(e) Where the license is found transferred or rented to another person;

(f) Where the advanced medical laboratory changes types of services, name, address and the licensee without obtaining permission from the appropriate organ;

(g) Where the license is not renewed in accordance with Section 2.4 of thsi standard;

(h) Where the advanced medical laboratory is legally closed or ceases operation;

(i) Where the advanced medical laboratory is found operating while suspended by appropriate organ;

(j) Where the Advanced medical laboratory is found operating out of the scope of services stated under thsi standard;

2.6.4. At least 30 days prior to voluntary surrender of its license where approved by the appropriate organ, or order of revocation, refusal to renew, or suspension of license, the Advanced medical laboratory must notify each client and the patient's physician the intended closure.

2.6.5. Each license in the licensee's possession shall be the property of the authority or appropriate organ and shall be returned to the authority or appropriate organ immediately upon any of the following events:

(a) Suspension or revocation of the license;

(b) Refusal to renew the license;

(c) Forfeiture of a license; or

(d) Voluntary discontinuance of the operation by the licensee.

2.6.6. If the authority or appropriate organ determines that operational or safety deficiencies exist, it may require that all admissions to the Advanced medical laboratory cease. This may be done simultaneously with, or in lieu of, action to revoke license and/or impose a fine. The authority or appropriate organ shall notify to the laboratory in writing of such determination.

2.6.7. The authority or appropriate organ shall order and ensure in collaboration with appropriate local health authorities the immediate removal of patients from the Advanced medical laboratory whenever it determines there is imminent danger to the patients' health or safety.

2.6.8. The license shall be returned to the authority or appropriate organ within five (5) working days from voluntary surrender, order of revocation, expiration, or suspension of license.

2.6.9. The authority or appropriate organ shall issue to the advanced medical laboratory a written notification on reasons for denial, suspension or revocation of the license.

2.7. Right to Fair Hearing

2.7.1. Any applicant made subject to action by the authority or appropriate organ for denial or suspension or revocation of license or who is assessed a fine under terms of thsi standard shall have the right to a fair hearing in accordance with relevant laws.

2.7.2. Fair hearing shall be provided/ arranged by the authority or appropriate organ whenever there is an official compliant submitted to this body and it shall be open for media.

2.8. Information to be disclosed

2.8.1. Evidence based information received by the authority or appropriate organ through inspection and other true sources about the laboratory shall be disclosed to the public in such a way to indicate the public a decision maker or self regulator for its own health.

2.8.2. Whenever public disclosure is necessary, the authority or appropriate organ shall forward inspection reports to the advanced medical laboratory at least 15 days prior to public disclosure.

2.8.3. Any citizen has the right to obtain information on the official profile of services of any licensed medical laboratory from the appropriate organ.

2.8.4. Anyone who is interested in establishing a advanced medical laboratory shall have the right to be provided with information concerning the standards required by the authority or appropriate organ at any working day.

Section 3: Governance

3.1. Organization and Management

3.1.1 A government owned Advanced medical laboratory may have a governing board, Chief Executive Officer (CEO)or manager, Licensee and necessary staffs indicated in thsi standard.

3.1.2 Except for Share Company where its Board of Directors shall be deemed as Governing Board, other private advanced medical laboratories licensed otherwise under the Commercial Code shall not be required to have such organizational structure.

3.1.3 The Board of Management of nongovernmental Advanced medical laboratory licensed according to Charities and Societies Proclamation No. 629/2009 shall be deemed as Governing Board.

3.1.4 The Board (whenever applicable) shall have the authority and responsibility for the direction and policy of the Advanced Medical Laboratory.

3.1.5 The Board (whenever applicable) of the Advanced medical laboratory may issue its own rules of procedures.

3.1.6 Without prejudice to powers and duties provided by the relevant laws, the Board responsibilities shall include:

(a) Approve all policies and guidelines to be used in the Advanced Medical Laboratory;

(b) Maintaining the Advanced Medical Laboratory's compliance with all applicable laws, its policies, procedures and plans of correction;

(c) Systems are in place for ensuring the quality of all medical laboratory diagnostic tests, care and saftey provided to patients;

(d) Designating and defining duties and responsibilities of the licensee save for the provision of relevant laws;

(e) Notifying the Authority in writing within thirty (30) working days when a vacancy in the licensee position occurs, including who will be responsible for the position until another person is appointed;

(f) Notifying the Authority in writing within thirty (30) working days when the vacancy of licensee is filled indicating effective date of the appointment and name of person appointed;

(g) At least once a year, reviewing the Medical Laboratory diagnostic services provided and the utilization of the Advanced medical laboratory resources; and

(h) Establishing a means for effective communication and coordination among the licensee, the laboratory staff of the various departments of Advanced Medical Laboratory.

3.1.7 Minutes of the Board Meeting shall be recorded, signed, and retained in the Advanced medical laboratory as a permanent record.

3.1.8 The Licensee shall be the secretary and non voting members of the Board.

3.1.9 The Board shall at least develop the following policies and procedures that are revised at least every three years:

(a) For human resource management;

(b) The Advanced medical laboratory environment, including, but not limited to, protection from communicable diseases, exposure to deleterious and hazardous substances and equipments

3.1.10 The Advanced medical laboratory shall develop and implement a complaint procedure for patients, families, visitors, and others. The procedure shall include, at least, a system for receiving complaints, a specified response time, assurance that complaints are referred appropriately for review, development of resolutions, and follow-up action.

3.1.11 There shall be an organizational chart of the Advanced medical laboratory and each service that shows lines of authority, responsibility, and communication between and within services.

3.1.12 There shall be a formal mechanism for communication among the Board, Licensee and the necessary laboratory staff.

3.1.13 The Advanced medical laboratory shall establish a mechanism for involving consumers in the formulation of the Advanced medical laboratory policy and implementation of activities.

3.2. Management Committee

3.2.1. A department head shall be assigned to each of the Advanced medical laboratory and administrative departments. The responsibility of department heads includes at least the following:

(a) Providing a written description of the services provided by the department

(b) Ensuring coordination and integration of these services with other departments when relevant.

(c) Recommending space, staffing, and other resources needed to fulfill the department's responsibility.

(d) Defining the education, skills, and education needed by each category of employee in the department.

(e) Ensuring that there is an orientation and continuing education program for the department's employees.

(f) Developing and implementing a department quality improvement program.

3.2.2. Any Advanced medical laboratory shall establish a Management Committee consisting of heads of the medical and administrative departments. The Licensee shall be the chairperson of the Committee.

3.2.3. The Committee shall be an adviser of the Licensee on the day to day management of the advanced medical laboratory.

3.2.4. The Committee shall meet upon regular basis. The minutes of the meeting shall be recorded and available to the Authority upon request.

Section 4: Client Rights and Responsibilities

4.1. Informed Consent

4.1.1. Each advanced medical laboratory shall protect and promote every patient's rights. This includes the establishment and implementation of written policies and procedures for the client right.

4.1.2. For undertaking any type of procedures and treatments an informed consent shall be required from the client or patient's next of kin or guardian.

4.1.3. An informed consent may not be required during emergency cases or life threatening situations where the client is not capable of giving an informed consent and his or her next of kin or guardian is not available.

4.1.4. Unless provided by the law or thsi standard, an informed consent of the client shall be taken verbally.

4.1.5. The advanced medical laboratory shall comply with relevant laws, national and international codes of ethics in the cases of vulnerable groups like children, women and geriatric patients when someone other than the client can give consent.

4.1.6. No photographic, audio, video or other similar identifiable recording is made of without prior informed consent of a patient.

4.2. Client Rights

Every advanced medical laboratory client shall at least have the following rights:

4.2.1. To receive reasonable, respectful and safe access to medical laboratory diagnostic services by competent personnel that the Advanced medical laboratory is required to provide according to thsi standard;

4.2.2. To receive medical laboratory services without discrimination based on race, age, color, religion, ethnicity, national or social origin, sex, sexual preferences, disabilities, diagnosis, source of payment or other status;

4.2.3. To retain and exercise to the fullest extent possible all the constitutional and legal rights to which the client is entitled by law;

4.2.4. To be informed of the names and functions of all Medical Laboratory professionals who are providing services to clients. These people shall identify themselves by introduction or by wearing a name badge;

4.2.5. To receive, to the extent possible, the services of a translator or interpreter to facilitate communication between the client and the Advanced Medical Laboratory's personnel if the client cannot understand the working language;

4.2.6. To receive information regarding the laboratory tests to be performed. If this information shall be important to the client, or if the client is not capable of understanding the information, the explanation shall be provided to his or her next of kin or guardian and be documented;

4.2.7. To have personal and physical privacy during Medical Laboratory Diagnostic Service. The client's privacy shall also be respected when Medical Laboratory personnel are discussing the client;

4.2.8. Confidential Medical Laboratory results in the patient's records shall not be released to anyone except upon the following conditions;

(a) If the client has approved the request,

(b) If another health care facility to which the client was transferred requires the information,

(c) If the release of the information is required and permitted by law.

(d) If the patient's identity is masked, the Advanced medical laboratory may release data about the client for studies containing aggregated statistics.

4.2.9. To know the price of services and procedures;

4.2.10. To receive a copy of the Advanced medical laboratory payment rates, regardless of source of payment. Upon request, the client or responsible party shall be provided with an itemized bill and an explanation of the charges if there are further questions. The client or responsible party has a right to appeal the charges. The Advanced medical laboratory shall provide the client or responsible party an explanation of procedures to follow in making such an appeal;

4.2.11. To obtain a copy of the patient's laboratory result.

4.2.12. To present his or her suggestion or grievances, without fear of retribution, to the Advanced medical laboratory staff member designated by the Advanced medical laboratory to respond to questions or grievances about client rights and to receive an answer to those grievances within a reasonable period of time without discrimination. The Advanced medical laboratory shall post the names, addresses, and telephone numbers of ethical officers of the Advanced medical laboratory and relevant external government agencies to which the client can lodge their complaints and ask questions.

4.3. Client Responsibilities

4.3.1. The list of a patient's responsibilities shall be posted at visible places of the Advanced Medicla Laboratory premises in local languages.

4.3.2. Every client shall have the following responsibilities:

(a) To provide, to the best of the his/ her knowledge, accurate and complete information;

(b) To report any changes in his/her condition or anything that appears unsafe to herself/himself or to the responsible health personnels or others;

(c) To be considerate of the rights and privacy of other clients;

(d) To respect their caregivers;

(e) To fulfill the financial obligations as promptly as possible;

(f) To keep all appointments and notify Advanced medical laboratory or the appropriate person when unable to do so;

(g) To observe the advanced medical laboratory policies and procedures, including those on smoking, cellular phones and noise;

(h) To be considerate of the advanced medical laboratory facilities and equipment and to use them in such a manner so as not to abuse them;

(i) Not to litter the advanced medical laboratory premises;

Section 5: Human Resource Management

5.1. General Requirements

5.1.1. The advanced medical laboratory shall have a responsible person who organizes and carries out the major functions of Human Resource Management (HRM).

5.1.2. The advanced medical laboratory shall make sure each service unit shall maintain the minimum number of staff with the qualifications, training and skills during working hours as per thsi standard.

5.1.3. The advanced medical laboratory shall ensure that all health professionals recruited are licensed as per the registration and licensing requirement of the appropriate organ.

5.1.4. No medical Laboratory professional shall practice his/her profession in the Advanced medical laboratory without having professional license from the appropriate organ.

5.1.5. The Advanced medical laboratory shall ensure that all Medical Laboratory professionals have received a copy of professional code of ethics and scopes of practice.

5.1.6. Each Advanced medical laboratory shall ensure and maintain evidence of current active licensure, registration, certification or other credentials for employees and contract staff prior to staff assuming job responsibilities and shall have procedures for verifying that the current status is maintained.

5.1.7. Whenever a licensed Medical Laboratory professional is terminated as a result of a job-related incident, the Advanced medical laboratory shall refer a report of the incident to the appropriate organ.

5.1.8. Every Medical Laboratory professional shall report to the advanced medical laboratory whenever he/she is infected with contagious diseases.

5.1.9. The advanced medical laboratory shall also establish a mechanism for screening Medical Laboratory professionals with contagious diseases.

5.1.10. The Medical Laboratory professional shall not practice his/her profession during the period of such infection and his/her rights provided under the relevant employment law and the Basic medical laboratory ’s HR manual shall be respected.

5.1.11. Medical Laboratory professionals shall have an occupational health screening by a physician or other qualified health professional prior to entering active status and at least once every Five (5) years thereafter.

5.1.12. Each health screening shall include a medical history, physical examination, and any indicated laboratory work and investigations.

5.1.13. The report of each examination shall be kept on file in the Advanced medical laboratory and shall be open to inspection by the control agency.

5.1.14. Each Advanced medical laboratory shall maintain a current employment record for each staff person. The record shall contain, at a minimum, information on credentials, health examination (fitness for duty), work history, current job description, evidence of orientation, in-service education/training and copies of annual evaluation.

5.1.15. The Advanced medical laboratory shall have human resource manual.

5.2. Staffing Plan

5.2.1. The Advanced medical laboratory shall avail as a minimum the staff requirement stated under this standard.

5.2.2. For additional staff a staffing plan shall be developed collaboratively by the different service units and management, which identifies the number and types of the staff.

5.2.3. The planning process shall use recognizable process for estimating the staffing need like Workload Indicator for Staffing Need (WISN) method.

5.2.4. The staffing plan shall be reviewed on an ongoing basis and updated as necessary.

5.2.5. The staffing plan shall define the following elements:

(a) The total number and types of staff needed for the Advanced medical laboratory as a whole and for each service unit,

(b) The total number and types of staff currently available for the Advanced medical laboratory as a whole and each service unit,

(c) The required education, skills, knowledge, and experience required for each position,

(d) The process and time period for reviewing and updating the plan shall be indicated. (The plan is periodically reviewed and updated as required, but it shall be done at least every two years.**)**

(e) Expected/existing workload.

5.2.6. The Advanced medical laboratory shall have in effect a contingency plan for assuring adequate staffing at all times. The plan shall detail policies and procedures to regulate closure of available services, if actual staffing levels fall below specified levels.

5.3. Job Description and Orientations

5.3.1. All staffs shall be provided with current written job descriptions and be oriented to their specific job responsibilities at appointment.

5.3.2. The job description shall include the title and grade of the position, specific function of the job, job requirement, reporting mechanism, evaluation criteria and description of job site and work environment.

5.3.3. The orientation program for all employees shall include three levels of orientation: Advanced medical laboratory wide, service unit and job specific.

5.3.4. Orientation to Advanced medical laboratory structure and administration shall be provided by Advanced medical laboratory management.

5.3.5. Orientation to Advanced medical laboratory policies, including all environmental safety programs, infection control, and quality improvement shall be provided.

5.3.6. Staff members who are not licensed to independently practice shall have their responsibilities defined in a current job description.

5.3.7. Each Advanced medical laboratory shall provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program shall include an explanation of:

(a) Job duties and responsibilities
(b) Sanitation and infection control programs of the Advanced Medical Laboratory;
(c) Organizational structure within the Advanced Medical Laboratory;
(d) Client rights;
(e) Client care policies and procedures relevant to the job;
(f) Personnel policies and procedures;
(g) Emergency procedures;
(h) The Disaster preparedness plan; and
(i) Reporting requirements.

5.4. Staff Education:

5.4.1. The Advanced medical laboratory shall ensure that staffs receive training in order to perform assigned job responsibilities.

5.4.2. Each staff member shall receive ongoing Continuing Professional Development (CPD) to maintain or advance his or her skills and knowledge

5.4.3. The CPD shall be relevant to the setting in which they work as well as to the continuing advancement of the Advanced medical laboratory

5.4.4. The Advanced medical laboratory shall decide the type and level of training for staff in accordance with National CPD guideline and then carry out and document a program for this training and education.

5.4.5. The Advanced medical laboratory shall provide and maintain evidence of CPD for staff. A record shall be maintained including dates, topics and participants

5.4.6. The Advanced medical laboratory shall periodically tests staff knowledge, skill and attitude through demonstration, mock events and other suitable methods. This testing is then documented.

5.5. Technical Staff

5.5.1. There shall be a policy of verifying qualifications, restrictions to practice and professional registration of all new employees and have a system in place to check re-registration details. There shall be documentation of staff licenses and training certificates.

5.5.2. There shall be a policy that strengthens involvement of medical laboratory staffs to take part in the ongoing Continuing Medical Education (CME).

5.5.3. Any Advanced medical laboratory department shall be organized under the leadership of a licensed Medical Laboratory Technologist.

5.5.4. The medical laboratory staff shall be responsible to the governing authority for medical laboratory diagnostic servives provided in the Advanced medical laboratory in accordance with the standards stipulated under the Advanced medical laboratory administration and shall:

(a) Participate in a Quality Assurance/Performance Improvement program to determine the status of Quality of service provided;

(b) Abide by Advanced medical laboratory and medical staff policies;

(c) Establish a disciplinary process for infraction of the policies

5.5.5. The medical laboratory staffs shall actively participate in the study of the Advanced medical laboratory associated infections and infection potentials and must promote preventive and corrective programs designed to minimize their hazards.

5.5.6. There shall be a medical laboratory staff available in the advanced medical laboratory all the time during working hours.

5.5.7. There shall be regular laboratory staff meetings to review the works of the members and to complete their administrative duties.

5.6. Employee's Health

5.6.1. The Advanced medical laboratory shall institute systems and processes that minimize employees' risks, protect employees and provide access to care when needed.

5.6.2. A comprehensive Occupational Health and Safety (OHS) program shall have the following components:

(a) Staff dedicated to coordinate OHS activities,
(b) Policies and Procedures that define components of the program,
(c) Training for staff on program components.

5.6.3. The following core elements of an OHS program shall be available in Advanced medical laboratory:
(a) The Advanced medical laboratory shall have an occupational health and safety policy and procedures in place to identify, assess and address identified health and safety risks to staff and prevent those risks that will potentially compromise their health and safety.
(b) The Advanced medical laboratory assesses and documents safety risks through formalized, structured assessments that are done at regular intervals.
(c) The assessments shall be logged in some format - for example a register or report
(d) The information gathered from the assessment shall be documented and reported to the management (management committee and boards).
(e) Interventions shall be designed and implemented to address the risks that are identified.

5.6.4. The Advanced medical laboratory shall provide personal protective equipment as per the Infection Prevention & control section of this standard.

5.6.5. The Advanced medical laboratory shall provide the following facilities to employees
(a) Adequate toilet and shower facilities.
(b) Cafeteria,
(c) Duty room as appropriate,

(d) Library (equipped with manuals, books and computers with internet).

5.7. Dress Code and Employee Identification Badge

5.7.1. Footwear shall be safe, supportive, clean, and non-noise producing.

5.7.2. No open toe shoes shall be worn.

5.7.3. Artificial nails are prohibited. Natural nails must be kept short and jewelry must be kept to a minimum.

5.7.4. Hair must be worn in a way that prevents contamination and does not present a safety hazard.

5.7.5. The dressing shall not interfere in any way the service provision.

5.7.6. The Advanced medical laboratory shall specify a particular style and/or color of uniform with different style/color code; separate for each Medical Laboratory saffs category, employee and trainees if available.

5.7.7. The employee shall keep the uniform neat, wrinkle free and in good repair.

5.7.8. The Advanced medical laboratory shall be responsible for providing employee identification badges.

5.7.9. The identification badge shall be worn at all times while at work and be easily visible, with name, profession and department facing outward.

Section 6: Advanced Medical Laboratory Service Standards

6.1. Practices

6.1.1. The Advanced medical laboratory shall have written policies and procedures and include at least the followings:

a) Procedure manuals (Standard Operating Procedure, SOP) or guidelines for all tests and equipment,
b) Report times for results (Established turn around time),
c) Quality assurance and control processes,
d) Inspection, maintenance, calibration, and testing of all equipment,
e) Management of reagents, including availability, storage, and testing for accuracy,
f) Procedures for collecting, identifying, processing, and disposing of specimens,
g) All normal ranges for all tests shall be stated,
h) Laboratory safety program, including infection control,
i) There shall be documentation of quality control data (internal and external quality control), calibration report, refrigerator readings and so on.

6.1.2. The Advanced medical laboratory shall have policies and procedures for the availability of paper based or electronic laboratory information management system (LIMS). The data management system shall include the followings:

a) Periodic reporting(monthly, quarterly),
b) Preliminary analysis and utilization of results,
c) Collection of useful and appropriate information,
d) Archiving and retrieval.

6.1.3. The Advanced medical laboratory shall have standardized data collection instruments and including at least the followings:

a) Laboratory request forms,
b) Laboratory report forms,
c) Laboratory specimen and results registers,

d) Monthly/ Quarterly reporting forms including

- Summary of tests conducted
- Summary of tests referred
- Summary of quality assurance report

e) Equipment and supplies inventory registers

f) Quality assurance record forms and registers

6.1.4. The Advanced medical laboratory shall develop monitoring and evaluation tools to assess activities including:

a) adherence to SOPs

b) adherence to safety guidelines

c) Quality assurance activities

d) Laboratory performance and workload

e) Laboratory services

6.1.5. The Advanced medical laboratory shall have policies and procedures for the availability of laboratory services including the emergency services.

6.1.6. The laboratory shall have procedures or (SOP) for proper specimen collection that address specific collection requirements such as:

a) Preferred sample type (venous, arterial, capillary, urine, spinal fluid)
b) Type of anticoagulant
c) Sample volume considered acceptable
d) Patient identification
e) Requirements for patient preparation and
f) Requirements for storage of specimens.

6.1.7. Policies and procedures shall be documented and communicated to concerned personnel.

6.1.8. The laboratory shall have a policy for making amendments and corrections to laboratory procedures and all amended laboratory procedures shall be reviewed and approved for use.

6.1.9. Test procedures developed by the laboratory (in-house procedures) must be validated and fully documented before being put into use. All procedures shall be in a language commonly understood by laboratory staff.

6.1.10. The laboratory shall follow standard operating procedures (SOP) and conduct routine quality assessments to ensure reliable and cost-effective testing of patient specimens.

6.1.11. Laboratory management shall review all operational procedures at regular intervals. The frequency should be every four month (at least annually).

6.1.12. The process of analysis shall be specified by validated written or electronic procedures maintained in and by the laboratory.

6.1.13. Procedures may be written by the laboratory staff or may be adapted from previously published materials including, but not limited to, product inserts, procedure or instrument manuals, textbooks, journals, or international guidelines.

6.1.14. Laboratory staff shall test quality control materials at least every eight hour and document in combinations suitable to detect analytical error.

6.1.15. The right patient with the right request form shall be identified during collection and delivery of result.

6.1.16. Requests for testing shall provide:

a) The name of the ordering physician or other person authorized to order testing
b) The clinician's working address
c) Type of primary sample collected
d) The anatomic site where appropriate
e) The test requested
f) Patient gender
g) Age
h) Pertinent clinical information as appropriate for purposes of test interpretation (Clinical Diagnosis)
i) Date and time of sample collection and receipt in the laboratory

6.1.17. There shall be SOP or criteria developed for acceptance or rejection of clinical samples.

6.1.18. Laboratory shall monitor the transportation of samples to the laboratory such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual or SOP and in a manner that ensures safety for carrier.

6.1.19. The laboratory shall maintain a record of all samples received.

6.1.20. Laboratory shall have a procedure for storage of clinical samples if it is not immediately examined.

6.1.21. client samples shall be stored only for as long as necessary to conduct the designated tests (or other permitted procedure) according to fixed storage times, and shall be destroyed safely and confidentially after storage.

6.1.22. Once a sample is used, it shall be maintained in the laboratory for a specified period of time (or as required by regulation) and at a temperature that ensures stability of the sample in the event the sample is needed for retesting.

6.1.23. The Advanced medical laboratory shall carry out clinical laboratory examinations including clinical chemistry, microbiology, hematology, coagulation, general immunology, serology, parasitology, urine and body fluid analysis, mycology, Hormonal tests, tumor markers and so on.

6.1.24. There shall be documentation of inspection and quality control of the tests done under the Advanced Medical Laboratory.

6.1.25. All Laboratory report

a) Shall have reference (normal) ranges specific for age and gender.
b) Shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained shall be 10 years for legal reason minimal errors or loss of patient test results.
c) In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be put together with the ordering laboratory report form.
d) Quality assured test results shall be reported on standard forms to the physician with the following minimum information:
    - client identification (client name, age, gender,)
    - Date and time of specimen collection
    - The test performed and date of report.
    - The reference or normal range
    - The laboratory interpretation where appropriate,
    - The name and initial of the person who performed the test, and the authorized signature of the person reviewing the report and releasing the results.
    - The Advanced medical laboratory address
e) Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them.
f) The laboratory shall have policies and procedures in place to protect the privacy of client and integrity of client records whether printed or electronic. Policies shall be established which define who may access client data and who is authorized to enter and change client results, correct billing or modify computer programs.

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

6.1.27. Safe disposal of samples shall be in line with standards prescribed under infection prevention

6.1.28. No eating, drinking, smoking or other application of cosmetics in laboratory work areas or in any area where workplace materials are handled.

6.1.29. No food and drink to be stored in the laboratory (may be stored in the rest area)

6.1.30. The medical laboratory shall have safety guideline. In addition, the laboratory shall protect the environment and public by assuring the disposal of laboratory waste in a legally and an environmentally friendly manner

6.1.31. Wearing of protective clothing of an approved design(splash proof), always fastened, within the laboratory work area and removed before leaving the laboratory work area

6.1.32. The laboratory must keep a record of the complaint. The record shall include the nature of the complaint, the date of occurrence, individuals involved, any investigations undertaken by the laboratory and resolution.

6.1.33. There shall be a written chemical hygiene plan that defines the safety procedures to be followed for all hazardous chemicals used in the laboratory. The plan defines at least the following:

a) The storage requirements
b) Handling procedures
c) Requirements for personal protective equipment
d) Procedures following accidental contact or overexposure
e) The plan is reviewed annually, and updated if needed, and is part of new employee orientation and the continuing education program.

6.1.34. The following laboratory tests shall be performed in an Advanced Medical Laboratory.

a) HEMATOLOGY

- White blood cell count
- Hemoglobin
- Hematocrit
- Differential count
- Platelet
- Reticulocyte count
- Hemoparasite
- RBC morphology
- MCV
- MCH
- MCHC
- Prothrobmin time
- Partial Tromboplastin time (PTT)
- Activated (aPTT)
- INR

- Iron
- Total Iron Binding Capacity (TIBC)
- Ferritin
- Folate (Folic Acid)
- Vitamin B12
- Erythrocytic Sedimentation Rate (ESR)

b) CLINICAL CHEMISTRY

- Glucose
- Uric Acid
- Creatinine
- Urea
- Alkaline Phosphatase
- Aspartate Aminotransferase(AST)
- Alanine Aminotransferase (ALT)
- Bilirubin, Direct
- Bilirubin, Total
- Albumin
- Globulin
- A/G Ratio
- Cholesterol
- Triglycerides
- High Density Lipoprotein(HDL)
- Low Density Lipoprotein (LDL)
- LDH
- LDL/HDL Ratio
- Sodium
- Potassium
- Chloride
- Calcium
- Phosphorous
- Magnesium
- CK (Creatinine Kinase)
- CK MB
- Troponin I
- Creatinine, 24 hr
- Creatinine Clearance
- Hemoglobin A1C
- Fructosamine
- Carbon Dioxide
- Glucose Tolerance Test (GTT)
- Lipase
- Amylase
- γ-GT
- Total protein, 24 hr. Urine
- Urine Calcium
- Serum Electrophoresis

c) CANCER MARKERS (Male)

- CA 125
- CA 19-9
- CEA
- AFP
- β HCG
- PSA
- Free PSA
- Testosterone

d) CANCER MARKERS (FEMALE)

- CA 125
- CA 19-9
- CEA
- AFP
- β HCG
- PAP Smear

e) HORMONAL TESTS

- Estradiol
- Follicle Stimulating Hormone (FSH)
- Free Thyroxin Index (FTI)
- Luteinizing Hormone (LH)
- Prolactin
- Progesterone
- T3 Uptake
- Thyroid Stimulating Hormone (TSH)
- Thyroxin (T4)
- T3

f) URINE AND BODY FLUID ANALYSIS

- Urine analysis Qualitative
- Urine Microscopy
- Body fluid Analysis

g) PARASITOLOGY

- Stool Examination
- Special parasitological tests

h) BACTERIOLOGICAL EXAMINATION

- Gram Stain
- AFB Stain
- Routine Bacteriologic Culture & DST*
- Tuberculosis Culture & DST*
- Special Stain

i) SEROLOGICAL TESTS AND OTHER TESTs

- Widal-weli fliex
- HBsAg
- H.Pylori
- RPR (syphilis)
- C-reactive Proteins
- ASO
- RH (Rheumatoid factor)
- ANA (Antinuclear Antibody)
- Toxoplasma, IgG
- Rubella, IgG
- Cytomegalovirus, IgG
- Herpes (HSV), IgG
- HIV/Ag/Ab
- HIV Viral Load
- CD4/CD8 (Count and %)
- CD45
- CD3
- CD4/CD8 Ratio
- Hepatitis B core Antibody, IgM
- Hepatitis Be Antigen
- Hepatitis Be Antibody
- Hepatitis B Core Antibody
- Hepatitis B Surface Antigen
- Hepatitis A IgM
- Hepatitis C Ab
- D-Dimer
- Paternity tests

6.2. Laboratory Premises

6.2.1. The Advanced medical laboratory shall have a well organized, adequately supervised and staffed clinical laboratory with the necessary space, facilities and equipment to perform those services commensurate with the Advanced Medical Laboratory's needs for its patients.

6.2.2. The laboratory working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste material to ensure client and staff protection from unnecessary risks at all time.

6.2.3. The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, and safety of personnel or patient care services.

6.2.4. The laboratory shall have adequate space and a safe environment to perform testing. It must provide adequate lighting, ventilation, water, waste and refuse disposal. Work areas shall be clean and well maintained. Precautions must be taken to prevent cross contamination.

6.2.5. The laboratory shall have controlled temperature of refrigerator for reagents, blood sample, calibrator, control materials which affect the analytical results.

6.2.6. The laboratory shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.

6.2.7. The laboratory shall be located and designed to

a) Provide suitable, direct access for patients
b) Allow reception of deliveries of chemicals
c) Allow safe disposal of laboratory materials and specimens.

6.2.8. Doors shall be located in places where entry and exit is easy and does not interfere with the laboratory benches or equipment.

6.2.9. Laboratory doors shall not be less than 1 m wide to allow easy access of equipment. In some areas, double doors, 1.2 m wide, shall be provided for passage of large equipment, such as deep-freezes.

6.2.10. All doors shall be opened towards the corridor.

6.2.11. There shall be effective separation between adjacent laboratory sections if there are incompatible activities.

6.2.12. The premise for advanced medical laboratory shall have a minimum of the following

Premises required	No of rooms required	Area required
Reception & waiting room	1	20 sq. m
Specimen collection room	1	12 sq. m
Hematology room	1	12 sq. m
Clinical chemistry room	1	16 sq. m
Medical Microbiology rooms	1	40 sq. m
Serology room	1	6 sq. m
Parasitology, urine & body fluid analysis room	1	9 sq. m,
Viral load rooms (Amplification, detection)	2	4 sq. m & 6 sq. m
Molecular & flow cytometer room	1	9 sq. m
Sterilization, disinfection and media preparation room	1	9sq. m
Recording and reporting room	1	4 sq. m
Store room	1	8 sq. m,
Staff room and office	1	9 sq. m
Toilets for patients (Separate, 2 for Male and 2 for female)	4	16 sq. m
Toilet with shower for staff (Separate for Male and female)	2	8 sq. m
Emergency shower	1	4sq.m,

6.2.13. The laboratory facilities shall meet at least the following:

a) The laboratory shall have a reliable supply of running water and at least 5000L reserve tank in case of interruption
b) At least two sinks shall be provided in each room, one for general laboratory use and the other reserved for hand washing.
c) Continuous power supply and backup generator in case of power interruption
d) Working surface covered with appropriate materials
e) Suitable stools for the benches. Bench tops shall be impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.
f) Internal surfaces, i.e. of floors, walls, and ceilings shall be :
    - Smooth, impervious, free from cracks, cavities, recesses, projecting ledges and other features that could harbor dust or spillage
    - Easy to clean and decontaminate effectively
    - Constructed of materials that are non-combustible or have high fire-resistance and low flame-spread characteristics

g) Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
h) Lockable doors and cupboards
i) Closed drainage from laboratory sinks to a septic tank
j) Facilities for disposal of contaminated materials and solid waste
k) Separate toilets/latrines for staff and patients
l) Emergency of safety services such as deluge showers and eye-wash stations, fire alarm systems and emergency power supplies shall be included in the laboratory services design specifications
m) Telephone and/or radio communication.

6.3. Laboratory Professionals

6.3.1. All laboratory services shall be directed by a licensed medical laboratory technologist with five yeas of experience and relevant MSc.
6.3.2. Medical laboratory staff shall be present at the Advanced medical laboratory to provide laboratory service at all times.
6.3.3. Students and other staff on attachment shall work under the direct supervision of a licensed medical laboratory technologist.
6.3.4. The Laboratory service shall have and maintain job descriptions, including qualifications to perform specific functions.
6.3.5. The Laboratory management shall provide adequate training, continuing education or access to training for technical staff, and assess staff competency at regular intervals.
6.3.6. Laboratory staff shall, at all times, perform their functions with adherence to the highest ethical and professional standards of the laboratory profession.
6.3.7. In general the following shall be the minimum laboratory staffing requirements.
a) Laboratory technologist with MSc #2 (one of them shall be medical microbiologist)
b) Laboratory Technologist, #4
c) Full time Laboratory technologist quality control officer, # 1
d) Supportive staff (clerk, cleaner)
e) The maximum number of staff shall vary based on the level of workload and working time.
f) Additional laboratory technicians may be recruited

6.4. Products

6.4.1. Laboratory shall be furnished with all items of equipment required for the provision of services.

6.4.2. All equipment shall be in good working order, routinely quality controlled, and precise in terms of calibration.

6.4.3. Laboratory shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It shall also have a document.

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

6.4.5. Laboratory shall have a documented and recorded Programme of preventive maintenance which at a minimum follows the manufacturer's recommendation.

6.4.6. Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices. Whenever equipment is found to be defective, it shall be taken out of service and clearly labeled.

6.4.7. The following minimum equipments and consumables shall be available in advanced medical laboratories

a) Fully automated clinical chemistry analyzer
b) Automated clinical chemistry analyzer
c) Fully
d) automated hematology analyzer
e) Hormonal assay analyzer
f) Electrophoresis machine
g) Viral load manchine
h) CD4 machine
i) Electrolyte analyzer
j) Microscope #5
k) Biological safety cabinet
l) Routine Culture and Drug sensitivity accessories (Package)
m) PH meter #2
n) Digital balance
o) Vortex mixer
p) Automatic Micropippet #10
q) Microhematocrit centrifuge
r) Microhematocrit reader
s) Differential counter #2
t) Tally counter # 3
u) Deep freezer
v) Centrifuge #3
w) Timer #6
x) Refrigerator #3
y) Distillation unit
z) Bunsen burner #2
aa) Autoclave
bb) Dry oven
cc) Blood roller/mixer #2
dd) Water bath

ee) Coagulation machine
ff) Blood roller/mixer
gg) Shaker
hh) Incubator #2

Section 7: Optional Services for Advanced Medical Laboratory

7.1. Pathology Services

7.1.1. Practices

7.1.1.1. The pathology unit of the advanced medical laboratory shall have written procedures and protocols for pathology service.

7.1.1.2. The pathology service shall be available for at least during working hours.

7.1.1.3. All tissues sent for pathology examination shall be subjected to examination macroscopically and/or microscopically by the pathologist.

7.1.1.4. A list of pathology examination and tissues which routinely require microscopic and or gross examinations shall be developed in advanced medical laboratory by the pathologist.

7.1.1.5. All pathology result reports shall be signed by the pathologist.

7.1.1.6. Signed reports of tissue examinations shall be sent back to the requesting physician to be filed in the patient's medical record and duplicate copies kept in the pathology service unit.

7.1.1.7. A tissue file paraffin blocks and slides shall be maintained in the laboratory.

7.1.1.8. There shall be quality assurance system for pathological investigations.

7.1.2. Premises

7.1.2.1. The laboratory shall have an organized separate pathology service area including

(a) Waiting area

(b) Specimen reception and Sectioning room

(c) Preparation/tissue processing and staining room

(d) Cytology examination room

(e) Reading room, as required

(f) Chemical Reagent Store(can be shared)

7.1.2.2. The service shall have the following offices

(a) Pathologists office

(b) Photography room

(c) Laboratory staff room with lockers (can be shared)

(d) Toilets for staff and patient (male and female) (can be shared)

7.1.3. Professionals

7.1.3.1. The pathology service shall be directed by a licensed pathologist.

7.1.3.2. The pathology service shall have the following staffing

(a) Pathologist

(b) Laboratory technologist or technician with training in tissue processing

(c) Receptionist (can be shared)

7.1.3.3. The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis).

7.1.4. Products

7.1.4.1. The pathology service shall have the following products:

(a) Waiting area:

- Chairs for customers

(b) Gross Room:

- Dissection table with cold and warm water
- Wheeled chair
- Tissue shelf store
- Lidded garbage container

(c) Tissue Processing Room:

- Embedding system laboratory tables
- Tissue processor –vacuum processor and Rotary processor
- Dry air oven
- Refrigerator
- Microtones
- Water bath

- HE staining table
- Fume extractor
- Knife sharpener

(d) Microscopy Reading Room:

- microscope
- metal stools

(e) Chemical Reagent Store:

- Fume extractor
- shelf

7.1.4.2. Cytology Examination room:

- Coach table
- Microscope
- Office table
- Reading table
- Mobile examination light
- Rotary chair
- Locker

7.1.4.3. Office facilities and furniture

7.2. Molecular Diagnostic Services

7.2.1. Practices

7.2.1.1. The molecular diagnostic unit of the advanced medical laboratory shall have:

a) Genetic tests for persons who have developed a disease
b) Genetic Testing for Carrier Detection
c) Genetic Testing to Predict Disorders
d) Presymptomatic Testing
e) Disease-Susceptibility Testing
f) Genetic Testing for Familial Tumors
g) Genetic Testing for Individual differential Drug Response
h) Prenatal Testing and Diagnosis
i) Mass-screening for Newborn Infants with Congenital Disorders

7.2.1.2. The molecular diagnostic unit shall have written policies and procedures and include at least the followings:

a) Molecular diagnostic unit shall have Procedure manuals, Standard Operating Procedure (SOP), protocols or guidelines for appropriate testing.
b) Report times for results (Established turn around time)
c) Procedures for collecting, identifying, processing, and disposing of specimens
d) All normal ranges for all tests shall be stated (if available).
e) Molecular diagnostic unit safety program, including infection control.
f) Availability of paper based or electronic information management.

7.2.1.3. The Molecular diagnostic unit shall have standardized data collection instruments and including at least the followings:

a) Request forms
b) Report forms
c) specimen and results registers

d) supplies inventory registers
e) The Molecular diagnostic unit shall have procedures or (SOP) for proper specimen collection that address specific collection requirements such as:
f) Preferred sample type (venous, arterial, capillary, urine, spinal fluid)
g) Type of anticoagulant (appropriate type of specimen collection tube)
h) Sample volume considered acceptable
i) Patient identification
j) Requirements for patient preparation and storage of specimens.

7.2.1.4. The right patient with the right request form shall be identified during collection and delivery of result.

7.2.1.5. There shall be SOP or criteria developed for acceptance or rejection of clinical samples.

7.2.1.6. Molecular diagnostic unit shall monitor the transportation of samples to the laboratory such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual or SOP and in a manner that ensures safety for carrier.

7.2.1.7. The Molecular diagnostic unit shall maintain a record of all samples received.

7.2.1.8. Once a sample is used, it shall be maintained in the Molecular diagnostic unit for a specified period of time (or as required by regulation) and at a temperature that ensures stability of the sample in the event the sample is needed for retesting.

7.2.1.9. The report/result issued by the Molecular diagnostic unit shall have reference (normal) ranges specific for age and gender.

7.2.1.10. Copies or files of reported results shall be retained by the Molecular diagnostic unit such that prompt retrieval of the information is possible. The length of time that reported data are retained shall be 10 years for legal reason minimal errors or loss of patient test results.

7.2.1.11. Quality assured test results shall be reported on standard forms to the physician with the following minimum information:

a) Patient identification (patient name, age, gender,)
b) Date and time of specimen collection
c) The test performed and date of report.
d) The reference or normal range (if available)
e) The Molecular diagnostic unit interpretation where appropriate,
f) The name and initial of the person who performed the test, and the authorized signature of the person reviewing the report and releasing the results.
g) Address of the sample collection site and the testing laboratory.

7.2.1.12. Molecular diagnostic unit results shall be legible, without transcription mistakes and reported only to persons authorized to receive them.

7.2.1.13. The Molecular diagnostic unit shall have policies and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic.

7.2.1.14. Policies shall be established which define who may access patient data and who is authorized to enter and change patient results.

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

7.2.1.16. Safe disposal of samples shall be in line with national infection prevention guideline and healthcare waste management directives/guidelines of Ethiopia.

7.2.1.17. There shall not be eating, drinking, smoking or other application of cosmetics in the molecular diagnostic unit or in any area where workplace materials are handled.

7.2.1.18. Food and drink shall not be stored in refrigerators.

7.2.1.19. Wearing of protective clothing of an approved design (splash proof), always fastened, within the molecular diagnostic unit and removed before leaving the unit.

7.2.1.20. The molecular diagnostic unit shall have safety guideline. In addition, the Specimen collection site shall protect the environment and public by assuring the disposal of waste in a legally and an environmentally friendly manner.

7.2.2. Premises

7.2.2.1. The molecular diagnostic unit shall have a well organized space, facilities and equipment to perform the required services.

7.2.2.2. The molecular diagnostic unit working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste material to ensure patient and staff protection from unnecessary risks at all time.

7.2.2.3. The molecular diagnostic unit shall have space allocated so that its workload can be performed without compromising the quality of work, and safety of personnel or patient.

7.2.2.4. The molecular diagnostic unit shall have controlled temperature of refrigerator for reagents, Clinical specimens, which affect the analytical results.

7.2.2.5. The molecular diagnostic unit shall be located and designed to

a) Provide suitable, direct access for patients
b) Allow safe disposal of materials and specimens.
c) Doors shall be located in places where entry and exit is easy and does not interfere with the benches or equipment.

7.2.2.6. Molecular diagnostic unit doors shall not be less than 1 m wide to allow easy access for patients.

7.2.2.7. The Molecular diagnostic unit room shall be separated by wall from the other rooms.

7.2.2.8. The premise of Molecular diagnostic unit shall have a minimum of the following rooms

Premises required	No of room required	Area required
Patient waiting area	1	9sq.m

Main specimen collection room	1	6sq.m
Specimen processing Room	1	6sq.m
Amplification room	1	9sq.m
One room for Detection	1	9sq.m
Staff change room	1	6sq.m
Mini store	1	6sq.m
Reporting, recording and result dispatch area	1	6sq.m

7.2.2.9. Except Amplification and Detection rooms the other rooms can be in one room with (full/half) partition.

7.2.2.10. The Molecular diagnostic unit facilities shall meet at least the following:

a) A reliable supply of running water.
b) At least one sinks shall be provided in each room and at least 5000L reserve tank in case of water interruption.
c) Continuous power supply
d) Working surface covered with appropriate materials
e) Suitable stools for the benches. Bench tops shall be impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.
f) Internal surfaces, i.e. of floors, walls, and ceilings shall be :
    - Smooth, impervious, free from cracks, cavities, recesses, projecting ledges and other features that could harbor dust or spillage
    - Easy to clean and decontaminate effectively
g) Closed drainage from sinks (to a septic tank or deep pit)
h) Deep pit to discard contaminated material or access to a simple incinerator

i) Separate toilets/latrines for staff and patients

j) Emergency of safety services such as deluge showers and eye-wash stations, fire alarm systems and emergency power supplies shall be included.

k) Telephone communication.

7.2.3. Professionals

7.2.3.1. The molecular diagnostic services shall be directed by medical laboratory technologist or any health professional specialized in Medical Genetics or Molecular Biology or Medical Biochemistry with at least two years of experience.

7.2.3.2. In addition, the molecular diagnostic unit shall have.

a) Two medical Laboratory technologist and

b) Supportive staff (can be shared)

7.2.4. Products

7.2.4.1. The molecular diagnostic unit shall be furnished with all items of equipment required for the provision of services.

7.2.4.2. The following minimum equipments and consumables shall be required

a) Equipment

- Gel documentation unit
- Gel Electrophoresis unit
- Centrifuge
- Ultra Freezer
- Fridge with -20 freezer
- Pipettes
- Electric generator
- Water purification unit
- Bunsen burner
- Electric or gas stove
- Autoclave
- Microwave oven
- Spinner or mini Centrifuge
- Water bath
- Thermostat or Heat module
- Shaker
- Vortex
- pH meter/pH strips
- Analytical balance
- PCR work station/laminar flow
- Microbiological incubators

b) Plastics and glassware

- PCR tubes strips
- PCR plates
- Pipette Tips
- Glass ware
- Storage Boxes
- Tube racks
- Petri dishes

c) **Reagents**

- DNA/RNA isolation kits
- DNA/RNA purification kits
- cDNA synthesis kit
- Enzymes/PCR reagents
- Fragment analysis markers
- Markers and Loading dye
- Buffers and Media

d) **Computers and softwares**

- Laptop computer
- Desk top computer
- Printer/fax/copier
- Softwares for sequence and fragment analysis
- Cell culture
- Western blot
- DNA protocol
- RNA protocol
- Protein Protocol
- Genomic sequencing
- Microscope
- IF kit
- Microbiology protocol

7.3. Specimen Collection Service Standards

7.3.1. Practices

7.3.1.1. The Specimen collection site of the advanced medical laboratory shall have written policies and procedures and include at least the followings:

a) Procedure manuals, Standard Operating Procedure (SOP) or guidelines for appropriate specimen collection and transport. (The main laboratory specimen collection and transportation SOP can be used)
b) Report times for results (Established turn around time)
c) Procedures for collecting, identifying, processing, and disposing of specimens
d) All normal ranges for all tests shall be stated
e) Specimen collection site safety program, including infection control

7.3.1.2. The Specimen collection site shall have policies and procedures for the availability of paper based or electronic information management.

7.3.1.3. The Specimen collection site shall have standardized data collection instruments and including at least the followings:

a) Request forms (regarding its content please refere the advanced medical laboratory service standards section of this document
b) Report forms (regarding its content please refere the advanced medical laboratory service standards section of this document
c) specimen and results registers
d) supplies inventory registers

7.3.1.4. The Specimen collection site shall get consultation from the main Laboratory on selection, quantification, procurement and storage of supplies.

7.3.1.5. The Specimen collection site shall have procedures or (SOP) for proper specimen collection that address specific collection requirements such as:

a) Preferred sample type (venous, arterial, capillary, urine, spinal fluid)
b) Type of anticoagulant (appropriate type of specimen collection tube)
c) Sample volume considered acceptable
d) Patient identification
e) Requirements for patient preparation and storage of specimens.

7.3.1.6. The right patient with the right request form shall be identified during collection and delivery of result.

7.3.1.7. There shall be SOP or criteria developed for acceptance or rejection of clinical samples.

7.3.1.8. Specimen collection site shall monitor the transportation of samples to the Specimen collection site such that they are transported, within time frame, within temperature interval specified in the primary sample collection manual or SOP and in a manner that ensures safety for carrier.

7.3.1.9. There shall be a dedicated transportation system which is free from hazards during transportation.

7.3.1.10. The Specimen collection site shall maintain a record of all samples received.

7.3.1.11. Specimen collection site shall have a procedure for storage of clinical samples if it is not immediately transported to the testing facility (main Laboratory).

7.3.1.12. Once a sample is used, it shall be maintained in the testing laboratory for a specified period of time (or as required by regulation) and at a temperature that ensures stability of the sample in the event the sample is needed for retesting.

7.3.1.13. Specimen collection site report shall follow:

a) All Specimen collection site test result/reports shall have reference (normal) ranges specific for age and gender.
b) Copies or files of reported results shall be retained by the Specimen collection site such that prompt retrieval of the information is

possible. The length of time that reported data are retained shall be 10 years for legal reason minimal errors or loss of patient test results.

c) Quality assured test results shall be reported on standard forms to the physician with the following minimum information:
   - Patient identification (patient name, age, gender,)
   - Date and time of specimen collection
   - The test performed and date of report.
   - The reference or normal range
   - The Specimen collection site interpretation where appropriate,
   - The name and initial of the person who performed the test, and the authorized signature of the person reviewing the report and releasing the results.
   - Address of the sample collection site and the testing laboratory.

d) Specimen collection site results shall be legible, without transcription mistakes and reported only to persons authorized to receive them.

e) The Specimen collection site shall have policies and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic.

f) Policies shall be established which define who may access patient data and who is authorized to enter and change patient results.

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

7.3.1.15. Safe disposal of samples shall be in line with national infection prevention guideline and healthcare waste management guidelines/directives of Ethiopia.

7.3.1.16. No eating, drinking, smoking or other application of cosmetics in Specimen collection site work areas or in any area where workplace materials are handled.

7.3.1.17. No food and drink shall be stored in the Specimen collection.

7.3.1.18. Wearing of protective clothing of an approved design (splash proof), always fastened, within the Specimen collection site work area and removed before leaving the Specimen collection site.

7.3.1.19. The Specimen collection site shall have safety guideline. In addition, the Specimen collection site shall protect the environment and public by assuring the disposal of waste in a legally and an environmentally friendly manner.

7.3.1.20. The Specimen collection site must keep a record of the complaint. The record shall include the nature of the complaint, the date of occurrence, individuals involved, any investigations undertaken by the Specimen collection site and resolution.

7.3.2. Premises

7.3.2.1. The Specimen collection site shall have a well organized space, facilities and equipment to provide services as per the main laboratory needs and clients.

7.3.2.2. The Specimen collection site working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste material to ensure patient and staff protection from unnecessary risks at all time.

7.3.2.3. The Specimen collection site shall have space allocated so that its workload can be performed without compromising the quality of work, and safety of personnel or patient.

7.3.2.4. The Specimen collection site shall have controlled temperature of refrigerator for reagents, blood sample, which affect the analytical results.

7.3.2.5. The Specimen collection site shall be located and designed to

a) Provide suitable, direct access for patients

b) Allow safe disposal of Specimen collection site materials and specimens.

7.3.2.6. Doors shall be located in places where entry and exit is easy and does not interfere with the Specimen collection site benches or equipment.

7.3.2.7. Specimen collection site doors shall not be less than 1 m wide to allow easy access for patients.

7.3.2.8. The specimen collection room shall be separated by wall from the other rooms.

7.3.2.9. The premise for Specimen collection site shall have a minimum of the following rooms

Premises required	**No of room required**	**Area required**
Patient waiting area	1	9sq.m
Main specimen collection room	1	6sq.m
Specimen processing room	1	9sq.m
Staff change room	1	6sq.m
Mini store	1	6sq.m
Reporting, recording and result dispatch area	1	6sq.m

7.3.2.10. The Specimen collection site facilities shall meet at least the following:

a) The Specimen collection site shall have a reliable supply of running water.

b) At least two sinks shall be provided in the specimen collection room, and one for Specimen collection site use and the other reserved for hand washing and at least 1000L reserve tank in case of interruption.

c) Continuous power supply

d) Working surface covered with appropriate materials

e) Suitable stools for the benches. Bench tops shall be impervious to water and resistant to moderate heat and the organic solvents, acids,

alkalis, and chemicals used to decontaminate the work surface and equipment.

f) Internal surfaces, i.e. of floors, walls, and ceilings shall be :
   - Smooth, impervious, free from cracks, cavities, recesses, projecting ledges and other features that could harbor dust or spillage
   - Easy to clean and decontaminate effectively

g) Closed drainage from Specimen collection site sinks (to a septic tank or deep pit)

h) Deep pit to discard contaminated material or access to a simple incinerator

i) Separate toilets/latrines for staff and patients

j) Emergency of safety services such as deluge showers and eye-wash stations, fire alarm systems and emergency power supplies shall be included in the Specimen collection site services design specifications

k) Telephone communication.

7.3.3. Professionals

7.3.3.1. All Specimen collection site services shall be directed by a licensed medical Laboratory technician.

7.3.3.2. In addition, the following shall be the minimum specimen collection site staffing requirements.

a) Two medical Laboratory technician

b) Supportive staff (clerk, cleaner...)

7.3.4. Products

7.3.4.1. Specimen collection site shall be furnished with all items of equipment required for the provision of services.

7.3.4.2. The following minimum equipments and consumables shall be required

a) Micropipettes of different volumes and pipette tips
b) Timer with alarm

c) Centrifuge
d) Refrigerator with timer
e) Roller or mixer
f) Specimen collection tubes of different type
g) Specimen collection cups for urine and stool
h) PC and a printer (if the data management system is electronic)
i) Power surge protectors
j) Mini generator

Section 8: Auxillary Services for Advanced Medical Laboratory

8.1. Infection Prevention

8.1.1. Practices

8.1.1.1. All activities performed for infection prevention shall comply with the national infection prevention guidelines.

8.1.1.2. Infection prevention and control shall be effectively and efficiently governed and managed.

8.1.1.3. The medical laboratory shall identify the procedures and processes associated with the risk of infection and shall implement strategies to reduce infection risk.

8.1.1.4. The medical laboratory shall perform the following infection risk-reduction activities:

a) equipment cleaning and sterilization in particular invasive equipment
b) disposal of infectious waste and body fluids
c) handling and disposal of blood and blood components
d) disposal of sharps and needles
e) Engineering controls, such as positive ventilation systems, biological hoods in laboratories and thermostats on water heaters.

8.1.1.5. The following written policies and procedures shall be maintained:

a) Hand hygiene
   - Standard precautions for hand hygiene
   - Personal protective measures
   - Monitoring and surveillance of hand hygiene practices
b) Transmission-based precautions
   - Contact precautions
   - Droplet precautions
   - Airborne precautions
c) Post-Exposure Prophylaxis programming (PEP) for some communicable diseases like rabies, HIV, meningitis
   - Standard precautions to follow
   - PEP policy
   - Procedures for PEP

d) Environmental infection prevention
   - General medical laboratory hygiene
   - Structural infection prevention
   - Physical medical laboratory organization

e) Waste management
   - Cleaning medical instruments
   - Implementation of a disposal system
   - Handling medical waste
   - Waste removal

8.1.1.6. The following specific standard precautions shall be practiced and the medical laboratory shall have it own guidelines:

a) Hand hygiene shall be performed after touching blood, body fluids, secretions, excretions, and contaminated items, both immediately after removing gloves and between patient contacts.
   - Thorough hand washing
   - Use disinfectants
   - Standard procedure for using anti-septic cleaner

b) The Medical laboratory staff shall consider that every patient is infectious

c) The Medical laboratory shall have personal protective equipment such as gloves, mask, eye protection (goggles) and face shield
   - Gloves shall be worn in the following situations but not limited to:
     - When there is direct contact with exposed wounds, blood, body fluids, body organs or any type of lesion.
     - When drawing blood or handling medical instruments
     - When there is contact with a patient who might be infectious.
     - When handling contaminated items.
     - When cleaning patient areas.
   - Gowns shall be worn when but not limited to:
     - Splatterring of blood or body fluids,
     - Performing waste collection for infectious waste,
     - Handling any type of medical waste,
   - Masks, goggles, or other types of face shields shall be worn when but not limited to:
     - Splattering of blood or body fluids to the face,
     - Handling biohazardous
     - Performing waste collection for hazardous or non-hazardous waste.

d) Any type of face shield that is apparently soiled or splattered with body fluids shall be washed and sterilized with a disinfectant.
e) Procedures shall be developed and implemented cleaning, and disinfecting environmental surfaces especially frequently touched surfaces by patients.
f) Used needles shall not be recapped, bent, broken, or manipulated by hand. Single handed scoop technique shall only be used when recapping is required.
g) Safety features shall be used when available and used "sharps" shall be placed in a puncture-resistant container specially designated bin for hazardous waste.

8.1.1.7. There shall be transmission-based precautions and the medical laboratory shall have its own guideline for the followings:

a) Contact precautions
- Shall be taken to reduce the risk of transmission through direct and indirect contact with an infectious patient.
- Shall be taken when a patient is known to have a specific disease that is easily transmitted by direct contact.
- Shall be taken for known multi-drug resistant disease, such as some forms of TB.
- Shall exercise strict barrier precautions for any type of contact with the patient and their surrounding environment.
- Do not share medical equipment between patients before sterilization
- Clean surfaces used by patients on daily basis
- Wash linens and surfaces after patient discharge
- Clean medical equipment

b) Droplet precautions
c) Airborne precautions (for diseases like SARS ,TB, Swine flu, etc)
- Negative pressure in relation to surrounding areas
- A minimum of 6-9 air exchanges per hour
- Air discharged outside the building and away from intake ducts, or through a high-efficiency filter if re-circulated
- Door kept closed whether or not patient is in the room
- After discharge door kept closed until sufficient time has elapsed to allow removal of airborne organisms
- Patient confined to room
- Room shall have toilet, hand washing and bathing facilities

8.1.1.8. Each Medical laboratory site shall train all staff on how to minimize exposure to blood-borne diseases. These include:

a) Immediate first aid
b) Reporting exposures
c) Assign area for starter packs 24-hours access per day
d) Counseling and testing for exposed staff
e) Reporting and monitoring protocols
f) Evaluate PEP program

8.1.1.9. The infection prevention committee or designate shall have written protocols, procedures and shall oversee the following activities and this shall be documented:

a) Developing the health facility annual infection prevention and control plan with costing, budgeting and financing
b) Monitoring and evaluating the performance of the infection prevention program by assessing implementation progress as well as adherence to IPC practice
c) Formulating a system for surveillance, prevention and control of nosocomial infections.
d) Reviewing surveillance data, reporting findings to management and other staff and identifying areas for intervention
e) Assessing and promoting improved IPC practice within the Medical laboratory
f) Developing an IEC strategy on IP for health-care workers
g) Ensuring the continuous availability of supplies and equipment for patient care management
h) Monitoring, providing data and measuring the overall impact of interventions on reducing infection risk

8.1.1.10. The Medical laboratory shall provide regular training on infection prevention and control practice to staff, patients and as appropriate, to family and caregivers

8.1.1.11. The following training guidelines shall be available

a) Prevention of the spread of infections
b) Improving the quality of client service
c) Promoting safe environment for both patients and staff

8.1.1.12. The Medical laboratory shall have procedures in place to minimize crowding and manage the flow of visitors. This shall include

a) Patient crowd control
b) Assess urgent and non-urgent cases
c) Patient sign-in
d) Caregiver control.

8.1.2. Premises

8.1.2.1. The medical laboratory shall have a dedicated office for IP officer,

8.1.2.2. The medical laboratory shall have a room or area for temporary storage of waste containers,

8.1.2.3. The Medical laboratory shall have a centralized sterilization room

8.1.2.4. The medical laboratory shall have incinerator with ash and burial pits.

8.1.3. Professionals

8.1.3.1. The Medical laboratory shall have a designated staff to serve as IP infection prevention and control officer.

8.1.3.2. The officer shall be a licensed IP trained laboratory technologist or nurse and knowledgeable of infection prevention principles and health care epidemiology.

8.1.4. Products

8.1.4.1. The Medical laboratory shall have the following adequate supplies and equipment needed for infection prevention and control practice.

a) Waste management equipment and supplies:
- Safety boxes
- Garbage bins
- Wheelbarrows
- Large garbage bin
- Plastic garbage bags

b) Cleaning
- Mop
- Bucket
- Broom
- Dust mop
- Cleaning cloth
- Detergent
- Bleach

c) Instrument processing:
- Autoclaves and steam sterilizers
- Test strips
- Boiler

- Oven
- Storage shelves for the medical equipment
- Chemicals & disinfectants: 0.5% chlorine solution (diluted bleach)
- Brushes (tooth brush for small items)

d) Hand hygiene

- Sinks (ward & other areas)
- Water container with faucet
- Soap dispenser
- Alcohol based hand rub
- Personal Towels
- Paper Towels

e) Personal Protective Equipment

- Heavy duty glove
- Surgical glove
- Latex or Nitrile glove
- Eye shield
- Goggle
- Visors
- Dust mask
- Respiratory mask
- Other types of face mask
- Plastic apron
- Other types
- Boots
- Other protective shoes
- Caps
- Face shield

8.2. Sanitation and Waste Management

8.2.1. Practices

8.2.1.1. Medical laboratory environment shall ensure the following conditions:

a) Clean sanitation and safe environment,
b) Access to continuous, safe and ample water supply

8.2.1.2. There shall be written procedures to govern the use of sanitation techniques in all areas of the Medical laboratory.

8.2.1.3. If the laboratory has ground water source, there shall be a written policy and procedures for ground water treatment,

8.2.1.4. Infectious and medical wastes shall be handled and managed according to the recent Health Care Waste Management National Guidelines/Directives.

8.2.1.5. Infectious and non infectious medical waste contained in disposable containers shall be placed temporarily for disposal or transport in leak proof drums, pails or portable bins. The containment system shall be leak proof, have tight-fitting covers and be kept clean and in good repair.

8.2.1.6. Reusable containers for infectious medical waste and general medical waste shall be thoroughly washed and decontaminated each time emptied according to the recent Health Care Waste Management National Guidelines/Directives

8.2.1.7. Reusable pails, drums, or bins used for containment of infectious waste shall not be used for containment of waste to be disposed of as noninfectious waste or for other purposes except after being decontaminated by procedures described in the latest Health Care Waste Management National Guidelines/Directives.

8.2.1.8. Segregation of health care waste shall includes the following procedures:

a) Separate different types of waste as per the guideline,
b) The Medical laboratory shall provide colored waste receptacles specifically suited for each category of waste,
c) Segregation shall take place at the source.
d) There shall be 3 bin systems used to segregate different types of waste in the Medical laboratory:

Segregation category	Color	Container
Non risk waste	Black	bag or bin
Infectious waste	Yellow	bag or bin

Sharp waste	Yellow	safety box
Heavy Metal	Red	secure container
Chemical bottles	White	bag or bin
Hazardous chemical wastes	yellow	bag or bin

8.2.1.9. Medical waste shall be disposed according to Health Care Waste Management National Guidelines/Directives by one of the following methods:

a) By incineration,
b) By sanitary landfill,
c) By burial at an approved landfill,
d) Chemical sterilization,
e) Gas sterilization (shall be handled safely).

8.2.1.10. The Medical laboratory shall have an organized waste disposal and/ or removal system and shall ensure the safe handling of all wastes.

8.2.1.11. Chemical and radioactive waste shall not be disposed of as solid waste or medical waste, & shall be disposed as per appropriate national guideline (Ethiopian Radiation Protection Authority requirements).

8.2.1.12. The laboratory shall have a medical waste management plan which includes at least the following:

a) Temporary storage of medical waste,
b) Segregation of medical waste,
c) Transport of medical waste,
d) Disposal of medical waste,

8.2.1.13. The Medical laboratory shall routinely clean and sanitize waiting areas at least twice daily and more when ever needed. Areas where there is blood splash shall be cleaned immediately.

8.2.1.14. The Medical laboratory shall ensure appropriate ventilation system.

8.2.1.15. In order to maintain a clean and safe environment, the Medical laboratory shall have an organized method for the transport and washing of linens.

8.2.1.16. Housekeeping items shall be cleaned and sanitized regularly.

8.2.1.17. The laboratory shall have Sewage disposal plan which shall fulfill the following conditions (according to Health Care Waste Management National Guidelines/Directives):

a) A functional sewerage system,
b) Dispose of sanitary waste through connection to a suitable municipal sewerage system,

c) Flush toilet system,
d) A designated waste storage room for solid waste &/ or a septic tank for liquid waste,
e) Written procedures defining instrument processing procedures (disinfection and sterilization).

8.2.1.18. The laboratory shall have Plumbing system that fulfill the following conditions:

a) An approved municipal water system,
b) An approved method of supplying hot water,
c) Supply piping within the building shall be according to the requirements in the standard mentioned under the physical facility,

8.2.1.19. The medical laboratory shall have the following supportive sanitation measures:

a) Clean water where there is no plumbing,
b) Hand hygiene practice,
c) Sterilization of medical instruments,
d) Alternatives to protective equipment.

8.2.2. Premises

8.2.2.1. The Medical laboratory sanitary system shall have:

a) Adequate flushing toilets and hand washing basins,
b) Plumbing setup stores,
c) Sanitary office,
d) Incinerator (if it is allowed to this laboratory by the national waste management and disposal directives),
e) Plot of land for Safe ash pit, Burial pit, Garbage bins,
f) Secured area for solid waste accumulation.

8.2.3. Professionals

8.2.3.1. Medical laboratory sanitation service shall be administered together with infection prevention activities.

8.2.3.2. In addition, the medical laboratory shall have:

a) Housekeeping staff such as cleaners and waste handlers,
b) Gardeners,

8.2.3.3. The Medical laboratory shall officially designate staff in charge of handling waste on a regular basis.

8.2.3.4. The assigned staff shall be responsible for the collection and disposal of waste products in the Medical laboratory.

8.2.3.5. Continuing education shall be provided to all personnel engaged in sanitation activities on the relevant procedures.

8.2.3.6. Staff shall be oriented on personal protection methods.

8.2.4. Products

8.2.4.1. The Medical laboratory shall have the following equipment and supplies required for sanitation activities but not limited to:

a) Incinerator
b) Safety boxes
c) Leak proof containers for waste
d) Trolley to transport waste
e) PPE (personal protective equipments)
f) Autoclave.
g) Pressure cooker/dry oven.
h) Cleaning supplies (detergents, disinfectants and other cleaning solutions etc).
i) Mops and dust bins

8.3. Housekeeping, Laundry and Maintenance Services

8.3.1. Practices

8.3.1.1. The housekeeping service shall have the following activities.

a) Basic cleaning such as dusting, sweeping, polishing and washing
b) Special cleaning of
    - Different types of floors
    - Wall & ceiling
    - Doors & windows
    - Furniture & fixtures
    - Venetian blinds
c) Cleaning and maintenance of toilet.
d) Water treatment, filtering & purification.

8.3.1.2. Maintain an adequate supply of clean white coat and gauns at all times

8.3.1.3. In the housekeeping service, the types and sources of offensive odors shall be identified, controlled and removed immediately

8.3.1.4. Collection, transportation and disposal of Medical laboratory wastes shall be supervised and controlled

8.3.1.5. The safety of fire, electrical and natural hazards in the risk areas in the Medical laboratory shall be supervised and controlled and shall work closely with Medical laboratory fire brigade and safety committee.

8.3.1.6. The designee shall identify, supervise and organize the control and eradication of pests, rodents and animal nuisance in the Medical laboratory.

8.3.1.7. The housekeeping staffs shall create pleasant environment to patients, staffs and visitors

8.3.1.8. The housekeeping staffs shall ensure proper lighting and ventilation in different Medical laboratory areas.

8.3.1.9. Regular surveillance of overhead and underground tank, proper cover, regular chlorination and cleaning shall be undertaken

8.3.1.10. The infection control measures shall be carried out in accordance with the Medical laboratory infection prevention standard

8.3.1.11. There shall be reserve electrical generator for power supply for continuous 24 hours.

8.3.1.12. Potable water and electrical services shall be available 24 hours a day and 365 days a year through regular or alternate sources.

8.3.1.13. There shall be a plant safety maintenance organization as described below:

a) A multidisciplinary safety committee that develops a comprehensive laboratory-wide safety program and reviewed.
b) A mechanism to report all incidents, injuries and safety hazards to the safety committee.
c) The multidisciplinary safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.

8.3.1.14. Facility maintenance services

a) The building maintenance service shall have written policies and procedures that are reviewed for routine maintenance, preventive maintenance and renovation maintenance.
b) The standby emergency generator shall be checked weekly, tested under load monthly, and serviced in accordance with accepted engineering practices.
c) Floors, ceilings, and walls shall be free of cracks and holes, discoloration, residue build-up, water stains, and other signs of disrepair.
d) Routine inspections of elevators shall be conducted.

8.3.1.15. Construction and renovation

a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.
b) The infection control program shall review areas of potential risk and populations at risk.

8.3.1.16. There shall be written protocols and procedures for medical laboratory equipment maintenance including:

a) Plan for equipment maintenance (both preventive and curative), replacements, upgrades, and new equipments
b) Safe disposal procedures
c) An effective tracking system to monitor equipment maintenance activity.
d) A monitoring method that ensures diagnostic equipment operates with predicted specificity and sensitivity.

8.3.1.17. The maintenance personnel including the management of the laboratory shall take basic trainings on the following issues and this shall be documented.

a) Building fabrics and utilities
b) Building services and economics
c) Planning maintenance demand
d) Preventive and routine maintenance practice

e) Maintenance with regard to IP and hygiene

8.3.1.18. Fire and emergency preparedness

a) The laboratory shall comply with the National Fire Protection standard
b) All employees, including part-time employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and evacuation from the building as part of their initial orientation and shall receive printed instructions on procedures and at least annually thereafter.
c) A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall.
d) Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydro-tested as required by manufacturer's instructions; and labeled with the date of the last inspection.
e) Fire detectors, alarm systems, and fire suppression systems shall be inspected and tested at least twice a year by a certified testing agency. Written reports of the last two inspections shall be kept on file.
f) There shall be a comprehensive, current, written preventive maintenance program for fire detectors, alarm systems, and fire suppression systems that includes regular visual inspection. This program shall be documented.

8.3.1.19. Housekeeping equipment or supplies used for cleaning in contaminated areas shall not be used in any other area of the laboratory before it has been properly cleaned and sterilized.

8.3.1.20. All areas of the laboratory, including the building and grounds, shall be kept clean and orderly.

8.3.1.21. There shall be frequent cleaning of floors, walls, woodwork and windows.

8.3.1.22. The premises shall be kept free of rodent and insect infestations.

8.3.1.23. Accumulated waste material and rubbish shall be removed at frequent intervals.

8.3.1.24. No flammable cleaning agents or other flammable liquids or gases shall be stored in any janitor's closet or other area of the laboratory except in a properly fire rated and properly ventilated storage area specifically designed for such storage.

8.3.1.25. If the laboratory does not have its own housekeeping and maintenance services; it may have a contract agreement with external organizations.

8.3.1.26. If the laboratory has given the housekeeping and maintenance services to a contarctor, the contractual agreement shall be filed and made accessible in the laboratory premises. In such cases the laboratory shall make sure that the standards mentioned for housekeeping and maintenance are adhered by the contractor.

8.3.2. Premises

8.3.2.1. There shall be separate space provided for the storage of housekeeping equipment and supplies

8.3.2.2. Office shall be available for the maintenance and the housekeeper.

8.3.2.3. Adequate space shall be available for janitor's closets and cleaning equipment & supplies.

8.3.2.4. Exits, stairways, doors and corridors shall be kept free of obstructions.

8.3.2.5. The laboratory shall have an alternate emergency power supply. If such emergency power supply is a diesel emergency power generator, there shall be enough fuel to maintain power for at least 24 hours.

8.3.3. Professionals

8.3.3.1. The designated officer shall plan, organize, co-ordinate, control and monitor all housekeeping and maintenance activities.

8.3.3.2. The housekeeping and maintenance personnels shall take basic trainings on the following issues and this shall be documented in their personal profile.

a) Basic principles of sanitation and peculiarity to laboratory environment.
b) Basic principles of personal hygiene
c) Basic knowledge about different detergent and disinfectants
d) Basic knowledge about cleaning equipments operation techniques and their maintenance.
e) Different processes of water treatment & purification, removing bacteria.
f) Basic principles of ventilation, composition of air, air flow, humidity and temperature.
g) Common types of odors and their sources of origin, identification and control.
h) Removal and control technique of different types of odors.
i) Various equipments and materials used for odor control operation.
j) Medical waste, source and generation of waste
k) Hazards of medical waste to population and community.
l) Principles of collection of different types of medical wastes

m) Operational procedures of equipments
n) Safety measures in operation
o) laboratory lay out, configuration work, flow of men, material and equipment in different areas. Air, water, noise, pollution, causes of pollution and their control and prevention.

8.3.3.3. In summary, if the service is not outsourced, the laboratory shall have

a) Designated personnel for housekeeping,
b) General maintenance personnel (electrician, plumber, painter, building maintenance technician and
c) Biomedical equipment maintenance technician.

8.3.4. Products

8.3.4.1. There shall be appropriate tools and testing equipments for medical equipment maintenance, calibration and validation.

8.3.4.2. The laboratory shall have the following tools, equipment & materials for housekeeping services.

a) Reserve electrical generator
b) Floor cleaning brush air
c) Floor wiping brush
d) Hockey type brush
e) Counter brush.
f) Ceiling brush
g) Glass cleaning / wiping brush.
h) Scrappers
i) Dustbins paddles.
j) Waste paper basket.
k) Plastic Mug
l) Plastic Bucket
m) Plastic drum
n) Wheel barrow
o) Water trolley
p) Ladder
q) Scraping pump
r) Spraying pump
s) Flit pump.
t) Rate trapping cage
u) Gum boots
v) Gown, Masks & Gloves
w) Torch
x) Manual sweeping machine.
y) Floor scrubbing/polishing machine
z) Wet vacuum cleaner.
aa) Dry vacuum cleaner portable
bb) Fumigation machine (Oticare)
cc) Bed pan washer.
dd) Cleaning material
ee) Deodorants & disinfectant
ff) Laundry cleaning material
gg) Insecticides & rodenticides
hh) Stain removal

Section Nine: Physical Facility Standards

9.1. General Requirements

9.1.1. A Medical laboratory shall fulfill minimum standards for the building which contains the facilities required to render those services contemplated in the application for license.

9.1.2. The Medical laboratory premises shall have dedicated territory/ compound with entrances.

9.1.3. Rooms shall have adequate light and ventilation.

9.1.4. Rooms shall promote patient dignity and privacy.

9.1.5. The laboratory premises shall ensure the availability of continous water supply & functional hand washing basin.

9.1.6. The arrangement of rooms shall consider proximity between related services.

9.1.7. Glass doors shall be marked to avoid accidental collision.

9.1.8. Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.

9.1.9. The medical laboratory facilities shall be well marked and easily accessible for persons with disability.

9.1.10. The medical laboratory shall have fire extinguisher placed in visible area.

9.1.11. The office layout shall be arranged in a way that ensures patient independence and comfort by label and service proximity.

9.1.12. The premises of medical laboratory shall have ceilings.

9.1.13. The Internal surfaces of the laboratory (floors, walls, and ceilings) shall be:

a) Smooth, impervious, free from cracks, recesses, projecting ledges and other features that could harbor dust or spillage,

b) Easy to clean and decontaminate effectively,

c) Constructed of materials that are non-combustible or have high fire-resistance and low flame-spread characteristics.

9.1.14. There shall be a waste disposal mechanism for all categories of wastes generated by the medical laboratory.

9.2. Site Selection Requirements

9.2.1. The entrance to the medical laboratory shall be clear, easy to road access,

9.2.2. The entrance to the medical laboratory shall be away from highways, railways, construction areas,

9.2.3. The medical laboratory should be located away from unordinary conditions of undue noises, smoke, dust or foul odors, and shall not be located adjacent to railroads, freight yards, grinding mills, chemical industries, gas depot and waste disposal sites.

9.2.4. Medical laboratory shall be provided with road access, water supply, electric city and communication facilities.

9.2.5. Medical laboratory should be well landscaped, therapeutic appealing scenery, attractive with green areas/beautiful trees and possible outdoor recreation facilities.

9.3. Construction Requirements

9.3.1. The Authority shall be consulted before commencement of any physical development planned for new laboratory facility; or remodeling of existing building for conformity to the standards.

9.3.2. Plans and specifications for construction or remodeling shall comply with Ethiopian Building Code.

9.3.3. The authority may be consulted on construction processes and milestones for conformity to the standards.

9.3.4. Upon completion of construction the authority shall inspect and issue an approval for operation of the medical laboratory if all the findings are in conformity to the standards.

9.3.5. There shall be approval from the authority when buildings constructed for other purposes are used for the operation of medical laboratory.

9.3.6. The construction shall comply with the following codes and guidelines to provide a safe and accessible environment:

a) The Ethiopian Building Proclamation 624/2009;
b) The Ethiopian Standard Building Code;
c) Life Safety Code (National Fire Protection Code);
d) National Electrical Design Code;
e) The Ethiopian Disability Code;
f) Other codes –Sanitation codes, environmental protection laws, water codes

9.3.7. Ways, paths and corridors to and between Medical laboratory buildings shall be well paved, smooth and friendly for people with disability.

9.3.8. Selected construction materials shall be used for special services in conformity to the Ethiopian Building Code.

9.4. Building Space and Elements

9.4.1. The medical laboratory shall have secured compound with dedicated entrance. If the medical laboratory is situated in multipurpose multi stair building all service units shall be together and accessible horizontally.

9.4.2. All horizontal and vertical circulation areas that include stairs, doors, windows, corridors, exits and entrances of the laboratory shall be kept clear and free of obstructions.

9.4.3. Size of rooms and space allocation shall consider room loadings based on the number of staff and clients involved, usable medical equipments available, available furniture and applicable functions.

9.4.4. The openings to the corridor shall be designed to allow easy movement of wheelchair.
9.4.5. The circulation ways and sub corridors shall be a minimum 2m wide.
9.4.6. Doors: Doors shall be able easy to open and close,
9.4.7. Doors swing into corridors shall be avoided.
9.4.8. Walls and ceilings of all rooms shall be suitable for easy washing.
9.4.9. Floors of the medical laboratory shall be easily cleanable, smooth, non- adsorptive, non-slippery.
9.4.10. Rooms shall be smooth, non-adsorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.
9.4.11. All walls and ceiling finishing materials used shall have a 1-hour fire rating (One hour rated products offer more than "one hour's" worth of fire protection).
9.4.12. Sanitary Finishing
    a) Toilet rooms shall be fitted with functional flush.
    b) Toilet rooms shall have floors, walls and ceilings fitted with washable finishing materials.
    c) Floors and walls penetrated by pipes, ducts, siphons and conduits shall be tightly sealed & smooth.

a) Electrical Finishing
    a) Room light luminescence shall be bright enough for staff activities
    b) All electrical fixtures inlets, outlets, appiances shall fulfill Ethiopia Electrical Safety requirements and if applicable fitted with safety guards,

9.4.13. **Outdoor Areas:** the outdoor area shall be equipped and situated to allow safe movement of clients, staff and visitors.
9.4.14. **Windows**: windows shall comply with LUX requirements of room space without compromising room temperature and ventilation.
a) Windows shall be a minimum of 50 cm wide x 100cm high. However, dimension shall be adjusted for the climate and bed capacity of the room.
b) Windows for medical laboratory shall be fitted to swing/ open to outside. In areas where security/ safety grids applied or wire mesh fitted, opening to the room can be allowed.
c) Windows for medical laboratory shall have open, fitted with wire mesh, at top portion for cross ventilation & uninterrupted circulation of air. Advanced technology can be used that maintain the air circulation.
9.4.15. **Vertical Circulation:** All functioning rooms shall be accessible horizontally.
a) Medical laboratory where functional units are at different floor shall have a mechanism of accessing all the functioning rooms horizontally- either by stairs, ramp or elevator.
b) Stairs: All stairways and ramps shall have handrails and their minimum width shall be 120cm.
c) All stairways shall be fitted with non slippery finishing materials
d) All stair threads, risers and flights shall comply with the Ethiopia Building proclamation.

e) Elevators (optional): Minimum cab dimensions required for elevator is 195cm x 130cm inside clear measurements and minimum width for hatchway and cab doors shall be 100cm.

f) Ramp (Optional): Ramps shall be designed with a slope of 6 to 9 percent, minimum width of 120 cm and the landing floor of 240cm wide on both sides.

9.4.16. Fire Safety Considerations:

a) One-Story Building: Wall, ceiling and roof construction shall be of 1-hour fire resistive construction as defined by National Fire Code. Floor systems shall be of non-combustible construction.

b) Multi-Story Buildings: Must be of two-hour fire resistive construction as defined in National Fire Code.

9.4.17. **Parking areas**:

a) Parking space shall have a clear mark for staff, clients and visitors with separate 10% of it for person with disability parking all as per Ethiopia Building Proclamation and building code.

b) General services of the medical laboratory that require loading unloading docks, heavier truck movement and temporary truck parking place shall be available.

c) The parking space shall not cross pedestrian walkways, if it is mandatory to cross, proper precaution measures such as Zebra cross, Speed Breaker, guiding notice and traffic stopping culverts or signals shall be provided.

9.5. Building Systems

Medical laboratory shall have building systems that are designed, installed and operated in such a manner as to provide safety, comfort and well being of its customers.

9.5.1. Water supply and plumbing:

a) Medical laboratory connected to municipal water system shall maintain the patency of the system, whenever there is any repair or modification to the underground lines and to the elevated tank or to the well or pump.

b) Medical laboratory connected to its own separate water supply system shall have certificate for safety by the concerned body.

c) Water reserves used in medical laboratory shall be protected from external contamination, cleaned and washed every 6month.

d) Supply piping within the building shall be in accordance with plumbing standards. Special care must be taken to avoid use of any device or installation which might cause contamination of the supply through back-siphonage or cross connections or the water distribution system shall be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

9.5.2. Sewerage and Waste Processing Systems

a) The medical laboratory shall maintain a sanitary and functioning sewage system in accordance with the national healthcare waste management guidelines and Ethiopian building code.

b) In addition, the facility shall fulfill the following requirements;

- The medical laboratory shall dispose all sanitary wastes produced in the laboratory through connection to a suitable municipal sewerage system. septic tank,
- Waste segregation shall be done for hazardous wastes before it is released to the municipal or private sewage system.
- The medical laboratory shall provide secluded secured area to collect, contain, process, and dispose of medical and general waste produced.
- The medical laboratory shall have incinerator with combustion level as recommended by the national healthcare waste management guidelines.

9.5.3. Ventilating and Air-Conditioning Systems:

a) Airflow shall move from clean to soiled locations. Air movement shall be designed to reduce the potential of contamination of clean areas.
b) Medical laboratory shall provide adequate ventilation and/or clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patients and employees.
c) There shall be a mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens and similar rooms at ten air changes per hour.
d) If mechanical ventilation system(s) is applied, the air changes per hour (hereafter "ACH") shall be as follows:
   - Care and treatment areas: five (5) ACH;
   - Procedure and airborne isolation areas: fifteen (15) ACH; &
   - Operating rooms: twenty (20) ACH.
e) Toilets, janitors' closets, soiled linen and similar areas shall have six (6) air changes per hour.
f) Areas occupied by patients shall have two (2) air changes per hour.

9.6. Electrical System

9.6.1. All facilities shall provide the minimum average illumination levels as follows or as per the Ethiopian Electrical Design Code:

a) General purpose areas: five (5) foot candles;
b) General corridors: ten (10) foot candles;
c) Personal care and dining areas: twenty (20) foot candles;
d) Reading and activity areas: thirty (30) foot candles;
e) Food preparation areas: forty (40) foot candles;
f) Hazardous work surfaces: fifty (50) foot candles;
g) Care and treatment locations: seventy (70) foot candles;
h) Examination task lighting: one hundred (100) foot candles;
i) Procedure task lighting: two hundred (200) foot candles;
j) Surgery task lighting: one thousand (1000) foot candles; and
k) Reduced night lighting in patient rooms and corridors.
l) Three hours Emergency light shall be provided in exit, entry and in all landing of staircase.

9.6.2. **Essential Power System**:

a) The electric installation in the medical laboratory shall fulfill the criteria set by ELPA,
b) The electric outlets shall be up to the safety standard of the country,
c) The medical laboratory shall have functional generator with fuel and assigned attendant.
d) Solar panels can also be used as backup power option where appropriate..

9.7. Fire Protection System

9.7.1. The medical laboratory shall comply with the National Fire Protection "Life Safety Code".

9.7.2. All employees, including part-time and contract or temporary employees shall be trained in procedures to be followed in the event of a fire and instructed in the use of fire-fighting equipment and evacuation from buildings as part of their initial orientation and at least annually thereafter.

9.7.3. All employees, including part-time and contract or temporary employees shall receive printed instructions on procedures to be followed in case of emergency.

9.7.4. A written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes, and fire extinguishers shall be posted conspicuously on a wall.

9.7.5. Fire extinguishers shall be visually inspected at least monthly; fully inspected at least annually, recharged, repaired and hydro-tested as required by manufacturer's instructions; and labeled with the date of the last inspection.

9.8. Medical Gas System, if applicable

9.8.1. The medical laboratory shall maintain the safety of medical gas and vacuum if provided centrally installed system or by means of portable equipment.

9.8.2. The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems shall comply with the requirements of the Life Safety Code (National Fire Protection agency proclamation).

9.8.3. The medical laboratory shall identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The medical laboratorys shall document such approvals for review and reference.

9.9. General Purpose Facilities

9.9.1. The medical laboratory shall provide and maintain a safe environment for the public and staff.

9.9.2. Existing and new facilities shall comply with the physical facility standards contained in this chapter.

9.9.3. Administrative Offices shall be located separately from care and treatment areas and shall be clearly labeled. It includes;

a) Administration office.

b) Finance and business office
c) Staff room(s) with toilet separate for male and female
d) Staff cafeteria
e) Visitors cafeteria (Optional)

9.9.4. **General Storage areas.** There shall be a two hour fire rated lockable room large enough to store.

9.9.5. **Maintenance Area**: Sufficient area for performing routine maintenance activities shall be provided and shall include office for maintenance engineer.

9.9.6. **Incinerator:** As per the national standards for incineration, the medical laboratory shall have functional incinerator with dedicated ash pit. The incinerator area shall be secured with fence and gate.

9.9.7. **Janitor rooms:** The medical laboratory shall have a separate room/ cubicle for janitors.

9.9.8. **Green area:** The medical laboratory shall dedicate at least 10% of the total compound for green area.