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STANDARD**

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Primary Clinic - Requirements

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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).

A Primary clinic 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.

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

SECTION ONE: GENERAL

1. Scope

- 1.1. This Ethiopian standard shall be applicable for all primary clinics 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 primary clinics.
- 1.3. Requirements of a primary clinic are stipulated under section two to twelve 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 primary clinic staff who is responsible for a given service

3.7

Primary Clinic

Shall mean a health facility in the category of primary healthcare that provides curative, preventive and promotive services at ambulatory basis only as indicated in this standard.

SECTION TWO: LICENSURE

2.1. General

- 2.1.1 This standard provides minimum requirements for the establishment and maintenance of primary clinic in order to protect the public interest by promoting the health, welfare, and safety of individuals.
- 2.1.2 No primary clinic 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 clinic shall not deliver those services stated by the license.

2.2. Application for licensure

- 2.2.1. No person shall operate a Primary clinic in Ethiopia without being licensed as required by appropriate law and this standard.
- 2.2.2. Any person desiring to operate a Primary clinic shall:
 - a) Complete the application form which shall contain information stated under article 2.2.6;
 - b) Pay the prescribed license fee; and
 - c) Provide any information or document stated on the application form.
- 2.2.3. A person desiring to operate a Primary clinic shall consult the appropriate organ on the plant design conformity with this standard before starting construction or renovation work.
- 2.2.4. An application for the initial licensure of primary clinic shall be submitted to the appropriate organ no later than ninety (90) days prior to the stated date of operation.

- 2.2.5. The first pre-licensing inspection shall be conducted by the appropriate organ upon application without service fee. In case of failure to comply with this 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 this standard for the third time, its application for licensure shall be suspended for three months.
- 2.2.6. The application for a Primary clinic license shall state services to be given and shall furnish other information as may be required by the appropriate organ including,
- a) Identification of the applicant/owner (name, citizen, address) and evidence for ownership (if the applicant is an authorized delegate, written delegation letter shall be submitted);
 - b) For existing health facility, name of owner and license number;
 - c) Name and location of the primary clinic;
 - d) Surrounding area of the primary clinic;
 - e) Types of services to be rendered;
 - f) Name, qualification, nationality and license copy of licensee;
 - g) Staffing (Number, type, qualification, work experience & original release and license copy of all health professionals);
 - h) Type of ownership: (Governmental, non- governmental, private for profit, private for non- profit, other governmental);
 - i) Number and type of administrative staff;
 - j) Physical facility design and its description;
 - k) Proposed use of idle space; (if any)
 - l) Owner of the building; (if rental, the agreement paper shall be submitted);
 - m) And other requirements which shall be made in close consultation with the stakeholders and according to the rules and regulations of the region and the country as well.
- 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 healthcare services are fit and adequate in accordance with this standard.
- 2.2.8. The license issued by the appropriate organ shall not be applicable for use by any other person or at any facility other than the designated one in the license. Whenever there is change in licensee or premises, the license shall be updated.
- 2.2.9. The license issued to a primary clinic in a specified /address cannot be used for another facility.

2.3. Initial/ New Licensure

- 2.3.1. Every primary clinic shall have a separate license. The 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. A primary clinic license shall specify the following:
 - (a) The name, and professional license and registration number of the licensee;
 - (b) The name and address of the primary clinic;
 - (c) Ownership of the primary clinic;
 - (d) Name of the owner,
 - (e) License number, issuance and expiration dates of the license.
 - (f) Signature and stamp of the appropriate organ and
 - (g) Notices/reminders prepared by the appropriate organ
- 2.3.3. Prior to initial licensure of the primary clinic, the appropriate organ shall conduct an on-site inspection to determine compliance with the applicable laws and standards governing the primary clinic.
- 2.3.4. The appropriate organ shall give a written report of the findings to the primary clinic upon the conclusion of the inspection.
- 2.3.5. A primary clinic with deficiencies shall correct them and submit written proof of correction of deficiencies.
- 2.3.6. The appropriate organ shall conduct a follow-up inspection to determine correction of deficiencies cited within ten (10) days following the one month (30 days) correction period or upon submission of notification from the primary clinic that the deficiencies have been corrected.
- 2.3.7. The appropriate organ shall deny the application for licensure to a primary clinic that has not corrected deficiencies. The applicant shall reapply for licensure when deficiencies are corrected.
- 2.3.8. The appropriate organ shall conduct an unannounced on-site inspection of the primary clinic shortly after the beginning of operation to assess the primary clinic's continued compliance with the laws and standards governing primary clinics.
- 2.3.9. The appropriate organ shall issue a replacement license where the originally issued license has been confirmed as lost or destroyed upon submission of an application supported by an affidavit.
- 2.3.10. The original license shall be posted in a conspicuous place at reception at all times.

2.4. Requirements for License Renewal

- 2.4.1. A license, unless suspended or revoked or under consideration in pending case, shall be renewable annually and the primary clinic shall submit an application for license renewal to the 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 appropriate organ filling the form prescribed by the appropriate organ ;

(b) Pay the prescribed license renewal fee;

(c) Provide copies of professional licenses for all permanent and temporarily employed health professionals of the clinic and

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

2.4.4. The appropriate organ shall renew a license for a primary clinic in substantial compliance with the applicable laws and this standard.

2.4.5. When the licensee can not avail himself for a period not more than 30 days for any reason, he/she shall assign an equivalent professional temporarily but with prior notification to the appropriate organ. If the licensee is going to be absent for more than the stated period, he/she shall replace the license.

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

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

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 primary clinic as the 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 licensee shall inform the appropriate organ any change in operation. Change of operation means any alteration of services that is substantially different from that reported on the primary clinic's most recent license application.

2.5.5. Any transfer as to person or place without the approval of the appropriate organ shall cause the immediate forfeiture of the license. That is the license shall not be assignable or transferable and shall be immediately void if the primary clinic 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 primary clinic is contemplated, the primary clinic shall notify the appropriate organ in writing and give the name and address of the proposed new owner.

- 2.5.7. When change of licensee of a primary clinic is contemplated, the primary clinic shall notify the 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 appropriate organ may suspend or revoke a license or order closure of a service or unit within the primary clinic, cease admissions to a primary clinic, order removal of patients from a primary clinic where it finds that there has been a substantial failure to comply with this standard.
- 2.6.2. Without prejudice to grounds of suspension provided under relevant laws, the appropriate organ shall suspend the license for 3 to 12 months in any of the following grounds:
- (a) Where the primary clinic is legally suspended;
 - (b) Where the primary clinic fails to practice medical ethics;
 - (c) Where the primary clinic engages in rendering services which are outside the competence of the clinic for which the license is obtained;
 - (d) Where the primary clinic fails to allow inspection pursuant to the law and this standard;
 - (e) When the primary clinic allows a professional who has been suspended by appropriate organ from practicing his profession;
 - (f) When the primary clinic fails to implement or fulfill comments and corrections given by the appropriate organ;
 - (g) When the primary clinic shown any act which constitutes a threat to the public health or safety;
 - (h) When the primary clinic fails to observe laws relating to health services and this standard;
 - (i) When the primary clinic fails to submit relevant information required under this standard.
- 2.6.3. Without prejudice to grounds of revocation provided under relevant laws, the appropriate organ shall revoke the primary clinic license from one to two years on any of the following grounds:
- (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 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 primary clinic 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 this standard;
 - (h) Where the primary clinic is legally closed or ceases operation;
 - (i) Where the primary clinic is found operating while suspended by appropriate organ;
 - (j) Where the primary clinic is found operating out of the scope of services stated under this 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 primary clinic must notify each patient and the patient's physician the intended closure.
- 2.6.5. Each license in the licensee's possession shall be the property of the appropriate organ and shall be returned to the 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 appropriate organ determines that operational or safety deficiencies exist, it may require that the service of the primary clinic cease. This may be done simultaneously with, or in lieu of, action to revoke license and/or impose a fine. The appropriate organ shall notify to the clinics in writing of such determination.
- 2.6.7. The appropriate organ shall issue to the primary clinic a written notification on reasons for denial, suspension or revocation of the license.
- 2.6.8. The license shall be returned to the appropriate organ within five (5) working days from voluntary surrender, order of revocation, expiration, or suspension of license.

2.7. Right to Fair Hearing

- 2.7.1. Any applicant made subject to action by the appropriate organ for denial or suspension or revocation of license or who is assessed a fine under terms of this section shall have the right to a fair hearing in accordance with relevant laws.
- 2.7.2. Fair hearing shall be provided/ arranged by the appropriate organ whenever there is an official complaint 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 appropriate organ through inspection and other true sources about the primary clinic 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 appropriate organ shall forward inspection reports to the primary clinic 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 primary clinic from the appropriate organ.
- 2.8.4. Anyone who is interested in establishing a primary clinic shall have the right to be provided with information concerning the standards required by the appropriate organ at any working day.

Section 3: Governance

3.1 . Technically the primary clinic shall be led/ managed by the Licensee.

3.2 The licensee of primary clinic shall be a:

- (a) Diploma nurse with a minimum of 5 years of experience or
- (b) BSc nurse & post basic BSc nurse with less than 2 years of relevant work experience before BSc program requires 3 years relevant work experience or,
- (c) Post basic BSc nurse with 2 - 5 years of relevant work experience before BSc program requires one year relevant work experience or,
- (d) Diploma nurse graduates who have joined post basic BSc program after 5 years of relevant work experience are exempted from work experience.

3.3 The primary clinic shall submit periodic reports to the respective appropriate organ to which it is responsible.

3.4 The head of the clinic or the Licensee shall be responsible for:

- (a) The protection of patients' health, safety, and well- being;
- (b) Meeting patient needs;
- (c) Reporting information on suspect of abuse, neglect and exploitation for children & people with mental incompetence;
- (d) Responding to reports from the appropriate regulatory body;
- (e) Total administration of the clinic.

Section 4: Client Rights and Responsibilities

4.1. Informed Consent

- 4.1.1 Each primary clinic shall protect and promote each client's rights.
- 4.1.2 For undertaking any type of treatments an informed consent shall be required from the client or client's next of kin or guardian.
- 4.1.3 For undertaking any type of procedures and treatments an informed consent shall be required from the patient or patient's next of kin or guardian.
- 4.1.4 An informed consent may not be required during emergency cases or life threatening situations where the patient is not capable of giving an informed consent and his or her next of kin or guardian is not available.
- 4.1.5 The primary clinic shall comply with relevant laws, national and international codes of ethics in the cases of vulnerable groups like children, women, geriatric patients etc when someone other than the patient can give consent.
- 4.1.6 No photographic, audio, video or other similar identifiable recording is made without prior informed written consent.
- 4.1.7 A primary clinic shall post list of fees & Service charges for clients in a visible place.

4.2. Client Rights

Every client of a Primary clinic shall at least have the following rights,

- 4.1.1. To receive safe health services,
- 4.1.2. To receive treatment and medical services without discrimination based on race, age, color, religion, ethnicity, national or social origin, sex, sexual preferences, handicap, diagnosis, source of payment or other status;
- 4.1.3. To retain and exercise to the fullest extent possible all the constitutional and legal rights to which the client is entitled by law;
- 4.1.4. To be informed of the names and functions of the clinic staff who are providing direct care to the client.
- 4.1.5. To receive an explanation of his or her health condition,
- 4.1.6. To have personal and physical privacy.
- 4.1.7. To be treated with courtesy, consideration, and respect for the client's dignity and individuality i.e. the right to care that respects the client's personal values and beliefs;
- 4.1.8. To refuse medication and treatment and to be informed of the medical consequences of refusing treatment except conditions which are threatening to the general public health;

- 4.1.9. To be free from physical and mental abuse, neglect, sexual harassment, sexual violence and exploitation;
- 4.1.10. To have personal and physical privacy during medical treatment and care,
- 4.1.11. To get confidential treatment. Information in the patient's records shall not be released to anyone outside the Primary clinic except the followings;
 - (a) If the client has approved the request,
 - (b) If the release of the information is required and permitted by law.
 - (c) If the patient's identity is masked
- 4.1.12. To obtain a copy of the patient's medical record, as per the standards set under the medical record section of this standard;
- 4.1.13. To be informed and participate in decisions relating to their care and participates in the development and implementation of a plan of care and any changes.
- 4.1.14. To present his or her suggestion or grievances.
- 4.1.15. To choose their treating nurse if
 - (a) there is conflict among the patient and the staff or
 - (b) the patient has justifiable reason or
 - (c) the clinic has another alternative.

4.3. Client Responsibilities

Every client shall have the following responsibilities:

- 4.3.1. To cooperate with the clinic staff;
- 4.3.2. To provide, to the best of the client's knowledge, accurate and complete information regarding past medical history;
- 4.3.3. To follow the course of treatment and instructions;
- 4.3.4. To report to the treating nurse any changes in his/her condition or anything that appears unsafe;
- 4.3.5. To respect the clinic staff;
- 4.3.6. To keep all appointments and notify the clinic when unable to do so;
- 4.3.7. To observe the clinic policies and procedures, including those on smoking, alcohol use, cellular phones, noise;
- 4.3.8. Not to litter the clinic premises.
- 4.3.9. For epidemic, the patient has the responsibility to cooperate and take the treatment or vaccination.
- 4.3.10. Report any changes in his/her condition or anything that appears unsafe to her/his self (the patient) or others.

Section 5: Human resource management

5.1. General Requirements

- 5.1.1 The primary clinic shall have responsible person who organizes /carries out the major functions of Human Resource Management (HRM).
- 5.1.2 The primary clinic shall ensure that all health professionals recruited are licensed as per the registration and licensing requirement of the appropriate organ.
- 5.1.3 The primary clinic shall ensure and maintain evidence of current active licensure, registration, certification or other credentials for employees and contract staff prior to letting to work and shall have procedures for verifying that the current status is maintained.
- 5.1.4 Whenever a licensed health-care professional is terminated as a result of a job-related incident, the primary clinic shall refer a report of the incident to the appropriate organ.
- 5.1.5 Each person who is involved in the performance of duties involving direct patient care shall have an occupational health screening prior to entering active status and once every five (5) years thereafter. A health professional shall not conduct health examination for himself/ herself.
- 5.1.6 The primary clinic shall keep on file the medical checkup reports of all staff and shall make available during inspection by the appropriate organ.
- 5.1.7 Each person who is involved in direct patient care and who has been absent from duty because of an illness that required to be reported to the MOH shall, prior to returning to duty, obtain certification from a physician or other qualified health professional, as provided for in the primary clinic's policies, that he or she may return to duty without apparent danger of transmitting the cause of the illness to any patient.
- 5.1.8 The primary clinic shall regularly follow the Immunization status of all employees and all other persons who routinely come in contact with patients or patient areas against selected communicable disease. Immunizations shall be in accordance with current guidelines developed by the Federal Ministry of health (FMoH).
- 5.1.9 The Primary clinic shall update the employment record for all staff. The record shall contain to a minimum: information on credentials, health examination (fitness for duty), work history, current job description, and evidence of orientation, in-service education / training and copies of annual evaluation.

5.1.10 The primary clinic shall notify the appropriate organ while hiring or terminating medical staff.

5.2. Staffing Plan

5.2.1. The primary clinic shall avail as a minimum the staff requirements stated under this standard.

5.2.2. The staffing plan shall define the following elements:

- (a) The total number and types of staff needed for the primary.
- (b) The total number of staff currently available for the primary clinic,
- (c) The required education, skills, knowledge, and experience required for each professional.
- (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.

5.3. Job Description and Orientations

5.3.1. All staff 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: the facility wise, service wise and job specific.

5.3.4. Organizational and administrative structure of the primary clinic shall be posted in a visible place and orientation to all staff working in the clinic shall be provided by the Primary clinic management.

5.3.5. Orientation to Primary clinic policies, including all environmental safety programs, infection control, and quality improvement shall be provided.

5.3.6. Staff members who are not licensed to practice independently shall have their responsibilities defined in their updated job descriptions.

5.3.7. The Primary clinic shall organize a system of provide & 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) Primary clinic 's sanitation and infection control programs;
- (c) Organizational structure within the Primary clinic ;
- (d) Patient rights;
- (e) Patient care policies and procedures relevant to the job;
- (f) Personnel policies and procedures;
- (g) Emergency procedures;
- (h) Reporting requirements for abuse, neglect or exploitation
- (i) What to rescored & report

5.4. Continuing education

- 5.4.1. The Primary clinic shall encourage and facilitate that staffs receive training in order to perform assigned job responsibilities.
- 5.4.2. The professional in the primary clinic shall receive ongoing Continuing Professional Development (CPD) or continuous medical education (CME) to maintain or advance his or her skills and knowledge.
- 5.4.3. The CPD/ CME shall be relevant to the setting in which they work as well as to the continuing advancement of the clinic.
- 5.4.4. The clinic 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 clinic shall provide and maintain evidence of CPD or CME for staff. A record shall be maintained including dates, topics and participants.

5.5. Medical Staff

- 5.5.1. The health professional shall be responsible to the governing authority for medical care and treatment provided in the primary clinic as per this standard and shall:
 - a) Participate in a Quality Assurance/ Performance Improvement program to determine the status of patient care and treatment;
 - b) Abide by Primary clinic and medical staff policies;
 - c) Establish a disciplinary process for infraction of the policies

- 5.5.2. The medical staff shall actively participate in the study of nosocomial (facility associated) infections and infection potentials and must promote preventive and corrective programs designed to minimize their hazards.
- 5.5.3. There shall be regular medical staff meetings to review the clinical works & administrative duties.

5.6. Employee's Health

- 5.6.1. The primary clinic 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 standards outlined below define the core elements of an OHS program and specify minimum requirements needed to address OHS issues.
 - a) The clinic 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 clinic assesses and documents safety risks through formalized, structured assessments that are done at regular intervals.
 - c) Interventions shall be designed and implemented to address the risks that are identified.
- 5.6.4. The primary clinic shall have a mechanism in place to address/ protect injuries that could lead to the transmission of blood-borne diseases (needle stick and other injuries).
- 5.6.5. The Primary clinic shall provide personal protective equipment, and facilitate access to prophylaxis measure.
- 5.6.6. The Primary clinic shall provide the following facilities to employees:
 - a) Cafeteria (meal for duty),
 - b) Break room Duty room (bed, table and chair, closet with lock),
 - c) Adequate toilet and shower facilities,

5.7. Dress Code and Employee Identification Badge

For areas involving direct patient contact:

- 5.7.1. Footwear shall be safe, supportive, clean, and non-noise producing,
- 5.7.2. Artificial nails are prohibited. Natural nails must be kept short and no jewelry shall be worn on finger or wrist,
- 5.7.3. Hair must be worn in a way that prevents contamination and does not present a safety hazard,
- 5.7.4. The clinic shall provide uniforms to employees. And employees shall wear the clinic uniforms all the time while on duty.
- 5.7.5. The dressing shall not interfere in any way the service provision.
- 5.7.6. The primary clinic may specify a particular style and/or color of uniform with different style/color code; separate for each human resource category,
- 5.7.7. The employee shall keep the uniform neat, wrinkle free and in good repair,
- 5.7.8. The Primary clinic shall prepare and make sure identification badges are worn by employees.
- 5.7.9. The identification badge shall be worn at all times while at work and be easily visible with name & profession.

Section 6: Service Standards

6.1. Practice

- 6.1.1. Primary clinic shall provide medical services that can be handled under the scope of the professional assigned to the primary clinic.
- 6.1.2. Emergency services as First Aid (ABC, arrest bleeding, first degree burn, immobilization for poly trauma)
- 6.1.3. Primary Level nursing services
- 6.1.4. Consultation of healthy living,
- 6.1.5. Nursing procedures:
 - a) Administration of Injection with prescription (Prescribed medicines),
 - b) Change Dressing with prescription and application of simple dressing,
 - c) Taking Vital sign,
 - d) Enema with prescription,
 - e) Ear irrigation simple foreign body removal following otoscopy,
 - f) Counseling and Referral of suspected/ potential STI, TB, HIV and other conditions
 - g) Treatment of mild to moderate dehydration and referral of severe dehydration cases
- 6.1.6. Written copies of nursing procedure manual shall be kept in the clinic for reference.
The manual shall be used at least to:
 - (a) Provide a basis for induction of newly employed nurse,
 - (b) Provide a ready reference on procedures for clinic staff.
 - (c) Standardize procedures and practice.
 - (d) Provide a basis for continued professional development in nursing procedures/techniques.
- 6.1.7. Primary clinic shall provide Maternal & Child Health (MCH) services under the scope of the professional:
 - a) Pregnancy planning,
 - b) Antenatal care follow up and referral,
 - c) Post partum care,
 - d) Consultation on infant feeding,
 - e) Growth monitoring,
- 6.1.8. Primary clinic shall provide delivery service attending spontaneous normal delivery;

- 6.1.9. Primary clinic shall provide Health promotion services:
- a) Give consultation on healthy living, nutrition, hygiene,
 - b) Provide information and health education on chronic illnesses like TB, HIV, STIs, DM, HTN, Asthma,
- 6.1.10. Specific public health program related services/interventions may be delivered in medium clinic upon approval if supported with additional trainings.
- 6.1.11. There shall be Patient medical chart for documenting the intervention or service rendered.
- 6.1.12. Copies of Nurses' code of professional practice shall be available and nurses shall abide by their code of professional practice relevant to their professional role.
- 6.1.13. There shall be a note or procedures for nurses to report any suggestive signs of child abuse, substance abuse and /or abnormal psychiatric manifestations by the patients and refer for appropriate care.
- 6.1.14. All medications administered by nursing personnel shall be prescribed by physician and/or authorized independent practitioner and shall be administered in accordance with prescribe orders and Codes of Professional Conduct and Ethics.
- 6.1.15. Primary clinic shall not hold prescriptions and practicing prescription writing is prohibited except emergency medicines.
- 6.1.16. Referral of patients which need further care shall be available.
- 6.1.17. Primary clinics shall have emergency medicines at all times. List of these medicines shall be according to the Authority's Emergency Medicines List specific to these type of facilities.
- 6.1.18. These health facilities shall get emergency medicines from suppliers licensed by the Authority.
- 6.1.19. It is prohibited to hold or dispense emergency medicines which are not registered and included in the emergency medicines list by the Authority.
- 6.1.20. It is prohibited to hold or dispense non-emergency medicines in these health facilities at any time.
- 6.1.21. These health facilities are not allowed to hold or dispense any donated medications without prior permission of the Authority.
- 6.1.22. Emergency medications shall be prescribed by an authorized prescriber and administered by nursing personnel with adequate information and counseling to the patient or care giver.

- 6.1.23. The health facility shall be responsible to report suspected ADR cases to the Authority and all adverse medication effects shall be noted in the patient's medication record.
- 6.1.24. These health facilities shall keep documentation which shows medicines source, date of purchase and receipt, inventory records, medicines waste disposal records and other relevant information
- 6.1.25. These health facilities shall keep medication records for emergency medicines which contains at least:
- a) Name of patient, sex, age and medical record number,
 - b) Diagnosis and allergy, if any,
 - c) Name of the drug, strength, dosage form and total dose given and route of administration,
 - d) Date dispensed,
 - e) Prescriber's name, qualification and signature,
 - f) Prescriber's address (name and address of health facility).
- 6.1.26. The health facility shall be responsible to make sure that medicines promotion made by suppliers or manufacturers in its premise is made by a licensed pharmacist in accordance with the country's laws.
- 6.1.27. Any clinical trial without the permission of the Authority is prohibited in these health facilities.
- 6.1.28. Disinfectants and other chemicals shall be stored separately from emergency medicines.
- 6.1.29. The storage condition shall provide adequate protection to the medicines and supplies from all environmental factors until time of use.
- 6.1.30. Medicines shall be kept in a secured, clean, ventilated cabinet and in accordance with the manufacturers' recommendation for storage conditions.
- 6.1.31. The primary clinic shall manage and dispose medicines waste in accordance with the directive issued by the Authority.
- 6.1.32. The primary clinic shall be accessible to authorized inspector of an appropriate organ.
- 6.1.33. Any practice other than the above mentioned ones shall be strictly prohibited.

6.2. Premises

The Primary clinic shall have:

- 6.2.1. Direct access to examination room for emergency,
- 6.2.2. Hand washing basin/ facility at examination and treatment room,
- 6.2.3. Cabinet/ cupboard with lock for equipments and supplies,
- 6.2.4. Staff changing corridor or room with cabinet, chairs, cupboard.
- 6.2.5. The facility shall maintain privacy and be friendly for persons with disability.
- 6.2.6. There shall be a note in visually accessible area that details the facilities working hours and list of services available in the facility.
- 6.2.7. The primary clinic shall have a minimum of the following premises set up:

Premises required	Number	Area required
• Reception, Registry/ Recording & Waiting area	1	12 sq. m
• Examination room	1	12 sq. m
• Treatment/ procedure/ injection room,	1	12 sq. m
• Toilet	2	8 sq. m
• Incinerator (mobile/ fixed) optional	1	
• Area for placenta pit (optional)	1	

6.3. Professional

- 6.3.1. A primary clinic shall be directed by a:
 - a) Diploma nurse with a minimum of 5 years of experience or
 - b) BSc nurse & post basic BSc nurse with less than 2 years of relevant work experience before BSc program requires 3 years relevant work experience or,
 - c) Post basic BSc nurse with 2 - 5 years of relevant work experience before BSc program requires one year relevant work experience or,
 - d) Diploma nurse graduates who have joined post basic BSc program after 5 years of relevant work experience are exempted.
- 6.3.2. There shall be written discrete job descriptions that detail the roles and responsibilities of all clinic personnel.
- 6.3.3. The primary clinic shall have the following staffing:-

Staffs required	# required
• Nurses	2
• Receptionist	1
• Cleaner	1

6.4. Product

6.4.1. The Primary clinic shall have the following equipments, instruments and consumables:

a) Equipments :

- Stethoscope,
- Thermometer(digital/ mercury),
- BP apparatus
- (sphygmomanometer with stethoscope),
- Measuring tape,
- Wrist watch/ wall clock,
- Weighing scale
- Otoscope set
- Glucometer,
- Examination light,
- Delivery set
- Dressing set,
- Minor suturing set,
- Enema set,
- Kidney basin,
- Plastic apron,
- Drapes/ Rubber sheets,
- Suction ball (optional),
- Waste basket,
- Sharp disposal boxes,
- Pickup forceps with jar,
- Sterilizer (steam autoclave/ hot air oven)
- Examination coach,
- Fetoscope
- IV stand,
- Storage shelves for the medical equipment, medicines and supplies
- Recording and Reporting materials

b) Consumables:

- Disposable glove
- Surgical glove
- Alcohol/ Iodine/ savlon,
- Gauze
- Bandage,
- Cotton
- IV Cannulae
- Adhesive tape,
- Surgical blades
- Tongue depressor,
- Splints (locally produced/ adapted),
- Foley Catheters,
- Tourniquets
- KY jelly
- Dressing packs
- Steri-strips for steam autoclave
- Disinfectant chemicals (Bleach)
- Disposable syringe with needle

6.4.2. The Primary clinic shall not hold any drugs, medical supplies or equipments which are not included in the Primary clinic drug list.

6.4.3. Medicines and supplies allowed for Primary clinics for executing the above mentioned services shall be according to the emergency drug list for the Primary clinic.

6.4.4. Emergency medicines allowed for primary clinic as per emergency medicine list prepared by EFMHACA

Section 7: Record Keeping and reporting

- 7.1 The Primary clinic shall maintain patient medical record, folder/register, reporting formats, tally sheets and other necessary forms as per the requirement in HMIS guidelines for that level of ambulatory healthcare service.
- 7.2 Medical record shall be maintained in written form for every patient.
- 7.3 The Primary clinic shall maintain such forms in a manner to ensure accuracy and easy retrieval.
- 7.4 Any medical record shall be kept confidential, available only for use by authorized persons or as otherwise permitted by law.
- 7.5 The Primary clinic shall have adequate space shelves and other furniture for keeping various forms and folders.
- 7.6 All entries in the patient's medical record shall be written legibly in permanent ink (blue or black color), dated, and signed by the recording person.
- 7.7 Patient medical records shall contain to a minimum:
 - a) Identification: Name of patient, age, sex, address
 - b) Presenting complaint/ Diagnosis,
 - c) Assessment/ diagnosis/ impression,
 - d) Medication and procedure,
 - e) Name and signature of treating nurse and date.
- 7.8 If a client or the client's legally authorized representative requests in writing, a copy of the medical record shall be given.
- 7.9 If client is provided with medical certificate, copy of certificate and other records shall be documented and/or recorded on the original medical record.
- 7.10 If the Primary clinic ceases to operate, the appropriate organ shall be notified in writing about how and where medical record will be stored at least 15 days prior to cessation of operation.
- 7.11 Medical records shall be destroyed as per the law by using techniques that assures confidentiality of the medical records.
- 7.12 The medical record shall be stored in a dedicated confidential space at the reception.
- 7.13 The medical record service shall have medical record, logbooks and shelves.

Section 8: Health Promotion

- 8.1. The Primary clinic shall give health promotion activities specified under this standard (based on the guidelines prepared by relevant health authority).
- 8.2. The Primary clinic shall plan, schedule and lead health promotion activities at the facility.

- 8.3. The Primary clinic shall have a planned approach to collaborate with other health service levels and other institutions and sectors on an ongoing basis. This shall include:
- a) Health promotion services are coherent with current provisions and health plans.
 - b) Cooperate with existing health and social care providers and appropriate regulatory bodies and groups in the community.
 - c) Documentation and patient information is communicated to the relevant recipient/follow-up partners.

Section 9: Housekeeping and Maintenance Services

9.1. Practices

- 9.1.1. 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.
- 9.1.2. Maintain an adequate supply of clean white coat and gauns at all times
- 9.1.3. In the housekeeping service, the types and sources of offensive odors shall be identified, controlled and removed immediately
- 9.1.4. Collection, transportation and disposal of primary clinic wastes shall be supervised and controlled
- 9.1.5. The safety of fire, electrical and natural hazards in the risk areas in the primary clinic shall be supervised and controlled and shall work closely with primary clinic fire brigade and safety committee.
- 9.1.6. The designee shall identify, supervise and organize the control and eradication of pests, rodents and animal nuisance in the primary clinic.
- 9.1.7. The housekeeping staffs shall create pleasant environment to patients, staffs and visitors
- 9.1.8. The housekeeping staffs shall ensure proper lighting and ventilation in different primary clinic areas.

- 9.1.9. Regular surveillance of overhead and underground tank, proper cover, regular chlorination and cleaning shall be undertaken
- 9.1.10. The infection control measures shall be carried out in accordance with the primary clinic infection prevention standard
- 9.1.11. There shall be reserve electrical generator for power supply for continuous 24 hours.
- 9.1.12. Potable water and electrical services shall be available 24 hours a day and 365 days a year through regular or alternate sources.
- 9.1.13. There shall be a plant safety maintenance organization as described below:
- a) A safety committee that develops a comprehensive clinic-wide safety program and reviewed.
 - b) A mechanism to report all incidents, injuries and safety hazards to the safety committee.
 - c) The safety committee shall review all reports and be responsible for ensuring that all reports are referred appropriately and follow-up action is documented.
- 9.1.14. 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.
- 9.1.15. 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.
- 9.1.16. There shall be written protocols and procedures for primary clinic 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.
- 9.1.17. The maintenance personnel including the management of the clinic 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
- 9.1.18. Fire and emergency preparedness
- a) The clinic 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.
- 9.1.19. Housekeeping equipment or supplies used for cleaning in contaminated areas shall not be used in any other area of the clinic before it has been properly cleaned and sterilized.
- 9.1.20. All areas of the clinic, including the building and grounds, shall be kept clean and orderly.
- 9.1.21. There shall be frequent cleaning of floors, walls, woodwork and windows.
- 9.1.22. The premises shall be kept free of rodent and insect infestations.
- 9.1.23. Accumulated waste material and rubbish shall be removed at frequent intervals.

- 9.1.24. No flammable cleaning agents or other flammable liquids or gases shall be stored in any janitor's closet or other area of the clinic except in a properly fire rated and properly ventilated storage area specifically designed for such storage.
- 9.1.25. If the clinic does not have its own housekeeping and maintenance services; it may have a contract agreement with external organizations.
- 9.1.26. If the clinic has given the housekeeping and maintenance services to a contractor, the contractual agreement shall be filed and made accessible in the clinic premises. In such cases the clinic shall make sure that the standards mentioned for housekeeping and maintenance are adhered by the contractor.

9.2. Premises

- 9.2.1. There shall be separate space provided for the storage of housekeeping equipment and supplies
- 9.2.2. Office shall be available for the maintenance and the housekeeper.
- 9.2.3. Adequate space shall be available for janitor's closets and cleaning equipment & supplies.
- 9.2.4. Exits, stairways, doors and corridors shall be kept free of obstructions.
- 9.2.5. The clinic 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.

9.3. Professionals

- 9.3.1. The designated officer shall plan, organize, co-ordinate, control and monitor all housekeeping and maintenance activities.
- 9.3.2. 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 clinic 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) clinic 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.

9.3.3. In summary, if the service is not outsourced, the clinic shall have

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

9.4.Products

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

9.4.2. The clinic shall have the following tools, equipment & materials for housekeeping services.

- | | |
|-----------------------------------|--------------------------------------|
| a) Reserve electrical generator | o) Water trolley |
| b) Floor cleaning brush | p) Ladder |
| c) Floor wiping brush | q) Scraping pump |
| d) Hockey type brush | r) Spraying pump |
| e) Counter brush. | s) Flit pump. |
| f) Ceiling brush | t) Rate trapping cage |
| g) Glass cleaning / wiping brush. | u) Gum boots |
| h) Scrappers | v) Gown, Masks & Gloves |
| i) Dustbins paddles. | w) Torch |
| j) Waste paper basket. | x) Manual sweeping machine. |
| k) Plastic Mug | y) Floor scrubbing/polishing machine |
| l) Plastic Bucket | z) Wet vacuum cleaner. |
| m) Plastic drum | |
| n) Wheel barrow | |

- | | |
|----------------------------------|---------------------------------|
| aa) Dry vacuum cleaner portable | ff) Laundry cleaning material |
| bb) Fumigation machine (Oticare) | gg) Insecticides & rodenticides |
| cc) Bed pan washer. | hh) Stain removal |
| dd) Cleaning material | |
| ee) Deodorants & disinfectant | |

Section 10. Infection Prevention

10.1. Practices

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

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

10.1.3. The primary clinic shall identify the procedures and processes associated with the risk of infection and shall implement strategies to reduce infection risk.

10.1.4. The primary clinic 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.

10.1.5. 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 primary clinic hygiene
 - Structural infection prevention
 - Physical primary clinic organization
- e) Waste management
 - Cleaning medical instruments
 - Implementation of a disposal system
 - Handling medical waste
 - Waste removal

10.1.6. The following specific standard precautions shall be practiced and the primary clinic shall have its 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 primary clinic staff shall consider that every patient is infectious
- c) The primary clinic 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:
 - Splattering 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.

10.1.7. There shall be transmission-based precautions and the primary clinic 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

10.1.8. Each primary clinic 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

10.1.9. 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 primary clinic
- 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

10.1.10. The primary clinic shall provide regular training on infection prevention and control practice to staff, patients and as appropriate, to family and caregivers

10.1.11. 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

10.1.12. The primary clinic 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.

10.2. Premises

- 10.2.1.1. The primary clinic shall have a dedicated office for IP officer,
- 10.2.1.2. The primary clinic shall have a room or area for temporary storage of waste containers,
- 10.2.1.3. The primary clinic shall have a centralized sterilization room
- 10.2.1.4. The primary clinic shall have incinerator with ash and burial pits.

10.3. Professionals

- 10.3.1.1. The primary clinic shall have a designated staff to serve as IP infection prevention and control officer.
- 10.3.1.2. The officer shall be a licensed IP trained nurse and knowledgeable of infection prevention principles and health care epidemiology.

10.4. Products

- 10.4.1.1. The primary clinic 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
- e) Personal Protective Equipment
- Heavy duty glove
 - Surgical glove
 - Latex or Nitrile glove
 - Eye shield
 - Goggle
 - Visors
 - Dust mask
 - Respiratory mask
- Alcohol based hand rub
 - Personal Towels
 - Paper Towels
- Other types of face mask
 - Plastic apron
 - Other types
 - Boots
 - Other protective shoes
 - Caps
 - Face shield

Section 11. Sanitation and Waste Management

11.1. Practices

- 11.1.1. Primary clinic environment shall ensure the following conditions:
- a) Clean sanitation and safe environment,
 - b) Access to continuous, safe and ample water supply
- 11.1.2. There shall be written procedures to govern the use of sanitation techniques in all areas of the primary clinic.
- 11.1.3. If the clinic has ground water source, there shall be a written policy and procedures for ground water treatment,
- 11.1.4. Infectious and medical wastes shall be handled and managed according to the recent Health Care Waste Management National Guidelines/Directives.
- 11.1.5. 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.
- 11.1.6. 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
- 11.1.7. 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.
- 11.1.8. Segregation of health care waste shall include the following procedures:
- a) Separate different types of waste as per the guideline,
 - b) The primary clinic 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 primary clinic:

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

11.1.9. 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).

11.1.10. The primary clinic shall have an organized waste disposal and/ or removal system and shall ensure the safe handling of all wastes.

11.1.11. 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).

11.1.12. The clinic 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,

11.1.13. The primary clinic 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.

11.1.14. The primary clinic shall ensure appropriate ventilation system.

11.1.15. In order to maintain a clean and safe environment, the primary clinic shall have an organized method for the transport and washing of linens.

11.1.16. Housekeeping items shall be cleaned and sanitized regularly.

11.1.17. The clinic 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).

11.1.18. The clinic 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,

11.1.19. The primary clinic 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.

11.2. Premises

11.2.1.1. The primary clinic 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 clinic 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.

11.3. Professionals

11.3.1. Primary clinic sanitation service shall be administered together with infection prevention activities.

11.3.2. In addition, the primary clinic shall have:

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

11.3.3. The primary clinic shall officially designate staff in charge of handling waste on a regular basis.

11.3.4. The assigned staff shall be responsible for the collection and disposal of waste products in the primary clinic.

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

11.3.6. Staff shall be oriented on personal protection methods.

11.4. Products

11.4.1. The primary clinic 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

Section12: Physical Facility Standard

12.1. General

A Primary clinic shall fulfill the minimum standards for the building which contains the facilities required to render the services contemplated in the application for license. The term "safe" used in this Section shall be interpreted in the light of compliance with the requirements of the latest country building codes presently in effect.

12.2. Site Selection Requirements

12.1.1 Entrance to the Primary clinic shall be:

- a) Clear & easy to road access,
- b) Away from highways, railways, construction areas,

12.1.2 There shall be secured boundaries, no access for animals,

12.1.3 The surrounding environment shall be free of undue conditions like excess sound/ noise, smoke, light (welding & cutting), or smells.

12.1.4 Primary clinic shall not be located adjacent to railroads, freight yards, airports, grinding mills, traffic pools, industrial plants and disposal plants

12.1.5 Primary clinic shall be provided with water supply and electricity and communication facilities based on the situation (Urban/ Rural).

12.3. Construction Requirements

12.3.1. The appropriate organ shall be consulted before commencement of any physical development or remodeling of existing building (rented premises) planned for Primary clinic.

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

12.3.3. There shall be an approval from the appropriate organ when buildings constructed for other purposes are used for the operation of primary clinic.

12.3.4. Upon completion of construction the appropriate organ shall inspect and issue an approval for operation of the Primary clinic if all the findings are in conformity to the standards.

12.3.5. 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
- 12.3.6. Ways, paths and corridors to and between Primary clinic buildings shall be paved, leveled smooth and friendly for people with disability.
- 12.3.7. The construction materials shall be sound proof and shall maintain audio visual privacy of clients in conformity to the Ethiopian Building Code.

12.4. Building Space and Elements

Size of rooms and space allocation shall consider room loadings based on the number of staff and clients involved.

12.4.1. Corridors:

- a) Patient serving corridors and circulation ways shall not be less than 1.2m wide,
- b) The openings to the corridor shall be designed to allow easy movement of patients with support or on wheelchair or stretchers.
- c) The circulation ways and corridors shall be a minimum 2m wide.

12.4.2. Doors:

- a) Doors shall be easy to open and close.
- b) Doors swing into corridors shall be avoided.
- c) Glass doors shall be marked to avoid accidental collision.

12.4.3. Examination and or procedure room(s): the examination room shall meet the following requirements:

- a) **Floor Area:** Floor area shall be 12sq. m for an examination room furnished with examination coach, physician table and 2 guest chairs, and a shelf or cabinet for instruments and reference materials.
- b) **Ceiling Height:** The ceiling height of the rooms shall not be less than 240 cm. Ceiling height needs to be determined based on the climate, the functional requirements considering air space, technical requirements, room size proportions and number of occupants.

- c) **Furnishings:** The furniture shall be washable and resistant for cleansing reagents that can control vandalism and avoid accidents.
- d) **Curtains:** rooms shall be equipped with curtains or blinds at windows.
- e) **Finishing:**
- Walls and ceilings of all rooms shall be suitable for easy washing.
 - Floors of the rooms shall be easily cleanable, smooth, non- adsorptive, non-slippery.
 - 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).
- f) **Sanitary Finishing**
- Toilet rooms shall be fitted with functional flush; if only pit latrine, ventilation shall be provided,
 - Hand washing facilities shall be supplied.
 - Floors and walls of toilet room shall be fitted with washable finishing materials.
 - Floors and walls penetrated by pipes, ducts, siphons and conduits shall be tightly sealed & smoothened.
- g) **Electrical Finishing**
- Room light luminescence shall be bright enough for staff activities.
 - All electrical fixtures inlets, outlets, appliances shall fulfill Ethiopia Electrical Safety requirements and if applicable fitted with safety guards,

12.4.4. 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.
- b) Windows for Primary clinic shall be open able or shall be fitted with opening at top portion, fitted with wire mesh, for cross ventilation & uninterrupted circulation of air. Advanced technology can be used that maintain the air circulation.

12.4.5. Outdoor Areas: the outdoor area shall be equipped and situated to allow safe movement/ flow of patients, care givers, staff and visitors.

- a) Walkways, connection roads and elevation differences shall be designed to allow smooth movements of coaches/stretchers and persons with disabilities.
- b) The outdoor traffic arrangement shall not cross each other.

12.4.6. Vertical Circulation: All functioning rooms shall be accessible horizontally.

- a) Primary clinic 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.
 - All stairways shall be fitted with non slippery finishing materials
 - All stair threads, risers and flights shall comply with the Ethiopia Building proclamation.
- c) **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.
- d) **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.

12.4.7. 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.

12.4.8. Parking areas:

- a) Primary clinic shall have reserved parking space for ambulance or emergency car.
- b) Parking space shall not obstruct direct entrance to the Examination room.

12.5. Building Systems

Primary clinic shall have building systems that are designed, installed and operated in such a manner as to provide safety, comfort and well being of the patient.

12.5.1. Water supply and plumbing:

- a) Primary clinic 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.
- b) Primary clinic connected to its own separate water supply system shall maintain the safety & shall have certificate for safety by the concerned body.
- c) Water reserves used in Primary clinic shall be protected from external contamination, shall be cleaned and washed every 6 months.
- 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.

12.5.2. Sewerage and Waste Processing Systems

- 5.2.1. The Primary clinic shall maintain a functioning sewage system in accordance with the national healthcare waste management guidelines and Ethiopian building code.
- 5.2.2. The Primary clinic shall provide secured area to collect, contain, process and dispose of medical and general waste produced.
- 5.2.3. Waste segregation shall be done for hazardous wastes from the source before it is released to the municipal or private sewage system.
- 5.2.4. The Primary clinic shall dispose all liquid wastes produced in the clinic through connection to a suitable municipal sewerage system or septic tank,
- 5.2.5. The Primary clinic shall have incinerator for solid waste that is disposed with combustion/ incineration.

12.5.3. 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) Primary clinic shall provide adequate ventilation and/or clean air circulation 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 rooms.
- 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,
 - Toilets, and similar areas shall have six (6) air changes per hour and,
 - Generally, areas occupied by patients shall have two (2) air changes per hour.

12.6. Electrical System

12.6.1. 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) Care and treatment locations: seventy (70) foot candles;
- d) Examination task lighting: one hundred (100) foot candles;

12.6.2. Essential Power System:

- a) The electric installation in the Primary clinic shall fulfill the criteria set by ELPA.
- b) The electric outlets shall be up to the safety standard of National Electrical Design Code;

12.7. Fire Protection System

The Primary clinic shall comply with the National Fire Protection "Life Safety Code".

12.8. Health Facility Environment

- a) The Primary clinic shall provide and maintain a safe environment for patients and the public.
- b) Existing and new facilities shall comply with the physical facility standards contained in this chapter.

12.9. Specific Service Areas

- a) Examination Rooms: each examination room shall have a minimum floor area of 12 square meters (3m x 4m) and a minimum of 90 cm clear dimension around two sides of the examination table or chair.

- b) Toilet Rooms: The Primary clinic shall provide toilet rooms with hand-washing sinks for patient and staffs separately. In addition the following requirements shall be ensured:
- Flush toilets or VIP latrines shall be available throughout the workplace.
 - Posted signs (written and/or visual messages) shall be indicated describing which is for ladies and gents.
 - Indicating arrows shall be located on the corridors.
- c) Incinerator: The Primary clinic shall have functional incinerator with dedicated ash pit. The incinerator area shall be clean and secured.

12.10. Functional Layout of the Health Facility

☐ Entrance ☐ reception/ registration/ patient waiting area ☐ Outpatient room/ procedure room ☐ toilet room(s) ☐ incinerator/ ash pit/ placenta pit