

CES xxx

**Compulsory
Ethiopian Standard**

**Second Edition
2018**

Internal Medicine Specialty Clinic Requirement



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Foreword

This Ethiopian Standard has been prepared under the direction of the Technical Committee for Health service .(TC 198) and published by the Ethiopian Standards Agency (ESA).

This Compulsory Ethiopian Standard cancels and replaces ES 3611:2012.

This Compulsory Ethiopian Standard cancels and replaces ES 186:2001.

Application of this standard is **COMPULSORY** with respect to clauses 4.1,4.8,4.9 and 5.0. A Compulsory Ethiopian Standard shall have the same meaning, interpretation and application of a "Technical Regulation"as implied in the WTO-TBT Agreement.

Implementation of this standard shall be effective as of 01 October 2013.

Internal Medicine Specialty Clinic Requirement

1. Scope

These Ethiopian standards provide minimum requirements for the establishment and maintenance of internal medicine specialty clinic with respect to practices, premises, professionals and products or materials put into use for the clinic.

2. Normative References

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 specialty clinic staff who is responsible for a given service.
- 3.7. **Internal medicine Specialty Clinic:** Shall mean a specialized health care facility where promotive, preventive, curative and rehabilitative specialty health services are provided at ambulatory level together with diagnostic facilities appropriate to this level of care.

4. General Requirement

- 4.1 The internal medicine speciality center shall be directed by an internist.
- 4.2 The internal medicine speciality clinic shall provide service at outpatient/ambulatory level only.
- 4.3 Emergency care with a qualified staff shall be available during working hours.
- 4.4 The speciality clinic shall have triage.
- 4.5 The internal medicine speciality clinic shall avail updated reference materials, treatment guidelines and manuals for common disease.
- 4.6 Diseases under national surveillance shall be notified to the FMOH through the proper reporting channel.
- 4.7 The medical record for patients shall include, but not limited to,
 - a. Pertinent history and physical examination
 - b. Documentation of Growth assessment: record of weight & height or length,
 - c. Documentation of a basic developmental assessment: sensory screenings, cognitive, &
 - d. Record of immunization status.
- 4.8 The speciality clinic shall have a program of continuous quality improvement for the service which includes regularly collecting and analyzing data to help identify health-service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data
- 4.9 The speciality shall establish quality team to improve quality of service deliveries.
- 4.10 The specialty clinic shall assess its staffs current knowledge and practice and observes utilization of national guidelines for the services it renders every six month.
- 4.11 The specialty clinic shall provide or facilitate training to their staffs.
- 4.12 The specialty clinic shall display the following at visible place:
 - (a) List of Services available in the specialty clinic during working hours & after working hours,
 - (b) List of Professionals and specialties working in the clinic during & after working hours,
 - (c) Updated list of Various fees and prices,

- 4.13 The internal medicine speciality clinic facilities shall be well marked and easily accessible for persons with disability.
- 4.14 The internal medicine speciality clinic shall have fire extinguisher placed in visible area.
- 4.15 All employees, including part-time and contract shall be trained in fire-fighting equipment and patient evacuation of clinic's buildings as part of their initial orientation and at least annually thereafter.
- 4.16 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 labelled with the date of the last inspection.
- 4.17 Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.
- 4.18 All patient care rooms shall be provided with running water supply & functional hand washing basin.
- 4.19 The Internal surfaces of the clinic (floors, walls, and ceilings) shall be:
- a. Smooth, impervious, free from cracks, recesses, projecting ledges.
 - 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.
- 4.20 The circulation ways and sub corridors shall be a minimum 2m wide.
- 4.21 Patient serving corridors shall not be less than 240cm wide,
- 4.22 Safety glass, tempered glass or plastic glass materials shall be used for paediatrics service units to avoid possible injuries.
- 4.23 Glass doors shall be marked to avoid accidental collision.
- 4.24 Internal medicine speciality clinic where functional units are at different floor shall have a mechanism of accessing all the functioning rooms horizontally either by stairs and ramp or stair and elevator.
- 4.25 The specialty clinic shall have established system for verbal and written communication about patient care.
- a. Verbal communication includes the communication with treating physician & other service units (like Laboratory & X-Ray units) & giving education for clients & families.

- b. Written communication includes use of clinical forms and nursing care plan for patients.

Nursing practice

4.26 The nursing service in the specialty clinic shall be directed by licensed professional nurse .

4.27 The Nursing service to a minimum shall include:

- a. Taking vital signs including pain score and anthropometric measurements for all clients visiting the clinic,
- b. Provide psychosocial assessment ,care evaluation and support for patients on the disease condition & recommended treatment,
- c. Provide basic health education to clients,

4.28 There shall be written protocol describing the responsibilities of nurses for the nursing process in the specialty clinic. Such policies shall be reviewed at least once every five years.

4.29 Nursing care shall be provided for all patients equally and without prejudice to age, sex, economic, social, political, ethnicity, religious or other status and irrespective of their personal circumstance.

4.30 Written copies of nursing procedure manual shall be made available to the nursing staff. The manual shall be used at least to:

- (a) Provide a basis for induction of newly employed nurses,
- (b) Provide a ready reference on procedures for all nursing personnel,
- (c) Standardize procedures and practice,
- (d) Provide a basis for continued professional development in nursing procedures/ techniques.

4.31 All patients kept for observation/resuscitation shall be under the supervision/ care of a licensed nurse at all times.

4.32 Nurses shall explain and seek informed consent from their patients or their relatives/ next of kin (for incompetent patients) before carrying out any procedure.

4.33 The Specialty clinic shall have established guidelines for verbal and written communication about patient care.

- (a) Written communication includes proper use of clinical forms, nursing Kardex, progress notes, and/or nursing care plan for each patient and discharge instructions.
- (b) Verbal and/or written communication: reporting to treating physician(s); nurse-to-nurse reporting; communication with other service units (laboratory, pharmacy, X-Ray, social work service).

4.34 There shall be a procedure for standardized, safe and proper administration of medications by nurses or designated clinical staff.

4.35 Allergies shall be listed on the front cover of the patient's chart or highlighted on the screen in a computerized system.

4.36 There shall be a protocol for reporting and documenting medication errors and adverse drug reactions by attending nursing personnel immediately to the nurse supervisor and prescriber and/or Pharmacist.

4.37 Patient discharge instructions shall be documented in the patient's medical record and verbal instruction shall be given.

4.38 There shall be a protocol or procedures for nurses to report any suggestive signs of child abuse, substance abuse and/ or abnormal psychiatric manifestations by the patients under their care.

4.39 There shall be a protocol that states the procedure to be followed for dying patients & dead body care.

4.40 The Internal medicine specialty clinic shall have a minimum number of the following staffing summary:

Professionals	Number of professionals
Internist	1
HO/GP (optional) for ART&TB clinic	1
GP/HO for emergency	1
Nurse	3
Laboratory personnel	1
Radiographer	1
Cleaners	2

Receptionist	1
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4.41 The number and type of technical staff shall be determined by the volume and type of work carried out (Workload Analysis)

5. Specific Requirement

5.1 Outpatient Services

5.1.1 Practices:

5.1.1.1 The specialty clinic shall provide the following outpatient services.

- a. Care of ambulatory patients and follow up of ambulatory patients for conditions.
- b. Preventive and health promotion services.
- c. Care for patients with chronic illnesses and do follow ups.

5.1.1.2 The outpatient service delivered in specialty clinic shall be provided by licensed internist.

5.1.1.3 The outpatient service shall be available during working hours. For clinic which is open extra hours, the time & the type of service available during after-working hours shall be posted at a visible place to the public.

5.1.1.4 Patient assessment at specialty clinic shall include;

- a. Comprehensive medical and social history,
- b. Physical examination including at least:
 - Vital sign (BP, PR, RR, T^o, pain assessment) height and weight,
 - Clinical examination pertinent to the illness,
- c. Diagnostics impression, and
- d. Laboratory and Imaging services
- e. Other medical workups when indicated.

5.1.1.5 The range of relevant treatment options and the clinical impression shall be fully described to client and/or their families and documented on patient's medical record accordingly.

5.1.1.6 The specialty clinic shall have national clinical protocols for management of at least common disease entities and locally significant diseases if any.

5.1.1.7 The specialty clinic shall have functional referral system which includes at least:

- a. List of conditions indicative for urgent referral,
- b. SOP for selection of cases for referral,

- c. Procedure for referring patients directly to respective (higher) services,
- d. List of potential referral sites with contact address (i.e., referral directory),
- e. Referral forms,
- f. Referral tracing mechanism (linkage),
- g. Feedback providing mechanism,
- h. Documentation of referred clients.

5.1.2 Premises

- 5.1.2.1 The outpatient service shall be well marked and easily accessible for disabled clients, elderly, children's and pregnant mother.
- 5.1.2.2 The outpatient service shall be located where access for ambulatory patients is the easiest and where in coming client would not have to pass through other care service outlets (pharmacy, laboratory etc).
- 5.1.2.3 Patient waiting area and Corridor shall be safe and child friendly.
- 5.1.2.4 The room arrangements of outpatient services shall consider proximity between related services with easy access to pharmacy, laboratory and other diagnostic services.
- 5.1.2.5 All outpatient rooms shall have adequate light, and ventilation.
- 5.1.2.6 All rooms for patient care shall be provided with running water supply & functional hand washing basin.
- 5.1.2.7 Communication system shall be connected with major functional areas.
- 5.1.2.8 The outpatient department shall have fire extinguishers placed in visible area.
- 5.1.2.9 All rooms for patient care shall promote patient dignity and privacy.
- 5.1.2.10 Premises for the internal medicine OPD clinic shall contain a minimum of the following;

Premises required	# required	Area required
• Reception, Recording-& Waiting area	1	30sq. m
• Recording room (optional if they used electronic recording)	1	9sq.m
• Examination room	1	12sq. M
• TB & ART treatment rooms(optional)	1	12sq.m
• Procedure room	1	9sq.m

• Immunization /Dressing/ Injection room	1	8 sq. m
• Toilet rooms (separate male/ female)	2	8 sq. m
• Store room for medical supplies,	1	12sq. m
• Utility room for cleaning and holding used equipments and/or Staff room for changing clothes),	1	

5.1.3 Professionals

5.1.3.1 An internist shall be physically available during regular working hours in the internal medicine specialty clinic.

5.1.3.2 An internist shall be responsible for the follow-up clinics.

5.1.3.3 The outpatient/ general medical service of the specialty clinic shall have the following staffing:

Professionals required	Minimum required	Number
Internist	1	
Health officer/General practitioner (Optional)	1	
Nurse	2	
Cleaner	1	
Receptionist	1	
Runner	1	

5.1.4 Products

5.1.4.1 The examination room shall have the following materials:

- | | |
|----------------------------------|-----------------------|
| a) Vital Sign and Diagnostic Set | • Reflex hammer |
| • Thermometer | • Snellen's chart |
| • Stethoscope | b) Examination couch, |
| • Sphygmomanometer | c) Weighing Scale |
| • Fundoscope | d) Refrigerator |
| • Otoscope | e) Trolley |
| • Pulseoxymeter | f) X-Ray Film viewer |

- g) Safety Box
- h) Folding screen 3 section
- i) Torch,
- j) Height measurement,
- k) Spatula, surgical and disposable gloves, antiseptics, cotton, gauze

5.1.4.2 The following products shall be available for procedure room

- | | |
|---|---|
| a) Examination Couch | r) Oxygen cylinder, |
| b) Lumbar puncture set, | s) Oxygen regulator/gauge, |
| c) Bone marrow aspiration set, | t) Oxygen mask/ nasal catheters, |
| d) Pleural (peritoneal) biopsy set,(optional) | u) Suction machine: |
| e) Dressing set, | v) Waste basket, |
| f) Pick up forceps, | w) Safety boxes, |
| g) Forceps, | x) Bed screens, |
| h) Drum, | y) Mobile Examination light, |
| i) Kidney dish, | z) Plastic apron, |
| j) Steam/ dry oven sterilizer, | aa) Drapes, |
| k) Catheterization set | bb) Spatula, surgical and disposable gloves, antiseptics, cotton, gauze |
| l) Wide bore needles for thoracentesis | cc) Rubber sheets, |
| m) Minor Set | dd) Connectors, |
| n) Dressing trolley | ee) Cushion bags, |
| o) Enema set, | |
| p) IV stand, | |
| q) Oxygen trolley, | |

5.1.4.3 The internal medicine specialty clinic shall avail emergency medicines as per the list of emergency medicines prepared by EFDA for this clinic

5.2 General Emergency Services

5.2.1. Practices

5.2.1.1 The specialty clinic shall provide emergency services related to the specialty at least during working hours without any prerequisite and discrimination.

5.2.1.2 The specialty clinic shall provide emergency observation service for conditions that do not need admission for more than 24 hours.

5.2.1.3 The emergency service shall provide basic life support as indicated for any emergency cases, which may include:

- a. Cardiopulmonary resuscitation (CPR),
- b. Airway management,
- c. Bleeding control,
- d. Shock management/ dehydration IV fluid resuscitation.

5.2.1.4 The Specialty clinic shall have protocols for the initial management of at least the following emergency cases and procedure as appropriate:

- a) CPR
- b) Shock,
- c) Severe Bleeding,
- d) Multiple fracture and injuries, poly trauma,
- e) Coma,
- f) Poisoning,
- g) Tetanus,
- h) Acute diarrhea (Severe dehydration),
- i) Seizure disorder,
- j) Air way obstruction,
- k) Cardiac emergencies
- l) Pain management
- m) Hypertension emergencies
- n) Psychiatric emergencies
- o) Meningitis
- p) Burn
- q) Acute abdomen

5.2.1.5 The speciality clinic shall have protocol for patient handover.

5.2.1.6 Every life saving emergency service shall be given to patients without any prerequisite and discrimination.

5.2.1.7 In conditions of emergency management, all interventions, medications administered and the clinical condition shall be communicated to the patient or

available family member following the emergency responses/ resuscitation measures.

5.2.1.8 Every procedure, medication and clinical condition shall be communicated to the patient or family member or next of kin after responding for urgent resuscitation measures.

5.2.1.9 If referral is urgent, it shall be done after providing initial stabilization and after confirmation of availability of the required service in the facility where the patient is to be referred to.

5.2.1.10 If the patient to be referred needs to be accompanied by a physician or other health professional during the referral process, the Specialty clinic shall arrange an ambulance and shall assign health personnel to accompany & assist patient.

5.2.2. Premises

5.2.2.1. The emergency premises shall be low traffic area and there shall be reserve parking place for ambulances.

5.2.2.2. Examination room(s) shall be ready and accessible for emergency

5.2.2.3. The emergency area shall have space to provide for the following tasks:

(a) Accepting patients and providing immediate care including emergency procedures,

(b) Admitting to provide resuscitation or observation for a maximum of 24 hours,

(c) Access to emergency medicines, supplies and equipment.

5.2.2.4. Resuscitation/ observation couches shall be arranged in a way 90cm away from walls and with a minimum of 1.2m space in between.

5.2.2.5. The emergency service shall have the following premises summary.

Rooms required	Number of rooms	Area required
Emergency examination room	1	12sq.m
Observation room	1	16sq.m
Toilet male & female (shared)	2	4 sq.m each

5.2.3. Professional

5.2.3.1. The specialty clinic shall avail medical staff for emergency conditions whenever need arises.

5.2.3.2. All medical staff handling emergencies shall have basic paediatrics emergency training.

Professionals required	Minimum Number required
General practitioner/ Health officer	1
Nurse	1
Cleaners	
Runner	

5.2.4. Products

5.2.4.1. The following equipment & supplies shall be available for emergency service in specialty clinics:

- | | |
|--|--|
| a. Resuscitation set, (2) | p. Kidney basin #2, |
| b. Ambu bag paediatric and adult(2 for each) | q. Oxygen supply with face mask, prong different size(3 one of them shall be portable) |
| c. BP apparatus(neonate up to adolescent size #1 for each) | r. EKG machine (optional) |
| d. Stethoscope #1, | s. Minor set, |
| e. Splints #2 | t. Nebulisers |
| f. Dressing set #2, | u. Urine Catheter |
| g. Suture set #2, | v. Spacers with and without face mask |
| h. IV stands #2 | w. NG tube different size |
| i. Resuscitation couches #2, | x. Pulseoximetry |
| j. Suction machine #2, | y. Glucometre |
| k. Emergency medicine cabinet,1 | z. Cardio respiratory monitor 1 |
| l. Bed screens, 3 section #1, | aa. Tourniquet |
| m. Cervical Collar | bb. Wheel chair |
| n. Mobile examination light | cc. Stretcher |
| o. Hard bord(lumbar brass) | |

dd. Laryngoscope Different size

ee. Endotracheal tube different size

Emergency Medication Management

- 5.2.4.2. Specialty clinics shall have emergency medicines at all times. List of these medicines shall be according to the Authority's Emergency Medicines list specific to the specialty clinic.
- 5.2.4.3. Emergency medicines & supplies shall be kept ready to use in Emergency room or observation room.
- 5.2.4.4. These health facilities shall get emergency medicines from suppliers licensed by the Authority.
- 5.2.4.5. Emergency medications shall be prescribed by an authorized prescriber and administered by nursing personnel with adequate information and counselling to the patient or care giver.
- 5.2.4.6. The specialty clinic shall be responsible to report suspected Adverse Drug Reaction (ADR) cases to the Authority and all adverse medication effects shall be noted in the patient's medication record.
- 5.2.4.7. It is prohibited to hold or dispense emergency medicines which are not registered or included in the emergency medicines list by the Authority.
- 5.2.4.8. It is prohibited to hold or dispense non-emergency medicines in specialty clinic at any time.
- 5.2.4.9. Specialty clinics are not allowed to hold or dispense any donated medications without prior permission from the Authority.
- 5.2.4.10. Specialty clinics shall keep documentation which shows description of medicines, medicines source, date of purchase and receipt, inventory records, medicines waste disposal records and other relevant information and produce whenever requested.
- 5.2.4.11. Specialty clinics 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)
 - g. Name & signature of the dispenser/ administrator of the drug.
- 5.2.4.12. Specialty clinics shall be responsible to make sure that medicines promotion made by suppliers or manufacturers in their premises is made by a licensed pharmacist in accordance with the country's laws.
- 5.2.4.13. Any clinical trial without the permission of the Authority is prohibited in these health facilities.
- 5.2.4.14. The storage condition for emergency medicines shall provide adequate protection to the medicines and supplies from all environmental factors until time of use.
- 5.2.4.15. Medicines shall be kept in a secured, clean, ventilated cabinet and in accordance with the manufacturers' recommendation for storage conditions.
- 5.2.4.16. Disinfectants and other chemicals shall be stored separately from emergency medicines.
- 5.2.4.17. Specialty clinics shall manage and dispose medicines waste in accordance with the directive issued by the Authority.
- 5.2.4.18. The emergency medicines & supplies for the specialty clinics shall be accessible to authorized inspector of an appropriate organ

5.3 Radiography Imaging Services

5.3.1 Practice

5.3.1.1 Basic Radiology service shall be available for the clinics.

5.3.1.2 The radiology service shall have written policies and procedures that are reviewed at least once every three years, and which shall include at least:

- a. Radiology Safety practices;
- b. Adverse reactions;
- c. Management of the critically ill patient during imaging procedures;
- d. Infection control, including patients in isolation;
- e. Timeliness of the availability of diagnostic imaging procedures and the results;
- f. Quality control program covering the inspection, maintenance, and calibration of all equipment.

- 5.3.1.3 There shall be a written protocol for managing medical emergencies in the radiological suite.
- 5.3.1.4 The radiology service unit shall be free of hazards to patients and personnel.
- 5.3.1.5 Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards, and radiation hazards.
- 5.3.1.6 The Specialty clinic shall post in easily visible place all the necessary signs & the approval certificate from the Ethiopian Radiation Protection Authority through periodic inspection.
- 5.3.1.7 The specialty clinic radiology unit shall keep documentation of the report for periodic readings of employee's exposure for radiation by the use of exposure meters or badge tests.
- 5.3.1.8 The specialty clinic shall make sure that the radiographer(s) put on personal TLD(s) whenever on operating the radiation emitting machines and TLD(s) are regularly monitored.
- 5.3.1.9 Requests for radiologic imaging examination shall contain a concise statement of reason for the examination.
- 5.3.1.10 Imaging results like X-ray films, US pictures, shall be labelled with minimum information that includes: date, patient's name, age, sex, location marks (L/R), name of institute and name of radiographer.
- 5.3.1.11 Imaging Reporting form shall have minimum information such as date, patient's name, age, sex, findings and name and signature of radiologist.

5.3.2 Premises

- 5.3.2.1 The radiology imaging unit for specialty clinic shall fulfill the design requirements of Ethiopian Radiation Protection Authority (ERPA) guidelines.

Rooms required	No. of Rooms Required	Area Required
• X-Ray room(s),		
• Conventional x-ray room	1	
• Dark room (if necessary)	1	
• Toilet with shower and hand washing basin	2	
• Patient dressing cubicle inside X-Ray room	1	
• Sub waiting area	1	
• Ultrasound room	1	12sq. m

5.3.3 Professional

- 5.3.3.1 The specialty clinic that has radiology imaging service shall have the following professionals:

Professionals required	Minimum required	Number
Radiologist	1	
Radiologist technologist/ radiographer	1	

5.3.3.2 A radiologist shall be available on call bases in specialty clinic where radiological interventions like U/S studies, Fluoroscopic study, and administration of radiologic contrasts are performed.

5.3.4 Products

5.3.4.1 Imaging equipments which shall be available for radiology services at Specialty clinic are indicated below:

- a. Standard conventional x-ray machine,
- b. Ultrasound,
- c. Fluoroscopy (optional)
- d. X-Ray viewing boxes
- e. Radiation protection equipments:
 - lead gloves,
 - lead apron,
 - lead goggle,
 - Gonad shields.
 - Abdominal shields
- f. Dark room film processing baths (if necessary),
- g. Drier (if necessary),

5.3.4.2 The X-Ray machine shall be regularly inspected, maintained, and calibrated by licensed organ or ERPA; appropriate records of maintenance shall be maintained.

5.3.4.3 All radiation generating equipments shall be installed within a room/ building with wall thickness that protects radiation to the surroundings, i.e., the minimum criteria set by the Ethiopian Radiation Protection Authority /International Atomic Energy Agency (IAEA).

5.3.4.4 Installation and un-installation of radiation emitting machines like X-Ray shall follow the safety procedures set by the Ethiopian Radiation Protection Authority during all procedures.

5.4 Medical laboratory service

5.4.1 Practices

5.4.1.1 The specialty clinic shall have a minimum of basic laboratory service.

5.4.1.2 The specialty clinic laboratory service shall provide Basic Haematology, Bacteriology, Clinical Chemistry, parasitology, urinalysis & Serology test profiles.

5.4.1.3 The internal medicine speciality clinical laboratory shall have the following minimum test descriptions;

a. Hematology tests:

- CBC
- Hemoparasite
- Blood group &RH
- Coagulation test
- Immunoassay (T3,T4,TSH)
- Cardiac marker
- Peripheral morphology
- Erythrocytes Sedimentation Rate (ESR)

b. Clinical chemistry:

- Glucose
- Albumin
- Uric acid
- Lipid profiles
- Hemoglobine A1c
- LDH
- Alpha Amylase
- Lipase
- Creatinine
- Blood Urea
- Alkaline Phosphatase
- Aspartate Aminotransferase (AST)
- Alanine Aminotransferase (ALT)
- Bilirubin, Direct
- AFP (optional)
- Bilirubin, Total
- Glucose Tolerance Test (GTT)(optional)
- γ -Glutamine Transferase (optional)
- Total protein, 24 hr. Urine
- Serum electrolyte

c. Urinalysis and body fluid analysis

- Urine HCG
- Urine analysis Qualitative
- Urine Microscopy
- Body fluid Analysis

d. Parasitology

- Stool Examination
- Occult blood test
- Modified AFP test
- H. pylori stool antigen test

e. Bacteriological examination

- Gram Stain
- AFB Stain
- Special Stain
- **(Indian ink)**

f. Serological tests and other tests

- Weli fliex
- HBsAg
- ANA
- CRP
- ASO
- RF
- HCV Anti body test
- H.pylori
- RPR (syphilis)
- HIV/Ab
- **ToxoIgG (optional)**

5.4.1.4 The internal medicine specialty clinic laboratory shall have written procedures for the following:

- a. Procedure manuals (Standard Operating Procedure, SOP) or guidelines for all tests and equipments,
- b. Report times for results(established turnaround time)
- c. Quality assurance and control processes,
- d. Inspection, preventive maintenance & calibration of all equipment,
- e. Management of reagents including availability, storage, and testing for efficacy,
- 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. Documentation of quality Assessment, calibration report and refrigerator readings.

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

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

5.4.1.7 The Specialty clinic Laboratory staff shall prepare criteria for acceptance and rejection of clinical specimens.

5.4.1.8 The Specialty clinic laboratory shall maintain a record of all samples received.

5.4.1.9 The laboratory for specialty clinic shall establish an external quality control system.

5.4.1.10 The specialty clinic Laboratory shall produce report which shall contain the following:

- a. All laboratory test result/reports shall have reference (normal) ranges.
- b. Copies or files of reported results 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 5 years for legal reason minimal errors or loss of patient test results.
- c. Reports shall be filed with the patient's medical record and duplicate copies shall be filed in the laboratory in a manner which permits ready identification and accessibility and with appropriate backup.
- d. In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be contained in the medical record.
- e. Quality assured test results shall be reported on standard forms to the general medical practitioner 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 name and initial of the person who performed the test, and the authorized signature of the person reviewing the report and releasing the results.
 - Specialty clinic address.
- f. Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them.
- g. The laboratory shall have protocol and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic. Protocols shall be established which define who may access patient data and who is authorized to enter and change patient results.

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

5.4.1.12 Safety signage shall be posted in the laboratory.

- 5.4.1.13 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.
- 5.4.1.14 There shall be a policy and procedure for regular calibration and running of control tests for laboratory equipments: semi-automated/ automated machines. Documentation shall be maintained.
- 5.4.1.15 Laboratory shall have a documented and recorded programme of preventive maintenance which at a minimum follows the manufacturer's recommendations.
- 5.4.1.16 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 labelled.
- 5.4.1.17 There shall be a written safety procedure for handling hazardous chemical reagents used in the laboratory. The procedure shall define at least the following:
- a) The storage requirements,
 - b) Handling procedures,
 - c) Requirements for personal protective equipment,
 - d) Procedures following accidental contact or overexposure,

5.4.2 Premises

- 5.4.2.1 There shall be separate sputum collection area.
- 5.4.2.2 The laboratory working environment shall be kept organized and clean, with safe procedures for handling of specimens and waste materials.
- 5.4.2.3 The laboratory shall have adequate lighting, ventilation, water, waste and refuse disposal.
- 5.4.2.4 The laboratory shall have controlled temperature of refrigerator. For which recordings shall be documented.
- 5.4.2.5 Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access. .
- 5.4.2.6 The laboratory facilities shall meet at least the following general requirements:
- a. Reliable supply of running water,
 - b. The laboratory rooms shall have two separate sinks, one for general laboratory use and the other reserved for hand washing,
 - c. Continuous power supply,
 - d. Fitted with laboratory benches, Working surface covered with appropriate water proof, corrosive resistance materials,

- e. Laboratory stools for the benches.
- f. Laboratory furniture shall be capable of supporting anticipated loading and uses.
- g. Spaces between benches, cabinets, and equipment shall be accessible for cleaning.
- h. Lockable doors and cupboards.
- i. Closed drainage from laboratory sinks (to a septic tank or deep pit)
- j. Separate toilets for staff and patients.

5.4.2.7 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.

Rooms required	No. of Rooms Required	Area Required
• Laboratory room (can be 1 room with open platform)	1	73 sq. m
○ Specimen collection room	1	6sq. m
○ Hematology & clinical chemistry	1	16sq. m
○ Parasitology, urinalysis & serology	1	9sq. m
○ Molecular & flow cytometry (Genexpert (CD4 optional)	1	6sq. m
○ Bacteriology,(culture optional)	1	6sq. m
○ Disinfection & sterilization room (shared)	1	9sq. m

5.4.3 Professionals

5.4.3.1 The laboratory service shall be directed by a licensed medical laboratory technologist.

5.4.3.2 The specialty clinic shall have & maintain Job descriptions including qualification for each lab staff.

5.4.3.3 The specialty clinic shall facilitate access to relevant trainings, continuing education and assess staff competency at regular intervals.

5.4.3.4 Laboratory staff shall, at all times, perform their functions with adherence to the highest ethical and professional standards of the laboratory profession.

5.4.3.5 The laboratory service shall have the following professionals;

Professional required	Number required
Laboratory technologist	1
Laboratory technician	3

5.4.4 Products

5.4.4.1 The internal medicine specialty clinic medical laboratory shall have the following equipments:

- a) Safety cabinet,(optional)
- b) Lab bench,
- c) Microscope, binocular
- r) Assorted lab glass wares,
- d) Centrifuge,
- s) Biohazard bag,
- e) Autoclave
- t) Safety box,
- f) Dry oven,
- u) Glucometer,
- g) Refrigerator with thermometer,
- v) Hemoglobinometer,
- h) Bunsen Burner,
- w) Autoclave
- i) ESR stand
- x) Staining rack
- j) ESR tubes,
- y) Electrolyte analyzer
- k) Distil Water /distillation apparatus,
- z) Western green tube
- l) Incubator,
- aa) Hemo cytometer
- m) WBC chamber,
- bb) Immune assay analyzer
- n) Differential counter,
- cc) Coagulation analyzer
- o) Hematology analyzer,
- dd) Plain tube
- p) Clinical Chemistry analyzer (semi-automated*/ automated),
- ee) Serum separator tube
- q) Water bath,

5.4.4.2 The minimum equipments for Clinical chemistry services:

- a) Clinical chemistry analyzer (Automated or semi automated)
- d) Micropipettes of different volumes
- b) Glucometer
- e) Timer with alarm
- c) Power surge protectors/UPS
- f) Printer

5.4.4.3 **The minimum equipments for Parasitology & Urine, body fluid analysis & Mycology:**

- a) Binocular Microscope,
- b) Slides

5.4.4.4 **The minimum equipment for Hematology:**

- a) Haemoglobinometer
- f) Haemocytometer
- b) Hematology analyzer (Automated)
- g) Differential counter
- c) Blood roller/mixer
- h) Tally counter
- d) Refrigerator
- i) Centrifuge
- e) Binocular microscope x10, x40, x100
- j) Timer
- k) Shaker/ Roller

5.4.4.5 Internal medicine specialty clinic should have viral load and CD4 machines.

5.4.4.6 The following minimum consumables, Lab Chemicals and solutions shall be required

- a) Wright stain
- b) Giemsa stain
- c) Formalin
- d) Oil immersion
- e) Carbol fuchsin
- f) Methylene blue
- g) Acetone
- h) Crystal violet
- i) Gram's iodine
- j) Methanol
- k) Safranin
- l) Glacial acetic acid
- m) Ether
- n) 75% alcohol
- o) 0.85% NaCl
- p) KOH
- q) Urine strip of 10 parameter
- r) HCG Test kit
- s) Occult blood reagents
- t) Vacutainer EDTA tube of 4ml
- u) Vacutainer plain tube of 10ml
- v) Vacutainer needle holder
- w) Vacutainer needle/Syringe with needle of different sizes
- x) Tourniquet
- y) Slide and cover slide
- z) Micropipette of different sizes (5 μ l -1000 μ l)
- aa) Thermometer
- bb) Conical urine test tubes
- cc) Disposable plastic pipettes (1 ml-5ml)
- dd) Sterile urine cups
- ee) Falcon tube
- ff) Stool cup
- gg) Nunc tubes(optional)
- hh) Cryoboxes
- ii) Test tube racks
- jj) Slide boxes
- kk) Lens paper
- ll) Disposable gloves
- mm) Cotton Roll
- nn) Applicator sticks
- oo) Biohazard plastic bag
- pp) Safety Box
- qq) ESR rack
- rr) Westergren tube
- ss) Test tube racks.

5.5 Record keeping & reporting services

5.5.1 Practice

5.5.1.1 Information contained in the medical record shall be complete and sufficiently detailed relative to the patient's history, physical examination, diagnosis, diagnostic procedures, medication administration and treatment

5.5.1.2 The specialty clinic shall maintain individual patient records,

5.5.1.3 The Specialty clinic shall maintain individual medical records in a manner to ensure accuracy and easy retrieval.

5.5.1.4 If a patient received medical intervention while on ambulance, the medical information of a patient & medication administered during ambulance service shall be documented in written and attached into the medical record.

5.5.1.5 The Specialty clinic shall establish a master patient index with a unique medical number/record for each patient

5.5.1.6 Patient medical record shall at least contain the following information:

- a. Identification (name, age, sex, address),
- b. History, physical examination, investigation results and diagnosis,
- c. Medication, procedure and consultation notes,
- d. Name and signature of treating physician ,
- e. If applicable, a signed Consent form(s). In case where someone other than the patient signs the forms, the reason for the patient's not signing it shall be indicated on the face of the form, along with the relationship of the signee to the patient.

5.5.1.7 Every piece of paper or format that contains a patient medical information shall carry the appropriate identification,

5.5.1.8 All medical records shall be kept confidential, available only for use by authorized persons or as otherwise permitted by law.

5.5.1.9 The clinic shall have a mechanism to track a medical record taken out for use until returned to the record room.

5.5.1.10 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.

5.5.1.11 Consent forms that patient sign shall be printed in an understandable format and the text written in clear, legible and non-technical language.

5.5.1.12 There shall be a mechanism to make medical records ready on appointment for use and to return seen cards back to the central medical record room within 24hrs.

5.5.1.13 If death happens in the clinic, the necessary information of the patient's death shall be documented in the patient's medical record upon death; date, time, any intervention, etc.,

5.5.1.14 Original medical records shall not leave Specialty clinic premises unless they are under court order or in order to safeguard the record in case of a physical emergency or natural disaster.

5.5.1.15 If a patient or his legally authorized representative requests in writing, a copy of the medical record shall be given.

5.5.1.16 If a patient is provided with medical certificates, copies of the certificate and other records shall be documented and/or recorded on the patient's medical record.

5.5.1.17 If the patient is referred to another facility on a non-emergency basis, the Specialty clinic shall prepare a transfer/referral note reflecting the patient's immediate needs; send a copy of this record to the receiving facility & maintain a copy to the medical record.

5.5.1.18 If the Specialty clinic ceases to operate, it shall notify the appropriate organ in writing about how and where medical records are stored at least 15 days prior to cessation of operation. The patient's choice on where to transfer his/her medical record shall be respected.

5.5.1.19 The Specialty clinic shall establish a procedure for removal of inactive medical records from the medical record room.

5.5.1.20 The specialty clinic shall destroy old medical records as per the law by using techniques that assure confidentiality. However, records which are active for more than ten years shall not be destroyed.

5.5.1.21 The specialty clinic shall have a written policy and procedure for medical record keeping which include at least:

- a. Procedures for record completion,
- b. Conditions & procedures for releasing medical information,
- c. Procedures for the protection of medical record information against the loss, tampering, alteration, destruction or unauthorized use.

5.5.1.22 The specialty clinic shall have procedure for keeping records, collecting data and reporting regularly specified reportable surveillance disease conditions for concerned public body-Zone/ Town/Sub-city.

5.5.1.23 Prescriptions and different request forms for investigation like laboratory, x-ray, etc. shall be revised and updated as per service need at least every five years.

5.5.2 Premises

5.5.2.1 The specialty clinic shall have a well secured, ventilated & illuminated room with adequate space for shelves for archiving medical records. This room can be together with the reception based on the volume.

5.5.2.2 The premises for medical record shall have enough space between and around shelves. The medical records shall be kept in shelves which are to a minimum 10cm above the floor.

5.5.2.3 The medical record room shall have the following areas:

a. Working area for Recording & sorting (can be the reception area)

b. Archive space with shelves

5.5.2.4 The medical record room shall have adequate light and ventilation.

5.5.2.5 There shall be fire extinguisher kept in a visible and identified place near the medical record room,

5.5.2.6 For facilities where medical records area shared with reception, medical records shall be stored in cabinets with locks.

5.5.3 Professional

5.5.3.1 The specialty clinic receptionist shall function as record room personnel with proper orientation.

5.5.4 Products

5.5.4.1 The record room of specialty clinic shall have the following materials:

a. Shelves,

b. Lockable cabinet,

c. Cardex,

d. Patient medical records,

e. Standard request papers & formats,

5.6 Health Promotion Services

5.6.1 Practice

5.6.1.1 The specialty clinic shall plan, schedule and carry out health promotion activities in the respective specialty.

5.6.1.2 The specialty clinic shall have a written policy and procedures for health promotion.

Which shall include:

- a. Content of health promotion package, the implementation media aiming at improving health outcomes for patients, relatives, staff and community.
- b. Allocating resources to the processes of implementation & regular review of the promotion package.
- c. Enlightening staffs on health promotion package.
- d. Ensuring that the clinic staff has relevant competences to perform health promotion activities and supports the acquisition of further competences as required.

5.6.1.3 The specialty clinic shall provide patients with information on significant factors concerning their health condition. Health promotion interventions shall be established in all patient pathways, & to a minimum shall include:

- a. Based on the health promotion needs assessment, the patient is informed of factors impacting on his/ her health and, in partnership with the patient, a plan for relevant activities for health promotion is agreed.
- b. Patients are given clear, understandable and appropriate information about their actual health condition, treatment, care and factors influencing their health.
- c. Health promotion is systematically offered to all patients based on the assessed needs.
- d. Information given to the patient and all health promoting activities are documented and evaluated, including whether expected and planned results have been achieved.

- e. All patients, staff and visitors have access to general information on factors influencing health.
- f. When necessary, an individual health promotion plan for a medical services shall be drawn up and documented into the patient's medical file;

5.6.1.4 The specialty clinic shall have policy for the establishment of a healthy workplace which shall include:

- a. Development and training of staff in health promotion skills.
- b. Implementation of a policy for a healthy and safe workplace providing occupational health for staff.
- c. Involvement of staff in decisions impacting on the staff's working environment.
- d. Availability of procedures to develop and maintain staff awareness on health issues.

5.6.1.5 The specialty clinic health promotion practice shall provide unbiased and evidence based information.

5.6.1.6 The specialty clinic shall prepare &/ or avail health promotional materials which shall be customer focused.

5.6.2 Premises

5.6.2.1 The specialty clinic shall have waiting area at reception with audio visual health promotion materials.

5.6.3 Professionals

5.6.3.1 It is not mandatory to assign staff for promotion in particular,

5.6.3.2 The specialist shall take the lead to identify priority conditions to prepare or avail promotion materials.

5.6.3.3 The nurse shall collect available promotion materials from respective parties and coordinate health promotion activities.

5.6.3.4 The expected health promotional activities shall be specified in the job description(s) of the nurse(s).

5.6.4 Products

5.6.4.1 The specialty clinic shall have Audio visual materials, TV set, DVD/ VCD, Radio, Tape-recorded at reception area,

5.6.4.2 The specialty clinic may have the following health promotional materials:

- a. Printed material (Posters, Brochures, Leaflets, Newspaper, Health bulletin),
- b. Audio- video IEC materials (audio cassettes, video cassettes),

FINAL DRAFT

FINAL DRAFT

5.7 Housekeeping & Maintenance Services

5.7.1 Practices

5.7.1.1 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.

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

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

5.7.1.4 Collection, transportation and disposal of specialty clinic wastes shall be supervised and controlled

5.7.1.5 The safety of fire, electrical and natural hazards in the risk areas in the specialty clinic shall be supervised and controlled and shall work closely with specialty clinic fire brigade and safety committee.

5.7.1.6 The designee shall identify, supervise and organize the control and eradication of pests, rodents and animal nuisance in the specialty clinic.

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

5.7.1.8 The housekeeping staffs shall ensure proper lighting and ventilation in different specialty clinic areas.

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

5.7.1.10 The infection control measures shall be carried out in accordance with the specialty clinic infection prevention standard

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

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

5.7.1.13 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.

5.7.1.14 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.

5.7.1.15 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.

5.7.1.16 There shall be written protocols and procedures for specialty 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.

5.7.1.17 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

5.7.1.18 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.

5.7.1.19 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.

5.7.1.20 All areas of the clinic, including the building and grounds, shall be kept clean and orderly.

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

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

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

5.7.1.24 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.

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

5.7.1.26 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.

5.7.2 Premises

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

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

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

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

5.7.2.5 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.

5.7.3 Professionals

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

5.7.3.2 The housekeeping and maintenance personnel 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.

5.7.3.3 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.

5.7.4 Products

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

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

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

5.8 Infection Prevention

5.8.1 Practices

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

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

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

5.8.1.4 The specialty 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.

5.8.1.5 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 specialty clinic hygiene
 - Structural infection prevention
 - Physical specialty clinic organization
- e. Waste management
 - Cleaning medical instruments
 - Implementation of a disposal system
 - Handling medical waste

- Waste removal

5.8.1.6 The following specific standard precautions shall be practiced and the specialty 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 specialty clinic staff shall consider that every patient is infectious

c. The specialty 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.

5.8.1.7 There shall be transmission-based precautions and the specialty 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

5.8.1.8 Each specialty 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

5.8.1.9 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 specialty 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

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

5.8.1.11 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

5.8.1.12 The specialty 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.

5.8.2 Premises

5.8.2.1 The specialty clinic shall have a dedicated office for IP officer,

5.8.2.2 The specialty clinic shall have a room or area for temporary storage of waste containers,

5.8.2.3 The specialty clinic shall have a centralized sterilization room

5.8.2.4 The specialty clinic shall have incinerator with ash and burial pits.

5.8.3 Professionals

5.8.3.1 The specialty clinic shall have a designated staff to serve as IP infection prevention and control officer.

5.8.3.2 The officer shall be a licensed IP trained nurse and knowledgeable of infection prevention principles and health care epidemiology.

5.8.4 Products

5.8.4.1 The specialty 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

- 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

FINAL DRAFT

5.9 Sanitation and Waste Management

5.9.1 Practices

5.9.1.1 Specialty clinic environment shall ensure the following conditions:

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

5.9.1.2 There shall be written procedures to govern the use of sanitation techniques in all areas of the specialty clinic.

5.9.1.3 If the clinic has ground water source, there shall be a written policy and procedures for ground water treatment,

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

5.9.1.5 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.

5.9.1.6 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

5.9.1.7 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.

5.9.1.8 Segregation of health care waste shall includes the following procedures:

- a. Separate different types of waste as per the guideline,
- b. The specialty 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 specialty clinic:

Segregation category	Color	Container
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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

5.9.1.9 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).

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

5.9.1.11 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).

5.9.1.12 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,

5.9.1.13 The specialty 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.

5.9.1.14 The specialty clinic shall ensure appropriate ventilation system.

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

5.9.1.16 Housekeeping items shall be cleaned and sanitized regularly.

5.9.1.17 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).

5.9.1.18 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,

5.9.1.19 The specialty 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.

5.9.2 Premises

5.9.2.1 The specialty 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.

5.9.3 Professionals

5.9.3.1 Specialty clinic sanitation service shall be administered together with infection prevention activities.

5.9.3.2 In addition, the specialty clinic shall have:

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

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

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

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

5.9.3.6 Staff shall be oriented on personal protection methods.

5.9.4 Products

5.9.4.1 The specialty 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

Bibliography

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

1. Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No. 661/2009
2. Ethiopian Food, Medicine and Healthcare Administration and Control Regulation No. 189/2010
3. National Health Policy of the Transitional Government of Ethiopia, 1993
4. National Drug Policy of the Transitional Government of Ethiopia, November 1993
5. Commercial Code of Ethiopia
6. Criminal Code of Ethiopia
7. Medicines Waste Management and Disposal Directive No 2/2011
8. Ethiopian National Guideline for Health Waste Management, 2008

9. Ethiopian Building Proclamation, No. 624/2009