

CES xxx

# Compulsory Ethiopian Standard

Second Edition  
2018

## Pediatric specialty clinic Requirements



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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.

## Pediatric Specialty Clinic Requirement

### 1. Scope

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

### 2. Normative Reference

### 3. Terms and Definitions

For the purpose of this standards the definition in paediatric specialty clinic and the following definitions shall apply

**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 center staff who is responsible for a given service

**3.7 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. A specialty clinic may have more than one specialty services at ambulatory level if the clinic complies with all requirements stated for each category of specialty services.

**3.8 Child:** Shall mean those children aged from newborn to 18 years.

### 4. General Requirement

- 4.1. The paediatric clinic shall provide service at outpatient/ambulatory level only.
- 4.2. Emergency care with a qualified staff shall be available during working hours.
- 4.3. The speciality clinic shall have triage.
- 4.4. The paediatric clinic shall avail updated reference materials, treatment guidelines and manuals for common paediatric problems.
- 4.5. Diseases under national surveillance shall be notified to the FMOH through the proper reporting channel.
- 4.6. The medical record for paediatric 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.
- 4.7. 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
- 4.8. The speciality shall establish quality team to improve quality of service deliveries.
- 4.9. 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.
- 4.10. The specialty clinic shall provide or facilitate training to their staffs.
- 4.11. 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,
- 4.12. The paediatrics speciality clinic facilities shall be well marked and easily accessible for persons with disability.
- 4.13. The paediatrics speciality clinic shall have fire extinguisher placed in visible area.
- 4.14. 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.
- 4.15. 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.
- 4.16. Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.
- 4.17. All patient care rooms shall be provided with running water supply & functional hand washing basin.
- 4.18. 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.

- 4.19. The circulation ways and sub corridors shall be a minimum 2m wide.
- 4.20. Patient serving corridors shall not be less than 240cm wide,
- 4.21. Safety glass, tempered glass or plastic glass materials shall be used for paediatrics service units to avoid possible injuries.
- 4.22. Glass doors shall be marked to avoid accidental collision.
- 4.23. Paediatrics 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.
- 4.24. 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**

- 4.25. The nursing service in the specialty clinic shall be directed by licensed paediatrics nurse or nurse.
- 4.26. 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,
- 4.27. 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.
- 4.28. 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.
- 4.29. 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.

- 4.30. All patients kept for observation/resuscitation shall be under the supervision/ care of a licensed nurse at all times.
- 4.31. Nurses shall explain and seek informed consent from their patients or their relatives/ next of kin (for incompetent patients) before carrying out any procedure.
- 4.32. 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).
- 4.33. There shall be a procedure for standardized, safe and proper administration of medications by nurses or designated clinical staff.
- 4.34. Allergies shall be listed on the front cover of the patient's chart or highlighted on the screen in a computerized system.
- 4.35. 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.
- 4.36. Patient discharge instructions shall be documented in the patient's medical record and verbal instruction shall be given.
- 4.37. 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.
- 4.38. There shall be a protocol that states the procedure to be followed for dying patients & dead body care.

## **5. Specific requirement**

### **5.1. Outpatient Services**

#### **5.1.1. Practices:**

**5.1.1.1** 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

**5.1.1.2** For non-emergency paediatric patients, the service shall be available during regular working hours.

**5.1.1.3** All children seeking service in the center shall be checked for their immunization status & managed accordingly.

**5.1.1.4** The paediatrics specialty centre shall provide comprehensive adolescent care.

**5.1.1.5** The general outpatient service at paediatric clinic shall include:

- a) Assessment and treatment of sick child,
- b) Immunization and well baby follow up,
- c) Growth and development monitoring with anticipatory nutritional advice guidance,
- d) Consultation on Nutritional feeding for child
- e) Follow up of babies and children with common infectious and chronic diseases like diabetes, asthma, cardiac, congenital problems, etc

**5.1.1.6** The outpatient service delivered in specialty clinic shall be provided by licensed paediatrician.

**5.1.1.7** 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°) pain assessment and anthropometric measurement,
  - Clinical examination pertinent to the illness,
- c) Diagnostics impression, and
- d) Laboratory and other medical workups when indicated.

**5.1.1.8** 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.

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

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

- a) List of conditions indicative for urgent referral,
- b) Standard operating procedure(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.

**5.1.1.11** The scope of the outpatient services shall be limited to those specialty services stated on the license.

## **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 The speciality center shall have dedicated play ground area for children provided with different toys.
- 5.1.2.4 Patient waiting area, children play ground and Corridor shall be safe and child friendly.
- 5.1.2.5 The room arrangements of outpatient services shall consider proximity between related services with easy access to pharmacy, laboratory and other diagnostic services.
- 5.1.2.6 All outpatient rooms shall have adequate light, and ventilation.
- 5.1.2.7 All rooms for patient care shall be provided with running water supply & functional hand washing basin.
- 5.1.2.8 Communication system shall be connected with major functional areas.
- 5.1.2.9 The outpatient department shall have fire extinguishers placed in visible area.
- 5.1.2.10 All rooms for patient care shall promote patient dignity and privacy.
- 5.1.2.11 Premises for the paediatric OPD clinic shall contain a minimum of the following;

Premises required	No. required	Area required
• Reception/ Recording & Waiting area	1	30 sq. m
• Examination/ Consultation room	1	12 sq. m
• Treatment/ procedure and Instrument processing room	1	12 sq. M
• Immunization room	1	9sq.m
• Minor OR(optional)	1	12 sq.m
• Nurse station(Staff Changing room)	1	12sq.m
• Emergency Observation room with 2 beds	1	20 sq. M
• Toilet room (male & female)	2	4sq. m each
• Staff toilet	1	4sq.m
• Store room for medical supplies,	1	6 sq. M
• Diaper changing area		
• Play ground area		

### 5.1.3 Professionals

- 5.1.3.1 The paediatric specialty clinic shall be directed by a licensed paediatrician.
- 5.1.3.2 The outpatient service of the paediatrics specialty clinic shall have the following staffing:

Professionals required	Minimum Number required
Paediatrician	1
General practitioner (Optional)	1
Nurse	3
Cleaner	
Receptionist	

### 5.1.4 Products

**5.1.4.1** Equipment for children Play ground area/room shall include at least the following:

- a. Play mat,
- b. Washable toys/ dolls,
- c. Safety guard/ fence

**5.1.4.2** The examination room shall have the following materials:

- a. Examination coach (child friendly),
- b. Thermometer, digital
- c. Stethoscopes, infant & paediatric
- d. BP apparatus different size, paediatric
- e. Reflex hammer
- f. Examination light,
- g. Growth curves,
- h. Pulseoximeter,
- i. MUAC tape
- j. Bowel,
- k. Diaper changing table,
- l. Ambu bag different size
- m. Bed pan (children),
- n. Urine bottle (children),
- o. X-Ray viewer,
- p. Folding Screen 3section
- q. Baby weighing scale,
- r. Stadiometer/ infantometer,
- s. Measuring tape,
- t. Otoscope/Ophthalmoscope,
- u. PICT kit

**5.1.4.3** The following products shall be available for procedure room

- a) Dressing set,
- b) Pick up forceps,
- c) Forceps,
- d) Drum,
- e) Kidney dish
- f) Steam/ dry oven sterilizer,
- g) Catheterization set
- h) Wide bore needles for thoracentesis
- i) Minor Set

**5.1.4.4** The following products shall be available for immunization room.

- a) Weight scale for child
- b) Vaccine carrier
- c) Thermometer
- d) WHO standard Refrigerator
- e) Cold box
- f) Growth monitoring chart
- g) EPI monitoring chart
- h) Height/ length scale
- i) MUAC tape

## **5.2. General Emergency Services**

### **5.2.1. Practices**

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

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

**5.1.4.7** 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.

**5.1.4.8** 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

**5.1.4.9** The speciality center shall have protocol for patient handover.

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

**5.1.4.11** 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.

**5.1.4.12** 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.

**5.1.4.13** 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.

**5.1.4.14** 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.

<b>Rooms required</b>	<b>Number of rooms</b>	<b>Area required</b>
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.

<b>Professionals required</b>	<b>Minimum Number required</b>
Paediatrician/ General practitioner	1
Health officer (optional)	1
Paediatric nurse/Nurse	2
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 )
- b. Ambu bag paediatric and adult(2 for each)
- c. BP apparatus(neonate up to adolescent size #1 for each)
- d. Stethoscope #1,
- e. Splints #2
- f. Dressing set #2,
- g. Suture set #2,
- h. IV stands #2
- i. Resuscitation couches #2,
- j. Suction machine #2,
- k. Emergency medicine cabinet,1
- l. Bed screens, 3 section #1,
- m. Cervical Collar
- n. Mobile examination light
- o. Hard bord(lumbar brass)
- p. Kidney basin #2,

- q. Oxygen supply with face mask, prong different size(3 one of them shall be portable)
- r. EKG machine (optional)
- s. Minor set,
- t. Nebulisers
- u. Urine Catheter
- v. Spacers with and without face mask
- w. NG tube different size
- x. Pulseoximetry
- y. Glucometre
- z. Cardio respiratory monitor 1
- aa. Tourniquet
- bb. Wheel chair
- cc. Stretcher
- dd. Laryngoscope Different size
- ee. Endotrachial 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. Minor Surgical Services (optional)**

#### **5.3.1 Practices**

- 5.3.1.1** The specialty clinic may provide minor surgical services.
- 5.3.1.2** Any specialty related minor surgical interventions performed under the specialty clinic shall be done by licensed specialist.
- 5.3.1.3** At specialty clinic level use of General Anaesthesia (GA), or performing major surgeries that need GA with or without use of anaesthesia machines are strictly prohibited.
- 5.3.1.4** The specialty clinic shall have list of minor surgical procedures that are allowed to be done at outpatient level. E.g., Circumcisions, lipoma excisions, abscess drainages, suturing of soft tissue injuries, external immobilization of closed and open fractures and other minor interventions.
- 5.3.1.5** Surgical interventions shall be recorded for each patient and documentation shall be integrated with the patient's medical record.

- 5.3.1.6** The preoperative (pre-procedure) assessment finding and diagnosis shall be recorded in their medical records for all patients prior to surgical intervention.
- 5.3.1.7** The specialist practitioner shall explain the disease condition, possible surgical intervention and outcome possibilities in clear, simple and understandable terms to the patient and/or next of kin or family/ guardian.
- 5.3.1.8** There shall be protocols that ensure & define the appropriateness and safety of the procedure before, during and immediately after minor surgery, including at least the following:
- a. Aseptic technique,
  - b. Sterilization and disinfections,
  - c. Selection of draping and gowning,
- 5.3.1.9** The specialty clinic shall have copy of management protocols at least for,
- a. pain management,
  - b. emergency/acute trauma management,
  - c. emergency resuscitation, Cardio Pulmonary Resuscitation (CPR),
- 5.3.1.10** The minor OR shall be kept clean at all time; clean after every procedure and it shall be cleansed thoroughly at least weekly.
- 5.3.1.11** Administration of minor regional blocks shall be monitored, which shall include:
- a. Prior to administration of any anaesthesia medication, a verbal & written informed consent shall be obtained for the surgical procedure & for the use of minor regional block/ anaesthesia and shall be documented in the medical record.
  - b. Each patient's physiologic status shall be monitored during anaesthesia and the results of the monitoring shall be documented in the patient's medical record, which includes a minimum of :
    - Pulse rate and rhythm.
    - Respiratory rate.
    - Temperature.
    - BP.
- 5.3.1.12** A written record of the anaesthetic agent and outcome of the procedure shall be kept as a permanent record in the patient's record.
- 5.3.1.13** Pain shall be assessed and controlled during and after any surgical procedures.
- 5.3.2 Premises**
- 5.3.2.1** The premises for surgical services in specialty clinic shall have Minor OR/ or procedure room with the following:

- a. Layout shall be with flow from change area, scrub area, to operating/ procedure area when viewed from entrance.
- b. Washable walls; crack free and of scrub-able Ceiling.
- c. Vicinity of plumbing fixtures, floors and walls penetrated by pipes shall be sealed & smoothed,
- d. Floor shall be smooth, easily cleanable and non-slippery, preferably made of marble or ceramic.
- e. Fitted with at least 2 fixed electric outlets,
- f. A line shall be clearly marked in red or green on the floor, beyond which no person shall be permitted to set foot without changing shoes or applying shoes cover.
- g. The scrub area shall be provided with sink and taps for running water. The taps for running water shall be hand free, manipulated with elbow or knee. (E.g. long arm valve gate).

### 5.3.3 Professional

5.3.3.1 Any specialty related minor surgical procedures shall be performed by licensed specialist in the discipline.

5.3.3.2 The minor surgical service shall have the following staffs.

Professional required	Number required
Paediatrician (shared )	1
Nurse	2

### 5.3.4 Products

5.3.4.1 There shall be the following products/ equipments for minor surgical services in specialty clinic:

- |  |  |
|--|--|
| <ol style="list-style-type: none"> <li>a. Minor OR/ procedure table,</li> <li>b. Instrument tray,</li> <li>c. IV stand,</li> <li>d. Mobile operation light,</li> <li>e. Oxygen source,</li> <li>f. Adjustable stool,</li> <li>g. Steam sterilizer,</li> <li>h. Sterilization Drums,</li> <li>i. Suction machine,</li> <li>j. Resuscitation set, ,</li> <li>k. Dressing trolley,</li> <li>l. Minor surgical set,</li> </ol> | <ol style="list-style-type: none"> <li>m. Kidney basin, 475ml,</li> <li>n. Galley pots,</li> <li>o. Surgical drape, fenestrated</li> <li>p. Bowls with stands,</li> <li>q. Glass medicine cabinet and shelve,</li> <li>r. Kick buckets,</li> <li>s. Minor OR Linen: <ul style="list-style-type: none"> <li>• Trousers, Surgical,</li> <li>• Top(shirts), Surgical,</li> <li>• Gown, Surgical, (Plain)</li> <li>• Cap, Surgical,</li> </ul> </li> </ol> |
|--|--|



- Masks, surgical,

#### 5.3.4.2 Supplies:

- |                          |  |
|--------------------------|--|
| a. Catheters,            | g. Zink oxide,   |
| b. S/ gloves,            | h. Surgical blades,                                    |
| c. Disposable glove,     | i. Suturing materials: absorbable,<br>non- absorbable, |
| d. Gauze: sterile, roll, | j. Vigo/ IV cannula,                                   |
| e. Cotton,               |  |
| f. Lidocain              |  |

**5.3.4.3 Medicines:** the clinic shall have local anaesthesia & emergency medicines according to the emergency drug lists prepared by EFDA for the specific specialty.

## 5.4. Medical laboratory service

### 5.4.1. Practices

- 5.4.1.1.** The clinical laboratory in the paediatrics specialty clinic shall provide basic laboratory services for hematology, chemistry, bacteriology, parasitology, cytology and serology tests.
- 5.4.1.2.** The specialty clinic laboratory shall have written procedures for the following:
- Procedure manuals (Standard Operating Procedure, SOP) or guidelines for all tests and equipments,
  - Report times for results(established turnaround time)
  - Quality assurance and control processes,
  - Inspection, preventive maintenance & calibration of all equipment,
  - Management of reagents including availability, storage, and testing for efficacy,
  - Procedures for collecting, identifying, processing and disposing of specimens,
  - All normal ranges for all tests shall be stated
  - Laboratory safety program, including infection control
  - Documentation of quality Assessment, calibration report and refrigerator readings.
- 5.4.1.3.** The laboratory shall follow standard operating procedures (SOP) and conduct routine quality assessments to ensure reliable and efficient testing of patient specimens.
- 5.4.1.4.** The process of analysis shall be specified by validated written or electronic procedures maintained in and by the laboratory.
- 5.4.1.5.** The Specialty clinic Laboratory staff shall prepare criteria for acceptance and rejection of clinical specimens.
- 5.4.1.6.** The Specialty clinic laboratory shall maintain a record of all samples received.
- 5.4.1.7.** The laboratory for specialty clinic shall establish an external quality control system.
- 5.4.1.8.** 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.

**5.4.1.9.** The specialty clinic laboratory shall maintain a record of all samples received and tests run.

**5.4.1.10.** Specialty clinic laboratory staff shall test quality control materials every day for equipment requiring frequent calibration.

**5.4.1.11.** Specialty clinic laboratory shall have a procedure for storage of clinical samples that are not examined immediately.

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

**5.4.1.13.** Safety signage shall be posted in the laboratory.

**5.4.1.14.** The lab professional shall wear protective clothing of an approved design (splash proof), always fastened, within the laboratory work area and removed before leaving the laboratory.

**5.4.1.15.** 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.

**5.4.1.16.** Laboratory shall have a documented and recorded programme of preventive maintenance which at a minimum follows the manufacturer's recommendations.

**5.4.1.17.** 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.

**5.4.1.18.** 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,

**5.4.1.19.** Specialty clinic laboratory team/ management shall review all operational procedures at **regular intervals**.

**5.4.1.20.** The specialty clinic laboratory service shall provide Basic Haematology, Bacteriology, Clinical Chemistry, parasitology, urinalysis & Serology test profiles. Based on the type of the clinic, complexity of the test profiles varies.

**a. HEMATOLOGY TESTS:**

- White blood cell count
- Hemoglobin
- Hematocrit
- Differential count
- Reticulocyte count (optional)
- Platelet
- Hemoparasite
- RBC morphology
- Erythrocytes Sedimentation Rate (ESR)

**b. CLINICAL CHEMISTRY:**

- Glucose
- Creatinine
- Blood Urea
- Alkaline Phosphatase
- Aspartate Aminotransferase (AST)
- Alanine aminotransferase (ALT)
- Bilirubin, Direct
- Bilirubin, Total
- Serum albumin

**c. URINALYSIS AND BODY FLUID ANALYSIS**

- Urine analysis Qualitative
- Urine Microscopy
- Body fluid Analysis

**d. PARASITOLOGY**

- Stool Examination
- H.pylori(optional)
- Special parasitological tests

**e. BACTERIOLOGICAL EXAMINATION**

- Gram Stain
- AFB Stain
- Special Stain

**f. SEROLOGICAL TESTS AND OTHER TESTS**

- ~~Widal-weli fliex~~
- HBsAg
- HBCAb(optional)
- Titer widal-welifliex
- HIV/Ag/Ab

**5.4.1.21.** Temperature of the refrigerator used to store laboratory reagents shall be strictly maintained below 8°C & daily temperature readings shall be documented.

**5.4.2. Premises**

**5.4.2.1.** The laboratory shall have adequate lighting, ventilation, water, waste and refuse disposal.

**5.4.2.2.** The laboratory shall have controlled temperature of refrigerator. For which recordings shall be documented.

**5.4.2.3.** The laboratory facilities shall meet at least the following general requirements:

- Reliable supply of running water,
- The laboratory rooms shall have two separate sinks, one for general laboratory use and the other reserved for hand washing,
- Continuous power supply,
- Fitted with laboratory benches, Working surface covered with appropriate water proof, corrosive resistance materials,
- Laboratory stools for the benches.
- Laboratory furniture shall be capable of supporting anticipated loading and uses.
- Spaces between benches, cabinets, and equipment shall be accessible for cleaning.
- Lockable doors and cupboards.
- Closed drainage from laboratory sinks (to a septic tank or deep pit)
- Separate toilets for staff and patients.

**5.4.2.4.** 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

**5.4.2.5.** The following shall be minimum space allocation for specialty clinic laboratory:

Rooms required	No. of Rooms Required	Area Required
----------------	-----------------------	---------------

• Laboratory room (can be 1 room with open platform)	1	42 sq. M
○ Specimen collection	1	6sq. M
○ Hematology & clinical chemistry	1	12sq. M
○ Parasitology, urinalysis & serology	1	9sq. M
○ Bacteriology	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.

Professional required	Number required
Laboratory technologist	1
Laboratory technician	1

### 5.4.4. Products

5.4.4.1. Paediatrics Specialty clinic medical laboratory shall have the following equipments:

- |  |                              |
|--|------------------------------|
| a) Safety cabinet,(optional)             | b) Lab bench,                |
| c) Autoclave                             | j) Incubator,                |
| d) Dry oven,                             | k) WBC chamber,              |
| e) Refrigerator with thermometer,        | l) Water bath,               |
| f) Bunsen Burner,                        | m) Assorted lab glass wares, |
| g) ESR stand                             | n) Biohazard bag,            |
| h) ESR tubes,                            | o) Safety box,               |
| i) Distil Water /distillation apparatus, |                              |

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:

- Binocular Microscope,
- Slides

5.4.4.4. The minimum equipment for Haematology:

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

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

## **5.5. Housekeeping & Maintenance Services**

### **5.5.1 Practices**

**5.5.1.1** 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.

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

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

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

5.5.1.5 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.

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

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

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

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

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

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

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

5.5.1.13 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.

5.5.1.14 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.

5.5.1.15 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.

5.5.1.16 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.

5.5.1.17 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

5.5.1.18 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.

5.5.1.19 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.

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

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

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

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

5.5.1.24 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.

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

5.5.1.26 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.

## **5.5.2 Premises**

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

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

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

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

5.5.2.5 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.

## **5.5.3 Professionals**

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

5.5.3.2 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.

5.5.3.3 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.

#### **5.5.4 Products**

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

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

- |                                 |                                   |
|---------------------------------|-----------------------------------|
| a. Reserve electrical generator | f. Ceiling brush                  |
| b. Floor cleaning brush air     | g. Glass cleaning / wiping brush. |
| c. Floor wiping brush           | h. Scrappers                      |
| d. Hockey type brush            | i. Dustbins paddles.              |
| e. Counter brush.               | j. Waste paper basket.            |

- k. Plastic Mug
- l. Plastic Bucket
- m. Plastic drum
- n. Wheel barrow
- o. Water trolley
- p. Ladder
- q. Scraping pump
- r. Spraying pump
- s. Flit pump.
- t. Rate trapping cage
- u. Gum boots
- v. Gown, Masks & Gloves
- w. Torch

- x. Manual sweeping machine.
- y. Floor scrubbing/polishing machine
- z. Wet vacuum cleaner.
- aa. Dry vacuum cleaner portable
- bb. Fumigation machine (Oticare)
- cc. Bed pan washer.
- dd. Cleaning material
- ee. Deodorants & disinfectant
- ff. Laundry cleaning material
- gg. Insecticides & rodenticides
- hh. Stain removal

## 5.6. Infection Prevention

### 5.6.1 Practices

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

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

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

5.6.1.4 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.

5.3.1.1. 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

5.6.1.5 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.

5.6.1.6 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

5.6.1.7 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

5.6.1.8 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

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

5.6.1.10 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

5.6.1.11 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.

## **5.6.2 Premises**

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

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

5.6.2.3 The specialty clinic shall have a centralized sterilization room

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

### 5.6.3 Professionals

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

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

### 5.6.4 Products

5.6.4.1 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

5.7.

## 5.8. Sanitation and Waste Management

### 5.7.1 Practices

5.7.1.1 Specialty clinic environment shall ensure the following conditions:

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

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

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

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

5.7.1.5 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.

5.7.1.6 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

5.7.1.7 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.

5.7.1.8 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:

5.7.1.9

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

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).

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

5.7.1.11 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).

5.7.1.12 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,

5.7.1.13 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.

5.7.1.14 The specialty clinic shall ensure appropriate ventilation system.

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

5.7.1.16 Housekeeping items shall be cleaned and sanitized regularly.

5.7.1.17 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).

5.7.1.18 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,

5.7.1.19 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.

## **5.7.2 Premises**

5.7.2.1 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.

## **5.7.3 Professionals**

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

5.7.3.2 In addition, the specialty clinic shall have:

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

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

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

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

5.7.3.6 Staff shall be oriented on personal protection methods.

## **5.7.4 Products**

5.7.4.1 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

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## **Bibliography**

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. National Health Policy of the Transitional Government of Ethiopia, 1993
- 2.4. National Drug Policy of the Transitional Government of Ethiopia, November 1993
- 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