

**CES 233**

# **Compulsory Ethiopian Standard**

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## **Surgery Specialty Clinic**



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**Foreword**

This Ethiopian Standard has been prepared under the direction of the Technical Committee for Healthcare practised. (TC 90) and published by the Ethiopian Standards Agency (ESA). This Compulsory Ethiopian Standard cancels and replaces ES 3620: 2012.

Application of this standard is COMPULSORY due to concerns to safeguard the public health with respect to clauses 4.0 to 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 January 2021.

## Surgery Specialty Clinic

### 1. Scope

The standard covers the minimum requirements with respect to practices, premises, professionals and Equipments, materials and Supplies put into use for surgical specialty Clinic.

### 2. Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ES 6627 Part 1-Health services-Terms and definitions

CES 246 -Part 2- Health services –General requirements

CES 247 -part 3-Health Services –Physical Infrastructure Requirements

### 3. Terminologies and Definitions

For the purpose of this standard the following definitions shall apply.

#### 3.1.

##### **Appropriate Organ**

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

#### 3.2.

##### **Appropriate Law**

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

#### 3.3.

##### **Authorized Person**

Any surgical service clinic staff who is responsible for a given service.

#### 3.4.

##### **Specialty Clinic**

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.

#### 3.5.

##### **Surgical Specialty Clinic**

A health facility which lies in secondary level health care system and provides a minimum of curative, preventive, rehabilitative and promotion services in ambulatory basis as stipulated in this standard. The Specialty clinic may have a maximum of 9 beds to provide 24hrs to 10 days of psychiatry emergency services.

### 4. General Requirements-

**4.1** Surgical specialty clinic shall be directed by a licensed surgeon.

**4.2** The clinic shall only provide services that shall be done at ambulatory/ outpatient level. Any surgical operative procedures under general anaesthesia or major regional blocks shall not be done at orthopaedic specialty clinic.

**4.3** 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.

**4.4** Triage shall be carried out before any administrative procedure such as registration as soon as a patient arrives in the clinic.

- 4.5** The clinic shall control the nursing visits, care, and execution of orders.
- 4.6** The surgeon shall be responsible for the follow-up clinics.
- 4.7** Administration of regional blocks and general anesthesia is prohibited. Any surgery/ procedure shall be done only by local anesthesia.
- 4.8** The specialty clinic is obliged to report diseases under national surveillance to the MOH through a responsible person/office at sub-city/ woreda/ town health offices
- 4.9** The specialty clinic shall avail emergency medicines as per the list of emergency medicines prepared by EFDA.
- 4.10** The specialty clinic shall have national clinical protocols for management of at least common disease entities and locally significant diseases if any.
- 4.11** The clinic shall avail updated reference materials, treatment guidelines and manuals like National TB and leprosy, pain management, Malaria treatment, ART.
- 4.12** 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.
- 4.13** The specialty 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.
- 4.14** The specialty clinic shall establish quality team to improve quality of service deliveries.
- 4.15** 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.
- 4.16** The specialty clinic shall provide or facilitate training to their staffs.
- 4.17** 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,
- 4.18** The surgery specialty clinic facilities shall be well marked and easily accessible for persons with disability.
- 4.19** The clinic shall have fire extinguisher placed in visible area.
- 4.20** 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.
- 4.21** 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.
- 4.22** Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.
- 4.23** All patient care rooms shall be provided with running water supply & functional hand washing basin.
- 4.24** The Internal surfaces of the clinic (floors, walls, and ceilings) shall be:
- a) Smooth, impervious, free from cracks,
  - 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.

- 4.25 The circulation ways and sub corridors shall be a minimum 2m wide.
- 4.26 Patient serving corridors shall not be less than 240cm wide,
- 4.27 Safety glass, tempered glass or plastic glass materials shall be used for paediatrics service units to avoid possible injuries.
- 4.28 Glass doors shall be marked to avoid accidental collision.
- 4.29 Surgery 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.
- 4.30 With regard to quality assurance and transparency:
  - a) The specialty clinic shall arrange system at outpatient clinic to collect feedback from clients,
  - b) The specialty clinic shall have formal administrative channel through which clients lodge their complaints and grievances,

### **Nursing practices**

- 4.31 The nurse(s) working in the specialty clinic is/are responsible for the nursing services to be available in the clinic
- 4.32 Nursing care shall be available in the specialty clinic for emergency care, patients unable to support themselves and other clients who need the care.
- 4.33 The nursing service in specialty clinic shall be rendered integrated with other services. There may not be a separate premise for nursing service.
- 4.34 There shall be accessible physical resources for nurses to implement the nursing process, as detailed under the products' section.
- 4.35 The Nursing service to a minimum shall include:
  - a) Taking vital signs for all clients visiting the clinic,
  - b) Perform psycho social assessment & care evaluation,
  - c) Provide psychosocial support for patients on the disease condition & recommended treatment,
  - d) Provide basic health education to clients,
- 4.36 Written copies of nursing procedure manual shall be available to the nursing staff. The manual shall be used at least to:
  - a) Provide a basis for induction of newly employed nurse(s),
  - 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.
- 4.37 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.
- 4.38 There shall be a procedure for standardized, safe and proper administration of medications by nurses or designated clinical staff including proper documentation of administered drugs.
- 4.39 All patients kept for observation/resuscitation shall be under the supervision/ care of a licensed nurse at all times.
- 4.40 Copies of Nurses' code of professional practice shall be available and all nurses shall abide by the code of professional practice.
- 4.41 Nurses shall explain and seek informed consent from their patients or their relatives/ next of kin (for incompetent patients) before carrying out any procedure.

- 4.42** Allergies shall be listed on the front cover of the patient's chart or, in a computerized system, highlighted on the screen.
- 4.43** There shall be a mechanism for nurses to report any suggestive signs of child abuse, substance abuse and /or abnormal psychiatric manifestations by the patients to treating physician.

## **5. Specific requirement**

### **5.1. Outpatient Services**

#### **5.1.1. Practices**

- 5.1.1.1.** The specialty clinic shall provide the following outpatient services/ functions as per the criteria below:
- a) Care of ambulatory patients and follow up of ambulatory patients for conditions in their respective discipline/ specialties
  - b) Preventive and health promotion services in their respective disciplines/ specialties
  - c) Care for patients with chronic illnesses in their respective discipline/ specialties and do follow ups
- 5.1.1.2.** The outpatient service delivered in specialty clinic shall be provided by licensed specialist
- 5.1.1.3.** The outpatient service shall be available during working hours
- 5.1.1.4.** Patient assessment at specialty clinic shall include
- a) Comprehensive medical and social history
  - b) Physical examination minimum includes:
    - Vital sign (BP, PR, RR, To) and weight,
    - Clinical examination pertinent to the illness,
  - c) Diagnostics impression, and
  - d) Laboratory and 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 common disease entities and locally significant diseases if any
- 5.1.1.7.** The specialty clinic shall keep its staff updated with current knowledge and practice and observe utilization of national guidelines for the services it renders
- 5.1.1.8.** The specialty clinic shall have functional referral system if appropriate national system exists
- 5.1.1.9.** The specialty clinic shall report diseases under national surveillance to the MoH through a responsible person person/office at sub-city/ woreda/ town health offices
- 5.1.1.10.** The services rendered at specialty clinic shall follow MoH national code
- 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 of the specialty clinic shall have examination room with the following facilities/ conditions:
- a) All rooms shall have adequate light and ventilation
  - b) All rooms for patient care shall promote patient dignity and privacy.
  - c) All rooms for patient care shall be provided with running water supply & functional hand washing basin.
  - d) The arrangement of rooms shall consider proximity between related services.
  - e) Potential source of accidents shall be identified and acted upon (floors shall not be slippery; there shall not be misfit in doorways and footsteps etc).

**5.1.2.2.** All rooms shall be well labelled/ marked/ and easily accessible for persons with disability.

**5.1.2.3.** The corridor to examination rooms shall be spacious enough to allow easy transport of emergency patients or patients with support.

**5.1.2.4.** The outpatient service shall have the following facilities/ conditions:

**Table 1: Requirements for outpatient service layout**

Premises required	Number required	Area required
Reception, Recording & Waiting area	1	30 sq. m
Examination room	1	12 sq. m
Minor OR	1	20sq.m
Emergency room with 2 resuscitation Couches	1	16 sq. m
Observation/ procedure room,	1	9 sq. m
Instrument processing and sterilization room	1	20sq.m
Toilet room (male & female)	2	
Store room for medical supplies,	1	12 sq. m
Incinerator (mobile/fixed),		

### 5.1.3. Professionals

**5.1.3.1.** Surgery Specialty clinic shall be directed by a licensed surgeon with relevant clinical work experience

**5.1.3.2.** All surgical procedures shall be done by a licensed/registered surgeon & In case procedures done by other health professional According to his/her scope of practice (registered of any graduate) with under supervision of licensed/registered surgeon

**5.1.3.3.** The surgery clinic shall have a minimum number of the following staffing:

**Table 2: Requirements for surgery clinic professionals**

Professionals	Number of professionals
Surgeon	1
GP/HO	2(optional)
Radiology Technologist	2
Radiologist	1(optional)
IESO	1
Msc anesthesia professional specialist	1
anesthesia professional	2
Nurse	2
Aneasthiologist/BSc aneashtetist /Anesth (Optional)	1
Cleaner	2
Reception	1

### 5.1.4. Equipments, materials & supplies

**5.1.4.1.** The examination room shall have the following equipments:

- a) Diagnostic Equipments need for examination room(s) minimum include:
  - Stethoscope,



- Otoscope,
- Ophthalmoscope,
- BP apparatus,
- Thermometer,
- Tuning fork,
- Tape measure,
- Snellen's chart,
- Magnifying glass
- Pulseoximeter,
- b) Reflex hammer,
- c) Examination/ pen torch,
- d) Time clock,
- e) Mobile examination light
- f) Examination couch & accessories specific to the specialty if necessary:
  - Gynaecology bed- only for Obs & Gyn clinic,
  - ENT table/ chair- for ENT,
  - Dental unit- for dentistry
  - Adjustable stool- for ophthalmology clinic, ENT clinic, dermatology clinic,
- g) X-Ray viewer,
- h) Dust bin,
- i) Table & chairs
- j) Resuscitation set (Ambu Bag, Endo- tracheal tube, Laryngoscope),
- k) Oxygen source, can be shared, O2 face Mask,
- l) Tracheostomy set,
- m) Splints, various types
- n) The clinic shall have the following equipment for nursing services (can be shared)
  - Dressing set
  - Bowels/ buckets for instrument processing
  - Pickup forceps with jar
  - Instrument tray and instrument trolley
  - Kidney basin ,
  - IV infusion stand
  - Sterilization drums with stands
  - Autoclave/ Steam Sterilizer
  - Personal protective equipment

## **5.2. Minor Surgical Service**

### **5.2.1. Practices**

**5.2.1.1.** The specialty clinic may provide minor surgical services.

**5.2.1.2.** Any specialty related minor surgical interventions performed under the specialty clinic shall be done by licensed specialist

**5.2.1.3.** At specialty clinic level shall use of General Anaesthesia (GA).

- 5.2.1.4.** The specialty clinic shall have list of minor surgical procedures that are allowed to be done at outpatient level.
- 5.2.1.5.** Surgical interventions shall be recorded for each patient and documentation shall be integrated with the patient's medical record.
- 5.2.1.6.** The preoperative (pre-procedure) assessment finding and diagnosis shall be recorded in their medical records for all patients prior to surgical intervention.
- 5.2.1.7.** The specialist practitioner shall notify the disease condition, in clear, simple and understandable terms to the patient and/or next of kin or family/ guardian with written/verbal consent.
- 5.2.1.8.** There shall be protocols that ensure & define the appropriateness and safety of the procedure before, during and immediately after minor surgery
- 5.2.1.9.** The specialty clinic shall have copy of management protocols minimum for
- a) pain management,
  - b) emergency/acute trauma management ,
  - c) emergency resuscitation & Cardio Pulmonary Resuscitation (CPR)
- 5.2.1.10.** Surgery Clinic shall provide minor surgical procedures under local anesthesia and minor regional blocks. Surgical procedures under general anesthesia & Spinal anesthesia and use of General anesthesia and spinal in this clinic are strictly prohibited
- 5.2.1.11.** Administration of minor regional blocks shall be monitored, which shall include:
- a) Prior to administration of any anesthesia medication, a verbal & written informed consent shall be obtained for the surgical procedure & for the use of minor regional block/ anesthesia and shall be documented in the medical record.
  - b) Each patient's physiologic status shall be monitored during anesthesia 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
- 5.2.1.12.** A written record of the anesthetic agent and outcome of the procedure shall be kept as a permanent record in the patient's record
- 5.2.1.13.** Pain shall be assessed and controlled during and after any surgical procedures.
- 5.2.1.14.** There shall be written list of minor surgical procedures and interventions provided in the clinic
- 5.2.1.15.** The surgical procedures shall allow for surgery specialty clinic the following:
- a) Excision of Mass/cyst- (breast, sub mandibular, uncomplicated lipoma, ganglion), & Ligation-hydrocele
  - b) Incision/ excision- wart removal, tattoo removal, abscess drainage biopsy
  - c) Orthopedics- immobilization, splinting, POP, (external fixation, wire removal)
  - d) Others which can be performed under LA such as Cystoscopy
- 5.2.1.16.** There shall be a clear policy for handling emergency surgical conditions.
- 5.2.1.17.** Any surgical procedure shall be performed only after appropriate history, physical examination, and indicated diagnostic tests are completed and documented in the patient's medical record
- 5.2.1.18.** The surgeon 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
- 5.2.1.19.** Except in life-threatening emergencies, the surgeon shall obtain an informed & written consent and this must be documented in the patient's medical record. For the case with life threatening condition or mental derangement, consent shall be obtained from next of kin, spouse, family member or guardian

**5.2.1.20.** Surgical interventions/procedures shall be written in the patient's record and in the procedure, room register immediately after each procedure and shall include at minimum: Patient identification, Diagnosis, Procedure performed, Anesthesia used, Surgical specimens removed if any, Date and time minor operation done, Post procedure diagnosis, Pain management, Name of surgeon and assistant if any and Signature of the surgeon

**5.2.1.21.** If specimen shall be sent for pathology examination:

- a) The surgeon shall fill the pathology form and the specimen container shall be properly labeled. The container shall be filled with 10% formalin
- b) The specimen shall be sent to appropriate pathology service by the patient or a family member or a relative

## **5.2.2. Premises**

**5.2.2.1.** 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 & smoothened
- d) shall be smooth, easily cleanable and non-slippery
- 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)

## **5.2.3. Professional**

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

## **5.2.4. Equipments, materials & supplies**

**5.2.4.1.** There shall be the following equipments for surgical services in specialty clinic:

- a) Minor OR/ procedure table ,
- b) Instrument tray,
- c) IV stand,
- d) Oxygen source,
- e) Steam sterilizer,
- f) Sterilization Drums,
- g) Suction machine,
- h) Resuscitation set (Ambu Bag, Endo- tracheal tube, Laryngoscope),
- i) Dressing trolley,
- j) Kidney basin, 475ml,
- k) Galley pots,
- l) Surgical drape, fenestrated, un- fenestrated
- m) Instrument tables, Mayo type
- n) Glass medicine cabinet and shelve,
- o) Minor OR Linen(Gown, Surgical, (Plain),

- p) Surgical Cap,
- q) Surgical Masks,
- r) Apron
- s) Mobile operation light,
- t) Oxygen source,
- u) Adjustable Stools,
- v) Mouth gauge,
- w) Dual head stethoscope,
- x) Leak proof container,
- y) Swab rack with drip trays,

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

### **5.3. General Emergency Services**

#### **5.3.1. Practices**

- 5.3.1.1.** The specialty clinic shall provide emergency services related to the specialty at least during working hours without any prerequisite and discrimination
- 5.3.1.2.** Examination room(s) shall be ready and accessible for emergency
- 5.3.1.3.** Infection prevention criteria shall be implemented during emergency handling and management as per the IP
- 5.3.1.4.** If referral is urgent, it shall be done after providing basic emergency and after confirmation of availability of the required service in the facility where the patient is to be referred to.
- 5.3.1.5.** There shall be established compliant handling mechanism
- 5.3.1.6.** The specialty clinic shall have a system that facilitates emergency patients to get priority access to services
- 5.3.1.7.** The specialty clinic shall provide emergency observation service for conditions that do not need admission
- 5.3.1.8.** The emergency service shall provide basic life support as indicated for any emergency cases, which may include Cardiopulmonary resuscitation (CPR), Airway management, bleeding control & Shock management/ IV fluid resuscitation
- 5.3.1.9.** The specialty clinic emergency service shall have protocol for initial management of common emergency conditions in the specialty

#### **5.3.2. Premises**

- 5.3.2.1.** There shall be emergency observation room for all specialty clinics.
- 5.3.2.2.** The emergency or observation room premises shall be low traffic area and there shall be reserve parking place for ambulances.
- 5.3.2.3.** The emergency area shall be spacious enough to provide a space 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.
- 5.3.2.4.** Resuscitation/ observation couches shall be arranged in a way 90cm away from walls and with a minimum of 1.2m space in between.

#### **5.3.3. Professional**

- 5.3.3.1.** The specialty clinic shall avail medical staff for emergency conditions whenever need arises.

**5.3.3.2.** All medical staff handling emergencies shall have basic knowledge & skills on emergency management under the specialty.

**5.3.4. Equipments, materials & supplies**

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

- a) Resuscitation set, adult, pediatrics,
- b) BP apparatus #1,
- c) Stethoscope #1,
- d) Splints,
- e) Dressing set #2,
- f) Suture set #1,
- g) IV stands #2,
- h) Resuscitation couches #1 for delivery,
- i) Suction machine #1,
- j) Emergency medicine cabinet,
- k) Bed screens, 3 section #1,
- l) Kidney basin #2,
- m) Oxygen supply,
- n) EKG machine

**5.3.4.2.** The specialty clinics shall have emergency medicines as per the list of emergency medicines prepared by EFMHCA

**5.4. Clinical Laboratory Service**

**5.4.1. Practices**

**5.4.1.1.** The clinical laboratory in the specialty clinic shall provide basic laboratory services for haematology, chemistry, bacteriology and serology tests

**5.4.1.2.** The clinical laboratory shall have the following minimum test descriptions.

- a) Hematology Tests: White blood cell count, Hemoglobin, Hematocrit, Differential count, Reticulocyte count & blood group, Platelet, Hemoparasite, RBC morphology can be outsourced, Erythrocytes Sedimentation Rate (ESR)
- b) Clinical Chemistry:- Glucose
- c) Urinalysis:- Urine analysis Qualitative & Urine Microscopy
- d) Parasitology:- Stool Examination
- e) Bacteriology Examination:- Gram Stain, AFB Stain, & Special Stain
- f) Serological Tests And Other Tests(not applicable for surgical speciality clinic):- Widal-weli flex, HBsAg-hepatice, H.pylori, RPR (syphilis),& HIV/Ag/Ab

**5.4.1.3.** The specialty clinic laboratory shall have written policies and procedures for the followings:

- a) Quality assurance and control processes
- b) Inspection, maintenance, calibration, and testing of all equipment
- c) Management of reagents, including availability, storage, and testing for accuracy
- d) Statement on Normal ranges for all tests
- e) Laboratory safety program, including infection control
- f) Documentation of calibration report, refrigerator readings and so on

**5.4.1.4.** The specialty clinic laboratory shall follow standard operating procedures (SOPs) criteria and conduct routine quality assessments to ensure reliable and cost-effective testing of patient specimens.

- 5.4.1.5.** Manuals, guidelines & Standard Operating Procedures (SOPs) shall be available for all tests and equipments available in the specialty clinic laboratory
- 5.4.1.6.** The specialty clinic laboratory shall have procedures (SOPs) for proper collection, identification, transport & disposal of specimen that address specific collection requirements
- 5.4.1.7.** Specialty clinic laboratory team/ management shall review all operational procedures at regular intervals
- 5.4.1.8.** The process of specimen analysis shall be specified by validated written or electronic procedures maintained in the laboratory.
- 5.4.1.9.** There shall be SOP or criteria developed for acceptance or rejection of clinical samples
- 5.4.1.10.** The specialty clinic laboratory shall maintain a record of all samples received and tests run
- 5.4.1.11.** Specialty clinic laboratory staff shall test quality control materials every day for equipment requiring frequent calibration
- 5.4.1.12.** Specialty clinic laboratory shall have a procedure for storage of clinical samples that are not examined immediately
- 5.4.1.13.** Specialty clinic laboratory report shall be made as follows:
- a) All laboratory test results/reports shall have reference (normal) ranges specific for age and gender if applicable
  - b) Copies/ 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
  - c) Reports shall be filed with the patient's medical record and duplicate copies shall be filed in the laboratory
  - d) In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be filed in the medical record
- 5.4.1.14.** Quality assured test results shall be reported on approved forms with the following minimum information:
- a) Patient identification (patient name, age, gender)
  - b) Date and time of specimen collection
  - c) The test performed and date of report
  - d) The reference or normal range
  - e) The laboratory interpretation where appropriate
  - f) The name and initial of the person who performed the test and the authorized signature of the person who reviewed the report and releases the results, and
  - g) Address of the laboratory/ clinic
- 5.4.1.15.** Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them such as the ordering physician or nursing staff in the specialty clinic
- 5.4.1.16.** No eating, drinking, smoking or other application of cosmetics in the laboratory work area is allowed
- 5.4.1.17.** No food and drink shall be stored in the laboratory
- 5.4.1.18.** Temperature of the refrigerator used to store laboratory reagents shall be strictly maintained below 8°C & daily temperature readings shall be documented
- 5.4.1.19.** 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
- 5.4.1.20.** Where services are provided by an outside laboratory, the types of services & procedures available & offered shall be documented in writing and available in the Specialty clinic

### 5.4.2. Premises

- 5.4.2.1.** The specialty clinics shall have a dedicated premise/ room for clinical laboratory services.
- 5.4.2.2.** The specialty clinic laboratory shall have the necessary space & facilities to collect specimens & perform testing in a safe environment.
- 5.4.2.3.** The laboratory working environment shall be kept organized, clean, and safe for handling specimens and waste materials.
- 5.4.2.4.** The following shall be minimum space allocation for specialty clinic laboratory:

**Table 3: Requirements for speciality clinic laboratory**

Premises required	No of rooms required	Minimum Area required
• Big room,	1	22 sq m
○ Specimen collection area,		4 sq. m
○ Hematology area		4 sq. m
○ Serology area		4 sq. m
○ Parasitology and urinalysis area		4 sq. m
○ Store place for chemicals (wall		6 sq. m
• Toilet room(male & female) Can shared	1	

- 5.4.2.5.** The laboratory facilities for speciality clinic shall meet in the minimum:
- The laboratory shall have a reliable supply of running water
  - The laboratory shall be well illuminated and ventilated
  - At least two sinks shall be provided in the big room, one for general laboratory use and the other reserved for hand washing
  - Lab bench working surface covered with appropriate materials
- 5.4.2.6.** Interior of the lab; floor, walls and ceiling shall be
- Smooth, free from cracks, cavities, recesses, projecting ledges and other features that could harbour dust or spillage
  - Washable, easy to clean
  - Constructed of materials that are non-combustible or have high fire resistance characteristics
- 5.4.2.7.** Laboratory furniture shall be capable of supporting anticipated loading and uses.
- 5.4.2.8.** Spaces between benches, cabinets, and equipment shall be accessible for cleaning.
- 5.4.2.9.** There shall be Lockable doors and cupboards.
- 5.4.2.10.** The lab sinks shall drain to closed drainage.
- 5.4.2.11.** Emergency of safety services such as deluge showers and eye-wash stations shall be included in the laboratory services design specifications.

### 5.4.3. Professionals

- 5.4.3.1.** The laboratory service at specialty clinic shall be directed by at least a licensed medical Laboratory Technician or laboratory technologist with experience
- 5.4.3.2.** Laboratory professional is not mandatory for Specialty clinics where clinical laboratory service is considered as optional
- 5.4.3.3.** All laboratory tests and analyses rendered at the clinic shall be done by laboratory professional
- 5.4.3.4.** Laboratory staff shall perform their functions with adherence to the highest ethical and professional criteria of the laboratory profession.

**5.4.3.5.** The clinic shall facilitate upgrade and continuous education access for its laboratory staff

#### **5.4.4. Equipments, materials & supplies**

**5.4.4.1.** Products for clinical laboratory service shall be available for specialty clinics where clinical lab service is mandatory

**5.4.4.2.** All clinical laboratory equipment in specialty clinic shall be in good working order, and routinely quality control and regularly calibrated

**5.4.4.3.** Clinical Laboratory shall have a program of preventive maintenance for every machine which at a minimum follows the manufacturer's recommendation

**5.4.4.4.** The specialty clinic laboratory service shall have the following equipments:

**5.4.4.5.** Binocular microscope #1, Centrifuge, Bunsen burner, Refrigerator with thermometer, Water bath, ESR rack, Timer, Shaker, Fully automated chemistry machine(optional), Hematology machine, Slide rack & Test tube racks

**5.4.4.6.** The laboratory reagents shall be stored labelled & monitored properly

### **5.5. Health Promotion Services**

#### **5.5.1. Practices**

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

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

#### **5.5.2. Premises**

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

#### **5.5.3. Professionals**

**5.5.3.1.** It is not mandatory to assign staff for promotion in particular

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

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

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

#### **5.5.4. Equipments, materials & supplies**

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

**5.5.4.2.** 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)

### **5.6. Radiography Imaging Services**

#### **5.6.1. Practice**

**5.6.1.1.** Basic Radiology service shall be available for specialty clinics.

**5.6.1.2.** 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

**5.6.1.3.** There shall be a written protocol for managing medical emergencies in the radiological suite

**5.6.1.4.** The radiology service unit shall be free of hazards to patients and personnel

**5.6.1.5.** Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards, and radiation hazards

**5.6.1.6.** 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

**5.6.1.7.** 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

**5.6.1.8.** 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

**5.6.1.9.** Requests for radiologic imaging examination shall contain a concise statement of reason for the examination

**5.6.1.10.** Imaging results like X-ray films, US pictures, shall be labeled with minimum information that includes: date, patient's name, age, sex, location marks (L/R), name of institute and name of radiographer

**5.6.1.11.** Imaging Reporting form shall have minimum information such as date, patient's name, age, sex, findings and name and signature of radiologist

#### **5.6.2. Premises**

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

**5.6.2.2.** The premise for imaging service shall fulfill the ERPA requirements & be functional only if licensed/ certified by ERPA

**5.6.2.3.** The radiology imaging unit shall have a minimum of the following premises set up:

**5.6.2.4.** Conventional x-ray room #1room, 24sq.m, Dark room (if necessary) #1room, 6sq. m, Toilet with hand washing basin# 2 rooms, 8sq. m, Patient dressing cubicle inside X-Ray room, #1, 4sq. m, Sub waiting area #1room, 12sq.m

#### **5.6.3. Professional**

**5.6.3.1.** The specialty clinic that has radiology imaging service shall have the following professionals: Radiological technologist #1, and b. Radiographer #1

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

#### **5.6.4. Equipments, materials & supplies**

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

- a)Standard conventional x-ray machine,
- b)Ultrasound,
- c) X-Ray viewing boxes,
- d) Radiation protection equipments: lead gloves, lead apron , lead goggle and Gonad shields

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

- 5.6.4.3. All radiation generating equipments shall be installed within a room/, i.e., the minimum criteria set by the Ethiopian Radiation Protection Authority.
- 5.6.4.4. 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.

## **5.7. Record Keeping & Reporting Services**

### **5.7.1. Practice**

- 5.7.1.1. The specialty clinic shall maintain individual patient records,
- 5.7.1.2. The Specialty clinic shall maintain individual medical records in a manner to ensure accuracy and easy retrieval.
- 5.7.1.3. 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.
- 5.7.1.4. The Specialty clinic shall establish a master patient index with a unique medical number/ record for each patient.
- 5.7.1.5. Patient medical record shall at least contain the following information:
  - a) Identification (name, age, sex, address),
  - b) History, physical examination,
  - c) investigation results and diagnosis,
  - d) Medication, procedure and consultation notes,
  - e) Name and signature of treating physician ,and If applicable, a signed Consent form(s)
- 5.7.1.6. Every piece of paper or format that contains a patient medical information shall carry the appropriate identification
- 5.7.1.7. All medical records shall be kept confidential, available only for use by authorized persons or as otherwise permitted by law
- 5.7.1.8. The clinic shall have a mechanism to track a medical record taken out for use until returned to the record room.
- 5.7.1.9. 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.
- 5.7.1.10. Consent forms that patient sign shall be printed in an understandable format and the text written in clear, legible and non-technical language
- 5.7.1.11. 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
- 5.7.1.12. 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
- 5.7.1.13. 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
- 5.7.1.14. If a patient or his legally authorized representative requests in writing a copy of the medical record shall be given to them.
- 5.7.1.15. 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.
- 5.7.1.16. If the Specialty clinic ceases to operate, it shall notify the appropriate organ in writing about how and where medical record are stored at least 15 days prior to cessation of operation.
- 5.7.1.17. The patient choice on where to transfer his/her medical record shall be respected

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

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

**5.7.1.20.** Procedures for record completion,

**5.7.1.21.** Conditions & procedures for releasing medical information,

**5.7.1.22.** Procedures for the protection of medical record information against the loss, tampering, alteration, destruction or unauthorized use.

**5.7.1.23.** 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.

#### **5.7.2. Premises**

**5.7.2.1.** 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

**5.7.2.2.** 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

**5.7.2.3.** The medical record room shall have the following areas:

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

**5.7.2.5.** Archive space with shelves

**5.7.2.6.** The medical record room shall have adequate light and ventilation

**5.7.2.7.** There shall be fire extinguisher kept in a visible and identified place

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

#### **5.7.3. Professional**

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

#### **5.7.4. Equipments, materials & supplies**

**5.7.4.1.** The record room of specialty clinic shall have the following materials:

**5.7.4.2.** Shelves, Lockable cabinet, Patient medical records, and standard request papers & formats

### **5.8. Housekeeping & Maintenance Services**

#### **5.8.1. Practices**

**5.8.1.1.** The housekeeping service shall have the following activities

**5.8.1.2.** Basic cleaning such as dusting, and washing

**5.8.1.3.** Special cleaning of Different types of floors, Wall & ceiling, Doors & windows, Furniture & fixtures, and Venetian blinds

**5.8.1.4.** Cleaning and maintenance of toilet

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

**5.8.1.6.** The house keeping staff shall ensure safe & clear environment

**5.8.1.7.** The house keeping service shall comply waste management directives

**5.8.1.8.** The house keeping service shall have fire safety system in placed

**5.8.1.9.** The house keeping service shall apply pest control management

**5.8.1.10.** Regular surveillance of overhead and underground tank, proper cover, regular chlorination and cleaning shall be undertaken and reserve water tanker shall be in place.

**5.8.1.11.** The infection control measures shall be carried out in accordance with as per the national infection prevention guidelines

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

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

**5.8.1.14.** 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

**5.8.1.15.** There shall be written protocols and procedures for specialty clinic equipment maintenance

**5.8.1.16.** The maintenance personnel including the management of the clinic shall take basic trainings on the following issues and this shall be documented

**5.8.1.17.** Building fabrics and utilities, Building services and economics, Planning maintenance demand, and Preventive and routine maintenance practice

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

## **5.8.2. Premises**

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

## **5.8.3. Professionals**

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

**5.8.3.2.** Housekeeping servants shall be trained waste management

## **5.8.4. Equipments, materials & supplies**

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

**5.8.4.2.** The clinic shall have appropriate tools, equipment & materials for housekeeping services

## **5.9. Infection Prevention**

### **5.9.1. Practices**

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

## **5.10. Sanitation and Waste Management**

### **5.10.1. Practices**

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

**5.10.1.2.** 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

**5.10.1.3.** 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

**5.10.1.4.** 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 Guidelines/ Directives

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

**5.10.1.6.** Separate different types of waste as per the guideline

**5.10.1.7.** The specialty clinic shall provide colored waste receptacles specifically suited for each category of waste

**5.10.1.8.** Segregation shall take place at the source

**5.10.1.9.** There shall be 3 bin systems used to segregate different types of waste in the specialty clinic:

**Table 4:Segregation category**

<b>Segregation category</b>	<b>Color</b>	<b>Container</b>
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

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

**5.10.1.11.** By incineration, By sanitary landfill, By burial at an approved landfill, Chemical sterilization, and Gas sterilization (shall be handled safely)

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

**5.10.1.13.** 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).

**5.10.1.14.** The clinic shall have a medical waste management plan which includes at least the following:

**5.10.1.15.** Temporary storage of medical waste, segregation of medical waste, transport of medical waste, and disposal of medical waste

**5.10.1.16.** 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

**5.10.1.17.** The specialty clinic shall ensure appropriate ventilation system

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

**5.10.1.19.** Housekeeping items shall be cleaned and sanitized regularly

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

**5.10.1.21.** A functional sewerage system

**5.10.1.22.** Dispose of sanitary waste through connection to a suitable municipal sewerage system

**5.10.1.23.** Flush toilet system

**5.10.1.24.** A designated waste storage room for solid waste &/ or a septic tank for liquid waste

**5.10.1.25.** Written procedures defining instrument processing procedures (disinfection and sterilization)

**5.10.1.26.** The clinic shall have Plumbing system that fulfill the following conditions:

**5.10.1.27.** An approved municipal water system

**5.10.1.28.** An approved method of supplying hot water

**5.10.1.29.** Supply piping within the building shall be according to the requirements in the requirement mentioned under the physical facility

**5.10.1.30.** The specialty clinic shall have the following supportive sanitation measures:

**5.10.1.31.** Clean water where there is no plumbing, Hand hygiene practice, Sterilization of medical instruments, and alternatives to protective equipment

## **5.10.2. Premises**

**5.10.2.1.** The specialty clinic sanitary system shall have:

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

## **5.10.3. Professionals**

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

**5.10.3.2.** In addition, the specialty clinic shall have:

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

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

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

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

**5.10.3.6.** Staff shall be oriented on personal protection methods

## **5.10.4. Equipments, materials & supplies**

**5.10.4.1.** The specialty clinic shall have the following equipment and supplies required for sanitation activities but not limited to: Incinerator, Safety boxes, Leak proof containers for waste, Trolley to transport waste, PPE (personal protective equipments), Autoclave, Pressure cooker/dry oven, Cleaning supplies (detergents, disinfectants and other cleaning solutions etc), and Mops and dust bins

## Organization and Objectives

The Ethiopian Standards Agency (ESA) is the national standards body of Ethiopia established in 2010 based on regulation No. 193/2010. ESA is established due to the restructuring of Quality and Standards Authority of Ethiopia (QSAE) which was established in 1970.

### ESA's objectives are:-

- ❖ Develop Ethiopian standards and establish a system that enable to check whether goods and services are in compliance with the required standards,
- ❖ Facilitate the country's technology transfer through the use of standards,
- ❖ Develop national standards for local products and services so as to make them competitive in the international market.

## Ethiopian Standards

The Ethiopian Standards are developed by national technical committees which are composed of different stakeholders consisting of educational Institutions, research institutes, government organizations, certification, inspection, and testing organizations, regulatory bodies, consumer association etc. The requirements and/or recommendations contained in Ethiopian Standards are consensus based that reflects the interest of the TC representatives and also of comments received from the public and other sources. Ethiopian Standards are approved by the National Standardization Council and are kept under continuous review after publication and updated regularly to take account of latest scientific and technological changes. Orders for all Ethiopian Standards, International Standards and ASTM standards, including electronic versions, should be addressed to the Documentation and Publication Team at the Head office and Branch (Liaisons) offices. A catalogue of Ethiopian Standards is also available freely and can be accessed in from our website.

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ESA, representing Ethiopia, is a member of the International Organization for Standardization (ISO), and Codex Alimentarius Commission (CODEX). It also maintains close working relations with the international Electro-technical Commission (IEC) and American Society for Testing and Materials (ASTM). It is a founding member of the African Regional Organization for Standardization (ARSO).

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